## Consumer-Driven Health Plans Still Rarely Used

BY JANE ANDERSON Contributing Writer

merican consumers and their employers are treading cautiously when it comes to switching from traditional, more comprehensive health insurance to consumer-driven health plans, with few actually adopting the new plans, according to survey results from the Employee Benefit Research Institute (EBRI) and the Commonwealth Fund.

In addition, satisfaction among members in consumer-driven health plans (CDHPs) was considerably lower than satisfaction among individuals in more traditional plans, and more members in CDHPs reported that they had delayed getting needed medical care.

The Consumerism in Health Care Survey tracks public opinion on consumer-driven and high-deductible plans, defined as those plans with deductibles of \$1,000 or more for employee-only coverage and \$2,000 or more for family coverage. The plans also feature one of two kinds of taxexempt savings accounts: health savings accounts (HSAs) and health reimbursement arrangements (HRAs).

Employees can use money in the accounts without tax penalty to pay for medical expenses not covered by their

"Consumer-driven health plans aim to control costs largely through demand-side incentives, and to make premiums more

affordable for the uninsured," said Karen Davis, Ph.D., president of the Commonwealth Fund, at a press teleconference sponsored by EBRI and the Commonwealth Fund.

But the survey found that the plans have been slow to catch on. Just 1% of the privately insured U.S. population aged 21-64 years, or 1.3 million individuals, were enrolled in CDHPs in September 2006, unchanged from the year before—despite the widespread attention the new plans have received.

And although another 7% (8.5 million adults) had plans with deductibles that were high enough to qualify for health sav-

Just 1% of the privately insured **U.S.** population aged 21-64 years, or 1.3 million individuals, were enrolled in CDHPs in September 2006.

ings accounts, they were not enrolled in such accounts.

Employers are cautiously awaiting data on the cost and effectiveness of these kinds of plans before switching their to coverage CDHPs, Davis said.

"The plans are not well known at this point," said Paul Fronstin, EBRI senior research associate. "Only 7% of the population responded that they are 'very familiar' with consumerdirected health plans, while 13% said they were 'somewhat familiar.' '

In addition, despite the expectations of some policy makers that the lower premiums and tax benefits of CDHPs would substantially reduce the number of people without health insurance, "we did find that individuals in consumer-directed plans were not more likely to have been uninsured than those enrolled in a conventional plan," Mr. Fronstin said.

Satisfaction lags in the plans, compared with more comprehensive health insurance, the survey found.

And, 38% of those with consumer-driven coverage said that they delayed or avoided getting needed health care because of cost over the last 12 months, compared with 19% of those with comprehensive insurance.

It's no surprise that employers and employees have been cautious in adopting CDHPs, because effecting change in the health insurance industry can be a very difficult undertaking, said Karen Atwood, senior vice president for national accounts at Blue Cross and Blue Shield of

"We are in the early stages of trying to understand how consumerism can be part of the solution," said Ms. Atwood, who noted that such plans also need to have tools in place to address lifestyle behaviors and choices.

"We need good plans, well-crafted network options, and incentives to reward people for doing the right thing," she added.

The survey of 3,158 U.S. adults aged 21-64 was conducted in September through a 14-minute Internet survey.

PROVIGIL® (modafinil) TABLETS [C-IV] BREF SUBBLATY: Consult Package Insert for Complete Prescribing

ingradiants. Waterists with abnormal levels of sleepiness who take PROWGE, should be achieved that their level of reckerfulness may not return to normal. Patients with excessive sleepiness, including those taking PROWGEL, should be frequently reassessed for their degree of sleepiness and, if appropriate, advised to avoid chrising or any other potentially dangerous activity. Prescribers should also be areas that patients may not acknowledge sleepiness or oflowsiness or sleepiness of oflowings specific activities.

steepiness during specific activities.

PRECAUTIONS: Diagnosis of Steep Disorders: PROVIGIL should be used only in potients who have had a complete evaluation of their excessive steepiness, and in whom a diagnosis of other nanoslopey, 05445, and/or SWSD has been made in accordance with ICSD or 05M diagnostic criteria. Such an evaluation usually consists of a complete history and physical examination, and it may be supplemented with testing in a laborationy setting. CPAP Use in Pathests with 055MS: In 05MtS; PROVIGIL to indicated as an adjunct to standard treatment(s) for the underlying obstruction. If continuous positive simaly pressure (SWP) is the tentinent of chalce for a patient, a manimal effort in next with PREP for an adventer control of their chinaria. to treat with CPMP for an adequate period of time should be made prior to initiating PRDIVIGIL. If PRDIVIGIL is used adjunctively with CPMP, the encou-agement of and periodic assessment of CPMP compliance is necessary. Benevat Patients should be castioned about operating an automobile or other agement of and periodic assistances of CWP compliance is necessary. 
Beaveral Patients should be causined above operating an automobile or new hazardous machinery until they are reasonably certain that PROVIEIL therapy will not adversely affect their ability to engage in such activities. Patients Dalag Cambiaceptives: The discrimenses of stencials contributing times may be reduced when used with PROVIEIL and for one month after discontinuation. Alternative or concentration reflectiveness of stencials contributing and for one month after discontinuation. Alternative or concentration of the PROVIEIL Candiscounts Système: In clinical studies of PROVIEIL, signs and symptoms including chest pain, palphatians, dyspinsa and transient schemic T-vavve tranges on ECS pain, palphatians, dyspinsa and transient schemic T-vavve tranges on ECS pain, palphatians, dyspinsa and transient schemic T-vavve tranges on ECS or left ventricular hypertrophy are in patients with a patients with a bistory of left ventricular hypertrophy or in patients with mittal valve prolapse or left ventricular hypertrophy are in patients with a recent history of left ventricular hypertrophy are in patients with a recent history of left ventricular hypertrophy are in patients with a recent history of left ventricular hypertrophy are in patients or discrimination of PROVIEIL registed neglection. Blood pressure in patients receiving PROVIEIL as compared to placebo. However, a greater proportion of patients or PROVIEIL registed new fortunes or placebo (27%). The differential use was slightly larger when only studies in CSAHS were The differential use was slightly larger when only studies in DSAHS were included, with 3.4% of patients on PROVIGIL and 1.1% of patients on placetor. requiring such alterations in the use of antihypertensive medication. Increase monitoring of blood pressure may be appropriate in patients on PRDVIGIL. Central Mervaus System: There have been reports of psychotic episodes monitoring of those pressure may be appropriate in patients on PRDVIGL. Centrol Merveuer System: There have been reports of psychotic episodes associated with PRDVIGL use. One healthy male valunteer developed ideas of informors, parameté detesions, and auditory hallocitations in association with multiple daily 600 mg doses of PRDVIGL and sleep deprivation. Caution should be exercised when PRDVIGL is given to patients with a history of psychosis. Patients with Source Resul Argunitement Treatment with PRDVIGL, resulted in much higher exposure to its inactive metabolite, modufinal acid, but not PRDVIGL itself. Patients with Source Reputile Angulaments. PRDVIGL should be administered at a reduced dose because its clearance is decreased. Enlarly Patients: Etierly patients may have diminished rerul and/or hepatic function; therefore, dosage reduction should be considered. Information for Patients: Physicians are advised to discuss the following with patients taking Patients: Physicians are advised to discuss the following with patients taking abnormal tendency to full acities. Therefore, patients who have abnormal levels of sleepiness. PRDVIGL is indicated for patients who have abnormal levels of sleepiness. PRDVIGL is indicated for patients who have abnormal levels of sleepiness. Patients; that permit such activities. Patients should not after their previous betavior with regard to potentially dangenous activities (e.g., driving, operating machinery) or other activities requiring appropriate levels of walerdiness, until and unless treatment with PRDVIGL, has been shown to produce levels of walerdiness that permit such activities. Patients should be advised that PRDVIGL is not a replacement for sleep. Patients should be advised that PRDVIGL is not a replacement for sleep. Patients should be advised that PRDVIGL is not a replacement for sleep. Patients should be advised that PRDVIGL is not a replacement for sleep. violationises, until and unless treatment with PROVIGE, has been shown to produce levels of wairafalness that pennit such activities. Partients should be advised that PROVIGEL is not a replacement for sleep. Patients should be informed that it may be critical that they continue to take their previously prescribed treatments (e.g., patients with CSAHS receiving CAAP should continue to do sel.) Patients should be informed of the availability of a patient information leafest, and they should be instructed to read the leafer prior to taking PROVIGE. Pregnancy: Patients should notify their physician if they became pregnant or infend to become pregnant during therepy. They should be cautioned of the avoidable contraceptives (including dept or implantable contraceptives) with PROVIGE, and for one month other decontinuation of therapy. Neverthey: Patients should notify their physician if they are breast feeding. Companion with PROVIGE, and for one month other decontinuation of therapy. Neverthey: Patients should notify their physician if they are breast feeding. Companion of the PROVIGE. Alweyte: Reaching the contraceptives provided in the patient of the patient provided in the patient provided in the patient of the patient provided in the patient provided in the patient of the patient provided in the patient provided in the patient provided in the patient of provided in a single-door study, simultaneous administration of PROVISE. by approximately one hour. Last administration of patient the patient provided in a single-door study, simultaneous administration of PROVISE. Do my with patients and provided in a single door of provided as a single door of provided and patients and kinetics of either drug. Dee incident of increased levels of changestrains and its active metabolite desmethylcientigramine has been reported. In the drug interaction study between PROVIGIL and ethinyl estradiol (EE<sub>2</sub>), on the same days as those for the plasma compling for EE; pharmacolinetics, a single dose of biscolare 0.155 mg was also administered. Mean  $C_{\rm max}$  and  $AUC_{\rm the}$  of biscolare decreased by 42% and 59%, respectively, and its elimination half-life was decreased by approximately as hour after the modafinit

treatment, in the absence of interaction studies with monoamine exidate (MDA) inhibitors, caution should be exercised. \*\*Drage:\*\*Na significant changes in the pharmacokinetics of worknic occurred in healthy subjects given one dose of worknin's and following choosic administration of PROVIGIL. However, more frequent monaturing of profitmentatin discensibility is advised when PROVIGIL is caudiministered with worknin. PROVIGIL once daily 200 mg/day for 7 days followed by 400 mg/day for 21 days decreased retirily estretail/\*\*Cause and AMCs, or by an ense 11% and 11% with no apparent change in the elimination rate. Dec interaction between PROVIGIL and cyclosporials board levels elementary for apparent change in the elimination rate. Dec interaction between PROVIGIL and cyclosporials board levels elementary for one month of PROVIGIL 200 mg/day, cyclosporine blood levels elementary. \*\*Decage adjustment for cyclosporine may be needed. \*\*Palantari Arteractions with drough That Arthriti, Indiana, at an elected. \*\*Palantari Arteractions with drough That Arthriti, Indiana, at an elected in principle of the cyclosporine may be needed. \*\*Palantari Arteractions with drough That Arthriti, Indiana, at an elected of the palantari and plantaria in the advisery from the palantary indianated and their Health's Explorers in vivit, custions should be expected when PROVIGIL to coadministrated with drugs that are metabolized by enzymes. In human hepatocytes, PROVIGIL produced a dose-related suppression of CYP203 activity suggesting a potential for metabolize interaction between PROVIGIL and substrates of this enzyme (eg. 5-venturin and plantarion), in beautity voluntiaria, charing potential in metabolize interaction between the production and more interaction and more related on the production and more related to a palantary interaction and more related to the palantary interaction and more related to the palantary interaction of provides ancillary metabolism of north incidens of CYP3044 desired and may be exceeded in the palantary int sis. There was no evidence of tumoricenesis associated



Michagenesis: There was no evidence of mutagenic or clastogenic potential of PROVIDIL. Impairment of Fertility: PROVIDIL was administered orally to male and ternale rats prior to and throughout mating and gestation at up to 23 times the recommended human dose of 200 registary on a registal basis with 23 times the recommended human close of 250 regictly on a reginal basis with no effect on tertility. Programey: Programey Category C: PROVIDIL adminis-tered entity to pregnant rats throughout the period of argangements caused, in the absence of maternal taxistity, an increase in recorptions and on increased incidence of hydromephroois and skaleful variations in the offspring at a dose of 200 registrative of times the recommended human dose of 200 registray or incidence of hydromophocois and sixelated variations in the offspring at a close of 200 mg/kg/stay (15 times the recommended human disse of 200 mg/kg on an mg/m² basis) but not at 100 mg/kg/stay. However, in a subsequent study of up to 480 mg/kg/stay (23 times the recommended human close on a mg/m² basis), which included maternally taxis closes, an advence effects on embryoletal development were sean. PROVIGIL, administrated orally to pregnant stabis throughout the period of arganogenesis at disease up to 100 mg/kg/stay (10 times the recommended human closes on a mg/m² basis) had no effects on embryoletal development. However, in a subsequent study in pegnant stabis, increased recommended human disease on a mg/m² basis, had no effects on an single litter (spen eye lids, fassed digits, sotated limbs), were observed at 180 mg/kg/stay (17 times the recommended human close on a mg/m² basis), a disea that was also maternally stocit. PRENINGIL, administrated carefully to eath throughout gestation and lacatation at disease up to 200 mg/kg/stay (16 times the recommended human close on a mg/m² basis), had no effects on the posturation development of the offspring. There are no adequate and well-controlled studies in pregnant women. PROV/GIL, should be used during pregnancy or if the potential baseful justifies the petential risk to the forest. Labor and Defferey. The effect of PROV/GIL, in labor and definely in humans has not been epithemicially investigated. Nursing Mathems: It is not known whether PROV/GIL, or its metabolites are excreted in human milk. Cautien should be used stade of them PROV/GIL is administrated to a marising verman.

PERATRIC USE: Safety and effectiveness in individuals between 16 years of age have not been established. Leakapenia has been reported in pediatric patients taking PROV/GIL.

**DEPOSITRIC USE:** Substy and effectiveness in individuals above 65 years of age

ADVERSE REACTIONS: PROVIGIL has been evaluated for safety in over 3500 patients, of whom more than 2008 patients with excessive sleepiness associated with primary disorders of sleep and wakefulness were given of least one dose of PROVIGIL. In clinical trials, PROVIGIL has been found to be generally will talensted and most adverse experiences were mild to moderate. The most commonly observed adverse events (±5%) associated with the use of PROVIGIL more frequently than placebo-treated patients in the placebo-

controlled clinical studies in primary disorders of sleep and solerhiless were headachs, nauses, nervousness, rhinitis, disn'hea, back pain, aneisty, insomnia, disziness, and dyspepsia. In the placebe-controlled stinical trials, 8% of the 504 patients who received PROVIDEL discontinued due to as adverse experience. The most frequent reasons for discontinuation that occurred at a higher rate for PROVIESE, than placebo patients were headache

(2%), raumes, arolety, discisees, incommis, chest pain, and nervousness (each <1%). The incidence of adverse experiences that occurred at a rate of ≥1% and were more frequent in patients treated with PROVIGIL than in placebo patients in the principal trials are listed below. Consult full prescribing information on adverse events. Body as a Whate: Headache, back pain, flux syndrome, thest pain, chills, nock rigidity Cardionascular: Hyperformation, tachycardia, palpitation, vasocillatation Digestive: Nausco, diarrhea, dyspeptia, dyn mouth, arroxida, constipation, abnormal liver function, fluture, mouth alcoration, thirs Hemistiphephatic: Ensonable fluture fluture, mouth alcoration, their Hemistiphephatic: Ensonable fluture fluture, and application, as a straight fluture, and discretic, spistaxis, asthmas Skiet/Appendages: Synating, herps simplex Special Senses: Amblyopia, abnormal vision, taste perversion, eye poin Wageperiste. Unite adversarially, hermaturia, pyrials (NEW Signer Chaeges: White there was no consistent change in mean values of heart rate or systelic and classfolic blood pressure, the requirement for antitypectensive that were clearly done related were headache and anxiety. NEW Signe Changes: While there was no consistent change in mean values of heart rate or systalic and disable blood pressure, the requirement for antihypertimative medication was slightly greater in patients or PROVIGIL compared to placebo. Weight Changes: There were no clinically significant differences in body weight change in patients treated with PROVIGIL compared to placebo heared patients. Leboratory Changes: Wean placens levels of gamma glaumythranetrase (RGT) and alkalizer phosphotose (RF) were higher following administration of PROVIGIL, but not placebo. New subjects, however, had GGT or AP elevations outside of the normal range. Shifts to higher, but not clinically significantly abnormed, EGT and AP values appeared to increase with time on PROVIGIL. No differences were apparent in attains aminotraneterose, separate aminotraneterose, trait protein, altitumin, or fatal britishis. EGC Changes: No toxalized-emerging potein, altitumin, or fatal britishis. EGC Changes: No toxalized-emerging potein, altitumin, or fatal britishis. EGC Changes: No toxalized-emerging potein, altitumin, or fatal britishis. EGC Changes: No toxalized-emerging potein, altitumin, or fatal britishis. EGC Changes: No toxalized-emerging potein, and of the protein administration of PROVIGIL.
Postmarketing Reperting: The following administration of PROVIGIL.
Postmarketing Reperting: The following administration of PROVIGIL and the protein and population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug expected. Decisions to include these reactions in labeling are typically based on one or more of the following factors: (1) seriousness of the reaction, (2) frequency of the reporting, or (3) strength of causal connection to PROVIGIL. Central Nerwous Systems: Symptoms of psychosis, symptoms of master Dermatelogis: Pare reports of serious shin reactions (including suspected causes of both enytherus multiforms a DRUG ABUSE AND DEPENDENCE: Abuse Patential and Dependence: In

addition to its waterlainess-promoting effect and increased locomotor activity in animals, in humans, PROVIGIL produces psychoactive and explined effects, alternations in mosel, perception, thinking and feelings spliced of other CNS stimulants. In vitro, PROVIGIL binds to the departime receptake site and CRS stimulants, to vitro, PROVINGIL brinch to the departine rougstake alter accesses in decease in extracellular departine, but no increase in departine release. PROVINGIL is reintocking, as evidenced by its self-administration in monkeys proviously trained to self-administer cockine. In some studies, PROVINGIL was also partially discriminated as stimulant-like. Physicians should follow patients closely, especially those with a history of discriminated as introductional actions of the patients closely, especially those with a history of the grandown stimulant (e.g., methylpheniate, amphetamine, or cocaine) abuse. In incliniduals experiment with other stimulants of the province of abuse. PROVINGIL produced psychoactive and explorers effects and feelings consistent with other scheduled CNS stimulants (methylpheniciate). Patients should be observed for signs of misuse or abuse. Withdrawati Following 9 weeks of PROVINGIL use in one US clinical trial, no specific symptoms of withdrawal were observed during 14 days at observation, although steepiness returned in narcoleptic patients.

specified dises 2-1000 mg/day (5 to 8 times the recommended daily dose of 200 mg/ have been administrated to 32 salipects, including 13 salipects who received doses of 1000 or 1290 mg/day for 7 to 21 consecutine days, in addition, several intentinual acute eventoses occurred, the two largest being neceived doses of 1000 or 1200 regictly for 7 to 21 consecutive days. In addition, several intentinal acute eventoes occamed the two largest being 4500 mg and 4000 mg taken by two subjects sperioripating in finelign depression studies. Name of these study subjects experienced any unexpected or life-threatening effects, Alverse experiences that were exported at these doses included excitation or agitation, insommia, and slight or modesate elevadoise included excitation or agitation, incommis, and signit or moderate eleva-tions in hemodynamic parameters. Other observed high-dose effects in clinical studies have included anxiety, irritability, aggressiveness, confusion, nervousness, tremor, polybistions, elego distiniturace, seasea, diamhea, and decisiosed profitorionible time. Firms poor-marketing emperience, there have been no neports of fatal overdoses involving PROVASIL, alone (doses up to 12 grams). Overdoses involving multiple drugs, including PROVASIL, have resulted in floatil outcomes. Symptoms most effect accompanying PROVASIL, overdose, alams or in combination with other drugs have included issumnia, resifiesaness, disorientation, confusion, escitation, hallucination, nassea, resifiesaness, disorientation, confusion, escitation, hallucination, nassea, resifiesaness, disorientation, confusion, escitation, hallucination, nassea, resifiesaness and properties of the studies of the studies of the studies of the studies of the course in a three-year-aid bey who ingested 800-1800 mg (50-65 mg/kg) of PROVISIL. The children mess spindar to those of sheets of PROVISIL overdose has been identified. Overdoses should be managed with primarily supportive care, including acclicusassian monitoring, threeds or gastric bavage should be cansidered. Them are no data to suggest the utility of dialysis or winary acid-fication or alkalinization in enhancing drug elimination. The physician should cansider contacting a poison-control center on the treatment of any overdose. tions in hemodynamic parameters. Other observed high-dose effects in

Manufactured for: Cephalon, Inc., West Chester, PA 19380

Cephalon