

POLICY & PRACTICE

Conscientious Refusal Controversy

Health and Human Services Secretary Mike Leavitt has called on the American Board of Obstetrics and Gynecology to honor the right of ob.gyns. to refuse to refer patients for abortion if they object to the procedure on moral or religious grounds. Last month, Mr. Leavitt wrote to the board seeking clarification on whether ob.gyns. would be putting their board certification at risk if they failed to follow ethical guidelines from the American College of Obstetricians and Gynecologists. Those guidelines, released late last year, advise physicians that they have an ethical duty to refer patients to other providers in a timely manner if they cannot provide reproductive services. In a letter at that time to ACOG fellows, ACOG President Kenneth Noller said that the committee opinion was not part of the college's "Code of Professional Ethics" and is not intended to be used in determining anyone's fellowship in the group. In addition, the committee opinion is not part of the criteria for certification or maintenance of certification by the American Board of Obstetrics and Gynecology. As a result of the "uncertain and mixed interpretation" of the opinion, the ACOG executive committee has asked the committee on ethics to hold a special meeting to reevaluate the guidance.

FDA Issues Keepsake Ultrasound Alert

The Food and Drug Administration is advising consumers to avoid the use of ultrasound imaging to create so-called keepsake videos during pregnancy, an unapproved use of the technology, according to the FDA. While there are no known risks associated with ultrasound imaging, there is also no clinical benefit to using it for keepsake purposes. In some cases, commercial operations have used ultrasound machines for up to an hour to create a video of a fetus. "Performing prenatal ultrasounds without medical oversight may put a mother and her unborn baby at risk," Robert Phillips, Ph.D., an FDA physicist, said in a statement. The agency is raising similar concerns about the over-the-counter purchase of Doppler ultrasound heartbeat monitors. These devices should be used only by a health care professional or under a health care provider's supervision, the FDA maintains.

Physician Group Calls for EC Education

Women and their physicians need to be better educated about emergency contraception, according to Physicians for Reproductive Choice and Health (PRCH). On the seventh annual "Back Up Your Birth Control Day" last month, members of the group called on Congress to help by passing the Emergency Contraception Education Act (S. 2108/H.R. 3372), which calls for the Health Resources and Services Administration to develop and disseminate to health care providers information on the use, safety, efficacy, and availability of emergency contraception. Even medical students are sometimes misinformed, according to Dr. Michelle Isley, a fellow with the PRCH. "I teach medical students about emergency contraception and many of them confuse the morning-after pill with medication abortion," she said in a statement. Giving women accu-

rate information about emergency contraception is even more important now that the medication is available without a prescription, according to the PRCH.

Violence Admissions Rise

Attempted murder, rape, fights, and other assaults accounted for nearly one-third of the violence-related treatment at hospitals in 2005, according to a report from the Agency for Healthcare Research and Quality. About 31% of violence-related admissions were for assaults, 66% for attempted suicide or self-injury, and 4%

were for sexual or other abuse. Children accounted for half of the abuse cases. Violence-related admissions, which cost \$2.3 billion in 2005, increased by 24,000 between 2002 and 2005. The AHRQ estimates that 23% of violence-related admissions were for Medicaid patients and 23% were among uninsured patients.

Survey: MDs Don't Get Enough Sleep

Physicians are not getting the sleep they need to function at their best during the day, and their current work schedules could be to blame, according to a survey from the American College of Chest Physicians. In the survey, 70% of physicians reported

needing at least 7-8 hours of sleep to function at their best. But on average, physicians reported sleeping 6.5 hours a night, and 43% of physicians indicated their current work schedule did not allow for adequate sleep. In addition, 22% reported not feeling refreshed upon waking at least a few nights a week. Almost all physicians (93%) reported drinking at least one caffeinated beverage a day, compared with 81% of the general population, but 84% of physicians said they are in very good or excellent health, compared with 56% of the general population. The survey included responses from 581 physicians.

—Mary Ellen Schneider

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Important Safety Information

ESTROGENS INCREASE THE RISK OF ENDOMETRIAL CANCER

Close clinical surveillance of all women taking estrogens is important. Adequate diagnostic measures, including endometrial sampling when indicated, should be undertaken to rule out malignancy in all cases of undiagnosed persistent or recurring abnormal vaginal bleeding. There is no evidence that the use of "natural" estrogens results in a different endometrial risk profile than synthetic estrogens at equivalent estrogen doses.

CARDIOVASCULAR AND OTHER RISKS

Estrogens with or without progestins should not be used for the prevention of cardiovascular disease or dementia.

The estrogen alone substudy of the Women's Health Initiative (WHI) reported increased risks of stroke and deep vein thrombosis (DVT) in postmenopausal women (50 to 79 years of age) during 6.8 and 7.1 years, respectively, of treatment with oral conjugated estrogens (CE 0.625 mg) alone per day, relative to placebo.

The estrogen-plus-progestin substudy of the WHI reported increased risks of myocardial infarction, stroke, invasive breast cancer, pulmonary emboli, and deep vein thrombosis in postmenopausal women (50 to 79 years of age) during 5.6 years of treatment with oral conjugated estrogens (CE 0.625 mg) combined with medroxyprogesterone acetate (MPA 2.5 mg) per day, relative to placebo.

The Women's Health Initiative Memory Study (WHIMS), a substudy of WHI study, reported increased risk of developing probable dementia in postmenopausal women 65 years of age or older during 5.2 years of treatment with CE 0.625 mg alone and during 4 years of treatment with CE 0.625 mg combined with MPA 2.5 mg, relative to placebo. It is unknown whether this finding applies to younger postmenopausal women.

Other doses of oral conjugated estrogens and medroxyprogesterone

acetate, and other combinations and dosage forms of estrogens and progestins were not studied in the WHI clinical trials and, in the absence of comparable data, these risks should be assumed to be similar. Because of these risks, estrogens with or without progestins should be prescribed at the lowest effective doses and for the shortest duration consistent with treatment goals and risks for the individual woman.

ENJUvia tablets should not be used in women with any of the following conditions: undiagnosed abnormal genital bleeding; known, suspected, or history of cancer of the breast; known or suspected estrogen-dependent neoplasia; active deep vein thrombosis, pulmonary embolism or a history of these conditions; active or recent (e.g., within the past year) arterial thromboembolic disease (e.g., stroke, myocardial infarction); liver dysfunction or disease; known hypersensitivity to the ingredients of ENJUvia tablets; or known or suspected pregnancy. There is no indication for ENJUvia in pregnancy. There appears to be little or no increased risk of birth defects in children born to women who have used estrogens and progestins from oral contraceptives inadvertently during early pregnancy.

The most common side effects in clinical trials were headache, pain, nausea, and breast pain.

ENJUvia tablets are taken orally, once daily, for the treatment of moderate-to-severe vasomotor symptoms associated with menopause and the treatment of moderate-to-severe vaginal dryness and pain with intercourse, symptoms of vulvar and vaginal atrophy, associated with menopause. When prescribing solely for the treatment of moderate-to-severe vaginal dryness and pain with intercourse, topical vaginal products should be considered. Patients should be started at the lowest approved dose of 0.3 mg ENJUvia daily. Subsequent dosage adjustment may be made based upon the individual patient response. This dosage adjustment should be periodically reassessed by the healthcare provider.

Please see adjacent page for brief summary of prescribing information, including Boxed Warning.

Reference: ENJUvia™ full prescribing information, Duramed Pharmaceuticals, Inc.

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