



Testimony of James McNulty
President, National Alliance for the Mentally Ill (NAMI)

Before the FDA's Psychopharmacologic Drugs Advisory
Committee

Concerning supplemental new drug application S-047
"Clozaril proposed for the treatment of suicidality in patients
with schizophrenia and schizoaffective disorder"

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Madam/Mr. Chairperson and distinguished members of the panel. My name is Jim McNulty and I am President of NAMI (the National Alliance for the Mentally Ill). With more than 220,000 members and 1,200 state and local affiliates, NAMI is the nation's largest grassroots organization dedicated to improving the lives of people with severe mental illnesses. I very much appreciate this opportunity to testify before you today.

Schizophrenia is a brain disorder that affects approximately two million Americans. Schizophrenia is one of the most devastating and debilitating of all severe mental illnesses. The positive or "psychotic" symptoms of schizophrenia, including delusions and hallucinations, are excruciatingly painful and debilitating for those who experience them. Numerous studies have revealed that the majority of individuals with schizophrenia do not have access to even minimally adequate treatment. The consequences of lack of treatment or inadequate treatment for schizophrenia can be devastating – homelessness, arrests, incarceration, or suicides.

The 1999 report of the U.S. Surgeon General revealed that mortality rates among persons with schizophrenia are significantly higher than that of the general population. The single largest contributor to this excess death rate is suicide. Studies reveal that 10 to 15 percent of all people with schizophrenia commit suicide. Many others attempt suicide or regularly experience suicidal thoughts. The human toll for individuals who suffer from schizophrenia and their families is incalculable.

The tragedy of suicide is compounded even further because schizophrenia today is very treatable. New anti-psychotic medications, coupled with psychosocial rehabilitation services and supports, make recovery very possible for most people who suffer from this brain disorder. Indeed, I know many individuals with schizophrenia who have recovered from the depths of despair and today are living independently, productively and with dignity in their communities.

Research has played a key role in facilitating the miracle of recovery for these individuals. Now, research is yielding even more promising information. The International Suicide Prevention Trial is a landmark study that confirms that Clozaril, an atypical anti-psychotic medication first approved in 1990, can significantly reduce the risk of suicidal behavior or suicide attempts among individuals suffering from schizophrenia or schizo-affective disorder.

For NAMI, news about any medication that reduces the risk of suicide or other tragic consequences of schizophrenia or schizo-affective disorder is welcomed. The costs of inadequate treatment of schizophrenia and other brain disorders are immense. The benefits of developing new treatments for these brain disorders are immeasurable. These benefits accrue not only to consumers, but to their families and to society as a whole.

The International Suicide Prevention Trial vividly illustrates the benefits of continuing research on medications after they are approved and on the market. Ongoing research is our best hope for unraveling the mysteries of brain disorders such as schizophrenia and restoring dignity and hope to those individuals who suffer from them. It is equally important to translate the promises of research into practice through rapid approval of medications shown through research to be effective. NAMI is very grateful

to the FDA for its efforts over the years to expedite the entry of new medications for the treatment of severe mental illnesses into the marketplace, after careful study of the safety and effectiveness of these medications.

Finally, I would like to take this opportunity to make one quick editorial comment. Budget deficits in most states and at the federal level threaten the continuing availability and accessibility of the most promising medications for the treatment of schizophrenia and other severe mental illnesses in the marketplace. While we appreciate the importance of balancing budgets, cost containment strategies that threaten access to potentially life-saving medications for severe mental illnesses do more harm than good in the long run. The hope generated by important studies such as the International Suicide Prevention Trial will only be realized if we successfully forestall these misguided cost containment efforts.

Thank you for affording me this opportunity to testify. I look forward to your questions and comments.

Draft Disclosure Statement

My name is James McNulty and I am president of NAMI (the National Alliance for the Mentally Ill). I do not have any personal or professional affiliation or consulting relationships with the pharmaceutical industry that result in financial gain for me. I do not own stock in Eli Lilly & Company or Novartis.

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