

POLICY & PRACTICE

New FDA Women's Health Director

Kathleen Uhl, M.D., has been named director of the Office of Women's Health at the Food and Drug Administration. Dr. Uhl, a family physician and a captain in the U.S. Public Health Service, most recently served as a supervisory medical officer in the FDA's Center for Drug Evaluation and Research. "Kathleen brings a breadth of professional experience, as well as a strong science background and passion for women's health, to her new position," said FDA Acting Commissioner Andrew von Eschenbach, M.D. Dr. Uhl's experi-

ence includes clinical practice, basic science and clinical research, drug application review, drug safety oversight, and women's health issues. Dr. Uhl also has dual faculty appointments at the Uniformed Services University of the Health Sciences in family medicine and in internal medicine.

Alternative Hormone Therapies

The FDA recently sent warning letters to 16 dietary supplement and hormone cream manufacturers for making unproven claims about their products. The companies were marketing their prod-

ucts as "alternative hormone therapy" for treating or preventing serious diseases including cancer, heart disease, and osteoporosis. In conjunction with the FDA's effort, the Federal Trade Commission is issuing letters to 34 Web sites that are making similar claims about "alternative hormone therapy" products. "FDA takes seriously its responsibility to protect consumers from products promoted with unproven claims," Margaret O'K. Glavin, associate commissioner for regulatory affairs, said in a statement. "It's particularly troublesome when these claims provide false hope to patients with serious or life-threatening conditions."

Trends in Prenatal Care

Nearly 84% of mothers began prenatal care in the first trimester of pregnancy in 2004, according to figures from the National Center for Health Statistics. That figure did not rise between 2003 and 2004 after more than a decade of increases in first-trimester prenatal care. Also in 2004, the percentage of women who did not begin prenatal care until the last trimester, or who had no care, increased from 3.56% in 2003 to 3.59% in 2004. The data are based on a 41-state reporting area. Preliminary U.S. birth data from the National Center for Health Statistics also shows that the percentage of infants delivered at less than 37 weeks' gestation rose to 12.5% in 2004 from 11.6% in 2000 and 10.6% in 1990.

Misusing Research Findings

In the debate over reproductive health issues, policymakers need to beware of faulty science and advocates who misuse research findings, according to an article in the November issue of the Guttmacher Report on Public Policy. Policymakers should put stock in the scientific process—peer review and published research methodology—not just in individuals or organizations with a similar ideology. For example, scientific reviews in 2003 and 2004 show there is no evidence linking abortion and breast cancer but many abortion opponents continue to rely on discredited studies to support legislation that requires that women be told of a link, according to the article. "Far too often in the uproar over sexual and reproductive health issues, the protections built into the scientific process are simply ignored," wrote Adam Sonfield, the article author and an associate at the Guttmacher Institute.

Switch to Electronic Records

Physicians too nervous to convert their offices to electronic health records can start with "baby steps" to make it less intimidating, Daniel Sands, M.D., said at a health care congress sponsored by the Wall Street Journal and CNBC. Physicians are often reluctant to leap into an EHR system because of its complexity and the expense involved, said Dr. Sands of Harvard University, Boston. One idea is to use electronic communications with patients and staff instead of using handwritten phone messages. "A simple step like that is a good way to get people engaged with technology."

—Mary Ellen Schneider



Brief Summary (See Package Brochure for Full Prescribing Information)

Rx only

Plan B® is intended to prevent pregnancy after known or suspected contraceptive failure or unprotected intercourse. Emergency contraceptive pills (like all oral contraceptives) do not protect against infection with HIV (the virus that causes AIDS) and other sexually transmitted diseases.

CONTRAINDICATIONS

Progestin-only contraceptive pills (POPs) are used as a routine method of birth control over longer periods of time, and are contraindicated in some conditions. It is not known whether these same conditions apply to the Plan B® regimen consisting of the emergency use of two progestin pills. POPs however, are not recommended for use in the following conditions:

- Known or suspected pregnancy
- Hypersensitivity to any component of the product
- Undiagnosed abnormal genital bleeding

WARNINGS

Plan B® is not recommended for routine use as a contraceptive.

Plan B® is not effective in terminating an existing pregnancy.

Effects on Menses

Menstrual bleeding patterns are often irregular among women using progestin-only oral contraceptives and in clinical studies of levonorgestrel for postcoital and emergency contraceptive use. Some women may experience spotting a few days after taking Plan B®. At the time of expected menses, approximately 75% of women using Plan B® had vaginal bleeding similar to their normal menses, 12-13% bled more than usual, and 12% bled less than usual. The majority of women (87%) had their next menstrual period at the expected time or within 7 days, while 13% had a delay of more than 7 days beyond the anticipated onset of menses. If there is a delay in the onset of menses beyond 1 week, the possibility of pregnancy should be considered.

Ectopic Pregnancy

Ectopic pregnancies account for approximately 2% of reported pregnancies (19.7 per 1,000 reported pregnancies). Up to 10% of pregnancies reported in clinical studies of routine use of progestin-only contraceptives are ectopic. A history of ectopic pregnancy need not be considered a contraindication to use of this emergency contraceptive method. Health providers, however, should be alert to the possibility of an ectopic pregnancy in women who become pregnant or complain of lower abdominal pain after taking Plan B®.

PRECAUTIONS**Pregnancy**

Many studies have found no effects on fetal development associated with long-term use of contraceptive doses of oral progestins (POPs). The few studies of infant growth and development that have been conducted with POPs have not demonstrated significant adverse effects.

STD/HIV

Plan B®, like progestin-only contraceptives, does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

Physical Examination and Follow-up

A physical examination is not required prior to prescribing Plan B®. A follow-up physical or pelvic examination, however, is recommended if there is any doubt concerning the general health or pregnancy status of any woman after taking Plan B®.

Carbohydrate Metabolism

The effects of Plan B® on carbohydrate metabolism are unknown. Some users of progestin-only oral contraceptives (POPs) may experience slight deterioration in glucose tolerance, with increases in plasma insulin; however, women with diabetes mellitus who use POPs do not generally experience changes in their insulin requirements. Nonetheless, diabetic women should be monitored while taking Plan B®.

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Drug Interactions

Theoretically, the effectiveness of low-dose progestin-only pills is reduced by hepatic enzyme-inducing drugs such as the anticonvulsants phenytoin, carbamazepine, and barbiturates, and the antituberculosis drug rifampin. No significant interaction has been found with broad-spectrum antibiotics. It is not known whether the efficacy of Plan B® would be affected by these or any other medications.

Nursing Mothers

Small amounts of progestin pass into the breast milk in women taking progestin-only pills for long-term contraception resulting in steroid levels in infant plasma of 1-6% of the levels of maternal plasma. However, no adverse effects due to progestin-only pills have been found on breastfeeding performance, either in the quality or quantity of the milk, or on the health, growth or development of the infant.

Pediatric Use

Safety and efficacy of progestin-only pills have been established in women of reproductive age for long-term contraception. Safety and efficacy are expected to be the same for postpubertal adolescents under the age of 16 and for users 16 years and older. Use of Plan B® emergency contraception before menarche is not indicated.

Fertility Following Discontinuation

The limited available data indicate a rapid return of normal ovulation and fertility following discontinuation of progestin-only pills for emergency contraception and long-term contraception.

ADVERSE REACTIONS

The most common adverse events in the clinical trial for women receiving Plan B® included nausea (23%), abdominal pain (18%), fatigue (17%), headache (17%), and menstrual changes. The table below shows those adverse events that occurred in ≥5% of Plan B® users.

Table 3 Adverse Events in ≥5% of Women, by % Frequency

Most Common Adverse Events	Plan B® Levonorgestrel N=977 (%)
Nausea	23.1
Abdominal Pain	17.6
Fatigue	16.9
Headache	16.8
Heavier Menstrual Bleeding	13.8
Lighter Menstrual Bleeding	12.5
Dizziness	11.2
Breast Tenderness	10.7
Other complaints	9.7
Vomiting	5.6
Diarrhea	5.0

Plan B® demonstrated a superior safety profile over the Yuzpe regimen for the following adverse events:

- Nausea: Occurred in 23% of women taking Plan B® (compared to 50% with Yuzpe)
- Vomiting: Occurred in 6% of women taking Plan B® (compared to 19% with Yuzpe)

DRUG ABUSE AND DEPENDENCE

There is no information about dependence associated with the use of Plan B®.

OVERDOSAGE

There are no data on overdosage of Plan B®, although the common adverse event of nausea and its associated vomiting may be anticipated.

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