November 2006: Birth Control

Plan B (Morning After Pill) Available OTC in U.S. Pharmacies 11/06

Where are Accurate Condom Labels?

US 'Foreign Aid' Consists of Billions of Condoms, Most Made in Alabama

Chilean Government Calls for Study on 'Plan B' Pill

Major US Study Shows Oral Contraceptives Increase Breast Cancer Risk by 44% in pre-menopausal women

New Devices and Options in Contraception - 60% of Unplanned Pregnancies Occur in Women Using Contraception

MORNING AFTER PILL AVAILABLE OTC IN U.S. PHARMACIES MID NOVEMBER. American women will be able to pick up abortifacient emergency contraception over the counter, to women 18 years and older, in their local pharmacies by midmonth [AP, 6Nov]. Barr Pharmaceuticals Inc. said shipments of the Plan B drug have begun through the corporation’s Duramed Pharmaceuticals unit. The U.S. Food and Drug Administration granted Duramed exclusive sales rights to Plan B for the next 3 years, Barr said. Girls under 18 will still require a prescription from their doctor. The FDA approved nonprescription sales of the drug in August, after a lengthy battle--opponents of the move warned the prescription-requirement for underage girls would be essentially meaningless, since there would be no way to prevent anyone 18 or older from purchasing the drug for a minor - even a sexual predator. The FDA responded to concerns by requiring Barr to “[m]onitor the effectiveness of the age restriction and the safe distribution of [nonprescription] Plan B to consumers [ages]18 and above and prescription Plan B to women under 18,” according to the Kaiser Daily Women’s Health Policy Report. The company said it would send “anonymous shoppers” into pharmacies to check if they were complying with age regulations, as well as distributing a safety booklet with the drug to ensure proper usage. Barr said it would not sell the product at gas stations or convenience stores. While advocates for the medication claim easy availability cuts down on abortion rates and unwanted pregnancies, a recent report from the United Kingdom admitted that both abortion and teen pregnancy rates had increased following the drugs’ release for nonprescription sales. “Despite the clear increase in the use of emergency contraception, abortion rates have not fallen in the UK. They have risen from 11 per 1,000 women aged 15-44 in 1984 (136,388 abortions) to 17.8 per 1,000 in 2004 (185,400 abortions),” researcher Anna Glasier wrote in the British Medical Journal in September. Related: Advisory Doctor to FDA Confirms Morning-After Pill Acts as Abortifacient
http://www.lifesite.net/ldn/2006/oct/06100408.html

President Bush Approves Over the Counter Early Abortion Pill, Pro-Life Base Decries Move
http://www.lifesite.net/ldn/2006/aug/06082101.html

UK Abortion Rates Continue to Climb Despite Increasing Emergency Contraception Use
http://www.lifesite.net/ldn/2006/sep/06091507.html [9Nov06, LifeSiteNews.com, Schultz, New York]

BIRTH CONTROL WHERE ARE ACCURATE CONDOM LABELS?

Senator Tom Coburn, (R-OK) has requested an investigation by the Government Accountability Office of the failure of the Food and Drug Administration to comply with the six year old law requiring medically accurate condom labels.

November 1, 2006

Gary L. Kepplinger

General Counsel

U.S. Government Accountability Office

Washington, DC 20548

Dear Mr. Kepplinger,

Thank you for providing me a copy of your October 18 letter to Secretary Leavitt regarding applicability of Section 317P of the Public Health Service Act to federally funded abstinence education programs.

As the author of this law, I have been concerned about the lack of enforcement of many of its provisions for some time. The law was written, in fact, because federal health agencies, condom manufactures and advocacy groups were failing to provide medically accurate information about the lack of effectiveness of condoms in preventing human papillomavirus (HPV) infection. Clearly, the information provided by any federally funded health program should be expected to be medically accurate.

If GAO does undertake an investigation of those receiving federal funds to determine compliance with this law, I would strongly encourage that such a review not be limited to abstinence programs but rather examine the full scope of federal programs and agencies that provide educational and other services related to sexually transmitted diseases.

Additionally, I am requesting that GAO investigate the failure of the Food and Drug Administration (FDA) to comply with the provision of the same law that requires the agency to "reexamine existing condom labels that are authorized pursuant to the Federal Food, Drug, and Cosmetic Act to determine whether the labels are medically accurate regarding the overall effectiveness or lack of effectiveness of condoms in preventing sexually transmitted diseases, including HPV." It has been six years since this law was signed and FDA has yet to issue guidance to ensure condom labels meet this criteria. As you noted in your letter, "Section 317P of the Public Health Service Act addresses human papillomavirus

specifically." Yet, condom labels do not currently mention the lack of effectiveness of condoms in protecting against HPV infection, which has been conclusively documented over the past decade.

In February 1999 in a letter to the U.S. House Commerce Committee, Dr.

Richard D. Klausner, then-Director of the National Cancer Institute, stated "Condoms are ineffective against HPV because the virus is prevalent not only in the mucosal tissue (genitalia) but also on dry skin of the surrounding abdomen and groin, and it can migrate from those areas into the vagina and the cervix. Additional research efforts by NCI on the effectiveness of condoms in preventing HPV transmission are not warranted."

In 2001, mere months after the law was signed, the National Institute of Allergy and Infectious Diseases issued a consensus report regarding condom effectiveness prepared with the input of other federal health agencies that found condoms reduced risk of HIV transmission and gonorrhea (for men only). "The Panel agreed that the published epidemiologic data were insufficient to draw meaningful conclusions about the effectiveness of the latex male condom to reduce the risk of transmission of genital ulcer diseases (genital herpes, syphilis and chancroid). For HPV, the Panel concluded that there was no epidemiologic evidence that condom use reduced the risk of HPV infection." These findings contradicted the more conclusive claims provided for decades. It is fair to say, based upon the available scientific data, any claims that exaggerate condom effectiveness beyond the NIAID findings are not medically accurate, as required by law.

More recently, in January 2004 the Centers for Disease Control and Prevention (CDC) issued a report that concluded "The available scientific evidence is not sufficient to recommend condoms as a primary prevention strategy for the

prevention of genital HPV infection."

These findings should be included in all federally funded programs "that that are specifically designed to address STDs" and condom labels, as required by law. Since you have already reviewed a component of the applicability of this law to recipients of federal funding, I would appreciate if GAO could also investigate the compliance of the same law by the FDA, a government agency, specifically mentioned in the law

As the author of Section 317P of the Public Health Service Act, I am disappointed that GAO did not consult with me when making the analysis of the law's intent. It seems reasonable that GAO, Congress and the public would benefit in the future if GAO analysis of Congressional intent was based upon discussions with the authors rather than guess work. Could you please provide a listing of any individuals or entities and their affiliations, including members of Congress or Congressional staff, that GAO met with when completing this review?

Thank you again and I would appreciate a timely response to this request. December 21 of this year marks the six year anniversary of the signing of this law and I am hopeful that a thorough GAO review of FDA actions may assist the agency come into compliance with the law.

Sincerely,

Tom A. Coburn, M.D.

U.S. Senator

[Abstinence Clearinghouse E-Mail Update, 11/09/06]

http://reform.house.gov/UploadedFiles/09.22.05%20FDA%20Eschenbach%20condoms%20response.pdf

9/29/05 letter to Acting Commissioner von Eschenbach asking why FDA has failed to comply with P.L. 106-554, almost 5 years old, requiring the FDA to ensure condom labels are medically accurate (pdf)

US ‘FOREIGN AID’ CONSISTS OF BILLIONS OF CONDOMS: Despite AIDS program's abstinence emphasis, US is still largest condom donor in the world. An article [28Oct06 New York Times] has exposed the self-serving business and political interests behind the U.S. export of billions of condoms to under-developed and developing countries as part of the nations’ foreign aid and international AIDS programs.

Despite the detrimental effects, both societal and physical of such so-called "aid", the past 2 decades have seen both Republican and Democratic senators alike treating the manufacture of billions of condoms as a purely economic perk and fighting for the manufacturing to remain in the US. The Bush administration has spent billions of dollars in its recently intensified global AIDS plan.

Of that money, one-third must be spent on promoting abstinence programs such as the Ugandan ABC program. However, that still leaves billions of new dollars for family planning and population control programs. Despite a Bush administration policy change in 2004 that let African countries use foreign aid for food, medical supplies and abstinence programs instead of solely for condom distribution, an even greater number of condoms are now being shipped each year with the false promise that they will protect against AIDS.

Over the last couple of decades, through its global plan to fight AIDS, the United States has supplied over 9 billion condoms to developing countries. This has made the US the largest condom donor in the world.

Dr. Robert Walley [medical director, Mater Care International] says that such condom-pushing policies are being implemented to the detriment of basic medical care. He says of funding, "While billions of dollars have been spent on abortion and birth control programs, only a small fraction is focused on providing emergency obstetric services."

Walley argues that foreign aid is used only to promote “reproductive health, which is the euphemism for abortion and contraception, to the population,” while women are being refused basic obstetric care because of lack of supplies and funding.

Dr. Margaret Ogola [medical director, Cottolengo Hospice, Nairobi, Kenya for HIV-positive orphans] stresses the fact that condom distribution from the western world has erroneously influenced African youth to believe that condoms are reliable in preventing AIDS and other STDs. Dr. Ogola says that the results of such ‘safe-sex’ indoctrination have been devastating to the young African population.

At a 1999 World Congress of Families in Geneva, she said that condoms have about a 30 percent failure rate and have facilitated the disregard of the traditional taboos surrounding sex outside marriage which in turn has lead to the AIDS epidemic throughout Africa.

In 2004, Dr. Hearst [University of California, San Francisco] gave a lecture on the alarming AIDS statistics in certain African countries. He says that as condom distribution numbers increase, so to do AIDS infection numbers increase at a similar rate. Hearst said that we are “raising a generation of young people in Africa that believe that condoms will prevent HIV." The numbers belie this belief and the young people of Africa are the victims that must suffer the consequences of such erroneous propaganda.

Uganda has one of the lowest AIDS rates in all of Africa. It dropped in recent years from a 30% rate to a 6% rate. Ugandan President Yoweri Museveni attributes this success in curbing the AIDS epidemic to their ABC abstinence program which promotes abstinence and sex only within a monogamous marriage. Museveni says that AIDS will only be successfully combated with "optimal relationships based on love and trust instead of institutionalized mistrust which is what the condom is all about."

Ugandan first lady and Museveni’s wife, Janet Museveni, has spoken widely on abstinence and the failure of condoms. At a youth conference in Kampala, Museveni exposed the ‘condom-pushers’ as money hungry and told African youth, "Don't give your airtime to anyone talking to you about using condoms." Rather, she encouraged abstinence until marriage saying, “You can choose to fight AIDS by saying no and be able to stay alive.”

With Museveni’s financial accusation ringing in one’s ears, it is interesting to see the financial statistics surrounding condom manufacturing.

The New York Times article reports that a factory in Alabama retains most rights to the US government condom contract and is set to manufacture some 201 million condoms for this upcoming year. It charges 5 cents a condom. Foreign manufacturers in Korea and China that will make 100 million condoms each charge 2 cents a condom.

Michael Brumas, spokesman for the current Alabama Republican Senator Jeff Sessions says, “What’s wrong with helping the American worker at the same time we are helping people around the world?”

As Bob Lester [former lawyer, United States Agency for International Development, USAID] said, “At the end of the day, it’s all a political process.” [Related: Condoms made in U.S. shape foreign aid policy http://www.iht.com/articles/2006/10/29/news/aid.php [EUFAULA, Alabama, 30Oct06, LifeSiteNews.com, Meg Jalsevac]

CHILEAN GOVERNMENT CALLS FOR STUDY ON ABORTIFACIENT “PLAN B” PILL. The Constitutional Tribunal of Chile has called for an investigative study into the abortifacient capacity of the morning-after pill, after a 6-4 vote last week. The Tribunal has decided to review a controversial policy to permit minors over the age of 14 access to the pill free of charge, without parental consent, implemented by the Ministry of Health in September despite strong objections throughout the country.

The Alliance for Chile, a coalition of the nation’s two leading conservative parties, fought for a re-evaluation of the Ministry’s decision, saying the policy violates the constitutional rights of the unborn child as well as the parental rights of the minor girl’s parents [Santiago Times, 23Oct].

Thirty-two members of the Alliance argued that as an abortifacient, the pill violates Chile’s law against abortion. The Chilean constitution contains a prohibition against abortion under any circumstances, including cases of rape or incest. Further, in a written statement, the Alliance accused the government of evading proper legal channels by resorting to administrative policy to push the decision through [Spero News].

The investigation results will lead to a new ruling on whether to allow the drug to be distributed to under-age girls without their parent’s knowledge or consent. Conservative Dep. Jose Antonio Kast said the Tribunal decision was “very important because it opens a discussion about the government’s ability, through ministerial resolutions, to violate rights guaranteed in the constitution.

“If the government wants to debate an issue related to the right to life or the rights of parents to educate their children, they should formally request a change to the Constitution in Congress. They should not make such decisions within the four walls of a ministry, assisted by a pair of pro-abortion consultants from nongovernmental organizations.” After the drug was approved for use by the Ministry of Health in 2001, the Chilean Supreme Court banned the pill on the grounds that it was in fact an abortifacient.

The Ministry of Health side-stepped that ruling on a technicality, however, by approving a different brand of the medication and guaranteeing availability for women over the age of 18. The country has been sharply divided on the

volatile issue. Mayors of several districts openly refused orders from the health ministry to ensure the drug was available for minor girls. The mayors backed the call for a review by the Constitutional Tribunal. Related: Chilean Court Reverses Its Decision and Allows Abortifacient ‘Morning After Pill’ http://www.lifesite.net/ldn/2006/sep/06092605.html

Chile Court Suspends Gov’t Plan to Distribute Free Morning-After Pill http://www.lifesite.net/ldn/2006/sep/06091505.html

Chile’s Mayors Refuse Morning After Pill Push http://www.lifesite.net/ldn/2006/sep/06090606.html

Chilean Supreme Court Orders Sale of Abortifacient Morning-After Pill http://www.lifesite.net/ldn/2005/dec/05120202.html [24Oct06, Schultz, Santiago, LifeSiteNews.com]

MAJOR U.S. STUDY SHOWS ORAL CONTRACEPTIVES INCREASE BREAST CANCER RISK 44%. A comprehensive analysis of world studies on the link between breast cancer and contraceptives published in the Mayo Clinic Proceedings journal in 10/06, the key article examines findings from a careful analysis of international studies conducted between 1980-2002.

Entitled “Oral Contraceptive Use as a Risk Factor for Pre-menopausal Breast Cancer: A Meta-analysis, the article finds an increased risk for breast cancer of 44% in pre-menopausal women who took or were taking OCs prior to their first pregnancy, compared to women who had not used oral contraceptives. Of the 23 studies examined, 21 showed an increased risk of breast cancer with OC use prior to a first pregnancy in pre-menopausal women. The combined results showed an over-all risk increase for breast cancer of 44 percent.

Dr. Chris Kahlenborn [lead author] said his entire team believes the standards of informed consent demand that women must be warned of the potential risk of pre-menopausal breast cancer before they take oral contraceptives. Breast cancer is the leading cause of cancer in women worldwide and the most common cause of cancer death in US women between age 20 and 59, the report stated, pointing out the breast cancer rates have risen steadily over the past four decades worldwide, and have risen even faster in developed countries, especially among young women.

The study re-enforces the 2005 classification of oral contraception as a Type 1 carcinogen (cancer-causing agent) to humans by the International Agency for Cancer Research.

Researchers have increasingly warned about an additional link between breast cancer and abortion, found to be significant in multiple studies throughout the world. The abortion/breast cancer link has been consistently ignored or denied, however, by leading cancer institutes in Europe and North America.

[To view the article: http://www.mayoclinicproceedings.com/pdf/8110/8110a1.pdf; See Polycarp Research Institute press release with graphs: http://www.polycarp.org/statement_mayo_clinic_article.htm; Related: Breast Cancer Incidence is Highly Correlated with Abortion Incidence – Researcher http://www.lifesite.net/ldn/2005/aug/05081005.html [press release, Polycarp Research Institute; G. Schultz, 25Oct06, Pittsburgh, LifeSiteNews.com]

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NOTE: While this NYT article promotes the available birth control devices/drugs as the solution to abortion, studies and quotes from abortion providers themselves show that contraception actually leads to abortion. For information on the link between contraception and abortion, click here.

It is interesting to note that this author is shocked that 60% of unplanned pregnancies occur while women are using contraception, yet turns right around and immediately promotes contraception as the solution to avoid these pregnancies and subsequent abortions. This is an amazing and unusual logic. It reminds this editor of G.K. Chesterton's insightful comment that the problem with common sense is that it's no longer common...

NEW DEVICES AND OPTIONS IN CONTRACEPTION. Every year in the United States, six million women become pregnant, and half of these pregnancies are unplanned. More than three-fourths of teenage pregnancies and half of the pregnancies among women approaching menopause are unexpected.

A shocking 60 percent of unplanned pregnancies occur in women using contraception, and nearly half of unplanned pregnancies end with an elective abortion. This should not be happening in a country with such a wide variety of contraceptive options.

Condoms, diaphragms, sponges, cervical caps, and spermicidal jellies and creams, which must be applied at times of sexual activity, often fail because couples are unprepared or unwilling to interrupt a moment of passion. But a broad range of hormonal contraceptives and intrauterine devices are highly effective in preventing pregnancy.

In the July issue of Mayo Clinic Proceedings, a team of physicians from the

Mayo Clinic College of Medicine in Scottsdale, Ariz., described the evolution of hormonal contraception, starting in 1960 with the approval of the first birth control pill by the Food and Drug Administration.

These early high-dose pills were soon linked to a high incidence of serious health problems, including blood clots and strokes, leading to a gradual and eventually drastic reduction in the hormone levels used for contraception.

Today, instead of the 150 micrograms of estrogen in the original oral contraceptive, there are just 30 to 35 micrograms in most pills, and two newer ones with just 25 micrograms of the estrogen ethinyl estradiol, which is used in all estrogen-containing contraceptives. There has also been a drastic reduction in doses of the progestins - synthetic progesterone – in oral contraceptives. Using more potent and selective progestins allows for lower estrogen doses without disrupting a woman's menstrual cycle. For example, the Mayo team noted, norgestimate, the progestin found in Ortho Cyclen and Ortho Tri-Cyclen, suppresses ovulation at doses lower than natural progesterone. It has almost no masculinizing effects and does not reduce the beneficial effects of estrogen on blood lipids (higher HDL's and lower LDL's).

For women who prefer less frequent menstruation, there are oral contraceptives taken continuously for 6 to 12 weeks - followed by a week of no pills - which are associated with fewer menstrual-related complaints.

Still, there are many women who have trouble remembering to take a pill every day, who may not want others to know about their use of contraception or whose sexual activity is too unpredictable to warrant a daily routine. In those cases, hormonal contraception can be delivered by other means, including injections, transdermal (through the skin) patches, vaginal rings, implantable devices and intrauterine devices.

The injectables, including Depo-Provera, a new progesterone-only contraceptive, have been associated with a number of undesirable effects, including altered menstrual bleeding, bone loss, mood disorders (these should not be used by women with a history of depression) and a significant delay in the return of fertility once the injections are stopped. A year after stopping the injections, 80 percent of women are ovulating again and can become pregnant.

Warning About the Patch

The contraceptive patch delivers continuous daily doses of a progestin and 20 micrograms of estrogen. It is applied weekly for three weeks, followed by a patch-free week during which menstruation occurs. The F.D.A. has warned, however, that patch users are exposed to higher levels of estrogen than are most pill takers, since the hormone passes directly through the skin into the blood stream. The patch is most effective in preventing pregnancy in women who weigh less than 200 pounds. It has not been linked to weight gain or adverse effects on blood lipids.

The vaginal ring, approved in 2001, releases daily doses of a progestin and 15 micrograms of estrogen. It can be inserted easily by the woman. It remains in place for three weeks, then is removed, and a new ring is inserted seven days later, after menstruation. An implanted device, which is expected to be available in the United States soon, releases only a progestin that prevents pregnancy by inhibiting ovulation and changing the consistency of the cervical mucus. It remains effective for three years, but only two years in obese women. Frequent or prolonged irregular bleeding is its main side effect. It must be medically implanted under the skin and removed medically as well. Normal cycles usually resume within three months after removal.

A hormone-releasing IUD, sold under the trade name Mirena, was approved by the F.D.A. in 2000 and remains the only such product available. It releases 20 micrograms of the progestinlevonorgestrel (LNG) each day at first,

declining to 10 micrograms by five years, after which time it must be replaced. Both the insertion and the removal are done by a physician.

It is 99.7 percent effective in preventing pregnancy - about as effective as female sterilization but completely reversible, studies have shown - and it has the benefits of suppressing growth of the uterine lining and decreasing

menstrual flow. Thus, it is especially useful for women with heavy periods and those who are approaching menopause, the Mayo team said. After a year of use, at least one woman in five with this type of IUD stops having periods altogether.

During the first three months of use, LNG IUD's can cause breakthrough bleeding and spotting, which lessens with continued use. The main complaints about LNG IUD's include higher rates of acne, dizziness, headaches, breast tenderness and weight gain, similar to the side effects of all other hormonal contraceptives, according to a report published in April 2005 in the journal Population Reports by the Johns Hopkins Bloomberg School of Public Health.

As effective and safe as IUD's are, they have never caught on with American women. Today, half a century after the first IUD became available, fewer than 1 percent of American women of childbearing age use one. A major setback in wider adoption of IUD's stemmed from the high risk of infection that was associated years ago with the Dalkon Shield, an IUD with a flawed design that is no longer marketed. Current IUD's are designed differently from the Dalkon Shield.

Women seeking a hormone-free method might consider one of the newer copper-containing IUD's on the market, like the ParaGard Copper T 380A, used by 75 million women worldwide, according to its manufacturer, FEI Women's Health L.L.C.. Studies have shown it to be more than 99 percent effective in preventing pregnancy. Copper IUD's with more than 250 millimeters of copper are as effective as the LNG IUD, but those with lower amounts of copper are less effective.

[NOTE: The mechanism of the IUD works by both prefertilization and postfertilization effects (i.e. post-fertilization effect may prevent embryo from implanting in uterine lining). Progesterone's artificial progestins also act by a post-fertilization effect. "If you must err, err on the side of life"...]

[J.E. Brody, 17Oct06, NY Times, http://www.nytimes.com/2006/10/17/health/17brody.html?ref=science]