

**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<sup>[1]</sup> filed by the respondents, thru the Office of the Solicitor General (OSG), seeking partial reconsideration of the August 24, 2016 Decision (*Decision*),<sup>[2]</sup> 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.<sup>[3]</sup>

### **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.<sup>[4]</sup> They contended that considering that the issuance of the certificate of product registration (CPR) by the FDA under Section 7.04, Rule 7<sup>[5]</sup> 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.<sup>[6]</sup>

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)<sup>[7]</sup> of Article 3,

Book I of the Implementing Rules and Regulations (*IRR*) of R.A. No. 9711,<sup>[8]</sup> and the "**regulatory/administrative powers**" exercised by the FDA under Section 2(c)(1)<sup>[9]</sup> 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 (*CDDR*) examined and tested the contraceptives for non-abortifacience,<sup>[10]</sup> 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.<sup>[11]</sup> The respondents, thus, prayed for the lifting of the Temporary Restraining Order (*TRO*).<sup>[12]</sup>

*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*<sup>[13]</sup> were inapplicable considering that: a) substantial evidence could not be used as a measure in determining whether a contraceptive drug or device was abortifacient;<sup>[14]</sup> 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;<sup>[15]</sup> c) the FDA was not bound by the rules of admissibility and presentation of evidence under the Rules of Court;<sup>[16]</sup> and d) the findings of the FDA could not be subject of the rule on *res judicata* and *stare-decisis*.<sup>[17]</sup>

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.<sup>[18]</sup> "[A] legislative rule is in the nature of subordinate legislation, designed to implement a primary legislation by providing the details thereof."<sup>[19]</sup> 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.<sup>[20]</sup>

**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.<sup>[21]</sup> 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**.<sup>[22]</sup>

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.<sup>[23]</sup> [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,<sup>[24]</sup> TRB,<sup>[25]</sup> NEA,<sup>[26]</sup> and the SEC,<sup>[27]</sup> among others. In *Diocese of Bacolod v. Commission on Elections*,<sup>[28]</sup> 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.<sup>[29]</sup> Substantive due process refers to the intrinsic validity of a law that interferes with the rights of a person to his property.<sup>[30]</sup> 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.<sup>[31]</sup>

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,"<sup>[32]</sup> 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.<sup>[33]</sup> 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-abortionifacient, 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.<sup>[34]</sup>  
[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 device 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*),<sup>[35]</sup> 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."<sup>[36]</sup> 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.<sup>[37]</sup>

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,<sup>[38]</sup> 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;

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

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

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

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

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

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

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

"(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*,<sup>[39]</sup> 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;
- 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.<sup>[40]</sup>

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 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.<sup>[41]</sup>

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 case of *Perez, et al. v. Philippine Telegraph and Telephone Company, et al.*,<sup>[42]</sup> 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*,<sup>[43]</sup> 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.

As applied to certification proceedings at the FDA, "substantial evidence" refers to the **best scientific evidence available**,<sup>[44]</sup> "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 sciencebased evidence.

#### *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."<sup>[45]</sup>

On this score, it should be clarified that the Decision simply enjoined the respondents from registering, recertifying, procuring, and administering only 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."<sup>[46]</sup> **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.<sup>[47]</sup>

#### *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.

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,<sup>[48]</sup> 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."<sup>[49]</sup>

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

**SO ORDERED.**

*Carpio, (Chairperson), Del Castillo, and Martires, JJ., concur.*  
*Leonen, J., I concur. See separate opinion.*

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<sup>[1]</sup> *Rollo*, pp. 406-744.

<sup>[2]</sup> *Id.* at 382-405.

[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: metaanalyses, 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.

[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]

[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.

[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.

[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.")

[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.

[33] Decision, p. 15.

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

[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.

[37] *Id.* at 10.

[38] Dated August 18, 2009.

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

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

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

[42] 602 Phil. 522, 540 (2009).

[43] 721 Phil. 34, 39-40 (2013).

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

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

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

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

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

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

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#### CONCURRING OPINION

LEONEN, J:

I concur that petitioners' comment should have been addressed by respondent in the re-certification proceedings. The submission of comments by the public is required by respondents' own procedures, which it violated by refusing to answer or even acknowledge the oppositions submitted.

Nevertheless, a certification and re-certification proceeding for the determination of non-abortifacience does not require a public hearing. The Food and Drug Administration, as a regulatory agency, does not exercise its quasi-judicial functions when it determines whether a contraceptive is safe, effective, and a non-abortifacient. In certification and re-certification proceedings, the Food and Drug Administration merely looks at the requirements of the law and applies it. Its scientific testing and gathering of medical and pharmacological data do not require an adjudication of rights of the parties before it. Public participation, however, is still necessary for purposes of transparency since any public act is subject to public scrutiny and criticism.

## I

The Food and Drug Administration was created by Republic Act No. 3720<sup>[1]</sup> to regulate food, drug, and cosmetic manufacturers and establishments.<sup>[2]</sup> In 1982, the Food and Drug Administration was abolished and its functions were assumed by the Bureau of Food and Drugs.<sup>[3]</sup> In 2009, the Bureau of Food and Drugs was renamed the Food and Drug Administration.<sup>[4]</sup> Republic Act No. 9711 outlined the Food and Drug Administration's regulatory capabilities, including the development and issuance of "standards and appropriate authorizations that would cover establishments, facilities and health products."<sup>[5]</sup>

Among the authorizations issued by the Food and Drug Administration is the Certificate of Product Registration<sup>[6]</sup> of all health products or "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,"<sup>[7]</sup> consistent with its mandate to "insure safe and good quality [supplies] of food, drug[s] and cosmetic[s]."<sup>[8]</sup>

Considering the highly technical nature of the registration and certification process, the Food and Drug Administration is further subdivided into four (4) research centers: first, the Center for Drug Regulation and Research; second, the Center for Food Regulation and Research; third, the Center for Cosmetic Regulation and Research; and fourth, the Center for Device Regulation, Radiation Health and Research.<sup>[9]</sup>

Prior to the issuance of a Certificate of Product Registration of an established drug,<sup>[10]</sup> the Center for Drug Regulation and Research must first review the technical specifications of the drug, in particular:

### 1. Application Letter

2. Valid License to Operate of manufacturer/trader/distributor/importer /exporter/wholesaler
3. Certificate of Brand Name Clearance
4. Agreement between Manufacturer and Trader or Distributor Importer/Exporter
5. General Information product's proprietary or brand name, official chemical name(s) and generic name(s) of active ingredient(s), molecular or chemical formula and structure, amount of active ingredient per unit dose, pharmaceutical form of the drug, indication, recommended dosage, frequency of administration, route and mode of administration, contraindication, warnings and precautions
6. Unit dose and batch formulation
  - Must be in full compliance with the latest official monograph (United States Pharmacopeia, British Pharmacopeia, Japanese Pharmacopeia, European Pharmacopeia, International Pharmacopeia); name and edition of the reference may be cited in lieu of submitting a detailed list of limits and tests; when an alternative procedure or limit is used, it shall be equal to or more stringent than the official requirement
  - For non-official or unofficial substances, separate list of technical specifications of each ingredient must include the ff:
    - Name of substance
    - detailed information on physical and chemical properties
    - ID tests
    - Purity tests
    - Assay
7. Technical/Quality Specifications of all Raw Materials including Packaging Materials
8. Certificate of Analysis of Active Ingredient(s)
9. Technical Specifications of the Finished Product
  - a) The appearance of the product (colour, shape dimensions,



- odour, distinguishing features, etc.)
- b) Identification of the active ingredient(s) (must include the specific identity test for the active moiety)
- c) Quantitative determination of active ingredient(s) (i.e. Assay)
- d) Test of impurities
- e) The appropriate tests concerning the pharmaceutical properties of the dosage form (e.g. pH, content uniformity, dissolution rate, disintegration, etc)
- f) Tests for safety, sterility, pyrogens, histamine, abnormal toxicity, etc. where applicable.
- g) Technical properties of containers
- h) For drug preparations which are subject of an official monograph, the technical/quality specifications of the finished product as stated in the monograph shall be complied with.

#### 10. Certificate of Analysis of the Finished Product

11. Pull description of the methods used, the facilities and controls in the manufacture, processing and packaging of the finished product.

12. Details of the assay and other test procedures of finished product including data analysis

13. Detailed report of stability studies to justify claimed shelf-life

14. Labeling materials

15. Representative sample

16. For imported products: Duly authenticated Certificate of Free Sale from the country of origin, and Duly authenticated government certificate attesting to the registration status of the manufacturer.<sup>[11]</sup>

New drugs,<sup>[12]</sup> on the other hand, require a longer review process before the issuance of a Certificate of Product Registration. The Center for Drug Regulation and Research must first review the following requirements and conduct a series of scientific tests before the issuance of a certification:

1. All requirements for Established Drugs as stated above
2. Certificate of the Medical Director
3. Reference Standard and its corresponding Certificate of Analysis
4. Pre-clinical Data

Before initial human studies are permitted, the full spectrum of pharmacologic properties of the new drug must be extensively investigated in animals. Animal researches are done to provide evidence that the drug has sufficient efficacy and safety to warrant testing in man.

#### a) Pharmacodynamics

- to identify the primary action of the drug as distinguished from the description of its resultant effects.
  - to delineate the details of the chemical interaction between drug and cell or specific receptor site(s), and
  - to characterize the full sequence of drug action and effects.
- i. Pharmacologic effects - properties relevant to the proposed indication and other effects. Pharmacodynamic data shall demonstrate the primary pharmacologic effect of the drug leading to its development for the intended use(s) or indication(s). It shall also show the particular tissue(s)/organ(s) affected by the drug and any other effect it produces on the various systems of the body.
  - ii. Mechanism of action including structure-activity relationship (SAR)

#### b) Pharmacokinetics

Pharmacokinetic data form the basis for prediction of therapeutic doses and suitable dosage regimen.

These data shall demonstrate the following:

- i. the rate and extent of absorption of the drug using the intended route of administration;
- ii. the distribution pattern including a determination of the tissues or organs where the drug and its metabolites are concentrated immediately after administration and the time course of their loss from this [sic] sites;
- iii. the metabolic pathway of the drug or its biotransformation and the biological metabolites;
- iv. the route of excretion of the drug and its principal metabolites and the amount of unchanged substance and metabolites for each route of excretion;
- v. the drug's half-life or the rate that it is eliminated from the blood, plasma or serum.

### c) Toxicity data

#### i. Acute Toxicity

Acute toxicity data shall show the median lethal dose of a drug. Ideally, the study shall be carried out in at least two (2) species of animals, one (1) rodent and the other non-rodent, using 5 dose levels with the appropriate number of test animals.

#### ii. Subchronic Toxicity

Subchronic toxicity studies are carried out using repeated daily exposure to the drug over a period of 21-90 days with the purpose of studying the toxic effects on target organs, the reversibility of the effects and the relationship of blood and tissue levels on the test animals

#### iii. Chronic Toxicity

Chronic toxicity studies constitute important steps in the analysis of a chemical. The entire lifetime exposure of an individual or animal to the environment or chemical is an on-going process which neither acute nor subchronic toxicity study can provide. The effect on animals when small doses of the drug are given over a long period of time may not be the same as when large doses are given over a short period.

#### iv. Special Toxicity Studies

#### v. [sic]

#### a. Reproduction Tests

1. Multigeneration reproduction study provides information on the fertility and pregnancy in parent animals and subsequent generations. The effects of a potentially toxic substance could be determined by the reproductive performance through successive generations such as adverse effects on the formation of gametes and on fertilization and to detect gross genetic mutations which may lead to fetal death, fetal abnormalities or inadequate development or abnormal reproductive capacity in the F1 generation. This study can also reveal adverse drug effects that occur during pregnancy or during lactation.

2. Teratologic study determines the effect of a chemical on the embryonic and fetal viability and development when administered to the pregnant female rodent (rat) or nonrodent (beagle dog or monkey) during the period of organogenesis.

3. Peri-natal and post-natal study determines the effects of drugs or chemical given to the pregnant animal in the final one-third of gestation

and continued throughout lactation to weaning of pups.

#### b. Carcinogenicity

Carcinogenicity tests in animals are required when the drug is likely to be given to humans continuously or in frequent short course periods to determine whether chronic administration can cause tumors in animals. Mice and rats are the rodents of choice while dogs or monkeys are preferred non-rodents. These tests may be designed to be incorporated in the protocol for chronic toxicity studies wherein the animals are exposed to the drug after weaning and continued for a minimum of two years. At least 3 dose levels are used with the highest dose approximating the maximal tolerated dose and the route should be similar to that anticipated in man. Repeated expert observation, palpation and thorough examinations of animals for any lumps or masses are essential. All animals must be thoroughly autopsied and histological examination of all organs should be carried out.

#### c. Mutagenicity

Mutagenicity tests have the primary objective of determining whether a chemical has the potential to cause genetic damage in humans. Animal model systems, both mammalian and non-mammalian together with microbial systems which may approximate human susceptibility, are used in these tests.

### 5. Clinical Data

a) Certification of an independent institution review board of approval of clinical protocol and monitoring of clinical trial

#### b) Clinical Investigation Data

##### i. Phase I Clinical Drug Trial

Phase I Clinical Drug Trial consists of initial testing of the study drug in humans, usually in normal volunteers but occasionally in actual patients. The number of subjects is small (N = 15 to 3). Safety evaluations are the primary objectives and attempt is made to establish the approximate levels of patient tolerance for acute and multiple dosing. Basic data on rates of absorption, degree of toxicity to organs (heart, kidney, liver, hematopoietic, muscular, nervous, vascular) and other tissue, metabolism data, drug concentrations in serum or blood and excretion patterns are also obtained. Subjects shall be carefully screened. Careful monitoring for adverse or untoward effects and intensive clinical laboratory tests are required. This study shall be conducted by an approved or accredited Clinical Pharmacologist. A written informed consent of subject is necessary.

## ii. Phase II Clinical Drug Trial

Phase I Clinical Drug Trials are initial studies designed to evaluate efficacy of the study drug in a small number of selected populations or patient for whom the drug is intended which may be open label or single or double blind. Blood levels at various intervals, adverse experiences, and additional Phase I data may be obtained. Small doses are gradually increased until the minimal effective dose is found. All reactions of the subjects are carefully recorded. Preliminary estimates of the dosage, efficacy and safety in man are made. The second part of Phase II consists of pivotal well controlled studied that usually represent the most rigorous demonstrations of a drug efficacy. Relative safety information is also determined in Phase II studies. A larger number of patients are enrolled into the second part ( $N = 60$  to 200 subjects). Phase II studies are conducted by accredited Clinical Pharmacologists. Phase II second part studies may be conducted by well qualified practitioners or clinicians who are familiar with the conditions to be treated, the drug used in these conditions to be treated, the drug used in these conditions and the methods of their evaluation. A written informed consent of patients-participants is needed.

## iii. Phase III Clinical Drug Trial

Phase III clinical drug trials are studies conducted in patient populations for which the drug is eventually intended. These studies generate data on both safety and efficacy in relatively large numbers of patients under normal use conditions in both controlled and uncontrolled studies. The number of patients required vary [sic] (1,000 to 10,000). These studies provide much of the information that is needed for the package insert and labelling of the drug. This phase may be conducted as a multicentric trial among accredited clinicians. The informed consent of participating subject is preferably in written form.

## iv. Bioavailability

Bioavailability studies are conducted to determine the rate and extent to which the active substance or therapeutic moiety is absorbed from a pharmaceutical form and becomes available at the site of action.

c) Name of investigator(s) and curriculum vitae

d) Name(s) of center/institution wherein the clinical investigation was undertaken

e) Protocol for local clinical trial<sup>[13]</sup>

Under Republic Act No. 10354,<sup>[14]</sup> the Food and Drug Administration is likewise given the authority to determine whether a drug or device is considered an abortifacient.<sup>[15]</sup> In order for a contraceptive to be considered medically safe and non-abortifacient, it must have been registered and approved by the Food and Drug Administration in accordance with its "scientific and evidence-based medical research standards."<sup>[16]</sup> In addition to the regular registration and certification process required for established drugs and new drugs, Market Authorization Holders (MAHs) must also undergo a process to determine if their contraceptive is safe and non-abortifacient.

Before the effectivity of Republic Act No. 10354, the Center for Drug Regulation and Research followed this procedure for the registration of contraceptives:

Step 1. The FDA receives applications of MAH [Market Authorization Holder] through its Public Assistance, Information and Receiving (PAIR) Unit.

Step 2. The FDA evaluates whether the MAH submitted complete documents for review.

Step 3. The FDA schedules and decks the application for registration to the evaluator.

Step 4. The Junior Evaluator of the CDRR Registration Section, Human Drugs-Chemistry Manufacturing and Controls Unit evaluates the contraceptive product for quality. The Junior Evaluator of the CDRR Registration Section, Human Drugs-Clinical Research Unit and FDA medical consultants evaluate the contraceptive product for safety and efficacy, as applicable.

Step 5. The Senior Evaluator of the CDRR Registration Section, Human Drugs-Chemistry Manufacturing and Controls Unit and Senior Evaluator of the Clinical Research Unit checks [sic] the findings of the Junior Evaluators.

Step 6. The FDA Consultants and the Evaluators meet for final assessment and recommendation.

Step 7. Issuance of CPR/Notice of Deficiencies/Letter of Denial.

Step 8. The FDA uploads a copy of the CPR at the FDA Inventory System. The FDA also uploads the product details such as registration number, generic name, brand name, dosage strength and form, the NIAH, and CPR Validity at the FDA website.

Step 9. Release of the CPR or letter through PAIR Unit.<sup>[17]</sup>

Republic Act No. 10354, however, explicitly outlines the steps the Food and Drug Administration must undertake in order to identify if a particular contraceptive or intrauterine device is non-abortifacient:

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.<sup>[18]</sup>

Upon the effectivity of the Implementing Rules and Regulations of Republic Act No. 10354, all "health care drugs, supplies, and products" with prior Certificates of Product Registration must undergo a re-certification process with the Food and Drug Administration to prove that they are safe and non-abortifacient.<sup>[19]</sup>

In order to aid the re-certification process of Marketing Authorization Holders of contraceptive drugs, the Center for Drug Regulation and Research formulated the steps to be undertaken:

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.<sup>[20]</sup>

In a certification proceeding for contraceptives, contraceptives must undergo both the scientific testing necessary for all drugs to test for its safety and efficacy. In addition, contraceptives must likewise be tested for non-abortifacience. Best evidence of non-abortifacience include "meta-analyses, systematic reviews, national clinical practice guidelines where available, and recommendations of international medical organizations."<sup>[21]</sup> In case of conflict, "more recent, better-designed, and larger studies shall be preferred."<sup>[22]</sup> The Food and Drug Administration is also authorized to constitute "an independent evidence review group (ERG) composed of leading experts in the fields of pharmacodynamics, medical research, evidence-based medicine, and other relevant fields."<sup>[23]</sup>

Re-certification proceedings, on the other hand, involve a preliminary review of the physiology of the female reproductive system and the classification, regulatory status, and mechanism of hormonal contraceptives in other countries, as well as a two-part evaluation process.<sup>[24]</sup> The first part is a review of the chemistry, manufacture, and control of the product while the second part evaluates all the scientific data submitted.<sup>[25]</sup>

The present controversy revolves around whether the Food and Drug Administration's authority to determine whether a contraceptive is non-abortifacient is quasi-judicial in nature, and therefore must adhere to the due process standards required of administrative proceedings.

Considering the Food and Drug Administration's heavy reliance on scientific data and the highly technical nature of the certification and non certification process, the proceeding is not quasi-judicial in nature.

## II

An administrative agency performs a quasi-judicial function when it has "the power to hear and determine questions of fact to which the legislative policy is to apply and to decide in accordance with the standards laid down by the law itself in enforcing and administering the same law."<sup>[26]</sup> Its quasi-judicial functions require the agency to "investigate facts or ascertain the existence of facts, hold hearings, weigh evidence, and draw conclusions from them as basis for their official action and exercise of discretion in a judicial nature."<sup>[27]</sup> Otherwise stated, an agency performs

a quasi-judicial function when it determines what the law is and adjudicates the rights of the parties before it.<sup>[28]</sup>

An administrative agency's quasi-judicial functions should not be confused with its administrative or executive functions. A purely executive or administrative function

connotes, or pertains, to "administration, especially management, as by managing or conducting, directing or superintending, the execution, application, or conduct of persons or things." It does not entail an opportunity to be heard, the production and weighing of evidence, and a decision or resolution thereon.<sup>[29]</sup>

On the other hand, an administrative agency exercises its quasi-judicial function when "it performs *in a judicial manner* an act which is essentially of an executive or administrative nature."<sup>[30]</sup> Thus, while the administrative agency is not expected to act like a court of law, it is still expected to listen to both sides and to render a decision explaining its reasons for its decision.<sup>[31]</sup>

As previously discussed, the Food and Drug Administration requires scientific, medical, and pharmacological data as well as numerous clinical studies in its registration, certification, and re-certification procedures. Due to the highly technical nature of the processes, none of the standards and procedures required in quasi-judicial proceedings would be applicable to it.

The standard of evidence required to establish the existence of a fact before a quasi-judicial tribunal is substantial evidence.<sup>[32]</sup> Substantial evidence is defined as "that amount of relevant evidence which a reasonable mind might accept as adequate to justify a conclusion."<sup>[33]</sup>

The United States Food and Drug Administration defines substantial evidence of a drug's effectiveness as:

"evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof."<sup>[34]</sup>

Republic Act No. 10354 mandates that the Food and Drug Administration use the "best evidence available" to ascertain whether a contraceptive is non-abortionifacient:

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.<sup>[35]</sup>

It would be absurd to presume that any evidence, which a reasonable mind may accept as adequate, would yield the same kind of evidence as clinical investigations by scientific experts, meta-analyses, systematic reviews, national clinical practice guidelines, and recommendations of international medical organizations. It also requires a review of the physiology of the reproductive system, the classification, regulatory status, and mechanism of hormonal contraceptives in other countries, and a review of all available scientific data in medical journals and textbooks. An independent evidence review group composed of leading experts in the fields of pharmacodynamics, medical research, evidence-based medicine, and other relevant fields may also be constituted to review the available data.<sup>[36]</sup>

What the law requires is not just a reasonable mind, but also scientific, medical, and pharmacological expertise. The necessary evidence in registration, certification, and re-certification proceedings cannot be equated to that required in a quasi-judicial tribunal.

Quasi-judicial agencies are also required to adjudicate only on the evidence submitted by the parties.<sup>[37]</sup> In certification and re-certification proceedings, however, the Food and Drug Administration cannot merely rely on the evidence submitted by the Marketing Authorization Holder or of the oppositors. The law requires it to use the "best evidence available."<sup>[38]</sup> This means that it must consider external and extraneous evidence not necessarily submitted by the applicants or oppositors, such as clinical studies, medical journals and textbooks, and safety guidelines and standards in other countries.

Rulings of quasi-judicial agencies are also appealable to the Court of Appeals under Rule 43 of the Rules of Court.<sup>[39]</sup> The Court of Appeals, however, does not have the technical expertise to review or overrule the scientific, medical, and pharmacological data of the Food and Drug Administration. Even the law recognizes the Food and Drug Administration's expertise on the matter:

(a) Abortifacient refers to any drug or device that induces 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 *upon determination of the FDA*.<sup>[40]</sup> (Emphasis supplied)

In *Imbong v. Ochoa*,<sup>[41]</sup> this Court further recognized that the Food and Drug Administration "has the expertise to determine whether a particular hormonal contraceptive or intrauterine device is safe and non-abortifacient."<sup>[42]</sup>

The Court of Appeals does not have the required medical and pharmacological background to review the numerous clinical studies performed by scientific, medical, and pharmacological experts, metaanalyses, systemic reviews, medical journals, and textbooks. It is not equipped to conclude matters of a highly technical nature. It cannot adjudicate on conflicting scientific studies to conclude which would have more weight. For this reason, the law specifically assigned the procedure to a specialized agency as part of its executive regulatory function.

It is also for this reason that the Implementing Rules and Regulations of Republic Act No. 9711 include the issuance of authorizations, including Certificates of Product Registration, as part of its regulatory functions, and not its quasi-judicial functions:

b. Quasi-Judicial Powers, Duties and Functions:

(1) To render decisions on actions or complaints before the FDA pursuant to the FDA Act of 2009, these Rules and Regulations, other existing laws, and FDA-promulgated issuances;

(2) To hold in direct or indirect contempt any person who disregards orders or writs issued by the FDA and impose the appropriate penalties following the same procedures and penalties provided in the Rules of Court;

(3) To administer oaths and affirmations and issue subpoena duces tecum and subpoena ad testificandum requiring the production of such books, contracts, correspondence, records, statement of accounts and other documents and/or the attendance and testimony of parties and witnesses as may be material to any investigation conducted by the FDA;

(a) To obtain information from any officer or office of the national or local governments, government agencies and its instrumentalities;

(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; and

(6) To impose the following administrative sanctions/penalties for violations of the provisions of the FDA Act of 2009, these Rules and Regulations, and where applicable, other relevant laws, after observance of and compliance with due process:

(i) Cancellation of any authorization which may have been granted by the FDA, or suspension of the validity thereof for such period of time as he/she may deem reasonable, which shall not exceed one (1) year;

(ii) A fine of not less than Fifty Thousand Pesos (Php50,000.00), but not more than Five Hundred Thousand Pesos (PhP500,000.00). An additional fine of not more than One Thousand Pesos (PhP1,000.00) shall be imposed for each day of continuing violation;

(iii) Destruction and/or appropriate disposition of the subject health product and/or closure of the establishment for any violation of the FDA Act of 2009, these Rules and Regulations, other relevant laws, and FDA promulgated issuances.

c. Regulatory Powers, Duties and Functions:

(1) *To issue appropriate authorizations that would cover establishments, facilities and health products[.]*<sup>[43]</sup> (Emphasis supplied)

Unlike other quasi-judicial proceedings, legal concepts such as *res judicata*, *stare decisis*, and finality of decisions also have no application in certification and re-certification proceedings.

Science relies on innovation. Even if the scientific community conducts repeated scientific testing and continuous research, conflicting studies and research may always arise to challenge each conclusion. The issuance of a Certificate of Product Registration does not bind the Food and Drug Administration from further testing and investigation. The long-term effects of a new drug are not determined by a final and executory Court of Appeals or Supreme Court decision. Hence, any person may file an action once the health product is "found to have caused the death, illness or serious injury to a consumer or patient, or is found to be imminently injurious, unsafe, [and] dangerously deceptive."<sup>[44]</sup>

The Food and Drug Administration is mandated to conduct Post Marketing Surveillance of contraceptives even after the issuance of the Certificate of Product Registration:

Section 7.09. Post-Marketing Surveillance. All reproductive health products shall be subjected to Post-Marketing Surveillance (PMS) in the country. The PMS shall include, but not be limited to: examining the health risk to the patient, and the risk of pregnancy because of contraceptive failure.

The FDA shall have a sub-unit dedicated to reproductive health products under the Adverse Drug Reaction Unit who will monitor and act on any adverse reaction or event reported by consumers and health professionals or workers. The system for reporting adverse drug reactions/events shall include online reporting at the FDA and DOH website, along with established reporting mechanisms, among others.

Companies with registered products shall be required to have a Post-Marketing Surveillance department, division, section, unit, or group that will monitor and investigate all health-related reactions or risks, or failure of the product to prevent pregnancy.<sup>[45]</sup>

Post Marketing Surveillance is conducted through sampling, inspecting drug establishments and outlets, and investigating adverse drug reactions.<sup>[46]</sup> Marketing Authorization Holders are likewise required to submit Periodic Safety Update Reports at regular intervals and Post-Authorization Safety Studies/Post-Authorization Efficacy Studies.<sup>[47]</sup> Marketing Authorization Holders may also conduct a Phase IV clinical trial when necessary.<sup>[48]</sup> Certifications of contraceptives cannot be considered "final and executory" if the Food and Drug Administration conducts further examinations on patients for health and pregnancy risks even after it certifies to its non-abortionifacience or if the Marketing Authorization Holders are required to monitor their products and conduct further testing.

The Food and Drug Administration's mandate under Republic Act No. 10354 to determine and certify if a contraceptive or intrauterine device is medically safe and non-abortionifacient is an exercise of its regulatory function for the "[protection] and [promotion] of the right to health of the Filipino people."<sup>[49]</sup> The "right of the State as *parens patriae*"<sup>[50]</sup> is a role that the Food and Drug Administration, as a regulatory agency, undertakes.

In a quasi-judicial proceeding, interested or affected parties must first be given the opportunity to be heard.<sup>[51]</sup> The primary consideration of administrative due process is the fairness in the procedure.<sup>[52]</sup>

Proceedings that are regulatory in nature, such as certification and recertification proceedings of contraceptives, do not require trial-type proceedings. Public participation is required only as a matter of transparency.<sup>[53]</sup> Oppositors are allowed to submit any data that addresses the science involved, which they believe may overturn the findings of the Food and Drug Administration. It is the duty of the Food and Drug Administration in certification and re-certification proceedings to acknowledge and consider any opposition from the public and address their concerns.

### III

At this point, it must be clarified that an *abortifacient* under Section 4 (a) of the Responsible Parenthood and Reproductive Health Act of 2012 (RH Law) is:

SEC. 4. Definition of Terms. - For the purpose of this Act, the following terms shall be defined as follows:

(a) *Abortifacient* refers to any drug or device that induces 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 upon the determination of the FDA.

Drugs or contraceptives that merely prevent fertilization are not *abortifacient*. Normally, fertilization occurs when a single sperm cell penetrates an egg cell inside a

woman's body.<sup>[54]</sup> In females, egg cells are produced through ovulation.

Ovulation is a complex biological process characterized and defined by periods of elevated hormone production.<sup>[55]</sup> Every month, the pituitary gland<sup>[56]</sup> releases a follicle stimulating hormone that promotes the growth of several ovarian follicles. These ovarian follicles each contain an immature egg cell. As these ovarian follicles grow, estrogen is released into the blood stream. Once the level of estrogen peaks, the pituitary gland produces a surge of luteinizing hormones that would signal the most mature follicle to release the egg cell into the fallopian tube.<sup>[57]</sup>

Although sperm cells have an average lifespan of three (3) to five (5) days within which to travel through the female's reproductive tract, there must be an available egg cell for fertilization to occur.<sup>[58]</sup> Contraceptives such as Implanon and Implanon NXT (Implanon) work specifically to prevent fertilization.

Implanon is a hormone-releasing subdermal implant that contains a progestin hormone called "etonogestrel."<sup>[59]</sup> It was first launched in Indonesia in 1998 and is now registered in approximately 80 countries.<sup>[60]</sup> The implant is a small flexible plastic rod that is inserted under the woman's non-dominant upper arm.<sup>[61]</sup> Considered as a highly effective<sup>[62]</sup> and convenient method of contraception, Implanon can provide protection for up to three (3) years.<sup>[63]</sup> While there are some reports of pregnancies among users, these appear to have been caused by the implant's incorrect insertion.<sup>[64]</sup>

The non-abortifacience of Implanon can be explained by its primary mechanism of action. First, it inhibits the surge of luteinizing hormones. This prevents the ovaries from releasing an egg cell into the fallopian tube. Second, Implanon thickens the cervical mucus, which hinders the passage of sperm cells into the uterus.<sup>[65]</sup> Implanon may also prevent "endometrial proliferation,"<sup>[66]</sup> the process in which the lining of the uterus thickens. This would make the uterus unsuitable to support a fertilized egg in the unlikely event that fertilization occurs.<sup>[67]</sup>

Implanon makes it impossible for the sperm cell to unite with an egg cell. Hence, it cannot be considered as an abortifacient. This is consistent with Section 4 (a) of the RH Law.

Another point of clarification is the typographical error found in the fallo of the ponencia. The ponente, in adopting a portion of Justice Mariano C. Del Castillo's Concurring Opinion<sup>[68]</sup> in *Imbong v. Ochoa*, had inadvertently equated the term conception with fertilization.

It bears stressing that this Court, in *Imbong v. Ochoa*, recognized that the question on when life begins is both a scientific and medical issue that can only be decided upon proper hearing and evidence.<sup>[69]</sup> The ponente in *Imbong*, who is also the ponente in this case, clarified that the notion that life begins at fertilization was his



personal opinion and was a view not shared by all members of this Court.<sup>[70]</sup>

Equating conception with fertilization creates the wrong impression that this Court had already determined the exact moment of when life begins. It glosses over the fact that medicine and science are evolving fields of study and disregards the ongoing debate on the matter.

The fields of science and medicine provide fertile grounds for discourse on the commencement of life. Some say that there is life only upon the implantation of a zygote in the mother's womb. Proponents of this theory assert that the viability of a fertilized ovum should be considered in determining when life begins. This is significant with regard to new discoveries in reproductive science.<sup>[71]</sup>

On the other hand, there are those who say that human life begins only when organs and body systems have already developed and are functioning as a whole. However, some put greater emphasis on the presence of an active brain.<sup>[72]</sup>

The debate transcends the fields of science and medicine. There are different religious interpretations and opinions on the commencement of life.

The traditional Catholic view holds that life begins at fertilization. This is generally shared by the followers of Buddhism, Sikhism, and Hinduism. However, some Catholics, including prominent philosophers, subscribe to the "theory of delayed animation." According to this theory, the human soul is infused at points after fertilization. Before this happens, there is no human being.<sup>[73]</sup>

Muslim scholars are also divided on the subject. Some believe that a fetus acquires a soul only in the fourth month of pregnancy, while others believe that a six-day embryo is already entitled to protection.<sup>[74]</sup>

Varied views among the Constitutional Commissioners also show that the issue of when life begins is not a settled matter. Thus, the term "conception" rather than "fertilized ovum" was adopted during their deliberations.<sup>[75]</sup>

The view that life begins at fertilization creates ethical dilemmas for assisted reproductive technologies, particularly in vitro fertilization.

In vitro fertilization is a procedure intended to assist in the conception of a child using modern science. In this procedure, the woman's ovaries are stimulated to produce multiple egg cells. These egg cells are later on retrieved for fertilization through insemination or "intracytoplasmic sperm injection."<sup>[76]</sup> In insemination, healthy sperm cells are mixed with healthy egg cells to produce embryos. In "intracytoplasmic sperm injection," a sperm cell is directly injected into each egg cell.<sup>[77]</sup> The latter is usually done when there are problems with semen quantity or quality or when prior in vitro fertilization cycles have failed.<sup>[78]</sup>



After successful fertilization, embryos are incubated for several days. Pre-implantation genetic testing may be conducted to screen embryos for genetic disorders before they are transferred to the uterus.<sup>[79]</sup>

The rate of success of in vitro fertilization is greatly affected by age.<sup>[80]</sup> To increase the chances of pregnancy, multiple embryos are transferred to the uterus.<sup>[81]</sup> Meanwhile, remaining embryos may be cryopreserved, donated to another, or disposed. However, not all embryos survive cryopreservation; some die during the freezing and thawing process.<sup>[82]</sup>

This is where the ethical dilemma arises. If life begins at fertilization, those who undergo in vitro fertilization are burdened on what to do with unused embryos. The disposal of embryos would necessarily entail disposal of human lives. Although parents may opt for donation or cryopreservation, these alternatives do not guarantee the survival of remaining embryos.

#### IV

Petitioners allege that the Food and Drug Administration, by failing to consider and act upon their opposition, had denied them of due process to which they are entitled under the Constitution. Under Section 1, Article III of the Constitution "no person shall be deprived of life, liberty, or property without due process of law."

However, it is not petitioners' life, liberty, or property that would be affected by a certification and re-certification proceeding. Petitioners, not being Market Authorization Holders, possess no property right that may be infringed by the Food and Drug Administration.

There is also no merit to the claim that petitioners' right to life would also be violated, much less affected, by a certification and re-certification proceeding. In the grand scheme of things, it is the unborn whose life is at stake. Though the cause of petitioners is noble, by no stretch of the imagination could they claim the exclusive right to protect the life of the unborn. The Food and Drug Administration, in the exercise of its regulatory function and as *parens patriae*, carries the significant task of safeguarding the life of the unborn when it determines whether a drug is medically safe for consumption. Parties do not have a monopoly over the protection of the life of the unborn.

Petitioners alleged that they submitted their preliminary oppositions to the list of contraceptives for re-certification.<sup>[83]</sup> The Food and Drug Administration, however, failed to act on the oppositions or reply to petitioners' inquiries.<sup>[84]</sup>

The approval of any drug as food product destined for public use is not a matter only between the applicant and the regulator. It affects public health. Ultimately, it is the consumers who are affected. Thus, the process of certification and re-certification is burdened with severe public interest.

Thus, comments and contributions at any stage of the process of certification made by those concerned should not be simply received and filed. The Food and Drug Administration should have gone beyond acknowledgment. It should have summarized the issues and contentions in opposition and addressed them. No trial type or even summary hearing is required. Rather than due process of law, this is the essence of public participation enshrined in our Constitution.

**ACCORDINGLY**, the Food and Drug Administration should be **ORDERED** to consider and respond to the oppositions filed regarding the re-certification of Implanon and Implanon NXT based on the standards contained in the Reproductive Health Law and the present revised standards contained in the present Implementing Rules and Regulations within 60 days from receipt of this decision. Upon promulgation of the resolution of the Food and Drug Administration, the Temporary Restraining Order issued in this case is automatically lifted.

THEREAFTER, the Food and Drug Administration and the Department of Health should amend its implementing rules in accordance with the decision and *Imbong v. Ochoa*.<sup>[85]</sup>

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<sup>[1]</sup> Food, Drug, and Cosmetic Act (1963).

<sup>[2]</sup> See Rep. Act No. 3720, chapt. III, sec. 4.

<sup>[3]</sup> See Exec. Order No. 851 (1982), sec. 4.

<sup>[4]</sup> See Rep. Act No. 9711, sec. 1.

<sup>[5]</sup> See Rep. Act No. 9711, sec. 5(m).

<sup>[6]</sup> See Implementing Rules and Regulations of Rep. Act No. 9711, Book II, art. I, sec. 3(B).

<sup>[7]</sup> See Implementing Rules and Regulations of Rep. Act No. 9711, Book I, art. I, sec. 5.

<sup>[8]</sup> See Rep. Act No. 3720, chapt. II, sec. 2.

<sup>[9]</sup> See Implementing Rules and Regulations of Rep. Act No. 9711, Book I, art. VII, sec. 1 (a) to (d).

<sup>[10]</sup> Defined in Adm. Order No. 67 (1989), sec. 3, 3.2.4 as "a drug the safety and efficacy of which has been demonstrated through long years of general use and can be found in current official USP-NF, and other internationally-recognized pharmacopoeia."

[11] Omnibus Motion, pp. 18-19 citing Adm. Order No. 67, (1989) and Bureau Circ. No. 5 (1997).

[12] Defined in Adm. Order No. 67 (1989), sec. 3, 3.2.2 as "a new chemical or structural modification of a Tried and Tested or Established Drug proposed to be used for a specific therapeutic indication, which has undergone adequate clinical pharmacology Phase I, II and III studies but which needs further Phase IV Clinical Pharmacology studies before it can be given regular registration."

[13] Omnibus Motion, pp. 20-24 citing Adm. Order No. 67 (1989) and Bureau Circ. No. 5 (1997).

[14] The Responsible Parenthood and Reproductive Health Act of 2012.

[15] See Rep. Act No. 10354, sec. 4(a) which provides:

Section 4. Definition of Terms - For purposes of this Act, the following shall be defined as follows:

(a) *Abortifacient* refers to any drug or device that induces 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 upon determination of the FDA.

[16] See Rep. Act No. 10354, sec. 3(e).

[17] Omnibus Motion, pp. 12-13.

[18] Implementing Rules and Regulations of Rep. Act No. 10354, sec. 7.04.

[19] Implementing Rules and Regulations of Rep. Act No. 10354, sec. 7.05.

[20] OSG Omnibus Motion, pp. 13-14, *rollo*, pp. 418-419.

[21] Implementing Rules and Regulations of Rep. Act No. 10354, sec. 7.04.

[22] Implementing Rules and Regulations of Rep. Act No. 10354, sec. 7.04.

[23] Implementing Rules and Regulations of Rep. Act No. 10354, sec. 7.04.

[24] OSG Omnibus Motion, pp. 13-14, *rollo*, pp. 418-419.

[25] OSG Omnibus Motion, pp. 13-14, *rollo*, pp. 418-419.

[26] *Smart Communications v. National Telecommunications Commission*, 456 Phil. 145, 156 (2003) [Per J. Ynares-Santiago, First Division] citing the Separate Opinion of J. Bellosillo, in *Commissioner of Internal Revenue v. Court of Appeals*, 329 Phil. 987, 1017 (1996) [Per J. Kapunan, First Division].

[27] *Id.* at 157.

[28] *See Santiago v. Bautista*, 143 Phil. 209 (1970) [Per J. Barredo, En Banc].

[29] *Villarosa v. Commission on Elections*, 377 Phil. 497, 506 (1999) [Per J. Gonzaga-Reyes, En Banc] citing the Concurring Opinion of J. Antonio in *University of Nueva Carceres v. Martinez*, 155 Phil. 126 (1974) [Per J. Barredo, Second Division].

[30] *Smart Communications v. National Telecommunications Commission*, 456 Phil. 145, 157 (2003) [Per J. Ynares-Santiago, First Division].

[31] *See* Concurring Opinion of J. Brion in *Perez v. Philippine Telegraph and Phone Company*, 602 Phil. 522, 545 (2009) [Per J. Corona, En Banc].

[32] *See* RULES OF COURT, Rule 133, sec. 5.

[33] RULES OF COURT, Rule 133, sec. 5.

[34] U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), *Guidance for Industry Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products* (1998) 6. Available at <<https://www.fda.gov/ohrms/dockets/98fr/9710Ogdl.pdf>> 6. (Last visited: November 22, 2016).

[35] Implementing Rules and Regulations of Rep. Act No. 10354, sec. 7.04.

[36] Implementing Rules and Regulations of Rep. Act No. 10354, sec. 7.04.

[37] *See Ang Tibay v. Court of Industrial Relations*, 69 Phil. 635 (1940) [Per J. Laurel, En Banc].

[38] Implementing Rules and Regulations of Rep. Act No. 10354, sec. 7.04.

[39] RULES OF COURT, Rule 43, sec. 1 provides:

Section 1. Scope. - This Rule shall apply to appeals from judgments or final orders of the Court of Tax Appeals and from awards, judgments, final orders or resolutions of or authorized by any quasijudicial agency in the exercise of its quasi-judicial functions. Among these agencies are the Civil Service Commission, Central Board of

Assessment Appeals, Securities and Exchange Commission, Office of the President, Land Registration Authority, Social Security Commission, Civil Aeronautics Board, Bureau of Patents, Trademarks and Technology Transfer, National Electrification Administration, Energy Regulatory Board, National Telecommunications Commission, Department of Agrarian Reform under Republic Act No, 6657, Government Service Insurance System, Employees Compensation Commission, Agricultural Inventions Board, Insurance Commission, Philippine Atomic Energy Commission, Board of Investments, Construction Industry Arbitration Commission, and voluntary arbitrators authorized by law.

[40] Rep. Act No. 10354, sec. 4(a).

[41] 732 Phil. 1 (2014) [Per J. Mendoza, En Banc].

[42] *Id.* at 161.

[43] Implementing Rules and Regulations of Rep. Act No. 9711, Book I, art. III, sec. 2 (b) and (c).

[44] Rep. Act No. 3720, sec. 4(k) as amended by Rep. Act No. 9711.

[45] Implementing Rules and Regulations of Rep. Act No. 10354.

[46] See FDA Circular No. 2013-004.

[47] See FDA Circular No. 2013-004.

[48] See FDA Circular No. 2013-004

[49] Rep. Act No. 9711, sec. 3.

[50] *Ponencia*, p. 9.

[51] Concurring Opinion of J. Brion in *Perez v. Philippine Telegraph and Phone Company*, 602 Phil. 522, 545 (2009) [Per J. Corona, En Banc].

[52] *Id.*

[53] See the ADM.CODE, Book VII, chapt. II, sec. 9(1) which provides:

Section 9. Public Participation. - (1) If not otherwise required by law, an agency shall, as far as practicable, publish or circulate notices of proposed rules and afford interested parties the opportunity to submit their views prior to the adoption of any rule.

[54] Dissenting Opinion of J. Leonen in *Imbong v. Ochoa*, 732 Phil. 1, 612 (2014) [Per J. Mendoza, En Banc].

[55] Crosta, Peter, *What is Ovulation? What is the Ovulation Calendar?*, MEDICAL NEWS TODAY, available at <[http://www.medicalnewstoday.com/articles/I50870.php#what\\_are\\_the\\_phases\\_of\\_ovulation](http://www.medicalnewstoday.com/articles/I50870.php#what_are_the_phases_of_ovulation)> (Last visited October 24, 2016).

[56] The pituitary gland is often referred to as the 'master gland.' It is primarily responsible for releasing hormones throughout the body. See *Pituitary Gland Disorders Symptoms*, HORMONE HEALTH NETWORK, available at <<http://www.honnone.org/diseases-and-conditions/pituitary/overview>> (Last visited October 24, 2016).

[57] *Id.*

[58] J. Leonen, Dissenting Opinion in *Imbong v. Ochoa*, 732 Phil. 1, 612 (2014) [Per J. Mendoza, En Banc].

[59] *Implanon*, available at <<https://www.drugs.com/implanon.html>> (Last visited October 21, 2016).

[60] *Rollo*, p. 388.

[61] *Implanon*, available at <<https://www.drugs.com/implanon.html>> (Last visited October 21, 2016).

[62] The Single Rod Contraceptive Implant, Association of Reproductive Health Professionals, last visited <<http://www.arhp.org/publications-and-resources/clinical-proceedings/Single-Rod/Efficacy>> (Last visited October 24, 2016). See also *Subdermal implantable contraceptives versus other forms of reversible contraceptives or other implants as effective methods of preventing pregnancy*, available at <[http://apps.who.int/rhl/fertility/contraception/CD001326\\_bahamondesl\\_com/en/](http://apps.who.int/rhl/fertility/contraception/CD001326_bahamondesl_com/en/)> (Last visited October 25, 2016); *Etonogestrel (Implanon), Another Treatment Option for Contraception*, available at <[https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2683610/pdf/ptj33\\_6p337.pdf](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2683610/pdf/ptj33_6p337.pdf)> (Last visited October 25, 2016); *A multicentre efficacy and safety study of the single contraceptive implant Implanon*, available at <<http://humrep.oxfordjournals.org/content/14/4/976.full.pdf+html>> (Last visited October 25, 2016); *The contraceptive efficacy of Implanon: a review of clinical trials and marketing experience*, available at <<https://www.ncbi.nlm.nih.gov/pubmed/18330813>> (Last visited October 25, 2016).

[63] *Implanon*, available at <<https://www.drugs.com/implanon.html>> (Last visited October 21, 2016). However, Implanon does not provide protection against HIV and other sexually transmitted diseases.

[64] *Implanon contraceptive implant examined*, available at <<http://www.nhs.uk/news/2011/01January/Pages/info-implanon-contraceptive-implant.aspx>> (Last visited October 25, 2016). See also *Implanon: 600 pregnancies despite contraceptive implant* <<http://www.bbc.com/news/health-12117299>> (visited October 24, 2016).

[65] See Dionne D. Maddox and Zahra Rahman, *Etonogestrel (Implanon), Another Treatment Option for Contraception*, available at <[https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2683610/#b4-ptj33\\_6p337](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2683610/#b4-ptj33_6p337)> (Last visited October 25, 2016).

[66] See *Etonogestrel*, available at <<https://www.drugs.com/ppa/etonogestrel.html>> (Last visited October 26, 2016).

[67] See *Proliferative Endometrium*, available at <<http://www.newhealthadvisor.com/ProliferativeEndometrium.html>> (Last visited October 26, 2016).

[68] Concurring and Dissenting Opinion of J. Del Castillo in *Imbong v. Ochoa*, 732 Phil. 1, 401 (2014) [Per J. Mendoza, En Banc].

[69] *Id.* at 137.

[70] *Id.*

[71] Dissenting Opinion of J. Leonen in *Imbong v. Ochoa*, 732 Phil. 1, 611-618 (2014) [Per J. Mendoza, En Banc].

[72] *Id.* at 616-618.

[73] *Id.* at 604.

[74] *Id.* at 605.

[75] *Id.* at 605-608.

[76] *In vitro fertilization*, available at <<http://www.mayoclinic.org/tests-procedures/in-vitro-fertilization/details/what-you-can-expect/rec-20206943>> (Last visited October 26, 2016).

[77] *Id.*

[78] *Id.*

[79] *Id.*

[80] See *IVF - Chance of Success*, HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY, <<http://www.hfea.gov.uk/ivf-success-rate.html>> (Last visited October 26, 2016).

[81] Dissenting Opinion of J. Leonen in *Imbong v. Ochoa*, 732 Phil. 1, 621-622 (2014) [Per J. Mendoza, En Banc].

[82] *Assisted Reproductive Technology a Guide for Patients*, available at <[https://www.asrm.org/uploadedFiles/ASRM\\_Content/Resources/Patient\\_Resources/Fact\\_Sheets\\_and\\_Info\\_Booklets/ART.pdf](https://www.asrm.org/uploadedFiles/ASRM_Content/Resources/Patient_Resources/Fact_Sheets_and_Info_Booklets/ART.pdf)> (Last visited on October 26, 2016).

[83] *ALFI, et al. v. Garin, et al.*, G.R. Nos. 217872 & 221866, August 24, 2016 [Per J. Mendoza, En Banc].

[84] *ALFI, et al. v. Garin, et al.*, G.R. Nos. 217872 & 221866, August 24, 2016 [Per J. Mendoza, En Banc].

[85] *Imbong v. Ochoa*. 732 Phil. 1 (2014) [Per J. Mendoza, En Banc].



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