Addendum to *The Christian and Birth Control*

**NOTE:** In the late 1990s, Christian Life Resources changed its name from WELS Lutherans for Life. Please note our updated name.

- **Page 7 Paragraph 1**: Use of a spermicide with a barrier method substantially increases effectiveness. Use of a spermicide alone shows failure rates at 82%, according to latest U.S. Food and Drug Administration [FDA] data from August 2013.

- **Page 7 Paragraph 2**: Christian Life Resources’ magazine, *Beginnings*, was renamed *Clearly Caring*.

- **Page 7 Paragraph 3**: The typical use effectiveness rate of the male condom is now at 82%, according to 2013 U.S. FDA statistics.

- **Page 7 Paragraph 4**: Same as above

- **Page 7 Last Paragraph**: 2013 FDA statistics for typical use effectiveness for the following barrier methods are as follows: male condom - 82%; female condom - 79%; diaphragm (used with a spermicide) – 88%; cervical cap (used with a spermicide) - 77%-83%. (The FDA does not show statistical typical use effectiveness information for vaginal contraceptive film, although WebMD reports a 74%-94% effectiveness rate. When used consistently and correctly along with the combined use of spermicides [like that in the film] and condoms, the film is about 97% effective, according to WebMD.)

- **Page 9**: The term, RU-486, is no longer used; it has been replaced with the name “mifepristone” (or “mifeprex,” the drug’s brand name).

- **Page 10 Paragraph 3**: The FDA approved RU-486 (now replaced with the name “mifepristone”) for use in the United States in September 2000. A post-marketing summary stated that about 1.52 million women received mifepristone until April 2011.

  In November 2004, the FDA announced that “black box” labeling changes in the packaging of the abortion drug mifepristone (which was then named 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. As of 2011, the drug is implicated in the deaths of 14 women; 8 of those deaths were associated with sepsis.

- **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 12**: There are two types of emergency contraception: 1) emergency contraceptive pills (ECPs) – simply referred to as “emergency contraceptives (ECs) or the “morning-after pill”; and, 2) the intrauterine device (IUD). ECPs are divided into three types: 1) combined ECPs containing both estrogen and progestin; 2) progestin-only ECPs; and 3) ECPs containing an antiprogesterin (either mifepristone or ulipristal acetate). Progestin-only ECPs have largely replaced the older combined ECPs, although all three are available in the United States.
Other terms/brand names for “emergency contraception” and “morning-after pill” are “Plan B One-Step,” and Plan B’s generic forms: “Next Choice,” “My Way,” “Take Action,” as well as the generic Levonorgestrel tablet. Plan B is the brand name for the type using progestin-only oral contraceptives; it is the most commonly-dispensed EC. “Plan B-One Step” was approved by the U.S. FDA in July 2009, and “Next Choice One Dose,” “My Way” were approved in 2012. The second-generation antiprogestin, ulipristal acetate, was approved by the FDA in August 2010 and is marketed under the brand name, ella.

NOTE: Progestin-only EC (like “Plan B One-Step”) is available over the counter without age restrictions to anyone in the United States. As of June 10, 2013, any woman or girl can purchase the “Plan B One-Step” without a prescription.

One-pill generics (“My Way” and “Next Choice One Dose”) are available on the shelf for consumers aged 17 and older; women aged 16 and younger need a prescription. Two-pill generics (Levonorgestrel tablets) are also available only behind the counter without a prescription if the woman is 17 years or older; younger women need a prescription.

NOTE: The progestin-only oral contraceptive birth control pill (sometimes referred to as the “mini-pill”) 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 has a 91% effectiveness rate, according to the FDA, 2013.

2013 statistics by the FDA indicate that 7 out of every 8 women who would have gotten pregnant will not become pregnant after taking “Plan B One-Step” or “Next Choice” (meaning over 22% of those who use those forms of emergency contraception still become pregnant). Of those who use ella, 6 or 7 of every 10 women who would have gotten pregnant will not become pregnant after taking the product (meaning 30%-40% of those who use ella still become pregnant.)

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.

NOTE: The brand name for the copper IUD is Paragard. FDA statistics as of 2013 indicate Paragard’s effective rate at 99.4% for perfect use; 99.2% for typical use.

NOTE: The brand name for the progesterone-releasing IUD is Mirena. FDA statistics as of 2013 indicate Mirena’s effective rate at 99.8% for both perfect and typical use.

According to FDA statistics from 2013, Depo-Provera’s effectiveness rate is listed at 94% for typical use and 99.8% for perfect use.

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.
Cyclo-Provera was known as *Lunelle*. It was approved for use by the FDA in 2000; on the American market in 2001. It was voluntarily recalled by its manufacturer, Pharmacia, in April 2002 after insufficient dosing was discovered. *Lunelle* was discontinued in the U.S. in October 2003.

Norplant distribution in the U.S. ended in 2002, and its production ended globally in 2008. A single-rod Norplant product, “Implanon,” was approved by the U.S. FDA in July 2006 and came on the market in November 2006. It is a thin, matchstick-sized implantable rod that contains the hormone progestin. It can be used for up to 3 years. An almost identical Implanon contraceptive implant known as “Nexplanon/Implanon NXT” adds barium sulphate to the core so it is detectable by x-ray. Nexplanon and Implanon NXT are 99.5% effective in typical and perfect use in preventing pregnancy, according to 2013 FDA data.

The typical use failure rate of withdrawal stands at 22%, according to 2013 data from the FDA.

The term “calendar method” should now replace the “rhythm method.” Other terms include “periodic abstinence,” and “fertility awareness.” The term, fertility awareness, is generally used as a broad term that includes tracking a woman’s basal body temperature, cervical mucus as well as her cycle length. The typical use success rate for fertility awareness-based methods stands at 76% for typical use, according to 2013 data from the FDA. The calendar method is found to be 91% effective for typical use, according to 2013 FDA data.

A new development in calendar-based methods was introduced in 2002 called the Standard Days Method. This method is promoted in conjunction with *CycleBeads*, a ring of colored beans which helps the user keep track of her fertile and non-fertile days. The FDA states the Standard Days Method is effective 88% for typical use and 95% for perfect use.

The sympto-thermal method is found to be 95.6% effective for perfect use, according to 2013 FDA data.

In its 2013 data, the FDA determined the typical use success rate of male sterilization (vasectomy) at 85%; the perfect use success rate stands at 99%.

In its 2013 data, the FDA determined the typical and perfect use success rate of female sterilization by tubal ligation at 95%.

In November 2002, “Essure,” a permanent, non-surgical sterilization procedure for women was approved for use in the United States. The “Essure” procedure is 99.74% effective based on five years of follow-up, 2013 FDA statistics show.

On June 24, 2015, the FDA informed the public about the increased risks associated with Essure on its government website. This came on the heals of a public petition that raised serious concerns about the product and resulted in the launch of an FDA investigation. Thousands of adverse events were reported to the FDA following use of the device. Then on
September 24, 2015, the FDA convened a public advisory committee meeting to discuss the safety and other health concerns about Essure that were not reflected in the labeling.

Page 27 Paragraph 1  
Cyclo-Provera was discontinued in the U.S. in October 2003.

Page 28 Footnote  
The Today Sponge was given regulatory approval for sale in the American retail market by the FDA in April 2005. It combines barrier and spermicidal methods to prevent conception. According to the manufacturer, the Today Sponge reports effectiveness for prevention of pregnancy at 89%-91% in perfect use. Typical use places the effectiveness rates at 80%-86%, according to 2013 statistics. In addition, other sources cite even poorer effectiveness rates for women who have given birth: 74% for perfect use and 68% for typical use.

The contraceptive patch, Ortho Evra, came on the market after its FDA approval in 2001. “The Patch” is a transdermal patch applied the skin that releases synthetic estrogen and progestin hormones to prevent pregnancy. Because of inconsistencies with data on its possible abortifacient nature, CLR cannot endorse its use at this time. In September 2006, a warning of the possibility of blood was placed on the Ortho Evra label by the FDA. On January 18, 2008, the U.S. Food and Drug Administration issued a new warning that use of the birth control patch, Ortho Evra, carries a higher risk of serious blood clots than women using birth control pills. The government agency cited the results of an epidemiological study showing an increased danger of blood clotting that could potentially lead to a lung embolism.

The birth control pill can lead to a higher risk for blood clots, heart attack, and stroke in women who smoke, especially if they are over 35 years of age. Combination estrogen and progestin birth control (including the patch) should NOT be used by women who are over 35 years of age and smoke because it can lead to a higher risk of blood clots, heart attack, and stroke.

The vaginal contraceptive ring (known as “NuvaRing”) was approved by the FDA in 2001. This a flexible device is left in place in the vagina for 3 weeks that releases the hormones progestin and estrogen to prevent pregnancy. Medical studies have further linked NuvaRing to life-threatening injuries such as strokes, heart attacks, deep vein thrombosis (a blood clot that forms in a vein that is not externally visible), and pulmonary embolism (when a blood clot breaks free and lodges in one of the lungs). Nearly 4,000 people were involved in a class-action lawsuit against Merck, including plaintiffs who had lost family as a result of NuvaRing use. In early 2014, all plaintiffs were offered a $100 million national settlement. In 2014, Merck, the manufacturer of NuvaRing, also included a black box warning in its packaging indicating that women over 35 years of age who smoke cigarettes should not use the product because of increased risks of cardiovascular events from combination hormonal contraceptives. Because of inconsistencies with data on its possible abortifacient nature, CLR cannot endorse its use at this time.

Among the contraceptive research on the horizon: a remote-control contraceptive implant using a micro-chip that can be activated and deactivated; a long-acting injectable hormonal contraceptive for men; a subdermal implant for men; a birth control pill for men; a biodegradable implant; a one-size-fits-all device similar to a diaphragm (known as Lea’s Shield); chemical scarring of the fallopian tubes for tubal sterilization; a pregnancy vaccine
that uses the body’s immune system response to prevent pregnancy; development of spermicidal as well as microbicidal birth control methods 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 99.7% effectiveness rate when used correctly and a 91% effectiveness rate when typically used, according to the FDA, 2013.

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

In 2012, the FDA stated manufacturers of birth control pills that contain the hormone drospirenone must carry a warning that they may increase the risk for potentially fatal blood clots. Drospirenone is a synthetic version of the female sex hormone progesterone, also referred to as progestin. Among the birth control pills containing this hormone are Bayer Healthcare Pharmaceutical’s Beyaz, Safyral, Yasmin, and Yaz brands, as well as several other brands (Gianvi, Loryna, Ocella, Syeda, and Zarah). The revised drug labels are required to inform the consumer that some studies have found as high as a threefold increase in the risk of blood clots among women taking these contraceptives, compared with those who took other progestin-containing pills.

In addition, the birth control pill can lead to a higher risk for blood clots, heart attack, and stroke in women who smoke, especially if they are over 35 years of age. Combination estrogen and progestin birth control (including the pills, ring or patch) should NOT be used by women who are over 35 years of age and smoke.

General Update: The vaginal contraceptive ring (known as “NuvaRing”) was approved by the FDA in 2001. This a flexible device is left in place in the vagina for 3 weeks that releases the hormones progestin and estrogen to prevent pregnancy. Because of inconsistencies with data on its possible abortifacient nature, CLR cannot endorse its use at this time. Medical studies have further linked NuvaRing to life-threatening injuries such as strokes, heart attacks, deep vein thrombosis (a blood clot that forms in a vein that is not externally visible), and pulmonary embolism (when a blood clot breaks free and lodges in one of the lungs). Nearly 4,000 people were involved in a class-action lawsuit against Merck, including plaintiffs who had lost family as a result of NuvaRing use. In early 2014, all plaintiffs were offered a $100 million national settlement. As with other hormonal forms of birth control, no clear evidence exists as to the efficacy of the third mechanism. In 2014, Merck, the manufacturer of NuvaRing, also included a black box warning in its packaging indicating that women over 35 years of age who smoke cigarettes should not use the product because of increased risks of cardiovascular events from combination hormonal contraceptives. Until conclusive evidence is produced to answer this question, CLR cannot condone or encourage the use of these forms of birth control.

In 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. This product should not be used if a woman smokes/uses tobacco or is over 35 years of age because smoking raises the risk of stroke, heart attacks, blood clots and high
blood pressure from hormonal birth control. “Seasonique,” also produced by the same company, has active pills and but replaces the placebo week with a low-dosage week of 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, in March 2004. In early 2006, a 24-day oral contraceptive, “Loestrin (R) 24 Fe,” was approved by the FDA. The manufacturer later replaced that product with “Minastrin 24 Fe,” a chewable tablet which provides 24 days of active hormones and four days of iron containing placebo pills. In December, 2006, the FDA approved “Femcon FE,” a chewable birth control pill. The spearmint-flavored “Femcon Fe” contains the same active ingredients as found in other combination oral contraceptives and works on a 28-day regimen (21 active tablets containing a progestin and an estrogen, as well as 7 inactive tablets). 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.

Yaz, a low-dose birth control contraceptive, was released to the American market in 2006. The drug is the low-dose version of its FDA-approved birth control pill Yasmin. Since its arrival on the U.S. market, a number of women who used the drug have suffered wide-ranging side effects including upper respiratory infections, high potassium levels, headaches, migraines, vaginal yeast infections and unusual vaginal discharge. More severe side effects from Yaz include anaphylactic reactions and severe and fatal blood clots. Despite the severe side effects and studies questioning the drugs’ safety, Yaz and Yasmin birth control pills have not been recalled by the FDA, and the drugs still remain on the market with only a four-sentence label change noting an increased risk of blood clots for all birth control pill users, not just Yaz. 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.

A single-rod Norplant product, “Implanon,” was approved by the U.S. FDA in July 2006 and came on the market in November 2006. It is a thin, matchstick-sized implantable rod that contains the hormone progestin. It can be used for up to 3 years. An almost identical Implanon contraceptive implant known as “Nexplanon/Implanon NXT” adds barium sulphate to the core so it is detectable by x-ray. Nexplanon and Implanon NXT are 99.5% effective in typical and perfect use in preventing pregnancy, according to 2013 FDA data. 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.

“Lybrel,” a low-hormone birth control pill that stops women’s periods, was approved by the U.S. FDA in May 2007. 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 emergency contraceptive, “Plan B-One Step,” was approved by the U.S. FDA in July 2009, and “Next Choice One Dose” and “My Way,” generic forms of “Plan B One-Step,” approved in 2012. The second-generation antiprogesterin, ulipristal acetate, was approved by the FDA in August 2010 and is marketed under the brand name, ella. These ECs are clearly abortifacient, and CLR cannot condone the use of these forms of birth control.

Among the contraceptive research on the horizon: a remote-control contraceptive implant using a micro-chip that can be activated and deactivated; a long-acting injectable hormonal contraceptive for men; a subdermal implant for men; a birth control pill for men; a biodegradable implant; a one-size-fits-all device similar to a diaphragm (known as Lea’s Shield) which is expected to become available in the United States (chemical scarring of the fallopian tubes for tubal sterilization; a pregnancy vaccine that uses the body’s immune system response to prevent pregnancy; development of spermicidal as well as microbicidal birth control methods to prevent not only pregnancy but also transmission of HIV and other STDs (sexually-transmitted diseases).

Human trials could begin in 2016 on a male reversible injectable called Vasalgel. The gel is injected into the vas deferens (the tube the sperm swim through), and the polymer works by blocking sperm. Vasalgel is reversed through a second injection which dissolves and flushes out the polymer.

The Population Council is also conducting research on: reversible non-hormonal contraception for men using a nasal spray, gel, implant, or patch; contraceptive topical gels or lotions that can be rubbed on the skin (the gel could be on the market by about 2015); an annual contraceptive ring for women (to replace the current monthly version).