



August 23, 2004

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

Dear Sir or Madam,

On behalf of the Suicide Prevention Action Network (SPAN USA), enclosed please find a statement on the use of antidepressants for the treatment of depression among children and adolescents for the upcoming Joint Meeting of the Psychopharmacologic Drugs Advisory Committee and the Pediatric Advisory Committee.

SPAN USA is the nation's only suicide prevention organization dedicated to leveraging grassroots support among suicide survivors (those who have lost a loved one to suicide) and others to advance public policies that help prevent suicide. The organization was created to raise awareness, build political will, and call for action with regard to creating, advancing, implementing and evaluating a national strategy to address suicide in our nation.

Thank you very much for the opportunity to express our opinion on this very important matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Lidia S. Bernik".

Lidia S. Bernik
Program Coordinator

2004N-0330

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Suicide claims the lives of over 4,000 young people each year, making it the third leading cause of death for those between the ages of 10 and 24. More youth between the ages of 15 and 24 die from suicide each year than from cancer, heart disease, birth defects, HIV/AIDS, influenza & pneumonia, stroke and chronic lung disease combined.¹

Of additional concern is the widespread nature of suicidal thoughts and behaviors. In 2003, the CDC's Youth Risk Behavior Surveillance reported that over the span of a year, 16.9 percent of high school students seriously considered attempting suicide while 8.5 percent made an actual suicide attempt.²

The evidence suggests that over 90 percent of children and adolescents who die by suicide have a mental disorder. The most common disorders that predispose to suicide are some form of mood disorder, most typically major depressive disorder.³

Among adults, psychotherapy and pharmacology, most notably antidepressants, are the forms of treatment that have been shown to be effective for treating major depressive disorder.⁴

Unfortunately, limited research has been conducted on the efficacy of antidepressants for treating depression and suicidal behavior among children and adolescents. The studies that have been conducted thus far have three major problems.

1. They have been too short in duration. The majority of the clinical trials conducted have lasted less than 10 weeks. This impedes us from knowing the longer term effects of the medication.⁵
2. They have screened out those at highest risk. For ethical reasons, those deemed to be suicidal at the outset of a clinical trial are generally excluded. This has prevented us from knowing about the effects of this medication on those at highest risk for suicide.⁶
3. Not all have been published. There have been clinical trials conducted whose results have never been released. Given the limited research, it is essential that all available data is made public and is thoroughly analyzed.⁷

The limited evidence available and the shortcomings of the research conducted thus far underscore the need for continued **and improved** research. It would be unwise to make a final decision which will have widespread consequences on partial or incomplete evidence.

Among the public health approaches available in the field of suicide prevention, screening and gatekeeper training have been widely used with young people. Both are based on the principle that suicide among young people is generally preceded by the signs and symptoms of a mental illness or other behavioral or emotional problem which can be treated. If we are to continue screening and identifying young people, it is imperative that we have safe and effective treatments to provide those identified at risk.

It is well established that the majority of young people with a diagnosable mental disorder do not receive mental health services. Given this reality, it is important to recognize that prematurely prohibiting the use of antidepressants for young people

with depression - one of the most widespread treatment methods - could discourage a significant number of people from seeking out help and ultimately do more harm than good.

What is important is that those involved in the treatment of a young person for depression be educated and informed. As a suicide prevention organization comprised mostly of individuals who have lost a loved one to suicide, we have heard innumerable devastating stories. Among them are many of mothers and fathers who sought out treatment for their children but were never educated or informed about the risks associated with their loved one's condition or treatment. In fact, in survivor of suicide support groups, nearly all parent survivors of the suicide of youth report that if they had only known 30 days before the suicide what they knew 30 days after the suicide, the life of the person may have been saved.

The fact is that most young people receiving treatment for depression or another mental illness do not get services from the specialty mental health sector but rather from schools, primary care providers, child welfare services, or juvenile justice.⁸ Psychiatrists prescribing antidepressants to youth with depression may know about the need for increased monitoring and vigilance, particularly during the first few weeks of treatment, but this is **vital knowledge** that must not be limited to those working within the mental health sector.

All those involved with the treatment of children and adolescents with depression should be forewarned about the potential risks and be informed as to what signs and symptoms are indicative of a potentially serious problem. This would include:

- health care providers,
- teachers and school personnel,
- parents and family members, and
- the young person receiving treatment

Patient education is a proactive action that can be taken and documented now. It is the least we can do while the requisite research is pursued and science produces safe and effective treatments.

Suicide has been a leading cause of death among young people for far too long. It is imperative that we not only increase awareness about suicide and educate the general public as to how to recognize the warning signs but that we ensure that we are providing those in need with treatments that have proven to be safe and effective. Any concerns about the efficacy of antidepressants for treating young people with depression must be addressed immediately. SPAN USA represents people who know all too well the terrible tragedy of suicide. We must act now...there are too many lives at risk to wait.

REFERENCES

¹ Office of Statistics and Programming, National Center for Injury Prevention and Control, 2001.

² Youth Risk Behavior Surveillance – United States, 2003, Centers for Disease Control and Prevention, 2004.

³ U.S. Department of Health and Human Services. *Mental Health: A Report of the Surgeon General*. Rockville, MD, 1999, p 150.

⁴ Ibid.

⁵ Gunnell, D. & Ashby, D. (2004). Antidepressants and suicide: what is the balance of benefit and harm? *British Medical Journal*, 329, 34-38.

⁶ Preliminary Report of the Task Force on SSRIs and Suicidal Behavior in Youth, American College of Neuropsychopharmacology, 2004, p. 11.

⁷ Wessely, S. & Kerwin, R. (2004). Suicide risk and the SSRIs. *Journal of the American Medical Association*, 292, 379-381.

⁸ U.S. Department of Health and Human Services. *Mental Health: A Report of the Surgeon General*. Rockville, MD, 1999, p.180.