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19 March 2015

Dr. JANETTE L. GARIN

Secretary-Designate, Department of Health
Sta. Cruz, Manila

Atty. NICOLAS B. LUTERO III, CESO III

Assistant Secretary of Health
OIC, Food and Drug Administration
Civic Drive, Filinvest Corporate City
Alabang, Muntinlupa City

Ms. MARIA LOURDES C. SANTIAGO, MSc, MM

Officer-in-Charge
Center for Drug Regulation and Research
Civic Drive, Filinvest Corporate City
Alabang, Muntinlupa City

Subject: **FDA CERTIFICATION OF CONTRACEPTIVE DRUGS
AND DEVICES UNDER THE RH LAW DECISION**

Dear Secretary Garin, Assistant Secretary Lutero, and Ms. Santiago:

I write on behalf of and as President of the Alliance for the Family Foundation Philippines, Inc. (ALFI). ALFI is a multi-sectoral organization committed to preserve and promote human life, marriage and family through sustained and vigilant effort. ALFI was a petitioner in one of the cases filed with the Supreme Court questioning the constitutionality of the RH Law.¹

This is on a matter of utmost importance – every Filipino’s right to life and right to health, as explained by the Supreme Court in its Decision on the RH Law (hereafter, the “RH Law Decision”).²

On October 08, 2014, in response to an invitation in the Food and Drug Administration (FDA) website, Alliance for the Family Foundation Philippines, Inc. (ALFI) filed its Preliminary Opposition to all the fifty (50) Applications for Re-Certification/Re-Evaluation filed by various pharmaceutical companies with the FDA. Our Preliminary Opposition was also directed against the twenty-seven (27) other contraceptive drugs

¹ G.R. No. 204934

² Consolidated cases of *Imbong, etc. vs. Hon. Ochoa, Jr., etc.* (G.R. No. 204819, 204934, 204957, 204988, 205003, 205043, 205138, 205478, 205491, 205720, 206355, 207111, 207172, 207563).



and devices that had existing FDA registrations³ but were not subject of any application for re-certification. ALFI's Preliminary Opposition was supported by voluminous reference materials annexed thereto as Volumes 1 and 2 all pointing to the conclusion that the listed contraceptive drugs and devices are all 'abortifacient' as the term is defined under the RH Law. It was then referred to the Center for Drug Regulation and Research (CDRR) with Reference/Tracking No. 20141008142055.

On November 24, 2014, ALFI filed seventy-seven (77) Individual Oppositions to each contraceptive drug/device previously registered by the FDA, including those subject of the applications for re-certification/re-evaluation. Each opposition was assigned a tracking number. Please see attached.

In a letter dated December 10, 2014 signed by Ms. Maria Lourdes C. Santiago, she acknowledged receipt on November 24, 2014 of all the 77 Individual Oppositions of ALFI.

To date, no public hearings or consultations on the Applications for Re-Certification and ALFI's Oppositions have been held and we are kept in the dark as to the real status of our Oppositions vis-à-vis the Applications.

In the meantime, there are disturbing newspaper reports that a team headed by the Department of Health conducted the implantations of Implanon in Cebu City in late February of this year. One such report said that "MORE than 200 mothers from 20 different barangays in Cebu City received a free implant yesterday morning from a team of medical experts from Manila."⁴

In another news article, Secretary Garin was quoted to have admitted and, in fact, defended the conduct of such implantations.⁵

Various calls made to the Center for Drug Regulation and Research of the FDA elicited information that certain contraceptive drugs and devices have been re-certified and new ones have been registered.

At this juncture, while you must be fully aware of the RH Law Decision and the imperatives on the government and on FDA that it contains, may we nonetheless state its salient points that have been disregarded, ignored and violated by your offices, officers and employees. As defined by the RH Law, "any drug or device that induces abortion, that is, which kills or destroys the fertilized ovum or prevents the fertilized ovum to reach and be implanted in the mother's womb, is an abortifacient." And pursuant to the RH Law's declared policy of providing access only to safe, legal and non-abortifacient contraceptives, "any product or supply included or to be included in the EDL (Essential Drugs List) must have a certification from the FDA that said product and supply is made available on the condition that *it cannot* be used as abortifacient." Therefore, contraceptives to be included in the PNDFS (Philippine National Drug Formulary System) 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

³ Per FDA website as of October 08, 2014

⁴ Sun Star Cebu, February 27, 2015. Attached is a photocopy.

⁵ Panay News, March 16, 2015. Attached is a photocopy.



womb, but also those that do not have the *secondary action* of acting the same way.” And this inclusion “becomes operative only after they have been tested, evaluated, and approved by the FDA” using the constitutional yardsticks thoroughly and extensively explained by the Supreme Court.

Recognizing the gravity of the consequences of distributing or making available to the public contraceptive drugs and devices, the Supreme Court issued a warning that “a heavy responsibility and burden are assumed by the government in supplying contraceptive drugs and devices, for it may be held accountable for any injury, illness or loss of life resulting from or incidental to their use.”

We, therefore, request your good offices to shed light on the status of the Applications for Re-Certification/Re-Evaluation and the Oppositions thereto.

Specifically, may we request your good offices —

[i] To provide us with certified true copies of the Certificates of Product Registration issued by the FDA and the complete list of contraceptive drugs and devices that have been re-certified and re-evaluated, as well as those that have been registered, for our guidance, if indeed the Applications for Re-Certification and Re-Evaluation have been granted and new registrations have been done;

[ii] To reconsider, cancel, and withdraw any and all Re-Certifications of the drugs and devices subject of our oppositions, as well as any Registrations made, and to prohibit in the meantime the sale, distribution, administration and use of the same;

[iii] To conduct public hearings/consultations on the Applications and Oppositions, the matter being impressed with great public interest; and

[iv] To refrain from procuring or pursuing the procurement of contraceptive drugs and devices in the meantime.

In light of the foregoing, please be informed that ALFI stands committed to pursue its advocacy for life and family and to this end, it will do everything within the purview of the law to promote and defend it, including the filing of criminal, civil and administrative actions against officers, employees and agents of government and government agencies responsible for the purchase, manufacture, distribution, sale, or administration of contraceptive drugs and devices. Damage suits for any injury, illness or loss of life resulting from or incidental to the use of contraceptive drugs and devices will also be filed.

We trust you will favorably act on our request and appeal and we look forward to receiving your reply within 15 working days from receipt hereof.⁶

Very truly yours,


Atty. MARIA CONCEPCION S. NOCHE
President, ALFI

⁶ Republic Act No. 6713



Copy furnished:

1. **Dr. NEMESIO GAKO**
Undersecretary, DOH

2. **Dr. VICENTE BELIZARIO, JR.**
Undersecretary, DOH

3. **Dr. ELMER G. PUNZALAN**
Assistant Secretary of Health
Office for Health Regulation
Sta. Cruz, Manila

4. **Dr. PAULINE UBIAL**
Assistant Secretary, DOH

5. **Dr. GERARDO BAYUGO**
Assistant Secretary, DOH

6. **Dr. MELISSA GUERRERO**
Program Manager
National Center for Pharmaceutical Access & Management
Department of Health
DOH EXECOM



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



CENTER FOR DRUG REGULATION AND RESEARCH

10 December 2014

Atty. Maria Concepcion S. Noche
President and Legal Counsel
ALLiance for the FAMILY Foundation Philippines, Inc.
Unit 206, Southgate Building, Finance Drive
Madrigal Business Park, Ayala Alabang
Muntinlupa City

Subject: Opposition to Application for Re-certification/ Re-evaluation

Dear Atty. Noche,

This is to acknowledge receipt of your opposition to application for re-certification/ re-evaluation of the following products filed with this Office last 24 November 2014:

Document Tracking No.	Product
20141124162106	NUVARING; Registration No. DR-XY30809
20141124162105	MINULET; Registration No. DR-XY7175
20141124162104	DB-10; Registration No. DRP-4426
20141124162103	NORDIOL; Registration No. DR-XY20610
20141124162102	AZUL; Registration No. DRP-2063-01
20141124162101	TRUST PILL
20141124162100	DEPO-GESTIN; Registration No. DRP-3643
20141124162059	FAMILA 28F; Registration No. DR-XY35393
20141124155732	CHLOE; Registration No. DRP-2496
20141124155731	DENISE; Registration No. DR-XY40669
20141124155730	ESTRELLE PLUS; Registration No. DR-XY40787
20141124155729	LOGYNON; Registration No. DR-XY9421
20141124155728	LIZA; Registration No. DRP-3751
20141124155727	ESTRELLE; Registration No. DR-XY40817
20141124155726	MEGESTRON; Registration No. DR-XY37692
20141124155725	GENERIC ETHINYLESTRADIOL + LEVONORGESTREL Registration No. DRP-610
20141124155724	FEMENAL; Registration No. DR-XY23240
20141124155723	GENERIC LYNSTRENOL; Registration No. DRP-2439
20141124153431	PROVESTIN; Registration No. DR-XY32846
20141124153430	PROVERA; Registration No. DR-XY22549
20141124153429	NORDETTE; Registration No. DR-XY23241
20141124153428	ORETAS; Registration No. DR-XY32035
20141124153427	MARVELON 28; Registration No. DR-XY2299
20141124153426	IMPLANON; Registration No. DR-XY27500



Document Tracking No.	Product
20141124153425	SAFE PILL; Registration No. DR-XY38579
20141124153424	MERCILON; Registration No. DR-XY21633
20141124153423	SEIF; Registration No. DR-XY8804
20141124153422	YAZ; Registration No. DR-XY34970
20141124151450	GRACIAL; Registration No. DR-XY26961
20141124151449	IMPLANON NXT; Registration No. DR-XY41412
20141124151448	EXLUTON; Registration No. DR-XY18077
20141124151447	NORFEM; Registration No. DR-XY38516
20141124151446	DB-5; Registration No. DRP-4428
20141124151445	AMBER; Registration No. DRP-2088-01
20141124151444	CHARLIZE; Registration No. DRP-2063
20141124151443	MICROPIL; Registration No. DR-7745
20141124151442	GENERIC DESOGESTREL; Registration No. DR-XY40822
20141124151441	ALTHEA; Registration No. DRP-339
20141124145229	DEPO-GESTIN; Registration No. DR-XY39023
20141124145228	LIZONYA; Registration No. DRP-3750
20141124145227	PROTEC; Registration No. DR-XY38297
20141124145226	MICROPIL PLUS; Registration No. DR-XY34401
20141124145225	RUBY; Registration No. DRP-2162
20141124145224	YASMIN; Registration No. DR-XY28181
20141124145223	ANCEA; Registration No. DR-XY38043
20141124145222	NICOLE; Registration No. DRP-2265
20141124144334	CERAZETTE; Registration No. DR-XY27146
20141124142520	FEMME; Registration No. DR-XY37779
20141124142511	GENERIC MEDROXYPROGESTERONE ACETATE Registration No. DR-XY30830
20141124142502	JULIANNE; Registration No. DRP-4297
20141124142452	DAPHNE; Registration No. DRP-2088
20141124142443	LADY; Registration No. DRP-337
20141124142424	PRIMOLUT N; Registration No. DR-4277
20141124142416	EVRA; Registration No. DR-XY29785
20141124141444	ESTELLE
20141124141443	GENERIC LYNESTRENOL; Registration No. DRP-2439
20141124141442	CONTROLLE; Registration No. DR-XY19742
20141124141441	CYBELLE; Registration No. DRP-4439
20141124141440	SOPHIA; Registration No. DRP-2802

Document Tracking No.	Product
20141124141439	NORIFAM; Registration No. DR-XY35422
20141124141438	DOPEREVA; Registration No. DR-XY32977
20141124141437	DEPOFEMME; Registration No. DR-XY40409
20141124131727	LEILA; Registration No. DRP-2138
20141124131726	DAPHNE
20141124131725	CRIMSON; Registration No. DRP-339-01
20141124131724	LYNDAVEL; Registration No. DRP-338
20141124131723	DEPOTRUST; Registration No. DR-XY34137
20141124131722	MELIANE; Registration No. DR-XY25428
20141124131721	MINIPIL; Registration No. DRP-3738
20141124130142	DIANE; Registration No. DR-XY6690
20141124130141	GENERIC ETHINYLESTRADIOL + LEVONORGESTREL; FERROUS FUMARATE Registration No. DR-XY34556
20141124130140	GENERIC ETHINYLESTRADIOL + LEVONORGESTREL; FERROUS FUMARATE Registration No. DRP-970
20141124130139	GYNERA; Registration No. DR-XY25163
20141124130138	QLAIRA; Registration No. DR-XY38455
20141124130137	SAFE PILL; Registration No. DR-XY38580
20141124130136	MIRENA; Registration No. DR-XY25174
20141124125755	BLUSH

Thank you.

Very truly yours,

Maria Lourdes C. Santiago
MARIA LOURDES C. SANTIAGO, MSc, MM
 OIC, Center for Drug Regulation and Research

Tracking No. : 20141210143352
 129/225



20141210143352

Friday, February 27, 2015

Gov't introduces new contraceptive in Cebu

MORE than 200 mothers from 20 different barangays in Cebu City received a free implant yesterday morning from a team of medical experts from Manila.

The implant, known as Implanon, is a "rod-looking" contraceptive that will prevent pregnancy within three years.

Dr. Jovith Indal, family planning head in Central Visayas, said that among the side effects of the medicine is a headache for the first three days following the procedure.

She also warned against abnormality in the menstruation period.

The team from Manila and representatives from the Department of Health 7, Department of Interior Local and Government 7, Department of Education 7, Population Commission (PopCom) 7 and the Philippine Health Insurance Corp. 7 conducted the implantation for the first time in Cebu City yesterday.

Mothers

The mothers went to the Barangay Tinago gym on MJ Cuenco Ave., Cebu City yesterday.

"Likayan nga masundan dayon kay lisud pud ang panahon. Usa pud ana ang financial ug sa imu pung health. (I'm avoiding another pregnancy because of the difficult times. I'm doing this for financial and health reasons)," said Arlene Minya of Barangay Lorega, one of the mothers who availed of the procedure.

"The medicine is not meant to decrease the childbirth rate in Cebu City. Instead, it's a choice of a mother to get pregnant or not," said Atty. Bruce Ragas, PopCom 7 director.

Free

Ragas said that the distribution of free Implanon helped those who cannot afford the procedure because it's expensive when done in private medical facilities.

The procedure costs between P8,000 and P12,000.

The medical team assured the mothers that the procedure is safe as it was approved and evaluated by the DOH.

According to the official Implanon website (<http://www.implanon-usa.com>), an Implanon is a flexible plastic rod about the size of a matchstick that contains a progestin hormone called etonogestrel, which helps prevent pregnancy.

The website advises mothers with Implanon to have it removed after three years. **(Gizelle Onrejas, AB Comm Intern, Naval State University)**



'4Ps MOTHERS GUINEA PIGS'

March 16, 2015

ILOILO City – Mothers who received contraceptive implants from the Department of Health (DOH) were not informed of the potential adverse effects, claimed two doctors.

The mothers were mostly beneficiaries of the Pantawid Pamilyang Pilipino Program (4Ps), according to Dr. Rene Josef Bullecer, country director of Human Life International (HLI) Pilipinas, and Dr. Dolores Octaviano, advocacy chair and president of Doctors for Life Philippines (DFLph).

“Mga nanay ng Pilipinas, ginawa kayong guinea pigs ng DOH including ng PopCom (Population Commission),” said Bullecer.

There were implantations of the intradermal contraceptive Implanon in Cebu and Bohol, according to Bullecer.

He and Octaviano claimed to have interviewed some of these women.

They were not informed of the adverse effects which may include increased chance of serious blood clots resulting in deep vein thrombosis, pulmonary embolism, retinal thrombosis, stroke, heart attack and death, said the two doctors.

Side effects may also include headache, joint pain, sore throat, trouble sleeping, breast pain and chills, they added.

According to Bullecer, some women complained of side effects and asked that their implants be removed. Unfortunately, he said, they were denied because the implants could only be removed after three years.

Bullecer advised mothers to make sure they are given a lecture about the contraceptives, and that they secure an agreement that the implants can be removed anytime, with the DOH providing assistance and compensation in case of adverse effects.

“We call for transparency. Tell them the truth about the side effects. This is deception and that hurts,” said Octaviano. She claimed knowing five patients from Iloilo province with similar complaints.

IMPLANON AND GARIN

According to its official website, Implanon is a “hormone-releasing birth control implant for use by women to prevent pregnancy for up to three years.”

The implant is a flexible plastic rod about the size of a matchstick and contains a progestin hormone called etonogestrel.”

Newly-appointed Health secretary Janette Garin told Panay News it is “highly unlikely” that these implants were done without the women’s consent.

“Let me check but ang implant insertion is very thorough. May counselling ina ya, may clearance, may verification and in fact may pregnancy test pa prior. Highly impossible and improbable nga wala consent. The consent is attached before the doctor inserts an implant,” she said.

Aside from the consent, she added, identification stickers, control numbers and the name of the patient were also attached.

Garin said if the two doctors can give names of patients who were not informed, she will check on what actually transpired.

She also denied that DOH refuses to remove the implants before three years. "It depends on the patient. If you want to remove it earlier, you can have it removed. The maximum effectively is up to three years. Some mothers had it taken out after two years kun gusto na nila magbusong," said Garin.

"If the patient proves nga nagka-heart attack sila, we will look into the case. But (Implanon) has been in the market for several years," she added.

In Iloilo, Implanon had been available for about eight years already, said Garin. But because of its prohibitive price, only patients of private doctors could mostly afford it.

Implanon used to cost P12,000 but now the price had dropped to between P5,000 to P8,000. Through rural health units, however, DOH makes it free.

"It will be made available through rural health centers and government hospitals and to be inserted by trained doctors. Doctors from the University of the Philippines Manila, Philippine General Hospital and Dr. Jose Fabella Memorial Hospital are the ones going around training our doctors," said Garin.

'UNCONSTITUTIONAL'

HLI and DFLph claimed the implants act as an abortifacient because it changes the lining of the uterus, making it impossible for a fertilized egg to take hold.

Implanon and the Responsible Parenthood and Reproductive Health Act of 2012 are unconstitutional because they violate Article II, Section 12 of the 1987 Constitution which recognizes the "...the sanctity of family life...the life of the mother and the life of the unborn from conception," said Bullecer.

He urged mothers who have the implants but did not give informed consents or were refused to have the implants removed to get a lawyer and file complaints.

Officials of the Department of Social Welfare and Development Region 6 could not be reached for comment as of this writing./PN