Written Comments on the Abortifacient Operations of Listed Contraceptives

Notifying the Food and Drug Administration of Issues Relevant to the Doctrinal Pronouncement of the Supreme Court in IMBONG V. EXECUTIVE SECRETARY (G.R. NO. 204819 AND THE CONSOLIDATED CASES) Regarding the Avoidance of Abortifacient Effects of Contraceptives

08 October 2014

PRO-LIFE PHILIPPINES FOUNDATION, INC.
Re-certification of Contraceptive Drugs

Notice

The Food and Drug Administration (FDA) is preparing to undertake the re-evaluation/re-certification of all contraceptive drugs and/or devices as required under the provisions of Republic Act No. 10354.

Concerned Marketing Authorization Holders (MAH) of contraceptive products have been required to manifest their interest to apply for the above certification and submit evidence in support of their application. These information may be accessed through the FDA website, www.fda.gov.ph and/or the FDA Office, subject to payment of reasonable costs for reproduction.

All concerned are hereby invited to give their written comments to said applications on or before 08 October 2014

<table>
<thead>
<tr>
<th>Company</th>
<th>Generic name</th>
<th>Dosage Strength</th>
<th>Dosage Form</th>
<th>Brand name</th>
<th>Registration number</th>
</tr>
</thead>
<tbody>
<tr>
<td>AAA Pharma, Inc.</td>
<td>Ethinyl Estradiol + Levonorgestrel + Ferrous Fumarate</td>
<td>30mcg/150mcg/60mg</td>
<td>Tablet</td>
<td>Protec</td>
<td>DR-XY38297</td>
</tr>
<tr>
<td></td>
<td>Medroxyprogesterone Acetate</td>
<td>150mg/mL</td>
<td>Solution for Injection (IM)</td>
<td>Depo-gestin</td>
<td>DRP-3643</td>
</tr>
<tr>
<td></td>
<td>Medroxyprogesterone Acetate</td>
<td>50mg/mL</td>
<td>Solution for Injection (IM)</td>
<td>Depo-gestin</td>
<td>DR-XY39023</td>
</tr>
<tr>
<td></td>
<td>Medroxyprogesterone Acetate</td>
<td>150mg/mL</td>
<td>Suspension for Injection (IM)</td>
<td>Protec</td>
<td>DR-YX42049</td>
</tr>
<tr>
<td>Amtol Pharma Imports, Inc.</td>
<td>Norethisterone Enanthate + Estradiol Valerate</td>
<td>50 mg/ 5mg per mL</td>
<td>Solution for Injection (IM)</td>
<td>Norifam</td>
<td>DR-YX35422</td>
</tr>
<tr>
<td></td>
<td>Levonorgestrol + Ethinylestradiol + Ferrous fumarate</td>
<td>30 mg/ 150 mg/60 mg</td>
<td>Film-Coated Tablet</td>
<td>Famila 28F</td>
<td>DR-YX35393</td>
</tr>
<tr>
<td>Bayer Phils, Inc.</td>
<td>Drosipirenone + Ethinyl Estradiol</td>
<td>3 mg/30 mcg</td>
<td>Tablet</td>
<td>Yasmin</td>
<td>DR-YX38181</td>
</tr>
<tr>
<td></td>
<td>Drosipirenone + Ethynl Estradiol</td>
<td>3 mg/20 mcg</td>
<td>Tablet</td>
<td>Yaz</td>
<td>DR-YX34970</td>
</tr>
<tr>
<td></td>
<td>Estradiol Valerate + Dienogest</td>
<td></td>
<td>Film-Coated Tablet</td>
<td>Olaire</td>
<td>DR-YX38455</td>
</tr>
<tr>
<td></td>
<td>Gestodene + Ethinylestradiol</td>
<td>75 mcg/30 mcg</td>
<td>Tablet</td>
<td>Gynera</td>
<td>DR-YX25163</td>
</tr>
<tr>
<td></td>
<td>Gestodene + Ethinylestradiol</td>
<td>75 mcg/20 mcg</td>
<td>Tablet</td>
<td>Meliane</td>
<td>DR-YX25428</td>
</tr>
<tr>
<td></td>
<td>Levonorgestrel</td>
<td>53 mg (20 mcg/24 hrs)</td>
<td>Intruterine Delivery System</td>
<td>Mirena</td>
<td>DR-YX25174</td>
</tr>
<tr>
<td></td>
<td>Levonorgestrel + Ethinylestradiol</td>
<td>50 mcg/30 mcg</td>
<td>Tablet</td>
<td>Logynon 21</td>
<td>DR-YX9421</td>
</tr>
<tr>
<td></td>
<td>Levonorgestrel + Ethinylestradiol</td>
<td>150 mcg/30 mcg</td>
<td>Tablet</td>
<td>Self</td>
<td>DR-YX8004</td>
</tr>
<tr>
<td>Chemway Pharma, Inc.</td>
<td>Cyproterone Acetate + Ethinylestradiol</td>
<td>2 mg/35 mcg</td>
<td>Film-Coated Tablet</td>
<td>Cybelle</td>
<td>DRP-4439</td>
</tr>
<tr>
<td></td>
<td>Drosipirenone + Ethinylestradiol</td>
<td>3 mg/20 mcg</td>
<td>Film-Coated Tablet</td>
<td>Lizelle</td>
<td>DRP-4625</td>
</tr>
<tr>
<td></td>
<td>Drosipirenone + Ethinylestradiol</td>
<td>3 mg/30 mcg</td>
<td>Film-Coated Tablet</td>
<td>Liza</td>
<td>DRP-3751</td>
</tr>
<tr>
<td></td>
<td>Drosipirenone + Ethinylestradiol</td>
<td>3 mg/20 mcg</td>
<td>Film-Coated Tablet</td>
<td>Lizonya</td>
<td>DRP-3750</td>
</tr>
<tr>
<td></td>
<td>Levonorgestrel + Ethinylestradiol</td>
<td>100 mcg/20 mcg</td>
<td>Film-Coated Tablet</td>
<td>Minipil</td>
<td>DRP-3738</td>
</tr>
<tr>
<td>DKT Phils., Inc.</td>
<td>Cyproterone Acetate + Ethinyl Estradiol</td>
<td>2 mg/35 mcg</td>
<td>Tablet</td>
<td>Chloe</td>
<td>DRP-2496</td>
</tr>
<tr>
<td></td>
<td>Cyproterone Acetate + Ethinyl Estradiol</td>
<td>2 mg/35 mcg</td>
<td>Tablet</td>
<td>Althea</td>
<td>DRP-339</td>
</tr>
<tr>
<td></td>
<td>Gestodene + Ethinyl Estradiol</td>
<td>75mcg/30mcg</td>
<td>Tablet</td>
<td>Sophia</td>
<td>DRP-2802</td>
</tr>
<tr>
<td></td>
<td>Levonorgestrol + Ethinyl Estradiol</td>
<td>150 mcg/30 mcg</td>
<td>Tablet</td>
<td>Julianne</td>
<td>DRP-4297</td>
</tr>
<tr>
<td></td>
<td>Levonorgestrol + Ethinylestradiol</td>
<td>150 mcg/30 mcg</td>
<td>Tablet</td>
<td>Lady</td>
<td>DRP-337</td>
</tr>
<tr>
<td></td>
<td>Levonorgestrol + Ethinylestradiol</td>
<td>125 mcg/30 mcg</td>
<td>Tablet</td>
<td>Denise</td>
<td>DR-YX40669</td>
</tr>
<tr>
<td></td>
<td>Levonorgestrol + Ethinyl Estradiol + Ferrous Fumarate</td>
<td>125mgc/ 30mcg/ 75mg</td>
<td>Tablet</td>
<td>Ruby</td>
<td>DRP-2162</td>
</tr>
<tr>
<td>Name</td>
<td>Strength</td>
<td>Form</td>
<td>Brand</td>
<td>Code</td>
<td></td>
</tr>
<tr>
<td>----------------------------------------------------------------------</td>
<td>-----------------------------------</td>
<td>--------------------</td>
<td>---------------------</td>
<td>------</td>
<td></td>
</tr>
<tr>
<td>Levonorgestrel + Ethinyl Estradiol + Ferrous Fumarate</td>
<td>150 mcg/ 30mcg/ 75mg</td>
<td>Tablet</td>
<td>Charlive</td>
<td>DRP-2063</td>
<td></td>
</tr>
<tr>
<td>Levonorgestrel + Ethinyl Estradiol Ferrous Fumarate</td>
<td>125mcg/ 30mcg/ 75mg</td>
<td>Tablet</td>
<td>Trust Pill</td>
<td>DRP-336-01</td>
<td></td>
</tr>
<tr>
<td>Lynestrenol</td>
<td>500 mcg</td>
<td>Tablet</td>
<td>Daphne</td>
<td>DRP-2088</td>
<td></td>
</tr>
<tr>
<td>Lynestrenol</td>
<td>500 mcg</td>
<td>Tablet</td>
<td>Leila</td>
<td>DRP-2138</td>
<td></td>
</tr>
<tr>
<td>Medroxyprogesterone Acetate</td>
<td>150 mg/mL</td>
<td>Suspension for Injection (IM)</td>
<td>Lyndavel</td>
<td>DRP-338</td>
<td></td>
</tr>
<tr>
<td>Medroxyprogesterone Acetate</td>
<td>50 mg/mL</td>
<td>Suspension for Injection (IM)</td>
<td>DepoTrust</td>
<td>DR-XY34137</td>
<td></td>
</tr>
<tr>
<td>Medroxyprogesterone Acetate</td>
<td>50 mg/mL</td>
<td>Suspension for Injection (IM)</td>
<td>DepoTrust</td>
<td>DRP-363</td>
<td></td>
</tr>
<tr>
<td>Medroxyprogesterone Acetate</td>
<td>150 mg/mL</td>
<td>Suspension for Injection (IM/SC)</td>
<td>None</td>
<td>DR-XY30830</td>
<td></td>
</tr>
<tr>
<td>Dyna Drug, Corp.</td>
<td>Medroxyprogesterone acetate</td>
<td>150 mg/mL</td>
<td>DepoFemme</td>
<td>DR-XY40409</td>
<td></td>
</tr>
<tr>
<td>Norethisterone + Ethinylestradiol</td>
<td>400 mcg/ 35 mcg</td>
<td>Tablet</td>
<td>Micropol</td>
<td>DR-7745</td>
<td></td>
</tr>
<tr>
<td>Norethisterone + Ethinyl Estradiol + Ferrous Fumarate</td>
<td>400 mcg/35 mcg/ 75 mg</td>
<td>Tablet</td>
<td>Micropol Plus</td>
<td>DR-XY34401</td>
<td></td>
</tr>
<tr>
<td>Global Pharmatrade</td>
<td>Levonorgestrel + Ethinylestradiol + Ferrous Fumarate</td>
<td>30 mcg/150 mcg/60 mg</td>
<td>Film-Coated Tablet</td>
<td>Femme</td>
<td>DR-XY37779</td>
</tr>
<tr>
<td>Lloyd Labs, Inc.</td>
<td>Desogestrel</td>
<td>75 mcg</td>
<td>Estrelle</td>
<td>DR-Y40817</td>
<td></td>
</tr>
<tr>
<td>Desogestrel + Ethinylestradiol</td>
<td>150 mcg/20 mcg</td>
<td>Tablet</td>
<td>Estrelle Plus</td>
<td>DR-XY40787</td>
<td></td>
</tr>
<tr>
<td>Desogestrel + Ethinylestradiol</td>
<td>150 mcg/30 mcg</td>
<td>Tablet</td>
<td>Mercolon</td>
<td>DR-XY21633</td>
<td></td>
</tr>
<tr>
<td>Desogestrel + Ethinylestradiol</td>
<td>150 mcg/30 mcg</td>
<td>Tablet</td>
<td>Marvelon 28</td>
<td>DR-XY2299</td>
<td></td>
</tr>
<tr>
<td>Desogestrel + Ethinylestradiol</td>
<td>125 mcg/ 30 mg; 25 mcg/ 40 mcg</td>
<td>Tablet</td>
<td>Gracial (transferred to Aspen Philippines, Inc.)</td>
<td>DR-XY26961</td>
<td></td>
</tr>
<tr>
<td>Merck Sharp &amp; Dohme (L.A.), Corp.</td>
<td>Etonogestrel</td>
<td>68 mg</td>
<td>Implanon NXT</td>
<td>DR-XY41412</td>
<td></td>
</tr>
<tr>
<td>Etonogestrel</td>
<td>68 mg</td>
<td>Implant (for Subdermal use)</td>
<td>Implanon</td>
<td>DR-XY27500</td>
<td></td>
</tr>
<tr>
<td>Etonogestrel + Ethinylestradiol</td>
<td>11.7 mg/2.7 mg</td>
<td>Controlled Release Vaginal Ring</td>
<td>Nuvaring</td>
<td>DR-XY30809</td>
<td></td>
</tr>
<tr>
<td>Lynestrenol</td>
<td>500 mcg</td>
<td>Tablet</td>
<td>Exlution</td>
<td>DR-XY18077</td>
<td></td>
</tr>
<tr>
<td>Desogestrel</td>
<td>75 mcg</td>
<td>Tablet</td>
<td>Cerazette</td>
<td>DR-XY27146</td>
<td></td>
</tr>
<tr>
<td>Nomegestrol acetate + Estradiol (as Hemihydrate)</td>
<td>2.5 mcg/1.5 mg</td>
<td>Film-Coated Tablet</td>
<td>Zoely</td>
<td>DR-XY43109</td>
<td></td>
</tr>
<tr>
<td>Pfizer Phils, Inc</td>
<td>Levonorgestrel + Ethinylestradiol</td>
<td>150mcg/ 30mcg</td>
<td>Nordette</td>
<td>DR-XY23241</td>
<td></td>
</tr>
</tbody>
</table>

Follow-up

Inquiries

Center for Drug Regulation and Research: + 63 2 857 1999
Center for Food Regulation and Research: + 63 2 857 1992
Center for Cosmetic Regulation and Research: + 63 2 857 1994
Center for Device Regulation, Radiation Health and Research: + 63 2 749 9443

Releasing Administration and Finance Office - Releasing: + 63 2 857 1841

Seminars
Policy and Planning Office - Academy: + 63 2 857 1876
This letter notifies the Food and Drug Administration (“Administration”) of issues relevant to the above-titled subject and brings attention to the Administration’s functions and duties under Sec. 9 of R.A. 10354 (RH Law):

“SEC. 9. x x x For the purpose of this Act, any product or supply included or to be included in the EDL must have a certification from the FDA that said product and supply is made available on the condition that it is not to be used as an abortifacient.” (R.A. 10354)

in relation to the pronouncements of the Supreme Court in IMBONG V. EXECUTIVE SECRETARY (G.R. 204819):

“x x x Section 9 [of the RH Law] calls for the certification by the FDA that these contraceptives cannot act as abortive. With this, together with the definition of an abortifacient under Section 4 (a) of the RH Law and its declared policy against abortion, the undeniable conclusion is that contraceptives to be included in the PNDFS and the EDL will not only be those contraceptives that do not have the primary action of causing 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, but also those that do not have the secondary action of acting the same way.”

I. IS THERE ANY INFORMATION INDICATING THAT ANY OF THESE LISTED CONTRACEPTIVE PILLS MAY, IN ANY WAY, OPERATE AS AN ABORTIFACIENT?

Abortifacient operation of:

FAMILIA 28F (DR-XY35393), MIRENA (DR-XY25174), LOGYNON 21 (DR-XY9421), SEIF (DR-XY8804), MINIPIL (DRP-3738), JULIANNE (DRP-4297), LADY (DRP-337), DENISE (DR-XY40669), RUBY (DRP-2162), CHARLIZE (DRP-2063), TRUST PILL (DR-XY33601), FEMME (DR-XY37779), and NORDETTE (DX-XY23241)

THE ADMINISTRATION IS REMINDED that as early as October 2001, the Administration, after due process, recommended the recall of a contraceptive found to operate as an abortifacient, through a letter-report addressed to the Secretary of Health which reads in totality:
10 October 2001

HON. MANUEL M. DAYRIT, MD, MSC
Secretary
Department of Health
Manila

Subject: In the Matter of Levonorgestrel 750 mcg Tablet Brand: POSTINOR BFAD Registration No. DR-XY26140

Dear Mr. Secretary:

This is in response to your directive contained in your communication dated June 13, 2001, requiring this Office "to take all appropriate actions in the immediate recall of POSTINOR and the consequent cancellation of its CPR and to prohibit its further use, dispensing, sale and distribution in the local market," if proven to be abortifacient, following a letter-complaint of ABAYPAMILYA FOUNDATION through its President, Ramon A. Pedrosa dated May 08, 2001, seeking the recall of the above Certificate of Product Registration on the ground that Levonorgestrel 750 mcg Tablet is abortifacient, hence, illegal under existing laws and the Constitution.

By way of antecedents, this Office received on 23 April 1999 an application for registration for Levonorgestrel 750 mcg. Tablet filed by EURO GENERICS INT'L. PHILS., INC., the drug's importer. Among the documents included in the application is the printed drug insert which reads as follows:

LEVONORGESTREL

DESCRIPTION
Each tablet contains 0.75 mg. Of Levonorgestrel ([d]-13-beta-ethyl-17-alpha-ethinyl-17-beta-hydroxygon-4en-3-one), a totally synthetic progestogen. The inactive ingredients present are lactose and starch.

CLINICAL PHARMACOLOGY Levonorgestrel (Gedeon Ritcher LTD-EGIP) is believed to act to prevent ovulation, fertilization and implantation. It is not effective once the process of implantation has begun.

INDICATION Levonorgestrel (Gedeon Ritcher LTD-EGIP) is an emergency contraceptive which can be used to prevent pregnancy if taken within 72 hours (three days) following unprotected intercourse or a contraceptive accident.

As an emergency contraceptive, Levonorgestrel (Gedeon Ritcher LTD-
EGIP) is indicated following any unprotected act of sexual intercourse, including:

When no contraception has been used
When a contraceptive method may have failed, including

- Condom rupture, slippage or misuse
- Diaphragm or cap dislodgement, breakage or early removal
- Failed coitus interruptus
- Miscalculation of periodic abstinence method
- IUD expulsion
- Missed regular oral contraceptive pills for three or more days in a cycle
- In cases of sexual assault

The drug is manufactured by Gedeon Richter Ltd. of Hungary. It is licensed to Schwarz Pharma and is distributed in the Philippines by Zuellig Pharma Corporation.

Following the standard evaluation and testing procedures provided in BFAD rules and regulations, Certificate of Product Registration No. DR-XY26140 was issued for Levonorgestrel 750 mcg Tablet (Postinor) on April 24, 2000.

x x x

Discussion

In its letter-complaint, ABAYPAMILYA states:

"Studies about Levonorgestrel reveal that it is an abortifacient. Levonorgestrel operates to prevent a fertilized ovum from implanting into the uterus and thus aborts a pregnancy that has already began. It may be noted that implantation of the human embryo takes place around the 6th day after fertilization, with the human embryo now being a multi-cellular structure known as a blastocyst."

Part I

The complaint dated May 8, 2001 included a paper written by JOHN WILKS (Annex "B" of letter-complaint) stating that "conception is the beginning of a pregnancy, taken to be the precise moment that a spermatozoon enters the female secondary oocyte, resulting in the formation of a viable human zygote."

The paper of WILKS cited the medical textbook of MOORE & PERSAUD which states that, "Human development begins at fertilization, the process during which a male gamete or sperm . . . unites with a female gamete or oocyte . . . to form a single cell called a zygote. This highly specialized, totipotent cell marks the beginning of each of us
as a unique individual."

Citing the WILKS paper, complainant goes on to say that, "abortifacient drugs or devices are defined as those whose action is operative after conception has occurred."

The meaning of conception and fertilization is, we believe, the key in determining the legality of the registration of Levonorgestrel 750 mcg. Tablet. Stated another way, the answer to the question -- "When does human life begin?" determines the answer to the final question -- "Is the action of Levonorgestrel in the woman's reproductive system directed against a new human being as to characterize the drug as abortifacient?"

FIRST, on the question of "When does human life begin?".

1. Dr. CORAZON T. LIM, M.D. of the Philippine Obstetrical and Gynecological Society (POGS) wrote this Office:

"When does life begin? Majority believe that life begins at fertilization."

DR. LIM cited an article entitled "Life Begins at Conception," by PAUL A. BYRNE, M.D. (Neonatologist, American Board of Pediatrics, Sub-Board of Neonatal Prenatal medicine of the American Board of Pediatrics) published in VITAL SIGNS, September-October 1993, where Dr. Byrne wrote:

"Many textbooks on human embryology state that a new human life begins at conception (See e.g. Langman, Medical Embryology, p. 3 (1963): 'The development of a new individual commences with fertilization.' Thomas, Introduction to Human Embryology, p. 52 (1968); 'Fertilization is significant in that new life is created . . .'; O'Rahilly, Developmental Stages in human Embryos, p. 9 n. 1; 'the initiation of new life occurs at that moment when fertilization is completed by fusion of the two sets of chromosomes.'

"I have never read a medical text or heard of any doctor writing or stating that what exists at conception is not a new human life."

She also cited DR. JEROME LEJEUNE, (Medical Doctor, Doctor in Science, Professor of Fundamental Genetics for over 20 years, and discoverer of the genetic cause of Down's syndrome) who had stated that it is important to understand the meaning of fertilization as the beginning of a human being.

2. NERISA CINCO-CALIMON of the Philippine College of Pharmaceutical Medicine referred to the textbook by MOORE & PERSAUD, The Developing Human: Clinically Oriented Embryology (pp 2-18) which states that "a zygote is the beginning of a new human being (an embryo). Human development begins at fertilization, the process during which a male gamete or sperm . . . unites with a female gamete or oocyte . . . to form a single cell called zygote."
3. The product licensee, SCHWARZ PHARMA PHILS. INC, does not go by the above definitions of conception/fertilization. Instead, it cited Emergency Contraceptive Pills: Medical and Service Delivery Guidelines (Consortium for Emergency Contraception, October 2000) wherein it is written:

"Data from studies of high-dose oral contraceptives indicate that the two ECP regimens described in these guidelines do not cause abortion; that is, they do not interrupt or damage a pregnancy, defined as beginning after implantation has occurred."

Grounded on such "definition" of pregnancy, it is the position of SCHWARZ PHARMA PHILS. that when Levonorgestrel acts to prevent implantation, as it admittedly does, there is nothing interrupted because prior to implantation, pregnancy has not begun, that is, no human life has begun to exist.

4. Central to the submission of ABAYPAMILYA FOUNDATION is a letter dated August 28, 2001 (Annex "A") addressed to this Office by Prof. Dr. DIANNE NUTWELL IRVING, M.D., M.A., Ph. D. of the United States (with Curriculum Vitae included.)

Dr. IRVING wrote:

"The major issue concerns when a new living human being begins to exist. Scientifically, there is no question whatsoever that this occurs at fertilization - in vivo, or in vitro. By the time of implantation, the living human embryo is approximately already 5-7 days old. This is not a 'religious', 'prolife', or subjective 'belief' or 'opinion', but rather it is an objective scientific fact that has been known scientifically for over a hundred years, e.g., with the publication of Wilhelm His' (the 'Father of Human Embryology'), Anatomie menschlicher Embryonen (Leipzig: Vogel, 1880-1885).

Dr. IRVING also cited MOORE & PERSAUD (6th ed.), "a zygote is the beginning of a new human being." She further cited LARSEN, Human Embryology (1997), "In this text, we begin our description of the developing human with the formation and differentiation of the male and female sex cells or gametes, which will unite at fertilization to initiate the embryonic development of a new individual . . ."; O'RAHILLY & MULLER, HUMAN EMBRYOLOGY & TERATOLOGY, "Fertilization is an important landmark because, under ordinary circumstances, a new, genetically distinct human organism is thereby formed. The ill-defined and inaccurate term pre-embryo . . . is not used in this book"; and CARLSON, HUMAN EMBRYOLOGY AND DEVELOPMENTAL BIOLOGY, (1994) which states in particular that, "Human pregnancy begins with the fusion of an egg and a sperm."

We note Dr. Irving's statement that "the scientific experts who are the experts on the issue of when a human being begins to exist, and on subsequent early human development from fertilization on, are human embryologists. Although many attempt to cast even the scientific issue in 'subjective' terms, it needs to be realized that in the science of human
embryology these scientific experts are professionally required to follow definitions of terms according to an International Nomina Embryologica Committee (INEC). This international committee meets every 3-5 years to examine, update and clarify which human embryological facts are scientifically demonstrated, accurate, and acceptable for human embryologists worldwide to employ in their own research, teaching and textbooks. In other words, these scientific definitions are not arbitrary, nor are they 'relative'. And among human embryologists globally there is 100% consensus on these objective scientific facts. If other scientists and physicians are not aware of these scientific facts, that is more a reflection of their lack of knowledge and/or credentials, rather than a reflection of any 'confusion' on these scientific facts."

5. Mr. JOHN WILKS, Pharmacist from Australia, as addressed to this Office a paper dated August 22, 2001 (Annex "B", with Curriculum Vitae) wherein he traces the historical perspective and origins of what he calls the "embryological error" which spawned the dissociation of conception from fertilization, and its re-association with implantation. He wrote:

The origins of this embryological error can be traced back to the text Obstetric-Gynecologic Terminology, published by the American College of Obstetrics and Gynecology (ACOG) in 1972.

In this text, conception was specified to be "the implantation of the blastocyst." Conception was not, according to this revised definition, one and the same with fertilization. Consequently, pregnancy was re-defined as "the state of a female after conception and until termination of the gestation."! As a consequence of this new definition, any interference with the viability of the human embryo, from the time of its creation until the time of implantation, was no longer an abortifacient action. According to this 'new' definition, no pregnancy (apparently) existed; hence no abortifacient actions are possible.

Having re-defined conception, which began the process of dismantling the continuum of fertilization, conception and pregnancy, a further reworking of pregnancy was initiated and approved at a meeting of the International Federation of Gynecology and Obstetrics (FIGO), in 1985. The Committee on Medical Aspects of Human Reproduction was asked by FIGO to "develop an accurate definition of pregnancy."

That --

As a consequence of the ACOG action in 1972, and the subsequent redefining of pregnancy in 1985, there has been an increasing trend in the deviations from definitional orthodoxy. Some examples of the re-defining of pregnancy are:

"The prevention of pregnancy before implantation is contraception and not abortion." 2 (Glasier 1997)
Mr. WILKS emphasized that --

These statements are, in the strictest sense of the word, non-sense. A woman is pregnant because fertilization has been completed and conception has occurred, not because implantation has taken place. Implantation is, from both a time and developmental perspective, separate to conception/fertilization. Implantation of the human embryo takes place around the sixth day after fertilization with the human embryo now a multi-cellular structure known as a blastocyst. As Mosby's correctly states: "Pregnancy - the gestational process, comprising the growth and development within a woman of a new individual from conception through the embryonic and fetal periods to birth.

I respectfully draw your attention to another example of meaning manipulation. Those who seek to promote postcoital birth control re-name the human embryo a "pre-embryo", a "fertilized ovum" or a "fertilized egg." Again, these are non-sense terms without any basis in science. They are ideological definitions only, fully in conflict with contemporary embryology. To recall: "Human development begins with fertilization, a process during which a sperm unites with an oocyte (ovum)." (Their emphasis). This distinction in terminology is critical. The full range of bioethical issues linked to the morning-after pill is centred upon this point.

This Office took time in going over the compendium of medical writings-standard textbooks and medical journals, including the submissions addressed to this Office by the above named resource persons both, Filipino and foreign authorities whose respective professional background in the medical and pharmaceutical community (See Curriculum Vitae, Annexes "A-1", "B-1" and "C-1") sufficiently qualify them to speak on this issue with authority. We likewise considered the paper cited by the SCWARZ PHARMA, product licensee.

This Office can only rely on the objective and scientific fact generally accepted in the medical profession that "life begins at conception and the moment of conception is when the ovum is fertilized by the sperm that there is human life." This fact was earlier recognized by the framers of the present 1987 Constitution, as gleaned from the Record of the Constitutional Commission (Vol. 4, p. 668, pointed out in Annex "B" of the letter of ABAYPAMILYA to the Secretary of Health dated May 08, 2001.) According to the Constitution:

"The State . . . shall equally protect the life of the mother and the life of the unborn from conception . . ." (Article II, Sec. 12)

thus, expressly recognizing the right to life from the moment of conception.

According to noted Constitutional authority, FR. JOAQUIN BERNAS, S.J. who was part of the 1986 Constitutional Convention:

"The intention is to protect life from its beginning, and the assumption is

Part II

With the above fact in correct perspective, we now consider the question of whether or not Levonorgestrel 0.75 mg. has an abortifacient action.

The drug insert submitted to this Office by the applicant, EURO GENERICS INT'L. PHILS., INC. indicates that Levonorgestrel inhibits implantation:

"CLINICAL PHARMACOLOGY
Levonorgestrel (Gedeon Ritcher LTD-EGIP) is believed to act to prevent ovulation, fertilization and implantation."

So does the product literature attached by SHWARZ PHARMA to its written submission to this Office:

"INDICATIONS
Levonorgestrel is an emergency contraceptive preparation that can prevent conception if it is taken within 72 hours following unprotected intercourse. It is a progestogen inhibiting the implantation of the ovum into the endometrium, stimulating the motility of the oviduct and increasing the viscosity of the cervical mucus."

We note that standard medical textbooks already refer to the anti-implantation effect of certain drugs. This is pointed out by Dr. IRVING as follows:

"It is also an objective scientific fact that the use of many 'contraceptives' can be abortifacient, including the 'morning-after pill', or 'emergency contraception', as stated by Moore (a member of the INEC9):


"Inhibition of Implantation: The administration of relatively large doses of estrogens ('morning-after pills') for several days, beginning shortly after unprotected sexual intercourse, usually does not prevent fertilization but often prevents implantation of the blastocyst. Diethylstilbestrol, given daily in high dosage for 5 to 6 days, may also accelerate passage of the dividing zygote along the uterine tube (Kalant et al., 1990.) Normally, the endometrium progresses to the secretory phase of the menstrual cycle as the zygote forms, undergoes cleavage, and enters the uterus. The large amount of estrogen disturbs the normal
balance between estrogen and progesterone that is necessary for preparation of the endometrium for implantation of the blastocyst. Postconception administration of hormones prevent implantation of the blastocyst is sometimes used in cases of sexual assault or leakage of a condom, but this treatment is contraindicated for routine contraceptive use..." (Annex "A", p. 3).

DR. CHRIS KAHLENBORN confirms these facts in his paper, *The Morning After Pill: Analysis of Mechanism of Action & Side Effects*, (Annex "C" and "C-1"). Dr. KAHLENBORN writes:

"All the evidence to date supports the contention that emergency contraception does not always inhibit ovulation and that it unfavorably alters the endometrial in regard to implantation. In addition, the reduced rates of observable pregnancy over the expected rates in women who receive hormonal EC in the ovulatory or post-ovulatory phase point to an abortifacient effect. Thus, the available medical evidence suggests that an abortifacient effect is likely one of the significant mechanisms by which EC reduces rates, even if given prior to ovulation."

So does Pharmacist, Mr. WILKS, as follows:

"...the levonorgestrel [LNG] approach clearly has an anti-developmental impact on the endometrium.

"Work by Kubba et al (1986) specifically referred to levonorgestrel, noting its ability to change "the nature" of the hormonal receptors within the endometrium. Dr Rabone (1990) reported that levonorgestrel caused a reduction in the number of estrogen and progesterone receptors within the endometrium. As Dr Rabone reported: "The concentration of these receptors is critical for the normal development of the endometrium to a stage that will support implantation.

"Simon and co-workers have also reported that altered estradiol/progesterone ratios (E2/P), which will occur with high doses of levonorgestrel, are associated with the impairment of endometrial receptivity." (Annex "B", pp. 8-9)

To us, what is of great concern is simple fact pointed out by Mr. WILKS that:

"...the levonorgestrel-only post-coital dose is equal to taking 40 to 50 standard once-a-daily progesterone-only birth control pills." (Annex "B", pp. 9-10).

The same facts were presented to us by local medical doctors who submitted their written responses to this Office:
1. The Philippine Obstetrical and Gynecological Society Foundation, Inc. (POGS):

"These potent progestogens such as Postinor do not prevent fertilization but inhibits implantation by decidualizing the endometrium rendering it non-receptive to implantation. In this case the so called Postinor is considered abortifacient."

2. The Philippine College of Pharmaceutical Medicine:

"Human development begins at fertilization, when a sperm unites with an oocyte to form a single cell, a zygote. A zygote is the beginning of new human being. When you prevent this new human being from being implanted in the uterus, pregnancy is terminated and ABORTION occurs.

"Postinor can therefore be considered as abortifacient. The use of abortifaciens is illegal and not allowed in the Philippines."

3. The Philippine Medical Association (PMA):

"It is the firm view of the PMA that intentional abortion is or assisted abortion directly or indirectly or in any manner whatsoever is criminal in nature. In view henceforth, condemns the use of drugs or medicines or any device for purposes of inducing abortion.

"Henceforth, if Postinor is indeed found to be abortifacient, then the PMA supports the call for recall and delisting from BFAD's registry of drug products."

The Consumer Act of the Philippines (RA 7394), one of the laws enforced by this Office, prohibits the importation of drugs which are dangerous to health. It states:

ART. 89. Mislabeled Drugs and Devices. -- A drug or device shall be deemed to be mislabeled:

i) if it is dangerous to health when used in the dosage, or with the frequency of duration prescribed, recommended or suggested in the labeling thereof;

ART. 15. Imported Products. --

a) Any consumer product offered for importation into the customs of the Philippine territory shall be refused admission if such product:

x x x 2) is or has been determined to be injurious, unsafe and dangerous.
ART. 18. Prohibited Acts. -- It shall be unlawful for any person to:

a) manufacture for sale, offer for sale, distribute in commerce, or import into the Philippines any consumer product which is not in conformity with an applicable consumer product quality or safety standard promulgated in this Act.

Conclusion

Even as this Office had notified interested parties and invited written submissions before resolving this issue pursuant to the procedural guidelines contained in Adm. Order No. 66, s. 1989, the same Administrative Order states in paragraph 2.3:

"2.3 -- This procedure of review and evaluation does not preclude however the BFAD from submitting a recommendation to immediately ban a drug and all products containing it in cases where there is a clear finding of serious or lethal toxicity constituting undue risk to public safety. In which cases, the BFAD shall submit its finding and recommendation, together with records of substantial evidence to the Secretary of Health for immediate action."

We therefore find that Levonorgestrel 750 mcg marketed as Postinor is not registrable in the Philippines. We recommend:

1. That Certificate of Product Registration No. DR-XY26140 dated April 24, 2000 issued to EURO GENERICS INT'L. PHILS., INC. be cancelled;

2. That the Department prohibit the further importation, use, dispensing, sale and distribution in the local market of Levonorgestrel 750 mcg - Postinor;

3. That all existing inventories of the drug in any warehouse, enclosure, pharmacy, whether public or private, be immediately reported and delivered to the Department, through the BFAD, for immediate proper disposition.

(SIGNED) WILLIAM TORRES, Ph. D.
Director (Sgd.) 1/10/01
BASED ON THE FOREGOING, THE ADMINISTRATION IS NOTIFIED that the contraceptive items named below contain the same active ingredient found in POSTINOR (LEVONORGESTREL):

- FAMILIA 28F (DR-XY35393)
- MIRENA (DR-XY25174)
- LOGYNON 21 (DR-XY9421)
- SEIF (DR-XY8804)
- MINIPIL (DRP-3738)
- JULIANNE (DRP-4297)
- LADY (DRP-337)
- DENISE (DR-XY40669)
- RUBY (DRP-2162)
- CHARLIZE (DRP-2063)
- TRUST PILL (DR-XY3601)
- FEMME (DR-XY37779)
- NORDETTE (DX-XY23241)

CONSIDERING THAT these contraceptive items carry the equivalent active ingredient found in POSTINOR which operates to be the primary catalyst in causing a series of biological events in a woman’s body to operate as an abortifacient, the Administration is hereby notified of the imminent abortifacient operations of the foregoing contraceptive items.

CONSIDERING FURTHER THAT the Administration’s recommendations against POSTINOR have not been challenged nor revoked, the application of the precautionary principle is most appropriate in this matter considering that the Constitution protects the life of the unborn from the moment of conception which refers to the moment of fertilization (IMBONG V. EXECUTIVE SECRETARY, G.R. No. 204819)

II. IS THERE ANY INFORMATION INDICATING THAT ANY OTHER OF THESE LISTED CONTRACEPTIVE ITEMS OPERATE AS AN ABORTIFACIENT?

Abortifacient operation of the Intra-uterine Devices (IUD) MIRENA (DR-XY25174)

THE ADMINISTRATION IS NOTIFIED OF medical journals and related literature, which describe the abortifacient action of the IUD, such as:

“The Pill and the IUD: Some Facts for an Informed Choice”
Published by The Couple to Couple League
Cincinnati, Ohio
“The IUD does little or nothing to interfere with sperm migration or fertilization (conception). It achieves its birth control effect primarily by preventing the newly conceived human life from implanting in the uterine lining (endometrium) and is thus an abortifacient.  x  x  x

Most scientists would now accept that the effect [of the IUD] in most species, including man, is exerted at implantation.  x  x  x “\(^1\)

In the light of current, accepted medical definitions of contraception, abortifacient, pregnancy, conception, and abortion, the conclusion is that the primary action of the IUD must be classed as abortifacient.  x  x  x “\(^2\)

“An Evaluation of Intrauterine Devices”
By Thomas W. Hilgers
Human Life Center
Collegeville, Minnesota

“Present knowledge indicates that the mechanism of action of the IUD on the endometrium, myometrial activity, and the intrauterine biochemical and biological milieu is destructive in nature; under these conditions the blastocyst is unable to survive.  x  x  x

“New Insights on the Mode of Action of Intrauterine Contraceptive Devices in Women”
By Alvarez, MD, Brach, MT, Fernandez, MD, Guerrero, MD,
Fertility and Sterility, Vol. 49, No. 5, May 1988, The American Fertility Society

“Fertilized ova are less likely to reach the uterine cavity containing an IUD  x  x  x

“Since numerous studies have shown profound alterations of the human endometrium during IUD use, a widely accepted concept is that a preimplantation embryo entering such environment is unlikely to survive.”

CONTRACEPTIVE TECHNOLOGY UPDATE
August 1997 Supplement

“WHAT IS the Copper T IUD? An IUD is a small device which is placed into the uterine cavity. In the vertical and horizontal arms of the Copper T 380A IUD there is some copper. The IUD slowly gives off copper into the uterine cavity. Copper stops sperm from making their way

---


up through the uterus into the tubes. **Copper would also stop a fertilized egg from successfully implanting on the lining of the uterus if fertilization occurs.**

**ParaGard ®**
**Intrauterine Copper Contraceptive Model T 380A**
*Patient Information for an Informed Decision p. 4-7*

**“Special Risk Factors**

**Special Risk Factors for Pelvic Infection**

**Special Risk Factors for Ectopic Pregnancy**

The following adverse reactions have been reported and may be caused by the ParaGard:

- Abdominal infection or adhesions
- (scar tissue)
- Anemia
- Backache
- Bowel Obstruction
- Cervical infection or erosion
- Cysts on ovaries and tubes
- Death
- Delayed menstruation
- Difficult removal
- Ectopic pregnancy
- Embedment (IUD surrounded by uterine tissue)
- Expulsion
- Fainting and pain at the time of insertion or removal
- Fragmentation (breakage) of the ParaGard
- Spotting between periods
- Miscarriage
- Pain and cramps
- Painful intercourse
- Pelvic infection (PID), which may result in surgical removal of your reproductive organs, including hysterectomy
- Perforation of the uterus or cervix
- Pregnancy
- Prolonged or heavy menstrual flow
- Infected miscarriage followed, in some cases, by blood poisoning, which can lead to death
- Vaginal discharge

**“The Birth Control Game: GAMBLING WITH LIFE”**
*By David Sterns, MD, Gina Sterns, RN, BSN, and Pamela Yaksich*
*With documentations by Pharmacists for Life*

“The primary mechanism of Intrauterine Devices (IUDs) is abortifacient (abortion inducing). While they may occasionally prevent conception (i.e. fertilization; that is, where the egg and the
sperm unite in the fallopian tube), this is not the main mechanism of action. When conception occurs, the fertilized egg (a new human being by every medical and biblical definition) arrives in the uterus 6 to 10 days later. If an ID\UD is in place, this tiny human encounters a hostile uterine environment and is unable to implant itself into the uterine wall. Thus, he or she is aborted—the IUD has caused the death of this new life in the uterus.

THE ADMINISTRATION IS FURTHER NOTIFIED that the abortifacient action of MIRENA Levonorgestrel is NOT DENIED by its Philippine distributor.

The drug insert of MIRENA Levonorgestrel IUD reads:

“The local mechanism by which continuously released levonorgestrel enhances contraceptive effectiveness of the IUS has not been conclusively demonstrated. Studies of MIRENA\® prototypes have suggested several mechanisms that prevent pregnancy: thickening of cervical mucus preventing passage of sperm into the uterus, inhibition of sperm capacitation or survival, and alteration of the endometrium.”

ON THIS POINT, THE ADMINISTRATION IS FURTHER REMINDED of the pronouncement of the Supreme Court in Imbong v. Executive Secretary (G.R. No. 204819):

“[The] RH Law mandates that protection must be afforded from the moment of fertilization. By using the word "or," the RH Law prohibits not only drugs or devices that prevent implantation, but also those that induce abortion and those that induce the destruction of a fetus inside the mother's womb. Thus, an abortifacient is any drug or device that either:

(a) Induces abortion; or
(b) Induces the destruction of a fetus inside the mother's womb; or
(c) Prevents the fertilized ovum to reach and be implanted in the mother's womb.” (Emphasis supplied)

In further support of our submissions on this matter, we submit along with this letter a copy of the book “A CONSUMER'S GUIDE TO THE PILL AND OTHER DRUGS" by John Wilks.

Respectfully submitted.

(original signed)
Ms. Lorna B. Melegrito
Pro-life Philippines Foundation, Inc.
Copy furnished:

Petitioners in the RH Law cases: VIA EMAIL
SPouses James and Lovely-Ann C. Imbong
Alliance for the Family Foundation Philippines, Inc.
Task Force for Family and Life Visayas, Inc.
Serve Life Cagayan de Oro, Inc.
Expedito A. Bugarin, Jr.
Eduardo B. Olague
Philippine Alliance of XSeminarians, Inc.
Doctors for Life
Spouses Francisco and Maria Fenny C. Tatad
Millennium Saint Foundation, Inc.
John Walter B. Juat
Couples for Christ Foundation, Inc.