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Republic of the Philippines  
Supreme Court  
Manila

EN BANC

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

G.R. No. 200431

Present:

GESMUNDO, *Chief Justice*,  
PERLAS-BERNABE,  
LEONEN,  
CAGUIOA,  
HERNANDO,  
CARANDANG,  
LAZARO-JAVIER,  
INTING,  
ZALAMEDA,  
LOPEZ, M.,  
GAERLAN,  
ROSARIO, and  
LOPEZ, J., *JJ.*

SENATORS PILAR JULIANA "PIA" S. CAYETANO and FRANKLIN "FRANK" M. DRILON,  
Petitioners-Intervenors,

-versus-

PHILIPPINE TOBACCO INSTITUTE, INC.,  
Respondent.

REPRESENTATIVE EDCEL C. LAGMAN,  
Respondent-Intervenor.

Promulgated:  
July 13, 2021

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DECISION

**LEONEN, J.:**

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

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

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

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

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

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<sup>1</sup> *Rollo* pp. 73–78. The January 27, 2012 Decision was penned by Acting Presiding Judge Romulo SG. Villanueva of the Regional Trial Court of Las Piñas City, Branch 255.

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

<sup>3</sup> See Executive Order No. 85 (1982), sec. 4.

<sup>4</sup> Executive Order No. 175 amended, among others, the title of Republic Act No. 3720 to "Foods, Drugs and Devices, and Cosmetics Act."

<sup>5</sup> 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.

<sup>6</sup> Republic Act No. 9711 (2009), sec. 1.

<sup>7</sup> Republic Act No. 9711 (2009), sec. 3 and Republic Act No. 3720 (1963), sec. 4, as amended by Republic Act No. 9711 (2009), sec. 5.

<sup>8</sup> Republic Act No. 9711 (2009), sec. 22 reads:

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

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

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

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

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

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

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<sup>9</sup> *Rollo*, pp. 179–226, Petition for Declaratory Relief.

<sup>10</sup> *Id.* at 179.

<sup>11</sup> *Id.* at 182.

<sup>12</sup> *Id.* at 195.

<sup>13</sup> *Id.* at 198–199.

<sup>14</sup> *Id.* at 198–200.

<sup>15</sup> *Id.* at 194.

<sup>16</sup> *Id.* at 189.

<sup>17</sup> *Id.* at 187–188.

**BOOK II****ARTICLE III***Tobacco and Other Products*

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

SECTION 2. Tobacco. — The DOH, tasked with protecting the public's health against the injurious effects arising from the use of tobacco and tobacco products, has the responsibility of regulating tobacco and tobacco products through the FDA.

- a. Rules and Other Issuances to Implement this Section. Within a reasonable period from the date of effectivity of these Rules and Regulations, the FDA shall prepare and recommend for the approval to the Secretary of Health, the appropriate rules and regulations and other issuances to implement this Section.
- b. Protection against Tobacco Industry Interference. The FDA shall act to protect the formulation and implementation of rules and regulations under this Section from commercial and other vested interests of the tobacco industry, including organizations, entities, associations, individuals, and others that work to further the interests of the tobacco industry.

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

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

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

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

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<sup>18</sup> Id. at 216–218.

<sup>19</sup> Id. at 219.

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

## **BOOK II**

### **ARTICLE I**

#### *Licensing of Establishments and Registration of Health Products*

##### SECTION 1. General Provisions. —

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

....

### **ARTICLE II**

#### *Labeling of Health Products*

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

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### **ARTICLE V**

#### *Advertisements, Promotions, Sponsorship, and Other Marketing Activities*

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

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

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

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<sup>20</sup> Id. at 208–213.

<sup>21</sup> Id. at 208.

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

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

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

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

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

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

On September 28, 2011, the Regional Trial Court denied PTI’s move for injunction,<sup>27</sup> and on December 15, 2011, denied its move for reconsideration.<sup>28</sup>

Later, in a January 27, 2012 Decision,<sup>29</sup> the Regional Trial Court ruled

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<sup>22</sup> Id. at 260, Answer.

<sup>23</sup> Id. at 232–236.

<sup>24</sup> Id. at 242.

<sup>25</sup> Id. at 249.

<sup>26</sup> Id. at 254.

<sup>27</sup> Id. at 1140–1144, RTC Order.

<sup>28</sup> Id. at 73, RTC Decision.

<sup>29</sup> Id. at 73–78.

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

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

MR. POLIG (Head, Legal Department, Bureau of Food and Drugs) Yes, Madam-Chairman. While the definition on health products, particularly the last portion, practically covers every . . . every pro . . . other products that may have an effect on health on it is my . . . my opinion that since the . . . the law on that covers like tobacco is a special law, separate . . . hindi na po siya kasama dito Your Honor. (Exhibit D 45-46).<sup>33</sup> (Emphasis in the original)

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

The dispositive portion of the Regional Trial Court Decision reads:

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

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<sup>30</sup> Id. at 78.

<sup>31</sup> Id. at 76-77.

<sup>32</sup> Id. at 77.

<sup>33</sup> Id.

<sup>34</sup> Id. at 76.

SO ORDERED.<sup>35</sup>

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

On August 28, 2012, PTI filed its Comment<sup>37</sup> to the Petition.

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

On December 17, 2013, respondent-intervenor Representative Edcel C. Lagman filed his Opposition-in-Intervention.<sup>39</sup>

On September 9, 2014, this Court required the parties and intervenors to file their memoranda.<sup>40</sup>

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

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

Petitioners emphasize that the Department of Health's primary responsibilities of formulating and implementing health policies and

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<sup>35</sup> Id. at 78.

<sup>36</sup> Id. at 13–72, Petition for Review.

<sup>37</sup> Id. at 498–538, Comment.

<sup>38</sup> Id. at 1089–1139, Petition-in-Intervention.

<sup>39</sup> Id. at 1214–1290, Opposition-in-Intervention.

<sup>40</sup> Id. at 1893–1894.

<sup>41</sup> Id. at 25, Petition for Review.

<sup>42</sup> Id. at 45–50.

<sup>43</sup> Id. at 53–55 and 1868–1870.

<sup>44</sup> Id. at 56–58, 1857, and 1860.

<sup>45</sup> Id. at 61–62 and 1858–1859.

programs were neither amended nor repealed by Republic Act No. 9211.<sup>46</sup> Republic Act No. 9711, on the other hand, was enacted to strengthen the State's regulatory and enforcement capacity over health products.<sup>47</sup> These laws do not confuse or merge the functions of the Food and Drug Administration and the IAC-Tobacco, petitioners say.<sup>48</sup>

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

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

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

Petitioners-intervenors also contend that Republic Act No. 9211 does not address all obligations required under the WHO FCTC.<sup>57</sup> It "regulates only certain aspects [of the tobacco industry], particularly sale and distribution, signages, smoke-free places, textual warnings on cigarette packages, advertisements, promotions and sponsorship."<sup>58</sup> The IAC-Tobacco's task is merely compliance monitoring and program development, petitioners-intervenors say, while the implementation of programs and projects lies with the member-agencies of the IAC-Tobacco.<sup>59</sup>

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<sup>46</sup> Id. at 62 and 1864-1865.

<sup>47</sup> Id. at 65.

<sup>48</sup> Id. at 1874 and 1876.

<sup>49</sup> Id. at 32-35 and 1852-1853.

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

<sup>51</sup> Id. at 98-104. Protection of the Bureaucracy against Tobacco Industry Interference.

<sup>52</sup> Id. at 37, 1850, and 1856.

<sup>53</sup> Id. at 39-43 and 1853-1855.

<sup>54</sup> Id. at 1098.

<sup>55</sup> Id. at 1097.

<sup>56</sup> Id. at 1097-1099 and 1838.

<sup>57</sup> Id. at 1113.

<sup>58</sup> Id. at 1111.

<sup>59</sup> Id. at 1115-1116.

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

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

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

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

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

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<sup>60</sup> Id. at 1101.

<sup>61</sup> Id. at 1101–1109 and Memorandum for Petitioners-Intervenors, pp. 12–19.

<sup>62</sup> Id. at 1096.

<sup>63</sup> Memorandum for Petitioners-Intervenors, pp. 7–8.

<sup>64</sup> Id. at 8.

<sup>65</sup> *Rollo*, pp. 506–507, Comment.

<sup>66</sup> Id. at 508 and Memorandum for Respondent, p. 36.

<sup>67</sup> Id. at 515 and Memorandum for Respondent, p. 22.

<sup>68</sup> Id. at 521–522.

<sup>69</sup> Id. at 513 and Memorandum of Respondent, pp. 18–19.

<sup>70</sup> Id. at 513.

advertising, sponsorship, and marketing of tobacco products.<sup>71</sup>

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

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

Respondent-intervenor adds that Republic Act No. 9211 effectively amended the Department of Health’s general powers on health matters under the Administrative Code.<sup>78</sup> He opposes the inclusion of tobacco products and the tobacco industry in the Implementing Rules pursuant to DOH Memorandum No. 2010-0126, Joint Memorandum Circular No. 2010-01, and the WHO FCTC, claiming that petitioners “were tasked to implement solely the provisions of [Republic Act No. 9711], not any administrative fiat or international covenant which could stand on their own.”<sup>79</sup> He adds that the WHO FCTC is “addressed principally to the State Parties’ legislature, not to mere administrative bodies.”<sup>80</sup>

Respondent-intervenor contends that having “[d]ual jurisdiction will definitely spawn conflicts and confusion which may be inimical to the government’s health agenda on tobacco products.”<sup>81</sup> With the Department of Health’s vast functions in protecting the people’s health, it would allegedly “be best for a specialized agency like the IAC-Tobacco to focus on a particular[ly] deleterious product [which is] tobacco.”<sup>82</sup> He points out that ascertaining the correctness of the legislature’s wisdom behind excluding

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<sup>71</sup> Id. at 528–532.

<sup>72</sup> Id. at 535 and Memorandum for Respondent, p. 58.

<sup>73</sup> Id.

<sup>74</sup> Memorandum for Respondent-Intervenor, p. 22.

<sup>75</sup> Id. at 1228, Opposition-in-Intervention, and Memorandum for Respondent-Intervenor, p. 26.

<sup>76</sup> Id. at 1225 and Memorandum for Respondent-Intervenor, p. 23.

<sup>77</sup> Id. at 1229 and Memorandum for Respondent-Intervenor, p. 27.

<sup>78</sup> Id. at 1285 and Memorandum for Respondent-Intervenor, pp. 50–51.

<sup>79</sup> Memorandum for Respondent-Intervenor, p. 53.

<sup>80</sup> Id.

<sup>81</sup> *Rollo*, p. 1245, Opposition-in-Intervention.

<sup>82</sup> Id.

tobacco products and the tobacco industry from the coverage of Republic Act No. 9711 is beyond the authority of any court or administrative body to correct or defy.<sup>83</sup>

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

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

Subsumed under this are two issues:

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

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

The Petition is granted.

## I

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

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

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<sup>83</sup> Id. at 1258-1259.

<sup>84</sup> Id. at 1248.

<sup>85</sup> Id.

<sup>86</sup> Id.

<sup>87</sup> CONST., art. II, sec. 15 and ADM. CODE, Book IV, Title IX, Ch. 1, sec. 1.

<sup>88</sup> ADM. CODE, Book IV, Title IX, Ch. 1, sec. 2.

its powers and functions are:

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

- (1) *Define the national health policy and formulate and implement a national health plan* within the framework of the government's general policies and plans, and present proposals to appropriate authorities on national issues which have health implications;
- (2) Provide for health programs, services, facilities and other requirements as may be needed, subject to availability of funds and administrative rules and regulations;
- (3) Coordinate or collaborate with, and assist local communities, agencies and interested groups including international organizations in activities related to health;
- (4) *Administer all laws, rules and regulations in the field of health*, including quarantine laws and food and drug safety laws;
- (5) Collect, analyze and disseminate statistical and other relevant information on the country's health situation, and require the reporting of such information from appropriate sources;
- (6) *Propagate health information and educate the population on important health, medical and environmental matters which have health implications*;
- (7) Undertake health and medical research and conduct training in support of its priorities, programs and activities;
- (8) Regulate the operation of and issue licenses and permits to government and private hospitals, clinics and dispensaries, laboratories, blood banks, drugstores and such other establishments which by the nature of their functions are required to be regulated by the Department;
- (9) *Issue orders and regulations concerning the implementation of established health policies*; and
- (10) Perform such other functions as may be provided by law.<sup>89</sup>  
(Emphasis supplied)

As the national technical authority on health, the Department of Health serves as the key government agency for promoting tobacco control in the country. In 1987, the then Non-Communicable Disease Control Service,<sup>90</sup> under the Department's Public Health Services, developed a five-year national smoking control plan as its primary strategy in the lung cancer prevention program. The plan aimed to reduce the national prevalence of smoking by 10% in 1997, render all the department facilities smoke-free by

<sup>89</sup> ADM. CODE, Book IV, Title IX, Ch. 1, sec. 3.

<sup>90</sup> Created under Executive Order No. 119, January 30, 1987.

1993, and ban smoking among elementary and high school students.<sup>91</sup> To increase public awareness against smoking, it launched its anti-smoking campaign in the 1990s, through its “Yosi Kadiri” iconic mascot and media campaigns, to illustrate the detrimental effects of cigarette smoking on the health of both smokers and non-smokers.<sup>92</sup>

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

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

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

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<sup>91</sup> Administrative Order No. 122 (2003), A Smoking Cessation Program to support the National Tobacco Control and Healthy Lifestyle Program.

<sup>92</sup> Chino Leyco, *Gov't revives 'Yosi Kadiri' mascot vs. smoking*, MANILA BULLETIN, May 16, 2019, available at <[https://doh.gov.ph/sites/default/files/news\\_clips/051619-0005.pdf](https://doh.gov.ph/sites/default/files/news_clips/051619-0005.pdf)> (last accessed on August 26, 2021).

<sup>93</sup> Republic Act No. 7394 (1992), art. 2.

<sup>94</sup> Republic Act No. 7394 (1992), art. 2.

<sup>95</sup> Republic Act No. 7394 (1992), Title II, Chapters 1 to III.

<sup>96</sup> Republic Act No. 7394 (1992), art. 75.

<sup>97</sup> Republic Act No. 7394 (1992), art. 109.

<sup>98</sup> Republic Act No. 7394 (1992), art. 4(ak) states:

ak) “Hazardous substance” means:

(1) (i) Any substance or mixture of substances which is toxic, corrosive, irritant, a strong sensitizer, flammable or combustible, or generates pressure through decomposition, heat or other means, if such substance or mixture or substances may cause substantial injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable ingestion by children;

(ii) Any substance which the department finds to be under the categories enumerated in clause (1) (i) of this paragraph;

(iii) Any radioactive substance, if, with respect to such substance as used in a particular class of article or as packaged, the Department, upon approval of the Department determines by regulation that the substance is sufficiently hazardous to require labeling in accordance with this section in order to protect the public health;

(iv) Any toy or other articles intended for use by children which the director may, by regulation, determine the presence of an electrical, mechanical or thermal hazard.

(2) This term shall not apply to food, drugs, cosmetics, and devices nor to substances intended for use as fuels when stored in containers and used in the heating, cooking or refrigeration system of a house, but such term shall apply to any article which is not in itself a pesticide but which is a hazardous substance, as construed in clause (a) of paragraph (1), by reason of bearing or containing such harmful substances described therein.

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

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

That same year, the Department of Health issued Administrative Order No. 8, prohibiting smoking in all its offices, agencies, hospitals, and premises nationwide. A 100% smoke-free policy was later established for all government agencies, local government units, and state universities,<sup>102</sup> as well as in public utility vehicles and land transportation terminals.<sup>103</sup>

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

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<sup>99</sup> Republic Act No. 7394 (1992), art. 77.

<sup>100</sup> Republic Act No. 7394 (1992), art. 94 provides:

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

<sup>101</sup> Republic Act No. 7394 (1992), arts. 6 and 75 state:

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

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

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

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

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

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

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

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

Shortly after, on September 23, 2003, the Philippines became a signatory to the World Health Organization Framework Convention on Tobacco Control (WHO FCTC), which was ratified on June 6, 2005.<sup>113</sup> The WHO FCTC embodies the WHO’s tobacco-free initiative, recognizing that

<sup>104</sup> Republic Act No. 9211 (2003), sec. 33.

<sup>105</sup> Republic Act No. 9211 (2003), sec. 5.

<sup>106</sup> Republic Act No. 9211 (2003), sec. 22.

<sup>107</sup> Republic Act No. 9211 (2003), sec. 26.

<sup>108</sup> Republic Act No. 9211 (2003), sec. 13.

<sup>109</sup> Republic Act No. 9211 (2003), sec. 39.

<sup>110</sup> Republic Act No. 9211 (2003), sec. 13.

<sup>111</sup> Republic Act No. 9211 (2003), sec. 39.

<sup>112</sup> Took effect on April 9, 2004, 15 days after its publication on March 25, 2004.

<sup>113</sup> United Nations Treaty Collection,  
<[https://treaties.un.org/pages/ViewDetails.aspx?src=TREATY&mtdsg\\_no=IX-4&chapter=9&clang=\\_en](https://treaties.un.org/pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IX-4&chapter=9&clang=_en)> (last accessed on July 30, 2021).

the enjoyment of the highest attainable standard of health is a basic constitutional right.<sup>114</sup>

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

1. protection from exposure to tobacco smoke in indoor workplaces, public transport, indoor public places, and other public places;<sup>116</sup>
2. regulation of tobacco products’ contents, emissions,<sup>117</sup> and disclosures;<sup>118</sup>
3. packaging and labelling regulations;<sup>119</sup>
4. education and public awareness measures;<sup>120</sup>
5. comprehensive ban/restrictions on tobacco advertising, promotion and sponsorship;<sup>121</sup>
6. measures to combat illicit trade;<sup>122</sup>
7. prohibition of sale by, and to, minors;<sup>123</sup>
8. measures to promote cessation of tobacco use and adequate treatment for tobacco dependence;<sup>124</sup> and
9. reduction of tobacco industry interference in setting and implementing public health policies.<sup>125</sup>

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

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

<sup>115</sup> WHO Framework Convention on Tobacco Control (2003), art. 6.

<sup>116</sup> WHO Framework Convention on Tobacco Control (2003), art. 8.

<sup>117</sup> WHO Framework Convention on Tobacco Control (2003), art. 9.

<sup>118</sup> WHO Framework Convention on Tobacco Control (2003), art. 10.

<sup>119</sup> WHO Framework Convention on Tobacco Control (2003), art. 11.

<sup>120</sup> WHO Framework Convention on Tobacco Control (2003), art. 12.

<sup>121</sup> WHO Framework Convention on Tobacco Control (2003), art. 13.

<sup>122</sup> WHO Framework Convention on Tobacco Control (2003), art. 15.

<sup>123</sup> WHO Framework Convention on Tobacco Control (2003), art. 16.

<sup>124</sup> WHO Framework Convention on Tobacco Control (2003), art. 14.

<sup>125</sup> WHO Framework Convention on Tobacco Control (2003), art. 5(3).

<sup>126</sup> WHO Framework Convention on Tobacco Control (2003), art. 20.

<sup>127</sup> WHO Framework Convention on Tobacco Control (2003), art. 21.

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

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

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

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

On July 15, 2014, Republic Act No. 10643 or the Graphic Health Warnings Law was enacted, recognizing the Philippines' obligation under the WHO FCTC "to inform every person of the health consequences of

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

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

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

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

<sup>132</sup> Republic Act No. 10351 (2012), sec. 5.

tobacco consumption and exposure to tobacco smoke; to enact effective measures to curb and reduce tobacco use, especially among the youth; and to protect public health policy from the commercial and vested interests of the tobacco industry.”<sup>133</sup> The law also acknowledged the Philippines’ duty under Article 11 of the WHO FCTC to adopt and implement effective health warnings on tobacco products.<sup>134</sup> It expressly repealed Section 13 of Republic Act No. 9211 on cigarette package warnings, and DOH Administrative Order No. 2010-0013. Republic Act No. 10643 is implemented by administrative orders<sup>135</sup> issued by the Department of Health which establish the templates of the required graphic health warnings.

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

## II

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

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

The Regional Trial Court is incorrect.

### II (A)

The enactment of Republic Act No. 9711, geared toward strengthening the State’s regulatory capacity and enforcement of compliance with regulations over health products,<sup>138</sup> finds support in the Constitution. 

<sup>133</sup> Republic Act No. 10643 (2014), sec. 2.

<sup>134</sup> Republic Act No. 10643 (2014), sec. 2.

<sup>135</sup> Administrative Order No. 2014-0037, as amended by Administrative Order Nos. 2014-0037-A, 2014-0037-B, and 2019-0009.

<sup>136</sup> *Rollo*, p. 75, RTC Decision.

<sup>137</sup> *Id.* at 77.

<sup>138</sup> Republic Act No. 9711 (2009), sec. 3 provides:

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

Article II, Section 15 states:

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

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

SECTION 12. The State shall establish and maintain an effective food and drug regulatory system and undertake appropriate health manpower development and research, responsive to the country's health needs and problems.

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

- (a) To enhance and strengthen the administrative and technical capacity of the FDA in the regulation of establishments and products under its jurisdiction;
- (b) To ensure the FDA's monitoring and regulatory coverage over establishments and products under its jurisdiction; and
- (c) To provide coherence in the FDA's regulatory system for establishments and products under its jurisdiction.<sup>140</sup>

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

- (a) *To administer the effective implementation of this Act and of the rules and regulations issued pursuant to the same;*
- (b) *To assume primary jurisdiction in the collection of samples of health products;*
- (c) *To analyze and inspect health products in connection with the implementation of this Act;*
- (d) *To establish analytical data to serve as basis for the preparation of*

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and maintain an effective health products regulatory system and undertake appropriate health manpower development and research, responsive to the country's health needs and problems. *Pursuant to this policy, the State must enhance its regulatory capacity and strengthen its capability with regard to the inspection, licensing and monitoring of establishments, and the registration and monitoring of health products.* (Emphasis supplied)

<sup>139</sup> Republic Act No. 9711 (2009), sec. 4.

<sup>140</sup> Republic Act No. 9711 (2009), sec. 4.

*health products standards, and to recommend standards of identity, purity, safety, efficacy, quality and fill of container;*

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

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

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

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

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

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

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

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

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

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

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

*l*

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

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

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

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

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

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

We rule for petitioners.

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

<sup>141</sup> Republic Act 3720 (1963), sec. 4, as amended by Republic Act No. 9711 (2009).

<sup>142</sup> *Rollo*, pp. 1857–1858 and 1871, Memorandum for Petitioners.

<sup>143</sup> *Id.* at 46, Petition for Review.

<sup>144</sup> Memorandum of Respondent, pp. 39–41.

<sup>145</sup> *Id.* at 18–19.

<sup>146</sup> *Id.* at 19.

contrary, the IAC-Tobacco's authority under Republic Act No. 9211 does not cover the regulation of the health aspects of tobacco products.

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

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

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

- 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 supplied)

Republic Act No. 9211 created the IAC-Tobacco,<sup>147</sup> which "shall have the *exclusive* power and function to administer and implement" the law:

Section 29. *Implementing Agency.* — An Inter-Agency Committee — Tobacco (IAC-Tobacco), which shall have the *exclusive power and function to administer and implement the provisions of this Act*,

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<sup>147</sup> Republic Act No. 9211 (2003), sec. 3(g).

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:

- 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;

The Department Secretaries may designate their Undersecretaries as their authorized representatives to the IAC.<sup>148</sup> (Emphasis supplied)

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

#### I. Healthful Environment

- 1) Smoking Ban in Public Places<sup>149</sup> and Designation of Smoking and Non-Smoking Areas in establishments;<sup>150</sup>

#### II. Access Restrictions

- 1) Access restrictions to tobacco-related vending machines, self-service facilities, and other similar mechanisms;<sup>151</sup>
- 2) Retailer compliance to standards imposed on tobacco-related self-serving facilities;<sup>152</sup>
- 3) Minimum age sales of tobacco products;<sup>153</sup>
- 4) Ban on sale of tobacco products near school perimeters and other facilities frequented by minors;<sup>154</sup>
- 5) Required signage on point-of-sale establishments offering tobacco products;<sup>155</sup>

<sup>148</sup> Republic Act No. 9211 (2003), sec. 29.

<sup>149</sup> Republic Act No. 9211 (2003), sec. 5.

<sup>150</sup> Republic Act No. 9211 (2003), sec. 6.

<sup>151</sup> Republic Act No. 9211 (2003), secs. 7 and 8.

<sup>152</sup> Republic Act No. 9211 (2003), sec. 8.

<sup>153</sup> Republic Act No. 9211 (2003), sec. 9.

<sup>154</sup> Republic Act No. 9211 (2003), sec. 10.

<sup>155</sup> Republic Act No. 9211 (2003), sec. 11.

### III. Advertising and Promotion

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

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

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

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

....

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

c. *National Smoking Cessation Program*. — *A National Smoking Cessation Program shall be undertaken with the approval of the IAC-Tobacco.* The implementing rules and guidelines to reinforce this program shall be submitted to the IAC-Tobacco

<sup>156</sup> Republic Act No. 9211 (2003), sec. 13.

<sup>157</sup> Republic Act No. 9211 (2003), sec. 14.

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

<sup>159</sup> Republic Act No. 9211 (2003), sec. 23.

<sup>160</sup> Republic Act No. 9211 (2003), sec. 25.

<sup>161</sup> Republic Act No. 9211 (2003), sec. 27.

<sup>162</sup> Republic Act No. 9211 (2003), sec. 22.

<sup>163</sup> Republic Act No. 9211 (2003), sec. 26.

<sup>164</sup> Republic Act No. 9211 (2003), sec. 24.

<sup>165</sup> Republic Act No. 9211 (2003), sec. 31 provides:

Section 31. *Compliance Monitoring*. — Not later than one (1) year after the date of the effectivity of this Act, and annually thereafter, the IAC-Tobacco shall submit to the President of the Philippines and to both Houses of Congress a Compliance Monitoring Report on the compliance of the manufacturers on all applicable laws and ordinances with respect to the manufacture and distribution of tobacco products.

The report shall contain pertinent information on the methods, goals and implementation program of said manufacturers with respect to the requirements of this Act.

by the Secretary of Health within three (3) months after the effectivity of this Act.

- d. *Research and Development Program.* — *The IAC-Tobacco shall establish a research and development program to be spearheaded by the NTA in cooperation with the DOST, which will undertake studies concerning technologies and methods to reduce the risk of dependence and injury from tobacco product usage and exposure, alternative uses of tobacco and similar research programs.*
- e. *National Tobacco-Free Public Education Program.* — *State Universities and Colleges and Technical and Vocational Schools shall provide scholarship programs for dependents of tobacco growers for which the administrator of the NTA shall provide implementing rules and guidelines. The guidelines shall be submitted to the IAC-Tobacco within three (3) months after the effectivity of this Act.*
- f. *Displaced Cigarette Factory Workers' Assistance Program.* — *The Secretary of Labor and Employment, with the concurrence of the IAC-Tobacco shall establish a program to assist displaced, terminated/separated or retrenched cigarette factory workers as a result of the enactment of this Act. The Secretary of Labor in coordination with the NTA and DTI shall provide the rules and guidelines to effectuate this program and submit the same to the IAC-Tobacco within three (3) months after the effectivity of this Act.*
- g. *Health Programs.* — *The IAC-Tobacco, in consultation with the DOH, shall be responsible for awarding grants to all medical institutions for the purpose of planning, carrying out, and evaluating activities related to smoking-related illnesses. The IAC-Tobacco shall submit to Congress and the President of the Philippines the annual report of expenditures related to this program.*
- h. *Withdrawal Clinics.* — *The DOH shall establish smoking withdrawal clinics to provide counseling regarding the hazardous health effects of tobacco/cigarette smoking and to rehabilitate smokers from the hazardous effects of such products.*

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

Meanwhile, Section 25 of Republic Act No. 9711 clearly establishes that the law shall cover *all* health products, except for *acts covered by special laws*. Hence, matters *not covered* by special laws remain under the Food and Drug Administration's broad regulatory authority. Exceptions are strictly construed and "extend only as far as their language fairly

warrants[.]”<sup>166</sup> Moreover, “particular clauses and phrases of a statute should not be taken as detached and isolated expressions, but the whole and every part thereof must be considered in fixing the meaning of any of its parts.”<sup>167</sup> Respondent cannot truncate Section 25 and only focus on a particular phrase to suit its desired interpretation.

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

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

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

*Information Program*

SECTION 34. *Information Drive.* — *Consistent with the provisions of this Act, the DOH shall, in cooperation with the DepEd and with the assistance of the Philippine Information Agency (PIA), undertake a continuous information program on the harmful effects of smoking.*

The DOH shall enlist the active participation of the public and private sectors in the national effort to discourage the unhealthy habit of smoking.

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

<sup>167</sup> *Gaanon v. Intermediate Appellate Court*, 229 Phil. 139, 146 (1986) [Per J. Gutierrez, Jr., Second Division].

<sup>168</sup> Republic Act No. 9211 is entitled “An Act Regulating the Packaging, Use, Sale, Distribution and Advertisements of Tobacco Products and For Other Purposes.” See also Republic Act No. 9211 (2003), secs. 5–28.

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

<sup>170</sup> Memorandum for Respondent-Intervenor, p. 50.

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

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

## II (B)

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

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

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

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

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

<sup>172</sup> See Republic Act No. 3720 (1963), sec. 10(ff), as amended by Republic Act No. 9711 (2009).

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

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

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

### III

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

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

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

REP VALDEZ: Thank you, Madam Chair. Thank you, Senator Legarda, for the honor of proposing these amendments. This is actually, Your

<sup>174</sup> See Memorandum for Respondent-Intervenor, pp. 26–27.

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

<sup>176</sup> Republic Act No. 9711 (2009), sec. 5.

Honor, a follow-up of the proceedings during the Bicameral Conference that we had on February 23 where the Honorable Senator Legarda sought to clearly exclude from the coverage of the proposed law those that are already covered by special laws particularly sugar, tobacco and coconut . . . that the powers, Your Honor please, of the FDA shall not include those that are already covered . . . .

.....

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

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

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

REP. VALDEZ: Yes, Your Honor.

.....

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

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

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

SEN. LEGARDA: I think, if I may add, the strength of this new law, Congressman Locsin, should also be founded in its capability. It will be allowed to coordinate, to cooperate with already existing specialized agencies in the exercise of its functions because it's not only the health that is concerned, it's the economic aspect, the way it affects agriculture

and all the farmers down the drain. So I don't think we will – what's the word, emasculate the new law or destrengthen or soften the – weaken the powers of BFAD. We simply did not want to confuse all the various sectors in the . . .

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

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

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

THE CHAIRPERSON (SEN. CAYETANO, P.): I agree because the confusion may arise that these special laws somehow cover the health aspect when it is really not their expertise even if they claim that they have some kind of say in it. *So, I tend to agree with Congressman Locsin that it should be very clear that this law, the FDA bill will be now in-charge of the health aspect. And in that sense, it's suppletory to whatever the mandate the special laws have on those products but the health aspects is an FDA affair.*<sup>177</sup> (Emphasis supplied)

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

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

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

<sup>177</sup> Memorandum of Petitioners-Intervenors, pp. 13–16.

<sup>178</sup> CONST., art. XIII, sec. 12 states:

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

*Article 3*  
*Objective*

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

....

*Article 5*  
*General Obligations*

1. Each Party shall develop, implement, periodically update and review comprehensive multisectoral national tobacco control strategies, plans and programmes in accordance with this Convention and the protocols to which it is a Party.
2. Towards this end, each Party shall, in accordance with its capabilities:
  - (a) establish or reinforce and finance a national coordinating mechanism or focal points for tobacco control; and
  - (b) *adopt and implement effective legislative, executive, administrative and /or other measures and cooperate, as appropriate, with other Parties in developing appropriate policies for preventing and reducing tobacco consumption, nicotine addiction and exposure to tobacco smoke.*
3. *In setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law.*
4. The Parties shall cooperate in the formulation of proposed measures, procedures and guidelines for the implementation of the Convention and the protocols to which they are parties.

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

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

5. The Parties shall cooperate, as appropriate, with competent international and regional intergovernmental organizations and other bodies to achieve the objectives of the Convention and the protocols to which they are Parties.
6. The Parties shall, within means and resources at their disposal, cooperate to raise financial resources for effective implementation of the Convention through bilateral and multilateral funding mechanisms.<sup>180</sup> (Emphasis supplied)

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

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

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

....

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

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

- i. Testing, measuring and regulation of the contents and emissions of tobacco products;<sup>183</sup>
- ii. Regulation of tobacco product disclosures to governmental authorities and to the public of information about the toxic

<sup>180</sup> WHO Framework Convention on Tobacco Control (2003), art. 5.

<sup>181</sup> Guidelines for Implementation, Article 5.3, available at <<https://fctc.who.int/publications/m/item/guidelines-for-implementation-of-article-5.3>> (last accessed on July 30, 2021).

<sup>182</sup> WHO Framework Convention on Tobacco Control (2003), art. 6.

<sup>183</sup> WHO Framework Convention on Tobacco Control (2003), art. 9.

constituents of the tobacco products and the emissions that they may produce;<sup>184</sup>

iii. Packaging and labeling of tobacco products, including;

(1) Information on constituents and emissions on outside packaging and labeling;<sup>185</sup>

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

iv. Ban on all forms of tobacco advertising, promotions and sponsorship by any means that are false, misleading or deceptive or likely to create an erroneous impression about the tobacco product's characteristics, health effects, hazards or emissions.<sup>187</sup>

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

As explained in *David v. Senate Electoral Tribunal*:<sup>192</sup>

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

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

<sup>184</sup> WHO Framework Convention on Tobacco Control (2003), art. 10.

<sup>185</sup> WHO Framework Convention on Tobacco Control (2003), art. 11(2).

<sup>186</sup> WHO Framework Convention on Tobacco Control (2003), art. 11(1)(a).

<sup>187</sup> WHO Framework Convention on Tobacco Control (2003), art. 13(4)(a).

<sup>188</sup> WHO Framework Convention on Tobacco Control (2003), Preamble.

<sup>189</sup> WHO Framework Convention on Tobacco Control (2003), art. 3.

<sup>190</sup> Memorandum for Petitioners-Intervenors, p. 27.

<sup>191</sup> CONST., art. VII, sec. 21 reads:

SECTION 21. No treaty or international agreement *shall be valid and effective* unless concurred in by at least two-thirds of all the Members of the Senate. (Emphasis supplied)

<sup>192</sup> 795 Phil. 529 (2016) [Per J. Leonen, En Banc].

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

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

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

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

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

**WHEREFORE**, the Petition is **GRANTED**. The January 27, 2012 Decision of the Regional Trial Court in SCA Case No. 11-0013, which declared void the Rules and Regulations Implementing Republic Act No.

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<sup>193</sup> Id. at 614–615.

<sup>194</sup> Implementing Rules and Regulations of Republic Act No. 9711 (2011), secs. 3–4 state:  
SECTION 3. Other Products. — *Nothing in the FDA Act of 2009 shall be deemed to modify the jurisdiction of other specialized agencies and special laws only insofar as the acts covered by these specialized agencies and laws except the health aspects of such products.*  
SECTION 4. Identification of Policy Areas. — The FDA shall promulgate the appropriate rules and regulations and other issuances to identify and define the policy areas that *are not covered by specialized agencies and special laws*, including, but not limited to, those covered by Republic Act No. 9211, Executive Order No. 245, Executive Order No. 18, and Presidential Decree No. 1468.<sup>194</sup> (Emphasis supplied)

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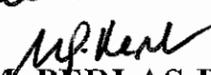
9711 insofar as it regulates tobacco products and the tobacco industry is **REVERSED and SET ASIDE.**

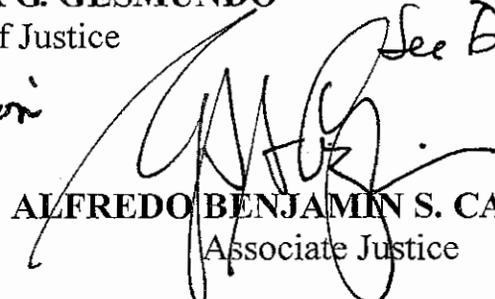
**SO ORDERED.**

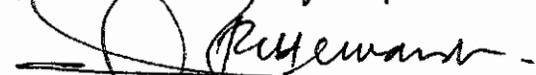
  
**MARVIC M.V.F. LEONEN**  
 Associate Justice

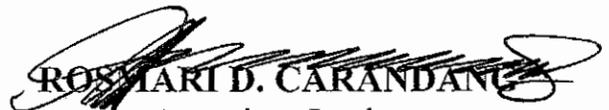
WE CONCUR:

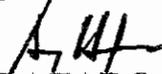
*I join Justice Caguioa  
 Dissenting Opinion*  
  
**ALEXANDER G. GESMUNDO**  
 Chief Justice

*Please see Concurring opinion*  
  
**ESTELA M. PERLAS-BERNABE**  
 Associate Justice

*See Dissent.*  
  
**ALFREDO BENJAMIN S. CAGUIOA**  
 Associate Justice

*See Dissenting Opinion*  
  
**RAMON PAUL L. HERNANDO**  
 Associate Justice

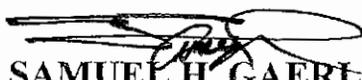
  
**ROSMARI D. CARANDANG**  
 Associate Justice

*See Separate Concurring Opinion*  
  
**AMY C. LAZARO-JAVIER**  
 Associate Justice

  
**HENRI JEAN PAUL B. INTING**  
 Associate Justice

  
**RODIL V. ZALAMEDA**  
 Associate Justice

  
**MARIO V. LOPEZ**  
 Associate Justice

  
**SAMUEL H. GAERLAN**  
 Associate Justice

  
**RICARDO R. ROSARIO**  
 Associate Justice

  
**JHOSEP Y. LOPEZ**  
Associate Justice

**CERTIFICATION**

Pursuant to Section 13, Article VIII of the Constitution, I certify that the conclusions in the above Decision had been reached in consultation before the case was assigned to the writer of the opinion of the court.

  
**ALEXANDER G. GESMUNDO**  
Chief Justice