

Commentary

The Antidepressant Controversy: The Growth Of A New Area Of Litigation

By
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[Editor's note: Karen Barth Menzies is an attorney at Baum Hedlund in Los Angeles and has been involved in litigating claims involving injuries stemming from selective serotonin reuptake inhibitors for more than a decade. In addition to handling nearly 5,000 Paxil withdrawal cases, Ms. Menzies represents approximately 100 individuals and families involving Paxil and Zoloft-induced suicide or suicide attempts. Ms. Menzies is lead counsel as well as a member of the Plaintiffs Steering Committee in the Paxil withdrawal multidistrict litigation (MDL 1574) pending in the U.S. District Court for the Central District of California. In addition to her courtroom activities, Ms. Menzies has testified about the dangers of SSRIs before the California State Assembly and the Food and Drug Administration's Psychopharmacologic Drugs Advisory Committee. Copyright 2004, the author. Replies to this commentary are welcome.]

According to a Harris Poll reported in the July 16 New York Times: "No industry has fallen as far or as fast in public esteem in recent years as the pharmaceutical industry." The Harris Poll found that "respondents [to the poll] who say they have a positive attitude about the pharmaceutical industry has fallen 35 points since 1997, more than for any other industry. Drug makers now share the bottom of the rankings with oil, managed care and tobacco companies."

The pharmaceutical industry's transgressions over the past 15 years are finally catching up to it. The antidepressant controversy is revealing

the pharmaceutical companies' deception, their interest in profits over safety, the scientific flaws of modern prescription drug research and the dangerous consequences of over-promotion. Through the tenacious efforts of victims, advocates, grassroots organizations, and experts with unshakeable integrity, reform appears to be on the horizon. Antidepressant litigation has played an important part in exposing these troubling issues.

The Ulterior History Of Antidepressant Litigation

Unbeknownst to many, antidepressant suicide litigation has been ongoing for more than 14 years. It began in 1990 with the blockbuster antidepressant Prozac, the first in a class of drugs called selective serotonin reuptake inhibitors (SSRIs). Baum Hedlund was involved in these cases from the beginning of this litigation and has continued to litigate antidepressant drug cases continually for the past 14 years.

More than 150 Prozac suicide cases were filed in federal courts across the country during the early 1990s. Because of the volume, a Multidistrict Litigation ("MDL") was established in Prozac manufacturer Eli Lilly & Co.'s hometown of Indianapolis. Wrongful death cases involving subsequently approved SSRIs such as Pfizer Inc.'s Zoloft and GlaxoSmithKline's Paxil, emerged later in the 1990s and eventually expanded to other antidepressants such as Wyeth's Effexor, Forest Pharmaceutical Inc.'s Celexa and Solvay Pharmaceuticals' Luvox.

In addition to plaintiffs alleging that these antidepressants have caused loved ones to take their own lives, individuals have taken legal action against GSK for withdrawal symptoms and dependence experienced when attempting to reduce or discontinue taking Paxil. The plaintiffs claim that GSK is liable because it failed to adequately warn and misrepresented in its advertising Paxil's ability to cause these conditions.

SSRI Trials

Of all of the antidepressant suicide cases, only three have ever made it to trial. Most cases have been quietly "resolved" and an unknown number were dropped following a verdict in the first Prozac case to go to trial (explained below). Others have fallen prey to summary judgment motions on such issues as actual causation, Daubert, and most recently to the federal preemption defense.

Of the three cases to go to trial, two have been tainted by suspicions of fraud and secrecy. The first SSRI trial took place in Louisville, Ky., in 1994. The official title was Fentress v. Shea Communications et al., (No.90-CI-06033, Ky. Cir. Ct., Jefferson Co.), but most people called it "the Wesbecker case" (as a member of the Plaintiffs' Steering Committee [PSC], we feel it is worth noting that the PSC was opposed to selecting this case as the first to go to trial). The case involved a man who, after ingesting Prozac, went into his workplace and opened fire with an AK-47 assault rifle and other weapons. He killed eight people and injured 12 others before he turned a gun on himself and committed suicide. The case resulted in a 9-to-3 verdict in Lilly's favor.

At the time, Lilly touted the verdict as the death-knell to the Prozac suicide litigation and proclaimed Prozac vindicated. However, following the verdict, rumors began to spread that Lilly had entered into a secret settlement before the verdict, which required plaintiffs' counsel to agree not to present to the jury some of the most damning evidence against Lilly, including the fact that Lilly had previously been charged criminally for failing to report to the FDA deaths related to one of its other drugs.

When the judge in the Wesbecker case found out about the secret settlement, he was furious. He

complained to a reporter from the British Broadcasting Company (BBC): "After the verdict came in, Eli Lilly gave it a great deal of publicity and various people went on television and on the radio and in the newspapers proclaiming that this was a vindication of Prozac . . . I think the public has a right to expect that a trial is a bona fide contest and not some sort of show that one side puts on with the consent of the other to influence public opinion. Because it was done to discourage other plaintiffs and to help settle the pending lawsuits for less money than they might have been settled otherwise. Between these two parties, each side got what they wanted. But I think a bigger issue is whether the system was somehow corrupted a little bit, and I believe it was."

The judge ultimately took the matter to the Kentucky Supreme Court, which found that "there was a serious lack of candor with the trial court and there may have been deception, bad faith conduct, abuse of the judicial process and, perhaps even fraud." The judge was later able to revoke the defense verdict and recorded the case as dismissed with prejudice as settled. The value of the settlement remains secret, but we have heard that it was in excess of \$20 million.

The second case to go to trial was a Prozac homicide/suicide case called Forsyth v. Eli Lilly, (No. 95-00185, D. Hawaii), which had been remanded after the close of the MDL. I sat second chair to veteran trial lawyer Andy Vickery of Houston's Vickery & Waldner. The case was tried in Hawaii in the spring of 1999. The case involved a man in his 60s who, after taking Prozac for 11 days, killed his wife of 35 years by stabbing her 15 times with a serrated steak knife. He then propped a butcher knife on a kitchen stool and thrust himself on top of it. Following a three-week trial and two days of deliberations, the jury returned a verdict for Lilly. Within minutes of the jury being dismissed, one of the jurors, distraught over the verdict, walked across the street from the courthouse and called us from a pay phone. She complained that one of the jurors had coerced her and other jurors to vote in favor of Lilly. Other jurors corroborated her story, but our efforts to get the verdict overturned on grounds of juror bias failed. We filed an appeal in the Ninth Circuit U.S. Court of Appeals on

grounds that the judge excluded crucial evidence during the trial.

While the Forsyth case was on appeal, we discovered that Lilly had withheld evidence requested during discovery. Specifically, we learned from a Boston Globe article that, just three months before the trial, Lilly entered into an agreement to purchase for \$90 million the exclusive rights to a patent for a new and improved Prozac, one which claimed to reduce Prozac's side effects of suicide and violence. We immediately filed a new case for fraud on the court. During the pendency of the two cases (the one on appeal and the new fraud action), a settlement was reached.

The third and last, so far, of the suicide cases to make it to trial was Tobin, et al. v. SmithKline Beecham, (No. 00-CV-0025, D. Wyo.), which involved a man who was prescribed the SSRI Paxil. Two days after he began taking Paxil, Donald Schell killed his wife, daughter and infant granddaughter, then himself. Andy Vickery represented the plaintiff and tried the case in Wyoming in 2001. This time, the jury found that Paxil was a proximate cause of the triple homicide and suicide, and awarded the plaintiff over \$6 million dollars. GSK appealed the verdict and the case was settled during the appeal.

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Evolution And Recent Events In The Antidepressant Controversy

A significant event, which served as the catalyst to the current SSRI controversy, occurred in October 2002 when the BBC aired a program called "The Secrets of Seroxat" (Paxil is called Seroxat in the United Kingdom). In its program, the BBC boldly took GSK to task on the risks of withdrawal and suicide with Paxil. Following its airing, the BBC received an unprecedented response, over 65,000 telephone calls and e-mails, the majority from individuals who had suffered withdrawal, suicidality or who had lost loved ones to suicide on Paxil or one of the other SSRIs.

British regulators moved fast to contain the public uproar, appointing a panel of experts to examine the Paxil clinical trial database to see if the risk was real. They began their review with children and adolescents and on June 10, 2003, announced that "[n]ew data from clinical trials in children and adolescents . . . do not demonstrate efficacy in depressive illness . . . and show an increase in the risk of harmful outcomes including episodes of self-harm and potentially suicidal behavior in the [Paxil] group compared to placebo. Various analyses suggest that the risk of these outcomes is between 1.5 and 3.2 times greater with [Paxil] compared to placebo."

Six months later, on Dec. 10, 2003, the U.K. regulators announced that they would contra-indicate the use of all SSRIs in children and adolescents, except Prozac, which Lilly itself, does "not recommend" for children and adolescents in the U.K. The findings in the U.K. were alarming — for example, the regulators found that: "The commonest reason for discontinuation of treatment [with Zoloft] was suicidal thoughts/self harm . . ."

The U.K. regulators concluded: "The data show a consistently higher incidence of suicidal thoughts and self harm in children and adolescents with depression treated with sertraline [Zoloft], which is in the region of twice the apparent placebo rate" It made similar findings for other SSRIs and stated that the risk/benefit balance was unfavorable for Paxil, Zoloft, Effexor, Luvox, Celexa, and Lexapro. U.K. regulators are continuing their review of the adult data. According to a recent report in *The Guardian*, a popular U.K. newspaper, an announcement is expected this fall warning of a risk of suicide in the adult population, as well.

SSRI-Suicide Risk Downplayed In U.S.

Meanwhile, in the United States, the Food and Drug Administration issued a Public Health Advisory on Oct. 27, 2003, regarding SSRIs and suicidality in the pediatric population, stating that "preliminary data suggest an excess of such reports for patients assigned to several of these antidepressant drugs compared to those assigned to placebo." Despite this public announcement, FDA officials were consistently quoted in the media downplaying the risk.

On Feb. 2, 2004, an FDA Advisory Committee hearing was held to review the risk of suicide in children and adolescents taking antidepressants. The day before the hearing, the *San Francisco Chronicle* revealed that a senior FDA epidemiologist, Dr. Andrew Mosholder, had conducted an analysis of the clinical trial data and found an up to three times higher risk of suicidal behavior in children and adolescents taking antidepressants compared to placebo.

Dr. Mosholder's analysis was squelched by senior FDA officials, including Dr. Robert Temple, who would not allow Mosholder to present his findings. The circumstances and events surrounding the FDA's suppression of Mosholder's report would later result in a U.S. Senate investigation. Notwithstanding the FDA's efforts to keep things under wraps, the advisory panelists strongly urged the FDA to immediately warn about the risk of suicidal behavior.

On March 22, 2004, the FDA finally responded via a Public Health Advisory. It asked the antide-

pressant manufacturers to place, in the warning section of their drug's label, a warning that both children and adults should be monitored closely at the beginning of drug therapy, or when a patient's dosage is increased or decreased, for signs of "worsening depression," or "emergent suicidality [that] is severe, abrupt in onset, or was not part of the presenting symptoms."

In this advisory, the FDA also stated that, "health care providers should be aware that worsening of symptoms . . . might be a result of drug therapy." The symptoms listed are: "anxiety, agitation, panic attacks, insomnia, irritability, hostility, impulsivity, akathisia (extreme restlessness), hypomania, and mania." The FDA Advisory was issued within days after FDA officials were contacted by an investigator from Iowa Senator and whistleblower advocate Chuck Grassley's office.

Most of the companies swiftly complied with the FDA's March 22, 2004 warnings request, with one exception. Pfizer was the last company to comply, resisting the FDA mandate until late August. This was despite the fact that it began warning Canadian doctors on May 26 of an association between Zoloft and an "increased risk of suicidal ideation and behavior over that of placebo" for those under 18; and that for both adults and children, patients should be monitored for suicidality, "emotional changes" and "agitation-type" events such as: "akathisia, agitation, disinhibition, emotional lability, hostility, aggression, depersonalization." Pfizer also sent a "Dear Health Care Professional" letter to Canadian physicians regarding this updated warning. Meanwhile, Pfizer and the FDA maintained their sanctimonious opposition to Americans buying Canadian drugs like Zoloft for less, claiming the drugs do not meet the "high" standards imposed by the FDA.

On Sept. 13 and 14, an FDA advisory committee hearing, designed as a follow-up to the February 2, 2004 advisory committee hearing, is scheduled to take place to address the outcome of a re-analysis of the clinical trial data conducted by researchers from Columbia University. Rather than accept its own epidemiologist's findings that a suicide risk exists, FDA officials took over six months to re-ana-

lyze the data. Columbia's re-analysis reportedly has confirmed Dr. Mosholder's conclusions that there is a suicide risk and that the risks outweigh the benefits. Dr. Mosholder's conclusion, now

confirmed by the Columbia re-analysis, should compel the FDA to contra-indicate SSRIs for use in children and adolescents, just as the U.K. regulators did a year ago. ■