Subject: **House Bill No. 2029**
House Bill No. 2550
House Bill No. 16
House Bill No. 2042

Dear Rep. Joson:

I am aware of the pending legislation in your Committee and wish to submit my findings about **artificial contraceptives** for your guidance on the four House Bills to be taken up during a Public Hearing on January 25, 2005. As a licensed Obstetrician/Gynecologist practicing in the Philippines, I have done comprehensive research on this matter.

I hope you will consider this research and **disallow passage** of subject House Bills.

Very truly yours,

Leah P. Zamora
Licensed Obstetrician-Gynecologist

Encl.

These seem to be such simple and obvious requirements. Yet, on these grounds alone, **not one of the widely available methods of modern contraception would be acceptable**.

The side effects of hormonal contraceptives and intrauterine devices (IUDs) are major reasons why 40 to 70 percent of users in the Third World abandon these methods within two years. Fear of side effects prevents a further 25 to 33 percent from using them at all. In developed countries, women are abandoning these methods as well. Pill use in the United States dropped from 61 percent in 1973 to 45 percent in 1982.

A growing number of scientific studies have exposed the adverse effects of contraceptives. In 1975, half of all maternal deaths in the United States were caused by contraceptive complications. Each year, one woman in every 500 pill users In the United Kingdom is hospitalized due to adverse effects. Two-thirds of women using Depo-Provera bleed so frequently that they require blood transfusion.

Awareness of the adverse effects of artificial methods of contraception should make legislators reconsider their position on these methods. I oppose HB 2029, 16, 2550 and 2042 if only because of the adverse effects of artificial contraceptive methods.

ADVERSE EFFECTS OF ARTIFICIAL CONTRACEPTIVE METHODS

I. Hormonal contraceptives
   - A. estrogen plus progestin contraceptives
   - B. progestational contraceptives

II. Mechanical methods
   - A. IUD
   - B. barrier methods

III. Permanent sterilization
   - A. Tubal ligation
   - B. Hysterectomy
   - C. Vasectomy

7. hypertension
8. venous and arterial thrombosis
9. migraine headaches
10. other effects:
    - delayed menses after discontinuation of use
    - decreased amount of breast milk in lactating mothers
    - increased cervical mucus production
    - vaginitis / vulvovaginitis
    - hyperpigmentation of the face & forehead
    - weight gain
    - depression
    - nausea
    - breast tenderness
    - acne
    - nervousness

It must also be stressed that combination OCPs do not provide protection against sexually transmitted infections.

SUPPORTING EVIDENCE

I. NEOPLASIA

Hormonal contraceptives are unlikely causes of cancer. They have a **protective effect against cancer of the ovary and endometrium**.

However, there are reports indicating **increased risk of pre-cancerous and cancerous lesions of the cervix, breast, and liver** among OCP users.

A. CERVIX
- There is a correlation between the risk of **pre-invasive cervical cancer** and combination OCP use.
- Risk of **invasive cancer** increases after 5 years of use.

B. BREAST
- The Collaborative Group on Hormonal Factors in Breast Cancer (1996) studied more than 53,000 women with breast cancer.
  - There was a **small but significant increase in relative risk of breast cancer** in women currently taking combination OCPs, and even within 10 years of discontinued use.
  - With current OCP use or within 5 years, the **risk of breast cancer diagnosis is increased by about 25%**.
  - The increased risk of breast cancer in current OCP users is limited to localized disease, and OCP users have a significantly reduced incidence of disease that has spread beyond the breast.
- **Relative risk for developing breast cancer is 1.24 among OCP users**.

(usually mestranol) for prolonged periods.
  - Stopping the combination OCP and resection of the tumor have been recommended, although some tumors disappear spontaneously upon discontinuation of the OCP.
  - Use of newer, low-dose preparations appears to have reduced the incidence of such tumors.

II. METABOLIC EFFECTS

Combination OCPs have a wide range of metabolic effects that are often combined and overlapping.

A. LIPOPROTEINS AND LIPIDS

- Combination OCPs **increase triglycerides and total cholesterol**
  - Estrogens: decreases the concentration of low-density lipoproteins
    increases the concentration of high-density lipoproteins
  - Progestins: reverse effect
- **The importance of such changes in the development of arterial vascular disease such as myocardial infarction ("heart attack") or stroke is not clear, but is a cause for concern.**

B. CARBOHYDRATE METABOLISM

- Combination OCPs may (1) **intensify pre-existing diabetes** or may prove sufficiently diabetogenic to (2) **induce clinically apparent disease in susceptible women.**
  - Combination OCPs **decrease glucose tolerance** as a direct effect of the estrogen dose.
  - Progestins **increase insulin secretion and create insulin resistance**.
  - The risk of inducing clinically apparent disease in susceptible women is low because in the great majority of women, the effect on carbohydrate metabolism is slight.
  - DIabetogenic effects are often reversible with discontinuation of use.
- The **onset of insulin-dependent diabetes may be accelerated** among combination OCPs users who had diabetes during pregnancy (GDM or gestational diabetes).
  - The incidence of diabetes among these women increased tenfold.

C. PROTEIN METABOLISM

- Estrogens **increase the hepatic production of various globulins**.
  i. Increase in angiotensinogen
     Angiotensinogen is associated with **"pill-induced" hypertension**.
  ii. Increase in clotting factors (fibrinogen, factors II, VII, IX, X, XII, XIII)
     These factors may increase the incidence of **venous and arterial thrombosis**.

III. CARDIOVASCULAR EFFECTS

There are a number of **uncommon but significant cardiovascular risks** associated with combination OCP use.

A. THROMOBOEMBOLISM

- The risk of deep vein thrombosis (DVT) and pulmonary embolism has been estimated to **increase by 3- to 11-fold** in combination OCP users.
- Over-all relative risk is 4.

C. HYPERTENSION
- The association between combination OCP use and hypertension has been apparent since the 1960's.
- This association is **due to both estrogen and progesterone**.
- Unfortunately, women destined to develop hypertension with OCP use cannot be identified in advance.
- Normal blood pressure levels may return to after stopping OCP use.

D. MYOCARDIAL INFARCTION (HEART ATTACK)
- Combination OCPs are associated with an increased risk of myocardial infarction in non-smokers.
  - Relative risk is 3 among OCP users who do not smoke.
- **Smoking is an independent risk factor for myocardial infarction, but it may be enhanced by combination OCP use**.
  - Relative risk is 10 among OCP users who smoke.
- Risk is increase in women who smoke more than 15 cigarettes a day and are more than 35 years of age.

E. MIGRAINE HEADACHES
- The frequency and intensity of headaches may improve or worsen.
- **Combination OCP use is avoided since some migraines may be indistinguishable from mild or impending stroke**.
- A history of migraine headaches is associated with an increased risk of thrombotic and hemorrhagic strokes. Combination OCP use may enhance this risk.

IV. EFFECTS ON REPRODUCTION

A. POST-PILL AMENORRHEA
- Ovulation usually resumes promptly after stopping combination OCP use.
- 90 percent of women would have regular ovulation within 3 months.
- There may be **reduced conception rates within 6 months** of discontinued use.

B. LACTATION
- Combination OCP use in nursing mothers can **reduce the amount of breast milk**. Thus they are not prescribed for mothers who are breastfeeding.
- Progestin-only pills have little effect on lactation.

V. OTHER EFFECTS

A. CERVICAL MUCORRHEA
B. VAGINITIS / VULVOVAGINITIS
C. HYPERPIGMENTATION OF THE FACE & FOREHEAD
D. WEIGHT GAIN
E. DEPRESSION
F. NAUSEA BREAST TENDERNESS
G. ACNE
I. NERVOUSNESS

9. known or suspected pregnancy

WARNING

Cigarette smoking increases the risk of serious cardiovascular side effects from combination OCP use.

- Risk increases with age, and is quite marked in women over age 35.
- Risk increases with heavy smoking (15 or more cigarettes per day).

Women who use combination OCPs should strongly be advised not to smoke.

PROGESTATIONAL CONTRACEPTIVES

A. ORAL PROGESTINS (mini-pills)
B. INJECTABLE PROGESTIN CONTRACEPTIVES

Oral progestins have not achieved widespread popularity because of a much higher incidence of irregular bleeding and a higher pregnancy rate. They **impair fertility without always inhibiting ovulation**, probably by **producing cervical mucus that impedes sperm penetration** and by **altering endometrial maturation to thwart successful blastocyst implantation**.

Disadvantages of injectable progestin contraceptives are similar to those of oral progestin-only pills.

MAJOR DISADVANTAGES

1. contraceptive failure
2. higher incidence of ectopic pregnancy when contraception fails
3. irregular uterine bleeding
4. ovarian functional cysts develop more frequently
5. time of intake must be constant → if a woman takes the pill even three hours late, a back-up form of contraception is needed for the next two days

CONTRAINDICATIONS

1. women with unexplained uterine bleeding, especially older women
2. history of ectopic pregnancy
3. previous functional ovarian cysts

The Food and Drug Administration has required the same package insert labeling of contraindications for both combination and progestin-only OCPs.

9. breast tenderness
10. depression (< 5% incidence)

It must again be stressed that progestational contraceptives do not provide protection against sexually transmitted infections.

SUPPORTING EVIDENCE

I. NEOPLASIA
- Within the 1st five years of use, there was a two-fold increase in the incidence of **breast cancer**. But over-all risk was not increased.
- Risk of **cervical carcinoma-in-situ** may be increased.

II. EFFECTS ON REPRODUCTION
- prolonged amenorrhea
- abnormal uterine bleeding during and after use → 2/3 of women bleed so frequently that they require blood transfusion
- prolonged anovulation after discontinuation → return of fertility is delayed but not prevented

III. LOSS OF BONE MINERAL DENSITY IN LONG-TERM USERS
- This is a potential problem in users 18 – 39 years of age.
- It is reversible after discontinuation of use.
- Adolescent DMPA users should take calcium (1,500 mg / day).

IV. OTHER EFFECTS
- Weight gain: 1.5 – 4 kg in the 1st year of use, with continued weight gain thereafter
- Headaches
- Breast tenderness
- Depression (< 5% incidence)

It must again be stressed that IUDs do not provide protection against sexually transmitted infections.

SUPPORTING EVIDENCE

I. UTERINE PERFORATION AND ABORTION

- The earliest adverse effects are **associated with insertion**.
  a. Clinically apparent or silent perforation may occur, either while sounding the uterus or inserting the IUD.
  b. Abortion of an unsuspected pregnancy may occur.
- Incidence : 1.1 per 1,000 insertions
- Frequency of complications depends on the skill of the operator and the precautions taken to avoid interrupting a pregnancy.
- Devices may migrate spontaneously into and through the uterine wall, but **most perforations occur, or at least begin, at the time of insertion**.

II. UTERINE CRAMPING AND BLEEDING

- Uterine cramping and bleeding are likely to develop soon after insertion, and persist for variable periods.
- Cramping may be reduced by taking non-steroidal anti-inflammatory medications prior to insertion and during menses.

III. HEAVY OR PROLONGED BLEEDING

- Blood loss during menstruation is usually doubled with the use of Cu T 380A, and it **may be so great as to cause iron-deficiency anemia**.
- Approximately 10-15% of IUD users have it removed for this problem.

IV. INFECTION

- **Pelvic infections, septic abortions, and tubo-ovarian abscesses** have developed with IUD use.
- There is a risk of **severe pelvic infections resulting in sterility** → IUD users are up to 9 times more likely to develop a sterilizing infection as compared to non-users.
- **Deaths due to sepsis** have also been reported.
- With suspected infection, the IUD should be removed, and antibiotics given.
- The major risk of infection is due to insertion.
  - There is a small increased risk of infection up to the first 20 days following insertion.
  - Any infection after 45 to 60 days from insertion should be considered sexually transmitted.
- Women may also be at **greater risk of HIV infection**. And HIV-infected women should not use IUDs.

V. PREGNANCY WITH IUD

- If the tail of the IUD is visible through the cervix, it should be removed.
- The abortion rate is 54% if the device is left in the uterus, compared to 25% if the IUD is removed.

VI. ECTOPIC PREGNANCY

- IUDs provide less protection from ectopic pregnancies.
- With contraceptive failure, the risk of ectopic pregnancy is increased.
- Women at high risk for ectopic pregnancy should not use IUDs.

CONTRAINDICATIONS TO THE USE OF COPPER T 380A

1. pregnancy or suspicion of pregnancy
2. abnormalities of the uterus resulting in distortion of the uterine cavity
3. acute pelvic inflammatory disease (PID) or a history of PID
4. postpartum endometritis or infected abortion in the past 3 months
5. known or suspected uterine or cervical malignancy, including unresolved abnormal paps smear
6. genital bleeding of unknown etiology
7. untreated acute cervicitis or vaginitis
8. Wilson disease
9. allergy to copper
10. patient or her partner with multiple sexual partners
11. conditions associated with increased susceptibility to infections with microorganisms including, but not limited to leukemia, acquired immune deficiency syndrome, and intravenous drug abuse
12. genital actinomycoses
13. previously inserted IUD not yet removed

CONTRAINDICATIONS TO THE USE OF PROGESTASERT

1. pregnancy or suspicion of pregnancy
2. history of ectopic pregnancy or a condition that predisposes to ectopic pregnancy
3. presence or history of PID or factors that predispose to PID
4. patient or her partner with multiple sexual partners
5. presence or history of one or more sexually transmitted infections including, but not limited to gonorrhea or chlamydial infections
6. postpartum endometritis or infected abortion
7. incomplete involution of the uterus following an abortion or childbirth
8. previously inserted IUD still in place
9. previous pelvic surgery that may be associated with an increased risk of ectopic pregnancy (surgery of the fallopian tubes, surgery for pelvic adhesions or endometriosis)
10. abnormalities of the uterus resulting in distortion of the uterine cavity or uteri that measure < 6 cm or > 10 cm by sounding
11. known or suspected uterine or cervical malignancy, including unresolved abnormal paps smear
12. genital bleeding of unknown etiology
13. cervicitis or vaginitis unless and until infection has been eradicated and has been shown to be nongonococcal and nonchlamydial
14. genital actinomycoses
15. conditions or treatments associated with increased susceptibility to infections with microorganisms including, but not limited to leukemia, diabetes, history of endocarditis or certain types of heart disease that are associated with increased risk of endocarditis, acquired immune deficiency syndrome, and conditions requiring chronic corticosteroid therapy
16. intravenous drug abuse

- **Latex sensitivity** has been reported.
- Slippage and displacement rate is 8%.
- Breakage rate for latex condoms: 1.1%
- Breakage rate for polyurethane condoms: 7.2%

FEMALE CONDOM (VAGINAL POUCH)

- Slippage and displacement rate is 3%.
- Breakage rate: 0.6%
- Higher pregnancy rate than male condom (21% vs 14% with typical use, 5% vs 3% with perfect use)

SPERMICIDAL CONTRACEPTIVES

- Although studies have shown that spermicides are not teratogenic (cause fetal malformations), a court decision in *Wells versus Ortho Pharmaceutical* was rendered in favor of the plaintiff in a suit alleging that congenital malformations were caused by maternal spermicide exposure.
- Provides only **partial protection** against sexually transmitted infections, including gonorrhea, and probably papillomavirus and HIV.

DIAPHRAGM PLUS SPERMICIDAL CONTRACEPTIVES

- Diaphragm should not be removed for at least 6-8 hours after intercourse.
- Rarely, it may cause **toxic shock syndrome**, thus it is advised that the diaphragm be removed after the 6-8 hour period, or at least the next morning.
- It should not be kept in place longer than 24 hours as **ulceration of the vaginal epithelium** may occur.
- There is a slight but real increase in **urinary tract infections**.

4. Rarely, pulmonary embolism
5. Spontaneous re-anastomosis (re-connection of the tubes)
    - Failure rate after 1 year: 0.55 per 100 women
    - Failure rate after 5 years: 1.31 per 100 women
    - Failure rate after 10 years: 1.85 per 100 women
5. Ectopic pregnancy after failed sterilization
    - 50% of pregnancies that occur after failed electrocoagulation are ectopic
    - 10% of pregnancies that occur after failure of a ring, clip, or tubal resection are ectopic
6. Complications when performed under laparoscopy, and electrocautery is used:
    - bowel injury in 1 – 6 % (hemorrhage, puncture, or cautery of the bowel).

HYSTERECTOMY

1. Anesthetic complications
2. Hemorrhage
3. Urinary tract injury

VASECTOMY

1. Sterility is not immediate – achieved after 3 months or about 20 ejaculations
2. Hematoma – 5% of subjects
3. Sperm granulomas – inflammatory responses to sperm leakage.
4. Failure rate is < 1% due to: unprotected intercourse soon after the procedure, failure to occlude the vas deferens, and spontaneous reanastomosis / recanalization.

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