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

Promulgated:

July 13, 2021

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DISSENTING OPINION

HERNANDO, *J.:*

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

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

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

Sections 3[1] and 4[2] of RA 9711 pronounce the overall policy and objectives of the law to strengthen and rationalize the regulatory capacity of

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[1] SECTION 3. It is hereby declared a policy of the State to adopt, support, establish, institutionalize, improve and maintain structures, processes, mechanisms and initiatives that are aimed, directed and designed to: (a) protect and promote the right to health of the Filipino people; and (b) help establish and maintain an effective health products regulatory system and undertake appropriate health manpower development and research, responsive to the country's health needs and problems. Pursuant to this policy, the State must enhance its regulatory capacity and strengthen its capability with regard to the inspection, licensing and monitoring of establishments, and the registration and monitoring of health products.

[2] SECTION 4. This Act has the following objectives: (a) To enhance and strengthen the administrative and technical capacity of the FDA in the regulation of establishments and products under its jurisdiction; (b) To ensure the FDA's monitoring and regulatory coverage over establishments and products under its jurisdiction; and (Ca) To provide coherence in the FDA's regulatory system for establishments and products under its jurisdiction.

the FDA to ensure the safety of food, medicine, health products, and the like made available to the public. Clearly, RA 9711 seeks to establish and maintain an effective health product regulatory system.

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

> The petitioners likewise question the delegation by Congress to the FDA of the power to determine whether or not a supply or product is to be included in the Essential Drugs List *(EDL)*.
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> The Court finds nothing wrong with the delegation. The FDA does not only have the power but also the competency to evaluate, register and cover health services and methods. It is the only government entity empowered to render such services and highly proficient to do so. It should be understood that health services and methods fall under the gamut of terms that are associated with what is ordinarily understood as "health products." In this connection, Section 4 of R.A. No. 3720, as amended by R.A. No. 9711 reads:
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> > SEC. 4. To carry out the provisions of this Act, there is hereby created an office to be called the Food and Drug Administration (FDA) in the Department of Health (DOH). Said Administration shall be under the Office of the Secretary and shall have the following functions, powers and duties:
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> > "(c) **To analyze and inspect health products** in connection with the implementation of this Act;
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> > x x x x
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> > "(h) **To conduct appropriate tests on all applicable health products prior to the issuance of appropriate authorizations to ensure safety, efficacy, purity, and quality;**
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> > x x x x
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> > "(k) **After due process, to order the ban, recall, and/or withdrawal of any health product found to have caused death, serious illness or serious injury to a consumer or patient, or is found to be imminently injurious, unsafe, dangerous, or grossly deceptive**, and to require all concerned to implement the risk

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[3] 732 Phil. 1 (2014).

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

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

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

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

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

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

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

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

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

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

> The inclusion of this phrase in the IRR offends a basic tenet in the exercise of the rule-making power of administrative agencies. After all, the power of administrative officials to promulgate rules in the implementation of a statute is necessarily limited to what is found in the legislative enactment itself. The implementing rules and regulations of a law cannot extend the law or expand its coverage, as the power to amend or repeal a statute is vested in the Legislature. **Thus, if a discrepancy occurs between the basic law and an implementing rule or regulation, it is the former that prevails, because the law cannot be broadened by a mere administrative issuance — an administrative agency certainly cannot amend an act of Congress. Had the Legislature really wanted ordinary fax transmissions to be covered by the mantle of the Electronic Commerce Act of 2000, it could have easily lifted without a bit of tatter the entire wordings of the UNCITRAL Model Law.**[11] (Emphasis supplied, citations omitted.)

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

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

In *Review Center Association of the Philippines v. Ermita*,[12] the Court struck down executive issuances, Executive Order No. 566 and Commission on Higher Education (CHED) Memorandum Order No. 30, Series of 2007,

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[9] Supra note 7.
[10] The United Nations Commission on International Trade Law.
[11] *MCC Industrial Sales Corporation v. Ssangyong Corporation,* supra note 7 at 426.
[12] Supra note 7.

which provided for the CHED's regulation of review centers and effectively expanded the coverage of RA 7722, the Higher Education Act of 1994. We ruled therein that the CHED may only exercise its rule-making power within the confines of its jurisdiction under RA 7722:

> The scopes of EO 566 and the RIRR clearly expand the CHED's coverage under RA 7722. The CHED's coverage under RA 7722 is limited to **public and private institutions of higher education and degree-granting programs in all public and private post-secondary educational institutions.** EO 566 directed the CHED to formulate a framework for the regulation of review centers and similar entities.
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> The definition of a review center under EO 566 shows that it refers to one which offers "**a program or course of study that is intended to refresh and enhance the knowledge or competencies and skills of reviewees obtained in the formal school setting in preparation for the licensure examinations**" given by the PRC. It also covers the operation or conduct of review classes or courses provided by individuals whether for a fee or not in preparation for the licensure examinations given by the PRC.
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> **A review center is not an institution of higher learning as contemplated by RA 7722.** It does not offer a degree-granting program that would put it under the jurisdiction of the CHED. A review course is only intended to "refresh and enhance the knowledge or competencies and skills of reviewees." A reviewee is not even required to enroll in a review center or to take a review course prior to taking an examination given by the PRC. Even if a reviewee enrolls in a review center, attendance in a review course is not mandatory. The reviewee is not required to attend each review class. He is not required to take or pass an examination, and neither is he given a grade. He is also not required to submit any thesis or dissertation. Thus, programs given by review centers could not be considered "programs x x x of higher learning" that would put them under the jurisdiction of the CHED.
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> Further, the "similar entities" in EO 566 cover centers providing "review or tutorial services" in areas not covered by licensure examinations given by the PRC, which include, although not limited to, college entrance examinations, Civil Services examinations, and tutorial services. These review and tutorial services hardly qualify as programs of higher learning.
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> x x x x
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> **Administrative agencies exercise their quasi-legislative or rule-making power through the promulgation of rules and regulations. The CHED may only exercise its rule-making power within the confines of its jurisdiction under RA 7722. The RIRR covers review centers and similar entities which are neither institutions of higher education nor institutions offering degree-granting programs.**[13] (Emphasis supplied, citations omitted)

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

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

> Petitioner insists that the Department Order is an invalid exercise of the rule-making power delegated to the Secretary of Education as it supposedly disregards PTAs' and PTCAs' purposes, not only as partners of the Department of Education in the implementation of programs, but also as a watchdog against "abuses, mismanagement, inefficiency[,] and excesses of public officials within the public school system." Petitioner also assails the Department Order's limitation of official recognition to PTAs, and no longer to PTCAs, as being contrary to law.
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> x x x x
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> Petitioner is in error for asserting that the assailed Department Order is contrary to the statutes it aims to put into effect as it fails to put PTCAs on the same footing as PTAs.
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> Article 77 of the Child and Youth Welfare Code provides for the organization and purposes of PTAs:
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> > Article 77. Parent-Teacher Associations. — Every elementary and secondary school shall organize a parent-teacher association *for the purpose of providing a forum for the discussion of problems and their solutions, relating to the total school program, and for insuring the full cooperation of parents in the efficient implementation of such program.* All parents who have children enrolled in a school are encouraged to be active members of its PTA, and to comply with whatever obligations and responsibilities such membership entails.
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> > Parent-Teacher Association[s] all over the country *shall aid the municipal and other local authorities and school officials in the enforcement of juvenile delinquency control measures, and in the implementation of programs and activities to promote child welfare.* x x x

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

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

> Section 8. Rights of Parents. — In addition to other rights under existing laws, all parents who have children enrolled in a school have the following rights:
>
> 1. The right to organize by themselves and/or with teachers *for the purpose of providing a forum for the discussion of matters relating to the total school program, and for ensuring the full cooperation of parents and teachers in the formulation and efficient implementation of such programs.*
>
> 2. The right to access to any official record directly relating to the children who are under their parental responsibility. x x x

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

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

> Section 3. Purposes and Objectives. — The purposes and objectives of this Act are:
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> x x x x
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> (d) To ensure that schools and learning centers receive the kind of focused attention they deserve and that educational programs, projects and services take into account the interests of all members of the community[.]

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

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

> and programs, providing technical assistance and support to the ECCD service providers in consultation with coordinating committees at the provincial, city/municipal, and barangay levels, as provided for in Section 8 of this Act, and monitoring of ECCD service benefits and outcomes. The Department of Social Welfare and Development (DSWD), the Department of Education, Culture and Sports (DECS), the Department of Health (DOH), the Department of the Interior and Local Government (DILG), the Department of Labor and Employment (DOLE), the Department of Agriculture (DA), the Department of Justice (DOJ), the National Economic and Development Authority (NEDA), and the National Nutrition Council (NNC) shall jointly prepare annual ECCD for work plans that will coordinate their respective technical assistance and support for the National ECCD Program. They shall consolidate existing program implementing guidelines that ensure consistency in integrated service delivery within the National ECCD System.
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> (1) The DECS shall promote the National ECCD Program in schools. ECCD programs in public schools shall be under the joint responsibility of their respective school principal/school-head and parents-teachers-community association (PTCA) within the standards set forth in the National ECCD System and under the guidance of the City/Municipal ECCD Coordinating Committee for the effective and equitable delivery of ECCD services. It shall also make available existing facilities of public elementary schools for ECCD classes.

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

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

> I. General Policy
>
> 1. Every elementary and secondary school shall organize a Parents-Teachers Association (PTA) for the purpose of providing a forum for the discussion of issues and their solutions related to the total school program and to ensure the full cooperation of parents in the efficient implementation of such program.
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> *Every PTA shall provide mechanisms to ensure proper coordination with the members of the community*, provide an avenue for discussing relevant concerns and provide assistance and support to the school for the promotion of their common interest. Standing committees may be created within the PTA organization

> to coordinate with community members. Regular fora may be conducted with local government units, civic organizations and other stakeholders to foster unity and cooperation. x x x
>
> Republic Act No. 8980 does mention PTCAs, but this is only in the specific context of the National Early Childhood Care and Development (ECCD) System. The ECCD System "refers to the full range of . . . programs that provide for the basic holistic needs of young children ***from birth to age six (6)***." It is not even an education program and does not involve the age range of students — elementary to high school — that is relevant to the Department Order. In any case, an isolated and passing mention does not equate to a mandate.
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> Petitioner's invocation of Republic Act Nos. 9155 and 8980 only serve to muddle the issues by entreating considerations that are irrelevant to the purposes of the statute (*i.e.*, the Child and Youth Welfare Code) that actually pertains to and requires the organization of PTAs.
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> From the previously quoted provisions of the Child and Youth Welfare Code and the Education Act of 1982, the purposes for which the organization of PTAs is mandated are clear. First, a PTA is to be a forum for discussion. Second, a PTA exists to ensure the full cooperation of parents in the implementation of school programs. The assailed Department Order serves these purposes.
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> By ensuring fiscal transparency and accountability, and by providing the basic framework for organization and official recognition, the Department Order ensures that PTAs exist and function in a manner that remains consistent with the articulated purposes of PTAs under the Child and Youth Welfare Code and the Education Act of 1982. A framework for organization ensures that PTAs are properly organized and are both adequately representative of and limited only to those interests that are appropriate to the education of children in elementary and high school. Measures for fiscal transparency and accountability ensure that PTAs are not hampered by pecuniary or proprietary interests that have nothing to do with the effective implementation of school programs. Finally, mechanisms for official recognition ensure that only those associations that organize and conduct themselves in a manner that is consistent with these purposes are privileged with state sanction.[15] (Citations omitted)

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

> (1) Their promulgation must be authorized by the Legislature;
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> (2) They must be within the scope of the authority given by the Legislature;
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> (3) They must be promulgated in accordance with the prescribed procedure; and

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[15] Id. at 439-444.

(4) They must be reasonable.[16]

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

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

Petitioners concluded, thus:

> In the case at bar, the subject IRR was issued within the limits of the authority conferred by law. The provisions of the IRR did not supplant the Constitution, the enabling law and other existing laws.[17]

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

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

In *Metropolitan Manila Development Authority (MMDA) v. Bel-Air Village Association, Inc.*,[19] the Court delved into the nature of police power as inherent in the Legislative branch endowed with plenary power to make, amend, and repeal laws. Such power can be exercised only by Congress or upon a valid delegation of legislative power to the President and

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[16] *Rollo*, p. 1837, citing *Lokin, Jr v. Commission on Elections*, supra note 7.
[17] Id. at 1841.
[18] *Ople v. Torres*, 354 Phil. 948 (1998), citing Fisher, *Constitutional Conflicts Between Congress and the President* (4th ed.), pp. 106-107.
[19] 385 Phil. 586 (2000).

administrative boards. We thus held that based on its enabling law, the MMDA does not exercise police power and cannot enact rules ordering the opening of a private road within a private subdivision:

> Police power is an inherent attribute of sovereignty. It has been defined as the power vested by the Constitution in the legislature to make, ordain, and establish all manner of wholesome and reasonable laws, statutes and ordinances, either with penalties or without, not repugnant to the Constitution, as they shall judge to be for the good and welfare of the commonwealth, and for the subjects of the same. The power is plenary and its scope is vast and pervasive, reaching and justifying measures for public health, public safety, public morals, and the general welfare.
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> It bears stressing that police power is lodged primarily in the National Legislature. It cannot be exercised by any group or body of individuals not possessing legislative power. The National Legislature, however, *may delegate* this power to the President and administrative boards as well as the lawmaking bodies of municipal corporations or local government units. Once delegated, the agents can exercise *only* such legislative powers as are conferred on them by the national lawmaking body.[20]

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

> Respecting the President's authority to order the implementation of the Project in the exercise of the police power of the State, suffice it to stress that the powers vested in the DOTC Secretary to establish and administer comprehensive and integrated programs for transportation and communications and to issue orders, rules and regulations to implement such mandate (which, as previously discussed, may also be exercised by the President) have been so delegated for the good and welfare of the people. Hence, these powers partake of the nature of police power.
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> Police power is the plenary power vested in the legislature to make, ordain, and establish wholesome and reasonable laws, statutes and ordinances, not repugnant to the Constitution, for the good and welfare of the people. This power to prescribe regulations to promote the health, morals, education, good order or safety, and general welfare of the people flows from the recognition that *salus populi est suprema lex*— the welfare of the people is the supreme law.
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> While police power rests primarily with the legislature, such power may be delegated, as it is in fact increasingly being delegated. By virtue of a valid

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[20] Id. at 601-602.
[21] 557 Phil. 121 (2007).

> delegation, the power may be exercised by the President and administrative boards as well as by the lawmaking bodies of municipal corporations or local governments under an express delegation by the Local Government Code of 1991.
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> The authority of the President to order the implementation of the Project notwithstanding, the designation of the MMDA as the implementing agency for the Project may not be sustained. It is *ultra vires*, there being no legal basis therefor.
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> **It bears stressing that under the provisions of E.O. No. 125, as amended, it is the DOTC, and not the MMDA, which is authorized to establish and implement a project such as the one subject of the cases at bar.** Thus, the President, although authorized to establish or cause the implementation of the Project, must exercise the authority through the instrumentality of the DOTC which, by law, is the primary implementing and administrative entity in the promotion, development and regulation of networks of transportation, and the one so authorized to establish and implement a project such as the Project in question.
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> **By designating the MMDA as the implementing agency of the Project, the President clearly overstepped the limits of the authority conferred by law, rendering E.O. No. 179 *ultra vires*.**[22] (Citations omitted)

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

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

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

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[22] Id. at 140-142.

delegation from Congress saw to placing guidelines in the implementation by petitioners of the FDA Act.

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

> The explicit directive of the afore-quoted statutory and regulatory provisions, garnered from a plain reading thereof, is that respondents, as operators/lessors of neighborhood shopping centers, should provide parking and loading 1spaces, in accordance with the minimum ratio of one slot per 100 square meters of shopping floor area. **There is nothing therein pertaining to the collection (or non-collection) of parking fees by respondents. In fact, the term "parking fees" cannot even be found at all in the entire National Building Code and its IRR.**
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> Statutory construction has it that if a statute is clear and unequivocal, it must be given its literal meaning and applied without any attempt at interpretation. Since Section 803 of the National Building Code and Rule XIX of its IRR do not mention parking fees, then simply, said provisions do not regulate the collection of the same. x x x
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> x x x x
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> Hence, in order to bring the matter of parking fees within the ambit of the National Building Code and its IRR, the OSG had to resort to specious and feeble argumentation, in which the Court cannot concur.
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> The OSG cannot rely on Section 102 of the National Building Code to expand the coverage of Section 803 of the same Code and Rule XIX of the IRR, so as to include the regulation of parking fees. The OSG limits its citation to the first part of Section 102 of the National Building Code declaring the policy of the State "to safeguard life, health, property, and public welfare, consistent with the principles of sound environmental management and control"; but totally ignores the second part of said provision, which reads, "and to this end, make it the purpose of this Code to provide for all buildings and structures, a framework of minimum standards and requirements to regulate and control their location, site, design, quality of materials, construction, use, occupancy, and maintenance". While the first part of Section 102 of the National Building Code lays down the State policy, it is the second part thereof that explains how said policy shall be carried out in the Code. **Section 102 of the National Building Code is not an all-encompassing grant of regulatory power to the DPWH Secretary and local building officials in the name of life, health, property, and public welfare. On the contrary, it limits the regulatory power of said officials to ensuring that the minimum standards and requirements for all buildings and structures, as set forth in the National Building Code, are complied with.**

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[23] 616 Phil. 587 (2009).

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

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

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

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

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

Tobacco Products are not Health Products

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

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

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

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[24] Id. at 606-608.

The succeeding sentence of RA 9711 is qualified by the enumeration in the preceding sentence which, though these may have a negative effect on health, have a claimed therapeutic benefit which outweighs the negative effects. Thus, the power of the FDA to determine what are health products should be construed through the prism of *ejusdem generis*[25] in accordance with the first sentence enumerating what are health products.

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

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

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

The objectives of the FDA Act are consistent with its conferment of general powers to regulate establishments and products under its jurisdiction.[28]

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

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

[27] Section 10(e) of Republic Act No. 3720, as amended by Republic Act No. 9711:
SEC. 10. For purposes of this Act, the term:
x x x x
(e) 'Food' means any processed substance which is intended for human consumption and includes drink for man, beverages, chewing gum and x x x.

[28] SECTION 4 of Republic Act No. 9711:
This Act has the following objectives:
(a) To enhance and strengthen the administrative and technical capacity of the FDA in the regulation of establishments and products under its jurisdiction;
(b) To ensure the FDA's monitoring and regulatory coverage over establishments and products under its jurisdiction; and

These are not the sole provisions to which the FDA IRR must adhere to. All the provisions thereof, including Article III on Tobacco and Other Products, must be anchored and clearly refracted from the law.

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

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

> SEC. 4. To carry out the provisions of this Act, there is hereby created an office to be called the Food and Drug Administration (FDA) in the Department of Health (DOH). Said Administration shall be under the Office of the Secretary and shall have the following functions, powers and duties:
>
> x x x x
>
> (i) To require all manufacturers, traders, distributors, importers, exporters, wholesalers, retailers, consumers, and non-consumer users of health products to report to the FDA any incident that reasonably indicates that said product has caused or contributed to the death, serious illness or serious injury to a consumer, a patient, or any person;
>
> (j) To issue cease and desist orders *motu propio* or upon verified complaint for health products, whether or not registered with the FDA: *Provided,* That for registered health products, the cease and desist order is valid for thirty (30) days and may be extended for sixty (60) days only after due process has been observed;
>
> (k) After due process, to order the ban, recall, and/or withdrawal of any health product found to have caused the death, serious illness or serious injury to a consumer or patient, or is found to be imminently injurious, unsafe, dangerous, or grossly deceptive, and to require all concerned to implement the risk management plan which is a requirement for the issuance of the appropriate authorization;
>
> (l) To strengthen the post market surveillance system in monitoring health products as defined in this Act and incidents of adverse events involving such products[.]

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

(c) To provide coherence in the FDA's regulatory system for establishments and products under its jurisdiction.

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

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

> 1. *Rationale*
>
> Republic Act No. 3720, also known as the "Food, Drug and Cosmetic Act", as amended, and Republic Act No. 9711, also known as the "Food and Drug Administration (FDA) Act of 2009" and its Implementing Rules and Regulations were all enacted to establish an effective regulatory system for the authorization, registration, and monitoring of health products.
>
> Section 5 (i) of Republic Act No. 9711 mandated the FDA to require all manufacturers, traders, distributors, importers, exporters, wholesalers, retailers, consumers and non-consumer users of health products to report to the FDA any incident that reasonably indicates that a product has caused or contributed to the death, serious illness or serious injury to a consumer, a patient, or any person. Moreover, Section 5 (k) of the same law empowers the FDA, after due process, to order the ban, recall, and/or withdrawal of any health product found to have caused the death, serious illness or serious injury to a consumer or patient, or is found to be imminently injurious, unsafe, dangerous, or grossly deceptive, and to require all concerned to implement the risk management plan which is a requirement for the issuance of the appropriate authorization.
>
> Recall is the method of withdrawing or correcting unsafe or hazardous health products from the distribution chain that may present a health hazard to the consumer or user. It is an action taken by establishments involved in the supply chain (*e.g.*, manufacturers, distributors, or retailers) as (1) part of their responsibility to protect the public health and well-being, (2) compliance to the appropriate good practices (*e.g.*, good manufacturing, distribution, or storage practices), and (3) compliance to existing standards and regulations.
>
> x x x x
>
> 3. *Scope*
>
> This FDA Circular shall apply to all licensed manufacturers, traders, distributors (importers, exporters, and wholesalers), and retailers of health products.

Thus, within the envisioned regulatory system of the FDA over health products, the regulation of tobacco products is equivalent to a prohibition because of petitioners' submission that these are hazardous. Applying RA 9711, the FDA IRR, and FDA Circular No. 2016-012 to tobacco products, the

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[29] Dated July 25, 2016.

FDA would have nothing more to regulate since tobacco products *per se* would be banned, recalled, and or withdrawn from the market.

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

ARTICLE III is inconsistent with Tobacco-Specific Legislation.

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

First. Section 25 of RA 9711 provides:

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

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

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

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[30] Republic Act No. 9211, Republic Act No. 10643 and Executive Order No. 245.
[31] See *Dela Cruz v. Paras*, 208 Phil. 490 (1983).
[32] See *Gerochi v. Department of Energy*, 554 Phil. 563, 584 (2007).
[33] 774 Phil. 31 (2015).

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

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

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

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

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

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

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

In his concurring opinion in *Unduran*, Justice Jose P. Perez submits that the jurisdiction of the NCIP ought to be definitively drawn to settle doubts that still linger due to the implicit affirmation done in *The City Government of Baguio City, et al. v. Atty. Masweng, et al.* of the NCIP's jurisdiction over cases where one of the parties are not ICCs/IPs.

> In *Unduran* and as in this case, **we are hard[-]pressed to declare a primary and/or exclusive and original grant of jurisdiction to the NCIP over all claims and disputes involving rights of ICCs/IPs where there is no clear intendment by the legislature.**
>
> **Significantly, the language of Section 66 is only clear on the nature of the claim and dispute as involving rights of ICCs/IPs, but ambiguous and indefinite in other respects. While using the word "all" to quantify the number of the "claims and disputes" as covering each and every claim and dispute involving rights of ICCs/IPs, Section 66 unmistakably contains a proviso, which on its face restrains or limits the initial generality of the grant of jurisdiction.** (Emphasis supplied)
>
> *Unduran* lists the elements of the grant of jurisdiction to the NCIP: (1) the claim and dispute involve the right of ICCs/IPs; **and** (2) both parties have exhausted all remedies provided under their customary laws. Both elements must be present prior to the invocation and exercise of the NCIP's jurisdiction.
>
> Thus, despite the language that the NCIP shall have jurisdiction over all claims and disputes involving rights of ICCs/IPs, we cannot be confined to that first alone and therefrom deduce primary sole NCIP jurisdiction over all ICCs/IPs claims and disputes **to the exclusion of the regular courts**. If it were the intention of the legislative that: (1) the NCIP exercise primary jurisdiction over, and/or (2) the regular courts be excluded from taking cognizance of, claims and disputes involving rights of ICCs/IPs, the legislature could have easily done so as in other instances conferring primary, and original and exclusive jurisdiction to a specific administrative body. x x x[34] (Emphasis supplied, citations omitted)

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

Still and all, petitioners insist that the proviso retained with the FDA the regulatory power over the **health aspect** of the already excluded products, to wit: "That nothing in this Act shall be deemed to modify the sole and exclusive jurisdiction of other specialized agencies and special laws **only insofar as the acts covered by these specialized agencies and laws,** including, but not limited to, those covered by RA 9211, Executive Order No. 245, Executive Order No. 18, and Presidential Decree No. 1468."[35] This is evidently not so.

There is nothing in the use of the phrase "only insofar as the acts covered by these specialized agencies and laws"[36] which delineated the FDA's retention of regulatory powers over the health aspect of certain products, *e.g.*, tobacco (RA 9211 and EO 245), sugar (EO 18), and coconut (PD 1468). The intention to exclude tobacco products from regulation by the FDA is

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[34] Id. at 46-48.
[35] REPUBLIC ACT No. 9711, Section 25.
[36] REPUBLIC ACT No. 9711, Section 25.

especially true since two agencies already oversee, administer and regulate it and the tobacco industry: (1) IAC-Tobacco, and (2) the National Tobacco Administration (NTA).

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

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

> Republic Act No. 9211
>
> SECTION 4. *Definition of Terms.* - As used in this Act:
>
> x x x x
>
> s. "Tobacco Product"— refers to any product that consists of loose tobacco that contains nicotine and is intended for use in a cigarette, including any product containing tobacco and intended for smoking or oral or nasal use. Unless stated otherwise, the requirements of this Act pertaining to cigarettes shall also apply to other tobacco products[.]
>
> Republic Act No. 10643
>
> SECTION 4. *Definition of Terms.* –
>
> x x x x
>
> (f) "*Tobacco Products*" means products entirely or partly made of leaf tobacco as raw material, which are manufactured to be used for smoking, sucking, chewing or snuffing, or by any means of consumption.

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

> SECTION 2. *Policy.* - It is the policy of the State to protect the populace from hazardous products and promote the right to health and instill health consciousness among them. It is also the policy of the State, consistent with the Constitutional ideal to promote the general welfare, to safeguard the interests of the workers and other stakeholders in the tobacco industry. For these purposes, the government shall institute a balanced policy whereby the use, sale and advertisements of tobacco products shall be regulated in order to promote a healthful environment and protect the citizens from the hazards

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

> of tobacco smoke, and at the same time ensure that the interests of tobacco farmers, growers, workers and stakeholders are not adversely compromised.

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

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

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

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

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

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

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

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[38] *Destileria Ayala, Inc. v. Tan Tay Co*, 74 Phil. 301 (1943).
[39] See Section 29 of Republic Act No. 9211.
[40] 757 Phil. 212 (2015).

promotion." **Therefore, with this regulatory power conferred upon the IAC-Tobacco by RA 9211, the DOH and the BFAD have been effectively and impliedly divested of any authority to act upon applications for tobacco sales promotional permit, including PMPMI's.**

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

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

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

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

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[41] Id. at 226-228.
[42] 529 U.S. 120.

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

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

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

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

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

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

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

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[43] *Francisco, Jr. v. House of Representatives*, 460 Phil. 830 (2003).
[44] 391 Phil. 84 (2000).

> "In seeking to nullify an act of the Philippine Senate on the ground that it contravenes the Constitution, the petition no doubt raises a justiciable controversy. Where an action of the legislative branch is seriously alleged to have infringed the Constitution, it becomes not only the right but in fact the duty of the judiciary to settle the dispute. . . . The duty (to adjudicate) remains to assure that the supremacy of the Constitution is upheld.' Once a 'controversy as to the application or interpretation of a constitutional provision is raised before this Court . . ., it becomes a legal issue which the Court is bound by constitutional mandate to decide. '
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> x x x x
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> "As this Court has repeatedly and firmly emphasized in many cases, it will not shirk, digress from or abandon its sacred duty and authority to uphold the Constitution in matters that involve grave abuse of discretion brought before it in appropriate cases, committed by any officer, agency, instrumentality or department of the government."

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

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

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

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

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

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[45] Id.
[46] 599 Phil. 387 (2008).
[47] Id.
[48] 646 Phil. 452 (2010)

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

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

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

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

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

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

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

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[49] Id.
[50] 721 Phil. 416 (2013).
[51] Id. at 520.
[52] 737 Phil. 457 (2014).
[53] Id. at 533.
[54] Supra note 7.

> In United States (US) constitutional law, a facial challenge, also known as a First Amendment Challenge, is one that is launched to assail the validity of statutes concerning not only protected speech, but also all other rights in the First Amendment. These include religious freedom, freedom of the press, and the right of the people to peaceably assemble, and to petition the Government for a redress of grievances. After all, the fundamental right to religious freedom, freedom of the press and peaceful assembly are but component rights of the right to one's freedom of expression, as they are modes which one's thoughts are externalized.
>
> In this jurisdiction, the application of doctrines originating from the U.S. has been generally maintained, albeit with some modifications. While this Court has withheld the application of facial challenges to strictly penal statutes, it has expanded its scope to cover statutes not only regulating free speech, but also those involving religious freedom, and other fundamental rights. The underlying reason for this modification is simple. For unlike its counterpart in the U.S., this Court, under its expanded jurisdiction, is mandated by the Fundamental Law not only to settle actual controversies involving rights which are legally demandable and enforceable, but also to determine whether or not there has been a grave abuse of discretion amounting to lack or excess of jurisdiction on the part of any branch or instrumentality of the Government. Verily, the framers of Our Constitution envisioned a proactive Judiciary, ever vigilant with its duty to maintain the supremacy of the Constitution.
>
> Consequently, considering that the foregoing petitions have seriously alleged that the constitutional human rights to life, speech and religion and other fundamental rights mentioned above have been violated by the assailed legislation, the Court has authority to take cognizance of these kindred petitions and to determine if the RH Law can indeed pass constitutional scrutiny. To dismiss these petitions on the simple expedient that there exist no actual case or controversy, would diminish this Court as a reactive branch of government, acting only when the Fundamental Law has been transgressed, to the detriment of the Filipino people.[151] (Emphasis in the original, citations omitted)

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

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

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

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

doctrine of hierarchy of courts and one by one dismissed the assertions of petitioner GIOS Samar as factual questions properly cognizable by the lower courts, specifically the Regional Trial Courts.

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

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

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

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

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

The *ponencia* focuses on the known harmful health effects of tobacco which squarely falls within the definition of health products and in turn, within the FDA's competence and mandate "to ensure the safety and quality of health products." It holds that any other contrary reading would be illogical

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

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

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

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

– *in that*— the FDA can regulate cosmetics due to its effects on health but not tobacco products.

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

> SECTION 9. Section 10, subsections (a), (e), (f), (g), (h), (i), (q), (r), (v), and (w) of Republic Act No. 3720, as amended, are hereby further amended, and new subsections (x), (y), (z), (aa), (bb), (cc), (dd), (ee), (ff), (gg), (hh), (ii), (jj), (kk), (ll), and (mm) are hereby added to read as follows:
>
> "SEC. 10. For the purposes of this Act, the term:
>
> "(h) 'Cosmetics' means any substance or preparation intended to be placed in contact with the various external parts of the human body or with the teeth and the mucous membranes of the oral cavity, with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odor, and/or protecting the body or keeping them in good condition.

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

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

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

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

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

> SECTION 4. Definition of Terms. — As used in this Act:
>
> r. "Tobacco" — refers to agricultural components derived from the tobacco plant, which are processed for use in the manufacturing of cigarettes and other tobacco products;
>
> s. "Tobacco Product" — refers to any product that consists of loose tobacco that contains nicotine and is intended for use in a cigarette, including any product containing tobacco and intended for smoking or oral or nasal use. Unless stated otherwise, the requirements of this Act pertaining to cigarettes shall also apply to other tobacco products;

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

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

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

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

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[61] G.R. No. 229861, July 2, 2018.
[62] 488 Phil. 311 (2004).
[63] *People v. Ejercito,* supra.
[64] AN ACT TO EFFECTIVELY INSTILL HEALTH CONSCIOUSNESS THROUGH GRAPHIC HEALTH WARNINGS ON TOBACCO PRODUCTS otherwise known as The Graphic Health Warnings Law enacted on July 15, 2014.

> SECTION 2. Declaration of Principles. — The State shall protect and promote the right to health of the people and instill health consciousness among them.
>
> The State shall protect consumers from trade malpractices and from substandard tobacco products.
>
> The State accepts that, as a State-Party to the World Health Organization's Framework Convention on Tobacco Control (FCTC), a treaty that reaffirms the right of all people to the highest standards of health, the Philippines is obliged to inform every person of the health consequences of tobacco consumption and exposure to tobacco smoke; to enact effective measures to curb and reduce tobacco use, especially among the youth; and to protect public health policy from the commercial and vested interests of the tobacco industry.
>
> The State is cognizant of the Philippines' duty under Article 11 of the FCTC which is to adopt and implement by September 2008 effective health warnings on tobacco products that should describe the harmful effects of tobacco use.
>
> The State recognizes that based on empirical data, text warnings have been shown to be insufficient in conveying the dangers of tobacco products while Graphic Health Warnings have been shown to be more effective in conveying the truth about the dangers of exposure and consumption of tobacco smoke.

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

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

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

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[65] Supra note 42.

the apparent lacunae, the US Congress enacted the law specifically providing for the US FDA's authority to regulate the manufacture, distribution, and marketing of tobacco products.

CONCLUSION

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

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

RAMON PAUL L. HERNANDO
Associate Justice