**HIGHLIGHTS OF THE APRIL 26, 2017 SUPREME DECISION**
**(On the Petition Questioning the Implementation of the RH Law)**
***(G.R. No. 217872 – 2nd Petition filed)***

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*1. Does the TRO remain in effect?*

The TRO which was issued by the SC on June 17, 2015 remains in effect.

*2. Does it refer only to Implanon and Implanon NXT?*

With regard to the prohibition from procuring, selling, distributing, dispensing or administering, advertising and promoting: the TRO applies to "Implanon" and "Implanon NXT".

With regard to granting any and all pending applications for registration/re-certification: the TRO covers ALL reproductive products and supplies, including contraceptive drugs and devices. However, FDA may act on pending applications for registration/re-certification **PROVIDED** FDA observes the requirements of due process**.**

The TRO as issued and affirmed on August 24, 2016 is unchanged; hence, it stands. The clarification in the April 26, 2017 SC Decision should be read in the light of the entire decision which unequivocally voided all certifications and re-certifications made by FDA that did not comply with the requirements of due process.

*3. Until when is the TRO effective?*

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

*4. What is covered by the April 26, 2017 SC Decision?*

ALL LISTED DRUGS, INCLUDING IMPLANON AND IMPLANON NXT, are covered by the Decision.

Please be reminded that the certifications/re-certifications of 77 contraceptive drugs and devices, including Implanon and Implanon NXT, were questioned by ALFI before the Supreme Court. However, FDA claimed that they made only 47 certifications/re-certifications. Please see lists below.

*5. What does the April 26, 2017 SC Decision say about the certifications/re-certifications of these contraceptive drugs and devices?*

The SC said that ALL the certifications/re-certifications of contraceptive drugs and devices made in violation of the constitutional right to due process are **VOID**. Hence, these contraceptives presently have no licenses, and cannot and should not be sold, purchased, distributed, or administered.

The pertinent portion of the Decision is quoted below:

> Due to the failure of the respondents to observe and comply with the basic requirements of due process, the court if 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.

*6. What did the SC order the FDA to do?*

The SC ordered the FDA to: (a) conduct the necessary hearings to determine not only the safety but also the non-abortifacience of contraceptive drugs and devices, and (b) to observe the requirements of due process in the said hearings.

*7. What are the requirements of due process that need to be observed by FDA in the hearings?*

**The cardinal rights of due process are:**[1]

a) The right to a hearing - to present his own case and submit evidence in support thereof.

b) The tribunal must consider the evidence presented.

c) The decision must be supported by the evidence presented.

d) The evidence to support a finding or conclusion must be "substantial." Substantial evidence is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.

e) 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.

f) The tribunal or any of its judges, therefore, 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.

g) The tribunal 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 reasons for the decisions rendered.

*8. What are the standards that the FDA should observe in the conduct of the hearings and in coming up with a decision/conclusion?*

The FDA should observe, follow and be guided by the "**standards of the Reproductive Health Law, as construed in *Imbong v. Ochoa***."[2]

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[1] *Ang Tibay v. Court of Industrial Relations*

[2] Dispositive portion, April 26, 2017 SC Decision; *Imbong v. Ochoa refers to the April 08, 2014 SC Decision on the consolidated petitions filed questioning the constitutionality of the RH Law.*

The standards are: (a) "that which does not harm or destroy the life of the unborn from conception/fertilization," and (b) NO mechanism of action which "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."

*9. How should the FDA weigh the evidence that will be presented during the hearings?*

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."[3]

*10. How many days was FDA given to decide the case?*

The FDA was directed to decide the case **within sixty (60) days *from the date it will be deemed submitted for resolution.***

*11. What else did the SC order the FDA to do?*

The SC further ordered the FDA (and DOH) to "amend the Implementing Rules and Regulations of R.A. No. 10354 so that it would be strictly compliant with the mandates of the Court in *Imbong v. Ochoa*."

*12. How about the DOH, what was it directed by the SC to do?*

DOH was directed to:

(a) In coordination with other concerned agencies, formulate the rules and regulations or guidelines which will govern the purchase and distribution/dispensation of the products or supplies 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

[3] Dispositive portion, August 24, 2016 Decision which is deemed affirmed.

shall be strictly regulated in order that they will sufficiently safeguard the right to life of the unborn.

(b) Generate the complete and correct list of the government's reproductive health programs and services under the RH Law which will serve as the template for the complete and correct information standard. The DOH is likewise directed to distribute copies of this template to all health care service providers covered by the RH Law.

*13. What is the only modification introduced by the April 26, 2017 SC Decision?*

From the decision of the FDA, the appeal should be to the Office of the President from the decision of the FDA,[4] not to the Court of Appeals directly as previously provided. The decision of the OP may then be brought to the Court of Appeals, then to the Supreme Court, if necessary.

14. *What do we do now?*

Remain vigilant and ensure that DOH and FDA comply strictly with the basic requirements of due process and with the orders of the Supreme Court.

**LIST OF 47 CONTRACEPTIVE DRUGS AND DEVICES WHICH FDA ADMITTED TO HAVE CERTIFIED/RE-CERTIFIED**

[4] We know however that this will be an exercise in futility because we can expect how the OP will decide. However, resort to the CA, then to the SC, if warranted, is still available.

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|---|---|
| ***Re-certified on 27 Nov 2014*** | 26. NORDETTE |
| 1. ALTHEA | 27. RUBY |
| 2. CHLOE | 28. TRUST PILL |
| 3. CYBELLE | 29. CHARLIZE |
| 4. CERAZETTE | 30. FEMME |
| 5. GRACIAL | 31. GENERIC (Medroxyprogesterone Acetate) |
| 6. MARVELON 28 | 32. LYNDAVEL |
| 7. MERCILON | 33. DEPOTRUST (DRP-363) |
| 8. YASMIN | 34. DEPOTRUST (DR-XY34137) |
| 9. YAZ | 35. DEPOFEMME |
| 10. LIZELLE | 36. ZOELY |
| 11. LIZA | 37. MICROPIL |
| 12. LIZONYA | 38. MICROPIL PLUS |
| 13. QLAIRA | ***Re-certified 13 March 2015*** |
| 14. IMPLANON | 39. FAMILIA 28F |
| 15. IMPLANON NXT | 40. PROTEC |
| 16. NUVARING | 41. MIRENA |
| 17. SOPHIA | 42. DAPHNE |
| 18. GYNERA | 43. LEILA |
| 19. MELIANE | 44. EXLUTON |
| 20. LOGYNON 21 | 45. PROTEC |
| 21. MINIPIL | ***Re-certified 1 June 2015*** |
| 22. DENISE | 46. DEPO-GESTIN (DRP 3643) |
| 23. SEIF | 47. DEPO-GESTIN (DR-XY39023) |
| 24. JULIANNE | |
| 25. LADY | |

**LIST OF 77 CONTRACEPTIVE DRUGS AND DEVICES WHOSE CERTICATIONS/RE-CERTIFICATIONS WERE OPPOSED BY ALFI**

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| 1. ALTHEA | 40. SAFE PILL 30mcg + 250mcg |
| 2. CRIMSON | 41. NORDIOL 21 |
| 3. CYBELLE | 42. GENERIC (Ethinyl Estradiol + Levonorgestrel) |
| 4. CHLOE | 43. EVRA |
| 5. ESTELLE | 44. NORIFAM |
| 6. DIANE 35 | 45. MICROPIL |
| 7. ANCEA | 46. MICROPIL PLUS |
| 8. MERCILON | 47. CONTROLLE |
| 9. GRACIAL | 48. NORFEM |
| 10. MARVELON 28 | 49. FEMENAL |
| 11. LLOYD LABS DESOGESTREL & ETHINYL ESTRADIOL | 50. QLAIRA |
| 12. YASMIN | 51. CERAZETTE |
| 13. YAZ | 52. SINGAPORE GENEBIO INC. DESOGESTREL |
| 14. LIZA | 53. LLOYD LABS DESOGESTREL |
| 15. LIZONYA | 54. MIREN |
| 16. BLUSH | 55. DEPOFEMME |
| 17. TRUST PILL | 56. DEPO-GESTIN (DRP 3643) |
| 18. CHARLIZE | 57. DEPO-GESTIN (DR-XY39023) |
| 19. FAMILIA 28 F | 58. DEPEREVA |
| 20. GENERIC (DKT PHILS) (Ethinyl Estradiol + Levonorgestrel + Ferrous Fumarate) | 59. DEPOTRUST |
| 21. GENERIC (DKT PHILS) (Ethinyl Estradiol + Levonorgestrel + Ferrous Fumarate) | 60. PROVERA |
| 22. AZUL | 61. PROVESTIN |
| 23. NICOLE | 62. LYNDAVEL |
| 24. PROTEC | 63. GENERIC (Medroxyprogesterone Acetate) |
| 25. FEMME | 64. MEGESTRON |
| 26. RUBY | 65. DB-10 |
| 27. NUVARING | 66. DB-5 |
| 28. GYNERA | 67. ORETAS |
| 29, SOPHIA | 68. PRIMOLUT N |
| 30. MELIANE | 69. EXLUTON |
| 31. MINULET | 70. DAPHNE |
| 32. DENISE | 71. AMBER |
| 33. LADY | 72. LEILA |
| 34. LOGYNON 21 | 73. GENERIC (Lynestrenol-DKT Phils)) |
| 35. NORDETTE | 74. DAPNE |

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|---|---|
| 36. SEIF | 75. GENERIC (Lynestrenol – Famy Care LTD) |
| 37. MINIPIL | 76. IMPLANON |
| 38. JULIANNE | 77. IMPLANON NXT |
| 39. SAFE PILL 30mcg + 150mcg | |