



American Life League, Inc.

Before I formed you in the womb, I knew you... Jeremiah 1:5
Total Protection For All Innocent Human Beings!

Testimony

Thursday, June 29, 2000

Food and Drug Administration
Gaithersburg, Maryland

Re: Regulation of OTC Products
Focus: birth control pills

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00N-1256

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Ladies and Gentleman, I am Judie Brown, president of American Life League, Inc (ALL). 375,000 American families support ALL. Our international headquarters are located in Stafford, Virginia. Our goal as an educational non-profit is the protection of every single human being from the time his or her life begins at conception/fertilization. Thank you for the opportunity to speak with you this morning on a critically important question: whether or not the birth control pill should become an over-the-counter drug.

American Life League's ultimate concern is that the past performance of the Food and Drug Administration (FDA) on the critical life and health questions involving the birth control pill indicate a lack of appropriate oversight, not to mention honesty in requiring pharmaceutical firms to label the Pill accurately.

The record is clear: for the past 35 years the FDA has worked diligently to collaborate with pharmaceutical firms and population control ideologues for the purpose of constructing new definitions for pregnancy, personhood and abortion. Additionally, from the beginning, the FDA turned a blind eye to the potential for serious health hazards; dangers the Pill did and does pose to all women of childbearing age.

Internal FDA communications dating back to 1960 indicate that the Pill was deemed safe, even though rigorous opposition to such a determination existed. And the initial declaration of safety was based, according to authors Robert G. Marshall and Charles Donovan, on a sampling of less than 140 women, none of whom were teens.¹ To this day, as a matter of fact and record, there have been no long-range clinical studies done involving thousands of women to discern whether or not a female who began using the pill in her mid-teens suffers deleterious affects to her health and well being.

¹ "Blessed are the Barren," Robert Marshall and Charles Donovan, page 214, Ignatius Press, 1991 ("Thus, on the basis of 132 of 897 women who used the Pill for a relatively short period of time, a powerful oral steroid unique in the history of medicine was pronounced safe and beneficial for all women of childbearing age.").

Though it is certainly true that the composition of the Pill itself has changed over these past 40 years, the health hazards for women remain real. Most recently, as you know, *The Lancet* medical journal published a study by the New Zealand Ministry of Health indicating that over the past 10 years, 20 women have died of pulmonary embolism. The research suggests that for every 10 thousand women taking oral contraceptives, one a year will die. And the study suggests that the risk is twice as high for women who are taking third generation pills.²

William F. Colliton, M.D., noted obstetrician/gynecologist, has repeatedly pointed out that the evidence continues to build that "American women are experiencing an epidemic of breast cancer, so that today one in eight females is expected to encounter this disease during the course of her lifetime. In my opinion this is an iatrogenically³ induced problem. My confreres have yielded to the *estrogens forever* pitch and prescribed BCP's for the 10.4 million American women now using these products for contraception. Incidentally, the BCP, to the best of my knowledge, is **the only drug in the PDR prescribed for perfectly healthy women to thwart their normal fertility**, a goal which can be accomplished in several other ways without side effects."⁴

In other words, the Pill is a potentially dangerous chemical compound for women, and is deadly for human beings starting their lives in utero. Which brings me to the next point of concern regarding the *honesty in labeling* requirements of the Food and Drug Administration. In fact, when it comes to the birth control pill, it is clear there are no such requirements.

Human embryology teaches beyond a reasonable doubt that a human being begins at conception (fertilization) when the sperm and the egg unite. That new individual zygote (a.k.a. a human being, a person) is not his mother, not his father, but a distinctly different human being with his own

² Parkin, et al., "Oral contraceptives and fatal pulmonary embolism," *The Lancet*, 355:6/17/00:2133-2134.

³ IATROGENIC - A secondary condition that is caused by the treatment of a primary condition. A condition that results from the administration of medical care.

⁴ Letter to Christine Hikawa, Vice President, ABC Inc from William F. Colliton, M.D., FACOG, 4/30/00.

unique DNA. This is evidenced in many scientific studies and textbooks. It is a fully documented, irrefutable fact.⁵

That being the case, one would have expected the Food and Drug Administration to explain in detail that the birth control pill may chemically abort the person whose life begins at conception. A warning should have been posted on all birth control pill package inserts, from the very first such insert. None has been evidenced, however, even though women have a right to know, in plain English, that the pill they are about to ingest may kill a baby whose life has already begun.

The **political definition** of pregnancy as a process alleged to begin at implantation⁶, five to seven days after it actually has begun at conception, has affected the FDA's attitudes regarding the various drugs and devices over which it has authority. This is why the FDA has failed to be totally honest with American women regarding the manner in which the Pill kills the embryonic person, not to mention the manner in which the Pill can work to jeopardize the female's health, if not life itself.

In one volume alone more than 500 clinical citations exist pointing the various concerns I have raised today regarding the birth control pill.⁷

Such readily available clinical and scientific evidence is sufficient to place the FDA in the position of

- (a) belatedly requiring that all birth control pills carry a warning regarding the potential the Pill has to kill the embryonic human being,
- (b) emphasizing the risks in a way that promotes far greater discussion between the physician and his patient prior to the first prescription even being written, and

⁵ Dianne Nutwell Irving, MA, Ph.D., "When do human beings begin?" <http://www.all.org/abac/dni003.htm>.

⁶ A Declaration of Life by Pro-life Physicians, signed by more than 200 practicing physicians in the USA, distributed by American Life League Inc.:

"Whether eventual control of implantation can be reserved the social advantage of being considered to prevent conception rather than to destroy an established pregnancy could depend upon something so simple as a prudent habit of speech;" Bent Boving, 1963.

⁷ John Wilks, B. Pharm, M.P.S., "A Consumer's Guide to the Pill and Other Drugs," 565 pages, National Book Store Inc., Third revised edition, 2000.

(c) immediately ceasing considerations of the Pill ever being an over-the-counter drug.

Therefore American Life League calls upon you today to withdraw the Pill from consideration as an over-the-counter drug. That is the very least the FDA can do. Thank you.