

Link: <http://news.bbc.co.uk/2/hi/programmes/panorama/2982797.stm>

Introduction

Last October Panorama revealed the dark and shocking side of Seroxat, one of the world's favourite anti-depressants.

The feedback to that film was unprecedented with thousands of people contacting the programme.

For many who take the drug it is a tremendous help but in e-mails and phone calls many Panorama viewers said they showed signs of violence, addiction, self-harm and suicide.

This second investigation into Seroxat, "Emails from the Edge" has been driven by the viewers' response.

Link:

<http://news.bbc.co.uk/nol/shared/spl/hi/programmes/panorama/transcripts/emailsfromtheedge.txt>

PANORAMA

Seroxat: e-mails from the Edge

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Seroxat is an anti-depressant which helps millions of people around the world but what about those it doesn't help?

GIRL: Two years ago I tried to take my own life by slashing my wrists with a rusty knife, and last October I finally understood why.

SHELLEY JOFREY: In October last year Panorama raised concerns about one of the world's best selling antidepressants. We examined claims that Seroxat is addictive.

GIRL: Headaches, muscle pains, sweating, trembling.

JOFREY: But it can make some people self-harm.

MAN: This – cigarette burns, and there's sort of razor marks there as well.

JOFREY: And that it can even provoke suicide and violence in some people who take it.

MAN: He shot and killed the three women that he loved most in the world.

JOFREY: Your response to last October's programme was unprecedented. There were 67,000 phone calls to the BBC helpline. Panorama received nearly 1,400 e-mails. We read all of them. The same

theme cropped up time and time again – until you saw that programme, many of you had thought you were alone.

MAN: Watching Panorama was the first time that I'd ever made a link between my condition and Seroxat.

WOMAN: It was strange to learn from a TV programme rather than your GP what these side effects were.

MAN: I thought yes, brilliant, somebody is actually taking notice.

JOFREY: In that programme Glaxo SmithKline denied their advice to patients was misleading.

GLAXO: The information clearly says that Seroxat is not addictive and it is not.

JOFREY: But tonight they're backtracking on that advice.

GLAXO: It's quite clear that the phrase "Seroxat is not addictive" was poorly understood.

JOFREY: There is a government regulator, the Medicine's Control Agency, whose job it is to monitor drug safety. But your e-mails reveal how it's failing in its duty to protect patients. So many e-mails and within them so many stories. It was clear that they merited further investigation, so we called in the experts. Charles Medawar has been researching drug safety for over three decades. And Doctor Andrew Herxheimer is a pharmacologist whose world renowned for his work on medicine side effects. Actually reading every one of the e-mails was a daunting task, and not one they initially relished.

Dr ANDREW HERXHEIMER

Pharmacologist

I thought it was a huge chore really but when I got down to actually reading them, it wasn't. Time sort of disappeared because I could get.. they were so interesting, so riveting.

CHARLES MEDAWAR

Social Audit

If you looked at any one of the 1400 e-mails it might not tell you very much and it might be mainly distinguished by not telling you nearly enough. But then you put them altogether and you get immersed in these data and you look at the key points that some of them are making, and they come across as so vivid.

JOFREY: Vivid e-mails about violence.

WOMAN: The worst, I personally feel, was when I attacked my daughter. I held her head in my hands and I was hitting her head on the floor over and over again.

JOFREY: Vivid e-mails about addiction.

WOMAN: I was driving around pharmacies begging them to give me a packet of Seroxat.

JOFREY: Vivid e-mails about suicide.

MAN: There was my son with a leather belt around his neck and he was dead.

JOFREY: Yet so many of your stories have been ignored.

MAN: So I said to him: "Doctor I'm dreaming about murdering children." And he just started to laugh.

JOFREY: Seroxat has been a lifesaver for many people suffering from severe depression, but according to your e-mails and phone calls, for some it can have a very different effect.

What did you actually find?

MEDAWAR: The raw figures? There were 16 accomplished suicides, there were 47 cases of attempted suicide and I mean serious, and I think there were 92 cases of people who had thoughts of harming themselves or others, but I mean quite marked thoughts, emotional turmoil would be putting it mildly.

If you are concerned about any issues raised in this programme, a helpline number will follow. You should not stop any medical treatment without first consulting your doctor. BBC Helpline Number: 0800 88 88 09

JOFREY: These cases underline the failure of the drugs regulator, the Medicines Control Agency. The MCA has an early warning system that's supposed to ring alarm bells if a prescription drug produces harmful side effects. A system, it boasts, is one of the best in the world, yet it's a system that doesn't take complaints direct from patients, which might explain why the MCA maintained after the last programme that there's no need for new concerns about Seroxat. They declined to be interviewed for this programme. But the company that makes Seroxat, GlaxoSmithKline, agreed to read all your e-mails. Nearly half of them contained complaints about Seroxat.

Dr ALISTAIR BENBOW

Head of European Clinical Psychiatry

GlaxoSmithKline

Anybody who suffers side effects of any sort I feel every sympathy for, but that does have to be balanced by the enormous benefit that is seen by many millions of patients around the world. In those e-mails there were a considerable number of people who talked about the positive benefit that Seroxat had given them.

JOFREY: Seroxat earns GlaxoSmithKline almost two billion pounds a year. Only Prozac is a more

popular antidepressant, both are in a class of drugs known as SSRIs. GPs use Seroxat to treat not just depression but anxiety, phobias, even shyness. It's a drug that's improved the lives of many people, and one in five of your e-mails said we should have emphasized that more in last October's Panorama.

GIRL: It was almost as if the people on that program weren't actually taking the same drug as I was. It did not relate at all to my experiences with Seroxat.

MAN: Seroxat has allowed me to continue with my life basically. It's taken away the anxiety and the depression down to a point where I now feel more relaxed than I ever have done.

GIRL: I was just mortified that they hadn't looked at the good side of it.

MAN: I would say to the makers of Seroxat that they have made a drug that's seriously helped a very large number of people and they should be quite proud.

Panorama, October 2002

JOFREY: But what most troubled critics of our last programme was a case we featured from America. A triple murder and suicide in Wyoming that had been blamed on Seroxat.

[News Bulletin]

The Wyoming State Crime Lab Team is in Gillette tonight reconstructing the scene that left four people dead. Neighbours can't believe Donald Schell, his wife Rita, their daughter Debbie Tobin and her 9 month old daughter area dead.

JOFREY: And some of you couldn't believe that Seroxat was responsible. Mr Shell had been on the drug for just two days and taken just two tablets when he killed his wife, daughter, granddaughter and then himself.

TIM 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. The Don that I knew wasn't that time of person. The only thing that had changed was the medicine that he was taking.

Reconstruction

JOFREY: GlaxoSmithKline blamed Mr Schell's depression. But when it came to court and the jurors heard all the evidence, they agreed with the family, Seroxat had provoked Donald Shell to murder and then commit suicide. Some of your e-mails were sceptical to say the least.

MAN: Total rubbish. Unworthy of Panorama.

WOMAN: It is ridiculous to suggest a man killed his entire family after taking just two tablets.

MAN: Malicious, unresearched docu-soap. Any further episodes I watch will be taken with a pinch of salt.

MAN: Quite a number of people, including a number of health professionals were very critical of that aspect of the programme. They simply didn't believe that two tablets could have such an effect.

JOFREY: This was despite evidence in that programme from Doctor David Healy. As an expert in the Wyoming court case he was given unique access to GlaxoSmithKline archive of clinical trial results. There he found results from the 1980s when Seroxat was tested on volunteers, people with no trace of mental illness. He discovered that up to a quarter of these healthy people became disturbed after just a few days on Seroxat.

DAVID HEALY: It seemed clear that some people who went on the drugs had no major problems, but equally clear that others who went on the drugs ended up more restless, in a state of mental turmoil, complaining about dreams, nightmares and a range of things like this.

JOFREY: Doctor Healy said it was this mental turmoil that turned Donald Schell into a killer. That clearly struck a chord with some of you. Mental turmoil after just a few tablets was something that was vividly described in your e-mails.

MAN: There were certainly ten reports in the sample of Panorama e-mails which described very, very convincingly that yes, a dose or two could have exactly that kind of effect.

MAN: On the day of taking Seroxat I woke up, and my temperature inside my head felt really hot. As the day progressed it got worse and worse until in the evening it felt like the inside of my skull was boiling. I went to bed and I started thinking that everybody was out to get me. I started to feel angry, murderous, I wanted to kill my partner and my family. I've never felt like that before. I sat on the edge of the bed holding my knees up against me because I knew that if I moved I would kill everybody.

WOMAN: My husband took Seroxat for four days and tried to kill me. Dawn Owen, Helswick, Cheshire.

JOFREY: This is the house Dawn Owen once shared with her husband. It was their dream home. Two years ago they were doing it up together.

DAWN OWEN

We had everything. We were really happy. We had all our plans for the future, waiting for our first granddaughter to come along, you know.. it was just... life was great really.

JOFREY: But Dawn says the pressures of work and doing up the house finally took their toll on her

husband. He became stressed and anxious. Dawn took him to the GP who prescribed Seroxat. Soon after starting the tablets he became agitated and had terrible nightmares. On the fourth morning, after the fourth tablet, he lay in bed talking to his wife.

DAWN: Next thing I know, my husband had punched me, put the pillow over my face. At the time I didn't know that he was stabbing me. So I ended up with three puncture wounds through... that had come through the pillow. When I managed to pull the pillow down, I saw the knife coming. At the same time my daughter appeared here. She was 7 months pregnant and she got the next knife in her back. But she pushed him off me. If my daughter hadn't come in at that time, I'm 100% sure I wouldn't be here now.

JOFREY: Thankfully both women survived. Afterwards, Dawn's husband went upstairs and tried to hang himself. He's still too upset to talk publicly about it all. But Dawn is adamant it was completely out of character.

DAWN: I know it's not his fault. I know he wasn't that type of person. I worry about him, how he is now, but I feel guilty I can't help him. But I can't deal with what happened to me.

JOFREY: Now Dawn Owen and her husband are getting divorced. The dream home is up for sale. You have seen a number of viewers who reported this fairly rapid, intense reaction to Seroxat being thrown into a state of mental chaos. Are you taking these reports seriously?

Dr ALASTAIR BENBOW

Head of European Clinical Psychiatry
GlaxoSmithKline

We take every single safety report seriously. Absolutely every single one. And anybody... my heart goes out to anybody who experiences any of the symptoms of depression or the side effects related to the treatment of course.

JOFREY: So do you accept that this could be a side effect from Seroxat?

BENBOW: No. Based on all the data available to us I don't believe it is. I thin...

JOFREY: So you'll look for anything else to blame apart from your best-selling drug.

BENBOW: No. No, no, quite clearly there are side effects which appear as a result of this serious medicine.

Panorama, October 2002

JOFREY: The patient information leaflet that comes with Seroxat doesn't warn that the drug can throw some people rapidly into mental turmoil. But there's one thing it states unequivocally, Seroxat is not addictive. Yet Seroxat attracts more complaints by far about withdrawal problem than any other

prescription medicine. For last October's Panorama, Helen Kellsell kept a video diary. It showed how she suffered while trying to wean herself off the drug.

HELEN KELSELL: As I take each step there's this shock in my head that's completely throwing me off balance.

GIRL: When I saw Helen, holding her camcorder and explaining how she found it difficult to walk along because electric shocks were knocking her off balance, that really struck a chord with me.

MEDAWAR: Over and over again you find users trying to come off this drug in the Panorama e-mails are describing these weird electric shock sensations in the head, "zaps" they sometimes call them or "electric head" or.. and they make them intensely dizzy and there's obviously a lot of visual distortion that goes on, and it's a very distinctive and very marked side effect.

JOFREY: A very marked side effect that patients have been complaining about for years. Yet there's no clear warning about it on the Seroxat information leaflet. It's only since reading all your e-mails to Panorama that Glaxo SmithKline has conceded it needs to spell out much more clearly the sorts of withdrawal symptoms people may suffer.

BENBOW: We are strengthening the information on side effects, particularly on stopping, so that there is greater clarity in terms of the exact wording. So for instance we have in the information leaflet that you may get sensory disturbances. But it was clear to talking to patients that some of them sensory disturbance is a bit of a medical term – what does that mean? So we are going to specifically strengthen it and talk about some of the thing which those patients in the e-mails, in phone calls, ringing us, writing to us have said, and one of those for instance would be the electric shocks.

JOFREY: This isn't the only climb down following your e-mails. Last October Doctor Benbow was adamant that withdrawal problems were not a sign of addiction. But it turned out he was using a strictly medical definition of addiction.

Panorama, October 2002

BENBOW: Addiction is characterized by a number of different criteria which includes craving, which includes increasing the dose of drugs to get the same effect, and a number of other features and these are not exhibited by Seroxat.

JOFREY: 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.

BENBOW: If you use that limited description of addictive then most prescription medicines could be defined as addictive.

WOMAN: They were playing on words. We shouldn't need to get dictionaries out when there are so many of us out here who are actually suffering.

WOMAN 2: I'd like to tell the makers of this drug to try it themselves, and to come back to me in five years time and tell me that it's not addictive.

JOFREY: Using that medical definition of addiction, GlaxoSmithKline's leaflet says you cannot become addicted to the Seroxat. Those words were approved by the Medicines Control Agency. Yet the MCA's own rules say leaflets must be written in terms that patients can understand.

WOMAN: From reading the information that GSK gave with the medicine, there's no way I could have known that I was going to suffer as I have.

Dr JIM KENNEDY

Royal College of General Practitioners

It is very important to tell patients up front on Seroxat and other drugs like it, that there may be difficulties in coming off the drug, and that there may be at the very least a habit forming potential with that drug in some patients.

JOFREY: When we interviewed Doctor Benbow last year he steadfastly denied that Seroxat could be habit-forming or addictive, and he refused to accept that the leaflet was misleading. Your patient leaflet is meant to help and inform patients, isn't it.

BENBOW: Yes it is, and it does I believe.

JOFREY: Well not according to the people we've spoken to who feel they were not warned that that it could happen to them. They read you can't become addicted to Seroxat and thought they could stop the drug any time they wanted.

BENBOW: No, the reality is they can stop the drug. It is true that....

JOFREY: But they can't stop any time they want.

BENBOW: Yes they can and the information clearly says that Seroxat is not addictive and it is not. It is true that they....

JOFREY: What a difference six months and 1400 e-mails can make.

BENBOW: Additionally it was quite clear from talking to patients, and as a doctor that's very, very important to me, it's quite clear that the phrase "Seroxat is not addictive" was poorly understood by them.

JOFREY: That was very obvious from the e-mails.

BENBOW: Yes. Now we therefore had a decision to make. Whilst acknowledging that patients will get symp... or may get symptoms on stopping Seroxat, although we still don't think – and I'm absolutely certain that Seroxat is not addictive – that language was clearly misunderstood and therefore we have proposed that we will take out that specific wording.

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BBC Helpline Number: 0800 88 88 09

JOFREY: This is a major turnaround for GlaxoSmithKline. Since reading your e-mails they're now proposing to abandon the advice they so recently defended. But any change to the wording can only go ahead with the regulator's say so and that hasn't happened yet. We wanted to interview someone from the Medicines Control Agency to ask why they approved the previous wording when it was misleading to patients. But no one was willing to come on this programme.

MEDAWAR: To be honest I sometimes wonder if the world wouldn't be a better place if the regulators just packed up and went away. They are the last to find out what is actually happening because they don't think that patient reports are scientific.

JOFREY: Among the most disturbing patient reports were 23 about children who'd had a terrible time on the drug. Seroxat has not been approved as safe for use in under 18s but doctors are allowed to prescribe it to them if they think it may help them.

GIRL: It was actually my 14th birthday. School noticed that I was really depressed and so my mum made a doctor's appointment for me and the doctor just told me to take these tablets.

GIRL2: When I was first prescribed Seroxat I was around 16 years old. I was prescribed them because I'd suffered quite a lot of depression and my parents wanted to help me solve my problems.

MOTHER: My teenage daughter was on Seroxat in 2001. Whilst on it she was having hallucinations, nightmares, was suicidal and self-harming. Julie Workman, Witney, Oxfordshire.

JOFREY: Holly Workman was just 14 years old when she was diagnosed with depression. Throughout the previous year she'd had a pretty rough time both at home and at school.

HOLLY WORKMAN

My parents split up and stuff like that. That sort of made me a bit unhappy and I got bullied for quite a long time which just made me a bit worse really.

MOTHER: She was diagnosed as being severely depressed and the psychiatrist said she ought to go onto

antidepressants. I wasn't happy about that and questioned a lot about side effects, about withdrawal symptoms, how long she'd need to be on them, that sort of thing because it seems a pretty massive thing for a young teenager not only to be diagnosed with severe depression but to be told they need to be on antidepressants. The response I got was well if she had a broken leg, would we refuse to have the leg put in plaster?

JOFREY: But when she took Seroxat Holly quickly became anxious and agitated and she began to have horrific nightmares.

HOLLY: There was this person that looked like the devil and he was just covered in blood. He was telling me to kill people and he was saying if I didn't kill people, then I'd have to kill myself and stuff like this.

JOFREY: And the nightmares soon took on a grim reality.

MOTHER: There was one particular day, school rang, could I come to school straightaway, that Holly had injured herself.

HOLLY: I just walked out my lesson and I went into the science block because there's nobody normally around the old science block. So I sat down there and I just kind of cut my arm.

JOFREY: For Holly and her family it was the start of a nightmare few months. On bad days she would cut herself six or seven times, and she even started to list all the ways she could kill herself.

HOLLY: Cutting myself until I bleed, slitting my throat, walking in front of a bus, all sorts of things going from one extreme to the other really. Stealing a car and driving it off a cliff, jumping off a bridge, all sorts of things.

MOTHER: I spent most of 2001 convinced she was going to be dead by Christmas.

HOLLY: The one I actually wanted to do the most was I wanted to sit in front of a mirror and watch myself bleed to death.

JOFREY: Holly's depression had led to disturbed thoughts before she took Seroxat. But it was only on the drug that she self-harmed or actually attempted suicide. Some of the other children who e-mailed us said the same thing.

GIRL1: When I was taking Seroxat within the first week I did self-harm. I started off by cutting my arms with scissors or razors.

GIRL2: And I just put the point to my arms and just scrape until it bled.

GIRL1: I did attempt suicide a couple of times by taking overdoses and slitting my wrist.

GIRL2: There was points where I did just want to die.

HOLLY: I knew that this wasn't what I was like.

JOFREY: Did you ever associate it with Seroxat at the time?

HOLLY: Well I guess I thought it was something to do with them, but then a part of me thought no, they wouldn't have given me them if they were going to hurt me.

JOFREY: Doctors who prescribe Seroxat to children may not be aware of the results of a recent clinical trial in America costing millions of dollars it was funded by GlaxoSmithKline. We revealed last October that more than 5% of the depressed children given Seroxat in that study became suicidal within weeks of going on the drug.

Dr ALASTAIR BENBOW

Head of European Clinical Psychiatry

GlaxoSmithKline

Whilst self-harm and suicidal thoughts are clearly a feature of depression, they have not been shown in carefully done studies to be a feature of treatment with these medicines.

JOFREY: Well in the carefully done study, it was the biggest study of its kind in America, more children became suicidal on Seroxat than on placebo – sugar pills.

BENBOW: Yes, that may be true in that particular study, but if you look at...

JOFREY: Well that's pretty worrying, isn't it?

BENBOW: No, that's part of the pieces of evidence that we have to gather together to decide together with the regulatory authorities and obviously they are the appropriate people to assess this. They will look at all the data that's been generated in children.

JOFREY: The Medicines Control Agency relies on clinical trial data to work out whether a drug is safe to be prescribed. In the 1960s it was thalidomide, a very different drug to Seroxat, that highlighted the need for medicines to be monitored for side effects long after they've been approved as safe. It was only when thousands of pregnant women had taken thalidomide that doctors discovered the devastating effect the drug could have on their babies. So the government launched an early warning system that's called the "Yellow Card" reporting scheme. It's nearly 40 years old now and relies heavily on doctors to make it work. If they suspect someone has been harmed by a drug they're expected to fill out a yellow card and send it to the MCA but few doctors ever do, and the Medicines Control Agency doesn't accept reports from patients.

CHARLES MEDAWAR

Social Audit

It's desperately inadequate and it's inadequate because only a tiny fraction of the numbers of reportable adverse effects are actually reported. It really wouldn't be unfair to characterise this as a system which is...which predominantly doctors ignore.

JOFREY: To test this claim we asked Holly Workman to ring her previous GP, the one who prescribed her Seroxat. Holly is convinced the drug prompted her to self-harm and attempt suicide when she was just 14. She asks him to fill out a Yellow Card.

HOLLY: [on telephone] There's been things in the papers about the safety of Seroxat and there was that programme that Panorama did.

JOFREY: The doctor tells her: "Panorama is going down the pan" and he's not prepared to fill out a yellow card for her.

Dr JIM KENNEDY

Royal College of General Practitioners

I certainly think that any patient reports are of great value. The patient is the person actually taking the drug. They have the best idea of what's happening to them. It's very important that they report these things to the prescribing doctor, and it's important that the prescribing doctor reports them to the monitoring authorities because it's only by collecting that kind of data that we can make a real assessment of the effects – positive and negative – of a medication.

JOFREY: So if in doubt, a GP really ought to fill one of these cards out.

KENNEDY: Absolutely.

MAN1: When I spoke to my GP about the problems I was having with the medication he wasn't convinced that I wasn't making it all up.

MAN2: I told him explicitly about the dreams I was having and he just started to laugh. So I said to him: "Doctor I don't find this very funny because I'm dreaming about murdering children."

JOFREY: The problem is, if doctors don't believe you, they won't report your suspicions to the regulator on a yellow card. So, with the help of the leading mental health charity "Mind" we drew up a Panorama yellow card, then we asked hundreds of you who e-mailed us to answer detailed questions about your experience with Seroxat – 239 people filled them out. Then we asked the Royal College of Psychiatrists to recommend one of its members, someone independent, to read the completed yellow cards. They chose Doctor Alfred White.

Dr ALFRED WHITE

Royal College of Psychiatrists

The first impression was the vast majority of the people shouldn't have been on the drug in the first place. There were hardly any, if any, that I saw where I felt convinced that they had an illness which would be appropriate. It's an extremely good antidepressant, extremely useful drug for the right illness, can be lifesaving. And if you give it to anybody with life problems then you're going to over prescribe it and you're going to cause problems as well as solving them.

JOFREY: Is it any wonder if it's over prescribed though? More than a third of our respondents said they were put on Seroxat after just five or ten minutes with their often hard-pressed doctors.

That surely isn't long enough to diagnose depression and prescribe a drug like Seroxat?

KENNEDY: Certainly it is good practice to spend an appropriate amount of time on diagnosing and monitoring depression. It is probably not appropriate to spend such a short time as five or so minutes on this kind of problem.

JOFREY: And it gets worse. More than two thirds said their doctors gave them no warning that stopping Seroxat could be difficult. Even more worrying, almost 30% of respondents said they began to have thoughts of self-harm or suicide on Seroxat when they'd never had them before.

RICHARD BROOK

Chief Executive, Mind

I mean how can we in all consciousness just sit here and say it's not a problem when you hear those stories. The very least they should be investigated, looked at and listened to, and the very least we should have answers that actually are compatible with our knowledge, and if we don't have that, to continue down this road seems to me totally irresponsible.

JOFREY: Most damning of all, Panorama has discovered that the number of suicides that may be linked to Seroxat has been significantly underreported to the regulator. The MCA has been notified of seven suicides in the last two years. But Panorama has been told of eleven, none of which, as far as the families are aware, has been reported to the MCA.

BROOK: You could take one view of this which is the regulators playing Russia roulette with people's lives. It's not listening to people, it's listening to selective evidence, it's not taking the real evidence which is people's experiences.

WOMAN: The suicidal thoughts only happened while I was taking the drug. They've never happened before or after.

MAN: My father was on Seroxat for four days. On the fourth day of taking them he was in possession of a hunting gun and he went to a local wood and shot himself.

MAN2: He put a loop in the belt and put his head through the loop and let himself hang. His own weight killed him. That's what I believe Seroxat did to my son.

GRAHAM ALDRED: My interest in this is the tragic death by suicide of my wife Rhona. She was on day 11 of Seroxat. Graham Aldred, Cheshire, England. Rhona was somebody who had, I think, remarkable strength and she was a very determined person. She would fight for issues that she believed in. What happened was totally out of her character. It was completely uncharacteristic.

JOFREY: Graham Aldred's wife, Rhona, was diagnosed with depression by her GP in October 2001. She was prescribed Seroxat. Over the next 11 days Rhona kept a record in her diary of how she was feeling.

ALDRED: Friday 26th October, 2001: "Black day, pouring with rain. Went to the doctor's, saw a locum, a new young doctor, prescribed me antidepressants."

Now I didn't know much about antidepressants and so all I did was read the patient information leaflet and found that it was fairly innocuous. It didn't advise about any harmful effects that could arise from this drug. How wrong we were.

JOFREY: Day 3 on Seroxat Rhona's diary suggests she's becoming increasingly disturbed.

ALDRED: Tuesday 30th October: "Graham was out when I got in and I was a bit worried as I have said some terrible things to him in the morning about our relationship."

The worst thing that happened quite soon was that Rhona's emotions were switched off. She became switched off emotionally, and she couldn't.. didn't laugh anymore. Now this was coupled with extremely violent, horrible nightmares.

Thursday, 1st November: "Woke up 6am with apprehension running over me, then felt sick and dry mouthed and restless when I got up, walking up and down. Graham wants me to carry on with the Seroxat. I blame the above symptoms on it."

JOFREY: After 11 days of mental turmoil Rhona Aldred sat down and wrote her final diary entry.

ALDRED: "Trace of sleet on Kinder, dreadful night. Messed up the morning by playing half an hour tennis and then leaving tennis to go to see the optician. But it didn't work either. Bought some fish and some dish draining racks. Don't feel like eating though. Graham offered to take me to the park. When can I start living again. Feel like I've burnt my boats."

What happened was that Rhona left the house some time after I left the house, and drove with the vacuum cleaner hose in the car to a little lane that has a rather nice name called Oakham Bank Lane that I didn't know then. She drove about 8 miles and backed the car under a holly bush so that it would

partially hidden, and taped the hose to the exhaust pipe, and then got in the car, started the engine and just sat there and waited. I think she died in the sunset. It was a most beautiful sunset.

JOFREY: Graham is convinced that Seroxat was the trigger for his wife's suicide, and hers is not the only case. After the last programme another 15 people contacted Panorama with similar suspicions.

FATHER: I find it very difficult to believe that Adrian would have done this on his own. Adrian was not depressed. Adrian was not suicidal. Adrian didn't like pain. Adrian wanted to live, he was full of life.

WIFE: The month before he had said to me that he must be the luckiest man alive, he'd got a lovely wife, a lovely family, a lovely home and no money worries. There was absolutely no reason at all for him to commit suicide.

Dr ALISTAIR BENBOW

Head of European Clinical Psychiatry

GlaxoSmithKline

Now not everybody who tragically takes their own life will say to people: "I'm feeling suicidal, I'm going to kill myself." In fact many people who have decided that they're going to do that, deliberately withhold that information from their friends and family.

JOFREY: So in spite of the stories that our viewers have told us, your views remain unchanged on this, you don't believe that Seroxat can, even in a small number of cases, provoke self-harm or suicide?

BENBOW: Tragic though these cases are, we do not believe that... I do not believe that Seroxat causes people to take their own lives or self-harm.

JOFREY: Both the manufacturer and the regulator have long maintained that Seroxat reduces the risk of suicide. But Doctor David Healy has recently uncovered evidence that suggests the opposite is true. Through lawyers in America Doctor Healy got hold of some confidential GlaxoSmithKline trial results. He says they show the risk of suicide in depressed patients increases when they take Seroxat. This is data that both the drug company and the regulator have had for 13 years.

Dr DAVID HEALY

Director, North Wales Department of

Psychological Medicine

The evidence is that roughly one person in sixty that goes on this drug makes a suicide attempt. Now you have to contrast that with the people going on placebo or sugar pill, and the rate there is one person in five hundred and fifty. That's nine or ten times less. The risk on the drug is nine or ten times greater than the risk on sugar pill.

BENBOW: We have been asked by the regulatory authorities to provide all our information related to

suicides and I can tell you the data that we provide to them clearly shows no link between Seroxat and an increased risk of suicide – no link.

JOFREY: So does the research suggest a link or doesn't it? Doctor Healy has been pressing the MCA for an answer for over a year. Last November he and Doctor Herxheimer were finally invited to meet them to present their concerns.

HEALY: I really don't want to be on a programme like this saying that there are figures pointing to a hazard from the drug if someone can actually explain to me why these figures don't mean that there's a hazard. Now the answer from the MCA has been nothing. They didn't offer me any reasons back there and then or since as to why there isn't a hazard on the drug, and they haven't taken any action either.

JOFREY: Doctor Healy has so far waited six months, yet the MCA seems in no hurry to answer. When we point out to them, they confirm they haven't even begun to reanalyse the clinical trial data on Seroxat and suicide.

GRAHAM ALDRED

It's just staggering. It's just incompetence... it's worse. If it was another industry, if we were talking about aeroplanes and aeroplane engines then the words 'corporate manslaughter' would be mentioned.

If you are concerned about any issues raised in this programme, a helpline number will follow. You should not stop any medical treatment without first consulting your doctor. BBC Helpline Number: 0800 88 88 09

JOFREY: Graham Aldred is in no doubt that Seroxat caused the death of his wife Rhona. She had never expressed any suicidal thoughts. The change in her behaviour on the drug was rapid and marked. Graham has sent Rhona's diary and her medical records to North Wales to be examined by Doctor Healy. Today we come with him to hear Doctor Healy's assessment of the case.

HEALY: The things that leap out at me from what you say are things like the nightmares, this is very, very common. Strange nightmares, violent nightmares, and this can happen when you go on the drug, or when you halt it. A certain restlessness that people get, it's not just a physical restlessness, it's a mental restlessness.

ALDRED: Yes, yes.

HEALY: And you said Rhona's mind seemed to be in chaos.

ALDRED: Yes.

HEALY: That's very like what... well they're the kinds of things I look for from what people say.

JOFREY: Did Seroxat kill Rhona Aldred?

HEALY: Yes, I think you can be pretty confident that it did. Her death happened within the classic timeframe of deaths that happen on this group of drugs. She had nightmares, restlessness, mood swings, all of which occurred very quickly after she went on the drug, and I think can make all of us fairly confident that yes, if she hadn't had this drug, she wouldn't have killed herself and she would be here now today.

JOFREY: Doctor Healy may be convinced about Rhona Aldred, but neither the regulator nor GlaxoSmithKline regards individual case reports like hers as compelling evidence. Will you be proposing any change to the leaflet on this issue?

BENBOW: No we won't, because the information available does not support that conclusion and we must be driven, as always, by facts and data. Anecdotes of course important but they're not the same as carefully controlled work to look at these things.

CHARLES MEDAWAR

Social Audit

I defy any scientist, any good scientist to look at the data that you accumulated and not conclude there is a problem. You'd have to be from another planet not to see that there is a serious problem and moreover that this is a problem that the regulators have so far missed.

WOMAN1: My message to the MCA would be you're obviously not doing your job properly otherwise we wouldn't be where we are now, on this programme that Panorama is doing, investigating all these suicides and people are addicted to the drug and can't get off.

WOMAN2: There are side effects, there are things happening to too many of us out here to be ignored.

JOFREY: The e-mails you sent us haven't been ignored. Doctor Herxheimer and Charles Medawar have analyzed them all and written the results up into a medical paper. That paper has been peer reviewed. It's on the Panorama website now and has just been published in an international medical journal.

MEDAWAR: It was an absolutely conscious decision simply to let the e-mails speak for themselves. All we did really was to string together these powerful and impressive and deeply credible reports. If it doesn't make a huge difference and a... a seismic difference to evaluation of drug effects in future I would be very, very surprised. Don't ask me how long it will take.

JOFREY: The regulator has reviewed the safety of Seroxat and the other SSRI antidepressants four times. Each time it has decided none of the causes suicide and none of them is addictive. But just six weeks after our last programme and six weeks after the regulators said there was no need for new concerns, Health Minister Hazel Blears announced another intensive review of the drugs. But that has since descended into farce. In March the review committee had to be disbanded when it was revealed that

half the members had shareholdings in GlaxoSmithKline. The Regulator is now trying to put together a new committee.

Drug inquiry thrown into doubt over members' links with manufacturers

Dr ANDREW HERXHEIMER

Pharmacologist

If they do not reach a different conclusion from previous reviews, that will reflect very badly on them, and I think that restructuring of the regulatory body and replacement of some of the staff would be an inescapable consequence.

JOFREY: The MCA says that this time they will be listening to patients, but how seriously will they take them? Back in February we offered to give them the yellow cards we'd collected as evidence of what some patients say they've experienced on Seroxat. They said: "Thanks but no thanks". However, since the embarrassment over the committee members financial links, they've had a change of heart and a change of name. The MHRA, as they're now known, say they'd be happy to consider the yellow cards as part of their review.

Dr DAVID HEALY

Director, North Wales Department of
Psychological Medicine

They seem to review these things from the point of view of the company. They seem to be waiting for the public out there to prove there is a problem with the drug, rather than acting to make sure that people aren't at risk.

JOFREY: The mental health charity 'Mind' is now demanding a truly independent review, a review that takes into account the experiences, good and bad, of Seroxat users.

RICHARD BROOK

Chief Executive, Mind

If the regulator does nothing now and further people die, and ultimately it was proved to be something in relation to Seroxat, then the Regulator would be guilty. The Regulator must resolve this issue.

WOMAN: If I were to have a message for the regulators it would be test it and test it again. Do not allow these drugs to come onto the market without being absolutely certain of the potential side effects.

MAN: This drug devastated my life, my wife's and my life, and I would not like this to happen to anyone else. But certainly I wouldn't like it to happen to young people. I think that Seroxat should be banned until such times as it's improved.

MAN2: Your drug does help a lot of people but it also destroys a lot of lives, like it's destroyed my son.

My son Adrian was 19 years of age – 19.

Seroxat is an anti-depressant which helps millions of people around the world. You should not stop any medical treatment without first consulting your doctor.

JOFREY: Next week Panorama investigates America's neo-conservatives. The small and unelected group of right-wingers who critics claim have hijacked the White House and are making the world a more dangerous place. If you're concerned about issues raised in tonight's programme, you can call the BBC helpline. Seroxat has helped many people and you should not stop taking any medication without consulting your doctor. Glaxo and some other contributors to this programme are taking part in a live discussion now on the web. Join us on the Panorama website.

www.bbc.co.uk/panorama

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