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PRESS RELEASE
For Immediate Release

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As Deadline Nears, DOH and FDA Remain Silent on Calls for Transparency and Due Process

Requests for Rules and Guidelines Mandated by the Supreme Court for Certifications/Re-Certifications of Contraceptives as Safe and Non-Abortifacient Remain Unanswered.

In the ongoing controversy over approval of contraceptives, the Food and Drug Administration (FDA) issued via its website Advisory 2017-253 dated August 21, 2017 inviting all concerned to submit within 10 days their petitions and corresponding evidence on the mechanism of action of 51 contraceptives. Presumably, these will be used as evidence in the certification and re-certification process by the FDA to determine the abortifacience or non-abortifacience as well as the safety of these contraceptives.

An earlier FDA Advisory – "Aide Memoire SC TRO on Contraceptives", dated 31 July 2017 — stated that summary hearings were to begin on August 21, 2017, a national holiday. Alliance for the Family Foundation Philippines, Inc. (ALFI), in letters delivered on August 7, 2017, August 15, 2017, and August 23, 2017, requested both the DOH and the FDA that it be provided as soon as possible with the following documents which FDA said had already been prepared and finalized:

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" that are also strictly compliant with the High Court's Decision;

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3. Schedule for the "first round of summary hearings under the amended procedure", 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 are "strictly compliant with the mandates of the Supreme Court."

ALFI made the foregoing requests because the DOH and FDA were ordered to prepare them by the Supreme Court in its various decisions and resolutions which have now become final and executory. Most importantly, they constitute the minimum requirements of basic due process which the Supreme Court noted ALFI was deprived of in FDA proceedings in the past.

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 — notice, public hearing, findings based on evidence on record and disclosed to the parties, among others.

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, ALFI urges DOH and the FDA to comply with and observe the standards and requirements that have been duly laid down, and we ask them to start the process right by providing ALFI with the requested documents.

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