Smoking Ban Leveraged Abstinence by 4.1%

BY HILLEL KUTTLER

BALTIMORE — Minnesota's passage of a ban on smoking in bars and restaurants made smokers 4.1% more likely to quit, compared with pre-ban smokers.

The state's 2007 enactment of the Freedom to Breathe Act had a significant effect on abstinence, although it was not as strong a factor as a smoker having a high level of confidence in quitting (12.3%), de-

gree of utilization of cessation programs (7.8%-18.4%), and use of nicotine replacement therapy (7.5%) and other medications, according to a poster presented at the annual meeting of the Society for Research on Nicotine and Tobacco.

The cross-sectional study surveyed 2,917 people enrolled in four tobacco cessation programs conducted by ClearWay Minnesota, a nonprofit smoking cessation research and public outreach group.

The study data reflect the period 2 years prior to the 2007 enactment and 1 year afterward. Data were collected at each participant's time of enrollment in the cessation program and then each individual was surveyed 7 months later.

The study, conducted by Professional Data Analysts (PDA), a Minneapolis firm, found that the statewide ban's influence was "diluted" in areas that already had a ban-for each year of living in such areas, smokers were 2.5% less likely to have the ban affect their decision to remain abstinent.

Julie Rainey, PDA's vice president, surmised that smokers who had already been living under a local ban had by then adapted their behaviors by stepping outside to smoke or by not smoking at all.

The statewide ban further affected social norms, because "smoking was more stigmatized," she said.



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

WARNING: Suicidality and Antidepressant Drugs

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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 caregivers should be advised of the need for close observation and communication with the prescriber. Pristig is not approved for use in pediatric patients [see Warnings and Precautions (5.1), Use in Specific Populations (8.4), and Patient Counseling Information (17.1 in the full prescribing information)].

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

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CONTRAINDICATIONS: Hypersensitivity—Hypersensitivity to desvenlafaxine succinate, venlafaxine hydrochloride or to any excipients in the Pristiq formulation. Monoamine Oxidase Inhibitors (Molls) 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 treatment 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].

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WARNINGS AND PRECAUTIONS: Clinical Worsening and Suicide Risk-Patients with major depressive disorder (MDD), both adult and pediatric, may experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality) or unusual changes in behavior, whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs. Suicide is a known risk of depression and certain other psychiatric disorders, and these disorders themselves are the strongest predictors of suicide. There has been a long-standing concern, however, that antidepressants may have a role in inducing worsening of depression and the emergence of suicidality in certain patients during the early phases of treatment. Pooled analyses of short-term placebo-controlled studies of antidepressant drugs (SSRIs and others) showed that these drugs increase the risk of suicidality in children, adolescents, and young adults (ages 18-24) with major erduction with antidepressants compared to placebo in adults beyond age 24; there was a reduction with antidepressants compared to placebo-controlled studies in children and adolescents with MDD, obsessive-compulsive disorder (DCD), or other psychiatric disorders included a total of 24 short-term studies of antidepressant drugs in over 4,400 patients. The pooled analyses of placebo-controlled studies in children and adolescents with MDD, obsessive-compulsive disorder (DCD), or other psychiatric disorders included a total of 24 short-term studies of 9 antidepressant drugs in over 7,000 patients. The pooled analyses of placebo-controlled studies in adults with MDD or other psychiatric disorders included a total of 24 short-term studies of 9 antidepressant drugs in over 7,000 patients. There was considerable variation in risk of suicidality mong drugs, but a tendency toward an increase in the younger These risk dirences (incl.) placebo inference in the number of cases of sucidality per 1000 petients treated) are provided in Table 1 of the full prescribing information. No suicides occurred in any of the pediatric studies. There were suicides in the adult studies, but he number was not sufficient to reach any conclusion about droy effect on suicide. It is unknown whether the suicidality risk extends to longer-lens, and the suicides of the provided in the suicides of the provided in the suicides of the suicidality and unusual changes in the suicides of the suicides o

3 consecutive on-therapy visits. In clinical studies, regarding the proportion of patients with sustained hypertension, the following rates were observed: plazobo (0.5%), Pristiq 50 mg (1.3%), Pristiq 100 mg (1.3%), And Pristiq 400 mg (2.3%), Analyses of patients in Pristiq controlled studies who met criteria for sustained hypertension revealed a dose-dependent increase in the proportion of patients who developed sustained hypertension revealed a dose-dependent increase in the proportion of patients who developed sustained hypertension. Abnormal Bleeding-SSRs and SRNs can increase the risk of bleeding events. Concomitant use of aspirin, other drugs that affect platelet function, nonsteroidal anti-inflammatory drugs, warrain, and other anticoagulants can add to this risk. Bleeding events related to SSRs and SNRs have ranged from ecchymosis, hematoma, epistaxis, and petechiae to life-threatening hemorrhages. 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 should be an intracoular pressure or those at risk of acute narrow-angle glaucoma (angle-closure) glaucoma) should be monitored. Activation of Mania/Hypomania. Druin gal MIDO and VMS (vasomotor symptoms) phase 2 and phase 3 studies, mania was reported for approximately 0.1% of patients when the pristing Activation of mania/Hypomania has also been reported in a small proportion of patients with major affective disorder who were treated with other marketed antidepressants. As with all antidepressants, Pristiq should be used cautiously in patients with a history or family history of mania or hypomania. Cardiovascular, cerebrovascular, or lipid metabolism disorders glese Adverse Reactions (6.7), Increases in blood pressure and heart rate were observed in clinical studies with Pristiq, Pristiq has not been evaluated by systematically in patients with a recent history of myocardial infarction, unstable heart diseases, uncontrolled hypertension by have been tail proposed. It is a distribution of the proposed with Pristig who present with progressive dyspnea, cough, or chest discomfort. Such patients lid undergo a prompt medical evaluation, and discontinuation of Pristig should be considered.

Interstitial lung disease and eosinophilic pneumonia associated with veniataxine (the parent drug of Pristig) de treapy have been rarely reported. The possibility of these adverse events should be considered in patients in treated with Pristig who present with progressive dyspnea, cough, or chest discomfort. Such patients eshould undergo a prompt medical evaluation, and discontinuation of Pristig should be considered.

ADVERSE REACTIONS: Clinical Studies Experience: The most commonly observed adverse reactions in Pristig-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, insomina, hyperhidrosis, and or placebo in the 50 or 100-mg dose groups) were nausea, dizziness, insomina, hyperhidrosis, and conscipation, sominolence, decreased appetite, anviety, and specific male sexual function disorders. Adverse reactions reported as reasons for discontinuation of treatment. The most common adverse reactions reported as reasons for discontinuation of treatment. The most common adverse reactions reported as reasons for discontinuation of ventile to the pristig-treated patients in the short-term studies, up to 9 months, the most common was vomiting (2%). Common adverse reactions in placebo-controlled times and the pristig-treated MDD patients at any dose in the 8-week, placebo-controlled, fixed-dose, premarketing clinical studies. In general, the adverse reactions were most frequent in the first week of treatment. Cardiac tid disorders: Palpitations, Ventile, and the pristight of the pristight

d controlled clinical studies with doses of 50-400 mg, systolic orthosetatic hypotension (decreases ≥30 mm Hg from supine to standing position) occurred more frequently in patients. 265 years of age receiving Pristio, 167:137, 179-189, position occurred more frequently in patients. 265 years of age receiving Pristion (187:137) was placed to 75.73, 47.138, Aboverse Received and and age receiving Pristion (187:137) was placed to 75.73, 47.138, Aboverse Received and support and the pristion of the pristing floration of the pristing fl

recommended dose in patients with hepatic impairment is 50 mg/day. Dose escalation above 100 mg/day is not recommended [see Clinical Pharmacology (12.6)].

OVERDOSAGE: Human Experience with Overdosage—There is limited clinical experience with desvenlariaxine succinate overdosage in humans. In premarketing clinical studies, no cases of fatal acute overdose of desvenlariaxine were reported. The adverse reactions reported within 5 days of an overdose >600 mg that were possibly related to Pristiq included headache, vorniting, agitation, dizziness, nausea, constipation, diarrhea, dry mouth, paresthesia, and tachycardia. Desventialaxine (Pristiq) is the major active metabolite of venlariaxine. Overdose experience reported with enalfaziaxine (the parent drug of Pristiq) is presented below; the identical information can be found in the Overdosage section of the venlataxine package insert. In postmarketing experience, overdose with venlariaxine (the parent drug of Pristiq) is presented below; the identical information can be found in the Overdosage section of the venlataxine package insert. In postmarketing experience, overdose with venlariaxine (the parent drug of Pristiq) has occurred predominantly in combination with alcohol and/or other drugs. The most commonly reported events in overdosage include tachycardia, changes in level of consciousness (ranging from somnolence to coma), mydriasis, serzorus, and vomiting. Electrocardiogram changes (eg, prolongation of TI interval, bundle branch block, QRS prolongation), sinus and ventricular tachycardia, bradyceradia, hypotension, rhabdomyolysis, vertigor, liver necrosis, serotionis syndrome, and death have been reported. Published retrospective studies report that venlataxine overdosage may be associated with an increased risk of fatal outcomes compared to that observed with SSRI antidepressant products, but lower than that for tricyclic antidepressants. Epidemiological studies have shown that venlafaxine-treated patients have a higher pre-existing burden of suicide risk fa This brief summary is based on Pristiq Prescribing Information W10529C009, revised Septe

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