EN BANC

G.R. No. 200431 — THE DEPARTMENT OF HEALTH, represented by SECRETARY ENRIQUE T. ONA, and THE FOOD AND DRUG ADMINISTRATION, represented by DIRECTOR SUZETTE HENARES-LAZO, *petitioners*, ***versus*** **PHILIPPINE TOBACCO INSTITUTE, INC.,** *respondent*.

SENATORS PILAR JULIANA S. CAYETANO and FRANKLIN M. DRILON, *petitioners-intervenors*.

REPRESENTATIVE EDCEL C. LAGMAN, *respondent-intervenor*.

Promulgated:

July 13, 2021

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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

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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.

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

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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 (GRP)*, 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.

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

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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.

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.
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> 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

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[22] Id. at 619-621.

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.*

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

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

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

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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.

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]

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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.

> 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.

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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.

> 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.

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[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.

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 farmers, 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

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

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.
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> (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.

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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.

> 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

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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.

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

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[56] Supra note 41.

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

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.

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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[.]

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)

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[65] Supra note 33.
[66] Id. at 316.

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.

ALFREDO BENJAMIN S. CAGUIOA
Associate Justice