SEVENTEENTH CONGRESS OF THE)
REPUBLIC OF THE PHILIPPINES)
Second Regular Session)

S E N A T E

COMMITTEE REPORT NO. 368

Submitted by the Committees on Accountability of Public Officers and Investigations (Blue Ribbon); Health and Demography; and Finance on APR 30 2018.

Re: **Privilege Speech of Sen. Richard J. Gordon delivered on October 11, 2016 on THE ALLEGED ₱3.5 BILLION WORTH OF QUESTIONABLE DENGUE VACCINES THAT HAD BEEN ADMINISTERED BY THE DOH TO 280,000 STUDENTS WITHOUT PASSING THROUGH WHO PREQUALIFICATION REQUIREMENTS; and P.S. Res. Nos. 557 & 563 (both on the Dengue Vaccination Program of the Department of Health) by Senators Joseph Victor G. Ejercito and Grace Poe, respectively.**

Recommending its approval.

Sponsor: Senator Richard J. Gordon

MR. PRESIDENT:

The Committees on Accountability of Public Officers and Investigations (Blue Ribbon); Health and Demography; and Finance have conducted an inquiry, in aid of legislation, on the ***Privilege Speech of Sen. Richard J. Gordon delivered on October 11, 2016 on THE ALLEGED ₱3.5 BILLION WORTH OF QUESTIONABLE DENGUE VACCINES THAT HAD BEEN ADMINISTERED BY THE DOH TO 280,000 STUDENTS WITHOUT PASSING THROUGH WHO PREQUALIFICATION REQUIREMENTS; and P.S. Res. Nos. 557 & 563 (BOTH ON THE DENGUE VACCINATION PROGRAM OF THE DOH) by Senators Joseph Victor G. Ejercito and Grace Poe***, respectively.

The Committees have the honor to submit their Report, after conducting an inquiry, to the Senate.

Recommending the adoption of the recommendations contained herein.

INTRODUCTION

PRIMUM NON NOCERE (First, Do No Harm)

Doctors, before they enter into the practice of medicine, generally swear to an oath that contains the phrase, "*primum non nocere*;" or first, do no harm. This principle, supposedly first enunciated as far back as the time of Hippocrates, and the ancient Greeks, is not an empty shibboleth: That "(G)iven an existing problem, it may be better not to do something, or even to do nothing, than to risk causing more harm than good."

There is even a greater responsibility imposed upon doctors and decision-makers of government public health programs, where "public office is a public trust," and that public officers and employees must at all times be accountable to the people, serve them with utmost **responsibility**, **integrity**, loyalty, and **efficiency**, act with patriotism and justice, and lead modest lives."

The government, through the Department of Health (DOH) conducted a mass vaccination program in early 2016. It involved the introduction into the bodies of 830,000 – out of a million thence primarily targeted – school-age children an injectable substance – CYD-TDV also known by its brand name "DENGVAXIA," that was supposed to protect them from the ill-effects of a dengue infection that could be brought about by a mosquito vector. This program cost us ₱3.5 Billion (₱3,500,000,000.00).

This investigation was undertaken to determine whether efficiency, effectiveness and ethics characterized the mass dengue vaccination program that was undertaken shortly before the elections of 2016, or whether the program's implementation was characterized by malfeasance,

misfeasance, or non-feasance, what with the ever increasing complaints coming from parents about their children getting sick after receiving the vaccine; and, more tragically, too, because of reports of children dying after injection of the vaccine.

After a series of hearings, research, reading, and inspection of documents, Your Committees have found the following, which will be discussed *seriatim* in later pages:

ISSUE NO. 1: There was no effective vaccine against Dengue existing. There was not an urgent need for a mass public vaccination for Dengue The program was not a priority;

ISSUE NO. 2: Dengvaxia was not the correct way to go in preventing Dengue infections;

ISSUE NO. 3: Dengvaxia was not properly, ethically and legally procured;

ISSUE NO. 4: There was no proper preparation or administration in the conduct of the vaccination. Neither was full and proper information provided to parents and guardians; thus, no informed consent was validly given.

I. BACKGROUND

This is a tale full of pain and anguish. This is a story of skewed priorities, administrative shortcuts, and lack of empathy for Filipino children- all for the sake of politics, political convenience, political expediency, and electoral victory.

The national elections are in the horizon. Aquino was at the cusp of being in and out of power.

Amidst this milieu, we can now understand unmistakably why the DOH was made to undergo a sub-national mass vaccination of school-age children targeting originally a million of them.

The DOH is mandated under the law, the Administrative Code, that the State is mandated to "protect and promote the health of the people... endeavor to make essential goods, health and other social services available to all the people at affordable cost; [and] establish and maintain and effective food and drug regulatory system."

Given this, it is the President's responsibility to appoint a professional. He had Enrique Ona as his Secretary, a respected National Kidney and Transplant Institute(NKTI) director. But Dr. Enrique Ona- under very unclear and quite mysterious circumstances, resigned from the Department. Aquino stated that it was Ona who introduced to him the idea of a vaccine against dengue – Dengvaxia- that may be used in the Philippines. Ona denies this. The former President also claimed that Ona was with him when he went to China, and presumably would have been present in the discussions with Sanofi. Ona also denied this.

Instead of relying on a professional doctor with excellent credentials and unsullied reputation, he chooses a politician who comes from an influential and powerful political clan.

The bureaucracy was made such that whenever Aquino met with Sanofi, a signal was exhibited to the Department concerned and its bureaucrats that he

was interested in this. That Sanofi was a favoured entity. Things came to a boil most especially after he negotiated with Sanofi in Paris on December 2015.

There was no National Immunization Council (NIC) recommendation. The NIC is an external advisory group to the Expanded Program on Immunization (EPI) office of the DOH. Aquino should not have allowed Garin to hold concurrent positions as the Secretary of Health and as Officer-in-Charge of FDA. This is a clear violation of Art. VII, Sec. 13 of the Constitution.

He knew or should have known, because information was readily available to him at that time, that Dengvaxia was fraught with danger. At best, it did not work for the targeted vaccinees, and it was least effective for the dengue strain endemic to the Philippines. Dengvaxia was a drug sold by a company, Sanofi-Pasteur, well-known for bribery and unethical conduct around the world. Information could have been easily sought, if he had shown any curiosity or deep interest.

Dengvaxia was not utilized anywhere in the world, except in Brazil (for a limited, targeted use for 300,000 children). It was not allowed in Malaysia. It was allowed in Singapore but only for private use where there is a one-on-one relationship between patient and doctor. And, it was not licensed in France, Sanofi's headquarters.

Dengvaxia was not licensed here in the Philippines. The government could not have also bought it, even if it were licensed, because it had no exemption or was not listed in the Philippine National Drug Formulary (PNDF).

When Aquino and Garin went on to conduct mass vaccination, they thereby discriminated against, afforded less care, and displayed lack of affection for the poor, because the impoverished had no choice but to avail themselves of free injections performed mostly by non-doctors who had neither the time nor the capacity to skillfully conduct post-injection monitoring.

Aquino and Garin meet with Sanofi in Paris in December, where he and Garin negotiated a discount. This was not only improper, it violated rules on procurement in that a bidding would have been required. For all intents and purposes, the bidding that was conducted by Philippine Children's Medical Center (PCMC) later to acquire the drug was already *lutong macao*.

They and their ilk wronged the poor and suffering Filipinos for the sake of political expediency and greed. One need not be a lawyer to conclude that indeed a grave social injustice was committed here.

He did not exercise utmost diligence expected of a President when, without a hint of care, he went ahead with the program even if:

a. The trials were not over, and therefore incomplete;
b. He deliberately refused to heed the warnings that were given out by experts as to its dangers. He did not listen, nor paid attention to those who really knew how long the ill-effects on injected children would be.

He approves the Special Allotment Release Order (SARO) and Notice of Cash Allocation (NCA) in amazing record time, and even during a holiday period.

He violated the human rights of parents/guardians of these impoverished Filipino children, when no comprehensive and intelligent information was given

them pre-introduction of the vaccine. Informed consent could not have been validly given thus. He laid the foundation for the parents' and guardians' sleepless nights, continuing apprehension, never-ending anxiety, and unremitting disquietude.

His sins and transgressions has put the lives of Filipino children in grave peril.

Your Committees have also found the following individuals and corporations liable for this tragedy- laden mass vaccination program (their individual liability, and reasons for so finding them liable will also be discussed at length as we go along this Report):

A. Former President Benigno S. Aquino III

Aquino is liable.

Aquino is primarily and ultimately responsible. Here is why—

1. President Aquino is liable because he is the prime mover and the decision maker of the entire process. None of this could have happened without his initiation, without his knowledge, and without his approval. The former President had a reputation for micromanaging, e.g., what happened in Mamasapano.
2. He already had designs for this type of a program early on, cemented especially after he met Sanofi officers in Beijing during APEC November 2014. But before his designs could come to fruition he needed someone malleable, someone aggressive, and an equally

political person to head the DOH. Exit thus Dr. Enrique Ona-under very unclear, quite mysterious, circumstances.

3. Aquino stated that it was Ona who introduced to him the idea of a vaccine against dengue – Dengvaxia, that may be used in the Philippines. Ona denies this. That if at all he was the one who introduced the idea must be seen in the context of an informal conversation and not in the form of a policy proposal. The former President claimed that Ona was with him when he went to China, and presumably would have been present in the discussions with Sanofi. Ona denied this again. He said he could not have been with him in China as he already was on leave at that time. Instead of relying on a professional doctor with excellent credentials and unsullied reputation, he chooses a politician who comes from an influential and powerful political clan. Enter Dr. (and former Congresswoman) Janette Garin, who was not a public health doctor but a politician.

4. The bureaucracy was such that whenever Aquino met with Sanofi, a signal was exhibited to the Department concerned and its bureaucrats that he was interested in this product. Thus, things came to a boil most especially after he negotiated with Sanofi in Paris on December 2015. After that, all processes achieved lightning-speed. And it became easy for Garin to coopt the DOH professionals by appointing her own cronies to the FDA.

Thus, the DOH could not perform its mandate well under the law. Under the Administrative Code, the State is mandated to "protect and promote the health of the people... endeavor to make essential

goods, health and other social services available to all the people at affordable cost; [and] establish and maintain and effective food and drug regulatory system."

The President should have been able to rely on the DOH. Under the law, the primary function of the DOH "is the promotion, protection and delivery of health services and through regulation and encouragement of providers of health goods and services."

Moreover, Aquino should not have allowed Garin to hold concurrent positions as the Secretary of Health and as Officer-in-Charge of FDA. This is a clear violation of Art. VII, Sec. 13 of the Constitution, which provides that, "[t]he President, Vice-President, the Members of the Cabinet, and their deputies or assistants shall not, unless otherwise provided in this Constitution, hold any other office or employment during their tenure." Later on, Garin would appoint her friends and favorites to the FDA. This is where the system failed. As one former Secretary of Health had said, one should not mix health and politics.

5. It was wrong, unethical and illegal for Aquino and Garin to negotiate with Sanofi on Dengvaxia.

   a. There was no National Immunization Council (NIC) recommendation. The NIC is an external advisory group to the Expanded Program on Immunization (EPI) office of the DOH. This Committee was created through Ministry Order Number 327-A series of 1986 and serves to provide direction and

technical support on policies and plans pertaining to immunization and provide an avenue for coordinating all aspects of the Philippine immunization program. It is supposed to meet twice a year, on a March and on a September. It could not have made a recommendation for EPI's review, and for the Secretary's issuance, as it was rendered inactive.

b. He knew or should have known, because information was readily available to him at that time, that Dengvaxia was fraught with danger. At best it did not work for the targeted vaccinees, and it was least effective for the dengue strain endemic to the Philippines. At worst, it could be lethal to seronegative children (those who had not been bitten by a mosquito vector and infected beforehand). There were warnings sent out by local experts, as well as by an eminent dengue expert abroad (Dr. Scott Halstead) about Dengvaxia's dangers. Information could have been easily sought, if he had shown any curiosity or deep interest.

c. Dengvaxia was a drug sold by a company, Sanofi-Pasteur, well-known for bribery and unethical conduct around the world.

d. Dengvaxia was not utilized anywhere in the world, except in Brazil (for a limited, targeted use). It was not allowed in Malaysia. It was allowed in Singapore but only for private use where there is a one-on-one relationship between patient and doctor. And, it was not licensed in France, Sanofi's headquarters.

e. At the time of negotiation, Dengvaxia was not licensed here in the Philippines. The government could not have also bought it, even if it were licensed, because it had no exemption or was not listed in the Philippine National Drug Formulary (PNDF). This cannot be denied.

f. Even, assuming for the sake of argument, that Dengvaxia already had a license from the Food and Drug Administration (FDA) it still would have been illegal for Aquino and Garin to buy the drug. The license was only for dispensation of the vaccine on a doctor's prescription basis. This means that there was an engaged or paid doctor to inject the vaccine and thereafter monitor the patient. But when Aquino and Garin went on to conduct mass vaccination, they thereby discriminated against, afforded less care, and displayed lack of affection for the poor, because the impoverished had no choice but to avail themselves of free injections performed mostly by non- doctors who had neither the time nor the capacity to skillfully conduct post-injection monitoring. They and their ilk wronged the poor and suffering Filipinos for the sake of political expediency and greed. One need not be a lawyer to conclude that indeed a grave social injustice was committed here.

g. The vaccine cost us ₱1,000 per injection, compared with a health economist's estimate that it should only be in the region of ₱600+, or with that of Brazil's cheaper acquisition cost. The total budget was ₱3.5 B, large enough to be allotted without the President's initiation and imprimatur.

6. Aquino and Garin meet with Sanofi in Paris in December, where he and Garin negotiated a discount. This was not only improper, this violated rules on procurement in that a bidding would have been required. For all intents and purposes, the bidding that was conducted by Philippine Children's Medical Center (PCMC) later to acquire the drug was already *lutong macao*. The negotiations in Paris already sealed the deal. This cannot be denied. And, another sin after another.

7. He did not exercise utmost diligence expected of a President when, without a hint of care, he went ahead with the program even if:
   a. The trials were not over, therefore not complete;
   b. He deliberately refused to heed the warnings that were given out by experts as to its dangers. He did not listen, nor paid attention to those who really knew how long the ill-effects would be.
   c. The drug was very expensive, compared with other countries' acquisition cost.

8. He approves the Special Allotment Release Order (SARO) and Notice of Cash Allocation (NCA) in amazing record time, and even during a holiday period. There definitely was undue haste in the procurement of this hazardous vaccine. The inordinate haste thus paved the way for regulatory capture and cooptation of bureaucrats in the DOH. He further sinned again.

9. He violated the human rights of parents/ guardians of these impoverished Filipino children when no proper, and intelligent information was given them pre-introduction of the vaccine. Informed

consent could not have been validly given thus. He laid the foundation for the parents' and guardians' sleepless nights, continuing apprehension, never-ending anxiety, and unremitting disquietude. They worry incessantly that come tomorrow, or the next, the dreaded ill-effects of Dengvaxia may come a-visiting their children.

10. His sins and transgressions has put the lives of Filipino children in grave peril.

His fault, his fault, his most grievous fault.

B. Former Secretary of Health Jannette L. Garin;

C. Former Secretary Florencio Abad

D. Dr. Julius Lecciones;

E. Dr. Kenneth Hartigan- Go;

F. Dr. Lourdes Santiago;

G. Dr. Melody Zamudio;

H. Dr. Lyndon Lee Suy;

I. Dr. Joyce Ducusin;

J. Dr. Mario Baquilod;

K. Sanofi- Pasteur

L. Zuellig Pharma Corp. and F.E. Zuellig Pharma (ZPC-FEZP)

II. THE FACTS (TIMELINE)

DATE	
March 3, 2014	Philippines Food and Drug Administration Dengue (FDA) Consultation Meeting. Objective is to present updates on the development of Dengue vaccine clinical development and confirm the proposed registration strategy in 2015.
October 3, 2014	Atty. Nicolas B. Lutero III was designated as the OIC Director General of the FDA. (He will serve up to May 4, 2015.)

October 28, 2014	Sec. Ona went on a medical leave on October 28 allegedly due to his personal health issues. Sec. Garin becomes OIC Department of Health (DOH) Secretary.
November 9, 2014	Pres. Aquino, during the APEC Conference, took time to meet with Sanofi Senior Vice President Jean-Luc Lewinski at the Philippine Embassy in Beijing, China.
December 19, 2014	Sec. Ona resigns. (Meanwhile, Sec. Garin has been acting as OIC DOH Secretary from the time Dr. Ona was on leave, since October 2014.)
January 21, 2015	Sanofi Pasteur submitted its application for registration with the FDA and paid fees even if the submission is incomplete, likewise called "Rolling Submission." (2 months after the Aquino-Sanofi meeting in Beijing)
February 17, 2015	Sec. Garin becomes DOH Secretary. (3 months after the Aquino-Sanofi meeting in Beijing)
March 2, 2015	Sec. Garin changes key personnel 4 months after the Aquino-Sanofi meeting in Beijing: 1. Ma. Lourdes Santiago, OIC of Center for Drug Regulation and Research (CDRR) was re-assigned as Acting Deputy Director General for Field Regulatory Operations Office (FROO) 2. Melody Zamudio, OIC of the CDRR Licensing and Registration Division became the OIC of CDRR
May 4, 2015	End of Atty. Lutero's designation as OIC DG of the FDA. (6 months after the Aquino-Sanofi meeting in Beijing)
May 5 – Nov. 3, 2015	Sec. Garin holds concurrent positions as DOH Sec and OIC of FDA. (6 months after the Aquino-Sanofi meeting in Beijing)
May 8, 2015	Completion of Sanofi requirements with the FDA. (Sec. Garin is acting FDA at this time)
May 11, 2015	Sanofi requests Sec. Garin for exemption from generic labeling.
May 14, 2015	Sec. Janette Garin went to Paris, France and met with Sanofi Pasteur Officials. (Sec. Garin is acting FDA DG at this time.)
May 15, 2015	• Sec. Janette Garin visits Sanofi Pasteur Neuville Dengue Vaccine Facility. (Sec. Garin is acting FDA DG at this time.) • Advance notice/Copy (meeting in Switzerland); Technical Consultation with Nat'l Regulatory Agency to Review Dengue Vaccine Dossier: summary – trip to Switzerland (July 28 – 30, 2015)
May 18, 2015	Email of Lulu Santiago to Grace L. Medina cc: Melody M. Zamudio: *"Kumpleto na ba? Any submission recently? Please advise. Meeting Sec. Garin later to inquire about the progress."*? Email Subject: Sanofi Pasteur's Rolling Submission of Dengue Vaccine
May 18 – 26, 2015	Sec. Garin went to WHO Assembly Meeting in Geneva.

June 9, 2015	Sec. Janette Garin negotiated with Sanofi to reduce the cost of the vaccines (in Manila).
October 29, 2015	Sanofi applied to be included in the Philippine National Drug Formulary. This will allow all government hospitals and pharmacies to use Dengvaxia.
November 3, 2015	Sec. Garin relinquishes her position as OIC DG of FDA as concurrent DOH Secretary and FDA.
November 4, 2015	Sec. Garin designates Ma. Lourdes Santiago as OIC DG of FDA (Term of office: Nov 4, 2015 - August 2016)
November 17, 2015	Sanofi Pasteur CEO and President Oliver Charmeil met with Philippine officials, including DOH in Manila during the APEC Summit.
December 1, 2015	President Benigno S. Aquino III meets with Sanofi officials for the second time in a year – this time in Paris, and negotiates a discount with Sec. Garin.
December 2, 2015	Sec. Garin (while still in Paris) sent an e-mail to then FDA OIC DG Ma. Lourdes Santiago asking her when the CPR for Dengvaxia will be released.
December 10, 2015	Garin submitted a proposal to DBM for Health Facilities Enhancement Program Funding & Procurement of 3 million doses of Dengvaxia for 1 million vaccinees.
December 11, 2015	Dr. Mariano Baquilod submitted justification for the procurement of dengue vaccine under the National Dengue Prevention Program upon instruction of the Office of the Secretary of Health- Dr. Joyce Ducusin. This should have been used as basis before the proposal submitted to DBM by Sec. Garin for Health Facilities Enhancement Program – which was done a day before. *This is highly irregular.*
December 18, 2015	FDA OIC Ma. Lourdes Santiago sent an e-mail to Grace Medina (one of the evaluators of Dengvaxia), copy furnished Melody Zamudio, asking for status on the completion of the Dengvaxia review for her meeting with Sec. Garin regarding the matter. (This was made pursuant to the follow-up of Sec. Garin's email on Dec. 2, 2015) *It shows that they have not yet completed the review and yet Sec. Garin already requested for the budget ahead of Dr. Baquilod's recommendation submitted on Dec. 11, 2015.*
December 22, 2015	FDA approved the marketing of the Dengvaxia as a prescription drug. FDA issued Certificate of Product Registration and approved the label as presented by Sanofi. Signed by Melody Zamudio.
December 23, 2015	MEMORANDUM for President issued by DBM Secretary Florencio Abad recommending: Funding of projects from FY2015 savings from the Miscellaneous Personnel Benefit Fund (MPBF) and Pension Gratuity Fund (PGF) so they can be obligated and/or disbursed before the end of 31 December 2015. *This is 22 days after the meeting of Pres. Aquino with Sanofi in Paris.*

December 28, 2015	1. DBM asked Expanded Program for Immunization (EPI) to prepare procurement documents for the dengue vaccine. 2. Dr. Ducusin requested for exemption from the Formulary as instructed by the Secretary of Health.
December 29, 2015	SARO released and signed by ES Paquito Ochoa, by authority of the President.
January 2016	Sec. Garin informed Dr. Julius Lecciones, Executive Director of the Philippine Childrens' Medical Center, about the plan to implement Dengvaxia vaccination.
January 4, 2016 published by ABS-CBN	Sec. Garin announces on national television in an interview with Karen Davila that children will be given an anti-dengue vaccine.
January 7, 2016	During the FEC Meeting, Dr. Ducusin said that they are not ready to implement the program and this was not part of the plans for 2016, but since this was approved by DBM, the program would proceed, in spite of the fact that Dr. Ducusin asked for an exemption following the instructions of Sec. Garin on Dec. 28, 2015.
January 25, 2016	Arrival of 145,250 doses of Dengvaxia. (Manufactured on October 31, 2014) – over a month and a half after the Paris meeting with Pres. Aquino.
January 27, 2016	Usec. Kenneth Hartigan-Go sent an e-mail to Lulu Santiago, Melissa Guerrero, Beng and Lyndon Lee Suy requesting for urgent protocol to prevent preventable problems, for briefing to the President.
February 1, 2016	Pre-bid Conference was conducted by PCMC.
February 3, 2016	FEC recommends one-year exemption for use of Dengvaxia on a limited basis for phased and localized and staged procurement, and subject to other conditions. Sec. Garin issued Certificate of Exemption of Dengue Tetravalent Vaccine.
February 9, 2016	Sanofi's 2015 Earning's Call - Sanofi CEO Oliver Brandicourt announced that initial shipments of the vaccines arrived in the Philippines at the end of January 2016.
February 11, 2016	Additional Doses of Dengvaxia arrived in the Philippines - 397,225 doses, manufactured on October 31, 2014
February 15, 2016	Scheduled submission and opening of bid
February 19, 2016	MOA between DOH and PCMC was finalized and notarized.
March 2, 2016	Notice of Cash Allocation was issued by DBM to DOH amounting to P4.5 B. (P3.5 B of which is for Dengue)
March 8, 2016	Notice of Award issued by PCMC to Zuellig
March 8, 2016	Fund transferred to PCMC total amount of P 3B DISBURSEMENT VOUCHER signed by Sec. Garin was issued for transferring of funds to PCMC.
March 9, 2016	PURCHASE ORDER was issued by PCMC to Zuellig Pharma.

March 11, 2016	Issuance of Notice to Proceed by PCMC to Zuellig Pharma.
April 14, 2016	WHO SAGE released guidelines for use of Dengue vaccine
May 8, 2016	Election Day for national and local government officials
June 23, 2016	MOA between PCMC and Zuellig for the contract price of P 3B
August 4, 2016	Nela Charade G. Puno became the DG of FDA
February 10, 2017	Arrival of 598,550 doses of Dengvaxia manufactured on September 28, 2015; 16,260 doses of Dengvaxia manufactured on September 25, 2015; and 388,625 doses of Dengvaxia manufactured on September 25, 2015
November 29, 2017	Official statement from Sanofi regarding the possible adverse effects of Dengvaxia on seronegative: "...Based on up to six years of clinical data, the new analysis evaluated long-term safety and efficacy of Dengvaxia in people who had been infected with dengue prior to vaccination and those who had not. The analysis confirmed that Dengvaxia provides persistent protective benefit against dengue fever in those who had prior infection. For those not previously infected by dengue virus, however, the analysis found that in the longer term, more cases of severe disease could occur following vaccination upon a subsequent dengue infection..."
December 29, 2017	FDA Director General Nela Charade Puno fines Sanofi and suspends clearance for Dengvaxia.

III. FINDINGS AND EXPLANATION

ISSUE NO. 1: **There was no effective vaccine against Dengue existing. There was not an urgent need for a mass vaccination for Dengue. The program was not a priority.**

FINDINGS:

Dengvaxia was never truly established as a safe, efficacious, cost-effective, and ethically acceptable vaccine for use against dengue unlike those against polio, measles, rubella, diphtheria, pertussis, tetanus, and hepatitis-B,

among others. There had not been at that time; verily there is none up to today. The deliberate and willful use of Dengvaxia on 830,000 people on a wide scale has put a lot of lives at risk.

The President deemed necessary the procurement of Dengvaxia even if it wasn't established as a safe, efficacious, cost-effective and ethically acceptable vaccine for use against dengue, and despite prior warnings from several health experts.

DISCUSSION:

WHY IS IT NOT SAFE?

Dengue is a mosquito-borne viral disease that is present in all regions of the world but is predominantly endemic in warm and tropical places. Dengue virus is transmitted by female mosquitoes mainly of the species *Aedes aegypti* and, to a lesser extent, *Ae. albopictus*. This mosquito also transmits chikungunya, yellow fever and Zika infections. The virus is transmitted to humans through the bites of infected female mosquitoes. After a virus incubation for 4–10 days, an infected mosquito is capable of transmitting the virus for the rest of its life.

Infected symptomatic or asymptomatic humans are the main carriers and multipliers of the virus, serving as a source of the virus for uninfected mosquitoes. Patients who are already infected with the dengue virus can transmit the infection (for 4–5 days, up to a maximum of 12) via Aedes mosquitoes after their first symptoms appear.

There are 4 distinct, but closely related, serotypes of the virus that cause dengue (DEN-1, DEN-2, DEN-3 and DEN-4). Recovery from infection by one serotype provides lifelong immunity against that particular serotype. However,

cross-immunity to the other serotypes, after a patient's recovery, is only partial and temporary. Subsequent infections by other serotypes increase the risk of developing severe dengue. By exemplification: if a person is bitten by a mosquito carrying DEN-2, he/she after recovery will develop a lifetime immunity against DEN-2; he/she may have immunity for DEN-1, DEN-3, and DEN-4 but that immunity, if at all present, will only be for some of the three but not all. That partial immunity will likewise be temporary, or will wane in the future. Thus, a person who has previously been bitten is in a subsequent bite predisposed to severe dengue.

It is usually the second episode of infection that can result in severe dengue, that if not properly managed can cause life-threatening complications due to plasma leaking, fluid accumulation, respiratory distress, severe bleeding, or organ impairment. The disease is characterized by a high fever that abates, followed by warning signs that occur 3–7 days after the first symptoms in conjunction with a decrease in temperature (below 38°C/100°F) accompanied by a range of possible symptoms such as: severe abdominal pain, persistent vomiting, rapid breathing, bleeding from the nose, gums, vomiting blood, bloody stools, fatigue, and restlessness. The next 24–48 hours of the critical stage can be lethal; however, this can be managed by timely and appropriate medical care to arrest complications and minimize the risk of death.

Dengue is widespread throughout the tropics, with local variations in risk influenced by rainfall, temperature and unplanned rapid urbanization.[1]

There was, and there still is, no known cure for or medicine against a dengue infection. The World Health Organizations says that, "There is no specific

[1] http://www.who.int/mediacentre/factsheets/fs117/en/

treatment for dengue fever. For severe dengue, medical care by physicians and nurses experienced with the effects and progression of the disease can save lives – decreasing mortality rates from more than 20% to less than 1%. Maintenance of the patient's body fluid volume is critical to severe dengue care.[2]

In the ASEAN, it was only the Philippines that introduced Dengvaxia without the benefit of a more extensive Stage IV or post-marketing surveillance studies or monitoring of the effects of the drugs on a manageable population size over a longer period of time. Singapore gave a license for Dengvaxia but for limited use in the age-group 12-45 as a prescription drug, i.e., that a doctor prescribes its use, with a concomitant assurance that the doctor who had administered it could closely monitor the patient on whom the vaccine was injected. Its Ministry of Health did not recommend the rolling out of Dengvaxia vaccination as a national program as it would not be a clinically and cost-effective means to tackling dengue infection. In Malaysia, not only did they not allow mass use but they did not allow private use, as well. Sanofi was required to go through Stage-IV of clinical testing before Malaysia would allow continuance of registration. They, in Malaysia, felt that the 60% efficacy rate for all serotypes was not convincing for large-scale use. Besides, they claimed, that Dengvaxia was shown to be least effective against the most current prevalent type in Malaysia, DEN-2. It must be noted that DEN-2 is also the most prevalent in the Philippines.

The makers of Dengvaxia is Sanofi- Pasteur, a pharmaceutical company that is, like any other for-profit entities, rooted in making profits for its owners/shareholders/investors. It is not an eleemosynary corporation. While it may be credited for the manufacture of drugs that may have helped cure diseases or ease the pains of long-suffering patients; it has a sordid past:

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[2] http://www.who.int/mediacentre/factsheets/fs117/en/

1. French pharmaceutical giant Sanofi-Aventis has agreed to pay $190 million to settle a probe into whether it overcharged U.S. government health care programs, the government and company said Sept. 10. The U.S. Department of Justice said the firm agreed to the payments to federal and state governments "to resolve allegations that the company caused false claims to be filed with Medicare and other federal health programs as a result of the company's alleged fraudulent pricing and marketing of drugs."
2. French drugmaker Sanofi-Aventis was fined $52.6 million by the French competition authority May 13 for marketing practices that discouraged sales of generic versions of the company's blood thinner Plavix.
3. HUF 9,000,000 fine against Sanofi. In its decision No. OGYEI/53987/2016 of October 9, 2017, the National Institute of Pharmacy and Nutrition ("OGYEI") fined Sanofi-Aventis Zrt HUF 9,000,000 (approx. EUR 29,100) for providing prohibited payments (transfer of value) to healthcare professionals.
4. Competition agency fines Sanofi-Aventis, two distributors almost UAH 140 mln for supplies in 2010-2011.
5. In its 18 October judgment the French Cour de Cassation upheld the €40.6m fine imposed on Sanofi-Aventis ("Sanofi") by the French Competition Authority ("FCA") in May 2013 and affirmed the judgment of the Paris Court of Appeal. The FCA found that Sanofi abused its dominant position in violation of Art. 102 of the Treaty on the Functioning of the European Union ("TFEU") and art. L.420-2 of the French Commercial Code by denigrating generic competitors of its drug Plavix on the French clopidogrel mat.

6. Sanofi, France's largest drugmaker, is the latest foreign firm to be implicated in a corruption crackdown carried out by Chinese authorities. The Paris-based company has been accused of paying bribes, disguised as research grants, totaling 1.69 million yuan to 503 doctors at 79 hospitals in Beijing, Shanghai, Guangzhou and Hangzhou in 2007, state-owned news agency Xinhua reported.

7. On 3 September 2015, Genzyme Corp, a biotech subsidiary of Sanofi, had distributed promotional material for Seprafilm that implied that Seprafilm had been proven safe and effective for use in gynecologic cancer surgeries, even though Seprafilm's FDA-approved label cautioned that the device had not been clinically evaluated in the presence of malignancies. A $32.5 M fine was imposed against it.[3]

8. On December of 2012, Sanofi US violated the False Claims Act by giving physicians free units of Hyalgan in violation of the Anti-Kickback Statute, to induce them to purchase and prescribe the product. The settlement also resolves allegations that Sanofi US submitted false average sales price (ASP) reports for Hyalgan that failed to account for free units distributed contingent on Hyalgan purchases. The government alleges that the false ASP reports, which were used to set reimbursement rates, caused government programs to pay inflated amounts for Hyalgan and a competing product. A $109 M fine was imposed.[4]

9. From 2007 to 2012, allegations were made in the Middle East and East African countries that Sanofi bribed the doctors in Eastern African

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[3] https://www.justice.gov/opa/pr/genzyme-corporation-pay-325-million-resolve-criminal-liability-relating-seprafilm

[4] https://www.justice.gov/opa/pr/sanofi-us-agrees-pay-109-million-resolve-false-claims-act-allegations-free-product-kickbacks

and Middle East Countries to persuade them to prescribe its drugs. The alleged bribes involved gifts and other perks.[5]

We can go on and on.

Given the above information, already available when we entered into the contract, it behooved us in government to have looked closely into the company and should have considered its history when we entered into an agreement with them. Most of the information we have culled about Dengvaxia and Sanofi's history of improprieties were, and still are, facts available in the public domain.

Dengvaxia was first introduced into the Philippines when Sanofi included our country in the clinical trials of the drug. With the cooperation of local counterparts – e.g. Dr. Rosario Capeding – Sanofi conducted Phase III trials in San Pablo City Laguna, and Cebu City in June 2011-13. The trials were supposed to end in November of 2017 yet. But for reasons known only to them, former President Aquino and former Secretary Garin, endeavoured to rush pell-mell into mass vaccination in early 2016.

If there indeed was savings from the budget of government, the monies could have been better spent to address more effectively on other vaccines that are not available nationwide or any of the top ten causes of morbidity and mortality. How many thousands of Filipinos die of these diseases without even seeing a doctor, much less the inside of a hospital? Six out of 10 sick Filipinos die without seeing a doctor, revealed a 1990 study by the UPecon Foundation,

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[5] https://www.reuters.com/article/sanofi-corruption/sanofi-says-told-u-s-about-bribery-claims-in-africa-mideast-idUSL6N0S14H320141006

Inc. (UFI) of the UP School of Economics (SE). Twenty years later, the same statistics held true, according to the UP National Health Institute.[6]

WHY IS IT NOT EFFICACIOUS?

- In Malaysia, they felt that the 60% efficacy rate for all serotypes was not convincing for large-scale use.
- On March 28, during the election campaign, the Dengue SBI Command Center Duty commences. In a press conference, DOH Secretary Janette Garin proudly said the Dengvaxia vaccine has undergone over 20 years of study and extensive clinical trials and has been vetted by international medical experts, even earning the approval of the World Health Organization (WHO).[7] It must be stressed that Garin here was touting a half-truth, at best; or a lie, at worst. The WHO does not approve nor license drugs. While undeniably there were clinical trials conducted to determine efficacy and safety of Dengvaxia, the clinical trials here were not yet over, and the results thus were incomplete.

WHY IS IT NOT COST EFFECTIVE?

The total budget of the EPI is only ₱3.3 Billion for vaccines against 11 diseases namely tuberculosis, hepatitis B, influenza, poliomyelitis, diphtheria, tetanus, pertussis and measles, mumps, rubella and pneumococcal infections not only protect individuals, but arrest the spread of the disease for the whole country. This, as opposed to Dengvaxia vaccine amounting to ₱3.5 Billion

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[6] https://upd.edu.ph/economics-for-better-health/

[7] https://www.rappler.com/science-nature/life-health/127318-doh-dengue-vaccine-safety

targeted for just one disease and for only 3 vote-rich regions to begin with, and another 1 eventually.

The government introduced vaccination as part of the dengue prevention and control program in 2016, by providing an additional ₱3.5 Billion for this singular vaccine. Dengue vaccination is not part of the current EPI. The concept of "herd immunity" is critical for mass vaccination programs. The primary consideration for introducing a new vaccine would be to be able to interrupt the transmission of a disease by sufficiently protecting large segments of a population through development of antibodies in the vaccinees. The EPI program for the whole country is premised on the principle of herd immunity. Thus vaccines against tuberculosis, hepatitis B, influenza, poliomyelitis, diphtheria, tetanus, pertussis and measles, mumps, rubella and pneumococcal infections not only protect individuals, but arrest the spread of the disease.

In general, vector-borne diseases are more difficult to control without elimination of the Aedes aegypti vector. The total budget of the EPI is only ₱3.3 Billion. It is noted that coverage for the EPI for the fully immunized child (FIC) has dropped from 95% in 1995 to 62% in 2015,[8] and a major measles outbreak occurred throughout the country in 2014. Some highly effective vaccines, including those against pneumococcal infection causing pneumonia which is a leading cause of death among children under 5, is not available in all regions of the country due to lack of funds. In short, this novel vaccination intervention conceived to cover only schoolchildren in Regions 3, 4-A, and NCR was going to – and did – cost government monies nearly equivalent as that for EPI for all regions altogether, and would potentially create individual protection for some

[8] Department of Health, National Health and Demographic Survey 2017

children but would be unable to create "herd immunity" or break the transmission of dengue in the areas specified or even in the age-group targeted.

WHY IS IT NOT ETHICALLY ACCEPTABLE?

Here was not a simple mistake, or simple negligence. The administration leaders Aquino and Garin just did not give two hoots. They knew, because they were informed that the drug had not finished its trials yet. Yet they ignored the warnings.

There even were earlier warnings that were made known to, or that Sanofi had known or should have known. A Reuters article entitled, "Did Sanofi, WHO ignore warning signals on dengue vaccine?" said "Four decades ago, Dr. Scott Halstead, a leading figure in dengue research, first proposed that antibodies from an initial exposure to one of four types of the disease could increase the risk of a potentially lethal complication called severe dengue when a person is infected a second time, a process know (*sic*) as antibody-dependent enhancement or ADE." Halstead, an adjunct professor at the Uniformed Services University of the Health Sciences in Bethesda, Maryland, said when he saw Sanofi's 2015 paper, he was convinced the increased risk that some children would contract severe dengue was evidence of ADE. Halstead wrote a series of papers published in Vaccine, the Journal of Infectious Diseases and other journals urging Sanofi and the WHO to proceed with caution in rolling out the vaccine.

During the 13 March 2018 hearing, Dr. Scott Halstead had these to say regarding his communications with Sanofi:

1. "In 2001 on, I organized annual meetings where I invited Sanofi and all the different vaccine manufacturers. So, I've been watching the Dengvaxia come from an idea all the way through to fully realize the product."[9]

2. "As you can see, because I've been listening to Sanofi every year for 15 years and in summer of 2015 when the three-year review of Sanofi results was published in the New England Journal of Medicine and when I read that two to five-year old children were hospitalized at a high rate than they ..., if I've been here, you would have seen me, I fell off my chair."[10]

3. "This vaccine very likely was sensitizing seronegatives so that when they experience their first dengue infection, they were more sick. That is why this is the class that I can see. xxx In other words, the vaccine is leaving you with antibodies that are not protective but they are actually able to change the nature of the subsequent infection. ."[11]

4. "So that is why in that paper I made a suggestion that before the Dengvaxia is given to anybody, there should be a blood test so that the people who were seronegatives will be excluded and the people who were seropositives who will benefit—there is a benefit to the Sanofi vaccine that they could be identified and vaccinated. And everybody said, "Ha, ha, ha. Nobody has ever done that before. That is impossible." But, I am sorry, it is not ha, ha, ha. It is not impossible.

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[9] JLFLORES III-1 March 13, 2018 10:27 a.m.

[10] JLFLORES III-1 March 13, 2018 10:27 a.m. 7

[11] SMVilladiego IV-1 March 13, 2018 10:37 a.m.

> We have tested, made and used by millions of people all over the world and it's a different requirement. But what this vaccine required was to have a pre-test screen so that the vaccine can be directed to people who benefited."[12]

Sadly, the warnings did not end there. The Formulary Executive Council, during deliberations for a proposed Dengvaxia exemption, conditionally recommended approval of the drug's exemption, but urged that eight (8) conditions as pre-requisites towards its approval be followed:

a. Phased and localized implementation of the vaccination program;
b. Staged procurement;
c. There should be an FDA-approved risk management plan from Sanofi-Pasteur as part of the pharmacovigilance requirement of the FDA;
d. An approved protocol for post-licensure study by Sanofi;
e. Plan for training of personnel and implementation by the EPI;
f. Operational guidelines on the use and administration of the dengue vaccine;
g. Appropriate risk communication to parents and schoolchildren about the extent of protection provided by the vaccine. Therefore, personal protection and environmental interventions should continue to be implemented;
h. The DOH should actively monitor the outcomes in order to determine the real clinical value of the dengue vaccine that will help determine the real time cost-effective price for the government.[13]

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[12] Ibid.

[13] Minutes, Third Meeting of the FEC, 1 February 2016

On the hearing of 13 March 2018, Dr. Imelda Peña of FEC admitted that six out of the eight conditions laid out by the FEC were not complied with by the DOH. Of the eight conditions recommended by the FEC, Dr. Garin disregarded most of the important recommendations, exempted Dengvaxia from the National Drug Formulary, bought the drug, and approved its introduction and implementation through mass vaccination.

Tragically, dire warnings, recommended conditions before approval, strong suggestions, and other notices went unheeded. The leadership of government, and those especially at the DOH, were hell-bent on implementing the vaccination program. That Garin ignored the well-thought-out and strong advice of experts shocks the conscience. Former Undersecretary Dr. Kenneth Hartigan-Go in an FEC meeting explained that Dengue vaccine purchase was not planned; however, a political decision to allot the budget from the national agencies' savings was already made by a higher committee. He also emailed, on 27 January 2016 at 8:09am Lourdes Santiago, Melissa Guerrero, Regina Obligacion, **and Lyndon Lee-Suy** "to fast-track this work; otherwise we all get into trouble or create preventable problems. Please give 99.9% of your effort to resolve this. Pick up the phone and talk to each other. Keep me informed by noon pls…" Just because FEC says so as recom (*sic*) does not mean absolute requirement as such. Exercise of science is not easy but the decision-maker is DOH." In bureaucratese, these communications smacked of hectoring the FEC to speed up the process, even if haste was not necessary. What is more disappointing, if not nauseating, is that a scientist allowed politics to trump science.

Alas, because of the political decisions made supposedly on their behalf: for the children who were vaccinated with Dengvaxia, the possibility of future tragic

and severe infections still and will continue to hang – like the proverbial Damocles sword – over their heads, even up to their adulthood.

The testimony of Dr. Antonio Dans, during the last hearing of 13 March 2018, warned us of the grim possibility that initial reduction in severe dengue in the early years after vaccinations will give rise to severe dengue cases that will be seen first among the young; the rise in severe dengue may later be seen in all age groups; and that the rise in severe dengue may persist into adult life.

It cannot be gainsaid, thus, that there was prior evidence that seronegative children should not be vaccinated. The Phase 3 trial was not yet over, the New England Journal of Medicine 24 September 2015 Hadinegoro, et al. article on the long term safety and efficacy of a dengue vaccine said that **monitoring was still continuing** in order to evaluate **a potential predisposition** in vaccinated persons to increased severity of the disease. Relative risk, by Year 3, among the young was computed at 7.4 (for <5 years old), and 8.3 (for <9years old). This viewed in relation with a norm that relative risk for a drug's safety, should ideally be less than 1. Furthermore, of the four dengue strains, DEN-2 is most prevalent in the Philippines and Dengvaxia is not the proper vaccine. Ironically, the drug is least effective, among the four strains, against DEN-2.

Mr. Leroy (Sanofi Vice President) mentioned, among others, that it (Dengvaxia) works better with "**(a) population who already have contracted the dengue virus"** (i.e., stronger efficacy for those who have already been previously infected.) This statement was made in 1 December 2015 during a meeting with the former President and Garin. Thus, Sanofi knew that Dengvaxia had better efficacy in seropositive children. He had not disclosed however that the drug was deleterious to seronegative persons.

Dengvaxia did not even have a country-of-origin approval, violating "Part I, Section 3, For imported products, b. Certificate of Pharmaceutical Product issued by the competent authority in the country of origin according to the current WHO format."[14] Neither did it have countries of reference, e.g., US FDA, TGA Australia, or from Japan – a deviation from the customary practice in DFA.

France, where Sanofi is headquartered, has not allowed Sanofi use. In point of fact, a Reuter article of 6 December 2017 said, "Documents issued in 2016 by the Haut Conseil de la Sante Publique, a public body close to the French health ministry, show France's overseas territories were also warned of risks linked to the vaccine. The health body advised in June 2016 that the vaccine not be used in territories such as the Caribbean islands of La Martinique and Guadalupe and French Guiana on the grounds that its effectiveness was not demonstrated with people who had not previously been exposed to the virus. In October 2016, it also warned of safety risks."[15]

But, our leaders, nonetheless, saw fit to introduce Dengvaxia even while the trials were not concluded (it was supposed to end in November of 2017), even after they were made aware of the potential risks, despite knowing that the drug was least effective against the most prevalent strain hereabouts, and in spite of the knowledge that Dengvaxia was not licensed in France – its home country. It can never be said that the decision to launch Dengvaxia was evidence-based (as should have been the case); otherwise other countries would have allowed the use of the drug for mass vaccination. But they did not, they

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[14] Philippine FDA Rules

[15] https://uk.reuters.com/article/uk-sanofi-dengue-france/france-advised-against-sanofis-dengue-drug-for-its-territories-idUKKBN1DZ2BU

instead decided to either postpone the approval, or allowed its use but NOT for mass vaccination.

ISSUE NO. 2: Dengvaxia was not the correct way to go in preventing Dengue infections.

FINDINGS:

Dengue does not belong to the top 10 causes of morbidity and mortality in the Philippines hence there was no special need for vaccination, much less Dengvaxia. In fact, of the 560,605 registered deaths from all causes and all ages in 2015, deaths caused by suspected dengue is 598 or .001% of total deaths in the country.

DISCUSSION:

In the Philippines today, the top ten causes of mortality are:

1. Diseases of the heart
2. Diseases of the vascular system
3. Malignant neoplasms, or cancers
4. Pneumonia
5. Accidents
6. Tuberculosis, in all forms
7. Chronic lower respiratory diseases
8. Diabetes mellitus
9. Nephritis, nephrotic syndrome, and nephrosis
10. Certain conditions in the perinatal period

The top ten cases of morbidity are;

1. Acute Respiratory Infection

2. Acute Lower Respiratory Tract Infection and Pneumonia
3. Bronchitis/Bronchiolitis
4. Hypertension
5. Acute Watery Diarrhea
6. Influenza
7. Urinary Tract Infection
8. TB Respiratory
9. Injuries
10. Disease of the Heart

As can be seen, dengue (and its four strains: DEN-1 up to -4) is not among the top ten causes of deaths hereabouts; neither is it among the top ten causes of illnesses. Dengue infections in 2015 numbered 72,627, with 372- 598 deaths[16]. It is noted that the number of cases of dengue reported by the Department of Health are "suspected cases", based only on clinical manifestations and that testing for dengue among individuals who are hospitalized for fever is not a routine examination in the Philippine government program for dengue prevention and control. Suffice it to say that dengue, while debilitating, needs to be properly diagnosed and that dengue is difficult to distinguish from chikungunya, Zika, and influenza among others. In the Philippines, infections of DEN-2 are documented to be more common than other serotypes.

The previous effort of government was mainly vector control – to prevent the mosquitoes from breeding, flying around, and infecting people. Emphasis was placed on cleaning the surroundings, removing or ridding from the

[16] https://www.rappler.com/nation/143318-doh-philippines-dengue-updates-january-august-2016 -suggest we use the DOH website statistics. I think this is not correct.

environment places where the vectors could lay eggs and breed, etc. Defogging, although believed by many to be ineffective as it just drove away the mosquitoes from one place to another, was still nonetheless undertaken. Nonetheless, even if you do just full vector control and defogging there are 100,000 – 200,000 suspected cases of dengue occur every year (based on 2015 DOH data) – most of which are mild. In 2015, to reiterate, there were 560,605 registered deaths from all causes and all ages. This gives us a mortality rate of .001% for dengue.

ISSUE NO. 3 : Dengvaxia was not properly, ethically and legally procured.

FINDINGS:

The hearings provided us a clear picture of a process that can only be characterized by the phrase "undue haste." *(Inapura masyado).*

The former President Aquino meets with representatives of Sanofi. He met with Jean-Luc Lowinski, Senior Vice President for the Asia Region of Sanofi at the Philippine Embassy in Beijing, People's Republic of China on 9 November 2014. Here they mentioned to the President that they have been developing a vaccine for dengue which will hopefully be out by 2015 (the year following).

The second meeting was held on 1 December 2015. Former President Aquino III together with DOH Secretary Janette Garin went to Paris for the UN Conference on Climate Change. During this visit, President Aquino received Sanofi Pasteur officials at the Hotel Scribe, Paris.

Based on the notes of the Philippine Ambassador to France, Sec. Garin said that "there is now a faster FDA approval process in the Philippines. Normally it

would take two to three years for licensing approval but this was reduced to 500 days and now, one year."[17]

On the final result of the vaccine, Mr. Leroy (Sanofi Vice President) mentioned, among others, that it **works better with (a) population who already have contracted the dengue virus (i.e., stronger efficacy for those who have already been infected.)**

In that meeting, Garin was already talking about a faster approval in re FDA processes; while Sanofi talked about the vaccine being more effective for those previously infected, *or for those who were seropositive*. Aquino and Garin were also negotiating with Sanofi already as to the price.

In an interview with Karen Davila, posted in YouTube on 4 January 2016, she beamed with undisguised giddiness that, "we are proud to be part(sic) of the dengue vaccine... just after Christmas, the President found out that the total cost(burden) of dengue was P16 Billion a year (on another occasion the former President asserted that P58.2 Billion would be needed to address the problems brought about by dengue) ...NCR, Regions 3 and 4-A carry ¾ of the total burden of dengue...safety had not been established for those above 45 years old (thus they were not included)...during the APEC napag-usapan na bumaba yung presyo...When the President visited Paris for the COP 21, he had a meeting with the executive of this company and we were given an additional 34% discount... part of the agreement was that for every private patient that will be injected or that will be procuring the vaccine, part of the income will be used to subsidize the government..."

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[17] Reference the DFA notes

Here she tells us that they (although she only mentioned the President, she was also there during that meeting) were able to get a substantial discount. That could only be reached through a negotiation, through a "tawaran." This brings the question, how can the President negotiate a commercial transaction, period? Additionally, how can he negotiate for the supply of a drug that was not even a part of the National Drug Formulary, much less licensed by the FDA for use in the Philippines?! How can he negotiate with the supplier of the vaccine sans compliance with the Procurement Law?

Verily, something was very rotten here. Laws were definitely not being followed, broken even, e.g., the Procurement Act, to mention only one.

While still in Paris, Garin emails her subordinates in Manila on December 2, 4:17am, "Hi Lulu, when will the CPR for Dengue vaccine be probably released?" Ms Santiago (Lulu) replies on the same day at 11:29am, "We are trying the (*sic*) have the final assessment report done until second week of December po. THE EVALUATORS ARE JUST FINALIZING THE EVALUATION REPORT OF THE SAFETY AND EFFICACY PART OF THE DOSSIER. I'll keep you posted po Ma'am." Garin finally sent her email in response, "Okay, just keep me posted. Thank you." Garin was following up, or hurrying up, the approval process with her subordinate. It appears that every time Aquino and/or Garin meets with Sanofi officials, the processes moved along at a faster pace.

It must be borne in mind that Garin also had her own meetings with Sanofi previous to this. While concurrently DOH Secretary and FDA Officer-in-Charge (she designated herself such in a memo. This designation lasted from 5 May 2015 to 3 November 2015) she met with Sanofi officials on 14 May 2015. Sanofi (Mr. Guiallame Leroy) inquired on the possibility of having the vaccine launched

in the Philippines, possibly in the presence of the President." Garin expressed some concerns, but generously offered Sanofi tips on how to overcome possible problems, Sec. Garin inquired on the prices of the vaccine and stated that it may be too expensive for PH government to fully cover and may not be possible to include in the 2016 DOH budget. But, appearing to teach Sanofi how to ensure success, she presented the following scenarios as feasible:

Sanofi and private sector will launch the vaccine, Garin commented that it would be difficult for DOH to buy vaccines if it is not yet being used in the Philippines. A private launch and widespread "private use" will create a demand for the vaccine and will thus pave the way for DOH to include in succeeding years' budget.[18] The day following, Garin visited the Sanofi Pasteur Neuville Dengue Vaccine Facility. Information was given her by Sanofi that the facility was a big investment on the part of the company as it did not follow the normal model for the launch of a vaccine. Normally, pharmaceutical companies build industrial facilities only after the licensing and approval of the product. From start to finish of the production process, it would take 18-24 months to produce the vaccine. Inventory is not kept but the question is, why were there deliveries that showed several manufacturing dates of Dengvaxia that showed that Sanofi already had them already in stock?

After the December meeting, things now move swiftly.

By December 10th (2015), Garin submits a proposal to Department of Budget and Management (DBM) for Health Facilities Enhancement Program (HFEP) funding, as well as procurement for three (3) million doses of Dengvaxia. The following day, December 11th, Dr. Mario Baquilod (Director IV, Disease

[18] Reference the DFA notes

Prevention and Control Bureau, DOH) upon instruction of the Office of the Secretary, submits justifications for the procurement of dengue vaccine under the National Dengue Prevention Program (NDPP). Note that this justification is written for the purpose of funding the program, not for exemption from the National Drug Formulary. Nonetheless, here is a strange situation where a justification is proffered only after a proposal had already been submitted- a case of putting a cart before the horse.

By December 18th, of the same year, FDA OIC Dr. Maria Lourdes Santiago emails Grace Medina, one of the Dengvaxia evaluators, copy furnished Melody Zamudio, asking her on the status of the Dengvaxia review as she will meet Garin regarding the matter.

On December 21st or three days later, a meeting was held where declaration of savings was discussed – to **augment** items of appropriations for various urgent projects. This can be gleaned from a Memorandum for the President by Secretary Florencio Abad. Notice, however, that the meeting was to discuss augmentation (of current programs), not funding of a new program. Contained in the GAA was funding for EPI (Expanded Program for Immunization), which did not include anti-dengue vaccine as an item or as part of EPI. Thus, if any augmentation was to be made it definitely should not be for buying Dengvaxia.

The day following, 22 December 2015 (this was about three weeks after the President negotiated and got a discount from Sanofi, according to Garin), The Food and Drug Administration (FDA) approved the marketing of the Dengue Tetravalent Vaccine (Dengvaxia), by issuing a Certificate of Product Registration

(CPR). The CPR was signed by Dr. Melody Zamudio. This happens two working days after Santiago's email to Medina, copy furnished Zamudio.

There was a memorandum from former DBM Secretary Florencio Abad to the President dated 23 December 2015 requesting for authority to declare savings to augment items of appropriation for various urgent projects.

By the 28th, a Monday, Feast of the Holy Innocents, DBM asked EPI to prepare procurement documents for the dengue vaccine. On this same day, or only two working days after Dengvaxia's CPR release, the DOH – Family Health Office submitted a request to Sec. Garin for Philippine National Drug Formulary (PNDF) exemption per EO No. 49 s.1993.

Things are now moving at break-neck speed. The PNDF exemption is very important here, because unless a drug is listed, government cannot buy that drug.

On 29 December 2015, a memorandum is sent from former Executive Secretary Paquito N. Ochoa, Jr. to Secretary Abad informing the latter that the President approved the "DBM REQUEST FOR AUTHORITY TO USE SAVINGS TO AUGMENT ITEMS OF APPROPRIATION FOR VATIOUS URGENT PROJECTS," which included, *inter alia*, Yolanda-related projects for DPWH and Dengue vaccine for DOH, sourced from savings from the FY 2015 Miscellaneous Personnel Benefits Fund (MPFB) and savings from the FY 2014 GAA. On the **very same day**, a SARO was issued amounting to ₱3,556,155,900.00 in favor of DOH for the procurement of Dengue Vaccines for NCR, Regions III and IV-A. This is most unusual in, and hasty for government, that only two working days would elapse from a letter request (Abad's), to approval (by the President), and finally

to the issuance of a SARO. This was for a procurement of Dengue vaccine: a drug that was approved by the FDA only a week before. Dengvaxia was **not** even included in the PNF, and neither was an exemption from the PNF extant. While most government processes move glacially, especially during December, here was a case where the opposite happened—a Christmas miracle indeed.

Former Commissioner Bartolome Fernandez, in a 12 March 2018 letter submitted to the Committee had this to say in connection with the use of savings: "What was further unsettling was the alleged remark of the former Budget Secretary Abad made during the Senate hearing on the controversial transaction that 'it is normal for the government to use savings to purchase medicines.' It appears then that Abad was skating on thin ice, as it were, by making such an assertion. The questioned use of savings in the premises coupled with the absence of legislative appropriation to provide funding support thereto is an egregious error that has raised 'red flags.' "Clearly, the alleged use of savings, absent any supporting legislative appropriation to purchase the anti-dengue vaccines, is assailable as legally and constitutionally infirm."

On a January 4, 2016 published interview,[19] the first work-day in the New Year, Garin announced on national television that public school students in NCR, Regions 3, and 4-A will be selected to have three doses of dengue vaccines. How she could have announced, much less conducted, a dengue vaccination boggles the mind: there was only one dengue vaccine available in the world: Sanofi's Dengvaxia. While the drug may already have been granted a CPR only four (4) working-days before her announcement, she still could not have acquired it for government's mass vaccination: (1) FDA classified the vaccine as a prescription drug – necessitating a doctor's prescription and

[19] https://www.youtube.com/watch?v=SdpjZKLCFTs

monitoring; (2) government was not allowed to buy it as it was not in the list of drugs in the PNF; (3) neither did it have an exemption; and, (4) she was told in her visit to Sanofi Pasteur Neuville Dengue Vaccine Facility that. "(n)ormally, pharmaceutical companies build industrial facilities only after the licensing and approval of the product. From start to finish of the production process, it would take 18-24 months to produce the vaccine. Inventory is not kept." If true, Sanofi could only have commenced delivery the following year still.

Furthermore, in a statement made by Thomas Triomphe of Sanofi under oath, "(o)ur understanding was that the Philippine government **may** want to prioritize the Dengue vaccination program. We want it to be ready to serve the needs of the public which is why we import it in our warehouse and our own consignment. Should there be an order, we will deliver. Should there not be an order, we will not deliver. It is also to be noticed that we did the exact same thing for the private market; you import the product before launching the product. So, that is exactly what we did for public and private markets." In the 22 December 2015 minutes of the meeting of the FDA working group for approval of Dengvaxia, the representative (Anna Lea Remandes, Regional Area Manager) of SANOFI explicitly stated that "priority would be given to use of the vaccine by the Philippine government." How and why would SANOFI assume that the Philippine government would be the priority market when the drug was still being considered for licensing as a prescription drug and there was yet no approval for its inclusion in the Philippine National Formulary?

But we see here that she was absolutely confident that she and government would be able to acquire the vaccine. How then could she be so sure that the vaccine was going to be available? It is because in her and Former President Aquino's early December 2015 meetings with Sanofi they had most

certainly already placed an order for the vaccines. She even proudly crowed in an interview that the President and she were given a 34% discount. For one to be able to avail oneself of such a big discount, the sellers would have to know beforehand how many one was going to order, even before the procurement/bidding process started. And Sanofi, contrary to their statement in December, already had the drugs in stock and were ready to deliver. Because if Sanofi was truthful, when they previously said that it was going to take 18-24 months to produce, they could not have delivered in time for the mass vaccination. Both Garin and Sanofi are dissembling to justify the undue haste in acquiring the vaccine and in injecting it to unsuspecting children. To our grave misfortune, as they all committed serious ethical and legal transgressions against our people, the injected children's future remain dark.

That everything happened so fast is an understatement. Things were now moving at the speed of light.

After announcing to the public about the forthcoming anti-dengue mass vaccination, the Board of Trustees of the Corporate Specialty Hospitals (Chaired also by Secretary Garin) resolved on its January 19, 2016 meeting that the PCMC shall implement the Dengue Vaccine Operational research in Regions 3 and 4-A. Also raised during the said meeting was the issue on exemption of the vaccine from the Formulary, where Garin tasked Dr. Hartigan-Go to attend to the matter. On January 21, 2016, two days after the Board of Trustees designated PCMC to implement the program, a purchase request for Dengvaxia vaccine was made by PCMC.

On January 25, 2016, 145,250 doses of Dengvaxia arrived in the country though the formal bidding have not yet started and a certificate of exemption

from PNF had not been issued. How could that have been possible – unless they knew that there already was a market for it? It has then become apparent, that the order had been made by Aquino and Garin when they were in Paris, which is why she confidently made her statement on January 4 announcing the launch, and also why the shipments arrived even before the pre-bidding conference was held on 1 February 2016. The wheels had been greased and the machinery was running smoothly. It cannot be denied that Garin knew she was going to buy, and Sanofi knew that it was going to be able to successfully sell the vaccines even long before all obstacles – the required government procedures – were ironed out; and, those who were assigned sentinels to man the ramparts of government were already coopted.

On 3 February 2016, Garin issued a Certificate for the Exemption of Dengue Tetravalent Vaccine from the PNDF contrary to FEC recommendations. In order to pursue further her unholy designs, she had to do this- the drug had arrived, money was already provided for by Malacañang, and she had made the announcement to the people of the Philippines. All systems go. There was no turning back.

On 11 February 2016, another 397,225 doses of Dengvaxia arrived in the Philippines. They now had more than half a million doses by this time. On the very same day, Zuellig Pharma submitted their bidding document. In the bid form, PCMC was the procuring entity (sans a PCMC and DOH MOA, with the funds still with DOH). The opening of the bid/s was scheduled for two business days after (15 February 2016). The following day, 16 February 2016, representatives of BAC technical working group, and pre-audit section conducted a visit at the Zuellig Pharma warehouse of the Dengue vaccine.

On 19 February 2016, a Memorandum of Agreement between DOH and PCMC was finalized and notarized. This operatively transfers monies to PCMC from DOH, after the latter receives it from Malacañang. But note that this was made after PCMC had previously bid out its order for 3,000,000 vaccine doses. In short, PCMC had a bidding conducted even if it didn't have the money for it. Isn't it logical or legal that before bidding is conducted by an agency of government that a certification that it has money be first assured or issued?

On 2 March 2016, an NCA was issued by DBM to DOH amounting to 4.5B; four working days later, by 8 March 2016, a Notice of Award was issued to Zuellig Pharma Corp. JVA with F.E. Zuellig Pharma (ZPC-FEZP). And, on the same day the funds are transferred from DOH to PCMC in the amount of ₱3B (disbursement voucher). The day after (9 March 2016), a Purchase Order was issued by PCMC to Zuellig Pharma. As of this time, no MOA between PCMC and Zuellig had yet been notarized. It was only on 23 June 2016 when the Memorandum of Agreement between PCMC and Zuellig Pharma was finalized months after the first vaccination salvo, and just five (5) working days before the terminus of the Aquino administration.

On 11 March 2016, a Notice to Proceed to "supply and deliver 600,000 vials of Dengue Tetravalent Vaccine was issued; the next working day (on March 14, 2016), delivery of collateral/peripheral supplies to DOH Logistic and Management Division (LMD) was made. At this time, there still was no MOA between PCMC and Zuellig.

COMELEC Resolution 9981 is issued prohibiting the release, disbursement or expenditures of public funds from March 25 to May 8, 2016.

On March 28, during the election campaign, the Dengue SBI Command Center Duty commences. In a press conference, DOH Secretary Janette Garin proudly said the Dengvaxia vaccine has undergone over 20 years of study and extensive clinical trials and has been vetted by international medical experts, even earning the approval of the World Health Organization (WHO).[20] It must be stressed that Garin here was touting a half-truth, at best; or a lie, at worst. The WHO does not approve nor license drugs. While indubitably there were clinical trials conducted to determine efficacy and safety of Dengvaxia, the clinical trials here were not yet over, and the results thus were incomplete.

Sadly, we also discovered during the investigation the presence of regulatory capture in DOH and FDA processes. Regulatory Capture "is a form of government failure which occurs when a regulatory agency, created to act in the public interest, instead advances the commercial or political concerns of special interest groups that dominate the industry or sector it is charged with regulating."[21]

The process, of application for approval to the time Dengvaxia was finally approved for use by FDA, exempted from the National Drug Formulary, procured by government, and injected into our children, was characterized by regulatory capture, evident in the following:

a. Former President Aquino and Secretary Garin had decided to procure the vaccine and already negotiated a discount even before the drug was issued a CPR in December 2015;

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[20] https://www.rappler.com/science-nature/life-health/127318-doh-dengue-vaccine-safety

[21] https://www.google.com.ph/search?q=what+is+regulatory+capture%3F&rlz=1C1CHBF_enPH722PH722&oq=what+is+regulatory+capture%3F&aqs=chrome..69i57j0l5.11551j1j4&sourceid=chrome&ie=UTF-8

b. The FDA, through Dr. Lourdes Santiago and without informing her OIC, Atty. Nicolas Lutero, allowed Sanofi a rolling- application process. A regular process requires that an applicant for new drugs complete all mandatory forms before they are allowed to submit an application, and then made to pay fees to FDA. In Sanofi's case, the company submitted its initial paperwork 21 January 2015. It still had an incomplete dossier. Sanofi was able to complete the requirements only on 15 May 2015;

c. FDA technical experts are nominated to attend the WHO NRA review of the dengue dossier. Undersecretary Gerardo Bayugo appoints Imelda Mateo, a pulmonologist and putative classmate of Garin as one of the FDA technical experts to represent the Philippines in international discussions on Dengvaxia. Through not an organic staff of the FDA, Imelda Mateo later represents the FDA in the FEC discussions on Dengvaxia.

d. Dengvaxia was granted a CPR for prescription drugs for five years by FDA, under the signature of Melody Zamudio, without requiring post-marketing surveillance. Typically, the FDA will provide a provisional license pending post-marketing surveillance prior to giving a one year license. The rationale is to hold the pharmaceutical company accountable for possible adverse events that can occur when a drug is introduced into the market. Dengvaxia, while a novel product, was given an unconditional five-year license by the FDA and was not required to manage or care for patients who may have developed adverse effects;

e. Sanofi's Risk Management Plan assumes that there will be pharmacovigilance with reporting from doctors who prescribe the drug. Since mass vaccination was not administered mostly by doctors, reports on adverse events were ignored, disregarded, or dismissed. When mass

vaccination was announced, the pharmacovigilance plan should have been changed. This did not happen prior to roll-out;

f. Dengvaxia was not in the Formulary list. But an exemption was made in its favor by Garin;

g. The exemption by Garin was granted in spite of about eight "conditionalities" recommended by FEC- most were not followed by her;

h. Dr. Kenneth Hartigan-Go urged the FEC to rush the exemption of Dengvaxia. Hartigan- Go moves to and from government and Zuellig Foundation. Zuellig Foundation is mainly an adjunct of Zuellig Pharma. He also holds a Zuellig- funded position at the Asian Institute of Management;

i. The purchase price for the drug was ₱1, 000 per dose ($20). This, in contrast with the presentation on the SANOFI-funded cost effectiveness study presented to the FEC by health economist Dr. Hilton Lam, who gave an estimate of P654.25 each,[22] per dose as "cost effective." When compared to the cost of Dengvaxia in Brazil where a localized roll-out was implemented, the estimated cost was $42, compared to the Philippine cost at $60 for 3 doses.

j. Final payments to Zuellig indicate that the total payments of government for Dengvaxia was not ₱3.0 billion as indicated in the NCA, but ₱2.8 billion, also indicating 200 million pesos unaccounted for. We wonder where it went?

k. Sanofi in contravention of existing rules, submitted to-and was accepted by-Dr. Benjamin Co of the FDA Center for Drug Regulation and Research (CDRR), a flash drive containing data to comply with requirements; although the rules say that such documents should be

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22 https://www.rappler.com/nation/191058-doh-budget-dengue-vaccination-program-too-big-economist

filed at a designated area-FDA Action Center, not anywhere else. Curiously, Dr. Benjamin Co was a signatory of the letter sent to Garin advising her against Dengvaxia.

National elections were nigh, when the program was implemented. The administration was about to end its six-year term, and they had their own person who the president had chosen to succeed him. Farfetched? We believe not, given all circumstances that occurred here. Cynical? Definitely. None can be more uncaring than a President and Health Secretary who, in the guise of delivering a social service, were really doing it for the sake of electoral victory.

In the context of elections coming up, the ideal situation is to see a President more careful, more circumspect. An outgoing leader is expected to act judiciously, and with great prudence, lest his legacy be tarnished. He/she, too, would not want to be perceived that he/she is taking advantage of a social service program for purely political purposes. But here, the President and Garin just did not care – damn the torpedoes, full speed ahead! Allowing Dengvaxia was bad enough – spending ₱3.5B for it was appalling.

Aquino and Garin knew that there is the Procurement Act that regulates government procurement; yet, they chose to negotiate, by themselves, a supposed discount from Sanofi. They were notified of the probable ill-effects of Dengvaxia on previously un-infected children; yet they chose, with utter lack of empathy, to distribute and inject. They chose to disregard the dangers and willy-nilly exposed our children to what-are-appearing-now-to-be the harm they were previously warned about. They acted in bad faith. There was willful, wanton, and reckless disregard for the safety of the children. Aquino broke his oath by not doing justice to every man.

The President and Garin opted to pursue their selfish agenda, cheered on by people who were forced to agree. They were on a spending spree, buying Dengvaxia, releasing monies for supposed health centers and dental facilities. There was no satiating their thirst and hunger for spending. Aside from increasing the profile of their candidates, it is probable that they, through this vaccination program were trying to muster resources in order to fatten a campaign kitty.

That said, we do not want to appear to belittle this horrible infectious disease. Au contraire. But, it is our responsibility too to say that the drug was not the way to go; that there would not have been greater harm had we decided to wait for a better drug. Furthermore, prudence dictates that prior to implementing a mass vaccination program, confirmatory testing of dengue cases in hospitals should have been made mandatory to establish the real baseline for the disease. There was no emergency; there was no urgency for us to justify what we find now to have been a reckless and irresponsible, nay illegal, policy decision. Worse, this was done proximate to an election exercise in that year.

ISSUE NO. 4: There was no proper preparation or administration in the conduct of the vaccination. Full and proper information provided to parents and guardians, so it could be said that they had validly given informed consent, was not given.

FINDINGS:

The consent form given to the parents does not contain the possible adverse effects and other relevant information such as contraindication and

precaution. It can thus be accurately said that the parents could not have genuinely granted consent.

DISCUSSSION:

A very important principle in health services or programs is the patient's right to know, for this right is the very basis of free choice. This is such a moral imperative that in Finland, they have rights so enshrined:

A patient is entitled to **receive information** about their state of health, **treatment**, treatment alternatives, and the **effects of treatment**. Information about treatment and treatment alternatives must be **volunteered without prompting from the patient and explained in such a way that is understood by the patient**. The patient also has the right to refuse this information. A patient is entitled to receive information about their state of health, treatment, treatment alternatives, and the effects of treatment. Information about treatment and treatment alternatives must be volunteered without prompting from the patient and explained in such a way that is understood by the patient. The patient also has the right to refuse this information.[23]

The WHO, although discussing about genomics, provided for a patient's right to be informed applicable to what happened during the program:

"...there is also growing international consensus that all patients have a fundamental right to privacy, to the confidentiality of their medical information, to consent to or to refuse treatment, and to be informed about relevant **risk to**

[23] http://www.hus.fi/en/patients/patients-rights/right-to-be-informed/Pages/default.aspx

them of medical procedures."[24] This principle applies more relevantly here, too, especially in mass vaccination.

The DOH in its website for Eversley Childs Sanitarium also provides for a "Right to Informed Consent to Diagnostic and Treatment Procedures."[25]

The right to be informed is of great importance because no patient, no patient's parent or guardian can give valid informed consent without being educated about the treatment one is getting before-hand, or the drug one is going to be injected with. In this program, the parents were not fully informed of possible anaphylaxis, or other adverse effects including severe dengue disease or even death; government failed to give full and complete information. It can thus be accurately said that the parents could not have genuinely granted consent.

In a report submitted by SANOFI to the FDA entitled "Response to questions of 22 December 2015", the company had already disclosed to the Philippine government that there were four identified risks associated with Dengvaxia: 1) allergies and anaphylaxis; 2) viscerotropism and neurotropism; 3) severe dengue and 4) waning of the effects of the vaccine

Despite this document, the FDA did not require that this be placed on the label. This information was not contained in the consent form given to parents. The consent form given to the parents does not contain the possible adverse effect and other relevant information such as contraindication and precaution which were included in the DOH Department Memorandum dated February 24,

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[24] http://www.who.int/genomics/public/patientrights/en/

[25] http://ecs.doh.gov.ph/patients-corner/patients-rights

2016. This is the reason why many parents complained later that they didn't know what they were saying yes to. They thought they were saying yes to the usual vaccinations from DOH that were long-standing, had safe track records, and which had practically no adverse events following immunization. Garin, and his cohorts, did not only impair the right of the individual to be intelligently informed; she, and her kind, also denied parents and patients their individual autonomy.

An autonomous person is defined as an individual who is capable of self-legislation and is able to make judgments and actions based on his/her particular set of values, preferences, and beliefs. In medical practice, autonomy is usually expressed as the right of competent adults to make informed decisions about their own medical care. The principle underlies the requirement to seek the consent or informed agreement of the patient before any investigation or treatment takes place.

"...(I)t can be difficult to negotiate diverse values and beliefs in sharing information necessary for decision-making, (*but*) this does not excuse a failure to respect a patient's autonomous decision: "respect for autonomy is not a mere ideal in health care; it is a professional obligation. Autonomous choice is a right, not a duty of patients." (Beauchamp and Childress 2001, 63).[26] Garin, and her kind, by denying individual autonomy, denied the parents and their children the very quintessence of existence – freedom.

The DOH, here, was cavalier in its handling of this new drug. The DOH Spokesperson during the implementation phase of Dengvaxia, Dr. Lyndon Lee Suy, played a public role in creating the impression that Dengvaxia was

[26] https://www.iep.utm.edu/autonomy/#SH4b

completely harmless. He was, in Goebbels-like fashion, quick to dismiss all reports of adverse events and to diminish the possibility of harm. He publicly described the vaccine as "like all other vaccines, where the most you might expect would be some pain at the injection site or a fever for a few days". In fact, even after the Sanofi disclosure of potential harm to patients who were seronegative, Dr. Lee Suy who had been reinstated as DOH spokesperson, trivialized the meaning of severe dengue as "possibly just a little nose bleeding and fever that is higher than usual."[27]

What is most disquieting is the thought that the DOH was so insensitive as to commit discrimination against the poor. Those who could afford to have their own private pediatricians or physicians had professionals explaining well to the patients or to their parents risks and benefits of the drug. The relationship between doctor and young patient was one-to-one. But the poor had no choice but to trust whichever healthcare provider was available to inject the drug unto them en masse. Hence when sickness and death occurred among vaccinees, the poor had no one to turn to. What they feel right now, and we cannot blame them for so feeling, is that the government betrayed their trust, for no parent who was truthfully and fully informed would have allowed his/her child to have been injected with Dengvaxia.

The parents feel that they had misplaced their faith, and the adverse consequence of this is the people's current lack of trust in even our long-established immunization programs.

When the program was in full swing, 830,000 children were injected with what the facts tell us now was an "experimental" vaccine. The clinical trials for it

[27] These are from press conferences of the DOH in April 2016 and January 2018

were not over yet. Phase III in the Philippines was supposed to end only in November 2017, but government enforced its use despite incomplete data, despite the warnings of Drs. Halstead, Danses, Lansang, et al. There was no blood testing conducted on the children to determine their serostatus. Government and Sanofi were already previously warned about the dangers of injecting seronegative persons. But Aquino, Garin and Sanofi paid no heed. They precipitously went into implementing the program, making many of us feel that our children were used as "guinea pigs" for a drug that had not yet shown itself to be provably safe and efficacious. No, we cannot be blamed for feeling this. In fact, Sanofi belatedly, citing ostensibly continuing studies, applied for label change in November 2017. They now tell us that a warning should be issued directing that the drug not be used for seronegative children, for the reason that the danger for severe dengue in previously seronegative children is high, and that hospitalizations post-second infection may be likely. Now, they tell us; but only after the mass had been undertaken, and much later than when they were previously warned of this possibility. Sanofi hid facts and concealed signals of harm.

Garin, for reasons known only to her, took it upon herself to designate the Philippine Children's Medical Center (PCMC) as lead agency for the implementation of this massive – with PCMC's limited capacity – vaccination drive. Previously, in a Board of Trustees meeting of the Corporate Specialty Hospitals (19 January 2016), the immunization program was discussed and the Board, chaired by Garin, decided that PCMC shall implement the dengue vaccine operational research in Regions 3 and 4-A. the issue on the exception(*sic*) from the formulary was raised, and the Chairman tasked Usec. Hartigan-Go (also a Trustee) to attend to this matter.

On 31 March 2016, Dengue Vaccination in Bataan is launched, and an 11-year old boy, John Paul Rafael, was vaccinated. Three (3) days later, Rafael developed diarrhea and fever. He was taken to Bagac Community and Medicare Hospital Philippines, where he was diagnosed with amoebiasis. After experiencing difficulty of breathing, fever and cough, he was admitted to Isaac Catalina Medical Center where he was diagnosed with severe pneumonia, congenital heart failure and electrolyte imbalance. By 10 April 2016, he was transferred to Bataan General Hospital. Rafael dies the following day. The case was presented to the DOH National Adverse Event Following Immunization Committee (NAEFIC) for review, after which the committee said that it is coincidental that the boy had cardiac arrest after immunization.

IV. ACCOUNTABILITY

A. Former President Benigno S. Aquino III

President Aquino is liable because he is the prime mover and the decision maker of the entire process. None of this could have happened without his knowledge. The former President had a reputation for micromanaging, e.g., what happened in Mamasapano.

The President has the principal and ultimate responsibility of protecting the health of people – he failed us. The term "the buck stops here" is not an empty phrase. In this particular case, he failed the country in these instances:

1. He had meetings with Sanofi: in Beijing during the 2014 APEC, and in France during the COP21 meet. Every time the meeting occurred, a signal was projected to his subordinates that he is interested in Sanofi and Dengvaxia. The projection of inordinate interested was such, because the approval process became faster after a meeting is held;

2. He did not ask his staff about the background of Sanofi, given that its background is not necessarily stellar, which could easily be found out in this day and age. The excuse of "Hindi ko alam" is not anymore acceptable;

3. He didn't even bother to find out why we are the only ones using the vaccine on a mass scale, while Singapore limited it to private use and Malaysia disallowed it;

4. He used ₱3.5 Billion of taxpayer's money to:

   a) Buy a largely untested drug, against one disease and for only 3-4 but vote-rich regions (III, IV-A, and NCR, and later Cebu), and which was not even in the list of the top ten causes of mortality and morbidity of the country. A discerning and well-intentioned leader would have exercised greater caution and paused considering the cost (₱3.5 Billion) for only one vaccine.

   b) He wasted the people's money by spending ₱3.5 Billion for a single preventable disease as against ₱3.3 Billion budget of EPI covering 11 preventable diseases, covering the whole country for an entire year;

   c) In wanton and reckless disregard of the safety of 1 million children, he forced upon them immunizations of a harmful drug. In fine, he endangered the lives of almost a million impoverished Filipino children up to their adult lives.

5. He, together with Garin, went to Paris to negotiate with Sanofi for Dengvaxia, a drug not even registered yet, much less qualified for government purchase;

6. He appointed Garin who acted, in concert with him, to bring the vaccine to the Philippines. This appointment, an act of patronage politics, bad as it already was, was worsened by enfeebling agencies

in the DOH that led to regulatory capture. No one in the bureaucracy could anymore say "no" to him and her (Hartigan-Go, "a political decision"; Ducusin, Dec 28 and January 7 flip-flopping. None could anymore speak truth to power;

7. He approved the requests and releases of monies through his ES for this tragedy- laced program;

8. He and his cohorts, Garin, Lecciones, Hartigan-Go, Santiago, Baquilod, et al. committed grave human rights abuse by violating the right to INFORMED CONSENT of the parents or guardians of the children to be immunized without informing them fully of the dangers of the "experimental" drug. The parents or guardians of the children now suffer from sleepless nights, anxiety, mental anguish, nervousness, useless expense, and apprehension. Their progenies were injected without the parents' valid informed consent;

9. He violated his oath by not doing justice to every man (definitely not to the parents/guardians and the children) and consecrating himself to the service of the Nation;

10. The decision to declare savings near the end of 2015 was his. Monies from supposed savings were released upon his orders. The final decision to undergo mass Dengvaxia was also his. Garin's acts in pursuit of the vaccination were also his. Under the doctrine of qualified political agency, department secretaries are alter egos or assistants of the President and their acts are presumed to be those of the latter unless disapproved or reprobated by him;

11. In sum, he must not be allowed to weasel his way out by saying that Sec. Ona recommended Dengvaxia, which Sec. Ona later denied. Aquino said that Ona was with him in Beijing, which Ona later denied. Aquino thereafter appoints politician Garin, after Ona resigns, then he

is off to Paris to negotiate. The Chairman had to ask him – did you know who you were dealing with? Did you know that doctors recommended against it? It could not have been so coincidental that every time he leaves, he meets with Sanofi. The moment she was appointed, she was off to the races, meeting with Sanofi 3 months – 3 months subsequently. Thereafter, 6 months after the meeting with Sanofi, Garin held concurrent positions as the Secretary of Health and as the OIC of FDA, violating Art. VII, Sec. 13 of the Constitution, which provides that, "[t]he President, Vice-President, the Members of the Cabinet, and their deputies or assistants shall not, unless otherwise provided in this Constitution, hold any other office or employment during their tenure;"

12. This betrayal cannot go unpunished.

B. Accountability of Cohorts

Obvious conspiracy between the President and Garin was made clear during our hearings. The confederacy to procure and inject *en masse* was not merely ill-advised, or unwise. It was criminal. The following law violations would not have been committed without the indispensable cooperation of those responsible. Each of the persons we will mention below was responsible, were participants **in a conspiracy** using machinations that cheated government of scarce resources and endangered the lives of our youth. Others profited, others were enablers, or worse facilitated the implementation of this sad chapter in our health policy history. Pieces of testimony and documents have shown that people in government, up to the topmost level were responsible: for the purchase, the introduction and injections, the grave disregard for adverse effects on the health of our young children, and the damage it has caused civil service and its processes.

We therefore recommend that the following be further investigated or, where evidence will suffice, prosecuted for violations of the following laws:

A. Anti-graft and Corrupt Practices Act (**RA 3019)**

a. Sec. 3 (g). "Entering, on behalf of the Government, into any contract or transaction manifestly and grossly disadvantageous to the same, whether or not the public officer profited or will profit thereby."

ELEMENTS:

1. The Accused is a public officer.
2. The Accused entered into a contract/transaction for and on behalf of the Government
3. The contract/transaction is manifestly and grossly disadvantageous to the Government, whether or not the accused profited or will profit thereby, charge the following:
   a. Former President Benigno S. Aquino III;
   b. Former Secretary of Health Janette L. Garin;
   c. Former Secretary Florencio Abad;
   d. Dr. Julius Lecciones of PCMC;

b. Sec. 3 (a). "Persuading, inducing or influencing another public officer to perform an act constituting a violation of rules and regulations duly promulgated by competent authority or an offense in connection with the official duties of the latter, or

allowing himself to be persuaded, induced, or influenced to commit such violation or offense."

First Mode: Offense of the Public Officer who persuaded/induced/influenced another

1. The Accused is a public officer.
2. The Accused persuaded, induced or influenced another public officer to perform an act.
3. The Act performed by virtue of the said persuasion, inducement or influence constitutes a violation of rules and regulations duly promulgated by competent authority or an offense in connection with the official duties of the other.

Second Mode: Offense of the OTHER Public Officer so persuaded/induces/influenced

1. The Accused is a public officer.
2. The Accused allowed himself to be persuaded, induced or influence by another public officer to perform an act.
3. The Act constitutes a violation of rules and regulations duly promulgated by competent authority or an offense in connection with the official duties of the other, charge the following:
   a. Former Secretary of Health Janette L. Garin;
   b. Dr. Julius Lecciones;
   c. Dr. Kenneth Hartigan- Go;
   d. Dr. Lourdes Santiago;
   e. Dr. Melody Zamudio;
   f. Dr. Joyce Ducusin

g. Dr. Mario Baquilod

c. Sec. 3 (i). "Directly or indirectly becoming interested, for personal gain, or having a material interest in any transaction or act requiring the approval of a board, panel or group of which he is a member, and which exercises discretion in such approval, even if he votes against the same or does not participate in the action of the board, committee, panel or group.

Interest for personal gain shall be presumed against those public officers responsible for the approval of manifestly unlawful, inequitable, or irregular transaction or acts by the board, panel or group to which they belong."

ELEMENTS:

1. The Accused is a public officer.
2. The Accused is a member of a board, panel or group which exercises discretion in the approval of a transaction.
3. He becomes directly or indirectly interest for personal gain or has a material interest in any transaction or act requiring the approval of the board, panel or group, which he is a member, charge the following:
   a. Former Secretary of Health Janette L. Garin;
   b. Dr. Kenneth Hartigan- Go;
   c. Dr. Julius Lecciones;

d. Sec. 3 (j). "Knowingly approving or granting any license, permit, privilege or benefit in favor of any person not qualified for or not

legally entitled to such license, permit, privilege or advantage, or of a mere representative or dummy of one who is not so qualified or entitled.

ELEMENTS:

1. The Accused is a public officer.
2. The Accused has authority to grant a license, permit, privilege or benefit in favor of any person.
3. The Accused knowingly granted a license, permit, privilege or benefit in favor of another person.
4. The person to whom such permit is granted is not legally entitled to such license, permit, privilege or advantage, charge the following:
   a. Former Secretary of Health Janette L. Garin;
   b. Dr. Melody Zamudio

B. Code of Conduct and Ethical Standards for Public Officials and Employees (RA6713)

a. "Section 4(b) Public officials and employees shall perform and discharge their duties with the highest degree of excellence, professionalism, intelligence and skill. xxx They shall endeavor to discourage wrong perceptions of their roles as dispensers or peddlers of undue patronage."

ELEMENTS:

1. The Accused is a public officer.

2. By his Acts, he encouraged wrong perceptions of their roles as dispensers or peddlers of undue patronage, charge the following:

   a. Former President Benigno S. Aquino III;

   b. Former Secretary of Health Janette L. Garin

   c. Former Secretary Florencio Abad;

   d. Dr. Julius Lecciones of PCMC;

   e. Dr. Kenneth Hartigan- Go;

   f. Dr. Lourdes Santiago;

   g. Dr. Melody Zamudio;

   h. Dr. Joyce Ducusin

   i. Dr. Mario Baquilod

C. Perjury/ False testimony

"Art. 183. False testimony in other cases and perjury in solemns affirmation. – The penalty of arresto mayor in its maximum period to prision correccional in its minimum period shall be imposed upon any person, who knowingly makes untruthful statements and not being included in the provisions of the next preceding articles, shall testify under oath, or make an affidavit, upon any material matter before a competent person authorized to administer an oath in cases in which the law so requires.

Any person who, in case of a solemn affirmation made inlieu of an oath, shall commit any of the falsehoods mentioned in this and the three preceding articles of this section, shall suffer the respective penalties provided therein."

ELEMENTS:

1. The Accused testifies under oath, makes an affidavit, upon any material matter before a competent person authorized to administer an oath in cases in which the law requires.
2. The Accused knowingly makes untruthful statements.
    1. Lyndon Lee Suy – He was the head of the immunization program under Garin. In the DOH hierarchy, this plan would have passed through him first before it finally reached the Office of the Secretary. He was also one of those who went around immunizing children during the time of Dengvaxia implementation; he was Director III of the Infectious Disease Office and the Environmental and Occupational Health Office. While these Offices are under the Disease Prevention and Control Bureau, the program manager was under him.

        In the hearing of 13 March this year, while he said that he was not involved anymore with Dengue clearly he still was.

D. Suits must be filed for violations of provisions of the Civil Code on Quasi-delicts (Art. 2176, New Civil Code: Whoever by act or omission causes damage to another, there being fault or negligence, is obliged to pay for the damage done. Such fault or negligence, if there is no pre-exiting contractual relation between the parties, is called a quasi-delict and is governed by the provision of this Charter.) against Sanofi for having sold a defective product, endangering, hurting, and may be even killing children who were injected with Dengvaxia. Criminal cases against the company's officers and employees must also be

considered insofar as this fiasco is concerned, as well as possible co-principal participation in criminal violations of the above-mentioned public officers.

E. Art. 220. Illegal use of public funds or property. – Any public officer who shall apply any public fund or property under his administration to any public use other than that for which such fund or property were appropriated by law or ordinance shall suffer the penalty of *prision correccional* in its minimum period or a fine ranging from one-half to the total of the sum misapplied, if by reason of such misapplication, any damage or embarrassment shall have resulted to the public service. In either case, the offender shall also suffer the penalty of temporary special disqualification.

The essential elements of this crime, more commonly known as **TECHNICAL MALVERSATION**, are:

1. the offender is an accountable public officer;
2. he applies public funds or property under his administration to some public use; and
3. the public use for which the public funds or property were applied is different from the purpose for which they were originally appropriated by law ordinance.

The fund could not be released through a Special Allotment Release Order (SARO) and Notice of Cash Allocation (NCA), without the participation and approval of President Aquino and Secretary Abad, who realigned the savings from the Miscellaneous Personnel Benefits Fund (MPBF) and committed technical malversation for

programming funding to an activity that was not appropriated a budget by Congress. To get a SARO alone is very hard, but to get a SARO from savings of this magnitude of P3.5 B leaves no doubt that it can only be done with the President's knowledge and approval.

VI. RECOMMENDATIONS:

In order to assuage grave fears and terror in the minds of parents/guardians of children who were injected with Dengvaxia, your Committees recommend the following:

1. Provide sufficient budget for monitoring, - in particular sero-testing to determine who were previously seronegative-, diagnosis, treatment, and rehabilitation of ALL children injected with Dengvaxia. The monies that were recovered from Sanofi, representing unused vaccines, may be directed towards the above-endeavor;
2. The DOH must complete its master list of those who were injected with Dengvaxia so that we will know those who should be closely monitored. The DOH needs to recover its reputation soonest, and must take pains in order to regain the people's trust. It must perform its job admirably and prove to the people that they will, at all times, only have their welfare in mind. Otherwise we will face a greater mess- and large increases of cases that could have been prevented by vaccination in the future- when parents continue to refuse to have their children immunized because of fear.
3. Legal action shall be taken by the Philippine government against SANOFI toward establishment of an indemnity fund for children who were vaccinated to provide them with financial assistance for medical care throughout their lifetimes;

4. Legislation separating the Food and Drug Administration, and the Formulary Executive Council from the Department of Health, making the former independent;

5. Pass legislation that will require pharmaceutical companies to publicly disclose all health professionals, organizations and institutions that benefit from sponsorship of conferences, research grants, travels, honoraria, among others- to further help government in defining clearly medical-ethical boundaries that must never be crossed. We have become witnesses to how unethical practices have pervaded public health activities here. We must start envisioning a regime in health and medicine where unholy alliances between doctors, pharmaceutical companies, hospitals, clinics, and laboratories are eradicated. We must look forward to a state of affairs where there is **"The Physician Payments Sunshine Act,"** a healthcare law to increase transparency of financial relationships between health care providers and pharmaceutical and medical device manufacturers.

6. Pass legislation on the creation of an independent disease control and surveillance agency, (the equivalent of Centers for Disease Control in the United States) impervious to political blandishments and bullying – within the Department of Health that can arbitrate against political decisions that are not based on evidence – with staff who have advanced and specialized technical training in epidemiology and public health.

7. To Dr. Halstead's question, "what can we do for all those children, mothers and fathers who are threatened by a vaccine-related serious dengue infection at some future date?" We are in agreement with his suggestion, "...that the clinical care of hospitalized dengue children be upgraded and that special training in dengue acute care treatment

should be offered to all hospital-based physicians... This must be done in the Philippines."

In view thereof, the DOH must submit a program to be properly funded by the Congress to see to it that all dengue cases are provided for with extreme care and are checked right away provided to all children.

The government, DOJ and the DOH, must support the families and provide technical assistance, and when the time comes to file a class suit against Sanofi.

8. Parents who were not informed thoroughly well or those not informed at all about the risks of Dengvaxia before their children were injected with it, should band together and exact accountability from the perpetrators- Sanofi, and government officials responsible for this chaos.

9. The DOJ and the Ombudsman are urged to collaborate in order to see to it that justice is done, that those who are accountable must be held to face cases. These agencies are urged to take judicial notice of proceedings in the legislature- particularly, the Senate; and read the reports.

10. To urge the DOH to overhaul the Department and remove bad eggs responsible for this catastrophe.

11. To urge the DOH to take serum samples of Dengvaxia vacinees who are currently in hospitals due to dengue-like illness for an Anti-NS1 test by the University of Hawaii. This test will determine if a child was seronegative before Dengvaxia was given.

12. That we thank wholeheartedly experts who had lent their expertise and allowed us to profit from their mastery of the intricacies of

dengue and Dengvaxia. Without their unselfish contributions, this Report would not have been complete:

a. Dr. Scott Halstead- who came all the way from the United States and spent time sharing his knowledge of ADE, dengue, Dengvaxia, viscerotropism, neurotropism, etc;

b. Drs. Antonio and Leonila Dans- who educated us on infectious diseases arcana;

c. Dr. Anthony Leachon- who patiently spent much time helping us understand the ins and outs of medicine-licensing and registration processes; and

d. Dr. Susan P. Mercado- who helped us discover and appreciate vital information, and translated important medico-technical jargon.

Final words

The greatest fraud in Dengvaxia was in the misrepresentation by Sanofi that it was safe. They told us that the vaccine can be injected sans prior serostatus determination, despite knowing that the vaccine was not safe for all. It took Sanofi a year and a half before telling us otherwise. For that perfidy, they must be made accountable. Reparation may be awarded as assistance for recovery, it can help families pull through in these their uncertain times; but, the harm inflicted cannot be done away with.

There is a beneficial- to- consumers- business practice, that when car manufacturers sell defective cars, a recall process is made, cars are replaced or repaired, and those harmed by the defect compensated. Why? Because the buyers and those driving had every right to expect that the vehicles they were driving met all the safety standards. Similarly, airline passengers have every right

to expect that the planes they are riding are airworthy and capable of bringing them safely to their destinations. Sanofi was not expected to do less.

The Dengvaxia vaccination sadly has been a mess resulting in greater danger to children who had been injected. It bears re-emphasizing that the parents currently now are suffering from sleepless nights, anxiety, mental anguish, nervousness, useless expense, and apprehension. Their progenies were injected without the parents' valid informed consent. Absolutely no parent who was truthfully and fully informed: that the drug was still in its third-phase and thus not yet ready, would have allowed his/her child to have been injected with Dengvaxia.

There is also a lesson to be learned here: never mix public health with politics. The folly of appointing politicians to leadership positions in the DOH- ideally a purely technical/public health office- has come back to haunt us. Three administrations ago, a former Congressman was appointed by the then-President to lead the DOH. That eight-month incumbency was marred by corruption, and disastrous performance which led to the politician's resignation from office. Nearly twenty years later, government tragically commits the same mistake.

But this is not to say that all vaccines are bad, or that vaccinations can have deleterious effects. We as a nation have, time and again, embarked on vaccinations against measles, polio, diphtheria, pertussis, tuberculosis, etc. The world has practically been rendered polio- free because of immunization (vaccination) efforts. Those time-tested drugs/vaccines must continue to be distributed and introduced into our children by government, if we are to save them from preventable diseases and the cost accompanying illnesses that can be avoided. The DOH must repair its broken wings and regain the trust of the

public, as its sentinel. The DOH must also intensify its programs so that all of us are educated about the beneficial effects that vaccinations can bring to our country.

Many continue to get away with malfeasance, misfeasance or non-feasance. A big sector believes that there is impunity in the country. The events here happened because of a President who practically did not care a whit for the health of his children, supported and enabled by a Secretary of Health who acted like a wolf in a chicken coop.

It becomes our collective obligation therefore to break the myth that those responsible are able to get away with it, and that there is immunity and exemption from punishment here. We must thus assure our constituents that we will not waver, we will not falter, and we will emerge victorious in our pursuit of justice.

Fiat justitia, ne pereat mundus.

I support the recommendation related to health measures as well as remedial measures for affected children. I will propose amendment for better fiscal management; but I have reservations on the findings of

Respectfully submitted:

JOSEPH VICTOR G. EJERCITO
Chairman
Committee on Health and Demography

LOREN B. LEGARDA
Chairman
Committee on Finance

RICHARD J. GORDON
Chairman
Committee on Accountability of Public Officers & Investigations

Members:

SONNY ANGARA**

PAOLO BENIGNO "BAM" AQUINO IV***

I concur as regards Sanofi & DOH but dissent as regards inclusion of Pnoy & non-inclusion of Abad.

WIN GATCHALIAN* With reservations. - May Dengvaxia

FRANCIS "CHIZ" G. ESCUDERO**

GREGORIO B. HONASAN II**

RISA HONTIVEROS**

PANFILO M. LACSON***

EMMANUEL "MANNY" D. PACQUIAO*

FRANCIS "KIKO" N. PANGILINAN***

With Reservations.
More accountability to DOH implementors, Sanofi.
GRACE POE*
When President had intentions to solve dengue, but should have exercised due diligence.
Will interpellate, amend
justice to families affected & integrity of vaccination system.

Respectfully submitted:

JOSEPH VICTOR G. EJERCITO
Chairman
Committee on Health and Demography

LOREN B. LEGARDA
Chairman
Committee on Finance
– see committee reservations on the page of report

RICHARD J. GORDON
Chairman
Committee on Accountability of Public Officers & Investigations

Agree with most recommendations but do not believe there is criminal liability on the former president Aquino,

Members:

SONNY ANGARA**

PAOLO BENIGNO "BAM" AQUINO IV***

WIN GATCHALIAN* with reservations. - may amend

FRANCIS "CHIZ" G. ESCUDERO**

GREGORIO B. HONASAN II**

RISA HONTIVEROS**

PANFILO M. LACSON***

EMMANUEL "MANNY" D. PACQUIAO*

FRANCIS "KIKO" N. PANGILINAN***

GRACE POE*

With Reservations:
More accountability to DOH implementors, Sanofi.
Then President had intentions to solve dengue, but should have exercised due diligence.
Will interpellate, armed justice to families affected & integrity of vaccination system.

will seek clarification thru interpellation and propose amendments; will look into additional measures to protect the welfare of children who were administered with Dengvaxia and ensure that they get timely, efficient and continuous medical care/ treatment for [illegible] against the vaccine's adverse effects.

CYNTHIA A. VILLAR***

JUAN MIGUEL "MIGZ" F. ZUBIRI***

ANTONIO "SONNY" F. TRILLANES**

JOEL VILLANUEVA****

will interpellate
may amend

MARIA LOURDES NANCY S. BINAY****

LEILA M. DE LIMA*****

Ex-Officio Members:

RALPH G. RECTO
President Pro-Tempore

VICENTE C. SOTTO III
Majority Floor Leader

I concur with "moving forward initiatives", like help for special children and ask us. Sonja but dispute re reminder liability of President Aquino

FRANKLIN M. DRILON
Minority Floor Leader

HON. AQUILINO "KOKO" PIMENTEL III
President
Senate of the Philippines
Pasay City

* - Member, Blue Ribbon Committee
** - Member of the three Committees
*** - Member, Blue Ribbon Committee and Committee on Finance
**** - Member, Committees on Health and Demography & Finance
***** - Member, Committee on Health and Demography

Republic of the Philippines
Senate
Pasay City

Franklin M. Drilon
Senate Minority Leader

25 April 2018

Senator RICHARD J. GORDON
CHAIRMAN
Committee on Accountability of Public Officers
and Investigations (Blue Ribbon)
Senate of the Philippines

RECEIVED
Office of Senator Richard J. Gordon
Legislative Office
Date: 04.26.18 KDA

Thru : **Atty. Rodolfo Noel S. Quimbo**
Director General
Blue Ribbon Oversight Office Management

Dear **Senator Gordon:**

This refers to the Dissenting Vote submitted by Minority Leader Franklin M. Drilon last 19 April with regard to the draft report by the committees on Accountability of Public Officers and Investigations (Blue Ribbon), Health and Demography, and Finance on the joint inquiry into the "Dengvaxia" controversy.

Subsequent to our filing, our office noticed typographical/printing errors on pages 1, 5, 25, 26, 27 and 28. Upon instruction of the Minority Leader, we are submitting another copy of his Dissenting Vote as corrected.

Thank you.

Very truly yours,

Atty. RENATO N. BANTUG, Jr.
Chief of Staff

Enclosure:
As stated

Copy Furnished:

Atty. Lutgardo B. Barbo
Secretary, Senate of the Philippines

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GSIS Building, Financial Center, Pasay City, Philippines
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To be ignorant of one's ignorance
is the malady of the ignorant. –
Amos Bronson Alcott

I pay heed to this saying – nay, warning.

As *ex officio* member of the three congressional committees that conducted the joint inquiry into the Dengvaxia controversy, I am duty-bound to not only base my conclusions on some legitimate evidence, but to consider all available evidence before making such conclusions.

We cannot select segments of evidence that fit our desired conclusion while hiding or ignoring those that tend to refute it. We must harness a truly representative set of facts that will overcome our ignorance and unearth the truth about a given issue.

Despite volumes upon volumes of committee transcripts and official documents, we found no conclusive scientific evidence to support the conclusion that any of the reported deaths were in any way connected to Dengvaxia. Certainly, this matter should be studied by qualified pathologists. But until there is such conclusive scientific evidence that Dengvaxia caused or contributed to their deaths, we can only concede how ignorant we remain of whether or not there is any correlation at all.

Surely, if and when it is indubitably established that Dengvaxia is the proximate cause of the deaths in question, all those involved should be made to account – without exception. During President Aquino and Secretary Garin's term, 280,000 children were vaccinated. During President Duterte and Secretary Ubial's term, over 400,00 were vaccinated. Declaring certain personalities guilty at this point would not only be premature but would also reinforce impressions of the politicization of a legitimate public health concern that must be addressed in a clinical manner.

I therefore cast my **DISSENTING VOTE** to this Report.

FRANKLIN M. DRILON

The Report pins the primary responsibility on Aquino who allegedly caused the purchase of Dengvaxia and in the process caused irreversible damage, possibly death to children, anxiety, sleepless nights, mental anguish, and unneccessary expense on the part of parents and guardians.

In citing *Garcia v. People*, the Report refers to Article 4 of the Revised Penal Code which provides that *criminal liability shall be incurred by any person committing a felony, although the wrongful act be different from that which he intended.* In order for a person to be liable for a felony under this provision, the following elements must be present:

a. an **intentional felony** was committed
b. the wrong done to the aggrieved party be the **direct, natural and logical consequence** of the felony committed by the offender

First Element: Intentional Felony Was Not Committed

Criminal liability is incurred by a person committing a felony, which means that the person should have been committing an act by means of *dolo* or with malice. Absent criminal intent, there can be no felony. The Supreme Court defines dolo or malice as follows:

> "... the term "*dolo*" or "malice" is a complex idea involving the elements of freedom, intelligence, and intent. The element of intent is described as the state of mind accompanying an act, especially a forbidden act. It refers to the purpose of the mind and the resolve with which a person proceeds. On the other hand, the term "felonious" means, *inter alia*, malicious, villainous, and/or proceeding from an evil heart or purpose. With these elements taken together, the requirement of intent in intentional felony must refer to malicious intent, which is a vicious and malevolent state of mind accompanying a forbidden act."[2]

The Court has in various instances ruled that malice is negated by the existence of good faith –

> The felony, being *malum in se*, requires malice; hence, good faith, or the absence of malice or bad faith, prevents incipient criminality from arising. The anti-graft court cited cases where this Court held that

[2] Jamandron v. People, G.R. No. 195224, 15 June 2016.

disadvantage on the part of the government is unmistakable, obvious, and certain.[37]

Moreover, to prove that a transaction is grossly disadvantageous, it must be shown that the transaction is going to cause the government a serious disadvantage in that what it will receive is not commensurate with what it is committed to give.[38]

In the instant case, the Report asserts that the purchase of Dengvaxia was disadvantageous to the government because the money could have been used for more worthy government projects; or that since Dengvaxia is not 100 percent effective (or could result to more severe dengue symptoms for seronegatives), the money used to pay for the vaccines should have been devoted to some other use. This situation however is not contemplated under the provision of the anti-graft law on disadvantageous contracts. If there were other pharmacological companies that offered a similar dengue vaccine for a lower price and the Aquino government nonetheless opted to buy Dengvaxia, then there may be a case for violation of the said law.

The Report also asserts that the purchase of Dengvaxia is disadvantageous because the vaccine may cause seronegatives to experience severe dengue symptoms. The duty of the government, however, is to protect the greater majority. As discussed above, even the WHO declared that Dengvaxia is beneficial to endemic countries like the Philippines, despite Sanofi's 29 November 2017 announcement. On 22 December 2017, the WHO issued the "Updated Questions and Answers related to the dengue vaccine Dengvaxia and its use" which states that "in the areas in the Philippines where Dengvaxia was introduced, the seroprevalence was estimated to be at least 85 percent. **A seroprevalence of 85 percent means that 85 percent of the population is seropositive and will benefit from Dengvaxia**. In such a high transmission setting, every 1 excess case within a 5 year period of hospitalized dengue in vaccinated seronegatives is offset by 18 cases prevented in vaccinated seropositives, and 1 excess severe dengue in vaccinated seronegatives by 10 prevented severe cases in vaccinated seropositive."

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37 *Ibid.*

38 DOJ Opinion No. 108, s. 1985.

The impact of vaccination versus non-vaccination on 830,000 individuals, in settings where 90percent of the population had previous dengue infection, is estimated to result in total reduction of 10,900 dengue hospitalizations and 2,800 severe dengue cases over 5 years. Even for the seronegatives, to whom the vaccine is not recommended, they would only exhibit traditional dengue symptoms if they do get infected with the dengue virus after having been bitten by a mosquito.

Thus, it may not be said that the contract for the purchase of Dengvaxia was disadvantageous to the government.

LIABILITY FOR ALLEGED HASTE IN PROCURING DENGVAXIA

The Report expresses suspicion on the regularity of the purchase of Dengvaxia on the basis of the apparent haste in concluding the sale transaction.

The alleged haste in the purchase of Dengvaxia was explained at the Senate hearing on 11 December 2017, when President Aquino delivered his preliminary statement quoted above, which explained the process by which he and his government reached the decision to procure the vaccine.

As early as 2010, or five years before the purchase of Dengvaxia, President Aquino was already discussing the problem of dengue with Sec. Ona. He was informed that a lot of people were contracting dengue; in Region 8, there was an increase of 1,409 percent in the number of those who were infected with dengue; if there were 200,000 cases of dengue every year, and that number could increase by 1,409 percent, it was possible to have 2.8 million cases of dengue cases. Those infected would need blood transfusion, and may be hospitalized; and may have to be financially supported by the government; for the 2.8 million infected with dengue, at PhP 20,800 estimated hospitalization expenses per patient, the government would have to spend 58.2 billion pesos; he found out that a dengue vaccine was invented; it went through the necessary regulatory processes; it had been previously approved for use in Mexico and Brazil; he did not hear any objection to the vaccine. As to the meeting with Sanofi, in Dec. 2015, he went to Paris for the COP21 Conference, a meeting among different countries to discuss the problem of climate change. As in all his travels, he met with interested investors, among them Vivapolis, Airbus, Jacobi Carbons, CRH, Usine IO, and Sanofi. Sanofi informed him about Dengvaxia.

Hence, with all the information before him, he had to solve the dengue problem. If Sanofi did not make its disclosure on 29 November 2017, and President Aquino decided to let Filipinos suffer from dengue even when a dengue vaccine was available, the people would probably accuse him of neglect and he would be blamed by the mothers whose children died of dengue.

Considering the 1,409 percent increase in dengue cases in Region 8 alone, and the possible expenses of the government amounting to over 50 billion pesos, it is clear that President Aquino and the other government officials who participated and implemented the dengue vaccination program of the government, acted promptly and correctly under the circumstances. They may not be held liable for the said purchase.

The explanation of President Aquino is logical and credible. The dengue problem is serious. He was presented with a remedy. As a caring President, he had the moral obligation to prevent more Filipinos from contracting and dying from dengue. The outrage about the vaccine seems to stem from misunderstanding the effects and benefits of the vaccine.

The impact of vaccination versus non-vaccination on 830,000 individuals, in settings where 90 percent of the population had previous dengue infection, is estimated to result in **total reduction** of 10,900 dengue hospitalizations and 2,800 severe dengue cases over 5 years.

Even for the seronegatives, to whom the vaccine is not recommended, they would only exhibit traditional dengue symptoms if they do get infected with the dengue virus after having been bitten by a mosquito.

The vaccine does not make people ill with dengue; the virus carried by a mosquito does. No deaths have been shown to have resulted from the vaccine.

Notably, on 22 December 2017, the WHO issued the "Updated Questions and Answers related to the dengue vaccine Dengvaxia and its use" which states that "in the areas in the Philippines where Dengvaxia was introduced (mainly through school programmes), the seroprevalence was estimated to be at least 85%. A seroprevalence of 85% means that 85% of the population is seropositive and will benefit from Dengvaxia. In such a high transmission setting, every 1 excess case within a 5 year period of hospitalized dengue in vaccinated seronegatives is offset by

18 cases prevented in vaccinated seropositives, and 1 excess severe dengue in vaccinated seronegatives by 10 prevented severe cases in vaccinated seropositive." Thus, this confirms the overall efficacy and safety of the dengue vaccine.

The discussion of the dengue problem began in 2010, and the problem of dengue has been existing for decades, the purchase of the vaccine in 2015 can be hardly characterized as hasty.

Parenthetically, the Report states that Sec. Ona denied meeting with President Aquino about the dengue problem. Sen. Gordon believes Sec. Ona and not President Aquino. He did not, however, explain why Sec. Ona is more trustworthy. In any event, it cannot be denied that many Filipinos get infected with dengue. The problem has been existing for as long as we can remember.

There was no violation of the procurement law

The procurement processes leading to the purchase of Dengvaxia for the public immunization program have already been reviewed and investigated by the Integrity Management Committee of the DOH.[39] According to then Secretary of Health Paulyn Ubial, she "commissioned the review after the congressional hearing in December [2016] x x x and the procurement, the FEC exemption were all within the bounds of law and within the bounds of policy."[40] Thus, the alleged irregularities in the procurement process can all be addressed by the Integrity Management Committee's report.

There was no undue haste in the procurement of the dengue vaccine. The then controlling 2009 Implementing Rules and Regulations of R.A. No. 9184 ("GPRA-IRR") provides the maximum periods and earliest possible time for action on specific procurement activities.[41] Under the GPRA-IRR, the earliest possible time for the procurement of goods is 28 calendar days, while the maximum period is 80 calendar days.[42] The procurement of the dengue vaccine took 46 calendar days,

39 TSN, 11 December 2017, II-3, p. 115.
40 TSN, 11 December 2017, II-6, pp. 274-275.
41 GPRA-IRR, Sec. 38.1
42 See Annex "C" of the GPRA-IRR.

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is the malady of the ignorant. –
Amos Bronson Alcott

I pay heed to this saying – nay, warning.

As *ex officio* member of the three congressional committees that conducted the joint inquiry into the Dengvaxia controversy, I am duty-bound to not only base my conclusions on some legitimate evidence, but to consider all available evidence before making such conclusions.

We cannot select segments of evidence that fit our desired conclusion while hiding or ignoring those that tend to refute it. We must harness a truly representative set of facts that will overcome our ignorance and unearth the truth about a given issue.

Despite volumes upon volumes of committee transcripts and official documents, we found no conclusive scientific evidence to support the conclusion that any of the reported deaths were in any way connected to Dengvaxia. Certainly, this matter should be studied by qualified pathologists. But until there is such conclusive scientific evidence that Dengvaxia caused or contributed to their deaths, we can only concede how ignorant we remain of whether or not there is any correlation at all.

Surely, if and when it is indubitably established that Dengvaxia is the proximate cause of the deaths in question, all those involved should be made to account – without exception. During President Aquino and Secretary Garin's term, 280,000 children were vaccinated. During President Duterte and Secretary Ubial's term, over 400,00 were vaccinated. Declaring certain personalities guilty at this point would not only be premature but would also reinforce impressions of the politicization of a legitimate public health concern that must be addressed in a clinical manner.

I therefore cast my **DISSENTING VOTE** to this Report.

FRANKLIN M. DRILON

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I therefore cast my **DISSENTING VOTE** to this Report.

FRANKLIN M. DRILON

DISSENTING VOTE
of Minority Leader FRANKLIN M. DRILON
to Committee Report No. ___
of the Committee on Accountability of Public Officers and Investigations (Blue Ribbon), Committee on Health and Demography, and Committee on Finance

Shorn of non-essentials, the root of the present controversy on Dengvaxia can be attributed to the following announcement of Sanofi:

"**PARIS, FRANCE – 29 November 2017** – Sanofi will ask health authorities to update information provided to physicians and patients on its dengue vaccine Dengvaxia® in countries where it is approved. The request is based on a new analysis of long-term clinical trial data, which found differences in vaccine performance based on prior dengue infection.

"Based on up to six years of clinical data, the new analysis evaluated long-term safety and efficacy of Dengvaxia in people who had been infected with dengue prior to vaccination and those who had not. The analysis confirmed that Dengvaxia provides persistent protective benefit against dengue fever in those who had prior infection. For those not previously infected by dengue virus, however, the analysis found that in the longer term, more cases of severe disease could occur following vaccination upon a subsequent dengue infection.

"*'These findings highlight the complex nature of dengue infection. We are working with health authorities to ensure that prescribers, vaccinators and patients are fully informed of the new findings, with the goal of enhancing the impact of Dengvaxia in dengue-endemic countries,'" said Dr. Su-Peing Ng, Global Medical Head, Sanofi Pasteur.*

"About half of the world's population lives in countries where four serotypes of dengue virus are in circulation. Every year an estimated 390 million dengue infections are reported. People can be infected with dengue up to four times in their lifetime and they can get severely ill after any of these infections. Surveillance data from some endemic countries indicate that between 70 and 90 percent of people will have been exposed to dengue at least once by the time they reach adolescence. There are many factors that can lead to severe dengue infection. However, the highest risk of getting more severe disease has been observed in people infected for the second time by a different dengue virus.

"Dengvaxia is currently indicated in most of the countries for individuals 9 years of age and older living in a dengue-endemic area. In this indicated population, Dengvaxia has been shown to prevent 93 percent of severe disease and 80 percent of hospitalizations due to dengue over the 25 month phase of the large-scale clinical studies conducted in 10 countries in Latin America and Asia where dengue is widespread.

"**Proposed Label Update**

"Based on the new analysis, Sanofi will propose that national regulatory agencies update the prescribing information, known as the label in many countries, requesting that healthcare professionals assess the likelihood of prior dengue infection in an individual before vaccinating. Vaccination should only be recommended when the potential benefits outweigh the potential risks (in countries with high burden of dengue disease). For individuals who have not been previously infected by dengue virus, vaccination should not be recommended.

"The Sanofi label proposal will be reviewed by national regulatory agencies in each of the countries where the vaccine is registered or under registration. Following their review, each agency might amend the company proposed label.

"**Financial Information**

Taking this information into account and expected future sales, Sanofi will record a charge reflecting depreciation of inventories as well as accelerated depreciation of some tangible and intangible assets in its fourth quarter results. The impact on the Business Net Income (BNI) is still under assessment but it is expected to be in the range of €100 million after tax. Despite this impact, Sanofi confirms the guidance provided on November 2nd of broadly stable Business EPS(1) at CER in 2017 versus 2016, barring unforeseen major adverse events.

"**About Dengue**

"Dengue is a painful, debilitating mosquito-borne viral disease for which there is no treatment. Almost 4 billion people are living at risk of dengue and these people can be sickened by dengue not just once but as many as four times in their lifetimes.

"Dengue hits hardest during rainy season outbreaks that spread rapidly in the urban growth centers of endemic countries. The World Health Organization has called on countries with dengue to employ an integrated approach to dengue prevention and management, with the aim of reducing deaths due to dengue by 50 percent and related disease and disability by 25 percent by 2020.

"(1) Business net income is a non-GAAP financial measure (see Appendix 8 of our November 2, 2017 financial release for a definition)."[1]

Following such announcement, certain personalities and groups expressed outrage over the dengue immunization program of the Department of Health (DOH) pursuant to which, about 800,000 public school children were inoculated with

[1] Sanofi updates information on dengue vaccine. (2017, November 29). *Sanofi*. Retrieved 16 April 2018, from http://mediaroom.sanofi.com/sanofi-updates-information-on-dengue-vaccine/

Dengvaxia from the period April 2016 (284,319 children during the administration of former President Benigno Simeon C. Aquino III) to July 2017 (415,681 children in the present administration).

On 11 December 2017, the Committee on Accountability of Public Officers and Investigations (Blue Ribbon), the Committee on Health and Demography, and the Committee on Finance reopened their probe into the dengue vaccine controversy.

After a number of hearings, the draft Committee Report ("Report") was released on 11 April 2018. It recommended the filing of charges against former President Benigno C. Aquino III, former Health Secretary Janette Garin, and former Budget Secretary Florencio Abad among others, for violation of the Revised Penal Code, R.A. No. 3019 or the Anti-Graft and Corrupt Practices Act, Civil Code and Universal Declaration of Human Rights.

LIABILITY FOR ALLEGED VIOLATION OF THE REVISED PENAL CODE

A. INTENTIONAL FELONY

The Report concludes that Aquino, Garin, and Abad are primary conspirators who must be criminally liable for all the tragedy, damage, and possible deaths resulting from the Dengvaxia mass vaccination program. The Report cites the case of *Garcia v. People* wherein the Supreme Court held that a person committing a felony is responsible for all the natural and logical consequences resulting from it, though the unlawful act performed is different from the one intended.

The basic premise of the Report is that Dengvaxia harms the children who were vaccinated. Thus the Report recommends the prosecution of those who approved its use, and in particular, the Former President Benigno Aquino III. The Report concludes: (1) "When Aquino and Garin went on to conduct mass vaccination, they thereby discriminated against, afforded less care, and displayed lack of affection for the poor"; (2) "They and their ilk wronged the poor and suffering Filipinos for the sake of political expediency and greed"; (3) "He deliberately refused to heed the warnings that were given out by experts as to its dangers".

The Report pins the primary responsibility on Aquino who allegedly caused the purchase of Dengvaxia and in the process caused irreversible damage, possibly death to children, anxiety, sleepless nights, mental anguish, and unneccessary expense on the part of parents and guardians.

In citing *Garcia v. People*, the Report refers to Article 4 of the Revised Penal Code which provides that *criminal liability shall be incurred by any person committing a felony, although the wrongful act be different from that which he intended.* In order for a person to be liable for a felony under this provision, the following elements must be present:

a. an **intentional felony** was committed
b. the wrong done to the aggrieved party be the **direct, natural and logical consequence** of the felony committed by the offender

First Element: Intentional Felony Was Not Committed

Criminal liability is incurred by a person committing a felony, which means that the person should have been committing an act by means of *dolo* or with malice. Absent criminal intent, there can be no felony. The Supreme Court defines dolo or malice as follows:

> "... the term "*dolo*" or "malice" is a complex idea involving the elements of freedom, intelligence, and intent. The element of intent is described as the state of mind accompanying an act, especially a forbidden act. It refers to the purpose of the mind and the resolve with which a person proceeds. On the other hand, the term "felonious" means, *inter alia*, malicious, villainous, and/or proceeding from an evil heart or purpose. With these elements taken together, the requirement of intent in intentional felony must refer to malicious intent, which is a vicious and malevolent state of mind accompanying a forbidden act."[2]

The Court has in various instances ruled that malice is negated by the existence of good faith –

> The felony, being *malum in se*, requires malice; hence, good faith, or the absence of malice or bad faith, prevents incipient criminality from arising. The anti-graft court cited cases where this Court held that

[2] Jamandron v. People, G.R. No. 195224, 15 June 2016.

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good faith is a valid defense for it negates criminal intent on the part of the accused.[3]

The doctrine in Garcia v. People cannot apply to the former President's act of approving the procurement of Dengvaxia. He cannot be held liable under Art. 4 of the Revised Penal Code.

The first element - that an intentional felony was committed is conspicuously absent. It is clear that **President Aquino did not act with malice or dolo in procuring the vaccine** –

- He acted in good faith, upon the advice and reports of his Secretary of Health, then Sec. Ona;
- When Sanofi began selling Dengvaxia, there was no evidence of an increased risk of severe dengue in seronegative individuals aged 9 years and above. President Aquino could not have known of the possible adverse effect of the vaccine on seronegatives;

In his statement before the Blue Ribbon Committee Hearing on 11 December 2017, President Aquino explained the factors and the decision-making process that led to the procurement of the vaccine, which clearly illustrate that his decision was motivated by nothing but good faith, armed with what he believed to be the correct and accurate information at the time. The decision was arrived at with reasonable basis and does not, by any stretch of imagination proceed from a villainous or evil heart or purpose that characterizes dolo or malice -

> *Nagsimula po ang pagtutok ko sa Dengue sa Pilipinas matapos kong matanggap ang memo ni Secretary Ike Ona, dated 23 Aug. 2010.* ***Sa briefing sa akin, lahat ng serotypes o uri ng Dengue narito daw po sa Pilipinas; hindi din daw seasonal ang Dengue, at walang gamot para rito.*** *Malaon po, sasabihin sakin ni Sec. Ona na may nagde-develop ng vaccine para sa lahat ng strain.*
>
> *Matagal na ngang problema ang Dengue sa atin. Nung bata pa ako, may sakit na tinatawag na H-Fever. Pag nagkwekwentuhan ang matatanda tungkol sa H-Fever, madalas kasunod nun ang pagsabing may naospital na nangangailangan pa ng blood transfusion. Itong H-Fever, atin pong napag-alaman, ay ang Philippine Hemorrhagic Fever, na mas kilala ngayon bilang Dengue.*

[3] People v. Sandiganbayan, G.R. Nos. 168188-89, 16 June 2006.

Pag tinamaan ka ng isang serotype ng Dengue, magiging immune ka roon pero hindi sa ibang strain. *Naibalita po sakin: May isang dating Speaker of the House na naospital nang 2 beses dahil sa Dengue, at sabi po niyang mukhang nagkaroon pa ng pangatlong uri sa mga taong lumipas. May isa namang European ambassador na na-assign dito sa atin, na sa pagmamahal niya sa Pilipinas ay gumawa ng brochure ng tourist destinations natin para sa mga kababayan niya sa kanilang lenggwahe. Siya po, 2 beses nagka-Dengue. Tayong lahat rito, siguradong may kakilalang na-Dengue ng minsan o ilang ulit.*

Sa memo po ni Sec. Ona, naka-highlight ang 5 rehiyong may pinaka-mataas na ulat ng Dengue. 3 sa 5, higit 100% ang increase*. May isa po, 1409.5% increase o 14 na beses ang itinaas. Di po maipaliwanag kung bakit 14 times umangat ang kaso ng Dengue sa Region 8, na di naman kasing congested tulad ng Metro Manila o Metro Cebu.* ***Mas kalat ang populasyon ng Region 8, at mas malayo ang ibyabyahe ng lamok na may Dengue, kumpara rito sa Metro Manila na dikit-dikit ang bahay. Tanong: Kung sa hindi highly urbanized na lugar, 1409.5% increase, paano na sa talagang dense at urbanized?***

Ang nakakatakot dito: ***Kung tinatayang may 200,000 cases ng Dengue kada taon, at posibleng umangat ng 14 beses ang bilang tulad sa nangyari sa Region, ang potensyal na pwedeng magka-sakit ay 2.8 milyon.*** *Yan po ang dami ng Pilipino na baka kailangan ng blood transfusion, na baka kailangang ipasok sa mga ospital, na baka kailangang suportahan ng ating gobyerno, lalo na kung siya ay matanggal sa trabaho at arawang swelduhan. Diin ko po: Noong panahong iyon, inuumpisahan pa lang natin ang pagsaayos sa Philhealth. Sa kabuuan ng aking termino, sa mga pagkakataong nadadaan ako sa intersection ng Quirino at Osmeña, may nakikita akong electronic billboard na sinasabi: May dengue ka, ang halaga 20,800 na gastos sa ospital; kung wala, kumuha ka ng medical health insurance. Yun pa ay advertisement ng isang health insurance provider. Kung di po maipaliwanag kung bakit sumipa ng 14 times ang Dengue sa Region 8, di po natin masasabi kung paano natin mapipigilan ito. Ang estima para sa isa sa mga worst case scenario:* ***Sa 2.8 million na kataong na-Dengue, i-multiply mo sa 20,800, ang buong gastos: 58.2 billion pesos.***

Ang tugon po ng gobyerno sa mga panahong iyon: Tinigil natin ang indiscriminate fogging na itinataboy ang lamok na may Dengue sa kabilang barangay. Nag-activate ang DOH ng Dengue express lanes sa mga ospital ng gobyerno. Nag-install ang DOST ng Insecticide-Treated Screens at Mosquito Ovicidal/Larvicidal (OL) Traps. Yung National Dengue Prevention and Control Program, malinaw ang resulta:

Bumagsak mula sa 1,057 nung 2010 patungong 317 sa Oktubre 2015 ang bilang ng namatay dahil sa Dengue.

Dec. 2015, nagpunta po ako sa Paris para sa COP21, kumperensya ng mga bansa para tugunan ang climate change. Gaya ng lahat ng byahe natin, kinausap natin ang maraming namumuhunan, partikular na ang Vivapolis, Airbus, Jacobi Carbons, kumpanyang CRH, tumungo sa Usine IO, at pati na rin ang Sanofi. Sinabi sa atin noon na ready na ang Sanofi sa bakuna.

Yung ganitong uri ng gamot, maraming taon inaabot ang development para masiguro talaga ang efficacy at lalo na ang safety. Naalala ko po bilang halimbawa: Noong 1960s, may gamot na Thalidomide, na ibinenta para sa morning sickness, na nagbunsod sa deformities sa mga sanggol ng mga babaeng kumuha nito. Kaya nagpasa noong 1962 ang U.S. Congress ng Kefauver-Harris amendments para sa Federal Food, Drug, and Cosmetic Act, at naghigpit ng mga proseso ang U.S. FDA. Ang intindi natin sa Dengvaxia, natapos na ang lokal at international processes nito. Tiningnan namin ang U.S. FDA; may 5 steps ito: Discovery and Development, Preclinical Research, Clinical Research, FDA Review, at Post-Market Safety Monitoring. Paliwanag sa akin, dumaan ang Dengvaxia sa isa sa mga phases ng U.S. FDA. Diin ko na rin po: ***Di lang Pilipinas ang nag-apruba sa Dengvaxia. Nauna sa atin ang Mexico at Brazil. Diin ko lalo: Sa aking pakiwari, at pag-unawa, dumaan na po ito sa lahat ng proseso para malaman ang kanyang efficacy at mas importante ang kanyang safety.***

Nung ilunsad natin ang programa sa Zambales nung April 2016, ipinakita sa akin ang isang presentation na nakasaad ang ilang bakunang dekada nang napapakinabangan ng mga may-kaya pero kailan lang naibigay sa publiko. Gaya po ng bakuna para sa Polio, Rabies, at Pneumonia. Diin ko lang po, ang obligasyon ng gobyerno, na siguruhin, gaya ng sinabi ni President Magsaysay na: ***"Those who have less in life should have more in law." Hindi ko po naisip ipagkait sa pinaka-nangangailangan at nanganganib ang proteksyon ng bakuna.***

xxx

Diin ko lang po: ***Bago nagdesisyon ang gobyerno sa Dengvaxia, habang nagdedesisyon, at maski pagkatapos magdesisyon, wala pong nagparating sa akin ng pagtutol sa naturang bakuna. Kaya natin inilunsad ito sa NCR, CALABARZON, at Central Luzon, dahil ayon sa datos ng DOH, ito po ang tatlong pinaka-apektadong mga rehiyon nung 2015 kaugnay ng Dengue.***

Kung di lumabas itong sinabi ng Sanofi, at nagdesisyon akong hayaan na lang na magdusa pa ang karaniwang Pilipino gayong may bakuna na, palagay ko ngayon, iba ang tanong ninyo at asunto sakin: Bakit mo pinabayaan ang kababayan mo? Paano ko ipapaliwanag sa mga nanay ang pagkamatay sa kanilang mga anak, kung meron na palang proteksyon na ipinagkait sa kanila?

Ulitin ko po: ***2010 pa lang po may problema na tayo sa Dengue. 1409% ang paglobo nito sa Region 8, na posible ring mangyari sa buong bansa.*** *Nangako akong iiwan ko ang Pilipinas na mas maganda kesa sa aking dinatnan. Kaakibat noon ang pagbawas sa gastos, kaba, at pasanin ng aking mga Boss, ang sambayanang Pilipino.*

New Discovery on Effect of Dengvaxia on Seronegatives

When Sanofi began selling Dengvaxia, there was no evidence of an increased risk of severe dengue in seronegative individuals aged 9 years and above.

The decision to use the dengue vaccine in the public immunization program was indeed affirmed by the WHO position paper released in July 2016. This position paper provided guidelines on important considerations for introducing the vaccine, specifically: 1) use of the vaccine should only be considered in areas where a high proportion (preferably at least 70%) of the community had already been exposed to the virus; 2) the vaccine should only be provided to people 9 years of age and above; and 3) people being vaccinated should receive 3 doses. The Philippines met these criteria, especially in the three regions where the immunization program was implemented.

The Report claims that Pres. Aquino "knew or should have known, because information was readily available to him at that time, that Dengvaxia was fraught with danger; that "at best, it did not work for the persons vaccinated, and it was least effective for the dengue strain endemic to the Philippines". **Yet, before Sanofi released its statement on the vaccine's possible negative effect on seronegatives, how could Pres. Aquino have known them?** Further, the statements that Dengvaxia "was fraught with danger" and that it was "least effective for the dengue strain endemic to the Philippines" are baseless assumptions.

Second Element: There is no proof that Dengvaxia was the Proximate Cause of the Children's Deaths

The second element, is that the wrong done must be the proximate cause of the resulting injury or damage.

> Proximate cause is defined as that cause, which, in natural and continuous sequence, unbroken by any efficient intervening cause, produces the injury, and without which the result would not have occurred. More comprehensively, proximate cause is that cause acting first and producing the injury, either immediately or by setting other events in motion, all constituting a natural and continuous chain of events, each having a close causal connection with its immediate predecessor, the final event in the chain immediately effecting the injury as natural and probable result of the cause which first acted, under such circumstances that the person responsible for the first event should, as an ordinarily prudent and intelligent person, have reasonable ground to expect at the moment of his act or default that an injury to some person might probably result therefrom.[4]

On 19 December 2017, Justice Secretary Vitaliano Aguirre authorized and directed the Public Attorney's Office (PAO) to "extend free legal assistance in civil, criminal and administrative cases to all possible victims of Dengvaxia-related injuries, illnesses and deaths" through Department Order 792. PAO's Dr. Erwin Erfe conducted autopsies on children whose deaths were suspected of being related to Dengvaxia. Thereafter, PAO and Dr. Erfe announced that over 30 cadavers exhibited patterns consistent with severe dengue.

The PGH Dengue Investigative Task Force however stated that the panel did not find that the deaths were caused by Dengvaxia. It recommended further investigations in order to clarify the nature of the association with vaccination or the cause of death.

Other than PAO's statements and other baseless conclusions, there is indeed no concrete, scientific proof that Dengvaxia caused the deaths of those inoculated.

In fact, even the prominent scientist and dengue expert, Dr. Scott Halstead, said that mere autopsy could not determine if a person died of dengue –

[4] Dr. Fernando Solidum v. People. G.R. No. 192123, 10 March 2014.

> **Please be aware that the diagnosis of Dengvaxia cannot be based on an autopsy.** In any child that dies post Dengvaxia, there have to be two things: One is unequivocal evidence that the infection was caused by dengue virus. And that can be done either by virus isolation or RNA identification or NS1; the second is, we need to know whether the vaccine in that particular individual was given when the individual was a seronegative or seropositive.[5]

While the Report quotes some parts of Dr. Halstead's presentation, it failed to consider all of Dr. Halstead's statements, among which is that the vaccine itself does not cause any illness whatsoever –

> From everything we know, **the actual vaccine virus, Dengvaxia, does not cause any illness whatsoever....** 40 or 50 years ago, the United States marketed a measles vaccine which (was) licensed. And what happened there is two years after the measles vaccine were given, children acquired measles but it wasn't just ordinary measles, it was a very severe measles and a measles that end in death. And in both the instance of Sanofi and the measles vaccine, **it's the immune response to the vaccine that leaves you at risk to a much more severe disease**.[6]

Considering that there is no conclusive proof to establish that Dengvaxia was the proximate cause of the deaths of the children whose bodies were autopsied by the PAO, it is evident that the second element of Article 4 of the Revised Penal Code is not met.

It is significant to note that Dengvaxia was licensed based on the results of two large clinical trials in five (5) countries in Asia and in five (5) countries in Latin America. These trials included over 30,000 participants. It has been approved by regulatory authorities in 19 countries for use in endemic areas in persons aged 9-45 years. All other countries that have approved the use of Dengvaxia have been informed about the new data on the vaccine. Yet, to date, the Philippines is the only country that stopped the use of Dengvaxia due to safety concerns. It is only in the Philippines that people have imputed injuries and deaths of vaccinated children on Dengvaxia.

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[5] Committee Hearing dated 13 March 2018.
[6] Committee Hearing Dated 13 March 2018.

B. MALFEASANCE, MISFEASANCE, NONFEASANCE

While failing to specify the particular acts committed by former President Aquino, the Report concludes that he is guilty of malfeasance, misfeasance and nonfeasance.

The Report merely says that "*all these acts constitute malfeasance, misfeasance, and nonfeasance. All in the name of politics. He placed premium on political gain or even greed over the lives of innocent children. His greatest sin is simply not caring. As supposed father of the nation, he should have done better. By his acts, he violated ethics, did no homework, and did not exercise the extraordinary diligence of a good father of a nation.*"

Malfeasance is defined as the performance of some act, which ought not to be done. Misfeasance is the improper performance of some act, which might lawfully done. Nonfeasance meanwhile is the omission of some act, which ought to have been performed.

The Report does not explain which particular acts constitute malfeasance, misfeasance or nonfeasance – which acts could President Aquino have done lawfully but did not do properly, which acts was he supposed to have performed but did not, and which acts did he do which he should not have done.

C. TECHNICAL MALVERSATION

Under Article 220 of the Revised Penal Code, technical malversation is committed by a public officer when he or she disburses public funds or property for a purpose other than what is dictated by law or ordinance.

The use of the MPBF Savings to procure Dengvaxia is allowed by law

No less than the 1987 Constitution recognizes the President's authority to augment, by law, existing items within his office from savings in other items of appropriation. In the landmark case of *Araullo v. Aquino*,[7] the Supreme Court laid

[7] Araullo v. Aquino, G.R. No. 209287, 1 July 2014, 728 SCRA 1.

down the requisites for the valid transfer of appropriated funds under Section 25(5), Article VI of the 1987 Constitution, namely:

(1) There is a law authorizing the President, the President of the Senate, the Speaker of the House of Representatives, the Chief Justice of the Supreme Court, and the heads of the Constitutional Commissions to transfer funds within their respective offices;

(2) The funds to be transferred are savings generated from the appropriations for their respective offices; and

(3) The purpose of the transfer is to augment an item in the general appropriations law for their respective offices.[8]

The first requisite is present in this case, as Section 69 of the 2015 GAA General Provisions expressly authorizes the President, among others, to use and transfer savings:

> "Sec. 69. Use of Savings. - **The President** of the Philippines, the Senate President, the Speaker of the House of Representatives, the Chief Justice of the Supreme Court, the Heads of Constitutional Commissions enjoying fiscal autonomy, and the Ombudsman are hereby **authorized to use savings in their respective appropriations to augment actual deficiencies incurred for the current year in any item of their respective appropriations.** An item of appropriation shall pertain to the amount appropriated for a program, activity or project authorized in this Act."[9]

The second requisite has also been met, since the funds to be transferred are savings generated from the MPBF, an appropriation under the control of the Executive Branch, as clearly stated in Special Provision No. 4, XL. of the 2015 GAA.

> 4. Appropriations under the Miscellaneous Personnel Benefits Fund. - **The amounts appropriated herein shall be administered by [the] Executive branch. Savings from said fund may be used to augment deficiency in the budget of** the Judicial Branch, Legislative Branch and **the Executive Branch** of the government including Constitutional Commissions and Offices, subject to Section 35, Chapter 5, Book VI[10] of E.O. No. 292 x x x[11]

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8 *Id.*, at 132-133.

9 Emphasis and underscoring supplied.

10 EO No. 292, Book VI, Chapter 5, Section 35 reads: "**SECTION 35. Special Budgets for Lump-Sum Appropriations.**—Expenditures from lump-sum

It cannot be said that the MPBF was illegally used, since it was only the savings generated from said fund that was reallocated to augment another project within the Office of the President—the Expanded Program for Immunization ("EPI") under the DOH. The EPI was an item found under Republic Act No. 10651 otherwise known as the "General Appropriations Act of 2015". This fulfills the third requisite outlined in *Araullo*; that the purpose of the transfer is to augment an item in the GAA for one's respective office.

In *Abdulla v. People*,[12] the Supreme Court upheld petitioner's argument that the public funds subject of the case, having already been established to form part of *savings*, ceased to be appropriated by law or ordinance for any specific purpose.[13] The Court acquitted the petitioner of the charge of technical malversation because she applied savings from the lump sum appropriation of the Sulu State College to cover the terminal leave benefits of secondary school teachers.[14] The Supreme Court found that there was no provision in the law particularly appropriating the savings

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appropriations authorized for any purpose or for any department, office or agency in any annual General Appropriations Act or other Act and from any fund of the National Government, shall be made in accordance with a special budget to be approved by the President, which shall include but shall not be limited to the number of each kind of position, the designations, and the annual salary proposed for which an appropriation is intended. This provision shall be applicable to all revolving funds, receipts which are automatically made available for expenditure for certain specific purposes, aids and donations for carrying out certain activities, or deposits made to cover to cost of special services to be rendered to private parties. Unless otherwise expressly provided by law, when any Board, head of department, chief of bureau or office, or any other official, is authorized to appropriate, allot, distribute or spend any lump-sum appropriation or special, bond, trust, and other funds, such authority shall be subject to the provisions of this section.

In case of any lump-sum appropriation for salaries and wages of temporary and emergency laborers and employees, including contractual personnel, provided in any General Appropriation Act or other Acts, the expenditure of such appropriation shall be limited to the employment of persons paid by the month, by the day, or by the hour."

11 Rep. Act. No. 10651 (2015); emphasis and underscoring supplied.

12 G.R. No. 150129, 6 April 2005, 455 SCRA 78.

13 *Id.*, at 95.

14 *Id.*, at 93.

for payment of salary differentials only; hence, the third element[15] of technical malversation was absent.[16] The Supreme Court emphasized:

> "In the absence of a law or ordinance appropriating the public fund allegedly technically malversed x x x the use thereof for another public purpose x x x will not make the accused guilty of violation of Article 220 of the Revised Penal Code."[17]

Essentially, what can be culled from *Abdulla* is that funds classified as savings are not considered appropriated by law or ordinance, thus, they can logically be used for other public purposes.

In this case, President Aquino was well within his Constitutional authority in using the savings from the MPBF to fund the Dengvaxia procurement.

Lump-sum allocation for EPI includes vaccines for endemic diseases like dengue

As discussed above, among the projects identified to be funded by the 2015 MPBF Savings is the dengue vaccination (NCR, III, IV-A) under the EPI. The specific budget for EPI is mentioned in page 1198, Volume 110, No.1 of the 2015 GAA.

Furthermore, 2015 GAA DOH Special Provisions also mentions EPI:

> 17. Preventive Health Care Program. - The amounts appropriated herein under Disease Prevention and Control shall be used exclusively for the following preventive health care programs: (i) Health Emergency Management; (ii) Elimination of Disease as Public Threat; (iii) Rabies Control Program; (iv) **Expanded Program on Immunization** x x x [18]

The same 2015 Special Provisions also includes a detailed provision regarding the purchase and allocation of vaccines, to wit:

> 10. Purchase and Allocation of Drugs, Medicines and Vaccines. - The amount of Seven Billion Eight Hundred Eighty Five Million Seven Hundred Fifty Four Thousand Pesos (P7,885,754,000) **appropriated herein for** drugs, medicines and **vaccines shall be used for the procurement of** drugs, medicines and **vaccines** including

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15 That such public fund or property has been appropriated by law or ordinance.

16 *Id.*, at 95.

17 *Id.*, *citing* Parungao v. Sandiganbayan, G.R. No. 96025, 15 May 1991, 197 SCRA 173.

18 Rep. Act. No. 10651 (2015), XIII, item 17 *available at* https://www.dbm.gov.ph/wp-content/uploads/GAA/GAA2015/GAA%202015%20Volume%201%20with%20UACS/DOH.pdf (last accessed 5 April 5, 2018); emphasis and underscoring supplied.

medical and dental supplies for distribution to DOH retained hospitals and other health care facilities: PROVIDED, That releases from said amount shall be made upon submission by the DOH of its distribution list of the drugs, medicines and vaccines per health care facility in every province: PROVIDED, FURTHER, That in the preparation of the distribution list, the DOH shall allocate eighty percent (80%) of the drugs, medicines and vaccines to provinces where: (i) there are large number of poor families or households under the NHTS-PR by the DSWD; and (ii) the absolute number of poor and the incidence of poverty are high as identified in the latest official poverty statistics of the PSA-NSCB: PROVIDED, FURTHERMORE, That any available allotment from the procurement of drugs, medicines and vaccines shall be used to purchase additional drugs, medicines and vaccines to be distributed in accordance with the above-stated allocation. Notwithstanding the allocation of drugs, medicines and vaccines as provided in the above distribution list submitted by the DOH to the DBM, **the Secretary of Health may reallocate the provision of drugs, medicines and vaccines when necessitated by the occurrence of disease outbreaks, calamities and other emergencies during the year**. The procurement of drugs, medicines and vaccines by the DOH, including regional hospitals, medical centers and special hospitals, shall strictly comply with R.A. No. 9502, E.O. No. 821, s. 2009, and the Philippine National Drug Formulary: PROVIDED, That bulk procurement of drugs, medicines, and vaccines, including medical or dental supplies, equipment and instruments may also be allowed, subject to compliance with R.A. No. 9184 and its IRR, and pertinent auditing laws, rules and regulations. x x x[19]

Under the doctrine of necessary implication, it is understood that dengue vaccines are included in the general term "vaccines." Indeed, the Supreme Court has explained the doctrine in such manner:

> No statute can be enacted that can provide all the details involved in its application. There is always an omission that may not meet a particular situation. x x x So-called gaps in the law develop as the law is enforced. One of the rules of statutory construction used to fill in the gap is the doctrine of necessary implication. The doctrine states that what is implied in a statute is as much a part thereof as that which is expressed. **Every statute is understood, by implication, to contain all such provisions as may be necessary to effectuate its object and purpose, or to make effective rights, powers, privileges or jurisdiction which it grants, including all such collateral and subsidiary consequences as may be fairly and**

19 *Id.*, at XIII, item 10; emphasis and underscoring supplied.

> **logically inferred from its terms**. *Ex necessitate legis*. And every statutory grant of power, right or privilege is deemed to include all incidental power, right or privilege. This is so because the greater includes the lesser, expressed in the maxim, *in eo plus sit, simper inest et minus*.[20]

Hence, although the appropriation refers to vaccines in general, common sense dictates that the budget necessarily stretches to cover specific vaccines which the DOH Secretary, in her discretion, may deem appropriate for the needs of the Filipino public. Dengue, which is endemic in the Philippines at the time of the procurement, is one such disease for which specialized vaccines are a welcome development.

Moreover, 2015 GAA Special Provisions explicitly gives the Secretary of Health power to "reallocate the provision of drugs, medicines and vaccines when necessitated by the occurrence of disease outbreaks, calamities and other emergencies during the year."[21] Implicit in this authority is the judgment to decide which drug, medicine, or vaccine must be distributed to address a given emergency.

Another DOH budgetary item on dengue prevention is found under "Disease Prevention and Control":[22]

> Other infectious diseases and emerging and re-emerging diseases including HIV/AIDS, **dengue**, food and water-borne diseases – 743, 907,000

In light of the foregoing, there is no basis to argue that the DOH budget, and by extension, its EPI budget, did not include the dengue vaccine.

Transfer of funds from the MPBF to the EPI to cover the procurement of the vaccine does not constitute the crime of technical malversation

Aquino, et al. are not liable for technical malversation because the public funds used were already classified as savings, hence the third and fourth elements, that the public fund or property has been appropriated by law or ordinance and that

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20 Atienza v. Villarosa, G.R. No. 161081, 10 May 2005 *citing* Chua v. Civil Service Commission, G.R. No. 88979, 7 February 1992, 206 SCRA 65.

21 *Supra* note 14.

22 Republic Act No. 10651, page 1200, Volumes 110, No. 1)

the public officer applies the same to a public use other than for which such fund or property has been appropriated by law or ordinance, are necessarily absent.

Again, in the case of *Abdulla,*[23] the Supreme Court upheld petitioner's argument that the public funds in question, having been established to form part of savings, ceased to be appropriated by law or ordinance for any specific purpose.[24]

Proceeding from this ruling, and as already discussed in the earlier subheading, since funds classified as savings are not considered appropriated by law or ordinance, they can thus be used for other public purposes. Indeed, it must again be stressed that the President's authority to augment, by law, existing items within his office from savings in other items of appropriation, is embodied in the 1987 Constitution.

Given that the requisites for a valid transfer of appropriated funds as per *Araullo* have all been met, it is clear that there was no misapplication of funds to begin with. The President is empowered by no less than the Constitution to transfer savings, by law, to augment an item in the GAA for his respective office. Since this power is discretionary upon him, and the funds used to procure the Dengvaxia were precisely savings from an appropriation under the Executive Branch, no technical malversation could have taken place.

LIABILITY FOR ALLEGED VIOLATION OF REPUBLIC ACT NO. 6713

The Report also finds that President Aquino, Secretaries Abad and Garin, as well as the other doctors mentioned violated Section 4b of Republic Act No. 6713 otherwise known as the Code of Code of Conduct and Ethical Standards for Public Officials and Employees -

> Section 4(b) Public officials and employees shall perform and discharge their duties with the highest degree of excellence, professionalism, intelligence and skill. xxx They shall endeavor to discourage wrong perceptions of their roles as dispensers or peddlers of undue patronage."

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23 *Supra* note 17.

24 Abdulla v. People, G.R. No. 150129, 6 April 2005, 455 SCRA 78, 93.

Proper Diligence Was Exercised By President Aquino

The Report goes on to state:

> Nothing was heard from the President to stop it. He did not check any periodicals or any doctors advised against it; Brazil only used it on a small scale, Singapore and Malaysia – just for private use but here in PH he allowed public use and mass inoculation
>
> xxx
>
> 4. In procuring the drug, he did not bother to ask his subordinates, his researchers, various experts, or even check the internet, if the vaccine is safe, efficacious, and ethical. He should have found out that there were experts who warned about antibody dependent enhancement (ADE) which meant that there could be severe infections. And, there would be a waning effect shortly and these bad effects could last a lifetime.
>
> 5. Experts, both foreign and local, were already objecting to its use. He deliberately refused to heed the warnings that were given out by experts as to its dangers. Neither did he listen nor paid attention to those who really knew how long the ill-effects would be.
>
> 6. No country was using it. Malaysia rejected it. Singapore allowed it only for private use. Brazil only allowed it for limited use for one province of about 300,000 children. Prudence would have cautioned a wise leader to ask questions why we were going to use it at all but he placed premium on vote-rich regions (NCR, III, and IV-A, and later, Cebu).

To say that the President did not do his homework prior to approving the vaccine is inaccurate. As thoroughly explained in the earlier discussions, President Aquino made a policy decision based on the best available data existing at the time. Decision-making entails the selection of the most reasonable choice among different options presented, based on the information given. The President has to deal with various issues that plague the country, and thus to a large extent, has no choice but to trust the advice of his Cabinet secretaries and those under their departments to help him come up with the most logical decision on the most pressing issues which beset the country.

An executive has the difficult yet important role of determining the country's policies, based on what he deems to be the most pressing issues affecting its

people. Decisions are guided only by information available at any given time and anything that comes after that can only be the product of hindsight analysis. A subsequent discovery that would have changed the way the decision was made should not be taken against the decision-making authority. The Executive should be able to rely to a reasonable extent on the good faith of his subordinates. The case of *Arias vs. Sandiganbayan*[25] explains -

> We can, in retrospect, argue that Arias should have probed records, inspected documents, received procedures, and questioned persons. It is doubtful if any auditor for a fairly sized office could *personally* do all these things in all vouchers presented for his signature. The Court would be asking for the impossible. All heads of offices have to rely to a reasonable extent 'on their subordinates and on the good faith of those prepare bids, purchase supplies, or enter into negotiations. If a department secretary entertains important visitors, the auditor is not ordinarily expected to call the restaurant about the amount of the bill, question each guest whether he was present at the luncheon, inquire whether the correct amount of food was served and otherwise *personally* look into the reimbursement voucher's accuracy, propriety, and sufficiency. There has to be some added reason why he should examine each voucher in such detail. Any executive head of even *small* government agencies or commissions can attest to the volume of papers that must be signed. There are hundreds of document, letters and supporting paper that routinely pass through his hands. The number in bigger offices or departments is even more appalling.

Safety and Efficacy of the Vaccine

It must be remembered that Sanofi obtained the required regulatory approvals for Dengvaxia after clinical and efficacy evaluations of the vaccine, including a phase III study program involving over 30,000 study participants in 10 endemic countries in Asia and Latin America. These studies met regulatory authority criteria for registration of the vaccine and included a long-term safety follow-up phase of evaluation as recommended by WHO for all dengue vaccine programs. If there were objections to the vaccine, the objections were based on theories and not hard, scientific evidence. It appears that while some individuals opined that the dengue vaccine should be studied further, the majority opinion was that Dengvaxia was ready for the market. Indeed, according to WHO, even after Sanofi's 29

[25] G.R. No. 81563, 19 December 1989.

November 2017 announcement, Dengavaxia is still recommended for areas where dengue is endemic, such as the Philippines.

So what does the announcement really mean? The announcement of Sanofi basically says that Dengvaxia provides persistent protective benefit against dengue fever in those who had prior infection or "seropositives"; but it can cause severe dengue for those who have not previously been infected or "seronegatives".

According to experts, 9 out of 10 children aged nine and above have been infected with at least one strain of dengue ("seropositives"). The rest (seven) would not know that they are already seropositive. These statements were not refuted. Hence, out of 800,000 children vaccinated with Dengvaxia, 80,000 of them would be seronegative.

Based on the result of the study of Sanofi, the effect on seronegatives is that they would have a 0.2% risk of experiencing traditional dengue symptoms, such as fever and headaches, if they do get infected with the dengue virus after having been bitten by a mosquito.

If the 80,000 seronegatives are not bitten by mosquitos carrying dengue, they will not be sick with dengue. In theory, if all of the 80,000 children are bitten by mosquitos carrying dengue, then .02 percent of them or 1,600 **may** experience severe dengue. It is not a certain occurrence. They may not experience severe dengue even if they are seronegative.

Nevertheless, Sanofi's findings that Dengvaxia may cause more severe dengue symptoms if the children vaccinated are seronegatives were disclosed in November 2017, and not earlier. **Can former President Aquino be faulted for having purchased an imperfect vaccine, the imperfections of which were discovered after the implementation of the vaccination program?**

It is likewise important to know that different vaccines work in different ways. Further, no vaccine is 100 percent effective.

According to the Center for Disease Control and Prevention's *Morbidity and Mortality Weekly Report*, the Center tracked flu cases among 1,700 children and adults across the US. They found the flu shot was 36 percent effective overall, meaning it reduced a person's risk of getting sick with flu and going to a doctor's office by about a third. However, the flu vaccine's effectiveness against H3N2 was

only 25 percent. In an earlier study from Canada, the flu vaccine was found to be only 17 percent effective against H3N2.

Vaccines that help protect against pneumococcal disease work well, but cannot prevent all cases. Studies show that at least 1 dose of pneumococcal conjugate vaccine protects only 45 in 100 adults 65 years or older against pneumococcal pneumonia.

To understand vaccine failure: Juan has 3 children. Theoretical disease X kills 2 out of 3 children if they are not vaccinated. A vaccine against disease X is only 50% effective. Therefore if Juan uses vaccine X on his children, one child will still die. That means the vaccine worked as it was supposed to. It did not kill one child, it actually saved one child.

Will the US Government be liable for recommending the flu or pneumococcal vaccine if it turns out that they are only 50 percent or less effective? Certainly not. To date, the US government encourages its citizens to undergo vaccination.

Neither Pres. Aquino nor Sanofi represented that Dengvaxia is 100 percent effective. Indeed, there is no vaccine that is 100 percent effective. Accordingly, Pres. Aquino, Sec. Garin, and other government officials involved in the vaccination may not be held liable for the reason that in some cases, the vaccine did not appear to work. Apparently, there is a misunderstanding on how vaccines work. Perhaps the government could have spent the PhP 3 Billion for some more worthy project. But this is a judgment call that they were in a position to make. It is unfair for the people to judge them based on hindsight.

Expert Opinions Considered

WHO was of the opinion that the vaccine is beneficial to endemic countries. While, Dr. Halstead and a few doctors may have opined that Dengvaxia should not have been used for mass vaccinations, there are more scientists belonging to the 19 countries that approved Dengvaxia, who are of the contrary opinion. The Report does not explain why Dr. Halstead and not the WHO, should be believed.

On 9 March 2016, Dr Bhanu Pratap, **Health Coordinator for the International Federation of Red Cross and Red Crescent Societies (IFRC)**

in Philippines, said the introduction of the vaccine is "a positive move, especially for those living in the worst affected areas and for children".

> "The IFRC plans to support Philippine Red Cross health teams and volunteers to spread awareness of the vaccine to health centres and communities as part of the overall Epidemic Preparation and Response Plan. "Through its donor network, the Philippine Red Cross provides 53% of the Philippines' total blood supply. Some dengue sufferers require platelet transfusions to stop internal bleeding. Blood platelets are essential for normal blood clotting, but donation and extraction is a time-consuming process. **According to Dr. Pratap, the vaccine would help reduce the burden on health and blood facilities, especially in areas that are already stretched to the limit, and on the donated blood supply**."[26]

Contrary to the allegations in the Report, the Philippines was not the only country that approved use of the vaccine. Mexico was in fact the first country to grant regulatory approval to Dengvaxia.[27] In the same year that the Philippines implemented its vaccination program, Dengvaxia's public program introduction in Mexico was also recommended by that country's national vaccination council following the WHO's endorsement of its safety, efficacy and public health value in endemic settings.[28]

Even ahead of Mexico, Brazil "launched its first public immunization program against dengue fever, with 500,000 people to be injected with the world's first authorized vaccine against the disease. The initial roll out was done in the Brazilian state of Parana."[29]

The vaccine's approval was preceded by 20 years of research,[30] all the more reason to believe that the drug has undergone sufficient testing.

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[26] http://www.who.int/immunization/diseases/dengue/q_and_a_dengue_vaccine_dengvaxia_use/en/

[27] https://www.kff.org/news-summary/mexico-becomes-first-country-to-grant-regulatory-approval-to-sanofis-dengue-vaccine/

[28] https://www.sanofipasteur.com/media/Project/One-Sanofi-Web/sanofipasteur-com/en/media-room/docs/PR_20160912_MexicoStartsDengueVaccinations_EN.pdf

[29] http://www.gmanetwork.com/news/lifestyle/healthandwellness/577532/brazil-launches-first-dengue-vaccine-campaign-drug-maker/story/

[30] https://www.bloomberg.com/news/articles/2015-12-09/world-s-first-dengue-vaccine-approved-after-20-years-of-research

LIABILITY FOR VIOLATION OF R.A. NO. 3019 OTHERWISE KNOWN AS THE ANTI-GRAFT AND CORRUPT PRACTICES ACT

The Report also concludes that former President Aquino, former Secretary of Health Janette Garin, former Secretary Florencio Abad, and Dr. Julius Lecciones violated Section 3 (g) of R.A. No. 3019.

The said provision makes it unlawful for any public officer to enter, on behalf of the government, into "any contract or transaction which is **manifestly and grossly disadvantageous** to the government, whether or not the public officer profited or will profit thereby."

To be liable under Section 3 (g) of RA 3019, the following requisites must concur:

1. That the accused is a public officer;
2. That he entered into a contract or transaction on behalf of the government; and
3. That such contract or transaction is grossly and manifestly disadvantageous to the government.[31]

Manifest means "obvious to the understanding, evident to the mind . . . and is synonymous with open, clear, visible, unmistakable, indubitable, evident and self-evident." Gross means "flagrant, shameful, such conduct as is not to be excused."[32]

While the phrase is not defined by statute, it has been the subject of several opinions and decisions. In *Sajul v. Sandiganbayan,*[33] the Court defined manifest as "something evident to the senses, open, obvious, notorious, unmistakable etc.,"[34] and gross as "glaring, reprehensible, culpable, flagrant, shocking etc."[35] In *Hontiveros-Baraquel v. Toll Regulatory Board,*[36] the Supreme Court clarified:

> "When one uses the term 'grossly disadvantageous to the government,' the allegations in support thereof must reflect the meaning accorded to the phrase. 'Gross' means glaring, reprehensible, culpable, flagrant, and shocking. It requires that the mere allegation shows that the

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31 Braza v. Sandiganbayan, G.R. No. 195032, 20 February 2013, 691 SCRA 471, 490.
32 Morales v. People, G.R. No. 144047, 26 July 2002, 385 SCRA 259, 260.
33 G.R. No. 135294, 20 November 2000, 345 SCRA 248, 267.
34 *Ibid.*
35 *Id.*
36 G.R. No. 181293, 23 February 2015, 751 SCRA 271.

disadvantage on the part of the government is unmistakable, obvious, and certain.[37]

Moreover, to prove that a transaction is grossly disadvantageous, it must be shown that the transaction is going to cause the government a serious disadvantage in that what it will receive is not commensurate with what it is committed to give.[38]

In the instant case, the Report asserts that the purchase of Dengvaxia was disadvantageous to the government because the money could have been used for more worthy government projects; or that since Dengvaxia is not 100 percent effective (or could result to more severe dengue symptoms for seronegatives), the money used to pay for the vaccines should have been devoted to some other use. This situation however is not contemplated under the provision of the anti-graft law on disadvantageous contracts. If there were other pharmacological companies that offered a similar dengue vaccine for a lower price and the Aquino government nonetheless opted to buy Dengvaxia, then there may be a case for violation of the said law.

The Report also asserts that the purchase of Dengvaxia is disadvantageous because the vaccine may cause seronegatives to experience severe dengue symptoms. The duty of the government, however, is to protect the greater majority. As discussed above, even the WHO declared that Dengvaxia is beneficial to endemic countries like the Philippines, despite Sanofi's 29 November 2017 announcement. On 22 December 2017, the WHO issued the "Updated Questions and Answers related to the dengue vaccine Dengvaxia and its use" which states that "in the areas in the Philippines where Dengvaxia was introduced, the seroprevalence was estimated to be at least 85 percent. **A seroprevalence of 85 percent means that 85 percent of the population is seropositive and will benefit from Dengvaxia**. In such a high transmission setting, every 1 excess case within a 5 year period of hospitalized dengue in vaccinated seronegatives is offset by 18 cases prevented in vaccinated seropositives, and 1 excess severe dengue in vaccinated seronegatives by 10 prevented severe cases in vaccinated seropositive."

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37 *Ibid.*

38 DOJ Opinion No. 108, s. 1985.

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The impact of vaccination versus non-vaccination on 830,000 individuals, in settings where 90percent of the population had previous dengue infection, is estimated to result in total reduction of 10,900 dengue hospitalizations and 2,800 severe dengue cases over 5 years. Even for the seronegatives, to whom the vaccine is not recommended, they would only exhibit traditional dengue symptoms if they do get infected with the dengue virus after having been bitten by a mosquito.

Thus, it may not be said that the contract for the purchase of Dengvaxia was disadvantageous to the government.

LIABILITY FOR ALLEGED HASTE IN PROCURING DENGVAXIA

The Report expresses suspicion on the regularity of the purchase of Dengvaxia on the basis of the apparent haste in concluding the sale transaction.

The alleged haste in the purchase of Dengvaxia was explained at the Senate hearing on 11 December 2017, when President Aquino delivered his preliminary statement quoted above, which explained the process by which he and his government reached the decision to procure the vaccine.

As early as 2010, or five years before the purchase of Dengvaxia, President Aquino was already discussing the problem of dengue with Sec. Ona. He was informed that a lot of people were contracting dengue; in Region 8, there was an increase of 1,409 percent in the number of those who were infected with dengue; if there were 200,000 cases of dengue every year, and that number could increase by 1,409 percent, it was possible to have 2.8 million cases of dengue cases. Those infected would need blood transfusion, and may be hospitalized; and may have to be financially supported by the government; for the 2.8 million infected with dengue, at PhP 20,800 estimated hospitalization expenses per patient, the government would have to spend 58.2 billion pesos; he found out that a dengue vaccine was invented; it went through the necessary regulatory processes; it had been previously approved for use in Mexico and Brazil; he did not hear any objection to the vaccine. As to the meeting with Sanofi, in Dec. 2015, he went to Paris for the COP21 Conference, a meeting among different countries to discuss the problem of climate change. As in all his travels, he met with interested investors, among them Vivapolis, Airbus, Jacobi Carbons, CRH, Usine IO, and Sanofi. Sanofi informed him about Dengvaxia.

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Considering the 1,409 percent increase in dengue cases in Region 8 alone, and the possible expenses of the government amounting to over 50 billion pesos, it is clear that President Aquino and the other government officials who participated and implemented the dengue vaccination program of the government, acted promptly and correctly under the circumstances. They may not be held liable for the said purchase.

The explanation of President Aquino is logical and credible. The dengue problem is serious. He was presented with a remedy. As a caring President, he had the moral obligation to prevent more Filipinos from contracting and dying from dengue. The outrage about the vaccine seems to stem from misunderstanding the effects and benefits of the vaccine.

The impact of vaccination versus non-vaccination on 830,000 individuals, in settings where 90 percent of the population had previous dengue infection, is estimated to result in **total reduction** of 10,900 dengue hospitalizations and 2,800 severe dengue cases over 5 years.

Even for the seronegatives, to whom the vaccine is not recommended, they would only exhibit traditional dengue symptoms if they do get infected with the dengue virus after having been bitten by a mosquito.

The vaccine does not make people ill with dengue; the virus carried by a mosquito does. No deaths have been shown to have resulted from the vaccine.

Notably, on 22 December 2017, the WHO issued the "Updated Questions and Answers related to the dengue vaccine Dengvaxia and its use" which states that "in the areas in the Philippines where Dengvaxia was introduced (mainly through school programmes), the seroprevalence was estimated to be at least 85%. A seroprevalence of 85% means that 85% of the population is seropositive and will benefit from Dengvaxia. In such a high transmission setting, every 1 excess case within a 5 year period of hospitalized dengue in vaccinated seronegatives is offset by

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Hence, with all the information before him, in his opinion, he had to solve the dengue problem. If Sanofi did not make its disclosure on 29 November 2017, and Pres. Aquino decided to let Filipinos suffer from dengue even when a dengue vaccine was available, the people would probably accuse him of neglect and he would be blamed by the mothers whose children died of dengue.

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18 cases prevented in vaccinated seropositives, and 1 excess severe dengue in vaccinated seronegatives by 10 prevented severe cases in vaccinated seropositive." Thus, this confirms the overall efficacy and safety of the dengue vaccine.

The discussion of the dengue problem began in 2010, and the problem of dengue has been existing for decades, the purchase of the vaccine in 2015 can be hardly characterized as hasty.

Parenthetically, the Report states that Sec. Ona denied meeting with President Aquino about the dengue problem. Sen. Gordon believes Sec. Ona and not President Aquino. He did not, however, explain why Sec. Ona is more trustworthy. In any event, it cannot be denied that many Filipinos get infected with dengue. The problem has been existing for as long as we can remember.

There was no violation of the procurement law

The procurement processes leading to the purchase of Dengvaxia for the public immunization program have already been reviewed and investigated by the Integrity Management Committee of the DOH.[39] According to then Secretary of Health Paulyn Ubial, she "commissioned the review after the congressional hearing in December [2016] x x x and the procurement, the FEC exemption were all within the bounds of law and within the bounds of policy."[40] Thus, the alleged irregularities in the procurement process can all be addressed by the Integrity Management Committee's report.

There was no undue haste in the procurement of the dengue vaccine. The then controlling 2009 Implementing Rules and Regulations of R.A. No. 9184 ("GPRA-IRR") provides the maximum periods and earliest possible time for action on specific procurement activities.[41] Under the GPRA-IRR, the earliest possible time for the procurement of goods is 28 calendar days, while the maximum period is 80 calendar days.[42] The procurement of the dengue vaccine took 46 calendar days,

39 TSN, 11 December 2017, II-3, p. 115.
40 TSN, 11 December 2017, II-6, pp. 274-275.
41 GPRA-IRR, Sec. 38.1
42 See Annex "C" of the GPRA-IRR.

benefit from Dengvaxia. In such a high transmission setting, every 1 excess case within a 5 year period of hospitalized dengue in vaccinated seronegatives is offset by 18 cases prevented in vaccinated seropositives, and 1 excess severe dengue in vaccinated seronegatives by 10 prevented severe cases in vaccinated seropositive." Thus, this confirms the overall efficacy and safety of the dengue vaccine.

The discussion of the dengue problem began in 2010, and the problem of dengue has been existing for decades, the purchase of the vaccine in 2015 may can be hardly characterized as hasty.

Parenthetically, the Report states that Sec. Ona denied meeting with Pres. Aquino about the Dengue problem. Sen. Gordon believes Sec. Ona and not Pres. Aquino. He did not, however, explain why Sec. Ona is more trustworthy. In any event, it cannot be denied that many Filipinos get infected with dengue. The problem has been exis

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40 TSN, 11 December 2017, II-6, pp. 274-275.
41 GPRA-IRR, Sec. 38.1.
42 *See* Annex "C" of the GPRA-IRR.

which is only slightly shorter than the average between the earliest possible and maximum periods:

Actual Date	Activities	Number of Days	
		Actual	**GPRA-IRR**
23 January 2016	Advertisement/Posting of Invitation to Bid and Issuance and Availability of Bidding Documents	7 calendar days ("cd")	7 cd
1 February 2016	Pre-Bid Conference	1 cd (14 days before the submission of bids)	1 cd (12 days before the submission of bids)
15 February 2016	Submission and opening of bids	1 cd	1 cd
16 to 19 February 2016	Post-qualification	3 cd	1 cd
8 March 2016	Approval of Resolution/Issuance of Notice of Award	17 days	2 cd (1 cd for BAC Resolution and 1 cd for issuance of Notice of Award)
8-10 March 2016	Contract Preparation and Signing	2 cd	2 cd (1 cd for contract preparation and 1 cd for contract signing)
Unknown	Approval of Contract by Higher Authority	unknown	1 cd
11 March 2016	Issuance of Notice to Proceed	1 cd	1 cd
TOTAL		**46 cd**	**28 cd**

Thus, the supposed speed by which the dengue vaccine was procured can hardly be considered unusual, as the relevant regulation even provides for a shorter period of time.

LIABILITY FOR ALLEGED VIOLATION OF THE RIGHT TO INFORMATION

The Report gravely misunderstands the nature of the right to information as a universal human right. It alleged that President Aquino violated the human rights, specifically the right to information, of parents/guardians of these impoverished Filipino children when no proper and intelligent information was given to them prior to the introduction of the vaccine.

Freedom of information as a universal human right and an integral part of the freedom of expression is defined as the right to access information held by public

bodies. In a nutshell, right to information, in many countries, including the Philippines by virtue of Executive Order No. 2 series of 2016, means mandating timely response to citizen requests for information held by the government. This also means that access to official records, and to documents and papers pertaining to official acts, transactions, or decisions, shall be afforded any requesting citizen subject only to limitations provided by law. This reflects the fundamental premise that all information held by governments and governmental institutions is in principle public and may only be withheld for legitimate reasons.

Some examples of violations of the right to information as held by the Supreme Court are: denial of the request for information on the civil service eligibilities of certain persons employed as sanitarians in the Health Department of Cebu City;[43] failure to furnish a list of the names of Batasang Pambansa members belonging to the UNIDO and PDP-Laban who were able to secure GSIS loans through the intervention of then First Lady Imelda Marcos and certified true copies of documents evidencing their respective loans upon request;[44] refusal to answer a letter requesting for the names of executive officials holding multiple positions in government, copies of their appointments, and a list of the recipients of luxury vehicles seized by the Bureau of Customs and turned over to Malacanang;[45] and refusal of Comelec to disclose or publish the names of the nominees of the various party-list groups.[46]

It then goes without saying that alleging violation of the human right to information is not applicable in a case where the public officers involved supposedly failed to provide proper and intelligent information to the parents of potential risks prior to the introduction of a vaccine.

For these reasons, I DISSENT.

Respectfully submitted.

FRANKLIN M. DRILON

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[43] Legaspi vs. Civil Service Commission, G.R. No. L-72119, May 29, 1987
[44] Valmonte vs. Belmonte, G.R. No. 74930, February 13, 1989
[45] Gonzales vs. Narvasa, G.R. No. 140835, August 14, 2000
[46] BA-RA 7941 vs. Comelec, G.R. No. 177271, May 4, 2007

Senate
Office of the Secretary

Republic of the Philippines
Senate

'18 APR 30 P4 :02

Office of Senator Leila M. de Lima

RECEIVED

LML-LE-30D18-097

30 April 2018

Ms. Ma. Antoniette Aristoza
Director III
Senate Bills and Index

Re: Filing of the undersigned's Separate Dissenting Report
in the Dengvaxia Vaccine Probe

Dear **Director Aristoza**:

We understand that earlier today, a Committee Report was filed with your office by Sen. Richard J. Gordon, as Chairman of the Blue Ribbon Committee, relative to: (1) his PRIVILEGE SPEECH DELIVERED ON OCTOBER 11, 2016 ON THE ALLEGED P3.5 BILLION WORTH OF QUESTIONABLE DENGUE VACCINES THAT HAD BEEN ADMINISTERED BY THE DOH TO 280,000 STUDENTS WITHOUT PASSING THROUGH WORLD HEALTH ORGANIZATION (WHO) PREQUALIFIED REQUIREMENTS; and (2) PSR Nos. 557 and 563 of Senators J.V. Ejercito and Grace Poe, respectively.

The undersigned is hereby submitting her **Separate Dissenting Report** to said Committee Report pursuant to Section 22 of the Rules of Procedure Governing Inquiries in Aid of Legislation. Kindly file this Separate Dissenting Report together with the Committee Report of Senator Gordon, in line with said provision.

Very truly yours,

LEILA M. DE LIMA

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Copy furnished:

SEN. RICHARD J. GORDON
Chairman, Blue Ribbon Committee

SEN. JOSEPH VICTOR G. EJERCITO
Chairman, Committee on Health and Demography

SEN. LOREN B. LEGARDA
Chairperson, Committee on Finance

SEN. AQUILINO "KOKO" PIMENTEL III
Senate President

SEN. RALPH G. RECTO
Senate President Pro-Tempore

SEN. VICENTE C. SOTTO III
Majority Leader

SEN. FRANKLIN M. DRILON
Minority Leader

SEN. GRACE L. POE
SEN. MARIA LOURDES NANCY SOMBILLO BINAY
SEN. SONNY M. ANGARA
SEN. PAOLO BENIGNO AQUINO IV
SEN. FRANCIS "CHIZ" G. ESCUDERO
SEN. SHERWIN GATCHALIAN
SEN. GREGORIO B. HONASAN II
SEN. RISA HONTIVEROS
SEN. PANFILO "PING" M. LACSON
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SEVENTEENTH CONGRESS OF THE)
REPUBLIC OF THE PHILIPPINES)
Second Regular Session)

'18 APR 30 P4 :02

RECEIVED

SENATE

SEPARATE DISSENTING REPORT OF SEN. LEILA M. DE LIMA

to Committee Report No. ____

of the Committee on Accountability of Public Officers and Investigations (Blue Ribbon), Committee on Health and Demography, and Committee on Finance,

Re : PRIVILEGE SPEECH OF SEN. GORDON DELIVERED ON OCTOBER 11, 2016 ON THE ALLEGED P3.5 BILLION WORTH OF QUESTIONABLE DENGUE VACCINES THAT HAD BEEN ADMINISTERED BY THE DOH TO 280,000 STUDENTS WITHOUT PASSING THROUGH WORLD HEALTH ORGANIZATION (WHO) PREQUALIFIED REQUIREMENTS

PROPOSED SENATE RESOLUTION NO. 557 - RESOLUTION DIRECTING THE PROPER SENATE COMMITTEE TO CONDUCT AN INQUIRY, IN AID OF LEGISLATION, ON THE DENGUE IMMUNIZATION PROGRAM OF THE DEPARTMENT OF HEALTH VIS-À-VIS THE SANOFI PASTEUR'S NEW CLINICAL FINDINGS ON THE VACCINE DENGVAXIA'S ADVERSE EFFECTS TO ITS RECIPIENTS (by Senator Ejercito)

PROPOSED SENATE RESOLUTION NO. 563 - RESOLUTION DIRECTING THE PROPER SENATE COMMITTEE TO INVESTIGATE, IN AID OF LEGISLATION, THE REPORTED DANGER OF THE SCHOOL-BASED DENGUE VACCINATION PROGRAM OF THE DEPARTMENT OF HEALTH (DOH) WITH THE OBJECTIVE OF CRAFTING MEASURES THAT WILL ENSURE THE SAFETY AND EFFICACY OF GOVERNMENT-SPONSORED IMMUNIZATION PROGRAMS; STRENGTHEN PARTICIPATORY AND TRANSPARENT GOVERNANCE; AND HOLD ACCOUNTABLE PERTINENT GOVERNMENT OFFICIALS AND PHARMACEUTICAL MANUFACTURERS IN THIS REGARD (by Senator Poe)

MR. PRESIDENT:

I join the dissent of Sen. Franklin M. Drilon to the Blue Ribbon Committee Report on the Dengvaxia investigation subject of the October 11, 2016 privilege speech of Sen. Richard J. Gordon, and PSR Nos. 557 and 563. Furthermore, I object to the said Committee Report based on my own appreciation of the facts established vis-à-vis their presentation in the Committee Report.

THE NARRATIVE

The central premise of the Committee Report behind the conclusions arrived at therein is that the supposed haste that allegedly characterized the procurement of the Dengvaxia vaccine was caused by none other than a pre-meditated scheme hatched by the Aquino Administration to use the public immunization program as some sort of a campaign tool for the May 2016 presidential elections. This is not surprising, as this appears to be the recurring theme insinuated by the Chairman of the Committee in all seven hearings of the Dengvaxia investigation. The problem, therefore, with the conclusions in the report is that they are based on a premise that was never proven throughout the entire investigation: that the Aquino Administration merely used the Dengvaxia public immunization program to win the May 2016 presidential elections. This was not proven even by mere circumstantial evidence that excludes any other rational explanation to the procurement and implementation of the program.

It was never proven throughout the entire investigation that anybody got a bribe, commission or one way or another profited from the whole affair. Not a single witness was presented to prove that a single public official, from former President Benigno S. Aquino III and former DOH Secretary Janette Garin, to the lowliest FDA official, enriched himself or herself from the whole transaction.

On these allegations of graft and corruption that permeates the whole Committee Report, not a single iota of hard evidence was presented so as to categorically exclude any other explanation as the reason behind the Aquino Administration's implementation of the dengue immunization program.

But once the Committee Chairman has already settled with this unproven assumption as the central feature of the Dengvaxia procurement and public immunization program, it became difficult for him to look the other way, and entertain the feasibility of other rationales for the policy decisions and actions pursued by the government in pushing for the Dengvaxia procurement and public immunization. In a sense, he has already put on blinders, and this is shown in the Committee Report that appears to be more of the Chairman's personal political manifesto against former President Benigno S. Aquino III than anything else.

The blinders were worn so tight there was no room for the presentation of the government narrative as expounded during the hearings, a narrative that offered an alternative explanation to the actions that the report condemns as hasty and reckless. But when approached from the government perspective, what the report calls hasty and reckless actions become urgent measures to overtake the next wave of infections brought by a killer virus.

According to the DOH Integrity Management Committee's "*Report on the Introduction of the Tetravalent Dengue Vaccine in the Department of Health Immunization Program*", the Philippines ranked first in dengue prevalence in the Western Pacific Region in the years 2013 to 2015.[1] Moreover, from a 15-year high of 57,818 dengue cases reported in 2009, the situation further worsened to 173,033 in 2010, or an increase of 199%. It further

[1] P. 14.

increased to 200,415 cases reported in 2015, with 50% of the cases coming from the three highly urbanized regions, *viz.*, Regions III, IV-A, and NCR.

Since 2010, the pressure on the government to find a solution to the rapidly increasing dengue cases and the concomitant increase in health care costs was becoming real. Hopes were high that the dengue vaccine being developed by Sanofi-Pasteur would provide part of the solution.

Indeed, dengue was not a Top Ten killer. Nevertheless, it was still a killer. This is what was impressed upon President Aquino as early as 2010 by then DOH Sec. Enrique Ona:

> **MR. AQUINO.** xxx Nagsimula po ang pagtutok ko sa dengue sa Pilipinas matapos kong matanggap ang memo ni Secretary Ike Ona, dated ika-23 ng Agosto taong dalawang libo at sampu. Sa briefing sa akin, lahat ng serotypes o uri ng dengue narito na raw po sa Pilipinas. Hindi din daw seasonal ang dengue at walang gamot para dito. Malaon po, sasabihin sa akin ni Secretary Ona na may mga nagde-develop ng vaccine para sa lahat ng mga strain na ito. xxx
>
> Sa memo po ni Secretary Ona, naka-highlight ang limang rehiyong may pinakamataas na ulat ng dengue. Tatlo sa lima, higit isandaang porsyento ang itinaas. May isa po, 1,409.5 percent increase o 14 na beses ang itinaas. xxx Ang nakakatakot dito, kung tinatayang may dalawang-daang libong kaso ng dengue, halimbawa, kada-taon, at posibleng umangat ng labing-apat na beses ang bilang tulad sa nangyari sa Region VIII, ang potential na pwedeng magkasakit, pwedeng umabot ng 2.8 million. xxx[2]
>
> **xxx** **xxx** **xxx**

[2] TSN, December 14, 2017, pp. 19-21.

> **MR. AQUINO.** xxx So, 2010, Secretary Ona tells me that we have this problem. So, various interventions were done but vector control intervention, as the technical term, does not seem to be sufficient to fully address the problem. He informed me that Sanofi, and there is another company xxx was also developing another vaccine xxx but it was behind Sanofi in terms of stage of development.
>
> So, every follow-up was where are we already in terms of being able to use this vaccine throughout the time that he served as secretary of health from 2010 to 2014.[3]
>
> **xxx** **xxx** **xxx**
>
> **MR. AQUINO.** Well, the bottom line is, August 23, 2010, there's a problem and there's no complete solution that is afforded and there is a potential solution somewhere on the horizon. And now they're saying that this potential is an actuality. And, yes, I believe I would have said something like I was excited.[4]

The fact of communicating to President Aquino the sense of urgency on the dengue problem as early as 2010 -- with the objective of shaping public policy, including considering the future roll-out of a vaccine under development -- was corroborated by Sec. Ona:

> **MR. ONA.** xxx This was of great interest to me since dengue fever is not only rampant in the Philippines, almost appearing all-year round and was also being used as one of the measures of our public health performance by the public. xxx
>
> xxx I recall in more than one occasion that I mentioned in passing to then President Aquino of a possible dengue vaccine that may be ready any

[3] TSN, December 14, 2017, pp. 121-122.
[4] TSN, December 14, 2017, p. 148.

> time soon. However, we did not allocate any budget for the dengue vaccine for 2015 – that was the year after I resigned – since I consider this vaccine was still at its developmental stage and was undergoing further observation and evaluation. xxx [5]

However, this fact was not only not mentioned in the report, but it was even factually misrepresented in order to attribute the idea of using the dengue vaccine exclusively to Sec. Garin. Attributing it exclusively to Sec. Garin, of course, supports the Dengvaxia-for-Elections narrative of the Chairman. I quote several portions of the records of the hearing that make it impossible for the Chairman to not only miss these in his report, but to actually misrepresent Sec. Ona's role:

> **Mr. ONA.** I was secretary of Health from June 2010 to December 2014, a period of four and a half years. During this period, the Sanofi Pasteur Pharma group would request a briefing for me on the status of the clinical trial of their anti-Dengue vaccine being tested in South East Asia including the Philippines, as well as several other countries in South America. This occurred almost annually during my term as secretary. xxx
>
> xxx I had high hopes that [sic] many others that the vaccine being developed would eventually control this mosquito-borne disease that afflicts more than a 100,000 Filipinos or patients annually and scares so many of our foreign visitors and tourists. xxx
>
> xxx Unfortunately, during all these times until the end of my term, the Sanofi staff, though optimistic, never claimed that the vaccine was ready for general use and only gave vague projection to me of the time when it may be ready for launching.[6]
>
> **xxx** **xxx** **xxx**

[5] TSN, January 22, 2018, pp. 17-18.
[6] TSN, January 22, 2018, pp. 17-18.

MS. GARIN. xxx I remember there were two meetings that we were requested by Secretary Ona to attend and hear out updates on the dengue vaccine because as he mentioned to us, the department intends to roll it out in the public by July of 2015. That was his pronouncement in 2014.

THE CHAIRMAN (SEN. GORDON). Which drug was that?

MS GARIN. The dengue vaccine, Your Honor.

THE CHAIRMAN (SEN. GORDON). Which drug manufacturer?

MS. GARIN. The Dengvaxia, Your Honor. Because when we –

THE CHAIRMAN (SEN. GORDON). So, Secretary Ona told you that he was going to roll out Dengvaxia on July 2015?

MS. GARIN. Yes, Your Honor. And he made a press conference I think June or July of 2014.[7]

xxx **xxx** **xxx**

MS. GARIN. xxx And to take off, Your Honor, for the record, allow me to submit the policy development process for the dengue public program because as of September in 2014 during the meeting in the Office of the Secretary where I was still an undersecretary and the phase three clinical trials of the dengue vaccine in Latin America was presented, Secretary Ona inquired on the price of the vaccine and communicated to Dr. Lyndon Lee Suy and Asec Eric Tayag to come up with mechanisms to estimate the need and prioritize recipient of the vaccines. This was done in good

[7] TSN, December 14, 2017, p. 120.

> faith, considering the data that was presented to the Department at that time. xxx[8]
>
> **xxx** **xxx** **xxx**
>
> **THE CHAIRMAN (SEN. GORDON).** But Secretary Ona said he was not endorsing it.
>
> **MS. GARIN.** Your Honor –
>
> **THE CHAIRMAN (SEN. GORDON).** And you endorsed it.
>
> **MS. GARIN.** Your Honor, he conducted a press conference sometime in September and July 2014 endorsing the vaccine after their company presented before the Office of the Secretary in our presence the results of phase 3 clinical trials.[9]

The Committee Report also made Ona's resignation from the DOH appear to be a mystery, thereby insinuating that Ona was forced to take a leave in October 2014 and eventually resign because he was against the President's scheme to use the dengue vaccine for the May 2016 Elections. This insinuation is repeated several times in the report, even when the records of the hearing are clear on Sec. Ona's categorical denial of this malicious account of the reasons behind his resignation:

> **THE CHAIRMAN (SEN. GORDON).** And you said here, tinanong ko kayo, "May tampuhan ba kayo?" Bakit kayo biglang magle-leave? You are such a very qualified person, suddenly magle-leave kayo.
>
> **MR. ONA.** I have answered that before, Your Honor.

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[8] TSN, January 22, 2018, p. 102.
[9] TSN, February 21, 2018, p. 120.

THE CHAIRMAN (SEN. GORDON). No, I want you to clarify that answer, Dr. Ona. And I want you to be very candid because this is important. Because kung anu-ano ang pumapasok sa isipan ko. Kasi, again, if you look at the way it happened, you took a leave of absence on the 28th. Two weeks later, on November 14, they are talking to Sanofi, the President is talking to Sanofi. And you said you are not going to recommend Sanofi, correct?

MR. ONA. Hindi ho pa iyon – we did not even consider that or even discussed that at that moment, Your Honor.

THE CHAIRMAN (SEN. GORDON). Hindi niyo kinonsider (consider) iyong Sanofi?

MR. ONA. No.[10]

xxx **xxx** **xxx**

THE CHAIRMAN (SEN. GORDON). And yet this President met with him again in France on December, the following year.

Now, mukhang – ano ba iyong alitan ninyo? Tampuhan ba iyon o ayaw mo bang pumayag doon sa Sanofi?

MR. ONA. It has nothing to do with Sanofi.

THE CHAIRMAN (SEN. GORDON). Good, good, good. I am glad that you say that. Ano iyong tampuhan ninyo?

MR. ONA. Well, it was –

THE CHAIRMAN (SEN GORDON). If you are welcome to kuwan – if you are willing to –

[10] TSN, February 6, 2018, p. 139.

MR. ONA. It's just a feeling po that at that time, there were issues wherein I felt the President did not trust anymore my advice on him.

THE CHAIRMAN (SEN. GORDON). Why is that?

MR. ONA. It started ho with –

THE CHAIRMAN (SEN GORDON). Did you have access to him?

MR. ONA. Well, it started even with the issue noon ho noong pneumonia vaccine...

THE CHAIRMAN (SEN. GORDON). Right.

MR. ONA. ...and even with the issue noong ebola, you're very familiar with that, I think, Your Honor.

THE CHAIRMAN (SEN GORDON). Yes. I even –

MR. ONA. We discussed that. And as a matter of fact, I was very, very strong in my recommendation that we send assistance to Africa.

THE CHAIRMAN (SEN. GORDON). I remember that.

The Red Cross sent one. And unfortunately, the country did not send any.

MR. ONA. But the President just ignored that suggestion. As a matter of fact, I even volunteered to head the team to go to Africa at that time. There was special request even from the British government, from Prime Minister Cameron, for assistance from us to send health workers. And I was very, very strong in my recommendation because I felt that that was the least that we could do with the help that the other countries had

given to us during the typhoon in Leyte. And so, therefore, I felt that there was a certain amount of maybe responsibility for us to really assist the world community and WHO, then the CDC in the United States as well as even in UK during that time.

THE CHAIRMAN (SEN. GORDON). At tama lang po iyon because tumulong naman sa atin, ano ho? At saka hindi naman masamang tumulong kung kaya.

So, iyon ang hindi ninyo pagkakaintindihan. Sabi ninyo nawalan kayo ng access. Bakit kayo nawalan ng access?

MR. ONA. It's not nawala ho. It's just that we could not get that time to be able to sit down with the President.

THE CHAIRMAN (SEN. GORDON). You were the Secretary of Health and you could not get the time?

MR. ONA. That's exactly what happened, Your Honor.[11]

If there is any one person to whom the reasons behind Sec. Ona's resignation should be clear, it should be the Chairman. He was in a one-on-one cross-examination with the witness. The witness categorically told him that his resignation has nothing to do with either Sanofi or his refusal to go on board the procurement of Dengvaxia.

And yet, in the Committee Report, the reason behind Sec. Ona's resignation remains a great mystery for the Chairman, and is one of the major "findings" he uses to insinuate that Sec. Ona was forced to resign because he refused to go on board the Dengvaxia procurement. Despite Sec. Ona's categorical clarification on the reasons for his resignation, the Committee

[11] TSN, February 6, 2018, pp. 145-147.

Report simply has to gloss over this and maintain that these reasons remain a mystery, because the fact that Sec. Ona resigned for reasons other than the Dengvaxia issue does not fit the Dengvaxia-for-Elections narrative the Chairman already tailored for the Committee Report.

The timeline of the Dengvaxia saga in the Philippines therefore did not start with the resignation of Sec. Ona and the meeting of President Aquino with Sanofi representatives in Beijing on November 9, 2014. It started as early as 2010, when Sec. Ona warned the President about the urgency of the dengue problem and the 1,400 per cent increase in cases in one region, thereby making the President aware of the increasing threat of dengue that has ceased to become seasonal, instead becoming a year-long phenomenon. It is also at this time that President Aquino was made aware of a vaccine under development that they hoped can provide a solution to an emerging public health disaster. This was to continue every year as Sec. Ona updated himself on Sanofi's vaccine development and clinical trials in Southeast Asia almost every year, according to Sec. Ona himself.

But again, policies, plans, meetings, and discussions since 2010 were not included in the timeline of the Committee Report, as this did not fit the Dengvaxia-for-Elections narrative. The timeline had to conveniently start in the latter part of 2014 when, according to the desired narrative, President Aquino forced Sec. Ona to resign because he did not agree with the President's plan to use Dengvaxia for the Liberal Party's presidential election campaign in 2016.

THE SCIENCE

The next agenda of the Committee Report was to demonize Dengvaxia. On a matter where experts are equally divided, the report made it out to appear that President Aquino and Sec. Garin knowingly bought poison for injection

into the bodies of Filipino children, just short of the genocide accusation hurled at them by some quarters.

The Chairman may not believe it, but there was actually reasonable ground for the government to act as it did in the procurement of the dengue vaccine. It was explained by resource persons as best as they could in the hearings, even at the risk of being cut-off by the Chairman once the explanations became too reasonable and convincing.

The vaccine after all was approved for use by the national regulatory agencies of 20 countries. The WHO Strategic Advisory Group of Experts eventually came out with a position that did not prohibit the use of the vaccine, or declared it as some sort of a poison as the Committee Report would have us believe, but quite the contrary said it can be considered for use in countries and areas with high seroprevalence, or where the larger percentage of the population was already most likely infected with the virus, because it is in these areas where the vaccine has been adequately tested to be most efficacious. The Philippines and Brazil where it was launched as a public immunization program fit these descriptions of areas where the dengue virus was endemic.

This was the explanation of Dr. Gundo Weiler, Country Representative of the World Health Organization in the Philippines.

> **MR. WEILER.** xxx Now, this position paper did not make a blanket recommendation to countries to introduce the dengue vaccine but rather recommended that the countries consider the introduction of dengue vaccine only in areas where there is a high burden of disease. Now, the paper listed a number of conditions that should be met by countries if they want to actually consider introducing the vaccine. It also listed benefits and risks and other issues that the countries should take into consideration when making this decision.

> xxx Now, the first set relates to conditions that should be met for a country to actually consider whether to introduce the vaccine. So, this includes: there should be a high prevalence of dengue in the country, in the target group. Ideally, more than 70 percent of people should have been exposed to dengue prior to vaccination; there should be a comprehensive dengue control strategy in the country; there should be capacity in place to monitor and manage the adverse effects following vaccination; and a dengue surveillance system that is able to detect and report hospitalized and severe dengue.
>
> So, these were the overall conditions set out for countries to actually consider introduction. And in mid-April, these were the considerations first published by this advisory group. And in mid-April, WHO acknowledged that these overall conditions appeared to be met in the Philippines, so that, indeed, the Philippines can consider the introduction and the use of this vaccine.
>
> xxx So, in terms of the benefits, WHO said that the overall vaccine appeared to be efficacious in preventing dengue. In terms of risk, the paper said that in people nine years and older, in the study group for which we had data at that time, the statistical increase in the risk of severe dengue was not observed. However, the paper did note that in the light of the limited data available, there was a theoretical risk that previously uninfected people in those people vaccination [sic] could increase the occurrence of severe dengue. And the paper said that this would require more research to confirm.[12]

In fact, because of the WHO position paper, the DOH Second Expert Panel under former DOH Secretary Paulyn Ubial recommended the expansion of the dengue vaccination program to include Region VII and other highly endemic areas in October 2016. So even Sec. Ubial, one of the early objectors to the public immunization who remarked all throughout the hearings that she

[12] TSN, December 14, 2017, pp. 27-29.

never agreed to the entire methodology of the public introduction of Dengvaxia in such a large-scale manner, actually expanded it from Regions III, NCR, and IV-A to include Region VII, other highly endemic areas, and even community-based, instead of school-based. This is because world-recognized experts, especially the WHO, were already saying that the vaccine worked under conditions which the Philippines exhibited. Otherwise, the DOH under Sec. Ubial should have just simply shut it down upon her assumption into office.

> **SEN. DRILON.** And after you consulted the second panel, you continued the program and increased the coverage geographically to Region VII. Is that a correct statement?
>
> **MS. UBIAL.** Yes, Your Honor.
>
> **SEN. DRILON.** Why?
>
> **MS. UBIAL.** Because there was approximately 2.4 billion worth of vaccines that is already in the warehouse and about to be delivered that we cannot use if we do not continue the program. And that was the dilemma on my shoulders.
>
> **SEN. DRILON.** Are you saying that you approved this and expanded it simply because there were vaccines in stock and not because it is a program worth implementing?
>
> **MS. UBIAL.** Your Honor, at that point in time, it was licensed by the Food and Drug Administration. It was approved to be implemented by the World – the position paper of the World Health Organization came out July 2016. So that was out. And then the expert panel was convened and they recommended that it be expanded to the region with the similar situation as III, IV-A and NCR and with the conditions that were in the position paper of WHO, Your Honor.

SEN. DRILON. So you were convinced independently that regardless of whether or not there was enough stock, this program is worth continuing because of these circumstances that you mentioned?

MS. UBIAL. Actually, Your Honor, what they call as an increase risk for patients with no exposure to dengue, at that point in time, Your Honor, is considered a theoretical risk. So it would be very difficult on my part when later on, after all these studies have been done, and they tell you the theoretical risk is not anymore a risk. We found out that it is no longer happening.

So how can I face the people where I wasted 2.5 billion vaccines [sic] and there is no risk at all? I cannot tell the future. I cannot tell that Sanofi will come out on November 29, 2017 and tell us that the risk is real. It's not a theory anymore.[13]

xxx **xxx** **xxx**

MS GARIN. Your Honor, when the program was conceptualized in coordination with PSMID, PIDSP and the World Health Organization, it was very clear that the immunization will take part in public schools in the three highly endemic areas, in a school-based setting as the six vaccines in the school-based immunization program. It was never discussed that it will be done community-based because monitoring and meeting the parents will be more difficult. So again, allow me to repeat. The program under my time was school-based for Grade IV students above nine years old to cover NCR, Region IV and Region III. Wala po doon iyong sa adults. Wala rin po doon iyong house to house.

THE CHAIRMAN (SEN. GORDON). Iyong Region VII, wala rin doon?

MS. GARIN. Wala, Your Honor. The proposal was actually six regions.

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[13] TSN, December 14, 2017, pp. 245-246.

THE CHAIRMAN (SEN. GORDON). Three regions.

MS. GARIN. No, no. The initial proposal was six regions but it was trimmed down to three.

THE CHAIRMAN (SEN. GORDON). Three.

MS. GARIN. Three lang iyong in-approve.

THE CHAIRMAN (SEN. GORDON). Tapos iyong Region VII, kalian pumasok?

MS. UBIAL. Sir, after the second expert panel recommended its expansion to Region VII and other highly endemic areas.

THE CHAIRMAN (SEN. GORDON). When was that po?

MS. UBIAL. October 2016.[14]

Even before the WHO position paper, these were already the working analyses that Sec. Garin was grappling with before the roll-out of the vaccine. The WHO position paper is basically the same information she was already getting in her meetings with WHO directors on vector control, vaccination, and dengue management:

MS. GARIN. Your Honor, after hearing ... the Halstead theory and some of the apprehensions, again, I actually went to Geneva on the sidelights of the executive board meeting of the World Health Organization and I've requested a pull-out meeting for the directors involved in vector control in vaccination and dengue management. xxx

[14] TSN, February 21, 2018, pp. 277-278.

> **MS. GARIN.** xxx my first question to them was: "Were you with them" – and I was referring to Sanofi – "Were you with them when the vaccine was being developed?" And they said, "Yes, we are throughout with them not only with Sanofi but with the other companies as well in the development of the vaccine." And if I may quote them, they said, "It is a thoroughly studied vaccine and we have full confidence on it. But never guarantee that dengue will be out of the picture because no vaccine is 100 percent effective. Further, Your Honor, they said xxx
>
> **MS GARIN.** ... "Monitoring and surveillance is important." And then I asked them, "How about the 66 or 65 percent efficacy, is that justifiable?" And we were told, Your Honor, that the 93 percent reduction in severity and the 80 percent reduction in hospitalization is part of the objectives.[15]

This was the set of information that both the believers and non-believers in the Dengvaxia public immunization program possessed. The same set of working analysis that was considered as expert opinions at that time still convinced even non-believers like Sec. Ubial not only to continue with the program upon her assumption to the DOH leadership, but even to expand it. Because as she said, who was she to predict whether the "theoretical risk" on the seronegatives will remain theoretical or not?

These were basically the same parameters of decision-making that Sec. Garin was also working with before the policy decision on the Dengvaxia procurement was made. They were just not packaged in a WHO position paper that came out later and which Sec. Ubial had the benefit of relying upon. It was basically the same information, but the Committee Report set different standards on the decision-making of Sec. Garin, on the one hand, and Sec. Ubial, on the other. One was held liable for believing in the dominant working expert analysis on the risks and benefits of the vaccine, the other was not.

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[15] TSN, February 21, 2018, pp. 244-246.

In the end, the dominant science prevailed, in both instances, for Sec. Garin and Sec. Ubial. For Sec. Garin, the series of consultations she conducted, including those with WHO directors and experts, were enough. For Sec. Ubial, the WHO position paper covering for the expansion of the program to Region VII was enough. What is clear is that Dengvaxia has benefits as well as risks, and the reason why the experts, including WHO, considered the dengue vaccine for use in countries with high seroprevalence is because they concluded, based on the clinical trials of Sanofi-Pasteur, that its benefits outweighed the risks.

The December 22, 2017 WHO update, released after the November 29, 2017 disclosure of Sanofi-Pasteur on the confirmed risk to seronegatives, maintains the conclusion that the benefits of Dengvaxia in terms of prevented hospitalizations and cases of severe dengue among seropositives remain, although it is highly doubtful that the WHO will recommend any national or large-scale dengue vaccination program anytime soon, short of being assured of 100% seroprevalence. What is clear is that vaccinated seronegatives are exposed to the same risks as unvaccinated seropositives.[16] According to the WHO update:

> The expected number of cases prevented or induced in a vaccinated population will depend on the seroprevalence in a particular country and on the incidence of dengue infections. For example, in the areas in the Philippines where Dengvaxia® was introduced (mainly through school programmes), the seroprevalence was estimated to be at least 85%. A seroprevalence of 85% means that 85% of the population is seropositive and will benefit from Dengvaxia®. In such a high transmission setting,

[16] "The new analysis by Sanofi Pasteur suggests a similar rate of severe and hospitalized dengue between unvaccinated seropositive persons and vaccinated seronegative persons. The clinical severity in the vaccinated seronegative group was similar to that of severe cases in the unvaccinated seropositive group." World Health Organization, "Updated Questions and Answers related to the dengue vaccine Dengvaxia and its use", 22 December 2017.
http://www.who.int/immunization/diseases/dengue/q_and_a_dengue_vaccine_dengvaxia_use/en/

> every 1 excess case within a 5 year period of hospitalized dengue in vaccinated seronegatives is offset by 18 cases prevented in vaccinated seropositives, and 1 excess severe dengue in vaccinated seronegatives by 10 prevented severe cases in vaccinated seropositives.
>
> In the dengue transmission settings of the clinical trials with varying degrees of seroprevalence in different countries, during the 5 year follow-up after vaccination, there was a reduction of about 15 cases of hospitalized dengue and 4 cases of severe dengue per 1,000 seropositive persons vaccinated. For 1,000 seronegative persons vaccinated, there was an increase of about 5 cases of hospitalized dengue and 2 cases of severe dengue.[17]
>
> Accounting for prevented and induced cases, if the vaccine is administered in a population with a high seroprevalence, there is still a significant benefit in terms of reduction of severe dengue and hospitalizations due to dengue.

Should the government under President Aquino and the DOH under Sec. Garin have waited, or let the succeeding administration wait and decide, instead of relying on the available science coming from international and local experts? Should President Aquino have just ignored Secretary Ona's warning of a 1,400 percent increase in dengue cases in Region VIII, and that this could happen nationwide?

Of course, everything now is taken with the benefit of hindsight and, to a certain extent -- in the words of the Chairman himself -- appears to be a case of Monday morning quarterbacking. Regardless, still, in the absence of clear and categorical evidence of interests other than public health -- such as an election campaign or fat Sanofi commissions -- driving the decision-makers, the

[17] World Health Organization, "Updated Questions and Answers related to the dengue vaccine Dengvaxia and its use", 22 December 2017.
http://www.who.int/immunization/diseases/dengue/q_and_a_dengue_vaccine_dengvaxia_use/en/

Committee Report cannot automatically equate reliance on available science vouched for by experts to graft and corruption.

THE PROCEDURE

On August 29, 2017, the DOH Integrity Management Committee adopted the "*Report on the Introduction of the Tetravalent Dengue Vaccine in the Department of Health Immunization Program.*" According to said report:

> On December 11, 2015, DPCB submitted a justification to then Health Secretary Garin for the introduction of the dengue vaccine as part of the National Dengue Prevention and Control Program citing several reasons.
>
> The introduction of dengue vaccine (Dengvaxia) immunization among eligible children in the three regions (Region III, Region IV-A and NCR) was based on the disease burden of dengue, its potential economic and public health impact and availability of government funds.
>
> On December 29, 2015, DBM issued the SARO for the dengue vaccine procurement indicating the source as the "Regular Agency Fund, FY 2015 General Appropriations Act (GAA), RA 1065". With the issuance by DBM of the SARO, the detailed planning, the procurement, and the implementation of the school-based immunization (SBI) project for dengue vaccine was expedited.
>
> Notwithstanding such expediency, however, there were no irregularities in the registration of the dengue vaccine by the FDA. It had been registered by several regulatory agencies of early adopter countries and FDA agreed to a "rolling submission" because the dengue vaccine was a novel vaccine and considered a major medical breakthrough.

> There were likewise no irregularities in the exemption of the dengue vaccine from the PNDF based on E.O. No. 2, s. 1993 and DOH AO No. 2012-0023.
>
> The PCMC also complied with the Government Procurement and Reform Act (R.A. 9184) and its Implementing Rules and Regulations (IRR) in procuring the dengue vaccine.[18]

The DOH Integrity Management Committee under Sec. Ubial found no irregularities in the Dengue Vaccine Immunization Program, from the issuance of an FDA CPR, its exemption from the National Formulary, up to the procurement of the dengue vaccine itself.

As early as June 22, 2012, Sanofi Pasteur's dengue vaccine Dengvaxia was already within the radar of the Food and Drug Administration (FDA). At this time, the drug company presented its clinical briefing Package on its dengue vaccine to the FDA-Clinical Trial Unit (CTU) in connection with its subsequent application for registration. Then again, on September 10, 2012 and March 3, 2014, Sanofi Pasteur submitted documents ("*Dengue Vaccine First Efficacy Results from CYD23 Clinical Study*") and presented updates ("*Updates on the Dengue Vaccine Registration and Clinical Development*") in a consultation meeting with FDA. On August 14, 2014, Sanofi Pasteur presented to FDA the "*Results and Analysis of the Dengue Vaccine Phase III Efficacy Trial*". On September 29, 2014, the acting FDA Director General signed a collaboration letter on the "Joint Evaluation of Dengue Vaccines" with other participating countries, viz., Brazil, Colombia, Indonesia, Malaysia, Mexico and Thailand.[19]

This shows the early timeline of the dengue vaccine with the FDA, with the very first entry two years earlier than the March 3, 2014 entry in the

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[18] P. 19.

[19] DOH Integrity Management Committee, "Report on the Introduction of the Tetravalent Dengue Vaccine in the Department of Health Immunization Program", August 29, 2017, p. 9.

Committee Report. At the time Sanofi Pasteur submitted its application for product registration with the FDA on January 21, 2015, the FDA was already conversant with the new drug, having been briefed on it by Sanofi Pasteur at least four times in the past three years. From January 21, 2015 until product registration on December 22, 2015, or for eleven (11) months, the FDA studied and reviewed the application of Sanofi Pasteur for Dengvaxia. As stated in the Integrity Management Committee Report:

> The timeline of Dengvaxia's product registration would indicate that it took eleven (11) months and six (6) days before the CPR was issued from the date of submission of the first set of documents. According to Ms. Melody M. Zamudio of FDA-CDRR, this was longer than the prescribed period of evaluation of eight (8) months.[20]

FDA's processing of Dengvaxia's Certificate of Product Registration was elaborated upon several times during the hearings by its Director General at that time, Ms. Lourdes Santiago.

> **MS. SANTIAGO.** Your Honor, sa pamantayan po ng Food and Drug Administration, noong mag-apply ang Sanofi for dengue vaccine, na-satisfy po niya ang requirements for quality, safety and efficacy. Kasama rin po ang Pilipinas sa naunang napasama doon sa clinical trial Phase I at mayroon din po tayong mga kasama doon sa Phase II and Phase III. At that time po na inaprubahan ng Food and Drug Administration iyong vaccine, natapos na po nila iyong clinical trials as a requirement for product registration. xxx[21]

xxx **xxx** **xxx**

[20] P. 11.
[21] TSN, February 21, 2018, p. 150.

> **MS. SANTIAGO.** xxx The Dengvaxia is actually a new drug application. And under the existing FDA Citizen's Charter, it should be processed in 254 days. xxx
>
> **MS. SANTIAGO.** xxx in my experience for new drugs especially if it is considered as medical breakthrough, a major medical breakthrough, it would be processed earlier.
>
> There are some drugs that has been processed in six months' time. Like, for example, Bedaquiline, intended to cure TB. And there's another monoclonal ng antibody, the brand name is Keytruda Generic name is Pembdizumab intended for non-small cell lung cancer. It's processed in six months to seven months' time.
>
> There are even drugs that are processed shorter than Dengvaxia.[22]

The 11-month processing time for the Certificate of Product Registration of Dengvaxia fell within the regular processing time for a regular drug. There was no haste in its approval. Obviously, the Certificate of Product Registration was necessary before the vaccine could be considered for procurement by the government, but the FDA had more than enough time to process it, for anyone to say that its approval was rushed and was done only for purposes of government procurement by the end of December of 2015. The absence of haste in the processing of Dengvaxia's CPR therefore does not fall within the Committee Report's Dengvaxia-for-Elections narrative.

The FDA approval gave the government the opportunity to push through with the dengue immunization program, but it would be working on a very tight schedule if it was going to be implemented by 2016. This much was clear. The urgency was explained by President Aquino during the hearing:

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[22] TSN, December 14, 2017, pp. 156-157.

> **MR. AQUINO.** So the end result is if you do not do this at this point in time, you are practically saying that the first implementation of this vaccine will be in 2017 because it will be for the next budget cycle which will be under the new administration. And, of course, assuming that there's a learning curve also at the beginning of the administration, there is no guarantee that it will happen in the 2017 year. xxx
>
> **MR. AQUINO.** From our perspective, the choice is simple: We can implement it at this point in time for the protection, or wait at least a year, as a minimum, and expose our people to a risk that could have been prevented because of this vaccine. And again, may we just state for the record, what we had then was none of this warning that happened in November 2017.[23]

But this didn't mean that laws had to be broken or that shortcuts had to be taken. The procurement itself was found regular by the DOH Integrity Management Committee. In addition, according to the representative of the DBM (Ms. Cristina B. Clasara) during the hearings, the release of big-item SAROs at the end of the year was not unusual after the decision of the Supreme Court in the DAP case of *Araullo v. Aquino (G.R. 209287, July 1, 2014 & February 3, 2015)* that allowed the determination and use of savings only at the end of the year:

> **THE CHAIRMAN (SEN. GORDON).** xxx On December 29, wow, SARO, three and a half billion! That's going to be a record.
>
> DBM, have you ever had any record na nakapaglabas ng three and a half billion in so many days?
>
> Toot toot.
>
> **MS. CLASARA.** Possible, Your Honor.

[23] TSN, December 14, 2017, p. 167.

THE CHAIRMAN (SEN. GORDON). No, no. Hindi ko tinatanong kung possible. Ilang beses kayong nakapagpadala. Sige. Mukhang maraming beses na.

MS. CLASARA. Very recent lang, sir.

THE CHAIRMAN (SEN. GORDON). Very recent.

MS. CLASARA. We have prepared po a SARO again also for DOH, Your Honor.

THE CHAIRMAN (SEN. GORDON). Ano iyong SARO na iyan?

MS. CLASARA. It was savings coming from the mega rehab centers that was not pushed through. So it was –

THE CHAIRMAN (SEN. GORDON). Ah, iyan iyong dapat maglalagay ng mga little clinics.

MS. CLASARA. Oho. So hindi po siya natuloy.

THE CHAIRMAN (SEN. GORDON). Pero natuloy. Nakagastos ng one billion, hindi ba?

MS. CLASARA. Iyon pong natira ay ini-request po nila. So that's mga two billion nga din po yata iyong request nila.

THE CHAIRMAN (SEN GORDON). Ano iyon?

MS. CLASARA. Mga around two billion something po iyon.

THE CHAIRMAN (SEN. GORDON). Ang -- ?

MS. CLASARA. Iyon po iyong ni-request nila – around two billion. I'm not sure with the amount. But the excess amount was –

THE CHAIRMAN (SEN. GORDON). Sino ang nag-request sa DOH?

MS. CLASARA. The Department of Health po.

THE CHAIRMAN (SEN. GORDON). Sino nga doon?

MS. CLASARA. It was Secretary –

THE CHAIRMAN (SEN GORDON). Secretary Duque?

MS. CLASARA. It happened po in December 2017.

MR. DUQUE. Yes. I got in November 6, Mr. Chairman.[24]

xxx **xxx** **xxx**

MS. CLASARA. Iyon pong end of the year na ganyan, bakit ginagawa ba iyan natural, in the past po kasi before the Supreme Court decision in the DAP case, ginagawa po iyan hindi at the end of the year. Parang pwede po siya kasi kung bakante po ang position – xxx

MS. CLASARA. Or kung mayroon pong natapos – just like po iyong mega rehab center alam mo na na hindi itutuloy dahil nag-donate po ang China so hindi mo kailangang hintayin ang towards the end of the year. Pero ito po because of the DAP decision, nalalaman po at dini-determine iyan towards the end of the year.[25]

The release of SAROs for big amounts at the end of the year is no longer irregular because of the Supreme Court decision in *Araullo v. Aquino*. As the

[24] TSN, February 6, 2018, pp. 157-159.
[25] TSN, February 6, 2018, p. 162.

DBM representative said, it was now only natural that savings are used up and SAROs released at the end of the year. This by itself does not connote any irregularity in the funding of PAPs from savings. Again, as it turns out, the release of 3.5 billion pesos for the DOH dengue vaccination program with the use of savings at the tail-end of 2015 was nothing out of the ordinary, and therefore no longer fits the Dengvaxia-for-Elections narrative. Otherwise, all multi-billion peso releases using savings every year-end should be investigated.

Minus the Chairman's innuendos, insinuations, and sound effects (i.e., "toot toot") all throughout the hearings on the irregular character of a year-end multi-billion peso SARO, the facilitation of the 3.5 billion peso SARO for the dengue vaccination program therefore appears to be natural, especially in light of the priority given to it by President Aquino for reasons he already explained during the hearing that dengue cases were increasing and more Filipinos are going to be hospitalized if the vaccine is not rolled-out soon.

A REVIEW OF *ARAULLO*

To the Aquino Administration then, the rationale presented by the DOH for the immediate release of funds requested was not only reasonable but also compelling. The use of the Miscellaneous Personnel Benefit Funds (MPBF) to augment the Expanded Program on Immunization was the only feasible and practical option for the substantial requirements of the program in early 2016.

In the first place, the use of savings to augment the depleted funds of the Expanded Program on Immunization was allowed by law. Section 25(5), Article VI of the 1987 Constitution authorizes the President to use savings to augment actual deficiencies in programs, activities and projects in the GAA. Section 69 of the 2015 GAA and subsequent GAAs reiterate this provision. At the same

time, Section 70 of the General Provisions of the 2015 GAA includes the MPBF as one of its sources of savings, to wit:

> xxx savings may likewise refer to available balances of appropriations arising from unused compensation and related costs pertaining to: (i) unfilled, vacant or abolished positions; (ii) non-entitlement to allowances and benefits; (iii) leaves of absence without pay; and (iv) unutilized pensions and retirement benefits arising from the death of pensioners, decrease in the number of retirees and other related causes.

The Supreme Court in *Araullo v. Aquino (supra)* also recognizes the MPBF as a source of savings:

> xxx if an agency has unfilled positions in its plantilla and did not receive an allotment and NCA for such vacancies, appropriations for such positions, although unreleased, may already constitute savings for that agency xxx.

Since there were available savings, the only question then was if the dengue immunization program was covered by an appropriation item in the 2015 GAA. The appropriation cover of the dengue immunization program in the 2015 GAA was the Expanded Program on Immunization which had been provided an initial appropriation of P3.236 billion. Under this appropriation, all the vaccination programs of the DOH are funded, including their regular immunization programs for babies, pregnant women and senior citizens, and those for vaccines that may be developed during the course of the year. There is no separate item of appropriation for each of these types of vaccination programs. It has been the practice of the DOH to provide for this lump sum appropriation in anticipation of new vaccines that may become available during the course of budget implementation.

This practice is not unique to the DOH. The DPWH has a lump sum called Various Infrastructure Locally Funded Projects or VILP, which provides appropriation for yet undetermined local projects that may be needed during the course of the year. A number of agencies are provided Quick Response Funds (QRFs), which are appropriations to provide for contingencies, such as when the DepEd needs funding to repair flodded schools, or the DSWD provides food bags to victims of calamities or humanitarian disasters. These events cannot be anticipated and provided with appropriation in advance. The QRF provides the appropriation cover so funding can be extended to them.

Once deficient, these lump sum appropriations can be augmented through the use of savings as authorized by the President.

In *Araullo v. Aquino (supra)*, the Supreme Court justified this practice:

> Congress cannot anticipate all issues and needs that may come into play once the budget reaches its execution stage. Executive discretion is necessary at that stage to achieve a sound fiscal administration and assure effective budget implementation. The head of office, particularly the President, require flexibility in their operations under performance budgeting to enable them to make whatever adjustments are needed to meet established work goals under changing conditions. In particular, the power to transfer funds can give the President the flexibility to meet unforeseen events that may otherwise impede the efficient implementation of PAPs set by Congress in the GAA.

The Court even cited Prof. Louis Fisher, an American Constitutional scholar, to drive home the point on the importance of executive leeway in the use of savings. According to the Court:

> There are many number of reasons why obligation and outlays by administrators may have to differ from appropriations by legislators.

> Appropriations are made many months, and sometimes years, in advance of expenditures. Congress acts with imperfect knowledge in trying to legislate in fields that are highly technical and consistently undergoing change. New circumstances and developments will make obsolete and mistaken the decisions reached by Congress at the appropriations stage. It is not practicable for Congress to adjust to each new development by passing separate appropriations laws. Were Congress to control expenditures by confining administrators to narrow statutory details, it would perhaps protect its power of the purse, but it would not protect the purse. The realities and complexities of public policy require executive discretion for the sound management of public funds.

In light of this, the Committee Report charges against President Aquino for the release of the SARO to fund the dengue vaccination program using savings from the MPBF, in effect augmenting the EPI appropriations item in the 2015 GAA, have no legal basis. President Aquino's decision did not constitute technical malversation. It involved the use of savings to augment a deficient but existing item of appropriation.

Section 25(5), Article VI of the 1987 Constitution authorizes the President, among others, "to use savings in their respective appropriations to augment actual deficiencies incurred for the current year in any item of their respective appropriations". Sections 69 to 71 of the General Provisions of the 2015 GAA restate this constitutional authorization on the use of savings, defines the sources of savings, which includes the MOBF, and determines when augmentation can be made. This reiteration is provided in every general appropriations law passed by Congress.

CONCLUSION

The Committee Report is characterized by an abundance of malice and an absence of objectivity. It was tailored to fit the Chairman's Dengvaxia-for-Elections narrative.

First, the timeline and facts are misrepresented, if not distorted. The role of Sec. Ona in the policy proposal to eventually use a dengue vaccine to counter the dengue crisis is erased. His reason for resignation is maliciously characterized as a mystery, despite Sec. Ona's categorical answer that his resignation had nothing to do with the Dengvaxia issue. The fact is the DOH leadership has been in touch and was being briefed by Sanofi Pasteur on the dengue vaccine since 2010. The DOH was actually on notice all through out the term of Sec. Ona and was conversant with the clinical trials of the vaccine way before President Aquino's first meeting with Sanofi Pasteur at the tail-end of 2014. The decision to procure Dengvaxia once it was approved by national regulatory agencies did not suddenly crop up in 2014. It was already on the table since 2010.

Second, the Dengvaxia vaccine was demonized in the Committee report. While the latest WHO update still maintains the vaccine's efficacy and safety among seropositives, the Committee Report made out the public immunization program to be a disaster. The fact that probably 85 percent of its recipients, considered most probably seropositive even by the WHO, are more protected from dengue infection after vaccination is ignored. Sec. Garin is pilloried, while her successors who not only continued, but even expanded the coverage of the program, are excused, even when all of them basically relied on the same science.

Third, the procedure undertaken was made out to be irregular, even in the absence of evidence that it was attended by graft and corruption. From the hearings, it was clear that the FDA registration of the vaccine followed the regular period and procedure like any ordinary drug. With regard the release of

big year-end SAROs, the representative of the DBM under Sec. Benjamin Diokno made it clear that these are now natural and not exceptional. This is because the case of *Araullo v. Aquino* only allows the determination of savings at the end of the year. The Chairman makes much of the approval of 3.5 billion pesos in such a short period of time, when legally that is now the only period of time allowed by the Supreme Court when savings can be determined and augmentation can be made, i.e., at the end of the year.

For the Committee Chairman, the whole Dengvaxia affair has been attended by irregularities from the very start. According to him, all these irregularities were premeditated and intentional, because the objective was nefarious in itself, i.e., to use the dengue immunization program to win the May 2016 presidential elections. Once the Chairman has decided that the supposed irregularities can only be explained by this alleged objective of the Aquino Administration in the release of the dengue immunization funds, its actions which by themselves are legal automatically became illegal. But in order to do this, the Committee Report arbitrarily cut out relevant events in the timeline and distorted facts which were otherwise clearly and categorically established during the hearings.

The Chairman does not believe the narrative of the Aquino government on why year-end savings were used to augment the EPI appropriations of the DOH. He has already authored the Dengvaxia-for-Elections narrative. This then becomes the problem of the Committee Report. It is wholly based on a premise that is not supported by any concrete and categorical evidence. And just because some facts and accounts do not fit the Chairman's narrative, they are either not mentioned, or worse, they are misrepresented in the report. This is how the truth has evaded the Committee Report.

This Separate Dissenting Report is, therefore, an effort to present the government narrative, not to whitewash the facts, but to temper an overly

enthusiastic rendition of what took place among decision-makers during that time, and their effort to safeguard three hyperendemic regions from the dengue virus.

With the science that is presently available after the November 29, 2017 Sanofi Pasteur disclosure, it is barely questionable that because of high seroprevalence in the selected regions, the dengue immunization program of the Aquino government actually benefitted more than it put at risk the recipients of the dengue vaccine. It is a choice that when made even today cannot still be considered as criminal negligence. More so at that time, when the decision-makers had no way of knowing that they were even making that choice.

Respectfully submitted.

30 April 2018.

LEILA M. DE LIMA