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SPECIAL SECOND DIVISION

[G.R. No. 217872, April 26, 2017]

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, VS. 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. 221866]

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, MARIETTA C. GORREZ, ROLANDO M. BAUTISTA, RUBEN T. UMALI, AND MILDRED C. CASTOR, PETITIONERS, VS. 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.

R E S O L U T I O N

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. 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)(I) 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.

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)(I)[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 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.

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.

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 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 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.
>
> **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 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 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, x x x." *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;