REPUBLIC OF THE PHILIPPINES
SUPREME COURT
Manila

THE DEPARTMENT OF HEALTH, represented by **SECRETARY ENRIQUE T. ONA**, and **THE FOOD AND DRUG ADMINISTRATION**, represented by **DIRECTOR-GENERAL SUZETTE HENARES-LAZO,** *Petitioners*, **-and-** **SENATOR PILAR JULIANA "PIA" S. CAYETANO,** and **SENATOR FRANKLIN "FRANK" M. DRILON.** *Petitioners-Intervenors,* **-versus-** **HONORABLE JUDGE ROMULO SG. VILLANUEVA** in his official capacity as Presiding Judge of Branch 255, Regional Trial Court, Las Piñas City; and **PHILIPPINE TOBACCO INSTITUTE, INC.,** *Respondents.* x----------x	**G.R. No. 200431** **SCA Case No. 11-0013**

PETITION-IN-INTERVENTION

Petitioners-Intervenors **SENATOR PILAR JULIANA "PIA" S. CAYETANO** and **SENATOR FRANKLIN "FRANK" M. DRILON** (hereafter, "**Intervenors**") by counsel, respectfully state:

FACTUAL ANTECEDENTS

1. On August 18, 2009, Republic Act No. 9711, otherwise known as the Food and Drug Administration Act (hereafter, the "**FDA Act**") was enacted in order to strengthen the State's regulatory capacity and enforce compliance with regulations over health products. It created the office of the Food and Drug Administration (hereafter, the "**FDA**") under the Department of Health (hereafter, the "**DOH**"), tasked to assist in carrying out the provisions of the FDA Act. Together, the DOH and the FDA have full, plenary and exclusive jurisdiction over all products that have an effect on a person's health.

2. On March 14, 2011, Health Secretary Enrique T. Ona announced the approval and issuance of the Rules and Regulations Implementing the FDA Act (hereafter, the "**FDA IRR**") paving the way for a more robust FDA. The development of the regulatory authority of the Philippine FDA over tobacco products mirrors those of other countries with exemplary FDA bodies, such as Canada and the United States.

2.1. Canada has made more progress in tobacco control in recent years than other countries in the world. Its Food Directorate, for example, has successfully caused a dramatic decline of five percent (5%) in the smoking population through regular public consultations, survey monitoring, product labeling, and other measures.[1]

[1] Gardner, Amanda, FDA proposes graphic health warnings on cigarette packs, Bloomberg Businessweek, November 10, 2010, available at http://www.businessweek.com/lifestyle/content/healthday/645759.html.

2.2. Similarly, in 2010, the US FDA enforced a comprehensive tobacco control strategy.[2] Other countries in turn have patterned their efforts after these models in the hopes of improving their health concerns.

3. Racing to block the government's move for stronger regulation of tobacco products, the Philippine Tobacco Institute (hereafter, the "**PTI**") on June 30, 2011 filed a Petition for Declaratory Relief with Application for the Issuance of a Temporary Restraining Order and/or Writ of Preliminary Injunction to prohibit the DOH and FDA from enforcing the FDA IRR, and to declare it null and void. PTI primarily alleges that the FDA IRR unduly covers tobacco products, purportedly contrary to the provisions of the FDA Act and Republic Act No. 9211, otherwise known as the Tobacco Regulation Act (hereafter, the "**R.A. 9211**").

4. On September 28, 2011, Branch 255 of the Regional Trial Court of Las Piñas (hereafter the "**RTC**" or "**trial court**") denied PTI's application for the issuance of a writ of preliminary injunction for lack of merit.

A copy of the RTC Order on the application for injunction is attached hereto as **Annex A**.

5. On January 27, 2012, the RTC rendered the assailed *Decision*, ruling in favor of PTI and declaring the FDA IRR void insofar as it regulates tobacco products and the tobacco industry. The DOH and FDA were directed to refrain from enforcing the FDA IRR provisions on tobacco products and the tobacco industry.

---

[2] U.S. Food and Drug Administration, U.S. Department of Health and Human Services, last accessed May 23, 2012, available at http://www.fda.gov/TobaccoProducts/default.htm.

A copy of the RTC Decision on the Petition for Declaratory Relief is attached hereto as **Annex B.**

6. In its *Decision*, the trial court primarily relied upon: (1) PTI's interpretation of Section 25 of the FDA Act, and (2) the testimony of Atty. Emilio Polig, on the proper construction of the definition of "health products." The RTC held, thus:

> x x x the clear language of Section 25 of R.A. No. 9711 states that **tobacco products or "those covered by Republic Act No. 9211", are excluded from the coverage of R.A. No. 9711 and consequently, the regulatory authority of the FDA**. With the exclusion of tobacco products from the jurisdiction of the FDA and the recognition of **the Inter-Agency Committee-Tobacco's exclusive jurisdiction to regulate the same under R.A. No. 9211**, it was highly irregular for the respondents (DOH and FDA) to include tobacco products under Article III of the IRR.
>
> x x x
>
> Furthermore, the literal application of Section 25 of R.A. No. 9711 will not result in absurdity and is in fact consistent with the present legal system governing tobacco regulation. **Connected with Section 25 of R.A. No. 9711 is R.A. No. 9211, which is the primary law regulating tobacco products. Clearly R.A. No. 9711 did not include tobacco products because said products are already being regulated under R.A. No. 9211.**
>
> x x x
>
> Also, this court notes x x x **the Congressional deliberations relevant to the enactment of R.A. No. 9711, supports the recognition of the exclusive authority of the Inter-Agency Committee-Tobacco under R.A. No. 9211 to regulate tobacco products.** (Emphasis supplied)

7. Intervenors submit that the **Trial Court incorrectly relied on portions of the deliberations** invoked by the PTI on the interpretation of Sec. 25 and Sec. 10(ff) of the FDA Act. Intervenors are in the best position to present the material portions of the

deliberations, to permit the courts to better understand the true intent of the legislature at the time the law was adopted, as they represent the public interest as concerned citizens guided by years of experience as incumbent Senators, with Intervenor Senator Cayetano being the Chairperson of the Bicameral Conference Committee on the Disagreeing Provisions of Senate Bill No. 1652 and House Bill No. 3293 (hereafter the "**Bicameral Conference Committee**" or "**Congressional Deliberations**") and a co-author of the FDA Act who was actually present during the deliberations thereon.

7.1. Senate Bill No. 1652 and House Bill No. 3293 address the lack of technical capability, manpower and resources of the FDA, all of which hinders FDA to effectively perform its duties as a regulatory, licensing and monitoring agency.[3] These bills aimed primarily to strengthen the FDA by updating the regulations and prohibitions on the manufacture, tampering, labeling, importation, exportation, sale, distribution and transfer of health products.

7.2. Intervenors, as ordinary citizens, represent and invoke the public's paramount interest and overriding right to life and health, which the DOH and FDA sought to protect when it issued the FDA IRR.

8. To date, the DOH and FDA have filed a Petition for Certiorari under Rule 65 of the Rules of Court with the Supreme Court, on the ground that the Trial Court judge acted without or in

[3] Senate Bill No. 1652, An act strengthening and rationalizing the regulatory capacity of the bureau of food and drugs (BFAD) by establishing adequate testing laboratories and field offices, upgrading its equipment, augmenting its human resource complement, giving authority to retain its income and for other purposes, amending certain sections of Republic Act No. 3720, as amended, and appropriating funds thereof, [hereinafter Senate Bill], 14th Congress, First Regular Session, Explanatory Note.

excess of jurisdiction, or with grave abuse of discretion amounting to lack or excess of jurisdiction in issuing the Decision dated January 27, 2012, which case is still pending resolution.

ISSUES

I.
WHETHER THE DOH AND FDA HAVE REGULATORY AUTHORITY OVER TOBACCO PRODUCTS

II.
WHETHER THE FDA IRR COMPLIES WITH ALL THE REQUISITES FOR A VALID ADMINISTRATIVE REGULATION

DISCUSSION

> "An agency charged with such a broad array of vital health protection responsibilities, yet one that lacks the tools to carry out those responsibilities, is in serious danger. And hence, so is the American public."[4]
>
> -Charles Edwards

I. THE DOH AND FDA HAVE AUTHORITY TO REGULATE TOBACCO PRODUCTS, AND ARE AUTHORIZED TO ISSUE RULES AND REGULATIONS OVER THE SAME

9. Respondent PTI claims that the DOH and FDA have no authority to issue the FDA IRR and to include provisions concerning tobacco, allegedly due to Section 25 of the FDA Act, which supposedly removed tobacco products from their regulatory

[4] U.S. FDA homepage, "*FDA Commissioner Margaret A. Hamburg's Statement on the Passing of Dr. Charles Edwards*," 2011, available at: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm270458.htm

authority and jurisdiction. According to PTI, R.A. 9211 is the primary law on tobacco regulation, and the Inter-Agency Committee-Tobacco (hereafter the "**IACT**") created thereunder has exclusive jurisdiction to regulate tobacco products. Consequently, the DOH and FDA are purported to be devoid of power and authority to issue rules, regulations and administrative orders concerning tobacco products.

10. The trial court ruled in favor of the PTI, chiefly relying upon PTI's argument that Section 25 of the FDA Act excludes tobacco products from the coverage of the law and the regulatory authority of the DOH and FDA, and that the IACT has exclusive authority to regulate tobacco products. The trial court concluded that Petitioners encroached upon the authority of the IACT when it included provisions relating to tobacco in the FDA IRR.

11. Tobacco products are "health products" as defined under the FDA Act, since their use in the manner for which they are intended definitely affects public health. Furthermore, Section 25 of the FDA Act actually confirms that the DOH and FDA retain jurisdiction over the same. The FDA IRR never divested the IACT of its jurisdiction over tobacco products, as the FDA Act empowers the FDA to regulate health-related matters pertaining to tobacco that have not been placed within the jurisdiction of IACT.

12. Thus, the trial court seriously erred in ruling that portions of the DOH and FDA have no regulatory authority over tobacco products, and in declaring the FDA IRR null and void.

The express intent of the FDA Act is to strengthen the FDA and to broaden its regulatory authority.

The FDA Act governs all "health products", defined as products that have an effect on health. Tobacco products undoubtedly qualify as a health product as they have been proven, scientifically, to cause disease and death.

13. The express intent of the FDA Act is to strengthen the FDA and to broaden the coverage of its regulatory authority. The FDA Act expanded the products subject to the FDA's jurisdiction to include all those that may have an effect on health. Section 25 thereof states that the FDA Act shall govern "all health products," which, based on Section 10(ff) of the same law, refers to "products that may have an effect on health," apart from food, drugs, cosmetics, devices, and household/urban hazardous products, among others.

14. The intent to include tobacco products within the coverage of the FDA Act and the regulatory authority of the FDA is clearly apparent from the express provisions of the FDA Act. Tobacco products undoubtedly qualify as a health product under the FDA Act, as they have been scientifically proven to cause disease and death. An interpretation that seeks to exclude tobacco products from the regulatory authority of the DOH and FDA would not only be contrary to the express provision of the law, but would also be absurd. For instance, while detergents fall within the powers of the FDA to regulate due to its hazard to health upon possible accidental ingestion, a tobacco product that is scientifically proven to be a direct cause of disease and death when used precisely as intended would be immune to any rule or regulation of the DOH and FDA for purposes of protecting public health. This absurdity cannot be countenanced.

15. Respondent PTI and the trial court misinterpreted the *proviso* of Section 25 of the FDA Act. Its wording is being erroneously utilized by the tobacco industry to argue that it imposes a limitation on the FDA's regulatory authority over all health products, as it makes express reference to other special laws and agencies, including R.A. 9211, Executive Order No. 245 creating the National Tobacco Administration, Executive Order No. 18 creating the Sugar Regulatory Administration, and Presidential Decree No. 1468 or the Revised Coconut Industry Code.

16. The *proviso* does not exclude sugar, coconut and tobacco products from the coverage of the FDA Act, but only provides the suppletory application of the FDA Act by stating that it shall not modify the jurisdiction of other specialized agencies over these products as provided by existing special laws. The health aspect of these products, which is not within the competence of such existing agencies, thus remains within the jurisdiction and regulatory authority of the FDA and DOH. Section 25 of the FDA Act provides, thus:

> SEC. 25. Coverage. – This Act shall govern **all health products**: Provided, That nothing in this Act shall be deemed to modify the sole and exclusive jurisdiction of other specialized agencies and special laws **only insofar as the acts covered by these specialized agencies and laws**, including, but not limited to, those covered by Republic Act No. 9211, Executive Order No. 245, Executive Order No. 18, and Presidential Decree No. 1468.[5] (Emphases supplied)

17. The above provision is clear in establishing that the FDA Act shall cover "all health products." The subsequent clause in the provision provides a limitation only insofar as certain acts have been covered by the special laws and agencies specified therein. By

[5] An Act Regulating the Packaging, Use, Sale, Distribution and Advertisements of Tobacco Products and for Other Purposes, Republic Act No. 9211 [R.A. 9211], June 23, 2003.

necessary implication, matters not covered by the special laws remain under the broad regulatory authority of the FDA over all health products. This is consistent with the rule in statutory construction that laws should be read together and harmonized with a view to giving effect to both.[6]

18. R.A. 9211 and the FDA Act are not conflicting. Read together, the FDA Act applies in a suppletory character over matters not embraced by R.A. 9211. This is supported by the testimony of herein Intervenor Senator Cayetano during the Bicameral Conference Committee:

> THE CHAIRPERSON (SEN. CAYETANO, P.): I agree because the confusion may arise that these special laws somehow cover the health aspect when it is really not their expertise even if they claim that they have some kind of say in it. So, I tend to agree with Congressman Locsin that it should be very clear that this law, the FDA bill will be now in-charge of the health aspect. And in that sense, **it's suppletory to whatever the mandate the special laws have on those products but the health aspects [sic] is an FDA affair**.[7] (Emphases supplied)

19. Thus, with respect to health products also covered by special laws or corresponding agencies, the FDA Act or the DOH and FDA, as the case may be, shall suppletorily regulate those aspects or areas that are not covered by the special laws, the health aspect in particular. Section 25 of the FDA Act does not diminish the power of the DOH and FDA to promulgate rules and regulations covering tobacco products, which would be contradictory to the purpose of the law in strengthening the FDA, but rather recognizes that some health products, such as sugar, coconut and tobacco, are already regulated in aspects other than health by special laws and agencies. This,

---

[6] Vinzons-Chato v. Fortune Tobacco Corporation, G.R. No. 141309, June 19, 2007.
[7] The Bicameral Conference Committee on the Disagreeing Provisions of Senate Bill No. 1652 and House Bill No. 3293 [Bicameral Conference Committee] 19 May 2009, 2:05pm.

however, does not negate the comprehensive jurisdiction of the DOH and FDA in matters respecting public health.

20. It must be emphasized that Section 25 in no way diminishes the full regulatory power of the DOH, which is even strengthened and expanded further by the FDA Act. The only purpose of Section 25 is to ensure that "nothing [in the FDA Act] shall be deemed to modify" the existing jurisdiction of other specialized agencies "only insofar as the acts covered by these specialized agencies and laws"– which jurisdiction is clearly limited and delineated in the special laws mentioned above. The special laws expressly mentioned in Section 25 actually have very limited jurisdiction as defined under the said laws. They do not mandate "sole and exclusive jurisdiction" over all aspects of regulation of tobacco, sugar, and coconut products such that the broad jurisdiction of FDA over the health aspect of said products would be negated.

21. The definition of health products under Section 10(ff) necessarily includes tobacco products since they have an **undeniable, scientifically proven adverse effect on health**. Supporting the argument of DOH and FDA, the second sentence is separable from the first sentence, revealing that health products "also refer to products that have **an effect on health** which require regulations as determined by the FDA."

22. No less than this Honorable Court recognized the hazardous effects of tobacco when it issued Supreme Court Administrative Circular No. 9-99 banning smoking in courts and declared in no uncertain terms that "**Smoking,** [which] is established to be **hazardous to health both for the smokers and the passive smokers**". In 2005, the Supreme Court reiterated the hazards of

smoking when it issued S.C. Administrative Circular 29-2005 and declared that "it is the policy of the government to promote a healthful working environment for its employees and to **protect them from the harmful effects of tobacco smoke.**"

23. In the case of *Estate of Ortega v. Court of Appeals,*[8] the Supreme Court continued to affirm what science has long established. It held that **"**Lung cancer is a disease in which malignant (cancer) cells form in the tissues of the lung. Its **main cause is tobacco use**, including smoking cigarettes, cigars, or pipes, now or in the past. While there are indeed other risk factors for lung cancer, their effect on lung cancer, even if said factors are taken together, is **very small compared to the effect of tobacco smoking**."

24. Tobacco kills more than five (5) million people each year.[9] It kills half of its users, when used as intended by their manufacturers. A burning cigarette works as a miniature chemical waste dump that results in the formation of still more toxins.[10] As the tobacco industry continues to design and market products to expand its markets, exploiting opportunities to undermine prevention and cessation efforts, the call for an effective government regulation, through the DOH and FDA, is necessary to protect public health. **Tobacco, as a public health priority, properly falls under the definition of "health products."**

---

[8] Estate of Ortega v. Court of Appeals, G.R. No. 175005, April 30, 2008.

[9] WHO, Why tobacco is a public health priority, available at http://www.who.int/tobacco/health_priority/en/ (last accessed April 22, 2012)

[10] WHO, Tobacco: deadly in any form or disguise, available at www.who.int/tobacco/communications/events/wntd/2006/Report_v8_4May06.pdf (last accessed April 22, 2012).

The records of the deliberations of the Bicameral Conference Committee reveal that the consensus of the legislators was to include tobacco products within the coverage of the FDA Act and the regulatory authority of the FDA, pursuant to the intent to strengthen the FDA and to preserve its primacy as the authority on health in general and health products.

25. Assuming for the sake of argument that the law is vague, Intervenors, as concerned citizens who are incumbent Senators, and Intervenor Senator Cayetano being one of the sponsors and co-authors of the FDA Act, shed light on the intention of the lawmakers in enacting the law through this Petition. As will be discussed at length herein, it is the intent of the legislature for the FDA to have jurisdiction over tobacco products. The records of the deliberations of the Bicameral Conference Committee of both houses of Congress confirm that the consensus of the legislators was to include tobacco products within the coverage of the FDA Act and the regulatory authority of the FDA, in line with the intent to strengthen the FDA and to preserve its primacy as the authority on health in general and health products.

26. In discussing the coverage of the law on 19 May 2009, Representative Teodoro L. Locsin, Jr. requested for clarification on the disputed proviso of Section 25, saying that the existing regulatory agencies of sugar, coconut and tobacco, do not have the capability of regulating the health effects of the said products. Representative Locsin emphasized that Section 25 must not be viewed as preventing the FDA from regulating tobacco. Herein Intervenor Senator Cayetano likewise strongly emphasized that Section 25 of the FDA Act must be read to mean that the FDA is in charge of the health

aspect of such products (sugar, coconut and tobacco), suppletory to existing special laws and the mandate of existing regulatory agencies. Thus:

> REP. LOCSIN: Madam Chair, may I ask, Your Honor, Senator Legarda, do any of these agencies - sugar, coconut, tobacco - have the capability to enhance FDA that we have envisioned to monitor the health effects of the products of each of these sectors? I think none of them do, none of them has the capabilities to monitor the health effects of any of these products that the new BFAD will have. **Unless there is actually a scientific component to RA 9211, because I don't want this to be seen as preventing BFAD, the new BFAD from making a declaration against tobacco** if they feel the way the surgeon general in the United States does. He probably has no authority to do it but nobody can stop him either and say, "Whatever the tobacco, coconut, or sugar industry say, we say, 'Too much consumption of sugar is bad for your health.'" I just don't want that to be...
>
> x x x
>
> THE CHAIRPERSON (SEN. CAYETANO, P.): I agree because the confusion may arise that these special laws somehow cover the health aspect when it is really not their expertise even if they claim that they have some kind of say in it. So, I tend to agree with Congressman Locsin that it should be very clear that this law, the FDA bill will be now in-charge of the health aspect. And in that sense, it's suppletory to whatever the mandate the special laws have on those products but the health aspects is an FDA affair.[11] (Emphases supplied)

27. The following excerpts of the deliberations of the Bicameral Conference Committee are material to revealing the intent of the lawmakers to grant FDA authority over the health aspects of all products, including tobacco:

> REP. VALDEZ: Thank you, Madam Chair. Thank you, Senator Legarda, for the honor of proposing these amendments. This is actually, Your Honor, a follow-up of the proceedings during the Bicameral Conference that we had on February 23 where the Honorable Senator Loren Legarda sought to exclude clearly from the coverage of the proposed law those that are already covered by special laws particularly sugar, tobacco and coconut x x x that the

[11] Bicameral Conference Committee, 2:05pm.

powers, Your Honor please, of the FDCDA shall not include those that are already covered x x x

x x x

THE CHAIRPERSON (SEN. CAYETANO, P.): **But just to clarify. This does not in any way extend beyond the actual coverage of those special laws.** So, like I said, if the special law referred to the subsidy to coconut growers, that what we're saying that BFAD will not get involved there, 'no. But **with respect to the health aspect, to the extent that BFAD monitors all health products, then BFAD will still be involved.**

REP. VALDEZ: For as long as they are covered by the special law, Your Honor please, then it will be covered by the BFAD.

THE CHAIRPERSON (SEN. CAYETANO, P.): For as long as that act is not covered by the special agency.

REP. VALDEZ: Yes, Your Honor.

x x x

REP. LOCSIN: Madam Chair, **may I ask, Your Honor, Senator Legarda, do any of these agencies - sugar, coconut, tobacco - have the capability to enhance FDA that we have envisioned to monitor the health effects of the products of each of these sectors? I think none of them do, none of them has the capabilities to monitor the health effects of any of these products that the new BFAD will have.** Unless there is actually a scientific component to RA 9211, because **I don't want this to be seen as preventing BFAD, the new BFAD from making a declaration against tobacco** if they feel the way the surgeon general in the United States does. He probably has no authority to do it but nobody can stop him either and say, "Whatever the tobacco, coconut, or sugar industry say, we say, 'Too much consumption of sugar is bad for your health.'" I just don't want that to be...

SEN. LEGARDA: **My only concern is, there should not be any duplication of laws so that there's no confusion. But to prevent the new BFAD from becoming strong in its implementation, I think, would defeat the purpose of this law. So I support you in a sense that we should, of course, strengthen the power of BFAD**. But my concern in not including all these three commodities is the duplication and the confusion of the sectors concerned whether these are big industries coconut, tobacco...

REP. LOCSIN: I can see that. But, Madam Chair, perhaps in the body of the proposed legislation, we can emphasize that the new BFAD will have the power to investigate the health effects of any product in Philippine agriculture.

SEN. LEGARDA: I think, if I may add, the strength of this new law, Congressman Locsin, should also be founded in its capability. It will be allowed to coordinate, to cooperate with already existing specialized agencies in the exercise of its functions because it's not only the health that is concerned, it's the economic aspect, the way it affects agriculture and all the farmers down the drain. So I don't think we will - what's the word, emasculate the new law or destrengthen or soften the - weaken the powers of BFAD. We simply did not want to confuse all the various sectors in the implementation of the new law.

REP. LOCSIN: So when it comes to health, Madam Chair, BFAD's power is all encompassing and can reach into these areas?

THE CHAIRPERSON (SEN. CAYETANO, P.): In fact I was thinking in Section 26, just to clarify that further. In the very last sentence, it says, "This Act shall be applied in suppletory character." The intention of that was to say that the BFAD, the new FDA law and BFAD's previous function continues to exist but really what we really need to be sure is not misinterpreted is that BFAD, the new FDA is the authority as far as health is concerned. So I was thinking and you did make a very simple statement that, I guess something like, with respect to the health aspect, the FDA shall continue to exercise its mandate. Something like that so that there is no confusion. I think the records will bear out all that - do you hear me? Okay.

REP. LOCSIN: But, **Madam Chair, I'm arguing for double jurisdiction in the sense that unless it is clear that the tobacco authority has the capability to monitor the health consequences of the products they regulate, then BFAD should have supervening authority to interfere**

THE CHAIRPERSON (SEN. CAYETANO, P.): I agree because the confusion may arise that these special laws somehow cover the health aspect when it is really not their expertise even if they claim that they have some kind of say in it. So, I tend to agree with Congressman Locsin that it **should be very clear that this law, the FDA bill will be now in-charge of the health aspect.** And in that sense**, it's suppletory to whatever the mandate the special laws have on those products but the health aspects is an FDA affair.**[12] (Emphases supplied)

28. Intervenor Senator Cayetano attests to the legislative intent that clearly reveals that FDA Act covers the health aspect of tobacco, sugar and coconut. The FDA Act applies suppletorily to special laws covering the products mentioned. Although Section 26, which spells out the suppletory character of the law, was deleted, its

[12] Bicameral Conference Committee, 2:05pm

effects remain the same. The lawmakers agreed to remove such provision merely due to the redundancy in the law, as can be gleaned from the following deliberations:

> REP. LAGMAN: Thank you, Madam Chair. Now, with respect to Section 26, the second sentence, "This Act shall be applied in a suppletory character," can we include just to put an emphasis "with respect to food and drug products?"
>
> x x x
>
> THE CHAIRPERSON (SEN. CAYETANO, P.**): Well, actually, all health products** because health products is defined. It's a defined term that covers the cosmetic products, everything. **So, what it is really saying is, "This Act shall apply with respect to all health products."**
>
> x x x
>
> REP. GARCIA: Madam Chair, after health products, are we providing the exceptions?
>
> THE CHAIRPERSON (SEN. CAYETANO, P.): In Section 26, no more. I think all we are saying in Section 26 is that, **insofar as health products are concerned, this law will apply insofar as the health aspect of the health products are concerned, without enumeration anymore.** I guess it's meant to -- it's further to Section 26.
>
> REP. GARCIA: That is after we have inserted the exception?
>
> THE CHAIRPERSON (SEN. CAYETANO, P.): Yes. So, in other words, we are clarifying in Section 26, that Section 25 says that, "This Act shall not cover the following products which are covered by special law." And then Section 26, further says, "However, **this law shall apply with respect to the health products and the health aspect of the health products**." Some wording to that effect.
>
> REP. LAGMAN: Not covered by the special law.
>
> THE CHAIRPERSON (SEN. CAYETANO, P.): The health aspect which is not covered -- yeah, because the special law will only govern insofar as what is stated in those special laws.
>
> REP. LOCSIN: I think you should keep it that way and then, "This Act shall be applied in a suppletory character with regard to their health aspect."
>
> x x x

REP. LOCSIN: **I think this Section 26 can be left as it is.**

THE CHAIRPERSON (SEN. CAYETANO, P.): **Actually, it's not even necessary.**

REP LOCSIN: That's also true.

THE CHAIRPERSON (SEN. CAYETANO, P.): **It's kinda redundant.**

REP. LAGMAN: Yeah, it's redundant altogether. We might as well remove it. That is not anymore a useful surplusage.

x x x

THE CHAIRPERSON (SEN. CAYETANO, P.): x x x May I just raise concern, 'no. **On Section 25 and 26, we just agreed to delete 26. But the BFAD is just ensuring that our intention here is that they will continue to do the work they were doing with respect to health products because they wanted us to include the suppletory effect. But my understanding is that this provision exactly says what we want to say which is they will continue to govern health products.** So... [13] (Emphases supplied)

29. The trial court, in its *Decision*, relied on a mere opinion cited by the PTI. The Decision adopted only the following portion of the entire deliberations of the Bicameral Conference Committee on 23 February 2009:

MR. POLIG (Head, Legal Department, Bureau of Food and Drugs) Yes, Madam Chairman. While the definition on health products, particularly the last portion, practically covers every... every pro... other products that may have an effect on health, it is my... my opinion that since the... the law on that covers like tobacco is a special law, separate... hindi na po siya kasama dito Your Honor.[14] (Emphasis supplied)

30. The trial court inaccurately and erroneously relied on this single portion of the congressional deliberations, without even bothering to ascertain whether this statement was in fact the legislative intent of the Committee. As previously emphasized,

[13] Bicameral Conference Committee, 2:15pm.
[14] The Bicameral Conference Committee on the Disagreeing Provisions of Senate Bill No. 1652 and House Bill No. 3293 [Bicameral Conference Committee] 23 February 2009, 12:35pm.

Section 25 of the FDA Act confirms the comprehensive regulatory powers of the DOH, through the FDA, over all health products. It does not, in any way, diminish the comprehensive jurisdiction of the DOH, but only ensures that the FDA Act shall not modify the jurisdiction of other specialized agencies over specific acts covered by special laws.

30.1. First, the statement cited by PTI and the trial court is merely an opinion of Mr. Polig, as reflected from his statement: "...it is my opinion that..." Atty. Polig is not a member of Congress. The Bicameral Conference Committee invited him merely as a resource person to assist the legislature in drafting the FDA Act. His opinion does not represent the intent of the legislature, as it was only one of the many factors taken into consideration by the legislature as they drafted the FDA Act.

30.2. In fact a reading of the 23 February 2009 deliberations of the Bicameral Conference Committee where the foregoing manifestation was made shows that the legislature never adopted the view of Atty. Polig. In the subsequent deliberations on Section 25 of the FDA Act held three (3) months later on 19 May 2009, the legislature emphasized that the FDA and DOH should still regulate the health aspect of the products covered by special laws and agencies, such as tobacco. A close reading of the two sessions of the Bicameral Conference Committee clearly shows that the two deliberations appear inconsistent, as shown below:

23 February 2009	19 May 2009
MR. POLIG: Yes, Madam Chairman. While the definition on health products, particularly the last portion, practically covers every... every pro... other products that may have an effect on health, it is my opinion that since the law on... covers like tobacco is a special law, hindi na po siya kasama dito, Your Honor. [It is no longer included, Your Honor.] 12:35pm. (Translation supplied)	SEN. LEGARDA: ...whatever covers the present tobacco, sugar and coconut industry we will just make sure that this law will not duplicate what is already covered in the laws governing them now. But whatever is beyond the extent of the existing law, of course, will be covered by the BFAD, I think just for clarification. 1:45pm.
	THE CHAIRPERSON (SEN. CAYETANO P): ...the FDA bill will now be in-charge of the health aspect. And in that sense, it's suppletory to whatever mandate the special laws have on those other products but the health aspect is an FDA affair. 2:05pm.

30.3. The May 19 deliberations contain portions that appear to be inconsistent with those of the February 23 deliberations, to the extent that only one of the two can stand in force. As Chairperson of both deliberations, Intervenor Senator Cayetano respectfully submits that the position in the May 19 deliberations is entitled to greater weight, being the later discussion. Similar to the principle of lex posterior derogat priori, it is the later position that reflects the true intent of the legislators. Further, the May 19 deliberations is a follow-up of the unfinished discussion of February 23 on the topic, as Representative Valdez raised,[15] and thus contains the final resolution of the legislators on this issue.

[15] Bicameral Conference Committee, 1:35pm.

30.4. Third, the May 19 deliberations provide a more elaborate exchange over the concern of whether tobacco products are covered by the FDA Act, whereas the February 23 deliberations simply mentioned in passing the issue on the special laws. Based on the Bicameral Conference Committee report, the earlier deliberations on R.A. No. 9211 in relation to the FDA Act, constitute more or less five (5) pages only (pp. 88-93), logged in at 12:25-12:35 p.m. The entire discussion on this issue spanned only ten (10) minutes. On the other hand, the deliberations on May 19 dedicated twenty-eight (28) pages (pp. 92-119), logged in at 1:35pm-2:15 p.m. or forty (40) minutes in total of the legislators' time. Intervenors thus respectfully submit that the May 19 deliberations are more relevant, in point, credible, and entitled to greater weight, considering that they contain the final resolution of the legislators on the issue of whether the FDA retains regulatory authority over tobacco products, reached only after a more thoughtful discussion and thorough process of deliberation.

31. Further, Intervenors express their dismay at the action of the PTI in misquoting and misrepresenting the contents of the May 19, 2009 congressional deliberations, thus misleading the trial court into rendering its assailed Decision. The PTI deliberately cited mere segments of the deliberations to suit its interest, thus calculatedly distorting the truth. In its petition, PTI quoted testimonials of Senator Loren Legarda and Representative Lagman, without following through to the succeeding dialogues in order to truly reflect the import of the deliberations. PTI cited the following selective portions of the deliberations to mislead the court:

> SEN. LEGARDA: I'm a non-smoker and I'm one of the authors of RA 9211 with Flavier 'no. Just to -- yes, because all your concerns are covered by the law which we authored. Meaning, the advertising, the health aspects so what this says was, whatever is covered by 9211 should not be covered anymore by this new law we're doing.
>
> x x x
>
> REP. LAGMAN: The health issues with respect to tobacco are already covered by Republic Act No. 9211. So there is no need to duplicate that power and jurisdiction under BFAD. (1:45pm)

32. These two testimonials are only the beginning of an extensive discussion on the R.A. 9211 and the suppletory role of the FDA Act. The PTI conveniently neglected to include other portions of the deliberations that finally concludes with:

> THE CHAIRPERSON (SEN. CAYETANO, P.): I agree because the **confusion may arise that these special laws somehow cover the health aspect when it is really not their expertise even if they claim that they have some kind of say in it.** So, I tend to agree with Congressman Locsin that **it should be very clear that this law, the FDA bill will be now in-charge of the health aspect. And in that sense, it's suppletory to whatever the mandate the special laws have on those products but the health aspects is an FDA affair.**[16] (Emphases supplied)

33. At the end of the discussion on Section 25 of the FDA Act, the legislators focused their attention on Section 26, a provision that originally declared that the FDA Act applies in a suppletory character to R.A. 9211, as previously discussed. The lawmakers, however, agreed to delete this provision, recognizing that such is "redundant altogether," as per Representative Lagman. Therefore, the FDA, having been vested the regulatory powers in the field of health, indubitably fills the void insofar as the health aspect of tobacco products not covered by the special law is concerned.

---

[16] Bicameral Conference Committee, 2:05pm.

R.A. 9211 or the Tobacco Regulation Act is not exhaustive of all areas relating to tobacco products and the tobacco industry that are subject to regulation. The FDA Act fills the void with respect to the health aspect.

The exclusive jurisdiction of the IACT is limited, pertaining only to the administration and implementation of the provisions of R.A. 9211, not over tobacco products and the tobacco industry as a whole.

34. The powers of the IACT, on the one hand, and the DOH and FDA, on the other, are separate and distinct. The IACT is charged with "the exclusive power and function to administer and implement the provisions" of R.A. 9211.[17] The DOH and FDA are the administrative bodies charged with the primary responsibility of protecting and promoting the people's right to health, for which purpose, they have been tasked to regulate the health aspect of any and all health products, including tobacco products.

35. R.A. 9211 actually does not cover all aspects of tobacco products and the tobacco industry, and regulates only certain aspects thereof, particularly sale and distribution, signages, smoke-free places, textual warnings on cigarette packages, advertisements, promotions and sponsorship. Some of the areas not covered by R.A. 9211 include incorporation and regulation of tobacco companies, registration of brand names, environmental consequences of tobacco production, graphic health warnings, illicit trade in tobacco, misleading descriptors, additional labeling for public health purposes, tobacco industry interference in policy-making on health.

[17] R.A. 9211, Sec. 29.

36. Clearly, R.A. 9211 is not exhaustive of all areas relating to tobacco products and the tobacco industry that may be the subject of regulation. The FDA Act fills in the void with respect to the health aspect that is not covered by R.A. 9211, as emphasized by Representative Locsin and Intervenor Senator Cayetano. Such law did not remove the primary responsibility of the DOH in formulating, planning, implementing, and coordinating policies and programs in the field of health. The DOH, through the FDA, remains the principal organization charged with the responsibility of protecting and promoting health, and this comprehensive jurisdiction pertains to all products that may have an effect on health, including tobacco products.

37. Respondent PTI and the trial court also relied upon the supposed exclusive jurisdiction of the IACT to regulate the tobacco industry and tobacco products. This reliance is misplaced. The exclusive jurisdiction of the IACT pertains only to the administration and implementation of the provisions of R.A. 9211, not over tobacco products and the tobacco industry as a whole. Section 3 and Section 29 of R.A. 9211 provides that the IACT has exclusive power and function to administer and implement only the provisions of the law itself, to wit:

> SEC. 3. Purpose. – It is the main thrust of this Act to:
>
> x x x
>
> g. Create an Inter-Agency Committee on Tobacco (IAC-Tobacco) to oversee the implementation of **the provisions of this Act.**
>
> SEC. 29. Implementing Agency. – An Inter-Agency Committee-Tobacco (IAC-Tobacco), which shall have the exclusive

> power and function to administer and implement **the provisions of this Act**, is hereby created.[18] (Emphases supplied)

38. As earlier pointed out, R.A. 9211 is not comprehensive in scope and does not cover all aspects of the regulation of the tobacco industry and tobacco products. Clearly, the authority of the IACT is limited to implementing matters covered by R.A. 9211, which is not all-encompassing as erroneously insisted by PTI and the trial court. This necessarily implies that authority on matters not covered by R.A. 9211 belongs elsewhere. Clearly, the IACT was not created to be an all-encompassing organization with jurisdiction over tobacco products and the tobacco industry as a whole, but only with respect to the enforcement of the measures provided in R.A. 9211, which regulates only certain aspects of tobacco and does not cover health. The tobacco industry, being a complex enterprise built on the production and marketing of a product with grave health consequences, involves other factors apart from those specified in R.A. 9211 that must be subject to governmental regulation.

39. The World Health Organization Framework Convention on Tobacco Control (hereafter, the "**WHO FCTC**") enumerates many other aspects of the tobacco industry and tobacco products that are not covered by R.A. 9211, including, but not limited to the following:

a. Protect public health policies from commercial and other vested interests of the tobacco industry (Art. 5.3);
b. Adopt price and tax measures to reduce the demand for tobacco (Art. 6);
c. Adopt non-price measures to reduce the demand for tobacco (Art. 7);
d. Extend protection to the people from exposure to tobacco smoke (Art. 8);

[18] R.A. 9211, Section 3 and 29.

e. Regulate the contents of tobacco products (Art. 9);
f. Regulate tobacco product disclosures (Art. 10);
g. Regulate the packaging and labeling of tobacco products (Art. 11);
h. Educate, communicate, train and raise public awareness about the dangers of tobacco (Art. 12);
i. Ban tobacco advertising, promotion and sponsorship (Art. 13);
j. Demand reduction measures concerning tobacco dependence and cessation (Art. 14);
k. Control the illicit trade in tobacco products (Art. 15);
l. Ban sales to and by minors (Art. 16);
m. Support economically viable alternative to tobacco growing (Art. 17);
n. Protect the environment and the health of persons (Art. 18); and
o. Promote research, surveillance and exchange of information (Art. 20).

40. On the other hand, R.A. 9211 was enacted prior to the entry of the WHO FCTC intro force in the Philippines, and only touches on portions of the obligations set forth under the latter. R.A. 9211 is limited to the following aspects of tobacco products:

a. Prohibitions on smoking in public places, and designated smoking and non-smoking areas (Sec. 5 and 6);
b. Ban on vending machines and self-service facilities (Sec. 7);
c. Ban on minimum age sales (Sec. 9);
d. Restriction on sale of tobacco products within school perimeters or other places frequented by minors (Sec. 10);
e. Requirement of signage in point-of-sale establishments (Sec. 11);
f. Textual warnings on cigarette packages (Sec. 13);
g. Ban on tobacco advertising in mass media except in point-of sale establishments (Sec. 14);
h. Restrictions on advertising (restrictions on print media advertising; outdoor advertising; advertising in cinemas; advertising in television,; advertising in audio, video and computer cassettes/discs and

similar medium; advertising in internet and similar medium (Sec. 15-21)

i. Restrictions on tobacco promotions (ban on the participation of minors; restrictions on communications to consumers about tobacco promotions, limitation of promotions to point-of-sale adult only facilities, restriction on telephone communications, ban on product placement, restriction on branding of merchandise other than smoking-related items, ban on branding of items marketed or likely to be used by minors, and ban on advertisements on shopping bags (Sec. 23)
j. Ban on naming rights for the naming or use of sports leagues or teams, and stadiums or arenas (Sec. 24);
k. Restriction and ban on sponsorship of sport, concert, cultural art or event, individual and team athletes, artists, or performance; and (Sec. 25)
l. Restriction on sampling (Sec. 27).

41. It is readily apparent that not all obligations required to be performed under the WHO FCTC are addressed in R.A. 9211. The WHO FCTC has formed part of the law of the land, having been signed and ratified by the Philippines. Thus, in order to comply with the obligations set forth by the WHO FCTC, the DOH and the FDA should be able to exercise jurisdiction with respect to the health aspect of tobacco products.

42. The scope of the regulatory power of the IACT by virtue of R.A. 9211 is, therefore, limited at best. To fill the void, all other aspects not covered by R.A. 9211 are governed by the FDA Act with respect to the health aspect.

43. Even then, the power of the IACT under R.A. 9211 is actually limited to only compliance monitoring[19] and the

[19] Section 31 of RA 9211 provides:
Section 31. Compliance Monitoring - Not later than one (1) year after the date of the effectivity of this Act, and annually thereafter, the IAC-Tobacco shall submit to the President of the Philippines

development of programs and projects within a five (5) year period.[20] Actual implementation of programs and projects under R.A. 9211 remains the responsibility of the respective member-agencies of the IACT, such as the DOH and the Department of Trade and Industry (DTI). Nothing in R.A. 9211 vests upon the IACT any power other than that of monitoring compliance therewith and program development.

44. That the role of the IACT is strictly confined to compliance monitoring and the development of programs and projects is recognized by the IACT itself, as shown by the Rules and Regulations Implementing Republic Act No. 9211, otherwise known as the Tobacco Regulation Act of 2003 (hereafter the "**R.A. 9211 IRR**"), as well as the Monitoring and Enforcement Guidelines of the Tobacco Regulation Act and its Implementing Rules and Regulations (hereafter the "Monitoring and Enforcement Guidelines"), both of which were issued by the IACT itself. In the R.A. 9211 IRR, only the functions of the secretariat of the IACT were provided.

45. In the Monitoring and Enforcement Guidelines, **the IACT itself recognized the authority of the DOH to regulate tobacco products when it specifically identified the DOH as the "pilot**

---

and to both Houses of Congress a Compliance Monitoring Report on the compliance of the manufacturers on all applicable laws and ordinances with respect to the manufacture and distribution of tobacco products.
The report shall contain pertinent information on the methods, goals and implementation program of said manufacturers with respect to the requirements of this Act.

[20] Section 33 of RA 9211 directs the provision of the following programs and projects for a period not exceeding five (5) years:

a. Tobacco Grower's Assistance Program;
b. Tobacco Growers Cooperative;
c. National Smoking Cessation Program;
d. Research and Development Program;
e. National Tobacco-Free Public Education Program;
f. Displaced Cigarette Factory Workers' Assistance Program;
g. Health Programs; and
h. Withdrawal Clinics

agency" for monitoring and enforcing compliance with the provisions of R.A. 9211 on smoke-free environments, warnings on cigarette packages, advertising, promotions and sponsorship. Further, **the IACT explicitly stated therein that nothing in the Monitoring and Enforcement Guidelines should be construed so as to preclude or diminish the exercise by the DOH of its administrative functions pursuant to its mandate under other existing laws, rules and regulations,** such as the Administrative Code, the FDA Act, and the WHO FCTC.

A copy of the Monitoring and Enforcement Guidelines is hereto attached as **Annex C.**

46. The FDA Act therefore applies in a suppletory character to R.A. 9211. On matters of health, regulatory jurisdiction falls with the DOH and FDA, not the IACT. To emphasize, the IACT does **not** have sole and exclusive jurisdiction over tobacco products and the tobacco industry, but only with respect to the implementation of R.A. 9211. The FDA IRR was issued pursuant to the mandatory provision of the FDA Act, not R.A. 9211, which directed the DOH and the FDA to issue the FDA IRR covering all products that may have an effect on health. The provision therein relating specifically to tobacco was deemed necessary in order to clarify that the FDA shall govern the health aspect of tobacco products. The FDA IRR moreover implements the WHO FCTC, which obliges State Parties to act to protect their public health policies on tobacco control from commercial and other vested interests of the tobacco industry. As the competent national authority in the Philippines with the mandate to formulate, plan, implement and coordinate policies and programs in the field of health, the DOH and FDA were thus correct to issue the FDA IRR and to include provisions on tobacco products therein.

47. Tobacco companies have long recognized and submitted to the jurisdiction of the FDA over tobacco products. Up to 2009, five years after the enactment of R.A. 9211, Philip Morris Philippines Manufacturing, Inc. ("**PMPMI**") and JT International Philippines Inc. filed several applications with the BFAD for conduct of their promotional activities. In 2008, PMPMI sued the DOH and BFAD to nullify the BFAD's decision denying the issuance of a promotion permit for PMPMI's Gear Up promo and direct the DOH and BFAD to issue the required permit and process all future applications for PMPMI's promotional activities. PMPMI even noted that its application for sales promotional permit comply with the requirements of RA 9211. **At a time when R.A. 9211 was already effective and even before the strengthening of the FDA's authority, the FDA was already regulating the industry and the tobacco companies recognized this jurisdiction.**

48. Thwarted, however, by the DOH's renewed vigilance over the regulation of tobacco products, the tobacco industry has been intent on finding a way to elude regulation and constrain the Philippine government to inaction. By erroneously insisting that the IACT has the exclusive jurisdiction over **anything** related to tobacco, the industry has managed to cripple our government agencies while our legislature grapples to strengthen our administrative agencies to make full use of their expertise. To weaken the FDA now, after a clear mandate to strengthen its authority, is contrary to both the express provision and spirit of the FDA Act.

49. The continuing authority of the DOH to regulate tobacco products in respect of its health aspect is also evident in other provisions of R.A. 9211. Section 34 thereof expressly vested upon the

DOH the duty to undertake the information drive on the harmful effects of smoking "to discourage the unhealthy habit of smoking". The DOH thus remains the leading authority as regards the health aspect of tobacco products. Section 34 of R.A. 9211 provides:

> SEC. 34. Information Drive. – Consistent with the provisions of this Act, the DOH shall, in cooperation with the DepEd and with the assistance of the Philippine Information Agency (PIA), undertake a continuous information program on the harmful effects of smoking.
>
> The DOH shall enlist the active participation of the public and private sectors in the national effort to discourage the unhealthy habit of smoking.[21]

50. The DOH, through the FDA, retains full jurisdiction in the field of health, and consequently over the regulation of all products that affect health, in line with its primary function and mandate under the Administrative Code of 1987 (hereafter the "**Administrative Code**"):

> SEC. 2. Mandate. - The Department shall be primarily responsible for the formulation, planning, implementation, and coordination of policies and programs in the field of health. The primary function of the Department is the promotion, protection, preservation or restoration of the health of the people through the provision and delivery of health services and <u>through the regulation</u> and encouragement of providers <u>of health goods</u> and services.
>
> SEC. 3. Powers and Functions. - The Department shall:
>
> x x x
>
> (4) Administer **all laws, rules and regulations in the field of health**, including quarantine laws and food and drug safety laws;
>
> x x x
>
> (9) Issue orders and regulations concerning the implementation of established health policies[22] (Emphases supplied)

[21] R.A. 9211, Section 34.
[22] Administrative Code, Section 2 and 3

51. The broad powers of the DOH over such products is reiterated in Republic Act No. 7394, otherwise known as the Consumer Act of the Philippines ("**Consumer Act**"), which designates the DOH as the implementing agency of the policy on consumer products, specifically with respect to food, drugs, cosmetics, devices and substances.[23] This includes the power to promulgate and adopt consumer product quality and safety standards, and packaging and labeling.[24] The DOH, as an implementing agency, is further mandated to "strengthen the Bureau of Food and Drugs."[25]

52. The DOH and FDA, by virtue of their broad and general power in the field of health, clearly remain as the regulatory bodies charged with promoting and protecting the right to health of the people.

II. THE FDA IRR COMPLIES WITH ALL THE REQUISITES FOR A VALID ADMINISTRATIVE REGULATION.

53. The increasing complexity of society and modern life inevitably carries with it complex problems that could no longer be handled efficiently by the three main branches of government. Administrative offices such as the DOH have therefore been necessary to carry out the powers, functions and responsibilities that

---

[23] The Consumer Act of the Philippines [Consumer Act], Republic Act No. 7394, Art. 6.

[24] Article 7. Promulgation and Adoption of Consumer Product Standards. – The concerned department shall establish consumer product quality and safety standards which shall consist of one or more of the following:

a) requirements to performance, composition, contents, design, construction, finish, packaging of a consumer product;
b) requirements as to kind, class, grade, dimensions, weights, material;
c) requirements as to the methods of sampling, tests and codes used to check the quality of the products;
d) requirements as to precautions in storage, transporting and packaging;
e) requirements that a consumer product be marked with or accompanied by clear and adequate safety warnings or instructions, or requirements respecting the form of warnings or instructions.

[25] Consumer Act, Art. 21.

could no longer be effectively performed by the traditional branches of government alone. These responsibilities are better accomplished through these administrative agencies as they can devote more time and expertise to the specific fields tasked to them. Towards these ends, the rule-making power or quasi-legislative function is one of the two principal powers bestowed upon administrative agencies. It refers to the authority delegated by the law-making body to make rules and regulations within legal limits. Pursuant to its quasi-legislative power, administrative agencies have the authority to issue administrative rules and regulations in order to implement the law and the legislative policy fixed by the legislature. To be valid, only four (4) requisites must be met:

a. Their promulgation must be authorized by the Legislature;
b. They must be within the scope of the authority given by the Legislature;
c. They must be promulgated in accordance with the prescribed procedure; and
d. They must be reasonable.[26]

54. To resolve the issue of whether the FDA IRR is valid, these aforementioned criteria must be met. The Intervenors respectfully submit that the FDA IRR satisfies all the foregoing requisites.

The DOH and FDA issued the FDA IRR pursuant to Section 22 of the FDA Act, which expressly vested upon the DOH the power to promulgate the implementing rules and regulations therefor, as well as CSC-DOH Joint Memorandum Circular 2010-01 in accordance with Article 5.3 of the WHO FCTC.

[26] Lokin, Jr. v. COMELEC, G.R. Nos. 179431-32 and G.R. No. 180443, June 22, 2010.

55. The first requisite is satisfied, as the promulgation of the FDA IRR is authorized by the legislature through the FDA Act and the WHO FCTC.

56. The DOH and FDA issued the FDA IRR pursuant to Section 22 of the FDA Act, which expressly vested upon the DOH the power to promulgate the implementing rules and regulations therefor. Section 22 of the FDA Act provides:

> Section 22. Implementing Rules and Regulations. - The DOH shall promulgate, in consultation with the FDA, the implementing rules and regulations of this Act within one hundred twenty (120) days after the passage of this Act. [27](Emphasis supplied)

57. The inclusion of provisions in the FDA IRR on protection against tobacco industry interference is also mandated by Article 5.3 of the WHO FCTC, which directs State Parties to act to protect its public health policies on tobacco control from the commercial and other vested interests of the tobacco industry. The WHO FCTC is a treaty that has been ratified by the Philippines and concurred in by the Senate in 2005. It is, for all intents and purposes, considered national law in the Philippines in accordance with Section 21, Article VII of the Constitution, and must be complied with as well. There was therefore proper legal basis for including provisions concerning protection against tobacco industry interference in the assailed FDA IRR.

58. Furthermore, the FDA IRR was issued in accordance with Article 5.3 of the WHO FCTC as implemented by the Philippines

[27] FDA Act, Section 22.

through Joint Memorandum Circular 2010-01 of the Civil Service Commission (hereafter, the "**CSC**") and the DOH on "Protection of the Bureaucracy Against Tobacco Industry Interference," which strives to protect the public health policies of the government from commercial and vested interests of the tobacco industry. The CSC-DOH Joint Memorandum Circular limits unnecessary interaction with the tobacco industry, and requires heads of national government agencies (thus including the FDA) to disseminate information about the addictive and harmful nature of tobacco products and tobacco industry interference with tobacco control policies, and amend their agencies' respective codes of conduct to incorporate guidelines for necessary interactions with the tobacco industry.[28] The issuance of the relevant portions of the FDA IRR was in full compliance with CSC-DOH Joint Memorandum Circular in accordance with the Philippines' treaty obligations under Article 5.3 of the WHO FCTC.

A copy of the CSC-DOH Joint Memorandum Circular is hereto attached as **Annex D.**

The FDA IRR is consistent with the Constitution, and in fact advances its policy on the protection and promotion of the people's right to health and the establishment of an effective food and drug regulatory system.

The inclusion of provisions on tobacco products in the FDA IRR is consistent with the FDA's full jurisdiction over all health products, recognizing the injurious effects of tobacco products on health.

[28] Civil Service Commission and Department of Health Joint Memorandum Circular No. 01, s. 2010, Protection of the bureaucracy against tobacco industry interference, June 29, 2010.

The FDA IRR does not seek to supplant the provisions of R.A. 9211, nor the jurisdiction of the IACT, but merely provides for the regulation of the health aspect of tobacco products, in view of its health effects.

59. The second requisite is also satisfied, as the provisions of the FDA IRR are consistent with the Constitution and its enabling laws, the FDA Act and the WHO FCTC. Under this requisite, to be valid, an administrative issuance must remain within the scope of the authority given by the legislature. It must not be ultra vires, that is, it must not go beyond the limits of the authority conferred. It must be consistent with the Constitution, its enabling statute, as well as other existing laws.

60. The FDA IRR is consistent with the Constitution, and in fact advances the policies embodied in Article II, Section 15 and Article XIII Sections 11 and 12, enjoining the protection and promotion of the people's right to health and the establishment of an effective food and drug regulatory system, thus:

> Article II. Declaration of Principles and State Policies.
>
> Sec. 15. The State shall protect and promote the right to health of the people and instill health consciousness among them.
>
> Article XIII. Social Justice and Human Rights.
>
> Sec. 11. The State shall adopt an integrated and comprehensive approach to health development which shall endeavor to make essential goods, health and other social services available to all the people at affordable cost. There shall be priority for the needs of the under-privileged, sick, elderly, disabled, women, and children. The State shall endeavor to provide free medical care to paupers.

> Section 12. The State shall **establish and maintain an effective food and drug regulatory system** and undertake appropriate health, manpower development, and research, responsive to the country's health needs and problems. (Emphases supplied)

61. The FDA IRR conforms to the foregoing Constitutional provisions directing the protection and promotion of health, and strives to implement the same. The inclusion of provisions on tobacco products in the FDA IRR is consistent with the Constitutional policy of protecting and promoting the people's right to health. Tobacco is the only product scientifically proven to cause disease and death when used precisely as intended. It constitutes a health product as defined in the FDA Act, and is therefore properly subject to regulation by the DOH and FDA, considering its dire repercussions on health and life.

62. The FDA IRR is also consistent with its enabling laws, the FDA Act and the WHO FCTC.

62.1. The FDA Act lays down the policy and standards to which the FDA IRR must conform in order to be valid. The FDA Act mandates the adoption of structures, processes, mechanisms and initiatives aimed to (i) protect and promote the right to health of the Filipino people, and (ii) help establish and maintain an effective health products regulatory system responsive to the country's health needs and problems. Moreover, one of its stated objectives is to ensure the FDA's monitoring and regulatory coverage over establishments and products under its jurisdiction. The FDA Act explicitly provided that it shall cover "all health products," which includes all products that may have an effect on health. The relevant provisions of the FDA Act are hereunder reproduced:

> SEC. 3. It is hereby declared a policy of the State to adopt, support, establish, institutionalize, improve and maintain structures, processes, mechanisms and initiatives that are aimed, directed and designed to: (a) protect and promote the right to health of the Filipino people; and (b) help establish and maintain an effective health products regulatory system and undertake appropriate health manpower development and research, responsive to the country's health needs and problems. Pursuant to this policy, the State must enhance its regulatory capacity and strengthen its capability with regard to the inspection, licensing and monitoring of establishments, and the registration and monitoring of health products.
>
> SEC. 4. This Act has the following objectives:
>
> (a) To enhance and strengthen the administrative and technical capacity of the FDA in the regulation of establishments and products under its jurisdiction;
> (b) To ensure the FDA's monitoring and regulatory coverage over establishments and products under its jurisdiction; and
> (c) To provide coherence in the FDA's regulatory system for establishments and products under its jurisdiction.
>
> xxx
>
> SEC. 25. Coverage. – This Act shall govern all health products: Provided, That nothing in this Act shall be deemed to modify the sole and exclusive jurisdiction of other specialized agencies and special laws only insofar as the acts covered by these specialized agencies and laws, including, but not limited to, those covered by Republic Act No. 9211, Executive Order No. 245, Executive Order No. 18, and Presidential Decree No. 1468.

62.2. The FDA IRR complies with the foregoing standards. The inclusion of provisions on tobacco products in the FDA IRR is consistent with the FDA's full jurisdiction over all health products, while recognizing the injurious effects of tobacco products on health. The FDA IRR is moreover very clear in stating that it governs only the health aspect of tobacco products, and shall not modify the jurisdiction of other specialized agencies, such as the IACT. As a precaution, the

FDA IRR further directs the FDA to specifically identify and define the policy areas that are not covered by the other specialized agencies and special laws. Pertinent provisions of the FDA IRR are hereunder reproduced for easy reference:

> ARTICLE III
> TOBACCO AND OTHER PRODUCTS
>
> Sec. 1. Rationale. The FDA has full jurisdiction over the regulation of all health products.
>
> Sec. 2. Tobacco. The DOH, tasked with protecting the public's health against the injurious effects arising from the use of tobacco and tobacco products, has the responsibility of regulating tobacco and tobacco products through the FDA.
>
> a. Rules and Other Issuances to Implement this Section. Within a reasonable period from the date of effectivity of these Rules and Regulations, the FDA shall prepare and recommend for the approval to the Secretary of Health, the appropriate rules and regulations and other issuances to implement this Section.
>
> x x x
>
> Sec. 3. Other Products. Nothing in the FDA Act of 2009 shall be deemed to modify the jurisdiction of other specialized agencies and special laws only insofar as the acts covered by these specialized agencies and laws except the health aspect of such products.
>
> Sec. 4. Identification of Policy Areas. The FDA shall promulgate the appropriate rules and regulations and other issuances to identify and define the policy areas that are not covered by specialized agencies and special laws, including, but not limited to, those covered by Republic Act No. 9211, Executive Order No. 245, Executive Order No. 18, and Presidential Decree No. 1468.

62.3. A perusal of the above provisions shows that nothing therein contradicts any provision of the FDA Act or R.A. 9211. It does not seek to supplant the provisions of the latter law, nor the jurisdiction of the IACT. It merely provides

for the regulation of the health aspect of tobacco products, in view of the health effects of tobacco products, which thus necessitate regulation of its health aspect by the DOH and FDA.

62.4. The inclusion of provisions in the FDA IRR on protecting the DOH and FDA against tobacco industry interference in its formulation and implementation of public health policies is moreover consistent with the WHO FCTC. Article 5.3 of the WHO FCTC provides that State Parties, in setting and implementing their public health policies with respect to tobacco control, must act to protect such policies from commercial and other vested interests of the tobacco industry, to wit:

> Article 5
> General Obligations
>
> 3. In setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law.

62.5. The FDA IRR conforms to the foregoing provision of the WHO FCTC. The DOH and FDA are the government agencies primarily responsible for the formulation and implementation of the Philippines' policies on health, including those relating to tobacco control. The DOH has moreover been expressly designated by the IACT as the pilot agency for implementing many measures under R.A. 9211. As the principal government agencies on health and being at the forefront of the tobacco control initiative, it was therefore necessary for the DOH and FDA to establish measures that

would insulate them from undue influence and interference by the tobacco industry in their performance of their duties. The DOH and FDA thus correctly included in the FDA IRR measures that would safeguard against tobacco industry interference, to wit:

> ARTICLE III
> TOBACCO AND OTHER PRODUCTS
>
> Sec. 2. Tobacco. The DOH, tasked with protecting the public's health against the injurious effects arising from the use of tobacco and tobacco products, has the responsibility of regulating tobacco and tobacco products through the FDA.
>
> x x x
>
> b. Protection against Tobacco Industry Interference. The FDA shall act to protect the formulation and implementation of rules and regulations under this Section from commercial and other vested interests of the tobacco industry, including organizations, entities, associations, individuals, and others that work to further the interests of the tobacco industry.
>
> The FDA shall not deal with the tobacco industry or individuals or entities that work to further the interests of the tobacco industry, except to the extent strictly necessary to effectively regulate, supervise, or control the tobacco industry in relation to tobacco and tobacco products.

62.6. The above provisions of the FDA IRR on protection against tobacco industry interference are consistent with the WHO FCTC, and are necessary for the proper fulfillment of the obligation of the DOH and FDA to regulate the health aspect of tobacco.

63. The FDA IRR is consistent with R.A. 9211 and other existing laws.

63.1. A review of the provisions of the FDA IRR on tobacco shows that nothing therein contravenes R.A. 9211. It does not seek to supplant the provisions of R.A. 9211, nor the jurisdiction of the IACT. It merely provides for the regulation of the health aspect of tobacco products, in view of their health effects, which thus necessitates regulation by government health agencies.

63.2. The DOH and FDA were actually very clear in their effort to avoid overlapping of jurisdiction, in compliance with Section 25 of the FDA Act, by expressly providing in the FDA IRR that it shall not modify the jurisdiction of other special agencies, and by tasking the FDA with the responsibility of identifying and defining the policy areas that are not covered by special laws and agencies, thus:

> Sec. 4. Identification of Policy Areas. The FDA shall promulgate the appropriate rules and regulations and other issuances to identify and define the policy areas that are not covered by specialized agencies and special laws, including, but not limited to, those covered by Republic Act No. 9211, Executive Order No. 245, Executive Order No. 18, and Presidential Decree No. 1468.

63.3. As earlier discussed, R.A. 9211 regulates only certain aspects of tobacco products, particularly, their sale and distribution, signages, smoke-free places, textual warnings on cigarette packages, advertisements, promotions and sponsorship. In the Monitoring and Enforcement Guidelines, the IACT itself actually specifically designated the DOH as the pilot agency for monitoring and enforcing compliance with nearly all of these aspects: smoke-free places, textual warnings

on cigarette packages, advertising, promotions and sponsorship.

63.4. The IACT itself expressly provided in the Monitoring and Enforcement Guidelines it issued that nothing therein should be construed so as to preclude or diminish the exercise by the DOH of its administrative functions pursuant to its mandate under other existing laws, rules and regulations, such as the Administrative Code, the FDA Act, and the WHO FCTC.

63.5. The PTI's allegations about the FDA IRR are therefore baseless, as the latter simply executes the very responsibility given the DOH by the IACT itself.

The third requisite has been complied with, as the FDA IRR was promulgated in accordance with prescribed procedure.

64. The third requisite has been complied with, as the FDA IRR was promulgated in accordance with prescribed procedure.

65. As a general rule, prior notice and hearing are not required or essential to the validity of rules and regulations issued in the exercise of quasi-legislative powers, since there is no determination of past events or facts that have to be established or ascertained.[29]

[29] Dagan vs. Philippine Racing Commission, G.R. No. 175220, 12 February 2009; see also Philippine Consumers Foundation, Inc. v. Secretary of Education, Culture and Sports, G.R. No. 78385, August 31, 1987

66. In the instant case, the DOH and FDA even went beyond the minimum procedural requirements for the benefit of the public. Public hearings were conducted prior to the issuance of the FDA IRR on July 21, 2010 at the University of the Philippines Law Center and on August 6, 2010 in Cebu.

The inclusion of tobacco products within the purview of the regulatory authority of DOH and FDA is reasonable and necessary towards achieving the State's goals of protecting and promoting public health.

67. The fourth requisite is satisfied, as the FDA IRR is reasonable.

68. To be valid, an administrative issuance must not be unreasonable or discriminatory. The provisions thereof must bear a reasonable relation to the purpose sought to be achieved.[30] For example, the use of early warning devices,[31] the prohibition of heavy vehicles in public streets on weekends and holidays,[32] and the requirement of passing a nationwide examination[33] were considered justified for purposes of traffic safety, improvement of traffic conditions, and improvement of the quality of graduates, respectively.

69. In the instant case, the inclusion of tobacco products in the FDA IRR is obviously reasonable. The primary responsibility and function of the DOH is to (i) promote, protect, preserve or restore the

[30] Dagan vs. Philippine Racing Commission, G.R. No. 175220, 12 February 2009.
[31] Agustin v. Edu, G.R. No. L-49112, February 2, 1979.
[32] Bautista v. Junio, G.R. No. L-50908, January 31, 1984.
[33] Tablarin v. Gutierrez, G.R. No. 78164, July 31 1987.

health of the people through the regulation of health goods, and (ii) to administer all laws, rules and regulations in the field of health. The DOH and the FDA are the principal government agencies tasked to implement the State's policy of protecting and promoting the people's right to health.

70. The regulation of the health aspect of tobacco products and the institution of safeguards against tobacco industry interference in the formulation and implementation of public health policies on tobacco control as provided in the FDA IRR merely execute the foregoing function and responsibility of the DOH and FDA. They are reasonable measures towards achieving the goal of protecting and promoting the health of the people. The inclusion of tobacco products within the purview of the regulatory authority of DOH and FDA is reasonable and necessary towards achieving the State's goals of protecting and promoting public health.

71. Tobacco has deleterious effects on public health - both towards smokers and non-smokers, regardless of age. Indeed, it is the only legal consumer product that is lethal when used precisely as intended. Hence, the regulation of the health aspect of tobacco products and the protection of the DOH and FDA from tobacco industry interference as they perform their duties are necessary and reasonable measures for the protection and promotion of the right to health. The FDA IRR upholds this right. The DOH thus validly exercised its rule-making power in providing that tobacco products are subject to the jurisdiction of the FDA, as the agency responsible for regulating health products.

72. All told, Intervenors implore the Honorable Court to rule in favor of the validity of FDA IRR, in recognition of the continued

authority of the DOH and FDA over the health aspect of tobacco products, with utmost dispatch and finality.

PRAYER

WHEREFORE, premises considered, it is respectfully prayed that the Honorable Court set aside the *Decision* dated 6 February 2012 of the Regional Trial Court of Las Piñas, Branch 255, and render judgment upholding the validity of the Rules and Regulations Implementing Republic Act No. 9711 or the Food and Drug Administration (FDA) Act of 2009 and recognizing the continued regulatory authority of the DOH and FDA over the health aspect of tobacco products.

Other reliefs as may be just or equitable under the premises are likewise prayed for.

Respectfully submitted.

Makati City for the City of Manila, 10 April 2013.