June 23, 2009

Janet Woodcock, M.D., Director
Center for Drug Evaluation and Research
Food and Drug Administration
Department of Health and Human Services

Dear Dr. Woodcock:

On behalf of the Academy of Medical Psychology and the American Board of Medical Psychology, I am writing to oppose your recent decision to support tranquilization as a stand-alone intervention for children without the necessary and proper safety standards (listed below) that are enforced. This is an unscientific approach to the treatment of childhood bipolar disorder and schizophrenia and it assumes a narrow and unitary etiology that is not supported by the scientific literature. This approach implies or directly approves a "medication only" technique and seeks to masquerade it as a "Treatment Plan" or "first line and adequate approach to these illnesses" without adequate scientific justification.

By failing to acknowledge the benefits of behavioral evaluations and interventions, the FDA is in essence supporting a medication only approach, whereby the FDA runs the risk of becoming complicit in the inadequate diagnosis that is rampant in the literature. SAMSHA, NIDA, NIH, and the IG have reported on such studies of America's facilities, including inadequate treatment, and in misinforming and misleading the public. This appears to run counter to the FDA's mission of "protecting" the public and in safeguarding the health and welfare of our citizens.

If you believe that it is important to "control" these children with "maintenance techniques," which in fact may be helpful components in the context of a comprehensive treatment plan, and if you want to present the FDA as "scientific" and align with the available science on these disorders, we would suggest that the following safeguards be required for the use of these medications with vulnerable populations (children, the elderly, and SMI patients):

There should regulation of the use of these medications which calls for (prior to prescription):

1. Accurate diagnosis by specialists (child psychologists or psychiatrists with complete family psychosocial history, diagnostic testing-neuropsychological evaluation where indicated, and family mental health assessment.
2. Specified on-going periodic blood tests, and heart, kidney, and liver examination.
3. Individual behavioral therapy for the child, individual psychotherapy for any parent found to be suffering from a mental disorder, parenting training, and family therapy co-terminus with the use of these dangerous drugs.
4. Mandatory drug holidays and re-assessment after each 12 month period of use.

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5. If obesity occurs (more than 20lb gain on the average), psychological interventions for this disorder must be co-terminus with use of the medications.

The Academy of Medical Psychology is a national organization that was formed to register psychologists who have completed a designated course of training and experience in the area of psychopharmacology and related sciences. The American Board of Medical Psychology awards the Board-certified Diplomate to those who have demonstrated advanced competence in the specialty of medical psychology and psychopharmacology. Many of our members are safely prescribing medication in states that have passed legislation allowing them to do so. We believe that safe prescribing includes the guidelines included above.

We also wish to indicate that utilizing a medication only approach as a "first line treatment", in which these medications have no history in science of creating change or remediation of the underlying condition, is only a "technique", and should not be considered treatment or a treatment plan in and of itself.

We should point out that medication only approaches without significant diagnostic studies in these very difficult to differentiate early life problems which can emanate from many different etiological sources are not the "practice of science", but rather guesswork.

We state further that medication only approaches without psychological and family interventions in these cases is not the practice of science (given what we know in the scientific literature), best practices, or safe interventions. Medication only approaches in this regard are "maintenance and patient control" oriented (powerful tranquilizers) techniques and do not address change and maturation and capitalization on the autoplasticity of the central nervous system well chronicled in the scientific literature.

Finally, we believe that long-term use of "medication only" techniques have well established long-term use potential for damage to the patient (dependable science) and are therefore not appropriate as "an only component of a treatment plan" (dangerous approach and patient safety issue).

Sincerely,

James K. Childerston, Ph.D., ABMP
President – Academy of Medical Psychology
President – American Board of Medical Psychology

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Academy of Medical Psychology

Dr. Thomas Laughren, Director
Division of Psychiatric Products
Food and Drug Administration
Thomas.Laughren@fda.hhs.gov.

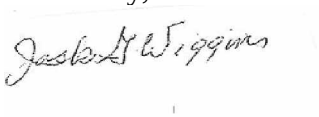
September 8, 2009

Dear Dr. Laughren,

The Academy of Medical Psychology wrote Dr. Woodcock about our concerns stimulated by the approval of Geodon without a majority vote by the Advisory Committee at its June 5 or 6, 2009 meeting. This letter (attached) also outlined our view that failure to support behavioral interventions in conjunction with the approval of these medications placed the FDA in an untenable position of endorsing psychotropic medications as a "stand alone" treatment for mental disorders when published research evidence shows the combination of medications and behavioral treatments produce the best treatment outcomes.

Dr. Woodcock's letter of referral to you was acknowledged by Mark Gonitzke on July 16, 2009. It is now over two months since AMP's original letter was sent by President Childerston. I write to inquire when we can expect a response and comment from you on this letter. Our next Board meeting is September 16, 2009. We would like to consider your reply at that meeting.

Yours truly,



Jack G. Wiggins, Ph.D., Secretary
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c. jane.woodcock@fda.hhs.gov

FDA Risk Communication Advisory Committee letter for November 12 day 13th, 2009

Ms. Lee Zwanziger, Federal Officer
Risk Communications Advisory Committee
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring , MD 20993

Lee.Zwanziger@fda.hhs.gov

November 5, 2009

Dear Ms. Zwanziger,

The Academy of Medical Psychology (AMP) and the American Board of Medical Psychology (ABMP) welcomes this opportunity to share our views on risk communication with your Advisory Committee. We are also pleased to have access to "FDA's Strategic Plan for Risk Communication" (Fall, 2009). We believe the FDA's Strategic Plan provides an excellent scientific foundation for tactical implementation of specific goals for safe and effective treatments using approved medications. We believe that effective tactical policies need to be developed to implement the strategic plan. There is a wealth of scientific literature reporting that were comprehensive treatment plans that include behavioral interventions on a timely basis are more effective and less costly for the recovery process than medications alone. A major purpose of this submission to the FDA Risk Communication Advisory Committee is to illustrate how the concomitant use of behavioral intervention can enhance the safe and effective use of medications in the treatment of health conditions.

The Academy recognizes the inherent difficulties of developing safe effective medications through clinical trials. We also are aware of the risks in attempting to extrapolate the safety of medications deemed safe by clinical trials on one population to another population where the data is lacking are limited. This poses special risks when attempting to judge the safety of medications used for the treatment of children the safety and effectiveness of the medications are based on clinical trials on adult populations.

Dr. Laughren, Director of Psychiatric Product Division of the FDA, responded to AMP's letter to Dr. Woodcock in early October (attached). He indicated that the FDA does not have the authority or expertise to recommend various diagnostic or the various psychological or family interventions that we propose. Director Laughren does acknowledge that it is generally understood among health care providers that drug treatment would not occur in isolation. However, his position illustrates the current clinical practice with most prescriptions for psychotropic medications being written by primary care physicians without collaboration with a mental health specialist. This

indicates a potential public hazard in these cases where mental health specialists are not involved. Dr. Laughren also stated that medication is best provided as part of a comprehensive treatment program. We agree with that position and urge that behavioral interventions be included as part of the comprehensive treatment program as a "best practices" model. If the FDA is silent about the best practices model that includes both psychopharmacology and behavioral intervention in the comprehensive treatment program, this may make the FDA complicit in potential endangerment of the public health.

It is the Academy's view that the FDA has responsibility to provide explicit directions to healthcare providers, patients, as well as families and caregivers about how medications can best be used safely to achieve the most effective treatment outcomes. It is our opinion that the FDA should not depend upon the current expertise of primary care practitioners alone to oversee the outcomes of uses of approved medications for mental conditions that require specialty care. The FDA needs to make a clear statement that primary care providers meet the standard of collaboration that articulates an appropriate comprehensive treatment plan that illustrates "best practices."

Experience has taught that medications deemed safe effective by clinical trials may not yield the expected results in clinical practice. Also, there can be unintended consequences of medications when used in practice. Wording of indications what a medication is to be used for and how it is to be prescribed can be misunderstood or misinterpreted. This is also true of warnings about this and contraindications of medications. Rudd, Cordero and Bryan (2009) investigated possible over reactions to FDA "blackbox" for warnings in the use of antidepressants for children. They report reductions in access to treatment and general practitioners not prescribing antidepressant medications possibly related to "black box" warnings by the FDA.

Public concerns about suicidal ideation and suicidal attempts possibly due to the use of SSRI antidepressant medications resulted in the FDA issued a "black box" warnings on antidepressant medications is an example of the need for better risk communications by the FDA. The replication of psychopharmacological treatment studies show that the combined therapy using medications and behavioral interventions are safe and more effective than either medication alone or psychotherapy alone. Dr. Marc Stone, Senor Reviewer of the FDA, in his reply to AMP about his study on suicidality, wrote that the combined behavioral treatment used in combination with antidepressant medication resulted in a significant reduction in suicidal ideation and attempts. However, the FDA did not collect information about the positive effects of behavioral interventions and its research designs. Therefore, the Academy urges that the directions and indications for use of medications include information about the most effective use of medication and a comprehensive treatment plan. It is essential as such directions and information accurately include behavioral intervention as an integral part of a comprehensive

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treatment plan comprehensive treatment plan.

In another study Cordero, Ruud, Brian and Corso found a 91% error rate in general practitioners understanding of warning label. Thus, explicit information on safety and expected effectiveness of medications for a health condition need to be communicated to practitioners. However, "safety" and "effectiveness" are abstract terms that do not have the same meanings to all practitioners. The abstract Hippocratic admonition, "do no harm" does not assure safe and effective use of medications even though the prescribing patterns are well intended by practitioners.

It has been the experience of practitioners of Medical Psychology that most of the medications employed for mental conditions are prescribed by primary care providers who are not prepared or have time in their practices to offer follow-up specialty care required for mental conditions. This current practice pattern has been referred to in the literature as "usual care" by offering a prescription and then in frequent periodic medication reviews. Prescribing psychotropic medications without adequate diagnostic, follow up and psychological management of impinging personality traits results in a lower of efficacy rate per medications that are suggested by clinical trials and may actually increase the possibility of patient harm.

A comprehensive plan should include information about adverse effects to be monitored during the implementation of the treatment plan. It is frequently noted in the literature that adverse effects found in clinical trials are minimized or under reported in the literature. Correll et al, report a potential case of inadequate information titled "Cardiometabolic Risk of Second Generation Antipsychotic Medications During First-time Use in Children and Adolescents." They reported a rapid weight gain with major long-term health risks to the cardiovascular system. Their recommendation is for more frequent evaluations and monitoring. The Academy's recommendation would also include explicit information regarding the required timely behavioral interventions, as well.

Another of the Academy's concerns is that the FDA has referred to behavioral interventions as "adjunctive" or "supportive" treatments rather than first-line interventions. We urge that the FDA re-evaluate behavioral interventions as first line treatment. We recommend:

1. When the scientific literature supports behavioral interventions to be effective treatments equivalent to or superior to medications that behavioral interventions be considered first-line treatments.

2. If the combined use of medication and behavioral intervention are shown to yield superior outcomes to either medication or behavioral intervention alone that the combined behavioral/mediation treatment be deemed first-line care.

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3. If medications alone are not shown to be equal or superior to behavioral interventions or the combined medication/behavioral care, then treatment by medications alone would be considered "adjunctive" or "supportive" care.

Thank you for the opportunity to present these recommendations outlining areas where the FDA can be of material assistance in improving treatments using medications with concomitant use of behavioral interventions. We welcome your comments to the Academy's recommendations.

Cordially,
Jack G. Wiggins, Ph.D., Secretary
Academy of Medical Psychology and
American Board of Medical Psychology

Attachments or Enclosures:

1.Academy of Medical Psychology letter to Dr. Woodcock June 23, 2009

2. Letter from Dr. Laughren to Academy of Medical Psychology October 7, 2009

3. Dr. Marc Stone's reply to Dr. Wiggins August 2009

References:

Ruud, M.D., Cordero, L., & Bryan, C.J. (2009) What Every Psychologist Should Know About the Food and Drug Administration' Black Box Warning Label for Antidepressants. Professional Psychology: Research and Practice, vol40., No4. PP 321-326

Cordero, L., Ruud, M.D., Bryan, C.J. (2008) Accuracy of General Practitioners' Understanding of the FDA Black Box Warning Label Primary Care and Community Psychiatry, vol.13, 109-114

Correll (2009)Cardiometabolic Risk of Second Generation Antipsychotic Medications During First-time Use in Children and Adolescents, JAMA vol302, 16,
Oct 28,2009

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