

Health Reform Plan May Debut This Month

BY ALICIA AULT

WASHINGTON — The three committees with jurisdiction over health care in the House of Representatives will make their health reform “framework” public early this month, Rep. Henry Waxman (D-Calif.) said at a forum sponsored by the policy analysis firm Avalere Health.

Rep. Waxman, chairman of the House Energy and Commerce Committee, said that his staff, along with the staffs of both the Ways and Means and the Education and Labor committees, have been working together to create a “proposal that will allow all three to start from a common point.”

Once the framework has been developed, House Republicans will be brought into the process, Rep. Waxman said. After the plan has been released publicly, the three committees will hold hearings to get “viewpoints from stakeholders,” he added.

Then the committees will work with the Rules Committee and the House leadership to bring the bill to the House floor. Rep. Waxman predicted passage of a reform bill by the end of July in the House and by the end of the year for both the House and the Senate.

Rep. Waxman was less certain regarding the substance of the legislation. “It must solve the problems of coverage, cost, and quality together,” he said.

The bill will build on what’s now in

place, including Medicare, Medicaid, and private insurance, he said. But he left no doubt where he stood on having a government-supported “public plan” as an option for those who could not buy insurance in the private market.

“This system will work better if there is a public health insurance plan available as an alternative to private health insurance,” Rep. Waxman said, with opportunity for private insurers to compete.

Rep. Waxman said that he was confident that health reform will succeed in 2009, noting that President Barack Obama has given it a high priority, and that House and Senate leaders, as well as almost all other players in the debate, are unified in achieving that goal.

Not surprisingly, Rep. Waxman said that he sees action by the Energy and Commerce Committee as a significant predictor of how health reform will fare

in the Congress overall. Noting that the panel has 59 members, the chairman said that the panel makes up 15% of the House and numerically represents 60% of the Senate. The committee balances urban and rural areas, and conservative and liberal ideologies, he said. “If we can find consensus in the Energy and Commerce Committee,” he said, “we’ll be pretty close to what we need in the House and Senate.”

YAZ® (drospirenone and ethinyl estradiol) Tablets

Brief Summary of Prescribing Information

INDICATIONS: 1. YAZ is indicated for the prevention of pregnancy in women who elect to use an oral contraceptive. 2. YAZ is also indicated for the treatment of symptoms of premenstrual dysphoric disorder (PMDD) in women who choose an oral contraceptive as the method of contraception. The effectiveness of YAZ for PMDD has been demonstrated for more than three menstrual cycles but has not been evaluated for longer-term use. Moderate to severe migraines in women at least 14 years of age, who have no known contraindications to oral contraceptive therapy and have achieved menarche. YAZ should be used for the treatment of acne only if the patient desires an oral contraceptive for birth control. **CONTRAINDICATIONS:** YAZ® should not be used in women who have the following: •Renal insufficiency •Hepatic dysfunction •Adrenal insufficiency •Thrombophlebitis or thromboembolic disorders •A past history of deep-vein thrombophlebitis or thromboembolic disorders •Cerebral-vascular or coronary-artery disease (current or history) •Valvular heart disease with thromboembolic complications •Severe hypertension •Diabetes with vascular involvement •Headaches with focal neurological symptoms •Major surgery with prolonged immobilization •Known or suspected carcinoma of the breast •Carcinoma of the endometrium or other known or suspected estrogen-dependent neoplasia •Unexplained abnormal genital bleeding •Cervical dysplasia •Cervical intraepithelial neoplasia •Cervical cancer •Cervical cancer in situ •Cervical cancer (malignant) or active liver disease •Heavy smoking (≥15 cigarettes per day) and over age 35 •Hypersensitivity to any component of this product. **WARNINGS:**

Cigarette smoking increases the risk of serious cardiovascular side effects from oral contraceptive use. This risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age. Women who use oral contraceptives should be strongly advised not to smoke.

YAZ contains 3 mg of the progestin drospirenone that has antimineralocorticoid activity, including the potential for hyperkalemia in high-risk patients, comparable to a 25 mg dose of spironolactone. YAZ should not be used in patients with conditions that predispose to hyperkalemia (i.e., renal insufficiency, hepatic dysfunction and adrenal insufficiency). Women receiving daily, long-term treatment for chronic conditions or diseases with medications that may increase serum potassium should have their serum potassium level checked during the first treatment cycle. Medications that may increase serum potassium include ACE inhibitors, angiotensin II receptor antagonists, potassium-sparing diuretics, potassium supplement, heparin, aldosterone antagonists, and NSAIDs. The use of oral contraceptives is associated with increased risks of several serious conditions including venous and arterial thrombotic and thromboembolic events (such as myocardial infarction, thromboembolism, stroke), hepatic neoplasia, gallbladder disease, and hypertension. 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, hyperlipidemias, obesity and diabetes. Practitioners prescribing oral contraceptives should be familiar with the following information relating to these risks. The information contained in this package insert is based primarily on studies carried out in patients who used oral contraceptives with higher formulations of estrogens and progestagens than those in common use today. The effect of long-term use of the oral contraceptives with lower formulations of both estrogens and progestagens remains to be determined. Throughout this labeling, epidemiologic 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 that among nonusers. The relative risk does not provide information on the actual clinical occurrence of a disease. Cohort studies provide a measure of attributable risk, which is the difference in the incidence of disease between oral contraceptive users and nonusers. The attributable risk does provide information about the actual occurrence of a disease in the population. For further information, the reader is referred to a text on epidemiologic methods. 1. THROMBOEMBOLIC DISORDERS AND OTHER VASCULAR PROBLEMS: a. Myocardial infarction: An increased risk of myocardial infarction has been attributed to oral contraceptive use. 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 oral contraceptive users has been estimated to be two to six. The risk is very low under the age of 30. Smoking in combination with oral contraceptive use has been shown to contribute substantially to the incidence of myocardial infarctions in women in their mid-thirties or older and with smoking accounting for the majority of excess cases. Mortality rates associated with circulatory disease have been shown to increase substantially in smokers over the age of 35 and nonsmokers over the age of 40 among women who use oral contraceptives. Oral contraceptives may compound the effects of well-known risk factors, such as hypertension, diabetes, hyperlipidemia, age and obesity. In particular, women who are already at increased risk of atherosclerotic disease, or who have other risk factors, such as cigarette smoking and an elevated blood cholesterol, may be at greater risk. b. Cerebrovascular disease: Oral contraceptives have been shown to increase both the relative and attributable 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, 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 nonmigraine users to 14 for users with severe hypertension. The relative risk of hemorrhagic stroke is reported to be 1.2 for nonsmokers who used oral contraceptives, 2.6 for smokers who did not use oral contraceptives, 7.6 for smokers who used oral contraceptives, 1.8 for nonmigraine users and 25.7 for users with severe hypertension. The attributable risk is also greater in older women. Oral contraceptives also increase the risk for stroke in women with other underlying risk factors such as certain inherited or acquired thrombophilias, hyperlipidemias, and obesity. Women with migraine (particularly migraine with aura) who take oral contraceptives may be at increased risk of stroke. c. Venous thromboses: Oral contraceptives with high doses of oral contraceptives: A positive association has been observed between the amount of estrogen and progestogen in oral contraceptives and the risk of vascular disease. A decline in serum high-density lipoproteins (HDL) has been reported with many progestational agents. A decline in serum high-density lipoproteins has been associated with an increased incidence of ischemic heart disease. Because estrogens increase HDL cholesterol, the net effect of an oral contraceptive depends on a balance achieved between doses of estrogen and progestogen and the nature and absolute amount of progestogen used in the contraceptive. The amount of both hormones should be considered in the choice of an oral contraceptive. Minimizing exposure to estrogen and progestogen is key to good principles of therapy. For any particular estrogen/progestogen combination, the dosage regimen prescribed should be one that contains the least amount of estrogen and progestogen that is effective for the individual patient. Health care providers should be aware of the use of oral contraceptive agents should be started on preparations containing the lowest estrogen content that is judged appropriate for the individual patient. e. Persistence of risk of vascular disease: There are two studies which show persistence of risk of vascular disease for ever-users of oral contraceptives. In a study in the United States, the risk of developing myocardial infarction after discontinuing oral contraceptives persists for at least 9 years for women aged 40 to 49 years who had used oral 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 oral contraceptives, although excess risk was very small. However, both studies were performed with oral contraceptive formulations containing 50 micrograms or more of estrogen. 2. CARCINOMA OF THE REPRODUCTIVE ORGANS AND BREASTS: Numerous epidemiologic studies have been performed on the incidence of breast, endometrial, ovarian and cervical cancer in women using oral contraceptives. Although the risk of having breast cancer diagnosed may be slightly increased among current and recent users of combined oral contraceptives (RR=1.24), this excess risk decreases over time after combination oral contraceptive discontinuation and by 10 years after cessation the increased risk disappears. The risk does not increase with duration of use and no consistent relationships have been found with dose or type of steroid. The patterns of risk are also similar regardless of a woman's reproductive history or her family breast cancer history. The subgroup for whom risk has been found to be significantly elevated is women who first used oral contraceptives before age 20, but because breast cancer is so rare at these young ages, the number of cases attributable to this early oral contraceptive use is extremely small. Breast cancers diagnosed in current or previous OC users tend to be less clinically advanced than in never users. Women who currently have or have had breast cancer should not use oral contraceptives because breast cancer is a hormonally-sensitive tumor. Some studies suggest that oral contraceptive use has been associated with an increase in the risk of contralateral 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 of the relationship between oral contraceptive use and breast and cervical cancers, a cause-and-effect relationship has not been established. 4. HEPATIC NEOPLASIA: Benign hepatic adenomas are associated with oral contraceptive use, although the incidence of benign tumors 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 a large, benign, hepatic adenoma may cause death through intra-abdominal hemorrhage. Studies from Britain have shown an increased risk of developing hepatocellular carcinoma in long-term (≥8 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. 5. OCULAR LESIONS: There have been clinical case reports of retinal thrombosis associated with the use of oral contraceptives, which may lead to partial or complete loss of vision. Oral contraceptives should be discontinued if there is unexplained partial or complete loss of vision; onset of proptosis or diplopia; papilledema; or retinal vascular lesions. Appropriate diagnostic and therapeutic measures should be undertaken immediately. 6. ORAL CONTRACEPTIVE USE BEFORE OR DURING EARLY PREGNANCY: Extensive epidemiologic studies have revealed no increased risk of birth defects in women who have used oral contraceptives prior to pregnancy. Studies also do not suggest a teratogenic effect, particularly in the first trimester, in women with severe hypertension who have started on hormonal contraceptives during early pregnancy. However, oral contraceptives do induce withdrawal bleeding should there be a pregnancy. Oral contraceptives should not be used during pregnancy to treat threatened or habitual abortion. (See CONTRAINDICATIONS) It is recommended that for any patient who has missed two consecutive periods, pregnancy should be ruled out. If the patient has not adhered to the prescribed dosing schedule, the possibility of pregnancy should be considered at the time of the first missed period. Oral contraceptive use 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 oral contraceptives and estrogens. More recent studies, however, have shown that the relative risk of developing gallbladder disease among oral contraceptive users may be minimal. The recent findings of minimal risk may be related to the use of oral contraceptive formulations containing lower hormone doses of estrogens and progestagens. 8. CARBOHYDRATE AND LIPID METABOLIC EFFECTS: Oral contraceptives have been shown to cause glucose intolerance in a significant percentage of users. Oral contraceptives containing greater than 75 micrograms of estrogens cause hypersulinism, while lower doses of estrogen cause less glucose intolerance. Progestagens increase insulin secretion and create insulin resistance, this effect varying with different progestational agents. However, in the nondiabetic woman, oral contraceptives appear to have no effect on fasting blood glucose. Because of these demonstrated effects, prediabetic and diabetic women should be carefully observed while taking oral contraceptives. A small proportion of women will have persistent hypertriglyceridemia while on the pill. As discussed earlier (see WARNINGS 1a and 1d.), changes in serum triglycerides and lipoprotein levels have been reported. The recent findings of minimal risk may be related to the use of oral contraceptive formulations containing lower hormone doses of estrogens and progestagens. 9. ELEVATED BLOOD PRESSURE: Women with severe hypertension should not be started on hormonal contraceptives (see CONTRAINDICATIONS). An increase in blood pressure has been reported in women taking oral contraceptives and this increase is more often in older oral contraceptive users and with continued use. Data from the Royal College of General Practitioners and subsequent randomized trials have shown that the incidence of hypertension increases with increasing concentrations of progestagens. Women with a history of hypertension or hypertension-related diseases, or renal disease should be encouraged to use another method of contraception. If women with hypertension elect to use oral contraceptives, they should be monitored closely, and if significant elevation of blood pressure occurs, oral contraceptives should be discontinued. For most women, elevated blood pressure will return to normal after stopping oral contraceptives and there is no difference in the occurrence of hypertension among ever- and never-

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