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*, *v.* **PHILIPPINE TOBACCO INSTITUTE,** *Respondent.*

Promulgated:

July 13, 2021

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CONCURRING OPINION

PERLAS-BERNABE, *J.*:

I concur.

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

To recount, the case began when respondent Philippine Tobacco Institute, Inc. (PTI) filed a petition for declaratory relief before the Regional Trial Court of Las Piñas City, Branch 255 (RTC) seeking to prohibit the enforcement of the FDA IRR on the ground that it unduly expands RA 9711, insofar as it classified tobacco products as "health products," and hence, unduly placed the same under the FDA's regulatory power.[2]

PTI contended that under RA 9211,[3] otherwise known as the "Tobacco Regulation Act of 2003," it is the Inter-Agency Committee on Tobacco (IAC-Tobacco) which has exclusive jurisdiction over tobacco products, including

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

2 See *ponencia*, pp. 3-6.

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

its health aspects, and not the FDA. As basis, it cited Section 25[4] of RA 9711 which specifically excluded tobacco products from the FDA's jurisdiction.[5]

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

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

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

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

On this score, it is worthy to point out that RA 9211 provides for the inclusion of warnings on cigarette packages, such as "GOVERNMENT WARNING: Cigarette Smoking is Dangerous to Your Health;"

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

5 See *ponencia*, p. 5

6 See id. at 6.

7 See id. at 6-7.

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

9 RA 9711 provides:

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

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

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

> Section 25. *Coverage.* – This Act shall govern all health products: *Provided,* **That nothing in this Act shall be deemed to modify the sole and exclusive jurisdiction of other specialized agencies and special laws only insofar as the acts covered by these specialized agencies and laws, including, but not limited to, those covered by Republic Act No. 9211** [or **the Tobacco Regulation Act of 2003**], Executive Order No. 245, Executive Order No. 18, and Presidential Decree No. 1468. (emphasis supplied)

However, a study of the Congressional deliberations on RA 9711 would reveal that the **legislature apparently intended to include tobacco as a health product, which is subject to regulation by the FDA at least insofar as its health aspect is concerned**. As stated during the deliberations, "[t]he confusion may arise that these special laws somehow cover the health aspect when it is really not their expertise even if they claim that they have some kind of say in it. x x x [I]t should be very clear that this law, the FDA bill[,] will be now in-charge of the health aspect. And in that sense, [it is] suppletory to whatever mandate the special laws have on those products but the health aspects is an FDA affair,"[13] *viz.*:

> REP. LOCSIN. Madam Chair, may I ask, Your Honor, Senator Legarda, **do any of these agencies – sugar, coconut, tobacco – have the capability to enhance FDA that we have envisioned to monitor the health effects of the products of these sectors**? I think none of them [does], none of them has the capabilities to monitor the health effects of any of these products that the new [Bureau of Food and Drugs (BFAD)] will have. **Unless there is actually a scientific component to RA 9211, because I [do not] want this to be seen as preventing BFAD, the new BFAD[,] from making a declaration against tobacco** if they feel the way the surgeon general in the United States does. x x x

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[10] See Section 13 of RA 9211.

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

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

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

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

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

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

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

THE CHAIRPERSON (SEN. CAYETANO, P.). In fact, I was thinking in Section 26 just to clarify that further. In the very last sentence, it says, "This Act shall be applied in suppletory character." The intention of that was to say that the BFAD, the new FDA law and BFAD's previous function continues to exist but really what we really need to be sure is not misinterpreted, is that BFAD, **the new FDA is the authority as far as health is concerned.**

So I was thinking and you did make a very simple statement that, I guess something like, **with respect to the health aspect, the FDA shall continue to exercise its mandate**. Something like that so that there is no confusion. I think the records will bear out all that – do you hear me? Okay.

x x x x

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

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

> **whatever mandate the special laws have on those products but the health aspects is an FDA affair.**[14] (emphases supplied)

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

> REP. LOCSIN. I think this Section 26 can be left as it is.
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> THE CHAIRPERSON (SEN. CAYETANO, P.). Actually, [it is] not even necessary.
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> REP. LOCSIN. [That is] also true.
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> THE CHAIRPERSON (SEN. CAYETANO, P.). [It is] [kind of] redundant.
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> REP. LAGMAN. Yeah, [it is] redundant altogether. We might as well remove it. That is not anymore a useful surplusage.
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> THE CHAIRPERSON (SEN. CAYETANO, P.). So we go to Section 25 *na lang*.
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> x x x x
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> THE CHAIRPERSON (SEN. CAYETANO, P.). x x x May I just raise concern, *'no*. **On Section 25 and 26, we just agreed to delete 26**. But the BFAD is just ensuring that our intention here is that they will continue to do the work they were doing with respect to health products because they wanted us to include the suppletory effect. But my understanding is that **this provision exactly says what we want to say which is they will continue to govern health products**. x x x[15] (emphases supplied)

For these reasons, it appears that notwithstanding RA 9211 which created the IAC-Tobacco, Congress intended for tobacco products to be considered as health products, which limited aspect falls under the regulatory jurisdiction of the FDA. Verily, **Section 25 of RA 9711** – which essentially provides that the FDA shall have jurisdiction over health products except "only insofar as the acts covered by these specialized agencies and laws" – **does not preclude the FDA's retention of regulatory powers over the health aspect of certain products, such as tobacco**. The reasonable harmonization therefore would be that, insofar as tobacco products are concerned, Section 25 maintains both the jurisdiction of the FDA and the IAC-Tobacco. On the one hand, the FDA has regulatory jurisdiction only over the

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

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

health aspect of tobacco products, such as the determination of the amount of nicotine in tobacco products; on the other hand, the IAC-Tobacco has regulatory jurisdiction over all the other aspects of tobacco products, such as packaging, use, sale, distribution, and advertisements, which are the functions and processes provided for under RA 9211. To repeat, as stated in Section 29 of RA 9211, the IAC-Tobacco "shall have the exclusive power and function to administer and implement the provisions of this Act." RA 9211 is distinct and separable from the FDA Act (*i.e.*, RA 9711) in that it does not directly regulate the health aspects of tobacco.

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

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

> BOOK II
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> x x x x
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> ARTICLE III
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> Tobacco and Other Products
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> SECTION 1. *Rationale.* – The FDA has full jurisdiction over the regulation of all health products.
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> 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.
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> 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

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

to the Secretary of Health, the appropriate rules and regulations and other issuances to implement this Section.

b. Protection against Tobacco Industry Interference. The FDA shall act to protect the formulation and implementation of rules and regulations under this Section from commercial and other vested interests of the tobacco industry, including organizations, entities, associations, individuals, and others that work to further the interests of the tobacco industry.

The FDA shall not deal with the tobacco industry or individuals or entities that work to further the interests of the tobacco industry, except to the extent strictly necessary to effectively regulate, supervise, or control the tobacco industry in relation to tobacco and tobacco products.

SECTION 3. *Other Products.* – Nothing in the FDA Act of 2009 shall be deemed to modify the jurisdiction of other specialized agencies and special laws only insofar as the acts covered by these specialized agencies and laws <u>except the health aspects of such products.</u>

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 **<u>that are not covered by specialized agencies and special laws, including, but not limited to, those covered by Republic Act No. 9211</u>**, Executive Order No. 245, Executive Order No. 18, and Presidential Decree No. 1468. (emphases and underscoring supplied)

ACCORDINGLY, I vote to **GRANT** the petition.

ESTELA M. PERLAS-BERNABE
Senior Associate Justice