

# WALL STREET JOURNAL

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## MEDICINE

### Scientists Fail to Persuade FDA on Prozac

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INDIANAPOLIS—The Food and Drug Administration weighed in heavily on the side of Eli Lilly & Co. in rejecting claims that the popular anti-depressant drug Prozac is connected to murder, suicide or other maladies.

The FDA action follows a yearlong campaign against Prozac by the Church of Scientology that had sought to persuade the federal agency, through a formal petition, to ban U.S. sales of the Lilly drug.

But the FDA found that a Scientology-founded group called the Citizens Commission for Human Rights hadn't demonstrated links between the drug, known chemically as fluoxetine hydrochloride, and suicidal thinking.

"The data and information available at this time do not indicate that Prozac causes suicidality or violent behavior," said the federal agency in rejecting a call from the Scientologists to ban the sale of the drug.

Prozac, the world's top-selling anti-depressant, has been prescribed for more than four million people and is expected to reach more than \$1 billion in sales this year. If so, Prozac would become Lilly's top-selling product. So the stakes were high when the Scientologists—longtime opponents of psychiatry and psychiatric drugs—set their sights on Prozac.

Lilly hailed the FDA action against what it termed the Scientologists' campaign of "dangerous deception" that is "a menace to the public health as it attempts to frighten patients away."

Prozac doesn't work for about one-third of the patients who take it. But for those who are aided, Prozac has fewer side effects than other drugs previously on the market and often has greatly improved patients' mental states.

Sanford Block, head of the church's Citizens Commission, said he expects to provide further information to the FDA allegedly linking Prozac and suicide. Mr. Block, who calls Prozac a "killer drug," noted the agency will hold hearings on the safety of anti-depressants in general.

In addition to concluding Prozac isn't linked to suicide, the FDA found no demonstrable connection between Prozac and movement disorders known as tardive dyskinesia and tardive dyskinesia.

"FDA's review revealed no basis for concluding that Prozac caused these adverse clinical events" brought to its attention by either Lilly or the Citizens Commission, the agency reported. The agency focused, for example, on material in a peti-

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### FDA Rejects Claims By Scientology Group About Prozac Drug

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tion from the Scientology group purportedly tying suicide and attempted suicide cases to Prozac.

In doing so, the agency concluded that "these data provide no way of distinguishing the role of the patients' underlying medical condition and the role of the drug in causing these suicidal events."

The FDA report announcing its rejection of the church's petition noted that "depression itself is highly associated with suicide" and concluded that clinical data from Lilly tend to disprove the assertions made by the Scientology group.

The FDA also found that "assertions that Prozac leads depressed patients to obsess more about suicide than depressed patients not on the drug cannot be substantiated."

Some medical reports on small numbers of depressed patients have shown an increased tendency toward suicidal thinking after taking Prozac, though these findings deal mostly with patients already inclined toward such thoughts or with serious obsessive-compulsive disorders. Moreover, Harvard professor Martin Teicher, who authored one of those reports, said the Scientology group seriously distorted the findings of his study, which focused on only six patients.

Prozac, unlike some other anti-depressants on the market, doesn't cause drowsiness or a "drugged" feeling. It energizes patients and makes others jittery, factors that some physicians theorize could pose problems in a small number of patients.

Lawsuits have been filed in several states by patients who contend their suicide attempts were caused by the drug. In addition, defendants in some murder cases have argued—thus far unsuccessfully—that Prozac made them commit their crimes.

Scientology, which treats its members through therapy that has been denounced as quackery by psychiatrists and doctors, has attacked other drugs and seeks also to condemn all anti-depressants. Prozac became the latest target of the group after becoming a popular remedy for a large population of clinically depressed people.

The National Mental Health Association described the Lilly drug as "an extremely useful drug therapy in the treatment of depression" and added it "applauds the FDA's decision to reject the Citizens Commission's baseless petition."

And the American Psychiatric Association said the FDA had "chosen science over sensationalism" and said "it is depression, the illness, which kills by causing suicide in as many as one in six patients."