Republic of the Philippines
Supreme Court
Manila

FIRST DIVISION

VENUS COMMERCIAL CO., INC., *Petitioner,*	**G.R. No. 240764**
-versus-	Members: GESMUNDO, *C.J., Chairperson,* CAGUIOA, LAZARO-JAVIER, LOPEZ, M.,* and LOPEZ, J., *JJ.*
THE DEPARTMENT OF HEALTH and THE FOOD AND DRUG ADMINISTRATION, *Respondent.*	Promulgated: NOV 18 2021

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DECISION

LAZARO-JAVIER, *J.*:

The Case

This petition for review on *certiorari* under Rule 45 of the Rules of Court assails the following dispositions of the Court of Appeals in CA-G.R. SP No. 144844 entitled *Venus Commercial Co. Inc. v. The Department of Health and the Food and Drug Administration*:

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* On official leave.

1. **Decision**[1] dated February 23, 2018 which declared as valid Food and Drug Administration (FDA) Personnel Order No. 2014-220 and consequently dissolved the *writ* of permanent injunction issued by the trial court in Special Civil Case No. SCA 14-010-MN; and

2. **Resolution**[2] dated July 11, 2018 which denied petitioner's motion for reconsideration.

Antecedents

Republic Act No. 9711 (RA 9711), otherwise known as the Food and Drug Administration (FDA) Act of 2009[3] states *inter alia*:

> **Section 1.** The Bureau of Food and Drugs (BFAD) is hereby renamed the Food and Drug Administration (FDA).
>
> **Section 2.** This Act shall be known as the "Food and Drug Administration (FDA) Act of 2009."

The law bears its underlying policy and objectives, *viz.*:

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

To achieve these objectives, RA 9711 amended Section 4 of Republic Act No. 3720 (RA 3720),[4] *viz.*:

> **SEC. 4.** To carry out the provisions of this Act, there is hereby created an office to be called the Food and Drug Administration in the Department of

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1 Penned Justice Eduardo B. Peralta, Jr. and concurred in by Associate Justices Elihu A. Ybañez and Ronaldo Roberto B. Martin, *rollo*, pp. 12-32.
2 *Rollo*, pp. 8-11.
3 Food and Drug Administration Act of 2009, Republic Act No. 9711, Approved on August 18, 2009.
4 Food, Drugs, and Cosmetics Act, Republic Act No. 3720, Approved on June 22, 1963.

Health. Said Administration shall be under the Office of the Secretary and shall have the following functions, powers and duties:

x x x x

(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.[5]

Further Section 10 of RA 3720[6] was also amended, as follows:

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

(a) "*Board*" means the Board of Food and Drug Inspection.

x x x x

(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.

More, a new Section 30 was introduced in RA 3720, *viz.*:

A new Section 30 and a new headnote "Additional Powers and Functions of the Director-General" are hereby added to Republic Act No. 3720, which shall read as follows:

SEC. 30. The Director-General shall also exercise the following powers:

x x x x

(4) To issue orders of seizure, to seize[,] and hold in custody any article or articles of food, device, cosmetics, household hazardous substances and health products that is adulterated, counterfeited, misbranded or unregistered, or drug, in-vitro diagnostic reagent, biologicals, and vaccine that is adulterated or misbranded, when introduced into domestic commerce pending the authorized hearing under Republic Act No. 3720, as amended, Executive Order No. 175 (1987), and Republic Act No. 7394, otherwise known as the Consumers Act of the Philippines;

As for the acts punishable under RA 9711, Section 11 of RA 3720 was amended in this wise:

Sec. 10. Section 11, subsections (a), (b), (d), (g), (j), (k), and (l) of Republic Act No. 3720, as amended are hereby further amended to read as follows:

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5 Food and Drug Administration Act of 2009, Republic Act No. 9711, Approved on August 18, 2009.
6 *Id.*

Sec. 11. The following acts and the causing thereof are hereby prohibited:

(a) The manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising, or sponsorship of any health product that is adulterated, unregistered or misbranded."

(b) The adulteration or misbranding of any health product."

x x x x

(d) The giving of a guaranty or undertaking referred to in Section twelve [12](b) hereof which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect, signed by, and containing the name and address of the person or entity from whom he received in good faith the health products or the giving of a guaranty or undertaking referred to in Section twelve [12](b) which guaranty or undertaking is false.

x x x x

(g) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to health products if such act is done while such article is held for sale (whether or not the first sale) and results in such article being adulterated or misbranded *Provided*, That a retailer may sell in smaller quantities, subject to guidelines issued by the FDA.

x x x x

(j) The manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertisement, or sponsorship of any health product which, although requiring registration, is not registered with the FDA pursuant to this Act.

(k) The manufacture, importation, exportation, sale, offering for sale, distribution, transfer, or retail of any drug, device or in-vitro diagnostic reagent; the manufacture, importation, exportation, transfer or distribution of any food, cosmetic or household/urban hazardous substance; or the operation of a radiation or pest control establishment by any natural or juridical person without the license to operate from the FDA required under this Act.

(l) The sale, offering for sale, importation, exportation, distribution or transfer of any health product beyond its expiration or expiry date, if applicable.

x x x x

Accordingly, the aforesaid prohibited acts are penalized under Section 12, *viz.*:

(a) Any person who violates any of the provisions of Section eleven [11] hereof shall, upon conviction, suffer the penalty of imprisonment ranging from one (1) year but not more than ten (10) years or a fine of not less than Fifty thousand pesos (P50,000.00) but not more than Five hundred thousand

pesos (P500,000.00), or both, at the discretion of the court: *Provided*, That if the offender is a manufacturer, importer or distributor of any health product, the penalty of at least five (5) years imprisonment but not more than ten (10) years and a fine of at least Five hundred thousand pesos (P500,000.00) but not more than Five million pesos (P5,000,000.00) shall be imposed. *Provided, further*, That an additional fine of one percent (1%) of the economic value/cost of the violative product or violation, or One thousand pesos (P1,000.00), whichever is higher, shall be imposed for each day of continuing violation: *Provided, finally*, That health products found in violation of the provisions of this Act and other relevant laws, rules and regulations may be seized and held in custody pending proceedings, without hearing or court order, when the director-general has reasonable cause to believe from facts found by him/her or an authorized officer or employee of the FDA that such health products may cause injury or prejudice to the consuming public.

x x x x

Should the offense be committed by a juridical person, the Chairman of the Board of Directors, the president, general manager, or the partners and/or the persons directly responsible therefore shall he penalized.

Should the offense be committed by a foreign national, he/she shall, in addition to the penalties prescribed, be deported without further proceedings after service of sentence.

x x x x

Following the enactment of RA 9711, amending RA 3720, the Department of Health (DOH), in consultation with the FDA issued Department Circular 2011-0101, otherwise known as the Implementing Rules and Regulations (IRR) of RA 9711,[7] providing thus:

Article III:
Office of the Director-General

x x x x

Section 2: Duties and Functions of the Director-General. x x x

x x x x

b. Quasi-Judicial Powers, Duties and Functions:

x x x x

(5) To issue orders of seizure, to seize and hold in custody any article or articles of food, device, cosmetics, household hazardous substances and health products that are adulterated, counterfeited, misbranded or unregistered; or any drug, in-vitro diagnostic reagents, biologicals, and vaccine that is adulterated or misbranded, when introduced into domestic commerce pending the authorized hearing under the FDA Act of 2009, these Rules and Regulations, and as far as applicable, other relevant laws; x x x

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7 The Rules and Regulations Implementing Republic Act No. 9711- The Food and Drug Administration Act of 2009, Department-Circular 2011-0101, Issued on March 22, 2011.

x x x x

The present case came to be when FDA received a letter dated April 7, 2014 from EcoWaste Coalition[8] regarding the alleged **high lead content** of Artex Fine Water Colors manufactured by petitioner Venus Commercial Co., Inc. (Venus), *sans* FDA approval.

Acting thereon, FDA purchased samples of Artex Fine Water Colors from Merriam Webster Bookstore Binondo Branch and VMZ Guadalupe Shopping Center and subjected them to laboratory analysis. The results showed that the amount of lead in each sample exceeded the maximum tolerable limits prescribed by FDA.

Consequently, on May 28, 2014, the FDA Acting Director-General issued FDA Personnel Order No. 2014-220,[9] *viz.*:

> SUBJECT: Authority for Certain Food and Drug Regulation Officers of the RFO-NCR **to Proceed and Enter Venus Commercial Company, Inc.** located at 10 University Ave., Malabon City, **Conduct Inspection, Seizure of Violative Artex Fine Water Colors and/or Padlocking of the Establishment.**
>
> Information received by this Office reveals that the product Artex Fine Water Colors, which is being distributed in the market, does not conform to specification of test conducted, exceeding the allowed limit for lead content. Further, the product appears to be manufactured/distributed by Venus Commercial Company, Inc. with address at 10 University Ave. Malabon City. Verification with the records of this Office shows also that aforesaid establishment has no valid license to operate as manufacturer/distributor of the questioned product.
>
> Consistent with the mandate to strengthen post market surveillance system, objective to undertake vigilant monitoring of establishments and health products, and under authority to conduct inspection, in the interest of service, authority is hereby given to the following Food and Drug Regulation Officers of the RFO-NCR to proceed and enter at Venus Commercial Company, Inc. located at 10 University Ave., Malabon City, conduct inspection, and if confirmed manufacturing and/or distributing Artex Fine Water Colors, to seize the same and/or padlock the Establishment.[10]

x x x x

On May 29, 2014, FDA agents went to petitioner's office in Malabon City to implement FDA Personnel Order No. 2014-220 but the security guards did not allow them in. The FDA agents were consequently constrained to leave, but not without first serving Venus a Notice of Violation Report. They

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8 Eco Waste Coalition is an independent non-profit environmental network promoting chemical safety and zero waste, *unpaginated.*

9 *Unpaginated.*

10 *Id.*

also advised the company that they would return to implement the Order on another date.

A few days later, or on June 4, 2014, Venus filed the petition below for *certiorari* and prohibition with application for *writ* of preliminary injunction and/or temporary restraining order (TRO)[11] docketed as SCA 14-010-MN. The case was raffled off to the Regional Trial Court-Branch 74, Malabon City.

In the petition, Venus sought to **declare as unconstitutional Section 30(4)[12] of RA 3720, as amended by RA 9711, and Section 2(b) paragraph (5),[13] Article III of the IRR** for allegedly violative of its constitutional right against illegal search and seizure, as well as the constitutional command that searches and seizures be covered by judicial warrants or orders. Venus also assailed, for being supposedly an undue delegation of legislative power, **Section 10(ff)[14] of the amended law**. Finally, it sought to **invalidate FDA Personnel Order No. 2014-220** for being purportedly violative of its right to due process.

For their part, respondents[15] argued that aside from confirming through laboratory analysis the high lead content of the product samples of Artex Water Colors, FDA also got to verify that Venus did not have a license to operate as a manufacturer of household urban hazardous materials and that the subject water colors are not FDA registered.

Following the denial of Venus' prayer for temporary restraining order, the trial court proceeded to hear its prayer for *writ* of preliminary injunction. Venus' operations manager Joel Nell Coteng (Operations Manager Coteng)

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11 *Id.* at 14.

12 SEC. 30. The Director-General shall also exercise the following powers:
x x x x
(4) To issue orders of seizure, to seize and hold in custody any article or articles of food, device, cosmetics, household hazardous substances and health products that is adulterated, counterfeited, misbranded or unregistered, or drug, in-vitro diagnostic reagent, biologicals, and vaccine that is adulterated or misbranded, when introduced into domestic commerce pending the authorized hearing under Republic Act No. 3720, as amended, Executive Order No. 175 (1987), and Republic Act No. 7394, otherwise known as the Consumers Act of the Philippines.
(Food, Drugs, and Cosmetics Act, Republic Act No. 3720, Approved on June 22, 1963).

13 Article III: Office of the Director-General
x x x x
Section 2: Duties and Functions of the Director-General
x x x x
b. Quasi-Judicial Powers, Duties and Functions:
x x x x
(5) To issue orders of seizure, to seize and hold in custody any article or articles of food, device, cosmetics, household hazardous substances and health products that are adulterated, counterfeited, misbranded or unregistered; or any drug, in-vitro diagnostic reagents, biologicals, and vaccine that is adulterated or misbranded, when introduced into domestic commerce pending the authorized hearing under the FDA Act of 2009, these Rules and Regulations, and as far as applicable, other relevant laws.
(The Rules and Regulations Implementing Republic Act No. 9711- The Food and Drug Administration Act of 2009, Department-Circular 2011-0101, Issued on March 22, 2011).

14 Section 10(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.
(Food and Drug Administration Act of 2009, Republic Act No. 9711, Approved on August 18, 2009).

15 *Rollo,* pp. 15-16.

testified that the concerned FDA Operatives were simply armed with FDA Personnel Order No. 2014-220, *sans* any document bearing the so-called confirmatory test results on the supposed high lead content of Artex Fine Water Colors. Besides, Venus was not even charged with any administrative offense relative to their product with supposed high lead content.

Respondents did not present any countervailing evidence.

By **Order**[16] dated July 25, 2014, the trial court granted Venus' prayer for *writ* of preliminary injunction, *viz.:*

> From the evidence thus presented in this case, it appears and so the [c]ourt finds that the issuance of FDA Personnel Order No. 2014-220 failed to observe and comply with the requirements of due process of law. Petitioner's witness unequivocally declared that petitioner received no notice from the FDA as regards to any tests being conducted by the FDA on the product. Moreover, from an initial reading and determination of the questioned FDA issuance, it is apparent that such issuance was based on mere "[I]nformation received by this [the FDA] Office" which is hearsay evidence.
>
> There is likewise no doubt that no search or seizure order was issued by any court in this case.
>
> Finding a clear violation of petitioner's right to due process of law and its right against unreasonable searches and seizures, and respondent FDA's act of enforcing FDA Personnel Order No. 2014-220 on May 29, 2014 with threat of repeating the same, the issuance of a *writ* of preliminary injunction as provisional remedy is in order, so as to maintain the status quo until the main case is heard and resolved on the merits.
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> x x x x

During the trial proper, petitioner did not present any further evidence as it simply adopted the earlier testimony of Operations Manager Coteng. Respondents, on the other hand, presented one of its biochemists, Jenifer G. Cordero, who testified that she conducted laboratory examinations on the two (2) samples of Artex Water Colors submitted to them. The tests results showed that both samples exceeded the allowable lead content limits by 3,700% and 5,600%, respectively.

Ruling of the Trial Court

By **Decision**[17] dated September 23, 2015, the trial court stated that it avoided the issue of constitutionality and focused solely on the factual basis of FDA Personnel Order No. 2014-220. It ruled that **since there was no showing that laboratory tests were actually done** on the product samples, the right of Venus to due process was violated, hence, the impugned FDA Personnel Order No. 2014-220 is void. The decision pertinently stated:

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16 *Id.* at 40.

17 *Unpaginated.*

> Considering that based on the evidence on record before this [c]ourt there is **no clear showing that the samples actually tested by respondent FDA were the products of petitioner which were sought to be summarily seized without benefit of due process of law**, the [c]ourt has no other alternative but to uphold the right of the petitioner to be secure in its property against unreasonable seizures in this case.
>
> Inasmuch as there is sufficient factual and legal basis to grant the relief prayed for in this petition as herein above discussed without delving into the issue of constitutionality of the assailed provision of RA 3720, this court, in the exercise of its sound discretion[,] resolves to restrain from ruling said issue. Only FDA Personnel Order No. 2014-220 issued on May 28, 2014 by Food and Drug Administration Acting Director-General Keneth Y. Hartigan-Go, MD., **insofar as it orders the seizure and padlocking of petitioner's establishment, is declared null and void for having been issued with grave abuse of discretion and/or lack of jurisdiction and in violation of petitioner's right to due process of law**. (Emphases supplied)
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> x x x x
>
> WHEREFORE, the *writ* of preliminary injunction is hereby made PERMANENT. FDA Personnel Order No. 2014-220 issued on May 28, 2014 is hereby **declared NULL and VOID** insofar as it orders the **immediate seizure** of Artex Fine Water Colors and **padlocking of the premises** of Venus Commercial Company, Inc., with address at 10 University Ave., Malabon City, without due process of law. (Emphases supplied)
>
> SO ORDERED.[18]

Respondents' partial motion for reconsideration was denied per **Order**[19] dated December 4, 2015.

Proceedings before the Court of Appeals

On appeal,[20] respondents, through the Office of the Solicitor General (OSG), brought to fore the authority of the FDA Director-General to issue FDA Personnel Order No. 2014-220 pursuant to Section 30(4)[21] of RA 3720, as amended. Respondents emphasized that in view of the trial court's avoidance to resolve the constitutionality of the aforesaid provision, the same remains valid, hence, should be fully implemented.

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18 *Id.*

19 *Rollo*, p. 17.

20 *Id.* at 70.

21 Section 30(4). To issue orders of seizure, to seize[,] and hold in custody any article or articles of food, device, cosmetics, household hazardous substances and health products that is adulterated, counterfeited, misbranded or unregistered, or drug, in-vitro diagnostic reagent, biologicals, and vaccine that is adulterated or misbranded, when introduced into domestic commerce pending the authorized hearing under Republic Act No. 3720, as amended, Executive Order No. 175 (1987), and Republic Act No. 7394, otherwise known as the Consumers Act of the Philippines.
(Food, Drugs, and Cosmetics Act, Republic Act No. 3720, Approved on June 22, 1963).

Respondents, nonetheless, still defended the constitutionality of Sections 30(4)[22] and 10(ff)[23] of RA 3720, as amended, and Section 2(b)[24] paragraph (5), Article III of the IRR, as well as FDA Personnel Order No. 2014-220. They argued that Section 30(4) was a police power measure meant to protect public health and safety. At any rate, the **search of establishments** suspected to be producing toxic products made available to the consuming public was **a form of administrative search** which was not violative of the right against illegal search and seizure guaranteed under Article III, Section 2[25] of the 1987 Constitution. For that matter, **prior notice and hearing** will render **illusory** the authority of the FDA Director-General under **Section 30(4)**. In any case, the **inspection and closure to be carried out** by the FDA personnel were **temporary and preventive** subject to the right of the affected party to be heard.

In response,[26] Venus reiterated that Section 30(4) of the law and Section 2(b) paragraph (5), Article III of the IRR, as well as FDA Personnel Order No. 2014-220 **violated its right against warrantless search and seizure**. Further, Section 10(ff)[27] of the law constituted an **undue delegation of legislative powers** since the FDA Director-General was effectively clothed with unlimited discretion to classify health products. Lastly, Venus asserted there was no law permitting the Director-General of the FDA to padlock a production facility.

Ruling of the Court of Appeals

Under its assailed **Decision**[28] dated February 23, 2018, the Court of Appeals reversed and consequently dissolved the *writ* of permanent injunction.

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22 *Id.*

23 Section 10(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.
(Food and Drug Administration Act of 2009, Republic Act No. 9711, Approved on August 18, 2009).

24 Article III, Section 2(5). To issue orders of seizure, to seize[,] and hold in custody any article or articles of food, device, cosmetics, household hazardous substances and health products that are adulterated, counterfeited, misbranded or unregistered; or any drug, in-vitro diagnostic reagents, biologicals, and vaccine that is adulterated or misbranded, when introduced into domestic commerce pending the authorized hearing under the FDA Act of 2009, these Rules and Regulations, and as far as applicable, other relevant laws;
(The Rules and Regulations Implementing Republic Act No. 9711- The Food and Drug Administration Act of 2009, Department-Circular 2011-0101, Issued on March 22, 2011).

25 Section 2. The right of the people to be secure in their persons, houses, papers, and effects against unreasonable searches and seizures of whatever nature and for any purpose shall be inviolable, and no search warrant or warrant of arrest shall issue except upon probable cause to be determined personally by the judge after examination under oath or affirmation of the complainant and the witnesses he may produce, and particularly describing the place to be searched and the persons or things to be seized.
(Article III, 1987 Constitution).

26 *Id.* at 14 and 15.

27 Section 10(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.
(Food and Drug Administration Act of 2009, Republic Act No. 9711, Approved on August 18, 2009).

28 *Rollo*, pp. 13-32.

First. Section 30(4) of RA 3720, as amended, was a **police power legislation designed to protect the consuming public against unsafe and poor-quality products** made available in the market.[29] At any rate, contrary to the claim of Venus, **Section 30(4) afforded the establishments concerned an opportunity to be heard**, thus:

> SEC. 30. The Director-General shall also exercise the following powers:
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> x x x x
>
> (4) To issue orders of seizure, to seize, and hold custody any article or articles of food, device, cosmetics, household hazardous substances and health products that is adulterated, counterfeited, misbranded or unregistered, or drug in-vitro diagnostic reagent, biologicals, and vaccine that is adulterated or misbranded, when introduced into domestic commerce pending the authorized hearing under Republic Act No. 3720, as amended, Executive Order No. 175 (1987), and Republic Act. No. 7394, otherwise known as the Consumers Act of the Philippines.
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> x x x x

Second. The laboratory findings here constituted probable cause to effect administrative warrantless search and seizure insofar as the toxic products of Venus were concerned.

Third. Section 10(ff) did not constitute undue delegation of legislative power. It did not grant the FDA Director-General unbridled discretion in formulating the criteria for classifying and determining what constituted health products.[30]

Fourth. The authority of the FDA Director-General to padlock an establishment pending hearing was impliedly included in the express statutory power of the FDA Director-General "to issue orders of seizure, to seize and hold custody any articles of food, device, cosmetics, household hazardous substances and health products that is adulterated, counterfeited, misbranded or unregistered, or drug in-vitro diagnostic reagent, biologicals, and vaccine that is adulterated or misbranded, when introduced into domestic commerce pending the authorized hearing under RA 3720, as amended, Executive Order

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29 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.
(Food and Drug Administration Act of 2009, Republic Act No. 9711, Approved on August 18, 2009).

30 Section 10(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.
(Food and Drug Administration Act of 2009, Republic Act No. 9711, Approved on August 18, 2009).

No. 175 (1987),[31] and Republic Act No. 7394 (RA 7394), otherwise known as the Consumers Act of the Philippines.[32]

The motion for reconsideration of Venus was subsequently denied under **Resolution**[33] dated July 11, 2018.

The Present Petition

Petitioner[34] now prays that the foregoing dispositions of the Court of Appeals be reversed and set aside; Section 30(4) of RA 3720, as amended, and Section 2(b) paragraph (5), Article III of the IRR, being violative of its right against warrantless search and seizure, and Section 10(ff) being an improper delegation of legislative power, respectively, be declared unconstitutional; and FDA Personnel Order No. 2014-220, being **akin to a judicial search warrant and violative of its right to due process** and self-incrimination be invalidated, too.

In addition, petitioner assails for the first time the constitutionality of Section 12(a) of RA 3720, as amended, *viz.*:

> **SEC. 12.** (a) Any person who violates any of the provisions of Section eleven [11] hereof shall, upon conviction, suffer the penalty of imprisonment ranging from one (1) year but not more than ten (10) years or a fine of not less than Fifty thousand pesos (P50,000.00) but not more than Five hundred thousand pesos (P500,000.00), or both, at the discretion of the court: *Provided*, That if the offender is a manufacturer, importer or distributor of any health product, the penalty of at least five (5) years imprisonment but not more than ten (10) years and a fine of at least Five hundred thousand pesos (P500,000.00) but not more than Five million pesos (P5,000,000.00) shall be imposed: *Provided, further*, That an additional fine of one percent (1%) of the economic value/cost of the violative product or violation, or One thousand pesos (P1,000.00), whichever is higher, shall be imposed for each day of continuing violation: ***Provided, finally*, That health products found in violation of the provisions of this Act and other relevant laws, rules and regulations may be seized and held in custody pending proceedings, without hearing or court order, when the director-general has reasonable cause to believe from facts found by him/her or an authorized officer or employee of the FDA that such health products may cause injury or prejudice to the consuming public.**[35] (Emphases supplied)

Petitioner argues that should FDA Personnel Order No. 2014-220 be implemented, the seizure of Artex Fine Water Colors will have the strong tendency to incriminate it under Section 11[36] of RA 3270. In such a case, the prosecution of petitioner for the prohibited acts under the law will proceed utilizing the evidence procured during a search and seizure operations by the

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31 Foods, Drugs, and Devices, and Cosmetics Act, Executive Order No. 175, May 22, 1987.
32 The Consumer Act of the Philippines, Republic Act No. 7394, Approved on April 13, 1992.
33 *Rollo*, pp. 8-11.
34 *Id.* at 36-63.
35 Food and Drug Administration Act of 2009, Republic Act No. 9711, Approved on August 18, 2009.
36 Section 11, Chapter VI, Prohibited Acts under RA 3720. Food, Drugs, and Cosmetics Act, Republic Act No. 3720, Approved on June 22, 1963. (As amended)

FDA.[37] Besides, the constitutional guarantee that a search warrant shall be issued by a neutral, detached, and unbiased judge will be rendered futile if the FDA Director-General himself or herself is allowed to issue the same.[38] More, the implementation of FDA Personnel Order No. 2014-220 is not one of the circumstances which justify a warrantless search and seizure since under the attendant circumstances here, FDA had sufficient time to secure a judicial search and seizure warrant insofar as the subject watercolors are concerned.[39]

On the other hand, respondents,[40] through Solicitor General Jose C. Calida, Assistant Solicitor General Henry S. Angeles, and State Solicitor Louie Brian Sze, counter that the issues here concern administrative searches and seizures conducted for regulatory purposes and not for the purpose of determining criminal liability. The validity of an administrative search does not hinge on the probable cause standard, but on the reasonableness of the search in the context of the regulatory scope of the issuing agency. Respondents avow that FDA was acting within the bounds of reason when it issued FDA Personnel Order No. 2014-220.

Respondents further defend FDA's authority to temporarily close the establishment suspected of producing toxic products similar to the "close now, hear later" procedure of the Monetary Board. It is a necessary aspect of police power.

Finally, respondents clarify that the objective of FDA Personnel Order No. 2014-220 is not to determine criminal liability but to protect public health.

Issues

First. Do Sections 12(a) and 30(4) of RA 3720, as amended and Section 2(b) paragraph (5), Article III of Department Circular No. 2011-0101 violate the Constitutional proscription against unreasonable searches and seizures?

Second. Does Section 10(ff) constitute an invalid delegation of legislative power?

Third. Does FDA Personnel Order No. 2014-220 violate the guarantee against due process and the right against self-incrimination?

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37 *Rollo*, p. 59
38 *Id.*
39 *Id.* at 60-61.
40 *Unpaginated.*

Ruling

Power of Judicial Review

The power of judicial review is conferred on the judicial branch of government under Section 1,[41] Article VIII of the 1987 Constitution. It sets to correct and restrain any act of grave abuse of discretion amounting to lack or excess of jurisdiction by any branch of Government and may, therefore, be invoked to nullify actions of the legislative branch which have infringed the Constitution.[42]

Father Joaquin Bernas explained judicial power in this wise:

> Judicial power, in essence, is the power of a court to settle actual controversies between real and conflicting parties through the application of a law. It therefore necessarily involves a search for an applicable law. And if the applicable law is either a statute or a constitutional precept, and the two are irreconcilably in conflict, the court must choose between the two. But since the Constitution is superior to any act of the legislature, it being an enactment of the sovereign people, the Constitution must govern the case. As Marshall put it: "So if a law be in opposition to the Constitution; if both the law and the Constitution apply to a particular case, so that the court must either decide the case conformably to the law, disregarding the Constitution; or conformably to the Constitution, disregarding the law; the court must determine which of these conflicting rules governs the case. This is of the very essence of judicial duty." It is not therefore an abstract "revisory power over the action of Congress."[43]
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The power of judicial review is part and parcel of the Court's judicial power and is a power inherent in all courts.[44] In ***In Re: Save the Supreme Court Judicial Independence and Fiscal Autonomy Movement***,[45] the Court enumerated the requisites for judicial review, *viz.*:

> (1) there must be an actual case or controversy calling for the exercise of judicial power;
> (2) the person challenging the act must have the standing to question the validity of the subject act or issuance; otherwise stated, he must have a personal and substantial interest in the case such that he has sustained, or will sustain, direct injury as a result of its enforcement;
> (3) the question of constitutionality must be raised at the earliest opportunity; and

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41 Section 1. The judicial power shall be vested in one Supreme Court and in such lower courts as may be established by law.
Judicial power includes the duty of the courts of justice to settle actual controversies involving rights which are legally demandable and enforceable, and 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.

42 See *ANGKLA: Ang Partido ng mga Pilipinong Marino, Inc. v. Commission on Elections*, G.R. No. 246816, September 15, 2020.

43 Joaquin Bernas, The 1987 Constitution of the Republic of the Philippines: A Commentary (2009 edition.)

44 *Villanueva v. Judicial and Bar Council,* 757 Phil. 534, 561 (2015).

45 751 Phil 30, 36 (2015).

(4) the issue of constitutionality must be the very *lis mota* of the case.

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There is no question regarding the presence of the first and second requisites here. The question though lies on the presence of the third and fourth requisites.

The question of constitutionality must be raised at the earliest opportunity.

As a general rule, the question of constitutionality must be raised at the earliest opportunity so that if not raised in the pleadings, ordinarily, it may not be raised during trial, and if not raised during trial, it will not be considered on appeal.[46] ***Matibag v. Benipayo***[47] enunciated:

> x x x However, it is not the date of filing of the petition that determines whether the constitutional issue was raised at the earliest opportunity. The earliest opportunity to raise a constitutional issue is to raise it in the pleadings before a competent court that can resolve the same, such that, "if it is not raised in the pleadings, it cannot be considered at the trial, and, if not considered at the trial, it cannot be considered on appeal."
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Dasmariñas Water District v. Monterey Foods Corporation[48] further held:

> We have ruled time and again that the constitutionality or validity of laws, order, or such other rules with the force of law cannot be attacked collaterally. There is a legal presumption of validity of these laws and rules. Unless a law or rule is annulled in a direct proceeding, the legal presumption of its validity stands.
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> Besides,
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> x x x [a] law is deemed valid unless declared null and void by a competent court; more so when the issue has not been duly pleaded in the trial court. **The question of constitutionality must be raised at the earliest opportunity.** x x x The settled rule is that courts will not anticipate a question of constitutional law in advance of the necessity of deciding it. (Emphasis supplied)
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In ***Umali v. Executive Secretary***,[49] the constitutionality of the creation of the Presidential Commission on Anti-Graft and Corruption was raised only in the motion for reconsideration of the trial court's decision. The Court did

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46 See *Garcia v. Drilon*, 712 Phil. 44, 78 (2013).
47 429 Phil. 554, 578 (2002).
48 587 Phil. 403, 416 (2008).
49 365 Phil. 77, 78 (1999).

not entertain the constitutional issue as it was not raised at the earliest opportunity.

In ***Gobenciong v. Court of Appeals***,[50] the constitutionality of the Ombudsman Act was not raised before the Office of the Ombudsman or at the very least, before the Court of Appeals. The Court ruled that it cannot consider the issue of constitutionality that was raised too late in the day and for the first time in Gobenciong's petition for review on *certiorari* filed before the Court.

Here, it is a matter of record that Venus raised the constitutionality of Sections 10(ff) and 30(4) of the amended law, Section 2(b) paragraph (5), Article III of Department Circular No. 2011-0101, and FDA Personnel Order No. 2014-220 right off *via* its complaint below. Undeniably, it did so at the earliest opportunity.

But as for Section 12(a), *viz.*:

> **SEC. 12.** (a) Any person who violates any of the provisions of Section eleven [11] hereof shall, upon conviction, suffer the penalty of imprisonment ranging from one (1) year but not more than ten (10) years or a fine of not less than Fifty thousand pesos (P50,000.00) but not more than Five hundred thousand pesos (P500,000.00), or both, at the discretion of the court: *Provided*, That if the offender is a manufacturer, importer or distributor of any health product, the penalty of at least five (5) years imprisonment but not more than ten (10) years and a fine of at least Five hundred thousand pesos (P500,000.00) but not more than Five million pesos (P5,000,000.00) shall be imposed: *Provided, further*, That an additional fine of one percent (1%) of the economic value/cost of the violative product or violation, or One thousand pesos (P1,000.00), whichever is higher, shall be imposed for each day of continuing violation: ***Provided, finally,*** **That health products found in violation of the provisions of this Act and other relevant laws, rules and regulations may be seized and held in custody pending proceedings, without hearing or court order, when the director-general has reasonable cause to believe from facts found by him/her or an authorized officer or employee of the FDA that such health products may cause injury or prejudice to the consuming public.**[51] (Emphases supplied)

The same is being raised for the first time only here and now. While this is so, however, we will not dismiss the petition based thereon since Section 12(a) is so closely intertwined with, and inseparable from, both Sections 10(ff) and 30(4) of the amended law, Section 2(b) paragraph (5), Article III of Department Circular No. 2011-0101,[52] and FDA Personnel Order No. 2014-220 that our disposition pertaining to them will definitely impact Section 12(a). Hence, we are taking cognizance of the challenge against Section 12(a) and will resolve it, together with Sections 10(ff) and 30(4) of the amended law, Section 2(b) paragraph (5), Article III of

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50 573 Phil. 613, 642 (2008).

51 Food and Drug Administration Act of 2009, Republic Act No. 9711, Approved on August 18, 2009.

52 The Rules and Regulations Implementing Republic Act No. 9711- The Food and Drug Administration Act of 2009, Department-Circular 2011-0101, Issued on March 22, 2011.

Department Circular No. 2011-0101[53] and FDA Personnel Order No. 2014-220.

Interestingly, Venus never raised the constitutionality of Section 4(j) of RA 3720, as amended by RA 9711, granting FDA the power to issue cease and desist orders *motu proprio* or upon verified complaint for health products, whether or not registered with the FDA, *viz.:*

> 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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> x x x x
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> (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.[54]
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Even then, should we sustain the assailed provisions – Sections 10(ff), 12(a), and 30(4) of the amended law, the power of FDA to issue cease and desist orders *motu proprio* under the last sentence of Section 4(j) – will be deemed upheld, too. Conversely, should we declare the aforesaid provisions unconstitutional, Section 4(j) will have to fall, too, as a necessary consequence. In both instances, we proceed from the fact that all three (3) provisions are closely intertwined with, and inseparable from, Section 4(j).

The question of constitutionality is the very lis mota of the case

We now go to the fourth requisite for judicial review – **The question of constitutionality is the very *lis mota* of the case.**

Lis mota is a Latin term meaning the cause or motivation of a legal action or lawsuit. The literal translation is "litigation moved." Under the rubric of *lis mota*, in the context of judicial review, the Court will not pass upon a question of unconstitutionality, although properly presented, if the case can be disposed of on some other ground, such as the application of the statute or the general law. The petitioner must be able to show that the case cannot be legally resolved unless the constitutional question raised is determined.[55]

Sotto v. Commission on Elections[56] explained:

> It is well-established rule that a court should not pass upon a constitutional question and decide a law to be unconstitutional or invalid, unless such question is raised by the parties and that when it is raised, if the

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53 *Id.*

54 Food and Drug Administration Act of 2009, Republic Act No. 9711, Approved on August 18, 2009.

55 Supra note 42.

56 76 Phil. 516, 522 (1946).

> record also presents some other ground upon which the court may rest its judgment, that course will be adopted and the constitutional question will be left for consideration until a case arises in which a decision upon such question will be unavoidable.
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Parcon-Song v. Parcon,[57] citing *Sps. Mirasol v. Court of Appeals,* expounded that the presumption of constitutionality is anchored on the doctrine of separation of powers. The Court should, therefore, not assume that legislative and executive acts were done without thoughtful consideration:

> As regards the *second issue*, petitioners contend that P.D. No. 579 and its implementing issuances are void for violating the due process clause and the prohibition against the taking of private property without just compensation. Petitioners now ask this Court to exercise its power of judicial review.
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> Jurisprudence has laid down the following requisites for the exercise of this power: First, there must be before the Court an actual case calling for the exercise of judicial review. Second, the question before the Court must be ripe for adjudication. Third, the person challenging the validity of the act must have standing to challenge. Fourth, the question of constitutionality must have been raised at the earliest opportunity, and lastly, the issue of constitutionality must be the very *lis mota* of the case.
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> As a rule, the courts will not resolve the constitutionality of a law, if the controversy can be settled on other grounds. The policy of the courts is to avoid ruling on constitutional questions and to presume that the acts of the political departments are valid, absent a clear and unmistakable showing to the contrary. To doubt is to sustain. This presumption is based on the doctrine of separation of powers. This means that the measure had first been carefully studied by the legislative and executive departments and found to be in accord with the Constitution before it was finally enacted and approved.
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> The present case was instituted primarily for accounting and specific performance. The Court of Appeals correctly ruled that PNB's obligation to render an accounting is an issue, which can be determined without having to rule on the constitutionality of P.D. No. 579. In fact, there is nothing in P.D. No. 579, which is applicable to PNB's intransigence in refusing to give an accounting. The governing law should be the law on agency, it being undisputed that PNB acted as petitioners' agent. In other words, the requisite that the constitutionality of the law in question be the very *lis mota* of the case is absent. Thus[,] we cannot rule on the constitutionality of P.D. No. 579.
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[57] G.R. No. 199582, July 2, 2020.

Notably, the parties here have no quibble that the constitutionality of Sections 10(ff), 12(a), and 30(4) is the very ***lis mota*** of the present case. Specifically, it hinges on these constitutional issues: 1) Does Section 10(ff constitute an improper delegation of legislative power? 2) Do Sections 12(a) and 30(4) of the amended law, Section 2(b) paragraph (5), Article III of Department Circular No. 2011-0101[58] amount to illegal search and seizure? 3) Does FDA Personnel Order No. 2014-220 violate Venus' right to due process and its right against self-incrimination?

As stated, Venus has pointedly raised these issues in view of the threatened seizure of its watercolor products and closure of its establishment. To be sure, this clear and imminent threat arising from the so-called unconstitutional provisions is capable of repeating itself. Hence, for purposes of stability, economy, and peace of mind of the parties, the issue of constitutionality ought to be resolved here and now, once and for all.

True, the trial court claimed to have avoided the foregoing constitutional issues as it supposedly chose to rule only on the factual basis of FDA Personnel Order No. 2014-220 exclusively from the prism of due process.

But truly, there is no way the issue of constitutionality can be avoided here. This simply means that the trial court could not have resolved the validity of FDA Personnel Order No. 2014-220 independent of the provisions of the FDA Law and its IRR. For the lifeline and due process component of FDA Personnel Order No. 2014-220 are actually derived from Sections 10(ff), 12(a), and 30(4), as well as from Section 2(b) paragraph 5 of Article III of the IRR.

Sections 12(a) and Section 30(4) of the law, as well as Section 2(b) paragraph (5), Article III of Department Circular No. 2011-0101 does not violate the Constitutional proscription against unreasonable searches and seizures

Section 2, Article III of the 1987 Constitution protects the right of the people against unreasonable searches and seizures, thus:

> **SECTION 2.** The right of the people to be secure in their persons, houses, papers and effects against unreasonable searches and seizures of whatever nature and for any purpose shall be inviolable, and no search warrant or warrant of arrest shall issue except upon probable cause to be determined personally by the judge after examination under oath or affirmation of the complainant and the witnesses he may produce, and particularly describing the place to be searched and the persons or things to be seized.

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[58] The Rules and Regulations Implementing Republic Act No. 9711- The Food and Drug Administration Act of 2009, Department-Circular 2011-0101, Issued on March 22, 2011.

Verily, warrantless searches and seizures are generally considered unreasonable. To be regarded otherwise, government-led search and seizure must generally be sanctioned by a judicial warrant issued in accordance with the requirements prescribed in the foregoing constitutional provision.[59]

The issuance of a search warrant must be premised on a finding of probable cause; that is, the existence of such facts and circumstances which would lead a reasonably discreet and prudent man to believe that an offense has been committed and that the objects sought in connection with the offense are in the place to be searched.[60]

This rule, though admits of exceptional instances when warrantless searches and seizures are considered permissible, *viz.*: (1) consented searches; (2) searches incidental to a lawful arrest; (3) searches of a moving vehicle; (4) seizures of evidence in plain view; (5) searches incident of inspection, supervision, and regulation sanctioned by the State in the exercise of its police power; (6) customs searches; (7) stop and frisk searches; and (8) searches under exigent and emergency circumstances.[61]

Of particular significance here are the searches incident of inspection, supervision, and regulation sanctioned by the State in the exercise of its police power. They are better known as administrative searches.

Police Power of the State

Police power is not capable of an exact definition, but has been purposely veiled in general terms to underscore its comprehensiveness to meet all exigencies and provide enough room for an efficient and flexible response to conditions and circumstances, thus, assuring the greatest benefits.[62] Accordingly, it has been described as "the most essential, insistent and the least limitable of powers, extending as it does to all the great public needs."[63]

It is broadly defined as the State's authority to enact legislation that may interfere with personal liberty or property in order to promote the general welfare.[64] ***Gerochi v. Department of Energy***[65] described police power, *viz.*:

> x x x [P]olice power is the power of the state **to promote public welfare by restraining and regulating the use of liberty and property**. It is the most pervasive, the least limitable, and the most demanding of the three fundamental powers of the State. The justification is found in the Latin maxim *salus populi est suprema lex* (the welfare of the people is the supreme law) and *sic utere tuo ut alienum non laedas* (so use your property as not to injure the property of others). As an inherent attribute of

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59 See *Pilapil, Jr. v. Cu*, G.R. Nos. 228608 & 228589, August 27, 2020.
60 See *People v. Sison*, G.R. No. 238453, July 31, 2019.
61 Supra note 59.
62 *Carlos Superdrug Corporation v. DSWD*, 553 Phil. 120, 132 (2007).
63 *Id.*
64 See *Council of Teachers and Staff of Colleges and Universities of the Philippines v. Secretary of Education*, G.R. Nos. 216930, 217451, 217752, 218045, 218098, 218123 & 218465, October 9, 2018.
65 554 Phil. 563, 579-580 (2007).

> sovereignty which virtually extends to all public needs, police power grants a wide panoply of instruments through which the State, as *parens patriae*, gives effect to a host of its regulatory powers. We have held **that the power to "regulate" means the power to protect, foster, promote, preserve, and control, with due regard for the interests, first and foremost, of the public, then of the utility and of its patrons.** (Emphases supplied)
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The proper exercise of police power requires compliance with the following requisites: (a) the interest of the public generally, as distinguished from those of a particular class, require the interference of the State; and (b) the means employed are reasonably necessary to the attainment of the objective sought to be accomplished and not unduly oppressive upon individuals.[66] In fine, there must be a concurrence of a lawful subject and lawful method.[67]

Lawful Object

The law is a legitimate exercise of police power if it has general welfare for its object.[68] In ***Didipio Earth-Savers' v. Gozun***,[69] the Court distinguished police power and the power of eminent domain in this wise:

> [The] property condemned under police power is usually noxious or intended for a noxious purpose; hence, no compensation shall be paid. Likewise, in the exercise of police power, property rights of private individuals are subjected to restraints and burdens in order to secure the general comfort and prosperity of the state. Thus, an ordinance prohibiting theaters from selling tickets in excess of their seating capacity (which would result in the diminution of profits of the theater-owners) was upheld valid as this would promote the comfort, convenience and safety of the customers. In ***U.S. v. Toribio***, the court upheld the provisions of Act No. 1147, a statute regulating the slaughter of carabao for the purpose of conserving an adequate supply of draft animals, as a valid exercise of police power, notwithstanding the property rights impairment that the ordinance imposed on cattle owners. x x x
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In ***Carlos Superdrug Corporation v. DSWD***,[70] Section 4(a) of RA 9257 was assailed for allegedly taking private property for public purpose without just compensation. The Court sustained the provision, ratiocinating that property rights must bow to the primacy of police power because property rights, though sheltered by due process, must yield to the general welfare.

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66 See *DECS v. San Diego*, 259 Phil. 1016, 2021 (1989).
67 See *Lucena Grand Central Terminal, Inc. v. JAC Liner*, 492 Phil. 314, 322 (2005).
68 Supra note 62.
69 520 Phil. 457, 476-477 (2006); citing *U.S. v. Toribio*, G.R. No. L-5060, January 26, 1910.
70 Supra note 62 at 132.

In ***William Case, et al. v. La Junta de Sanidad de Manila***,[71] the plaintiff was ordered by the Director of Health to make connections to the new sewer system because the sanitary conditions of his premises were found to be poor. The Order was issued in compliance with Ordinance No. 125 of the City of Manila which regulated and enforced the use of sewers and drains in the city. Plaintiff alleged that Ordinance No. 125 was void for being allegedly unreasonable, unjust, and oppressive and that the health authorities were without legal authority to require him to connect his premises to the new sewer system. The Court ruled that Ordinance No. 125 was clearly designed to preserve and protect the health, comfort, and convenience of the inhabitants of the thickly populated City of Manila. Therefore, it falls within what is generally known as the police power of the Government. Since Ordinance No. 125 was adopted by express authority of law, and being a reasonable exercise of the police power of the State, the same is valid and enforceable. This power of the State has but few limitations when it is exercised to secure the peace, safety, health, morals, and the best and highest interests of the public.

Here, FDA was created under RA 9711, amending RA 3720, to ensure the safety, efficacy, or quality of health products which include food, drugs, cosmetics, devices, biologicals, vaccines, in-vitro diagnostic reagents, radiation-emitting devices or equipment, and household/urban hazardous substances, including pesticides and toys, or consumer products that may have an effect on health which require regulations as determined by the FDA.[72]

In her Sponsorship Speech, then Senator Loren Legarda envisioned a more vigilant regulatory body through the new FDA that will support and upgrade government's protection of the right to health, *viz.*:

> I have envisioned a more vigilant regulatory body that will support and improve the protection of the right to health of the Filipino people. The FDCDA[73] will undertake appropriate health manpower development and research that are responsive to the country's health manpower development and research that are responsive to the country's health needs and problems. The regulatory capacity of now-existing BFAD will be enhanced and strengthened to ensure a more effective inspection, licensing, and monitoring of food and drugs. The leaps and bounds of development in food and health since the founding of the Bureau of Food and Drugs as well as the unprecedented integration of world economy through increased flow of trade in recent years call for a food and drug regulatory system that has the attributes of the FDCDA which this bill seeks to create.[74]
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71 G.R. No. L-7595, February 4, (1913).

72 FDA Mandate. Accessed from https://www.fda.gov.ph/about-fda/ August 18, 2021.

73 Prior to the enactment of the FDA Act of 2009, the Senate Bill No. 2645 calls for the conversion of the Bureau of Food and Drugs (BFAD) to Food, Drugs, Cosmetics and Devices Administration (FDCDA). Senate Journal. Fourteenth Congress, Second Regular Session, Session No. 26, October 6, 2008. (Accessed from https://legacy.senate.gov.ph/lisdata/899412329!.pdf/ December 12, 2021).

74 *Id.*

Sections 12(a) and 30(4) of the law, as well Section 2(b) paragraph (5), Article III of Department Circular No. 2011-0101[75] are clearly designed to protect the health and safety of the people against exposure to and use of hazardous products. More, FDA Personnel Order No. 2014-220 was specifically issued to prevent Venus from selling toxic watercolors to protect the public, especially the young children from the risks of ingesting the same or from coming in contact with the toxic high lead component of the product. There is no question that public health was the lawful subject of the police power legislation here.

This brings us to the means employed by the law to attain its professed objectives, specifically whether these means are reasonably necessary and not unduly oppressive upon individuals.

Lawful Means

In order to fulfill its mandate, Sections 12(a) and 30(4) expressly authorized the FDA Director-General to issue orders for search and seizure and hold in custody products that fell within the ambit of hazardous substances contemplated by law. Section 12(a) specifically granted the Director-General the power to seize and hold in custody, pending proceedings, *sans* hearing or court order, whenever the Director-General had reasonable cause to believe that such health products may cause injury or prejudice to the consuming public. On the other hand, FDA Personnel Order No. 2014-220 was issued to direct the FDA regulation officers not only to enter the premises of Venus and seize subject watercolors found to be hazardous, but also to padlock the production facility.

In ***People of the Philippines v. O'Cochlain***,[76] the Court recognized that administrative searches are allowed in certain situations where special needs arise and securing a prior search warrant is rendered impracticable, *viz:*

> U.S. courts have permitted exceptions to the Fourth Amendment when "special needs, beyond the normal need for law enforcement, make the warrant and probable cause requirement impracticable" such as work-related searches of government employees' desks and offices, warrantless searches conducted by school officials of a student's property, government investigators conducting searches pursuant to a regulatory scheme when the searches meet "reasonable legislative or administrative standards," and a State's operation of a probation system. The Fourth Amendment permits the warrantless search of **"closely regulated" businesses**; "special needs" cases such as schools, employment, and probation; and "checkpoint" searches such as airport screenings under the administrative search doctrine.
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> Searches and seizures are ordinarily unreasonable in the absence of individualized suspicion of wrongdoing. **However, because administrative searches primarily ensure public safety instead of detecting criminal wrongdoing, they do not require individual**

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75 The Rules and Regulations Implementing Republic Act No. 9711- The Food and Drug Administration Act of 2009, Department-Circular 2011-0101, issued on March 22, 2011.

76 G.R. No.229071, December 10, 2018.

> **suspicion. Where the risk to public safety is substantial and real, blanket suspicionless searches calibrated to the risk may rank as "reasonable."** (Emphases supplied)
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Section 2, Article III of the Constitution was patterned after the Fourth Amendment[77] to the Constitution of the United States of America.[78] Having been derived almost verbatim from this source, the Court may turn to the relevant doctrinal pronouncements of the U.S. Federal Supreme Court and State Appellate Courts.[79]

In 1967, the U.S. Supreme Court decided two (2) companion cases – ***Camara v. Municipal Court***[80] and ***See v. City of Seattle***[81] – involving warrantless administrative searches where the U.S. Supreme Court upheld the property owner's right to refuse entry to an inspector. The U.S. Supreme Court held that unless the inspector secured the property owner's consent, he must have a warrant to conduct an administrative search.[82] The U.S. Supreme Court, however, set a different standard for warrants for administrative searches. It decreed that rather than needing a specific reason to believe that the particular building to be searched was in violation of the law, probable cause for the inspection could be based on the reasonable goals of code enforcement.[83] Thus, for the agency seeking the warrant, it only needed to show that a valid public interest justified the intrusion to fulfill the requisite probable cause.[84]

Another is ***United States v. Biswell***.[85] There, the U.S. Supreme Court upheld a warrantless inspection and seizure of firearms pursuant to a valid authorizing statute, the Gun Control Act of 1968. Unannounced, even frequent, inspections were essential to effective enforcement and deterrence; and a person involved in this pervasively regulated business must expect periodic inspections.[86] Unlike the standard laid down in ***Camara*** and ***See***, the Court in ***Biswell*** ordained that neither consent nor a warrant was necessary. When inspecting a business in a pervasively regulated industry, the legality of the search depended not on consent, but on the authority of a valid statute.[87]

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77 Amendment IV. The right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated, and no warrants shall issue, but upon probable cause, supported by oath or affirmation, and particularly describing the place to be searched, and the persons or things to be seized.

78 See *Saluday v. People*, 829 Phil. 65, 81 (2018).

79 See *People v. Marti*, 271 Phil. 51, 57 (1991), as cited in *Pollo v. Chairperson Constantino-David, et al.*, 675 Phil. 225, 249 (2011).

80 387 U.S. 52 (1967).

81 387 U.S. 541 (1967).

82 Supra note 80.

83 *Id.*

84 *Id.*

85 406 U.S. 311 (1972).

86 *Id.*

87 *Id.*

Last, in ***United States v. Jamieson-McKames Pharmaceuticals***,[88] executives of a drug company were charged with violating the U.S. Federal Food, Drug, and Cosmetic Act for counterfeiting, adulteration, and misbranding of drugs. In defense, the pharmaceutical executives argued that the searches and seizures conducted by the FDA agents were in violation of the Fourth Amendment to the Constitution.[89] Ruling in favor of the FDA, the U.S. Court of Appeals for the Eighth (8th) Circuit[90] pronounced that the drug manufacturing industry was included within the class of closely regulated businesses and that inspections made by FDA agents were reasonable in the interest of the general public. In other words, the warrantless searches and seizures contemplated in Section 374 of the Federal Food, Drug, and Cosmetic Act were valid, *viz.:*

> In sum, the authorizing statute now before the Court was not painted with so broad a brush as the one rejected in **Barlow's**, the enforcement needs are more critical in the drug-manufacturing field, and the interests of the general public are more urgent. We hold that inspections authorized by Section 374 are "reasonable" and therefore not inconsistent with the Fourth Amendment. Thus, this case falls within the "carefully defined classes of cases" which are an exception to the search warrant requirement. We share, to a degree, the fears expressed by appellants that many businesses are thoroughly regulated by the United States, and that an undue extension of our rationale might obliterate much of the Fourth Amendment protection. On balance, however, we are persuaded that the capacity for good or ill of the manufacture of drugs for human consumption is so great that Congress had power to enact Section 374(a).[91]
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In this case, FDA Personnel Order No. 2014-220 was issued after the FDA Director-General confirmed reports about the hazardous lead content of Artex Fine Water Colors and following the confirmatory results of chemical analysis of product samples. Since the subject water colors are intended for the use of young students and children in general, the FDA Director-General found it necessary to immediately order the seizure of the water colors and to order the temporary closure of the establishment to prevent further harm to this vulnerable sector of the public.

On this score, the Court finds that the means employed by the legislature to protect public health and safety against the production and sale of hazardous products in the market are not only necessary but reasonable and

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88 651 F.2d 532, 8th Circuit 1981. https://law.justia.com/cases/federal/appellate-courts/F2/651/532/158553/. (Accessed on December 20, 2021).

89 Amendment IV. The right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated, and no warrants shall issue, but upon probable cause, supported by oath or affirmation, and particularly describing the place to be searched, and the persons or things to be seized.

90 On March 22, 1982, the U.S. Supreme Court in 455 U.S. 1016, denied the *Writ of Certiorari* by *Jamieson Mc-Kames Pharmaceuticals, Inc.* Thus, the Decision rendered by the 8th Circuit Court stands. https://cite.case.law/us/455/1016/11376907/ (Accessed December 20, 2021).

91 Supra note 87, citing *Marshall v. Barlow's, Inc.* 436 U.S. 307 (1978), and *Camara v. Municipal Court,* 387 U.S. 523 (1967).

fair. The administrative search ordered by the Director-General under the FDA Personnel Order No. 2014-220, therefore, is fair and reasonable especially since Venus did not even have a license to operate as a manufacturer of household urban hazardous materials; and most important, the subject water colors are not FDA registered. Indubitably, FDA Personnel Order No. 2014-220 was issued to ensure public safety pursuant to the exercise of FDA's regulatory authority.

There was no undue delegation of legislative power.

The rule is what has been delegated, cannot be delegated, or as expressed in the Latin maxim: *potestas delegata non delegari potest*.[92] This doctrine is based on the ethical principle that such a delegated power constitutes not only a right but a duty to be performed by the delegate by the instrumentality of his own judgment acting immediately upon the matter of legislation and not through the intervening mind of another.[93] Congress may, however, delegate to another branch of the Government the power to fill in the details in the execution, enforcement, or administration of a law.[94] But, it is essential, to forestall a violation of the principle of separation of powers, that said law be a valid delegation of legislative power.

In determining whether a statute constitutes an undue delegation of legislative power, the Court has adopted two (2) tests: the completeness test and the sufficient standard test. Under the **first test,** the law must be complete in all its terms and conditions when it leaves the legislature such that when it reaches the delegate, the only thing he or she will have to do is to enforce it.[95] The **second test** or the sufficient standard test, mandates that there should be adequate guidelines or limitations in the law to determine the boundaries of the delegate's authority and prevent the delegation from running riot.[96] Simply put, valid delegation requires: (1) the completeness of the statute making the delegation; and (2) the presence of a sufficient standard.[97]

To determine completeness, the policy to be executed, carried out, or implemented by the delegate must be set forth therein.[98] All the terms and provisions of the law must leave nothing to the delegate except to implement it. What only can be delegated is not the discretion to determine what the law should be but the discretion to determine how the law shall be enforced.[99]

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92 See *Rodrigo v. Sandiganbayan,* 369 Phil. 103, 110 (1999).
93 See *United States vs. Barrias,* 11 Phil. 324 (1908).
94 See *Echegaray v. Secretary of Justice,* 358 Phil. 410, 442 (1998).
95 Supra note 64.
96 See *Department of Trade and Industry v. Steelasia Manufacturing Corp.,* G.R. No. 238263, November 16, 2020.
97 *Id.*
98 Supra note 64.
99 Supra note 97.

More relevant here, however, is the presence of sufficient standard under the law. To be sufficient, the standard must specify the limits of the delegate's authority, announce the legislative policy, and identify the conditions under which it is to be implemented.[100] Enforcement of a delegated power may only be effected in conformity with a sufficient standard, which is used to map out the boundaries of the delegate's authority, and thus prevent the delegation from running riot. The law must contain the limitations or guidelines to determine the scope of authority of the delegate.[101]

First. RA 3720, as amended, is complete in itself. Section 3 thereof sets forth the policy to be carried out or implemented by the delegate, the FDA:

> SEC. 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.

Second. The law fixes a standard and the limits of such standards are sufficiently determinate or determinable. Consistent with the State policy to protect and promote the right to health of the Filipino people and maintain an effective health products regulatory system, the legislature strengthened the FDA's regulatory power over "health products," *viz.*:

> SEC. 10. For the purposes of this Act, the term:
>
> (ff) 'Health products' means food, drugs, cosmetics, devices, biologicals, vaccines, in-vitro diagnostic reagents and household/urban hazardous substances and/or a combination of and/or a derivative thereof. It shall also refer to products that may have an effect on health which require regulations as determined by the FDA.

Whether the final sentence of Section 10(ff) gave the FDA unbridled authority to determine what constitutes a health product, hence, void, is wholly immaterial here. Just the same, petitioner's Artex Fine Water Colors would still be classified as "health products" within the regulatory jurisdiction of the FDA.

To be sure, petitioner's Artex Fine Water Colors squarely falls under "household/urban hazardous substances" as defined in Section 10(gg) of RA 3720 as amended, thus:

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100 *BOCEA v. Teves*, 677 Phil. 636, 656 (2011).
101 Supra note 97.

"(gg) 'Household/urban hazardous substance' is:

"(1) **Any substance or mixture of substances intended for individual or limited purposes and which is toxic**, corrosive, an irritant, a strong sensitizer, is flammable or combustible, or generates pressure through decomposition, heat or other means, **if such substance or mixture of substances may cause substantial injury or substantial illness during or as a proximate result of** any customary or **reasonably foreseeable ingestion by children**, but shall not include agricultural fertilizer, pesticide, and insecticide, and other economic poisons, radioactive substance, or substances intended for use as fuels, coolants, refrigerants and the like;

"(2) Any substance which the FDA finds to be under the categories enumerated in clause (1) of this paragraph;

"(3) Any toy or other **articles intended for use by children which the FDA may determine to pose** an electrical, **chemical**, physical, or thermal **hazard**; and

"(4) This term shall not apply to food, drugs, cosmetics, devices, or 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 an agricultural pesticide but which is a hazardous substance, as construed in paragraph (1) of this section, by reason of bearing or containing such harmful substances described therein. (Emphasis supplied)

Hence, We rule that there is no undue delegation of legislative power in this case.

FDA Personnel Order No. 2014-220 did not violate Venus' right to due process and right against self-incrimination

Alliance for the Family Foundation, Philippines, Inc. v. Garin[102] laid down the aspects of due process: substantive and procedural, *viz.*:

> x x x In order that a particular act may not be impugned as violative of the due process clause, there must be compliance with both the substantive and the procedural requirements thereof. Substantive due process refers to the intrinsic validity of a law that interferes with the rights of a person to his property. Procedural due process, on the other hand, means compliance with the procedures or steps, even periods, prescribed by the statute, in conformity with the standard of fair play and without arbitrariness on the part of those who are called upon to administer it.[103]
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> x x x x

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102 809 Phil. 897-965 (2017).

103 *Id.* at 920.

In ***Pollution Adjudication Board v. Court of Appeals***,[104] the Court sustained the *ex parte* cease and desist orders issued by the Pollution Adjudication Board enjoining Solar Textile Finishing Corporation from utilizing its wastewater pollution source installations which were discharging untreated wastewater directly into a canal leading to the adjacent Tullahan-Tinejeros River. We ordained that the ordinary requirements of procedural due process yield to the necessities of protecting vital public interests.

> *Ex parte* cease and desist orders are permitted by law and regulations in situations like that here presented precisely because stopping the continuous discharge of pollutive and untreated effluents into the rivers and other inland waters of the Philippines cannot be made to wait until protracted litigation over the ultimate correctness or propriety of such orders has run its full course, including multiple and sequential appeals such as those which Solar has taken, which of course may take several years. The relevant pollution control statute and implementing regulations were enacted and promulgated in the exercise of that pervasive, sovereign power to protect the safety, health, and general welfare and comfort of the public, as well as the protection of plant and animal life, commonly designated as the police power. It is a constitutional commonplace that the ordinary requirements of procedural due process yield to the necessities of protecting vital public interests like those here involved, through the exercise of police power. The Board's *ex parte* Order and *Writ* of Execution would, of course, have compelled Solar temporarily to stop its plant operations, a state of affairs Solar could in any case have avoided by simply absorbing the bother and burden of putting its WTP on an operational basis. Industrial establishments are not constitutionally entitled to reduce their capitals costs and operating expenses and to increase their profits by imposing upon the public threats and risks to its safety, health, general welfare and comfort, by disregarding the requirements of anti-pollution statutes and their implementing regulations.[105]
>
> x x x x

Further, ***LLDA v. Court of Appeals***[106] decreed that in the exercise of LLDA's express powers as a regulatory and quasi-judicial body with respect to pollution cases in the Laguna Lake region, LLDA's authority to issue a "cease and desist order" is, perforce, implied. Otherwise, it may well be reduced to a "toothless" paper agency.

The same rule applies here. Relevantly, the power of the FDA Director-General to seize products in violation of the FDA Act pending hearing was thoroughly discussed during the house deliberations on the FDA Act:

> **REP. RODRIGUEZ.** x x x
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> [T]his is about the seventh sentence from the last line of Section 12, it says here:

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104 272-A Phil. 66, 69 (1991).
105 *Id.* at 78-79.
106 301 Phil. 299, 313 (1994).

"x x x PROVIDED FURTHER, THAT, THE HEALTH PRODUCTS FOUND IN VIOLATION OF THE PROVISIONS OF THIS ACT AND OTHER RELEVANT LAWS, RULES AND REGULATIONS MAY BE SEIZED AND HELD IN CUSTODY PENDING PROCEEDINGS PURSUANT TO SECTION 26(D) OF REPUBLIC ACT 3720, AS AMENDED IN SECTION 12 HEREOF x x x" And here is the questionable provision, it says here: "WITHOUT HEARING OR COURT ORDER" x x x

x x x WITHOUT HEARING OR COURT ORDER, it says here, WITHOUT HEARING OR COURT ORDER, WHEN THE DIRECTOR[-]GENERAL HAS PROBABLE CAUSE TO BELIEVE FROM FACTS FOUND BY HIM OR AUTHORIZED OFFICER OR EMPLOYEE OF THE FDA THAT THE HEALTH PRODUCTS MAY CAUSE INJURY OR PREJUDICE x x x

x x x x

REP. PINGOY. Thank you, Mr. Speaker, the said provision under Sec. 12, which was stated by the Gentleman, is just a reiteration of Article 10 of the Consumer Act or the Republic Act 7394; that BFAD can confiscate or seize injurious, dangerous, unsafe product and they can do that if this will affect public health, Mr. Speaker.

x x x x

REP. PINGOY. Mr. Speaker, after the product has been held in custody, the FDA will have – they will conduct hearing and it is where they will have the affected person or entity will – the hearing, the area or the place where they – after their preliminary findings of the said prohibited act, this is where they will or the board will – or the Director[-]General will know whether such a person is guilty or not, Mr. Speaker.

x x x x

REP. PINGOY. Mr. Speaker, the reason or the purpose of custody is only to prevent possible disposal. It is without prejudice to the outcome of the hearing or appeal, Mr. Speaker.

x x x x

REP. PINGOY. x x x [T]he procedure is that the BFAD will do the inspection and if there are findings that it violates BFAD regulations, it will seize for custody such products and after that, they will do the hearing and have their judgment. That is the procedure, Mr. Speaker.

REP. RODRIGUEZ. Mr. Speaker, this Representation is satisfied after being shown that the chart. **First, there is a seizure without court order bccause precisely, if you have a court order they will run away with the products. And after that is repossessed, then we have the proceedings to finally be able to dispose of the matter**. The only problem here is that we have a law which has truncated the BFAD law. But we got explanation, I now agree that there should be without hearing or court order at the first instance of seizing it and then after it is seized, then there's a hearing, to

> determine whether it should be permanent destroyed or seized. [107] (Emphases supplied)
>
> x x x x

Verily, there is no violation of due process to speak here. To recall, Venus was served with a Notice of Violation Report when the FDA Operatives went to their establishment on May 29, 2014. Also, under Section 30(4), the confiscation of the hazardous products is without prejudice to the outcome of the authorized hearing or appeal.

Although Section 4(j) authorized the FDA to issue cease and desist orders *motu proprio* or upon verified complaint for both registered and unregistered health products, it also contained a proviso that for registered health products, the cease and desist order was only valid for thirty (30) to sixty (60) days after due process had been observed. Notably, the IRR of the FDA Act provided the procedure for notice and hearing:

> ARTICLE V
> SERVICE OF PLEADINGS AND OTHER PAPERS
>
> **Sec. 2.** Service of Summons, Notices, Decisions and Orders. (a) Summons, notices, and copies of decisions and orders shall be served on the parties to the case personally by the duly authorized process server or other authorized officer of the FDA, or by registered mail, and such other acceptable modes of service. (b) The serving officer shall submit his return within three (3) days from date of service thereof, stating legibly in his return his name, the name of person served, and the date of receipt, which return shall be immediately attached to and shall form part of the records of the case. If no service was effected, the serving officer shall state the reason therefore in his return.
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> ARTICLE III
> OFFICE OF THE DIRECTOR-GENERAL
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> x x x x
>
> Section 2: Duties and Functions of the Director-General
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> x x x x
>
> b. Quasi-Judicial Powers, Duties and Functions:
>
> x x x x
>
> (5) To issue orders of seizure, to seize and hold in custody any article or articles of food, device, cosmetics, household hazardous substances and health products that are adulterated, counterfeited, misbranded or unregistered; or any drug, in-vitro diagnostic reagents, biologicals, and vaccine that is adulterated or misbranded, when introduced into domestic commerce pending the authorized hearing

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107 Plenary hearing on House Bill No. 3293, 14th Congress, Regular Session, February 26 and 27, 2008. House Journal No.62, pp. 14-15.

under the FDA Act of 2009, these Rules and Regulations, and as far as applicable, other relevant laws.

ARTICLE VII
PROCEEDINGS BEFORE THE FDA

Sec. 3. Temporary and/or Preventive Measure Order. At any time after the commencement of the administrative action and before judgment, a temporary and for preventive measure order may be issued by the FDA. a. The Regional Field Director may issue cease and desist orders *motu proprio* or upon verified complaint for health products, whether or not registered with the FDA. However, for registered health products, the cease and desist order is only valid for thirty (30) days but it may be extended for another sixty (60) days if deemed appropriate, in a summary hearing, by the Regional Field Director.

ARTICLE VIII
PRELIMINARY CONFERENCE

Sec. 1. Preliminary Conference/Clarificatory Hearing. Except on *motu proprio* cases/ the Regional Field Director, may upon motion of any party schedule the Preliminary Conference, which shall not be later than fifteen (15) days from the receipt of the Answer, to consider the following issues: (1) The simplification of the issues; (2) The necessity or desirability of amendments to the pleadings; (3) The possibility of obtaining stipulations or admissions of facts and of documents; (4) Such other matters as may aid in the prompt disposition of the case.

When deemed appropriate by the Regional Field Director or upon motion by either party, clarificatory hearing may be held during the Preliminary Conference.

ARTICLE X
POSITION PAPER

Sec. 1. Submission of Position Paper and Supporting Evidence.

(a) In cases where a Preliminary Conference/Clarificatory hearing is conducted, within fifteen (15) days from the termination thereof, the parties shall simultaneously submit their respective position paper with supporting affidavits and other documentary evidence.

(b) In *motu proprio* cases, the respondent shall submit his/her position paper with supporting affidavits and other documentary evidence within fifteen (15) days from receipt of the Summons.

(c) The supporting affidavits shall take the place of direct testimony. Affidavits and supporting documentary evidence which were annexed to the complaint or formal charge, and the answer, as the case may be, and forming part of the records of the case, are deemed automatically reproduced for purposes of presentation of evidence and need not be annexed to the position Papers. They shall, however, be distinctly identified for reference in the position paper.

x x x x

Now that we have settled the issue of due process, we move on to the argument that FDA Personnel Order No. 2014-220 is violative of the right of Venus against self-incrimination. Venus argues that should the aforesaid Order be implemented, the seized water colors will have a strong tendency to be used as incriminating evidence against it.

The argument is utterly misplaced.

To begin with, FDA Personnel Order No. 2014-220 was never executed, hence, no watercolor was even seized by the FDA operatives. It bears to stress that the right against self-incrimination must be invoked at the proper time, that is, when a question calling for an incriminating answer is propounded.[108] Necessarily then, the right against self-incrimination may only be invoked where there is already an actual case, whether criminal, civil, or administrative; not before.[109] The argument of Venus, therefore, on the supposed violation of its right against self-incrimination is misplaced, if not premature.

The Director-General is authorized to padlock erring establishments

True, there is no express provision in RA 3720, as amended, authorizing the FDA Director-General to padlock a production facility pending hearing before the FDA. This authority, however, is deemed subsumed in the statutory powers of the FDA Director-General "(to) issue orders of seizure, to seize and hold in custody any article or articles of food, device, cosmetics, household hazardous substances and health products that are adulterated, counterfeited, misbranded, or unregistered; or any drug, in-vitro diagnostic reagents, biologicals, and vaccine that is adulterated or misbranded." In other words, the grant of such authority to the FDA Director-General necessarily includes all such powers, even those not expressly stated, that are necessary to effectuate such authority.[110] This is the **doctrine of necessary implication.**

> No statute can be enacted that can provide all the details involved in its application. There is always an omission that may not meet a particular situation. What is thought, at the time of enactment, to be an all-embracing legislation may be inadequate to provide for the unfolding events of the future. So-called gaps in the law develop as the law is enforced. One of the rules of statutory construction used to fill in the gap is the doctrine of necessary implication. **The doctrine states that what is implied in a statute is as much a part thereof as that which is expressed. Every statute is understood, by implication, to contain all such provisions as may be necessary to effectuate its object and purpose, or to make effective rights, powers, privileges or jurisdiction which it grants, including all such collateral and subsidiary consequences as may be fairly and logically inferred from its terms.** *Ex necessitate legis.* **And every statutory grant of power, right[,] or privilege is**

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108 See *Suarez v. Tengco*, 111 Phil. 1100, 1101-1102 (1961).

109 See *Morfe v. Mutuc*, 130 Phil. 415, 440 (1968).

110 See *Robustum Agricultural Corp. v. Department of Agrarian Reform*, G.R. No. 221484, November 19, 2018.

> **deemed to include all incidental power, right[,] or privilege**. This is so because the greater includes the lesser, expressed in the maxim, *in eo plus sit, simper inest et minus*.[111] (Emphases supplied)

Another, Section 30(6) of RA 3720, as amended by RA 9711,[112] specifically allows the Director-General to "exercise such powers and functions as may be necessary for the effective implementation of this Act." This catch-all provision clearly grants the Director-General all necessary and incidental powers that are reasonably germane to his or her functions under the law. This is supplemented by Section 22[113] of the law which mandates the DOH to promulgate, in consultation with the FDA, IRR of the law within 120 days after its passage. This is precisely why Article VII, Section 3, paragraph (b)(2)[114] of the IRR was enacted by the DOH. It specifically provided that the Director-General can order the padlocking of establishments suspected to have violated the FDA Act for the purpose of preventing the disposition or tampering of evidence, the continuance of acts being complained of, and the flight of the respondent, as the case may be.

> ARTICLE VII
> PROCEEDINGS BEFORE THE FDA
>
> x x x x
>
> **Sec. 3.** Temporary and/or Preventive Measure Order. At any time after the commencement of the administrative action and before judgment, a temporary and /or preventive measure order may be issued by the FDA.
>
> x x x x
>
> b. With prior approval of the Director-General, the Regional Field Director, for the purpose of preventing the disposition or tampering of evidence, the continuance of acts being complained of, and the flight of the respondent, as the case may be, may order:
>
> (1) The seizure of the health products subject of the complaint or action;
> (2) **The padlocking of the warehouse, building, factory, store, shop, or any other structure where the said health products are contained or stored;**
> (3) The withholding of such health products from being transported or transferred;
> (4) The seizure of paraphernalia, machines, vehicles and the like believed to have been used in the commission of the offense. (Emphasis supplied)

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111 *Id.*

112 (6) To exercise such powers and functions as may be necessary for the effective implementation of this Act.

113 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.

114 The Rules and Regulations Implementing Republic Act No. 9711- The Food and Drug Administration Act of 2009, Department-Circular 2011-0101, issued on March 22, 2011.

Finally, the FDA's power to temporarily seize and close a suspected erring establishment pending hearing is akin to the "close now, hear later" policy of the Monetary Bank. Thus, in ***Central Bank of the Philippines v. Court of Appeals***,[115] the Court pronounced that the "close now and hear later" scheme is grounded on practical and legal considerations to prevent unwarranted dissipation of the bank's assets and as a valid exercise of police power to protect the depositors, creditors, stockholders, and the general public.

The promotion of public health is a fundamental obligation of the State.[116] The protection of the public, especially children, from impure or hazardous substances is a primordial governmental concern. Undoubtedly, the FDA Act, as amended was enacted in the exercise of the police power of the State in order to promote and preserve public health and safety.

ACCORDINGLY, the Court **DENIES** the petition and **DECLARES** Sections 10(ff), 12(a), and 34(4) of Republic Act No. 3720, as amended by Republic Act No. 9711, as well as Section 2(b), paragraph (5), Article III of Department Circular No. 2011-0101 and FDA Personnel Order 2014-220 to be **NOT UNCONSTITUTIONAL**.

SO ORDERED.

AMY C. LAZARO-JAVIER
Associate Justice

WE CONCUR:

ALEXANDER G. GESMUNDO
Chief Justice

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115 292-A Phil. 669, 679 (1993).
116 See *Beltran v. Secretary of Health*, 512 Phil. 560, 585 (2005).

See Concurring Opinion

ALFREDO BENJAMIN S. CAGUIOA
Associate Justice

(On official leave)
MARIO V. LOPEZ
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's Division.

ALEXANDER G. GESMUNDO
Chief Justice

FIRST DIVISION

G.R. No. 240764 – VENUS COMMERCIAL CO., INC., *petitioner, versus* **THE DEPARTMENT OF HEALTH and THE FOOD AND DRUG ADMINISTRATION,** *respondents.*

Promulgated:

NOV 18 2021

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CONCURRING OPINION

CAGUIOA, *J.*:

I concur with the *ponencia*'s declaration that Sections 12(a)[1] and 30(4)[2] of Republic Act (R.A.) No. 3720,[3] as amended by R.A. No. 9711,[4] and Section 2(b), paragraph 5,[5] Article III of the Implementing Rules and

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1 SEC. 12. (a) Any person who violates any of the provisions of Section eleven hereof shall, upon conviction, suffer the penalty of imprisonment ranging from one (1) year but not more than ten (10) years or a fine of not less than Fifty thousand pesos (P50,000.00) but not more than Five hundred thousand pesos (P500,000.00), or both, at the discretion of the court: *Provided,* That if the offender is a manufacturer, importer or distributor of any health product, the penalty of at least five (5) years imprisonment but not more than ten (10) years and a fine of at least Five hundred thousand pesos (P500,000.00) but not more than Five million pesos (P5,000,000.00) shall be imposed: *Provided, further*, That an additional fine of one percent (1%) of the economic value/cost of the violative product or violation, or One thousand pesos (P1,000.00), whichever is higher, shall be imposed for each day of continuing violation: *Provided, finally*, That health products found in violation of the provisions of this Act and other relevant laws, rules and regulations may be seized and held in custody pending proceedings, without hearing or court order, when the director-general has reasonable cause to believe from facts found by him/her or an authorized officer or employee of the FDA that such health products may cause injury or prejudice to the consuming public.

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Should the offense be committed by a juridical person, the Chairman of the Board of Directors, the president, general manager, or the partners and/or the persons directly responsible therefor shall be penalized.

Should the offense be committed by a foreign national, he/she shall, in addition to the penalties prescribed, be deported without further proceedings after service of sentence.

2 SEC. 30. The Director-General shall also exercise the following powers:

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(4) To issue orders of seizure, to seize and hold in custody any article or articles of food, device, cosmetics, household hazardous substances and health products that is adulterated, counterfeited, misbranded or unregistered, or drug, in-vitro diagnostic reagent, biologicals, and vaccine that is adulterated or misbranded, when introduced into domestic commerce pending the authorized hearing under Republic Act No. 3720, as amended, Executive Order No. 175 (1987), and Republic Act No. 7394, otherwise known as the Consumers Act of the Philippines[.]

3 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 COSMETIC ACT," approved on June 22, 1963.

4 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, otherwise known as the "FOOD AND DRUG ADMINISTRATION (FDA) ACT OF 2009," approved on August 18, 2009.

5 **Sec. 2. Duties and Functions of the Director-General.** As head of the FDA, the Director-General shall exercise the following powers and perform the following duties and functions:

Regulations of R.A. No. 9711[6] are not unconstitutional. I write this opinion only to expound on my view that the final sentence of Section 10(ff)[7] of R.A. No. 3720, as amended, which grants respondent Food and Drug Administration (FDA) regulatory authority over health products, should be circumscribed by a holistic reading of the entire law.

Indeed, by virtue of the principle of subordinate legislation, Congress may delegate the authority to promulgate rules for the implementation of statutes.[8] This is in recognition of the increasing complexity of the issues that must be addressed, as well as the expertise that administrative bodies possess in enforcing the broad policies of a legislation.[9]

Even so, the delegated authority to the administrative agency is not a legislative function — rather, it is a matter of law-execution. The delegating statute must therefore be complete in itself and provide adequate standards. When the nature of the delegated power is purely legislative in nature, the Court can strike down the statute as unconstitutional for violating the principle of separation of powers.[10]

In this case, I agree with the *ponencia* that R.A. No. 3720, as amended by R.A. No. 9711, satisfies both the completeness and sufficient standards test. There are adequate guidelines in the law within which respondent Department of Health (DOH) and the FDA must conform in the performance of their rule-making functions. This includes, to my mind, the limits to the FDA's exercise of discretion in determining whether a product is a health product under Section 10(ff) of R.A. No. 3720, as amended.

It is a well-settled principle that a law must not be read in truncated parts; each and every provision thereof must be considered in order to

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x x x x

b. Quasi-Judicial Powers, Duties and Functions:

x x x x

(5) To issue orders of seizure, to seize and hold in custody any article or articles of food, device, cosmetics, household hazardous substances and health products that are adulterated, counterfeited, misbranded or unregistered; or any drug, in-vitro diagnostic reagents, biologicals, and vaccine that is adulterated or misbranded, when introduced into domestic commerce pending the authorized hearing under the FDA Act of 2009, these Rules and Regulations, and as far as applicable, other relevant laws[.]

6 THE RULES AND REGULATIONS IMPLEMENTING REPUBLIC ACT NO. 9711 - THE FOOD AND DRUG ADMINISTRATION ACT OF 2009, approved on March 22, 2011.

7 SEC. 10. For the purposes of this Act, the term:

x x x x

(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.

8 See *The Conference of Maritime Manning Agencies, Inc. v. Philippine Overseas Employment Administration*, G.R. No. 114714, April 21, 1995, 243 SCRA 666, 675.

9 See *Eastern Shipping Lines, Inc. v. POEA*, No. L-76633, October 18, 1988, 166 SCRA 533, 544.

10 See *ABAKADA Guro Party List v. Ermita*, G.R. Nos. 168056, 168207, 168461, 168463 & 168730, September 1, 2005, 469 SCRA 14, 116-121.

produce a harmonious whole.[11] For this reason, Section 10(ff) of R.A. No. 3720, as amended, should not be read in isolation but rather, in conjunction with the other provisions of the law. In considering what other products could come within the purview of its regulatory jurisdiction, the FDA is bound not only by the standard that such product "may have an effect on health".[12] If this were the case, practically any product would have an effect on health, whether intended or otherwise. Just to set an extreme example, a hammer can be considered to "have an effect on health" because in the hands of a murderer, it can be used as a weapon to cause death. As such, if this were the sole standard to which the FDA should conform, an absurd situation would result where the FDA can arrogate unto itself the authority to define its own regulatory jurisdiction. Surely, this goes beyond supplying the details within the scope of the statutory authority granted to it by the legislature.[13]

I maintain that a careful reading of R.A. No. 3720, as amended by R.A. No. 9711, provides the proper context in which products could be regulated by the FDA. In the declaration of policy of R.A. No. 9711, the express purpose of the amendatory statute is to institutionalize the FDA and enhance its regulatory capacity over health products.[14] In line with this, the FDA's functions were expanded and its structure was organized to make room for "Centers" to effectively regulate health products, to wit:

> SEC. 5. The FDA shall have the following centers and offices:
>
> (a) The Centers shall be established per major product category that is regulated, namely:
>
> (1) Center for **Drug** Regulation and Research (to include **veterinary medicine, vaccines and biologicals**);
>
> (2) Center for **Food** Regulation and Research;
>
> (3) Center for **Cosmetics** Regulation and Research (to include **household hazardous/urban substances**); and
>
> (4) Center for **Device** Regulation, Radiation Health, and Research.
>
> x x x x (Emphasis supplied)

These Centers significantly correspond to each category of health product in Section 10(ff), *i.e.*, "food,[15] drugs,[16] cosmetics,[17] devices,[18]

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11 *Philippine International Trading Corporation v. Commission on Audit*, G.R. No. 183517, June 22, 2010, 621 SCRA 461, 469.

12 R.A. No. 3720, as amended by R.A. No. 9711, Sec. 10(ff).

13 *The Conference of Maritime Manning Agencies, Inc. v. Philippine Overseas Employment Administration*, supra note 8.

14 R.A. No. 9711, Sec. 3.

15 R.A. No. 3720, as amended by R.A. No. 9711, Sec. 10(e).

16 Id., Sec. 10(f).

17 Id., Sec. 10(h).

18 Id., Sec. 10(g).

biologicals, vaccines, in-vitro diagnostic reagents[19] and household/urban hazardous substances[20] and/or a combination of and/or a derivative thereof." Clearly, in construing the boundaries of the FDA's discretion, the express legislative purpose of R.A. No. 9711 — that is, to regulate health products that are within the strengthened technical and administrative capacity of the FDA — is instructive. It may only regulate health products of the same class or kind as those comprising "health products" in Section 10(ff), as these are the only products that the legislature deemed to be within its administrative expertise.

In other words, Section 10(ff) does not grant the FDA a blanket license to extend its regulatory jurisdiction beyond what is necessary and allowed to implement the law. It cannot be used by the FDA as basis to assume jurisdiction over products simply by virtue of its perceived effect on health. Relatedly, Section 25 of R.A. No. 9711 excludes products within the jurisdiction of specialized agencies, even if these may have an effect on health:

> SEC. 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)

In all, the entire law, read as a whole, serves to limit the boundaries of the FDA's exercise of its power of subordinate legislation. Needless to state, as an agency created by Congress, the breadth and scope of its functions cannot be made to depend on its own determination of whether a certain product is a health product under Section 10(ff) of R.A. No. 3720, as amended. If the Court were to rule otherwise, the FDA's unfettered exercise of its delegated rule-making power could dangerously venture into areas of policy.

Based on these premises, I concur with the *ponencia* in denying the Petition.

ALFREDO BENJAMIN S. CAGUIOA
Associate Justice

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[19] Id., Sec. 10(hh).
[20] Id., Sec. 10(gg).