

CONTRACEPTIVE TECHNOLOGY

U P D A T E[®]

A Monthly Newsletter for Health Professionals



New methods gain favor with women, but Pill use remains strong

Survey results: Patch use drops, contraceptive ring sees uptick

Review the contraceptive options offered at your facility as you head to the next examination room. What choices do you have to present to your next patient?

The contraceptive vaginal ring (NuvaRing, Organon; West Orange, NJ) and the transdermal contraceptive (Ortho Evra, Ortho-McNeil Pharmaceutical; Raritan, NJ) have become standard options at many facilities since both were approved by the Food and Drug Administration (FDA) in 2001. About 80% of participants in the 2006 Contraception Survey conducted by *Contraceptive Technology Update* say they offer NuvaRing, up from 76% in 2005.

NuvaRing is starting to catch on, reports **Jackie Boddin**, MSN, RN-C, ARNP, program director/nurse practitioner at the Southwest Wisconsin Community Action Program Reproductive Health Care Center in Platteville, WI. "More clients are willing to try the method," she notes. "Many

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EXECUTIVE SUMMARY

The NuvaRing contraceptive vaginal ring and the Ortho Evra transdermal contraceptive have become standard options at many family planning facilities.

- The Food and Drug Administration has released updated labeling on Ortho Evra; the updated labeling carries results from two studies of the drug. The label continues to recommend that women with concerns or risk factors for thromboembolic disease talk with their health care provider about using Ortho Evra vs. other contraceptive options.
- The manufacturer of Ortho Evra announced price increases mid-2006 for the patch and other oral contraceptives. While the company has since lowered the amount of the price increase on the patch and five of its most popular pills, many federally funded family planning clinics are adjusting formularies to cope with the increase in costs.

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were squeamish about inserting it themselves at first, but those who have tried it are very happy with the method and have no desire to switch.”

NuvaRing is a popular option at the University of Chicago Student Care Center, says **Cherie Dupuis, RN, MSN, NP**, a nurse practitioner at the facility. Graduate students, resident physicians,

and medical students find favor with the method, while younger patients stick with the Pill, she notes.

NuvaRing releases a continuous low dose of the estrogen ethinyl estradiol and the progestin etonogestrel at an average rate of 0.120 mg etonogestrel and 0.015 mg ethinyl estradiol per day over a 21-day period of use.

Patch use falls off

Results of the 2006 survey show a slight drop when it comes to the Ortho Evra contraceptive patch. About 88% of participants said their facility now offers the patch, compared to about 93% in 2005. Each transdermal patch contains 20 mcg of the estrogen ethinyl estradiol and 150 mcg of the progestin norelgestromin, the primary active metabolite of norgestimate. Designed to be changed once a week and worn for three weeks, it consists of an adhesive medicated layer worn against the skin, protected by a waterproof polyester layer.

Edward Linn, MD, chairman of the OB/GYN department and director of the Centre for Women's Health at Rush North Shore Medical Center in Skokie, IL, says “We are prescribing less Evra and slightly more NuvaRing. Patients were very eager to try Evra when it was launched; however, there is less demand for the product for initial use.”

Beth Sperring, ARNP, a nurse practitioner at the Suwannee County Health Department in Live Oak, FL, says that response to Ortho Evra has been favorable, although the negative press the method received this year has affected patient requests for the option. Information from two case control studies of the patch released earlier in 2006 indicates that while there is no increased risk of heart attack or stroke, data are conflicting when it comes to venous thromboembolism (VTE).^{1,2}

Results from the first study suggest that risk of nonfatal VTE for the patch is similar to the risk for pills containing similar hormonal components. Findings from the second study, whose interim results were released by the patch's manufacturer and have not yet been published, indicate an approximate twofold increase in the risk of VTE in patch users compared with those using a comparable oral contraceptive (OC). The FDA now has updated the labeling to include this information from the two studies.

A previous update in November 2005 had added a bolded warning that the patch exposes women to higher total amounts of estrogen than a typical birth control pill containing 35 mcg estrogen. (See

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Editorial Questions

Questions or comments?
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the resource listing, right, to access information on the revised label.)

What does the new label information mean to women who are using or considering using Ortho Evra? The FDA, in a question and answer sheet regarding the September 2006 updated labeling, says, "Even though the results of the two studies are conflicting, the results of the second epidemiology study support FDA's concerns regarding the potential for Ortho Evra use to increase the risk of blood clots in some women. The label has recommended and continues to recommend that women with concerns or risk factors for thromboembolic disease talk with their health care provider about using Ortho Evra vs. other contraceptive options."³

Is price a problem?

Many publicly funded family planning clinics did a double-take this summer when Ortho-McNeil, manufacturer of the Ortho Evra patch and other oral contraceptives, raised its prices on such methods. While the company has subsequently dropped the amount of the increase on the patch and five of its most popular pills, prices still are higher than previously paid by clinics.

In the past, Ortho-McNeil has offered birth control options to public clinics at lower prices than retail through the federal program 340B. The federal formula used to calculate 340B prices takes into account a drug's commercial price and its Medicaid price. While the formula for pricing is confidential, the company previously was charging pennies for OC packs and \$10-\$12 for Ortho Evra.⁴

According to a May 2006 financial report for Johnson & Johnson of New Brunswick, NJ, Ortho-McNeil's parent company, the company's hormonal contraceptive segment experienced an operational sales decline of 15.7% primarily due to generic competition in oral contraceptives, partially offset by strong growth in its low-dose pill, Ortho Tri-Cyclen Lo.⁵ The patch experienced what Ortho termed a "significant decline" in sales as a result of labeling changes and negative media coverage concerning product safety.⁵ The decline in sales may have influenced the subsequent price increase; the company has issued no statement on the increase.

The National Family Planning and Reproductive Health Association (NFPRHA), which negotiates pricing with Ortho on behalf of public clinics, announced in September 2006 that Ortho had dropped its increase on five pills. According to

RESOURCE

The Food and Drug Administration (FDA) has posted the September 2006 updated labeling for Ortho Evra, as well as a question-and-answer sheet, on its web site, www.fda.gov. Under "Products FDA Regulates," click on "Drugs," then under "September 20," click on "Ortho Evra Information" to access the information.

NFPRHA, the following five oral contraceptives have been lowered to \$3.20 per cycle:

- Ortho-Novum 7/7/7;
- Ortho-Cyclen;
- Ortho Tri-Cyclen;
- Ortho Micronor;
- Ortho Tri-Cyclen Lo.

Ortho's new prices reflect a 92-94% discount off list price, NFPRHA states.⁶ NFPRHA also was able to negotiate a reduction on the price increase for the patch. The cost of the Ortho Evra patch initially jumped from \$10-\$12 to more than \$22 during the initial increase; the new price is \$15.⁴

Even with the drops in price, many family planning facilities will be taking a hard look at upcoming budgets and formularies to see which Ortho methods will continue to be in use. Inflation-adjusted funding through Title X has declined by two-thirds since 1980, according to the New York City-based Guttmacher Institute.⁷

NuvaRing is priced at \$15 at the Women's Clinic at the University of Florida Student Health Care Center in Gainesville and thus has proven popular with patients, says **Phylis Craig**, ARNP, clinic supervisor. "Many students on the patch came in to change methods when they learned of the potential problems with it," she notes. "We are now doing new starts on the patch, but the cost makes it one of our least-used methods."

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Which OCs do you choose? Readers exchange views

When it comes to prescribing an oral contraceptive (OC) for your patient, which one do you select? Participants in the 2006 Contraception Survey conducted by *Contraceptive Technology Update* say their No. 1 oral contraceptive (OC) of choice for a 21-year-old nonsmoker is Yasmin, a monophasic pill containing 3 mg drospirenone and 0.030 mg ethinyl estradiol from Berlex, Wayne, NJ.

This is the first year that Yasmin has led the nonformulary category. It swapped its second-place 2005 position with Ortho Tri-Cyclen Lo (Ortho-McNeil Pharmaceutical, Raritan, NJ), which led the category for the previous two years. Ortho Tri-Cyclen Lo is a triphasic pill, containing 25 mcg estrogen for 21 days and three different doses of the progestin norgestimate (180 mcg daily/days 1-7; 215 mcg daily/days 8-14; 250 mcg daily/days 15-21).

EXECUTIVE SUMMARY

When it comes to oral contraceptives (OCs), Yasmin, a monophasic pill containing drospirenone and ethinyl estradiol, is the top choice for healthy young women, say participants in the 2006 Contraception Survey.

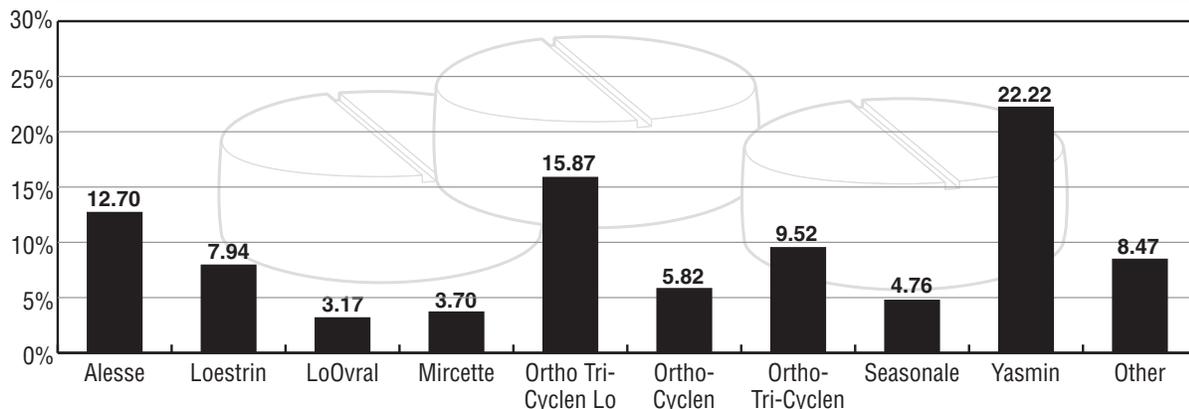
- When formulary dictates choice, survey participants named Ortho Tri-Cyclen Lo, a multiphasic pill, as their first selection for young nonsmoking women.
- New pills now join the contraceptive options list: Loestrin 24 Fe and Yaz, two pills with shortened pill-free intervals, and Seasonique and Quasense, two extended-regimen OCs.
- About 37% of 2006 survey participants report that more than half of their patients leave the office with an OC prescription in hand, mirroring 2005's figures.

"The OC Yasmin is probably the chosen office OC because of the possible benefit of the progestin contained and possibly because of insurance coverage," says **Philip Ivey, MD, FACOG**, an obstetrician/gynecologist in private practice in Casa Grande, AZ.

Other leading choices in the nonformulary category include Alesse, a monophasic 20-mcg pill from Wyeth Pharmaceuticals, Collegeville, PA, and Ortho Tri-Cyclen a 35 mcg ethinyl estradiol phasic pill also marketed by Ortho-McNeil. (See the graphic, below, of top nonformulary pills.)

When bound by formulary, about 24% of 2006 survey participants say they write prescriptions for Ortho Tri-Cyclen Lo for young nonsmoking women. Alesse and Yasmin were other leading choices in the 2006 formulary category.

Assume you could prescribe any pill for a woman initiating combined pills and there were no formulary issues dictating which pills you could prescribe. Which pill would you (or a clinician in your program) prescribe for a 21-year-old nonsmoking woman?



Survey profile

A total of 189 providers participated in the *Contraceptive Technology Update's* 2006 Contraception Survey, which monitors contraceptive trends and family planning issues among readers. Results were tallied and analyzed by AHC Media LLC, in Atlanta, publisher of *CTU* and more than 60 other medical newsletters and sourcebooks.

About 52% of responses came from nurse practitioners or registered nurses. Physicians represented about 40% of the responses. Health educators/counselors made up less than 1% of the response group. About 6% listed other professions. Some 81% of respondents identified themselves as care providers, with nearly 12% involved in administration.

Some 38% of the respondents said they were employed at public health facilities, with about 32% working in private practice settings. About 14% listed student health centers as their place of employment, with some 5% working in hospitals. The remaining 10% reported employment in other settings.

When it comes to location of their employment, 41% said they worked in an urban setting. About 33% said they were employed in a rural facility, while 25% listed a suburban location. ■

Ortho Tri-Cyclen Lo is the first-choice formulary selection for **Wendy Blank, DO**, director of the Women's Clinic at Kansas State University's Lafene Health Center in Manhattan. She says she likes using lower-dose OCs, as well as the NuvaRing (Organon; West Orange, NJ) for birth control starts. Cost is a consideration for Blank's patients, because they are college students, she notes.

Clinicians now have more options when it comes to pill selection; 2006 saw the addition of a number of new formulations, including Loestrin 24 Fe (Warner Chilcott, Rockaway, NJ), an oral contraceptive with 24 days of active hormonal therapy and four days of iron-containing placebo pills, and Yaz (Berlex), another pill with a 24-day dosing regimen.

Loestrin 24 Fe contains 24 pills formulated with 20 mcg ethinyl estradiol and 1 mg norethindrone acetate, with four pills of 75 mg ferrous fumarate. The Yaz formulation contains 24 pills of 20 mcg ethinyl estradiol and 3 mg drospirenone, with four placebo pills. Reducing or eliminating the number of hormone-free days should aid in decreasing the incidence of ovulation and pregnancy that occurs in typical oral contraceptive use when women fail

to begin their pill packs on time.

More options also are available when it comes to extended regimen contraceptives: Seasonique (Duramed Pharmaceuticals, a subsidiary of Barr Pharmaceuticals; Pomona, NY) and Quasense (Watson Pharmaceuticals; Corona, CA).

Seasonique is packaged with 84 tablets of 0.15 mg levonorgestrel and 0.03 mg ethinyl estradiol, and seven tablets of 0.01 mg ethinyl estradiol. Quasense is Watson's generic equivalent of Duramed's Seasonale contraceptive, which is formulated with 84 tablets of 0.15 mg levonorgestrel and 0.03 mg ethinyl estradiol, and seven placebo tablets.

While other methods such as the contraceptive patch and vaginal ring have gained popularity with family planning patients, the Pill still holds a top spot, say participants in the 2006 *CTU* survey. About 37% of 2006 participants report that more than half of their patients leave the office with an OC prescription in hand, mirroring 2005's figures.

Betsy Martinez, PA-C, a physician assistant at the Taos (NM) Public Health Office, says Pill usage is the same or perhaps increased at her facility. Clinicians emphasize the Pill's excellent safety and effectiveness record and discuss the fact that there is no significant weight gain with the method, she notes. Emphasize this point when discussing pill use with patients: Although weight gain is often named as the reason for nonuse or discontinued use of OCs, studies fail to associate use of low-dose OCs with significant weight gain.^{1,2}

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Readers share strategies on OC use

Your next patient is a newly divorced 41-year-old woman who wants to use an oral contraceptive (OC). When you check her chart, you note that she smokes 10 cigarettes a day. What is your next move?

EXECUTIVE SUMMARY

When it comes to providing pills, participants in the 2006 Contraception Survey say Alesse, a monophasic 20-mcg pill, is the leading pill choice for women who have experienced nausea during previous pill use. Alesse also was named as the top choice for a 42-year-old contracepting woman.

- Survey participants vote thumbs down when it comes to providing oral contraceptives for older women who smoke. About 81% say they will not give pills to smokers ages 35-39, and about 93% say they refuse pills to smokers ages 40 and older.
- Pills should remain prescription-only, say most 2006 survey participants. About 69% are against over-the-counter access.

Offer her other forms of birth control, say participants in the 2006 Contraception Survey conducted by *Contraceptive Technology Update (CTU)*. About 81% of survey participants say they will not write prescriptions for women ages 35-39 who smoke 10 cigarettes a day. For women ages 40 and older who smoke, about 93% say they will not prescribe OCs.

“Most women that I see in the 35-39 and over-40 age groups who smoke have other health issues as well, including obesity, high cholesterol, and hypertension,” says **Glenda Martinez, RN, ARNP**, a nurse practitioner at Clark County Health Department in Winchester, KY. “Barrier methods are most favorable with them — sometimes sterilization or Mirena,” which is the levonorgestrel intrauterine system (IUS) from Berlex Laboratories, Montville, NJ.”

According to *Contraceptive Technology*, “the older the smoker, the more cigarettes she smokes, and the more concomitant cardiovascular problems she faces, the less likely she is to be a candidate for OCs.”¹ Offer such women effective progestin-only methods, such as depot medroxyprogesterone acetate (DMPA, Depo-Provera; Pfizer, New York City, and Medroxyprogesterone Acetate Injectable Suspension USP; Teva USA, North Wales, PA) and the IUS, the authors advise.

Along with prescribing a safe birth control method, clinicians should encourage and aid women to stop smoking, or to significantly reduce the number of cigarettes each day.¹ Use Internet resources such as www.smokefree.gov, a site operated by the Tobacco Control Research Branch of the National Cancer Institute, for tips on smoking cessation. Click on “Get More Materials to Help You

Quit” and “Fact Sheets and FAQ” to access several fact sheets and a set of frequently asked questions.

If a woman is in her 40s, healthy and a non-smoker, she is a potential candidate for combined oral contraceptives. Not only will she benefit from regulation of menstrual bleeding, she will be reducing the risks of irregular bleeding and endometrial hyperplasia associated with anovulatory cycling during the perimenopausal years.¹ When it comes to pill options for older women, about 39% of participants in the 2006 survey choose Alesse, a monophasic 20 mcg pill from Wyeth Pharmaceuticals, Collegeville, PA. Other leading selections include Loestrin, a monophasic 20 mcg pill from Duramed, a subsidiary of Barr Pharmaceuticals, Pomona, NY, and Ortho Tri-Cyclen Lo, a multiphasic 25 mcg pill from Ortho-McNeil Pharmaceutical, Raritan, NJ.

Many women may experience nausea when beginning use of a new OC. Which pill do survey participants prescribe for women who have experienced nausea on previous OCs?

About half (44%) of 2006 participants choose Alesse, as their top pill choice for such women. Alesse continues to lead all choices in this survey category; it has held the top spot since 1999. Other top selections in the 2006 survey include Ortho Tri-Cyclen Lo and Loestrin (Organon; West Orange, NJ).

When it comes to initiating combined OC use in postpartum women who are not breast-feeding, about 40% of 2006 survey participants say they will begin pill use four to six weeks after delivery. About 30% say they start pills one to three weeks postpartum, while about 13% begin OC use upon hospital discharge.

For breast-feeding women who wish to use progestin-only pills, about 43% indicate they will initiate pill use four to six weeks postpartum, while about 24% say they begin pill use one to three weeks following delivery. About 23% state they start minipills upon hospital discharge.

While oral contraceptives provide reliable birth control, they also offer noncontraceptive benefits; use of combined OCs can lead to reduced risk of ovarian cancer and endometrial cancer.¹

How do you approach women with information on the noncontraceptive benefits of OCs? **Cindy Morgan, RN, MSN**, a public health nurse at Sanders County Health Department in Thompson Falls, MT, uses the initial visit to speak to all women about the benefits of OCs, especially women who have a family history for ovarian cancer. She then reminds women at each annual visit about the benefits they

are gaining from OC use.

Should OCs be moved to over-the-counter status? Most 2006 CTU survey participants say, "No"; about 69% of 2006 participants gave a thumbs down, representing a slight drop from 2005's 72% level.

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Intrauterine method making inroads in use

Intrauterine contraception is highly convenient. It provides long-term protection against pregnancy, and the method is promptly reversible. Where does it fit in your facility's cafeteria of options?

According to participants in the 2006 Contraception Survey conducted by *Contraceptive Technology Update*, the intrauterine device (IUD) is moving up the list of contraceptive choices. About 46% of participants say they have performed six or more insertions in the past year, a 10% jump from the 35% level reported in 2005.

Two intrauterine contraceptives are available in the United States: the Mirena levonorgestrel intrauterine system (Mirena LNG IUS, Berlex; Wayne, NJ) and the Copper T 380A intrauterine device (ParaGard IUD, Duramed, a subsidiary of Barr Pharmaceuticals, Pomona, NY). The ParaGard IUD is approved for 10 years of contraception; the

EXECUTIVE SUMMARY

More women are moving toward long-term reversible contraception with the T380A Copper T intrauterine device (ParaGard IUD) and the levonorgestrel intrauterine system (Mirena IUS). About 46% of 2006 Contraception Survey participants say they have performed six or more insertions in the past year.

- IUDs are very safe for most women. Almost all women can use IUDs safely, including nursing mothers.
- Intrauterine contraception no longer is contraindicated for women with a history of sexually transmitted diseases or pelvic inflammatory disease (PID) unless a patient currently has acute PID or engages in sexual behavior suggesting a high risk for PID.

RESOURCE

- **The Association of Reproductive Health Professionals (ARHP) has a new freely downloadable patient information brochure, A Woman's Guide to Understanding IUDs, available in English and Spanish at its web site, www.arhp.org. Click on "Patient Education," "Online Brochures," and the brochure title.**

Mirena is approved for five years of birth control.¹

What has led to the uptick in use? More aggressive marketing may have influenced the growth; while the Copper T 380A has been in use in the United States since 1988, its ownership now is under Duramed, which markets several women's health care products. Duramed acquired the marketing rights to the ParaGard with its November 2005 acquisition of North Tonawanda, NY-based FEI Women's Health, the longtime manufacturer of the ParaGard device.

More providers may be looking at the LNG IUS as a treatment option for menorrhagia. A 2006 systematic review of scientific studies indicates that while use of conservative surgery reduces blood loss more than the IUS, the two treatments appear about equal in terms of patient satisfaction.²

Edward Linn, MD, chairman of the OB/GYN department and director of the Centre for Women's Health at Rush North Shore Medical Center in Skokie, IL, says his facility is performing more IUD insertions and is using more Mirena (IUSs) for control of menorrhagia. More patients are aware of the IUD's effectiveness and safety, he says.

IUDs are very safe for most women, according to the Association of Reproductive Health Professionals (ARHP).³ (See resource listing, above, for information on ARHP's downloadable patient brochure on IUD use.) Almost all women can use IUDs safely, including nursing mothers. Those who should not have an IUD inserted include:

- currently have a sexually transmitted infection;
- are allergic to copper or the hormone levonorgestrel;
- do not have a normal-shaped uterus;
- or have cervical or endometrial cancer.³

More women are potential candidates for ParaGard following the Food and Drug Administration (FDA) 2005 updated labeling for the device. The updated labeling now states:

- The device is approved for nulliparous women in stable relationships from ages 16

through menopause.

- ParaGard no longer is contraindicated for women with a history of sexually transmitted diseases (STDs) or pelvic inflammatory disease (PID) unless a patient currently has acute PID or engages in sexual behavior suggesting a high risk for PID.

- Mutual monogamy no longer is a user requirement, although use by women in a stable relationship is encouraged.⁴

When it comes to birth control, women are looking for simple, effective methods that do not interfere with their hectic lifestyles. According to a new national survey, more women than men say that romance is one of the top three activities they postpone due to life's everyday demands. Two-thirds of these women say they are not in the mood for romance after a stressful day as compared to 50% of men. However, more than three-quarters of both sexes agree that simplifying their busy lives would free them to be more romantic.⁵

Philip Ivey, MD, FACOG, an obstetrician/gynecologist in private practice in Casa Grande,

AZ, says he is seeing more insertions of the Mirena IUS at his office due to the method's ease of use, as well as its effect on the menses and cramping, and efficacy.

"Several office staffers use it," Ivey says of the method. "Patients query them and are quickly convinced."

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EC: Family planners weigh in on method use

Will you change your prescribing practice with the Food and Drug Administration's (FDA) recent approval of over the counter (OTC) status for the emergency contraceptive Plan B?

Responses to the 2006 *Contraceptive Technology Update* survey, conducted before the FDA approval, show that family planners are firmly behind easy access to emergency contraception (EC). About 87% report their facilities prescribe EC onsite and provide EC pills at any time, slightly above 2005's figures. About 66% say they prescribe advance provision of EC, almost a 10% jump from 2005's statistics.

The FDA gave approval in August 2006 to Pomona, NY-based Barr Pharmaceuticals' request to provide nonprescription access to the company's levonorgestrel EC pill, Plan B.

The FDA approval does not provide "all access" to the drug, though. Plan B will remain prescription-only for women younger than age 18; women and men ages 18 and older will be able to buy the drug without a prescription at participating pharmacies. The nonprescription version of the drug will be kept behind pharmacy counters, and proof of age must be shown prior to purchase.

Duramed, Barr Pharmaceutical's subsidiary, plans to introduce the dual-status Rx/OTC version of the product before the end of the calendar year.¹

Advance prescription of EC still is important for women of all ages, because insurance may not pay for the behind-the-counter packs, says **Anita Nelson, MD**, professor in the obstetrics and gynecology department at the University of California in Los Angeles (UCLA) and medical director of the women's health care programs at Harbor-UCLA

EXECUTIVE SUMMARY

Family planners are firmly behind access to emergency contraception (EC), according to results of the 2006 Contraception Survey: about 87% report their facilities prescribe EC onsite and provide EC pills at any time. About 66% say they prescribe advance provision of EC, almost a 10% jump from 2005's statistics.

- The Food and Drug Administration gave approval in August 2006 to Barr Pharmaceuticals' request to provide nonprescription access to the company's levonorgestrel EC pill, Plan B. The drug will remain prescription-only for women younger than age 18. Women and men ages 18 and older will be able to buy the drug without a prescription at participating pharmacies. The nonprescription version of the drug will be kept behind pharmacy counters, and proof of age must be shown prior to purchase.

Medical Center in Torrance.

How much will Plan B cost over-the-counter? The price has not been decided and may vary by pharmacy; prescription price for the drug now ranges from \$20-\$50. "Have patients shop around for the best price," Nelson advises. "Plan B may be expensive at some pharmacies."

Even when the nonprescription Plan B goes on the market, women will need to continue to hear about EC. In reviewing studies of EC use,²⁻¹¹ **James Trussell**, PhD, professor of economics and public affairs and director of the Office of Population Research at Princeton (NJ) University, says the following lessons are applicable:

- Emergency contraceptive pills are not used nearly frequently enough.
- Women underestimate their risk of pregnancy.
- More education is necessary.
- The OTC switch is necessary — but not sufficient — for solving this problem.
- Major public health impact is unlikely.¹²

California, Washington, Alaska, Hawaii, New Mexico, Maine, New Hampshire, Massachusetts, and Vermont have legislation in place allowing specially trained pharmacists to provide Plan B to women without a doctor's prescription. In addition, a few pharmacists in Montana provide Plan B under collaborative agreement with physicians. What will happen in the pharmacy access states where women already can get Plan B without a doctor's prescription when the nonprescription drug hits market shelves?

According to the recently redesigned web site, not-2-late.com, the FDA ruling will not change existing pharmacy access programs unless those states pass new legislation to change them. In pharmacy access states, women younger than the age of 18 still will be able to obtain Plan B without a doctor's prescription through specially trained and licensed pharmacists, the site reports.

Where do you stand when it comes to EC? **Lori Jagoda**, PHN, a public health nursing supervisor at Amador County Health Department in Jackson, CA, says her facility is giving out more Plan B in advance, so clinicians are not seeing as many walk-in requests as in the past.

"We have initiated giving out Plan B to have on hand to all clients who come in to start a method birth control; in addition, if a client comes in for ECPs, we give them an extra pack to have on hand if they need it before starting a regular method of birth control," she states. "One of our local pharmacies has also partnered with us and dispenses ECPs to those seeking it after hours and weekends."

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COMING IN FUTURE MONTHS

■ Is ibuprofen needed for intrauterine insertions?

■ Single dose therapy approved for treatment of oral herpes

■ Postmenopausal therapy: Review the choices

■ How to integrate the contraceptive implant into your practice

■ Microbicide update: What methods are in the pipeline?



Unintended Pregnancy Reduction Act introduced

By **Cynthia Dailard**
Senior Public Policy Associate
Guttmacher Institute
Washington, DC

In May 2006, Hillary Clinton (D-NY) and Harry Reid (D-NV) — two senators with vastly different positions on abortion — stood together to introduce landmark legislation promising to significantly reduce the number of abortions in this country. Their bill, the Unintended Pregnancy Reduction Act, would build on state-level initiatives designed to extend Medicaid coverage of family planning services to additional low-income women.

A new analysis confirms that the approach would significantly reduce this country's high rate of unintended pregnancy, and therefore the need for abortion, by helping to reverse disturbing trends in contraceptive use that are placing more American women — and low-income women in particular — at risk of having an unplanned, and often unwanted, pregnancy. The need for this legislation became clear following the release of a groundbreaking new report by the New York City-based Guttmacher Institute, *Abortion and Women's Lives*, which paints a disturbing picture of two very different Americans — one in which middle and upper-class women are continuing decades of progress in reducing unintended pregnancy and abortion, and the other in which poor women are facing more unplanned pregnancies and growing rates of abortion.¹

According to the institute, between 1994 and 2001, the unintended pregnancy rate for poor women shot up by 29%, even as it fell 20% for more affluent women. A poor woman in the United States now is nearly four times as likely as a more affluent woman to have an unplanned pregnancy, five times as likely to have an unintended birth, and more than three times as likely to have an abortion as her higher-income counterpart.

These trends can be explained, in part, by patterns of contraceptive use. Between 1995 and

2002, contraceptive use fell slightly among all women at risk of unintended pregnancy (women who are sexually active and able to become pregnant, but who are not seeking a pregnancy), but precipitously among poor women.

These dramatic findings struck a chord with Sens. Clinton and Reid, who quickly moved to introduce legislation designed to rectify this situation. Their bill would require states to provide coverage of Medicaid family planning services to individuals using the same income levels used to determine eligibility for Medicaid-funded prenatal, labor, delivery, and postpartum care. States are required to provide coverage of pregnancy-related care to women with incomes up to 133% of the federal poverty level, and many states go up to 185% of poverty and beyond. This stands in sharp contrast to the regular income eligibility ceiling set by most states for Medicaid, which averages only 67% of poverty nationwide, and dips as low as 20% in Alabama, Arkansas, and Louisiana.

In so doing, the Clinton-Reid bill, and companion legislation introduced by Rep. Nita Lowey (D-NY) in the House, would establish the nationwide principle that low-income women who would qualify for Medicaid if they became pregnant should have the opportunity and means to avoid pregnancy if they so choose.

This legislation builds on the examples of a number of states that have already adopted such a "parity" approach. In fact, 16 states already have expanded their Medicaid programs in this fashion; these states, however, have had to jump through bureaucratic hoops of seeking federal permission (by obtaining a "waiver") to do so. These states include Alabama, Arkansas, California, Iowa, Louisiana, Michigan, Mississippi, New Mexico, New York, North Carolina, Oklahoma, Oregon, South Carolina, Washington, and Wisconsin; Minnesota extends eligibility for contraceptive services to women with an income up to 200% of poverty, but extends eligibility for pregnancy-related services to 275%. Four states (Illinois, Massachusetts, Pennsylvania, and Texas) are awaiting federal approval for their waiver applications.

Fortunately, these states are being rewarded for their efforts. A 2003 federally funded evaluation of six states' Medicaid family planning expansions found that each state realized substantial net savings associated with the costs of unplanned births.² For example, Arkansas saved nearly \$30 million in a single year, while Oregon saved \$20 million. Similarly, a recently published evaluation of

California's program found that in 2002, its program alone helped women avoid 205,000 pregnancies, including 79,000 abortions and 94,000 births, including 21,400 to teens.³

Furthermore, a new analysis by the Guttmacher Institute suggests that the Clinton-Reid approach of expanding Medicaid coverage for contraception so that it matches Medicaid coverage for pregnancy-related care on a national level would have a dramatic impact on unintended pregnancy and abortion rates. It would enable low-income women to prevent a total of nearly 500,000 unwanted pregnancies annually, including 200,000 abortions. By helping them to prevent an estimated 225,000 unplanned births, such an effort also would save \$1.5 billion in annual federal and state expenditures.⁴ The impact of all this on women's lives, the lives of their families, and low-income communities would be enormous.

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CE/CME Instructions

Physicians and nurses participate in this continuing medical education/continuing education program by reading the articles, using the provided references for further research, and studying the questions at the end of the issue. Participants should select what they believe to be the correct answers and refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material. After completing this activity with the **December** issue, you must complete the evaluation form provided and return it in the reply envelope provided in that issue to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you. ■

CE/CME Questions

After reading *Contraceptive Technology Update*, the participant will be able to:

- **identify** clinical, legal, or scientific issues related to development and provisions of contraceptive technology or other reproductive services.
 - **describe** how those issues affect services and patient care.
 - **integrate** practical solutions to problems and information into daily practices, according to advice from nationally recognized family planning experts.
17. What new information is contained in the updated labeling for Ortho Evra?
 - A. It contains results from two studies, one of which supports concerns regarding the potential for Ortho Evra use to increase the risk of blood clots in some women.
 - B. It has a new black box warning.
 - C. It advises patients to wear the patch for four weeks.
 - D. It says that nursing mothers may use the patch for contraception.
 18. What are the names of the two new oral contraceptives approved in 2006 with shortened pill-free intervals?
 - A. Loestrin 24 and Apri
 - B. Loestrin 24 and Yaz
 - C. Enjuvia and Yaz
 - D. Lutera and Yaz
 19. What were the results of a 2006 systematic review of scientific studies regarding surgery vs. use of the levonorgestrel intrauterine system (LNG) for treatment of menorrhagia?
 - A. Surgery is more cost-effective than use of the IUS in treatment of menorrhagia.
 - B. The IUS poses more dangers to a woman's health than surgery.
 - C. While use of conservative surgery reduces blood loss more than the IUS, the two treatments appear about equal in terms of patient satisfaction.
 - D. Neither approach is effective in treatment of menorrhagia.
 20. When the nonprescription form of the emergency contraceptive Plan B is available in retail pharmacies in states without previous access laws, who may buy it?
 - A. Women and men ages 21 and older will be able to buy the drug with proof of age.
 - B. Women and men ages 16 and older will be able to buy the drug with proof of age.
 - C. The drug will be available for sale to all ages.
 - D. Women and men ages 18 and older will be able to buy the drug with proof of age.

Answers: 17. A; 18. B; 19. C; 20. D.

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