POLICY PRACTICE æ

Abortion Ban in the Courts

The "Partial Birth Abortion Act of 2003" was ruled unconstitutional last month by the U.S. Court of Appeals for the 8th Circuit. The ruling was based on the law's failure to provide an exception in cases where a woman's health was at stake. The law, which bans the so-called "partial birth" abortion procedure, has already been declared unconstitutional in three federal courts. The U.S. Department of Justice has filed appeals in each case, and this is the first of those appeals to be decided. The government can now seek a rehearing before the full 8th Circuit Court of Appeals or try to bring the case before the U.S. Supreme Court. The National Right to Life Committee's legislative director, Douglas Johnson, said in a statement that the successor to Justice Sandra Day O'Connor-who recently announced her retirement—would cast the deciding vote on whether the "partial birth" abortion method remains legal, if the case goes to the Supreme Court.

Talking About HPV

Less than 20% of women who participated in a recent survey said their health care provider had ever discussed the connection between the human papillomavirus (HPV) and cervical cancer. The survey, commissioned by the Association of Reproductive Health Professionals, examined women's knowledge about HPV and cervical cancer and their interactions with health care providers. About 88% of women surveyed said they were very likely to turn to their health care provider for information on reproductive or gynecologic health issues. However, 43% of women said they had not heard of HPV. The survey was conducted among 1,000 women who were aged 18-

Alternatives to Malpractice Litigation

Proposed legislation that would provide grants to states to explore alternatives to the current medical malpractice system is gaining support from the American College of Obstetricians and Gynecologists. The "Fair and Reliable Medical Justice Act" (S. 1337) authorizes the secretary of Health and Human Services to award up to 10 demonstration-project grants to states to develop alternatives to the malpractice tort system. The legislation, which was introduced by Sen. Mike Enzi (R-Wyo.) and Sen. Max Baucus (D-Mont.), allows states to test three alternatives systems of dispute resolution—early disclosure and compensation, administrative determination of compensation, and special health care courts. Although ACOG has supported national reform and a cap on noneconomic damages, the college said that state demonstration projects would be a way to explore strategies that complement a national solution. "This legislation is an important step in the right direction toward fostering a reliable system of medical justice and enacting common sense reforms that protect patients, halt lawsuit abuse, and keep doctors in practice." ACOG President Michael T. Mennuti, M.D., said in a statement. The bill was referred to the Senate Committee on Health, Education, Labor, and Pensions.

Meeting Mammography Goals

More than 75% of women age 40 years and older reported in surveys that they have had a mammogram in the past 2 years, according to a study published in the July/August issue of the American Journal of Health Promotion. This exceeds the Healthy People 2010 target of 70% of women age 40 and older having a mammogram in the last 2 years. While the overall results were positive, some subgroups of women continue to have low use of mammograms. For example, women without health insurance, women who do not have a personal doctor, and women who have not received preventive care are lagging behind, according to the study. The study analyzed results from the 2002 Behavioral Risk Factor Surveillance Survey and the National Health Interview Survey.

Family Planning Use

Publicly funded family planning clinics are serving more clients than ever, according to a report from the Alan Guttmacher Institute. Title X family planning clinics reported serving more than 5 million people in 2004—about a 1% increase over 2003. Of the women clients, 86% (more than 4 million) reported that they use some contraceptive method. In addition, 6% of clients said they are not currently using a contraceptive method because they were pregnant at their last clinic visit. The remaining 8% report not using a contraceptive method for some other reason. About 47% of contraceptive users reported taking oral contraceptives, 18% reported using contraceptive injections, and 18% reported using condoms. But more women are also starting to use other methods, such as contraceptive patches and rings, according to the report. The 2004 Family Planning Annual Report is available online at www.guttmacher.org.

-Mary Ellen Schneider



CONTRAINDICATIONS: Oral contraceptives should not be used in women who currently have the following conditions: * Thrombophlebitis or thromboembolic disorders * A past history of deep vien thrombophlebits or thromboembolic disorders * Cerebrovascular or coronary artery disease (current or history) * Valvalar hard risease with thrombopenic complications * Uncontrolled Integretation * Diabetes with vascular involvement * Headaches with focal neurological symptoms * Major surgery with prolonged immobilization * Known or suspected extension and the breast or per somal history of breast cancer * Canning of the endometrium or other known or suspected strongen edependent neoplesia * Undiagnosed ahnorma genital blaeding * Cholestatic jaundice of pregnancy or jaundice with prior pill use * Hepatic adenomas or carcinomas, or active liver disease * Known

remains to be determined.

Throughout this labeling, epidemiological studies reported are of two types: retrospective or case control studies and prosp control studies provide a measure of the relative risk of a disease, namely, a ratio of the incidence of a disease among or among nonusers. The relative risk does not provide information on the actual clinical occurrence of a disease. Cohort studies risk which is the difference in the incidence of disease between ord contrazepite users and nonusers. The attitibut mation about the actual occurrence of a disease in the population. For further information, the reader is referred to a teo.

1. Thronotheribiol Disorders and Other Vascualer Problems: Use of Secsonale® provides women with more hor basis than convention monthly oral contraceptives containing similar strength synthetic estrogens and prospesin year). While this added exposure may pose an additional risk of thrombotic and thromboembolic diseases, studies not suggested an increased risk of these disorders.

2. Macroardial Infantifice in increased risk of mocrardial Infantific in a Increased risk of mocrardial Infantific in American Infantific in American Increased risk of mocrardial Infantific in American Infantific in American Infantific in American In

- Cerebrovascular Diseases: Oral contraceptives have been shown to increase both the relative and attributable risks of cerebrovascular persents (thrombotic and hemorrhagic strokes), although in general, the risk is grateste among older (.58) years), hypertensive more who also smoke. Hypertensive must found to be a risk factor for both users and nonusers, for both types of strokes, while smoking interacted to increase the risk for hemorrhagic strokes. In a large study, the relative risk of thrombotic strokes has been shown to range from 3 for normotensive users to 14 for users with severe hypertension. The relative risk of hemorrhagic stroke is reported to be 1.2 for nonsmokers who used and contraceptives, 2.6 for smokers who did not use oral contraceptives, 7.7 for smokers who used oral contraceptives, 1.8 for more and 2.5 for our such was severe hypertension. The attributable risk is also greater in older women. Oral contraceptives and 2.5 for to sensitive with other underlying risk factors such as certain inherberd or acquired thrombophilias, hyperlepideriens, and obserily Women with migranie (particularly migraine with aural) who take combination or alcontraceptives may be at an increased risk of stroke.
- colorly migraine wint valid, who have continuitation of a contradeptives. A positive association has been observed between the amount of estro-phelated Risk of Vascular Disease from Oral Contraceptives. A positive association has been observed between the amount of estro-and progestogen in oral contraceptives and the risk of vascular disease. A decline in serum high-density hipporteins (HDL) has been riched with many progestational agents. A decline in serum high-density hipporteins has been associated with an increased infoliocen-chemic heart disease. Because estrogens increase HDL choisterol, the net effect of an oral contraceptive depends on a balance were between doses of estrogen and progestogen and the nature and absolute amount of progestogen used in the contraceptive. The unit of both hormones should be considered in the choice of an oral contraceptive.

Carcinoma of the Reproductive Organs and Breasts: Numerous epidemiological studies have been performed on the incic endometrial, ovarian and cervical cancer in women using oral contraceptives. Although the risk of having breast cancer diagnose

- Hepatic Repolarias: Denign hepatic adenomas are associated with or all contrapellive use, although their occurrence is rare in the United States Indirect calculations have estimated the attributable risk to be in the range of 3.3 cases/100,000 for users, a risk that increases after four or more years of use. Rupture of hepatic adenomas may cause death through intra-abdominal hermorthage. Studies from Britain have shown an increased risk of developing hepatocellular cardinoma in long-term (58 years) oral contraceptive users. However, these cancers are extremely rare in the U.S., and the attributable risk (the excess incidence) of liver cancers in oral contraceptive users approaches less than one per million users.

- indemiological studies have revealed no increased risk of birth defects in women who have used oral contraceptives prior to preg-ies also do not suggest a teratogenic effect, particularly in so far as cardiac anomalies and limb-reduction defects are concerned, when enterthy during early pregnancy (see CONTRANDICATIONS section).

 stration of oral contraceptives to induce withdrawal bleeding should not be used as a test for pregnancy. Oral contraceptives should

discontinuation of oral contraceptives and evaluation of the cause. (See WARNINGS, 1c.)

Bleeding Irregularities: When prescribing Seasonale®, the convenience of fewer planned merses (4 per year instead of 13 per year) should be weighed against the inconvenience of increased intermenstrual bleeding and/or spotting. The clinical trial (SEA 301) that compared the efficacy of Seasonale® (91-day cycles) to an equivalent dosage 28-day cycle regimen also assessed intermenstrual beleding, the participants in the study were composed primarily of women with bad used oral contraceptives previously as opposed to new users. Women with a history of breakthrough bleeding/spotting ≥ 10 consecutive days on oral contraceptives were excluded from the study, More Seasonale® (98-day cycle regimen). Table 4 shows the percentages of women with ≥ 7 days and ≥20 days of intermenstrual spotting and/or bleeding in the Seasonale® and the 28-day cycle treatment groups.

Table 4. Percentage of Subjects with Intermenstrual Bleeding and/or Spotting lays of intermenstrual Percentage of Subjects.

35% 15% Cycles 1-4 (N=194) Cycles 10-13 (N=158)

- Lipid Disorders: Women who are being treated for hyperlipidemias should be followed closely if they elect to use oral contraceptives. Some progestogens may elevate LDL levels and may render the control of hyperlipidemias more difficult. (See WARNINGS 1d.) progestopers may elevate LD. Levels and may render the control of hyperfipidemias more difficult. (See WARNINGS 1d.) in patients with familial defects of lopportein metabolism receiving estrogen-containing preparations, there have been case re ports of significant elevations of plasma trighycarides leading to pancreatilis. Lever Function: If jaundice develops in any woman receiving such drugs, the medication should be discontinued. Steroid hormones may be poorty metabolized in patients with impaired fiver function. Plud Retention: Oral contraceptives may cause some degree of fluid retention. They should be prescribed with caution, and only with careful monitoring, in petients with conditions which might be aggravated by fluid retention.

 Fenotional Disorders: Women with a history of depression should be carefully observed and the drug discontinued if depression recurs to a serious degree. Patients becoming significantly depressed with leading oral contraceptives should stop the medication and use an alternate method of contraception in an attempt to determine whether the symptom is drug related.

- - tion information.

 I. Herbal products Herbal products containing St. John's Wort (hypericum perforatum) may induce hepatic enzymes (cytochrome P450) and p-glycoprotein transporter and may reduce the effectiveness of contraceptive steroids. This may also result in breakthrou gh bleeding, meaning the standing and calculated with or-administered drugs: Co-administration of advoratalin and certain combination or all contraceptives containing ethiny estandial increase AUC values for ethiny is estandio by approximately 20%. Ascorbic acid and ademinophen ray increase plasma ethiny estradiol levels, possibly by inhibition of conjugation. CYP 3A4 inhibitors such as tracorazole or ketoconazole may norcease plasma formore levels.

Changes in plasma levels of co-administered drugs: Combination hormonal contraceptives containing some synthetic estrogens (e.g. estadiol) may inhibit the metabolism of other compounds. Increased plasma concentrations of cyclosporin, prednisolone, and theophylic been reported with concomitant administration of combination and contraceptives. hibit the metabolism of other compounds. Increased plasma concentrations of cyclosporini thit concomitant administration of combination oral contraceptives. Decreased plasma co nee of temazepam, salicylic acid, morphine and clofibric acid, due to induction of conjugation ad with combination oral contraceptives.

- administered with combination or al contraceptives.

 addinism with Laboratory Tests: Certain endocrine and liver function tests and blood components may be affected by or all contraceptives: Increased prothrombin and factors VII, VIII, IX, and X; decreased antithrombin 3; increased norepinephrine-induced platelet aggregability. Increased thyroid-binding globulin (TBG), leading to increased circulating total thyroid-binding addinity and the devoted TBG, free 17 erest update is decreased, reflecting the elevated TBG, free 14 concentration is unatleted.
- Other binding proteins may be elevated in serum. Sex hommone binding proteins may be elevated in serum. Sex hommone binding globulins are increased and result in elevated levels of total circulating sex steroids and corticoids; how biologically active levels remain unchanged. Triglycerides may be increased and evels of various other lipids and lipoproteins may be affected. Glucose tolerance may be decreased.
- Serum foldel levels may be depressed by oral contraceptive therapy. This may be of clinical significance if a woman becomes pregnan shortly after describinging oral contraceptives.

10. Carcinogenesis: See WARNINGS section.

11. Pregnancy: Pregnancy Category X See CONTRAINDICATIONS and WARNINGS sections.

12. Nursing Mothers: Small amounts of oral contraceptive steroids and/or metabolites have been identified in the milk of nursing mothers, and a few adverse effects on the child have been reported, including jounder and breast enlargement. In addition, oral contraceptives given in the pose partum period may interfere with lacation by decreasing the quantify and quality of breast milk [prossible, the nursing mother should be advised not to use oral contraceptives but to use other forms of contraception until she has completely weared her child.

13. Pediatric Use: Safety and efficacy of Seasonale® bables have note near established in women of reproductive age. Safety and efficacy are expected to be the same in postpubertal adolescents under the age of 16 and users 16 and older. Use of Seasonale® before menarche is not indicated.

14. Geriatric Use: Seasonale® blabets have not been studied in women who have reached menopause.

INFORMATION FOR THE PATIENT: See Patient Labeling in the full prescribing information.

ADVERSE REACTIONS: An increased risk of the following serious adverse reactions has been associated with the use of oral contraceptives (see WARNINGS section): "Thromosphelibetis" Arriard informationoblism - Pulmonary embolism • Myocardial Infarction • Cerebral hemorrhage • Cerebral thrombosis* + Hypertension • Gallibladder disease • Hepatic adenomas or being in liver tumors

There is evidence of an association between the following onditions and the use of oral contraceptives: Measurement in thrombosis • Retinal thrombosis The following adverse reactions have been reported in patients receiving oral contraceptives and are believed to be drug-related. *Nausea • Vorniting Castrionistical symptoms (such as abdominal caranges and blading) "Freakthrough bleeding", Sooting • Change in mentical independence of a magnetization of change in embodial or page the functionary of the page throu

• Anaphylactic/anaphylactio/ reactions, including urticaria, angioedema, and sevier reactions with respiratory and circulatory symp. The following adverse reactions have been reported in users of oral contraceptives and the association has been reither conflict etc. Premenstrial Syndrome • Cataracts. • Optic neuritis which may lead to partial or complete loss of vision • Cystitis-like syndro. • Nevousness. • Disturben: Loss of sata plate: Fortheran untilforme • Fortheran condexion. • Hemorratige ceruption • Impaction • Hemolytic uremic syndrome • Dudd-Chairs syndrome • Aone • Changes in libido • Collis • Pancreatits • Dysmenorrhea OVERDOSAGE: Serious ill effects have not been reported following acute ingestion of large doses of oral contraceptives by young childring cause nausea, and withdrawal bleeding may occur in females.

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