SECOND DIVISION

G.R. No. 217872 – 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. MONTIERO, MARIETTA C. GORREZ, ROLANDO M. BAUTISTA, RUBEN T. UMALI, and MILDRED C. CASTOR, petitioners, **v. 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 for petitioners, JOSE S. SANDEJAS, ROSIE B. LUISTRO, ELENITA S.A. SANDEJAS, EMILY R. LAWS, EILEEN Z. ARANETA, SALVACION C. MONTIERO, MARIETTA C. GORREZ, ROLANDO M. BAUTISTA, RUBEN T. UMALI, and MILDRED C. CASTOR,** petitioners, **v. HON. JANETTE L. GARIN, SECRETARY-DESIGNATE OF THE DEPARTMENT OF HEALTH, NICOLAS B. LUTERO III, ASSISTANT SECRETARY OF HEALTH, OFFICER-IN-CHARGE, FOOD AND DRUG ADMINISTRATION, and MARIA LOURDES C. SANTIAGO, OFFICER-IN-CHARGE, CENTER FOR DRUG REGULATION AND RESEARCH**, respondents.

Promulgated:
26 APR 2017

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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[1] to regulate food, drug, and cosmetic manufacturers and establishments.[2] In 1982, the Food and Drug Administration was abolished and its functions were assumed by the Bureau of Food and Drugs.[3] In 2009, the Bureau of Food and Drugs was renamed the Food and Drug Administration.[4] 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."[5]

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

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.[9]

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

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1 Food, Drug, and Cosmetic Act (1963).
2 *See* Rep. Act No. 3720, chapt. III, sec. 4.
3 *See* Exec. Order No. 851 (1982), sec. 4.
4 *See* Rep. Act No. 9711, sec. 1.
5 *See* Rep. Act No. 9711, sec. 5(m).
6 *See* Implementing Rules and Regulations of Rep. Act No. 9711, Book II, art. I, sec. 3(B).
7 *See* Implementing Rules and Regulations of Rep. Act No. 9711, Book I, art. I, sec. 5.
8 *See* Rep. Act No. 3720, chapt. II, sec. 2.
9 *See* Implementing Rules and Regulations of Rep. Act No. 9711, Book I, art. VII, sec. 1 (a) to (d).
10 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."

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:
    - o Name of substance
    - o detailed information on physical and chemical properties
    - o ID tests
    - o Purity tests
    - o 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.[11]

New drugs,[12] 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.

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[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."

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. Biovailability

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[13]

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

Under Republic Act No. 10354,[14] the Food and Drug Administration is likewise given the authority to determine whether a drug or device is considered an abortifacient.[15] 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."[16] 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.
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> Step 7. Issuance of CPR/Notice of Deficiencies/Letter of Denial.
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> 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

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[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).

> 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.[17]

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.[18]

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.[19]

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[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.

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.[20]

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."[21] In case of conflict, "more recent, better-designed, and larger studies shall be preferred."[22] 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."[23]

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.[24] 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.[25]

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

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[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.

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."[26] 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."[27] 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.[28]

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.[29]

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."[30] 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.[31]

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.

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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].

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

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."[34]

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

> 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.[35]

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.[36]

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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/971OOgdl.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.

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.[37] 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."[38] 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.[39] 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*.[40] (Emphasis supplied)

In *Imbong v. Ochoa*,[41] 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."[42]

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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 quasi-judicial 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.

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, meta-analyses, 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*[.][43] (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."[44]

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

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[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.

> 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.[45]

Post Marketing Surveillance is conducted through sampling, inspecting drug establishments and outlets, and investigating adverse drug reactions.[46] Marketing Authorization Holders are likewise required to submit Periodic Safety Update Reports at regular intervals and Post-Authorization Safety Studies/Post-Authorization Efficacy Studies.[47] Marketing Authorization Holders may also conduct a Phase IV clinical trial when necessary.[48] 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-abortifacience 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-abortifacient is an exercise of its regulatory function for the "[protection] and [promotion] of the right to health of the Filipino people."[49] The "right of the State as *parens patriae*"[50] 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.[51] The primary consideration of administrative due process is the fairness in the procedure.[52]

Proceedings that are regulatory in nature, such as certification and re-certification proceedings of contraceptives, do not require trial-type proceedings. Public participation is required only as a matter of transparency.[53] 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

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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.

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.[54] In females, egg cells are produced through ovulation.

Ovulation is a complex biological process characterized and defined by periods of elevated hormone production.[55] Every month, the pituitary gland[56] 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.[57]

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.[58] Contraceptives such as Implanon and Implanon NXT (Implanon) work specifically to prevent fertilization.

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[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/150870.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.hormone.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].

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

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.[65] Implanon may also prevent "endometrial proliferation,"[66] 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.[67]

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.

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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/> (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> (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> (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/Proliferative-Endometrium.html> (Last visited October 26, 2016).

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[68] 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.[69] 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.[70]

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.[71]

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.[72]

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

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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.

human soul is infused at points after fertilization. Before this happens, there is no human being.[73]

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.[74]

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.[75]

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."[76] 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.[77] The latter is usually done when there are problems with semen quantity or quality or when prior in vitro fertilization cycles have failed.[78]

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.[79]

The rate of success of in vitro fertilization is greatly affected by age.[80] To increase the chances of pregnancy, multiple embryos are transferred to the uterus.[81] Meanwhile, remaining embryos may be cryopreserved, donated

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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].

to another, or disposed. However, not all embryos survive cryopreservation; some die during the freezing and thawing process.[82]

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.[83] The Food and Drug Administration, however, failed to act on the oppositions or reply to petitioners' inquiries.[84]

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[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> (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].

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*.[85]

MARVIC M.V.F. LEONEN
Associate Justice

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