

2006 Addendum to The Christian and Birth Control

- Page 7 Paragraph 1 Use of a spermicide with a barrier method substantially increases effectiveness. Use of a spermicide alone shows failure rates between 50-80%, according to latest U.S. Food and Drug Administration [FDA] data from August 2002. The World Health Organization showed in its 2002 study widely varied typical use failure rates of use of spermicide alone, from less than 2% to 59%.
- Page 7 Paragraph 3 The typical use effectiveness rate of the male condom is now at 89%, according to U.S. FDA statistics as of August 2002.
- Page 7 Paragraph 4 Same as above
- Page 7 Last Paragraph The August 2002 FDA statistics for typical use effectiveness for the following barrier methods are as follows: male condom - 89%; female condom - 79%; diaphragm (used with a spermicide) - 83%; cervical cap (used with a spermicide) - 83%. (The FDA does not show statistical typical use effectiveness information for vaginal contraceptive film. However, a 1999 study conducted by Raymond & Dominik showed a 75% effectiveness rate among women within six-months' use.)
- Page 9 The term, RU-486, is no longer used; it is now known by its name "mifepristone" (or "mifeprex," the drug's brand name).
- Page 10 Paragraph 3 The FDA approved RU-486 for use in the United States in September 2000. A study published in January 2003 by the Alan Guttmacher Institute estimated that six (6) percent of U.S. abortions (more than 37,000) involved the use of abortion pills in the first six months of 2001.
- In November 2004, the FDA announced that "black box" labeling changes in the packaging of the abortion drug mifepristone (also known as RU-486) would begin. Danco Laboratories produces mifepristone under its trade name Mifeprex. These revised warnings, the highest level issued by the FDA, indicate the risks such as serious bacterial infections, sepsis, and bleeding and death (the drug is implicated in the death of an 18-year-old Californian, Holly Patterson, who took the abortion drug and suffered septic shock following uterine inflammation. She died in September, 2003.)
- Page 10 Paragraph 6 In September 1996, the FDA issued a letter of approval for use of mifepristone in the United States for abortion purposes. Final approval came in September 2000. (See above regarding "black box" warning issued by the FDA in November 2004.)
- Page 14 Paragraph 3 Other terms/brand names for "emergency contraception" and "morning-after pill" are "post-coital contraception," "Preven," "Ovral," and "Plan B." Preven was discontinued by its manufacturer in April 2004. Ovral is the brand name for the type of emergency contraception which uses combined (estrogen and progestin) oral contraceptives. Plan B is the brand name for the type using progestin-only oral contraceptives; it is the most commonly dispensed EC.
- Page 14 Paragraph 4 NOTE: The morning-after pill is available by doctor's prescription. On May 6, 2004, the FDA officially rejected over-the-counter (OTC) sale of the morning-after pill.

- Page 14 Paragraph 5 NOTE: The progestin-only “minipill” is another clearly-abortifacient form of birth control. The hormone in this pill reduces and thins the uterine lining which inhibits implantation of a baby in the uterine wall. This product was given FDA approval in 1973 and has a 98% effectiveness rate, according to the FDA, August 2002.
- Page 14 Paragraph 6 Statistics by the FDA (as of August 2002) indicate that almost 20% of those who use emergency contraception still become pregnant.
- Page 15 Footnote 2 NOTE: In December 2000, the FDA approved the use of Mirena, the first new intra-uterine device on the U.S. contraceptive market since 1988.
- Page 15 Paragraph 3 NOTE: The brand name for the copper IUD is *Paragard*[®].
- Page 15 Paragraph 3 NOTE: The brand name for the progesterone-releasing IUD is *Progestasert*[®].
- Page 18 DEPO-PROVERA: Paragraph 4 According to Depo’s website (November 2003), Depo-Provera’s effectiveness rate is listed at 99.7 percent, when used as directed.
- In November 2004, the FDA issued its most strident “black box” warning on the packaging of Depo-Provera. The warning links the use of the drug with significant bone density loss. Evidence shows that women who use the injectable for longer periods of time experience greater bone loss. In addition, the bone density may not be reversible when its use is discontinued. An FDA release states that the labeling warns patients not to use the drug for more than two years unless all other birth control methods are deemed inadequate.
- Page 18 CYCLO-PROVERA Paragraph 1 Cyclo-Provera is now known as Lunelle. Lunelle was approved for use by the FDA in 2000; on American market in 2001. It was voluntarily recalled by its manufacturer, Pharmacia, in April 2002 after insufficient dosing was discovered. Lunelle is presently unavailable.
- Page 18 NORPLANT Paragraph 1 Norplant is effective over 99% of the time, according to the U.S. FDA, August 2002.
- A single-rod Norplant product, “Implanon,” is under review by the FDA and is awaiting approval (*Contraceptive Technology Update*, August 2004)
- Page 22 Paragraph 6 The term “rhythm method” should now be termed the “calendar method.” Other terms include “periodic abstinence” and “fertility awareness.”
- Page 23 Paragraph 6 FDA approval was given for the VasClip, a new device to be used in vasectomy procedures. The Vasclip is a less invasive alternative to traditional vasectomy because it eliminates cutting, suturing, and cauterizing of the vas deferens. Safety and efficacy research has not been published in any peer-reviewed journal. The company, Vasclip Co. of Roseville, MN, states that material is being readied for publication. (*Contraceptive Technology Update*, August 2003)

Page 28 Footnote The Today Sponge, which was withdrawn from the U.S. market in 1995, was given regulatory approval for sale in the American retail market by the U.S. Food and Drug Administration in April 2005.

The contraceptive patch, Ortho Evra, is now on the market after its FDA approval in 2001. Because of inconsistencies with data on its possible abortifacient nature, CLR cannot endorse its use at this time. (March/April 2003, *Beginnings*)

A report is expected to be released by the Institute of Medicine, an independent research arm of the National Academy of Sciences, in early 2004 with recommendations for contraceptive development. Among the possible new high-tech approaches/techniques: 1) Enabling an egg, perhaps by disabling proteins on the egg's surface, to block sperm penetration; 2) Preventing maturation of a specific sperm protein in order to prevent fertilization of an egg (a reversible male method pill is being developed by the Population Council, New York); 3) Preventing sperm from traveling up through the uterus to the fallopian tubes (several birth control types are being worked on by the Population Council including a pill, implant, and vaginal ring); 4) Inhibiting egg release from an egg follicle in the ovaries. (Source: "Contraception of the future," Jacqueline Stenson, MSNBC)

The *FDA Consumer* reports that development of spermicidal as well as microbicidal birth control methods continue to prevent not only pregnancy but also transmission of HIV and other STDs (sexually-transmitted diseases).

Page 29 Paragraph 2 The combination "pill" (which uses two hormones, estrogen and progestin, to suppress ovulation) has a 99% effectiveness rate when used correctly, according to the FDA, August 2002.

Page 29 Last Paragraph Oral contraceptives also improve severe acne problems in women.

Page 30 Paragraph 4 *The Journal of the American Medical Association* released its studies correlating repeated use of oral contraceptives and breast cancer.

General Update (Chapter 8): In September 2003, the U.S. FDA approved "Seasonale," the first extended-cycle oral contraceptive. This form of birth control pill is specifically designed to reduce the frequency of a woman's period — from one time per month to four times a year. This type of birth-control pill involves taking 12 weeks of active pills and a week's worth of inactive pills. Clinical studies showed some users experienced increased breakthrough bleeding and spotting. Seasonale became available to the public in late 2003. As with other hormonal forms of birth control, no clear evidence exists as to the efficacy of the third mechanism. Until conclusive evidence is produced to answer this question, CLR cannot condone or encourage the use of these forms of birth control.

"NuvaRing," a vaginal contraceptive ring, was given FDA approval in 2001. It is a flexible barrier-method ring that is inserted into the vagina and releases the hormones, progestin and estrogen. As with other hormonal forms of birth control, no clear evidence exists as to the efficacy of the third mechanism. Until conclusive evidence is produced to answer this question, CLR cannot condone or encourage the use of these forms of birth control.

The U.S. FDA approved Ovcon 35, the first chewable oral contraceptive tablet. The product is expected to hit the market in last spring 2004. The pill has the same hormonal combination as the conventional tablet form of Ovcon. (Contraceptive Technology Update, February 2004, Vol. 25, No. 2, Page 16-17) As with other hormonal forms of birth control, no clear evidence exists as to the efficacy of the third mechanism. Until conclusive evidence is produced to answer this question, CLR cannot condone or encourage the use of these forms of birth control.

According to Contraceptive Technology Update (February 2004), a spray-on contraceptive is now being researched.

Although marketable new types of male contraception are far off on the horizon, Schering AG of Berlin, Germany, and Organon International of Oss, the Netherlands, are conducting trials to evaluate six dose combinations of etonogestrel in implant form and testosterone undecanoate in injection form. No U.S. trials are currently being done, according to a Schering spokeswoman. The contraceptive's projected U.S. marketing is estimated for 2009, if studies indicate success. (*Contraceptive Technology Update*, April 2004)

A single-rod Norplant product, "Implanon," is under review by the FDA and is awaiting approval. (*Contraceptive Technology Update*, August 2004)

In mid-November 2004, the FDA issued an "approvable letter" to the drug company Berlex, for its new low-dose contraceptive YAZ. The drug is the low-dose version of its FDA-approved birth control pill Yasmin. YAZ's dosing regimen is for 24 consecutive days followed by four days of placebo to induce a menstrual period (most OCs are taken for 21 consecutive days followed by seven days of placebos). [Berlex release, 11/18/04].

On February 22, 2006, Warner Chilcott announced that the U.S. FDA approved its 24-day oral contraceptive, Loestrin (R) 24 Fe, which provides 24 days of active hormones and four days of iron containing placebo pills.

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