EN BANC

G.R. No. 200431 – ***Department of Health represented by Secretary Enrique T. Ona and Food and Drug Administration, represented by Director Suzette Henares-Lazo v. Philippine Tobacco Institute, Inc.; Senator Franklin "Frank" Drilon and Senator Pilar Juliana "Pia" S. Cayetano and Edcel C. Lagman, intervenors***

Promulgated:

July 13, 2021

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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]

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[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.

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.**
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> ....
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> We deny the petition.
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> 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.
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> 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.
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> 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**

[4] 809 Phil. 65, 68-82 (2017).
[5] 718 Phil. 294, 305-306 (2013).

> **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.**
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> ....
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> **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.
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> 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

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[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.

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

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[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.

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**

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[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.

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 undersoring 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.
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> 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.
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> 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...
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> ....

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[14] G.R. No. 247471, July 7, 2020.
[15] G.R. No. 217910, September 3, 2019.

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....
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> ....

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.**
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> **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.**
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> **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.
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> **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.
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> 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**

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[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.

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:

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[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).

> 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

[22] Food and Drug Administration (FDA) Act of 2009, Republic Act No. 9711, August 18, 2009.

> 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**:

1. SECTION 5. Smoking Ban in Public Places.
2. SECTION 6. Designation of Smoking and Non-smoking Areas.

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[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.

3. SECTION 7. Prohibition and/or Regulation of Vending Machines, Self-Service Facilities.
4. SECTION 8. Removal of all non-compliant tobacco-related self-service displays or facilities, advertising, labeling and other items.
5. SECTION 9. Prohibition of Minors from Using, Selling Cigarettes.
6. SECTION 10. Prohibition of Sale of Tobacco Products Within School Perimeters.
7. SECTION 11. Signage Requirements.
8. SECTION 12. Requirement of Proof of Age Verification.
9. SECTION 13. Warnings on Cigarette Packages.
10. SECTION 14. Warnings in Advertising.
11. SECTION 15. Restrictions on Advertising.
12. SECTION 16. Restrictions on Print Media Advertising.
13. SECTION 17. Restrictions on Outdoor Advertising.
14. SECTION 18. Restrictions on Advertising in Cinemas.
15. SECTION 19. Restrictions on Television and Radio Advertising.
16. SECTION 20. Restrictions on Advertising in Audio, Video and Computer Cassettes/Discs and Similar Medium.
17. SECTION 21. Restrictions on Advertising on the Internet and Similar Medium.
18. SECTION 22. Ban on Advertisements.
19. SECTION 23. Restrictions on Tobacco Promotions.
20. SECTION 24. Naming Rights.
21. SECTION 25. Restrictions on Sponsorships.
22. SECTION 26. Ban on Sponsorships.
23. SECTION 27. Prohibition on the Distribution of Samples of Tobacco Products to Persons Below 18 Years Old.
24. 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
25. SECTION 34. Information Drive.
26. 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

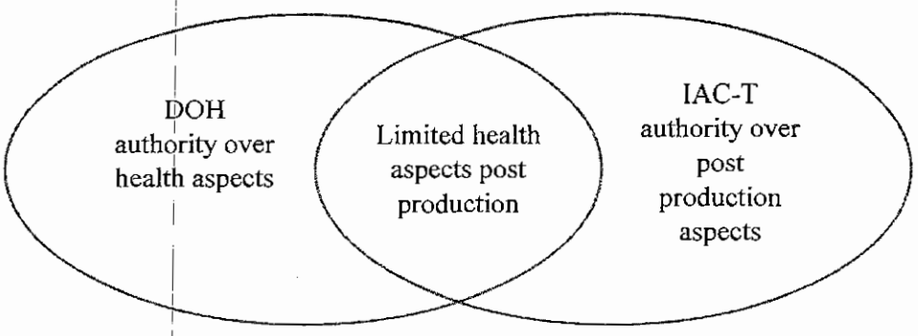
regulate **all health aspects** relating to tobacco and tobacco products under RA 9211.[26]

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:



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

[26] J. Caguioa, Reflections, p. 11.
[27] *Id.* at 12.

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.**

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[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.

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.

AMY C. LAZARO-JAVIER
Associate Justice

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[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.