## Use of Personal Health Records Doubles to 7%

BY ANNE C. ZIEGER

hile the use of personal health records is gaining popularity, still only 1 in 14 Americans report having used one, according to a survey of 1,849 patients.

About 7% of respondents to the survey sponsored by the California Health-Care Foundation said they used a personal health record (PHR). That's more

than double the 2.7% who reported using PHRs in a 2008 study conducted by the Markle Foundation.

Among the reasons cited by those who do not use a PHR were concern over the data privacy, the perception that they don't need such a tool, and fears that PHRs might cost too much or take up too much time, according to Sam Karp, vice president of programs for CHCF.

Of those who reported PHR use, 26%

reported using one sponsored by their health care provider, while 51% used one provided by their health insurer.

While PHRs users tend to be young, highly educated white men with relatively high incomes, patients with chronic illnesses and those with lower-than-average income and educations were more likely to report benefiting from using a PHR, according to the survey results.

For example, 55% of respondents with-

out a college degree reported that after using a PHR, they asked their provider questions they otherwise would not have asked. Also, 58% of users with incomes of less than \$50,000 said that they felt more connected to their doctors as a result of using a PHR. Further, 40% of PHR-using respondents with two or more chronic conditions reported that they had taken steps to improve their health, the researchers said.

## Arristia *desvenlafaxine* Extended-Release Tablets

BRIEF SUMMARY. See package insert for full Prescribing Information. For further p and current package insert, please visit www.wyeth.com or call our medical department toll-free at 1-800-934-5556.

WARNING: Suicidality and Antidepressant Drugs

WARNING: Suicidality and Antidepressant Drugs Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of Major Depressive Disorder (MDD) and other psychiatric disorders. Anyone considering the use of Pristiq or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and carejivers should be advised of the need for close observation and communication with the prescriber. Pristiu is not al worselling, succeasing, or unusual stranges in benevity, remines and encyrice straight ad of the need for close observation and communication with the prescrible, Pristiq is no ved for use in pediatric patients [see Warnings and Precautions (5.1), Use in Specifi ations (8.4), and Patient Counseling Information (17.1 in the full prescribing information]. ed of the ne

INDICATIONS AND USAGE: Pristiq, a selective serotonin and norepinephrine reuptake inhibitor (SNRI), is indicated for the treatment of major depressive disorder (MDD).

Is indicated for the treatment of major depressive disorder (MUU). **CONTRAINDICATIONS: Hypersensitivity**-Hypersensitivity to desvenlafaxine succinate, venlafaxine hydrochloride or to any excipients in the Pristiq formulation. **Monoamine Oxidase Inhibitors**-Pristiq must not be used concomitantly in patients taking monoamine oxidase inhibitors (MAOIs) or in patients who have taken MAOIs within the preceding 14 days due to the risk of serious, sometimes fatal, drug interactions with SNRI or SSRI Teratment or with other serotonergic drugs. Based on the half-life of desvenlafaxine, at least 7 days should be allowed after stopping Pristiq before starting an MAOI [see Dosage and Administration (2.5) in the full prescribing information].

SNRI or SSRI treatment or with other servitaring and Suicide Niek-Patients with major depressive days should be allowed after stopping Pristip before starting an MAOI [see Dosage and Administration (2.5) in the full prescribing information. WARNINGS AND PRECATIONES: Clinical Worsening and Suicide Niek-Patients with major depressive mergence of suicidal ideation and behavior (suicidal) in crusinal changes in behavior, whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs. Suicida is a known risk of depression and certain other psychiatric disorders, and these disorders themselves are the strongest predictors of suicide. There has been along-standing concern, however, that antidepressant may have a role in inducing worsening of depression and the emergence of suicidally in certain patients during the early phases of treatment. Pooled analyses of short-term blacebo-controlled tradies of antidepressant drugs (SSRIs and Others) showed that threes drugs increase in the risk of suicidality in children, adolescents, and young adults (ages 18-24) with major depressive disorder (MOD) and other psychiatric disorders. Short-term studies did not show an increase in the risk of suicidality in children adolescents with MDD, obsessive-compulsive disorder (COL), or other psychiatric disorders included a total of 24 short-term studies did fung studies of an indicers in adults in certain a disorder scheric for adults and drugs studied. There were differences in disorders included a total of 24 short-term studies did fung studies of 11 antidepressant drugs in over 77,000 patients. There was considerable variation in risk of suicidality and strong and across indicators. These risk differences (drug-placebo difference in the number vas not sufficient to reach ary or physic bysic disorders included a studie of the suicidality raise durations. These risk differences (drug-placebo difference in the number vas not sufficient to reach ary oreactions to border in the younge WARNINGS AND PRECAUTIONS: Clinical Worsening and Suicide Risk-Patients with major deprehyperthermia), neuromuscular aberrations (eg, hypereflexia, incoordination) and/or gastrointestinal symptoms (eg, nausea, wornting, diarrhea). Serotonin syndrome in its most severe form can resemble neuroleptic malignant syndrome, which includes hyperthermia, muscle rigidity, autonomic instability with possible rapid fluctuation of vital signs, and mental status changes. Patients should be monitored for the emergence of serotonin syndrome or NMS-like signs and symptoms. The concomitant use of Pristig with MAOIs intended to treat depression is contraindicated [*see Contraindications (4.2]*]. If concomitant treatment of Pristig with a 5-hydroxytrptamine receptor agoinst (triptan) is clinically warranted, careful observation of the patient is advised, particularly during treatment initiation and dose increases. The concomitant use of Pristig with serotonin precursors (such as tryptophani) is ontically warranted, careful observation of the patient is advised, particularly during treatment initiation and dose increases. The concomitant use of Pristig with serotonin precursors (such as tryptophanis) is not recommended. Treatment with Pristig and any concomitant serotonergic or antidopaminergic agents, including antipsychotics, should be discontinued immediately if the above events occur, and supportive symptomatic treatment should be initiated. **Elevated Blood Pressure** - Patietts receiving Pristig should have regular monitoring of blood pressure since dose-dependent increases were observed in clinical studies. Pre-existing hypertension should be compromised by increases in blood pressure. Cases of elevated blood pressure requiring immediate treatment have been reported with Pristig. <u>Sustained hypertension</u>. Sustained blood pressure while receiving Pristig either dose reduction or discontinuation should be considered [*see Adverse Reactions (6.1)*]. Treatment with Pristig in controlled studies was associated with sustained hypertension, defined as treatment emergent supine diastolic blood pressu

3 consecutive on-therapy visits. In clinical studies, regarding the proportion of patients with sustained hypertension, the following rates were observed: placebo (0.5%), Pristiq 50 mg (1.3%), Pristiq 100 mg (0.7%), Pristiq 200 mg (1.1%), and Pristiq 400 mg (2.3%). Analyses of patients in Pristiq controlled studies who met criteria for sustained hypertension. Abnormal Bleeding-SSRis and SNRIs can increase the risk of bleeding events. Concomitant use of aspirin, other drugs that affect platelet function, nonsteroidal anti-inflammatory drugs, warfarin, and other anticoagulants can add to this risk. Bleeding events. Concomitant use of aspirin, other drugs that affect platelet function, nonsteroidal anti-inflammatory drugs, warfarin, and other anticoagulants can add to this risk. Bleeding events related to SSRis and SNRIs have ranged from ecclymosis, hematoma, epistaxis, and petchiae to life-threatenges. Patients should be cautioned about the risk of bleeding associated with the concomitant use of Pristiq and NSAIDs, aspirin, or other drugs that affect coagulation or bleeding. Narrow-angle Glaucoma-Mydriasis has been reported in association with Pristiq, therefore, patients with raised intraocular pressure or those at risk of acute narrow-angle glaucoma (angle-closure glaucoma) should be z and phase 3 studies, mania was reported for approximately 0.1% of patients treated with Pristiq. Activation of Mania/Hypomania-During all MDD and VMS (vasomotor symptoms) phase 2 and phase 3 studies, mania was reported for approximately 0.1% of patients treated with Pristiq. Activation of mania/hypomania-During all MDD and VMS (vasomotor symptoms) phase 1 advised in administering Pristiq to patients with a sits of patients with a sits or patients with raise, clication studies with Pristiq. Activation of mania/hypomania has also been reported in a studies with Pristiq of the patients with the appearance of move critical infarction, unstable heart disease, uncontrolled hypertension, or cerebrovascular of lipid metabolism disorde Ineductie, Initiation events occurred more fraquer, ladgue, abundia uteans, and the period service of the servi subat ning usease and cosing/intermentation associated with venialization (the particulary of instance) app have been arrely reported. The possibility of these adverse events should be considered in patients ed with Pristiq who present with progressive dyspnea, cough, or chest discomfort. Such patients ild undergo a prompt medical evaluation, and discontinuation of Pristiq should be considered.

should undergo a prompt medical evaluation, and discontinuation of Pristid should be considered. **ADVERSE REACTIONS: Clinical Studies Experience:** The most commonly observed adverse reactions in Pristid-treated MDD patients in short-term fixed-dose studies (incidence ≥5% and at least twice the rate of placebo in the 50- or 100-mg dose groups) were nausea, dizziness, insomnia, hyperhidrosis, constipation, somnolence, decreased appetite, anxiety, and specific male sexual function disorders. Adverse reactions reported as reasons for discontinuation of treatment- The most common adverse reactions leading to discontinuation in at least 2% of the Pristid-treated patients in the short-term studies, up to 8 weeks, were nausea (4%); dizziness, headache and vomiting (2%). <u>Common adverse reactions in placebo-controlled</u> <u>MDD studies-</u> Table 3 in full PI shows the incidence of common adverse reactions in tal cocurred in >2% <u>OF Pristid-treated MDD patients at any dose in the 8-week placebo-controlled</u> up to 8 weeks, were nausea (4%), dizzhess, headache and vomiting (2% each); in the long-term study, up to 9 months, the most common was vomiting (2%). <u>Common adverse reactions in placebe-controlled MDD studies</u>. Table 3 in tull PI shows the incidence of common adverse reactions in a locabe-controlled. MDD studies. In general, the adverse reactions were most frequent in the first week of treatment. <u>Cardiac</u> disorders: Palpitations, Tachycardia, Blood pressure increased; <u>Gastrointestinal disorders</u>: Nausea, Dry mouth, Diarrhea, Constipation, Vomiting; <u>General disorders and administration site</u> conditions. <u>They constipation</u>, Vomiting; <u>General disorders and administration site</u> conditions and <u>urtimary disorders</u>: Drziness, Somnolence, Headache, Tremor, Paraesthesia, Disturbance in attention; <u>Psychiatric Disorders</u>: Inversite, Anxiety, Nervousens, Irritability, Abnormal dreams; <u>Benal and urtimary disorders</u>: Unirary hesitation; <u>Bespiratory, thoracic, and mediastinal disorders</u>: Yawning; <u>Skin and urinary disorders</u>: Hyperhidrosis, Rash; <u>Special Senses</u>: Vision blurred; Mydriasis, Tinnitus, Dysgeusia; <u>Vascular Disorders</u>: Hyperhidrosis, Rash; <u>Special Senses</u>: Vision blurred; Mydriasis, Tinnitus, Dysgeusia; <u>Vascular Disorders</u>: Hyperhidrosis, Bash; <u>Special Senses</u>: Vision blurred; Mydriasis, Tinnitus, Dysgeusia; <u>Vascular Disorders</u>: Hyperhidrosis; Cashi and <u>Subculation disorder</u>; <u>Elcaulation adverse reactions abnormal, Elaculation delayed, Erectile dysfunction; <u>Mesonas observed in premarketing clinical studies</u>; <u>Mannore</u>, Synchaid, <u>Cisorders</u> – Hypersensitivity, <u>Anorgasmia, Other adverse reactions observed in premarketing clinical studies; <u>Merco adverse</u>, eractions observed in premarketing clinical studies; <u>Merco adverse</u>, erections occurring at an incidence of <2% in MDD patients treated with Pristiq vere: *Immune system* disorders – Hypersensitivity, *Investigations*. Weintori, *Scychaitric disorders* – Derbostalet, *Nervous system disorders* – Musculoskeletal stiffness. *Pscychaitric di</u></u>* differences were observed between Pristiq-treated and placebo-treated patients for 0T, 0Tc. PR, and ORS intervals. In a throrough 0Tc study with prospectively determined criteria, desventafaxine did not cause 0T prolongation. No difference was observed between placebo and desventafaxine treatments for the ORS interval. *Vital sign changes*-Table 7 summarizes the changes that were observed in placebo-controlled, short-term, premarketing studies with Pristiq in patients with MDD (doses 50 to 400 mg). Relative to placebo, Pristiq was associated with mean increase of up to 2.1 mm Hg in systolic blood pressure, 2.3 mm Hg in diastolic blood pressure, and 4.1 bpm with supine pulse. At the final on-therapy assessment in the 6-month, double-blind, placebo-controlled, phase, there was no statistical difference in mean weight gain between Pristiq uring and placebo-treated patients. *Orthostatic hypotension*- In the short-term, placebo-

controlled clinical studies with doses of 50-400 mg, systolic orthostatic hypotension (decrease ≥30 mm Hg from supine to standing position) occurred more frequently in patients ≥65 years of age receiving Pristiq (8,0%, 7/87) versus placebo (2,5%, 1/40), compared to patients ≥65 years of age receiving Pristiq (8,0%, 7/87) versus placebo (0,7%, 8/1,218). Adverse Reactions Identified During Post-Approval Use-The following adverse reaction has been identified during post-approval use of Pristiq. Because post-approval reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure: *Skin and subcutaneous tissue disorders* – Angioedema. DRUG INTERACTIONS: Central Nervous System (NS)-Active Agents-The risk of using Pristiq in combination with other CNS-active drugs [see Warnings and Precautions (5.13). Monoamine Oxidase Inhibitors (MAOIs)-Adverse reactions, some of which were serious, have been reported in patients who have recently been discontinued from a monoamine oxidase inhibitor (MAOI) and started on antidepressants with pharmacological properties similar to Pristiq (SNRIs or SSRIs), or who have recently had SNRI or SSRI therapy discontinued prior to initiation of an MAOI [see Contraindications (4.2), Serotonergic Drugs- Based on the mechanism of action of Pristiq and the potential for serotonin syndrome, caution is advised when Pristiq is coadministered with other drugs that may affect the serotonergic neurotransmitter systems [see Warnings and Precautions (5.2), Drugs that Interfere with Hemostasis. Ejdemiological studies of case-control and cohort design have demonstrated an association between use of psychotropic Hugs that interfere with serotonin reuptake and the occurrence of upper astivintestinal bleeding. These studies have also shown that concurrent use of an NSAID or aspirin may potentiate this risk of bleeding. Altered anticoagulant effects, including increased bleeding, ha . Clinical studies have shown that desventafaxine does not have a clinically relevant effect on CYP2D6 can result in higher concentrations of that drug. <u>Drugs metabolized by CYP3A4 (midzadam)</u>. *In vitro*, desventafaxine does not inhibit or induce the CYP3A4 isozyme. Concomitant use of Pristiq with a drug metabolized by CYP3A4 can result in lower exposures to that drug. <u>Drugs metabolized by CYP1A2, 2A6, 2C5, 2C9, and 2C19</u>. *In vitro*, desventafaxine does not inhibit CYP1A2, 2A6, 2C5, and 2C19 isozymes and would not be expected to affect the pharmacokinetics of Pristiq are unlikely to be affected by drugs that are metabolized by these CYP isozymes. **P-glycoprotein Transporter**. *In vitro*, desventafaxine is not a substrate or an inhibitor for the P-glycoprotein transporter. The pharmacokinetics of tricitig are unlikely to affect the pharmacokinetics of drugs that are substrates of the P-glycoprotein transporter. Electroconvulsive therapy combined with Pristiq treatment. **USE IN SPECIFIC POPULATIONS: Pregnancy**- Patients should be advised to notify their physician if they become pregnant or intend to become pregnant druing therapy. <u>Tratogenic effects</u>- Pregnancy Category C- There are no adequate and well-controlled studies of Pristiq in pregnant rom. <u>Therefore</u>, Pristiq should be used during pregnancy only if the potential benefits. Justify the potential inskes. <u>Non-teratogenic effects</u>- Neonates exposed to SNRis (Serotonin and Norepinephrine Reuptake Inhibitors), or SSRis (Selective Serotonin Reuptake Inhibitors), or possible, ad rug discontinuation syndorme. It should be noted that, in some cases, the clinical findings have included respiratory distress, cyanosis, apnea, seizures, temperature instability, feeding difficulty, vonting, hypoprotian, hypertelixai, tremori, itteriness, inribability, and constant crying. These features are consistent with either a direct toxic effect of Pristig atom in the third timester have developed complications requiring prolonged diverga apregnant woman with Pristiq dur

OVERDOSAGE: Human Experience with Overdosage. There is limited clinical experience with desvenlatavine succinate overdosage in humans. In premarketing clinical studies, no cases of fatal acute overdose of desvenlatavine were reported. The adverse reactions reported within 5 days of an overdose >600 mg that were possibly related to Pristiq included headache, vomiting, agitation, dizzinesa, nuseea, constipation, diarrhea, dry mouth, parsethesia, and tachycardia. Desvenlatavine (Pristiq) is the major active metabolite of ventafaxine. Overdose experience reported with ventafaxine (Pristiq) is the major active metabolite of ventafaxine. Overdose experience reported with ventafaxine (Pristiq) is the major active metabolite of ventafaxine in the overdosage sections reported during a package insert. In postmarketing experience, overdose with ventafaxine (the parent drug of Pristiq) has occurred predominantly in combination with alcohol and/or other drugs. The most commonly reported vents in overdosage include tachycardia, changes in level of consciousness (ranging from somolence to coma), mydriasis, seizures, and vomiting. Electrocardiogram changes (eg, prolongation of 01 interval, bundle branch block, QRS prolongation), sinus and ventricular tachycardia, bradycardia, hypotersion, rhabdomy/dyis, vertigo, liver necrosis, sertonin syndrome, and death have been reported. Publisher derrospective studies report that ventafaxine overdosage may be associated with an increased risk of fatal outcomes compared to that observed with SRI antidigenessant products, but lower than that for tricycic antidepressants. Epidemiological studies have shown that ventafaxine reperients are a higher pre-existing burden of suicide risk factors than reported. Verification of endoced that the second seco This brief summary is based on Pristiq Prescribing Information W10529C009, revised September 2009

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