



ACNP

American College of Neuropsychopharmacology

Contact: Betsy Murrett 202-745-5107
Sharon Reis 202-745-5103

New Report Concludes SSRI Antidepressants Do Not Increase Suicidal Behavior in Youth with Depression

ACNP Presents Findings As FDA Opens Hearings

Washington, DC, January 21, 2004—SSRI* antidepressants do not increase the risk of suicidal thinking or suicide attempts in youth, according to a new report released today by the American College of Neuropsychopharmacology (ACNP). The report also noted that several SSRIs have been shown to be effective for treating depression in this population. ACNP appointed a special task force of the nation's leading scientists in the field to review the available research on the use of antidepressants and youth under 18 years of age.

“The evidence linking SSRIs to suicide is weak,” said J. John Mann, M.D., Co-Chair of the ACNP Task Force and Professor of Psychiatry at Columbia University College of Physicians and Surgeons, and Chief, Department of Neuroscience, New York State Psychiatric Institute. “There are strong lines of evidence in youth—from clinical trials, epidemiology and autopsy studies—that led the ACNP Task Force to conclude that SSRIs do not cause suicide in youth with depression.”

ACNP established the Task Force after regulatory agencies in the United States and United Kingdom voiced concerns in 2003 about the possibility that treatment of depression in children and adolescents with SSRIs may increase the risk for suicide. The FDA is convening an advisory committee hearing to review the issue on Feb. 2, 2004.

“The most likely explanation for the episodes of attempted suicide while taking SSRIs is the underlying depression, not the SSRIs,” said Graham Emslie, M.D., Co-Chair of the ACNP Task Force and Chief, Division of Child and Adolescent Psychiatry and Professor of Psychiatry, The University of Texas Southwestern Medical Center at Dallas. “The potential benefits of SSRIs outweigh the risks.”

The ACNP Task Force reviewed clinical trials of more than 2,000 youth and found that there were no statistically significant increases in suicide attempts, self-harm, and suicidal thinking related to SSRI use. Importantly, they found that there were no suicide deaths in any of the trials.

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**SSRIs or Selective Serotonin Reuptake Inhibitors are a widely used category of antidepressants, which includes such drugs as fluoxetine (Prozac®) and paroxetine (Paxil®).*

The ACNP Task Force concluded that if anything, the increased use of SSRIs appears to have lowered the risk of suicide worldwide based on a review of epidemiology studies from several countries. The group noted that the rate of youth suicide in 15 countries has declined by an average of 33 percent over the past 15 years. This period of time coincides with increases in prescribing rates for SSRIs.

The ACNP Task Force also cited an autopsy study, which suggests that suicide is more likely when depressed individuals do not take their medication, rather than when they take it. A study of adolescent suicides found that of the 24 percent who had been prescribed antidepressants, none tested positive for SSRIs at the time of their death.

The Task Force found several SSRI trials that showed efficacy in treating depression in youth, while other trials failed to demonstrate efficacy. They noted that differences in drug effectiveness across clinical trials may be from differences in methodology and recommended additional study.

The report concluded that another category of antidepressants known as tricyclics were ineffective in patients under 18 years of age. Other forms of treatment were found to be not widely available to youth, or insufficient data were available to support their effectiveness.

Childhood depression is a serious public health problem that carries the risk of suicide. ACNP urged clinicians to ask depressed patients about suicide, suicidal thinking, and plans for suicide.

The report also includes research and regulatory recommendations. ACNP urged that all data held by FDA or pharmaceutical companies should be made rapidly available to allow ACNP and other research organizations to conduct an independent evaluation of the risks and benefits of SSRIs in youth and adults with depression and other mood disorders.

Evidence reviewed includes all published clinical trial data in youth. The Task Force also obtained and reviewed unpublished data from several drug companies and data reported to the United Kingdom's drug regulatory agency.

“The Task Force emphasizes that its findings and recommendations are preliminary,” said Mann. “While ACNP reviewed all published data and some unpublished data, it does not have access to a substantial amount of data available to the FDA or to pharmaceutical companies.”

The full version of the ACNP Task Force report will be released in the spring or early summer of 2004. For a copy of the executive summary of preliminary findings, visit www.acnp.org or call Betsy Murrett at 202-745-5107.

Members of the Task Force include: **Graham Emslie, M.D.**, Co-Chair of the ACNP Task Force and Chief, Division of Child and Adolescent Psychiatry and Professor of Psychiatry, The University of Texas Southwestern Medical Center at Dallas; **J. John Mann, M.D.**, Co-Chair of the ACNP Task Force and Professor of Psychiatry at Columbia University College of Physicians and Surgeons, and Chief, Department of Neuroscience, New York State Psychiatric Institute; **William Beardslee, M.D.**, Psychiatrist-in-Chief and Chair, Children's Hospital Department of Psychiatry, Professor of Child Psychiatry, Harvard Medical School; **Jan Fawcett, M.D.**, Professor of Psychiatry, University of New Mexico, ACNP member; **Andrew Leon, Ph.D.**, Professor of Biostatistics in Psychiatry and Professor of Public Health Weill Medical College of Cornell University; **Herbert Meltzer, M.D.**, Professor of Psychiatry & Pharmacology, Director Division of Psychopharmacology, President, Collegium Internationale Neuropsychopharmacologicum, Vanderbilt University Medical Center, ACNP member; **Fredrick Goodwin, M.D.**, Research Professor of Psychiatry and Director, Psychopharmacology Research Center, George Washington University, ACNP member; **David Shaffer, M.D.**, Professor of Child Psychiatry, and Professor of Psychiatry and Pediatrics, Columbia University College of Physicians and Surgeons, Director, Division of Child Psychiatry, New York State Psychiatric Institute; **Karen Wagner M.D., Ph.D.**, Director, Division of Child and Adolescent Psychiatry, Professor and Vice Chair, Department of Psychiatry and Behavioral Sciences, University of Texas Medical Branch, Galveston, ACNP member; and **Neal Ryan, M.D.**, Professor of Psychiatry, Western Psychiatric Institute & Clinic, University of Pittsburgh, ACNP member.

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ACNP, founded in 1961, is a professional organization of more than 700 leading scientists, including four Nobel Laureates. The mission of ACNP is to further research and education in neuropsychopharmacology and related fields in the following ways: promoting the interaction of a broad range of scientific disciplines of brain and behavior in order to advance the understanding of prevention and treatment of disease of the nervous system including psychiatric, neurological, behavioral and addictive disorders; encouraging scientists to enter research careers in fields related to these disorders and their treatment; and ensuring the dissemination of relevant scientific advances.

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