**Practice Trends** OB.GYN. NEWS • May 1, 2005

### POLICY R PRACTICE

### **Controversial Abstinence Site**

A new government Web site aimed at helping parents talk to their teens about sex and abstinence is drawing fire from reproductive-rights advocates. The Web site, www.4parents.gov, features interactive tools, statistics, and conversation starters to enable parents to discuss sex and relationships, sexually transmitted diseases, peer pressure, and abstinence. "These issues are some of the most important choices teens face physically and emotionally," HHS Secretary Mike Leavitt said in a statement. "Parents have a tremen-

dous amount of influence on their children, and we want them to talk with their teens about abstinence so that they can stay safe and healthy." But the site has been criticized for providing inaccurate information about the effectiveness of condoms and making claims that "abortion complications" are a major cause of infertility. Critics, including the Planned Parenthood Federation of America, said the site also uses some loaded terms, including "unborn child" in reference to a fetus or embryo. "This Web site presents wrong and biased information as fact," Planned Parenthood interim President Karen Pearl said in a statement.

### **EC Legislation Fails**

Colorado Governor Bill Owens (R) vetoed legislation last month that would have required all hospitals in his state to provide rape victims with information about the availability of emergency contraception. Gov. Owens said he objected to the legislation because it would not have provided victims with the "full, balanced and detailed array of information" needed to make a decision about emergency contraception. In addition, he said the bill did not include provisions to protect the right of hospitals with religious affiliation or moral objections to emergency contraception to opt out of the requirement. While the bill offered health care professionals the right to decline to offer emergency contraception, it did not provide that option to institutions, Gov. Owens said. "This bill would violate fundamental constitutional principles by forcing an institution to say things to patients that it explicitly does not believe to be morally or ethically valid," Gov. Owens said in his veto message.

### **Contraceptive Access**

Elsewhere in the states, Illinois Governor Rod Blagojevich (D) filed an emergency rule last month clarifying that state pharmacies that sell contraceptives must accept and fill such prescriptions without delay. The action comes after complaints filed against a licensed Illinois pharmacy that refused to dispense prescription contraceptives. "Our regulation says that if a woman goes to a pharmacy with a prescription for birth control, the pharmacy is not allowed to discriminate who they sell it to and who they don't. The pharmacy will be expected to accept that prescription and fill it in the same way, and in the same period of time they would fill any other prescription," Gov. Blagojevich said. "No delays. No hassles. No lecture. Just fill the prescription."

# STDs Among Lesbians

Lesbians and bisexual women who participated in a focus group reported that the need to protect against sexually transmitted diseases (STDs) is primarily a concern for heterosexual women, according to a study published in the March issue of Perspectives on Sexual and Reproductive Health (Perspect. Sex. Reprod. Health 2005;37:6-12). The focus group included 23 lesbian and bisexual women between the ages of 18 and 29. Focus group participants also had limited knowledge of bacterial vaginosis and the potential for commons STDs, such as genital herpes, to be transmitted between women. These findings point to the need to design interventions that explain the risk of STD transmission between women, the study authors said. The authors also advises that interventions are most likely to be successful when they are framed in terms of sexual enjoyment and healthy sexuality instead of disease.

# **Prenatal Testing Legislation**

New federal legislation aims to improve the information that expectant parents receive when a prenatal test is positive for conditions such as Down syndrome and spina bifida. The Prenatally Diagnosed Condition Awareness Act (S. 609/H.R. 1353) is sponsored by Sen. Sam Brownback (R-Kan.) and Sen. Edward Kennedy (D-Mass.). "We have been able to screen for certain conditions in the womb for quite some time now, but I'm concerned that we don't have a great track record for handling that information very well," Sen. Brownback said. The legislation is aimed at improving epidemiologic understanding of prenatally diagnosed conditions, ensuring confidentiality, and supporting health care providers who perform prenatal tests and deliver results. The bill would also authorize a study of the effectiveness of existing health care and family support services for children with disabilities and their families.

References: 1. Data on file, Sanofi-Synthelabo Inc. 2. IMS Health, National Prescription Audit Plus, MAT May 2004.



## **BRIEF SUMMARY**

INDICATIONS AND USAGE

WARNINGS

sleep disturbances may be the presenting manifestation of a physical or psychiatric disorder, symptomatic treatment of insomnia should be initionly after a careful evaluation of the patient. The failure of insomnia to remit 7 to 10 days of treatment may indicate the presence of a primary psychiatric or medical illness which should be evaluated. Worsening of insomnia or the gence of new thinking or behavior abnormalities may be the consequence unrecognized sychiatric or physical disorder. Such findings have emerged g the course of treatment with sedative/hypnotic drugs, including Ambien. use some of the important educations of the control of the con

regence of new thinking or behavior abnormalities may be the consequence numerognized psychiatric or physical disorder. Such findings have emerged ng the course of treatment with seadstu-flynotic drugs, including Ambien, sue some of the important adverse effects of Ambien appear to be dose at give Precautions and Dosage and Administration), it is important to use smallest possible effective dose, especially in the elderly, variety of abnormal thinking and behavior changes have been reported to ir in association with the use of seadstu-flynopricis. Some of these changes be characterized by decreased inhibition (eg. aggressiveness and extroverthat seemed out of character, similar to effects produced by alcohol and r CNS depressants. Other reported behavioral changes have included rebehavior, apitation, hallucinations, and depersoanization. Amnesia and r neuropsychiatric symptoms may occur unpredictably. In primarily essed patients, worsening of depression, including suicidal thinking, has i reported in association with the use of sedative/hypnotics. can rarely be determined with certainty whether a particular instance of the small behaviors listed above is drug induced, spontaneous in origin, or a tof an underlying psychiatric or physical disorder. Nonetheless, the emerace of any new behavioral sign or symptom of concern requires careful and editate evaluation.

with withdrawal from other CNS-depressant drugs (see Drug Abuse and nudence).

nbien, like other sedative/hypnotic drugs, has CNS-depressant effects. Due e rapid onset of action, Ambien should only be ingested immediately prior ping to bed. Patients should be cautioned against engaging in hazardous pations requiring complete mental alertness or motor coordination such as ating machinery or driving a motor vehicle after ingesting the drug, includotential impairment of the performance of such activities that may occur the following ingestion of Ambien. Ambien showed additive effects when comdunity that chold not should also be oned about possible combined effects with other CNS-depressant drugs, ge adjustments may be necessary when Ambien is administered with such ts because of the potentially additive effects.

Information for patients: Patient information is printed in the complete prescribing information.

ratory tests: There are no specific laboratory tests recommended.

Laboratory tests: Inere are no specinc laboratory tests recommended. Drug interactions CNS-active drugs: Ambien was evaluated in healthy volunteers in single-dose interaction studies for several CNS drugs. A study involving haloperial adplidem revealed no effect of haloperidol on the pharmacokinetics or pharma-codynamics of zolpidem. Imipramine in combination with zolpidem produced no pharmacokinetic interaction other than a 20% decrease in peak levels of imipramine, but there was an additive effect of decreased alertness. Similarly, chlopromazine in combination with zolpidem produced no pharmacokinetic interaction, but there was an additive effect of decreased alertness and psy-chomotor performance. The lack of a drug interaction following single-dose administration does not predict a lack following chronic administration. An additive effect on psychomotor performance between alcohol and zolpi-dem was demonstrated.

rn was demonstrated. A single-dose interaction study with zolpidem 10 mg and fluoxetine 20 mg at eady-state levels in male volunteers did not demonstrate any clinically signifi-

nificant alterations in zolpidem pharmacokinetics were found.

Drug/Laboratory test interactions: Zolpidem is not known to interfere with commonly employed clinical laboratory tests. In addition, clinical data indicate that zolpidem does not cross-react with benzodiazepines, opiates, barbiturates, cocaine, cannabinoids, or amphetamines in two standard urine drug screens.

Carcinogenesis, mutagenesis, impairment of fertility
Carcinogenesis: Zolpidem was administered to rats and mice for 2 years at detary dosages of 4, 18, and 80 mg/kg/day, In mice, these doses are 26 to 520 times or 2 to 35 times the maximum 10-mg human dose on a mg/kg or mg/m² basis, respectively. In rats these doses are 41 to 876 times or 6 to 115 times the maximum 10-mg human dose on a mg/kg or mg/m² basis, respectively. No evidence of carcinogenic potential was observed in mice. Renal liposarcomas were seen in 4/100 rats (3 males, 1 female) receiving 80 mg/kg/day and a renal lipoma was observed in one male rat at the 18 mg/kg/day dose. Incidence rates of lipoma and liposarcoma for zolpidem were comparable to those seen in historical controls and the tumor findings are thought to be a spontaneous occurrence.

Mutagenesis: Zolpidem did not have mutagenic activity in several tests includ-

controls and the tumor findings are thought to be a spontaneous occurrence. Mutagenesis: Caplidem did not have mutagenic activity in several tests including the Ames test, genotoxicity in mouse lymphoma cells in vitro, chromosomal aberrations in cultured human lymphocytes, unscheduled DNA synthesis in rat hepatocytes in vitro, and the micronucleus test in mice.

Impairment of fertility: In a rat reproduction study, the high dose (100 mg basek(g) of 20pidem resulted in irregular estrus cycles and prolonged precoital intervals, but there was no effect on male or female fertility after daily oral doses of 4 to 100 mg basek(g) of 5 to 130 times the recommended human dose in mg/m². No effects on any other fertility parameters were noted.

Pregnancy

Ferdagenic effects: Category B. Studies to assess the effects of zolpidem on numan reproduction and development have not been conducted.

Teratology studies were conducted in rats and rabbits.

In rats, adverse maternal and fetal effects occurred at 20 and 100 mg base/kg and included dose-related maternal lethargy and ataxia and a dose-related trend o incomplete ossification of fetal skull bones.

In rabbits, dose-related maternal sedation and decreased weight gain occurred at all doses tested. At the high dose, 16 mg base/kg, there was an ncrease in postimplantation fetal loss and underossification of sternebrae in riable fetuses.

This drug should be used during pregnancy only it clearly needed.

Nonteratogenic effects: Studies to assess the effects on children whose mother took zolpidem during pregnancy have not been conducted. However, childre born of mothers taking sedative/hypnotic drugs may be at some risk for with drawal symptoms from the drug during the postnatal period. In addition, neona tal flaccidity has been reported in infants born of mothers who received sedative hypnotic drugs during pregnancy.

Labor and delivery: Ambien has no established use in labor and delivery.

abor and oelivery: Ambien has no established use in labor and celivery. Mursing mothers: Studies in lactating mothers indicate that between 0,004 and .019% of the total administered dose is excreted into milk, but the effect of zolpi-em on the infant is unknown. The use of Ambien in nursing mothers is not recommended. Pediatric use: Safety and effectiveness in pediatric patients below the age of 18 have not been established.

have not been established.

Geriatric use: A total of 154 patients in U.S. controlled clinical trials and 897 patients in non-U.S. clinical trials who received zolpidem were ≥60 years of age. For a pool of U.S. patients receiving zolpidem at doses of ≤10 mg or placebo, there were three adverse events occurring at an incidence of at least 3% for zolpidem and for which the zolpidem incidence was at least twice the placebo incidence (ie, they could be considered drug related).

Adverse Event	Zolpidem	Placebo
Dizziness	3%	0%
Drowsiness	5%	2%
Diarrhea	3%	1%

Abuse and dependence: Studies of abuse potential in former drug ab that the effects of single doses of zolpidem tartrate 40 mg were simi identical, to diazepam 20 mg, while zolpidem tartrate 10 mg was diff

effects of single doses or zopresen tentral to mg was difficult to disfrom placebo.

I. to diazepam 20 mg, while zolpidem tartrate 10 mg was difficult to disfrom placebo.

Iiverhypnotics have produced withdrawal signs and symptoms following
discontinuation. These reported symptoms range from mild dysphoria
omnia to a withdrawal syndrome that may include a bedominal and may
spe, vomiting, sweating, tremors, and convulsions. The U.S. clinical trial
nee from zolpidem does not reveal any clear evidence for withdrawal
ne. Nevertheless, the following adverse events included in DSM-III-R oriruncomplicated sedative/hypnotic withdrawal were reported at an incifi s1% during U.S. clinical trials following placebos substitution occurring
48 hours following last zolpidem treatment: fatigue, nausea, flushing,
addeness, uncontrolled crying, emesis, stomach cramps, panic attack,
sness, and abdominal discomfort. Rare post-marketing reports of abuse,
rence and withdrawal have been received,
riduals with a history of addiction to, or abuse of, drugs or alcohol are at
ed risk of habituation and dependence; they should be under careful surse when receiving any hypnotic.

OVERDOSAGE

OVERDOSAGE

mended treatment: General symptomatic and supporting be used along with immediate gastric lavage whe nous fluids should be administered as needed. Flumazeniton, pulse, blood pressure, and other appropriate signs and general supportive measures employed. Sedating of following polipiem overdosage. Zolipidem is not dialyz possibility of multiple drug ingestion should be considered.

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