

Link: <http://news.bbc.co.uk/2/hi/programmes/panorama/2310197.stm>

Introduction

Seroxat is one of the world's biggest selling and most successful anti-depressants.

But this Panorama investigation discovers the drug may have a darker side - the programme reports that people can get hooked on it, suffering serious withdrawal symptoms when they try to come off it.

For some it can lead to self harm and even suicide. But little warning of these possible side effects accompanies the drug.

These are accusations that the drug's maker GlaxoSmithKline denies.

The programme follows one Seroxat user and charts her nine month struggle to wean herself off it.

Panorama also spoke to Dr David Healy, an expert on the drug who has had access to confidential Seroxat studies in the GlaxoSmithKline archives.

Link: <http://news.bbc.co.uk/2/shared/spl/hi/programmes/panorama/transcripts/seroxat.txt>

PANORAMA
THE SECRETS OF
SEROXAT

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SHELLEY JOFRE: The chances are you, or someone you know, is taking Seroxat. It's almost overtaken Prozac as Britain's most popular antidepressant. Prescribed for everything from anxiety to stress, Seroxat has transformed the lives of millions. But for some, the 'happy pills' have a darker side.

HELEN KELSALL: If I'd known what I would have had to go through, there is no way that I would have started taking the drug.

JOFRE: Internet chat rooms are packed with complaints from people who claim they are addicted to Seroxat. Others say it can be a prescription for violence, suicide and self-harm.

ED CASEY: I was burning myself with cigarettes. I was taking the blades out of disposable razors and sort of cutting my arms and my chest.

DR HEALY: If they aren't the right drug for you, they can cause a range of problems. They can make you suicidal, they can throw you into a state of mental turmoil, and even if they are the right drugs for you, in some instances they can leave you hooked.

JOFRE: After just two days on Seroxat one man slaughtered his family.

ANDY VICKERY: He shot and killed the three women that he loved most in the world, his wife, his daughter and his 9 month old granddaughter.

JOFRE: The company that makes Seroxat has long known about safety concerns. Tonight the evidence that's remained under lock and key here in Essex for 15 years.

Video diary, May 2002:

HELEN: I'm 22, I live in London. I've been taking Seroxat for four and a half years. It was originally prescribed to me to stop me having panic attacks. These are them. I've wanted to come off it for quite a few years now but when I stopped taking it, I was so ill that I had to start taking it again and doctors kept telling me that it was impossible to be addicted to them.

JOFRE: Helen Kelsall's problems began as a teenager. Beneath her vivacious shell her confidence was crumbling. Seroxat was supposed to be her cure.

HELEN KELSALL

I've been having panic attacks and I was also doing my A-levels at the time, and I probably was a bit depressed as well, but mainly the panic attacks because I've had some quite serious ones and I had ended up in hospital a couple of times, and I didn't really know what they were, and at that time I didn't really know how to do research into your own medical things and I trusted what the doctor said, so I started taking them and that's how it's been from there.

I'm feeling really crap. Shocks.. head shocks really throwing me off. Headaches, muscle pains, sweating, trembling. As I take each step there's this shock in my head that's completely throwing me off balance.

JOFRE: Using a video camera, Helen has been keeping a unique record of her long running struggle with Seroxat. She's been trying to wean herself off the drug since the start of the year, but it's not easy. The tablets are so potent she can't just stop taking them. That makes her feel too ill. The only way she can make small enough reductions in dose is to chop the tablets up.

The withdrawal symptoms have forced Helen to miss much of her university course this year. She's in danger of failing her degree.

HELEN: I'm going into my final year of my masters degree. I can't afford to take time off because I'm ill and because I'm getting these shocks and this nausea. I've already had enough problems with university that's come about from this withdrawal, and I can't carry on like that.

JOFRE: Seroxat is second only to Prozac as the nation's favourite antidepressant. It's one of the drugs that has revolutionized the treatment of mental illness. Taking Seroxat can transform people's lives, but stopping it can be a nightmare.

TELEPHONE: Hello, Medication helpline....

JOFRE: The Maudsley Hospital in London runs a national information service for people taking psychiatric medicines. Trouble coming off Seroxat is the number one complaint from callers. Doctors too report far more withdrawal problems from patients on Seroxat than on any other drug.

DAVID TAYLOR

Chief Pharmacist, Maudsley Hospital If a patient is to stop taking Seroxat suddenly, then usually they would quite soon become quite anxious. They may feel very dizzy and unsteady on their feet. Often people experience electric shock sensations. They may also have a fever and feel generally unwell and they also may experience mood changes or very vivid nightmares for example.

JOFRE: The information leaflet that accompanies Seroxat says these symptoms are not common and will generally disappear within a few days of stopping the drug. It says: "Remember, you cannot become addicted to Seroxat." Not unreasonably perhaps, many think that means they can stop taking Seroxat whenever they want.

TAYLOR: Although people might suspect that the effects that they're getting are caused by stopping the medication, very few are aware that that might be the case. Very few have been forewarned that they might experience these kind of symptoms.

June 2002

HELEN: When the doctor said this is going to help and it's not got any downside which is effectively what they said, I just thought.. oh, brilliant, absolutely brilliant. Now I realise that they couldn't really have been more wrong.

JOFRE: Helen isn't the only one. On the Internet she's found hundreds of others who had no idea what to expect when coming off Seroxat. And like Helen, many have had withdrawal symptoms that are worse than their original illness.

HELEN: Visual distortions, almost like hallucinations. Small tingle rapidly blasting up my torso. This guy is saying: "I find the worst side-effects is the feeling of sickness and giddiness, like you're roaring drunk and the world is spinning." Somebody else saying: "Don't try to come off it cold turkey, it's not recommended." That must be so disturbing.

JOFRE: Seroxat is one of a family of five antidepressants known as SSRIs. They're the wonder drugs of the last decade offering a cure for everything from anxiety to depression to phobias. Millions of people have been helped by them and they're extremely popular with doctors.

Dr ANDY CLAYTON

Medical Director, Derby Mental Health Trust

They're so simple, you don't need to be a genius to prescribe antidepressants and they get seven out of ten people better in a couple of months and they're not even very expensive.

JOFRE: Cheap, effective and apparently even Seroxat withdrawal symptoms can be beneficial.

CLAYTON: Interestingly I've actually found the withdrawal effect to be quite handy for a few people. I've had several patients who've come to see me in clinic and said: "I actually sort of stopped taking my antidepressant doc because I thought I didn't need it. But after a day or so I felt a little twitchy, a little uncomfortable and it made me realise I did need it."

JOFRE: But wouldn't that just be the withdrawal effect?

CLAYTON: Well exactly, that's the withdrawal effect that they had noticed for a day or so and it had prompted them to go back on the pills which is very helpful.

JOFRE: Helpful or not the drug's maker, Glaxo SmithKline, is satisfied patients know exactly what to expect before they start taking Seroxat.

Dr ALASTAIR BENBOW

Head of European Clinical Psychiatry

GlaxoSmithKline's Seroxat is a generally well tolerated medicine that's been used extensively around the world over the last ten years. As with all serious medicines.. all prescription medicines, Seroxat does have side effects, but these are clearly stated in the information that's made available to doctors and to patients.

JOFRE: Many patients, though, complain the information isn't clear. They say they've been misled by the company's reassurance that Seroxat is not addictive. Because of this, thousands of people both here and in America are now taking legal advice.

Your leaflet says: "Remember, you cannot become addicted to Seroxat" but that's not true, is it?

BENBOW: Yes it is true. There is no reliable evidence that Seroxat can cause addiction or dependence, and this has been borne out by a number of independent clinical experts, by regulatory authorities around the world, by the Royal College of Psychiatrists and a number of other groups.

JOFRE: If people can't stop taking a drug when they want to stop taking it, they're addicted, aren't they?

BENBOW: No, that's not correct. The definition of addiction is not as you describe it. Addiction is characterized by a number of different criteria which includes craving, which includes increasing the dose of drug to get the same effect and a number of other features, and these are not exhibited by Seroxat.

JOFRE: That's not, with respect, what the Oxford English dictionary says. It says Addiction is having a compulsion to take a drug the stopping of which produces withdrawal symptoms. Now we've spoken to plenty of people who say they're compelled to take Seroxat because stopping it produces withdrawal symptoms - they're addicted.

BENBOW: If you use that limited description of addictive, then most prescription medicines could be defined as addictive. Beta blockers which are used for the treatment...

JOFRE: This is the common usage of the word, this is what people are understanding addicted to mean, and you're misleading them in the patient leaflet by saying they can't become addicted.

BENBOW: No, we are not misleading them. The information in the patient leaflet and in the information we supply to doctors, is based on fact. It's based on data which is generated during clinical trials and during the marketing of the product over the last ten years.

Dr DAVID HEALY

Director, NorthWales Dept of Psychological Medicine

They should be framing these things in language that patients will understand. Now what most patients will understand that Seroxat is not addictive means is that if I take this drug I can halt it and I won't have a problem halting it. Well that's not true.

July 2002

HELEN: This is my final week of having one day where I get a whole tablet. So next week I'll be on half a tablet every day. And to be honest I'm really dreading it.

[Advertisement]

The kids are fine. Why are you always so anxious? Family and friends may not understand chronic anxiety – PAXIL
Dad, you're always so tense. Are you mad at me?

Honey you can't keep losing sleep, it makes you so irritable.

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Chronic anxiety can affect your relationships, your work, your life. Available by prescription only

JOFRE: If Seroxat is big here, it's massive in the States. There it's called Paxil and, unlike in Britain, it can be advertised direct to the public.

NICK ALCOCK

Pharmaceutical Company Analyst

Datamonitor

Well in 1999 Glaxo SmithKline were estimated to spend around 30 million advertising Paxil in the US. In 2000 this figure had probably risen to just around 90 million.

JOFRE: And it was money well spent. Sales of the drug earned Glaxo SmithKline nearly 2 billion pounds last year. Another reason for its phenomenal success is that it's licensed to treat more illnesses than any other antidepressant, illnesses you may not yet have heard of, like generalized anxiety disorder.

ALCOCK: Glaxo SmithKline sought out indications in anxiety disorders to essentially increase the number of patients who can actually take the drugs.

JOFRE: So the more patients they get, the more money they get.

ALCOCK: Precisely.

[Advertisement]

With the help of Paxil you can see someone you haven't seen in a while - yourself.
Hey, I remember you.

JOFRE: On both sides of the Atlantic, criticism of Seroxat is growing. There's evidence that in the first few weeks of taking the drug it can make people more anxious. Some research suggests this can happen in up to a quarter of patients, throwing them into a temporary state of mental turmoil.

HEALY: What you've got to realise is by mental turmoil here, we mean a state where people are having thoughts and impulses that they've never had before, thoughts of harming themselves or harming others. They haven't been having these thoughts at all, but within a few days of being on the drug they begin to have thoughts like this.

JOFRE: Ed Casey's ambition was to make it as a musician. With some friends in his home town of Newport he formed a band six years ago. They recorded a couple of singles and for a while things were looking good.

ED CASEY

I was in a band, yeah, that was good fun. When we started to do that, that was really good. It started off really, really well, so that side of my life was excellent. The other side, I was sort of feeling not very nice about myself. My confidence started to go. I started not to like myself, and then I started to suffer from anxiety and that was really, really scary.

JOFRE: Scary for Ed and for his parents. His mother took him to see the doctor. The doctor prescribed Seroxat. But shortly after going on the drug the son she knew began to change.

GLYNIS CASEY

The one thing he said was he didn't feel real sometimes, it was very strange but just in his manner really, he just became very much more introverted I suppose and liable to just go off into a mood for nothing at all really.

JOFRE: And things were to get worse, much worse. Within a fortnight of starting on Seroxat Ed started mutilating himself.

Would you mind showing me what you did?

ED: No, not at all. I'll have to strip off. There across the top of my shoulder and on my chest. These cigarette burns and there's sort of razor marks there as well.

JOFRE: Had you ever done anything like that before?

ED: Never. Never, no.

JOFRE: When you found out what Ed was doing can you remember how you felt?

GLYNIS: I just couldn't understand it to be honest, but obviously was very concerned about him, just wanted him to get some help so we could get to the bottom of it really so he could get better.

ED: I went back to the doctor just a month after I first started to take Seroxat and that's sort of little while after the burning and what have you had started. They said continue taking Seroxat and see how it goes.

JOFRE: So there was no suggestion it was the drug causing it?

ED: No, not at all.

JOFRE: Side effects usually occur in the early stages of taking the drug. In Ed's case the self harm stopped after a few months. It never occurred to him at the time that the drug might have been the cause. But why should it? There was no warning. Glaxo SmithKline denies that Seroxat is linked to self-harm, just as they deny it's addictive.

HELEN: This is what I've woken up to this morning, an enormous leak in my roof, just what I could really do without right now. I've got really awful head shocks and I'm just.. I've woken up and I'm.. I can't get through to anyone to sort this problem out. I'm going to have to miss another day of uni and I'm feeling terrible. I'm not really in the mood to do this. I'm so fed up.

JOFRE: It's taken a legal battle on the other side of the world to finally lay bear the secrets of the Seroxat, secrets that have been locked away for 15 years. The case began four years ago in Gillette, Wyoming, home to retired oil man Donald Shell and his wife Rita. They'd just become grandparents and were enjoying a visit from their daughter and the baby. Tim Tobin, their son-in-law, was on his way to join them all at the weekend. But when he got to the house he realized something was wrong.

TIM TOBIN

I started noticing things like the paper was still in the front door. I went to the neighbour's house and he said he hadn't seen them, and I, at that point, became frantic.

MIKE WENZ

Gillette Police Department

I met Mr Tobin outside standing in front of the residence. He told me that he was concerned about his family and that he thought that they were inside and something may have happened to them.

TOBIN: He wouldn't open the door so I broke the window out of the rear door and I ran upstairs and the policeman was behind me, and that's when I found everybody.

WENZ: We found three adults and about a ten month old infant that had been shot to death that were all laying on the floor in the bedroom.

13TH February 1998

The Wyoming State Crime Lab Team is in Gillette tonight reconstructing the scene that left four people dead. Neighbours can't believe Donald Shell, his wife Rita, their daughter Debbie Tobin and her 9 month old daughter are dead. They were all found in this house Friday night in an upstairs bedroom with gunshot wounds all to the head.

JOFRE: By all accounts Donald Shell was a doting grandfather. For ten years on and off, though, he'd been depressed, depressed but never suicidal according to his medical records, and he had no history of violence or aggression.

TOBIN: I felt like something had almost turned him into a monster and.. because there's no way that anybody in their right mind would do something like that, it was just horrible. The Don that I knew wasn't that type of person. The only thing that had changed was the medicine that he was taking, the Paxil.

JOFRE: Paxil is the American brand name for Seroxat. Donald Shell had been on Paxil for just two days and taken just two tablets before the carnage. His family could see only one explanation. The drug must have turned Don into a killer. They decided to take Glaxo SmithKline, the world's second largest drug company to court. But the company was not about to let its best-selling drug take the blame. That much was obvious when the family's lawyer took a sworn statement from the company's then head of world-wide safety, Doctor Ian Hudson. This is his interview recorded on video and later played to the jurors in court. He was asked a number of times if Paxil was linked to violence or suicide.

Reconstruction

Voice of Andy Vickery, Tim Tobin's lawyer:

How many instances are there in which Paxil has been reported to SmithKline Beecham to be temporarily associated with acts of aggression or suicidality?

Actual video evidence

Dr IAN HUDSON

Worldwide Director of Safety

SmithKline Beecham 1999-2001

Could you clarify what you mean by that, "temporally associated"? I'm not sure what you mean.

VICKERY: I mean that a patient becomes homicidal or suicidal within a relatively short period of time from either taking Paxil or getting an increase in dose of Paxil.

HUDSON: You haven't defined what you mean by a relatively short period of time, but I would also have to go back and.. I don't know the answer to that question. I would need to go back and discuss that with people within my department.

JOFRE: Tim Tobin's lawyer struggled to get a clear answer from him on the question of Paxil and suicide.

VICKERY: If a doctor reported to your company 'Hey, I think Paxil caused this man to be aggressive or suicidal' explain to me why you would not make your own determination of whether he was right or wrong.

HUDSON: We would review the reported event, we would decide whether there are confounded factors, but the sorts of events that we're talking about here, or perhaps I should ask you to clarify which events we are talking about here actually.

ANDY VICKERY, Tim Tobin's lawyer:

I do not believe that was an adequate response. I think that a company that sells mind altering drugs to the public, particularly in the volume that this entire class of drugs sells, has an obligation to thoroughly investigate any instance where their drug may be the cause of violence or suicide or death.

JOFRE: Glaxo SmithKline maintained it was depression, not the drug that made Donald Schell kill, but here at Harlow in Essex, the company keeps a vast archive of clinical trial results including trials in which Seroxat was tested on healthy people with no hint of depression. For 15 years these results remained confidential until the Wyoming case. The judge granted the family an order to allow an expert into the archive to examine these files. The man they chose was Doctor David Healy, an expert on SSRIs who'd just got some disturbing results from trials of a drug similar to Seroxat.

Dr DAVID HEALY

Director, North Wales Department of Psychological Medicine

We'd run a trial where we're given a group of healthy volunteers working in this unit and SSRI. These included GPs, consultant psychiatrists, senior nurses, all of whom were both healthy and senior and responsible. And what we'd seen was when people went on the wrong drug for them, that they went through a state of mental turmoil on to becoming frankly suicidal.

JOFRE: Doctor Healy's task was to find out if Seroxat had produced similar side effects when it was tested on healthy people. If so, it could be crucial evidence in the case.

VICKERY: The drug companies in a suicide case for example will say well, the person committed suicide because they were depressed. Well, if you have a healthy volunteer who is not depressed, that takes that out of the equation, and so the effects that those people have on the drugs are very important as giving us some indication of what this drug can do to people.

HEALY: In the Tobin -v- SmithKline trial I had to file a report, and expert report for this trial, and as part of that.. some months beforehand I'd asked to get access to the archives. It was only in the last week before I had to file the final report that I got access to the archives.

JOFRE: Doctor Healy's task bordered on the impossible. He had just two days to find and read all Glaxo SmithKline's confidential studies on healthy people. He knew it was going to be difficult. He didn't realize quite how difficult until he got there.

Reconstruction

HEALY: What I was faced with when I got there was a long room with a series of files. I'm told there are over 250 thousand sheets of paper there, a quarter of a million sheets of paper. When I saw what I was actually faced with my heart literally sank. I had no real idea about how to go about trying to work out what I could learn from all this.

Reconstruction

JOFRE: A few files were missing from the archive but in just two days Doctor Healy read all the available studies the company had done on healthy people. The secrets of Seroxat were finally beginning to unfold.

HEALY: It seemed clear that some people that went on the drugs had no major problems, but equally clear that others who went on the drug ended up more restless, in a state of mental turmoil, complaining about dreams, nightmares and a range of things like this. These don't seem to have been explored further in any great detail.

Reconstruction

JOFRE: He discovered around one in four suffered these sorts of side-effects on Seroxat, even when they were on normal doses and even when they'd only been taking it for a few days. And remember, these were people with no previous sign of mental illness.

In his evidence to the court in Wyoming, Doctor Healy's conclusion was clear. It wasn't depression that made Donald Shell kill three generations of his own family, it was Seroxat, a conclusion Doctor Hudson was reluctant to accept.

Reconstruction

Voice of Andy Vickery, Tim Tobin's lawyer:

You're telling me under oath it's simply impossible for SmithKline Beecham to decide whether Paxil did or did not cause Mr Schell to murder his wife, his daughter, his granddaughter and then to commit suicide. Is that right sir?

Actual video evidence

Dr IAN HUDSON

Worldwide Director of Safety
SmithKline Beecham

HUDSON: It is impossible on an individual case basis for individual courts to assign causality, especially in a very complicated area such as this, that is why, when we have issues, we review all the available data and make a determination on the basis of all the available data whether there is an issue or not.

HEALY: Listening to Ian Hudson in court, I have to say that I didn't get any feel that he was actually concerned about the welfare of people going on this drug. But I have to say that it seemed to me that he was much more concerned about the welfare of the company.

JOFRE: The Wyoming jurors were unanimous in their verdict. They decided Seroxat was the main factor in the four deaths. Glaxo SmithKline was found guilty of failing to warn patients and doctors of the drug's dangers and ordered to pay over \$6 million in damages.

VICKERY: We feel elated. Justice has been done.

TOBIN: It felt like people had looked independently from my pain and looked at the facts as everybody had brought them together, and everybody had their chance and time to put in their facts and their witnesses and in the end those people actually felt that what we were saying was right.

Dr ALASTAIR BENBOW

Head of European Clinical Psychiatry
GlaxoSmithKline

There is no reliable clinical evidence that Seroxat causes violence, aggression or homicide. This tragic, tragic case is something that does occur from time to time in patients who are depressed.

JOFRE: This man had no history of suicidal thoughts or tendencies. The jurors sat and listened to all the evidence and decided that there were four deaths that were mainly caused by Seroxat. Your company was found guilty of negligence. You can't ignore that.

BENBOW: No, nor would we want to ignore it. This was a tragic case but we remain firmly convinced that Seroxat did not cause the tragic events in this case.

JOFRE: A fortnight after the verdict the company added a warning to patient leaflets in Britain, but the wording still avoids any suggestion that Seroxat itself may cause suicidal thoughts. "Occasionally the symptoms of depression may include thoughts of harming yourself or committing suicide. Until the full antidepressant effect of your medicine becomes apparent, these symptoms may increase in the first few weeks of treatment."

It sounds to me here like you're trying to have it both ways. You're trying to say the risk increases when you start taking the drug but it's nothing to do with the drug. It's a meaningless warning.

BENBOW: No, the warning is there and has been agreed with the regulatory authorities which basically is to tell doctors, look, you have a patient who is depressed, they are at risk of suicide. Don't just think, just because you've started them on antidepressants, that they are not going to remain at risk of suicide immediately. The fact is that antidepressants take a while to work.

JOFRE: Even after the historic Wyoming verdict, it's business as usual for the company. They still maintain their best-selling drug does not cause self-harm, suicide or addiction.

It's now 8 months since Helen Kelsall started her Seroxat withdrawal programme. She's had trouble making small enough reductions in dose with the tablets.

August 2002

HELEN: It looks like... well... we'll see.

JOFRE: So she's switching to a liquid version because it's easier to measure out. Helen hopes to kick it completely in a month or so.

HELEN: Oh God!

JOFRE: The company's claim that Seroxat is not addictive was also undermined by the evidence brought to light in Wyoming. Glaxo SmithKline's own research showed even some healthy people suffered withdrawal effects when they stopped the drug.

Dr DAVID HEALY

Director, North Wales Department of Psychological Medicine.

Yes, it was clear from early on that the company had recognized that people who had been on this drug even for a relatively brief periods of time could go through withdrawal when they halt it. And they ran healthy volunteer trials to look at this further and found that in some instances up to 85% of the volunteers who had been on this drug for only two or three weeks had withdrawal problems when they halted.

JOFRE: 85%! That's most of the people who took it.

HEALY: Yes.

Reconstruction

JOFRE: The company says that in that study the frequency of problems was generally comparable to those suffered by people who were just given sugar pills. But Doctor Healey maintains withdrawal symptoms from Seroxat were more frequent and much more serious. Of course if the data was publicly available this sort of dispute could be easily resolved.

Why should this information be secret?

BENBOW: It's not secret, it's been made...

JOFRE: Well I can't see it so it's secret.

BENBOW: No, but you are not a clinician or a health care professional. The consent forms for the healthy volunteers clearly say who we can and who we can't...

JOFRE: So if my GP wants to see it, can he see it?

BENBOW: The data effect... he is not... Your GP is a clinician, if he asked to see some of the data then of course he could see the data... if it was appropriate.

JOFRE: But Doctor Healey is a clinician and he needed an American court order to see the data.

HEALEY: Not only can you not see what I've seen, but I've made notes on those as well and you can't even see my notes, and it seems extraordinary to me that really that the only way anyone can get to see things like this is

through a legal case, and not even a legal case happening here in the UK but one that happens over in the US. It's difficult to call it scientific and it's hard to see how it can be good for patients.

JOFRE: Drugs that are considered safe for patients are given a license by the medicines control agency. They saw the healthy volunteer data before they licensed Seroxat and remained satisfied there's insufficient evidence to link the drug to suicide. But no one was willing to be interviewed for this programme. Now there's a new market that Glaxo SmithKline is hoping to tap into, and it raises new concerns about the drug's possible side effect. This Texas office block is home to one of the many private clinics in America where Seroxat and drugs like it are being tested on a whole new group of patients - children.

KATHY HARPST

Vice President: Bayou City Research

Hi, welcome to Bayou City Research. Here's where we do pharmaceutical research in trials on children and adolescents from any psychiatric disorder that we have. They come in here and they help themselves to crackers, cookies - free candy, free crackers, free sodas.

JOFRE: So they like coming here.

KATHY: Yes, we let them.. everybody here just helps themselves, as soon as they come in they... it's like home here. That's how we wanted to make them feel comfortable.

JOFRE: The clinic advertises for children in local newspapers and it's not just free cookies they get for taking part.

PATTI BLACKWELL

Study Co-ordinator, Bayou City Research

They get a travel reimbursement and for several studies, some studies it has to be approved by the regulatory board. We did a study where the children got reimbursed \$25 each time they came in. The other incentive is that they get their medication free. So these are drugs that maybe would cost several hundred dollars a month in the pharmacy they're actually getting free in the research.

JOFRE: Sounds generous until you realise just how much Glaxo SmithKline stands to gain if trials like these are successful. The patent which gives the company its lucrative monopoly on producing Seroxat runs out soon. A new license offers a way of extending it.

NICK ALCOCK

Pharmaceutical Company Analyst

Datamonitor

In the United States, if a company such as Glaxo SmithKline can gain an additional licence for the treatment of children, it means that they get a six month extension to their overall patent.

JOFRE: And is that worth a lot of money?

ALCOCK: For Paxil it's worth.. six month's worth of sales is around a billion dollars, so yes.

JOFRE: That billion dollar windfall now looks tantalisingly close, thanks to a recent study co-written by American child psychiatrist Neal Ryan. It was the biggest ever trial of Seroxat in children funded by Glaxo SmithKline. The depressed children who took Seroxat did better than those who took an older drug, or were just given sugar pills. That's the good news. The bad news is that ten of the ninety-three children on Seroxat suffered serious psychiatric problems within weeks of going on the drug. Most of them had to be hospitalized.

There were five children out of ninety-three children on Seroxat who had suicidal thoughts and gestures. Another five out of that ninety-three had serious psychiatric side effects. Don't you think parents would be worried about that if their child was to be given this drug?

Dr ALASTAIR BENBOW
Head of European Clinical Psychiatry
GlaxoSmithKline

I think what parents would be more worried about is the risk that their children have of committing suicide and other symptoms of severe depression if no treatment was available. I think parents would want treatments to be properly evaluated during clinical trials before their children are given any medicine.

JOFRE: But the evidence here suggest that their children might be at more risk of suicide if they go on Seroxat.

BENBOW: No, the evidence is not there, there is no statistical difference between the groups. The reality of the situation is that in this trial, Seroxat was generally well tolerated by this difficult-to-treat-population.

JOFRE: Seroxat has yet to be formally approved as safe for children, but some doctors who found it useful in adults are already prescribing the drug to their younger patients. They're allowed to do this, but they're unlikely to be aware of the recent trial results.

Dr DAVID HEALY
Director, North Wales Department of Psychological Medicine

Thoughts of self-harm and actual self-harm episodes are happening much more frequently on this drug than on the older drug it was being compared with are than on sugar pills, and I'm pretty sure that very few GPs or consultant psychiatrists treating children up and down the UK with this drug will have a clue of results like this.

JOFRE: Seroxat was prescribed nearly five million times last year. It's hugely popular and even the drug's critics acknowledge a great many people have been helped by it, butt here is concern that patients aren't being given the full picture before they start taking Seroxat.

For Helen Kelsall life is just starting to get back to normal. She took her final dose of Seroxat last month. But she's angry that it's taken the best part of a year to withdraw from a drug she was assured was non-addictive.

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HELEN: If I knew five years ago what I know now about the drug, I never would have taken it, and that's what it boils down to. I didn't know what it would do to me, and I would have never made the choice to take it had I known, and that's pretty much the strength of it, so there you go.

JOFRE: If you're concerned about issues raised in this programme you can call the BBC help line on 0800 88 88 09. You should not stop taking any medication without consulting your doctor. On Thursday Glaxo SmithKline won a court case in America allowing them to market Seroxat as non-habit forming. But on the same day in Britain they were found in breach of the drug industry's code of practice for playing down the drug's withdrawal problems. There's other information on our website where you can join us for an online discussion at 3pm tomorrow.

www.bbc.co.uk/panorama

A reminder of the number to call if you've been affected by the issues in tonight's programme and would like details of organisations that can provide information and support.

The BBC Action Line : 0800 888809 All calls are free and confidential

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