

is fraught with dangers."<sup>15</sup> But such warnings did not impede approval.

On April 22, 1960, Dr. Pasquale DeFelica, assistant chief of the FDA's New Drug Branch, sent G. D. Searle and Company a letter approving the marketing of Enovid for contraceptive purposes.<sup>16</sup> In a May 11, 1960, memo to FDA commissioner George Larrick, William P. Kesserich (FDA) wrote, "We have concluded that the drug is safe."<sup>17</sup> The conclusion was based on tests of 897 women who had used the Pill for 10,427 cycles. However, only "sixty-six patients have taken Enovid for twenty-four cycles or more to thirty-eight and an additional sixty-six women have continued medication for twelve or more cycles to twenty-one."<sup>18</sup>

This small sample providing the margin of supposed safety was kept from the public until the Kesserich memo surfaced in the course of Senate subcommittee hearings in 1962 and 1963.<sup>19</sup> Even then the revelation was practically ignored by the media.<sup>20</sup>

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.

The previously hesitant Guttmacher, then chairman of PPFA's medical committee, became an eager convert. He wrote that it was "safe and proper to include these compounds in the armamentarium of medically prescribed contraceptives."<sup>21</sup> Much press publicity followed, along with hard-sell tactics from the drug industry.

For example, Searle urged its sales people to avoid any mention of side effects like cancer and nausea and to "make the doctors want to use" Enovid by portraying it as "the most effective contraceptive known to man."<sup>22</sup>

The Pill helped ensure the power, prestige, and profits of both Planned Parenthood and the drug companies. Supporters of the Pill followed a simple but effective strategy.

First, they created a pill-taking habit without apparent concern about how

<sup>15</sup> Alan Guttmacher and Hilliard Dubrow, "The Present Status of Contraception," *Journal of the Mt. Sinai Hospital*, vol. 26, no. 2 (March-April 1959): 124.

<sup>16</sup> Letter of Pasquale DeFelica to William Grassen of G.D. Searle and Co., April 22, 1960, Food and Drug Administration, Public Affairs Office, files.

<sup>17</sup> Senate Select Committee on Small Business, Subcommittee on Monopoly, *Competition Problems in the Drug Industry*, pt 17, app. 15, 91st Cong., 2d sess., 1970, 7323.

<sup>18</sup> *Ibid.*

<sup>19</sup> Morton Mintz, *The Therapeutic Nightmare* (Boston: Houghton Mifflin, 1965), 276-78.

<sup>20</sup> Morton Mintz, "The Pill—Press and Public at the Expert's Mercy," *Columbia Journalism Review*, Spring 1969, 4-16.

<sup>21</sup> Quoted in *Planned Parenthood News*, PPFA no. 28, Fall 1966, 1.

<sup>22</sup> Senate Select Committee on Small Business, Subcommittee on Monopoly, *Competition Problems in the Drug Industry*, pt 15, app. 15, 91st Cong., 2d sess., 1970, attachment to J. Harold Williams testimony, 6268-71.

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<sup>23</sup> Dr. John Rock, 79-81, 86.

<sup>24</sup> Alan Guttmacher (February 1966): 67-

<sup>25</sup> Herbert Ratner, (1973): 98-99.

<sup>26</sup> *Ibid.*

<sup>27</sup> *Ibid.*; see also, P sponsored by G. D. S

BLESSED ARE THE BARREN

The Social Policy of Planned Parenthood

By  
Robert G. Marshall  
and  
Charles A. Donovan

1991

IGNATIUS PRESS    SAN FRANCISCO

## Research letters

## Oral contraceptives and fatal pulmonary embolism

Lianne Parkin, David C G Skegg, Meg Wilson, G Peter Herbison, Charlotte Paul

See Commentary page 2088

In a national case-control study of fatal pulmonary embolism in New Zealand women of childbearing age, we estimated that current users of combined oral contraceptives had a relative risk of 9.6 (95% CI 3.1–29.1). From national distribution data, the absolute risk of death from pulmonary embolism in current users was estimated to be 10.5 per million woman-years.

Since nearly all studies showing associations between oral contraception and venous thromboembolism (VTE) have involved non-fatal events, the possibility of referral or diagnostic bias has been suggested.<sup>1</sup> Such bias is unlikely in a study of fatal cases, since most young women who die unexpectedly are referred for necropsy. We studied fatal pulmonary embolism among all New Zealand women aged 15–49 years. Cases were identified from deaths between January, 1990, and August, 1998, certified with the underlying cause as codes 415.1, 451, or 453, from the International Classification of Diseases, ninth revision. We obtained clinical details and the names of family physicians from coroners' and police reports and hospital records; if necessary, we also wrote to the next of kin to ask for the name of the family physician. Of 43 women identified, four had insufficient evidence for the diagnosis of pulmonary embolism, and three did not normally live in New Zealand.

For the 36 eligible women, we asked the family physicians if an investigator (LP) could examine the records of the case and four controls. Every family physician agreed, but for seven cases the records had been lost. For the remainder of cases, the diagnosis had been confirmed by necropsy in 26, by ventilation-perfusion scans and pulmonary angiography in two, or by two independent physicians using standard criteria in one.<sup>2</sup> The median age was 32 years. We used the date of onset of the fatal episode as an index date.

For each case we selected four controls from the same family physician's group practice who had the same year of birth as the case (except five controls who were each born in an adjacent year). The controls were selected randomly from an age-sex register in 27 practices (computerised in all except one), and in the other two practices by random selection of medical records. We excluded potential controls if they were not normally resident in New Zealand, or did not belong to the practice, on the index date. The cases and controls had been with the same practices for an average of 8.2 years and 8.0 years, respectively. We obtained information about medical and contraceptive histories from the group practice and any family-planning-clinic records, by the same approach for cases and controls.

Current use of oral contraceptives was defined as prescribed use at any time during the 3 months before the index date. We excluded women who had reached the menopause (one case, five controls) or who had a history of VTE (two further cases). 17 (65%) of 26 cases and 25 (23%) of 111 controls were current users of combined oral contraceptives (table). We calculated odds ratios and 95% CI for VTE, by use of unconditional logistic regression. We did not use matched analysis since unstable estimates were obtained because of sparse data.

If we took non-users of any combined oral contraceptive as the reference group, the odds ratio (adjusted for age, weight, and family physician's practice) for all current users was 9.6 (95% CI 3.1–29.1). If we omitted controls with excluded cases, the adjusted odds ratio increased slightly to 10.2. Two cases had other potential causes of VTE (long-term immobility or major surgery); neither was using oral contraceptives. When such cases and controls were excluded, the odds ratio increased to 11.7 (3.5–38.5).

The women who died while using oral contraceptives had a median age of 29. Only three cases were first-time users of any combined oral contraceptive (with durations of use 3 months, 18 months, and 40 months, respectively). Third-generation oral contraceptives, containing desogestrel (seven deaths) or gestodene (five), were the most commonly used by the cases. Two cases were using a contraceptive pill that contains cyproterone acetate and ethinylloestradiol, and the odds ratio for such women was 17.6 (2.7–113). A study by WHO also found a high odds ratio of 14.9 (3.7–59.4) for this product.<sup>2</sup>

Only six (35%) deaths among cases using oral contraceptives had been reported to the Centre for Adverse Reactions Monitoring (CARM). CARM had been notified of a further death from pulmonary embolism (confirmed by necropsy) in a woman taking a contraceptive containing desogestrel, which had been miscoded in national mortality data. Contraceptive-supply data provided by the Ministry of Health showed that there were up to 1 717 153 woman-years of use of combined oral contraceptives in New Zealand during the period of the study, during which 18 users died. Thus, the absolute risk of death from idiopathic pulmonary embolism in women taking combined oral contraceptives was estimated to be 10.5 (6.2–16.6) per million woman-years. This estimate is probably conservative, since family-physician records could not be found for several cases and we ignored deaths for which pulmonary embolism was not certified as the underlying cause.

This death rate was higher than expected because the annual incidence of VTE in oral-contraceptive users has been estimated at one or two per 10 000 women, with a case fatality rate of only 1–2%.<sup>2</sup> The high mortality in New Zealand may partly reflect the extensive use of third-generation oral contraceptives, which seem to carry a higher

Progestogen in combined oral contraceptive	Cases	Controls	Crude odds ratio (95% CI)	Adjusted odds ratio (95% CI)*
Non-user	9	86	1.0	1.0
Levonorgestrel	3	8	3.6 (0.88–15.0)	5.1 (1.2–21.4)
Desogestrel or gestodene	12	15	7.6 (2.8–20.9)	14.9 (3.5–64.3)
Cyproterone acetate	2	1	19.1 (1.6–232)	17.6 (2.7–113)
All types	17	25†	6.5 (2.6–16.1)	9.6 (3.1–29.1)

\*Adjusted for age (by individual year), weight (four categories, including missing values), and clustered on practice.

†One control using combined oral contraceptive containing norethisterone.

Current use of combined oral contraceptives

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risk of VTE than older contraceptives.<sup>3</sup> Another case-control study of oral contraceptives and fatal pulmonary embolism, which involved deaths in England and Wales between 1986 and 1988,<sup>4</sup> would have included few if any women using these preparations. A death rate of 14 per million woman-years (based on six deaths) can be derived from a later cohort study.<sup>5</sup> Deaths from pulmonary embolism are rare among users of oral contraceptives, but the absolute risks should not be thought of as "infinitesimal, of no clinical importance and definitely of no public health significance".<sup>1</sup>

This study was funded by the New Zealand Ministry of Health. We thank family physicians and the Family Planning Association for their assistance, and David Coulter and Janelle Ashton for information from CARM.

- 1 Spitzer WO. The aftermath of a pill scare: regression to reassurance. *Hum Reprod Update* 1999; 5: 736-45.
- 2 WHO Collaborative Study. Venous thromboembolic disease and combined oral contraceptives: results of international multicentre case-control study. *Lancet* 1995; 346: 1575-88.
- 3 Walker AM. Newer oral contraceptives and the risk of venous thromboembolism. *Contraception* 1998; 57: 169-81.
- 4 Thorogood M, Mann J, Murphy M, Vessey M. Risk factors for fatal venous thromboembolism in young women: a case-control study. *Int J Epidemiol* 1992; 21: 48-52.
- 5 Jick H, Jick SS, Gurewich V, Myers MW, Vasilakis C. Risk of idiopathic cardiovascular death and nonfatal venous thromboembolism in women using oral contraceptives with differing progestagen components. *Lancet* 1995; 346: 1589-93.

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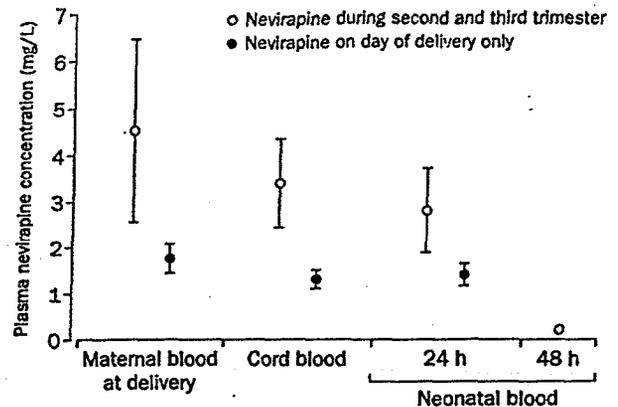
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## Pharmacological implications of lengthened in-utero exposure to nevirapine

G P Taylor, E G H Lyall, D Back, C Ward, G Tudor-Williams

Given as a single dose to the mother during labour, nevirapine can protect the neonate from HIV-1 infection for up to 7 days. However, after maternal nevirapine therapy during pregnancy, neonatal plasma concentrations of nevirapine decline more rapidly, suggesting in-utero liver enzyme induction.

Mother-to-child transmission of HIV-1 can be reduced to less than 2% by avoidance of breastfeeding, elective caesarean section, and perinatal zidovudine.<sup>1</sup> Also, when given as a single oral dose to the mother once labour has been established, nevirapine rapidly crosses the placenta and has a lengthened half-life in the neonate such that therapeutic plasma concentrations can be sustained for 7 days with only one additional oral dose given to the neonate after 48-72 h.<sup>2</sup> With this intervention, early peripartum transmission of HIV-1 can be reduced by 50% compared with zidovudine taken during the same period.<sup>1</sup> Current guidelines recommend that triple antiretroviral therapy rather than zidovudine monotherapy should be started during the second and third trimesters of pregnancy for women with symptomatic HIV-1 infection, high viral load, or low CD4-lymphocyte counts.<sup>3</sup> A regimen of nevirapine with two nucleoside analogue reverse-transcriptase inhibitors (NRTIs) is frequently prescribed because of its simplicity, tolerability, and efficacy. However, with the exception of zidovudine, didanosine, and, during the last 2 weeks of gestation, lamivudine, antiretroviral therapy pharmacokinetics during pregnancy have not been



Mean plasma nevirapine concentrations in mothers at delivery in umbilical-cord blood, and in neonates at 24-48 h. Bars indicate SDs.

reported. We measured steady-state nevirapine plasma concentrations in women prescribed nevirapine (plus two NRTIs) during the second and third trimesters of pregnancy, and in their babies.

18 pregnant women (15 African, two white, and one Asian) were treated with nevirapine-containing regimens according to national guidelines.<sup>4</sup> For antiretroviral-naïve mothers the combination of nevirapine, zidovudine, and lamivudine was commonly the first-line therapy. The therapy of mothers who conceived at the time of treatment was only changed in the case of viral failure or side-effects. For mothers previously exposed to antiretroviral therapy or for whom therapy had failed, new regimens were chosen after testing for genotypic resistance. The women were advised of the potential risks and benefits of therapy, and gave informed consent for therapeutic drug monitoring and for nevirapine concentration to be measured using the same blood sample taken for diagnostic HIV-1 DNA PCR. Nevirapine 200 mg daily was prescribed for the first 2 weeks, and thereafter 200 mg twice daily, with the regular doses taken on the day of delivery. Three mothers took their initial dose of nevirapine during labour or shortly before elective caesarean section. Whole blood was centrifuged after venesection and plasma stored at -20°C until analysis for nevirapine concentration by high-performance liquid chromatography.

Plasma nevirapine concentrations are shown in the figure. In the three mothers who started nevirapine on the day of delivery, mean neonatal nevirapine plasma concentrations at 24 h (1.39 mg/L) were 81% of maternal concentrations (1.71 mg/L), and 107% of cord concentrations (1.29 mg/L).

In the 15 mothers who were treated during pregnancy, the mean maternal plasma concentrations at the end of the first 4 weeks of therapy (4.62 mg/L) and at delivery (4.45 mg/L), were more than 400 times the reported median inhibitory concentration of nevirapine for wild-type HIV-1.<sup>5</sup> The mean concentration in cord blood (3.41 mg/L) was 76% of maternal nevirapine concentration at delivery ( $p=0.03$ , paired  $t$  test). 24 h after delivery the mean neonatal concentration (2.71 mg/L) was 60% of the maternal concentration at delivery ( $p=0.01$ ). Because this suggested more rapid clearance of nevirapine than expected, venesection of one infant was deferred until 48 h after delivery. In this neonate the plasma nevirapine concentration (0.2 mg/L) was only 5% of the concentration in cord blood and 3% of the concentration in maternal blood.

Steady-state plasma nevirapine concentrations during the second and third trimesters of pregnancy were similar to published data for non-pregnant adults,<sup>5</sup> which suggests that the dose of nevirapine does not require adjustment in

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April 30, 2000

Judie's  
FYI  
A (O)

Christine Hikawa, Vice President  
Broadcast Standards and Practice, ABC, Inc.  
77 West 66<sup>th</sup> Street  
New York, NY 10023-6298

Dear Ms. Hikawa,

I am in receipt of a letter to you from Judie Brown, President of the American Life League, your reply, and a photocopy of an ad for Ortho Tri-Cyclen. Mrs. Brown and I object to what is clearly an unconscionable appeal to consideration by teenagers to request a prescription for this product as "the only one clinically proven to help your skin look better too?". You state, "We also worked with the advertiser to ensure that the commercial was directed only to responsible adults." That statement is an assault on the intellect by both you and Ortho. There is no way that any TV appeal of the kind reflected in the magazine advertisement enclosed is going to be hidden from the teenage community. You add a similar assault by stating: "We disagree with you that this ad is 'focused on acne'".

As you are undoubtedly aware, since their first appearance in 1960, the birth control pills (BCP's) have experienced an ever decreasing dose of estrogen. This is because estrogen was the offending agent in causing embolic complications, sometimes lethal in their results. As you also are aware, American women are experiencing an epidemic of breast cancer, so that today 1 in 8 females is expected to encounter this disease during the course of a lifetime. In my opinion this is a iatrogenically 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. For confirmation of my suspicion about the connection between the BCP and breast cancer, see *Can a Christian Take the Pill?*, C. Kahlenborn, published by One More Soul. To see the results of the marketing of the BCP and IUD in 1960, study the 2 graphs enclosed for your perusal. You should also understand that \$4,085,000,000 has been spent under Title X authorization with no impact on the teenage pregnancy problem over the past 29 years, except causing this catastrophe to worsen.

If you are truly interested in offering young women advice that will help their physical and spiritual well being, put them in touch with Best Friends or some other agency dedicated to educating them about chastity and their beauty in God's eyes. Thank you for considering my concerns.

Sincerely,

William F. Colliton, Jr., M.D.  
Clinical Professor of Obstetrics and Gynecology (Ret.)  
George Washington University Medical Center

# American Bioethics Advisory Commission



## **When do human beings begin? 'Scientific' myths and scientific facts**

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### **I. Introduction:**

The question as to when a human being begins is strictly a scientific question, and should be answered by human embryologists - not by philosophers, bioethicists, theologians, politicians, x-ray technicians, movie stars or obstetricians and gynecologists. Current discussions on abortion, human embryo research (including cloning, stem cell research and the formation of mixed-species chimeras) and the use of abortifacients involve specific claims as to when the life of every human being begins. The purpose of this article is to focus directly on just some of the "scientific" myths, and on the objective scientific facts that ought to ground these discussions. At least it will clarify what the actual international consensus of human embryologists is with regard to this relatively simple scientific question. If the "science" used to ground these various discussions is incorrect, then any conclusions will be rendered groundless and invalid.

### **II. Brief background on the accurate human embryological facts:**

Understanding just a few basic human embryological terms accurately can considerably clarify the drastic difference between the "scientific" myths that are currently circulating throughout the literature, and the actual objective scientific facts. This would include such basic terms as: "gametogenesis", "oogenesis", "spermatogenesis", "fertilization", "zygote", "embryo" and "blastocyst". Only brief scientific descriptions will be given here for these

terms. Further, more complicated, details can be obtained by investigating any well-established human embryology textbook in the library, such as some of those referenced below. Please note that the scientific facts presented here are not simply a matter of my own opinion. They are direct quotes and references from some of the most highly respected human embryology textbooks, and represent a consensus of human embryologists internationally.

To begin with, scientifically something very dramatic occurs between the processes of gametogenesis and fertilization - the change from two simple PARTS of a human being, i.e., a sperm and an oocyte (usually referred to as an "ovum" or "egg"), which simply possess "human life" into a new, genetically unique, newly existing, individual, live human BEING, an embryonic single-cell human zygote. That is, parts of a human being have actually been transformed into something very different from what they were before; they have been changed into a single, whole human being. During this process, the sperm and the oocyte cease to exist, and a new human being is produced.

To understand this, it is already known that each kind of living organism has a specific number and quality of chromosomes which are characteristic for each member of a species (the number can vary only slightly if the organism is to survive). For example, the characteristic number of chromosomes for a member of the human species is 46 (plus or minus, e.g., in human beings with Down's or Turner's syndromes). Every somatic cell in a human being has this characteristic number of chromosomes, including the sex gametes - the sperm and the oocyte. Sperms and oocytes are derived from primitive germ cells in the developing fetus by means of the process known as "gametogenesis". Because each gamete normally has 46 chromosomes, the process of "fertilization" can not take place until the total number of chromosomes in each gamete are cut in half. This is necessary so that after their fusion at fertilization the characteristic number of chromosomes in a single individual member of the human species (46) can be maintained. To accurately see why a sperm or an oocyte are considered as only possessing human life, and not as human beings themselves, one need look at the basic scientific facts involved in the processes of gametogenesis and of fertilization.

As the human embryologist Larsen states it, gametogenesis is the process that converts primordial germ cells (primitive sex cells) into mature sex gametes - in the male (spermatozoa, or sperms), and in the female (definitive

oocytes). The timing of gametogenesis is different in males and in females. Spermatogenesis in males begins at puberty, and continues throughout adult life. The process involves the production of spermatogonia from the primitive germ cells, which in turn become primary spermatocytes, and finally spermatids - or mature spermatozoa (sperms). These mature sperms will have only half of the number of their original chromosomes - i.e., the number of chromosomes has been cut from 46 to 23, and therefore they are ready to take part in fertilization.

Oogenesis begins in the female during fetal life. The total number of primary oocytes - about 7 million - is produced in the female fetus' ovaries by 5 months of gestation in the mother's uterus. By birth, only about 700,000 - 2 million remain. By puberty, only about 400,000 remain. The process involves the production of oogonia from primitive germ cells, which in turn become primary oocytes, which become definitive oocytes only at puberty. This definitive oocyte is what is released each month during the female's menstrual period, but it still has 46 chromosomes. In fact, it does not reduce its number of chromosomes until and unless it is fertilized by the sperm, during which process the definitive oocyte becomes a secondary oocyte with only 23 chromosomes.

This halving of the number of chromosomes in the gametes takes place by the process of meiosis. Many people confuse meiosis with a different process known as mitosis, but there is an important difference. Mitosis involves the normal division of a somatic, or body, cell in order to increase the number of those cells during growth and development. The resulting cells contain the same number of chromosomes as the previous cells - in human beings, 46. Meiosis involves the halving of the number of chromosomes which are normally present in a somatic cell (here, in the sex gametes - the precursors of the sperm and the definitive oocyte) in order for fertilization to take place. The resulting cells have only half of the number of chromosomes as the previous cells - in human beings, 23

One of the best and most technically accurate explanations for this critical process of gametogenesis is by Ronan O'Rahilly, the human embryologist who developed the classic Carnegie stages of human embryological development. He also sits on the international board of *Nomina Embryologica* (which determines the correct terminology to be used in human embryology textbooks internationally):

Gametogenesis is the production of [gametes], i.e., spermatozoa and oocytes. These cells are produced in the gonads, i.e., the testes and ovaries respectively. ... During the differentiation of gametes, diploid cells (those with a double set of chromosomes, as found in somatic cells [46 chromosomes]) are termed primary, and haploid cells (those with a single set of chromosomes [23 chromosomes]) are called secondary. The reduction of chromosomal number ... from 46 (the diploid number or  $2n$ ) to 23 (the haploid number or  $n$ ) is accomplished by a cellular division termed meiosis. ... Spermatogenesis, the production of spermatozoa, continues from immediately after puberty until old age. It takes place in the testis, which is also an endocrine gland, the interstitial cells of which secrete testosterone. Previous to puberty, spermatogonia in the seminiferous tubules of the testis remain relatively inactive. After puberty, under stimulation from the interstitial cells, spermatogonia proliferate ... and some become primary spermatocytes. When these undergo their first maturation division (meiosis 1), they become secondary spermatocytes. The second maturation division (meiosis 2) results in spermatids, which become converted into spermatozoa."

Oogenesis is the production and maturation of oocytes, i.e.; the female gametes derived from oogonia. Oogonia (derived from primordial germ cells) multiply by mitosis and become primary oocytes. The number of oogonia increases to nearly seven million by the middle of prenatal life, after which it diminishes to about two million at birth. From these, several thousand oocytes are derived, several hundred of which mature and are liberated (ovulated) during a reproductive period of some thirty years. Prophase of meiosis 1 begins during fetal life but ceases at the diplotene state, which persists during childhood. ... After puberty, meiosis 1 is resumed and a secondary oocyte ... is formed, together with polar body 1, which can be regarded as an oocyte having a reduced share of cytoplasm. The secondary oocyte is a female gamete in which the first meiotic division is completed and the second has begun. From oogonium to secondary oocyte takes from about 12 to 50 years to be completed. Meiosis 2 is terminated after rupture of the follicle (ovulation) but only if a spermatozoon penetrates. ... The term "ovum" implies that polar body 2 has been given off, which event is usually delayed until the oocyte has been penetrated by a spermatozoon (i.e., has been fertilized). Hence a human ovum does not [really] exist. Moreover the term has been used for such disparate structures as an oocyte and a three-week embryo, and therefore should be discarded, as a fortiori should "egg". (emphasis added)

Thus, for fertilization to be accomplished, a mature sperm and a mature human oocyte are needed. Before fertilization, each has only 23 chromosomes. They each possess "human life", since they are parts of a living human being; but they are not each whole living human beings themselves. They each have only 23 chromosomes, not 46 chromosomes - the number of chromosomes necessary and characteristic for a single individual member of the human species. Furthermore, a sperm can produce only "sperm" proteins and enzymes; an oocyte can produce only "oocyte" proteins and enzymes; neither alone is or can produce a human being with 46 chromosomes.

Also, note O'Rahilly's statement that the use of terms such as "ovum" and "egg" - which would include the term "fertilized egg" - is scientifically incorrect, has no objective correlate in reality, and is therefore very misleading - especially in these present discussions. Thus these terms themselves would qualify as "scientific myths". The commonly used term, "fertilized egg", is especially very misleading, since there is really no longer an egg (or oocyte) once fertilization has begun. A "fertilized egg" is a human being.

Now that we have looked at the formation of the mature haploid sex gametes, the next important process to consider is fertilization. O'Rahilly defines fertilization as:

... the procession of events that begins when a spermatozoon makes contact with a secondary oocyte or its investments, and ends with the intermingling of maternal and paternal chromosomes at metaphase of the first mitotic division of the zygote. The zygote is characteristic of the last phase of fertilization and is identified by the first cleavage spindle. It is a unicellular embryo. (emphasis added)

The fusion of the sperm (with 23 chromosomes) and the oocyte (with 23 chromosomes) at fertilization results in a live human being, a single-cell human zygote, with 46 chromosomes - the number of chromosomes characteristic of an individual member of the human species. Quoting Moore:

*Zygote:* This cell results from the union of an oocyte and a sperm. A zygote is the beginning of a new human being (i.e., an embryo). The expression fertilized ovum refers to a secondary oocyte that is impregnated by a sperm; when fertilization is complete, the oocyte becomes a zygote. (emphasis added)

This new single-cell human being immediately produces

specifically human proteins and enzymes (not carrot or frog enzymes and proteins), and directs his/her own growth and development (in fact this growth and development has been proven not to be directed by the mother). Finally, this new human being - the single-cell human zygote - is biologically an individual, a living organism - an individual member of the human species. Quoting Larsen:

... [W]e 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. (emphasis added)

In sum, a human sperm and a human oocyte are products of gametogenesis - each has only 23 chromosomes. They each have only half of the required number of chromosomes for a human being. They cannot singly develop further into human beings. They produce only "gamete" proteins and enzymes. They do not direct their own growth and development. And they are not individuals, i.e., members of the human species. They are only parts - each one a part of a human being. On the other hand, a human being is the immediate product of fertilization. As such he/she is a single-cell embryonic zygote, an organism with 46 chromosomes, the number required of a member of the human species. This human being immediately produces specifically human proteins and enzymes, directs his/her own further growth and development as human, and is a new, genetically unique, newly existing, live human individual.

After fertilization the single-cell human embryo doesn't become another kind of thing. It simply divides and grows bigger and bigger, developing through several stages as an embryo over an 8-week period. Several of these developmental stages of the growing embryo are denoted as a morula (about 4 days), a blastocyst (5-7 days), a bilaminar (two layer) embryo (during the second week), and a trilaminar (3-layer) embryo (during the third week).

### III. "Scientific myths" and scientific facts:

Given these basic facts of human embryology, it is easier to recognize the many scientifically inaccurate claims that have been advanced in the discussions about abortion, human embryo research, cloning, stem cell research, the formation of chimeras, and the use of abortifacients - and why these discussions obfuscate the objective scientific facts. The following is just a sampling of some of these current "scientific myths".

**MYTH 1:** "Prolifers claim that the abortion of a human embryo or a human fetus is wrong because it destroys human life. But human sperms and human ova are human life too. So prolifers would also have to say that the destruction of human sperms and human ova are abortions too - and that is ridiculous!"

**FACT 1:** As pointed out above in the background section, there is quite a difference, scientifically, between parts of a human being that only possess "human life" and a human embryo or human fetus that is an actual "human being". Abortion is the destruction of a human being. Destroying a human sperm or a human oocyte would not constitute abortion, since neither are human beings. The issue is not when does human LIFE begin, but rather when does the life of every human BEING begin. A human kidney or liver, a human skin cell, a sperm or an oocyte all possess human LIFE, but they are not human BEINGS - they are only parts of a human being. If a single sperm or a single oocyte were implanted into a woman's uterus, they would simply rot. They would not grow as human embryos or human fetuses who are human beings.

**MYTH 2:** "The product of fertilization is simply a 'blob', a 'bunch of cells', a 'piece of the mother's tissues'".

**FACT 2:** As demonstrated above, the human embryonic organism formed at fertilization is a whole human being, and therefore it is not just a "blob" or a "bunch of cells". This new human individual also has a mixture of both the mother's and the father's chromosomes, and therefore it is not just a "piece of the mother's tissues". Quoting Carlson:

... [T]hrough the mingling of maternal and paternal chromosomes, the zygote is a genetically unique product of chromosomal reassortment, which is important for the viability of any species. (emphasis added)

**MYTH 3:** "The immediate product of fertilization is just a 'potential' or a 'possible' human being - not a real existing human being".

**FACT 3:** As demonstrated above, scientifically there is absolutely no question whatsoever that the immediate product of fertilization is a newly existing human being. A human zygote is a human being. It is NOT a "potential" or a "possible" human being.

**MYTH 4:** "A single-cell human zygote, or embryo, or fetus

are not human beings, because they do not look like human beings".

**FACT 4:** As all human embryologists know, a single-cell human zygote, or a more developed human embryo, or human fetus is a human being - and that that's the way they are supposed to look at those particular periods of development.

**MYTH 5:** "The immediate product of fertilization is just an "it" - it is neither a girl nor a boy".

**FACT 5:** The immediate product of fertilization is genetically already a girl or a boy - determined by the kind of sperm which fertilizes the oocyte. Quoting Carlson again:

...[T]he sex of the future embryo is determined by the chromosomal complement of the spermatozoon. (If the sperm contains 22 autosomes and 2 X chromosomes, the embryo will be a genetic female, and if it contains 22 autosomes and an X and a Y chromosome, the embryo will be a genetic male.)

**MYTH 6:** "The embryo and the embryonic period begin at: implantation; 14-days; 3 weeks."

**FACT 6:** These are several of the most common myths perpetuated sometimes even within quasi-scientific articles - especially within the bioethics literature. As demonstrated above, the human embryo, who is a human being, begins at fertilization - not at implantation (about 5-7 days), 14-days, or 3 weeks. Thus the embryonic period also begins at fertilization, and ends by the end of the eighth week, when the fetal period begins. Quoting O'Rahilly:

Prenatal life is conveniently divided into two phases: the embryonic and the fetal. The embryonic period proper during which the vast majority of the named structures of the body appear, occupies the first 8 postovulatory weeks. ... the fetal period extends from 8 weeks to birth ... (emphasis added)

**MYTH 7:** "The product of fertilization, up to 14-days, is not an embryo; it is just a 'pre-embryo' - and therefore it can be used in experimental research, aborted or donated".

**FACT 7:** This scientific myth is perhaps the most common error, which pervades the current literature. The term "pre-embryo" has quite a long and interesting history (see Irving and Kischer, The Human Development Hoax: Time

To Tell The Truth! for extensive details and references), but it roughly goes back to at least 1979 in the bioethics writings of Jesuit theologian Richard McCormick in his work with the Ethics Advisory Board to the United States Department of Health, Education and Welfare, and those of frog developmental biologist Dr. Clifford Grobstein in a 1979 article in *Scientific American*, and most notably in his classic book, *Science and the Unborn: Choosing Human Futures* (1988). Both McCormick and Grobstein subsequently continued propagating this scientific myth as members of the Ethics Committee of the American Fertility Society, and in numerous influential bioethics articles, leading to its common use in bioethics, theological, and public policy literature to this day.

The term "pre-embryo" was also used as the rationale for permitting human embryo research in the British Warnock Committee Report (1984), and then picked up by literally hundreds of writers internationally, including e.g., Australian writers Michael Lockwood, Michael Tooley, Alan Trounson - and especially by Peter Singer (a philosopher), Pascal Kasimba (a lawyer), Helga Kuhse (an ethicist), Stephen Buckle (a philosopher) and Karen Dawson (a geneticist, not a human embryologist). Note that none of these is even a scientist, with the exception of Karen Dawson, who is just a geneticist.

Oddly, their influential book, *Embryo Experimentation*, (which uses the term "pre-embryo", and which contains no scientific references for its "human embryology" chart or its list of "scientific terms"), along with the work of theologian McCormick and frog developmental biologist Grobstein, was used in the United States as the scientific basis for the 1994 NIH Human Embryo Research Report. That Report concluded that the "preimplantation embryo" (they too originally used the term "pre-embryo") had only a "reduced moral status". (Both the Warnock Report and the NIH Report admitted that the 14-day limit for human embryo research was arbitrary, and could and must be changed if necessary). It is particularly in the writings of these and other bioethicists that so much incorrect science is claimed in order to "scientifically" ground the "pre-embryo" myth and therefore "scientifically" justify many of the issues noted at the beginning of this article. This would include abortion, as well as the use of donated or "made-for-research" early human embryo in destructive experimental human embryo research (such as infertility research, cloning, stem cell research, the formation of chimeras, etc.).

To begin with, it has been demonstrated above that the

immediate product of fertilization is a human being with 46 chromosomes, a human embryo, an individual member of the human species, and that this is the beginning of the embryonic period. However, McCormick and Grobstein claim that even though the product of fertilization is genetically human, it is not a "developmental individual" yet - and in turn, this "scientific fact" grounds their moral claim about this "pre-embryo". Quoting McCormick:

I contend in this paper that the moral status - and specifically the controversial issue of personhood - is related to the attainment of developmental individuality (being the source of one individual) ... It should be noted that at the zygote stage the genetic individual is not yet developmentally single - a source of only one individual. As we will see, that does not occur until a single body axis has begun to form near the end of the second week post fertilization when implantation is underway. (emphasis added)

Sounds very scientific. However, McCormick's embryology is already self-contradictory. The "single body axis" to which he refers is the formation of the primitive streak which takes place at 14 days. Implantation takes place at 5-7 days. McCormick often confuses these different periods in his writings. But McCormick continues:

This multicellular entity, called a blastocyst, has an outer cellular wall, a central fluid-filled cavity and a small gathering of cells at one end known as the inner cell mass. Developmental studies show that the cells of the outer wall become the trophoblast (feeding layer) and are precursors to the later placenta. Ultimately, all these cells are discarded at birth. (emphasis added)

The clear implication is that there is absolutely no relationship or interaction between these two cell layers, and so the "entity" is not a "developmental individual" yet. However, quoting Larsen:

These centrally placed blastomeres are now called the inner cell mass, while the blastomeres at the periphery constitute the outer cell mass. Some exchange occurs between these groups. ... The cells of this germ disc (the inner cell layer) develop into the embryo proper and also contribute to some of the extraembryonic membranes. (emphasis added)

Similarly, it is not factually correct to state that all of the cells from the outer trophoblast layer are discarded after birth. Quoting Moore:

The chorion, the amnion, the yolk sac, and the allantois constitute the fetal membranes. They develop from the zygote but do not participate in the formation of the embryo or fetus - except for parts of the yolk sac and allantois. Part of the yolk sac is incorporated into the embryo as the primordium of the gut. The allantois forms a fibrous cord that is known as the urachus in the fetus and the median umbilical ligament in the adult. It extends from the apex of the urinary bladder to the umbilicus. (emphasis added)

Since scientists, in trying to "reach" young students in a more familiar language, sometimes use popularized (but scientifically inaccurate and misleading) terms themselves, the ever-vigilant O'Rahilly expresses concern in his classic text about the use of the term "fetal membranes":

The developmental adnexa, commonly but inaccurately referred to as the "fetal membranes", include the trophoblast, amnion, chorion, umbilical vesicle (yolk sac), allantoic diverticulum, placenta and umbilical cord. They are genetically a part of the individual and are composed of the same germ layers. (emphasis added)

Consequently, it is also scientifically incorrect to claim that only the inner cell layer constitutes the "embryo proper". The entire blastocyst - including both the inner and the outer cell layers - is the human embryo, the human being.

Finally, McCormick claims that this "pre-embryo" has not yet decided how many individuals it will become, since the cells are totipotent and twinning can still take place. Therefore, they argued, there is no "individual" present until 14-days and the formation of the primitive streak, after which twinning cannot take place.

However, twinning is possible after 14 days, e.g., with fetus-in-fetu and Siamese twins. Quoting from O'Rahilly again:

Partial duplication at an early stage and attempted duplication from 2 weeks onward (when bilateral symmetry has become manifest) would result in conjoined twins (e.g., "Siamese twins"). (emphasis added)

And even Karen Dawson acknowledges this as scientific fact in her article in Embryo Experimentation:

After the time of primitive streak formation, other events are possible which indicate that the notion of "irreversible individuality" may need some review if it is to be considered

as an important criterion in human life coming to be the individual human being it is ever thereafter to be. There are two conditions which raise questions about the adequacy of this notion: conjoined twins, sometimes known as Siamese twins, and fetus-in-fetu. ... Conjoined twins arise from the twinning process occurring after the primitive streak has begun to form, that is, beyond 14 days after fertilization, or, in terms of the argument from segmentation, beyond the time at which irreversible individuality is said to exist. ... This situation weakens the possibility of seeing individuality as something irreversibly resolved by about 14 days after fertilization. This in turn raises questions about the adequacy of using the landmark of segmentation in development as the determinant of moral status. (emphasis added)

It is unfortunate that the NIH Human Embryo Research Panel did not read this particular portion of the Singer et al book before making their recommendations about the moral status of the early human embryo.

The scientific fact is that there is no such thing as a "pre-embryo" in the real world. The term is a complete myth. It was fabricated out of thin air in order to justify a number of things that ordinarily would not be justifiable. Quoting O'Rahilly, who sits on the international board of Nomina Embryologica, again:

The ill-defined and inaccurate term "pre-embryo", which includes the embryonic disk, is said either to end with the appearance of the primitive streak or to include neurulation. The term is not used in this book. (emphasis added)

Unfortunately, the convenient but mythological term "pre-embryo" will be used to "scientifically" justify several of the other "scientific myths" to follow, which in turn will justify public policy on abortion and human embryo research world-wide.

**MYTH 8:** "Pregnancy begins with the implantation of the blastocyst (i.e., about 5-7 days)."

**FACT 8:** This definition of "pregnancy" was initiated to accommodate the introduction of the process of in vitro fertilization, where fertilization takes place artificially outside the mother in a petri dish, and then the embryo is artificially introduced into the woman's uterus so that implantation of the embryo can take place. Obviously, if the embryo is not within the woman's body, she is not "pregnant" in the literal, traditional sense of the term. However, this artificial situation cannot validly be substituted back to redefine

"normal pregnancy", in which fertilization does takes place within the woman's body in her fallopian tube, and subsequently the embryo itself moves along the tube to implant itself into her uterus. In normal situations, pregnancy begins at fertilization, not at implantation. Quoting Carlson:

Human pregnancy begins with the fusion of an egg and a sperm, but a great deal of preparation precedes this event. First both male and female sex cells must pass through a long series of changes (gametogenesis) that converts them genetically and phenotypically into mature gametes, which are capable of participating in the process of fertilization. Next, the gametes must be released from the gonads and make their way to the upper part of the uterine tube, where fertilization normally takes place. Finally, the fertilized egg, now properly called an embryo, must make its way into the uterus, where it sinks into the uterine lining (implantation) to be nourished by the mother. (emphasis added)

**MYTH 9:** "The 'morning-after pill', RU486, and the IUD are not abortifacient; they are only methods of contraception".

**FACT 9:** The "morning-after pill", RU486, and the IUD can be abortifacient, if fertilization has taken place. Then they would act to prevent the implantation of an already existing human embryo - the blastocyst - which is an existing human being. If the developing human blastocyst is prevented from implanting into the uterus, then obviously the embryo dies. In effect, these chemical and mechanical methods of contraception have become methods of abortion as well. Quoting Moore:

The administration of relatively large doses of estrogens ("morning-after pill") 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 5-6 days, may also accelerate passage of the dividing zygote along the uterine tube ... 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 to 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. The "abortion pill" RU486 also destroys the conceptus by interrupting implantation because of interference with the

hormonal environment of the implanting embryo. ... An intrauterine device (IUD) inserted into the uterus through the vagina and cervix usually interferes with implantation by causing a local inflammatory reaction. Some IUDs contain progesterone that is slowly released and interferes with the development of the endometrium so that implantation does not usually occur. (emphasis added)

And since the whole human blastocyst is the embryonic human being - not just the inner cell layer - the use of chemical abortifacients that act "only" on the outer trophoblast layer of the blastocyst, e.g., methotrexate, would be abortifacient as well.

**MYTH 10:** "Human embryo research, human cloning, stem cell research, and the formation of chimeras are acceptable kinds of research because until implantation or 14 days there is only a 'pre-embryo', a 'potential' human embryo or human being present. A real human embryo and a human being (child) do not actually begin unless and until the 'pre-embryo' is implanted into the mother's uterus."

**FACT 10:** These claims are currently being made by bioethicists, research scientists, pharmaceutical companies and other biotech research companies - even by some members of Congress. However, they too are "scientific myths".

Scientifically it is perfectly clear that there is no such thing as a "pre-embryo", as demonstrated in Fact 7. As demonstrated in the background material, the immediate product of fertilization is a human being, a human embryo, a human child - the zygote. This zygote is a newly existing, genetically unique, genetically male or female, individual human being - it is not a "potential" or a "possible" human being. And this developing human being is a human being, a human embryo, a human child whether or not it is implanted artificially into the womb of the mother.

Fertilization and cloning are different processes, but the immediate products of these processes are the same. The immediate product of cloning is also a human being - just as in fertilization. It is not a "pre-embryo" or a "potential" human embryo or human being. Stem cell research obtains its "stem cells" by essentially exploding or otherwise destroying and killing a newly existing human blastocyst who is, scientifically, an existing human being. The formation of chimeras, i.e., the fertilization of a gamete of one species (e.g., a human ovum) with the gamete of another species (e.g., a monkey sperm) also results in an embryo which is

"half-human". All of these types of research have been banned by most countries in the world. And all of these types of research are essentially human embryo research - banned in the United States by Congress if federal funds are used.

**MYTH 11:** "Certain early stages of the developing human embryo and fetus, e.g., during the formation of ancestral fish gills or tails, demonstrates that it is not yet a human being, but is only in the process of becoming one. It is simply "recapitulating" the historical evolution of all of the species."

**FACT 11:** This "scientific myth" is yet another version of the "potential", "possible", "pre-embryo" myths. It is an attempt to deny the early human embryo its real identity as a human being and its real existence. But quoting once again from O'Rahilly:

The theory that successive stages of individual development (ontogeny) correspond with ("recapitulate") successive adult ancestors in the line of evolutionary descent (phylogeny) became popular in the 19th century as the so-called biogenetic law. This theory of recapitulation, however, has had a "regrettable influence in the progress of embryology" (citing de Beer). ... Furthermore, during its development an animal departs more and more from the form of other animals. Indeed, the early stages in the development of an animal are not like the adult stages of other forms, but resemble only the early stages of those animals.

Hence, the developing human embryo or fetus is not a "fish" or a "frog", but is categorically a human being - as has been already demonstrated.

**MYTH 12:** "Maybe a human being begins at fertilization, but a human person does not begin until after 14-days, when twinning cannot take place."

**FACT 12:** The question as to when a human person begins is a philosophical question - not a scientific question. I will not go into great detail here, but since many of the current popular "personhood" claims in bioethics are also based on mythological science, it would be useful to just look very briefly at these philosophical (or sometimes, theological) arguments for scientific accuracy as well.

Philosophically, virtually any claim for so-called "delayed personhood" involves the theoretical disaster of accepting that the idea or concept of a mind/body split has any correlate or reflects the real world. Historically this problem

was simply the consequence of wrong-headed thinking about reality, and was/is totally indefensible. It was abandoned with great embarrassment after Plato (even by Plato himself in his *Parmenides*!), but unfortunately resurfaces from time to time, e.g., as with Descartes in his *Meditations*, and now again with contemporary bioethics. And as in the question of when a human being begins, if the science used to ground these philosophical "personhood" arguments is incorrect, the conclusions of those arguments (which are based on that science) are also incorrect and invalid.

The particular argument in Myth 12 is also made by McCormick and Grobstein (and their numerous followers). It is based on their biological claim that the "pre-embryo" is not a developmental individual, and therefore not a person, until after 14 days when twinning can no longer take place. However, it has already been scientifically demonstrated here that there is no such thing as a "pre-embryo", and that in fact the embryo begins as a "developmental individual" at fertilization. Furthermore, twinning can take place after 14 days. Thus simply on the level of science, the philosophical claim of "personhood" advanced by these bioethicists is invalid and indefensible.

MYTH 13: "A human person begins with 'brain birth', the formation of the primitive nerve net, or the formation of the cortex - all physiological structures necessary to support thinking and feeling."

FACT 13: Such claims are all pure mental speculation, the product of imposing philosophical (or theological) concepts on the scientific data, and have no scientific evidence to back them up. As the well-known neurological researcher D. Gareth Jones has succinctly put it, the parallelism between brain death and brain birth is scientifically invalid. Brain death is the gradual or rapid cessation of the functions of a brain. Brain birth is the very gradual acquisition of the functions of a developing neural system. This developing neural system is not a brain. He questions, in fact, the entire assumption and asks what neurological reasons there might be for concluding that an incapacity for consciousness becomes a capacity for consciousness once this point is passed. Jones continues that the alleged symmetry is not as strong as is sometimes assumed, and that it has yet to be provided with a firm biological base.

MYTH 14: "A 'person' is defined in terms of the active exercising of 'rational attributes' (e.g., thinking, willing, choosing, self-consciousness, relating to the world around one, etc.), and/or the active exercising of 'sentience' (e.g., the

feeling of pain and pleasure)."

FACT 14: Again, these are philosophical terms or concepts, which have been illegitimately imposed on the scientific data. The scientific fact is that the brain, which is supposed to be the physiological support for both "rational attributes" and "sentience", is not actually completely developed until young adulthood. Quoting Moore:

Although it is customary to divide human development into prenatal (before birth) and postnatal (after birth) periods, birth is merely a dramatic event during development resulting in a change in environment. Development does not stop at birth. Important changes, in addition to growth, occur after birth (e.g., development of teeth and female breasts). The brain triples in weight between birth and 16 years; most developmental changes are completed by the age of 25. (emphasis added)

One should also consider simply the logical - and very real - consequences if a "person" is defined only in terms of the actual exercising of "rational attributes" or of "sentience". What would this mean for the following list of adult human beings with diminished "rational attributes": e.g., the mentally ill, the mentally retarded, the depressed elderly, Alzheimer's and Parkinson's patients, drug addicts, alcoholics - and for those with diminished "sentience", e.g., the comatose, patients in a "vegetative state", paraplegics and other paralyzed and disabled patients, diabetics or other patients with nerve or brain damage, etc.? Would they then be considered as only human beings but not also as human persons? Would that mean that they would not have the same ethical rights and protections as those adult human beings who are considered as persons? Is there really such a "split" between a human being and a human person?

In fact, this is the position of bioethics writers such as the Australian animal rights philosopher Peter Singer, the recently appointed Director of the Center for Human Values at Princeton University. Singer argues that the higher primates, e.g., dogs, pigs, apes, monkeys, are persons - but that some human beings, e.g., even normal human infants, and disabled human adults, are not persons. Fellow bioethicist Norman Fost actually considers "cognitively impaired" adult human beings as "brain dead". Philosopher/bioethicist R.G. Frey has also published that many of the adult human beings on the above list are not "persons", and suggests that they be substituted for the higher primates who are "persons" in purely destructive experimental research. The list goes on.

#### IV. Conclusions:

Ideas do have concrete consequences - not only in one's personal life, but also in the formulation of public policies. And once a definition is accepted in one public policy, the logical extensions of it can then be applied, invalidly, in many other policies, even if they are not dealing with the same exact issue - as happens frequently in bioethics. Thus, the definitions of "human being and of "person" which have been concretized in the abortion debates have been transferred to several other areas, e.g., human embryo research, cloning, stem cell research, the formation of chimeras, the use of abortifacients - even the issues of brain death, brain birth, organ transplantation, the removal of food and hydration, and research with the mentally ill or the disabled. But both private choices and public policies should incorporate sound and accurate science whenever possible. What I have tried to indicate is that in these current discussions, individual choices and public policies have been based on "scientific myth", rather than on objective scientific facts.

Nonetheless, as Winston Churchill once remarked, "Man will occasionally stumble over the truth, but usually manages to pick himself up, walk over or around it, and carry on!"

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# AMERICAN LIFE LEAGUE

## **A Declaration of Life by Pro-Life Physicians**

**Doctors—click [here](#) to add your name to the list!**

### **Introduction:**

Birth control pills, Depo-provera injections and Norplant implants achieve their anti-fertility effects primarily by causing temporary sterilization, secondarily by causing abortion by preventing the implantation of the approximately week old human from successfully attaching or "implanting" into the wall of the mother's womb, and thirdly by acting as a contraceptive barrier to sperm by thickening the cervical mucous. That some drugs promoted as contraceptives may really cause abortion has not been clear to many Americans for whom abortion presents serious moral questions.

### **Background of the Pill:**

Gregory Pincus, co-developer of the Pill, credits a visit from Planned Parenthood's founder Margaret Sanger who promised research money for the development of the Pill. i

Sanger, who supported abortion, was concerned about developing a Pill as a means of curbing the "population explosion." ii

Like Sanger, Pill supporters who shared Sanger's demographic concerns, such as Dr. Robert Kistner of Harvard, were less concerned about means than ends: "Our efforts to control population growth should not lead to mass guilt about methodology. It would be tragic if an effective postcoital pill or long-term progestational agent were declared illegal because of its abortifacient effect." iii

### **Conflict of Values: Guilt would be a problem for some.**

In 1962 Dr. Mary Calderone, then Medical Director of Planned Parenthood said that: "if it turns out that these intrauterine devices

operate as abortifacients, not only the Catholic Church will be against them, but Protestant churches as well." iv

Legal problems existed because the language of pre-Roe anti-abortion laws was such that the "broad language of statutes and cases would suggest that to use pre-implantation means on a pregnant woman would be unlawful ... manufacturers, distributors or sellers of the pre-implantation means might be prosecuted under statutes prohibiting the manufacture, distribution or sale of abortifacients." v

#### **Technology Meets Biology:**

Planned Parenthood's Dr Abraham Stone, noted in 1952 that any mechanical, chemical or "... biologic method that would prevent ovulation or fertilization merely prevent life from beginning ... Measures designed to prevent implantation fall into a different category. Here there is a question of destroying a life already begun." vi

The federal Department of Health, Education and Welfare also acknowledged this in a survey of birth control research: "All of the measures which impair the viability of the zygote at any time between the instant of fertilization and the completion of labor constitute, in the strict sense, procedures for inducing abortion. Administration of compounds whose mechanism of action is of this character to man either as an investigative procedure or as a practical birth control technique poses legal questions that have as yet not been resolved." vii

The problem was that most of the promising research included anti-implantation or abortion causing actions. viii

#### **Facts vs. Semantics:**

With biology such a stubborn thing, Pill promoters turned to semantics for a solution. Swedish researcher Bent Boving, at a 1959 Planned Parenthood-Population Council symposium noted that: "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." ix

The advice was not isolated. At the 1964 Population Council symposium Dr. Samuel Wishik pointed out that acceptance or rejection of birth control would depend on whether it cause an early abortion. Dr. Tietze, of Planned Parenthood and the Population Council suggested, as a public relations ploy, "not to disturb those people for whom this is a question of major importance." Tietze added that theologians and jurists have always taken the prevailing biological and medical consensus of their times as factual, and that "if a medical consensus develops and is maintained that pregnancy, and therefore

life, begins at implantation, eventually our brethren from the other faculties will listen." x

In 1965 the American College of Obstetrics and Gynecology (ACOG) responded with its own semantic answer: "CONCEPTION is the implantation of the fertilized ovum." xi

Not everyone accepted these manipulations. Dr. Richard Sosnowski said he was troubled: "... that, with no scientific evidence to validate the change, the definition of conception as the successful spermatoc penetration of an ovum was redefined as the implantation of a fertilized ovum. It appears to me that the only reason for this was the dilemma produced by the possibility that the intrauterine contraceptive device might function as an abortifacient." xii

#### **The Pill and Abortion:**

The federal Food and Drug Administration approved the Pill for limited use in 1960. First generation Pills allowed ovulation in 6.8% of menstrual cycles. xiii

(Because of health problems, Pill's high levels of estrogen were reduced, but less estrogen allows greater breakthrough ovulation.)

After much study a 1969 FDA Advisory Committee said the Pill's "high degree of contraceptive effectiveness [was] brought about through interference with several phases of the reproductive process. An influence on the hypothalamus ... is probably responsible for the ... inhibition of ovulation. ... The second major effect is on the endometrium. The progestin acts as an antiestrogen causing alteration in endometrial glands and as a progestin, causing pseudodecidual reactions. Both of these alter the ability of the endometrium to participate in the process of implantation." (Emphasis added.)

Longtime Planned Parenthood associate Dr. Lewis Hellman chaired the advisory committee, and Dr. Christopher Tietze of PP and the Population Council was a committee member along with other PP members. xiv

And former PP President Dr. Alan Guttmacher is also on record as recognizing the triple mode of action for the Pill. xv

#### **Pill Labeling:**

In December, 1976 the federal FDA proposed mandatory patient package inserts accompany all Pill prescriptions: "The Food and Drug Administration will regard as misbranded and subject to regulatory action any oral contraceptive that is shipped in interstate commerce ... after April 6, 1977 without labeling that is substantially the same as set forth in this notice." Thus, the FDA required Pill manufacturers to tell physicians that the Pill included a mode of action that every physician

would understand from his medical training to be an early abortion:  
"Combination oral contraceptives ... Although the primary mechanism of action is inhibition of ovulation, alterations ... in the endometrium (which reduce the likelihood of implantation) may also contribute to contraceptive effectiveness ... progestin oral contraceptives are known to ... exert a progestational effect on the endometrium, interfering with implantation, and, in some patients suppress ovulation." xvi

Physician package inserts for the Pill are still required in 1998, and they still use language that indicates the Pill, Depo provera and Norplant inhibit implantation. These chemicals "harden" lining of the womb (uterus) creating a hostile environment and thus make it harder for the tiny multicelled human being from implanting in the wall of the womb. This constitutes abortion at approximately one week of life. There is no definitive medical agreement as to what percent of times per monthly cycle this occurs.

We, the undersigned physicians, do therefore declare that the pill and similar birth control products act, part of the time, by design, to prevent implantation of an already created human being. These products clearly cause an early abortion and are - despite the semantic gymnastics of their ardent apologists -abortifacient.

We further declare that the so-called emergency contraceptive products being promulgated on the American people work in the same fashion and are also abortifacient.

**Click [here](#) to see updated list of physician endorsements.**

**Endnotes:**

- i. Gregory Pincus, *The Control of Fertility*, Academic Press, New York, 1965, p. 6; Planned Parenthood Federation of America, *Research Facilities, Activities and Accomplishments*, memo, 1/20/53, Margaret Sanger Collection, Library of Congress
- ii. Margaret Sanger, *Family Limitation*, 1st ed., 1914, 15-16, Margaret Sanger Collection, Library of Congress (MSCLC); Sanger Speech, Washington DC, (MSCLC) speech was first given in 1916 and delivered 119 times; letter from Sanger to Hanna Stone, 3/10/32 copy to Marjorie Provost (Sanger's handwriting) Sophia Smith Collection, Smith College.
- iii. Robert W. Kistner, MD, *The Pill*, Delacourt Press, 1969, p. 248.
- iv. Dr. Mary Calderone, discussion, *Mechanisms of Contraceptive Action*, in *Intrauterine Contraceptive Devices: Proceedings of the Conference*, held April 30-May 1, 1962, New York City, ed. C. Tietze and S. Lewitt, published by Excerpta Medica Foundation, 110.

- v. Sybil Meloy, "Pre-Implantation Fertility Control and the Abortion Law," *Chicago- Kent Law Review*, vol. 41 (1964): 183, 205-06. Planned Parenthood recognized in its amicus brief for *Roe v. Wade* that criminal abortion laws could be applied to the IUD because of its potential to prevent implantation. PPFA its physician group (APPP) Amicus brief on page 44 cited Cybil Meloy, and also said that prosecutors had not used state anti-abortion laws to outlaw the use of IUD's.
- vi. Abraham Stone, M.D., "Research in Contraception: A Review and Preview," presented at the Third International Conference of Planned Parenthood, Bombay, India Report of the Proceedings, November 24-29, 1952, no copyright, Family Planning Association of India, 101.
- vii. A Survey of Research on Reproduction Related to Birth and Population Control (as of January 1, 1963) US Department of Health, Education, and Welfare, Public Health Service, page 27.
- viii. Memo to Dr. Drill from Dr. Saunders, re: "Effects of Drugs on Mating in Rats," 12/9/54, Gregory Pincus Papers, Manuscript Division, Library of Congress; Abraham Stone, The Control of Fertility, *Scientific American*, April, 1954, vol. 190., no. 4, 31-33.
- ix. Bent Boving, "Implantation Mechanisms," in *Mechanisms Concerned with Conception*, ed. C. G. Hartman (New York: Pergamon Press, 1963), 386. Boving acknowledged (p. 321): "... the greatest pregnancy wastage, in fact, by far the highest death rate of the entire human life span, is during the week before and including the beginning of implantation, and the next greatest is in the week immediately following."
- x. Proceedings of the Second International Conference, Intra-Uterine Contraception, held October 2-3, 1964, New York City, ed. Sheldon Segal, et al., International Series, Excerpta Medica Foundation, No. 86, page 212.
- xi. ACOG Terminology Bulletin, Terms Used in Reference to the Fetus, Chicago, American College of Obstetrics and Gynecology, No. 1, September 1965.
- xii. Dr. Richard Sosnowski, head of the Southern Association of Obstetricians and Gynecologists "The Pursuit of Excellence: Have We Apprehended and Comprehended It?" *American Journal of Obstetrics and Gynecology*, vol. 150. No. 2 (September 15, 1984) 117.
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- xvi. Fed. Register Vol. 41, No. 236, Tuesday, December 7, 1976, 53634