Republic of the Philippines
Supreme Court
Baguio City

SPECIAL SECOND DIVISION

ALLIANCE FOR THE FAMILY FOUNDATION, PHILIPPINES, INC. (ALFI) and ATTY. MARIA CONCEPCION S. NOCHE, in her own behalf and as President of ALFI, JOSE S. SANDEJAS, ROSIE B. LUISTRO, ELENITA S.A. SANDEJAS, EMILY R. LAWS, EILEEN Z. ARANETA, SALVACION C. MONTEIRO, MARIETTA C. GORREZ, ROLANDO M. BAUTISTA, RUBEN T. UMALI, and MILDRED C. CASTOR, Petitioners, - versus - **HON. JANETTE L. GARIN, Secretary-Designate of the Department of Health; NICOLAS B. LUTERO III, Assistant Secretary of Health, Officer-in-Charge, Food and Drug Administration; and MARIA LOURDES C. SANTIAGO, Officer-in-Charge, Center for Drug Regulation and Research,** Respondents.	**G.R. No. 217872** Present: CARPIO, J., *Chairperson*, DEL CASTILLO, MENDOZA, LEONEN, and MARTIRES, *JJ.*
x - x	
MARIA CONCEPCION S. NOCHE, in her own behalf and as counsel of Petitioners, JOSE S. SANDEJAS, ROSIE B. LUISTRO, ELENITA S.A. SANDEJAS, EMILY R. LAWS, EILEEN Z. ARANETA, SALVACION C. MONTEIRO,	**G.R No. 221866**

MARIETTA C. GORREZ, ROLANDO M. BAUTISTA, RUBEN T. UMALI, and MILDRED C. CASTOR ,
Petitioners,

- versus –

HON. JANETTE L. GARIN, Secretary-Designate of the Department of Health; NICOLAS B. LUTERO III, Assistant Secretary of Health, Officer-in-Charge, Food and Drug Administration; and MARIA LOURDES C. SANTIAGO, Officer-in-Charge, Center for Drug Regulation and Research,
Respondents.

Promulgated:

26 APR 2017

x---[signature] x

RESOLUTION

MENDOZA, *J.*:

Subject of this resolution is the Omnibus Motion[1] filed by the respondents, thru the Office of the Solicitor General *(OSG),* seeking partial reconsideration of the August 24, 2016 Decision *(Decision),*[2] where the Court resolved the: [1] Petition for Certiorari, Prohibition, Mandamus with Prayer for Issuance of a Temporary Restraining Order and/or Writ of Preliminary Prohibitory and Mandatory Injunction (G.R. No. 217872); and the [2] Petition for Contempt of Court (G.R. No. 221866), in the following manner:

> WHEREFORE, the case docketed as G.R No. 217872 is hereby REMANDED to the Food and Drugs Administration which is hereby ordered to observe the basic requirements of due process by conducting a hearing, and allowing the petitioners to be heard, on the re-certified, procured and administered contraceptive drugs and devices, including Implanon and Implanon NXT, and to determine whether they are abortifacients or non-abortifacients.
>
> Pursuant to the expanded jurisdiction of this Court and its power to issue rules for the protection and enforcement of constitutional rights, the Court hereby:

[1] *Rollo*, pp. 406-744.
[2] Id. at 382-405.

1. DIRECTS the Food and Drug Administration to formulate the rules of procedure in the screening, evaluation and approval of all contraceptive drugs and devices that will be used under Republic Act No. 10354. The rules of procedure shall contain the following minimum requirements of due process: (a) publication, notice and hearing, (b) interested parties shall be allowed to intervene, (c) the standard laid down in the Constitution, as adopted under Republic Act No. 10354, as to what constitutes allowable contraceptives shall be strictly followed, that is, those which do not harm or destroy the life of the unborn from conception/fertilization, (d) in weighing the evidence, all reasonable doubts shall be resolved in favor of the protection and preservation of the right to life of the unborn from conception/fertilization, and (e) the other requirements of administrative due process, as summarized in *Ang Tibay v. CIR*, shall be complied with.

2. DIRECTS the Department of Health in coordination with other concerned agencies to formulate the rules and regulations or guidelines which will govern the purchase and distribution/dispensation of the products or supplies under Section 9 of Republic Act No. 10354 covered by the certification from the Food and Drug Administration that said product and supply is made available on the condition that it will not be used as an abortifacient subject to the following minimum due process requirements: (a) publication, notice and hearing, and (b) interested parties shall be allowed to intervene. The rules and regulations or guidelines shall provide sufficient detail as to the manner by which said product and supply shall be strictly regulated in order that they will not be used as an abortifacient and in order to sufficiently safeguard the right to life of the unborn.

3. DIRECTS the Department of Health to generate the complete and correct list of the government's reproductive health programs and services under Republic Act No. 10354 which will serve as the template for the complete and correct information standard and, hence, the duty to inform under Section 23(a)(l) of Republic Act No. 10354. The Department of Health is DIRECTED to distribute copies of this template to all health care service providers covered by Republic Act No. 10354.

The respondents are hereby also ordered to amend the Implementing Rules and Regulations to conform to the rulings and guidelines in G.R. No. 204819 and related cases.

The above foregoing directives notwithstanding, within 30 days from receipt of this disposition, the Food and Drugs Administration should commence to conduct the necessary hearing guided by the cardinal rights of the parties laid down in *CIR v. Ang Tibay*.

Pending the resolution of the controversy, the motion to lift the Temporary Restraining Order is DENIED.

With respect to the contempt petition, docketed as G.R No. 221866, it is hereby DENIED for lack of concrete basis.

SO ORDERED.[3]

Arguments of the Respondents

Part 1: Due Process need not be complied with as the questioned acts of the Food and Drug Administration (FDA) were in the exercise of its Regulatory Powers

In the subject Omnibus Motion, the respondents argued that their actions should be sustained, even if the petitioners were not afforded notice and hearing, because the contested acts of registering, re-certifying, procuring, and administering contraceptive drugs and devices were all done in the exercise of its regulatory power.[4] They contended that considering that the issuance of the certificate of product registration *(CPR)* by the FDA under Section 7.04, Rule 7[5] of the Implementing Rules and Regulations of Republic Act *(R.A.)* No. 10354 *(RH-IRR)* did not involve the adjudication of the parties' opposing rights and liabilities through an adversarial proceeding, the due process requirements of notice and hearing need not be complied with.[6]

Stated differently, the respondents assert that as long as the act of the FDA is exercised pursuant to its regulatory power, it need not comply with the due process requirements of notice and hearing.

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[3] Id. at 402-403.
[4] Id. at 414-430.
[5] Section 7.04. FDA Certification of Family Planning Supplies.
The FDA must certify that a family planning drug or device is not an abortifacient in dosages of its approved indication (for drugs) or intended use (for devices) prior to its inclusion in the EDL. The FDA shall observe the following guidelines in the determination of whether or not a drug or device is an abortifacient:
a) As defined in Section 3.01 (a) of these Rules, a drug or device is deemed to be an abortifacient if it is proven to primarily induce abortion or the destruction of a fetus inside the mother's womb or the prevention of the fertilized ovum to reach and be implanted in the mother's womb;
b) The following mechanisms do not constitute abortion: the prevention of ovulation; the direct action on sperm cells prior to fertilization; the thickening of cervical mucus; and any mechanism acting exclusively prior to the fertilization of the egg by the sperm;
c) In making its determination, the FDA shall use the best evidence available, including but not limited to: meta-analyses, systematic reviews, national clinical practice guidelines where available, and recommendations of international medical organizations
d) In the presence of conflicting evidence, the more recent, better-designed, and larger studies shall be preferred, and the conclusions found therein shall be used to determine whether or not a drug or device is an abortifacient; and
e) Should the FDA require additional expertise in making its determination, an independent evidence review group (ERG) composed of leading experts in the fields of pharmacodynamics, medical research, evidence-based medicine, and other relevant fields may be convened to review the available evidence. The FDA shall then issue its certification based on the recommendations of the ERG.
[6] *Rollo*, pp. 414-416.

Corollary to this, the respondents wanted the Court to consider that the FDA had delineated its functions among different persons and bodies in its organization. Thus, they asked the Court to make a distinction between the ***"quasi-judicial powers"*** exercised by the **Director-General of the FDA** under Section 2(b)[7] of Article 3, Book I of the Implementing Rules and Regulations *(IRR)* of R.A. No. 9711,[8] and the ***"regulatory/administrative powers"*** exercised by **the FDA** under Section 2(c)(1)[9] of the same. For the respondents, the distinction given in the above-cited provisions was all but proof that the issuance of CPR did not require notice and hearing.

After detailing the process by which the FDA's Center for Drug Regulation and Research *(CDRR)* examined and tested the contraceptives for non-abortifacience,[10] the respondents stressed that the Decision wreaked havoc on the organizational structure of the FDA, whose myriad of functions had been

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[7] Sec. 2. *Duties and Functions of the Director-General* x x x
b. *Quasi-Judicial Powers, Duties and Functions*:
x x x

[8] Otherwise known as the Food and Drug Administration Act of 2009.

[9] c. *Regulatory Powers, Duties and Functions*:
x x x

[10] Step 1. Identify contraceptive products in the database. Create another database containing the following details of contraceptive products: generic name, dosage strength and form, brand name (if any), registration number, manufacturer, MAH, and the period of validity of the CPR.
Step 2. Identify contraceptive products which are classified as essential medicines in the Philippine Drug Formulary.
Step 3. Retrieve the contraceptive product's file and the CPR duplicate of all registered contraceptive products. Create a database of the contraceptive product's history, including its initial, renewal, amendment, and/or variation applications.
Step 4. Conduct a preliminary review of the following:
a. general physiology of female reproductive system, including hormones involved, female reproductive cycle, and conditions of the female reproductive system during pregnancy.
b. classification of hormonal contraceptives;
c. regulatory status of the products in benchmark countries; and
d. mechanism of action of hormonal contraceptives based on reputable journals, meta-analyses, systemic reviews, evaluation of regulatory authorities in other countries, textbooks, among others.
Step 5. Issue a notice to all concerned MAHs, requiring them to submit scientific evidence that their product is non-abortifacient, as defined in the RH Law and Imbong.
Step 6. Post a list of contraceptive products which were applied for re-certification for public comments in the FDA website.
Step 7. Evaluate contraceptive products for re-certification.
A. Part I (Review of Chemistry, Manufacture and Controls)

1. Unit Dose and Finished Product Formulation
2. Technical Finished Product Specifications
3. Certificate of Analysis

B. Part II (Evaluation of Whether the Contraceptive Product is Abortifacient)

1. Evaluation of the scientific evidence submitted by the applicant and the public.
2. Review and evaluation of extraneous evidence, e.g., scientific journals, meta-analyses, etc.

Step 8. Assess and review the documentary requirements submitted by the applicant. Technical reviewers considered scientific evidence such as meta-analyses, systemic reviews, national and clinical practice guidelines and recommendations of international medical organizations submitted by the companies, organizations and individuals to be part of the review. [Emphases and Underling supplied]

carefully delineated in the IRR of R.A. No. 9711.[11] The respondents, thus, prayed for the lifting of the Temporary Restraining Order *(TRO)*.[12]

Part 2: The requirements of due process need not be complied with as the elements of procedural due process laid down in Ang Tibay v. CIR are not applicable

The respondents further claimed in their omnibus motion that the requirements of due process need not be complied with because the standards of procedural due process laid down in *Ang Tibay v. CIR*[13] were inapplicable considering that: a) substantial evidence could not be used as a measure in determining whether a contraceptive drug or device was abortifacient;[14] b) the courts had neither jurisdiction nor competence to review the findings of the FDA on the non-abortifacient character of contraceptive drugs or devices;[15] c) the FDA was not bound by the rules of admissibility and presentation of evidence under the Rules of Court;[16] and d) the findings of the FDA could not be subject of the rule on *res judicata* and *stare-decisis*.[17]

The respondents then insisted that Implanon and Implanon NXT were not abortifacients and lamented that the continued injunction of the Court had hampered the efforts of the FDA to provide for the reproductive health needs of Filipino women. For the respondents, to require them to afford the parties like the petitioners an opportunity to question their findings would cause inordinate delay in the distribution of the subject contraceptive drugs and devices which would have a dire impact on the effective implementation of the RH Law.

The Court's Ruling

After an assiduous assessment of the arguments of the parties, the Court denies the Omnibus Motion, but deems that a clarification on some points is in order.

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[11] Omnibus Motion, p. 37.
[12] *Rollo*, pp. 442-447.
[13] 69 Phil. 635 (1940).
[14] *Rollo*, pp. 430-431.
[15] Id. at 431-432, 442.
[16] Id. at 432-433.
[17] Id. at 433-434.

Judicial Review

The powers of an administrative body are classified into two fundamental powers: *quasi-legislative* and *quasi-judicial*. **Quasi-legislative power**, otherwise known as the power of subordinate legislation, has been defined as the authority delegated by the lawmaking body to the administrative body to adopt rules and regulations intended to carry out the provisions of law and implement legislative policy.[18] "[A] legislative rule is in the nature of subordinate legislation, designed to implement a primary legislation by providing the details thereof."[19] The exercise by the administrative body of its quasi-legislative power through the promulgation of regulations of general application does not, as a rule, require notice and hearing. The only exception being where the Legislature itself requires it and mandates that the regulation shall be based on certain facts as determined at an appropriate investigation.[20]

Quasi-judicial power, on the other hand, is known as the power of the administrative agency to determine questions of fact to which the legislative policy is to apply, in accordance with the standards laid down by the law itself.[21] As it involves the exercise of discretion in determining the rights and liabilities of the parties, the proper exercise of quasi-judicial power requires the concurrence of two elements: *one*, jurisdiction which must be acquired by the administrative body and *two*, **the observance of the requirements of due process**, that is, the **right to notice and hearing**.[22]

On the argument that the certification proceedings were conducted by the FDA in the exercise of its "regulatory powers" and, therefore, beyond judicial review, the Court holds that it has the power to review all acts and decisions where there is a commission of grave abuse of discretion. No less than the Constitution decrees that the Court must exercise its duty to ensure that no grave abuse of discretion amounting to lack or excess of jurisdiction is committed by any branch or instrumentality of the Government. Such is committed when there is a violation of the constitutional mandate that "no person is deprived of life, liberty, and property without due process of law." The Court's power cannot be curtailed by the FDA's invocation of its regulatory power.

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[18] Cruz, Philippine Administrative Law, p. 29 (2007 Edition).
[19] *Commissioner of Customs v. Hypermix Feeds Corporation*, 680 Phil. 681, 689 (2012), citing *Misamis Oriental Association of Coco Traders, Inc. v. Department of Finance Secretary*, G.R. No. 108524, November 10, 1994, 238 SCRA 63, 69-70.
[20] Cruz, Philippine Administrative Law, supra note 18 at 67.
[21] Id. at 88, citing *Gudmindson v. Cardollo*, 126 F2d. 521.
[22] Id. at 91.

In so arguing, the respondents cited Atty. Carlo L. Cruz in his book, *Philippine Administrative Law*.

Lest there be any inaccuracy, the relevant portions of the book cited by the respondents are hereby quoted as follows:

> x x x.
>
> B. The Quasi-Judicial Power
>
> x x x
>
> 2. *Determinative Powers*
>
> To better enable the administrative body to exercise **its quasi judicial authority**, it is also vested with what is known as *determinative* powers and functions.
>
> Professor Freund classifies them generally into the *enabling* powers and the *directing* powers. The latter includes the *dispensing*, the *examining*, and the *summary* powers.
>
> **The *enabling powers* are those that permit the doing of an act which the law undertakes to *regulate* and which would be unlawful with government approval**. The most common example is the issuance of licenses to engage in a particular business or occupation, like the operation of a liquor store or restaurant. x x x. [23] [Emphases and underscoring supplied]

From the above, two things are apparent: one, the "enabling powers" cover "regulatory powers" as defined by the respondents; and two, they refer to a subcategory of a quasi-judicial power which, as explained in the Decision, requires the compliance with the twin requirements of notice and hearing. Nowhere from the above-quoted texts can it be inferred that the exercise of "regulatory power" places an administrative agency beyond the reach of judicial review. When there is grave abuse of discretion, such as denying a party of his constitutional right to due process, the Court can come in and exercise its power of judicial review. It can review the challenged acts, whether exercised by the FDA in its ministerial, quasi-judicial or regulatory power. In the past, the Court exercised its power of judicial review over acts and decisions of agencies exercising their regulatory powers, such as DPWH,[24] TRB,[25] NEA,[26] and the SEC,[27] among others. In *Diocese of Bacolod v. Commission on Elections*,[28] the

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[23] Cruz, Philippine Administrative Law, supra note 18 at 41.
[24] *Mirasol et al. v. DPWH and TRB*, 523 Phil. 713, (2006).
[25] Id.
[26] *ZAMECO II Board of Directors v. Castillejos Consumers Ass'n. Inc. (CASCONA), et al.*, 600 Phil. 365, (2009).
[27] *SEC v. Court of Appeals,* 316 Phil. 903 (1995).
[28] G.R. No. 205728, January 21, 2015, 747 SCRA 1. ("This case pertains to acts of COMELEC in the implementation of its **regulatory powers**. When it issued the notice and letter, the COMELEC was allegedly enforcing election laws.")

Court properly exercised its power of judicial review over a Comelec resolution issued in the exercise of its regulatory power.

Clearly, the argument of the FDA is flawed.

Petitioners were Denied their Right to Due Process

Due process of law has two aspects: substantive and procedural. 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.[29] Substantive due process refers to the intrinsic validity of a law that interferes with the rights of a person to his property.[30] 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.[31]

The undisputed fact is that the petitioners were deprived of their constitutional right to due process of law.

As expounded by the Court, what it found to be primarily deplorable is the failure of the respondents to act upon, much less address, the various oppositions filed by the petitioners against the product registration, recertification, procurement, and distribution of the questioned contraceptive drugs and devices. Instead of addressing the petitioners' assertion that the questioned contraceptive drugs and devices fell within the definition of an "abortifacient" under Section 4(a) of the RH Law because of their "secondary mechanism of action which induces abortion or destruction of the fetus inside the mother's womb or the prevention of the fertilized ovum to reach and be implanted in the mother's womb,"[32] the respondents chose to ignore them and proceeded with the registration, recertification, procurement, and distribution of several contraceptive drugs and devices.

A cursory reading of the subject Omnibus Motion shows that the respondents proffer no cogent explanation as to why they did not act on the petitioners' opposition. As stated by the Court in the Decision, rather than provide concrete action to meet the petitioners' opposition, the respondents simply relied on their challenge questioning the propriety of the subject petition

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[29] *Republic of the Phils. v. Sandiganbayan*, 461 Phil. 598 (2003).
[30] *Ynot v. Intermediate Appellate Court*, No. L-74457, March 20, 1987, 148 SCRA 659.
[31] *Tatad v. Sandiganbayan*, 242 Phil. 563, 575-576 (1988).
[32] *Rollo* (G.R. No. 217872), p. 18.

on technical and procedural grounds.[33] The Court, thus, finds the subject motion to be simply a rehash of the earlier arguments presented before, with the respondents still harping on the peculiarity of the FDA's functions to exempt it from compliance with the constitutional mandate that "no person shall be deprived of life, liberty and property without due process of law."

The law and the rules demand compliance with due process requirements

A reading of the various provisions, cited by the respondents in support of their assertion that due process need not be complied with in the approval of contraceptive drugs or devices, all the more reinforces the Court's conclusion that the FDA did fail to afford the petitioners a genuine opportunity to be heard.

As outlined by the respondents themselves, the steps by which the FDA approves contraceptive drugs or devices, demand compliance with the requirements of due process *viz:*

> Step 1. Identify contraceptive products in the database. Create another database containing the following details of contraceptive products: generic name, dosage strength and form, brand name (if any), registration number, manufacturer, MAH, and the period of validity of the CPR.
>
> Step 2. Identify contraceptive products which are classified as essential medicines in the Philippine Drug Formulary.
>
> Step 3. Retrieve the contraceptive product's file and the CPR duplicate of all registered contraceptive products. Create a database of the contraceptive product's history, including its initial, renewal, amendment, and/or variation applications.
>
> Step 4. Conduct a preliminary review of the following:
>
> a. general physiology of female reproductive system, including hormones involved, female reproductive cycle, and conditions of the female reproductive system during pregnancy.
> b. classification of hormonal contraceptives;
> c. regulatory status of the products in benchmark countries; and
> d. mechanism of action of hormonal contraceptives based on reputable journals, meta-analyses, systemic reviews, evaluation of regulatory authorities in other countries, textbooks, among others.

[33] Decision, p. 15.

Step 5. Issue a notice to all concerned MAHs, requiring them to submit scientific evidence that their product is non-abortifacient, as defined in the RH Law and *Imbong*.

Step 6. Post a list of contraceptive products which were applied for re-certification for public comments in the FDA website.

Step 7. Evaluate contraceptive products for re-certification.

A. Part I (Review of Chemistry, Manufacture and Controls)

1. Unit Dose and Finished Product Formulation
2. Technical Finished Product Specifications
3. Certificate of Analysis

B. Part II (Evaluation of Whether the Contraceptive Product is Abortifacient)

1. Evaluation of the scientific evidence submitted by the applicant and the public.
2. Review and evaluation of extraneous evidence, e.g., scientific journals, meta-analyses, etc.

Step 8. Assess and review the documentary requirements submitted by the applicant. Technical reviewers considered scientific evidence such as meta-analyses, systemic reviews, national and clinical practice guidelines and recommendations of international medical organizations submitted by the companies, organizations and individuals, to be part of the review.[34] [Emphases and Underlining supplied]

The Court notes that the above-outlined procedure is deficient insofar as it only allows public comments to cases of *re-certification*. It fails to allow the public to comment in cases where a reproductive drug or device is being subject to the certification process *for the first time*. This is **clearly in contravention of the mandate of the Court in *Imbong* that the IRR should be amended to conform to it.**

More importantly, the Court notes that *Step 5* requires the FDA to issue a **notice** to all concerned MAHs and require them to submit scientific evidence that their product is non-abortifacient; and that *Step 6* requires the posting of the list of contraceptive products which were applied for re-certification **for public comments** in the FDA website.

If an opposition or adverse comment is filed on the ground that the drug or devise has abortifacient features or violative of the RH Law, based

[34] *Rollo*, pp. 418-419.

on the pronouncements of the Court in *Imbong* or any other law or rule, the FDA is duty-bound to take into account and consider the basis of the opposition.

To conclude that product registration, recertification, procurement, and distribution of the questioned contraceptive drugs and devices by the FDA in the exercise of its regulatory power need not comply with the requirements of due process would render the issuance of notices to concerned MAHs and the posting of a list of contraceptives for public comment a meaningless exercise. Concerned MAHs and the public in general will be deprived of any significant participation if what they will submit will not be considered.

Section 7.04, Rule 7 of the IRR of the RH Law *(RH-IRR)*,[35] relied upon by the respondents in support of their claims, **expressly allows the consideration of conflicting evidence**, such as that supplied by the petitioners in support of their opposition to the approval of certain contraceptive drugs and devices. In fact, the said provision mandates that the FDA utilize the "best evidence available" to ensure that no abortifacient is approved as a family planning drug or device. It bears mentioning that the same provision even allows an independent evidence review group (ERG) to ensure that evidence for or against the certification of a contraceptive drug or device is duly considered.

Structure of the FDA

As earlier mentioned, the respondents argue that the Decision "wreaked havoc on the organizational structure of the FDA, whose myriad of functions have been carefully delineated under R.A. No. 9711 IRR."[36] Citing Section 7.04, Rule 7 of the RH-IRR, the FDA insists that the function it exercises in certifying

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[35] Section 7.04. *FDA Certification of Family Planning Supplies.*
The FDA must certify that a family planning drug or device is not an abortifacient in dosages of its approved indication (for drugs) or intended use (for devices) prior to its inclusion in the EDL. The FDA shall observe the following guidelines in the determination of whether or not a drug or device is an abortifacient:
a) As define in Section 3.01 (a) of these Rules, a drug or device is deemed to be an abortifacient if it is proven to primarily induce abortion or the destruction of a fetus inside the mother's womb or the prevention of the fertilized ovum to reach and be implanted in the mother's womb;
b) The following mechanisms do not constitute abortion: the prevention of ovulation; the direct action on sperm cells prior to fertilization; the thickening of cervical mucus; and any mechanism acting exclusively prior to the fertilization of the egg by the sperm;
c) In making its determination, the FDA shall **use the best evidence available**, including but not limited to: meta-analyses, systematic reviews, national clinical practice guidelines where available, and recommendations of international medical organizations;
d) In the presence of conflicting evidence, the more recent, better-designed, and larger studies shall be preferred, and the conclusions found therein shall be used to determine whether or not a drug or device is an abortifacient; and
e) Should the FDA require additional expertise in making its determination, **an independent evidence review group (ERG) composed of leading experts in the fields of pharmacodynamics, medical research, evidence-based medicine, and other relevant fields may be convened to review the available evidence**. The FDA shall then issue its certification based on the recommendations of the ERG.

[36] Omnibus Motion, p. 37.

family planning supplies is in the exercise of its **regulatory power,** which cannot be the subject of judicial review, and that it is the **Director-General of the FDA** who exercises **quasi-judicial powers**, citing Section 2(b) of Article 3, Book I of the RH-IRR.[37]

The FDA wants the Court to consider that, as a body, it has a distinct and separate personality from the Director-General, who exercises quasi-judicial power. The Court cannot accommodate the position of the respondents. Section 6(a) of R.A. No. 3720, as amended by Section 7 of R.A. No. 9711,[38] provides that "(a) **The FDA shall be headed by a director-general** with the rank of undersecretary, xxx." *How can the head be separated from the body?*

For the record, Section 4 of R.A. No. 3720, as amended by Section 5 of R.A. No. 9711, also recognizes compliance with the requirements of due process, although the proceedings are not adversarial. Thus:

> Section 5. Section 4 of Republic Act No. 3720, as amended, is hereby further amended to read as follows:
>
> "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:
>
> "(a) To administer the effective implementation of this Act and of the rules and regulations issued pursuant to the same;
>
> "(b) To assume primary jurisdiction in the collection of samples of health products;
>
> "(c) To analyze and inspect health products in connection with the implementation of this Act;
>
> "(d) To establish analytical data to serve as basis for the preparation of health products standards, and to recommend standards of identity, purity, safety, efficacy, quality and fill of container;
>
> "(e) To issue certificates of compliance with technical requirements to serve as basis for the issuance of appropriate authorization and spot-check for compliance with regulations regarding operation of manufacturers, importers, exporters, distributors, wholesalers, drug outlets, and other

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[37] Id. at 10.
[38] Dated August 18, 2009.

establishments and facilities of health products, as determined by the FDA;

"x x x

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

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

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

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

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

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

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

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

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

> "(q) To exercise such other powers and perform such other functions as may be necessary to carry out its duties and responsibilities under this Act. [Emphases supplied]

The Cardinal Rights of Parties in Administrative Proceedings as laid down in Ang Tibay v. CIR

In *Ang Tibay v. CIR*,[39] the Court laid down the cardinal rights of parties in administrative proceedings, as follows:

> 1) The right to a hearing, which includes the right to present one's case and submit evidence in support thereof;
>
> 2) The tribunal must consider the evidence presented;
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> 3) The decision must have something to support itself;
>
> 4) The evidence must be substantial;
>
> 5) The decision must be rendered on the evidence presented at the hearing, or at least contained in the record and disclosed to the parties affected;
>
> 6) The tribunal or body or any of its judges must act on its or his own independent consideration of the law and facts of the controversy and not simply accept the views of a subordinate in arriving at a decision; and
>
> 7) The board or body should, in all controversial questions, render its decision in such a manner that the parties to the proceeding can know the various issues involved, and the reason for the decision rendered.[40]

In the Decision, the Court found that the FDA certified, procured and administered contraceptive drugs and devices, without the observance of the basic tenets of due process, that is, without notice and without public hearing. It appeared that, other than the notice inviting stakeholders to apply for certification/recertification of their reproductive health products, there was no showing that the respondents considered the opposition of the petitioners. Thus, the Court wrote:

> Rather than provide concrete evidence to meet the petitioners' opposition, the respondents simply relied on their challenge questioning the propriety of the subject petition on technical and procedural grounds. The Court notes that even the letters submitted by the petitioners to the FDA and the DOH seeking information on

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[39] 69 Phil. 635, 642-644 (1940).

[40] As cited and paraphrased in *Solid Homes v. Laserna*, 574 Phil. 69, 83 (2008).

> the actions taken by the agencies regarding their opposition were left unanswered as if they did not exist at all. The mere fact that the RH Law was declared as not unconstitutional does not permit the respondents to run roughshod over the constitutional rights, substantive and procedural, of the petitioners.
>
> Indeed, although the law tasks the FDA as the primary agency to determine whether a contraceptive drug or certain device has no abortifacient effects, its findings and conclusion should be allowed to be questioned and those who oppose the same must be given a genuine opportunity to be heard in their stance. After all, under Section 4(k) of R.A. No. 3720, as amended by R.A. No. 9711, the FDA is mandated to order the ban, recall and/or withdrawal of any health product found to have caused death, serious illness or serious injury to a consumer or patient, or found to be imminently injurious, unsafe, dangerous, or grossly deceptive, after due process.
>
> Due to the failure of the respondents to observe and comply with the basic requirements of due process, the Court is of the view that the certifications/re-certifications and the distribution of the questioned contraceptive drugs by the respondents should be struck down as violative of the constitutional right to due process.
>
> Verily, it is a cardinal precept that where there is a violation of basic constitutional rights, the courts are ousted from their jurisdiction. The violation of a party's right to due process raises a serious jurisdictional issue which cannot be glossed over or disregarded at will. Where the denial of the fundamental right to due process is apparent, a decision rendered in disregard of that right is void for lack of jurisdiction. This rule is equally true in quasi-judicial and administrative proceedings, for the constitutional guarantee that no man shall be deprived of life, liberty, or property without due process is unqualified by the type of proceedings (whether judicial or administrative) where he stands to lose the same.[41]

The Court stands by that finding and, accordingly, reiterates its order of remand of the case to the FDA.

Procedure in the FDA;
No Trial-Type Hearing

The Court is of the view that the FDA need not conduct a trial-type hearing. Indeed, due process does not require the conduct of a trial-type hearing to satisfy its requirements. All that the Constitution requires is that the FDA afford the people their right to due process of law and decide on the applications submitted by MAHs after affording the oppositors like the petitioners a genuine opportunity to present their science-based evidence. As earlier pointed out, this the FDA failed to do. It simply ignored the opposition of the petitioners. In the

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[41] *Rollo*, pp. 396-397.

case of *Perez, et al. v. Philippine Telegraph and Telephone Company, et al.*,[42] it was stated that:

> A formal trial-type hearing is not even essential to due process. It is enough that the parties are given a fair and reasonable opportunity to explain their respective sides of the controversy and to present supporting evidence on which a fair decision can be based.

In the fairly recent case of *Vivo v. Pagcor*,[43] the Court explained:

> The observance of fairness in the conduct of any investigation is at the very heart of procedural due process. The essence of due process is to be heard, and, as applied to administrative proceedings, this means a fair and reasonable opportunity to explain one's side, or an opportunity to seek a reconsideration of the action or ruling complained of. **Administrative due process cannot be fully equated with due process in its strict judicial sense, for in the former a formal or trial-type hearing is not always necessary**, and technical rules of procedure are not strictly applied. *Ledesma v. Court of Appeals* elaborates on the well-established meaning of due process in administrative proceedings in this wise:
>
> > x x x Due process, as a constitutional precept, does not always and in all situations require a trial-type proceeding. Due process is satisfied when a person is notified of the charge against him and given an opportunity to explain or defend himself. In administrative proceedings, the filing of charges and giving reasonable opportunity for the person so charged to answer the accusations against him constitute the minimum requirements of due process. The essence of due process is simply to be heard, or as applied to administrative proceedings, an opportunity to explain one's side, or an opportunity to seek a reconsideration of the action or ruling complained of. [Emphasis supplied; citations omitted]

Best Evidence Available

Section 5, Rule 133 of the Rules of Court provides:

> Section 5. In all cases filed before **administrative or quasi-judicial bodies**, a fact may be deemed established if it is supported by **substantial evidence**, or the amount of relevant evidence which a reasonable mind might accept as adequate to justify a conclusion.

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[42] 602 Phil. 522, 540 (2009).
[43] 721 Phil. 34, 39-40 (2013).

As applied to certification proceedings at the FDA, "substantial evidence" refers to the **best scientific evidence available**,[44] "including but not limited to: meta analyses, systematic reviews, national clinical practice guidelines where available, and recommendations of international medical organizations," needed to support a conclusion whether a contraceptive drug or device is an abortifacient or not. The FDA need not be bound or limited by the evidence adduced by the parties, but it can conduct its own search for related scientific data. It can also consult other technical scientific experts known in their fields. It is also not bound by the principle of *stare decisis* or *res judicata*, but may update itself and cancel certifications *motu proprio* when new contrary scientific findings become available or there arise manifest risks which have not been earlier predicted.

On the Competence of the Court
to review the Findings of the FDA

The fact that any appeal to the courts will involve scientific matters will neither place the actions of the respondents beyond the need to comply with the requirements of *Ang Tibay* nor place the actions of the FDA in certification proceedings beyond judicial review.

It should be pointed out that nowhere in Batas Pambansa Blg. 129, as amended, are the courts ousted of their jurisdiction whenever the issues involve questions of scientific nature. A court is not considered incompetent either in reviewing the findings of the FDA simply because it will be weighing the scientific evidence presented by both the FDA and its oppositors in determining whether the contraceptive drug or device has complied with the requirements of the law.

Although the FDA is not strictly bound by the technical rules on evidence, as stated in the Rules of Court, or it cannot be bound by the principle of *stare decisis* or *res judicata*, it is not excused from complying with the requirements of due process. To reiterate for emphasis, due process does not require that the FDA conduct trial-type hearing to satisfy its requirements. All that the Constitution requires is that the FDA afford the people their right to due process of law and decide on the applications submitted by the MAHs after affording the oppositors, like the petitioners, a genuine opportunity to present their science-based evidence.

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[44] *See* Section 7.04 (c) Rule 7 of the Implementing Rules and Regulations of R.A. No. 10354.

The Appellate Procedure;
Appeal to the Office of the President

Incidentally, Section 32 of R.A. No. 3720 and Section 9 of Executive Order *(E.O.)* No. 247 provide that any decision by the FDA would then be appealable to the Secretary of Health, whose decision, in turn, may be appealed to the Office of the President *(OP)*. Thus:

> Sec. 32. **The orders, rulings or decisions of the FDA shall be appealable to the Secretary of Health.** — An appeal shall be deemed perfected upon filing of the notice of appeal and posting of the corresponding appeal bond.
>
> An appeal shall not stay the decision appealed from unless an order from the Secretary of Health is issued to stay the execution thereof.
>
> Sec. 9. Appeals. — **Decisions of the Secretary** (DENR, DA, **DOH** or DOST) **may be appealed to the Office of the President.** Recourse to the courts shall be allowed after exhaustion of all administrative remedies.

In view thereof, the Court should modify that part of the Decision which allows direct appeal of the FDA decision to the Court of Appeals. As stated in the said decision, the FDA decision need not be appealed to the Secretary of Health because she herself is a party herein. Considering that the Executive Secretary is not a party herein, the appeal should be to the OP as provided in Section 9.

On the Prayer to Lift the TRO

The respondents lament that the assailed decision undermines the functions of the FDA as the specialized agency tasked to determine whether a contraceptive drug or device is safe, effective and non-abortifacient. They also claim that the assailed decision requiring notice and hearing would unduly delay the issuance of CPR thereby affecting public access to State-funded contraceptives. Finally, in a veritable attempt to sow panic, the respondents claim that the TRO issued by the Court would result in "a nationwide stockout of family planning supplies in accredited public health facilities *and* the commercial market."[45]

On this score, it should be clarified that the Decision simply enjoined the respondents from registering, recertifying, procuring, and administering only

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[45] *Rollo*, pp. 442-446.

those contraceptive drugs and devices which were the subjects of the petitioners' opposition, specifically Implanon and Implanon NXT. It never meant to enjoin the processing of the entire gamut of family planning supplies that have been declared as unquestionably non-abortifacient. Moreover, the injunction issued by the Court was only subject to the condition that the respondents afford the petitioners a genuine opportunity to their right to due process.

As the Decision explained, the Court cannot lift the TRO prior to the summary hearing to be conducted by the FDA. To do so would render the summary hearing an exercise in futility. Specifically, the respondents would want the Court to consider their argument that Implanon and Implanon NXT have no abortifacient effects. According to them, "the FDA tested these devices for safety, efficacy, purity, quality, and non-abortiveness prior to the issuance of certificates of registration and recertification, and after the promulgation of Imbong."[46] **The Court, however, cannot make such determination or pronouncement at this time.** To grant its prayer to lift the TRO would be **premature** and **presumptuous**. Any declaration by the Court at this time would have **no basis** because the FDA, which has the mandate and expertise on the matter, has to first resolve the controversy pending before its office.

This Court also explained in the Decision that the issuance of the TRO did not mean that the FDA should stop fulfilling its mandate to test, analyze, scrutinize, and inspect other drugs and devices. Thus:

> Nothing in this resolution, however, should be construed as restraining or stopping the FDA from carrying on its mandate and duty to test, analyze, scrutinize, and inspect drugs and devices. What are being enjoined are the grant of certifications/re-certifications of contraceptive drugs without affording the petitioners due process, and the distribution and administration of the questioned contraceptive drugs and devices including Implanon and Implanon NXT until they are determined to be safe and non-abortifacient.[47]

On Delay

The respondents claim that this judicial review of the administrative decision of the FDA in certifying and recertifying drugs has caused much delay in the distribution of the subject drugs with a dire impact on the effective implementation of the RH Law.

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[46] Omnibus Motion, pp. 40-41.

[47] *Alliance for the Family Foundation, Philippines, Inc. v. Garin*, G.R. Nos. 217872 & 221866, August 24, 2016.

In this regard, the respondents have only themselves to blame. Instead of complying with the orders of the Court as stated in the Decision to conduct a summary hearing, the respondents have returned to this Court, asking the Court to reconsider the said decision claiming that it has wreaked havoc on the organizational structure of the FDA.

Had the FDA immediately conducted a summary hearing, by this time it would have finished it and resolved the opposition of the petitioners. Note that there was already a finding by the FDA, which was its basis in registering, certifying and recertifying the questioned drugs and devices. The pharmaceutical companies or the MAHs need not present the same evidence it earlier adduced to convince the FDA unless they want to present additional evidence to fortify their positions. The only entities that would present evidence would be the petitioners to make their point by proving with relevant scientific evidence that the contraceptives have abortifacient effects. Thereafter, the FDA can resolve the controversy.

Indeed, in addition to guaranteeing that no person shall be deprived of life, liberty and property without due process of law,[48] the Constitution commands that "all persons shall have the right to a speedy disposition of their cases before all judicial, quasi-judicial and administrative bodies."[49]

WHEREFORE, the August 24, 2016 Decision is **MODIFIED**. Accordingly, the Food and Drug Administration is ordered to consider the oppositions filed by the petitioners with respect to the listed drugs, including Implanon and Implanon NXT, based on the standards of the Reproductive Health Law, as construed in *Imbong v. Ochoa*, and to decide the case within sixty (60) days from the date it will be deemed submitted for resolution.

After compliance with due process and upon promulgation of the decision of the Food and Drug Administration, the Temporary Restraining Order would be deemed lifted if the questioned drugs and devices are found not abortifacients.

After the final resolution by the Food and Drug Administration, any appeal should be to the Office of the President pursuant to Section 9 of E.O. No. 247.

As ordered in the August 24, 2016 Decision, the Food and Drug Administration is directed to amend the Implementing Rules and Regulations of

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[48] CONSTITUTION, (1987), Art. III, Sec. 1.
[49] CONSTITUTION, (1987), Art. III, Sec. 16.

R.A. No. 10354 so that it would be strictly compliant with the mandates of the Court in *Imbong v. Ochoa*.

SO ORDERED.

JOSE CATRAL MENDOZA
Associate Justice

WE CONCUR:

ANTONIO T. CARPIO
Associate Justice
Chairperson

MARIANO C. DEL CASTILLO
Associate Justice

MARVIC M.V.F. LEONEN
Associate Justice

SAMUEL R. MARTIRES
Associate Justice

ATTESTATION

I attest that the conclusions in the above Resolution had been reached in consultation before the case was assigned to the writer of the opinion of the Court's Division.

ANTONIO T. CARPIO
Associate Justice
Chairperson, Second Division

CERTIFICATION

Pursuant to Section 13, Article VIII of the Constitution and the Division Chairperson's Attestation, I certify that the conclusions in the above Resolution had been reached in consultation before the case was assigned to the writer of the opinion of the Court's Division.

MARIA LOURDES P. A. SERENO
Chief Justice