

THE DEPARTMENT OF HEALTH, REPRESENTED BY SECRETARY ENRIQUE T. ONA, AND THE FOOD AND DRUG ADMINISTRATION, REPRESENTED BY DIRECTOR SUZETTE HENARES-LAZO, PETITIONERS,

G.R. No. 200431. July 13, 2021

Ponente: LEONEN, J.

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LEONEN, J.:

Tobacco products are undoubtedly "health products" within the definition provided under Republic Act No. 9711, or the Food and Drug Administration Act of 2009, due to their harmful effects on health. As to their health aspect, tobacco products fall under the regulatory authority of the Food and Drug Administration.

This Court resolves the Petition for Review on Certiorari assailing the Regional Trial Court's ruling,[1] which nullified certain provisions of the Rules and Regulations Implementing Republic Act No. 9711 insofar as it regulates tobacco products and the tobacco industry.

In 1963, the Food and Drug Administration was established under the Department of Health per Republic Act No. 3720, or the Food, Drug, and Cosmetic Act. It was tasked with administering and implementing laws that guarantee "the safety and purity of foods, drugs and cosmetics being made available to the public." [2] The agency was abolished in 1982, and its functions were undertaken by the Bureau of Food and Drugs. [3] In 1987, certain provisions of Republic Act No. 3720 were amended by Executive Order No. 175. [4]

In 2009, Republic Act No. 9711 was enacted to reinforce the regulatory capacity of the Bureau, [5] which was then renamed the Food and Drug Administration, [6] now holding regulatory authority over all health products. [7]

In 2011, following Section 22 of the law, [8] the Department of Health, in coordination with the Food and Drug Administration, promulgated the pertinent Implementing Rules and Regulations of Republic Act No. 9711 (Implementing Rules).

The controversy in this case arose when the Philippine Tobacco Institute, Inc. (PTI) filed a Petition for Declaratory Relief with Application for the Issuance of a Temporary Restraining Order and/or Writ of Preliminary Injunction [9] before the Regional Trial Court. PTI sought to prohibit the enforcement of the Implementing Rules, and to declare it void for disregarding Republic Act No. 9711 and Republic Act No. 9211, or the Tobacco Regulation Act of 2003. [10]

PTI argued that under Republic Act No. 9211, the Inter-Agency Committee Tobacco (IAC-Tobacco) had exclusive jurisdiction over tobacco products, [11] including its health aspect. [12] It also contended that Section 25 of the Republic Act No. 9711 explicitly prohibited the Food and Drug Administration from taking cognizance of health products already regulated by other agencies. [13] The provision states:

SECTION 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.

PTI added that per congressional deliberations, the legislature intended to exclude tobacco products from the Food and Drug Administration's regulatory power.[14] It argued that even if the Health Secretary was designated as the permanent Vice Chairperson of the IAC-Tobacco under Republic Act No. 9211, the Department of Health's authority over tobacco products is limited to its membership in the committee;[15] as such, it could not allegedly issue rules on tobacco products and the tobacco industry.[16]

PTI then contested Book II, Article III of the Implementing Rules, which classified tobacco products as "health products," placing them under the Food and Drug Administration's regulatory authority.[17] It states:

BOOK II

ARTICLE III

Tobacco and Other Products

SECTION 1. Rationale. — The FDA has full jurisdiction over the regulation of all health products.

SECTION 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.

- 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.

- 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.

SECTION 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 aspects of such products.

SECTION 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.

PTI similarly pointed out that the restriction in the dealings between the Food and Drug Administration and the tobacco industry under Section 2(b), paragraph 2 above not only lacked statutory basis, but also violated the equal protection clause.[18] Limiting the Food and Drug Administration's interaction with the tobacco industry only on matters necessary for effective regulation "unduly discriminate[d] against the tobacco industry and ma[de] an invalid classification as it fail[ed] to impose the same burden on other private industries with interest in other health products regulated by the [Food and Drug Administration]."[19]

PTI also assailed Book II, Articles I, II, and V[20] of the Implementing Rules, which cover tobacco products. PTI argued that under Republic Act No. 9211, the IAC-Tobacco had "jurisdiction over the regulation of labeling, advertisements, promotions, sponsorships and marketing activities involving tobacco products." [21] The assailed provisions state:

BOOK II

ARTICLE I

Licensing of Establishments and Registration of Health Products

SECTION 1. General Provisions. —

- The manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising, or sponsorship of any health product without the proper authorization from the FDA is prohibited.

....

ARTICLE II

Labeling of Health Products

SECTION 1. General Provision. — Consistent with the state policy of protecting the consumer against hazards to health and safety and providing information and education to facilitate sound choice in the proper exercise of their rights, all health products must be labeled and conform to the requirements on labeling set by the FDA.

....

ARTICLE V

Advertisements, Promotions, Sponsorship, and Other Marketing Activities

SECTION 1. General Provision. — Consistent with the state policy of protecting the consumer against misleading, deceptive, false, erroneous impression regarding any health product's character, value, quantity, composition, merit, or safety, efficacy or quality, and in order to provide information and education to facilitate sound choice in the proper exercise of their rights, all advertisements, promotions, sponsorship, and other marketing activities about the health product must adhere to the standards, guidelines, and regulations of the FDA. For this purpose, advertisements, promotions, sponsorship, and other marketing activities on health products shall refer to those addressed to the general public in any form of media.

SECTION 2. General Rules on Advertisements, Promotions, Sponsorship, and Other Marketing Activities of any Health Product. —

- No health product that has not been registered or authorized shall be advertised, promoted or subjected to any marketing activities;

- No claim in the advertisement, promotion and sponsorship, and other marketing activities shall be made other than those contained in the approved label or packaging of the health product, or as duly approved by the FDA[.]

On the other hand, the Department of Health and the Food and Drug Administration insisted on the valid exercise of their rule-making power[22] and regulatory authority over tobacco products. They argued that tobacco products were allegedly "health products" under Section 10(ff) of Republic Act No. 3720, as amended by Republic Act No. 9711, due to their detrimental effects to health.[23] Section 10(ff) states:

SECTION 10. For the purposes of this Act, the term:

(ff) 'Health products' means food, drugs, cosmetics, devices, biologicals, vaccines, in-vitro diagnostic reagents and household/urban hazardous substances and/or a combination of and/or a derivative thereof. It shall also refer to products that may have an effect on health which require regulations as determined by the FDA. (Emphasis supplied)

They added that under Section 25 of Republic Act No. 9711, the Food and Drug Administration allegedly "retain[ed] jurisdiction over all health products (including tobacco products) on matters that are not covered by special laws." [24] They denied stripping the IAC-Tobacco of its exclusive authority to implement Republic Act No. 9211, the latter's powers being distinct from them. [25]

As to the protection against tobacco industry interference, the Department of Health and the Food and Drug Administration contended that the Implementing Rules were allegedly "consistent with the State's constitutional mandate to protect public health, as recognized in the various provisions of the [World Health Organization Framework Convention on Tobacco Control (WHO FCTC)]." [26]

On September 28, 2011, the Regional Trial Court denied PTI's move for injunction, [27] and on December 15, 2011, denied its move for reconsideration. [28]

Later, in a January 27, 2012 Decision, [29] the Regional Trial Court ruled on the merits and granted [30] PTI's petition. Relying on Section 25 of Republic Act No. 9711, it declared that tobacco products were expressly excluded from the coverage of the law, and hence, beyond the ambit of the Food and Drug Administration's regulatory power. Recognizing the IAC-Tobacco's exclusive jurisdiction over tobacco products under Republic Act No. 9211, the trial court ruled that it was improper for the Department of Health and the Food and Drug Administration to include tobacco products under Book II, Article III of the Implementing Rules. It also agreed with PTI that the other contested provisions, which consequently applied to tobacco products, would encroach on IAC-Tobacco's authority over the same activities under Republic Act No. 9211. [31]

The trial court also explained that Section 25 of Republic Act No. 9711 conformed with existing statutes, particularly with Republic Act No. 9211, the "primary law on regulating tobacco products." [32] It pointed out that congressional deliberations relevant to the enactment of Republic Act No. 9711 recognized the IAC-Tobacco's exclusive authority over tobacco products, citing the following testimony of Atty. Emilio Polig (Atty. Polig), Head of the Food and Drug Administration's Legal Department:

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 on 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. (Exhibit D 45-46). [33] (Emphasis in the original)

The trial court ruled that the Department of Health, as a member of the IAC-Tobacco through the Food and Drug Administration, could only regulate tobacco products through the IAC-Tobacco by providing inputs and proposals for the body's deliberation. Thus, it declared that the Department of Health and the Food and Drug Administration exceeded their rule-making powers in including the contested provisions of the Implementing Rules. [34]

The dispositive portion of the Regional Trial Court Decision reads:

WHEREFORE, premises considered, the petition is hereby GRANTED. The Implementing Rules and Regulations of R.A. No. 9711, insofar as it regulates tobacco products and the tobacco industry is declared void. Public Respondents Department of Health and Food and Drug Administration are hereby directed to refrain from enforcing the Implementing Rules and Regulations on tobacco products and the tobacco industry.

SO ORDERED. [35]

On March 29, 2012, the Department of Health and the Food and Drug Administration, through the Office of the Solicitor General, filed this Petition for Review.[36]

On August 28, 2012, PTI filed its Comment[37] to the Petition.

On April 11, 2013, petitioners-intervenors Senators Pilar Juliana S. Cayetano and Franklin M. Drilon filed their Petition-in-Intervention.[38]

On December 17, 2013, respondent-intervenor Representative Edcel C. Lagman filed his Opposition-in-Intervention.[39]

On September 9, 2014, this Court required the parties and intervenors to file their memoranda.[40]

Petitioners insist on the valid exercise of their regulatory powers.[41] To them, Section 25 clearly says that Republic Act No. 9711 governs all health products except those matters covered by special laws. Hence, the Food and Drug Administration allegedly retained its regulatory powers over tobacco products on matters affecting public health, which are not covered by Republic Act No. 9211.[42] Moreover, congressional deliberations allegedly reveal the lawmakers' intent to grant the Food and Drug Administration authority over the health aspects of all products, including tobacco.[43]

Petitioners repeat that due to their effects on health, tobacco products are "health products" under Section 10(ff) of Republic Act No. 3720, as amended, and thus fall under the regulatory authority of the Department of Health through the Food and Drug Administration.[44] This is despite the lack of a center under Section 5 of Republic Act No. 3720, as amended, which regulates tobacco products. After all, for petitioners, the Food and Drug Administration is empowered to create additional organizational units.[45]

Petitioners emphasize that the Department of Health's primary responsibilities of formulating and implementing health policies and programs were neither amended nor repealed by Republic Act No. 9211.[46] Republic Act No. 9711, on the other hand, was enacted to strengthen the State's regulatory and enforcement capacity over health products.[47] These laws do not confuse or merge the functions of the Food and Drug Administration and the IAC-Tobacco, petitioners say.[48]

Petitioners also explain[49] that of Book II, Article III, Section 2(b), paragraph 2 of the Implementing Rules on protection against tobacco industry interference is consistent with Department Memorandum Order No. 2010-0126[50] and Joint Memorandum Circular No. 2010-01,[51] and conforms to the Philippines' obligations under the WHO FCTC to protect public health policies from the vested interests of the tobacco industry.[52]

Moreover, petitioners argue that the tobacco industry's distinct classification allegedly rests on valid and reasonable standards and do not violate the equal protection clause.[53]

To these, petitioners-intervenors add that Section 25 of Republic Act No. 9711 did not diminish petitioners' powers to promulgate rules and regulations over tobacco products.[54] The proviso allegedly provides a limitation only insofar as certain acts have been covered by the special laws and agencies specified.[55] As to acts not covered, including the health aspect of tobacco products, they say that the law has suppletory application and that these remain within the regulatory authority of petitioners.[56]

Petitioners-intervenors also contend that Republic Act No. 9211 does not address all obligations required under the WHO FCTC.[57] It "regulates only certain aspects [of the tobacco industry], particularly sale and distribution, signages, smoke-free places, textual warnings on cigarette packages, advertisements, promotions and sponsorship."[58] The IAC-Tobacco's task is merely compliance monitoring and program development, petitioners-intervenors say, while the implementation of programs and projects lies with the member-agencies of

the IAC-Tobacco.[59]

Also citing congressional deliberations, petitioners-intervenors argue that "the consensus of the legislators was to include tobacco products within the coverage of [Republic Act No. 9711] and the regulatory authority of the [Food and Drug Administration]."[60] They add that the trial court erroneously relied on a mere opinion by Atty. Polig, as cited by respondent, which was also just a portion of the deliberations of the Bicameral Committee on February 23, 2009 and is not the intent of the Committee.[61]

Petitioners-intervenors echo petitioners in that tobacco products undeniably qualify as "health products" for their detrimental effects on health.[62] They say that ejusdem generis only applies in case of ambiguity and would not be "controlling where the plain purpose and intent of the Legislature would thereby be hindered and defeated." [63] Restricting the law's coverage only to the list under the definition of health products or of the same class as the latter, they say, would defeat the law's very objective.[64]

On the other hand, respondent counters that Republic Act No. 9211 bestows on the IAC-Tobacco the exclusive jurisdiction to regulate tobacco products, which includes their health aspect.[65] It asserts that the Department of Health cannot regulate tobacco products on its own, and that its authority is limited to being part of IAC-Tobacco.[66]

In contrast to what petitioners say, respondent argues that Republic Act No. 9711, as supported by congressional deliberations, points to the legislative intent to exclude tobacco products from the coverage of the law.[67] Likewise, tobacco products are allegedly not health products, they not being mentioned in Republic Act No. 9711, nor was there a specific center created under the law to regulate it.[68]

Respondent also argues that Section 25 of the law delimited the Food and Drug Administration's jurisdiction by explicitly divesting it of power over matters already under the exclusive jurisdiction of other regulatory agencies, such as the IAC-Tobacco under Republic Act No. 9211. It notes that Congress had decided not to give Republic Act No. 9711 application "in a suppletory manner to other special laws"[69] as seen in how this clause was omitted in the final version.[70] It adds that the Implementing Rules unduly encroach on the exclusive jurisdiction of the IAC-Tobacco over the labeling, advertising, sponsorship, and marketing of tobacco products.[71]

Respondent adds that Book II, Article III, Section 2(b), paragraph 2 of the Implementing Rules lacks basis and runs counter to constitutional and statutory provisions. It notes that the WHO FCTC is allegedly not self-implementing, which means that petitioners cannot use it as "basis of any right or obligation";[72] and that the restriction provided in the Implementing Rules violates respondent's right to equal protection.[73]

Respondent-intervenor supports respondent in that tobacco products are not "health products" under Section 10(ff) of Republic Act No. 3720.[74] He claims that the provision's second sentence, which states that health products are those that have an effect on health, must be construed as "akin in nature to those enumerated in the first sentence in application of the doctrine of ejusdem generis." [75] Tobacco products, he argues, are not included in the list [76] or germane to such class—unlike the health products enumerated which "have generally beneficial use, albeit, with potential harm[.]" [77] tobacco products have no health benefits.

Respondent-intervenor adds that Republic Act No. 9211 effectively amended the Department of Health's general powers on health matters under the Administrative Code.[78] He opposes the inclusion of tobacco products and the tobacco industry in the Implementing Rules pursuant to DOH Memorandum No. 2010-0126, Joint Memorandum Circular No. 2010-01, and the WHO FCTC, claiming that petitioners "were tasked to implement solely the provisions of [Republic Act No. 9711], not any administrative fiat or international covenant which could stand on their own." [79] He adds that the WHO FCTC is "addressed principally to the State Parties'

legislature, not to mere administrative bodies." [80]

Respondent-intervenor contends that having "[d]ual jurisdiction will definitely spawn conflicts and confusion which may be inimical to the government's health agenda on tobacco products." [81] With the Department of Health's vast functions in protecting the people's health, it would allegedly "be best for a specialized agency like the IAC-Tobacco to focus on a particular[ly] deleterious product [which is] tobacco." [82] He points out that ascertaining the correctness of the legislature's wisdom behind excluding tobacco products and the tobacco industry from the coverage of Republic Act No. 9711 is beyond the authority of any court or administrative body to correct or defy. [83]

Respondent-intervenor further argues that the Food and Drug Administration's assumption of jurisdiction over tobacco products will yield absurd results. It would allegedly be incredible to ensure the "safety, efficacy, purity and quality" [84] of tobacco products, the latter being hazardous. He adds that, although regulated, tobacco products remain to be "legitimate articles of commerce" [85] which cannot be banned for failing to conform to standards imposed by the Food and Drug Administration. [86]

For this Court's resolution is the main issue of whether or not the Regional Trial Court correctly nullified the Rules and Regulations Implementing Republic Act No. 9711 insofar as it included tobacco products and the tobacco industry in its coverage.

Subsumed under this are two issues:

First, whether or not Section 25 of Republic Act No. 9711 excludes the regulation of the health aspects of tobacco products from the Food and Drug Administration's authority; and

Second, whether or not tobacco products are "health products" under the definition provided under Section 10(ff) of Republic Act No. 3720, as amended by Section 9 of Republic Act No. 9711.

The Petition is granted.

I

Before delving into the issues, a brief overview of the government's tobacco control measures to reduce tobacco use in our country is apropos.

It is the State policy to "protect and promote the right to health of the people and instill health consciousness among them." [87] The Department of Health, as the government agency that chiefly responds to health concerns, is "primarily responsible for the formulation, planning, implementation, and coordination of policies and programs in the field of health." [88] Specifically, its powers and functions are:

SECTION 3. Powers and Functions. — The Department shall:

(1)

Define the national health policy and formulate and implement a national health plan within the framework of the government's general policies and plans, and present proposals to appropriate authorities on national issues which have health implications;

(2)

Provide for health programs, services, facilities and other requirements as may be needed, subject to availability of funds and administrative rules and regulations;

(3)

Coordinate or collaborate with, and assist local communities, agencies and interested groups including international organizations in activities related to health;

(4)

Administer all laws, rules and regulations in the field of health, including quarantine laws and food and drug safety laws;

(5)

Collect, analyze and disseminate statistical and other relevant information on the country's health situation, and require the reporting of such information from appropriate sources;

(6)

Propagate health information and educate the population on important health, medical and environmental matters which have health implications;

(7)

Undertake health and medical research and conduct training in support of its priorities, programs and activities;

(8)

Regulate the operation of and issue licenses and permits to government and private hospitals, clinics and dispensaries, laboratories, blood banks, drugstores and such other establishments which by the nature of their functions are required to be regulated by the Department;

(9)

Issue orders and regulations concerning the implementation of established health policies; and

(10)

Perform such other functions as may be provided by law.[89] (Emphasis supplied)

As the national technical authority on health, the Department of Health serves as the key government agency for promoting tobacco control in the country. In 1987, the then Non-Communicable Disease Control Service,[90] under the Department's Public Health Services, developed a five-year national smoking control plan as its primary strategy in the lung cancer prevention program. The plan aimed to reduce the national prevalence of smoking by 10% in 1997, render all the department facilities smoke-free by 1993, and ban smoking among elementary and high school students.[91] To increase public awareness against smoking, it launched its anti-smoking campaign in the 1990s, through its "Yosi Kadiri" iconic mascot and media campaigns, to illustrate the detrimental effects of cigarette smoking on the health of both smokers and non-smokers.[92]

In 1992, Republic Act No. 7934 or the Consumer Act of the Philippines was passed, aiming to protect consumer interest and promote general welfare[93] through the following measures:

- a)
protection against hazards to health and safety;
- b)
protection against deceptive, unfair and unconscionable acts and practices;
- c)
provision of information and education to facilitate sound choice and the proper exercise of rights by the consumer;
- d)
provision of adequate rights and means of redress; and
- e)
involvement of consumer representatives in the formulation of social and economic policies.[94]

The Department of Health is the implementing agency tasked to establish and enforce consumer product quality and safety standards,[95] compulsory labeling and fair packaging,[96] and advertising and sales promotion restrictions[97] relative to food, drugs, cosmetics, devices, and hazardous substances.[98] It may also require that labels of packaging indicate the following:

- a)
whether it is flammable or inflammable;
- b)
directions for use, if necessary;
- c)
warning of toxicity;
- d)
wattage, voltage or amperes; or
- e)
process of manufacture used if necessary.[99]

In relation to tobacco's health hazards, the law required that all cigarette packs carry a health warning: "Cigarette Smoking is Dangerous to Your Health." [100] The Department of Health likewise enforced labeling and packaging requirements,[101] issuing Administrative Order No. 10 in 1993. It provided that no cigarette without the warning statement would be allowed in the market beginning January 1, 1994, and would be seized by food and drug regulation officers.

That same year, the Department of Health issued Administrative Order No. 8, prohibiting smoking in all its offices, agencies, hospitals, and premises nationwide. A 100% smoke-free policy was later established for all government agencies, local government units, and state universities,[102] as well as in public utility vehicles and

land transportation terminals.[103]

In 1999, Republic Act No. 8749 or the Philippine Clean Air Act also prohibited under Article 5, Section 24 smoking in public buildings or enclosed public places, including public vehicles and other means of transport. It also banned smoking in any enclosed area outside one's private residence, private place of work, or any duly designated smoking area.

To further curtail the increasing tobacco consumption and its negative effects on health and the economy, Republic Act No. 9211 or the Tobacco Regulation Act was enacted on June 23, 2003. It regulated the use, sale, and advertisement of tobacco products while promoting healthy environments and mandating health programs and withdrawal clinics.[104] Smoking in public places like hospitals, clinics, and enclosed public places are banned.[105] All forms of mass media advertising were banned by July 1, 2008,[106] including the sponsorship of cultural and sporting events by the tobacco industry.[107]

The law adds that, by 2004, cigarettes advertisements and packs must bear a warning on specific health hazards caused by smoking. Warnings should include, on a rotating basis, separately or simultaneously, messages such as, "Cigarette Smoking is Dangerous to Your Health," "Cigarettes are Addictive," "Tobacco Smoke can Harm Your Children," or "Smoking Kills,"[108] amending Article 94 of the Consumer Act.[109] The law also requires that all tobacco packages contain either of the messages "NO SALE TO MINORS" or "NOT FOR SALE TO MINORS" on one panel.[110] The law expressly repealed DOH Administrative Order No. 10, as well as Administrative Order No. 24, series of 2003, which had also provided guidelines on cigarette labeling and advertisements.[111]

Under Section 29, the law also created the IAC-Tobacco, which was vested with the exclusive power and function to administer and implement the provisions of the law. Accordingly, the IAC-Tobacco issued Memorandum Circular No. 1, series of 2004, or the Implementing Rules and Regulations of the Tobacco Regulation Act of 2003.[112] As with the Tobacco Regulation Act, these Implementing Rules and Regulations cover a range of topics on tobacco control—providing definitions and standards for designated smoking areas, access restrictions, and restrictions on advertising, promotions, and sponsorships, among others.

Shortly after, on September 23, 2003, the Philippines became a signatory to the World Health Organization Framework Convention on Tobacco Control (WHO FCTC), which was ratified on June 6, 2005.[113] The WHO FCTC embodies the WHO's tobacco-free initiative, recognizing that the enjoyment of the highest attainable standard of health is a basic constitutional right.[114]

Being a party to the WHO FCTC, the Philippines committed to implement tobacco control measures such as price and tax policies.[115] It also committed to "adopt and implement effective legislative, executive and administrative or other measures" to reduce tobacco demand and consumption, including:

- protection from exposure to tobacco smoke in indoor workplaces, public transport, indoor public places, and other public places;[116]
- regulation of tobacco products' contents, emissions,[117] and disclosures;[118]
- packaging and labelling regulations;[119]
- education and public awareness measures;[120]
- comprehensive ban/restrictions on tobacco advertising, promotion and sponsorship;[121]
- measures to combat illicit trade;[122]

- prohibition of sale by, and to, minors;[123]
- measures to promote cessation of tobacco use and adequate treatment for tobacco dependence;[124] and
- reduction of tobacco industry interference in setting and implementing public health policies.[125]

The treaty also provides for international cooperation to support tobacco control, including scientific, technical, and legal cooperation and information sharing.[126] Finally, each state party is required to submit periodic reports on its implementation of the Convention.[127]

In accordance with the WHO FCTC, the Department of Health institutionalized the National Tobacco Prevention and Control Program, which would focus on five priority areas: (1) tobacco dependence and cessation; (2) protection from exposure to tobacco smoke; (3) education, communication, and training; (4) regulation of tobacco product disclosure; and (5) regulation of tobacco products' contents.[128]

In line with Articles 7 and 11 of the WHO FCTC, the Department of Health issued Administrative Order No. 2010-0013[129] on May 25, 2010, requiring graphic health information on tobacco product packages and prohibiting the promotion of any tobacco product using misleading descriptors. Also, aligned with the WHO FCTC, the Civil Service Commission and the Department of Health issued Joint Memorandum Circular No. 2010-01,[130] which provides guidelines for interactions with the tobacco industry under the policy protecting the bureaucracy against tobacco industry interference. The Department of Health further issued Memorandum No. 2010-0126,[131] with the same purpose but specific to protecting the Department against tobacco industry interference.

In 2011, the Department of Health, through the Food and Drug Administration, issued the Rules and Regulations Implementing Republic Act No. 9711 (Implementing Rules), incorporating provisions on tobacco product regulation and protection against tobacco industry interference.

As to price and tax measures, Republic Act No. 10351 or the Sin Tax Law was signed into law in 2012. In considerably increasing the specific excise tax on tobacco and tobacco products, the law raised the consumer price of cigarettes, discouraging consumption. The law also provided funds for the Universal Health Care Law.[132]

On July 15, 2014, Republic Act No. 10643 or the Graphic Health Warnings Law was enacted, recognizing the Philippines' obligation under the WHO FCTC "to inform every person of the health consequences of tobacco consumption and exposure to tobacco smoke; to enact effective measures to curb and reduce tobacco use, especially among the youth; and to protect public health policy from the commercial and vested interests of the tobacco industry." [133] The law also acknowledged the Philippines' duty under Article 11 of the WHO FCTC to adopt and implement effective health warnings on tobacco products.[134] It expressly repealed Section 13 of Republic Act No. 9211 on cigarette package warnings, and DOH Administrative Order No. 2010-0013. Republic Act No. 10643 is implemented by administrative orders[135] issued by the Department of Health which establish the templates of the required graphic health warnings.

This narrative clearly establishes that the Department of Health has been at the forefront of policymaking and implementation on matters affecting public health, including tobacco control programs.

II

This case involves the validity of the Implementing Rules of Republic Act No. 9711, insofar as it included the health aspects of tobacco products in the regulatory authority of the Department of Health through the Food and Drug Administration under Book II, Article III.

Respondent primarily argues that the inclusion of tobacco products disregards Republic Act No. 9211, which vested in the IAC-Tobacco exclusive power to regulate tobacco products, and Section 25 of Republic Act No. 9711, which excludes tobacco products from the Food and Drug Administration's jurisdiction.[136] Ruling for respondent, the Regional Trial Court held that petitioners erred in including tobacco products under Book II, Article III of the Implementing Rules.[137]

The Regional Trial Court is incorrect.

II (A)

The enactment of Republic Act No. 9711, geared toward strengthening the State's regulatory capacity and enforcement of compliance with regulations over health products,[138] finds support in the Constitution.

Article II, Section 15 states:

SECTION 15. The State shall protect and promote the right to health of the people and instill health consciousness among them.

Meanwhile, under Section 12 of Article XIII, on social justice and human rights, states:

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.

Republic Act No. 9711 created the Food and Drug Administration, which is tasked to carry out its provisions.[139] Aligned with the constitutional declarations, Republic Act No. 9711 aims:

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.[140]

Section 5 of Republic Act No. 9711, which amends Republic Act No. 3270, explicitly provides the specific functions and duties of the Food and Drug Administration:

(a) To administer the effective implementation of this Act and of the rules and regulations issued pursuant to the same;

(b) To assume primary jurisdiction in the collection of samples of health products;

(c) To analyze and inspect health products in connection with the implementation of this Act;

(d) To establish analytical data to serve as basis for the preparation of health products standards, and to

recommend standards of identity, purity, safety, efficacy, quality and fill of container;

(e) To issue certificates of compliance with technical requirements to serve as basis for the issuance of appropriate authorization and spot-check for compliance with regulations regarding operation of manufacturers, importers, exporters, distributors, wholesalers, drug outlets, and other establishments and facilities of health products, as determined by the FDA;

(f) To levy, assess and collect fees for inspection, analysis and testing of products and materials submitted in compliance with the provisions of this Act.

(g) To certify batches of anti-biotic and anti-biotic preparations in compliance with the provisions of this Act.

(h) To conduct appropriate tests on all applicable health products prior to the issuance of appropriate authorizations to ensure safety, efficacy, purity, and quality;

(i) To require all manufacturers, traders, distributors, importers, exporters, wholesalers, retailers, consumers, and non-consumer users of health products to report to the FDA any incident that reasonably indicates that said product has caused or contributed to the death, serious illness or serious injury to a consumer, a patient, or any person;

(j) To issue cease and desist orders *motu proprio* or upon verified complaint for health products, whether or not registered with the FDA: Provided, that for registered health products, the cease and desist order is valid for thirty (30) days and may be extended for sixty (60) days only after due process has been observed;

(k) After due process, to order the ban, recall, and/or withdrawal of any health product found to have caused the death, serious illness or serious injury to a consumer or patient, or is found to be imminently injurious, unsafe, dangerous, or grossly deceptive, and to require all concerned to implement the risk management plan which is a requirement for the issuance of the appropriate authorization;

(l) To strengthen the post market surveillance system in monitoring health products as defined in this Act and incidents of adverse events involving such products;

(m) To develop and issue standards and appropriate authorizations that would cover establishments, facilities and health products;

(n) To conduct, supervise, monitor and audit research studies on health and safety issues of health products undertaken by entities duly approved by the FDA;

(o) To prescribe standards, guidelines, and regulations with respect to information, advertisements and other marketing instruments and promotion, sponsorship, and other marketing activities about the health products as covered in this Act;

(p) To maintain bonded warehouses/ and/or establish the same, whenever necessary or appropriate, as determined by the director-general for confiscated goods in strategic areas of the country especially at major ports of entry; and

(q) To exercise such other powers and perform such other functions as may be necessary to carry out its duties and responsibilities under this Act.[141] (Emphasis supplied)

At the core of the present controversy is Section 25 of Republic Act No. 9711, which reads:

SECTION 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. (Emphasis supplied)

Petitioners argue for including tobacco products in the Implementing Rules, these being health products due to their hazardous effects on health.[142] Petitioners contend that under Section 25, the Food and Drug Administration "retains jurisdiction over health products (including tobacco products) on matters delving on the protection of public health—the same not being within the jurisdiction of other specialized agencies." [143]

Respondent counters that Republic Act No. 9211 encompasses the regulation of health matters concerning tobacco products and tobacco use.[144] While Section 25 acknowledges the Food and Drug Administration's authority over health products, it explicitly excluded products and industries governed by other laws.[145] Says respondent, the Food and Drug Administration "has no jurisdiction over tobacco products and the tobacco industry, which are under the sole and exclusive jurisdiction of the IAC-T[tobacco], as provided under [Republic Act No. 9211]." [146]

We rule for petitioners.

The mere acknowledgment in Section 25 of Republic Act No. 9711 that nothing in that law "shall be deemed to modify the sole and exclusive jurisdiction of other specialized agencies[,]" such as the IAC-Tobacco under Republic Act No. 9211, does not automatically place tobacco products outside the Food and Drug Administration's regulatory authority. Quite the contrary, the IAC-Tobacco's authority under Republic Act No. 9211 does not cover the regulation of the health aspects of tobacco products.

Recognizing the need to protect the people from hazardous products and, simultaneously, to protect the interest of various stakeholders and workers in the tobacco industry, Republic Act No. 9211 was enacted to further the government's "balanced policy" in regulating the use, sale, and advertisement of tobacco products:

Section 2. Policy. — It is the policy of the State to protect the populace from hazardous products and promote the right to health and instill health consciousness among them. It is also the policy of the State, consistent with the Constitutional ideal to promote the general welfare, to safeguard the interests of the workers and other stakeholders in the tobacco industry. For these purposes, the government shall institute a balanced policy whereby the use, sale and advertisements of tobacco products shall be regulated in order to promote a healthful environment and protect the citizens from the hazards of tobacco smoke, and at the same time ensure that the interests of tobacco farmers, growers, workers and stakeholders are not adversely compromised. (Emphasis supplied)

Hence, Republic Act No. 9211 holds the following objectives:

- Promote a healthful environment;
- Inform the public of the health risks associated with cigarette smoking and tobacco use;
- Regulate and subsequently ban all tobacco advertisements and sponsorships;
- Regulate the labeling of tobacco products;
- Protect the youth from being initiated to cigarette smoking and tobacco use by prohibiting the sale of tobacco products to minors;
- Assist and encourage Filipino tobacco farmers to cultivate alternative agricultural crops to prevent economic dislocation; and
- Create an Inter-Agency Committee on Tobacco (IAC-Tobacco) to oversee the implementation of the provisions of this Act. (Emphasis supplied)

Republic Act No. 9211 created the IAC-Tobacco,[147] which "shall have the exclusive power and function to

administer and implement" the law:

Section 29. Implementing Agency. — An Inter-Agency Committee — Tobacco (IAC-Tobacco), which shall have the exclusive power and/unction to administer and implement the provisions of this Act, is hereby created. The IAC-Tobacco shall be chaired by the Secretary of the Department of Trade and Industry (DTI) with the Secretary of the Department of Health (DOH) as Vice Chairperson. The IAC-Tobacco shall have the following as members:

- Secretary of the Department of Agriculture (DA);
- Secretary of the Department of Justice (DOJ);
- Secretary of the Department of Finance (DOF);
- Secretary of the Department of Environment and Natural Resources (DENR);
- Secretary of the Department of Science and Technology (DOST);
- Secretary of the Department of Education (DepEd);
- Administrator of the National Tobacco Administration (NTA);
- A representative from the Tobacco Industry to be nominated by the legitimate and recognized associations of the industry; and
- A representative from a nongovernment organization (NGO) involved in public health promotion nominated by DOH in consultation with the concerned NGOs;

The Department Secretaries may designate their Undersecretaries as their authorized representatives to the IAC.[148] (Emphasis supplied)

Accordingly, the IAC-Tobacco's implementing authority is limited to the acts under Republic Act No. 9211, which include:

I.

Healthful Environment

1) Smoking Ban in Public Places[149] and Designation of Smoking and Non-Smoking Areas in establishments;[150]

II.

Access Restrictions

1) Access restrictions to tobacco-related vending machines, self-service facilities, and other similar mechanisms;[151]

2) Retailer compliance to standards imposed on tobacco-related self-serving facilities;[152]

3) Minimum age sales of tobacco products;[153]

- 4) Ban on sale of tobacco products near school perimeters and other facilities frequented by minors;[154]
- 5) Required signage on point-of-sale establishments offering tobacco products;[155]

III.

Advertising and Promotion

- 1) Required printed warnings on cigarette packaging;[156]
- 2) Required warnings in all forms of tobacco advertising;[157]
- 3) Restrictions in all forms of tobacco advertising,[158] tobacco promotions,[159] sponsorships,[160] and sampling;[161]
- 4) Subsequent ban on tobacco advertisements[162] and sponsorships;[163]
- 5) Limitations on Naming Rights[164]

The law also mandates the IAC-Tobacco to monitor compliance with Republic Act No. 9211.[165] Section 33 further specifies the IAC-Tobacco's involvement in relevant programs under the law:

SECTION 33. Programs and Projects. — For a period not exceeding five (5) years, the National Government and the concerned departments and agencies shall provide the following programs and projects:

- Tobacco Growers' Assistance Program — This program shall be utilized to support financially the tobacco farmers who may be displaced due to the implementation of this Act or has voluntarily ceased to produce tobacco. . . .

. . . .

- Tobacco Growers' Cooperative. — This program shall promote cooperative programs to assist tobacco farmers in developing alternative farming systems, plant alternative crops and other livelihood projects . . .

- National Smoking Cessation Program. — A National Smoking Cessation Program shall be undertaken with the approval of the IAC-Tobacco. The implementing rules and guidelines to reinforce this program shall be submitted to the IAC-Tobacco by the Secretary of Health within three (3) months after the effectivity of this Act.

- Research and Development Program. — The IAC-Tobacco shall establish a research and development program to be spearheaded by the NTA in cooperation with the DOST, which will undertake studies concerning technologies and methods to reduce the risk of dependence and injury from tobacco product usage and exposure, alternative uses of tobacco and similar research programs.

- National Tobacco-Free Public Education Program. — State Universities and Colleges and Technical and Vocational Schools shall provide scholarship programs for dependents of tobacco growers for which the administrator of the NTA shall provide implementing rules and guidelines. The guidelines shall be submitted to the IAC-Tobacco within three (3) months after the effectivity of this Act.

- Displaced Cigarette Factory Workers' Assistance Program. — The Secretary of Labor and Employment, with the concurrence of the IAC-Tobacco shall establish a program to assist displaced, terminated/separated or retrenched cigarette factory workers as a result of the enactment of this Act. The Secretary of Labor in

coordination with the NTA and DTI shall provide the rules and guidelines to effectuate this program and submit the same to the IAC-Tobacco within three (3) months after the effectivity of this Act.

- Health Programs. — The IAC-Tobacco, in consultation with the DOH, shall be responsible for awarding grants to all medical institutions for the purpose of planning, carrying out, and evaluating activities related to smoking-related illnesses. The IAC-Tobacco shall submit to Congress and the President of the Philippines the annual report of expenditures related to this program.

- Withdrawal Clinics. — The DOH shall establish smoking withdrawal clinics to provide counseling regarding the hazardous health effects of tobacco/cigarette smoking and to rehabilitate smokers from the hazardous effects of such products.

If a smoker-minor voluntarily submits himself for treatment, counseling, or rehabilitation in a smoking withdrawal clinic located in any medical institution in the Philippines, or through his parent/guardian, the expenses incurred shall be a reimbursable outpatient service of the Philippine Health Insurance Corporation. (Emphasis supplied)

Meanwhile, Section 25 of Republic Act No. 9711 clearly establishes that the law shall cover all health products, except for acts covered by special laws. Hence, matters not covered by special laws remain under the Food and Drug Administration's broad regulatory authority. Exceptions are strictly construed and "extend only as far as their language fairly warrants[.]"[166] Moreover, "particular clauses and phrases of a statute should not be taken as detached and isolated expressions, but the whole and every part thereof must be considered in fixing the meaning of any of its parts."[167] Respondent cannot truncate Section 25 and only focus on a particular phrase to suit its desired interpretation.

It is evident from Republic Act No. 9211 that the IAC-Tobacco has limited jurisdiction over tobacco products and does not regulate all their aspects. Its implementing authority is only restricted to the acts provided under the law, which mainly include the regulation of distribution, access, sale, labeling, advertisements, sponsorships, and promotions of tobacco products.[168] Nothing in the law denotes that it holds authority over the health aspects of tobacco products.

Conversely, under Republic Act No. 9711, the Food and Drug Administration has regulatory authority over all health products, which include tobacco products. Under Section 25, the Food and Drug Administration retains its regulatory authority as to the health aspect of tobacco products, it being beyond IAC-Tobacco's implementing authority under Republic Act No. 9211. This interpretation is more in keeping with the oft-repeated rule on statutory construction that laws are interpreted not only to be consistent throughout its provisions, but also to be in harmony with other laws on a similar subject, to build a coherent system.[169]

Accordingly, there is no merit in respondent-intervenor's claim that insofar as the health aspects of tobacco products are concerned, Republic Act No. 9211 diminished the Department of Health's general authority on health concerns under the Administrative Code.[170] Section 34 of the law even recognized the Department of Health's capability on matters of health when it was designated to lead the information dissemination on the harmful effects of smoking:

Information Program

SECTION 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.

SECTION 35. Instruction on the Hazardous Effect of Smoking as Part of School Curricula. — Instruction on the adverse effects of cigarette/tobacco smoking, including their health, environmental and economic implications, shall be integrated into the existing curricula of all public and private elementary and high schools.

The DepEd Secretary shall promulgate such rules and regulations as may be necessary to carry out the above stated policy hereof, and, with the assistance of the Secretary of Health, and with the approval of the IAC-Tobacco, shall cause the publication and distribution of materials on the unhealthy effects of smoking to students and the general public. (Emphasis supplied)

II (B)

Besides, tobacco products are undeniably "health products" based on the definition provided in Section 10(ff) of Republic Act No. 3720, as amended by Section 9 of Republic Act No. 9711, which reads:

(ff) 'Health products' means food, drugs, cosmetics, devices, biologicals, vaccines, in-vitro diagnostic reagents and household/urban hazardous substances and/or a combination of and/or a derivative thereof. It shall also refer to products that may have an effect on health which require regulations as determined by the FDA. (Emphasis supplied)

This definition is clear "that there is no room for construction or interpretation, but only application." [171] Section 10(ff) comprises two parts. The first part refers to an enumeration of specific products considered as health products. The second part is a general statement that health products "shall also refer to products that may have an effect on health which require regulations as determined by the FDA." [172]

Tobacco use, as well as exposure to secondhand smoking, pose health hazards that cause death and disease among people. [173] Clearly, all products affecting health—including tobacco products—are within Food and Drug Administration's jurisdiction. The second part of the definition in Section 10(ff) even gives the Food and Drug Administration discretionary authority to determine which products require regulation.

Respondent-intervenor's view that tobacco products are not "health products" by the ejusdem generis principle is flawed. [174] The principle only applies in case of ambiguity, which is not the case here. Moreover, ejusdem generis would not control since restricting "health products" to the list provided under Section 10(ff) or to the same class would hinder the lawmaker's intent of strengthening the Food and Drug Administration's regulatory authority under Republic Act No. 9211. [175]

To sum, it would be misplaced to construe Section 25 of Republic Act No. 9711 as an express delineation which placed tobacco products beyond the Food and Drug Administration's regulatory authority. It is within the Food and Drug Administration's competence and mandate "to ensure safety, efficacy, purity, and quality" [176] of health products which, based on the definition under the law, clearly includes tobacco products. A contrary reading, in that the Food and Drug Administration could regulate cosmetics due to its effects on health but not tobacco products, would be illogical.

III

The inclusion of tobacco products in the coverage of the Implementing Rules is not only supported by the text of the law, but also by pertinent congressional deliberations. It likewise adheres to the Philippines' obligations under the WHO FCTC.

The Food and Drug Administration is an attached agency of the Department of Health. As such, the regulatory authority over the health aspect of tobacco products not only falls within its mandate, but more so within its competence and expertise.

This much is revealed in the deliberations of the Bicameral Conference Committee on Section 25 of Republic Act No. 9711. The legislative intent was that the health aspects of tobacco, sugar, and coconut are within the regulatory authority of Food and Drug Administration, consistent with the thrust of Republic Act No. 9211 to strengthen the regulatory, licensing, and monitoring powers of the Food and Drug Administration on health products. In this sense, it was made clear that Republic Act No. 9711 applies suppletorily to the special laws, with regard to the health effects of these products. Pertinent portions of the deliberations cited by the petitioners-intervenors are insightful:

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 Legarda sought to clearly exclude from the coverage of the proposed law those that are already covered by special laws particularly sugar, tobacco and coconut . . . that the powers, Your Honor please, of the FDA shall not include those that are already covered . . .

. . . .

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.

. . . .

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 [have] 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 . . . preventing BFAD, the new BFAD from making a declaration against tobacco if they feel the way 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 . . .

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 this 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 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 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.[177] (Emphasis supplied)

While not controlling, these deliberations are persuasive and support our interpretation of Section 25 of Republic Act No. 9711.

To emphasize, the IAC-Tobacco does not have sole and exclusive jurisdiction over tobacco products and the tobacco industry, but only over the implementation of Republic Act No. 9211. As to the health aspect of tobacco products, petitioners have the regulatory authority under Republic Act No. 9711. Therefore, they did not exceed their authority in promulgating the Implementing Rules in regulating tobacco products.

Parenthetically, the promulgation and enforcement of the Implementing Rules on the regulation of tobacco products follows the mandate of Article XIII, Section 12[178] of the Constitution to establish and maintain an effective regulating body and system to protect public health.

Moreover, the contested provisions in the Implementing Rules are aligned with our international commitment under the WHO FCTC which "address[es] the health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke worldwide." [179] Salient provisions of the WHO FCTC read:

Article 3

Objective

The objective of this Convention and its protocols is to protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke by providing a framework for tobacco control measures to be implemented by the Parties at the national, regional and international levels in order to reduce continually and substantially the prevalence of tobacco use and exposure to tobacco smoke.

. . . .

Article 5

General Obligations

1.

Each Party shall develop, implement, periodically update and review comprehensive multisectoral national tobacco control strategies, plans and programmes in accordance with this Convention and the protocols to which it is a Party.

2.

Towards this end, each Party shall, in accordance with its capabilities:

(a)

establish or reinforce and finance a national coordinating mechanism or focal points for tobacco control; and

(b)

adopt and implement effective legislative, executive, administrative and /or other measures and cooperate, as appropriate, with other Parties in developing appropriate policies for preventing and reducing tobacco consumption, nicotine addiction and exposure to tobacco smoke.

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.

4.

The Parties shall cooperate in the formulation of proposed measures, procedures and guidelines for the implementation of the Convention and the protocols to which they are parties.

5.

The Parties shall cooperate, as appropriate, with competent international and regional intergovernmental organizations and other bodies to achieve the objectives of the Convention and the protocols to which they are Parties.

6.

The Parties shall, within means and resources at their disposal, cooperate to raise financial resources for effective implementation of the Convention through bilateral and multilateral funding mechanisms.[180] (Emphasis supplied)

Article 5.3 of the WHO FCTC requires state parties to protect their tobacco control policymaking from tobacco industry interference. The WHO FCTC Guidelines reiterate this:

The purpose of the guidelines is to ensure that efforts to protect tobacco control from commercial and other vested interests of the tobacco industry are comprehensive and effective. Parties should implement measures in all branches of government that may have an interest in, or the capacity to, affect public health policies with respect to tobacco control.

The aim of these guidelines is to assist parties in meeting their legal obligations under Article 5.3 of the WHO FCTC. The guidelines draw on the best available scientific evidence and the experience of Parties in addressing tobacco industry interference.

....

The guidelines are applicable to government officials, representatives and employees of any national, state, provincial, municipal, local or other public or semi/quasi-public institution or body within the jurisdiction of a Party, and to any person acting on their behalf. Any government branch (executive, legislative and judiciary) responsible for setting and implementing tobacco control policies and for protecting those policies against tobacco industry interests should be accountable.[181] (Emphasis supplied)

Moreover, the WHO FCTC stipulates price and tax measures[182] and non-price measures to be implemented by state parties to reduce the demand for tobacco, including:

i.

Testing, measuring and regulation of the contents and emissions of tobacco products;[183]

ii.

Regulation of tobacco product disclosures to governmental authorities and to the public of information about the toxic constituents of the tobacco products and the emissions that they may produce;[184]

iii.

Packaging and-labeling of tobacco products, including;

(1) Information on constituents and emissions on outside packaging and labeling;[185]

(2) Ban on packaging or labeling means that are false, misleading, deceptive or likely to create an erroneous impression about the product's characteristics, health effects, hazards or emissions, including any term, descriptor, trademark, figurative or other sign that directly or indirectly creates the false impression that a particular tobacco product is less harmful than others;[186] or

iv.

Ban on all forms of tobacco advertising, promotions and sponsorship by any means that are false, misleading or deceptive or likely to create an erroneous impression about the tobacco product's characteristics, health

effects, hazards or emissions.[187]

The Philippines' entry into the WHO FCTC represents its commitment to "give priority to [its] right to protect public health";[188] in particular, to implement the above-stated tobacco control measures to "reduce continually and substantially the prevalence of tobacco use and exposure to tobacco smoke." [189] With the Senate's concurrence,[190] the WHO FCTC became operative as part of national law in accordance with Section 21, Article VII[191] of the Constitution.

As explained in *David v. Senate Electoral Tribunal*:[192]

The Senate's ratification of a treaty makes it legally effective and binding by transformation. It then has the force and effect of a statute enacted by Congress. In *Pharmaceutical and Health Care Association of the Philippines v. Duque III, et al.*:

Under the 1987 Constitution, international law can become part of the sphere of domestic law either by transformation or incorporation. The transformation method requires that an international law be transformed into a domestic law through a constitutional mechanism such as local legislation. The incorporation method applies when, by mere constitutional declaration, international law is deemed to have the force of domestic law.

Treaties become part of the law of the land through transformation pursuant to Article VII, Section 21 of the Constitution which provides that "[n]o treaty or international agreement shall be valid and effective unless concurred in by at least two-thirds of all the members of the Senate." Thus, treaties or conventional international law must go through a process prescribed by the Constitution for it to be transformed into municipal law that can be applied to domestic conflicts.

Following ratification by the Senate, no further action, legislative or otherwise, is necessary. Thereafter; the whole of government — including the judiciary — is duty-bound to abide by the treaty, consistent with the maxim *pacta sunt servanda*. [193] (Emphasis supplied)

Accordingly, as national health authority, the Department of Health, along with the Food and Drug Administration, must consider the country's commitments under the WHO FCTC in exercising their regulatory powers over health products.

From the standpoint of Republic Act No. 9711, the Constitution, and the WHO FCTC, petitioners acted within their powers in including Book II, Article III (Tobacco Products) in the Implementing Rules. There is no overlap of functions, as it is clear that petitioners have technical authority over matters of public health. At any rate, the Implementing Rules explicitly state that the rules and regulations and other issuances to be promulgated by the Food and Drug Administration will refer to policy areas that are not covered by specialized agencies and special laws.[194]

Respondent, representing major transnational tobacco companies in this country, proposes an interpretation of our law that will effectively remove them from petitioners' regulation. Its desired interpretation allows for tobacco companies to be principally regulated by the IAC-Tobacco, of which they happen to also be members. This not only leads to an absurd result, but it is also contrary to law and our international obligations.

WHEREFORE, the Petition is GRANTED. The January 27, 2012 Decision of the Regional Trial Court in SCA Case No. 11-0013, which declared void the Rules and Regulations Implementing Republic Act No. 9711 insofar as it regulates tobacco products and the tobacco industry is REVERSED and SET ASIDE.

SO ORDERED.

Carandang, Inting, Zalameda, M. Lopez, Gaerlan, Rosario, and J. Lopez, JJ., concur.

Gesmundo, C.J., join Justice Caguioa's Dissenting Opinion.

Perlas-Bernabe, J., please see concurring opinion.

Hernando, J., see dissenting opinion.

Lazaro-Javier, J., see separate concurring opinion.

Caguioa, J., see dissent.

[1] Rollo pp. 73-78. The January 27, 2012 Decision was penned by Acting Presiding Judge Romulo SG. Villanueva of the Regional Trial Court of Las Piñas City, Branch 255.

[2] Entitled "An Act to Ensure the Safety and Purity of Foods, Drugs, and Cosmetics Being Made Available to the Public By creating the Food and Drug Administration which shall administer and enforce the laws pertaining thereto" otherwise known as the "Food, Drug and Cosmetics Act" (1963).

[3] See Executive Order No. 85 (1982), sec. 4.

[4] Executive Order No. 175 amended, among others, the title of Republic Act No. 3720 to "Foods, Drugs and Devices, and Cosmetics Act."

[5] An Act Strengthening and Rationalizing the Regulatory Capacity of the Bureau of Food and Drugs (BFAD) by Establishing Adequate Testing Laboratories and Field Offices, Upgrading its Equipment, Augmenting its Human Resource Complement, Giving Authority to Retain Its income, renaming it the Food and Drug Administration (FDA), Amending Certain Sections of Republic Act No. 3720, as amended, and appropriating funds thereof.

[6] Republic Act No. 9711 (2009), sec. 1.

[7] Republic Act No. 9711 (2009), sec. 3 and Republic Act No. 3720 (1963), sec. 4, as amended by Republic Act No. 9711 (2009), sec. 5.

[8] Republic Act No. 9711 (2009), sec. 22 reads:

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.

[9] Rollo, pp. 179-226, Petition for Declaratory Relief.

[10] Id. at 179.

[11] Id. at 182.

[12] Id. at 195.

[13] Id. at 198-199.

[14] Id. at 198-200.

[15] Id. at 194.

[16] Id. at 189.

[17] Id. at 187-188.

- [18] Id. at 216-218.
- [19] Id. at 219.
- [20] Id. at 208-213.
- [21] Id. at 208.
- [22] Id. at 260, Answer.
- [23] Id. at 232-236.
- [24] Id. at 242.
- [25] Id. at 249.
- [26] Id. at 254.
- [27] Id. at 1140-1144, RTC Order.
- [28] Id. at 73, RTC Decision.
- [29] Id. at 73-78.
- [30] Id. at 78.
- [31] Id. at 76-77.
- [32] Id. at 77.
- [33] Id.
- [34] Id. at 76.
- [35] Id. at 78.
- [36] Id. at 13-72, Petition for Review.
- [37] Id. at 498-538, Comment.
- [38] Id. at 1089-1139, Petition-in-Intervention.
- [39] Id. at 1214-1290, Opposition-in-Intervention.
- [40] Id. at 1893-1894.
- [41] Id. at 25, Petition for Review.
- [42] Id. at 45-50.
- [43] Id. at 53-55 and 1868-1870.
- [44] Id. at 56-58, 1857, and 1860.
- [45] Id. at 61-62 and 1858-1859.
- [46] Id. at 62 and 1864-1865.
- [47] Id. at 65.
- [48] Id. at 1874 and 1876.

[49] Id. at 32-35 and 1852-1853.

[50] Id. at 86-96. Protection of the Department of Health, including all of its Agencies, Regional Offices, Bureaus or Specialized/Attached Offices/Units against Tobacco Industry Interference.

[51] Id. at 98-104. Protection of the Bureaucracy against Tobacco Industry Interference.

[52] Id. at 37, 1850, and 1856.

[53] Id. at 39-43 and 1853-1855.

[54] Id. at 1098.

[55] Id. at 1097.

[56] Id. at 1097-1099 and 1838.

[57] Id. at 1113.

[58] Id. at 1111.

[59] Id. at 1115-1116.

[60] Id. at 1101.

[61] Id. at 1101-1109 and Memorandum for Petitioners-Intervenors, pp. 12-19.

[62] Id. at 1096.

[63] Memorandum for Petitioners-Intervenors, pp. 7-8.

[64] Id. at 8.

[65] Rollo, pp. 506-507, Comment.

[66] Id. at 508 and Memorandum for Respondent, p. 36.

[67] Id. at 515 and Memorandum for Respondent, p. 22.

[68] Id. at 521-522.

[69] Id. at 513 and Memorandum of Respondent, pp. 18-19.

[70] Id. at 513.

[71] Id. at 528-532.

[72] Id. at 535 and Memorandum for Respondent, p. 58.

[73] Id.

[74] Memorandum for Respondent-Intervenor, p. 22.

[75] Id. at 1228, Opposition-in-Intervention, and Memorandum for Respondent-Intervenor, p. 26.

[76] Id. at 1225 and Memorandum for Respondent-Intervenor, p. 23.

[77] Id. at 1229 and Memorandum for Respondent-Intervenor, p. 27.

[78] Id. at 1285 and Memorandum for Respondent-Intervenor, pp. 50-51.

- [79] Memorandum for Respondent-Intervenor, p. 53.
- [80] Id.
- [81] Rollo, p. 1245, Opposition-in-Intervention.
- [82] Id.
- [83] Id. at 1258-1259.
- [84] Id. at 1248.
- [85] Id.
- [86] Id.
- [87] CONST., art. 11, sec. 15 and ADM. CODE, Book IV, Title IX, Ch. 1, sec. 1.
- [88] ADM. CODE, Book IV, Title IX, Ch. 1, sec. 2.
- [89] ADM. CODE, Book IV, Title IX, Ch. 1, sec. 3.
- [90] Created under Executive Order No. 119, January 30, 1987.
- [91] Administrative Order No. 122 (2003), A Smoking Cessation Program to support the National Tobacco Control and Healthy Lifestyle Program.
- [92] Chino Leyco, Gov't revives 'Yosi Kadiri' mascot vs. smoking, MANILA BULLETIN, May 16, 2019, available at <https://doh.gov.ph/sites/default/files/news_clips/051619-0005.pdf> (last accessed on August 26, 2021).
- [93] Republic Act No. 7394 (1992), art. 2.
- [94] Republic Act No. 7394 (1992), art. 2.
- [95] Republic Act No. 7394 (1992), Title II, Chapters I to III.
- [96] Republic Act No. 7394 (1992), art. 75.
- [97] Republic Act No. 7394 (1992), art. 109.
- [98] Republic Act No. 7394 (1992), art. 4(ak) states:
- ak) "Hazardous substance" means:
- (1) (i) Any substance or mixture of substances which is toxic, corrosive, irritant, a strong sensitizer, flammable or combustible, or generates pressure through decomposition, heat or other means, if such substance or mixture or substances may cause substantial injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable ingestion by children;
- (ii) Any substance which the department finds to be under the categories enumerated in clause (1) (i) of this paragraph;
- (iii) Any radioactive substance, if, with respect to such substance as used in a particular class of article or as packaged, the Department, upon approval of the Department determines by regulation that the substance is sufficiently hazardous to require labeling in accordance with this section in order to protect the public health;
- (iv) Any toy or other articles intended for use by children which the director may, by regulation, determine the presence of an electrical, mechanical or thermal hazard.
- (2) This term shall not apply to food, drugs, cosmetics, and devices nor to substances intended for use as fuels

when stored in containers and used in the heating, cooking or refrigeration system of a house, but such term shall apply to any article which is not in itself a pesticide but which is a hazardous substance, as construed in clause (a) of paragraph (1), by reason of bearing or containing such harmful substances described therein.

[99] Republic Act No. 7394 (1992), art. 77.

[100] Republic Act No. 7394 (1992), art. 94 provides:

Article 94. Labeling Requirements of Cigarettes. — All cigarettes for sale or distribution within the country shall be contained in a package which shall bear the following statement or its equivalent in Filipino: "Warning" Cigarette Smoking is Dangerous to Your Health". Such statement shall be located in conspicuous place on every cigarette package and shall appear in conspicuous and legible type in contrast by typography, layout or color with other printed matter on the package. Any advertisement of cigarette shall contain the name warning as indicated in the label.

[101] Republic Act No. 7394 (1992), arts. 6 and 75 state:

Article 6. Implementing Agencies. — The provisions of this Article and its implementing rules and regulations shall be enforced by:

- a) the Department of Health with respect to food, drugs, cosmetics, devices and substances;
- b) the Department of Agriculture with respect to products related to agriculture, and;
- c) the Department of Trade and Industry with respect to other consumer products not specified above.

Article 75. Implementing Agency. — The Department of Trade and Industry shall enforce the provisions of this Chapter and its implementing rules and regulations: Provided, That with respect to food, drugs, cosmetics, devices, and hazardous substances, it shall be enforced by the concerned department.

[102] Civil Service Commission Memorandum Circular No. 17 (2009), <<https://www.tobaccocontrollaws.org/files/live/Philippines/Philippines%20-%20CSC%20Memo%20Circular%20-%20national.pdf>> (last accessed on July 30, 2021).

[103] Department of Transportation and Communication, Land Transportation Franchising and Regulatory Board Memorandum Circular No. 2009-036 <<https://www.tobaccocontrollaws.org/files/live/Philippines/Philippines%20-%20LTFRB%20Memo%20Circular%20-%20national.pdf>> (last accessed on July 30, 2021).

[104] Republic Act No. 9211 (2003), sec. 33.

[105] Republic Act No. 9211 (2003), sec. 5.

[106] Republic Act No. 9211 (2003), sec. 22.

[107] Republic Act No. 9211 (2003), sec. 26.

[108] Republic Act No. 9211 (2003), sec. 13.

[109] Republic Act No. 9211 (2003), sec. 39.

[110] Republic Act No. 9211 (2003), sec. 13.

[111] Republic Act No. 9211 (2003), sec. 39.

[112] Took effect on April 9, 2004, 15 days after its publication on March 25, 2004.

[113] United Nations Treaty Collection, <https://treaties.un.org/pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IX-4&chapter=9&clang=_en> (last

accessed on July 30, 2021).

[114] Annex 2, WHO Framework Convention on Tobacco Control (2003), available at <<http://apps.who.int/iris/bitstream/handle/10665/42811/9241591013.pdf;jsessionid=8F790DD80F16142C3D60D0EB85235957?sequence=1>> (last accessed on July 30, 2021).

[115] WHO Framework Convention on Tobacco Control (2003), art. 6.

[116] WHO Framework Convention on Tobacco Control (2003), art. 8.

[117] WHO Framework Convention on Tobacco Control (2003), art. 9.

[118] WHO Framework Convention on Tobacco Control (2003), art. 10.

[119] WHO Framework Convention on Tobacco Control (2003), art. 11.

[120] WHO Framework Convention on Tobacco Control (2003), art. 12.

[121] WHO Framework Convention on Tobacco Control (2003), art. 13.

[122] WHO Framework Convention on Tobacco Control (2003), art. 15.

[123] WHO Framework Convention on Tobacco Control (2003), art. 16.

[124] WHO Framework Convention on Tobacco Control (2003), art. 14.

[125] WHO Framework Convention on Tobacco Control (2003), art. 5(3).

[126] WHO Framework Convention on Tobacco Control (2003), art. 20.

[127] WHO Framework Convention on Tobacco Control (2003), art. 21.

[128] DOH Administrative Order No. 2007-0004 (2007), available at <<https://dmas.doh.gov.ph:8083/Rest/GetFile?id=336699>> (last accessed on August 31, 2021).

[129] Requiring Graphic Health Information on Tobacco Product Packages, Adopting Measures to Ensure that Tobacco Product Packaging and Labeling Do Not Promote Tobacco By Any Means That are False, Misleading, Deceptive, or Likely to Create an Erroneous Impression, and Matters Related Thereto, available at <<https://dmas.doh.gov.ph:8083/Rest/GetFile?id=336829>> (last accessed on July 30, 2021).

[130] Protection of the Bureaucracy Against Tobacco Industry Interference, available at <<https://www.tobaccocontrolaws.org/files/live/Philippines/Philippines%20-%20JMC%202010-01%20-%20national.pdf>> (last accessed on July 30, 2021).

[131] Protection of the Department of Health, including all of its Agencies, Regional Offices, Bureaus or Specialized/ Attached Offices/Units, against Tobacco Industry Interference, available at <<https://www.tobaccocontrolaws.org/files/live/Philippines/Philippines%20-%20DOH%20Dept%20Memo%20on%20Industry%20Interference%20-%20national.pdf>> (last accessed on July 30, 2021).

[132] Republic Act No. 10351 (2012), sec. 5.

[133] Republic Act No. 10643 (2014), sec. 2.

[134] Republic Act No. 10643 (2014), sec. 2.

[135] Administrative Order No. 2014-0037, as amended by Administrative Order Nos. 2014-0037-A, 2014-0037-B, and 2019-0009.

[136] Rollo, p. 75, RTC Decision.

[137] Id. at 77.

[138] Republic Act No. 9711 (2009), sec. 3 provides:

Section 3. It is hereby declared a policy of the State to adopt, support, establish, institutionalize, improve and maintain structures, processes, mechanisms and initiatives that are aimed directed and designed to: (a) protect and promote the right to health of the Filipino people; and (b) help establish and maintain an effective health 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. (Emphasis supplied)

[139] Republic Act No. 9711 (2009), sec. 4.

[140] Republic Act No. 9711 (2009), sec. 4.

[141] Republic Act 3720 (1963), sec. 4, as amended by Republic Act No. 9711 (2009).

[142] Rollo, pp. 1857-1858 and 1871, Memorandum for Petitioners.

[143] Id. at 46, Petition for Review.

[144] Memorandum of Respondent, pp. 39-41.

[145] Id. at 18-19.

[146] Id. at 19.

[147] Republic Act No. 9211 (2003), sec. 3(g).

[148] Republic Act No. 9211 (2003), sec. 29.

[149] Republic Act No. 9211 (2003), sec. 5.

[150] Republic Act No. 9211 (2003), sec. 6.

[151] Republic Act No. 9211 (2003), secs. 7 and 8.

[152] Republic Act No. 9211 (2003), sec. 8.

[153] Republic Act No. 9211 (2003), sec. 9.

[154] Republic Act No. 9211 (2003), sec. 10.

[155] Republic Act No. 9211 (2003), sec. 11.

[156] Republic Act No. 9211 (2003), sec. 13.

[157] Republic Act No. 9211 (2003), sec. 14.

[158] Republic Act No. 9211 (2003), secs. 15, 16 (Print Media Advertising), 17 (Outdoor Advertising), 18 (Advertising in Cinemas), 19 (Television and Radio Advertising), 20 (Advertising in Audio, Video and Computer Cassettes/Discs and Similar Medium), and 21 (Advertising on the Internet and Similar Medium).

[159] Republic Act No. 9211 (2003), sec. 23.

[160] Republic Act No. 9211 (2003), sec. 25.

[161] Republic Act No. 9211 (2003), sec. 27.

[162] Republic Act No. 9211 (2003), sec. 22.

[163] Republic Act No. 9211 (2003), sec. 26.

[164] Republic Act No. 9211 (2003), sec. 24.

[165] Republic Act No. 9211 (2003), sec. 31 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 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.

[166] Nazareth v. Villar, 702 Phil. 319, 340 (2013) [Per J. Bersamin, En Banc].

[167] Gaanan v. Intermediate Appellate Court, 229 Phil. 139, 146 (1986) [Per J. Gutierrez, Jr., Second Division].

[168] Republic Act No. 9211 is entitled "An Act Regulating the Packaging, Use, Sale, Distribution and Advertisements of Tobacco Products and For Other Purposes." See also Republic Act No. 9211 (2003), secs. 5-28.

[169] Dreamwork Construction, Inc. v. Janiola, 609 Phil. 245 (2009) [Per J. Velasco, Jr. Third Division].

[170] Memorandum for Respondent-Intervenor, p. 50.

[171] See Wyeth Philippines, Inc. v. Construction Industry Arbitration Commission, G.R. Nos. 220045-48, June 22, 2020, <<https://elibrary.judiciary.gov.ph/thebookshelf/showdocs/1/66421>> [Per J. Leonen, Third Division].

[172] See Republic Act No. 3720 (1963), sec. 10(ff), as amended by Republic Act No. 9711 (2009).

[173] B. Bellew, M. Antonio, M. Limpin, L. Alzona, F. Trinidad, U. Dorotheo, R. Yapchiongco, R. Garcia, A. Anden, J. Alday, Addressing the Tobacco Epidemic in the Philippines: Progress since ratification of the WHO FCTC, available at <<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4463107/pdf/103.pdf>> (last accessed on August 26, 2021).

[174] See Memorandum for Respondent-Intervenor, pp. 26-27.

[175] See In re Catholic Archbishop of Manila v. Social Security Commission, 110 Phil. 606 (1961) [Per J. Gutierrez David, En Banc]. See also Republic Act No. 9711 (2009), sec. 4(a).

[176] Republic Act No. 9711 (2009), sec. 5.

[177] Memorandum of Petitioners-Intervenors, pp. 13-16.

[178] CONST., art. XIII, sec. 12 states:

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.

[179] See Department of Health, WHO Framework Convention on tobacco Control, available at <<https://doh.gov.ph/WHO-Framework-Convention-on-Tobacco-Control>> (last accessed on July 30, 2021).

- [180] WHO Framework Convention on Tobacco Control (2003), art. 5.
- [181] Guidelines for Implementation, Article 5.3, available at <<https://fctc.who.int/publications/m/item/guidelines-for-implementation-of-article-5.3>> (last accessed on July 30, 2021).
- [182] WHO Framework Convention on Tobacco Control (2003), art. 6.
- [183] WHO Framework Convention on Tobacco Control (2003), art. 9.
- [184] WHO Framework Convention on Tobacco Control (2003), art. 10.
- [185] WHO Framework Convention on Tobacco Control (2003), art. 11(2).
- [186] WHO Framework Convention on Tobacco Control (2003), art. 11(1)(a).
- [187] WHO Framework Convention on Tobacco Control (2003), art. 13(4)(a).
- [188] WHO Framework Convention on Tobacco Control (2003), Preamble.
- [189] WHO Framework Convention on Tobacco Control (2003), art. 3.
- [190] Memorandum for Petitioners-Intervenors, p. 27.
- [191] CONST., art. VII, sec. 21 reads:
- SECTION 21. No treaty or international agreement shall be valid and effective unless concurred in by at least two-thirds of all the Members of the Senate. (Emphasis supplied)
- [192] 795 Phil. 529 (2016) [Per J. Leonen, En Banc].
- [193] *Id.* at 614-615.
- [194] Implementing Rules and Regulations of Republic Act No. 9711 (2011), secs. 3-4 state:
- SECTION 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 aspects of such products.
- SECTION 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. 1468.194 (Emphasis supplied)

CONCURRING OPINION

PERLAS-BERNABE, J.:

I concur.

The crux of the present controversy is whether or not the Implementing Rules and Regulations (IRR) issued by the Food and Drug Administration (FDA) to implement Republic Act No. (RA) 9711,[1] otherwise known as the "Food and Drug Administration Act of 2009," went beyond the auspices of the statute it seeks to implement by according the FDA the authority to regulate tobacco products by classifying them as "health products."

To recount, the case began when respondent Philippine Tobacco Institute, Inc. (PTI) filed a petition for

declaratory relief before the Regional Trial Court of Las Pinas City, Branch 255 (RTC) seeking to prohibit the enforcement of the FDA IRR on the ground that it unduly expands RA 9711, insofar as it classified tobacco products as "health products," and hence, unduly placed the same under the FDA's regulatory power.[2]

PTI contended that under RA 9211,[3] otherwise known as the "Tobacco Regulation Act of 2003," it is the Inter-Agency Committee on Tobacco (IAC-Tobacco) which has exclusive jurisdiction over tobacco products, including its health aspects, and not the FDA. As basis, it cited Section 25[4] of RA 9711 which specifically excluded tobacco products from the FDA's jurisdiction.[5]

In response, petitioners Department of Health (DOH) and FDA posited that the FDA retains jurisdiction and regulatory powers over the health aspects of certain products, such as tobacco. Meanwhile, the IAC-Tobacco only has authority to oversee the implementation of the provisions of RA 9211. As such, there is nothing repugnant with the FDA IRR insofar as it regulates tobacco products as "health products." [6]

The RTC ruled in favor of PTI, and hence, nullified the provisions of the FDA IRR (i.e., Article III, Book II) insofar as it regulates tobacco products and the tobacco industry within the auspices of the FDA's jurisdiction.[7]

However, as correctly ruled by the ponencia, the RTC's ruling must be reversed.

Under Section 10 (ff) of RA 3720,[8] as amended[9] by RA 9711, "health products" is defined as "food, drugs, cosmetics, devices, biologicals, vaccines, in-vitro diagnostic reagents and household/urban hazardous substances and/or a combination of and/or a derivative thereof. It shall also refer to products that may have an effect on health which require regulations as determined by the FDA." While tobacco products are not mentioned under the first paragraph of this section, these nevertheless fall under the second paragraph of the said provision, since tobacco products clearly affect the health of people.

On this score, it is worthy to point out that RA 9211 provides for the inclusion of warnings on cigarette packages, such as "GOVERNMENT WARNING: Cigarette Smoking is Dangerous to Your Health;" "GOVERNMENT WARNING: Cigarettes are Addictive;" "GOVERNMENT WARNING: Tobacco Smoke Can Harm Your Children;" or "GOVERNMENT WARNING: Smoking Kills." [10] Meanwhile, RA 10643,[11] otherwise known as "The Graphic Health Warnings Law," added the requirement of placing graphic health warnings on the tobacco product package which accurately depicts the hazards of tobacco use, accompanied by textual warning related to the picture.[12] Palpably, these tobacco-specific laws recognize that tobacco products indeed "have an effect on health," which would necessarily make them fall under the definition of health products in RA 9711.

As earlier stated, PTI cited Section 25 of RA 9711, arguing that the same specifically excluded tobacco products from the jurisdiction of the FDA, because they are already put under the authority of other specialized agencies, i.e., the IAC-Tobacco. Section 25 of RA 9711 reads:

Section 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 [or the Tobacco Regulation Act of 2003], Executive Order No. 245, Executive Order No. 18, and Presidential Decree No. 1468. (emphasis supplied)

However, a study of the Congressional deliberations on RA 9711 would reveal that the legislature apparently intended to include tobacco as a health product, which is subject to regulation by the FDA at least insofar as its health aspect is concerned. As stated during the deliberations, "[t]he 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. x x x [I]t should be very clear that this law, the FDA bill[,] will be now in-charge of the health aspect.

And in that sense, [it is] suppletory to whatever mandate the special laws have on those products but the health aspects is an FDA affair,"[13] viz.:

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 these sectors? I think none of them [does], none of them has the capabilities to monitor the health effects of any of these products that the new [Bureau of Food and Drugs (BFAD)] will have. Unless there is actually a scientific component to RA 9211, because I [do not] 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. x x x

SEN. LEGARDA. My only concern is, there should not be any duplication of laws so that [there is] 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 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 is] not only health that is concerned, [it is] the economic aspect, the way it affects agriculture and all the farmers down the drain. So I [do not] think we will – [what is] the word, emasculate the new law or [de-strengthen] 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.

x x x x

REP. LOCSIN. But, Madam Chair, [I am] 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 is] suppletory to whatever mandate the special laws have on those products but the health aspects is an FDA affair.[14] (emphases supplied)

Further, the Congressional deliberations would also show that despite the deletion of a previously proposed Section 26, which was meant to provide for the suppletory character of RA 9711 to the special laws governing products such as tobacco (RA 9211 and Executive Order [EO] No. 245), sugar (EO No. 18), and coconut (Presidential Decree No. 1568), the legislature still intended RA 9711 to govern the health aspects of the products covered by these special laws through Section 25 of RA 9711, viz.:

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

THE CHAIRPERSON (SEN. CAYETANO, P.). Actually, [it is] not even necessary.

REP. LOCSIN. [That is] also true.

THE CHAIRPERSON (SEN. CAYETANO, P.). [It is] [kind of] redundant.

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

THE CHAIRPERSON (SEN. CAYETANO, P.). So we go to Section 25 na lang.

x 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. x x x[15] (emphases supplied)

For these reasons, it appears that notwithstanding RA 9211 which created the IAC-Tobacco, Congress intended for tobacco products to be considered as health products, which limited aspect falls under the regulatory jurisdiction of the FDA. Verily, Section 25 of RA 9711 – which essentially provides that the FDA shall have jurisdiction over health products except "only insofar as the acts covered by these specialized agencies and laws" – does not preclude the FDA's retention of regulatory powers over the health aspect of certain products, such as tobacco. The reasonable harmonization therefore would be that, insofar as tobacco products are concerned, Section 25 maintains both the jurisdiction of the FDA and the IAC- Tobacco. On the one hand, the FDA has regulatory jurisdiction only over the health aspect of tobacco products, such as the determination of the amount of nicotine in tobacco products; on the other hand, the IAC-Tobacco has regulatory jurisdiction over all the other aspects of tobacco products, such as packaging, use, sale, distribution, and advertisements, which are the functions and processes provided for under RA 9211. To repeat, as stated in Section 29 of RA 9211, the IAC-Tobacco "shall have the exclusive power and function to administer and implement the provisions of this Act." RA 9211 is distinct and separable from the FDA Act (i.e., RA 9711) in that it does not directly regulate the health aspects of tobacco.

Based on the foregoing, it is therefore possible to reconcile RA 9211 (which remains to be one of the special laws on tobacco and tobacco products) and RA 9711 (which is the general law on health products). Case law states that "[t]he rule is that on a specific matter, the special law shall prevail over the general law, which shall be resorted to only to supply deficiencies in the former. In addition, x x x [i]t is a canon of statutory construction that a later statute [(such as RA 9711 or the FDA Act)], general in its terms and not expressly repealing a prior special statute [(such as RA 9211 or the Tobacco Regulation Act of 2003)], will ordinarily not affect the special provisions of such earlier statute." [16] In this light, it is therefore my considered view that RA 9711 merely supplies the deficiencies in RA 9211 with respect to the health aspects of tobacco products (e.g., the amount of nicotine in tobacco products), which the latter does not cover.

In fine, as correctly ruled by the ponencia, Article III, Book II of the FDA IRR pertaining to tobacco should be upheld. As envisioned by the lawmakers, "the new FDA is the authority as far as health is concerned." To be sure, this Article recognizes that the mandate of the FDA is only limited to the products' health aspects and in turn, respects the mandates of specialized agencies, which include the IAC-Tobacco:

BOOK II

x x x x

ARTICLE III

Tobacco and Other Products

SECTION 1. Rationale. – The FDA has full jurisdiction over the regulation of all health products.

SECTION 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.

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.

SECTION 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 aspects of such products.

SECTION 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. (emphases and underscoring supplied)

ACCORDINGLY, I vote to GRANT the petition.

[1] Entitled "AN ACT STRENGTHENING AND RATIONALIZING THE REGULATORY CAPACITY OF THE BUREAU OF FOOD AND DRUGS (BFAD) BY ESTABLISHING ADEQUATE TESTING LABORATORIES AND FIELD OFFICES, UPGRADING ITS EQUIPMENT, AUGMENTING ITS HUMAN RESOURCE COMPLEMENT, GIVING AUTHORITY TO RETAIN ITS INCOME, RENAMING IT THE FOOD AND DRUG ADMINISTRATION (FDA), AMENDING CERTAIN SECTIONS OF REPUBLIC ACT NO. 3720, AS AMENDED, AND APPROPRIATING FUNDS THEREOF," approved on August 18, 2009.

[2] See ponencia, pp. 3-6.

[3] Entitled "AN ACT REGULATING THE PACKAGING, USE, SALE, DISTRIBUTION AND ADVERTISEMENTS OF TOBACCO PRODUCTS AND FOR OTHER PURPOSES," approved on June 23, 2003.

[4] Section 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] See ponencia, p. 5

[6] See *id.* at 6.

[7] See *id.* at 6-7.

[8] Entitled "AN ACT TO ENSURE THE SAFETY AND PURITY OF FOODS, DRUGS, AND COSMETICS BEING MADE AVAILABLE TO THE PUBLIC BY CREATING THE FOOD AND DRUG ADMINISTRATION WHICH SHALL ADMINISTER AND ENFORCE THE LAWS PERTAINING THERETO," approved on June 22, 1963.

[9] RA 9711 provides:

Section 9. Section 10, subsections (a), (e), (f), (g), (h), (i), (q), (r), (v), and (w) of Republic Act No. 3720, as amended, are hereby further amended, and new subsections (x), (y), (z), (aa), (bb), (cc), (dd), (ee), (ff), (gg), (hh), (ii), (jj), (kk), (ll), and (mm) are hereby added to read as follows:

x x x x

"(ff) 'Health products' means food, drugs, cosmetics, devices, biologicals, vaccines, in-vitro diagnostic reagents and household/urban hazardous substances and/or a combination of and/or a derivative thereof. It shall also refer to products that may have an effect on health which require regulations as determined by the FDA."

[10] See Section 13 of RA 9211.

[11] Entitled "AN ACT TO EFFECTIVELY INSTILL HEALTH CONSCIOUSNESS THROUGH GRAPHIC HEALTH WARNINGS ON TOBACCO PRODUCTS," approved on July 15, 2014.

[12] See Section 1, Rule III of the IRR of RA 10643.

[13] See Memorandum of petitioners DOH and FDA, p. 39.

[14] *Id.* at 37-39. See also The Bicameral Conference Committee on the Disagreeing Provisions of SBN 1652 and HBN 3293 on May 19, 2009, 1:55 p.m., pp. 1-4; and 2:05 p.m., p. 1.

[15] *Id.* at 39-40. See also The Bicameral Conference Committee on the Disagreeing Provisions of SBN 1652 and HBN 3293 on May 19, 2009, 2:05 p.m., pp. 5-6; and 2:15 p.m., p. 1.

[16] *Commissioner of Internal Revenue v. Philippine Airlines, Inc.*, 718 Phil. 309 (2013), citing *Commissioner of Internal Revenue v. Philippine Airlines, Inc.*, 609 Phil. 695 (2009).

DISSENTING OPINION

CAGUIOA, J.:

The ponencia grants the petition for review on certiorari of the Department of Health (DOH) and the Food and Drug Administration (FDA), which seeks to reverse the Decision[1] of Branch 255, Regional Trial Court of Las Piñas City (RTC) declaring void the provisions of the Rules and Regulations Implementing Republic Act (R.A.) No. 9711 insofar as they regulate tobacco products and the tobacco industry.[2] The ponencia holds that due to the known health hazards of tobacco products, these are "health products" within the definition of R.A. No. 9711, or the FDA Act of 2009. The DOH, in coordination with the FDA, is deemed to have acted within the confines of R.A. No. 9711 when it tasked the FDA with the responsibility of regulating tobacco and tobacco products in its implementing rules and regulations.[3]

I dissent.

The sole purpose of the rule-making power of an administrative agency is to implement the provisions of the delegating statute. For this purpose, the exercise of this power is necessarily limited to filling in the details of the statute. The administrative agency should craft the implementing regulation in conformity with the law it seeks to implement and cannot unduly expand the statute's application. To hold otherwise is to allow administrative agencies to venture into the amendment or repeal of a statute — a power that lies exclusively with Congress.[4]

In this case, the Court is asked to resolve whether R.A. No. 9711 contemplates the regulation of tobacco products. I disagree with the ponencia that it is "illogical"[5] to place tobacco and tobacco products outside the regulatory authority of the FDA. The DOH cannot arrogate unto itself the authority to designate the FDA as an additional regulatory body over tobacco and tobacco products. By providing this in the implementing rules of R.A. No. 9711, the DOH effectively expanded its application beyond the confines of the FDA's enabling law. I maintain that the Court should refrain from reading into the law what is not written in its text. I respectfully submit this Opinion to elaborate on my position and to emphasize the Court's duties in delineating the boundaries of the exercise of the delegated rule-making power of administrative agencies.

I.

Preliminarily, I disagree with the submission of Associate Justice Amy C. Lazaro-Javier (Justice Lazaro-Javier) that this case presents no actual case or controversy.[6]

Under Section 1, Article VIII of the Constitution, courts are empowered "to settle actual controversies involving rights which are legally demandable and enforceable." [7] Thus, even with the expanded power of judicial review, courts cannot adjudicate cases on the basis of hypothetical or assumed facts. There should be "a contrariety of legal rights that can be interpreted and enforced on the basis of existing law and jurisprudence." [8] In addition, the question presented should also be ripe for adjudication — meaning, there must be an "immediate or threatened injury to [the petitioner] as a result of the challenged action." [9] The court can only intervene when the act complained of on the part of the government is a "completed action" [10] giving rise to a "direct, concrete, and adverse effect on the petitioner." [11]

The requirement of an actual case or controversy proceeds from the elementary principle of separation of powers, which prevents courts from intruding into areas committed to other branches of the government. [12] There is no question, therefore, that these procedural prerequisites to the exercise of judicial review are imperative. However, I disagree with the view of Justice Lazaro-Javier that respondent Philippine Tobacco Institute, Inc. (PTI) could only raise "apprehensions and speculations of harassments" [13] on the conflicting interpretations on the extent of

the FDA's or the DOH's rule-making authority. Justice Lazaro-Javier further opines that, absent actual facts, the Court dangerously ventures into making policy decisions.[14]

As stated at the outset, I disagree with this view. It is clear from the ponencia that the main issue in this case is the validity of the DOH's exercise of its rule-making power pursuant to R.A. No. 9711. In particular, respondent PTI assails the provisions of the Rules and Regulations Implementing R.A. No. 9711, which included tobacco and other tobacco products within the regulatory authority of the FDA. PTI argues that there is nothing in R.A. No. 9711, the delegating statute, which covers tobacco or tobacco products. Petitioners DOH and FDA, and petitioner-intervenors Senator Pilar Juliana Cayetano and Senator Franklin Drilon, on the other hand, disagree. They insist that the mandate of the FDA, as well as the definition of "health products" under R.A. No. 9711,[15] is broad enough to include tobacco and tobacco products. Petitioners are contrarily asserting that Section 25 of R.A. No. 9711 confers to the FDA regulatory power over matters not within the ambit of R.A. No. 9211,[16] or the "Tobacco Regulation Act of 2003." [17]

In view of the foregoing, it is therefore untenable to argue that PTI is anchoring its claim on mere speculations. Surely, a determination on the validity of the provisions on the implementing rules directly affects the tobacco companies constituting PTI, as they would have to comply with the FDA's regulatory guidelines should the challenged provisions be upheld.

Furthermore, it is important to contextualize the requirement of "actual facts of injury or threats of injury"[18] in determining whether the case presents a justiciable controversy. In *SPARK v. Quezon City*,[19] the Court notably found that there exists an actual case or controversy "given the evident clash of the parties' legal claims." [20] Even without "actual facts," the Court proceeded to rule on the constitutionality of the curfew ordinances in several cities in Metro Manila, based on the assertions of the petitioners therein that the ordinances impair their constitutional rights.

In a similar manner, the Court, in *Inmates of the New Bilibid Prison v. De Lima*, [21] proceeded to pass upon the validity of the implementing rules to the statutory amendments on the computation of good conduct time allowance. The respondents therein directly argued that there was no actual case or controversy, and any claim of injury was premature and anticipatory. The Court, notably with the concurrence of Justice Lazaro-Javier, explicitly rejected the proposition that there should be concrete acts before the case becomes justiciable, thus:

There is an actual case or controversy in the case at bar because there is a contrariety of legal rights that can be interpreted and enforced on the basis of existing law and jurisprudence. Respondents stand for the prospective application of the grant of GCTA, TASTM, and STAL while petitioners and intervenors view that such provision violates the Constitution and Article 22 of the RPC. The legal issue posed is ripe for adjudication as the challenged regulation has a direct adverse effect on petitioners and those detained and convicted prisoners who are similarly situated. There exists an immediate and/or threatened injury and they have sustained or are immediately in danger of sustaining direct injury as a result of the act complained of. In fact, while the case is pending, petitioners are languishing in jail. If their assertion proved to be true, their illegal confinement or detention in the meantime is oppressive. With the prisoners' continued incarceration, any delay in resolving the case would cause them great prejudice. Justice demands that they be released soonest, if not on time.

There is no need to wait and see the actual organization and operation of the MSEC. Petitioners Edago, et al., correctly invoked Our ruling in *Pimentel, Jr. v. Hon. Aguirre*. There, We dismissed the novel theory that people should wait for the implementing evil to befall on them before they could question acts that are illegal or unconstitutional, and held that "(by) the mere enactment of the questioned law or the approval of the challenged action, the dispute is said to have ripened into a judicial controversy even without any other overt act." Similar to *Pimentel, Jr.*, the real issue in this case is whether the Constitution and the RPC are contravened by Section 4, Rule 1 of the IRR, not whether they are violated by the acts implementing it.

Concrete acts are not necessary to render the present controversy ripe. An actual case may exist even in the absence of tangible instances when the assailed IRR has actually and adversely affected petitioners. The mere issuance of the subject IRR has led to the ripening of a judicial controversy even without any other overt act. If this Court cannot await the adverse consequences of the law in order to consider the controversy actual and ripe for judicial intervention, the same can be said for an IRR. Here, petitioners need not wait for the creation of the MSEC and be individually rejected in their applications. They do not need to actually apply for the revised credits, considering that such application would be an exercise in futility in view of respondents' insistence that the law should be prospectively applied. If the assailed provision is indeed unconstitutional and illegal, there is no better time than the present action to settle such question once and for all.[22] (Emphasis supplied)

It is clear from the foregoing that the requirement of an actual case or controversy is satisfied when there is a contrariety of legal rights. Here, the parties rely on their respective interpretations of the related laws to bolster their position on whether tobacco and tobacco products are within the FDA's regulatory framework. The conflict between the administrative issuance of the DOH on the one hand, and the statute reorganizing the FDA on the other, is evidently not an issue that requires overt facts before the Court may adjudicate. In fact, the DOH and the FDA directly filed this Rule 45 petition with the Court on pure questions of law after the RTC had determined that the DOH overstepped its quasi-legislative authority in promulgating the assailed implementing rules. I therefore take exception to the submission of Justice Lazaro-Javier that there are no actual facts of injury, which effectively constrains the Court to render an opinion "on a state of assumed and hypothetical facts." [23] Verily, the requirement of actual case or controversy should not be confused and equated with the existence of overt acts, as issues in a case do not necessarily become "abstract, hypothetical or contingent questions" simply because there were no overt acts that preceded the filing of the petition.

In this connection, the remedy availed of in this case — a petition for declaratory relief — precisely contemplates scenarios where there are actual cases or controversies, but there has yet to be any overt act that constitutes any breach or violation of the statute, executive order or regulation, ordinance, or any other governmental regulation in question. To recall, the Rule 63 of the Rules of Court provides that:

SECTION 1. Who may file petition. — Any person interested under a deed, will, contract or other written instrument, whose rights are affected by a statute, executive order or regulation, ordinance, or any other governmental regulation may, before breach or violation thereof, bring an action in the appropriate Regional Trial Court to determine any question of construction or validity arising, and for a declaration of his rights or duties, thereunder. (Emphasis supplied)

According to jurisprudence, the requisites of an action for declaratory relief are:

1] the subject matter of the controversy must be a deed, will, contract or other written instrument, statute, executive order or regulation, or ordinance; 2] the terms of said documents and the validity thereof are doubtful and require judicial construction; 3] there must have been no breach of the documents in question; 4] there must be an actual justiciable controversy or the "ripening seeds" of one between persons whose interests are adverse; 5] the issue must be ripe for judicial determination; and 6] adequate relief is not available through other means or other forms of action or proceeding.[24]

Clear from the foregoing requisites is that it is enough that there be at least two adverse interests to constitute an actual justiciable controversy, and that the existence of an overt act is not only not required to be present, but is actually required to be absent.

In *Caltex v. Palomar*, [25] there were no overt acts yet that were done before judicial intervention was sought through a petition for declaratory relief. *Caltex* simply publicized a contest which would involve the use of mails, and it just sought clearance from the Postmaster General to use the facilities of the post office — which the latter

denied because it deemed the contest violative of the anti-lottery provisions of the 1983 Administrative Code. There was as yet no person who tried to participate in the contest by sending mail matter through the post office who was refused. There was as yet no "facts" as Justice Lazaro-Javier requires.[26] Nevertheless, the Court ruled on the petition as there was an actual case or controversy given the contrariety of legal rights as asserted by Caltex and the Postmaster General.

On the other hand, in *Ollada v. Central Bank*,[27] the Court dismissed the petition for declaratory relief because petitioner's right had already been violated before the petition for declaratory relief was filed. Insisting on the requisite that there must be no breach or violation before a petition for declaratory relief is filed, the Court said:

Petitioner commenced this action as, and clearly intended it to be one for Declaratory Relief under the provisions of Rule 66 of the Rules of Court. On the question of when a special civil action of this nature would prosper, we have already held that the complaint for declaratory relief will not prosper if filed after a contract, statute or right has been breached or violated. In the present case such is precisely the situation arising from the facts alleged in the petition for declaratory relief. As vigorously claimed by petitioner himself, respondent had already invaded or violated his right and caused him injury — all these giving him a complete cause of action enforceable in an appropriate ordinary civil action or proceeding. The dismissal of the action was, therefore, proper in the light of our ruling in *De Borja vs. Villadolid*, 47 O.G. (5) p. 2315, and *Samson vs. Andal*, G.R. No. L-3439, July 31, 1951 where we held that an action for declaratory relief should be filed before there has been a breach of a contract, statute or right, and that it is sufficient, to bar such action, that there had been a breach — which would constitute actionable violation. The rule is that an action for Declaratory Relief is proper only if adequate relief is not available through the means of other existing forms of action or proceeding (1 C.J.S. 1027-1028).[28] (Emphasis and underscoring supplied)

Respectfully, it is therefore error to require overt acts or "actual injury" in this case before the same could be said to be ripe for adjudication. It is simply incongruent to ask the same, especially in a case involving a petition for declaratory relief.

Finally, the Court need not speculate on the provisions of R.A. No. 9711 or the other relevant statutes on tobacco regulation in order to determine the boundaries of the DOH's rule-making power. The only necessary and undisputed fact in this case is the DOH's promulgation of the Rules and Regulations Implementing R.A. No. 9711, which gives rise to an actual controversy susceptible of judicial resolution. Needless to state, where an action of a political department is alleged to have infringed the Constitution or contravened a law, there should be no question on the propriety of the Court's exercise of its judicial power of review.[29]

II.

On the merits, I respectfully disagree with the ponencia in ruling that the provisions of the Rules and Regulations Implementing R.A. No. 9711, insofar as they placed tobacco and tobacco products within the regulatory authority of the FDA, are valid. I submit that the relevant provisions of the implementing rules were correctly stricken down by the RTC as an excessive exercise of the DOH and the FDA's rule-making authority under R.A. No. 9711.

The Court recognizes that the principle of subordinate legislation is necessary for the legislature to adapt to the numerous issues confronting the government. By entrusting administrative agencies with the task of filling in the details of the law, "administrative bodies may implement the broad policies laid down in a statute x x x which the Congress may not have the opportunity or competence to provide." [30] These implementing rules have the force and effect of law.[31]

Nevertheless, this delegated rule-making power is not a legislative function but only a mechanism for the

implementation of the law. The administrative agency is confined to supplying details within the scope of the statutory authority granted to it by the legislature. As aptly noted by Associate Justice Ramon Paul L. Hernando (Justice Hernando), the "specialized jurisdiction of administrative bodies x x x is not a license to expand, extend, or add anything to the law it seeks to implement thereby." [32]

This, to my mind, is the most significant consideration in this case. The delegated rule-making power of administrative agencies is circumscribed by the provisions of the Constitution or a law, especially the statute it administers, or which created it. The exercise of the quasi-legislative power cannot derogate or defeat the purpose of a statute, or expand its application. It is, at all times, confined within the four walls of the delegating statute. Any conflict between the statute and the implementing rule must be resolved in favor of the former: [33]

As early as 1970, in the case of *Teoxon vs. Members of the Board of Administrators (PVA)*, we ruled that the power to promulgate rules in the implementation of a statute is necessarily limited to what is provided for in the legislative enactment. Its terms must be followed for an administrative agency cannot amend an Act of Congress. "The rule-making power must be confined to details for regulating the mode or proceedings to carry into effect the law as it has been enacted, and it cannot be extended to amend or expand the statutory requirements or to embrace matters not covered by the statute." If a discrepancy occurs between the basic law and an implementing rule or regulation, it is the former that prevails. [34]

III.

In this case, R.A. No. 9711 reorganized the FDA and strengthened its mandate by broadening its jurisdiction from "food, drug and cosmetic" [35] to "health products" as defined under the law. Section 9 of R.A. No. 9711 defines "health products" as follows:

(ff) 'Health products' means food, drugs, cosmetics, devices, biologicals, vaccines, in-vitro diagnostic reagents and household/urban hazardous substances and/or a combination of and/or a derivative thereof. It shall also refer to products that may have an effect on health which require regulations as determined by the FDA.

The DOH was tasked to craft the implementing rules and regulations of R.A. No. 9711. [36] For this purpose, it promulgated the Rules and Regulations Implementing R.A. No. 9711, which included the following contentious provisions:

ARTICLE III

Tobacco and Other Products

SECTION 1. Rationale. — The FDA has full jurisdiction over the regulation of all health products.

SECTION 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.

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.

SECTION 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 aspects of such products.

SECTION 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.[37] (Emphasis supplied)

The DOH and FDA argue that by virtue of the second sentence in the definition of "health products," any product that has an "effect on health" may be regulated by the FDA. They maintain that this includes tobacco and tobacco products, the health aspect of which may be subject to FDA regulation.[38] This argument, to my mind, is belied by a holistic reading of R.A. No. 9711, in relation to tobacco-specific legislation.

In order to arrive at the true meaning of "health products," the Court must not read the second sentence of its definition in isolation. It must be considered together with the other parts of R.A. No. 9711, particularly, with respect to Section 25 of the law, which states:

SECTION 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. (Emphasis supplied)

As I see it, this provision carves out tobacco and tobacco products from the regulatory authority of the FDA, even with respect to the health aspect thereof. Contrary to the ponencia's claims, this reading is certainly not illogical as this is supported not only by R.A. No. 9711, but by R.A. No. 9211 as well.

The adverse effect of tobacco and tobacco products on a person's health is well-established. This is not an issue in this case and neither should this be the sole consideration in determining whether a product is a "health product." R.A. No. 9211, or the "Tobacco Regulation Act of 2003," recognizes the dangers of using tobacco products, as well as the need for a balanced policy on "the use, sale and advertisements of tobacco products x x x to promote a healthful environment and protect the citizens from the hazards of tobacco smoke, and at the same time ensure that the interest of tobacco fanners, growers, workers and stakeholders are not adversely compromised." [39] Among the purposes of R.A. No. 9211 is to promote a healthful environment and provide the public with information as to the health risks associated with cigarette smoking and tobacco use.[40]

In line with this, R.A. No. 9211 created the Inter-Agency Committee – Tobacco (IAC-T), which possesses the "exclusive power and function to administer and implement the provisions"[41] of the Act. The IAC-T is headed by the Secretary of the Department of Trade and Industry (DTI) as the Chairperson and the DOH Secretary as the Vice Chairperson,[42] consistent with the declared policy to balance the right to health with the interests of tobacco farmers, growers, workers, and other stakeholders.[43]

The IAC-T is tasked to oversee the implementation of R.A. No. 9211, which regulates the marketing[44] and labelling of tobacco products,[45] as well as its use,[46] sale, and distribution.[47] The DOH, on the other hand,

was specifically tasked to conduct a continuous information program on the harmful effects of smoking.[48]

Relatedly, R.A. No. 10643[49] or the "Graphic Health Warnings Law," was recently enacted to provide a more stringent requirement on the labels and packaging of cigarettes and tobacco products. This is in line with the World Health Organization's Framework Convention on Tobacco Control, to which the Philippines is a party. This legislation also reiterates the state policy to promote the right to health and aims to protect consumers from "trade malpractices and substandard tobacco products." [50] Several implementing agencies, including the IAC-T, were designated with specific roles to ensure compliance with R.A. No. 10643, to wit:

SECTION 16. Implementing Agencies. — For purposes of the implementation of this Act, the following government agencies are given these mandates:

(1)

The DOH shall issue the templates as required under Sections 6, 7 and 15.

(2)

The BIR shall ensure that cigarette stamps are not affixed on noncompliant packages and shall certify under oath that the products withdrawn are compliant with this Act.

(3)

The Inter-Agency Committee on Tobacco (IAC-T) created under Republic Act No. 9211 or the Tobacco Regulation Act of 2003 shall monitor compliance with the law, and motu proprio or upon any sworn written complaint, institute the appropriate action for any violation of this Act as provided under Section 14 and this section.

(4)

The DTI shall hear complaints filed by the IAC-T or any private citizen, corporation or organization, for any violation of this Act, and after notice and hearing, impose administrative fines of not more than Two million pesos (P2,000,000.00) for any violation of this Act, the proceeds of which will be used for health promotion campaigns on tobacco control of the DOH and the Department of Education (DepEd). The imposition of the administrative fines shall take into consideration the annual gross sales, capital investment and employee size of the manufacturers, importers and distributors, and in the case of retailers and sellers, their total assets.

(5)

The DepEd shall use Graphic Health Warnings templates to educate children on the ill-effects of tobacco and shall ensure that these are included in relevant subjects under the K-12 curriculum.

Within six (6) months from the effectivity of this Act, the Implementing Rules and Regulations (IRR) Committee led by the DOH and the DTI, and to be composed of the Department of Justice (DOJ), the Department of Finance (DOF), the Department of Environment and Natural Resources (DENR), the Department of Science and Technology (DOST), the DepEd, the National Tobacco Administration (NTA) and the Department of Agriculture (DA) shall draft and issue the IRR for its effective implementation, after public consultations with stakeholders

such as NGOs, farmers, and industry representatives: Provided, That the non-issuance of the IRR shall not prevent the coming into force of this Act. (Emphasis supplied)

The manufacture of tobacco and tobacco products, on the other hand, is regulated by the National Tobacco Administration (NTA).[51] While it does not primarily regulate the health aspect of tobacco products, it is mandated to enforce the relevant rules on the "production, standardization, classification, grading and trading of tobacco and tobacco products as may be necessary to attain its purposes and objectives and to pursue the policy of government on tobacco." [52]

In this regard, I respectfully disagree with how Senior Associate Justice Estela M. Perlas-Bernabe (Justice Perlas-Bernabe) reconciles R.A. No. 9211 and R.A. No. 9711. She submits that R.A. No. 9711 is the general law on health products, which grants "the FDA regulatory jurisdiction only over the health aspect of tobacco products," [53] while R.A. No. 9211 may be considered a special law on tobacco and tobacco products, which grants the IAC-T regulatory jurisdiction over "all the other aspects of tobacco products." [54] With due respect, bifurcating the regulatory framework of tobacco and tobacco products into "all other aspects" and "health aspects" fails to consider and properly appreciate the overarching structure set up by the Legislature regarding tobacco and tobacco products.

As mentioned, the DOH, to which the FDA is attached, is already part of the IAC-T. In fact, the DOH Secretary is not only a member, but a Vice Chairperson of the IAC-T.[55] This fact alone belies Justice Perlas-Bernabe's line of reasoning that R.A. No. 9711 was meant to regulate only the "health aspect" of tobacco and tobacco products whereas R.A. No. 9211 was meant to regulate only "all other aspects." To be sure, the DOH Secretary would not be made a part of the IAC-T if this view is correct.

Indeed, what is clear from the laws passed by the Legislature is that the government had adopted a multi-sectoral approach in regulating tobacco and tobacco products, considering the various components underlying the production of tobacco. For this purpose, the IAC-T is not only composed of the DOH Secretary, but also the Secretaries of the Department of Agriculture, the Department of Environment and Natural Resources, and the DTI, among others.[56] Thus, if the Court were to consider the "health aspect" separable from all other aspects, it follows that the various agencies comprising the IAC-T would likewise have regulatory jurisdiction over the corresponding "aspect" relevant to their agency. In my view, this contravenes the underlying purpose in the creation of an inter-agency arrangement, and the explicit functions of the IAC-T.

Indeed, a careful reading of R.A. No. 9211 reveals that in the regulation of the so-called other "aspects," such as packaging, use, sale, distribution, and advertisements,[57] the IAC-T does so already cognizant of the effects of tobacco products on a person's health in line with the declared State policy to protect its citizens from the hazards of tobacco products and tobacco smoke, viz.:

SECTION 2. Policy. - It is the policy of the State to protect the populace from hazardous products and promote the right to health and instill health consciousness among them. It is also the policy of the State, consistent with the Constitutional ideal to promote the general welfare, to safeguard the interests of the workers and other stakeholders in the tobacco industry. For these purposes, the government shall institute a balanced policy whereby the use, sale and advertisements of tobacco products shall be regulated in order to promote a healthful environment and protect the citizens from the hazards of tobacco smoke, and at the same time ensure that the interests of tobacco farmers, growers, workers and stakeholders are not adversely compromised.

SECTION 3. Purpose. — It is the main thrust of this Act to:

- a. Promote a healthful environment;
- b. Inform the public of the health risks associated with cigarette smoking and tobacco use;

- c. Regulate and subsequently ban all tobacco advertisements and sponsorships;
- d. Regulate the labeling of tobacco products;
- e. Protect the youth from being initiated to cigarette smoking and tobacco use by prohibiting the sale of tobacco products to minors;
- f. Assist and encourage Filipino tobacco farmers to cultivate alternative agricultural crops to prevent economic dislocation; and
- g. Create an Inter-Agency Committee on Tobacco (IAC-Tobacco) to oversee the implementation of the provisions of this Act. (Emphasis, italics, and underscoring supplied)

On this point, I agree with Justice Hernando's Dissenting Opinion in which he aptly points out that the mandate of the FDA is to ensure the safety of health products. For this purpose, it has the authority to recall products, which are found to have "caused the death, serious illness or serious injury to a consumer or patient" or "imminently injurious, unsafe, dangerous, or grossly deceptive."^[58] In light of the State's recognition of the health risks arising from the use of tobacco and tobacco products, it is incongruous for the FDA to simply "regulate" tobacco. The DOH is even tasked under R.A. No. 9211 to "enlist the active participation of the public and private sectors in the national effort to discourage the unhealthy habit of smoking."^[59]

In other words, it is untenable to argue that the FDA should regulate the health aspect of tobacco products and, in the same breath, acknowledge its adverse effects on the health. If the Court were to uphold the regulatory authority of the FDA, the exercise of its statutory mandate would essentially result in the prohibition — not the regulation — of tobacco and tobacco products,^[60] simply by virtue of an implementing rule. This effectively renders the powers of the IAC-T nugatory, and runs counter to the explicit purposes for which it was constituted. The proposed harmonization therefore would likely cause an administrative nightmare than harmony.

In fine, the statutory measures meant to regulate tobacco and tobacco products are all already premised on the harmful effects that these have on a person's health. This is acknowledged by these tobacco-specific statutes and by other executive issuances such as: Executive Order No. 26,^[61] which provides for the establishment of smoke-free places,^[62] and Executive Order No. 106,^[63] which prohibits the manufacture and sale of unregistered and adulterated heated tobacco products.^[64] The regulation of the health aspect of tobacco products is therefore already intrinsically woven into the respective mandates of the IAC-T and the NTA. Accordingly, I disagree with the majority's view that any product which has an "effect on health" covers tobacco and tobacco products that can be made subject to the FDA's authority under R.A. No. 9711.

It goes without saying that practically all products have an "effect on health." Take for instance firearms, which could arguably fall within this meaning because of the risks it poses to the health and safety of its owner and the public — not unlike the adverse and harmful effects of tobacco and tobacco products. As well, gasoline, whether ingested or used as fuel for motor vehicles, could be reasonably construed as a health product if the Court were to follow the same line of argument. That said, it is inconceivable to consider these products as health products that the FDA can regulate. Again, this interpretation is not only contradicted by the clear text of Section 25 of R.A. No. 9711, but would result in an absurd conclusion that grants the DOH and the FDA absolute authority over any and all products, even those outside their administrative expertise.

What the DOH and FDA are trying to do is to encroach on the authority and jurisdiction of the agencies to which Congress had explicitly granted the power to regulate tobacco and tobacco products. Thus, to grant the FDA this power is tantamount to repealing or amending the laws which created these agencies and which delineated the coverage of their respective authorities. This cannot be done — as this can only be done through the enactment of a

new law and not through the DOH's promulgation of the rules and regulation implementing the FDA's charter.

In this light, the Court's inquiry on whether the DOH validly exercised its delegated rule-making power should be answered in the negative. Notwithstanding the language in Section 9 of R.A. No. 9711 which defines "health products" as those that may have an "effect on health," neither the FDA nor the DOH has unbridled discretion to fill in the details of the law. Read in conjunction with Section 25 thereof, products and substances that are subject of special laws and specialized agencies are outside the operation of the law. Section 25 therefore qualifies the definition of "health products."

As such, the exercise of quasi-legislative power by the DOH is circumscribed by standards in R.A. No. 9711 as a whole. The DOH therefore exceeded the bounds of its authority when it expanded the coverage of the statute it sought to implement. On this point, the Court's ruling in *United BF Homeowner's Association v. BF Homes, Inc.*[65] is enlightening:

Moreover, where the legislature has delegated [to executive] or administrative officers and boards authority to promulgate rules to carry out an express legislative purpose, the rules of administrative officers and boards, which have the effect of extending, or which conflict with the authority-granting statute, do not represent a valid exercise of the rule-making power but constitute an attempt by an administrative body to legislate. "A statutory grant of powers should not be extended by implication beyond what may be necessary for their just and reasonable execution." It is axiomatic that a rule or regulation must bear upon, and be consistent with, the provisions of the enabling statute if such rule or regulation is to be valid.[66] (Emphasis supplied)

The expertise and competence of the FDA to ensure the safety and efficacy of health products is not in question. However, its authority to regulate should emanate from the law. It is not up to the DOH to craft the policy of the government insofar as the regulation of tobacco and tobacco products is concerned. Allowing the unfettered exercise of the rule-making power effectively sanctions the DOH or the FDA's exercise of policy-making powers, as their sole discretion on the scope and definition of "health products" would always prevail.

In all, I vote to DENY the petition and AFFIRM the January 27, 2012 Decision of Branch 255, Regional Trial Court of Las Piñas City in SCA Case No. 11-0013, which declared the provisions of the Rules and Regulations Implementing Republic Act No. 9711 void insofar as it regulates tobacco products and the tobacco industry.

[1] Rollo, pp. 73-78. Decision in SCA Case No. 11-0013 dated January 27, 2012, penned by Acting Presiding Judge Romulo SG. Villanueva.

[2] Ponencia, pp. 35-36.

[3] Id. at 22-31.

[4] *MCC Industrial Sales Corp. v. Ssangyong Corp.*, G.R. No. 170633, October 17, 2007, 536 SCRA 405, 453.

[5] Ponencia, p. 29.

[6] Separate Concurring Opinion of Associate Justice Amy C. Lazaro-Javier, pp. 1-9.

[7] *Joint Ship Manning Group, Inc. v. SSS*, G.R. No. 247471, July 7, 2020, accessed at <<https://elibrary.judiciary.gov.ph/thebookshelf/showdocs/1/66432>>.

[8] *Belgica v. Ochoa*, 721 Phil. 416, 519 (2013), citing *Province of North Cotabato v. Government of the Republic of the Philippines Peace Panel on Ancestral Domain (GRF)*, G.R. Nos. 183591, 183752, 183893, 183951, and 183962, October 14, 2008, 568 SCRA 402, 450-451.

[9] Belgica v. Ochoa, id. at 520.

[10] Kilusang Mayo Uno v. Aquino, G.R. No. 210500, April 2, 2019, 899 SCRA 492, 523.

[11] Id.

[12] Belgica v. Ochoa, supra note 8 at 525, citing Francisco, Jr. v. Toll Regulatory Board, G.R. Nos. 166910, 169917, 173630, and 183599, October 19, 2010, 633 SCRA 470, 492.

[13] Separate Concurring Opinion of Associate Justice Amy C. Lazaro-Javier, p. 3. Emphasis omitted.

[14] Id. at 3-6.

[15] R.A. No. 9711, Sec. 9, amending R.A. No. 3720 ("Food, Drug, and Cosmetic Act"), Sec. 10(ff).

[16] AN ACT REGULATING THE PACKAGING, USE, SALE, DISTRIBUTION AND ADVERTISEMENTS OF TOBACCO PRODUCTS AND FOR OTHER PURPOSES, approved June 23, 2003.

[17] Ponencia, pp. 10-11. See also rollo, pp. 45-51.

[18] Separate Concurring Opinion of Associate Justice Amy C. Lazaro-Javier, p. 4.

[19] 815 Phil. 1067 (2017).

[20] Id. at 1091.

[21] G.R. Nos. 212719 & 214637, June 25, 2019, 905 SCRA 599.

[22] Id. at 619-621.

[23] Separate Concurring Opinion of Associate Justice Amy C. Lazaro-Javier, p. 3.

[24] Ferrer, Jr. v. Roco, 637 Phil. 310, 317-318 (2010).

[25] 124 Phil. 763 (1966).

[26] See Separate Concurring Opinion of Associate Justice Amy C. Lazaro-Javier, p. 5.

[27] G.R. No. L-11357, May 31, 1962, 5 SCRA 297.

[28] Id. at 303.

[29] See Smart Communications, Inc. v. National Telecommunications Commission, 456 Phil. 145 (2003). See also National Federation of Hog Farmers, Inc. v. Board of Investments, G.R. No. 205835, June 23, 2020, accessed at <<https://elibrary.judiciary.gov.ph/thebookshelf/showdocs/1/66343>>.

[30] Eastern Shipping Lines, Inc. v. Philippine Overseas Employment Administration, G.R. No. 76633, October 18, 1988, 166 SCRA 533, 544.

[31] Id. at 545.

[32] Dissenting Opinion of Associate Justice Ramon Paul L. Hernando, p. 3, citing Lokin, Jr. v. COMELEC, 635 Phil. 372 (2010). See also Romulo, Mabanta, Buenaventura, Sayoc & De Los Angeles v. Home Development Mutual Fund, 389 Phil. 296 (2000).

[33] United BF Homeowner's Association v. BF Homes, Inc., G.R. No. 124873, July 14, 1999, 310 SCRA 304.

[34] Id. at 315.

[35] R.A. No. 3720 (AN ACT TO ENSURE THE SAFETY AND PURITY OF FOODS, DRUGS, AND COSMETICS BEING MADE AVAILABLE TO THE PUBLIC BY CREATING THE FOOD AND DRUG ADMINISTRATION WHICH SHALL ADMINISTER AND ENFORCE THE LAWS PERTAINING THERETO), Chapter III, Sec. 4.

[36] R.A. No. 9711, Sec. 22.

[37] The Rules and Regulations Implementing Republic Act No. 9711 — The Food and Drug Administration Act of 2009, Article III, approved March 22, 2011.

[38] Ponencia, p. 6.

[39] R.A. No. 9211, Sec. 2.

[40] Id., Section 3(a) and (b).

[41] Id., Section 29; This provision reads:

SECTION 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. The IAC-Tobacco shall be chaired by the Secretary of the Department of Trade and Industry (DTI) with the Secretary of the Department of Health (DOH) as Vice Chairperson. The IAC-Tobacco shall have the following as members:

- Secretary of the Department of Agriculture (DA);
- Secretary of the Department of Justice (DOJ);
- Secretary of the Department of Finance (DOF);
- Secretary of the Department of Environment and Natural Resources (DENR);
- Secretary of the Department of Science and Technology (DOST);
- Secretary of the Department of Education (DepEd);
- Administrator of the National Tobacco Administration (NTA);
- A representative from the Tobacco Industry to be nominated by the legitimate and recognized associations of the industry; and
- A representative from a nongovernment organization (NGO) involved in public health promotion nominated by DOH in consultation with the concerned NGOs;

The Department Secretaries may designate their Undersecretaries as their authorized representatives to the IAC.

[42] Id.

[43] Id., Sec. 2.

[44] Id., Secs. 14 to 26, which regulate the advertisement and sponsorships of tobacco products.

[45] Id., Sec. 13.

[46] Id., Secs. 5 to 6, which provide for designated smoking and non-smoking areas.

[47] Id., Secs. 7 to 12.

[48] Id., Sec. 34.

[49] AN ACT TO EFFECTIVELY INSTILL HEALTH CONSCIOUSNESS THROUGH GRAPHIC HEALTH WARNINGS ON TOBACCO PRODUCTS, approved July 15, 2014.

[50] Id., Sec. 2.

[51] Executive Order No. 245 (Implementing the Consolidation of All Tobacco Agencies and the Creation of the National Tobacco Administration, Prescribing Its Charter and For Other Purposes), issued July 24, 1987.

[52] Id., Sec. 3(B)(1).

[53] Concurring Opinion of Senior Associate Justice Estela M. Perlas-Bernabe, pp. 5-6.

[54] Id. at 6.

[55] R.A. No. 9211, Sec. 29.

[56] Supra note 41.

[57] Concurring Opinion of Senior Associate Justice Estela M. Perlas-Bernabe, p. 6.

[58] Dissenting Opinion of Associate Justice Ramon Paul L. Hernando, pp. 16-17, citing FDA Circular No. 2016-12 (Guidelines on Product Recall), issued July 25, 2016; and R.A. No. 3720, as amended by R.A. No. 9711, Sec. 4(i) to (l).

[59] R.A. No. 9211, Sec. 34.

[60] See also Dissenting Opinion of Associate Justice Ramon Paul L. Hernando, pp. 16-17.

[61] Providing for the Establishment of Smoke-Free Environments in Public and Enclosed Places, issued May 16, 2017.

[62] The relevant Whereas clauses state:

WHEREAS, the 1987 Constitution of the Republic of the Philippines declares that the State shall protect and promote the right to health of the people and instill health consciousness among them;

x x x x

WHEREAS, public health takes precedence over any commercial or business interest;

WHEREAS, an increasing number of Filipinos become afflicted with and die each year of tobacco-related diseases such as stroke, heart disease, emphysema, various cancers and nicotine addiction, and both the public and workers in facilities where smoking is allowed are most at risk from these and other tobacco-related diseases[.]

[63] Prohibiting the Manufacture, Distribution, Marketing and Sale of Unregistered and/or Adulterated Electronic Nicotine/Non-Nicotine Delivery Systems, Heated Tobacco Products and Other Novel Tobacco Products, Amending Executive Order No. 26 (s. 2017) and For Other Purposes, issued February 26, 2020.

[64] The relevant Whereas clause states:

WHEREAS, Article II, Sections 15 and 16 of the Constitution mandates the State to protect and promote the right to health of the people and instill health consciousness among them, as well as protect and advance the right of the people to a balanced and healthful ecology in accord with the rhythm and harmony of nature[.]

[65] Supra note 33.

[66] Id. at 316.

DISSENTING OPINION

HERNANDO, J.:

I maintain that the Department of Health (DOH) and the Food and Drug Administration (FDA) exceeded their rule-making powers in promulgating Article III, Book II of the FDA Implementing Rules and Regulations (IRR) which listed tobacco products as health products and carved out the FDA's regulatory jurisdiction over the same.

Article III, Book II of the FDA IRR shows that it indeed unduly expands Republic Act No. (RA) 9711, or The Food and Drug Administration Act of 2009 (FDA Act). While the delegation to the FDA to determine what are health products is proper, complete in itself, and with sufficient standards, the FDA IRR's provisions on tobacco products go beyond the purview of RA 9711, are inconsistent with RA 9711's provisions, and are contrary to other laws involving tobacco specific legislation.

First. On its face, RA 9711 does not purport to regulate tobacco products. Textually, the whole of RA 9711 does not mention tobacco products. It does not define tobacco products or declare a special treatment for tobacco products as a specific health concern.

Sections 3[1] and 4[2] of RA 9711 pronounce the overall policy and objectives of the law to strengthen and rationalize the regulatory capacity of the FDA to ensure the safety of food, medicine, health products, and the like made available to the public. Clearly, RA 9711 seeks to establish and maintain an effective health product regulatory system.

In *Imbong v. Ochoa, Jr.*[3] (*Imbong*), the Court sustained the delegation by Congress to the FDA, under RA 10354, or The Responsible Parenthood and Reproductive Health Act of 2012,[4] the determination of whether a supply or product is to be included in the essential drugs list, was sustained by the Court. *Imbong* held that the functions, powers and duties of the FDA are specific to enable the agency to carry out the mandates of the law, thus:

The petitioners likewise question the delegation by Congress to the FDA of the power to determine whether or not a supply or product is to be included in the Essential Drugs List (EDL).

The Court finds nothing wrong with the delegation. The FDA does not only have the power but also the competency to evaluate, register and cover health services and methods. It is the only government entity empowered to render such services and highly proficient to do so. It should be understood that health services and methods fall under the gamut of terms that are associated with what is ordinarily understood as "health products." In this connection, Section 4 of R.A. No. 3720, as amended by R.A. No. 9711 reads:

SEC. 4. To carry out the provisions of this Act, there is hereby created an office to be called the Food and Drug Administration (FDA) in the Department of Health (DOH). Said Administration shall be under the Office of the Secretary and shall have the following functions, powers and duties:

x x x x

"(c) To analyze and inspect health products in connection with the implementation of this Act;

x x x x

"(h) To conduct appropriate tests on all applicable health products prior to the issuance of appropriate authorizations to ensure safety, efficacy, purity, and quality;

x x x x

"(k) After due process, to order the ban, recall, and/or withdrawal of any health product found to have caused death, serious illness or serious injury to a consumer or patient, or is found to be imminently injurious, unsafe, dangerous, or grossly deceptive, and to require all concerned to implement the risk management plan which is a requirement for the issuance of the appropriate authorization;

x x x x

As can be gleaned from the above, the functions, powers and duties of the FDA are specific to enable the agency to carry out the mandates of the law. Being the country's premiere and sole agency that ensures the safety of food and medicines available to the public, the FDA was equipped with the necessary powers and functions to make it effective. Pursuant to the principle of necessary implication, the mandate by Congress to the FDA to ensure public health and safety by permitting only food and medicines that are safe includes "service" and "methods." From the declared policy of the RH Law, it is clear that Congress intended that the public be given only those medicines that are proven medically safe, legal, non-abortifacient, and effective in accordance with scientific and evidence-based medical research standards. x x x[5]

In *Imbong*, the Court affirmed Congress's determination that reproductive health products, which necessarily include services and methods, are to be regulated by the FDA pursuant to its powers.[6] Significantly, the RH Law explicitly legislated for regulation by the FDA reproductive health products, services and methods pursuant to the RH law's declared policy to provide the public only those medicines and health products that are proven medically safe, legal, non-abortifacient, and effective.

In marked contrast, there was no such delegation by Congress to the FDA in the present case. It is the DOH and the FDA, and not Congress, that effectively determined first that tobacco products are health products which ought to be regulated by the FDA. Ultimately, the exercise of the rule-making power is improper; petitioners' determination that tobacco products are health products is incorrect.

On several occasions, we have disallowed an excess of administrative rule-making power no matter its avowed public purpose.[7] The consistent stance of the Court has been that the specialized jurisdiction of administrative bodies which impels the allowance of delegation of legislative powers is not a license to expand, extend, or add anything to the law it seeks to implement thereby.[8]

In *MCC Industrial Sales Corporation v. Ssangyong Corporation*[9] (MCC), the Court reaffirmed the basic tenet that the power of administrative officials to promulgate rules in the implementation of a law is necessarily limited to what is found in the legislative enactment. The reinstatement of a phrase in the IRR on the definition of an electronic data message which had already been deleted by Congress in the ultimate enactment of the Electronic Commerce Act of 2000, RA 8792, albeit lifted from the Model Law on Electronic Commerce adopted by the UNCITRAL[10] from which majority of the provisions of the law were taken, expands the coverage of the law which an implementing rule and regulation cannot do. An implementing rule and regulation cannot extend the law or expand its coverage, as the power to amend or repeal a statute is vested in the Legislature:

The inclusion of this phrase in the IRR offends a basic tenet in the exercise of the rule-making power of administrative agencies. After all, the power of administrative officials to promulgate rules in the implementation of a statute is necessarily limited to what is found in the legislative enactment itself. The implementing rules and regulations of a law cannot extend the law or expand its coverage, as the power to amend or repeal a statute is vested in the Legislature. Thus, if a discrepancy occurs between the basic law and an implementing rule or regulation, it is the former that prevails, because the law cannot be broadened by a mere administrative issuance — an administrative agency certainly cannot amend an act of Congress. Had the

Legislature really wanted ordinary fax transmissions to be covered by the mantle of the Electronic Commerce Act of 2000, it could have easily lifted without a bit of tatter the entire wordings of the UNCITRAL Model Law.[11] (Emphasis supplied, citations omitted.)

Parenthetically, had the Legislature really intended for the FDA to regulate tobacco products, then it could have easily defined tobacco products as it did in previous legislation. In fact, Congress could have explicitly declared in Section 25 that RA 9711's coverage extends to the health aspect of certain products despite the wording of the proviso. Moreover, Congress could have retained the proposed section on the suppletory application of the FDA Act to special laws such as RA 9211.

Second. The last paragraph of Article 7 of the Civil Code could not be any clearer: "Administrative or executive acts, orders and regulations shall be valid only when they are not contrary to the laws or the Constitution."

In *Review Center Association of the Philippines v. Ermita*,^[12] the Court struck down executive issuances, Executive Order No. 566 and Commission on Higher Education (CHED) Memorandum Order No. 30, Series of 2007, which provided for the CHED's regulation of review centers and effectively expanded the coverage of RA 7722, the Higher Education Act of 1994. We ruled therein that the CHED may only exercise its rule-making power within the confines of its jurisdiction under RA 7722:

The scopes of EO 566 and the RIRR clearly expand the CHED's coverage under RA 7722. The CHED's coverage under RA 7722 is limited to public and private institutions of higher education and degree-granting programs in all public and private post-secondary educational institutions. EO 566 directed the CHED to formulate a framework for the regulation of review centers and similar entities.

The definition of a review center under EO 566 shows that it refers to one which offers "a program or course of study that is intended to refresh and enhance the knowledge or competencies and skills of reviewees obtained in the formal school setting in preparation for the licensure examinations" given by the PRC. It also covers the operation or conduct of review classes or courses provided by individuals whether for a fee or not in preparation for the licensure examinations given by the PRC.

A review center is not an institution of higher learning as contemplated by RA 7722. It does not offer a degree-granting program that would put it under the jurisdiction of the CHED. A review course is only intended to "refresh and enhance the knowledge or competencies and skills of reviewees." A reviewee is not even required to enroll in a review center or to take a review course prior to taking an examination given by the PRC. Even if a reviewee enrolls in a review center, attendance in a review course is not mandatory. The reviewee is not required to attend each review class. He is not required to take or pass an examination, and neither is he given a grade. He is also not required to submit any thesis or dissertation. Thus, programs given by review centers could not be considered "programs x x x of higher learning" that would put them under the jurisdiction of the CHED.

Further, the "similar entities" in EO 566 cover centers providing "review or tutorial services" in areas not covered by licensure examinations given by the PRC, which include, although not limited to, college entrance examinations, Civil Services examinations, and tutorial services. These review and tutorial services hardly qualify as programs of higher learning.

x x x x

Administrative agencies exercise their quasi-legislative or rule-making power through the promulgation of rules and regulations. The CHED may only exercise its rule-making power within the confines of its jurisdiction under RA 7722. The RIRR covers review centers and similar entities which are neither institutions of higher education nor institutions offering degree-granting programs.^[13] (Emphasis supplied, citations omitted)

In *Quezon City PTCA Federation, Inc. v. Department of Education*,^[14] the validity of Department Order (DO) No. 54, Series of 2009, which rationalized the mechanism for the organization and grant of official recognition to Parent-Teacher Associations (PTAs), was upheld by the Court because the exercise of the rule-making power was consistent with the enabling statutes. It was noted that the organization of PTAs at the school level and approval of the school head as a prerequisite for organization hewed closely to the provisions of the Education Act of 1982 and of the Child and Youth Welfare Code which expressly recognized the rights of parents to organize by themselves and/or with teachers. In contrast to PTAs and upon examination of the statutes DO No. 54 purportedly enforces, We found that the creation and organization of Parent-Teacher Community Associations (PTCAs) is not statutorily mandated, thus:

Petitioner insists that the Department Order is an invalid exercise of the rule-making power delegated to the Secretary of Education as it supposedly disregards PTAs' and PTCAs' purposes, not only as partners of the Department of Education in the implementation of programs, but also as a watchdog against "abuses, mismanagement, inefficiency[,] and excesses of public officials within the public school system." Petitioner also assails the Department Order's limitation of official recognition to PTAs, and no longer to PTCAs, as being contrary to law.

x x x x

Petitioner is in error for asserting that the assailed Department Order is contrary to the statutes it aims to put into effect as it fails to put PTCAs on the same footing as PTAs.

Article 77 of the Child and Youth Welfare Code provides for the organization and purposes of PTAs:

Article 77. Parent-Teacher Associations. — Every elementary and secondary school shall organize a parent-teacher association for the purpose of providing a forum for the discussion of problems and their solutions, relating to the total school program, and for insuring the full cooperation of parents in the efficient implementation of such program. All parents who have children enrolled in a school are encouraged to be active members of its PTA, and to comply with whatever obligations and responsibilities such membership entails.

Parent-Teacher Association[s] all over the country shall aid the municipal and other local authorities and school officials in the enforcement of juvenile delinquency control measures, and in the implementation of programs and activities to promote child welfare. x x x

The Education Act of 1982, a statute adopted subsequent to the Child and Youth Welfare Code, expressly recognizes the right of parents to organize by themselves and/or with teachers:

Section 8. Rights of Parents. — In addition to other rights under existing laws, all parents who have children enrolled in a school have the following rights:

1. The right to organize by themselves and/or with teachers for the purpose of providing a forum for the discussion of matters relating to the total school program, and/or ensuring the full cooperation of parents and teachers in the formulation and efficient implementation of such programs.
2. The right to access to any official record directly relating to the children who are under their parental responsibility. x x x

As is evident from the Child and Youth Welfare Code's use of the word "shall," it is mandatory for PTAs to be organized in elementary and secondary schools. As against this, the Child and Youth Welfare Code is silent on the creation of PTCAs. The Education Act of 1982 is equally silent on this. Hence, while the creation and/or organization of PTAs are statutorily mandated, the same could not be said of PTCAs.

However, petitioner argues differently. In support of its position, it cites Republic Act No. 9155, otherwise known as the Basic Education Act of 2001, more specifically its Section 3 (d), on its purposes and objectives:

Section 3. Purposes and Objectives. — The purposes and objectives of this Act are:

x x x x

(d) To ensure that schools and learning centers receive the kind of focused attention they deserve and that educational programs, projects and services take into account the interests of all members of the community[.]

Petitioner also cites Republic Act No. 8980, otherwise known as the Early Childhood Care and Development Act. More specifically, petitioner cites Section 7(a)(1) on implementing arrangements and operational structures:

Sec. 7. Implementing Arrangements and Operational Structures. — The implementation of the National [Early Childhood Care and Development or] ECCD System shall be the joint responsibility of the national government agencies, local government units, nongovernment organizations, and private organizations that are accredited to deliver the services or to provide training and technical assistance.

(a) Responsibilities of the National Government — National government agencies shall be responsible for developing policies and programs, providing technical assistance and support to the ECCD service providers in consultation with coordinating committees at the provincial, city/municipal, and barangay levels, as provided for in Section 8 of this Act, and monitoring of ECCD service benefits and outcomes. The Department of Social Welfare and Development (DSWD), the Department of Education, Culture and Sports (DECS), the Department of Health (DOH), the Department of the Interior and Local Government (DILG), the Department of Labor and Employment (DOLE), the Department of Agriculture (DA), the Department of Justice (DOJ), the National Economic and Development Authority (NEDA), and the National Nutrition Council (NNC) shall jointly prepare annual ECCD for work plans that will coordinate their respective technical assistance and support for the National ECCD Program. They shall consolidate existing program implementing guidelines that ensure consistency in integrated service delivery within the National ECCD System.

(1) The DECS shall promote the National ECCD Program in schools. ECCD programs in public schools shall be under the joint responsibility of their respective school principal/school-head and parents-teachers-community association (PTCA) within the standards set forth in the National ECCD System and under the guidance of the City/Municipal ECCD Coordinating Committee for the effective and equitable delivery of ECCD services. It shall also make available existing facilities of public elementary schools for ECCD classes.

Neither Republic Act No. 9155 nor Republic Act No. 8980 supports petitioner's contentions that PTCAs should stand on the same footing as PTAs and that their existence is statutorily mandated.

Republic Act No. 9155 does not even mention or otherwise refer to PTCAs. All it does is exhort that the interest of all members of the community should be taken into account in the administration of the country's basic education system. The Department Order does not run afoul of this. On the contrary, the Department Order specifically provides for PTAs' collaboration with members of the community:

I. General Policy

1. Every elementary and secondary school shall organize a Parents-Teachers Association (PTA) for the purpose of providing a forum for the discussion of issues and their solutions related to the total school program and to ensure the full cooperation of parents in the efficient implementation of such program.

Every PTA shall provide mechanisms to ensure proper coordination with the members of the community, provide an avenue for discussing relevant concerns and provide assistance and support to the school for the promotion of their common interest. Standing committees may be created within the PTA organization to

coordinate with community members. Regular fora may be conducted with local government units, civic organizations and other stakeholders to foster unity and cooperation. x x x

Republic Act No. 8980 does mention PTCAs, but this is only in the specific context of the National Early Childhood Care and Development (ECCD) System. The ECCD System "refers to the full range of . . . programs that provide for the basic holistic needs of young children from birth to age six (6)." It is not even an education program and does not involve the age range of students — elementary to high school — that is relevant to the Department Order. In any case, an isolated and passing mention does not equate to a mandate.

Petitioner's invocation of Republic Act Nos. 9155 and 8980 only serve to muddle the issues by entreating considerations that are irrelevant to the purposes of the statute (i.e., the Child and Youth Welfare Code) that actually pertains to and requires the organization of PTAs.

From the previously quoted provisions of the Child and Youth Welfare Code and the Education Act of 1982, the purposes for which the organization of PTAs is mandated are clear. First, a PTA is to be a forum for discussion. Second, a PTA exists to ensure the full cooperation of parents in the implementation of school programs. The assailed Department Order serves these purposes.

By ensuring fiscal transparency and accountability, and by providing the basic framework for organization and official recognition, the Department Order ensures that PTAs exist and function in a manner that remains consistent with the articulated purposes of PTAs under the Child and Youth Welfare Code and the Education Act of 1982. A framework for organization ensures that PTAs are properly organized and are both adequately representative of and limited only to those interests that are appropriate to the education of children in elementary and high school. Measures for fiscal transparency and accountability ensure that PTAs are not hampered by pecuniary or proprietary interests that have nothing to do with the effective implementation of school programs. Finally, mechanisms for official recognition ensure that only those associations that organize and conduct themselves in a manner that is consistent with these purposes are privileged with state sanction.[15] (Citations omitted)

From petitioners' own submissions in their Memorandum, they list the requisites for valid administrative rules and regulations:

- (1) Their promulgation must be authorized by the Legislature;
- (2) They must be within the scope of the authority given by the Legislature;
- (3) They must be promulgated in accordance with the prescribed procedure; and
- (4) They must be reasonable.[16]

While petitioners have demonstrated their compliance with requisites 1, 3 and 4, they failed however to substantiate their arguments anent the second requisite — that Article III of the FDA IRR is within the scope of RA 9711. Petitioners merely re-stated the policy for enactment of the law and the scope of the functions of the FDA without linking it to the exact provision in RA 9711 stating that tobacco products are health products.

The dearth of petitioners' argument on this score is further highlighted by their perfunctory discussion on delegated legislative power. From there petitioners drew conclusions of law that the FDA Act is complete in all its terms and with adequate guidelines, ultimately leaving only their enforcement by the appropriate authorities.

Petitioners concluded, thus:

In the case at bar, the subject IRR was issued within the limits of the authority conferred by law. The

provisions of the IRR did not supplant the Constitution, the enabling law and other existing laws.[17]

On the whole, I cannot abide by petitioners' determination that tobacco products are health products by the mere expedient of relying on the second sentence of the amended Section 10(ff) of RA 3720 which provides that any sort of product, goods, and merchandise that has an effect on health are considered health products. As correctly ruled by the Regional Trial Court, and as I shall hereafter discuss, Section 25 of RA 9711 clearly excludes tobacco products from the regulatory jurisdiction of the FDA.

Third. Regulations are not supposed to be a substitute for the general policymaking that Congress enacts in the form of a public law.[18] In this regard, petitioners' claim that RA 9711 is a police power measure does not bear on the validity of Article III of the FDA IRR classifying tobacco products as health products.

In *Metropolitan Manila Development Authority (MMDA) v. Bel-Air Village Association, Inc.*,^[19] the Court delved into the nature of police power as inherent in the Legislative branch endowed with plenary power to make, amend, and repeal laws. Such power can be exercised only by Congress or upon a valid delegation of legislative power to the President and administrative boards. We thus held that based on its enabling law, the MMDA does not exercise police power and cannot enact rules ordering the opening of a private road within a private subdivision:

Police power is an inherent attribute of sovereignty. It has been defined as the power vested by the Constitution in the legislature to make, ordain, and establish all manner of wholesome and reasonable laws, statutes and ordinances, either with penalties or without, not repugnant to the Constitution, as they shall judge to be for the good and welfare of the commonwealth, and for the subjects of the same. The power is plenary and its scope is vast and pervasive, reaching and justifying measures for public health, public safety, public morals, and the general welfare.

It bears stressing that police power is lodged primarily in the National Legislature. It cannot be exercised by any group or body of individuals not possessing legislative power. The National Legislature, however, may delegate this power to the President and administrative boards as well as the lawmaking bodies of municipal corporations or local government units. Once delegated, the agents can exercise only such legislative powers as are conferred on them by the national lawmaking body.^[20]

Thereafter, in a subsequent case, *Metro Manila Development Authority v. Viron Transportation Co., Inc.*,^[21] the Court affirmed the well-settled principle that the power of administrative agencies to prescribe regulations to promote health, morals, education, good order or safety, and general welfare of the people must have legal basis, i.e., tethered to the powers granted in its enabling law.

Respecting the President's authority to order the implementation of the Project in the exercise of the police power of the State, suffice it to stress that the powers vested in the DOTC Secretary to establish and administer comprehensive and integrated programs for transportation and communications and to issue orders, rules and regulations to implement such mandate (which, as previously discussed, may also be exercised by the President) have been so delegated for the good and welfare of the people. Hence, these powers partake of the nature of police power.

Police power is the plenary power vested in the legislature to make, ordain, and establish wholesome and reasonable laws, statutes and ordinances, not repugnant to the Constitution, for the good and welfare of the people. This power to prescribe regulations to promote the health, morals, education, good order or safety, and general welfare of the people flows from the recognition that *salus populi est suprema lex* — the welfare of the people is the supreme law.

While police power rests primarily with the legislature, such power may be delegated, as it is in fact increasingly being delegated. By virtue of a valid delegation, the power may be exercised by the President and

administrative boards as well as by the lawmaking bodies of municipal corporations or local governments under an express delegation by the Local Government Code of 1991.

The authority of the President to order the implementation of the Project notwithstanding, the designation of the MMDA as the implementing agency for the Project may not be sustained. It is ultra vires, there being no legal basis therefor.

It bears stressing that under the provisions of E.O. No. 125, as amended, it is the DOTC, and not the MMDA, which is authorized to establish and implement a project such as the one subject of the cases at bar. Thus, the President, although authorized to establish or cause the implementation of the Project, must exercise the authority through the instrumentality of the DOTC which, by law, is the primary implementing and administrative entity in the promotion, development and regulation of networks of transportation, and the one so authorized to establish and implement a project such as the Project in question.

By designating the MMDA as the implementing agency of the Project, the President clearly overstepped the limits of the authority conferred by law, rendering E.O. No. 179 ultra vires.[22] (Citations omitted)

I relate the foregoing to what has been discussed that rule-making power is legislative in character and can only be exercised by administrative officials and bodies only upon a statutory delegation of legislative power. Plainly, administrative agencies do not have inherent legislative power, more so police power. In their exercise of a validly delegated rule-making power, these bodies must toe the line under the aegis of their enabling law. That administrative bodies may only exercise such legislative powers as are conferred upon them should therefore brook no further argument.

Considering thus the emphasis made by petitioners on the harmful health effects of tobacco as against the range or scope of the subject matters that Congress may legislate on, if RA 9711 indeed contemplated (without articulation) that tobacco products be regulated by the FDA, then such a power ought to have been specifically carved out in the law. In reality, the regulation of tobacco products has been addressed in tobacco-specific legislation, in particular RA 9211 and RA 10643.

The public purpose of promotion and protection of public health harped on by petitioners, as well as our international obligation under the WHO FCTC, do not justify an all-encompassing grant of regulatory power over virtually any product determined by the FDA to have an effect on health. The delegation from Congress saw to placing guidelines in the implementation by petitioners of the FDA Act.

I draw a parallel in *Office of the Solicitor General v. Ayala Land, Inc.*,^[23] which declared the IRR of the National Building Code as ultra vires for promulgating a rule imposing on shopping centers the obligation to provide free parking spaces for their patrons:

The explicit directive of the afore-quoted statutory and regulatory provisions, garnered from a plain reading thereof, is that respondents, as operators/lessors of neighborhood shopping centers, should provide parking and loading spaces, in accordance with the minimum ratio of one slot per 100 square meters of shopping floor area. There is nothing therein pertaining to the collection (or non-collection) of parking fees by respondents. In fact, the term "parking fees" cannot even be found at all in the entire National Building Code and its IRR.

Statutory construction has it that if a statute is clear and unequivocal, it must be given its literal meaning and applied without any attempt at interpretation. Since Section 803 of the National Building Code and Rule XIX of its IRR do not mention parking fees, then simply, said provisions do not regulate the collection of the same.

x x x

x x x x

Hence, in order to bring the matter of parking fees within the ambit of the National Building Code and its IRR,

the OSG had to resort to specious and feeble argumentation, in which the Court cannot concur.

The OSG cannot rely on Section 102 of the National Building Code to expand the coverage of Section 803 of the same Code and Rule XIX of the IRR, so as to include the regulation of parking fees. The OSG limits its citation to the first part of Section 102 of the National Building Code declaring the policy of the State "to safeguard life, health, property, and public welfare, consistent with the principles of sound environmental management and control"; but totally ignores the second part of said provision, which reads, "and to this end, make it the purpose of this Code to provide for all buildings and structures, a framework of minimum standards and requirements to regulate and control their location, site, design, quality of materials, construction, use, occupancy, and maintenance". While the first part of Section 102 of the National Building Code lays down the State policy, it is the second part thereof that explains how said policy shall be carried out in the Code. Section 102 of the National Building Code is not an all-encompassing grant of regulatory power to the DPWH Secretary and local building officials in the name of life, health, property, and public welfare. On the contrary, it limits the regulatory power of said officials to ensuring that the minimum standards and requirements for all buildings and structures, as set forth in the National Building Code, are complied with.

Consequently, the OSG cannot claim that in addition to fixing the minimum requirements for parking spaces for buildings, Rule XIX of the IRR also mandates that such parking spaces be provided by building owners free of charge. If Rule XIX is not covered by the enabling law, then it cannot be added to or included in the implementing rules. The rule-making power of administrative agencies must be confined to details for regulating the mode or proceedings to carry into effect the law as it has been enacted, and it cannot be extended to amend or expand the statutory requirements or to embrace matters not covered by the statute. Administrative regulations must always be in harmony with the provisions of the law because any resulting discrepancy between the two will always be resolved in favor of the basic law.[24] (Emphasis supplied, citations omitted).

As in this case, there is nothing in RA 9711 which grants the FDA, in the guise of protecting public health, an all-encompassing grant of regulatory power over tobacco products because of its specific harmful health effects.

Section 2, Article III, Book II of the FDA IRR reads:

SECTION 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.

Ultimately, the grant of rule-making power is not a grant of unbridled discretion to the petitioners to regulate tobacco products. The determination of what constitutes health products not tethered to the exclusion of coverage found in Section 25 of RA 9711 is an exercise of unbridled discretion.

Tobacco Products are not Health Products

"Health products" is defined under Section 10(ff) of RA 3720 as amended by RA 9711 as follows:

(ff) 'Health products' means food, drugs, cosmetics, devices, biologicals, vaccines, in-vitro diagnostic reagents and household/urban hazardous substances and/or a combination of and/or a derivative thereof. It shall also refer to products that may have an effect on health which require regulations as determined by the FDA.

The foregoing definition laid down by Congress is one such standard and guideline in the delegation of power to prevent the delegate from running riot and exercising unbridled discretion. Another legislative guideline is the contentious Section 25 and specific provisions of special laws.

The succeeding sentence of RA 9711 is qualified by the enumeration in the preceding sentence which, though these may have a negative effect on health, have a claimed therapeutic benefit which outweighs the negative

effects. Thus, the power of the FDA to determine what are health products should be construed through the prism of ejusdem generis[25] in accordance with the first sentence enumerating what are health products.

The layman's definition of "health products" is consistent with the FDA's vast expanse of powers. It is a compound word composed of an attributive noun "health" that qualifies the second word "products." Used as an adjective, "health" means "of, relating to, or conducive to health." [26] Thus, it refers to products which claim to have a beneficial or therapeutic effect on health but do not fall within the enumeration in the first sentence of the amended Section 10(ff) of RA 3720. Health supplements logically fall under this category.

The argument of petitioners and Senators Franklin "Frank" M. Drilon (Senator Drilon) and Pilar Juliana "Pia" S. Cayetano (Senator Cayetano) that soft drinks, which likewise have no therapeutic effect, but are still regulated by the FDA, easily falls by the wayside. The very nomenclature "soft drinks" connotes a beverage and falls within the meaning of "food" specified in RA 9711.[27] As a drink for man, "soft drinks" are specifically regulated by the FDA.

The definition that I accord here with regard to health products and my conclusion that these do not include tobacco products is stacked against the primary power and function of the FDA to ensure the safety of health products available to the public. If tobacco products were to be regulated by the FDA, such would contradict the regulatory scheme conferred upon it by law.

The objectives of the FDA Act are consistent with its conferment of general powers to regulate establishments and products under its jurisdiction.[28] These are not the sole provisions to which the FDA IRR must adhere to. All the provisions thereof, including Article III on Tobacco and Other Products, must be anchored and clearly refracted from the law.

Demonstrably, the powers of the FDA call for the removal of health products which are found to have harmful health effects. The definition under the law to which petitioners anchor their regulation of tobacco products—the harmful health effects—is their very objection to the same.

Section 4 of RA 3720 as amended by RA 9711 enumerates the functions, powers and duties of the enhanced and strengthened FDA:

SEC. 4. To carry out the provisions of this Act, there is hereby created an office to be called the Food and Drug Administration (FDA) in the Department of Health (DOH). Said Administration shall be under the Office of the Secretary and shall have the following functions, powers and duties:

x x x x

(i) To require all manufacturers, traders, distributors, importers, exporters, wholesalers, retailers, consumers, and non-consumer users of health products to report to the FDA any incident that reasonably indicates that said product has caused or contributed to the death, serious illness or serious injury to a consumer, a patient, or any person;

(j) To issue cease and desist orders *motu proprio* or upon verified complaint for health products, whether or not registered with the FDA: Provided, That for registered health products, the cease and desist order is valid for thirty (30) days and may be extended for sixty (60) days only after due process has been observed;

(k) After due process, to order the ban, recall, and/or withdrawal of any health product found to have caused the death, serious illness or serious injury to a consumer or patient, or is found to be imminently injurious, unsafe, dangerous, or grossly deceptive, and to require all concerned to implement the risk management plan which is a requirement for the issuance of the appropriate authorization;

(l) To strengthen the post market surveillance system in monitoring health products as defined in this Act and

incidents of adverse events involving such products[.]

Ineluctably, following the FDA's conferred powers and its determination of what are health products, petitioners will be hard-pressed to retain tobacco products in the market.

Further, pursuant to its powers, the FDA issued Circular No. 2016-012[29] providing the Guidelines on Product Recall addressed to "All Licensed Establishments of Health Products and Other Concerned Stakeholders."

The Rationale and the Scope of FDA Circular No. 2016-012 reveal the scope and power of the FDA over health products that are proven unsafe or hazardous as what petitioners claim tobacco products to be:

1. Rationale

Republic Act No. 3720, also known as the "Food, Drug and Cosmetic Act", as amended, and Republic Act No. 9711, also known as the "Food and Drug Administration (FDA) Act of 2009" and its Implementing Rules and Regulations were all enacted to establish an effective regulatory system for the authorization, registration, and monitoring of health products.

Section 5 (i) of Republic Act No. 9711 mandated the FDA to require all manufacturers, traders, distributors, importers, exporters, wholesalers, retailers, consumers and non-consumer users of health products to report to the FDA any incident that reasonably indicates that a product has caused or contributed to the death, serious illness or serious injury to a consumer, a patient, or any person. Moreover, Section 5 (k) of the same law empowers the FDA, after due process, to order the ban, recall, and/or withdrawal of any health product found to have caused the death, serious illness or serious injury to a consumer or patient, or is found to be imminently injurious, unsafe, dangerous, or grossly deceptive, and to require all concerned to implement the risk management plan which is a requirement for the issuance of the appropriate authorization.

Recall is the method of withdrawing or correcting unsafe or hazardous health products from the distribution chain that may present a health hazard to the consumer or user. It is an action taken by establishments involved in the supply chain (e.g., manufacturers, distributors, or retailers) as (1) part of their responsibility to protect the public health and well-being, (2) compliance to the appropriate good practices (e.g., good manufacturing, distribution, or storage practices), and (3) compliance to existing standards and regulations.

x x x x

3. Scope

This FDA Circular shall apply to all licensed manufacturers, traders, distributors (importers, exporters, and wholesalers), and retailers of health products.

Thus, within the envisioned regulatory system of the FDA over health products, the regulation of tobacco products is equivalent to a prohibition because of petitioners' submission that these are hazardous. Applying RA 9711, the FDA IRR, and FDA Circular No. 2016-012 to tobacco products, the FDA would have nothing more to regulate since tobacco products per se would be banned, recalled, and or withdrawn from the market.

Lastly, it must be noted that tobacco-specific legislation[30] explicitly granted regulation of tobacco products, not its prohibition, ban, recall or withdrawal.[31] On the other hand, the power to "regulate" means the power to protect, foster, promote, preserve and control.[32]

ARTICLE III is inconsistent with Tobacco-Specific Legislation.

Article III, Book II of the FDA IRR is contrary to the statutes which specifically refer to the regulation of tobacco products.

First. Section 25 of RA 9711 provides:

SECTION 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. (Emphasis supplied)

Section 25 is clear as to the jurisdiction of the FDA over all health products. To recall, Section 9 thereof which amended Section 10(ff) of RA 3720 defines "health products." While using the word "all" to span the entire gamut of health products, Section 25 unmistakably contains a proviso which on its face limits the expansive grant of power—the regulation of all health products. Certainly, if tobacco products are not health products and excluded from the coverage of RA 9711, then it cannot be regulated by the FDA.

Lim v. Gamosa[33] is instructive on the language used to determine the scope of the bestowal of jurisdiction. While the subject matter in this case involved the exercise of quasi-judicial power by the National Commission on Indigenous Peoples (NCIP), the exercise thereof must still be derived from the enabling law:

Jurisdiction is the power and authority, conferred by the Constitution and by statute, to hear and decide a case. The authority to decide a cause at all is what makes up jurisdiction.

Section 66 of the IPRA, the law conferring jurisdiction on the NCIP, reads:

Sec. 66. Jurisdiction of the NCIP. — The NCIP, through its regional offices, shall have jurisdiction over all claims and disputes involving rights of ICCs/IPs: Provided, however, That no such dispute shall be brought to the NCIP unless the parties have exhausted all remedies provided under their customary laws. For this purpose, a certification shall be issued by the Council of Elders/Leaders who participated in the attempt to settle the dispute that the same has not been resolved, which certification shall be a condition precedent to the filing of a petition with the NCIP. x x x

The conferment of such jurisdiction is consistent with state policy averred in the IPRA which recognizes and promotes all the rights of ICCs/IPs within the framework of the constitution. Such is likewise reflected in the mandate of the NCIP to "protect and promote the interest and wellbeing of the ICCs/IPs with due regard to their beliefs, customs, traditions and[,] institutions."

In connection thereto, from *Bank of Commerce v. Planters Development Bank*, we learned that the provisions of the enabling statute are the yardsticks by which the Court would measure the quantum of quasi-judicial powers an administrative agency may exercise, as defined in the enabling act of such agency.

Plainly, the NCIP is the "primary government agency responsible for the formulation and implementation of policies, plans and programs to promote and protect the rights and well-being of the ICCs/IPs and the recognition of their ancestral domains as well as their rights thereto." Nonetheless, the creation of such government agency does not per se grant it primary and/or exclusive and original jurisdiction, excluding the regular courts from taking cognizance and exercising jurisdiction over cases which may involve rights of ICCs/IPs.

Recently, in *Unduran, et al. v. Aberasturi, et al.*, we ruled that Section 66 of the IPRA does not endow the NCIP with primary and/or exclusive and original jurisdiction over all claims and disputes involving rights of ICCs/IPs. Based on the qualifying proviso, we held that the NCIP's jurisdiction over such claims and disputes occur only when they arise between or among parties belonging to the same ICC/IP. Since two of the defendants therein were not IPs/ICCs, the regular courts had jurisdiction over the complaint in that case.

In his concurring opinion in *Unduran*, Justice Jose P. Perez submits that the jurisdiction of the NCIP ought to be definitively drawn to settle doubts that still linger due to the implicit affirmation done in *The City Government of*

Baguio City, et al. v. Atty. Masweng, et al. of the NCIP's jurisdiction over cases where one of the parties are not ICCs/IPs.

In Unduran and as in this case, we are hard[-]pressed to declare a primary and/or exclusive and original grant of jurisdiction to the NCIP over all claims and disputes involving rights of ICCs/IPs where there is no clear intentment by the legislature.

Significantly, the language of Section 66 is only clear on the nature of the claim and dispute as involving rights of ICCs/IPs, but ambiguous and indefinite in other respects. While using the word "all" to quantify the number of the "claims and disputes" as covering each and every claim and dispute involving rights of ICCs/IPs, Section 66 unmistakably contains a proviso, which on its face restrains or limits the initial generality of the grant of jurisdiction. (Emphasis supplied)

Unduran lists the elements of the grant of jurisdiction to the NCIP: (1) the claim and dispute involve the right of ICCs/IPs; and (2) both parties have exhausted all remedies provided under their customary laws. Both elements must be present prior to the invocation and exercise of the NCIP's jurisdiction.

Thus, despite the language that the NCIP shall have jurisdiction over all claims and disputes involving rights of ICCs/IPs, we cannot be confined to that first alone and therefrom deduce primary sole NCIP jurisdiction over all ICCs/IPs claims and disputes to the exclusion of the regular courts. If it were the intention of the legislature that: (1) the NCIP exercise primary jurisdiction over, and/or (2) the regular courts be excluded from taking cognizance of, claims and disputes involving rights of ICCs/IPs, the legislature could have easily done so as in other instances conferring primary, and original and exclusive jurisdiction to a specific administrative body. x x x[34] (Emphasis supplied, citations omitted)

Patently, tobacco products are not health products because the proviso in Section 25 specifically excluded it from the jurisdiction of the FDA.

Still and all, petitioners insist that the proviso retained with the FDA the regulatory power over the health aspect of the already excluded products, to wit: "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 RA 9211, Executive Order No. 245, Executive Order No. 18, and Presidential Decree No. 1468." [35] This is evidently not so.

There is nothing in the use of the phrase "only insofar as the acts covered by these specialized agencies and laws" [36] which delineated the FDA's retention of regulatory powers over the health aspect of certain products, e.g., tobacco (RA 9211 and EO 245), sugar (EO 18), and coconut (PD 1468). The intention to exclude tobacco products from regulation by the FDA is especially true since two agencies already oversee, administer and regulate it and the tobacco industry: (1) IAC-Tobacco, and (2) the National Tobacco Administration (NTA).

To emphasize, RA 9711 did not repeal the foregoing laws and executive orders. Moreover, under Section 33 of RA 9211, the NTA was accorded an additional mandate to implement various programs and projects. [37]

Notably, the special laws on the subject of tobacco regulation, RA 9211 and RA 10643, both deal with the health aspect of, and define, tobacco products, to wit:

Republic Act No. 9211

SECTION 4. Definition of Terms. - As used in this Act:

x x x x

s. "Tobacco Product"— refers to any product that consists of loose tobacco that contains nicotine and is intended for use in a cigarette, including any product containing tobacco and intended for smoking or oral or nasal use. Unless stated otherwise, the requirements of this Act pertaining to cigarettes shall also apply to other tobacco products[.]

Republic Act No. 10643

SECTION 4. Definition of Terms. -

x x x x

(f) "Tobacco Products" means products entirely or partly made of leaf tobacco as raw material, which are manufactured to be used for smoking, sucking, chewing or snuffing, or by any means of consumption.

Verily, the hazardous effect of tobacco products is necessarily intertwined with its status as a key agricultural product in the Philippines. The policy to balance the health and economic aspects of tobacco products and the tobacco industry is reflected in Section 2 of RA 9211 aptly titled The Tobacco Regulation Act of 2003:

SECTION 2. Policy. - It is the policy of the State to protect the populace from hazardous products and promote the right to health and instill health consciousness among them. It is also the policy of the State, consistent with the Constitutional ideal to promote the general welfare, to safeguard the interests of the workers and other stakeholders in the tobacco industry. For these purposes, the government shall institute a balanced policy whereby the use, sale and advertisements of tobacco products shall be regulated in order to promote a healthful environment and protect the citizens from the hazards of tobacco smoke, and at the same time ensure that the interests of tobacco farmers, growers, workers and stakeholders are not adversely compromised.

In short, the regulation of tobacco products is not solely a health concern.

Tobacco products have a dual aspect which tobacco-specific legislation has sought to balance; the wisdom behind the characterization and the balancing policy are within the exclusive realm of legislative discretion. Inquiry into the wisdom of laws is beyond the province of the Supreme Court.[38]

The balancing policy and dual aspect of tobacco regulation are again reflected in the creation of the IAC-Tobacco as the implementing agency of the provisions of RA 9211. The IAC-Tobacco is composed of various cabinet secretaries in the executive department and is chaired by the Secretary of the Department of Trade and Industry, with the Secretary of the DOH as Vice-Chairperson.[39]

Moreover, Section 30 of RA 9211 militates against all the assertions of petitioners as it specifies the unqualified application of the TRA to all tobacco products:

SECTION 30. Application to Tobacco Products. - The provisions of this Act shall apply to all tobacco products placed into commerce in the Philippines. Except as provided below, no provision of this Act shall apply to tobacco products intended or offered by the manufacturer for export and not for [retail] sale in the Philippines.

Recently, in *Department of Health v. Philip Morris Philippines Manufacturing, Inc.*[40] we had occasion to affirm the regulatory power conferred upon the IAC-Tobacco by RA 9211 which effectively divested the DOH and the FDA of any authority to act upon applications for tobacco sales promotional permit. We declared, thus:

Furthermore, the declared policy of RA 9211 where "promotion" is defined includes the institution of "a balanced policy whereby the use, sale and advertisements of tobacco products shall be regulated in order to promote a healthful environment and protect the citizens from the hazards of tobacco smoke" Hence, if the IAC-Tobacco was created and expressly given the exclusive authority to implement the provisions of RA 9211 in accordance with the foregoing State policy, it signifies that it shall also take charge of the regulation of

the use, sale, distribution, and advertisements of tobacco products, as well as all forms of "promotion" which essentially includes "sales promotion." Therefore, with this regulatory power conferred upon the IAC-Tobacco by RA 9211, the DOH and the BFAD have been effectively and impliedly divested of any authority to act upon applications for tobacco sales promotional permit, including PMPMI's.

Finally, it must be stressed that RA 9211 is a special legislation which exclusively deals with the subject of tobacco products and related activities. On the other hand, RA 7394 is broader and more general in scope, and treats of the general welfare and interests of consumers vis-à-vis proper conduct for business and industry. As such, *lex specialis derogat generali*. General legislation must give way to special legislation on the same subject, and generally is so interpreted as to embrace only cases in which the special provisions are not applicable. In other words, where two statutes are of equal theoretical application to a particular case, the one specially designed therefore should prevail.

In fine, the Court agrees with the CA that it is the IAC-Tobacco and not the DOH which has the primary jurisdiction to regulate sales promotion activities as explained in the foregoing discussion. As such, the DOH's ruling, including its construction of RA 9211 (i.e., that it completely banned tobacco advertisements, promotions, and sponsorships, as promotion is inherent in both advertising and sponsorship), are declared null and void, which, as a necessary consequence, precludes the Court from further delving on the same. As it stands, the present applications filed by PMPMI are thus remanded to the IAC-Tobacco for its appropriate action. Notably, in the proper exercise of its rule-making authority, nothing precludes the IAC-Tobacco from designating any of its pilot agencies (which, for instance, may even be the DOH) to perform its multifarious functions under RA 9211.[41] (Emphasis supplied, citations omitted)

On the whole, Article III of the FDA IRR contradicts tobacco-specific legislation by expanding the scope of the definition of health products and appropriating FDA regulation of tobacco products.

Significantly, a similar question on the jurisdiction of the United States of America Food and Drug Administration (US FDA) to regulate tobacco products was brought before the United States Supreme Court in *FDA v. Brown & Williamson Tobacco Corporation*.[42] In that case, the US Supreme Court considered the enabling law as a whole and found that the US Congress intended to exclude tobacco products from the US FDA's jurisdiction. The US Supreme Court noted the contradiction in the FDA's exercise of jurisdiction which would result in the complete removal of tobacco from the market. Any resulting ban would contradict the US Congress's clear intent as expressed in their tobacco-specific legislation. The US Supreme Court therefore concluded that there existed no room for tobacco products within the then prevailing US FDA Act.

Heeding the US Supreme Court's construction of the law and determining that the remedy laid with Congress to specifically legislate the FDA's regulatory jurisdiction over tobacco products, the US Congress enacted The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) which was signed into law on June 22, 2009. The aforesaid law specifically provided for the US FDA's authority to regulate the manufacture, distribution, and marketing of tobacco products.

It bears further repeating that tobacco products are covered by RA 9211 with short title "Tobacco Regulation Act of 2003" which same law is referred to by RA 9711, the FDA Act of 2009, in Section 25. That the right to health is constitutionally enshrined does not grant the FDA unbridled authority to exercise its power beyond the provisions of the empowering statute.

In all, the delegated rule-making power of administrative agencies ought to be exercised within the confines of the Constitution, the enabling statute, and other laws, such as tobacco-specific legislation. Consequently, the foregoing alleged violations in the FDA's exercise of administrative rule-making power calls to the fore our own power and duty that is judicial review.[43]

That there is an actual case or controversy is further emphasized by the opposing pleadings in intervention of legislators of RA 971— Senator Drilon and Senator Cayetano as Petitioners-In-Intervention and Congressman Edcel C. Lagman as Respondent-in-Intervention. Indeed, the crafters of our laws have opposing views on the the scope of FDA's regulatory jurisdiction and on the other laws covering the specific subject-matter of tobacco.

There are instances when this Court exercised the power of judicial review in cases involving newly-enacted laws.

In *Pimentel, Jr. v. Aguirre*,^[44] this Court fixed the point at which a legal issue matures into an actual case or controversy—at the pre-occurrence of an "overt act":

In the unanimous en banc case *Tañada v. Angara*, this Court held that when an act of the legislative department is seriously alleged to have infringed the Constitution, settling the controversy becomes the duty of this Court. By the mere enactment of the questioned law or the approval of the challenged action, the dispute is said to have ripened into a judicial controversy even without any other overt act. Indeed, even a singular violation of the Constitution and/or the law is enough to awaken judicial duty. Said the Court:

"In seeking to nullify an act of the Philippine Senate on the ground that it contravenes the Constitution, the petition no doubt raises a justiciable controversy. Where an action of the legislative branch is seriously alleged to have infringed the Constitution, it becomes not only the right but in fact the duty of the judiciary to settle the dispute. . . .The duty (to adjudicate) remains to assure that the supremacy of the Constitution is upheld.' Once a 'controversy as to the application or interpretation of a constitutional provision is raised before this Court . . . , it becomes a legal issue which the Court is bound by constitutional mandate to decide. '

x x x x

"As this Court has repeatedly and firmly emphasized in many cases, it will not shirk, digress from or abandon its sacred duty and authority to uphold the Constitution in matters that involve grave abuse of discretion brought before it in appropriate cases, committed by any officer, agency, instrumentality or department of the government."

In the same vein, the Court also held in *Tatad v. Secretary of the Department of Energy*:

". . . Judicial power includes not only the duty of the courts to settle actual controversies involving rights which are legally demandable and enforceable, but also the duty to determine whether or not there has been grave abuse of discretion amounting to lack or excess of jurisdiction on the part of any branch or instrumentality of government. The courts, as guardians of the Constitution, have the inherent authority to determine whether a statute enacted by the legislature transcends the limit imposed by the fundamental law. Where the statute violates the Constitution, it is not only the right but the duty of the judiciary to declare such act unconstitutional and void."

By the same token, when an act of the President, who in our constitutional scheme is a coequal of Congress, is seriously alleged to have infringed the Constitution and the laws, as in the present case, settling the dispute becomes the duty and the responsibility of the courts.^[45] (Emphasis supplied, citations omitted)

Thus, in *Province of North Cotabato v. Government of the Republic of the Philippines Peace Panel on Ancestral Domain*,^[46] this Court stated: "[t]hat the law or act in question is not yet effective does not negate ripeness."^[47]

Subsequently, this Court, in *Southern Hemisphere Engagement Network, Inc. v. Anti-Terrorism Council*^[48] stated:

The Court is not unaware that a reasonable certainty of the occurrence of a perceived threat to any constitutional interest suffices to provide a basis for mounting a constitutional challenge. This, however, is qualified by the requirement that there must be sufficient facts to enable the Court to intelligently adjudicate the issues.^[49] (Emphasis in the original)

This Court's liberality in scrutinizing a petition for an actual case or controversy was more recently illustrated in *Belgica v. Ochoa*[50] (*Belgica*). In *Belgica*, this Court found that there was an actual case or controversy:

The requirement of contrariety of legal rights is clearly satisfied by the antagonistic positions of the parties on the constitutionality of the "Pork Barrel System." Also, the questions in these consolidated cases are ripe for adjudication since the challenged funds and the provisions allowing for their utilization — such as the 2013 GAA for the PDAF, PD 910 for the Malampaya Funds and PD 1869, as amended by PD 1993, for the Presidential Social Fund — are currently existing and operational; hence, there exists an immediate or threatened injury to petitioners as a result of the unconstitutional use of these public funds.[51]

Belgica was followed by *Araullo v. Aquino III*,[52] where this Court stated:

An actual and justiciable controversy exists in these consolidated cases. The incompatibility of the perspectives of the parties on the constitutionality of the DAP and its relevant issuances satisfy the requirement for a conflict between legal rights. The issues being raised herein meet the requisite ripeness considering that the challenged executive acts were already being implemented by the DBM, and there are averments by the petitioners that such implementation was repugnant to the letter and spirit of the Constitution. Moreover, the implementation of the DAP entailed the allocation and expenditure of huge sums of public funds. The fact that public funds have been allocated, disbursed or utilized by reason or on account of such challenged executive acts gave rise, therefore, to an actual controversy that is ripe for adjudication by the Court.[53]

In *Spouses Imbong v. Ochoa*,[54] this Court found that there was an actual case or controversy, despite the Petition being a facial challenge:

The OSG also assails the propriety of the facial challenge lodged by the subject petitions, contending that the RH Law cannot be challenged "on its face" as it is not a speech regulating measure.

The Court is not persuaded.

In United States (US) constitutional law, a facial challenge, also known as a First Amendment Challenge, is one that is launched to assail the validity of statutes concerning not only protected speech, but also all other rights in the First Amendment. These include religious freedom, freedom of the press, and the right of the people to peaceably assemble, and to petition the Government for a redress of grievances. After all, the fundamental right to religious freedom, freedom of the press and peaceful assembly are but component rights of the right to one's freedom of expression, as they are modes which one's thoughts are externalized.

In this jurisdiction, the application of doctrines originating from the U.S. has been generally maintained, albeit with some modifications. While this Court has withheld the application of facial challenges to strictly penal statutes, it has expanded its scope to cover statutes not only regulating free speech, but also those involving religious freedom, and other fundamental rights. The underlying reason for this modification is simple. For unlike its counterpart in the U.S., this Court, under its expanded jurisdiction, is mandated by the Fundamental Law not only to settle actual controversies involving rights which are legally demandable and enforceable, but also to determine whether or not there has been a grave abuse of discretion amounting to lack or excess of jurisdiction on the part of any branch or instrumentality of the Government. Verily, the framers of Our Constitution envisioned a proactive Judiciary, ever vigilant with its duty to maintain the supremacy of the Constitution.

Consequently, considering that the foregoing petitions have seriously alleged that the constitutional human rights to life, speech and religion and other fundamental rights mentioned above have been violated by the assailed legislation, the Court has authority to take cognizance of these kindred petitions and to determine if the RH Law can indeed pass constitutional scrutiny. To dismiss these petitions on the simple expedient that there exist no actual case or controversy, would diminish this Court as a reactive branch of government, acting only when the Fundamental Law has been transgressed, to the detriment of the Filipino people.[151]

(Emphasis in the original, citations omitted)

Our disposition in *GIOS Samar, Inc. v. Department of Transportation and Communications*[55] (*GIOS Samar*) is quite telling of our holdings on the existence of an actual case or controversy.

In *GIOS Samar*, we amplified on the doctrine of hierarchy of courts which had long been recognized in our jurisdiction.[56] The petitioner therein questioned the constitutionality of the bundling of various Airport Projects instituted during the time of President Benigno Simeon C. Aquino III. In dismissing the case, the Court found that while the issues alleged by petitioner *GIOS Samar* are ostensibly constitutional and legal, the main issue on the bundling of the Airport Projects are inextricably intertwined with underlying questions of fact. From there, the Court proceeded to trace the history of the doctrine of hierarchy of courts and one by one dismissed the assertions of petitioner *GIOS Samar* as factual questions properly cognizable by the lower courts, specifically the Regional Trial Courts.

However, note that the constitutionality of the bundling of the Airport Projects is not the *lis mota* of the case. At the time of the disposition of *GIOS Samar* in 2019, and as early as November 14, 2016, the National Economic Development Authority (NEDA) Board approved the unbundling of the regional airport projects. On January 24, 2017 the DOTr published an advertisement inviting new players to participate in the bidding of the airport projects.[57]

Plainly, there was no longer any bundled Airport Projects to speak of and thus the case could have been dismissed for mootness. Yet, the Court proceeded to rule on the substantive issue of the allegations in the petition and ruled that the Court is not a trier of facts.

Moreover, the Court saw no need to discuss the necessity to establish injury or threat of injury by *GIOS Samar* as a result of the bundling of the Airport Projects. Evident from the facts in *GIOS Samar* is the lack of establishment of supposed substantial injury to "a non-governmental organization composed of subsistence farmers and fisherfolk from Samar, who are among the victims of Typhoon Yolanda relying on government assistance for the rehabilitation of their industry and livelihood"[58] by virtue of the bundling of the Airport Projects.

Although we have previously ruled that "in order for an association to have legal standing, it must establish the identity of its members, and present proof of its authority to bring the suit for and on behalf of its members,"[59] in *GIOS Samar*, we ruled on the petitions given the import of emphasizing the doctrine of hierarchy of courts.

In contrast, and as we have already laid out throughout our discussion of this case, there is an actual case or controversy which properly calls for the Court's exercise of its inherent power of judicial review.[60]

The ponencia focuses on the known harmful health effects of tobacco which squarely falls within the definition of health products and in turn, within the FDA's competence and mandate "to ensure the safety and quality of health products." It holds that any other contrary reading would be illogical – in that— the FDA can regulate cosmetics due to its effects on health but not tobacco products.

I disagree. "Cosmetics" are specifically defined in the FDA acts— Section 10 (h) of RA 3720, as amended by RA 9711. Section 9 of RA 9711 provides:

SECTION 9. Section 10, subsections (a), (e), (f), (g), (h), (i), (q), (r), (v), and (w) of Republic Act No. 3720, as amended, are hereby further amended, and new subsections (x), (y), (z), (aa), (bb), (cc), (dd), (ee), (ff), (gg), (hh), (ii), (jj), (kk), (ll), and (mm) are hereby added to read as follows:

"SEC. 10. For the purposes of this Act, the term:

"(h) 'Cosmetics' means any substance or preparation intended to be placed in contact with the various external

parts of the human body or with the teeth and the mucous membranes of the oral cavity, with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odor, and/or protecting the body or keeping them in good condition.

Cosmetics are included within the FDA's regulatory jurisdiction because the FDA Act provides so.

The FDA's mandate and its heightened powers over health products is not assailed or questioned. The harmful health effects of tobacco are conceded. In fact, Section 2 of RA 9211, the Tobacco Regulation Act, declares the legal policy on tobacco, thus:

SECTION 2. Policy. — It is the policy of the State to protect the populace from hazardous products and promote the right to health and instill health consciousness among them. It is also the policy of the State, consistent with the Constitutional ideal to promote the general welfare, to safeguard the interests of the workers and other stakeholders in the tobacco industry. For these purposes, the government shall institute a balanced policy whereby the use, sale and advertisements of tobacco products shall be regulated in order to promote a healthful environment and protect the citizens from the hazards of tobacco smoke, and at the same time ensure that the interests of tobacco farmers, growers, workers and stakeholders are not adversely compromised. (emphasis ours)

In my disposition herein, I am expectedly constrained by what the prevailing laws provide, both RA 9711, and tobacco-specific legislation, RA 9211. I cannot immediately discount that tobacco is an agricultural product of economic interest to different stakeholders such as tobacco farmers, growers, workers and stakeholders and thereby ignore a specific law thereon.

Undeniably, from legislation, tobacco is an agricultural product used in trade in the Philippines, to wit:

SECTION 4. Definition of Terms. — As used in this Act:

r. "Tobacco" — refers to agricultural components derived from the tobacco plant, which are processed for use in the manufacturing of cigarettes and other tobacco products;

s. "Tobacco Product" — refers to any product that consists of loose tobacco that contains nicotine and is intended for use in a cigarette, including any product containing tobacco and intended for smoking or oral or nasal use. Unless stated otherwise, the requirements of this Act pertaining to cigarettes shall also apply to other tobacco products;

We cannot simply apply the FDA Act, or RA 9711, to tobacco as a health product without considering the TRA, or RA 9211. In *People v. Ejercito*,^[61] citing *Teves v. Sandiganbayan*,^[62] we emphasized the rules of statutory construction that different statutes intersecting on the same subject matter should first be harmonized but in case of conflict, the statute dealing in detail with the subject matter, as opposed to the statute dealing with the subject in general terms, should prevail:

It is a rule of statutory construction that where one statute deals with a subject in general terms, and another deals with a part of the same subject in a more detailed way, the two should be harmonized if possible; but if there is any conflict, the latter shall prevail regardless of whether it was passed prior to the general statute. Or where two statutes are of contrary tenor or of different dates but are of equal theoretical application to a particular case, the one designed therefor specially should prevail over the other.^[63]

In this instance, the TRA, and its particular provisions on tobacco against the backdrop of a "Healthful Environment, Access restrictions, Advertising and Promotions, Implementing Agency and Application, Penal Provisions, Programs and Projects, Information Program and Miscellaneous Provisions" is patently the applicable law in the characterization of tobacco and tobacco products.

In addition, other aspects of tobacco regulation have been addressed in tobacco-specific regulation as Republic Act No. 10643[64] in compliance with our international obligations under the WHO FCTC. Section 2 of RA 10643 explicitly provides:

SECTION 2. Declaration of Principles. — The State shall protect and promote the right to health of the people and instill health consciousness among them.

The State shall protect consumers from trade malpractices and from substandard tobacco products.

The State accepts that, as a State-Party to the World Health Organization's Framework Convention on Tobacco Control (FCTC), a treaty that reaffirms the right of all people to the highest standards of health, the Philippines is obliged to inform every person of the health consequences of tobacco consumption and exposure to tobacco smoke; to enact effective measures to curb and reduce tobacco use, especially among the youth; and to protect public health policy from the commercial and vested interests of the tobacco industry.

The State is cognizant of the Philippines' duty under Article 11 of the FCTC which is to adopt and implement by September 2008 effective health warnings on tobacco products that should describe the harmful effects of tobacco use.

The State recognizes that based on empirical data, text warnings have been shown to be insufficient in conveying the dangers of tobacco products while Graphic Health Warnings have been shown to be more effective in conveying the truth about the dangers of exposure and consumption of tobacco smoke.

Significantly, the construction that tobacco products are health products is not inconsistent with our international commitments since we remain compliant by virtue of tobacco-specific legislation such as RA 10643. My opinion herein does not in any way dilute the heightened powers of the FDA granted in RA 9711 but is consistent with our state recognition and policy of the dual aspect of tobacco products involving both a health and economic aspect.

As for the submission that tobacco is a drug and cigarette is a device, suffice to state that the FDA itself in the assailed IRR considers tobacco as a health product falling within the scope of RA 9711. We cannot substitute our wisdom for that of legislators and administrative executors of the law.

The ruling in the US case of *FDA v Brown & Williamson Tobacco Corporation*,[65] regardless of the lack of unanimity in the ruling by the members of the US Supreme Court, and the consequent enactment by the US Congress of The Tobacco Control Act of 2009, speak volumes on the issue at hand. Where there was no specific law providing for FDA regulation of tobacco products, the US Supreme Court constricted the US FDA's exercise of jurisdiction by construing that tobacco is not a health product. Addressing the apparent lacunae, the US Congress enacted the law specifically providing for the US FDA's authority to regulate the manufacture, distribution, and marketing of tobacco products.

CONCLUSION

All told, I am hard-pressed to sustain petitioners' assertion that the FDA has authority to regulate tobacco products. The FDA IRR pertaining to tobacco products is contrary to the enabling law which failed to legislate for the FDA's regulation of tobacco products or confine it to the health aspect. As previously mapped out herein, Section 25 excluded a number of products, including tobacco, from the coverage of RA 9711. Lastly, Article III, Book II of the FDA IRR is contrary to other laws, i.e., tobacco-specific legislation.

ACCORDINGLY, I vote for the denial of the Petition for Review on Certiorari and the affirmance of the January 27, 2012 Decision of the Regional Trial Court, Branch 255, Las Piñas City in SCA Case No. 11-0013. Article III, Book II of the Rules and Regulations Implementing Republic Act No. 9711, or The Food and Drug Administration Act of 2009, promulgated on March 22, 2011 is void for expanding the law.

[1] SECTION 3. It is hereby declared a policy of the State to adopt, support, establish, institutionalize, improve and maintain structures, processes, mechanisms and initiatives that are aimed, directed and designed to: (a) protect and promote the right to health of the Filipino people; and (b) help establish and maintain an effective health 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.

[2] SECTION 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 (Ca) To provide coherence in the FDA's regulatory system for establishments and products under its jurisdiction.

[3] 732 Phil. 1 (2014).

[4] The Reproductive Health Law (RH Law).

[5] *Imbong v. Ochoa, Jr.*, supra note 3 at 206-208.

[6] See Section 4(k) of RA 3720 as amended by RA 9711.

[7] *GMA Network v. Commission on Elections*, 742 Phil. 174 (2014); *Lokin, Jr. v. Commission on Elections*, 635 Phil. 372 (2010); *Review Center Association of the Philippines v. Ermita*, 602 Phil. 342 (2009); *MCC Industrial Sales Corporation v. Ssangyong Corporation*, 562 Phil. 390 (2007); *Conte v. Commission on Audit*, 332 Phil. 20 (1996); *Luzon Polymers Corporation v. Hon. Presidential Assistant Clave*, 285 Phil. 286 (1992).

[8] *Lokin, Jr. v. Commission on Elections*, supra.

[9] Supra note 7.

[10] The United Nations Commission on International Trade Law.

[11] *MCC Industrial Sales Corporation v. Ssangyong Corporation*, supra note 7 at 426.

[12] Supra note 7.

[13] *Id.* at 364-365, 368.

[14] 781 Phil. 399, 422-423 (2016).

[15] *Id.* at 439-444.

[16] *Rollo*, p. 1837, citing *Lokin, Jr. v. Commission on Elections*, supra note 7.

[17] *Id.* at 1841.

[18] *Ople v. Torres*, 354 Phil. 948 (1998), citing *Fisher, Constitutional Conflicts Between Congress and the President* (4th ed.), pp. 106-107.

[19] 385 Phil. 586 (2000).

[20] *Id.* at 601-602.

[21] 557 Phil. 121 (2007).

[22] Id. at 140-142.

[23] 616 Phil. 587 (2009).

[24] Id. at 606-608.

[25] General terms follow the designation of particular things or classes of persons or subjects, the general term will be construed to comprehend those things or persons of the same class or of the same nature as those specifically enumerated. See *National Power Corp. v. Angas*, 284-A Phil. 39, 48 (1992).

[26] *Black's law Dictionary*, (6[th] Edition), Centennial Edition 1891-1991.

[27] Section 10(e) of Republic Act No. 3720, as amended by Republic Act No. 9711:

SEC. 10. For purposes of this Act, the term:

x x x x

(e) 'Food' means any processed substance which is intended for human consumption and includes drink for man, beverages, chewing gum and x x x.

[28] SECTION 4 of Republic Act No. 9711:

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.

[29] Dated July 25, 2016.

[30] Republic Act No. 9211, Republic Act No. 10643 and Executive Order No. 245.

[31] See *Dela Cruz v. Paras*, 208 Phil. 490 (1983).

[32] See *Gerochi v. Department of Energy*, 554 Phil. 563, 584 (2007).

[33] 774 Phil. 31 (2015).

[34] Id. at 46-48.

[35] REPUBLIC ACT No. 9711, Section 25.

[36] REPUBLIC ACT No. 9711, Section 25.

[37] See http://nta.da.gov.ph/about_mandates.html last visited January 23, 2020.

[38] *Destileria Ayala, Inc. v. Tan Tay Co*, 74 Phil. 301 (1943).

[39] See Section 29 of Republic Act No. 9211.

[40] 757 Phil. 212 (2015).

[41] Id. at 226-228.

[42] 529 U.S. 120.

[43] Francisco, Jr. v. House of Representatives, 460 Phil. 830 (2003).

[44] 391 Phil. 84 (2000).

[45] Id.

[46] 599 Phil. 387 (2008).

[47] Id.

[48] 646 Phil. 452 (2010)

[49] Id.

[50] 721 Phil. 416 (2013).

[51] Id. at 520.

[52] 737 Phil. 457 (2014).

[53] Id. at 533.

[54] Supra note 7.

[55] G.R. No. 217158, March 12, 2019.

[56] See The Provincial Bus Operators Association of the Philippines v. Department of Labor and Employment, G.R. No. 202275, July 17, 2018.

[57] https://ppp.gov.ph/in_the_news/p110-b-unbundled-regional-airport-projects-removed-from-ppp-bidding/; last visited June 17, 2021. See

[58] GIOS Samar v. DOTC, supra note 55.

[59] Alliance of Non-Life Insurance Workers of the Philippines v. Mendoza, G.R. No. 206159, August 26, 2020

[60] Falcis v. Civil Registrar General, G.R. No. 217910, September 3, 2019.

[61] G.R. No. 229861, July 2, 2018.

[62] 488 Phil. 311 (2004).

[63] People v. Ejercito, supra.

[64] AN ACT TO EFFECTIVELY INSTILL HEALTH CONSCIOUSNESS THROUGH GRAPHIC HEALTH WARNINGS ON TOBACCO PRODUCTS otherwise known as The Graphic Health Warnings Law enacted on July 15, 2014.

[65] Supra note 42.

SEPARATE CONCURRING OPINION

LAZARO-JAVIER, J.:

I concur in the erudite ponencia of Justice Marvic M.V.F. Leonen that tobacco and cigarettes are health products which are subject to regulation by the Department of Health (DOH) through the Food and Drugs Administration (FDA). But aside from that, I vote to dismiss the petition for declaratory relief of respondent Philippine Tobacco Institute (PTI) for lack of actual case or controversy.

There is no actual case or controversy

The most apparent defect of this case is the absence of any allegation of injury or threat of injury to respondent PTI. Where there is no such allegation of injury or threat of injury, there would also be no actual case or controversy,[1] an element in obtaining judicial review.[2] In the absence of both injury or threat of injury and an actual case or controversy, this case is not ripe for adjudication and must be dismissed.[3]

I am aware that this case was pursued as a petition for declaratory relief. However, this action is not exempt from either the injury or threat of injury or the actual case or controversy requirements.

De Borja v. PUMALU-MV[4] held:

Petitioners call upon us to disregard procedural rules on account of the alleged novelty and transcendental importance of the issue involved here. However, the transcendental importance doctrine cannot remedy the procedural defects that plague this petition. In the words of former Supreme Court Chief Justice Reynato Puno, "no amount of exigency can make this Court exercise a power where it is not proper." A petition for declaratory relief, like any other court action, cannot prosper absent an actual controversy that is ripe for judicial determination.

....

We deny the petition.

For a petition for declaratory relief to prosper, it must be shown that (a) there is a justiciable controversy, (b) the controversy is between persons whose interests are adverse, (c) the party seeking the relief has a legal interest in the controversy, and (d) the issue invoked is ripe for judicial determination. We agree with the CA when it dismissed De Borja's petition for being premature as it lacks the first and fourth requisites. We hasten to add that the petition, in fact, lacks all four requisites.

First, we find that De Borja's petition does not present a justiciable controversy or the "ripening seeds" of one as to warrant a court's intervention. A justiciable controversy is a definite and concrete dispute touching on the legal relations of parties having adverse legal interests, which may be resolved by a court of law through the application of a law. It must be appropriate or ripe for judicial determination, admitting of specific relief through a decree that is conclusive in character. It must not be conjectural or merely anticipatory, which only seeks for an opinion that advises what the law would be on a hypothetical state of facts.

In his five-page petition for declaratory relief, De Borja failed to provide factual allegations showing that his legal rights were the subject of an imminent or threatened violation that should be prevented by the declaratory relief sought. He simply went on to conclude that the construction or interpretation of the reckoning point of the 15-kilometer range of municipal waters under the 1998 Fisheries Code would affect his rights as he is "now exposed to apprehensions and possible harassments that may be brought about by conflicting interpretations of the said statute x x x." As to how these apprehensions and harassments shall come about, De Borja did not elaborate. Clearly, therefore, there is no actual or imminent threat to his rights which is ripe for judicial review....

In *Republic v. Roque*,^[5] the Court explained:

A perusal of private respondents' petition for declaratory relief would show that they have failed to demonstrate how they are left to sustain or are in immediate danger to sustain some direct injury as a result of the enforcement of the assailed provisions of RA 9372. Not far removed from the factual milieu in the Southern Hemisphere cases, private respondents only assert general interests as citizens, and taxpayers and infractions which the government could prospectively commit if the enforcement of the said law would remain untrammelled. As their petition would disclose, private respondents' fear of prosecution was solely based on remarks of certain government officials which were addressed to the general public. They, however, failed to show how these remarks tended towards any prosecutorial or governmental action geared towards the implementation of RA 9372 against them. In other words, there was no particular, real or imminent threat to any of them.

....

The possibility of abuse in the implementation of RA 9372 does not avail to take the present petitions out of the realm of the surreal and merely imagined. Such possibility is not peculiar to RA 9372 since the exercise of any power granted by law may be abused. Allegations of abuse must be anchored on real events before courts may step in to settle actual controversies involving rights which are legally demandable and enforceable.

Thus, in the same light that the Court dismissed the SC petitions in the Southern Hemisphere cases on the basis of, among others, lack of actual justiciable controversy (or the ripening seeds of one), the RTC should have dismissed private respondents' petition for declaratory relief all the same.

Here, respondent does not allege any injury it has suffered or any threat of suffering such injury as a result of the action of the FDA to classify tobacco as a health product and issue Article III, Book II of the Rules and Regulations Implementing RA 9711 (The Food and Drug Administration Act of 2009). What respondent could only refer us to are apprehensions and speculations of harassments that may be brought about by the conflicting interpretations of the breadth of rule-making authority given to the FDA in light of the amendments to its charter, RA 3720^[6] (1963), by RA 9711.^[7]

The importance of actual facts of injury or threats of injury cannot be overstated. This is because without such actual facts, the Court would in effect be rendering an opinion on a state of assumed and hypothetical facts. Other countries like Canada, India, and Nauru allow such process through what they call reference petitions, but the Philippines and the United States have no authority to do so because of the requirement of an actual case or controversy. Hence, for this doctrinal reason, it is my respectful stand that the Court ought to have called the attention of the courts below about this fatal defect and dismissed this case.

The absence of actual facts nesting the claim injury or threats of injury and actual case or controversy is critical for another reason – it deprives the Court of the exact boundaries of the relief to which respondent as then petitioner may perhaps be entitled and the obligations which petitioner now as respondent then must discharge or endure. The result of the our approach here is to establish an overbroad and over-encroaching binding doctrine – here, that the FDA has absolutely no jurisdiction over tobacco, period.

This is a dangerous precedent because we provide here no context as to when this doctrine would or should kick in. The actual facts of the injury or threat of injury would have supplied that limiting context.

By the end of our discussion here, we are unfortunately left with the same issue that this case should have properly resolved had there been actual facts – in what instances would the FDA have jurisdiction over tobacco and in what instances would it have to give way to other agencies' jurisdictions per Section 25^[8] of RA 9711?

By delving and resolving this issue sans actual facts, we might inappropriately adopt a policy decision as legally

binding doctrine – I respectfully say a POLICY decision since we totally ease out here the FDA without providing specific relief to a specific injury or threat of injury to respondent.

No doubt, I am crying for actual facts of injury or threat of injury, and of actual case or controversy. The reason is that the delineation of jurisdiction among the concerned administrative agencies, the FDA and the Inter-Agency-Tobacco Committee (under RA 9211[9]) included, is not all clear and brightly divided or apportioned. There are gaps and omissions and obvious difference of opinions on the impact of these gaps and omissions, which would have been clarified by the actual injury or threat of injury that respondent allegedly suffered as a result of the issuance of the assailed FDA implementing rule.

Has the FDA interfered with the advertisement and packaging of and sponsorship by tobacco products? Has the FDA meddled in the identification of smoking areas or the employment of minors in the sale of tobacco products? Has the FDA regulated respondent's tobacco manufacturing or pre-sale activities and if yes in what aspects? We do not and will never know because respondent posthaste filed the petition for declaratory relief just after the issuance of the assailed FDA implementing rule.

Indeed, had we required the statement of an actual case or controversy, inclusive of injury or threat of such injury, we would have clarified the boundaries of the relief we are giving to respondent. However, as things stand, we have decided to totally eliminate the FDA from anything about tobacco without the benefit of an actual case or controversy and without any injury or threat of injury. Courts are not like Congress which does not deal with justiciable controversies and adjudicative facts but policy decisions arising from legislative or social facts involving multitudes of peoples.[10] This is not the role of the courts since courts decide matters incrementally on a case-by-case basis.

In his Dissenting Opinion, my esteemed colleague Justice Caguioa insists that an actual case or controversy does not require overt acts showing a violation of one's rights. According to Justice Caguioa, "[t]he only necessary and undisputed fact in this case is the DOH's promulgation of the Rules and Regulations Implementing RA 9711,[11] which gives rise to an actual controversy susceptible of judicial resolution." Other than that, facts are not important in the case at bar. In support of his theory, Justice Caguioa invokes the Court's rulings in *Samahan ng Progresibong Kabataan (SPARK) v. Quezon City*[12] and *Inmates of the New Bilibid Prison v. De Lima*,[13] which purportedly rejected the proposition that there should be concrete acts before the case becomes justiciable.

I respectfully disagree.

Facts are important. Facts are needed for a contextualization of respondent's arguments using factual and evidentiary bases.

The reason for the need for facts is Section 25 of RA 9711, Food and Drug Administration Act of 2009:

SECTION 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. (emphases and underscoring added)

Clearly, the FDA is not prohibited from exercising its jurisdiction over health products unless such exercise intrudes into acts covered by the respective charters of other tobacco agencies. Hence, we need facts in this case to determine if the FDA has intruded into the other agencies' jurisdictions.

In other words, if respondent's only fact of interest is the passage of the DOH IRR confirming FDA jurisdiction over tobacco products, this is clearly insufficient. We need more facts if indeed the FDA has intruded into the acts

covered by these specialized agencies and laws. This is because not every act of jurisdiction of the FDA over tobacco products is ultra vires for being outside of the FDA's mandate and for being intrusive of other agencies' respective mandates. It depends on the acts of the FDA being complained of. It cannot just be because FDA has been confirmed by the DOH IRR to have some jurisdiction over tobacco and its devices.

Had Section 25 of RA 9711 been clear, categorical, and absolute that FDA had utterly no jurisdiction over tobacco and its devices, the mere enactment of the DOH IRR giving FDA jurisdiction over tobacco and its devices would have been enough to establish an actual case or controversy. This is because the mere enactment is the clear act or conduct that ripens the seeds, if not already the seeds themselves, of violation of another agency's right or mandate.

With all due respect to Justice Caguioa, his reliance on SPARK and Inmates is misplaced. For in these cases, there were clear and concrete acts which made the cases before the Court justiciable, i.e., the controversy was actual and ripe for adjudication.

In SPARK, the Court explicitly noted that:

[f]ollowing the campaign of President Rodrigo Roa Duterte to implement a nationwide curfew for minors, several local governments in Metro Manila started to strictly implement their curfew ordinances on minors through police operations which were publicly known as part of 'Oplan Rody.'... The case is likewise ripe for adjudication, considering that the Curfew Ordinances were being implemented until the Court issued the TRO enjoining their enforcement. The purported threat or incidence of injury is, therefore, not merely speculative or hypothetical but rather, real and apparent. (emphases and underscoring added)

Meanwhile, in Inmates, the Court held that the mere fact of petitioners' incarceration and continued incarceration provided the actual case or controversy even sans the overt act of an actual denial of a good conduct time allowance (GCTA) application. This is because, as the Court expressly stressed, "[w]ith the prisoners' continued incarceration, any delay in resolving the case would cause them great prejudice. Justice demands that they be released soonest, if not on time. . . ."

Verily, neither SPARK nor Inmates supports Justice Caguioa's claim that the only fact necessary here is the issuance of the Rules and Regulations Implementing RA 9711. They do not serve as justification to entertain respondent's petition for declaratory relief. Without the necessary ripening of seeds, the trial court should have dismissed respondent's petition.

I rest my case on the Court's recent ruling in *Manning Group Inc. v. Social Security System*[14] penned by Chief Justice Alexander G. Gesmundo and concurred in by Justice Caguioa, among others, no less. thus:

An actual case or controversy means an existing case or controversy that is appropriate or ripe for determination, not conjectural or anticipatory, lest the decision of the court would amount to an advisory opinion. The rule is that courts do not sit to adjudicate mere academic questions to satisfy scholarly interest, however intellectually challenging. The controversy must be justiciable — definite and concrete, touching on the legal relations of parties having adverse legal interests. In other words, the pleadings must show an active antagonistic assertion of a legal right, on the one hand, and a denial thereof, on the other; that is, it must concern a real, tangible and not merely a theoretical question or issue. There ought to be an actual and substantial controversy admitting of specific relief through a decree conclusive in nature, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.

Corollary to the requirement of an actual case or controversy is the requirement of ripeness. A question is ripe for adjudication when the act being challenged has had a direct adverse effect on the individual challenging it. For a case to be considered ripe for adjudication, it is a prerequisite that something has then been accomplished or performed by either branch before a court may come into the picture, AND the petitioner must allege the

existence of an immediate or threatened injury to himself as a result of the challenged action. He must show that he has sustained or is immediately in danger of sustaining some direct injury as a result of the act complained of.

Here, petitioners did not allege that they already sustained or are immediately in danger of sustaining some direct injury from R.A. No. 11199: The mere passage of the law does not per se absolutely determine the justiciability of a particular case attacking the law's constitutionality. Petitioners did not even allege that the law is already implemented against their interests. They simply gave a broad statement that "[t]he execution of Section 9-B of the 2018 SSS Law will definitely work injustice and irreparable damage to the petitioner manning agencies which are made to answer to so much liabilities as employer when it is not the seafarer's employer." Again, there must be an immediate or threatening injury to petitioners as a result of the challenged action; and not a mere speculation. (emphases and underscoring added)

In *Falcis III v. Civil Registrar General*,^[15] the Court also rejected the idea that the mere passage of a law per se makes for an actual case or controversy. Thus:

First, whether or not the mere passage of the Family Code creates an actual case or controversy reviewable by this Court...

....

It is not enough that laws or regulations have been passed or are in effect when their constitutionality is questioned. The judiciary interprets and applies the law. "It does not formulate public policy, which is the province of the legislative and executive branches of government." Thus, it does not – by the mere existence of a law or regulation – embark on an exercise that may render laws or regulations inefficacious

....

Ultimately, petitions before this Court that challenge an executive or legislative enactment must be based on actual facts, sufficiently for a proper joinder of issues to be resolved. If litigants wish to assail a statute or regulation on its face, the burden is on them to prove that the narrowly-drawn exception for an extraordinary judicial review of such statute or regulation applies.

When faced with speculations – situations that have not yet fully ripened into clear breaches of legally demandable rights or obligations – this Court shall refrain from passing upon the case. Any inquiries that may be made may be roving, unlimited, and unchecked. In contrast to political branches of government, courts must deal with specificities...

....

It is the parties' duty to demonstrate actual cases or controversies worthy of judicial resolution.

Pleadings before this Court must show a violation of an existing legal right or a controversy that is ripe for judicial determination....

....

Facts are the basis of an actual case or controversy. To reiterate, "there must be sufficient facts to enable the Court to intelligently adjudicate the issues." Thus, as illustrated in *Southern Hemisphere Engagement Network, Inc.*:

Petitioners' obscure allegations of sporadic "surveillance" and supposedly being tagged as "communist fronts" in no way approximate a credible threat of prosecution. From these allegations, the Court is being lured to render an advisory opinion, which is not its function....

....

Here, petitioner has no actual facts that present a real conflict between the parties of this case. The Petition presents no actual case or controversy.

Despite a goal of proving to this Court that there is a continuing and pervasive violation of fundamental rights of a marginalized minority group, the Petition is woefully bereft of sufficient actual facts to substantiate its arguments....

....

Petitioner presents no proof at all of the immediate, inextricable danger that the Family Code poses to him. His assertions of injury cannot, without sufficient proof, be directly linked to the imputed cause, the existence of the Family Code. His fixation on how the Family Code is the definitive [be]cause of his inability to find a partner is plainly non sequitur.

Similarly, anticipation of harm is not equivalent to direct injury. Petitioner fails to show how the Family Code is the proximate cause of his alleged deprivations. His mere allegation that this injury comes from "the law's normative impact" is insufficient to establish the connection between the Family Code and his alleged injury.

If the mere passage of a law does not create an actual case or controversy, neither can it be a source of direct injury to establish legal standing. This Court is not duty bound to find facts on petitioner's behalf just so he can support his claims. (emphases added)

I further refer to Justice Jardeleza's Concurring Opinion in *Falcis III*, to which Justice Caguioa also agreed, thus:

The petition presents no actual case or controversy.... Furthermore, a case is ripe for adjudication when the act being challenged has had a direct adverse effect on the individual challenging it. Something must have been accomplished or performed by either branch of Government before a court may come into the picture, and a petitioner must allege the existence of an immediate or threatened injury to him/her as a result of the challenged action.

On its face, it presents a hypothetical and contingent event, not ripe for adjudication, which is hinged on petitioner's future plan of settling down with a person of the same-sex.

Petitioner alleged that "the prohibition against the right to marry the same-sex injures [his] plans to settle down and have a companion for life in his beloved country." Yet as of the filing of the petition, petitioner has no partner. He lamented that his "ability to find and enter into a long-term monogamous same-sex relationship is impaired because of the absence of a legal incentive for gay individuals to seek such relationship." Significantly, however, even if he has a partner, petitioner admitted in open court that it is not automatic that his partner might want to marry him. Thus, petitioner cannot, did not or even attempted to, file an application for marriage license before the civil registry of his residence. (emphases added)

Similarly, respondent herein has never alleged that the IRR of RA 9711 is already being implemented against its interest. Thus, there has yet to be a ripening of seeds which is necessary to confer the courts with jurisdiction over respondent's petition for declaratory relief.

RA 9711 applies to tobacco

I would like to address the arguments raised for nullifying Article III, Book II of the Implementing Rules and Regulations of RA 9711.

1.

The language of RA 9711 does not expressly include tobacco as a health product.

2.

Construed in its totality, RA 9711 could not have intended to include tobacco within its regulatory mechanism since its inclusion would result in its prohibition and not merely its regulation, contrary to the legislative intent not to prohibit tobacco but only to regulate it. Prohibition will be the end-result because the FDA is statutorily mandated by RA 3270 as amended by RA 9711 to prohibit a product whose ill-effects outweigh its therapeutic effects, and the FDA has ruled that tobacco has only ill-effects and no therapeutic value whatsoever.

3.

Tobacco-specific legislations, especially those expressly mentioned in Section 25 of RA 9711 have divested the FDA of jurisdiction over tobacco.

a. Tobacco and cigarettes are health products

It is admitted that RA 9711 does not mention expressly tobacco. But this does not mean that RA 9711 does not apply to tobacco. We recognize though that softdrinks fall within RA 9711 because softdrinks can be classified under one of the categories regulated by RA 9711 – food.[16]

In the same manner, we do not have to search for the word tobacco in RA 9711 to be able to conclude cogently that tobacco falls within the ambit of this statute. So long as tobacco can be categorized under one of the regulated items in RA 9711, just like softdrinks, tobacco falls within the FDA's regulatory regime.

I most respectfully submit that tobacco falls within the definition of drug,[17] and cigarette within the definition of device,[18] and since both drug and device are also health products, tobacco and cigarette are also health products.[19] As such, tobacco and cigarette fall, within the regulatory jurisdiction of the FDA.

The other basis of the ruling that tobacco, and especially cigarette, is not subject to FDA jurisdiction, may be re-stated as follows –

1.

The inclusion of tobacco within the regulatory mechanism of RA 9711 would have meant its prohibition and not merely its regulation because tobacco's ill-effects totally outweigh its absent therapeutic value.

2.

Under RA 9711 the FDA would have no choice but to ban tobacco from the market because the FDA had already concluded that tobacco had only ill-effects and no therapeutic value.

3.

This inevitable action of the FDA – i.e., prohibition of tobacco – would be illegal because contrary to established legislative intent as expressed in Section 25 of RA 9711[20] and tobacco-specific legislations.

This rationale follows the thought-process in the United States Supreme Court case of *Food and Drug Admin. v. Brown & Williamson Tobacco Corp.*[21] Notably, a statutory amendment to the US FDA's charter was introduced in 2009, The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), which expanded the US FDA's authority to regulate the manufacture, distribution, and marketing of tobacco products, to address the otherwise adverse ruling in the *Brown & Williamson Tobacco Corp.* case and similar cases. Notably, the ruling in

Brown & Williamson Tobacco Corp. was not unanimous since a vigorous dissent was registered against the exclusion of tobacco from the US FDA's jurisdiction.

Going to our own FDA, tobacco is a drug: it is an article other than food that respondent knows and offers to be used to affect the structure of any function of the body of humans or animals. The science behind this effect on the structure of any function has been explained in the dissent in Brown & Williamson Tobacco Corp., as follows:

Although I now oversimplify, the FDA has determined that once nicotine enters the body, the blood carries it almost immediately to the brain. See 61 Fed.Reg. 44698-44699 (1966). Nicotine then binds to receptors on the surface of brain cells, setting off a series of chemical reactions that alter one's mood and produce feelings of sedation and stimulation. See *id.*, at 44699, 44739. Nicotine also increases the number of nicotinic receptors on the brain's surface, and alters its normal electrical activity. See *id.*, at 44739. And nicotine stimulates the transmission of a natural chemical that "rewards" the body with pleasurable sensations (dopamine), causing nicotine addiction. See *id.*, at 44700, 44721-44722. The upshot is that ***1320 nicotine stabilizes mood, suppresses appetite, tranquilizes, and satisfies a physical craving that nicotine itself has helped to create – all through chemical action within the body after being metabolized.

This physiology—and not simply smoker psychology—helps to explain why as many as 75% of adult smokers believe that smoking "reduce[s] nervous irritation," 60 Fed.Reg. 41579 (1995); why 73% of young people (10- to 22-year-olds) who begin smoking say they do so for "relaxation," 61 Fed.Reg. 44814 (1996); and why less than 3% of smokers succeed in quitting each year, although 70% want to quit, *id.*, at 44704. That chemistry also helps to explain the Surgeon General's findings that smokers believe "smoking [makes them] feel better" and smoke more "in situations involving negative mood." *Id.*, at 44814. And, for present purposes, that chemistry demonstrates that nicotine affects the "structure" and "function" of the body in a manner that is quite similar to the effects of other regulated substances. See *id.*, at 44667 (FDA regulates Valium, NoDoz, weight-loss products). Indeed, addiction, sedation, stimulation, and weight loss are precisely the kinds of product effects that the FDA typically reviews and controls. And, since the nicotine in cigarettes *170 plainly is not a "food," its chemical effects suffice to establish that it is as a "drug" (and the cigarette that delivers it a drug- delivery "device") for the purpose of the FDCA.

This is science. And, it has not been refuted by respondent in this case.

A cigarette is a health-related device as RA 9711[22] defines it: any device not used in health care but has been determined by the FDA to adversely affect the health of the people. A cigarette is a drug-delivery device.

Both tobacco and cigarette are health products: they are both "food, drugs, cosmetics, devices. . . ." and "products that may have an effect on health which require regulations as determined by the FDA."

Justice Caguioa ripostes that practically all products have an effect on health:

Take for instance firearms, which could arguably fall within this meaning because of the risks it poses to the health and safety of its owner and the public -- not unlike the adverse and harmful effects of tobacco and tobacco products. As well, gasoline, whether ingested or used as fuel for motor vehicles, could be reasonably construed as a health product if the Court were to follow the same line of argument. That said, it is inconceivable to consider these products as health products that the FDA can regulate....

With all due respect, Justice Caguioa is comparing apples and oranges with poison.

The reason why tobacco and cigarettes are under regulation of the FDA is not because they have negative impact on health per se, but because their only purpose is to negatively impact health. Unlike firearms which could be used for safety and protection and gasoline which is an everyday commodity, tobacco and cigarettes simply don't have any other use than poison the body. Thus, our only guide in determining which agency has authority to regulate such product is its sole purpose which is to negatively impact health. Based on this criterion it is the

DOH, through the FDA, which has authority to regulate such health product.

b. The FDA has jurisdiction over health products including tobacco and cigarettes

The otherwise expansive jurisdiction of the FDA is tempered by Section 25 of RA 9711. This is admitted even by the FDA itself. Section 25 states:

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.

To reiterate, it is in this portion of the rationale where the allegation and existence of the actual facts of the injury or threat of injury to respondent, if there had been any, assumes supreme importance. The nature of the injury or threat of injury – if otherwise alleged and of course proved – would have determined to what extent the FDA acted ultra vires or encroached the other agencies' respective jurisdictions. This underlying fact is extremely relevant because of the structure itself of Section 25.

Section 25 begins with an acknowledgement and affirmation of the FDA's jurisdiction over health products, which include drugs and devices (therefore tobacco and cigarettes) – "[t]his Act shall govern all health products. . . ."

It is only by way of an exception that it recognizes the jurisdictions of other specialized agencies and specialized laws. This means that without this qualification, RA 9711[23] would have actually amended or even repealed such statutes as RA 9211[24] and EO 245.[25]

In any event, the exception to the expansive FDA jurisdiction is qualified by two important qualifiers:

(i)

the other agencies' jurisdiction must be sole and exclusive (Section 25 itself already determined that the jurisdictions under RA 9211 and EO 245 are sole and exclusive); and

(ii)

the exception applies "only insofar as the acts covered by these specialized agencies and laws," here, RA 9211 and EO 245.

This means that the expansive FDA jurisdiction applies to tobacco and its derivative products except only insofar as the acts covered by RA 9211 and EO 245. Hence, we cannot immediately divest the FDA of any jurisdiction over tobacco and its derivatives without looking into the acts covered by RA 9211 and EO 245.

More important, we cannot castrate the FDA of any jurisdiction over tobacco and its derivatives solely because this exercise of jurisdiction may actually or effectively result in the prohibition of the sale or use of tobacco and its derivatives or more likely the particular commercial products thereof.

Whether the FDA's exercise of jurisdiction will cause the prohibition of tobacco or its derivatives is not the test of the propriety of the FDA's exercise of jurisdiction, as asserted here. Rather, the test is whether the exception to the FDA's jurisdiction over health products applies.

If particularized injury or threat of injury has been alleged and proved, it would have been easy to determine if the act done by the FDA falls within its RA 9711 jurisdiction or falls within the Section 25 exception for other

specialized agencies. The fact is that there are no facts, yet we proceeded to rule on this case as if there were facts constituting an actual case or controversy. Consequently, the resulting doctrines produced, I respectfully submit, are inaccurate and dangerous precedents. They do not address a particularized controversy or dispute but a social and policy decision that for this reason is overbroad and overreaching.

In any event, RA 9211 does not intend to cover the whole subject matter about tobacco. Instead, RA 9211 addresses only these specified acts and/or circumstances:

- SECTION 5. Smoking Ban in Public Places.
- SECTION 6. Designation of Smoking and Non-smoking Areas.
- SECTION 7. Prohibition and/or Regulation of Vending Machines, Self-Service Facilities.
- SECTION 8. Removal of all non-compliant tobacco-related self-Service displays or facilities, advertising, labeling and other items.
- SECTION 9. Prohibition of Minors from Using, Selling Cigarettes.
- SECTION 10. Prohibition of Sale of Tobacco Products Within School Perimeters.
- SECTION 11. Signage Requirements.
- SECTION 12. Requirement of Proof of Age Verification.
- SECTION 13. Warnings on Cigarette Packages.
- SECTION 14. Warnings in Advertising.
- SECTION 15. Restrictions on Advertising.
- SECTION 16. Restrictions on Print Media Advertising.
- SECTION 17. Restrictions on Outdoor Advertising.
- SECTION 18. Restrictions on Advertising in Cinemas.
- SECTION 19. Restrictions on Television and Radio Advertising.
- SECTION 20. Restrictions on Advertising in Audio, Video and Computer Cassettes/Discs and Similar Medium.
- SECTION 21. Restrictions on Advertising on the Internet and Similar Medium.
- SECTION 22. Ban on Advertisements.
- SECTION 23. Restrictions on Tobacco Promotions.
- SECTION 24. Naming Rights.
- SECTION 25. Restrictions on Sponsorships.
- SECTION 26. Ban on Sponsorships.
- SECTION 27. Prohibition on the Distribution of Samples of Tobacco Products to Persons Below 18 Years Old.
- SECTION 33. a. Tobacco Growers' 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; h. Withdrawal Clinics

- SECTION 34. Information Drive.

- SECTION 35. Instruction on the Hazardous Effect of Smoking as Part of School Curricula.

It is glaring that RA 9211 covers only post-production acts when the tobacco or its derivative is ready to be introduced to commerce and its after-effects. Section 30 of RA 9211 is clear on this matter, viz.:

Section 30. Application to Tobacco Products - This provision of this Act shall apply to all tobacco products placed into commerce in the Philippines. xxx (emphasis added)

Justice Caguioa nevertheless argues that the Health Secretary's vice-chairmanship of the IAC-T sufficiently vests said committee with authority to regulate all health aspects relating to tobacco and tobacco products under RA 9211.[26]

I respectfully differ.

The mere inclusion of the Health Secretary in the IAC-T does not mean that the agency surrenders its regulatory power over tobacco cigarettes in favor of the committee. Too, the policy declaration and statement of general purpose under Sections 2 and 3 of RA 9211 does not convincingly support his theory.[27] For under the specific provisions of RA 9211, the IAC-T has very limited concerns in relation to the health impact of tobacco products.

Specifically, the ambit of IAC-T's mandate under RA 9211 refers only to those mentioned therein – Smoking Ban in Public Places; Designated Smoking and Non-smoking Areas; Access Restrictions based on Age; Sale of Tobacco Products Within School Perimeters; Signages; Warnings on Cigarette Packages; Warnings in Advertising; Restrictions on Advertising; Restrictions on Print Media Advertising; Restrictions on Outdoor Advertising; Restrictions on Advertising in Cinemas; Restrictions on Television and Radio Advertising; Restrictions on Advertising in Audio, Video and Computer Cassettes/Discs and Similar Medium; Restrictions on Advertising on the Internet and Similar Medium; Ban on Advertisements; Restrictions on Tobacco Promotions; Naming Rights; Restrictions on Sponsorships; Ban on Sponsorships; Restrictions on Sampling to Minors. There are also Programs and Projects for which the IAC-T are responsible for. As regards health programs, the award of grants to hospitals for researches on smoke-related illnesses is the IAC-T's mandate.

Clearly, RA 9211 does not cover, for example, manufacturing health standards and health-related use standards. These pre-commerce concerns are therefore beyond the regulatory power of the IAC-T and falls squarely within the jurisdiction fo the FDA under RA 9711. To illustrate:

(image should be here)

To be sure, none of the provisions of RA 9211 squarely deal with the production and manufacture of tobacco and tobacco products. Surely, it would be a stretch to interpret RA 9211 as authorizing the IAC-T to regulate the production and manufacture of tobacco products when none of its provisions even make reference these activities. Thus, to fill this gap in RA 9211, the provisions of RA 9711 on the general authority of the FDA must come into play.

In fact, President Duterte issued last February 2020 his Executive Order No. 106 entitled PROHIBITING THE MANUFACTURE, DISTRIBUTION, MARKETING AND SALE OF UNREGISTERED AND/OR ADULTERATED ELECTRONIC NICOTINE/NON-NICOTINE DELIVERY SYSTEMS, HEATED TOBACCO PRODUCTS AND OTHER NOVEL TOBACCO PRODUCTS, AMENDING EXECUTIVE ORDER NO. 26 (S. 2017) AND FOR OTHER PURPOSES, which recognized and utilized the FDA's jurisdiction under RA 9711 to deal with Electronic Nicotine and Non-Nicotine Delivery Systems (ENDS/ENNDS) and heated tobacco products (HTPs). Particularly, the role of the FDA was delineated as follows: (i) registration of all e-liquids, solutions or

refills forming components of ENDS/ENNDS or HTPs; product standards for all devices forming components of ENDS/ENNDS or HTPs; licensing of all establishments engaged in the manufacture, distribution, importation, marketing and sale of ENDS/ENNDS, HTPs, or their components; licensing of entry/importation of ENDS/ENNDS, HTPs, and their components into the Philippine market.

On the other hand, EO 245 covers acts that are meant to "promote the development of the tobacco industry and to improve the quality of life of all those who depend upon the industry as a source of livelihood, especially the tobacco farmers" (Section 1). The powers and functions^[28] of the National Tobacco Administration (NTA) are circumscribed by these purposes under Section 2:

- a. To improve the economic and living conditions and raise the quality of life of the tobacco farmers including those who depend upon the industry for their livelihood; and
- b. To promote the balanced and integrated growth and development of the tobacco industry to help make agriculture a solid basis for industrialization.

Obviously, the NTA under EO 245 does not have jurisdiction over health aspects of tobacco and its derivatives. The NTA is concerned only with acts that can be described as economic and industry-related. Therefore, so long as the FDA does not regulate those acts referred to above as belonging to the NTA, the FDA would be within its right and authority to do so.

In the exercise of its jurisdiction, the FDA cannot act in a manner that would prevent the other specialized agencies from doing the acts covered by their specialized laws, here, RA 9211 and EO 245. This is pursuant to Section 25 of RA 9711.

But whether the FDA has breached this boundary must be resolved on a case-by-case basis.

For example, if a tobacco product has been laced with cyanide or illegal drugs, the FDA would be within its right and jurisdiction to prohibit this product from reaching the market. While this may have an impact on the NTA's mandate to protect the tobacco industry as an economic base for tobacco workers, though a small impact it may be, the resolution of this issue will not depend upon a bright-line rule but the balancing of interests. This inevitably calls for a fact-centered analysis – hence, the necessity for an actual case or controversy and the precise allegation and proof of injury or at least threat of injury. This inquiry cannot proceed on speculations or hypothetical assertions, much less, on the absence of facts as in the present case.

This segues to a clarification of the FDA's jurisdiction. Contrary to our holding, the FDA is not only concerned with a health product's safety and efficacy. There are other equally compelling standards under RA 9711 that the FDA must weigh and consider in the exercise of its jurisdiction. Some of these standards are:

- good quality,
- purity,
- rational use,
- strength,
- registration with FDA,
- compliance with regulations regarding operation of manufacturers, importers, exporters, distributors, wholesalers, drug outlets, and other establishments and facilities of health products,
- reasonable indication that a product has caused or contributed to the death, serious illness or serious injury to a

consumer, a patient, or any person,

- finding of imminent injury, or dangerous or grossly deceptive characteristics,
- presence of and implementation of a risk management plan,
- presence or strengthening of post market surveillance system in monitoring health products,
- adulteration or manufacturing, preparation or storage under unsanitary conditions,
- current good manufacturing practice,
- false or misleading labelling (but must tread carefully so as not to unduly usurp the functions of the Inter-Agency-Tobacco under RA 9211),
- transparency as to the methods used in and the facilities and controls used for the manufacture of a drug or device,
- assessment of the methods used in, and the facilities of a drug or device to determine adequacy to preserve its identity, strength, quality and purity, among others.

In addition, the FDA is not hamstrung to simply prohibit tobacco and its derivatives. RA 9711 has provided the FDA with an arsenal of remedies and enforcement actions when its standards are breached.[29] Before even that point is reached, RA 9711 has mandated FDA to observe procedural fairness before imposing any remedy or enforcement action, which includes coordinating with and hearing other specialized agencies and stakeholders.

Clearly, it is not correct for us to oust the FDA of any and all jurisdiction over tobacco and its derivatives. The language of RA 9711 precludes this conclusion. A sensible and sensitive reading of Section 25, RA 9711 and the specialized jurisdictions of other agencies disproves our conclusion. What is at stake is not an all or nothing proposition, but a nuanced harmonization and congruence of the several jurisdictions at play vis-à-vis the almighty tobacco.

ACCORDINGLY, I vote to grant the petition, reverse and set aside the decisions of the Regional Trial Court and the Court of Appeals, dismiss the petition for declaratory relief, and affirm the validity of Article III, Book II of the Implementing Rules and Regulations of RA 9711.

[1] *Belgica v. Executive Secretary*, G.R. No. 210503, October 8, 2019 [Belgica]: "Jurisprudence defines an actual case or controversy as one which 'involves a conflict of legal rights, an assertion of opposite legal claims, susceptible of judicial resolution as distinguished from a hypothetical or abstract difference or dispute.' Subsumed in the requirement of an actual case or controversy is the requirement of ripeness, and '[f]or a case to be considered ripe for adjudication, it is a prerequisite that something has then been accomplished or performed by either branch before a court may come into the picture, and the petitioner must allege the existence of an immediate or threatened injury to himself as a result of the challenged action.' To be sure, the Court may not wield its power of judicial review to address a hypothetical problem. 'Without any completed action or a concrete threat of injury to the petitioning party, the act is not yet ripe for adjudication.'"

[2] *Senate v. Ermita*, 522 Phil. 1, 27 (2006): "It is well-settled that the Court's exercise of the power of judicial review requires the concurrence of the following elements: (1) there must be an actual case or controversy calling for the exercise of judicial power; (2) the person challenging the act must have the standing to question the validity of the subject act or issuance; otherwise stated, he must have a personal and substantial interest in the case such that he has sustained, or will sustain, direct injury as a result of its enforcement; (3) the question of

constitutionality must be raised at the earliest opportunity; and (4) the issue of constitutionality must be the very *lis mota* of the case."

[3] *Belgica v. Executive Secretary*, *supra*.

[4] 809 Phil. 65, 68-82 (2017).

[5] 718 Phil. 294, 305-306 (2013).

[6] Preservation of Permanent Public Works and Monuments of Value to Philippine History and Culture, Act No. 3720, November 21, 1930.

[7] Food and Drug Administration (FDA) Act of 2009, Republic Act No. 9711, August 18, 2009.

[8] SECTION 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.

[9] Tobacco Regulation Act of 2003, Republic Act No. 9211, June 23, 2003.

[10] See e.g., Peter Applegarth, *Deciding Novel and Routine Cases Without Evidence*, 11 J. Tort L. 173, 206-07 (2018): "At least in some common law jurisdictions, judges recognize that they are ill-equipped to make policy decisions which involve the evaluation of social facts about which the court has little or no evidence on the record and slender *207 knowledge based upon reliable 'outside information'".

[11] Food and Drug Administration (FDA) Act of 2009, Republic Act No. 9711, August 18, 2009.

[12] 815 Phil. 1067-1174 (2017).

[13] G.R. No. 212719, June 25, 2019.

[14] G.R. No. 247471, July 7, 2020.

[15] G.R. No. 217910, September 3, 2019.

[16] RA 9711 relevantly states: "SECTION 9. Section 10, subsections (a), (e), (f), (g), (h), (i), (q), (r), (v), and (w) of Republic Act No. 3720, as amended, are hereby further amended, and new subsections (x), (y), (z), (aa), (bb), (cc), (dd), (ee), (ff), (gg), (hh), (ii), (jj), (kk), (ll), and (mm) are hereby added to read as follows: SEC. 10. For the purposes of this Act, the term: (e) 'Food' means any processed substance which is intended for human consumption and includes drink for man, beverages, chewing gum and any substances which have been used as an ingredient in the manufacture, preparation or treatment of food."

[17] RA 9711 relevantly states: "SECTION 9. Section 10, subsections (a), (e), (f), (g), (h), (i), (q), (r), (v), and (w) of Republic Act No. 3720, as amended, are hereby further amended, and new subsections (x), (y), (z), (aa), (bb), (cc), (dd), (ee), (ff), (gg), (hh), (ii), (jj), (kk), (ll), and (mm) are hereby added to read as follows: SEC. 10. For the purposes of this Act, the term: "(f) 'Drug' means: ... (3) articles (other than food) intended to affect the structure of any function of the body of humans or animals....

[18] RA 9711 relevantly states: "SECTION 9. Section 10, subsections (a), (e), (f), (g), (h), (i), (q), (r), (v), and (w) of Republic Act No. 3720, as amended, are hereby further amended, and new subsections (x), (y), (z), (aa), (bb), (cc), (dd), (ee), (ff), (gg), (hh), (ii), (jj), (kk), (ll), and (mm) are hereby added to read as follows: SEC. 10. For the purposes of this Act, the term: "(g) 'Device' means medical devices, radiation devices and health-related devices.... "(3) 'Health-related device' means any device not used in health care but has been determined by the

FDA to adversely affect the health of the people.

[19] RA 9711 relevantly states: "SECTION 9. Section 10, subsections (a), (e), (f), (g), (h), (i), (q), (r), (v), and (w) of Republic Act No. 3720, as amended, are hereby further amended, and new subsections (x), (y), (z), (aa), (bb), (cc), (dd), (ee), (ff), (gg), (hh), (ii), (jj), (kk), (ll), and (mm) are hereby added to read as follows: SEC. 10. For the purposes of this Act, the term: "(ff) 'Health products' means food, drugs, cosmetics, devices, biologicals, vaccines, in-vitro diagnostic reagents and household/urban hazardous substances and/or a combination of and/or a derivative thereof. It shall also refer to products that may have an effect on health which require regulations as determined by the FDA.

[20] SECTION 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.

[21] 529 U.S. 120 (2000).

[22] Food and Drug Administration (FDA) Act of 2009, Republic Act No. 9711, August 18, 2009.

[23] Food and Drug Administration (FDA) Act of 2009, Republic Act No. 9711, August 18, 2009.

[24] Tobacco Regulation Act of 2003, Republic Act No. 9211, June 23, 2003.

[25] Creation of the National Tobacco Administration, Executive Order No. 245, July 24, 1987.

[26] J. Caguioa, Reflections, p. 11.

[27] Id. at 12.

[28] Section 3, B. Specific Powers. – The NTA shall have the following specific powers and functions: 1. To promulgate and enforce rules and regulations on the production, standardization, classification, grading and trading of tobacco and tobacco products as may be necessary to attain its purposes and objectives and to pursue the policy of government on tobacco; 2. To conduct agricultural and industrial research and to establish, operate and maintain experimental stations; 3. To accept and receive financial and other support from private and other sources for the development and promotion of the Philippine tobacco industry; 4. To provide incentives and other financial assistance to tobacco growers and association thereof, directly in conjunction with accredited financial institutions; 5. Impose administrative sanctions for violation of the rules and the regulations issued by the NTA.

[29] RA 9711 empowers the FDA to impose measures in relation to licensing and registration, publicity and publication, and administrative sanctions. For instance, under Section 29, the FDA may impose these measures: Publicity and Publication, SECTION 29. (a) The Secretary may cause to be disseminated information regarding foods, drugs, devices, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health, or gross deception to the consumer. Nothing in this Section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Department.; Administrative Sanctions, SECTION 29-A. Administrative Sanctions. – Where there is finding of prohibited actions and determination of the persons liable thereto, after notice and hearing, the director-general is empowered to impose one or more of the following administrative penalties: (1) Cancellation of any authorization which may have been granted by the FDA, or suspension of the validity thereof for such period of time as the director-general may deem reasonable which shall not exceed one (1) year; (2) A fine of not less than Fifty thousand pesos (P50,000.00) but not more than Five hundred thousand pesos (P500,000.00). An additional fine of not more than One thousand pesos (P1,000.00) shall be imposed for each day of continuing violation; and (3) Destruction and/or

appropriate disposition of the subject health product, and/or closure of the establishment for any violation of this Act, as determined by the director-general.

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