



1036 06 05 24 01:37

August 19, 2004

Please find enclosed the following:

- The Statement of Kenneth Duckworth, M.D. On Behalf of NAMI (The National Alliance for the Mentally Ill) Before the Food and Drug Administration Psychopharmacologic Drugs Advisory Committee and the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee
- A NAMI Policy Research Institute Task Force Report on Children and Psychotropic Medication (Please circulate to the committee for their review.)
- A Press Release regarding the release of this report

2004N-0330

TS 1

**NAMI | The Nation's Voice on Mental Illness**

Colonial Place Three • 2107 Wilson Blvd., Suite 300 • Arlington, VA 22201-3042  
PH: 703.524.7600 • FX: 703.524.9094 • 1.800.950.NAMI (6264) • [www.nami.org](http://www.nami.org)



## ***Introduction***

Good afternoon. NAMI (the National Alliance for the Mentally Ill) greatly appreciates this opportunity to provide a statement on the critically important issue of the use of selective serotonin reuptake inhibitors (SSRIs) for children and adolescents with depression – specifically focused on concerns related to the potential for suicidal ideation and suicide attempts.

NAMI was founded as a grassroots family advocacy movement 25 years ago in Madison, Wisconsin. Today, NAMI has more than 220,000 consumer and family members nationwide dedicated to improving the lives of children and adults living with mental illnesses.

My name is Ken Duckworth and I am the Medical Director for NAMI. I am board certified in child and adolescent, adult and forensic psychiatry. I am also an Assistant Professor of Psychiatry at Harvard Medical School. I have held many clinical positions and from 2000 to 2003 served as the state medical director and Acting Commissioner for the Massachusetts Department of Mental Health. I maintain an active clinical practice in Massachusetts, in which I treat children, adolescents and adults with major depression and other psychiatric disorders.

## ***The Public Health Crisis in Children's Mental Health***

We support the FDA's investigation on the vitally important question of the safety and effectiveness of SSRIs to treat major depression in children and adolescents. However, it is essential that it be framed within a broader context.

We have seen report after report document the public health crisis in this country for children and adolescents living with mental disorders and their families. These reports include President Bush's New Freedom Commission Report on Mental Health issued in 2003 and former Surgeon General David Satcher's comprehensive report on mental health issued in 1999, followed by a report on children's mental health in 2000.

One in ten children today have a serious mental illness – however an alarming 80% are never identified or receive any treatment. (Surgeon General 1999, President Bush's New Freedom Commission Report 2003).

There are enormous barriers that prevent young people from being treated: stigma, a crisis in the shortage of children's mental health providers, discriminatory caps on mental health coverage, family "unfriendly" systems that are fragmented and lack accountability, a flawed health care delivery system that forces medical professionals to rush through visits with children and families, and overall, as the President's New Freedom Commission has noted, a mental health system in "shambles." As NAMI families and many other families across the country know, the consequences for this broken system are dire.

Suicide is the 3<sup>rd</sup> leading cause of death among youth aged 15-24 and 90% of those who commit suicide have a diagnosable and treatable mental disorder (CDC 1999, Surgeon General 1999). Sadly, far too many of those lost to suicide were never identified or receiving any mental health treatment.

The FDA's assessment of the risks of suicidal ideation and suicide attempts must occur in the context of both the broader systemic and statistical health crises.

Clearly, there is a great urgency in the need for federal, state and local leaders to help end these crises. NAMI will continue our work in providing recommendations on the essential reforms that should immediately be undertaken.

### ***NAMI Calls for Increased Research***

As an organization representing children and adults living with mental illnesses and their families, NAMI calls on this committee to help families across the country truly understand what the research and science tell us about the safety and effectiveness of SSRIs for treating children and adolescents with major depression. This issue has exploded in the nation's headlines, but not necessarily with the kind of precision that medical issues require.

The recently released TADS (Treatment for Adolescents with Depression Study) study, helps us to **begin** to understand the positive treatment outcomes that have been shown from treating youth with major depression with SSRI medication. "*Begin*" is the operative word here. This and other studies have raised questions that must be answered. They can only be answered through *more* research and *continuing* research.

- NAMI calls on the National Institute of Mental Health (NIMH) to make research on early onset mental illnesses – including major depression -- and the use of psychotropic medications for children a priority and to increase funding, accordingly. With so many children being prescribed psychotropic medications, we need more research and science to help guide the safe and effective use of these medications – including SSRIs.
- NIMH should develop a complete portfolio of basic, clinical, and intervention services research on children's mental disorders – with families involved in the design, implementation and outcome measures of the research. Families and treating providers need more data on the long-term effects and safety of psychotropic medication use in children.
- All of the data concerning the impact of SSRIs in children and adolescents must be made available to the public and independent researchers. It is critical so that families everywhere can make decisions about treatment options based on full knowledge of the risks and benefits. NAMI calls for public access to the complete results of all clinical and controlled trials regardless of the trial sponsor and outcome.

Anecdotal information is not enough when it comes to analyzing the safety and effectiveness of treatment options and should not drive policy and regulatory decisions.

One thing that we know for sure – for children and adolescents with mental illnesses, the greatest risk may be to do nothing at all. Mental illnesses are profound and life-threatening illnesses. Youth with untreated major depression commit suicide. That is the reality before we even begin to talk about treatment and medications. For some children, the use of psychotropic medications, including SSRIs, is effective and has dramatically improved the quality of their lives.

Like the outcomes found in the recently released TADs study, I have found in my own clinical practice that SSRIs are effective for some youth suffering from major depression. However, one size does not fit all when it comes to treating mental illnesses and sound clinical practice dictates that we provide individualized treatment.

### ***NAMI Calls for Evidence-Based Interventions***

Children and adolescents who are receiving treatment for major depression, especially those prescribed medications, should be closely assessed and carefully monitored as part of sound clinical practice. This includes an assessment and close monitoring for suicide risk and other adverse events regardless of the type of treatment that a child is receiving, however this is especially true when a child is prescribed medication.

The mental health treatment and service system must adopt evidence-based assessment and intervention approaches that call for clinicians to continually improve care by using the most current evidence and research to make decisions about the most appropriate care for a young person with a mental illness. Medical professionals should use this evidence-based intervention approach, in close consultation with families, especially when determining whether psychotropic medications, like SSRIs, are safe and appropriate to treat a child's illness.

Ultimately, the treating provider and the family must weigh the risks and benefits associated with providing treatment and determine the most appropriate treatment course for a child. This may need to include hospitalizations during periods of stabilization or transition or upon initiating the use of SSRIs. It also may include keeping in mind that an initial diagnosis of major depression treated with an SSRI may reveal or heighten adverse event risks if the underlying mood disorder that the child has is bipolar disorder, which may then require another appropriate treatment intervention.

Treatment protocols for the bipolar risk need to be established, publicized and implemented when a young person is prescribed an SSRI, as part of evidence-based treatment. Psychiatrists are well aware of the medications' potential risk of "activating" a child or adolescent who has a previously unknown vulnerability for bipolar disorder. This risk is greater for people who have bipolar illness in their family histories. There are strategies to mitigate this risk, but first the risk must be considered by all of those prescribing medication and translated to families. It should also be weighed against the risk of alternative interventions.

There is no conspiracy here. Only the limitations of a system that is far from perfect, addressing risks in a world in which there are few certain outcomes.

Children and adolescents with mental illnesses should only be diagnosed and treated by the best qualified mental health professionals and properly trained medical professionals. NAMI supports efforts to protect children from inaccurate diagnoses by ensuring that primary care and mental health providers are better informed and educated on the proper diagnosis and the most safe and effective treatment for all early onset mental disorders.

In the end, the debate on children and the use of SSRIs and other psychotropic medications must also address the critical need to ensure that all children and adolescents with mental disorders

have access to safe and effective treatment – with quality clinical care as an integral part of all aspects of the service delivery system.

### ***Inform Families and Child-Serving Professionals About Major Depression and Other Mental Disorders***

Families and child-serving professionals should receive appropriate information and education on the latest research related to the use of SSRIs and other psychotropic medications for children. They should also receive information on the availability of evidence-based and science-based treatment and services. Most parents and caregivers want to work closely with their child's treating provider and want to be part of the treatment team that weighs and considers the risks and benefits associated with treatment – whether it is psycho-social or medication interventions.

### ***Conclusion***

In summary, I would like to thank the committee for allowing NAMI to share our views on these critically important issues. In June of this year, the NAMI Policy Research Institute (NPRI) released a report on Children and Psychotropic Medications. NAMI has provided copies of that report to this committee and would ask that you please review the report as part of your deliberations.

The families that we represent from across the country call for increased research and the disclosure of all clinical data to help us understand the long- and short-term safety and efficacy of SSRIs to treat children and adolescents with depression.

Let us not lose sight of the broader systemic issues that often contribute to crises in children's mental health. Many families do not have access to mental health providers for their child.

At a very minimum:

- FDA policy should be based on a realistic appreciation of the role of ongoing scientific research, the transparency of research data, and a weighing of risks and benefits as part of sound clinical practice.
- Recognition of the broader systemic and statistical public health crises we face as a nation in the identification and treatment of children and adolescents for both major depression and the risk of suicide.
- Clear recognition of the relationship between SSRI treatment for major depression and underlying bipolar risks and the need for careful, well-publicized, monitoring protocols.

NAMI appreciates the careful deliberations that this committee is undertaking to assess this critical issue and this opportunity to provide a statement on an issue of great importance to families with children living with major depression and other mental illnesses.

For further information about NAMI's position on this issue or to learn more about NAMI, please contact NAMI – The Nation's Voice On Mental Illness – at 703-524-7600 and ask for either Kenneth Duckworth, M.D. or Darcy E. Gruttadaro, J.D., Director of the NAMI Child & Adolescent Action Center or visit the NAMI web site at [www.nami.org](http://www.nami.org).