Republic of the Philippines
Supreme Court
Manila

SECOND DIVISION

ALLIANCE FOR THE FAMILY FOUNDATION, PHILIPPINES, INC. (ALFI) and ATTY. MARIA CONCEPCION S. NOCHE, in her own behalf and as President of ALFI, JOSE S. SANDEJAS, ROSIE B. LUISTRO, ELENITA S.A. SANDEJAS, EMILY R. LAWS, EILEEN Z. ARANETA, SALVACION C. MONTIERO, MARIETTA C. GORREZ, ROLANDO M. BAUTISTA, RUBEN T. UMALI and MILDRED C. CASTOR, Petitioners,	**G.R. No. 217872**

- versus -

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

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

- versus -

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

G.R No. 221866

Present:

CARPIO, *J.*, *Chairperson*,
BRION,*
DEL CASTILLO,
MENDOZA, and
LEONEN, *JJ.*

Promulgated:

24 AUG 2016

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DECISION

MENDOZA, *J.*:

Subjects of this disposition are 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).

The subject petitions sprouted from *Imbong v. Ochoa* and other cases[1] *(Imbong)* where the Court declared Republic Act No. 10354 *(RH Law)* and its Implementing Rules and Regulations *(RH-IRR)* as not unconstitutional, save for several provisions which were declared as violative of the Constitution. The decretal portion of *Imbong* reads:

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* On Leave.

[1] G.R. Nos. 204819, 204934, 204957, 204988, 205003, 205043,205138, 205478, 205491, 205720, 206355, 207111, 207172 & 207563, April 8, 2014, 721 SCRA 146.

WHEREFORE, the petitions are PARTIALLY GRANTED. Accordingly, the Court declares R.A. No. 10354 as NOT UNCONSTITUTIONAL except with respect to the following provisions which are declared UNCONSTITUTIONAL:

1] Section 7 and the corresponding provision in the RH-IRR insofar as they: a) require private health facilities and non-maternity specialty hospitals and hospitals owned and operated by a religious group to refer patients, not in an emergency or life-threatening case, as defined under Republic Act No. 8344, to another health facility which is conveniently accessible; and b) allow minor-parents or minors who have suffered a miscarriage access to modem methods of family planning without written consent from their parents or guardian/s;

2) Section 23(a)(l) and the corresponding provision in the RH-IRR, particularly Section 5.24 thereof, insofar as they punish any healthcare service provider who fails and or refuses to disseminate information regarding programs and services on reproductive health regardless of his or her religious beliefs;

3) Section 23(a)(2)(i) and the corresponding provision in the RH-IRR insofar as they allow a married individual, not in an emergency or life-threatening case, as defined under Republic Act No. 8344, to undergo reproductive health procedures without the consent of the spouse;

4) Section 23(a)(2)(ii) and the corresponding provision in the RH-IRR insofar as they limit the requirement of parental consent only to elective surgical procedures;

5] Section 23(a)(3) and the corresponding provision in the RH-IRR, particularly Section 5.24 thereof, insofar as they punish any healthcare service provider who fails and/or refuses to refer a patient not in an emergency or life-threatening case, as defined under Republic Act No. 8344, to another health care service provider within the same facility or one which is conveniently accessible regardless of his or her religious beliefs;

6] Section 23(b) and the corresponding provision in the RH-IRR, particularly Section 5.24 thereof, insofar as they punish any public officer who refuses to support reproductive health programs or shall do any act that hinders the full implementation of a reproductive health program, regardless of his or her religious beliefs;

7] Section 17 and the corresponding provision in the RH-IRR regarding the rendering of pro bona reproductive health service in so far as they affect the conscientious objector in securing PhilHealth accreditation; and 8] Section 3.01(a) and Section 3.01(g) of the RH-IRR, which added the qualifier "primarily" in defining abortifacients and contraceptives, as they are *ultra vires* and, therefore, null and void for contravening Section 4(a) of the RH Law and violating Section 12, Article II of the Constitution.

The Status Quo Ante Order issued by the Court on March 19, 2013 as extended by its Order, dated July 16, 2013, is hereby LIFTED, insofar as the provisions of R.A. No. 10354 which have been herein declared as constitutional.

G.R. No. 217872

On May 28, 2014, barely two (2) months after the promulgation of the Court's decision in *Imbong*, the petitioners, who were among those against the constitutionality of the RH Law, wrote a letter[2] addressed to the Food and Drug Administration *(FDA)*, inquiring about the steps that the agency might have taken to carry out the decision of the Court. In reply[3] to this letter, the Office of the Solicitor General *(OSG)* assured the petitioners that both the Department of Health *(DOH)* and the FDA were taking steps to comply with the decision of the Court and that it would inform them of any developments. The petitioners claimed that, as of the date of filing, they had not heard anything anymore from the OSG.

Controversy began in September 2014, when petitioner Rosie B. Luistro chanced upon the FDA's Notice[4] inviting Marketing Authorization Holders *(MAH)* of fifty (50) contraceptive drugs to apply for re-evaluation/re-certification of their contraceptive products and directed "all concerned to give their written comments to said applications on or before October 8, 2014."

Petitioner Alliance for the Family Foundation, Inc. *(ALFI)* believed that the contraceptives enumerated in the Notice fell within the definition of "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."[5] For said reason, ALFI, through its president, Maria Concepcion S. Noche *(Noche)*, filed its preliminary opposition, dated October 8, 2014,[6] to all 50 applications with the FDA. The same opposition also questioned some twenty-seven (27) other contraceptive drugs and devices that had existing FDA registrations that were not subjects of any application for re-evaluation/re-certification.[7]

On November 24, 2014, ALFI filed its main opposition to all seventy-seven (77) contraceptive drugs.[8]

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[2] *Rollo* (G.R. No. 217872), pp. 112-114.
[3] Id. at 116.
[4] Id. at 119-122.
[5] Id. at 18.
[6] Id. at 17-18; See also *rollo* (G.R. No. 217872), p. 123.
[7] Id. at 19.
[8] Id. at 20.

On November 27, 2014, notwithstanding the pending opposition of the petitioners to the re-evaluation/re-certification of these contraceptive products, the FDA issued two (2) certificates of product registration[9] for the hormonal contraceptives, "Implanon" and "Implanon NXT."[10]

On March 19, 2015, ALFI wrote another letter[11] to the DOH and the FDA, reiterating its opposition to the applications for re-evaluation/re-certification. It requested, among others, that the agencies shed light on the status of their earlier opposition and that it schedule hearings and consultations regarding the applications for re-evaluation/re-certification.

The petitioners claimed that their requests had remained unanswered.

Hence, the petitioners instituted the subject petition for *certiorari,* contending that the FDA committed grave abuse of discretion, not only for violating the Court's pronouncements in *Imbong*, but also for failing to act on their opposition.

The petitioners also contend that due to lack of any procedure, rules and regulations and consultations for re-evaluation/re-certification of contraceptive drugs and devices, the FDA had also violated the rudimentary requirements of due process.[12] Invoking the Court's power under Section 5(5), Article VIII of the Constitution,[13] they seek that the Court "promulgate rules and/or disapprove (or approve) rules of procedure in order to adequately protect and enforce the constitutional right to life of the unborn."[14]

As for the certificates of product registration for the hormonal contraceptives, "Implanon" and "Implanon NXT," the petitioners contend that these certificates of product registration were issued *in haste* because they were released just three (3) days after the Senate Committee on Finance required FDA certifications for contraceptives as conditions for government funding for family planning commodities.[15]

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[9] Id. at 127-128.
[10] Id.
[11] Id. at 135-138.
[12] Id. at 45-46.
[13] Section 5. The Supreme Court shall have the following powers:
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(5) Promulgate rules concerning the protection and enforcement of constitutional rights, pleading, practice, and procedure in all courts, the admission to the practice of law, the integrated bar, and legal assistance to the under-privileged. Such rules shall provide a simplified and inexpensive procedure for the speedy disposition of cases, shall be uniform for all courts of the same grade, and shall not diminish, increase, or modify substantive rights. Rules of procedure of special courts and quasi-judicial bodies shall remain effective unless disapproved by the Supreme Court.
[14] *Rollo* (G.R. No. 217872), pp. 80-92.
[15] Id. at 46-50.

The petitioners further aver that even before the issuance of these certificates, the DOH, as early as February 2015, had been administering Implanon in Cebu City. Pointing to a news article in the Panay News,[16] they claim that respondent Health Secretary Janette L. Garin *(Secretary Garin)* even defended the decisions of the DOH to administer these contraceptives. The petitioners add that photographs of several tarpaulins[17] show that the DOH has undertaken the distribution of contraceptives as early as March 25, 2015.

The petitioners allege that despite the Court's declaration that several portions of the RH Law and the RH-IRR are unconstitutional, the DOH has not effected any amendment in the RH-IRR to conform with the Court's judgment. They claim that the RH-IRR posted on the DOH website still contain the provisions which were declared by the Court to be unconstitutional.[18]

Thus, the petitioners assert that absent any compliant rule of procedure issued by the FDA, or consultation regarding its re-evaluation/re-certification, or consideration of their opposition, the approval, procurement, distribution, administration, advertisement, and promotion of contraceptive use by the FDA and the DOH should be enjoined as they are tainted with grave abuse of discretion.[19]

In support of their prayer for the issuance of a Temporary Restraining Order and/or Writ of Preliminary Prohibitory and Mandatory Injunction, the petitioners assert that the actions of the FDA and the DOH violate the right to life of the unborn and, thus, must be restrained to ensure their protection.[20]

On June 17, 2015, the Court issued the Temporary Restraining Order *(TRO)*[21] enjoining the respondents from: [1] granting any and all pending applications for reproductive products and supplies, including contraceptive drugs and devices; and [2] procuring, selling, distributing, dispensing or administering, advertising, and promoting the hormonal contraceptives, "Implanon" and "Implanon NXT."

Comment of the Respondents

In their Comment,[22] the respondents, through the OSG, argued that petitioners failed to establish not only the direct injury that they had suffered,

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[16] Id. at 132-133.
[17] Id. at 134.
[18] Id. at 62-66.
[19] Id. at 92-98.
[20] Id. at 99-103.
[21] Id. at 146-147.
[22] Id. at 185-203.

or would suffer, but also the transcendental importance of the issues raised as a result of [1] the issuance of certificates of registration and the re-certification of contraceptive drugs and devices; and [2] the purchase of Implanon and Implanon NXT.

The OSG also contended that the petitioners violated the doctrine of hierarchy of courts for failing to allege any special and compelling reasons to justify their direct resort to the Court. For the OSG, the Court's concurrent jurisdiction with the lower courts to issue writs of *certiorari*, prohibition and mandamus did not give the petitioners the unrestrained freedom to file a Rule 65 petition directly before the Court.

The OSG further argued that the re-certification of contraceptive drugs and devices involved the scientific determination of fact and that it was conducted by the FDA in the exercise of its regulatory power. Thus, the OSG explained that the re-certification process conducted and the conclusions arrived at by the FDA [1] lay outside the ambit of a Rule 65 petition; [2] did not require any notice and hearing; and [3] need not comply with the standard of substantial evidence required in quasi-judicial proceedings. For the OSG, the FDA might even use extraneous and credible scientific data and was not limited by the evidence submitted by those seeking re-certification considering that Republic Act *(R.A.)* No. 3720[23] mandated that the FDA utilize "the latest medical knowledge."[24]

Finally, the OSG dismissed the petitioners' call for the Court to promulgate the necessary rules of procedure for re-certification, arguing that the rule-making power of the Court was confined to promulgating, approving or disapproving rules of procedure of courts and quasi-judicial bodies, and not to bodies like the FDA. The OSG asserted that the re-certification process undertaken by the FDA was not without basis, as the FDA was guided not only by the RH-IRR Law, but also by Bureau Circular *(BC)* No. 5, series of 1997, Administrative Order *(AO)* No. 2013-0021, AO No. 67, series of 1989, AO No. 2006-2021, AO No. 2005-0030, BC No. 2006-005, BC No. 2006-007, among many others.

In their Reply,[25] the petitioners pointed out that the Court sanitized the RH-IRR, dated March 15, 2013, by declaring Section 3.01(a) and Section 3.01(j) thereof as unconstitutional. For this reason and the acknowledged constitutional right to life of the unborn from fertilization, the mandate of the FDA was understood to necessarily include the duty to re-certify certain contraceptives that had already been approved and registered and had been made available to the public, but this time using the

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[23] Entitled "An Act to Ensure the Safety and Purity of Foods, Drugs, and Cosmetics Being Made Available to the Public by Creating the Food and Drug Administration Which Shall Administer and Enforce the Laws Pertaining Thereto."
[24] *Rollo* (G.R. No. 217872), pp. 191-198.
[25] Id. at 223-246.

constitutional yardsticks and standards expounded by the Court in its decision. In this process of registration and/or re-certification, the FDA had to ensure that only contraceptives that were non-abortifacient and safe would be purchased and distributed to the public.

The petitioners stated that the re-certification was not automatic and that there had to be an actual re-examination and re-testing of all contraceptives to ensure that they were compliant, not with the old standards utilized by the DOH and the FDA which, the Court had determined could open the floodgates to abortion, but with the new standards it laid out that aimed to ensure protection of the life of the unborn from injury or death starting from fertilization to implantation in the mother's womb.

The registration and/or re-certification of drugs are in the exercise of the quasi-judicial functions of the FDA. By registering and/or re-certifying the drugs listed in the Table and shown in the DOH list, the FDA has adjudicated in favor of the applications for re-certification of the pharmaceutical companies and against the oppositions of the petitioners.

The applications for registration and/or re-certification were granted by the FDA *without observing the basic tenets of due process - without due notice, without public hearing and without any supporting evidence in the face of clear and irrefutable evidence* of the abortifacient character of the registered/re-certified drugs.

The petitioners claim that viewed within the broad power of the Court to issue rules for the protection and enforcement of constitutional rights, the power to disapprove the rules of procedure of quasi-judicial bodies necessarily includes the power of the Court to look into the sufficiency of the rules of procedure of the FDA insofar as they adequately protect and enforce the constitutional right of the unborn from conception/fertilization. Also, this power to disapprove the said rules of procedure necessarily includes the power to modify them by requiring that such rules of procedure incorporate safeguards such as the rudimentary requirements of due process to meaningfully and sufficiently protect and enforce the constitutional right to life.

For the petitioners, both the principle of prudence and the precautionary principle are relevant and applicable in matters affecting and related to the right to life of the unborn. Thus, any uncertainty as to the adverse effects of making contraceptives universally accessible should be resolved in a way that will preserve and promote life and health. And the burden is on the proponent to prove that a contraceptive is non-abortifacient. Any doubt should always be resolved in favor of life and against anything that threatens or poses a risk to it.

Accordingly, the petitioners pray that the TRO be maintained.

G.R. No. 221866

The petitioners in this case, with the exception of ALFI, are the same as those in G.R. No. 217872. In their subject petition for contempt, the petitioners averred that notwithstanding the receipt of the TRO, respondent FDA continued to grant applications for registration and re-certification of reproductive products and supplies. According to them, the FDA website [26] showed that on November 13, 2015, several reproductive products and supplies, including the contraceptives "Implanon and Implanon NXT," had been granted certification and/or re-certification. This was confirmed by the Certification of Product Registration[27] of the FDA allowing the marketing of Implanon NXT until November 19, 2015.

The petitioners also mentioned the November 16, 2015 Letter[28] of DOH Undersecretary Lilibeth C. David *(USEC David)*, addressed to Senator Vicente C. Sotto III *(Senator Sotto),* informing him that the DOH granted the certification of several contraceptive drugs and family planning supplies and was submitting to the Senate a list of contraceptives and family planning supplies for its approval in the 2016 budget. Citing the Senate deliberations, the petitioners claimed that the DOH *deceived* the Senate so it would provide the necessary funding for these products by convincing the said body that the TRO only applied to the new applications for reproductive products and supplies, contraceptive drugs and devices and not to existing ones, which could be re-certified.

For the petitioners, by granting registration and/or re-certification of reproductive products and supplies, contraceptive drugs and devices, and by advertising that these products were available to the public through their website, the respondents have violated the TRO of the Court.

Additionally, in their Supplement to (Petition for Contempt of Court),[29] the petitioners averred that on December 21, 2015, the Philippine Health Insurance Corporation *(Philhealth)* issued Philhealth Circular No. 038-2015 which was about the "Subdermal Contraceptive Implant Package" to be offered by it in order "to increase access to long acting reversible family planning methods;" that the Chairperson of the Board of Directors of Philhealth was Secretary Garin; that Philhealth fell within the category of "respondents, their representatives, agents or other persons acting on their behalf that are enjoined from [2] procuring, selling, distributing, dispensing or administering, advertising and promoting the hormonal contraceptive

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[26] *Rollo* (G.R. No. 221866), pp. 40, 42-47.
[27] Id. at 41.
[28] Id. at 52.
[29] Id. at 59-68.

'Implanon' and 'Implanon NXT.'"; that Implanon is a subdermal implant; and that the circular is a clear attempt to go around the TRO.[30]

Thus, the petitioners pray that the respondents be held guilty of contempt of Court for disobeying the June 17, 2015 TRO issued by the Court.[31]

Comment of the Respondents

In its Comment,[32] the OSG denies petitioners' claim that the FDA continued to grant applications for registration and/or re-certification of a contraceptive drug or device despite the issuance of the Court's TRO on June 17, 2015. According to the OSG, the attached certified true copies of Certificates of Product Registration (CPR) of various contraceptive drugs and devices showed that the dates of registration and/or recertification of the questioned contraceptive drugs and devices, including the drug "Implanon" and "Implanon NXT," were all granted *prior to* the Court's issuance of its TRO on June 17, 2015.[33]

As to the registration of the drug Medrogest on September 23, 2015, the OSG, citing its own medical research, argues that the same is not a contraceptive drug and, therefore, not covered by the Court's TRO.[34]

Regarding the November 16, 2015 Letter of USEC David, the OSG contends that a reading of the letter would simply show that it was just to inform Senator Sotto of the status of recertification of contraceptive drugs *as of* November 13, 2015. For said reason, the OSG asserts that petitioners were in error in claiming that intra-uterine devices were granted re-certification on November 13, 2015.[35]

The OSG further argues that the FDA's act of posting of the product information on "Implanon" and "Implanon NXT" in its website was not made with the objective of advertising the questioned contraceptive drug but, rather, made by the FDA pursuant to its ministerial duty under Section 7.08, Rule 7, Chapter 2[36] of the Implementing Rules and Regulations of the RH Law.[37]

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[30] Id. at 61-62.
[31] Id. at 67.
[32] *Rollo* (G.R. 217872), pp. 267-313.
[33] Id. at 272-274.
[34] Id. at 276-277.
[35] Id. at 274-276.
[36] Section 7.08 Provision of Product Information. The FDA shall provide the public access to information regarding a registered reproductive health product. **Among others, the FDA shall post in its website all approved reproductive health products (generic and branded)** with all relevant information relevant to proper use, safety and effectiveness of the product, including possible side effects and adverse reactions or events. As appropriate, the FDA shall issue an advisory to inform the consumers about relevant developments regarding these products.
[37] *Rollo* (G.R. No. 217872), p. 276.

Finally, the OSG asserts that respondents should not be cited in contempt with respect to the implementation of Philhealth Circular No. 038-2015, not only because Philhealth is a separate entity not being administered by the Secretary of Health, but also because Philhealth was never impleaded as a party in G.R. Nos. 217872 and 221866. For the OSG, the Court's TRO only prohibits respondents from procuring, selling, distributing, dispensing, administering, advertising, and promoting "Implanon" and "Implanon NXT." It does not cover the public procurement, sale, distribution and availment of other registered and recertified intra-uterine devices *prior* to the FDA's receipt of the Court's TRO on June 29, 2015.[38]

Reply to the Comment

Petitioners once more insist that respondent were guilty of contempt, stating in their Reply[39] that despite the June 17, 2015 TRO of the Court, the Certificate of Product Registration for "Implanon NXT" submitted by respondents themselves not only showed that the "marketing authorization" of the contraceptive drug remained to be valid until November 19, 2015, but was also re-certified and extended after the June 17, 2015 TRO of the Court until May 29, 2020. Petitioners explain that "marketing authorization" as defined by the World Health Organization, is "[a]n official document issued by the competent drug regulatory authority for the purpose of marketing or free distribution of a product after evaluation safety, efficacy and quality. x x x"[40]

Regarding the implementation of PhilHealth Circular No. 038-2015, petitioners argue that PhilHealth is covered by the June 17, 2015 TRO of the Court even if it is not impleaded as a party because it is considered within the terms "respondents, their representatives, agents or other persons acting on their behalf" in Court's order. Citing Article IV, Section 14 of Republic Act No. 7875,[41] petitioners points out that PhilHealth is a government corporation attached to the Department of Health for policy coordination and guidance. They likewise point out that respondent Secretary Garin cannot disclaim liability considering that she is also the Chairperson of PhilHealth, and that other secretaries and other heads of the departments and agencies of government are members of the Board of PhilHealth.[42]

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[38] Id. at 277-278.
[39] Id. at 366-376.
[40] Id. at 370-371.
[41] SEC. 14. *Creation and Nature of the Corporation.* - There is hereby created a Philippine Health Insurance Corporation, which shall have the status of a tax-exempt government corporation attached to the Department of Health for policy coordination and guidance.
[42] *Rollo* (G.R. No. 217872), pp. 373-374.

Consolidation

On February 3, 2016, the Court ordered the consolidation of these two cases.[43]

The Court's Ruling

In resolving the foregoing petitions, it behooves the Court to first address the issues on whether the petitioners have the *locus standi* to file the subject petitions and whether their resort to the subject recourse is proper.

Petitioners have
Locus Standi

As stated above, the OSG questioned the legal standing of the petitioners to file the subject petition as citizens and taxpayers, not only because of their failure to establish any direct injury, but also because of their failure to show that the issues raised were of transcendental importance.

In *Imbong*, it was already stated that "(from) the declared policy of the RH Law, it is clear that Congress intended that the public be given only those medicines that are proven medically safe, legal, non-abortifacient, and effective in accordance with scientific and evidence-based medical research standards." Thus, the public, including the petitioners in these cases, have the right to question any approval or disapproval by the FDA of any drugs or devices which they suspect to be abortifacient on the ground that they were not properly tested or were done in haste or secrecy.

As early as *David v. Arroyo*,[44] the Court has already ruled that "[t]axpayers, voetrs, concerned citizens, xxx may be accorded standing to sue, provided that xxx for taxpayers, there must be a claim of illegal disbursement of public funds or that the tax measure is unconstitutional xxx for concerned citizens, there must be a showing that the issues raised are of transcendental importance which must be settled early. xxx"

Considering that the Court in *Imbong* already declared that the issues of contraception and reproductive health in relation to the right to life of the unborn child were indeed of transcendental importance,[45] and considering also that the petitioners averred that the respondents unjustly caused the allocation of public funds for the purchase of alleged abortifacients which would deprive the unborn of its the right to life, the Court finds that the petitioners have *locus standi* to file these petitions.

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[43] Id. at 255-256.
[44] 522 Phil. 705, 760 (2006).
[45] *Supra* note 1, at 285-286.

Certiorari proper to challenge acts of the FDA

As to the contention that the subject recourse is improper as it involves the FDA's exercise of its regulatory powers, suffice it to say that the Court has unequivocally declared that *certiorari*, prohibition and *mandamus* are appropriate remedies to raise constitutional issues and to review and/or prohibit/nullify, when proper, acts of legislative and executive officials as there is no other plain, speedy or adequate remedy in the ordinary course of law.[46]

Consequently, the Court dismisses the notion that the re-certification of contraceptive drugs and devices by the FDA in exercise of its regulatory function is beyond judicial review. After all, the Constitution mandates that judicial power include the duty of the courts of justice to settle actual controversies involving rights which are legally demandable and enforceable, and to determine whether or not there has been grave abuse of discretion amounting to lack or excess of jurisdiction on the part of any branch or instrumentality of the Government.[47]

Thus, *certiorari* is proper.

Violation of Due Process

It is on record that sometime in September 2014, the FDA issued a Notice[48] inviting MAH of fifty (50) contraceptive drugs to apply for re-evaluation/re-certification of their contraceptive products and directed "all concerned to give their written comments to said applications on or before October 8, 2014."

ALFI, in the belief that the contraceptives enumerated in the Notice fell within the definition of "abortifacient," filed its preliminary opposition, dated October 8, 2014, to all 50 applications with the FDA. The same opposition also questioned twenty-seven (27) other contraceptive drugs and devices that had existing FDA registrations which were not subjects of any application for re-evaluation/re-certification.

On November 24, 2014, ALFI formally filed its opposition to all the seventy-seven (77) contraceptive drugs, but despite the pending opposition to the re-evaluation/re-certification of these contraceptive products, the FDA

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[46] *Imbong v. Ochoa*, G.R. Nos. 204819, 204934, 204957, 204988, 205003, 205043, 205138, 205478, 205491, 205720, 206355, 207111, 207172 & 207563, April 8, 2014, 721 SCRA 146, 277-278; *Tanada v. Angara*, 338 Phil. 546, 575 (1997); *Macalintal v. COMELEC*, 453 Phil. 586 (2003); *Aldaba v. COMELEC*, 624 Phil. 805 (2010); *Magallona v. Ermita*, G.R No. 187167, July 16, 2011, 655 SCRA 476.

[47] Article VIII, Section 1, 1987 Constitution.

[48] *Rollo* (G.R. No. 217872), pp. 119-122.

issued two (2) certificates of product registration for the hormonal contraceptives, "Implanon" and "Implanon NXT."

On March 19, 2015, ALFI wrote another letter[49] to the DOH and the FDA, reiterating its opposition to the applications for re-evaluation/re-certification and requesting, among others, that the agencies shed light on the status of their earlier opposition and schedule hearings and consultations regarding the applications for re-evaluation/re-certification.

The petitioners' oppositions were all ignored.

Now, one of the guarantees sacrosanct in this jurisdiction is that no person shall be deprived of life, liberty or property without due process of law. An essential component of the Bill of Rights, the Due Process Clause, undoubtedly occupies a position of primacy in the fundamental law.

Due process of law has two aspects: substantive and procedural due process. 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.[50]

Substantive due process refers to the intrinsic validity of a law that interferes with the rights of a person to his property.[51] 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.[52]

Although administrative procedural rules are less stringent and often applied more liberally, administrative proceedings are not exempt from basic and fundamental procedural principles, such as the right to due process in investigations and hearings.[53]

In *Ang Tibay v. CIR*,[54] 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;
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> 2) The tribunal must consider the evidence presented;

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[49] Id. at 135-138.
[50] *Republic v. Sandiganbayan*, 461 Phil. 598 (2003).
[51] *Ynot v. Intermediate Appellate Court*, No. L-74457, March 20, 1987, 148 SCRA 659.
[52] *Tatad v. Sandiganbayan*, 242 Phil. 563, 575-576 (1988).
[53] *Montoya v. Varilla*, 595 Phil. 507, 520 (2008); *Civil Service Commission v. Lucas*, 361 Phil. 486, 491 (1999).
[54] 69 Phil. 635 (1940).

> 3) The decision must have something to support itself;
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> 4) The evidence must be substantial;
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> 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.[55]

After an assessment of the undisputed facts, the Court finds that the FDA certified, procured and administered such contraceptive drugs and devices, **without the observance of the basic tenets of due process, without notice and without public hearing,** despite the constant opposition from the petitioners. From the records, it appears that other than the notice inviting stakeholders to apply for certification/re-certification of their reproductive health products, there was no showing that the respondents notified the oppositors and conducted a hearing on the applications and oppositions submitted.

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)[56] 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

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

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

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.[57]

In re: Motion to Lift the
Temporary Restraining Order

Supplementing their Comment,[58] the OSG sought to have the June 17, 2015 TRO of the Court lifted, arguing that given the expiry date of these contraceptive drugs, the continued effectivity of the June 17, 2015 TRO of the Court would result in the waste of vast quantities of "Implanon" and "Implanon NXT" which remain in government warehouses. In addition to insisting on the safety of these contraceptive drugs, respondents added that the continued effectivity of the June 17, 2015 TRO of the Court would also result in the depleted supply of contraceptive drugs and devices in both accredited public health facilities and in the commercial market.

This was opposed by petitioners[59] who asserted that in light of the lack of any clear and transparent procedure and rules for the determination of the safety and non-abortifacient character of the contraceptive drugs, the June 17, 2015 TRO should be maintained. In support of their argument, petitioners cited the Principle of Prudence espoused by the Framers of the Constitution, that is, "should there be the slightest iota of doubt regarding questions of life and respect for human life, one must try to be on the safe side."[60]

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[57] *Montoya v. Varilla, supra* note 53, at 520-521.
[58] *Rollo* (G.R. No. 217872), pp. 316-326; *rollo* (G.R. No. 221866), pp. 96-103.
[59] *Rollo* (G.R. No. 217872), pp. 326-340.
[60] Id. at 329-330.

In view of the foregoing, the Court denies the motion to lift the TRO issued by this Court at this time. The public respondents, their representatives, agents or other persons acting on their behalf are still enjoined from distributing and administering the certified and re-certified drugs and devices, considering that the FDA will still be conducting a hearing on the opposition of the petitioners. **To lift the TRO at this time is to grant a motion for execution before a trial.**

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.

Any decision of the FDA is appealable to the Court of Appeals thru a Petition for Review under Rule 43 of the Rules of Court

The Court notes that Section 32 of R.A. No. 3720, as amended by R.A. No. 9711,[61] and its implementing rules provide that a party aggrieved by the orders, rulings or decision (or inaction) of the Director-General of the FDA has the remedy of appealing the same to the Secretary of Health. The Court likewise notes that under Section 9[62] of E.O. No. 247,[63] the decisions of the Secretary of Health would first have to be appealed to the Office of the President, in conformity with the doctrine of exhaustion of administrative remedies.

Notwithstanding, considering that the Secretary of Health is the principal respondent in these petitions, any decision by the FDA in this particular case should be directly appealable to the Court of Appeals *(CA)* through a petition for review under Rule 43 of the Rules of Court. Verily, procedural rules, whether issued by quasi-judicial agencies or embodied in

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[61] 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.

[62] 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.

[63] Entitled "Prescribing Guidelines and Establishing a Regulatory Framework for the Prospecting of Biological and Genetic Resources, their By-Products and Derivatives, for Scientific and Commercial Purposes; and for Other Purposes;" dated May 18, 1995.

statutes enacted by the Congress, are subject to alteration or modification by the Court in the exercise of its constitutional rule-making power.

In *First Lepanto Ceramics, Inc. v. Court of Appeals*,[64] the Court, on the strength of Circular No. 1-91 (now Rule 43 of the Rules of Court), allowed an appeal from the decision of the Board of Investment to the CA, notwithstanding the express provision of Section 82 of the Omnibus Investment Code of 1987[65] that any appeal from a decision of the Board of Investment should be directly taken to this Court within thirty (30) days from receipt of the order or decision, *viz:*

> x x x [T]his Court, pursuant to its Constitutional power under Section 5(5), Article VIII of the 1987 Constitution to promulgate rules concerning pleading, practice and procedure in all courts, and by way of implementation of B.P. 129, issued Circular 1-91 prescribing the rules governing appeals to the Court of Appeals from final orders or decisions of the Court of Tax Appeals and quasi-judicial agencies to eliminate unnecessary contradictions and confusing rules of procedure.
>
> Contrary to petitioner's contention, although a circular is not strictly a statute or law, it has, however, the force and effect of law according to settled jurisprudence. In *Inciong v. de Guia*, a circular of this Court was treated as law. In adopting the recommendation of the Investigating Judge to impose a sanction on a judge who violated Circular No. 7 of this Court dated September 23, 1974, as amended by Circular No. 3 dated April 24, 1975 and Circular No. 20 dated October 4, 1979, requiring raffling of cases, this Court quoted the ratiocination of the Investigating Judge, brushing aside the contention of respondent judge that assigning cases instead of raffling is a common practice and holding that respondent could not go against the circular of this Court until it is repealed or otherwise modified, as "(L)aws are repealed only by subsequent ones, and their violation or non-observance shall not be excused by disuse, or customs or practice to the contrary."
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> The argument that Article 82 of E.O. 226 cannot be validly repealed by Circular 1-91 because the former grants a substantive right which, under the Constitution cannot be modified, diminished or increased by this Court in the exercise of its rule-making powers is not entirely defensible as it seems. Respondent correctly argued that Article 82 of E.O. 226 grants the right of appeal from decisions or final orders of the BOI and in granting such right, it also provided where and in what manner such appeal can be brought. These latter portions simply deal with procedural aspects which this Court has the power to regulate by virtue of its constitutional rule-making powers.

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[64] G.R. No. 110571 March 10, 1994, 231 SCRA 30.
[65] Otherwise known as Executive Order 226.

The case of *Bustos v. Lucero* distinguished between rights created by a substantive law and those arising from procedural law:

> Substantive law creates substantive rights . . . . Substantive rights is a term which includes those rights which one enjoys under the legal system prior to the disturbance of normal relations (60 C.J., 980). Substantive law is that part of the law which creates, defines and regulates rights, or which regulates rights and duties which give rise to a cause of action, as oppossed to adjective or remedial law, which prescribes the method of enforcing rights or obtains a redress for their invasion.

Indeed, the question of where and in what manner appeals from decisions of the BOI should be brought pertains only to procedure or the method of enforcing the substantive right to appeal granted by E.O. 226. In other words, the right to appeal from decisions or final orders of the BOI under E.O. 226 remains and continues to be respected. Circular 1-91 simply transferred the venue of appeals from decisions of this agency to respondent Court of Appeals and provided a different period of appeal, i.e., fifteen (15) days from notice. It did not make an incursion into the substantive right to appeal.[66]

The fact that the FDA is not among the agencies enumerated in Rule 43 as subject of a petition for review to the CA is of no consequence. In *Cayao-Lasam v. Ramolete*,[67] the Court disagreed with the opinion of the CA that the enumeration of the agencies mentioned in Section 1 of Rule 43 was exclusive. Thus:

> Indeed, the PRC is not expressly mentioned as one of the agencies which are expressly enumerated under Section 1, Rule 43 of the Rules of Court. However, its absence from the enumeration does not, by this fact alone, imply its exclusion from the coverage of said Rule. The Rule expressly provides that it should be applied to appeals from awards, judgments, final orders or resolutions of any quasi-judicial agency in the exercise of its quasi-judicial functions. The phrase "among these agencies" confirms that the enumeration made in the Rule is not exclusive to the agencies therein listed.[68]

More importantly, to require the petitioners to first challenge any adverse decision of the FDA before the Secretary of Health and then to the Office of the President, will **unduly delay the final resolution of the**

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[66] *First Lepanto Ceramics, Inc. v. Court of Appeals, supra* note 64, at 38-39.
[67] 595 Phil. 56 (2008).
[68] Id. at 71.

current controversies. It should be remembered that in *Ginete v. Court of Appeals*,[69] it was held:

> Let it be emphasized that the rules of procedure should be viewed as mere tools designed to facilitate the attainment of justice. Their strict and rigid application, which would result in technicalities that tend to frustrate rather than promote substantial justice, must always be eschewed. Even the Rules of Court reflect this principle. The power to suspend or even disregard rules can be so pervasive and compelling as to alter even that which this Court itself has already declared to be final, as we are now constrained to do in the instant case.
>
> x x x
>
> **The emerging trend in the rulings of this Court is to afford every party litigant the amplest opportunity for the proper and just determination of his cause, free from the constraints of technicalities. Time and again, this Court has consistently held that rules must not be applied rigidly so as not to override substantial justice.**[70] [Emphasis Included]

Considering that in the case at bench, what is mainly involved is the protection of the constitutionally protected right to life of the unborn, this Court finds that any controversy involving it should be resolved in the most expeditious manner possible.

Petition for Contempt

In the absence of a clear contumacious act committed against the Court with respect to the TRO, contempt is not warranted. It has been shown that the questioned acts were performed or done *prior* to the issuance of the TRO. Moreover, the charge that the respondents are continuing to engage in the distribution of the contraceptive drugs Implanon and Implanon NXT has not been substantiated. The mere fact that the subject drugs were re-certified up to May 29, 2020 is not proof that they continue to violate the TRO. In fact, the respondents are praying that it be lifted which is an indication that they are respecting and observing it.

At any rate, this controversy would not have been brought about if only the public respondents acted in accordance with the mandate of the Court in *Imbong*. Despite the Court's pronouncements in *Imbong*, they have not amended the RH-IRR to conform to the said pronouncements. Several provisions were struck down by the Court as unconstitutional, but they remain in the RH-IRR. Positive steps should have been taken by the concerned agencies.

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[69] 357 Phil. 36 (1998).
[70] Id. at 51-53.

Moreover, the Court notes that the RH-IRR has failed to provide the procedural mechanism by which oppositors may challenge the safety and the non-abortifacient character of contraceptive drugs and devices. The FDA should address this glaring omission.

To be sure, and to avoid any dispute in the future, the Court will adopt and embody in the dispositive portion the studied instructions of one of their esteemed colleagues, Hon. Mariano C. Castillo, in his Concurring Opinion in *Imbong*. Due to the inaction of the public respondents, the Court will adopt them as part of this resolution to serve as guidelines for all concerned.

In line with pronouncements made herein and in the decision of the Court in *Imbong*, the FDA should afford the petitioners their constitutional right to due process by conducting a summary hearing on the applications and oppositions, guided by the cardinal rights of parties laid down in *Ang Tibay* as stated above, within thirty (30) days from receipt of this disposition.

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)(l) of Republic Act No. 10354. The Department of Health is DIRECTED to distribute copies of this template to all health care service providers covered by Republic Act No. 10354.

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

The above foregoing directives notwithstanding, within 30 days from receipt of this disposition, the Food and Drugs Administration should commence to conduct the necessary hearing guided by the cardinal rights of the parties laid down in *CIR v. Ang Tibay.*[71]

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.

JOSE CATRAL MENDOZA
Associate Justice

[71] *Supra* note 54.

WE CONCUR:

ANTONIO T. CARPIO
Associate Justice
Chairperson

(On Leave)
ARTURO D. BRION
Associate Justice

MARIANO C. DEL CASTILLO
Associate Justice

MARVIC M.V.F. LEONEN
Associate Justice

ATTESTATION

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

ANTONIO T. CARPIO
Associate Justice
Chairperson, Second Division

CERTIFICATION

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

MARIA LOURDES P. A. SERENO
Chief Justice