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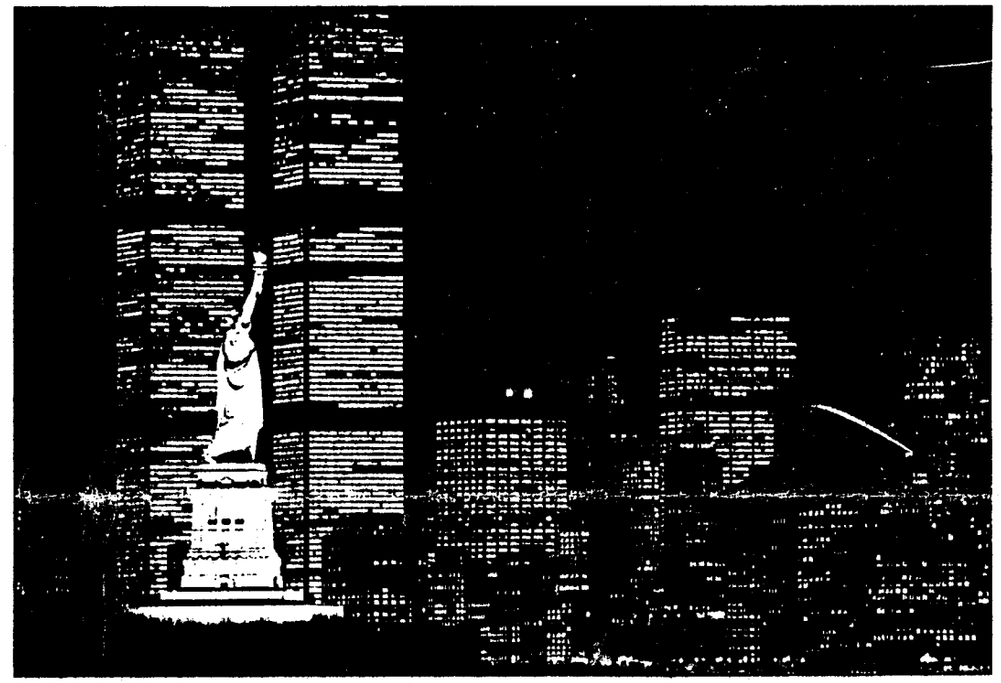
FDA Denies CCHR's Petition to Withdraw Prozac from the Market

by Rojean Wagner

The Food and Drug Administration has denied Scientology's Citizens Commission on Human Rights' (CCHR) petition to withdraw fluoxetine (Prozac) from the market, indicating in its report that CCHR's evidence was primarily based on five "unsubstantiated cases that cannot be adequately evaluated." The agency said that its Psychopharmacological Drugs Advisory Committee will review all pertinent data linking suicide and antidepressants in a late summer or early fall meeting. Although most of the media coverage has been about fluoxetine, the committee will look at all antidepressants available in the United States, an FDA spokesperson said.

Eli Lilly and Co. of Indianapolis blames CCHR "and a handful of product liability attorneys" for the high-profile negative media campaign that has focused on fluoxetine the past year, according to Edward A. West, the company's director of corporate communications. He said Lilly is looking forward to the FDA meeting in which scientific data concerning the relationship between suicide and antidepressant medication will be presented. "It's time to take the discussion of antidepressant therapy out of the celebrity talk show circuit and put it back into the hands of psychiatrists and others who treat depressed individuals," he said.

(Please turn to page 34)



City lights are beckoning a record number of psychiatrists to the 4th Annual U.S. Psychiatric Congress in New York City where they will master the latest clinical developments at more than 90 educational sessions. Please see page 51 for the final program agenda.

Petition Denied

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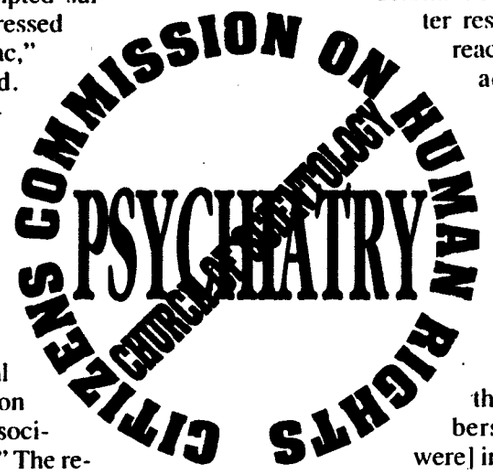
CCHR is also looking forward to the hearings, executive director Sanford Block told *The Psychiatric Times*. "One reason Prozac was so interesting to us was that it was touted so broadly." Block said the basis for CCHR's October 1990 petition to have fluoxetine withdrawn is that the drug's label does not warn that it may cause some people to become violent. "We have records of 120,000 deaths from Prozac, mostly from newspaper reports and family members calling; then we follow up and document them," he said. "Thirty-three of those people were murdered by people on Prozac."

FDA on Petition Denial

In its "Talk Paper" on the petition denial, the FDA said: "...the drug's labeling already notes that these [violent] behaviors have been reported among a small number of patients, and that signs of 'hostility' were observed in 1 in 100 to 1 in 1,000 Prozac patients in clinical trials. CCHR claims that Prozac is linked to far more violent behavior such as murder, however, and bases this on a handful of cases in which patients taking Prozac were involved in homicides. The data and information available at this time do not indicate that Prozac causes suicidality or violent behavior," the FDA concluded.

The agency said that controlled clinical trials "that allowed a direct comparison of the incidence of emergent suicidal thoughts and actions among individuals on Prozac, placebo, or other antidepressants failed to find any greater risk among those on Prozac." CCHR also did not substantiate its claims that fluoxetine leads patients to obsess more about suicide, the FDA said.

"CCHR based many of its claims that Prozac caused increased suicidality in depressed patients on increased frequency of adverse reaction reports of suicide and attempted suicide among depressed patients on Prozac," the report said. "These data, however, provide no way of distinguishing the role of the patients' underlying medical condition and the role of the drug in causing these suicidal events. Depression itself is highly associated with suicide." The report later indicates that CCHR provided only four anecdotal reports as evidence that fluoxetine induces suicidal behavior among nondepressed patients. Controlled studies using thousands of nondepressed patients, however, "showed no statistically significant increase in suicidal behavior or thinking among those on the drug compared to those taking placebo," the report said. In May, *The Psychiatric Times* reported that it had obtained copy of a letter from the CCHR to "Prozac Survivors" sent in December 1990 encouraging them to fill out and send in the attached FDA adverse reaction form, which may account for some increase in 1991 reports.



The FDA also denied that there is evidence that Prozac is addictive and refuted CCHR's claims that Prozac often causes tardive dystonia or tardive dyskinesia. The agency said fluoxetine's label "mentions that there have been rare instances where movement disorders have been reported." After researching adverse reaction reports citing addiction-related problems associated with fluoxetine, the FDA found 186 out of an estimated 16 million prescriptions. A representative sampling of these showed that "many [members of this group were] involved in the use of other drugs, misdiagnoses, or past histories of drug or alcohol abuse," the FDA reported.

Response to FDA Decision

Both the American Psychiatric Association and the National Mental Health Association (NMHA) issued statements applauding the FDA's decision and the message it sent about CCHR's anti-fluoxetine campaign. "The Food and Drug Administration has chosen science over sensationalism by rejecting the petition," according to Joseph English, M.D., APA president-elect and a member of *The Psychiatric Times'* editorial board. Preston Garrison, NMHA's executive director, also praised the FDA, claiming that the decision supports the organization's efforts to reduce the stigma associated with mental illness. "The FDA has today strengthened that message in rejecting a petition by a group that has demonstrated through its own brand of scare tactics a callous disregard for the mental health of this country," he said.

But CCHR was also enthusiastic about the FDA's decision. "We were encouraged that the FDA finally did something," Block said. "We've been nudging them for about a year." CCHR's interpretation of the FDA decision is that "they are open to receiving more data and they gave us some guidelines. We have a few cards up our sleeve," he said. One of the cards Block was willing to share was that CCHR planned to respond to the FDA letter—but not to the FDA, which he said is incapable of objectivity in the matter. "Our reply will be sent to [Louis W. Sullivan, M.D., Secretary of Health and Human Services]," Block said. "We believe the FDA is in a bind because they approved the drug and we know that drug companies put a lot of pressure on them, so we don't believe they are capable of being objective. Their job is to protect the health of Americans not the profits and reputation of the drug companies."

Lilly's spokesman said that the FDA's rejection of the petition because of insufficient data made it clear that "Scientology is based on deception and the entire campaign against Prozac reflects that same base—no facts, no science, just pure deception." ■