

KILLER SIDE EFFECTS



What GlaxoSmithKline Does Not Seem to Want Anyone to Know About Paxil

Individuals of all ages should be closely monitored for suicidal and homicidal thoughts and behaviours for at least 1-month after they start taking Paxil and after they increase their dosage. They should also be closely monitored after they stop taking Paxil.

By David Carmichael

*Dedicated to Ian James Carmichael 1992-2004
My son who I love and miss very much*

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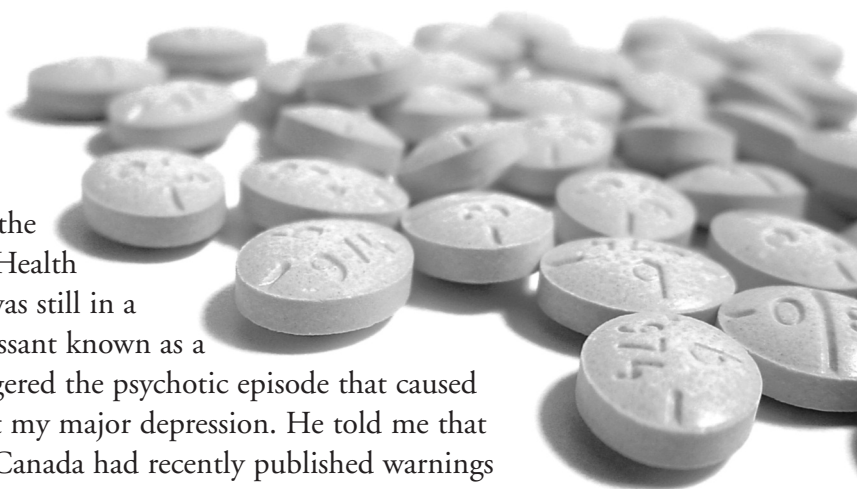
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Becoming aware of SSRI-induced psychosis

In February 2005, Dr. Hector, a forensic psychiatrist at the Secure Treatment Unit (STU) at the Brockville Mental Health Centre (BMHC) in Ontario, Canada, told me while I was still in a severe state of depression that Paxil, a popular antidepressant known as a selective serotonin reuptake inhibitor (SSRI), likely triggered the psychotic episode that caused me to kill my 11-year-old son Ian on July 31, 2004, not my major depression. He told me that the Food and Drug Administration (FDA) and Health Canada had recently published warnings about SSRIs and suicide. To support his view, Jim, a psychiatric nurse, brought me a photocopy of a few pages from the 1996 edition of the Compendium of Pharmaceuticals and Specialties (CPS), a guide for doctors published by the Canadian Pharmacists Association that lists all of the potential side effects of prescription drugs. Sure enough, delusions and psychosis were listed as rare side effects of Paxil, which means that GlaxoSmithKline, the manufacturer of Paxil, acknowledges that 1 in 1,000 people may become delusional and experience a psychotic episode while on the drug.



Dr. Hector had me taking 3 antidepressants (Effexor, Trazodone and Remeron) when he told me that Paxil probably triggered my acute homicidal psychotic episode. Looking back, I think Dr. Hector thought that this information might bring me out of my major depression more quickly than medication or, what he was seriously considering, electroconvulsive therapy. He was right. After 6 months of suffering through tremendous confusion and debilitating feelings of shame and guilt, I became angry, which seemed to help me recover. I wondered why I was not aware that I was playing a deadly lottery with Paxil; why my doctor did not know that psychosis (i.e., hallucinations and/or delusions) was a possible side effect of Paxil when he first prescribed me the drug in 2003; why the drug information given to me with my prescription did not list the most dangerous and potentially lethal side effects; and why the Canadian bestseller Guide to Drugs in Canada, published by the Canadian Pharmacists Association, did not identify delusions and psychosis as side effects of Paxil.

I will never know if I was that 1 in 1,000 and if Paxil did indeed make me severely delusional. There does, however, seem to be consensus among the forensic psychiatrists that I have seen since August 2004 that nobody knows exactly what triggers psychosis. If illegal psychotropic drugs such as marijuana, LSD, cocaine, and methamphetamine can trigger an acute psychotic episode that causes people to commit suicide and/or homicide, it seems reasonable to assume that Paxil, a prescribed psychotropic drug, can also trigger a violent psychotic episode.

Linking SSRI-induced suicide and homicide

The major differences between someone who commits suicide and/or homicide while experiencing SSRI-induced psychosis seems to be their delusions, or fixed-false beliefs, that prompts them to harm themselves and/or others.

In April and May 2008, I met with the family and friends of 18-year-old Nadia Kajouji, a Carleton University student who committed suicide 3 weeks after starting the SSRI Cipralext. Based on my understanding, her reaction to Cipralext was similar to my own on Paxil. After we both started taking a SSRI, we experienced the wind before the calm before the storm – which seemed to be a regression of adverse side effects from the agitated state of akathisia to severe psychosis.

The Wind

Within a week after Nadia started taking Cipralex, she was anxiously walking around her residence at Carleton University and crying for help. She apparently even told a security officer that she was severely anxious and having suicidal thoughts and that she needed help. Apparently, her cries for help were ignored.

Within the first few days after I started taking 40mg of Paxil, my anxiety got worse. I was agitated and irritated and had difficulty sitting still. My mind was racing with suicidal thoughts, so I increased my dosage. I knew that I could not commit suicide because of my family responsibilities. I thought increasing my dosage would help me get better sooner.

The Calm

The night before Nadia disappeared, she went skating on the Rideau Canal in Ottawa with a university friend. He told me that she seemed normal and was energetic. They skated for several kilometers on the canal. He told me that Nadia seemed to be stable and in a good mood. To him, she appeared to be recovering from what was previously diagnosed by a campus doctor as depression.

The increased dosage progressively decreased my anxiety, agitation and irritability. But I became increasingly delusional and psychotic. I started planning my suicide, then a murder-suicide until I eventually planned the murder of Ian. I was calm, organized and my concentration was improving. I went to business meetings and searched the internet to find out that I would have to spend at least 25 years in prison for killing Ian. Meanwhile, my wife Elizabeth was thinking that I was recovering from my depression like I did in 2003.

The Storm

Nadia disappeared on March 9, 2008. Late that night she told her friends she was going skating on the Rideau Canal again. Nadia apparently committed suicide by jumping off a bridge into the Rideau River. She did not leave a suicide note. Nadia might have thought that her family would understand why she committed suicide. Her room was left tidy and clean. Her father told me that she even made her bed before she disappeared, which was something they were often encouraging her to do at home. Her body was found in the Rideau River on April 20, 2008.

I killed Ian in the middle of the night on July 31, 2004. At 6:30am, I shaved, showered and took off my wedding ring. I didn't want the police to have it, so I put it in my bag, which I thought would end up with my wife Elizabeth. At 7:30, I packed up Ian's bag and my own. I took both bags to the van. At 9:00, I called 911. I calmly told the dispatcher that I was reporting a homicide, and that I had killed by son. She kept me on the line. I told her that I was not suicidal. Towards the end of the call, I moved away from the phone to put a plastic cup under the door so the door would be open for the police. I thought my family would understand why I killed Ian. The most difficult thing for me to hear was when a former boss visited me at the London Middlesex Detention Centre on August 3 and told me that my wife Elizabeth would never forgive me. In my psychotic state, I thought that Elizabeth and my daughter Gillian would be thanking me for saving Ian from a life of hell and for saving their lives. I was confused and devastated.

Validating Paxil-induced homicide

Within the first 10 days after I killed Ian (and while I was still severely psychotic), my lawyer hired a team of medical specialists to collect empirical evidence to help prove that my "psychotic episode" was triggered by my "major depression". This evidence was supposed to support the anecdotal evidence that the London Police collected from talking with my family, friends and colleagues indicating that I was in a major depression just before I killed Ian, which was the basis for my "not criminally responsible" defense. None of the evidence that my lawyer collected was presented at my trial probably because it would have been confusing to the Judge:

- I was not in a major depression a few days after I killed Ian according to my results from the Minnesota Multiphasic Personality Inventory (MMPI).
- My concentration was high a few days after I killed Ian, which is contrary to one of the major indicators of major depression (i.e., diminished ability to think or concentrate). I completed the MMPI in about 45 minutes. Comparatively - when I was being assessed at the Royal Ottawa Mental Health Centre (ROMHC) in early November 2004 - after not being properly treated for my major depression for 4 months at the London Middlesex Detention Centre and in the worst depressive state of my life - it took me about 3.5 hours over 2 days to complete the MMPI (with the results indicating that I was in a major depression).
- I scored very high on an IQ test a few days after I killed Ian - probably much higher than normal, which is contrary to being in a major depression.
- The psychiatrist at the London Middlesex Detention Centre reported that I was not psychotic when I killed Ian because I was not hallucinating (i.e., hearing voices or seeing things). He thought it was a mercy killing based on my 5 delusions that Ian was:
 1. In living hell
 2. Permanently brain damaged
 3. Going to kill my daughter
 4. Going to cause my wife to have a nervous breakdown
 5. Going to hurt other children
- My lawyer hired a forensic psychiatrist who met with me twice within 10 days of killing Ian. He could not report that I was psychotic at the time. My delusions were still strong for about 14-days after I killed Ian - and stopped taking Paxil.

According to Andy Vickery, a trial lawyer from Houston, Texas, big chemical drug pharmaceutical companies argue in wrongful death claims involving SSRIs that suicides and/or homicides are triggered by the "disease" (e.g., major depression), not the "drug". The evidence that my lawyer collected immediately after I killed Ian contradicts this argument. My "psychosis" was not triggered by my "major depression". Results from the psychometric tests indicate that I was not in a major depression at the time of the killing. It appears that Paxil shot me out of my depression into a severe psychotic state within 3-weeks of starting the drug and within 2-weeks of increasing my dosage from 40 to 60mg a day.

Finding a purpose

When I became aware that Paxil might have triggered my violent psychotic episode, I asked a few friends to ask their family doctors if the drug can cause psychosis. Some of the doctors did not even know what psychosis was and all of them were not aware that delusions and psychosis were listed in the Compendium of Pharmaceuticals and Specialties (CPS) as side effects of Paxil, even though this guide was in their offices. A few of the doctors even stated that Paxil could not trigger a psychotic episode.

A purpose became clear - I wanted to help educate the public, including doctors, about the most dangerous and potentially lethal side effects of Paxil.

Risking my freedom

Jim was an amazing resource while I was at the Secure Treatment Centre (STU) in Brockville from January to April 2005. After he shared the information with me from the Compendium of Pharmaceuticals and Specialties (CPS) in February, he warned me that speaking out about Paxil may prevent me from getting my freedom back. He shared a story about Dr. David Healy, one of the leading psychiatrists in the world who had his job offer rescinded in November 2000 as the Director of the Mood and Anxiety Disorders Clinic at the Centre for Addiction and Mental Health (CAMH) at the University of Toronto after speaking out publicly about some of the potentially lethal side effects of Prozac and other SSRIs. Jim even brought me a photocopy of the transcript from a 2001 CBC Current Affairs documentary on The National with Peter Mansbridge about Dr. Healy. It made me aware of how risky it might be for me to speak out publicly about Paxil until after my trial, and possibly until after I received an absolute discharge as a patient in the Ontario forensic psychiatric system.

CBC NEWS AND CURRENT AFFAIRS

TUESDAY JUNE 12, 2001

Introduction

PETER MANSBRIDGE: Tonight. The race is on. The unofficial launch of the Canadian Alliance leadership campaign. Too close to home. Children and pregnant women in Sydney, Nova Scotia, get tested for toxins. And gopher broke. Why Saskatchewan farmers are taking drastic action against these critters. Plus "Hard to Swallow."

UNIDENTIFIED MAN (1): I'm in the business of using these drugs to treat people.

MANSBRIDGE: He's a leading expert on antidepressant drugs such as Prozac. So why did one of Canada's top research centres suddenly leave him high and dry?

UNIDENTIFIED MAN (2): We feel that a number of his views could affect the quality of patient care.

MANSBRIDGE: A feature documentary.

ANNOUNCER: The National. From the Canadian Broadcasting Centre, here is Peter Mansbridge.

Dr. David Healy Affair

PETER MANSBRIDGE: The Centre for Addiction and Mental Health is one of the country's top research centres. It's affiliated with the University of Toronto. And recently it was rocked by a bitter controversy surrounding this man, Dr. David Healy. He's an expert on antidepressant drugs such as Prozac and the centre offered him a prestigious job. But then suddenly it changed its mind. The decision the critics say was influenced by the centre's relationship with powerful drug companies. Darrow MacIntyre has this feature documentary.

DARROW MACINTYRE: A quiet, small town in North Wales. It seems an unlikely place to find a man like David Healy, university professor and psychiatrist, renowned in medical circles from New York to Paris to London as one of Europe's eminent scientists. This time last year, Healy was about to leave Wales. Lured to Toronto by this university teaching hospital, the Centre for Addiction and Mental Health and the promise of his own research clinic there. Then one day last November, something strange happened. After almost two years of courting Dr. Healy and finally offering him the big job, senior staff at the centre abruptly decided to dump him. They say they found out just in a nick of time that Healy held certain unscientific views about a number of psychiatric drugs, views they say could harm patient care. But many in the academic community think their decision had less to do with science and more to do with money. What this is really about, they say, is the role drug companies play in influencing scientific debate. When it comes to antidepressants there are few people who know more than Dr. Healy. Especially about a group of drugs called SSRIs or Selective Serotonin Reuptake Inhibitors. The best known of these is Prozac, the most widely prescribed antidepressant in the world. But for a decade now, research has suggested that drugs like Prozac may actually cause some people to have suicidal urges. Nobody really knows how often, but Healy thinks often enough to be concerned.

DAVID HEALY: Let's say in the case of Prozac that it causes the problem; it will cause people to commit suicide at a rate of 1 in 1,000 people who actually go on the drug. To most people here a figure like that, that sounds like a fairly low figure. It sounds like a reasonable trade-off almost. But if 50 million people go on the drug, then that becomes 50,000 suicides which is maybe higher than there has been, but it becomes an awfully big figure. It's what the FDA call the public health multiplier which is a small hazard distributed among millions of people becomes a big problem.

MACINTYRE: Recently David Healy conducted studies aimed at trying to figure out just who is at risk and who isn't. Are you opposed to the use of SSRIs?

HEALY: Absolutely not. No. My Ph.D. thesis was on the serotonin reuptake system and I've been, I was one of the people when the SSRIs came out first who would have been much quicker than most of the rest of my colleagues to use this new group of drugs. I continue to put a very large number of people that I see on the drugs. And I believe as the research that we've done indicates that if you're really going to use the drugs properly and I'm in the business of using these drugs to treat people, is you're really going to find out who does well on these drugs, what you find out at the same time is who does poorly.

MACINTYRE: Dr. Healy's not the first one to document this problem. Doctors at Harvard University raised concerns about SSRIs and suicide years ago. Harvard lecturer and psychiatrist Joseph Glenmullen wrote about it in his book "Prozac Backlash". He says more doctors should listen to Healy.

JOSEPH GLENMULLEN: Dr. Healy for many, many years has been widely regarded as one of the leading psychiatrists in Europe and really in the world. His research is outstanding. And he's one of the few people who has continued to do research on the suicidality issue in particular and been a strong proponent of patients needing to get this kind of information.

MACINTYRE: Last summer, the centre made it official. They wanted Healy as the top scientist in their mood and anxiety disorders clinic. They offered him the director's job and he accepted.

HEALY: I felt very good about it. And I also brought over my family and certainly they all seemed reasonably open to the move as well. So we all began to get fairly excited.

MACINTYRE: At the time the centre had no problem with Healy's research. But someone else did.

CHARLES NEMEROFF: Hello. My name is Charles Nemeroff.

MACINTYRE: Chair of the Department of Psychiatry at Atlanta's prestigious Emory University, Dr. Charles Nemeroff is a highly respected and influential scientist. And a paid consultant to a dozen drug companies. A leading psychiatric magazine recently profiled him under the headline Boss of Bosses. Is the brash and controversial Charles Nemeroff, the most powerful man in psychiatry? Inside the authors wrote, Nemeroff is among the most coveted advisors to the pharmaceutical industry. And he fully expects to lead the corporate strategies of those he advises. Those who do not heed his advice are often the recipients of his wrath. Last summer at Cambridge University in England, Healy had a brush with the boss of bosses.

HEALY: Dr. Nemeroff came up to me in the course of the meeting in what was a very scary meeting between him and me and told me that my career would be destroyed if I kept on showing results like the ones that I'd just shown, that I had no right to bring out hazards of the pills like these.

MACINTYRE: In a written statement, a doctor who witnessed the confrontation told us, when it became clear that David Healy would not back down from his points of view, Nemeroff said that what Healy was publishing might harm the drug industry, specifically Eli Lilly. He, Charles Nemeroff, said that these people were ruthless and would go to great lengths to make life hard for academics who published articles associating suicide with Prozac.

HEALY: It was a fairly short encounter. It lasted about two or three minutes but a very scary one.

MACINTYRE: James Turk is with the Canadian Association of University Teachers. He says to a drug company concerned about profits, researchers like Healy could be seen as dangerous.

JAMES TURK: I mean he's one of the world's leading scholars on antidepressants. He's done clinical trials for some of the drug companies. But what he isn't is not in the drug companies'

pockets. And Healy's argument is that SSRIs are suitable for some patients but in fact can be very harmful for others. And the impression I get is that the drug companies want 100 percent of the market whereas if you do that research and Healy's right, that there are 40 percent or 50 percent of the people who currently get SSRIs for whom it's not appropriate, then the market is cut in half.

MACINTYRE: Just a few months after the Nemeroff incident, David Healy flew into Toronto on what should have been his last trip to the city as a visitor. He planned to give a lecture at his future place of employment, hire some staff, pick out some furniture for his office and meet with his new boss, David Goldbloom.

HEALY: He was keen for me to move from the U.K. much more than I was keen to move. He hoped that I would move within weeks whereas I had hoped I'd move for April 1st.

MACINTYRE: So it was a very positive day?

HEALY: Absolutely. Absolutely. Couldn't have been more positive.

MACINTYRE: And no hint for you that there was any trouble at all?

HEALY: Not the remotest of hints.

MACINTYRE: But that was about to change completely. Two days later, Dr. Healy delivered his lecture at the symposium. It was a sweeping review of the history of psychiatric drugs. He covered all the old ground about SSRIs and suicide and raised concerns about some new anti-psychotic drugs. But one of the main themes concerned conflict of interest with drug companies and the increase challenge doctors face in avoiding it. Members of the audience who filled out evaluations forms rated Healy's lecture the best of the lot. But it seems his new boss didn't agree.

HEALY: When I met Dr. Goldbloom that evening after the lecture, my guts told me that there was a much more serious problem than my head said that there could be. I saw a man who was more worked up than I've seen almost anyone else before ever. He seemed to me to be at risk of a stroke he was so worked up. It's an extraordinary switch to have happened just during the course of a few hours.

MACINTYRE: The centre wouldn't allow us to interview Dr. Goldbloom. Instead we were referred to the President and C.E.O. Paul Garfinkel. He says Healy's lecture was to blame.

PAUL GARFINKEL: Essentially, it was the extreme nature of his views with extraordinary extrapolations based on inadequate science, that really are scientifically irresponsible. For example, the view that anti-psychotics cause more harm than good.

MACINTYRE: Did Dr. Healy actually say that anti-psychotics do more harm than good? I believe that he claims he didn't actually say that.

GARFINKEL: I have to tell you, I wasn't at the lecture. But I've been told by a number of people that he essentially said that.

MACINTYRE: Dr. Garfinkel may not have heard the lecture but someone else did. Charles

Nemeroff. He was also scheduled to speak that day and it seems he didn't restrict his comments to the podium. Although he refuses to be interviewed, Dr. Nemeroff said through his lawyer, the centre asked for his opinion of Dr. Healy that day and he gave it. What he said then, we don't know, but later that day he flew to New York where we do know he told a meeting of the American Foundation for Suicide Prevention exactly what he thought about Healy. One scientist who was there said Nemeroff's attack was furious, angry, exercised, that the thrust was Healy was a nut.

GARFINKEL: I don't know anything about it. I do know that he has the right to say whatever he wants. I'm not, I don't stifle debate.

MACINTYRE: A few days later, the centre dumped Dr. Healy. Before the job offer was rescinded, were you aware of the confrontational nature of Dr. Nemeroff and Dr. Healy's relationship?

GARFINKEL: Um, I can't recall, I learned about it sometime after the lecture, probably around the same time as the job was rescinded.

MACINTYRE: Garfinkel says Nemeroff's opinion played a minor role, if any, that Healy's unscientific lecture was his undoing.

GARFINKEL: If he says that these medications cause suicide, our view of this is that this isn't about Prozac. This is about sweeping statements based on inadequate science. Frankly we'd be as concerned about aspirin as about Prozac. But there is no causal scientific link. There's no valid scientific evidence saying these drugs cause suicide.

MACINTYRE: That's certainly the position of Prozac maker Eli Lilly. Even though the company recently bought the rights to a new generation of Prozac, patented on the grounds that it's less likely than the current Prozac to cause severe anxiety leading to intense and violent suicidal thoughts and self-mutilation. Still Garfinkel insists the speech was so bad, it even raised questions about Healy's ability as a doctor.

GARFINKEL: We feel that a number of his views could affect the quality of patient care.

MACINTYRE: So you are suggesting that his view on SSRIs, for example, might lead him to not prescribe SSRIs? Is that what you mean?

GARFINKEL: It could, if you took an extreme view, if you said 30,000 people had killed themselves on SSRIs, that could frighten people away from treatment for depression.

MACINTYRE: But Dr. Healy is shocked at the suggestion.

HEALY: Well my reaction is considerable surprise. My hunch is that I've treated very many more people who were actually depressed than any other clinical person in there, but they seem to have acted without asking me anything at all. They're going around making claims about concerns that they have without really having the evidence that there's any, any real basis to the claims that they're making.

MACINTYRE: Besides, Healy says there was nothing in his lecture that day that he hadn't already published in his book "The Anti-Depressant Era" or said in previous speeches. Your

lecture that you gave on the 30th, what in that lecture do you think could've possibly caused the people at the Centre for Addiction and Mental Health to be concerned enough to withdraw a job offer?

HEALY: Well I can't see that there's anything in the actual lecture per se that would cause them to bite the contract. They had heard all of the stuff before. Other audiences have heard exactly the same lecture and the response has been extremely enthusiastic. It has not been hostile in any way at all.

MACINTYRE: James Turk says Canada's university teachers are demanding an explanation.

TURK: The suggestion that these folks heard something in his talk when his talk was really a distillation of what was in his highly regarded book on the same subject, it just can't be true. At least I don't think it can be true. But even if there were concerns raised in the talk, the thought that you'd take a job away from a world renowned expert in a field who you've hired because of some remarks in the course of a 30 minute lecture is astounding. I mean it's just unprecedented in Canadian universities or in any respectable teaching hospital.

MACINTYRE: When we come back, was it his science or something else?

NANCY ZETTLER: Does he have a right to feel like he's being conspired against? He sure does.

GARFINKEL: Let me set the record straight about Dr. Healy's so-called conspiracy theories.

DARROW MACINTYRE: These days drug companies are an essential part of academic research. In fact one doctor recently described them as the mortar in the walls of the medical establishment. There's no question their input is necessary but at what point does input become influence. It's a question scholars everywhere are asking themselves these days and since the Healy affair, many think the Centre for Addiction and Mental Health has crossed the line.

TURK: I think they took away the job because they didn't want someone asking probing questions about the role of pharmaceutical companies in shaping medical research.

GARFINKEL: We're extremely careful about conflict of interest with the pharmaceutical industry but in general, we're vigilant and we're proactive.

MACINTYRE: The centre's President Paul Garfinkel says most of his funding comes from sources other than drug companies.

GARFINKEL: Well over 80 percent of our research funding is in these non-industry related areas -- 18 percent is industry related and this 18 percent has been constant over the last few years. It's not growing. I mean, if I saw 18 become 22, become 30, I think I might be quite concerned.

MACINTYRE: While it's true the centre's overall portion of research funds from drug companies is around 18 percent, the figures for the mood and anxiety disorders clinic that Dr. Healy was supposed to head up are dramatically higher. Last year, 52 percent of the research dollars in that department came from drug companies, almost three times the centre's overall rate. Then there are corporate donations, including a \$1.5 million gift Eli Lilly pledged to the centre's

fundraising campaign last year. Such a close financial relationship inevitably comes with a close working relationship and lots of meetings between scientists including one on the very day David Healy delivered his lecture. On the day that he gave the lecture, there were a group of people from the centre at Lilly's headquarters in the States.

GARFINKEL: I understand that. I've learned that. Yeah.

MACINTYRE: Was there any kind of communication back and forth?

GARFINKEL: Actually zero. None.

MACINTYRE: Not a phone call?

GARFINKEL: Not a phone call.

MACINTYRE: As far as you know, did the subject of Dr. Healy come up at all at those meetings?

GARFINKEL: In Indianapolis?

MACINTYRE: Yeah.

GARFINKEL: I won't say 100 percent certainty, no.

MACINTYRE: How often do scientists from the centre meet with people from Eli Lilly? Is that a fairly regular...? I know they have their own staff of scientists.

GARFINKEL: I don't know. I couldn't answer you. I can tell you I encourage our people to meet with the very best people all over the world. If we're going to advance care, if we had people who are ill today and we're going to advance care, it's because we've mixed with the very best minds internationally.

MACINTYRE: There's no evidence anyone at Eli Lilly or any other drug company played a direct role in getting Healy dumped. But then Healy says they didn't have to. You don't think that they picked up the telephone and called somebody at the University of Toronto and said don't hire that guy, do you?

HEALY: The way the system is set up, I don't think that has to happen, but the outcome will be still the same.

MACINTYRE: James Turk thinks that outcome is clear.

TURK: I think what happened is there were people at CAMH and University of Toronto who were concerned about having a widely recognized critic, having a person who raises questions about corporate connections and the impact of that might get in the way of fundraising. So, there's enough evidence that the drug companies do intervene and try to put strings on that people can get worried. So they don't have to phone.

MACINTYRE: It happened to the folks who publish this journal on medical ethics recently after they printed an article by David Healy suggesting Prozac may be over prescribed, their largest donor Eli Lilly pulled its funding. But it may be Healy's work elsewhere that's really put him at

odds with the SSRI makers. As an authority on the drug's side effects, he's been asked to give expert testimony in a handful of court cases against the drug company.

HEALY: It's one thing for people to hear lectures on the hazards. It's a completely different thing for one of the companies to lose a legal case to some plaintiff who may have lost a wife, daughter, mother, father-in-law, whatever. And if that were to happen, the companies stand to lose a vast amount of money.

UNIDENTIFIED MAN (1): Elated. We feel elated. Justice has been done.

MACINTYRE: In fact, just last week, in a U.S. court a jury did decide this man killed his wife, his daughter, his granddaughter and himself because he was suffering from an adverse reaction to Paxil, a SSRI similar to Prozac but made by GlaxoSmithKline. An expert witness in the case, David Healy. From her law offices in downtown Chicago, lawyer Nancy Zettler has spent ten years battling drug companies in legal cases about SSRIs and suicide. She's seen those companies dig up and air any dirt they can to discredit critics, including Healy.

NANCY ZETTLER: Does he have a right to feel like he's being conspired against? Sure does. He's one of the few people in this country, in these cases here in the country, in the States, that's willing to stand up and testify. And he's one of the, he has very, he has no baggage as far as I know. There's no skeletons. And if there's nothing that they can try to dig out to throw at him at trial, then what better way than try to manufacture something.

MACINTYRE: Paul Garfunkel scoffs at the idea his staff was influenced by anyone.

GARFINKEL: Let me set the record straight about Dr. Healy's so-called conspiracy theories. We have never ever made an offer or rescinded an offer based on the impact of an external donor. Neither Eli Lilly nor any other corporation, nor any individual has affected or influenced our human resources matters.

MACINTYRE: What's this whole debate over Dr. Healy getting hired and then having the offer withdrawn? What's it done to their reputation at the centre and the university?

GARFINKEL: The centre is about many things. The centre is about standards. It's about quality. It's possible that over the years in psychiatry, if you look back historically, people allowed almost anything to be said. That affected how patients were treated. We're not going to do that.

MACINTYRE: What do you mean by that?

GARFINKLE: Well, a common theory when I was a student was the theory of the schizophrenogenic mother and that is there was something about the mother that caused schizophrenia. If you don't think that hurt families, let me tell you that was very, very bad for clinical care. Standards count. If you're going to make up a theory like that, you've got to have evidence.

MACINTYRE: And you're suggesting that what Dr. Healy is doing is something like that?

GARFINKEL: Oh no, no, no, no. Come on.

MACINTYRE: Not even in saying well...

GARFINKEL: I'm saying standards count. And you cannot make sweeping statements without the adequate back-up.

MACINTYRE: Healy says he's never done that but for him a big part of upholding standards is remaining vigilante about conflict of interest.

HEALY: But Dr. Garfinkel and I get money from the pharmaceutical industry. We speak for pharmaceutical companies, run trials for them, and it does bias you. We probably all hope that the bias is going to be a small little bias and it's a risk we just have to take. It's only not going to be an option as long as people don't feel that people like me and Paul Garfinkel haven't just become drug dealers. That we're like car salesman who sell you the car regardless of the hazards. They want people, want us to be people who will weigh the benefits and the risks and will let you know about the benefits and the risks, the pros and the cons and maybe even advise in some instances that you shouldn't have the pills at all.

MACINTYRE: The Centre for Addiction and Mental Health probably never dreamed that breaking David Healy's contract would spark the academic debate they're now embroiled in. A debate now about Healy's views on antidepressants and suicide but about his right to express those views publicly. A fundamental principle that underpins all scientific research and debate.

TURK: Here we have one of the top, if not the top psychiatric research facility and teaching hospital in the country saying we don't want someone who raises a certain set of fundamental questions about one of the most prescribed, widely prescribed classes of medicine in Canada. We don't want that here. That would say to me as a member of the public, well wait a minute. Are these folks really prepared to look at all sides of the question. Can we trust what's coming out of here? That's the dark cloud that the actions of the administration at CAMH and the University of Toronto have put over their own institution.

MACINTYRE: David Healy says he's not really disappointed that he's staying in Wales. After all, the U.K. is home for him. And it's where he's built a distinguished career. He is disappointed in the way the whole affair was handled by an institution he expected more from.

HEALY: The University of Toronto is clearly still one of the major universities in the world. There are very, very important issues here and it's going to take a big university to raise these issues, but raising these issues are also something that will make a university great. So there is a challenge here, both for the university and for the CAMH to rise to. I still think they can rise to them.

MACINTYRE: Are you disappointed in the Centre for Addiction and Mental Health?

HEALY: Yes.

MACINTYRE: For The National, I'm Darrow MacIntyre.

After Jim talked with me about the Dr. Healy story, he brought me photocopies of a May 2004 letter from Health Canada warning healthcare professionals about the dangers of prescribing Paxil to those under 18 years of age and a September 2004 story from the British Broadcasting Corporation (BBC) about an alleged GlaxoSmithKline cover up of negative research findings about Paxil.

The Dr. Healy affair, Health Canada warning and BBC story helped me realize that I needed to do something in the near future to help prevent Paxil-induced suicidal and/or homicidal tragedies.

HEALTH CANADA

MAY 2004

SUBJECT: STRONGER WARNING FOR SSRIs AND OTHER NEW ANTIDEPRESSANTS REGARDING POTENTIAL FOR BEHAVIOURAL AND EMOTIONAL CHANGES, INCLUDING RISK OF SELF-HARM. FOR PAROXETINE, THIS REPLACES THE INTERIM CONTRAINDICATION.

Dear Healthcare professional:

GlaxoSmithKline Inc. (GSK), following discussions with Health Canada, would like to inform you of important safety information regarding the possibility that selective serotonin reuptake inhibitors (SSRIs) and other newer antidepressants may be associated with behavioural and emotional changes, including risk of self-harm.

The new Class warning incorporated in the product monograph of paroxetine is provided below.

Please note this warning replaces the interim contraindication for Paxil (paroxetine) issued in July 2003 for patients under 18 years of age with major depressive disorder.

POTENTIAL ASSOCIATION WITH THE OCCURRENCE OF BEHAVIOURAL AND EMOTIONAL CHANGES, INCLUDING SELF-HARM.

Pediatrics: Placebo-Controlled Clinical Trial Data

Recent analyses of placebo-controlled clinical trial safety databases from SSRIs and other newer antidepressants suggest that use of these drugs in patients under the age of 18 may be associated with behavioural and emotional changes, including an increased risk of suicide ideation and behaviour over that of placebo.

The small denominators in the clinical trial database, as well as the variability in placebo rates, preclude reliable conclusions on the relative safety profiles among these drugs.

Adult and pediatrics: Additional data

There are clinical trial and post-marketing reports with SSRIs and other newer antidepressants, in both pediatrics and adults, of severe agitation-type adverse events coupled with self-harm or

harm to others. The agitation-type events include: akathisia, agitation, disinhibition, emotional lability, hostility, aggression, depersonalization. In some cases, the events occurred within several weeks of starting treatment.

Rigorous clinical monitoring for suicidal ideation or other indicators of potential for suicidal behaviour is advised in patients of all ages. This includes monitoring for agitation-type emotional and behavioural changes.

Discontinuation symptoms

Patients currently taking paroxetine should NOT be discontinued abruptly, due to risk of discontinuation symptoms. At the time that a medical decision is made to discontinue a SSRI or other newer antidepressant drug, a gradual reduction in the dose rather than an abrupt disruption is recommended.

It should be noted that a causal role of SSRIs and other newer antidepressants in inducing self-harm or harm to others has not been established. The possibility of a suicide attempt is inherent in depression and other psychiatric disorders, and may persist until remission occurs. Therefore, high-risk patients should be closely supervised throughout therapy with appropriate consideration to the possible need for hospitalization. The updated warnings inform practitioners that all patients being treated with SSRIs and other newer antidepressants should be rigorously monitored for clinical worsening, or onset/worsening of agitation-type adverse events, or other indicators of potential for suicidal behaviour.

Paroxetine is not indicated for use in the pediatric population, and controlled clinical studies with paroxetine in children and adolescents under 18 years of age with major depressive disorder fail to demonstrate efficacy.

New Information Added to the Consumer Information Section

The Consumer Information Section of the product monograph has been updated to reflect this new Class warning, and to advise patients that treatment with SSRIs and other newer antidepressants is most safe and effective when there is good communication with the treating physician about how the patient is feeling.

Background

In February 2004, a scientific advisory panel set up by Health Canada was asked to provide the clinical practice perspective on the pediatric clinical trial safety data, and the spontaneous post-marketing reports for SSRIs and other newer antidepressants. The panel agreed that a contraindication was not warranted for these medications, and supported Health Canada's recommendation for stronger warnings, while providing suggestions and comments.

GSK FACES ANTIDEPRESSANT LAWSUIT

GLAXOSMITHKLINE (GSK) IS FACING A LAWSUIT ALLEGING THAT IT COVERED UP NEGATIVE FINDINGS ON ITS ANTIDEPRESSANT PAXIL

The lawsuits were filed on behalf of children and teenagers who were prescribed Paxil, known as Seroxat in the U.K. and Europe.

They claim GSK suppressed data showing that Paxil increased suicidal tendencies in young people.

GSK had denied the allegations, and said it would defend itself in court.

Litigation

"We have publicly communicated the data in a variety of ways – in peer-reviewed journals, in presentations at major conferences, and in letters to physicians," a GSK spokesman said.

The lawsuit is the latest in series of legal battles GSK has had to fight over Paxil, once its best-selling drug.

Earlier this year, claims that some research into Paxil may have been withheld triggered an investigation by New York prosecutor Eliot Spitzer.

Last month, the company paid \$2.5m (£1.3m) to settle Mr Spitzer's inquiry.

It also agreed to publish the results of all clinical tests on its drugs since December 2000 on the internet.

The December cut-off date marks the point at which Glaxo Wellcome merged with Smithkline Beecham.

GSK is also fighting separate lawsuits brought by adult Paxil users who claim it caused adverse side-effects.

GSK shares were down 4 pence at £11.49 in early afternoon trade in London.

Preventing future tragedies

On September 30, 2005, I was judged in London to be "not criminally responsible on account of a mental disorder" for murdering Ian and was sent to Brockville Mental Health Centre (BMHC).

I was not sure when I was going to start sharing my own Paxil-induced violent psychotic experience, especially since most of the public warnings dealt specifically with the increased risk of suicide among children and youth. I also knew that speaking out might create problems at BMHC. But after reading a May 1, 2006 article in the Toronto Star about the risks of SSRIs among older adults and a May 13, 2006 article in the Brockville Recorder and Times about the suicide risks of young adults taking Paxil, the timing seemed right.

ELDERLY AT RISK USING SSRI DRUGS, STUDY FINDS

DANGERS IN FIRST MONTH OF ANTIDEPRESSANT USE
SUICIDE MUCH HIGHER IN EARLY THERAPY

BY ELAINE CARRY
STAFF REPORTER

Elderly patients who are prescribed a popular brand of antidepressants are five times more likely to commit suicide during the first month of therapy than those taking other drugs, a new study shows.

The study by the Institute for Clinical Evaluative Sciences, and independent research group, released today in the American Journal of Psychiatry, looked at 1,142 suicides among Ontario residents older than 65 over nine years.

While the majority weren't taking antidepressants, those who did were at far higher risk of committing suicide in the first month of treatment.

The antidepressants, called selective serotonin reuptake inhibitors, or SSRIs, - which include Prozac, Paxil and Zoloft - have already been the subject of strong warnings from drug companies and class-action lawsuits over their increased risk of suicide among children, adolescents and adults.

In Canada, where an estimated 1 million suffer from depression, the number of prescriptions for SSRIs has doubled in the past five years, with 17.5 million prescriptions filled last year alone.

No one has studied such a large population or looked specifically at seniors, despite the large numbers of them who are prescribed these drugs, said Dr. David Juurlink, the study's lead author.

The ICES researchers linked coroners' records with patient prescription data between 1992 and 2000 and found that one in every 3,300 seniors who started taking the drugs in the past month committed suicide.

Although the risk is small, "when you multiply it by the millions of Canadians taking these drugs, then you're talking about big numbers of people", Juurlink said.

Doctors not only should closely monitor patients taking these drugs in the first month of therapy, he said, "but we need to be more judicious in how we use these drugs. We prescribe them very liberally."

"These drugs are meant to treat depression, they're not a treatment for financial problems or job dissatisfaction or any of the other sort of unhappiness people might experience in life," he said.

"Because they are perceived as very safe, we are too free with them."

Suicide is the 11th leading cause of death in the elderly, he said.

A second Canadian study in the journal found bright, artificial light therapy is as effective as antidepressants in the treatment of winter depression.

The study, co-authored by Dr. Anthony Levitt, chief of psychiatry at Sunnybrook Health Sciences Centre, found both treatments produced an improvement in 67 percent of cases treated.

THE BROCKVILLE RECORDER AND TIMES

SATURDAY MAY 13, 2006

SUICIDE WARNING ISSUED FOR YOUNG ADULT PAXIL USERS

WASHINGTON (AP-CP) - The widely prescribed antidepressant Paxil may raise the risk of suicidal behaviour in young adults, its manufacturer and the U.S. Food and Drug Administration warned Friday in a letter to doctors.

The letter from GlaxoSmithKline and the FDA was accompanied by changes to the labelling of both Paxil and Paxil CR, a controlled-release version of the drug, also called Paroxetine. The medication belongs to a class known as selective serotonin reuptake inhibitors, or SSRIs.

No updated warning for Paxil is planned for Health Canada, which in 2004 ordered tougher wording on information labels for all SSRIs prescribed to Canadians of any age, spokesman Chris Williams said Friday in Ottawa.

"Rigorous clinical monitoring for suicidal ideation or other indicators of potential suicidal behaviour is advised in patients of all ages," the current monograph reads. "This includes monitoring for agitation-type emotional and behavioural changes."

The U.S. warning follows a recent analysis of clinical trial data from 15,000 patients treated with either Paxil or dummy pills, which revealed a higher frequency of suicidal behaviour in young adults treated with the drug.

The FDA reported that there was 11 suicide attempts - none resulting in death - among patients given Paxil in the trials. Just one patient on placebo attempted suicide.

Given the small number, the results "should be interpreted with caution," the FDA said. Eight of the 11 attempts were made by patients between the ages of 18 and 30. All trial patients suffered from psychiatric disorders, including major depression.

A GlaxoSmithKline spokesman did not immediately return a message seeking comment. However, in the letter to doctors, Dr. John Kraus, the company's director of clinical development for clinical psychiatry in North America, said GlaxoSmithKline PLC continues to believe the drug's benefits outweigh its risks.

The FDA stresses that all patients, especially young adults and those who are improving, should be carefully monitored when being treated with Paxil.

In 2004, the FDA ordered that strong warnings be put on antidepressant labels about the risk of suicidal tendencies in children put on the drugs, and began analyzing whether adults face a similar risk.

All antidepressants now carry warnings on their labels cautioning patients and doctors of the risk of suicidal behaviour.

Since 2004, there had been public warnings about Paxil use among children, youth, older adults, and young adults, but nothing about 30 to 65 year olds. It is hard to understand how research could demonstrate that Paxil could cause suicides and violent behaviour among every population group except the age group that makes up most of the workforce.

In June 2006, I talked with my wife Elizabeth and then 15-year-old daughter Gillian about my interest in sharing information about the lethal side effects of Paxil online. I knew that my effort to help educate the public might be perceived by my treatment team at BMHC, members of the Ontario Review Board (ORB) and many others as my effort to blame someone other than myself for the death of Ian. That certainly was not the case. I knew that I made many mistakes during my first major depression and relapse, particularly self medicating during my relapse by increasing my daily dosage of Paxil from 40 to 60mg.

We decided that it was time to do whatever we could to prevent tragedies like ours. We wanted to help prevent other families from going through the excruciating pain of losing a child, and that our efforts to help educate the public were worth the risk of potentially delaying my discharge and dealing with the collateral damage that we knew we would experience after our tragic story was shared publicly.

Constructing davidcarmichael.com

My first step in educating the public was to set up a website. In June 2006, our tragic story was shared at davidcarmichael.com along with Food and Drug Administration (FDA) and Health Canada warnings and a warning that:

Individuals of all ages should be closely monitored for suicidal and homicidal thoughts and behaviours for at least 1-month after they start taking Paxil and after they increase their dosage. They should also be closely monitored after they stop taking Paxil.

I posted information on my website that I thought would help other depression sufferers. One of the sections at davidcarmichael.com is “my mistakes”, which explains 10 of the many mistakes that I made which might have prevented my first major depression, relapse and, unquestionably, my acute homicidal psychotic episode:

1. Taking my mental health for granted
2. Not making time for me
3. Not exercising regularly
4. Getting caught up in the stigma
5. Not asking my doctor questions
6. Not seeing a psychiatrist
7. Not researching the rare side effects of Paxil
8. Weaning myself off Paxil
9. Going back on my previous prescription
10. Increasing my dosage

There is also a “through psychotic eyes” section that provides some disturbing insight into my calm, organized behaviour when I killed Ian; a section on “ssri-induced psychosis” which includes some of the evidence that supports the argument that Paxil triggered my psychotic episode, not my major depression; and a link to depressionsufferers.com, an online support group with information about treatment options, FDA and Health Canada antidepressant warnings, a message board and a chat room.

Contacting the media

On July 26, 2006, Andrea Yates of Houston, Texas was found not guilty by reason of insanity in the second murder trial in the June 2001 drowning deaths of her 5 children. She was found guilty of murder at her first trial in 2002. The jury at the second trial decided that she was delusional and psychotic when she killed her children. In the news stories that I watched or read following the second verdict, not one writer or broadcaster explained delusions or psychosis or discussed the possibility that the antidepressant Effexor might have triggered her psychotic episode. Effexor is apparently slightly different than a SSRI. It is in a category known as serotonin norepinephrine reuptake inhibitors (SNRIs).

In the days leading up to the murders, Andrea was apparently on twice the recommended maximum dosage of Effexor. Just days before the killings, her Effexor dosage was reduced to slightly more than the recommended dosage and another antidepressant, Remeron, was added. Remeron is classified as a noradrenergic and specific serotonergic antidepressant (NaSSA).

Even though Andrea was not on a SSRI, but a SNRI and NaSSA, there seems to be several similarities between her behaviour during her acute homicidal psychotic episode and my own. We were both:

- Acting out of love
- Calm and fully cooperative with the police
- Numb, docile and robotic during the killing
- Obsessed with worrying about our children
- Planning murders while severely psychotic
- Severely psychotic for several days after the murder

- Sure that our spouses would understand why we did it
- Considered compassionate loving parents by spouses and others
- Convinced that we did the right thing until the psychotic fog lifted
- Suffering from depression before the psychosis (Andrea postpartum/me major)
- Calm when we made phone calls after the killing (Andre to her husband/me to 911)
- Aware that we would be sacrificing our lives (Andrea the death penalty/me life in prison)

After speaking with Elizabeth and Gillian, we decided that it was time for me to speak out publicly. Psychosis had to be demystified. I knew that my psychotic episode did not resemble how "psychos" are often portrayed in movies and television shows such as Psycho, Criminal Minds, Law & Order, and CSI. I was calm, numb and my thoughts were well organized. I talked clearly and believed that killing Ian was the right thing to do. I shared every detail calmly with the police at 3 interrogation sessions without a lawyer. I did not want a lawyer. I knew I murdered Ian and was prepared to spend the rest of my life in prison. On August 2, 2006, I sent an email to the media.

EMAIL TO MEDIA

Subject: Killed my son 2-years ago while psychotic on Paxil

On July 31, 2004, 2-weeks after I started taking 60mg. of the antidepressant Paxil a day, I killed my 11-year-old son Ian. I was charged with first-degree murder. In November 2004, I was diagnosed by one of the leading forensic psychiatrists in the world as being in a "major depression" with "psychotic episodes" when I killed Ian. On September 30, 2005, I was judged (in London, Canada) to be "not criminally responsible" for murdering Ian on account of a mental disorder. I've shared my tragic story at davidcarmichael.com.

Paxil has lethal side effects. Research indicates that individuals of all ages should be closely monitored for suicidal and homicidal thoughts and behaviours for at least 1-month after they start taking Paxil and after they increase their dosage. Warnings about Paxil appeared in newspaper articles in May 2006.

GlaxoSmithKline, the manufacturer of Paxil, has been aware of the potentially lethal side effects of the drug for more than a decade. For example, the 1996 edition of the Compendium of Pharmaceuticals and Specialities (CPS), published by the Canadian Pharmacists Association, lists psychosis as a rare side effect of Paxil. Yet, many doctors in the United States were not aware of this risk until after they received a letter from GlaxoSmithKline and the Food and Drug Administration (FDA) in May 2006. Many Canadian doctors are still not aware that Paxil can induce psychosis. And none of the Paxil printouts from pharmacies that I've reviewed list psychosis as a possible side effect of this popular antidepressant (with worldwide sales in 2003 estimated at \$3 billion U.S.).

Please make the public aware that psychosis is a rare but potentially lethal side effect of Paxil.

Thank you for helping to prevent future suicidal and homicidal tragedies.

In memory of Ian - who I love and miss very much,

David Carmichael

Several newspapers and a few television stations responded to my email. On April 21, 2007, CTV's W-FIVE shared our story in Over the Edge. W-FIVE attempted to demystify psychosis and raised some important questions about the role that Paxil might have played in my homicide. Several of the questions that the producer developed were prompted by a BBC documentary that aired in the U.K. in January 2007 exposing how GlaxoSmithKline 'hid' the Paxil link to adolescent suicides.

Exposing GlaxoSmithKline

Two successful initiatives to challenge the efficacy of Paxil and the corporate ethics of GlaxoSmithKline were the BBC documentary in January 2007 and a book published in 2008 titled Side Effects: A Prosecutor, a Whistleblower, and a Best Selling Antidepressant on Trial.

BRITISH BROADCASTING CORPORATION (BBC)

MONDAY JANUARY 29, 2007

DRUG COMPANY 'HID' SUICIDE LINK

SECRET EMAILS REVEAL THAT THE UK'S BIGGEST DRUG COMPANY DISTORTED TRIAL RESULTS OF AN ANTIDEPRESSANT, COVERING UP A LINK WITH SUICIDE IN TEENAGERS

Panorama reveals that GlaxoSmithKline (GSK) attempted to show that Seroxat (Paxil) worked for depressed children despite failed clinical trials.

And that GSK-employed ghostwriters influenced 'independent' academics.

GSK told Panorama: "GSK utterly rejects any suggestion that it has improperly withheld drug trial information."

GSK faces action in the US where bereaved families have joined together to sue the company.

As a result, GSK has been forced to open its confidential internal archive.

Karen Barth Menzies is a partner in one of the firms representing many of the families.

Negative studies

She has examined thousands of the documents which are stored, box upon box, in an apartment in Malibu, California.

She said: "Even when they have negative studies that show that this drug Seroxat is going to harm some kids they still spin that study as remarkably effective and safe for children."

GSK's biggest clinical trial of Seroxat (Paxil) on children was held in the US in the 1990s and called Study 329.

Child psychiatrist Dr. Neal Ryan of the University of Pittsburgh was paid by GSK as a co-author of Study 329.

In 2002 he also gave a talk on childhood depression at a medical conference sponsored by GSK.

He said that Seroxat (Paxil) could be a suitable treatment for children and later told Panorama reporter Shelley Jofre that it probably lowered rather than raised suicide rates.

In amongst the archive of emails in Malibu, Shelley was surprised to find that her own emails to Dr. Ryan from 2002 asking questions about the safety of Seroxat (Paxil) had been forwarded to GSK asking for advice on how to respond to her.

She also found an email from a public relations executive working for GSK which said: "Originally we had planned to do extensive media relations surrounding this study until we actually viewed the results.

"Essentially the study did not really show it was effective in treating adolescent depression, which is not something we want to publicise."

Blind-eye-culture

But the article was published in the Journal of the American Academy of Child and Adolescent Psychiatry which says it ranks as number one in child mental health in the world.

The editor in chief of the British Medical Journal, Fiona Godlee, said that what she calls the "blind-eye culture of medicine" should be exposed by professionals.

She has written in response to the Panorama film: "We shouldn't have to rely on investigative journalists to ask the difficult questions.

"Reputations for sale are reputations at risk. We need to make that risk so high it's not worth taking."

The Medicine and Healthcare Products Regulatory Authority (MHRA) began a criminal investigation into GSK three years ago but no action has been taken yet.

A spokesperson told Panorama that the investigation has been given substantial additional resources and remains a high priority.

Seroxat (Paxil) was banned for under 18s in 2003 after the MHRA revealed that GSK's own studies showed the drug actually trebles the risk of suicidal thoughts and behaviour in depressed children.

THE BOSTON GLOBE

SATURDAY JULY 5, 2008

THE UNHEALTHY TIES THAT BIND FDA TO DRUG FIRMS

SIDE EFFECTS: A PROSECUTOR, A WHISTLEBLOWER, AND A BEST SELLING ANTIDEPRESSANT ON TRIAL

BY CHUCK LEDDY

In her new book Alison Bass obeys the most important rule of investigative journalism: She follows the money wherever it leads. In "Side Effects", her examination of mammoth pharmaceutical

companies and their pursuit of profits at any cost, she exposes the dark web of researchers, doctors, and regulators feeding at the Big Pharma trough and undermining public health in the process. The term for what Bass discovers is "systematic funding bias." As she makes abundantly clear, medical professionals taking money from Big Pharma tend to give Big Pharma what it wants.

The Food and Drug Administration is supposed to be looking out for public health and consumer safety by objectively reviewing drug trials submitted by pharmaceutical companies seeking approval for new drugs. But who pays the FDA for this important watchdog function? Big Pharma does. As Bass, a onetime Globe reporter, writes, "The industry's allocation of \$232 million in user fees represented 53 percent of the agency's entire drug review budget" in 2004. Does this funding system, which continues to this day, create the potential for the FDA to become indebted to the very industry it's supposedly regulating?

If Bass's investigation into the antidepressant Paxil, a multibillion-dollar cash cow for GlaxoSmithKline, is any indication, the FDA's public-watchdog function seems to need more teeth. She shows that Glaxo's research studies found that Paxil "failed to demonstrate any separation" between itself and a placebo (a sugar pill) in adolescents. Moreover, she contends Glaxo and its researchers either ignored or suppressed evidence that the pediatric use of Paxil could lead to thoughts of suicide. Glaxo "made no reference to the negative results" from these trials, instead recommending Paxil for pediatric use. Bass illustrates how Glaxo paid huge amounts of money to conduct these research trials, and how medical researchers in the pay of Glaxo worked to give the firm the positive study results it wanted.

Bass looks at a Paxil study conducted by a medical researcher whose employee, Donna Howard, came to believe that he "was playing fast and loose with the protocols for the Paxil study" and was suppressing evidence of suicidal thinking in patients by "not accurately coding these adverse events." Eventually she contacted the author. Bass finds that the researcher was receiving hundreds of thousands of dollars annually from Big Pharma.

With evidence of Paxil's problems mounting, the FDA belatedly required that a warning label be placed on the drug. Meanwhile, it took the New York attorney general's office to compel Glaxo to publicly disclose Paxil's link to suicidal thoughts. Bass provides a dramatic account of this lawsuit, following state attorney Rose Firestein as she digs up evidence of Glaxo's deceptive conduct. Firestein pursues a consumer-fraud case against Glaxo, arguing that "the negative study results on Paxil were material to a doctor's judgment in treating patients, and they had been concealed."

Glaxo eventually made a cash settlement and disclosed the negative studies. More important, notes Bass, the case "shone a spotlight into the black hole of drug research" and triggered "a growing outcry about the enormous influence the pharmaceutical industry wields over the practice of medicine." As Bass demonstrates, the free market is a powerful, creative force, but some things should never be put up for sale. Public health is one of them, and with the help of investigative journalism like "Side Effects", maybe "Money talks" will give way to the needs of public health. Stranger things have happened.

Denying any responsibility

Even after the January 2007 BBC Panorama documentary and the 2008 publication of Side Effects: A Prosecutor, a Whistleblower and a Bestselling Antidepressant on Trial, GlaxoSmithKline did not acknowledge any possibility that Paxil (Paroxetine) might have contributed to the May 6, 2007 suicide of 18-year-old Sara Carlin of Oakville, Ontario. In response to questions from The Oakville Beaver on Saturday October 18, 2008, Peter Schram, of Corporate Communications, GlaxoSmithKline, issued the statement that:

"Any suicide is tragic and the greatest risk for suicide is untreated depression. Paroxetine has been used by tens of millions of patients and has been proven to be a safe and effective treatment since its launch more than 15 years ago. The label contains instructions regarding the use of paroxetine and important safety information about the product."

"If patients have questions regarding the use of paroxetine, or the management of their depression, they should contact their healthcare professional.

Also, it is very important that patients do not stop taking paroxetine without first consulting with their doctor."

In an article about my homicide in the London Free Press on Wednesday August 9, 2006, Peter Schram stated:

"Paxil did not trigger Carmichael's actions."

"David Carmichael's case is certainly a terrible tragedy, however we do not believe Paxil played any part in this situation."

It appears that GlaxoSmithKline will continue to deny any responsibility for SSRI-induced suicides and/or homicides, even though delusions and psychosis are listed as rare side effects of Paxil (1 in 1,000) in the Compendium of Pharmaceuticals and Specialties (CPS), a guide for doctors published by the Canadian Pharmacists Association.

Treating major depression with Paxil

Paxil has probably helped millions of adults recover from major depression, including me. In July 2003, at the age of 45, I was debilitated by major depression. I could not find the energy or motivation to shower, had poor concentration, lost almost all confidence in my work abilities, and had negative thoughts racing through my head. Within 6 weeks of taking 40mg. of Paxil a day, I conducted 2 presentations and co-facilitated a workshop at the Can-Fit-Pro Conference in Toronto. In fact, I had my most financially successful year ever during my first major depression and just before my catastrophic relapse. I made more than \$150,000 consulting during the August 1, 2003 to July 31, 2004 fiscal year after taking Paxil for 8 months and then weaning myself off the drug because of negative sweating and sexual side effects.

I might have had a better chance of preventing my first major depression if my father talked about his mental illness. Reflecting back, my father was never diagnosed or treated for what I now recognize as major depression. He seemed to be debilitated by this illness for many years. At 50 years of age, in 1974, he decided not to work again. For many years, my mother took care of our family on a bank employee salary. I suspect that he was too ashamed and proud to talk about being depressed and there were not as many treatment options available to him as there are today. My father died at 67.

I will continue to talk about Paxil, not against this drug. There is little doubt in my mind that Paxil can effectively treat major depression among adult sufferers. But I will also talk about what I consider to be the lack of willingness of GlaxoSmithKline to make doctors and the public more aware that in rare cases Paxil can trigger an acute psychotic episode.

Approaching GlaxoSmithKline

When Peter Schram of GlaxoSmithKline told Jennifer O'Brien of the London Free Press in August 2009 that "Paxil did not trigger Carmichael's actions" and that "David Carmichael's case is certainly a terrible tragedy, however we do not believe Paxil played any part in this situation", I decided to approach the company.

On Tuesday August 15, 2006, I left a voice message with Amanda Pratt of the Media Relations department at GlaxoSmithKline asking Peter Schram to call me regarding a potential opportunity to collaborate in a public education initiative. I also commented on his quote in the London Free Press implying that Paxil could not have caused my psychosis, even though delusions and psychosis are listed as rare side effects of Paxil in the Compendium of Pharmaceuticals and Specialties (CPS), and have been listed in the CPS since at least 1996. Peter did not respond to my voice message.

On Friday August 18, 2006, I decided to leave a follow-up voice message with Amanda Pratt. I provide more details about the potential public education initiative. I proposed that GlaxoSmithKline become the exclusive sponsor of a website that I was developing for people suffering from depression (depressionsufferers.com). I also indicated that if they became the exclusive sponsor that I would work with them on the messaging on my website (davidcarmichael.com) and that my wife, daughter and I would not explore the possibility of pursuing any legal action against GlaxoSmithKline. I told her that I consider Paxil to be an effective antidepressant and shared how it helped me recover from my first major depression in 2003. There was no response to my voice message.

On Friday August 25, 2006, a representative from GlaxoSmithKline called Brockville Mental Health Centre (BMHC) and told them that I left threatening voice messages and was trying to extort money from them. This allegation was not reflected in a letter that I received from GlaxoSmithKline on August 31.

GLAXOSMITHKLINE INC. LETTER

August 29, 2006

Mr. David Carmichael
c/o Brockville Psychiatric Hospital
P.O. Box 1050
Brockville, ON
K6V 5W7

Dear Mr. Carmichael:

Thank you for your telephone inquiries (Aug 15 & 18, 2006), regarding potential sponsorship in support of an educational website focused on mental health.

GLAXOSMITHKLINE INC. LETTER

Further to your proposal to provide mental health education to patients, Canadian physicians are provided with complete monographs that contain information about specific medications indicated for depression, including adverse events that have been reported in association with their use. We believe that physicians are in the best position to evaluate whether the benefits outweigh the potential risks for a particular patient, in light of the patient's clinical picture, medical history and current situation.

GlaxoSmithKline currently supports and works with many charitable organizations, primarily in the areas of health care and health promotion (including mental health), science education, hospice palliative care and local community projects. Unfortunately, we are unable to support sponsorship requests from individuals at this time.

Thank you for contacting us.

Sincerely,

Leanne Kitchen-Clarke
Director, Corporate Communications
GlaxoSmithKline Inc.

Since Ms. Kitchen-Clarke had not seen my project proposal before denying my request, and recognizing that many companies make their sponsorship decisions in the last quarter of the fiscal year (e.g., October to December), I sent a sponsorship proposal to her on September 1, 2006 with a more detailed covering letter.

LETTER TO GLAXOSMITHKLINE INC.

September 1, 2006

Leanne Kitchen-Clarke
Director, Corporate Communications
GlaxoSmithKline Inc.
7333 Mississauga Road
Mississauga, Ontario
L5N 6L4

Dear Ms. Kitchen-Clarke:

Thank you for your August 29, 2006 letter in response to my voice messages (August 15 and 18, 2006). In your letter, you indicated that GlaxoSmithKline is "unable to support sponsorship requests from individuals at this time." My request is for a project that will commence in 2007.

LETTER TO GLAXOSMITHKLINE INC.

Please find attached a sponsorship proposal for co-founding depressionsufferers.com. This interactive anonymous online support group for people suffering from depression will be launched in February 2007.

I would appreciate it if GlaxoSmithKline would consider becoming the co-founder of this website and the exclusive corporate sponsor for a 5-year period (2007-2011).

Thank you for considering this public education opportunity. I would appreciate the opportunity to meet with you to discuss this proposal.

Sincerely,

David Carmichael

On September 14, 2006, I left a voice message for Ms. Kitchen-Clarke as a follow-up to my proposal. I requested a meeting for late October at the GlaxoSmithKline Head Office in Mississauga since I knew that my mother, who was living in an apartment in Brockville and was approved by my treating psychiatrist and treatment team at BMHC to take me into the community, would be travelling with me to Toronto at that time. I also mentioned that if I did not hear back from her by the end of September, I would assume that GlaxoSmithKline was not interested in exploring this sponsorship opportunity. Ms. Kitchen-Clarke did not respond.

In December 2007, I was told about the May 6, 2007 suicide of 18-year-old Sara Carlin of Oakville who was apparently taking Paxil when she hung herself in the basement of her home. So I decided to approach GlaxoSmithKline again recognizing that they had the resources to do a much better job than davidcarmichael.com at communicating the message that:

Individuals of all ages should be closely monitored for suicidal and homicidal thoughts and behaviours for at least 1-month after they start taking Paxil and after they increase their dosage. They should also be closely monitored after they stop taking Paxil.

On January 17, 2008, I called Peter Schram at GlaxoSmithKline and left a voice message indicating that I would like to sell davidcarmichael.com and depressionsufferers.com to GlaxoSmithKline. He did not return my call, so I sent another letter to Leanne Kitchen-Clarke.

LETTER TO GLAXOSMITHKLINE INC.

January 21, 2008

Leanne Kitchen-Clarke
Director, Corporate Communications
GlaxoSmithKline Inc.
7333 Mississauga Road
Mississauga, Ontario
L5N 6L4

LETTER TO GLAXOSMITHKLINE INC.

Dear Ms. Kitchen-Clarke:

As a follow-up to my voice message to Peter Schram on January 17, I would like to meet with GlaxoSmithKline to discuss the sale of two websites that I have constructed 1) davidcarmichael.com and 2) depressionsufferers.com.

If you do not contact me before January 31, I will assume that GlaxoSmithKline is not interested in exploring this purchasing opportunity.

Sincerely,

David Carmichael

cc. Peter Schram

Ms. Kitchen-Clarke did not respond.

Educating the public

GlaxoSmithKline appears to have done little to educate the public about the most dangerous side effects of Paxil. This big chemical drug pharmaceutical company seems to value shareholder profit over human life. What is most disturbing, however, is that GlaxoSmithKline hires scientists that seem to deceive colleagues, peers, doctors, and the public about the efficacy of drugs and medical devices. Dr. Charles Nemeroff, for example, the individual who allegedly influenced senior staff at the Centre for Addiction and Mental Health (CAMH) at the University of Toronto to rescind a job offer to Dr. David Healy in November 2000, apparently earned more than \$960,000 from GlaxoSmithKline from 2000 to 2007.

THE NEW YORK TIMES

MONDAY JANUARY 29, 2007

TOP PSYCHIATRIST DIDN'T REPORT DRUG MAKERS' PAY

BY GARDINER HARRIS

One of the nation's most influential psychiatrists earned more than \$2.8 million in consulting arrangements with drug makers from 2000 to 2007, failed to report at least \$1.2 million of that income to his university and violated federal research rules, according to documents provided to Congressional investigators.

The psychiatrist, Dr. Charles B. Nemeroff of Emory University, is the most prominent figure to date in a series of disclosures that is shaking the world of academic medicine and seems likely to force broad changes in the relationships between doctors and drug makers.

In one telling example, Dr. Nemeroff signed a letter dated July 15, 2004, promising Emory administrators that he would earn less than \$10,000 a year from GlaxoSmithKline to comply with federal rules. But on that day, he was at the Four Seasons Resort in Jackson Hole, Wyo., earning \$3,000 of what would become \$170,000 in income that year from that company — 17 times the figure he had agreed on.

The Congressional inquiry, led by Senator Charles E. Grassley, Republican of Iowa, is systematically asking some of the nation's leading researchers to provide their conflict-of-interest disclosures, and Mr. Grassley is comparing those documents with records of actual payments from drug companies. The records often conflict, sometimes starkly

"After questioning about 20 doctors and research institutions, it looks like problems with transparency are everywhere," Mr. Grassley said. "The current system for tracking financial relationships isn't working."

The findings suggest that universities are all but incapable of policing their faculty's conflicts of interest. Almost every major medical school and medical society is now reassessing its relationships with drug and device makers.

"Everyone is concerned," said Dr. James H. Scully Jr., the president-elect of the Council of Medical Specialty Societies, whose 30 members represent more than 500,000 doctors.

Dr. Nemeroff is a charismatic speaker and a widely admired scientist who has written more than 850 research reports and reviews. He was editor in chief of the influential journal *Neuropsychopharmacology*. His research has focused on the long-term mental health risks associated with child abuse as well as the relationship between depression and cardiovascular disease.

Dr. Nemeroff did not respond to calls and e-mail messages seeking comment. Jeffrey L. Molter, an Emory spokesman, wrote in an e-mail statement that the university was "working diligently to determine whether our policies have been observed consistently with regard to the matters cited by Senator Grassley."

The statement continued: "Dr. Nemeroff has assured us that: 'To the best of my knowledge, I have followed the appropriate university regulations concerning financial disclosures.'" On Friday night, Emory announced that Dr. Nemeroff would "voluntarily step down as chairman of the department, effective immediately, pending resolution of these issues."

Mr. Grassley began his investigation in the spring by questioning Dr. Melissa P. DeBello of the University of Cincinnati after The New York Times reported her connections to drug makers. Dr. DeBello told university officials that she earned about \$100,000 from 2005 to 2007 from eight drug makers, but AstraZeneca alone paid her \$238,000 during the period, Mr. Grassley found.

Then in early June, the senator reported to Congress that Dr. Joseph Biederman, a renowned child psychiatrist at Harvard Medical School, and a colleague, Dr. Timothy E. Wilens, had reported to university officials earning several hundred thousand dollars each in consulting fees from drug makers from 2000 to 2007, when in fact they had earned at least \$1.6 million each.

Then the senator focused on Dr. Alan F. Schatzberg of Stanford, president-elect of the American Psychiatric Association, whose \$4.8 million in stock holdings in a drug development company raised concerns.

Mr. Grassley has sponsored legislation called the Physician Payment Sunshine Act, which would require drug and device companies to publicly list payments to doctors that exceed \$500. Several states already require such disclosures.

As revelations from Mr. Grassley's investigation have dribbled out, trade organizations for the pharmaceutical industry and medical colleges have agreed to support the bill. Eli Lilly and Merck have announced that they would list doctor payments next year even without legislation.

The National Institutes of Health have strict rules regarding conflicts of interest among grantees, but the institutes rely on universities for oversight. If a university fails, the agency has the power to suspend its entire portfolio of grants, which for Emory amounted to \$190 million in 2005, although the agency rarely takes such drastic measures.

Dr. Nemeroff was the principal investigator for a five-year \$3.9 million grant financed by the National Institute of Mental Health for which GlaxoSmithKline provided drugs.

Income of \$10,000 or more from the company in any year of the grant — a threshold Dr. Nemeroff crossed in 2003, 2004, 2005 and 2006, records show — would have required Emory to inform the institutes and take steps to deal with the conflict or to remove Dr. Nemeroff as the investigator.

Repeatedly assured by Dr. Nemeroff that he had not exceeded the limit, Emory did nothing.

"Results from N.I.H.-funded research must not be biased by any conflicting financial interests," John Burklow, a spokesman for the health institutes, said in the kind of tough statement that in the past has rarely been followed by real sanctions. "Officials at Emory are investigating the concerns."

"Failure to follow N.I.H. standards" on conflict of interest, Mr. Burklow continued, "is very serious, and N.I.H. will take all appropriate action to ensure compliance."

In 2004, Emory investigated Dr. Nemeroff's outside consulting arrangements. In a 14-page report, Emory's conflict of interest committee detailed multiple "serious" and "significant" violations of university procedures intended to protect patients.

But the university apparently took little action against Dr. Nemeroff and made no effort to independently audit his consulting income, documents show.

Universities, too, can benefit from the fame and money the deals can bring — a point Dr. Nemeroff made in a May 2000 letter stamped "confidential" that he sent to the dean of Emory's medical school.

The letter, which was part of a record from a Congressional hearing, addressed Dr. Nemeroff's membership on a dozen corporate advisory boards (some of the companies' names have since changed).

"Surely you remember that Smith-Kline Beecham Pharmaceuticals donated an endowed chair to the department and that there is some reasonable likelihood that Janssen Pharmaceuticals will do so as well," he wrote.

"In addition, Wyeth-Ayerst Pharmaceuticals has funded a Research Career Development Award program in the department, and I have asked both AstraZeneca Pharmaceuticals and Bristol-Meyers [sic] Squibb to do the same. Part of the rationale for their funding our faculty in such a manner would be my service on these boards."

Universities once looked askance at professors who consulted for more than one or two drug companies, but that changed after a 1980 law gave the universities ownership of patents discovered with federal money.

The law helped give birth to the biotechnology industry and led to the discovery of dozens of life-saving medicines. Consulting arrangements soon proliferated at medical schools, and Dr. Nemeroff — who at one point consulted for 21 drug and device companies simultaneously — became a national model.

He may now become a model for a broad reassessment of industry relationships. Many medical schools, societies and groups are considering barring doctors from giving lectures on drug or device marketing.

For all his fame in the world of psychiatry, Dr. Nemeroff has faced ethics troubles before. In 2006, he blamed a clerical mix-up for his failing to disclose that he and his co-authors had financial ties to Cyberonics, the maker of a controversial device that they reviewed favorably in a journal he edited.

The Cyberonics paper led to a bitter e-mail exchange between Dr. Nemeroff and Claudia R. Adkison, an associate dean at Emory, according to Congressional records. Dr. Adkison noted that Cyberonics had not only paid Dr. Nemeroff and his co-authors but had also given an unrestricted educational grant to Dr. Nemeroff's department.

"I can't believe that anyone in the public or in academia would believe anything except that this paper was a piece of paid marketing," Dr. Adkison wrote on July 20, 2006.

Two years earlier, unknown to the public, Emory's conflict of interest committee discovered that Dr. Nemeroff had made more serious blunders, including failing to disclose conflicts of interest in trials of drugs from Merck, Eli Lilly and Johnson & Johnson.

His continuing oversight of a federally financed trial using GlaxoSmithKline medicines led Dr. Adkison to write Dr. Nemeroff on July 15, 2004, that "you must clearly certify on your annual disclosure form that you do not receive more than \$10,000 from GSK."

In a reply dated Aug. 4, Dr. Nemeroff wrote that he had already done so but promised again that “my consulting fees from GSK will be less than \$10,000 per year throughout the period of this N.I.H. grant.”

When he sent that letter, Dr. Nemeroff had already earned more than \$98,000 that year from GlaxoSmithKline. Three weeks later, he received another \$3,844.56 for giving a marketing talk at the Passion Fish Restaurant in Woodbury, N.Y.

From 2000 through 2006, Dr. Nemeroff earned more than \$960,000 from GlaxoSmithKline but listed earnings of less than \$35,000 for the period on his university disclosure forms, according to Congressional documents.

Sarah Alspach, a GlaxoSmithKline spokeswoman, said via e-mail that “Dr. Nemeroff is a recognized world leader in the field of psychiatry,” and that the company requires its paid speakers to “proactively disclose their financial relationship with GSK, and we believe that healthcare professionals are responsible for making those disclosures.”

Taking responsibility

Since I was young, there was nobody that I trusted more to know about health issues than my doctor. After reading the October 2008 article about Dr. Nemeroff in The New York Times, it seems that my trust was in many ways blind faith. If scientists are not sharing all of the information from clinical drug trials in peer reviewed journal articles, media interviews and during conference presentations, we cannot expect doctors to have the information that they need to help us make prudent treatment decisions. It is now more obvious than ever that I have to take more responsibility for my own physical and mental health.

I have tragically learned just how catastrophic major depression can be. Harvard University conducted a study just over a decade ago, in partnership with the World Health Organization and the World Bank, that identified major depression as the leading cause of disability (lost years of healthy living) among 15- to 44-year-olds in developed countries. The top 10 illnesses/conditions were:

1. Major depression
2. Alcohol use
3. Road traffic accidents
4. Schizophrenia
5. Self-inflicted injuries
6. Bi-polar disorder
7. Drug use
8. Obsessive-compulsive disorder
9. Osteoarthritis
10. Violence

I have also discovered that the most debilitating part of major depression is not the mental illness itself, it can be treated. It is the shame, silence and stigma that surround the illness:

- At least one in 10 people will experience a major depression in their lifetime. Yet families and friends are not likely to talk about it.
- Seventy-two percent of the people who suffer from depression are in the workforce, where depression is emerging as one of the most common disabilities. Studies indicate that 60% of employees maintain regular work hours when they are depressed. Yet colleagues and peers are not likely to talk about it.
- The numbers are growing among children and youth. In 2006, the Ontario Ministry of Children and Youth Services reported that 1 in 5 children in the province have a mental health problem. Yet families and teachers are not likely to talk about it.
- There is evidence to suggest that, as the population ages, more adults will experience depression. In some cases, depression will be an isolated disease among older adults. In other cases, it will be associated with aging-related illnesses such as stroke, Alzheimer's disease, heart disease and cancer. Yet families and caregivers are not likely to talk about it.

Unfortunately, less than one-third of the people who suffer from depression seek help. And when they do, most people equate treatment with antidepressant drugs. Between 1992 and 2003, after SSRIs were introduced, the number of prescriptions for antidepressants in England, for example, tripled from 9.9 million to 27.7 million. Over the same period, the cost of antidepressant prescriptions increased from 18.1 million pounds to 395.2 million pounds.

Depression sufferers will only be able to effectively take responsibility for their own mental health after they are provided with all of the information about the benefits and risks associated with different treatment options so they can make informed decisions with their doctors.

If Paxil does become the drug of choice, it is important to be aware that:

Individuals of all ages should be closely monitored for suicidal and homicidal thoughts and behaviours for at least 1-month after they start taking Paxil and after they increase their dosage. They should also be closely monitored after they stop taking Paxil.

It is incredibly tragic for many families that this type of message has not been effectively communicated to doctors and the public by GlaxoSmithKline.



About David Carmichael

After completing a Masters degree in Physical Education with a Coaching Specialization at York University in Toronto, Canada in 1985, David had a successful 20 year career with not-for-profit organizations in the sport and physical activity sectors.

- 1984 to 1985 – Program Coordinator at the Ontario Amateur Wrestling Association
- 1985 to 1987 - Development Officer at the Western Australian Amateur Wrestling Association
- 1988 to 1991 - High Performance Director at the Ontario Amateur Wrestling Association where he co-designed a long-term Wrestling Athlete Development Model for 10- to 29-year-olds in partnership with the Canadian Amateur Wrestling Association, Coaching Association of Canada (CAC) and the Ontario Ministry of Tourism and Recreation
- 1988 to 1998 - Director of Research and Development at the Ontario Physical and Health Education Association (OPHEA) and the creator of Sportability and Movability, fundamental multi-skill development programs for children
- 1992 and 1993 – Workshop Leader for Make the Active Choice, a joint project of the Ontario Ministry of Tourism and Recreation and the Parks and Recreation Federation of Ontario (PRFO) that promoted the role that recreation plays in preventing substance abuse among young people
- 1994 to 1996 – Member of the Provincial Advisory Council on Substance Abuse to the Ontario Minister of Health
- 1995 to 1999 – Member of the founding Management Committee for High Five, a quality assurance program for children's recreation and sport programs developed by Parks and Recreation Ontario (PRO)
- 1998 to 2001 - Director of National Projects at ParticipACTION where he managed Summer Active, Youth on the Run, the Sport for Your Child public education campaign, and conducted workshops for active living leaders, health promoters and public health professionals on Canada's Physical Activity Guide for Older Adults
- 2001 to 2004 – Province-wide Facilitator for the development of Community Sport Councils for the Sport Alliance of Ontario (SAO)
- 1988 to 1991/1999 to 2004 - Course Conductor on Long-Term Athlete Development for Levels 4/5 of the National Coaching Certification Program (NCCP) for the Coaching Association of Canada (CAC) at National Sport Leadership Conferences and the National Coaching Institute Ontario (NCIO)
- 2001 to 2004 – Manager of Let's Get Moving!, a community-based campaign of the Canadian Professional Coaches Association (CPCA) that fostered multi-sector collaboration in support of Quality Daily Physical Education (QDPE) and promoted the need for community based, participant-centred recreation and sport programs for all children and youth
- 2003 and 2004 – Facilitator for the development of Innovative Participation Projects that foster positive sport experiences with Ontario Special Olympics, Ontario Wheelchair Sports Association, RowOntario, Softball Ontario, Ontario Cerebral Palsy Sports Association, Ontario Volleyball Association, Gymnastics Ontario, and the Ontario Speed Skating Association

In July 2003, at the age of 45, David experienced his first major depression. He started taking 40mg. of the selective serotonin reuptake inhibitor (SSRI) Paxil a day. By September, he was feeling mentally healthy again. After forgetting to take Paxil for a few days in February 2004 and feeling well, David weaned himself off the drug. He suddenly started to experience the symptoms of major depression again 4-months later in July. His symptoms included insomnia, increased anxiety, low concentration, a lack of energy, and rapid weight loss. David put himself back on 40mg. of Paxil a day from a previous prescription that was filled in February.

A few days after David started taking Paxil again, he was having suicidal thoughts. David thought he could get rid of the thoughts and recover more quickly if he increased his dosage. On July 17, he started taking 60mg. of Paxil a day. Three days later, David planned his suicide. He went from planning his suicide to planning a murder-suicide to planning a murder. On July 31, 2004, David killed his 11-year-old son Ian in London, Ontario. He was charged with first-degree murder.

In November 2004, David was diagnosed by a leading forensic psychiatrist at the Royal Ottawa Health Care Group (ROHCG) as being in a "major depression" with "psychotic episodes" when he killed Ian. In May 2005, his assessment was supported by another leading forensic psychiatrist from the Centre for Addiction and Mental Health (CAMH), who was hired by the Crown Attorney.

On September 30, 2005, David was judged in London to be "not criminally responsible on account of a mental disorder" for murdering Ian and was sent to Brockville Mental Health Centre (BMHC).