Marlon | Kim

ALFI
ALLiance for the FAMILY Foundation Philippines, Inc.

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August 22, 2017

DEPARTMENT OF HEALTH
San Lazaro Compound
Tayuman, Sta. Cruz
Manila

Attention: **Dr. Paulyn Ubial, MD**
Secretary

FOOD AND DRUG ADMINISTRATION
Civic Drive
Filinvest City
Alabang 1781 Muntinlupa

Attention: **Ms. Nela Charade G. Puno, RPh**
Director General

Subject: **FDA ADVISORY 2017-253 and the Certification/Re-Certification of Contraceptive Products under Republic Act No. 10354, as Provided in the Supreme Court Decisions**

Mesdames and Gentlemen:

This is to reiterate the request of Alliance for the Family Foundation Philippines, Inc. (ALFI) expressed in its two (2) letters dated August 07, 2017 and August 14, 2017 that were duly received by your offices on August 07, 2017 and August 15, 2017, respectively. To date, we have yet to receive any form of response to both letters from either of your offices.

Specifically, ALFI requested for the following documents:

1. *Certification and re-certification processes which have been revised "to make it strictly compliant with the High Court's Decision,"*

2. *Finalized "amended Rules of Procedure/ Guidelines for the certification and re-certification of ALL contraceptive products,"*

as mentioned in the FDA Aide Memoire SC TRO on Contraceptives, 31 July 2017 (VI [A] and [B]);

3. *Schedule for the related "first round of summary hearings under the amended procedure this August 21, 2017" (VI [C]), and any other dates for such hearings; and*

4. *Revised Implementing Rules and Regulations of the Responsible Parenthood and Reproductive Health Act of 2012 (Republic Act No. 10354) that is "strictly compliant with the mandates of the Court."*

To put things in perspective, we hereby quote the pertinent portions of the ENTRY OF JUDGMENT from the Clerk of Court of the Second Division of the Supreme Court which the undersigned received on August 08, 2017 —

"This is to certify that on August 24, 2016 a decision rendered in the above-entitled case (G.R. No. 217872 and G.R. No. 221866) was filed in this Office, the dispositive part of which reads as follows:

"WHEREFORE, the case docketed as G.R. No. 217872 is hereby REMANDED to the Food and Drugs Administration which is hereby ordered to observe the basic requirements of due process by conducting a hearing, and allowing the petitioners to be heard, on the re-certified, procured and administered contraceptive drugs and devices, including Implanon and Implanon NXT, and to determine whether they are abortifacients or non-abortifacients.

Pursuant to the expanded jurisdiction of this Court and its power to issue rules for the protection and enforcement of constitutional rights, the Court hereby:

1. DIRECTS the Food and Drug Administration to formulate the rules of procedure in the screening, evaluation and approval of all contraceptive drugs and devices that will be used under Republic Act No. 10354. The rules of procedure shall contain the following minimum requirements of due process: (a) publication, notice and hearing, (b) interested parties shall be allowed to intervene, (c) the standard laid down in the Constitution, as adopted under Republic Act No. 10354, as to what constitutes allowable contraceptives shall be strictly followed, that is, those which do not harm or destroy the life of the unborn from conception/fertilization, (d) in weighing the evidence, all reasonable doubts shall be resolved in favor of the protection and preservation of the right to life of the unborn from conception/fertilization, and (e) the other requirements of administrative due process, as summarized in Ang Tibay v. CIR, shall be complied with.

2. DIRECTS the Department of Health in coordination with other concerned agencies to formulate the rules and regulations or guidelines which will govern the purchase and distribution/dispensation of the products or supplies under Section 9 of Republic Act No. 10354 covered by the certification from the Food and Drug Administration that said product and supply is made available on the condition that it will not be used as an abortifacient subject to the following minimum due

process requirements: (a) publication, notice and hearing, and (b) interested parties shall be allowed to intervene. The rules and regulations or guidelines shall provide sufficient detail as to the manner by which said product and supply shall be strictly regulated in order that they will not be used as an abortifacient and in order to sufficiently safeguard the right to life of the unborn.

3. DIRECTS the Department of Health to generate the complete and correct list of the government's reproductive health programs and services under Republic Act No. 10354 which will serve as the template for the complete and correct information standard and, hence, the duty to inform under Section 23 (a) (I) of Republic Act No. 10354. The Department of Health is DIRECTED to distribute copies of this template to all health care service providers covered by Republic Act No. 10354.

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

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

Pending the resolution of the controversy, the motion to lift the Temporary Restraining Order is DENIED.

With respect to the contempt petition, docketed as G. R No. 221866 it is hereby DENIED for lack of concrete basis.

SO ORDERED. "

"This is to further certify that the Court on April 26, 2017 adopted a resolution, the dispositive part of which reads as follows:

"WHEREFORE, the August 24, 2016 Decision is MODIFIED. Accordingly, the Food and Drug Administration is ordered to consider the oppositions filed by the petitioners with respect to the listed drugs, including Implanon and Implanon NXT, based on the standards of the Reproductive Health Law, as construed in Imbong v. Ochoa, and to decide the case within sixty (60) days from the date it will be deemed submitted for resolution.

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

After the final resolution by the Food and Drug Administration, any appeal should be to the Office of the President pursuant to Section 9 of E.O. No. 247.

As ordered in the August 24, 2016 Decision, the Food and Drug Administration is directed to amend the Implementing Rules and Regulations of R. A. No. 10354 so that it would be strictly compliant with the mandates of the Court in Imbong v. Ochoa.

SO ORDERED."

and that the same has, on June 15, 2017 become final and executory and is hereby recorded in the Book of Entries of Judgments."

In the said Decision and Resolution referred to above, ALFI and the undersigned were the petitioners; hence, they are unquestionably the interested parties. They are the petitioners whom the Supreme Court emphatically pronounced were deprived of their constitutional right to due process of law. Thus --

"The undisputed fact is that the petitioners were deprived of their constitutional right to due process of law.

As expounded by the Court, what it found to be primarily deplorable is the failure of the respondents to act upon, much less address, the various oppositions filed by the petitioners against the product registration, recertification, procurement, and distribution of the questioned contraceptive drugs and devices. Instead of addressing the petitioners' assertion that the questioned contraceptive drugs and devices fell within the definition of an "abortifacient" under Section 4(a) of the RH Law because of their "secondary mechanism of action which induces abortion or destruction of the fetus inside the mother's womb or the prevention of the fertilized ovum to reach and be implanted in the mother's womb," the respondents chose to ignore them and proceeded with the registration, recertification, procurement, and distribution of several contraceptive drugs and devices."

Lest our frail memory fail us, the Court laid down the cardinal rights of parties in administrative proceedings in *Ang Tibay v. CIR*, as follows:

1) The right to a hearing, which includes the right to present one's case and submit evidence in support thereof;

2) The tribunal must consider the evidence presented;

3) The decision must have something to support itself;

4) The evidence must be substantial;

5) The decision must be rendered on the evidence presented at the hearing, or at least contained in the record and disclosed to the parties affected;

6) The tribunal or body or any of its judges must act on its or his own independent consideration of the law and facts of the controversy and not simply accept the

views of a subordinate in arriving at a decision; and

7) The board or body should, in all controversial questions, render its decision in such a manner that the parties to the proceeding can know the various issues involved, and the reason for the decision rendered.

We request for the "finalized amended Rules of Procedure/Guidelines for the certification and re-certification of ALL contraceptive products," the schedule for the "summary hearings under the amended procedure," and the "revised implementing rules and regulations" of the RH Law not only because they are mentioned in the FDA Aide Memoire as having been prepared and finalized by your offices, but because they have been mandated by the Supreme Court in its various decisions and resolutions which have already become final and executory. And most importantly, they constitute the minimum requirements of basic due process which the Supreme Court noted ALFI was deprived of in your proceedings in the past.

Please be kindly informed that ALFI will continue to invoke and exercise its constitutional right to due process. ALFI expects a process that complies strictly with the mandates and constitutional standards laid down by the Supreme Court in *Imbong v. Ochoa* and related cases -- specifically, (i) the standards as to what constitute allowable contraceptives, which are, those which do not harm or destroy the life of the unborn from conception/fertilization and do not exhibit the mechanism of action that "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"; (ii) 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 (iii) the requirements of administrative due process, as summarized in *Ang Tibay v. CIR.*

Anything short of these constitutional standards is unacceptable.

In the spirit of fair play, transparency, and due regard for the decisions of the Supreme Court that have become final and executory, we urge you to comply and observe the standards and requirements that have been duly laid down. We ask you to start the process right by providing us with the requested documents.

Thank you.

Very truly yours,

Maria Concepcion S. Noche
President and Legal Counsel

Copy furnished by personal service:

1. DEPARTMENT OF HEALTH
San Lazaro Compound
Tayuman, Sta. Cruz, Manila
Attention: **Dr. Paulyn Ubial, MD**
Secretary

2. FOOD AND DRUG ADMINISTRATION
Civic Drive
Filinvest City
Alabang 1781 Muntinlupa
Attention: **Ms. Nela Charade G. Puno, RPh**
Director General

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

ACKNOWLEDGEMENT RECEIPT

The Food and Drug Administration (FDA) hereby acknowledges the receipt of your document with the following details and duly recorded in the FDA Inventory System (FIS):

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