DOWN THE BARREL OF A LAWYER

A letter arrived on May 9th 1997 from a Californian legal firm outlining the case of a man who had killed his wife and then himself, while on Prozac. My first reaction was dismissive. I was also bewildered at the fact that an American legal firm was approaching me. But I was due to attend an American Psychiatric Association meeting in San Diego two weeks later, 50 miles from Baum, Hedlund, Aristei, Guilford & Downey, who had made the request. So I contacted them.

The APA was in the process of rapid expansion on its way to becoming an international organization. Whereas in 1996 the World Psychiatric Association meeting had six to ten thousand delegates, the APA meeting registered sixteen thousand or more delegates. A large proportion of these were foreigners brought by pharmaceutical companies. Zeneca, whose antipsychotic, Seroquel, was heading towards launch, was bringing me.

I had an ulterior motive. In the course of researching the history of the antidepressants, I had become aware that the conventional history was wrong. An unknown from Cincinnati, Max Lurie, had made the first discovery of an antidepressant in 1953. I had tracked down all Luries in the Cincinnati area in 1996 and finally got through to Max Lurie, who was surprised by the call. He doubted whether anyone could regard his memories of 45 years previously as reliable, and turned down my offer to visit him. A year later after the overture from Zeneca to go to San Diego, I got back in touch with Max, to see if anything had changed. In the meantime, I had sent him a draft of what I proposed to say about his contribution and he had made some comments. Now to my surprise, he had changed his mind about meeting up. Otherwise, I probably wouldn't have gone to San Diego.

I let the lawyers know that I would fly straight to San Diego and first thing the following day would head for Cincinnati returning last thing at night. If they wanted me to look at material, they could send it to my San Diego hotel room and I would bring it with me on the plane to Cincinnati and meet with them the day after that.

Most legal briefs I had seen up till then had been no more than a few inches thick. But the material waiting for me in the Hilton Bay Hotel on the evening of May 24th filled two photocopier-sized boxes. The first box had a bundle sealed in black paper labeled "photographs". I quickly closed it again. There were photocopies of diaries kept by both William and June Forsyth. Then there were hundreds of pages of depositions from relatives, friends, medical staff, and others. Finally, there were statements from senior members of Eli Lilly, and experts for Lilly outlining why Prozac was not to blame in the death of William Forsyth or that of his wife June. There was too much to take all of it to Cincinnati, so I took the medical depositions rather than the testimony of family or friends.

By the time I met the lawyers, I had found that William Forsyth was a man in his sixties who had been under some stress. Relations with his wife had been

mixed for a few years. He had gone on Prozac and 10 days later butchered her and killed himself. It had come as a shock to those involved, even the treating doctors, one of whom, Randolph Neal, had speculated that some intruder must have done it. The intruder possibility had been out ruled by the police investigation. Another of the treating doctors, Riggs Roberts, had stated that this outcome had been beyond the realm of possibility.

Andy Vickery, William Downey, and Cindy Hall showed up. Downey took the lead. He was pretty clear that the evidence in this case strongly implicated Prozac. The bit of the evidence that I had seen didn't seem to be so clear-cut.

Cindy Hall was a deadpan paralegal. She fielded the technical questions that came up about what pieces of information might be in which deposition. She didn't look like she trusted me. Vickery seemed like a bored hanger on. He apparently would be the trial attorney should the case go to trial.

The conversation bobbed around. I told them that if I were Lilly I'd describe akathisia as like being wired with coffee and invite a jury to consider whether they would excuse a murderer just because he had drunk too much coffee. I outlined my involvement as a consultant for Lilly, but they didn't seem concerned. They made it clear that they needed me to make up my mind whether I could say with reasonable medical certainty that Prozac had been involved in the Forsyth case.

Reasonable medical certainty was a whole new idea for me. I can now quickly decide whether I can get to reasonable medical certainty on a case and don't have any philosophical agonies about what that might mean but there in the San Diego sun, I had no idea what it meant. I was still grappling with the concept two weeks later.

For the attorneys it meant being 51 per cent certain that Prozac had contributed to the deaths of William and June Forsyth. After it became clear that I wasn't going to be able to reach 51% that afternoon, the conversation began to wind down. Downey suggested that I read some of the children's testimonies on my way home.

Fishing out a checkbook, he also retained me. I didn't think I'd given any indication that I was likely to be involved in the case. They told me that they had to file in ten days. I didn't think I'd be able to make up my mind that quickly. I already knew that the daughter, Susan Forsyth, was involved in a Prozac Survivors Support Group and the son, Billy Jr., had traveled to Lilly's plant in Indianapolis and put leaflets on cars in the parking lot that drew the attention of Lilly employees to the idea that their company had produced and was marketing a drug which killed people. Lilly accused Billy Jr. of trespassing and the company painted all Prozac Survivor Groups as having links to either Peter Breggin or the Church of Scientology. This was not a case Lilly wanted to settle, and nothing about these aspects of it inclined me to sympathize with the Forsyths.

I didn't just have to make my mind up about William Forsyth; I had to work out what I was doing in this situation. At the APA meeting, there were other people it might be worth talking to. Six months previously, at an American College of Neuropsychopharmacology meeting I had met Tony Rothschild, who had been involved in writing up one of the more interesting series of Prozac cases. I had just published a book of interviews with senior figures in the field - The Psychopharmacologists[1]. Tony was one of the first people I'd met who actually had a copy. He had introduced himself at the ACNP meeting and let me know how much he had enjoyed the book. We'd both written about Prozac and its problems and were interested in the history of the field. Who better to make contact with? I knew he was at the meeting. I found his hotel number and left a voicemail.

When he got back to me that night, Rothschild expressed surprise that there were any more Prozac cases happening. He wasn't surprised that the lawyers had contacted me rather than him. As far as he knew, the way they did it was to do a Med-line search on anyone who had written in the area and based on that they might make contact. It wasn't a matter of knowing the quality of anyone's work. It was almost a chance thing whether they contacted you or not. When I asked my three lawyers why they got in touch with me, they had said that the profile of this case seemed to fit the profile of Alan L I'd described. But why hadn't they asked Tony Rothschild? They had written to him, they said, but got no answer. I was perplexed at why they hadn't gone for someone else from the States. Tony wasn't. A lot of things had gone on, he said.

While wandering in and out of the conference center that day and the next I could see the Church of Scientology demonstrators picketing the center. At one point, I passed a short, diffident looking man who had a Charles Beasley name badge on. I almost introduced myself.

What to do? I fixed to meet a number of industry friends at the meeting. Separately I sat two of them down and outlined the problem. It was a good opening line to be able to say I'd arrived in the hotel to be greeted with these gruesome photographs. But the discussion wasn't about whether they thought Prozac could trigger this kind of carnage or not. The problem was how would my industry contacts react, if I got involved in the case. Would other pharmaceutical companies take an attack on one of their number as an attack on all of them?

What I picked up was that broadly speaking they felt that if I felt the case was clear-cut on clinical grounds, I should go ahead. It didn't seem that these two people would think any the worse of me for being involved. But there was another message. Getting involved was the kind of thing that older men took on toward the end of their career, when they couldn't be hurt. How would a company hurt someone? These two didn't seem to know, or weren't saying.

I read Susan Forsyth's deposition on the way home. Contrary to what I had expected, the children's depositions were persuasive. They described

respectable parents and a relatively stable marriage. They described bewilderment. I began to get a clearer picture of what had happened.

William Forsyth's Story[2]

William Forsyth was born in Michigan in 1929. He moved to Los Angeles with his mother as a child. At Los Angeles City College, he studied business. In 1955, stationed at Scott Air Force Base in southern Illinois, he met June at a dance. June had been born in southern Illinois in 1936. She grew up in a small town. She was starting her first year of college studying English when she met Bill. They were married on the base six weeks later. They were then posted to West Germany for two years.

After returning home in 1957, the Forsyths moved to Los Angeles and began a car rental company with six Volkswagens they had shipped back from Germany. They were living out of a hotel initially but the company grew. They had two children, Susan and Billy Jr. By 1986, William Forsyth was a wealthy man, with a number of investment properties in apartment complexes. He was approached by Los Angeles airport, which wanted to buy the land on which his automobile business was based. He sold and retired.

Billy Jr. moved to Maui in 1981 and the Forsyth seniors began to visit Maui regularly when they became grandparents. During 1989 and 1990, they built a home on Maui at Kanapalli Hillside and in 1990, they moved to Maui full time. This was really June's dream. Billy Jr. had an attractive lifestyle there, taking anglers out in his boat deep-sea fishing and taking tourists out to watch the whales off Maui. There was a business to be built up there, which Bill Sr. might get involved in. He enjoyed going out on the boats. During this time, the children and their friends described a good relationship, with no hints of violence or danger.

After moving to Maui, Bill had some involvement with Billy's business but not to the extent that had once been envisaged. June, in contrast, took to the change like a duck to water. She got heavily involved with a Christian church, through which she made a range of friends. She was close to her son. She began to become more assertive. Far from retirement being a winding down, she seemed to see the situation as an opportunity for a new life. Rather than simply supporting her husband in the business, which provided for both of them, she was now free to look after herself. Things could be explored such as co-counseling aimed at deepening her relationship with Bill, now that he was with her so much more.

She would have liked it if he had been as keen on the new Church as she was. But he wasn't. Both of them were more church oriented than a comparable couple would be in a European setting. This was not a part of their life that I warmed to; although I later came to appreciate that it was something that many other Americans would find admirable. Initially, I was more inclined to swing in behind the questioning from Lilly's lawyers that June's pressure was oppressive for Bill and was causing problems. But the more I read the more difficult it became to sustain this interpretation.

It seemed from their line of questioning of Susan and Billy Jr. that the Lilly approach was to portray William Forsyth as a man, who had lengthy nervous problems, who had never really coped with retirement, and who was being oppressed by his wife and son. At one point the idea was even floated that his son and wife may have been conspiring against him to take away his money. This seemed far-fetched. William Forsyth was clearly having some difficulties as 1992 turned into 1993, but as I read the record he seemed a man who was at a loose end rather than one who was oppressed. There certainly didn't seem to be any clear ill will between himself and his wife. He appeared happy to go to church and was even committed to it.

He had spells of being worried in 1992, and he had communicated his discontent to his wife, his son, and others. On two occasions during the year, he had left Hawaii and gone back to Southern California, where he still had business interests. At one point it looked like he might even be leaving the marriage. But there had been no violence and he was only away for a few weeks.

While in Southern California on one of these trips, William Forsyth heard about a marital counsellor, Tom Brady. He went to see him and based on these visits arranged for June to come over and visit Brady with him for seven sessions. This seemed to make a difference. Brady's assessment of the case was interesting. This was a man used to conflict in marriage. He did not see the Forsyths as a relationship in serious difficulty. There were differences between them, as he saw it, there were adjustments to be made, but this was a relationship that had endured and would continue to endure.

While in California waiting for June to join him for their first session with Dr Brady, an apparently nervous William Forsyth went to a primary care physician, who prescribed Xanax (alprazolam). On this, his nerves got worse. Back in Hawaii, William Forsyth visited a Dr Riggs Roberts. Riggs Roberts was a psychiatrist in private practice. In December of 1992, Riggs Roberts diagnosed William Forsyth as being depressed. The kind of anxiety that some psychiatrists had been claiming for some years might conceal an underlying depression. Not a serious depression. Not suicidal. Not needing hospitalization. Riggs Roberts continued the Xanax and started Bill Forsyth on nortriptyline – Lilly's norepinephrine reuptake inhibitor from the 1960s.

Thirty years previously, Bill Forsyth had been drinking to excess. He stopped, began to go to AA, and had not, it seemed, touched alcohol for 30 years. He was unhappy about now taking pills. But he was also a man to do what his doctor told him to do, and during the course of the following weeks he probably took his pills as prescribed. They made some difference but it was not clear from the records just how much difference. Things still were not right, although whether the problems at this point stemmed from difficulties with June or with his prescribed drugs aggravating rather than relieving his symptoms was less clear. Riggs Roberts made medication changes. He added in trazodone (Desyrel), a sedative anxiolytic drug sometimes used to treat people who are depressed.

Locked perhaps into a medical model of what was going on, with no great reason (as I read the record) to believe that a drug was going to make a big difference and certainly not because the gravity of the situation demanded it, Riggs Roberts decided on another throw of the dice. He suggested to William Forsyth that he try Prozac. He gave him a supply of 20mgs pills to take one per day. The next day William Forsyth, having had his first pill, felt great and telephoned Riggs Roberts to say he was 200 per cent better. Riggs Roberts told him that he was having the Prozac miracle.

The miracle was short lived. The following day William Forsyth felt terrible. So bad that he informed his wife and later his son that he needed to go to hospital fast. Astonished, Billy Jr. called Riggs Roberts to inform him of what was going on. Roberts was very surprised. He tried to talk Billy out of taking his father to hospital, but William Forsyth was insistent, and Billy had already made arrangements to take his father to the Castle Medical Center on Oahu.

There, William Forsyth was admitted by one of the resident staff who noted that he did not seem to have the kind of condition that warranted admission. That Mr. Forsyth was so anxious to be admitted was doubly surprising given that this was a man who had never been a psychiatric patient in this life and probably never could have imagined being one. He was admitted under the care of Dr Randolph Neal, who saw him the following day. Dr Neal was also surprised at the admission. There were no notes made by the medical staff to indicate that they thought William Forsyth was suicidal. His Prozac had been stopped on the first day after his admission to the Castle Medical Center but was re-started the following day.

The records of his admission reveal a man who didn't settle. He did attend some groups and activities but appeared unable to settle down in a relaxed fashion to participate in anything that was happening. The records indicate that he left activities early and spent a good deal of time on his own.

Six days after admission he indicated that he wanted to go home. Unlike the attitude at the time of his request for admission in the first instance, the Castle medical staff was now somewhat uneasy about the idea of William Forsyth leaving them. They had no clear idea why he wanted to leave or why they felt uneasy. The Medical Center policy preferred that patients discharging themselves give notice. This is common, although it is not usually legally binding. The simple act of giving notice often deters someone and, as it turned out, Bill Forsyth didn't leave the following day. However he didn't settle either. Finally ten days after he had begun on Prozac, he left hospital.

June came to collect him. They went home and had a meal together that evening. Billy Jr. came and later described his father as looking shaky, gray and nervous. The descriptions given are of a very different man to what he had been several weeks previously. In court a video was later shown of William, before he started on Prozac, playing in the garden with his grandchildren and others from the family. The man in the video looked a relaxed man at ease with himself. Not a man who was seriously depressed.

That evening, the family agreed that clearly things had gone wrong in the previous week, but there was nothing they couldn't overcome if they pulled together. Billy and Kim were expecting their 4th child in less than two weeks – and Bill Sr got on tremendously well with the grandchildren. The 3rd of March was a new day. They would go out on the boat, whale spotting, with Billy Jr. This was something to look forward to and in the course of the following days they would sit down together and plan a more exciting and involved future.

When his parents didn't turn up by the time of the final boat trip of the day, Billy Jr. had become concerned. He came by their house in the early evening. It was still. He went in. He found his parents. Lying, as one police officer described it, in more blood than he had ever seen. William Forsyth had stabbed his wife June 15 times. He had then fixed up a serrated kitchen knife on a chair and impaled himself on it.

Being Deposed

By the time I got home, my mind was swinging around to thinking that this was the kind of case where it seemed that Prozac must have been involved. It was difficult to see any other way to explain the problem. There was no suicide note. There were no indications of premeditation. William Forsyth's behavior was inexplicable in terms of what had gone before. I aired the scenario with some colleagues, asking them whether they could they see any other way to explain what had happened or whether they could see any hazards of getting involved in this kind of case? No one had any other explanations. No one knew what getting involved in the case might mean.

By this stage, I had written to the Medical Protection Society with whom I was insured to find out whether my insurance would cover involvement in the case. A formality I thought. The reply from the MPS regretted that coverage did not extend to legal cases in the United States and they would advise me not to get involved. There was always a risk, they said, that the plaintiffs might take an action against one of the experts whom they felt had jeopardized their chances of winning.

I contacted Baum, Hedlund in the United States explaining this problem. The answer that came back was that this was a remote technical possibility -- although worryingly there did seem to be one case that offered a precedent. Bill Downey wrote me a letter of indemnification.

Its not clear if this letter would have counted for anything but with this in hand, I penned a report indicating that I believed on the balance of probabilities there seemed to be no other explanation for what happened but that Prozac had disturbed the equilibrium of William Forsyth's mind in such a manner that his death and the death of his wife followed as a consequence of that disturbance. I sent the report off. When nothing happened, I began to think that it might all have gone away.

A month later, I found out that I would have to be deposed. I had no idea what a deposition was. They don't happen in Britain. At this stage I knew nothing about the extensive depositions in the Wesbecker case. But, I knew enough

to know that being interrogated by lawyers might be scary. I had got round to reading Cornwell's account in The Power to Harm of Peter Breggin being but mugged on the witness stand. But I was in before I had a chance to know what I might be in to.

The deposition was set for a well-worn Hilton Hotel at John F Kennedy Airport. I arrived and was checking in when Bill Downey and Cindy Hall appeared. I pleaded for guidance on what was likely to happen and some indication as to how I should handle it but Bill said very little. No pointers were given. No hints offered as to what tack Lilly might take. I was led to believe that another of Downey's experts, Ron Shlensky, a forensic psychiatrist, had been deposed by Lilly a short time previously. Lilly's lawyer, Andy See, had focussed on scientific methods in general and randomized controlled trials in particular, which according to See were the gold standard in the field for demonstrating cause and effect. This seemed to be something new for everyone and no one seemed to have a clear fix on what the right answers were. Shlensky, according to Downey, had ducked and weaved on the issue. Bill seemed happy enough but from my perspective this sounded uncomfortable. If I ended up against the ropes, they weren't offering any quick duck and weave classes.

The deposition started at 8.00 the next morning in a small meeting room in the hotel. There was a long table that could have sat 20 people comfortably. At one end, Andy See was sitting with heaps of papers laid out in front of him and crates of documents lined up beside the table. I sat on the other side, with the court stenographer between us. Downey and Hall were also seated around the table with cartons of documents. See worked for Shook, Hardy and Bacon.

The questioning started[3]. Very early on, we ran into a problem. I was asked had I done research on the issue since I'd got involved in the case. How could I? I'd only been involved in the case for eight weeks. No one could do research on the subject in that period of time. So the answer was "no". See all but folded up his documents and left. It turned out that research for a lawyer was something very different to research for a medic. Research meant had I read something.

Then we got into randomized controlled trials and the nature of science. See's strategy was to ask, isn't it important to adhere to the highest standards of scientific methods? Are randomized controlled trials thought to be the gold standard in the clinical field? The next step would be to ask where were the randomized controlled trials showing that Prozac caused suicide? The trick was not to slip down this slope. I refused to accept any of the points being made by See. Tempers began to fray on both sides of the argument. There were a number of "if you'll just answer my questions, we will get done because we all want to get done". He only had until 4 o'clock in the afternoon to ask whatever he could or score whatever points he could. It had been agreed that this was the appropriate length of time. Besides I had a plane scheduled for 5.30. At one point he advised me that there were certain things

he had to get through and that I'd have to come back if he didn't. It was difficult to know from looking at Bill or Cindy what they made of it all.

See faced me with my 1994 words about data from several thousand patients counting for more in any scientific balance than a handful of anecdotes. Even with the written evidence from follow-up letters that this was meant ironically, he wanted me to agree my statement was meant literally[4]. "I wrote this article without thinking we were going to be going through the nitty-gritty. I didn't write it as a legal piece. As I keep saying to you I wrote it within a certain scientific convention about how you handle these issues". A scientific convention that dictated that scientists suggest that the earth might possibly be round rather than state unequivocally that it is.

See handed me a letter to the American Journal of Psychiatry written by a Dr Cynthia Hoover. Following Teicher's initial study, Hoover had written in to the American Journal of Psychiatry reporting a similar case[5]. But this wasn't the letter that See was now showing me. It was another one, from a year later, where the same patient had gone on imipramine and become suicidal. Clearly relishing the situation, Andy See put it to me that "In Dr Hoover's letter to the editor she states that because of the subsequent history of the patient .. the occurrence of suicidal ideation in this patient while he was taking fluoxetine was merely coincidental…. Doesn't Dr Hoover's subsequent report point up the problem of relying upon case reports of individual patients in order to come to conclusions about causation"?

But, Hoover had missed the fact that imipramine also had significant serotonin reuptake inhibiting properties. What she had done, pretty much as we had done with Alan L, was to unwittingly provide a test-retest report. This in fact strengthened rather than weakened the case against Prozac.

At one point, we got into homicide-suicide. Had I researched it? No. With regard to any person with major depression, it is not possible is it, See suggested, to predict whether that particular person will commit the act of homicide/suicide? This was relatively easy. Homicide-suicide was so rare in Britain that it would make the national news and therefore I could predict it wouldn't happen. If it happened, there would have to be some factor other than the usual course of events – such as Prozac. A few months after getting home, I was consulted on the case of Reginald Payne who had murdered his wife, Sally, in bed on the night of March 15th 1996 and, leaving a note on the fridge for his son not to go upstairs, had then thrown himself off a 200-foot cliff. He did so on the 10th day of a course of Prozac. The case had appeared in the national newspapers, although I had missed it at the time. I was later to hear about another American case. Brynn Hartman had gone on Zoloft and on the 10th day of treatment had shot her husband, Phil, and then herself.

Suddenly at 4:20 it was all over. Bill and Cindy were congratulatory in the escalator on the way down, but I was sure they said this kind of thing to all their witnesses? For me it had been a first. For them it was a routine chore. As we parted, he for his plane and me for mine, I asked Bill what would happen to the case. He said it would probably settle. After getting pumped

up, probably with the elation of survival, this was a let down. It had increasingly begun to seem to me that it was a clear-cut case. And some case needed to be won in order to make a difference. Had I only begun to feel it was winnable and clear-cut because the adversarial system forces us to take positions and then to start justifying our position? Bill wasn't sounding like a crusader. For him a settlement was a win. The clients got something if not an apology. The law firm got money. Cindy was a crusader. She felt passionately that Lilly was in the wrong, but she concealed her passion completely from me. Bill, unbeknownst to himself, wasn't going to live to see this case to its end. A cancer of his esophagus killed him. I never saw him again.

I flew home. Nothing disastrous had seemed to happen. The greatest embarrassment about the deposition, when reading it later was that the stenographer had clearly found my accent difficult.

General Causation

In the course of the deposition, Andy See had raised the question of what he called general causation. He confused me. I thought he was referring to whether I thought Prozac might even make healthy volunteers suicidal. I said I hadn't thought about trying this but it would be an interesting idea, which alarmed him. He clarified that what he meant was "Have you submitted for peer review the methodology that is the reasoning process behind using the categories of data or other information that you say you have relied upon to form your opinion in this case?" I didn't think I needed to – lots of textbooks covered this one. He thought I did need to.

Following the deposition, in response to efforts by Lilly to get me debarred, I put together a general causation statement outlining the basis of my views that Prozac could cause problems. This meant going back and revisiting questions of cause and effect. How did one prove a drug caused an adverse effect? Getting a grip of these issues led me to write an article that I sent to David Nutt, the editor of the Journal of Psychopharmacology. When working out where to send an article like this, many authors will weigh up the personality of the editor. Some editors wouldn't have the stomach for something like this. But this was also something an editor could have fun with by sending it out to one reviewer, whom he knew would be vehemently opposed to the idea that there were any problems with Prozac, and to another more supportive reviewer.

I got back a brief no-problems review and another one with three pages of criticisms, which came as close to abuse as one ever gets in the review process. But the covering letter from the journal made it clear that I didn't have to give up on this one. After considerable revision, drastic shortening and a covering letter to show how I was taking the points raised into account, I sent the article back. It went back to the second reviewer, who had further criticisms. "This paper remains apparently unchanged.., they still do not have the courtesy to the reader to fully report the findings of Beasley et al…, they continue to confuse agitation and akathisia…, the authors' grasp of the literature is modest and their grasp of data is apparently absent.., this paper

lets down the authors, the journal and, frankly, the scientific community"[6]. Nevertheless, after further revisions, David accepted the paper[7].

In the course of working this article up, it had become clear that it was time to revisit the Jick study[8]. In the deposition, See's focus had been on the relative risk of Prozac compared with dothiepin. Prozac appeared to be 2.1 times riskier than dothiepin. A figure of 2.0 was the conventional threshold at which epidemiologists get interested in a problem and think maybe there is something that warrants further study. A risk greater than 5.0 is very worrying. In the case of cigarettes and lung cancer, the risks are 15 times greater for smokers than with non-smokers. The level of the relative risk with Prozac was legally an important issue.

The Jick figures translated into a figure of 189 suicides per 100,000 patient years, rising to 272 per 100,000 patient years for those on their first month of treatment with Prozac. The conventional figures for depression were that people who were depressed had a 15% risk of committing suicide at some point during their life. This translates into a figure of roughly 600 suicides per 100,000 patient years. Against this background, one way to read the 189/100,000 patient years figure was that perhaps Prozac wasn't as good as other antidepressants in lowering the risk that stemmed from depression but that it nevertheless did lower that risk. Eli Lilly for example stressed that depressed patients were 79 times more likely to kill themselves than people who weren't depressed. These figures could leave someone in a position to argue that not only did Prozac not cause a problem but that there was a compelling moral case for ensuring that people who were depressed got on treatment in order to lower national suicide rates.

But it dawned on me that the Prozac figure needed to be compared not with the figure traditionally cited for people who were depressed but the figure for primary care depression. The figure for people who had never been hospitalized for their depression. These were the people who would get Prozac because it was not being used in hospital depression. This was the issue that Bob Temple from the FDA had flagged up at the FDA hearings on Prozac.

Along with a resident, Claus Langmaack, we looked more closely at the classic paper in the field by Samuel Guze and Eli Robins from Washington University in St Louis. This had appeared in 1970 in the British Journal of Psychiatry and from it came the magical figure of a 15% lifetime risk – 600 suicides per 100,000 patient years[9]. But the Guze and Robins paper was a two-page article that had summarized the results of fifteen studies of depressed patients followed up for risk of suicide from the pre-antidepressant German and Scandinavian literature. It was easy to believe that these hospitalized melancholics and severe manic-depressives had a 15% lifetime risk of suicide. But these weren't the patients who were being given Prozac.

As we worked through the figures, a publication from a research group in Southampton which had added more recent studies to the original Guze and Robins studies came out with a figure of 6% for the lifetime risk of suicide in

depressives[10]. But even this new figure only applied to hospitalized patients. What was the figure for non-hospitalized patients? Claus and I could show that if the hospital rate of suicide was applied to all patients who were now being diagnosed as being depressed, then rather than 5,000 suicides in Britain per annum from all causes, there would have to be 9,000 suicides from depression alone. The rate therefore had to be lower for non-hospitalized depression. But what was it?

A paper just out from Jed Boardman, looking at suicides from North Staffordshire, offered an answer. Boardman and colleagues had collected 212 suicides and unexplained deaths, from the nearly half a million people living in the North Staffordshire area, over a 5-year period [11]. He knew from the medical records, all of those who had died who had been in contact with the mental health services. This made it possible to model much more accurately what the rates for depressed patients not in contact with mental health services might be. Working on this Jed and I came up with a figure of less than 30 suicides per 100,000 patient years in this population of primary care depressives. Comparing this with the Jick figure of 272 per 100,000 patient years for patients in their first month of treatment with Prozac gave a ten times greater relative risk on Prozac[12].

We then found out that our modeled figure was in line with the only other figures that were available. A group of general practitioners in Holland had followed up their depressed patients over a 10-year period and came up with a figure of 33 suicides per 100,000 patient years[13]. Remarkably close to ours. But even more interesting was a study from Lundby in Sweden[14]. This was the study that gave Lilly its figure that patients who were depressed were 79 times more likely to commit suicide than patients who weren't depressed were. But what Lilly had done was to selectively compare the figure for hospitalised patients from this study with the figure for people who weren't depressed. This resulted in a 79 times greater rate for depressed people.

The Lundby study was a unique study looking at a small townland in Sweden over a 30-year period. Its drawback is that there were only several thousand people involved in the study. Its great advantage was the huge time frame involved. It also gave a figure for the suicide risk for patients who were depressed but had never been hospitalised. This was before the creation of modern depression, before the transformation of cases of Valium into cases of Prozac. In the Lundby study, a patient could have been off work for 6 months and still be registered as mildly depressed. The suicide rate for this form of mild depression was zero. This figure raised the possibility that mild depression might even confer some protection against suicide.

I later found a study from Simon and Von Korff who looked at suicides among depressed patients being treated by a health maintenance organization in Puget Sound. The figures, drawn from the early 1990s, showed non-hospitalized depressed patients committing suicide at a rate of 43 per one hundred thousand patients. But patients not given drugs for their depression had a rate of suicide or zero per one hundred thousand patients, reinforcing the possibility that mild depression could be in some way protective[15].

This sobering possibility raised many issues. One of these was the selective use of figures from the Lundby study by Lilly. Lilly hadn't cited the figure for mild depression. This was an easy mistake to make if you were operating from a bunker in Indianapolis, but the entire psychiatric community appeared to have let this one slip by. We had become complicit in persuading primary care physicians and other mental health workers to recognize and treat depressive disorders. We did so as part of efforts to detect depression, which sought justification in claims that treating depression would lower national suicide rates. There was no indication that anyone seemed to realize that the figures we so readily bandied about simply didn't apply.

Untimely

Meanwhile, shortly after my deposition, Lilly had sent a series of requests and supplemental interrogatories to the plaintiffs' attorneys. These were variations on the following theme: admit that no clinical trial or epidemiological study demonstrates a statistically significant difference in risk of akathisia or suicide or homicide between patients taking Prozac and those taking any other antidepressant. Even before waiting for a reply, Lilly's lawyers, Shook, Hardy and Bacon, in an application for summary judgment argued that the plaintiffs had failed to make an acceptable general case that Prozac could lead to suicide and or homicide. The judge, Alan Kay, overruled it.

Both Judge Kay and Lilly at this stage were focussing in on the Jick study. Lilly had provided a declaration from Herschel Jick that his study did not prove Prozac caused suicide – a statement I could have made if I were Jick. What was more alarming for me was the drift away from recognizing as Jick himself had done in an earlier paper that in this area, test-retest methods rather than epidemiological studies were the way to prove cause and effect[16].

Lilly came back at the issue with a declaration from Tony Rothschild that Rothschild's test-retest study proved nothing. They came back with further declarations from Jick. At this point, Judge Kay had to be admired for keeping his nerve. I didn't know when I might be knocked out of the whole thing. One of the Forsyths' experts had already got knocked out at this point, so this was no mere formality.

A motion for reconsideration of the original denial of summary judgment followed and then later a renewed motion for reconsideration. These motions were based on claims that the evidence I had been offering against Prozac was not adequate. Every one of these motions that arrived by courier or by fax was gut-wrenching and draining. They all required a quick turnaround. This went on right up to the week before the case was due to start in March 1999, leaving me unsure whether anything would ever happen.

In the midst of their other motions, Lilly filed a motion to disqualify me on the basis that they had consulted with me on legal issues in 1994. This was the meeting with Lilly's attorney, Cassady (chapter 4). Cassady declared that he had understood the meeting to be confidential and had accordingly shared privileged information. "The facts presented compel Dr Healy's

disqualification as an expert for plaintiffs". This motion was filed three months after the cut-off date for such motions. But more to the point, it was wrong. I'd have loved to get information out of Lilly in 1994 but none was forthcoming. Judge Kay dismissed the motion.

A PACIFIC FAULTLINE

Lilly filed motions right into the first week of March 1999 when the Forsyth trial was due to start in Hawaii. When I left Britain to travel to Hawaii, via a meeting in New York, I didn't know if the trial would actually go ahead. While in New York, faxes raising further questions from Lilly came through; could I answer quickly, send references, prepare statements.

I gave the lawyers my time of arrival in Hawaii. Then there was silence. Had the case settled at the last minute? Nothing came back to tell me whether anyone was going to meet me when I arrived. No one was waiting to meet me in the airport terminal. The phone number I had rang out. I was worried. Finally a man dressed in shorts and a Hawaiian shirt, with flowers around his neck, greeted me. It took time to recognize Andy Vickery, whom I had last met in San Diego, almost two years before.

The team was waiting at the house that was to be their base. This included Cindy Hall, Rhonda Hawkins, a paralegal in Vickery's office, Karen Barth, the junior attorney on the case from Baum Hedlund, and someone called Skip Murgatroyd, who apparently had taken time off from surfing. Bill Downey had died two months before.

This was a marriage of two companies. Vickery was a partner with Paul Waldner, and Rick Ewing in a small Houston company specializing in medical injury cases[17]. They had prosecuted recovered memory therapists in one of the first cases in this area, Abney V Spring Shadows Glen. This case led in 1996 to a substantial settlement in favor of a parent accused of abuse, and the closing down of the Dissociation Unit in Spring Shadows Glen hospital. This outcome would have made them heroes with biological psychiatrists most of whom are hostile to recovered memory therapy.

The others were part of Baum, Hedlund, which specialized in corporate cases. They had chased airline companies on safety issues. They also took on cases involving hemophiliacs infected with contaminated blood. The link that brought the companies together was Karen Barth, who had moved from Vickery and Waldner to Kannanack, Murgatroyd, Baum & Hedlund, some years previously. This was the Californian company, which had brought 15 Prozac cases, including that of Del Shannon, to the table in 1992 and through Paul Smith had settled 14 of them. Lilly didn't want to settle the 15th, the Forsyth case. Skip Murgatroyd, although now retired after several successful cases, far from being just a surfer, had been the first person the Forsyths contacted. During the early stages of the Prozac litigation in 1990 and 1991, he had helped obtain and review documents.

But I knew nothing of this background, and they knew little about me, which seemed extraordinary. Lots of their money might hang in my hands. My career might hang in theirs. It was my introduction to a world, in which, on one side, serried ranks of besuited attorneys worked in large legal offices for corporate clients. These lawyers regarded with disdain the informality of the ambulance chasers on the other side of the fence. It would have been a lot more comfortable to start off on the side of the suits.

The case started almost six years to the day after William Forsyth had murdered his wife and killed himself. A few weeks previously, there had been a final settlement hearing. Two years before, Susan had said they might settle if Lilly provided enough money so that they could mail every single clinician in the country with material warning them about the hazards. From what I could gather, there had been an offer large enough to cause Susan and Billy to pause and consider. How much? My guess was several million dollars.

Headquarters was a nine-bed-roomed house. There were boxes and boxes of files in the garage. Three computers had been installed, as well as fax and phone lines. All the key documents of the case were arranged in one of the living room areas - the operational center of the house. Things got going at 0600 a.m., and continued past midnight, as they sought to answer queries raised by the court and to map out strategies.

Going Legal

The judge was Alan Kay. At no point during the week that I was there, did Kay seem anything other than a thoughtful man. The first step in jury selection had been Judge Kay's. Faced with a juror panel, he could question and remove anyone who should not serve as a juror. The attorneys for either side then had the opportunity to question jurors based on their responses to the judge's questions. This could lead to the dismissal of a juror "for cause."

Following that, both sets of attorneys, Vickery and Barth for the plaintiffs and Andy See and Michelle Mangrum for Lilly, had three opportunities to remove a juror. These are called peremptory challenges. No reason has to be offered. Vickery was faced with a woman on Prozac whom Kay had not dismissed for cause, and three insurance claims managers. The wisdom is that insurance claims managers are the kiss of death for a plaintiff's case – but the woman on Prozac also had to go. Ugalde, one of the claims' managers, would have to stay, unless Lilly had wanted her removed. There was reason to think See might remove her – she had been involved in a prior lawsuit against a doctor who had failed to warn her mother of potential adverse reactions to a drug. But Lilly never asked her a question.

The 12 people on the jury dropped to 11, after one had found a conflict of interest through pharmaceutical company shares he possessed. In Court, the lawyers spent a great deal of their time looking at how the jury responded to different issues. They knew something about each of the jurors and their backgrounds, but how would they react to the case? One man slept a good deal of the way through. Another man admitted from the start that he had memory problems, but despite this, Judge Kay noted the man wasn't taking

notes. There were two young women who during jury deliberations just sat back and watched the others argue it out. One of those who did most of the arguing later on in the jury room was Julie Ugalde, a forceful woman whom Vickery expected to become the fore person of the jury.

In the body of the court, there were members of the legal teams, certain witnesses and lay watchers to feed impressions back to the lawyers. There was the local press. And there was a power-dressed woman, whom no one could place. She had appeared the day after Lilly lost a bid to have media coverage banned.

Skip Murgatroyd took me through key documents that might be presented to me on the stand. These included minutes from the Prozac Project Team as early as July of 1978 indicating that Lilly monitors had noticed that there were a large number of reports of patients developing akathisia and restlessness on the drug[18]. That one patient had even become psychotic. In response to this Lilly's Project Team had suggested that in future studies benzodiazepines could be co-administered in order to minimize the problem[19]. In the mid 1980s it became clear that Lilly had developed a problem with the German regulators, the BGA (Bundesgesundheitsamt), in whose opinion it seemed clear that the suicides observed in clinical trials of Prozac were attributable to the drug. When Prozac finally did get a license in Germany, it came with a clear warning that the drug could cause problems during the first few weeks of treatment and that it might be necessary to co-administer a sedative with it[20]. I had seen these documents before, but seeing them in this setting had a different impact. It was difficult to see how they would not stun a jury.

More was to come. A memo by Joe Wernicke, a clinical trial coordinator for Lilly from July 2nd 1986, conceded that the suicide factor, Item 3 on the Hamilton Rating Scale for Depression was not a sensitive indicator of suicidality[21]. This was the very point I had made in my letter to the BMJ in 1991, which Lilly had been at pains to deny (see chapter 3)[22]. This was the key to the adequacy of the Beasley study. In his response to my letter, Beasley had expressed surprise that I should question this point[23]. There were other memos showing they recognised the same flaws in the Beasley study that I had recognized[24].

From 1986, a key memo indicated that the number of suicide attempts on Prozac in Lilly's clinical trial database at that point were 47 on fluoxetine, 2 on tricyclic antidepressants and 1 on Mianserin[25]. Correlating these figures with other documents showing the numbers who had entered into clinical studies at this point made it clear that rates of suicide attempts were three to four times higher on Prozac than either on other antidepressants or on placebo[26].

In a September 1990 memo to Leigh Thompson, the chief scientist at Lilly, John Heiligenstein stated: we feel caution should be exercised in a statement that "suicidality and hostile acts in patients taking Prozac reflect the patients disorder and not a causal relationship to Prozac". Post-marketing reports are increasingly fuzzy and we have assigned Yes, reasonably related on several reports… You may want to note that trials were not intended to address the

issue of suicidality[27]. Here was apparently a frank admission from within Lilly that even the company itself had been forced to conclude that in some cases what was being reported to them was Prozac-induced suicide or suicidality.

Even more, this memo provided a clear statement that the company had a strategy, which was to blame the disease not the drug. This was reinforced by another memo to Leigh Thompson from Mitch Daniels from March 1991 regarding a forthcoming TV appearance, where he was encouraged to emphasize that: It's in the disease, not the drug[28]. The other messages were that Prozac was the most researched drug in history and, in an echo of the indalpine story, that the real people who were going to suffer because of all this controversy were the people denied access to Prozac. Here was the strategy that appeared to shape everything from the first response to the emerging problem to the Wesbecker tactics and the Rosenbaum article. Alongside memos showing that there had been an explicit strategy to blame the disease and not the drug were reports to Lilly of problems developing in patients, who weren't depressed – patients who had bulimia, for example[29]. This was just the kind of patient Bob Temple had flagged up at the September 1991 FDA hearing on antidepressants and suicide.

Just as surprising was the emergence in the papers of someone I knew: Paul Leber. Early on in the documents there was an internal FDA memo noting: Tony DeCiccio stated that Dr Laughren said "the firm has a friend in Dr Temple who wants an action letter by the end of this year"[30]. This was 1986, when the registration of fluoxetine was proceeding slowly and trickily. Then on February 7th 1990, the month the Teicher reports appeared, there was a memo from Leigh Thompson stating: I'm concerned about reports I get re UK attitude towards Prozac safety. Leber suggested a few minutes ago we should use CSM database to compare Prozac aggression and suicidal ideation with other antidepressants in UK. Although he is a fan of Prozac and believes a lot of this is garbage, he is clearly a political creature and will have to respond to pressures. I hope Patrick realizes that Lilly could go down the tubes if we lose Prozac and just one event in the UK can cost us that[31].

Then there was a letter by Lilly to the FDA regarding a summary of the safety experience with Prozac during its first two years of marketing, and a note at the bottom of the page stated "at the request of Lilly, Mr. A W DeCiccio was able to pull and destroy all copies of this submission except Dr T P Laughren's desk copy."[32] Tom Laughren had written a chapter on the assessment of the adverse effects of drugs with none other than Leigh Thompson, which had come out right about the time of the Wesbecker trial[33]. Regulators were supposed to co-operate with companies, but writing a chapter on the issue of drug-induced adverse events with personnel from a company involved in a major controversy such as Prozac-induced suicidality seemed extraordinary.

From July of 1990 there was a memo: Paul Leber called yesterday; I contacted him at 6.15am this morning. The call was about suicide. He asked that we FAX nothing to him unless he has agreed beforehand. Paul is taking a position in talking with outside folks today that Lilly and FDA were working together on the suicide issue and following closely the post-marketing events,

but that there are no denominators and the best that can be done is to put "a cap" on the number of events[34].

Later in the year, on September 12th, a Lilly memo between Max Talbott of regulatory affairs in Lilly and Leigh Thompson states: one possible strategy if FDA presses for an additional labeling change vis-a-vis suicide is a class-wide cautionary note; however we should take this position only as a last resort. A reply from Thompson states: that report MUST move swiftly through approval and to Dr Leber's hands... he is our defender[35]. I respected and indeed liked Paul Leber, but it was clear there were documents here than could paint him in a very bad light. Lilly was also, it seemed, prepared to have warnings put on all other antidepressants from all other companies; it was difficult to see this as other than an effort to avoid putting Lilly itself at a competitive disadvantage.

A further series of documents returned the story to Lilly's difficulties with the BGA. The first involved a memo from Claude Bouchy, the chief executive in Lilly Germany, to Leigh Thompson[36]. It was a memo re: Adverse Drug Event Reporting – Suicide, Fluoxetine, which stated: Hans (Weber) has medical problems with these directions and I have great concerns about it. I do not think I could explain to the BGA, a judge, to a reporter or even to my family why we would do this especially on the sensitive issue of suicide and suicidal ideation. There were then replies from Leigh Thompson explaining the problem that they were having about coding for suicidal ideation followed by a further response from Claude Bouchy in which he stated: I personally wonder whether we are really helping the credibility of an excellent ADE system by calling overdose what a physician reports as suicide attempt and by calling depression what a physician is reporting as suicide ideation[37].

On the Stand

When the case reconvened, David Capellulo, a friend of William Forsyth's, followed Billy Forsyth onto the stand, and Bobbi Comstock, a friend of June Forsyth's, followed him. This went on through until 3 o'clock, when the jury was dismissed. I was going to be on the stand that day but not in the main Forsyth case.

Lilly was to be given yet another chance to dislodge me as an expert, in a new type of hearing that had recently crept into this kind of case - a Daubert hearing. Daubert hearings were aimed at determining whether an expert's opinions were appropriate or not. Consulting later with senior colleagues in the United States who had been involved in many medico-legal cases on issues from tardive dyskinesia through to SSRI-induced suicidality, I found none who were aware of this new beast stalking the medico-legal jungle.

None of the lawyers seemed to know what they were doing. See, whose brief was to show that I didn't have the specialized expertise to address the issues in this case, mixed up arguments about randomized controlled trials with elements of the Forsyth case. Vickery looked prepared to fight fires but unsure where they might break out. The hearing continued the following morning. Finally Judge Kay decided that my credentials as an expert witness

had been tested thoroughly enough and he was satisfied as to my ability to testify on the case[38].

The jury was reconvened and the case went ahead. The first brief involved being examined by Vickery, who went through my background and reasons for involvement in this case. How would one establish cause and effect following the intake of a drug? What was the basis for saying Prozac made William Forsyth suicidal? It was going well. It looked like it was going to be sensational to be faced with the "documents", with the jury there to listen. See objected that I had not included these documents when deposed as part of the evidence I had used to come to my opinion and that therefore they should not be allowed in now. Judge Kay agreed.

At the midday recess, a woman approached me from the press, interested to hear more about what I had to say. I agreed to meet up with her at the end of the day. The unknown power-dresser in the court hovered nearby. At the end of the day, there was no sign of the journalist, and it had become clear that the stranger in the court was handling media relations for Lilly.

Vickery's examination went through the early afternoon. He looked impressively the part compared with the man in shorts and Lei who'd met me at the airport. I felt that his rapport with the jury probably struck the right combination of cleverness and humanity. Rhonda Hawkins caught the phenomenon best when I later commented on his transformation to her. "Yep", she said, "he cleans up real good."

On cross, See opened up with a statement about my 1994 article: Dr Healy in an article you wrote "these data from several thousand patients and the evidence that fluoxetine reduces suicidal ideation, must on any scientific scale outweigh the dubious evidence of a handful of case reports." Have I quoted you correctly? I said he had. He moved quickly on to his next point. I was surprised. I had expected him to provide me with the opportunity to explain that the point was made ironically and that the follow up correspondence made this point. When he asked me had he quoted accurately, I should have said no. In the matter of second-guessing what was going to happen next, I hadn't started well.

He then presented me with a paper by Meredith Warshaw and Marty Keller[39]. This paper had been extracted from a study called the Harvard/Brown Anxiety Disorders Research Program (HARP). See emphasized the Harvard connection. He asked me to read the conclusions of this. Wasn't it correct Dr Healy that this Harvard study had concluded that there was no increased risk of suicide from Prozac? I was given some time to look at the study, which I'd never bothered to read before. I pointed out that it was a study in anxious rather than depressed patients, and involved so few patients that no conclusions could be drawn.

Later that evening when I got a chance to look at the Warshaw and Keller paper, the problems of this study became more glaring. It was a small study, involving 654 patients of whom only 191 ever got Prozac. It did not have the

power to support the conclusions that See wanted to draw from it. But it was also a study in anxious patients in which the only suicide had occurred in a non-depressed anxious patient taking Prozac. As a consequence of earlier legal jousting, there was a ban on me mentioning anything to do with people who were not depressed becoming suicidal on Prozac. But if See had introduced the issue I was free to pick up and run with the theme. I had just missed it.

The following day, See introduced a range of documents that I could dismiss as being either Lilly-sponsored publications or not peer-reviewed publications. We got into a conversation about the work of Stuart Montgomery who with David Baldwin had produced a description of two patients who had become akathisic on Prozac, which showed a dose response relationship between their Prozac and their akathisia[40]. I was invited to comment on differences there might be between Montgomery and myself. I mentioned that we didn't see eye to eye on everything but otherwise got on fairly well. Over the course of a beer that evening, Skip Murgatroyd said I'd be able to read it all next week on the Internet. I froze. What had I said about anyone?

Good Guys & Bad Guys

After an evening meal, Andy Vickery wondered whether I could get involved in other cases. He had a case against Zoloft and Pfizer, involving a 13 year old boy, Matthew Miller, who had hung himself in the bathroom in the middle of the night, next door to his parents' bedroom, after a week on treatment. I could point to lots of reasons for not getting involved. Whatever about being able to blame a suicide on a drug, there was an issue of being able to persuade the jury that the company had also been in some way negligent. This it seemed could be done for Lilly but given that Paxil and Zoloft had come after the Prozac and suicide controversy had blown up, surely Pfizer and SmithKline would have managed to avoid leaving as obvious a set of footprints through the data as Lilly had left.

Besides, it didn't seem like such a good idea for someone with a career in psychopharmacology to be at war with all of the SSRI companies. Far from criticizing Pfizer, I had been to Japan the year before to lecture following an invitation from a friend in the company, Declan Doogan.

Going back to the documents, I questioned whether things were all that they seemed. The documents painted Paul Leber in a pretty bad light, but I was far from being convinced. I knew the man. For my money he was on the side of the angels. One of the other documents showed that he was advocating a large prospective study, which would have Teicher as a consultant. It was one thing for Thompson from Lilly to think Leber was Lilly's friend and defender. But was he? Just because Thompson thought it, did that make it so?

I had first met Paul Leber at the British Association for Psychopharmacology meeting, where I had presented my Prozac cases. An imposing man. Not one to buddy up to in a hurry. I next saw him featured on a BBC Panorama program, on the Halcion controversy. There the material had been presented

in such a fashion that it appeared that while nearly everybody else thought Halcion should be withdrawn from the market, Leber was standing firm in a manner that suggested he must be in the pocket of the industry. Books like Breggin's Toxic Psychiatry had all but claimed that Leber was controlled by the drug bosses. Talking Back to Prozac a few years later painted Leber as the supposed defender of the public who in fact was the defender of the pharmaceutical companies.

By this stage I had become the Secretary of the British Association for Psychopharmacology and was involved in issuing the invitations for the annual meeting, one of which regularly went to Paul Leber. The man presented his material well. People came to hear what he had to say about things. The drug companies came because clearly this was the man who controlled their entry into the marketplace and every nuance of what he might have to say was going to be analyzed closely. Off the platform, over a drink or a meal, he turned out to be friendly and upright. This man seemed to be a genuine type who in social gatherings didn't migrate toward the people it would look good to be seen with.

During one of these meetings in 1993, he introduced me to one of his colleagues and in the course of the conversation praised a new book on psychiatric drugs I had just published[41]. He was the first person I was aware of who had read this book that had just come out. It contained a piece saying clearly that antidepressants and in particular SSRIs could trigger suicidality. He didn't say that he liked the book except for the piece on SSRIs and suicide, he just said that he liked the book.

These contacts set up a further meeting. As part of an interview series as background research on the history of psychopharmacology, later published as The Psychopharmacologists Volumes 1, 2 & 3[42], it seemed a good idea to try and interview Paul Leber. He had contributed significantly to the issue of using placebos in clinical trials with antidepressants. The first interview was in Washington in June 1994. This meant that I got to know a lot about the man. I knew where he had trained. How his career had progressed. Why he had ended up in psychiatry, having begun in pathology. I knew why he'd ended up in the FDA. In all of this I heard a forceful but not an arrogant man.

When I mentioned Breggin's Toxic Psychiatry, he became defensive. These interviews were about seducing people into saying slightly more than they would have wished to say but certainly not losing the interview because they felt they had been pushed into things. Nothing much was said. It was just that he looked more uncomfortable than I'd expected. But there were reasons to explain this. I knew that in the Halcion controversy, opponents of the drug had taken extraordinary steps to take an action against Leber himself. In the ordinary course of events he would have been protected by virtue of being a government employee, but people had found ways it seemed to get at him individually. A picture emerged of someone who really was caught between the industry on one side and pressure groups on the other but not beholden to either. It seemed a vulnerable and lonely position to be in and maybe even a physically dangerous one.

The interview was never published. He still had several years to run with the FDA and he thought it would be imprudent. He promised to give me a further interview and in 1997 we got together again for an interview that was published just before Paul Leber left the FDA[43].

So when faced with Andy Vickery seemingly convinced that Leber was Lilly's friend in the FDA, I had difficulties. From what I knew of the man, putting him in the stand might be a good idea. He more than anyone else might have sunk Lilly. We were debating all this, when I launched into the influence of the Scientologists on the whole Prozac controversy. If they hadn't intervened US psychiatry wouldn't have stood behind Lilly the way it had.

At this point Andy stopped me. Cindy, he said, was a Scientologist. More than one person in the Baum, Hedlund firm was. He wasn't. Karen Barth wasn't. Rhonda Hawkins wasn't. But there was a Scientology connection. Bill Downey had been. I was stunned. It took time to come to grips with this. Was I now working for the Scientologists?

Cindy and Bill Downey had seemed very normal people to me. But then again I liked a lot of the people whom I knew from Lilly. I had great respect for Paul Leber, but who knew which side of the debate he was on? Could these Scientologists not be reasonable people, too? Cindy gave a story of being wild when younger. Of having had a life that was spiraling out of control from which she had been rescued by becoming a Scientologist. Her life had stabilized. She'd gone on to get married and have children. She was now working solidly. How could you complain about something that had done this for someone? Whatever about what Scientologists believed, the process of becoming a Scientologist had done the same thing for Cindy that the process of becoming a Christian or a Muslim or whatever had done for others. If this was the case, there had to be decent people within Scientology also.

The line between the good guys and the bad guys was blurring fast. I then blundered into praising Paul Smith based on the depositions I'd read, only to find that in this company, Smith was not one of the good guys. These were the lawyers taking an action against Paul Smith for breach of fiduciary trust.

The Show Must Go On

The case moved on through Amy Lee, a former local representative for Lilly, to Randolph Neal, the doctor from the Castle Medical Center who'd been in charge of William Forsyth's care while he was there. At one point, Vickery and Barth had hoped he would help their case. He had expressed incredulity when seen first after the case and offered the view that it must have been done a double murder by an intruder. William Forsyth was not a man who should have committed suicide or homicide[44].

As Neal took the stand, I noticed what I thought was a knowing glance between Julie Ugalde and a man who also had come in with Neal. It turned out Neal had brought an attorney with him and she worked for an insurance

company that had been represented by this legal company and she played golf regularly with the Hawaiian defense bar.

Examined by Vickery, Neal agreed that William Forsyth had not been suicidal. He agreed in fact that Mr. Forsyth had become aware that there was some mention of him being suicidal in the notes and that he had been very upset about this, as he most definitely was not suicidal. He agreed that Mr. Forsyth and his wife seemed to be getting on very well. The examination was genteel almost. This was strange, because either Neal had made a bad mistake failing to recognize the potential for extreme violence in William Forsyth and had discharged him inappropriately, or he had failed to recognize the effects of the drugs. There was no middle ground.

See took over[45]. He set up an easel on which he was to place a series of hugely enlarged copies of the Castle medical notes for both Neal and the jury to look at. He started into a series of questions. I can be slow to notice things, but I eventually noticed when Vickery interrupted to object to the "leading nature of these questions. This man isn't really a hostile witness to Mr See". He had interrupted after the 94th question, when 83 had been essentially answered yes, no or correct. The monotony had almost sent me to sleep but now I was awake. The answers became even more monosyllabic, ending up with 135 answers that were basically yes, no, or correct with only 16 going beyond that.

See went to take down the notes; Vickery stood up and asked him to leave them there. He asked Neal if it was hard for him to believe that any drug that he gave this man could have caused him to kill his wife and himself. Things were heating up. Vickery moved on to mention that he couldn't help but notice that Dr Neal had only given three answers – yes, no or correct. Had he been coached? No.

Q. Do you feel threatened? Has anybody threatened you in anyway?
A. No.
You could have heard a pin drop. Vickery moved on to ask "Why do you have your attorney here?" Neal replied that he had involved one from the beginning. Vickery then went back through the notes See had just worked his way through, dismantling Neal's testimony as he went. Then he went on to the final enlargement, which showed the discharge summary.
Q. The other document that you, as a doctor, dictate with respect to someone is the one when they get out, right?
A. Correct
Q. And you usually do that right away?
A. Sometimes I don't do it right away.
Q. You didn't in this case, did you?
A I did not.
Q. You didn't dictate your discharge summary until 20 days after this man was dead, did you?
A. That's correct.
Q. And you didn't dictate your discharge summary until after you already had a lawyer advising you, isn't that true sir?

A. That probably is correct.
Q. And is it not true, sir, that the lawyer that was advising you at the time you dictated the discharge summary was with Mr Burke's law firm that's representing Lilly in this case?
A. I believe that is correct.
Q. Now you said some things in this discharge summary that really help Eli Lilly, didn't you?
A. I don't know.
Q. Well you said, for example 'At the time of discharge, he was requesting to be discharged because he was in a hurry to get back to Maui to take care of business, and although it was my feeling that he might benefit from a couple more days' stay, he did not request to live."
After noting the Freudian slip about not requesting to live, Vickery confronted Neal with his handwritten notes the day before William Forsyth had left the hospital. Notes that said nothing about believing William Forsyth should stay in hospital. Notes that mentioned stopping the tranquilizer, Xanax, he had been on – not the kind of move that was consistent with feeling this was a man at risk. Vickery closed by asking Neal if he had warned Forsyth that he must continue to take the Inderal[46] that he had been put on. No, he hadn't.

This was marvelous theater. Any jury would have had to be impressed. I'd never seen anything quite like it. It was brief, but Neal had been eviscerated. However, the person most pleased in the courtroom was probably See.

At this stage I'd been there for an emotional roller-coaster of a week. For the rest of the people involved the ride wasn't over. Ron Shlensky was due to take the stand on Monday, as the next expert for the Forsyths. As an old-hand, he was amazed the trial was happening - no one could go through too many rides like this. I wondered if See and Mangrum were hunkered down in their bunker getting as deeply involved as the Forsyth team was.

I had updates over the next two weeks, on how Vickery was doing cross-examining people like Gary Tollefson from Lilly. Tollefson had joined Lilly in 1991 after the Prozac story had blown up. Vickery had wanted Beasley brought to the Court but Lilly refused to provide him and, to the surprise of Judge Kay as it had been to Judge Potter in Kentucky before him, they were apparently under no obligation to produce him. Leigh Thompson had left the company after the Wesbecker case. Tollefson had not been there when the documents that were at the heart of the case had been generated. Judge Kay ruled that some of the internal documents could not be admitted. It was a relatively easy matter to testify truthfully to many of the rest of them to not knowing exactly what they meant.

Tollefson was also faced with correspondence he had sent to the American Journal of Psychiatry complaining about the medico-legal precedent the Teicher report might have introduced. The theory was preliminary and potentially counter-productive, he had written. Teicher and Cole had replied with concern at the implication they should not bring things to clinicians' attention?[47] The letter had been written when Tollefson was seemingly an independent academic, but several months later he was a Lilly employee.

The next witness for Lilly was a professor of forensic psychiatry in Hawaii, Daryl Matthews[48]. On cross-examination from Vickery, some key issues emerged:
Q. Do you believe that if he had been kept in the hospital longer, that he would be alive today?
A. I think a lot would have depended on how he was treated and what happened in the course of his depression. He was suffering from a severe depression. He was discharged still severely depressed, and I think if his depression had been in remission, had been gone, that this would not have occurred.

Matthews had earlier criticized the fact that Williams Forsyth's Xanax had been halted - "Finally, it is noteworthy that Mr. Forsyth was discharged without Xanax as described above. He disliked the idea of taking Xanax. It may have well been helpful in reducing his symptoms."
Vickery was later to ask: Do you stand by that report?
A. I do.
Q. Do you stand by your testimony this morning that no more Xanax is one of the substantial factors that contributed to the deaths of Bill and June Forsyth?
A. I think it's probably true, yes.

See in opening for the defense had made an issue about the package insert for Prozac being enough. One of Lilly's witnesses was Byron Eliashoff, a psychiatrist in private practice in Honolulu. Vickery presented him with a copy of the package insert and a yellow highlighter pen[49].
Q. Doctor, .. I have, on page 2, highlighted .. the warning section. What I'd like for you to do, if you would, is find those warnings that Mr. See was asking you about that deal with akathisia or suicide or any of the kind of things that you think they have given proper warnings about, and highlight them in that document for me.
A. I believe in this earlier version of the drug insert, I don't believe there is a reference to akathisia. I'll have to read this. Do you have a larger copy? I'm having trouble reading this.
Q. I know. That's a problem for the prescribing physicians, too, isn't it, sir?
A. Not if they have time.
Q. Okay. Well, take your time because you've just sworn that this is an adequate warning, so take your time, if you would, and just highlight for us in yellow where the warnings are about this problem.
A. There's no reference in this section to suicide.
Q. Is there a reference to akathisia?
A. No, there is not.
Q. So at least in the warning's section of the package insert, there is nothing about either of those two things at the time this drug was prescribed for Mr. and Mrs. Forsyth; is that true?
A. Yes.
Q. Okay, sir. Now, you have testified, just a few minutes ago, that this package insert contains some warnings somewhere that fully apprise prescribing physicians of the dangers of akathisia or suicide, so all I'm asking

you to do is to find the language in there upon which you base your opinion that it's fully apprising them.
A. What I'm about to say is that the package insert is adequate for prescribing. It does not mention suicide because suicide is not a risk of using Prozac.
Judge Kay: Mr. Vickery wants you to read through the rest of the insert.
A. Well, I don't see a place to - - where akathisia or suicide is mentioned to highlight.
Q. Let's see if I can help you. I have now highlighted for you the precaution section. Is that different from the warning section?
A. Yes.
Q. And I highlighted for you what Eli Lilly had to say about suicide in the precaution section. Would you just read that for me the section about suicide or akathisia…..
A. "Suicide, the possibility of a suicide attempt is inherent in depression and may persist until significant remissions occur. Close supervision of high-risk patients should accompany initial drug therapy. Prescriptions for Prozac should be written for the smallest quantity of capsules consistent with good patient management in order to reduce the risk of overdose."
Q. Now, that doesn't say anything about Prozac causing either akathisia or suicide for some patients, does it?
A. That's correct.
Q. And, in fact, when it talks about overdose or prescriptions written for small numbers, the bells that go off in your head are overdose bells, don't they?
A. Yes. Well, that's part of it. Also, the reminder that suicide is inherent in depression.
Q. Which, of course, you knew as a psychiatrist anyway?.. Dr. Eliashof, are you able to point in that document, sir, in the entire document, anywhere in that document to where there's some warning about akathisia?
A. Did you highlight it for me?
Q. No, sir, I didn't do that one for me because I'm not the one that swore that it was adequate.

These exchanges did a lot to build the confidence of the Forsyth team, despite their failure to get the documents in. The highlighter pen had stood embarrassingly beside Eliashoff on the witness stand. Viktor Reus, a professor of psychiatry in San Francisco, another witness for Lilly had been faced with a Pfizer article by Roger Lane stating that akathisia could lead to suicide[50]. Reus conceded that SSRIs could cause akathisia. See later suggested to Vickery that this article was an attempt by Pfizer to skewer Lilly[51].

But See was not without his winners. Both William and June Forsyth had kept diaries. Many of the entries were from a time period well removed from the events of March 1993, which could be mined for dark forebodings of what was to come. These See picked over with Matthews. Nothing about them seemed much a problem to me. But absolutely normal people put all sorts of strange things into diaries and the Forsyth diaries could be certainly be used to portray an unhappy state of mind.

See's summing up stressed familiar messages -- Prozac was the most studied drug in history[52]. Major depression was a terrible illness that caused terrible things. William Forsyth never had akathisia. Lilly had offered sufficient warnings consistent with the evidence. They had also done tons of epidemiological studies. Throughout he came back to the testimony of Dr Healy -- it took up over a quarter of his summing up. To underline the contrast between Lilly's approach and mine, he threw in a predictable friend: "these data from several thousand patients and the evidence that fluoxetine reduces suicidal ideation must, on any scientific scale, outweigh the dubious evidence of a handful of case reports."

Vickery objected that See had never questioned me on this issue. See said he had. Judge Kay remembered that the issue had come up but nothing more about it. See was allowed proceed. "Questioning me" was a fascinating description of our brief exchange on this point.

Vickery's summing up finished on Billy Forsyth's efforts to go to Indianapolis and stick messages on the cars of Lilly employees and Susan's efforts to set up a Prozac Survivors' Group. Isn't this what you would do if you wanted to protect patients rather than just protect Prozac? If your priority is to save lives, you establish an Internet site and man an 800 number. If your priority is to try to get the company to warn doctors, you sit here and listen to your family get dragged through the mud.

The Verdict

The jury recessed. The stakes were huge. As I understood it, Lilly stood to lose up to $20 million. Not only that but the court would then go into a punitive damages phase. At this point among Vickery's options was to introduce a videotaped testimony from Judge Potter of the Wesbecker case. Potter would recount the story of how Lilly had settled the Wesbecker case but had managed to fool him and everyone else into thinking that the case had gone to a verdict. He would describe Lilly's efforts to block his scrutinizing the outcome and his final victory in having the verdict re-classified from won to settled. This and other testimony was likely to be extremely damaging to Lilly, which had just paid another company, Sepracor, $90 million, for the rights for one of the enantiomers of fluoxetine, a drug on which they could take out a new patent and have a genuine son of Prozac. Vickery would argue that setting a $90 million price tag on a molecule, from which Lilly might later earn up to $2 billion per year, also set a benchmark for punitive damages in the Forsyth case.

The jury went into recess. The first indications were not encouraging. According to Skip, they weren't asking for the right documents. If they'd asked for the documents early on, this would have been a good indicator that they had made their minds up that Lilly was guilty and wanted to confirm that. Perhaps they were going to take a long time deliberating and then get round to asking for the documents. But if they took a long time deliberating, the judge had an option to introduce a detonator. He could force them to make up their mind. Finally they began to ask for the documents. Judge Kay,

however, decided that while some documents could be shown in court, the jury couldn't access them

After two days, late on a Good Friday afternoon, the jury returned. There had been confusion. Apparently the judge had sent a letter to the jury requesting them to close their deliberations as soon as possible. The jury, it seems, had misinterpreted this. Federal court rules as they applied in this case, unlike the Wesbecker case in Kentucky, required unanimity. It seemed that some members of the jury believed that they had to come to an 11-0 verdict. It had become clear they could never come to an 11-0 verdict against Lilly and Prozac. This began to sway others. It was Easter weekend and they would have to stay there over the weekend.

On the Easter Saturday, I got a telephone call from Good Friday in Hawaii that the verdict had been in favor of Lilly. Vickery's brief call conveyed a sense of disbelief. Ten thousand miles away I was insulated. I could only guess what the mood in the bunker was like. What had happened?

I began to hear disjointedly from several members of the Forsyth team. After getting back to headquarters, they received a phone call from one of the jurors, Donna Grain, an older woman, unhappy at the verdict. She talked about pressure on her to vote for the defense. She filed an affidavit. Another juror Glen Mayeshiro followed two days later. Both would have voted for the Forsyths. Two others would also it seemed. But there was more.

In brief, the story that came out in the affidavits was that the initial jury vote had been 9-2 against Lilly and Prozac with only Julie Ugalde and Daniel Hong voting for Lilly. The affidavits suggested that Ugalde, from close to the start of the trial, had indicated that she was going to find it difficult to find against Lilly. This ran counter to the oath she had taken at the start that she could find either way. Armed with his affidavits, Vickery approached Judge Kay and filed motions for hearing on juror misconduct. A wholly unusual development. The hearing was held on July 1st 1999.

Julie Ugalde had been involved in a medical practice lawsuit against a doctor who had failed to warn about a possible drug hazard that had left her mother brain-damaged[53]. Donna Grain swore that Ugalde "seemed to base her decision about the doctors in this case being at fault on her own personal experience rather than on the evidence. She said that she did not trust any doctors and, if the Forsyths wanted money, they should sue the doctors not the drug company." Grain and Mayeshiro swore they had also heard her say she had a family member who had benefited from a new AIDS medication and for this reason she would never award damages against a pharmaceutical company. Counsel for Lilly argued that snatches of conversation had been misinterpreted by two jurors, but this was hard to reconcile with the fact that during the course of the trial the Court Reporter, Tina Stuhr, had raised with the plaintiffs' attorneys the possibility of getting one of the jurors removed -- Ugalde. Stuhr was concerned that Ugalde was not listening to the witnesses for the plaintiffs. Would in fact barely look at them. During Billy Forsyth's testimony she seemed openly hostile.

After hearing the testimonies, Kay finally ruled that this was just one of the hazards of the jury system. But, this hearing had gone to the heart of what had gone on in the jury room. The action taken had been solely against Eli Lilly. The Forsyths did not want either Randolph Neal or Riggs Roberts included in the action. People, it seems, don't want to sue their doctors.

Lilly, however, had implicated Randolph Neal in what had happened, with Matthews, their expert, testifying that had the Xanax not been stopped and if William Forsyth had been monitored properly, there was every chance he would still be alive. But almost the only clear reason why this would have been so was if Xanax was managing a Prozac-induced problem. This was exactly what the Germans had required to be in the labeling for Prozac, when it was finally licensed:

> Contraindications – Risk Patients – Risk of Suicide: "Fluctin does not have a general sedative effect on the central nervous system. Therefore, for his/her own safety, the patient must be sufficiently observed, until the antidepressive effect of Fluctin sets in. Taking an additional sedative may be necessary"[54].

Faced with Matthews' testimony on warnings in the trial, Vickery had tried yet again to bring the German warning into play, but Kay had overruled him.

Based on this, on April 20th, the Forsyth team filed a motion for an appeal based on a number of grounds. One was a claim that Alan Kay had misinterpreted or been unaware of important details of Hawaiian law, which imposed a strict product liability as the cost of doing business. Lilly had tried to water this down to responsibility for "danger that was known or knowable in light of the best scientific and medical knowledge available at the time of manufacture and distribution"[55]. Vickery had argued that this was a mistake and that under Hawaiian law, the focus was not on what Lilly knew but rather on what the doctors did not know. That under Hawaiian law a "product is defective if it contains substances that are dangerous to the user and does not contain directions or warnings regarding dangers in its use [that] were known or by the use of reasonabl[y] developed human foresight could have been known." The one possible exclusion from this might be in the area of prescription drugs – which in part were available on prescription supposedly because they were unavoidably unsafe.

The other main ground for appeal lay in the exclusion by Judge Kay of key documents such as the German warning or the memorandum by David Graham of the FDA, which offered the views that Lilly's trials were not intended to address the question of suicidality, that the Fava and Rosenbaum study supported an association between Prozac and suicidality and that there were flaws in the Beasley paper in the BMJ. Even though I had used some of the documents in replying to Lilly motions to have me disbarred, I wasn't allowed to testify to any of them in trial. Of 150 exhibits, Judge Kay had excluded 40 outright and made 17 available for cross-examination only. Not only did I not get a chance to comment on them but when jurors, faced with Ugalde asking them to show her the documentary evidence that there was any problem with Prozac, asked for 15 documents, they found they could only

be shown 1. Documents such as the memos on Lilly's strategy to blame the disease not the drug were denied to them.

As it turned out, there were even stronger grounds on which to appeal, which the Forsyth team missed. Vickery had in the course of the trial registered but had not appreciated the significance of another player in the courtroom -- Doug Norman. A patent lawyer working for Lilly. What was he doing at this trial?

[1] Healy D. The Psychopharmacologists, Chapman & Hall, London (1996)
[2] Based on depositions of Susan Forsyth 2/29/96; Riggs Roberts 3/4/96; Deborah Mihalek 3/6/96; Thomas Brady 3/6/96; Randolph Neal 3/8/96; Ann Blanchard 8/15/96; Mark Barrett 8/15/96; Kathleen Iannitello 8/15/96; Barbara Comstock 8/16/96; William Forsyth Jr 8/19/96; Jennifer Capelouto 9/18/1996;
[3] Quotes taken from Healy deposition in Forsyth Vs Eli Lilly, July 11th 1997.
[4] Healy D. The fluoxetine and suicide controversy. CNS Drugs 1, 223-231 (1994)
[5] Hoover C (1990). Additional cases of suicidal ideation associated with fluoxetine. American Journal of Psychiatry 147: 1570-1571 (1990). Hoover C
[6] With a review like this the author will often know who the reviewer is from aspects of their writing style, their arguments or even the font they print in. Being polite to this person when next you meet is all part of the game. In this case it was pretty obvious who the reviewer was.
[7] Healy D, Langmaak C, Savage M. Suicide in the Course of the Treatment of Depression. Journal of Psychopharmacology 13, 94-99 (1999)
[8] Jick S, Dean AD, Jick H. Antidepressants and suicide. British Medical Journal 310: 215-218 (1995)
[9] Guze S, Robins E. Suicide and primary affective disorder: a study of 95 cases. British Journal of Psychiatry 117, 437-438 (1970)
[10] Inskip HM, Harris EC, Barraclough B. Lifetime risk of suicide for affective disorder, alcoholism and schizophrenia. British Journal of Psychiatry 172, 35-37 (1998)
[11] Boardman AP, Grimbaldeston AH, Handley C, Jones PW, Willmott S. The North Staffordshire Suicide Study: a case-control study of suicide in one health district. *Psychological Medicine*, 29, 27-33 (1999)
[12] Data presented at British Association for Psychopharmacology Annual Meeting, Harrogate, July 1999. Boardman A, Healy D. Modeling suicide risk in affective disorders. European Psychiatry 16, 400-405 (2001).
[13] Weel-Baumgarten, E. van, Den Bosch, W. van, Den Hoogen, H. van, Zitman, F.G.. Ten year follow up of depression after diagnosis in general practice. *British Journal of General Practice*, 48, 1643-1646 (1998)
[14] Hagnell, O., Lanke, J., Rorsman, B.. Suicide rates in the Lundby study: mental illness as a risk factor for suicide. *Neuropsychobiology*, 7, 248-253 (1981)
[15] Simon GE, VonKorff M (1998). Suicide mortality among patients treated for depression in an insured population. American J Epidemiology 147, 155-160.
[16] Jick H, Ulcickas M, Dean A. Comparison of frequencies of suicidal tendencies among patients receiving fluoxetine, lofepramine, mianserin or trazodone. Pharmacotherapy 12, 451-454 (1992)
[17] Details of the two companies can be got on the Web on justiceseekers.com and bhagd.com.
[18] Fluoxetine Project Team Meeting Minutes August 1978. Exhibit 30 in Forsyth Vs Eli Lilly
[19] Fluoxetine Project Team Meeting Minutes July 23rd 1979.
[20] March 6, 1992 - German package insert (translation) - “Contraindications - Risk Patients - Risk of Suicide:”FLUCTIN (Prozac) does not have a general sedative effect on the central nervous system. Therefore, for his/her own safety, the patient must be sufficiently observed, until the antidepressive effect of FLUCTIN sets in. Taking an additional sedative may be necessary. This also applies in cases of extreme sleep disturbances or excitability.” (Exhibit 5 to Beasley Deposition).
[21] Memo by Dr J Wernicke 7/2/86. Exhibit 69 in Forsyth Vs Eli Lilly.
[22] Healy D, Creaney W. Antidepressant induced suicidal ideation. British Medical Journal 303, 1058-1059 (1991)
[23] Beasley C. British Medical Journal 303, 1059 (1991)
[24] Heiligenstein J. Memorandum to L Thompson. September 14th Exhibit 110 in Forsyth Vs Eli Lilly (1990)
[25] October 3rd 1986 memorandum from J Wernicke: Fluoxetine Suicides and Suicide Attempts. Exhibit 73 in Fentress Vs Eli Lilly.
[26] These documents unless otherwise stated were also exhibits in the Fentress case or in depositions associated with that case. Further details of each of these exhibits can be obtained on the company websites or from the legal offices of Nancy Zettler.

[27] Heiligenstein J. Plaintiff's exhibit 110 in Forsyth Vs Eli Lilly, Memo dated 14/9/90 from Lilly's Dr J Heiligenstein to Dr L Thompson 1990.
[28] Daniels E. Memo 15/4/91, to Leigh Thompson coaching for a television appearance, Forsyth Vs Eli Lilly, Plaintiffs' exhibit 123, 1991. See also deposition of Leigh Thompson in Fentress Vs Eli Lilly.
[29] June 1990 letter to Lilly by concerned physician – "some of these cases appear to be in patients taking Prozac for reasons other than depression." Exhibit 102 in Forsyth Vs Eli Lilly.
[30] Internal FDA memo Oct 23rd 1986, Exhibit 74 in Forsyth Vs Eli Lilly.
[31] February 7th 1990. Leigh Thompson memo, Exhibit 98 in Forsyth Vs Eli Lilly.
[32] March 26th 1990 Letter by Lilly to FDA, Exhibit 102 in Forsyth Vs Eli Lilly.
[33] Laughren TP, Levine J, Levine JG, Thompson WL. Premarketing safety evaluation of psychotropic drugs. In Prien RF, Robinson DS (eds.). Clinical Evaluation of Psychotropic Drugs. pp. 185-215 (1994)
[34] July 18th 1990, Memo regarding call from Paul Leber. Exhibit 104 in Forsyth Vs Eli Lilly.
[35] Sept 12th 1990, Lilly memo between Max Talbott (formerly of the FDA) and Leigh Thompson. Exhibit 109 in Forsyth Vs Eli Lilly.
[36] November 13th 1990, Memo from Claude Bouchy to Leigh Thompson. Exhibit 117 in Forsyth Vs Eli Lilly.
[37] November 14th 1990, Memo from Claude Bouchy to Leigh Thompson. Exhibit 118 in Forsyth Vs Eli Lilly.
[38] Forsyth trial transcript 3/9/99 to 3/12/99.
[39] Warshaw MG, Keller MB. The relationship between fluoxetine use and suicidal behavior in 654 subjects with anxiety disorders. Journal of Clinical Psychiatry 57, 158-166 (1996)
[40] Baldwin DS, Fineberg NA, Montgomery S. Fluoxetine, fluvoxamine and extra-pyramidal tract disorders. Int Clinical Psychopharmacology 6, 51-58 (1991)
[41] Healy D. Psychiatric Drugs Explained. Mosby Yearbooks Ltd, London. Second Edition 1996. (1993)
[42] Healy D. The Psychopharmacologists. Vol 1 (1996); Volume 2 (1998); Volume 3, Arnold, London. (2000)
[43] Leber P. Managing uncertainty. In Healy D, The Psychopharmacologists vol 2, Arnold, London pp. 607-622 (1998)
[44] Neal R. Deposition of Randolph Neal in Forsyth Vs Eli Lilly (1996)
[45] Forsyth Trial Transcript. From 3/12/99.
[46] Inderal is propranolol, a beta-blocker that Rothschild and Locke had reported eased Prozac induced akathisia.
[47] Tollefson G. Fluoxetine and suicidal ideation. American Journal of Psychiatry 147, 1691-1692 (1990); Teicher M, Glod CA, Cole JO. Dr Teicher and associates reply. American Journal of Psychiatry. 147, 1692-1693 (1990)
[48] Forsyth Vs Eli Lilly, Trial Transcript 3/23/1999.
[49] Forsyth Vs Eli Lilly, Trial Transcript 3/24/1999.
[50] Lane RM. SSRI-induced extrapyramidal side effects and akathisia: implications for treatment. J Psychopharmacology 12: 192-214 (1998)
[51] Personal communication from A Vickery. Whatever the reason for the Lane article, any senior contacts within the pharmaceutical I have asked about this article have suggested that there is no way this article could have gone forward for publication without senior figures in Pfizer knowing about it.
[52] Forsyth Vs Eli Lilly Trial Transcript, closing statements 3/30/1999.
[53] Evidentiary hearings to determine allegations of juror misconduct, Honolulu, Hawaii Transcript July 1st, 1999.
[54] March 6, 1992 - German package insert (translation) - "Contraindications - Risk Patients - Risk of Suicide:"Fluctin does not have a general sedative effect on the central nervous system. Therefore, for his/her own safety, the patient must be sufficiently observed, until the antidepressive effect of Fluctin sets in. Taking an additional sedative may be necessary. This also applies in cases of extreme sleep disturbances or excitability." (Exhibit 5 to Beasley Deposition).
[55] Appeal Brief, Forsyth Vs Eli Lilly April 20th 2000.