

therapeutic intervention should not be taken as an endorsement of medication as a stand-alone treatment.

Nevertheless, we do agree that, in pediatric patients with these serious disorders in particular, the diagnostic challenges are considerable, and further, that medication is best provided as part of a comprehensive treatment program. Consequently, we have already developed language for labeling to address these broad concerns. This language, once finalized, will be included both in Indications and Usage and in the Patient Counseling Information sections of labeling. This new language will be added to the drug products already approved for these disorders in pediatric patients and to any new approvals of pending applications.

We appreciate your letting us know of your concerns regarding this matter.

Sincerely,

A handwritten signature in cursive script that reads "Thomas Laughren".

Thomas Laughren, M.D.
Director, Division of Psychiatry Products
Center for Drug Evaluation and Research
FDA



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Center for Drug Evaluation & Research
10903 New Hampshire Avenue
Silver Spring, MD 20993

October 7, 2009

James K. Childerston, Ph.D.

&

Jack Wiggins, Ph.D.

4545 South 86th Street,
Lincoln, NE 68526

Dear Drs. Childerston and Wiggins,

This is in response to your letters from 6-23-09 to Dr. Janet Woodcock and to me on 9-8-09, regarding the use of atypical antipsychotic medications in the treatment of pediatric bipolar disorder and schizophrenia.

Your letters raise concerns about the proceedings of the June 5-6, 2009 meeting of the Psychopharmacologic Drugs Advisory Committee on pending applications for Zyprexa and Seroquel for the treatment of schizophrenia in pediatric patients, and for Zyprexa, Seroquel, and Geodon for the treatment of mania and mixed episodes in pediatric patients with bipolar 1 disorder. Although a majority of the committee did vote in favor of both the effectiveness and the safety of these treatments, FDA has not taken a final action on any of these pending applications. Consequently, I am precluded by law from discussing any of these applications specifically. Nevertheless, I can comment generally on the issues you raise.

You seem to be primarily concerned that FDA is advocating medication as a stand-alone treatment for these serious psychiatric illnesses in pediatric patients. It is, of course, true that FDA's specific role in terms of therapeutics is to evaluate proposed drug, biologic, and device applications. We have neither the legal authority nor the expertise to evaluate the various diagnostic approaches or the various psychological or family interventions you propose. Nor do we have the authority or expertise to recommend what particular health care practitioners should be involved in the total treatment plan for these very ill patients. It is, however, generally understood among health care practitioners that drug treatment would not occur in isolation. The fact that FDA does not comment on the value or the appropriateness of other aspects of a total