THE CONFLICTS OF INTEREST INCREASE

CCHR: EXPOSING THE DANGERS OF ANTIDEPRESSANTS AND OTHER PSYCHOTROPIC DRUGS—DESPITE FDA/PSYCHIATRIC-PHARMACEUTICAL COVER-UPS

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January 10: Illinois Chief Judge William A. Lewis wrote of having sentenced a Larry Walters to probation for the second degree murder of his father saying that the father was on Prozac which possibly caused him to go on an extremely violent rampage resulting in his son killing him in self defense.

January 31: Dr. Thomas Kurt of the FDA’s Southwest Region alerted the FDA headquarters in a memo about “Ten Deaths While on Prozac (fluoxetine) in Dallas County in One Year.”46

February 7: Three medical doctors reported in The New England Journal of Medicine patients “in whom suicidal ideation and fluoxetine [Prozac] treatment were strongly associated.” A 58-year-old man “was started on fluoxetine (20 mg/day). Three days later he had violent suicidal thoughts and tried to hang himself with a rope. The fluoxetine was discontinued, with a complete disappearance of suicidal ideation four days later.”47

March 29: Dr. Thomas Laughren, head of the Psychiatric Drug Products Division of the FDA wrote a memo clarifying the question of suicidality in association with Prozac and acknowledged that the issue was raised by CCHR in its Citizens Petition where there were occurrences of depression/suicidal ideation in non-depressed individuals being treated with the drug. He recommended that the product information sheet for Prozac include a statement about suicidal thoughts.48

March: Robert A. King, M.D., and others of Yale University School of Medicine published a study in the Journal of the American Academy of Child and Adolescent Psychiatry regarding the emergence of intense self-injurious behavior found in six adolescents aged 10 to 17 years old taking Prozac.49
April 1: Leigh Thompson defended reports that Prozac caused violence, blaming the reaction instead on mental illness.50 With Prozac sales reaching $1 billion, the drug was protected, despite the risks to individual and public safety.51 [See September 14, 1990 entry]

April 15: Memo to Leigh Thompson about upcoming TV appearance on 20/20, headed “MESSAGE GOALS—Whatever questions you are asked or direction the interview [sic] take, the three points that we want to establish are: (2) ‘It’s in the disease, not the drug.’...‘If pressed, or as a postscript to the above, then make the point that absolutely no evidence indicates that PROZAC as a cause of such behavior [suicide and violence]....”52

May: Alan Gelberg, Acting Chief of the Surveillance & Data Processing Branch of the FDA, stated: “Since marketed in 1988, by Eli Lilly, Prozac (fluoxetine) has had the highest number of adverse event reports submitted to the FDA National Adverse Drug Reaction Reporting (ADR) System database. The database dates back to 1969. In 1990, Prozac had the largest number of reports.” [By September 15, 1993, the FDA ADR Database had logged over 28,600 adverse reaction reports on Prozac.]53

May: Dr. William Wirshing, a UCLA psychiatrist, reported to the annual meeting of the American Psychiatric Association (APA) that five patients appeared to have developed akathisia from Prozac. Dr. Wirshing believed the akathisia had “led them all to contemplate suicide.”54

May 9: The national ABC TV show Prime Time ran a story on Prozac, titled, “What made them do it?” in which Leigh Thompson denied that the drug could cause suicide or violence.
June 3: CCHR wrote to FDA Commissioner Dr. David Kessler about Prozac having more ADRs than any other drug. Since December 1989, more than 3,000 people had reported to CCHR alone adverse reactions associated with Prozac, including suicidal thoughts and behaviors, hostility, violence, self-mutilation, agitation, and psychosis. CCHR had also recorded that persons taking the drug had murdered more than 34 people. [See June 2, 1993 entry re: Kessler’s admission that only 1% of adverse reactions were reported to the FDA.]

June 18: Eli Lilly’s Leigh Thompson told The Indianapolis News that there were “scientific” ways to determine if a patient was likely to kill him or herself and that the company was working with NIMH and the FDA on developing a suicide assessment scale.55 [See September 25, 1990 entry.] However, all suicide assessments are based on subjective, not scientific-based questions.

July 26: The FDA denied CCHR’s Citizens Petition, claiming that Prozac was safe and effective and “we do not believe there is evidence that Prozac causes suicidality or other violent thinking or behavior.”56 However, it agreed to “convene a meeting of its Psychopharmacological Drugs Advisory Committee [PDAC] to consider the issue of suicidality associated with antidepressant drugs, including Prozac.”

August 7: CCHR wrote to Dr. Louis W. Sullivan, Secretary of the Department of Health and Human Services requesting an investigation into why the FDA had dismissed the ADRs on Prozac and why its “Talk Paper” was released to Eli Lilly and other psychiatric trade organizations in advance of its public release to prepare a response, while the same opportunity was not given CCHR.57
August 8: FDA “Minutes of Meeting re: Prozac” written by Paul A. David, R.Ph., Consumer Safety Officer. Meeting was sponsored by Eli Lilly and attended by FDA officials Dr. Paul Leber, Dr. Thomas Laughren, Dr. C. Arnello and Paul David to discuss the upcoming PDAC hearing on

September 20. Dr. Leber said the hearing was to provide “full public scrutiny” and Commission discussion about the allegations of violence and suicide linked to antidepressants. Leber wanted it stressed that because of the high number of all adverse reactions reported on Prozac (15,000), that there should be a presentation on the limitations of Spontaneous Reporting System (SRS) to the FDA. Dr. C. Anello disagreed.

The memo stated, “In view of the importance attached by critics of Prozac to the volume of reports received, Dr. Leber urged Dr. Arnello to reconsider, but agreement on this issue was not reached.” The SRS’s Department of Epidemiology and Surveillance (DES) was urged to review all reports of completed suicide but it was decided in advance of the PDAC hearing that, “the review would most likely lead to a conclusion that the information was inadequate to support such an assessment, but substantiation of this point would be useful.”

August 23: CCHR filed a complaint with FDA Commissioner Dr. David A. Kessler about the FDA planning to only hold a one-hour hearing to review the concerns about 12 CCHR: Exposing the Dangers of Antidepressants and Other Psychotropic Drugs Prozac and requested the PDAC hearing be extended to a full day. [Subsequently extended to one day]
September 10: CCHR wrote Dr. Kessler about the conflicts of interest in the upcoming PDAC hearing detailing the financial links between its psychiatric members and drug manufacturers, including Eli Lilly, Sandoz, SmithKline Beecham, Merck, Bristol Meyers Squibb and Pfizer. Nine out of 10 panel members had financial conflicts regarding antidepressants, with 8 being psychiatrists, those most likely to make a living by prescribing antidepressants.

This included Dr. David Dunner who had financial interests totaling a half million dollars. CCHR found that Dunner’s conflict of interest waiver with the FDA failed to disclose two pending grants worth $250,000 from two pharmaceutical companies and that he had a series of engagements to speak at a series of seminars funded by Eli Lilly. He had also received more than $4 million in research grants from antidepressant manufacturers in the 8 years preceding the FDA hearing. The tenth panel member was a psychologist in the department of psychiatry at the University of Pittsburgh who was also a member of the Scientific Council of the National Alliance for Research on Schizophrenia and Depression, an organization heavily backed by drug companies.59

September 20: The FDA’s PDAC held a hearing into antidepressants causing suicidal ideation/behavior in patients and whether a package insert should warn the drug could cause suicidal behavior. CCHR presented evidence along with dozens of antidepressant victims. The evidence given by patients and their families to the FDA hearing was dismissed as anecdotal. Dr. Martin Teicher, who had slides that showed how Prozac could cause suicidality, was denied the right to present this evidence. Psychiatrists representing Eli Lilly made half of the formal presentations on the agenda, even though the FDA’s memo on the potential conflicts of interest said that the committee would not be dealing with or reviewing any specific drug or sponsor (manufacturer). Psychiatrists warned PDAC that any changes in Prozac labeling would undermine the public’s confidence in psychiatric drugs.60 The committee voted unanimously that antidepressants did not cause suicide and violent behavior. [Dr. David Dunner—see above entry—while not participating in the actual vote, was an advisory member.]
October 3: Dr. Robert Temple, Director of the Office of Drug Evaluation and Research, Department of Health and Human Services responded to CCHR’s letter of

August 7, and, not surprising, supported the findings of the PDAC hearing, which he had attended. Documents later obtained through the Freedom of Information Act revealed that Lilly’s clinical studies that were presented to the 1991 FDA hearing were known to be “inadequate.”61 Dr. Temple was senior to the Division of Neuropharmacological Drug Products, headed by Paul Leber.

In 1984, Dr. Temple had approved another antidepressant, Merital, for use, but six months later the drug was withdrawn from the market because of fatal strokes and hemolytic anemia—the excessive destruction (for example by chemical poisoning) of red blood cells. The manufacturer was criminally prosecuted for failing to report deaths and adverse reactions.62 Temple later testified before a Congressional hearing that the FDA knew the drug had risks, but he believed the “benefits” outweighed these.

“Most, marketed antidepressant drugs are known to be associated with multiple risks, some of them quite serious and also potentially fatal.”

October: In the U.S., “National Depression Screening Day” began as an annual October event, funded with a grant from Eli Lilly. Thousands of sites in hospitals, CCHR: Exposing the Dangers of Antidepressants and Other Psychotropic Drugs 13

corporations and universities around the country provided free “depression” screening that involved people answering a subjective questionnaire lasting less than 5 minutes. They then watched a video on how “treatable” depression was.63

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December: In a Harvard Medical School study, published in The Journal of Clinical Psychiatry, the researchers noted, three “depressed” inpatients that had attempted suicide while taking Prozac, were recommenced on the drug. In each case, they developed akathisia and commented that it was the same syndrome that precipitated their earlier suicide attempt. They again developed suicidal ideation, which abated only when they were discontinued on Prozac.64 14 CCHR: Exposing the Dangers of Antidepressants and Other Psychotropic Drugs