



**Suicide Awareness Voices of Education®**

January 23, 2006

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Division of Dockets Management  
Food and Drug Administration  
5630 Fishers Lane, Room 1061 (HFA-305)  
Rockville, MD, 20852

Re: Petition Number 2005P-0402

To Whom It May Concern:

Please accept this letter of support with regard to the Lithium Citizens Petition filed with your office as Petition Number 2005P-0402. I am pleased to offer my professional and SAVE's organizational support of this Petition and recommend the FDA permit amendment of the labeling for all lithium agents as noted in the Petition.

Based in Minneapolis, Minnesota since 1989, SAVE (Suicide Awareness Voices of Education) is a national non-profit agency. Our mission is to prevent suicide through public awareness and education, reduce stigma, and serve as a resource for those touched by suicide. Our agency reaches millions of people across the United States each year through our public awareness/media campaign; thousands are reached through educational and training programs; and we distribute tens of thousands of pieces of literature and resources in schools, churches, community organizations, medical offices, and conferences. Our website also serves as a primary tool for disseminating information with over 30 million hits per year from across the country and world.

As the Petition clearly points out and the data suggests, suicide is a significant issue facing everyone in our country. While it is true the economic costs are staggering, the real costs and suffering from suicide are experienced by parents, siblings, and other family members as well as spouses, friends and co-workers, and the list goes on and on. The impact is profound, lifelong and forever changing in those left behind. As stated by the former U.S. Surgeon General, suicide truly is a "public health crisis."

All major mental illnesses as classified in the DSM-IV-TR or the ICD are agonizing for the individual, their family and the community. Bipolar disorder, frequently misdiagnosed and under-diagnosed, is a particularly difficult disease to live with. Living day to day with frequent mood and behavior changes lends to a life without predictability. Constant struggles to delay the "crash" or slipping into an episode of depression with its suicidal ideation, attempts, and pain are only "balanced" by an elevated euphoria in a manic episode that leads to tragic life consequences resulting from impaired judgment and reasoning. Routine sleep cycles, eating patterns, concentration and attention abilities are just a few

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of the basic expectations most of us live with and count on to make it through each day. For those suffering with bipolar disorder there is never any routine, rhythm, or predictability. Rather, there is inner and exterior chaos that all too often leads to suicide. As the brain suffers with its chemical imbalance the toll it takes on the body is substantial as well.

Psychotherapy and social skills training for bipolar patients are important and to survival, both for the sufferer and their family. However, medication administration and management are vital, critical components to a comprehensive treatment plan for those living with bipolar disorder. A long established and well-known treatment includes the use of lithium drug products. This medication, as stated in the Petition, and known to researchers and clinicians alike, plays a major role in providing a sense of stability and consistency for bipolar sufferers. These salts work. In my professional career I have seen the positive benefits of these medications and endorse their use when appropriate. I also know that in a field where there has been little hope for progress in developing new medical treatments for these major mental illnesses, any form of treatment that can offer a hope is needed. While I do not know anyone who is confident a cure will soon be forthcoming, the hope that a highly used medication such as the lithium salts for bipolar disorder being designated with the labeling as recommended in the Petition offers all of us tremendous hope for the future and will prevent tragic loss of life.

Respectfully submitted,

  
Daniel J. Reidenberg, Psy.D., FAPA  
Executive Director-SAVE  
Fellow-American Psychotherapy Association