

Life Insight

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Introducing the Respect Life Program 2006-2007

Respect Life Program materials are now available for purchase (toll-free 866/ 582-0943) or download at www.usccb.org/prolife/programs/rlp/rlp0607.htm. This year's theme is *Created, loved, redeemed by God. Priceless!* That truth – that each human has inestimable value because of our relationship with our loving Creator – is the focus of this year's flier.

In *God Is Love*, Pope Benedict's first encyclical, the Holy Father explains how our own lives of discipleship must be shaped by this principle. We are called to personal, concrete, and practical acts of charity toward those whom God puts in our path. In addition, we should contribute to organized charitable activities through personal service and/or financial support. But even that is not enough. We also must work toward a just ordering of society by taking part in public life to help ensure that laws and policies respect the lives and dignity of all. Human lives are under attack especially through abortion, destructive embryo research, and assisted suicide/euthanasia of the disabled and dying. We are obligated to speak out on behalf of the vulnerable and voiceless, by writing letters to our elected representatives, voting, campaigning, and providing friends and colleagues with solid information on the grave moral issues of our day, many of which are addressed in this year's Respect Life articles.

Confused by media reports on stem cell research? Rev. Tad Pacholczyk, Ph.D. of the National Catholic Bioethics Center explains the ethics of embryonic and "adult" stem cell research in a clear, concise article entitled "The Ethics of Stem Cell Research."

The partial-birth abortion debate will be revisited when the U.S. Supreme Court hears oral arguments on November 8, 2006. Susan Wills, of the USCCB Pro-Life Secretariat staff, reviews ten legal, political, and social consequences of partial-birth abortion, and looks to the future in "Partial-Birth Abortion: A Bridge too Far."

The sexual revolution has left many Americans wounded physically, emotionally, and spiritually. But increasingly, young people are committing to chastity for reasons of both health and faith. In "Go Organic: The Scientific Case for Catholic Sexual Ethics," author Jennifer Roback Morse, Ph.D. demonstrates that sound science fully supports Church teaching on the meaning and purpose of human sexuality.

The meaning of marriage has been hotly debated as one state after another considers bans on same sex marriage. Maggie Gallagher, President of the Institute for

Marriage and Public Policy, explains "Why Marriage Matters to Children and to the Common Good."

Many who support the death penalty justify it in terms of seeking justice for victims' families. However, victims' families often oppose execution as an act of violence that cannot bring them justice or healing. In "Victim Advocates Against the Death Penalty," Andrew Rivas, head of the Texas Catholic Conference, introduces us to some family members of victims who work to end the death penalty.

Roxana Barillas, an expert on environmental concerns at the USCCB, describes some environmental dangers affecting children in the womb and how the USCCB is drawing attention to these risks, in "Protecting Children in their First Environment, the Womb."

These articles are available in short, pamphlet-length format in English and Spanish (printed for distribution in parishes, schools and other venues) and in full-length versions, complete with program models and suggested resources in English and Spanish, on the Secretariat's website and the Respect Life Program CD-ROM. The CD contains all programs materials (including liturgy guide and clip art) in English/Spanish, in PDF and MsWORD formats. The cost is only \$5.95, plus shipping.

FDA Approves Plan B for Over-the-Counter Sales: Winners and Losers

On August 23 the Food and Drug Administration (FDA) approved over-the-counter (OTC) sale of the "emergency contraceptive" Plan B for men and women 18 and older. Under a novel distribution scheme (one that is arguably outside FDA authority), girls under 18 will continue to need a prescription for Plan B. *Or will they?* There's nothing to prevent an older boyfriend of the minor girl, or older sister, brother or friend of the under-age couple from buying Plan B for them. So much for ensuring medical supervision of minors' use of Plan B!

Access under the unusual scheme may end up backfiring. At \$25-40 a packet, many women will still choose to get a doctor's prescription for Plan B rather than buying it over-the-counter, to have their insurance cover the cost. Teens, on the other hand, may be more likely than adults to buy Plan B over-the-counter through an adult to avoid creating an insurance record. One can even get a prescription online, based on an "assessment" that requires guessing the correct Yes or No answers to a series of questions even teens can figure out easily.

Example: “Do you want to become pregnant?” “Have you ever had a heart attack?” “Do you have valvular heart disease complicated by pulmonary hypertension, atrial fibrillation, or a history of subacute bacterial endocarditis?” (Note: You don’t have to understand the question. Just answer “No.”)

The only hurdle to obtaining Plan B is not very high: Plan B will *not* be sold (for now) in gas stations and convenience stores. This means consumers will be able to buy it at only about 100,000 places – pharmacies, health clinics, and those ubiquitous pharmacy counters in supermarkets and megastores like Wal-Mart and Target.

Who wins from the FDA decision?

The biggest winner is Barr Pharmaceutical. The company projects \$38 million in Plan B sales for 2006, and that figure is expected to *double* next year.

Planned Parenthood also stands to make impressive profits. Its Vice-President for Medical Affairs, Vanessa Cullins, MD, e-mailed this assurance to affiliate CEOs on February 9, 2004:

“Barr’s senior management has informed us that they are committed to hold intact public sector pricing and the Planned Parenthood special pricing at \$4.50 and \$4.25, respectively, for the next five years. This will remain valid whether the product becomes an over-the-counter product or continues with prescription status.”

A survey of Plan B prices at Planned Parenthood clinics across the country found that cost varies from \$18 to \$42, with an average of \$25 per packet. On average, therefore, Planned Parenthood is making over \$20 on each sale of Plan B. It reported selling 774,482 kits in 2003, for an estimated profit of over \$15 million.

Another winner is Acting FDA Commissioner Andrew von Eschenbach. Senators Hillary Rodham Clinton and Patty Murray blocked his nomination to head the FDA because of the agency’s delay in approving Plan B for over-the-counter sale. Within hours of approval, both Senators announced support for his nomination.

Also among the winners are the legions of guys who will pressure a girl to have sex, but don’t want to father a child. Cynthia Harper et al. of the University of California-San Francisco studied the role of male partners and relationships in determining whether women seek emergency contraception (EC) “when needed.” The researchers found that “factors measuring power dynamics, such as male dominant decision making, ... pressure for sex, ... as well as a strong desire to avoid pregnancy on the part of the male partner ... have a significant association with the use of EC. However, relationship factors known to be associated with use of other contraceptive methods, such as communication, satisfaction, and commitment, show no association with EC use” (Harper, CC, et al., *Sexual partners and the use of emergency contraception*, *American Journal of Obstetrics & Gynecology*, 2003 Oct; 189(4): 1093-1099). This is the perfect drug for male predators, who will now

be able to purchase that drug without question as long as they (not the girl) are 18.

Who loses from the FDA decision?

Millions of women will take Plan B, thinking it is an innocuous, safe, and effective way to avoid pregnancy. The FDA’s press release and accompanying “Plan B: Questions and Answers” refer to Plan B as “contraception” and claim it “safely and effectively prevents pregnancy.” News stories and editorials repeated these misleading claims, ignoring Plan B’s modes of action, risks and dubious effectiveness.

Maybe it is too much to expect that a drug company selling hormonal contraception would be sensitive to the moral dimensions of contraceptive use, even when such “contraception” has the potential to cause an early abortion. Nevertheless, Barr’s Plan B customers are entitled to know in clear language what they are taking and when they should or *should not* take it. Here the FDA has failed to protect the public. Barr is allowed to recommend Plan B use after unprotected intercourse, condom failure, or if a woman forgets her daily pills two days in a row. But unprotected intercourse and condom failure during the three weeks of the monthly fertility cycle when a woman is naturally *infertile* cannot result in pregnancy. Taking Plan B to “prevent pregnancy” during these three weeks a month subjects women to unnecessary discomfort, risk, and expense for no earthly reason. It’s like marketing the drug to octogenarian women, except that they already know they can’t get pregnant.

Many women simply do not understand the basics of the fertility cycle. One study reported in *International Family Planning Perspectives*, for example, found that fewer than half of the women seeking emergency contraception in the Netherlands had had unprotected intercourse at mid-cycle. Should not the FDA require Barr to explain in the package insert when it is *unnecessary* to take Plan B, to reduce the likelihood and risks of repeat use?

The side effects of Plan B are not trivial. The package insert describes the following as common: nausea, vomiting, stomach pain, tiredness, diarrhea, dizziness, breast pain, headache, and menstrual changes (more about that below).

As a public service, we describe below the important things the FDA and Barr did not tell the media and consumers about Plan B, its mode of action, risks and questionable effectiveness.

Can Plan B Cause an Early Abortion?

Apparently pharmacists and doctors can handle the truth about Plan B. A special report on EC by the American Pharmaceutical Association states in part:

Like oral contraceptives that are taken on a daily basis, emergency contraceptives might prevent pregnancy by inhibiting any of the events necessary for pregnancy to become established ...:

1. *Ovulation ...;*
2. *Fertilization ...;*
3. *Transport of the fertilized egg to the uterus; or*
4. *Implantation of the blastocyst in the endometrium (by creating changes in the endometrium unreceptive to implantation).*

(Emergency Contraception: The Pharmacist's Role, p. 3)

Note: "fertilized egg" (point 3) and "blastocyst" (point 4) are a newly conceived human who will die in the first week of life if prevented from traveling to, and implanting in, the mother's endometrium (lining of the womb) to be nourished for further growth and development. Inhibiting transport to the uterus also may result in an ectopic pregnancy that is potentially fatal for the mother as well as the embryo.

In the Plan B prescribing information for doctors, the FDA and Barr state that: "it may inhibit implantation (by altering the endometrium)." Pharmacists and doctors know that a failure to implant leaves the developing human embryo without the nutrition needed to survive. But someone decided women can't handle that truth! In the package insert for consumers, the FDA has approved this notice:

"Plan B works like a birth control pill to prevent pregnancy mainly by stopping the release of an egg from the ovary. It is possible that Plan B may also work ... by preventing attachment (implantation) to the uterus (womb), which usually occurs beginning 7 days after release of an egg from the ovary. Plan B will not do anything to a fertilized egg already attached to the uterus. The pregnancy will continue."

Does this confusing language satisfy the standard of informed consent? There's no mention of the event of conception or the creation of a new human life. It refers only to the "release of an egg from the ovary." Instead of pointing out that a week-old human being is prevented from attaching to the uterus, the patient information calls the child a "fertilized egg." Rather than informed consent, this language perpetuates what feminist icon Germaine Greer has called the "cynical deception of women by selling abortifacients as if they were contraceptives."

Even in the first week of life, before implantation, a human embryo is not simply a passive ball of cells floating down to the womb. He or she is actively growing and developing. Not long after conception, a new embryo signals his presence to his mother by producing the immuno-suppressive protein Early Pregnancy Factor which warns her immune system not to attack the embryo. This protein can be measured in the mother's blood just 36-48 hours after conception.

FDA and Barr claim that Plan B does not cause an abortion, because they define pregnancy as beginning with implantation. But the crux of abortion is not pregnancy per se. What's at issue is the taking of an innocent human life. Obstetricians define gestation as beginning on the first day of the last menstrual period

(LMP), about two weeks before conception! But it matters little whether one dates pregnancy by LMP, from conception when a new human individual comes into being, or from implantation one week later – it remains true that ending the life of a new human being between conception and birth is morally an abortion, not contraception.

Is Plan B Really "Safe"?

The safety of repeatedly taking emergency contraception (EC) has not been proved, so it is misleading to claim EC is safe. Plan B (1.5 mg of levonorgestrel) is equivalent to taking 40 daily Ovrette pills (0.0375 mg levonorgestrel) in a 12-hour period! With Plan B available over-the-counter, women may be tempted to take the drug every time they think it might be "necessary" due to unprotected sex, condom failure or missing regular birth control pills. This could be detrimental to their health.

Dr. Carol Ben-Maimon, testifying on behalf of Plan B's manufacturer before the FDA, conceded that with "repeat use, ... intermenstrual bleeding occurs in about 40 percent of women ... [and] there's a whole host of bleeding disorders when used initially" (Dec. 16, 2003 transcript, p. 299; available at www.fda.gov/ohrms/dockets/ac/03/transcripts/4015T1.pdf).

David A. Grimes, MD an abortionist and champion of Plan B, stated in a 2002 interview: "Repeated use of EC wreaks havoc on a woman's cycle, so the resulting menstrual chaos acts as a powerful deterrent to using this method too often" (interview available at www.medscape.com/viewarticle/442258). How reassuring. It's so dangerous that it's safe!

The United Kingdom's Department of Health has warned doctors of a "significantly increased risk" of ectopic pregnancy (6% versus the 2% occurring naturally) following use of emergency contraception containing levonorgestrel, the active ingredient in Plan B. The Plan B prescribing information for doctors notes a potential risk up to *five times* greater than normal.

Washington state, the United Kingdom, Scotland and Sweden experienced escalating rates of sexually-transmitted diseases (STD) with increased access to emergency contraception (EC). Without a doctor's visit to screen for STDs, many young women will be unaware that they are carrying and transmitting diseases that can impair their fertility, cause cervical cancer, or be incurable, lifelong conditions, such as herpes, genital warts and HIV/AIDS. The Alan Guttmacher Institute reports a cost of \$6.5 billion in 2000 to treat only new cases of STDs.

Does easy access to Plan B reduce abortions?

Kirsten Moore, president and CEO of Reproductive Health Technologies Project (Plan B advocates), told a National Press Club audience in December 2005 that "the experts had estimated that we would see a drop by up to half in the rates of unintended pregnancy and the rates of

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abortion. And in fact in the real world we're not seeing that" (quoted in A.W. Schachter, "'Plan B': What Science Can't Tell Us," *New York Post* Online Edition, Aug. 11, 2006).

Here's what we're seeing in the real world: Studies in Scotland (Anna Glasier, 2004), Sweden (T. Tyden, 2002), the U.K. (Sourafel Girma and David Paton, 2006), California (Tina Raine, 2005) and Washington state (Jacqueline Gardner, 2001) all show no reduction in abortion rates from greater access to emergency contraception. [Note: Further information about this research can be found at www.usccb.org/prolife/issues/abortion/ecfact906.htm]

Glasier concludes her article on this sadly realistic note:

"[It] is possible that EC may be less effective than we belief [sic]. Estimates of efficacy are unsubstantiated by randomized trials. Efficacy is based on rather unreliable data and a great many assumptions and have been questioned both in the past and more recently. ... While advanced provision of EC probably prevents some pregnancies for some women some of the time, the strategy did not produce the public health breakthrough hoped for."

To recap: For sound health reasons, women still need prescriptions for oral contraceptives, but they can now obtain 40 times the daily dose of one pill OTC in a Plan B packet. Plan B is recommended for every act of unprotected intercourse, condom failure, or 2 days of missed pills, even during the 75% of the time that a reproductive-aged woman could not become pregnant! On the other hand, women are told not to take Plan B

"frequently" because of the medical risks. The main factors weighing against "too frequent" use are "menstrual chaos," the other unpleasant side effects, and, of course, cost. Doctors and pharmacists know that Plan B may result in greatly increased risks of ectopic pregnancy and early abortions, but consumers should be kept in the dark because they might be discouraged from buying it. Plan B has been trumpeted as a sure-fire way to reduce unintended pregnancies and abortions by half, but studies have demonstrated no reduction in pregnancy or abortion rates with widespread use of EC. And yet virtually every newspaper in the country praised the FDA's action as a victory for women! Sadly, it's a victory for Barr, Planned Parenthood, Andrew von Eschenbach, and guys who pressure women into having sex (and can now pressure them into taking Plan B).

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