

# Social Security plans delayed. President's nominations

BY MARK PUENTE  
STAFF WRITER

Supporters of President Bush's Social Security plan say many young taxpayers could receive a late Christmas gift from the nation's top executive if he fulfills his campaign promise of revamping the system.

Bush plans to give young adults the option to choose among retirement plans by allowing workers to divert a portion of their payroll taxes, which now fund the program, into accounts filled with mutual funds or other investments.

But the president faces a variety of problems in getting a new plan through Congress. Democrats oppose the proposal, calling it an irresponsible use of the nation's money. The costs could be high. And the proposal is politically volatile because of its economic implications for taxpayers.

The Social Security system is in dire need of repair with millions of baby boomers getting ready to retire. Economists predict that in 2018, Social Security will start spending more money than it takes in — and that by 2042, the government will have depleted the Social Security Trust Fund.

“Social Security reform is not an option,” said Michael Tanner, director of health and welfare studies at the Cato Institute, a Washington D.C.-based libertarian think tank. “It has to be done.”

On the campaign trail, Bush called for legislation allowing young workers to put a portion of their payroll taxes into personal investment accounts. But he has not offered a detailed plan on how to divert the funds that now pay for the retirement program.

Administration officials say it is too early to speculate which plan the president will adopt.

Bush wants to give young people a stake in their own retirement, said Chad Kolton, press secretary

for the White House Office of Management and Budget.

“It’s an important principle,” he said. “The president believes having ownership over their retirement will make it viable in the future.”

But one pundit said revamping a system that is sometimes referred to as “the third rail of politics” would be a challenge for any president or legislator.

For years, politicians have put off changing the current system for fear of alienating voters.

“If you touch it, you’ll die,” said Jamie Carson, professor of political science at the University of Georgia. “But most people acknowledge it needs to be revised.”

Retirement is not a topic that many young people worry about at an early age. Recent college graduates are more concerned with the immediate future of finding a job and paying off student loans. Planning for something 40 years down the road is not a priority.

“We’re not suggesting they sit down nightly with the Wall Street Journal and choose between General Electric and General Motors’ stocks,” Tanner said.

All of the personal investment plans being discussed would be voluntary, and there would be no access to the funds if a person fell on hard times.

But Bush’s plan might create a shortfall in the system, and borrowing by the government could be necessary to establish the personal accounts because of the way Social Security pays for benefits.

“If we pay a little now, we will save a lot later,” Tanner said. “It would be like paying your credits off today. There are tough choices to make.”

Under the current system, the payroll taxes levied on workers provide benefits for people who are already retired. Supporters of Bush’s plan say it would not affect retirees.

“We have a moral obligation to

“If we pay a little now, we will save a lot later. It would be like paying your credits off today.”

MICHAEL TANNER, CATO INSTITUTE

the older generation,” said David John, a research fellow at the Heritage Foundation. “The promises have to be kept.”

Critics of the plan say the solutions being proposed are not the best options.

“It takes money out of a fund that is headed for bankruptcy,” said Barry Bosworth, an economist at the Brookings Institution. “It is a completely manageable problem. This whole business of trying to carve something out of something is absurd.”

Most upper-income Americans do not depend on Social Security alone when retiring. It is lower-income Americans who depend on the system the most.

But Bosworth said there is a pending crisis that is more important than Social Security.

An aging population is a problem, Bosworth said, and politicians just don’t want to discuss the health care costs associated with it.

Although Bush has said he gained a political mandate after the election, he will face an obstacle getting a Social Security plan passed in the U.S. Senate next year, where the Republicans have only a five-member majority.

“Congress tends to focus on issues that are immediate in crisis, like a new bridge on I-75,” John said. “This is an issue that requires them to think well ahead.”

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BY AARON PRUITT  
STAFF WRITER

The fastest-growing minority in America will soon gain a greater voice in the White House.

President Bush has nominated two Hispanic Americans for Cabinet positions in his second term: Carlos Gutierrez as secretary of commerce and Alberto Gonzales as attorney general.

The announcement of the two nominations excited some in the Hispanic community who were elated to see Latinos in the Cabinet.

“It is a good thing that a Latino is that high up in the government,” said Alma Ramirez, a social worker for El Centro Latino, a nonprofit organization based in Carrboro.

Several Hispanic organizations have endorsed the nominations, including the Latino Coalition, which stated in a press release that Gonzales is the “perfect choice for the next U.S. attorney general.”

But some experts are unsure whether Gutierrez and Gonzales will represent the Hispanic minority.

“It is a good thing that a Latino is that high up in the government. They could do something to help the community.”

ALMA RAMIREZ, EL CENTRO LATINO

“Just because someone has a Hispanic name doesn’t mean representation,” said Karen Kaufmann, a professor of government and politics at the University of Maryland-College Park.

“The notion of a singular Hispanic community is untrue. Mexican Americans make up one half of the Hispanic population in America, and they do not really relate with Cuban Americans, Venezuelans or Puerto Ricans.”

Kaufmann also said the appointments will have little effect on the Hispanic vote, which traditionally goes to Democrats but in which Bush made inroads Nov. 2.

“If it was as easy as appointing high-level positions, then African Americans would have voted for Bush, who appointed Condoleezza Rice and Colin Powell, and that didn’t happen.”

“The kinds of issues Latinos care about are the kinds of issues every

American cares about — a strong economy, health care, education for their children — and Democrats are perceived as better on those bread-and-butter issues.”

Kaufmann added that the nominations of Gutierrez and Gonzales were not about gaining votes or tokenism.

There are simply more qualified Hispanics to fill top-level positions, she said.

Experts say the nominations of Gutierrez and Gonzales are a step in the right direction for Hispanic representation.

“As the cycle continues, with more Hispanics going through the education system, there will be more qualified Latinos to fill prominent positions,” said Tina Siragusa, executive director of El Centro Latino.

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## Congress restructures visa limits

BY BROOKE M. GOTTLIEB  
STAFF WRITER

The visa reform bill passed by Congress this month will give 20,000 internationals with U.S. graduate degrees a better chance to obtain temporary jobs in the United States.

Congress passed the L-1 and H-

1B Visa Reform Act on Nov. 20 for the 2005 fiscal year in an effort to aid educated foreign workers into the country.

An L-1, or intracompany transferee, works for a company that has locations in the United States and in another country. For example, an American company would be

able to recruit an executive from an overseas branch with an L-1 visa for three years.

According to the U.S. Citizenship and Immigration Services Web site, “The H-1B is a nonimmigrant classification used by an alien who will be employed temporarily in a specialty occupation or as a fashion model of distinguished merit and ability.”

In other words, a U.S. company that seeks a specialist from overseas can hire someone for six years as an H-1B. The legislation would maintain the yearly cap for H-1B visa holders at 65,000.

But the first 20,000 applicants with a master’s or doctoral degree will not be included in the cap, allowing more people to obtain a visa.

In addition, the bill will no longer allow L-1 workers to be subcontracted to third-party employers. They also will be required to work for their petitioning employer for at least one year, instead of the six months previously required.

Gerry Chapman, an immigration and nationality lawyer from Chapman Law Firm in Greensboro, said that the improving economy allows employers to hire more workers, but that the H-1B cap already has been reached.

But he said that if there are not enough qualified employees in the United States, a company should be able to hire specialists from overseas.

“With my own experience, every single H-1B or L-1 who has come into the U.S. has had the effect of creating jobs for other U.S. workers,” he said.

The bill is a trade-off between supporters and opponents of increasing the number of H-1B visas issued to foreign workers.

“Opponents of the bill are missing the big picture,” he said. “They are seeing it as a zero-sum game, but (the visa holders’) presence in our economy has an exponentially beneficial effect.”

But the Institute of Electrical and Electronics Engineers-USA opposes the bill.

“We’re against the fact that (Congress) granted the additional 20,000 exemptions,” said Chris McManes, senior public relations coordinator for the organization’s U.S. branch.

“With an abundance of American workers looking for employment, we don’t think that additional foreign workers (are needed).”

A report released by the IEEE-USA on Nov. 19 states that unemployment in the United States dropped between the first and third quarters this year after the H-1B cap was lowered from 195,000 for the 2004 fiscal year.

“You have to look at the people who lost their jobs,” McManes said. “(In addition), when you increase the number of workers in any field, you can suppress wages.”

He also said the institute is concerned with the unfair treatment of foreign workers.

He said it does not want temporary foreign workers to be abused with insufficient salaries or the threat of losing their visas.

“We’re not against foreign workers; we’re not anti-immigrant,” he said. “We just feel that if U.S. companies want to bring in workers from overseas, they should be given a better opportunity to become U.S. citizens.”

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### ORTHO EVRA®

**(NORELGESTROMIN / ETHINYL ESTRADIOL TRANSFORMER SYSTEM)**

**Patients should be counseled that this product does not protect against HIV infection (AIDS) and other sexually transmitted diseases.**

**Key only**

ORTHO EVRA® is a combination transdermal contraceptive patch with a contact surface area of 20 cm<sup>2</sup>. It contains 6.00 mg norelgestromin and 0.75 mg ethinyl estradiol (EE), and releases 150 micrograms of norelgestromin and 20 micrograms of EE to the bloodstream per 24 hours.

**IMPORTANT NOTE** - This information is a brief summary of the complete prescribing information provided with the product and therefore should not be used as the basis for prescribing the product. This summary was prepared by deleting from the complete prescribing information certain text, tables and references. The physician should be thoroughly familiar with the complete prescribing information before prescribing the product.

**INDICATIONS AND USAGE:** ORTHO EVRA® is indicated for the prevention of pregnancy.

**Like oral contraceptives, ORTHO EVRA® is highly effective if used as recommended in this label.**

**ORTHO EVRA® has not been studied for use in emergency contraception.**

**CONTRAINDICATIONS:** ORTHO EVRA® should not be used in women who currently have the following conditions: 1. Thrombophlebitis, thromboembolic disorders 2. A past history of deep vein thrombophlebitis or thromboembolic disorders 3. Cerebrovascular or coronary artery disease (current or past history) 4. Vascular heart disease with complications 5. Severe hypertension 6. Diabetes with complicating factors 7. Headaches with focal neurological symptoms 8. Major surgery with prolonged immobilization 9. Known or suspected carcinoma of the breast or personal history of breast cancer 10. Carcinoma of the endometrium or other known or suspected estrogen-dependent neoplasias 11. Undeveloped genital warts 12. Cholestatic jaundice of pregnancy or jaundice with prior hormonal contraceptive use 13. Acute or chronic hepatic or renal disease with abnormal liver function 14. Hepatic adenomas or carcinomas 15. Known or suspected pregnancy 16. Hypersensitivity to any component of this product

**WARNINGS:**

**Cigarette smoking increases the risk of serious cardiovascular side effects in women taking hormonal contraceptives. This risk increases with age, especially in women over 35 years of age. Women who use hormonal contraceptives, including ORTHO EVRA®, should be strongly advised not to smoke.**

ORTHO EVRA® and other contraceptives that contain both an estrogen and a progestin are called combination hormonal contraceptives. There is no epidemiologic data available to determine whether safety and efficacy with the transdermal route of administration would be different than the oral route. Practitioners prescribing ORTHO EVRA® should be familiar with the following information relating to risks.

The use of combination hormonal contraceptives is associated with increased risks of several serious conditions including myocardial infarction, thromboembolism, stroke, hepatic disease, neoplasia, and gallbladder disease, although the risk of serious morbidity or mortality is very small in healthy women without underlying risk factors. The risk of morbidity and mortality increases significantly in the presence of other underlying risk factors such as hypertension, hyperlipidemia, obesity and diabetes.

The information contained in the package insert is principally based on studies carried out in women who used combination oral contraceptives with higher formulations of estrogens and progestins than those in common use today. The effect of long-term use of combination hormonal contraceptives with lower doses of both estrogen and progestin administered by any route remains to be determined.

Throughout this labeling, epidemiological studies reported are of two types: retrospective or case control studies and prospective or cohort studies. Case control studies provide a measure of the relative risk of a disease, namely, a ratio of the incidence of a disease among oral contraceptive users to the incidence of the disease among nonusers. Cohort studies provide a measure of relative risk, which is the difference in the incidence of disease between hormonal contraceptive users and nonusers. The attributable risk does not provide information about the actual occurrence of a disease in the population (adapted from refs. 2 and 3 with the author's permission). For further information, the reader is referred to a text on epidemiological methods.

**1. Thromboembolic Disorders And Other Vascular Problems. a. Thromboembolism:** An increased risk of thromboembolism and thrombotic disease associated with the use of hormonal contraceptives is well established. Case control studies have found the relative risk of venous thromboembolism to be 3 for the first 6 weeks of use of oral contraceptives, 1 to 1.1 for deep vein thrombosis or pulmonary embolism, and 1.5 to 6 for women with predisposing conditions for venous thromboembolic disease. Cohort studies have shown the relative risk to be somewhat lower, about 3 for new cases and about 4.5 for new cases requiring hospitalization. The risk of thromboembolism, especially pulmonary embolism, increases with longer use of oral contraceptives and is stopped if use is discontinued. A two- to four-fold increase in relative risk of post-operative thromboembolic complications has been reported with the use of hormonal contraceptives. The relative risk of venous thromboembolism in women who have had previous thromboembolic events is increased to 10 to 15. In women who have had previous thromboembolic events, the relative risk of venous thromboembolism should be discontinued at least four weeks prior to and for two weeks after elective surgery of a type associated with an increase in risk of thromboembolism and during and following prolonged immobilization. Since the immediate postoperative period is also associated with an increased risk of thromboembolism, oral contraceptives should be started no earlier than three weeks after delivery in women who elect not to breast-feed. In the large clinical trial (see 3.3.3 and 3.3.4) the incidence of venous thromboembolism was increased during ORTHO EVRA® use, and one case of post-operative non-fatal pulmonary embolism was reported following ORTHO EVRA® use. It is unknown if the risk of venous thromboembolism with ORTHO EVRA® use is different than that of combination oral contraceptives. As with any combination hormonal contraceptive, the clinician should be alert to the earliest manifestations of thrombotic disorders (pulmonary embolism, cerebrovascular disorders, and retinal thrombosis). Should any of these occur or be suspected, ORTHO EVRA® should be discontinued immediately.

**b. Myocardial Infarction:** An increased risk of myocardial infarction has been attributed to hormonal contraceptives. This risk is primarily in smokers or women with other underlying risk factors for coronary artery disease such as hypertension, hypercholesterolemia, morbid obesity, and diabetes. The relative risk of heart attack for current hormonal contraceptive users has been estimated to be 1.2 for non-smokers and 2 for smokers. This risk is very low under the age of 30. Smoking in combination with oral contraceptive use has been shown to contribute significantly to the incidence of myocardial infarctions in women in their mid-thirties or older with smoking accounting for the majority of excess cases. Mortality rates associated with coronary artery disease have been shown to increase in smokers, especially in those 35 years of age and older among women who use oral contraceptives. High-dose estrogen progestin compound effects of well-known risk factors, such as hypertension, diabetes, hyperlipidemia, and obesity. In particular, some progestins are known to decrease HDL cholesterol and cause glucose intolerance, while estrogens may create a state of hypertriglyceridemia. Hormonal contraceptives have been shown to increase blood pressure in some women. Hormonal contraceptives have been shown to increase blood pressure in some women. Hormonal contraceptives have been shown to increase the risk of heart disease. Hormonal contraceptives, including ORTHO EVRA®, must be used with caution in women with cardiovascular risk factors. Norelgestromin and ethinyl estradiol have minimal androgenic activity (see CLINICAL PHARMACOLOGY in full Prescribing Information). There is some evidence that the risk of myocardial infarction associated with hormonal contraceptives is lower when the progestin has minimal androgenic activity than when the activity is greater. **c. Cerebrovascular Disease:** Hormonal contraceptives have been shown to increase both the relative and absolute risks of cerebrovascular events (thrombotic and hemorrhagic strokes), although, in general, the risk is greatest among older (>35 years), hypertensive women who also smoke. Hypertension was found to be a risk factor for both users and nonusers. For both types of strokes, the relative risk is increased in women with other underlying risk factors. 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 non-smokers who use hormonal contraceptives, 2.6 for smokers who did not use hormonal contraceptives, 7.6 for smokers who used oral contraceptives, 1.3 for normotensive users and 25.7 for users with severe hypertension. The attributable risk is also greater in older women. **d. Dose-related risk of vascular disease from hormonal contraceptives:** There is some evidence that the risk of vascular disease associated with the use of low-dose estrogen progestin combination hormonal contraceptives is less than that of high-dose estrogen progestin combination hormonal contraceptives. In a study in the United States, the risk of developing myocardial infarction after discontinuing combination hormonal contraceptives persists for at least 6 years for women 40-49 years who had used combination hormonal contraceptives for five or more years, but this increased risk was not demonstrated in other age groups. In another study in Great Britain, the risk of developing cerebrovascular disease persisted for at least 6 years after discontinuation of combination hormonal contraceptives, although excess risk was very small. However, both studies were performed with combination hormonal contraceptives containing 50 micrograms of norethisterone or higher estrogens. It is unknown whether ORTHO EVRA® is distinct from other combination hormonal contraceptives with regard to the occurrence of venous and arterial thrombosis. 2. **Estimates of Mortality From Combination Hormonal Contraceptive Use:** One study analyzed the mortality rate from a variety of sources that have estimated the mortality rate associated with different methods of

contraception at different ages. These estimates include the combined risk of death associated with contraceptive methods plus the risk attributable to pregnancy or the event of method failure. Each method of contraception has its specific benefits and risks. The study concluded that with the exception of combination oral contraceptive users 35 and older who smoke, and 40 and older who do not smoke, mortality associated with all methods of birth control is low and below that associated with childbirth.

The observation of a possible increase in risk of mortality with age for combination oral contraceptive users is based on data from the 1970's but not reported until 1985. Current clinical recommendations involve the use of lower estrogen dose formulations and a careful consideration of risk factors. In 1986, the Fertility and Maternal Health Drugs Advisory Committee was asked to review the use of combination hormonal contraceptives in women 40 years of age and over. The Committee concluded that because cardiovascular morbidity and mortality may be increased with combination hormonal contraceptive use after age 40 in healthy non-smoking women (even with the newer low-dose formulations), there are also greater potential health risks associated with pregnancy in older women and with the alternative surgical and medical procedures that may be necessary if such women do not have access to effective and acceptable means of contraception. The Committee recommended that the benefits of low-dose combination hormonal contraceptive use by healthy non-smoking women over 40 may outweigh the possible risks. Although there is no clear evidence of an increased risk of mortality associated with ORTHO EVRA® use, women of all ages who use combination hormonal contraceptives should use the lowest possible dose formulation that is effective and meets the individual patient needs. 3. **Carcinoma of the Reproductive Organs And Breast:** Numerous epidemiological studies give conflicting reports on the relationship between breast cancer and COC use. The risk of having breast cancer diagnosed may be slightly increased among current and recent users of combination oral contraceptives. However, this excess risk appears to decrease over time after COC discontinuation and by 10 years after cessation the increased risk disappears. Some studies have shown an increased risk of breast cancer in current and recent users, but no consistent relationships have been found with dose or type of steroid. Some studies have found a small increase in risk for women who first use COCs before age 20. Most studies have not examined the risk of breast cancer with respect to a woman's reproductive history or her family breast cancer history. Information in current use of COCs may be less clinically advanced than in never-users. Women who currently have or have had breast cancer should not use hormonal contraceptives because breast cancer usually has a favorable prognosis. Stage development of the disease in combination contraceptive use has been associated with an increase in the risk of cervical intraepithelial neoplasia in some populations of women. However, there continues to be controversy about the extent to which such findings may be due to differences in sexual behavior and other factors. In spite of many studies that relate hormonal contraceptive use and cervical cancer, a cause-and-effect relationship has not been established. It is not known whether ORTHO EVRA® is distinct from oral contraceptives with regard to the above statements. 4. **Hepatic Neoplasia:** Benign hepatic adenomas are associated with hormonal contraceptive use. There is no epidemiologic data available to determine whether the absolute risk of developing hepatic adenomas would be different than the oral route. Practitioners prescribing ORTHO EVRA® should be familiar with the following information relating to risks. The use of combination hormonal contraceptives is associated with increased risks of several serious conditions including myocardial infarction, thromboembolism, stroke, hepatic disease, neoplasia, and gallbladder disease, although the risk of serious morbidity or mortality is very small in healthy women without underlying risk factors. The risk of morbidity and mortality increases significantly in the presence of other underlying risk factors such as hypertension, hyperlipidemia, obesity and diabetes. 5. **Retinal Thrombosis:** There have been clinical case reports of retinal thrombosis associated with the use of hormonal contraceptives. ORTHO EVRA® should be discontinued if there is a suspected partial or complete retinal artery or vein thrombosis or retinal papilledema; or retinal vascular lesions. Appropriate diagnostic and therapeutic measures should be undertaken immediately. 6. **Hormonal Contraceptive Use Before Or During Early Pregnancy:** Extensive epidemiological studies have revealed no increased risk of birth defects in women who have used oral contraceptives prior to pregnancy. Studies have also not shown a teratogenic effect, particularly in so far as cardiac anomalies and limb reduction defects are concerned, when oral contraceptives are taken inadvertently during early pregnancy. Combination hormonal contraceptives such as ORTHO EVRA® should not be used to induce vomiting/bleeding for a test for pregnancy. ORTHO EVRA® should not be used during pregnancy or while breastfeeding or during lactation. Hormonal contraceptives should be discontinued if pregnancy is confirmed. 7. **Gallbladder Disease:** Earlier studies have reported an increased lifetime relative risk of gallbladder surgery in users of hormonal contraceptives and estrogens. More recent studies, however, have shown that the relative risk of developing gallbladder disease among hormonal contraceptive users may be minimal. The recent findings of this disease in women related to the use of hormonal contraceptive formulations containing lower hormonal doses of estrogens and progestins. Combination hormonal contraceptives such as ORTHO EVRA® may increase the risk of gallbladder disease. 8. **Carbohydrate And Lipid Metabolic Effects:** Hormonal contraceptives have been shown to increase the risk of hypertriglyceridemia, persistent or previously asymptomatic women. Women with a history of combination hormonal contraceptive-related cholestasis are more likely to have the condition recur when they restart combination hormonal contraceptive use. 9. **Hypertension And Blood Pressure:** Hormonal contraceptives have been shown to increase blood pressure in some women. However, in the non-diabetic women, combination hormonal contraceptives appear to have no effect on fasting blood glucose. Pre-diabetic and diabetic women in particular should be carefully monitored while taking combination hormonal contraceptives such as ORTHO EVRA®. 10. **Glucose Tolerance:** In women who have normal glucose tolerance, the use of combination hormonal contraceptives was not associated with clinically significant changes in fasting blood glucose levels. There were no clinically significant changes in glucose levels over 24 cycles of use. Moreover, glucose tolerance tests showed no clinically significant changes from baseline to cycles 3, 12 and 24. In a 6-cycle clinical trial with ORTHO EVRA®, there were no clinically significant changes in fasting blood glucose from baseline to end of treatment. A small proportion of women will have persistent hypertriglyceridemia while taking hormonal contraceptives. As discussed earlier (see WARNINGS 1a and 1b), changes in serum triglycerides and lipoprotein levels have been reported in women taking combination hormonal contraceptive use. 11. **Diabetes Mellitus:** Hormonal contraceptive use should not be started on hormonal contraceptive. Women with a history of hypertension or hypertension-related diseases, or renal disease should be encouraged to use another method of contraception. If hypertension-related diseases are diagnosed during contraceptive use and if a clinically significant elevation of blood pressure occurs, ORTHO EVRA® should be discontinued. For most women, elevated blood pressure will return to normal after stopping hormonal contraceptive use, and there is no difference in the occurrence of hypertension between former and never users. An increase in blood pressure has been reported in women using combination hormonal contraceptives and this increase is more likely in older hormonal contraceptive users and with extended duration of use. Data from the Royal College of General Practitioners and subsequent randomized trials have shown that the incidence of hypertension increases with increasing duration of use. 12. **Bleeding Irregularities:** Nausea, vomiting, or other symptoms resembling a gastrointestinal disorder, or the development of headache with a new pattern that is recurrent, persistent or severe requires discontinuation of ORTHO EVRA® and evaluation of the cause. 13. **Bleeding Irregularities:** Breakthrough bleeding and spotting are sometimes encountered in women using ORTHO EVRA®. Non-hormonal causes should be considered and adequate diagnostic measures taken to rule out malignancy, oral pathology, or pregnancy in the event of breakthrough bleeding, as in the case of an abnormal vaginal bleeding. If pathology has been excluded, a change to another contraceptive product may resolve the bleeding. In the event of amenorrhea, pregnancy should be ruled out before instituting use of ORTHO EVRA®. Some women may encounter amenorrhea or oligomenorrhea after discontinuation of hormonal contraceptive use, especially when such a condition was pre-existent. **Bleeding Pattern:** In the clinical trial most women started their withdrawal bleeding on the fourth day of the drug-free interval, and the median duration of withdrawal bleeding was 5 to 6 days. In average 26% of women per cycle had 7 or more total days of bleeding and/or spotting (this includes both withdrawal flow and breakthrough bleeding and/or spotting). 12. **Ectopic Pregnancy:** Ectopic as well as intrauterine pregnancy may occur in contraceptive failures. 13. **PRECAUTIONS:** Women should be counseled that ORTHO EVRA® does not protect against HIV infection (AIDS) and other sexually transmitted infections. 1. **Body Weight:** 158 lbs (70 kg); Results of clinical trials suggest that ORTHO EVRA® may be less effective in women with body weight  $\geq$  198 lbs (90 kg) than in women with lower body weights. 2. **Physical Examination And Follow-Up:** It is good medical practice for women using ORTHO EVRA® to have annual medical and physical examinations. 3. **Fluid Retention:** Standard physical examination, however, may be deferred until after initiation of hormonal contraceptives if requested by the woman and judged appropriate by the clinician. The physical examination should include special reference to blood pressure, breasts, abdomen and pelvic organs, including, but not limited to, genital examination. 4. **Smoking:** Women who are heavy or persistent smokers should be advised to discontinue ORTHO EVRA® use. 5. **Smoking:** Women who are heavy or persistent smokers should be advised to discontinue ORTHO EVRA® use. 6. **Smoking:** Women who are heavy or persistent smokers should be advised to discontinue ORTHO EVRA® use. 7. **Smoking:** Women who are heavy or persistent smokers should be advised to discontinue ORTHO EVRA® use. 8. **Smoking:** Women who are heavy or persistent smokers should be advised to discontinue ORTHO EVRA® use. 9. **Smoking:** Women who are heavy or persistent smokers should be advised to discontinue ORTHO EVRA® use. 10. **Smoking:** Women who are heavy or persistent smokers should be advised to discontinue ORTHO EVRA® use. 11. **Smoking:** Women who are heavy or persistent smokers should be advised 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