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Until 12 a.m., January 27, 2004

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Antipsychotic Drugs Raise Obesity, Diabetes and Heart Disease Risks:

Joint Panel Urges Increased Screening, Monitoring of Side Effects

(Alexandria, VA) – People who take antipsychotic drugs for the treatment of a variety of mental illnesses may be at increased risk for obesity, diabetes and high cholesterol – all of which can lead to heart disease. Because of this, a joint panel of the American Diabetes Association, American Psychiatric Association, American Association of Clinical Endocrinologists, and the North American Association for the Study of Obesity has issued a consensus statement asking doctors to carefully screen and monitor patients on these medications for signs of rapid weight gain or other problems that could lead to diabetes, obesity and heart disease and refer them to specialists if necessary.

The consensus statement, published in the February issue of *Diabetes Care*, outlines guidelines for doctors treating people with a class of drugs known as second-generation antipsychotics (SGAs). These drugs, the use of which has soared in recent years, are used to treat a variety of mental illnesses, including: schizophrenia spectrum disorders; bipolar disorder; dementia; psychotic depression; autism and developmental disorders; and, to a lesser extent, delirium; aggressive behavior; personality disorders; and posttraumatic stress disorder.

The panel concluded that “there is considerable evidence” that treatment with SGAs can lead to rapid weight gain and that most of the weight gained is fat. Studies also show an association between SGA use and the development of pre-diabetes, diabetes, and elevated blood lipid levels. In some cases, SGA use has also been associated with diabetic ketoacidosis (DKA), which can be life-threatening. While weight gain was associated with first-generation antipsychotics, data regarding other metabolic effects are not available.

The panel also concluded that the SGAs differ in their risk profiles and that some SGAs, such as clozapine and olanzapine, while effective treatment options, raise a greater risk of weight gain, diabetes and lipid disorders than others. The statement notes that “...Even for those medications associated with an increased risk of metabolic side effects, the benefits to specific patients could outweigh the potential risks.” Thus, while risks reviewed in this study should influence choice of medication, the need to balance benefits and a wide range of risks underscores the importance of tailoring treatments to individual patients.

-- More --

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Antipsychotic Drugs/Page 2

Therefore, the panel recommended that doctors prescribing antipsychotic drugs first perform baseline screenings of:

- Personal and family history of obesity, diabetes, dyslipidemia (cholesterol and triglyceride levels), blood pressure or cardiovascular disease;
- Weight and height;
- Waist circumference;
- Blood pressure;
- Fasting plasma glucose; and
- Fasting lipid profile.

The panel also recommended that referral to specialists be considered if problems with significant weight gain, new onset diabetes, or other cardiovascular risk factors occur and that nutrition and physical activity counseling be provided to all patients who are taking antipsychotic medications and are overweight or obese.

The panel recommended frequent follow-up monitoring of any patient receiving SGA therapy, and concluded that people at greatest risk for these complications should be prescribed SGAs least likely to cause them.

The panel concluded that more research is needed to more clearly define the risks associated with SGAs. In the meantime, as with all drugs, the undesirable side effects associated with SGAs should be an important consideration.

Diabetes Care, published by the American Diabetes Association, is the leading peer-reviewed journal of clinical research into the nation's fifth leading cause of death by disease. Diabetes also is a leading cause of heart disease and stroke, as well as the leading cause of adult blindness, kidney failure and non-traumatic amputations. For more information about diabetes, visit the American Diabetes Association Web site www.diabetes.org or call 1-800-DIABETES (1-800-342-2383).

The consensus development conference was supported in part by an educational grant from AstraZeneca, Bristol-Myers Squibb Co., Janssen Pharmaceutical Products, Eli Lilly and Co., and Pfizer Inc.

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From: CN=Elizabeth Colliot/OU=AM/O=LLY
Subject: Selection of Verbatims from Marketplace Tracker
Attachments: Top of mind W1Psychs.doc

Attached is a word document with selected verbatims from the 1st question (brand impressions) for the non-decliner psychs in the Marketplace Tracker Us Wave 1 market research study. I have chosen these verbatims either because they are worth noting as something we should keep our eyes on or because they represent the majority of responders (this is evident when you read the document). I have provided Mark and Tim with the total verbatims and would be happy to share those with anyone interested.

Mark, Tim and I are meeting Thursday to discuss the US "road show" presentation and the key global tracking slides. I plan to present at Denice's staff on March 15th from 10:30-11am and am working with Diana to get on a US Brand Manager's staff meeting. An executive summary will be ready to hand out for the 15th.

Please let me know if you have any questions.



Top of mind W1Psychs.doc

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