



Seroxat on trial: DRUG Giant set for legal battle

More than 20 Scots are preparing to take GlaxoSmithKline to court over antidepressant

By Liam McDougall

Enabling people to do more, feel better and live longer - three principles that British pharmaceutical giant GlaxoSmithKline claims form the basis of its 'global quest'. The multi-billion pound firm - the second largest in the world prides itself as a world leader in the manufacture of a range of treatments, including antibiotics and cancer medicines. But its

money-spinner comes from the production of Seroxat, an antidepressant that is aggressively marketed by the company as an addiction-free answer to anxiety. Chances are you already know someone who takes Seroxat. GPs in the UK have been prescribing the drug since 1991 to control everything from

prescriptions have been written in more than 100 countries. However, while Glaxo may be keen to tell its shareholders that the drug is now the most-prescribed antidepressant in the world, what it does not want known is that around 800 people across the UK are about to launch a potentially catastrophic legal action against the drugs giant alleging that Seroxat has devastated their lives. The Big Issue in Scotland has learned that the civil action-which includes more than 20 Scots-will claim that, far from being addiction-free, Seroxat is impossible to give up without users suffering a litany of serious side-effects,

including vertigo, memory loss, aggression and feelings of suicide. If successful, the result could expose a major medical scandal that has been kept secret for more than a decade. Glaxo could be forced to pay out millions in compensation over its so-called

In the US, where Seroxat is people who claim to have suffered severe withdrawal reactions after taking the drug have filed a lawsuit in Los Angeles. According to leg papers, seen by The Big Issue in Scotland, the US lawyers accuse the British-based "fraud, deceit and negligence".

Their damning complaint document claims "Paxil creates both physical and psychological dependency" and that "GSK [GlaxoSmithKline] has suppressed information about the severe withdrawal reactions of its drug".

It adds: "GSK has known for years the distinct characteristics of Paxil which make it prone to cause withdrawal reactions when discontinued. Paxil has the highest incidence rate of withdrawal adverse experiences of any antidepressant drug in the world."

The legal action is backed by a potentially explosive discovery by a leading British psychiatrist, who last year was allowed access to the archives of GlaxoSmithKline as part of a separate civil action in the US against the manufacturers.

David Healy, director of the North Wales department of psychological medicine, discovered confidential studies at its headquarters in Harlow, Essex, which indicated the company - then SmithKline Beecham-realised in the 1980s that healthy volunteers were suffering withdrawal symptoms when they stopped taking the drug after only a couple of weeks.

Healy, who was called as an expert witness in the case, found that in one study as many as 85 per cent of volunteers - company staff with no depression problems - complained of suffering agitation, insomnia and other adverse effects.

On average about half the volunteers who took part

in a group of studies specifically designed to detect withdrawal problems suffered symptoms which suggested they had become physically dependent on the drug.

On the back of this and other evidence,

the jury in Wyoming ordered GlaxoSmithKline to pay 4.6m to the family of Donald Schell, 60, who killed his wife, daughter and granddaughter, then himself, after two days on Seroxat.

Last month, respected Los Angeles

judge Mariana Pfaelzer ruled that GSK must pull its television adverts for Paxil which state that the drug is "non-habit forming".

Despite growing concern in the US legal system over the drug, The Big Issue can reveal that GlaxoSmithKline is still producing a patient information leaflet in the UK which insists that users cannot develop a dependency to Seroxat. The brochure states:

Serious side-effects include vertigo, memory loss, aggression and suicidal thoughts

"These tablets are not addictive." It continues that withdrawal symptoms some may experience "are not common and are not a sign of addiction".

Charles Medawar, a member of the World Health Organisation's (WHO) expert advisory panel

on Drug Policies and Management, says he is becoming increasingly alarmed at the volume of horror stories from people who have tried to stop using Seroxat.

On the back of this evidence, Medawar describes the content of

GlaxoSmithKline's UK patient information leaflet as "a disgrace". "It is intensely misleading," he says. "It must now be blindingly obvious [to GSK] that the leaflet needs to change. The position is completely indefensible. It is complete nonsense and a disgrace."

Medawar, who is also director of Social Audit, a campaign group dedicated to researching antidepressants and other SSRIs - selective serotonin reuptake inhibitors, such as Seroxat and Prozac - has written to the government's Medicines Control Agency (MCA) demanding they force Glaxo to change the wording, but no action has yet been taken.

The lack of movement on the issue has frustrated Medawar, especially after he received a letter in July from the regulating body in which its own staff admitted it had been sent more complaints about withdrawal reactions from paroxetine, the generic name for Seroxat, than any other type of drug.

Medawar insists he will write again to the MCA urging them to take the issue seriously.

'More than a quarter of CSM experts have links to GSK'

The Committee on Safety of Medicines is an expert organisation that advises on whether new products should be granted a marketing authorisation and ensures that all licensed drugs are safe.

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PHOTOGRAPH: LOUIS FLOOD

A drugs discussion website run by Medawar has received hundreds of postings from people across the UK and overseas claiming to suffer from serious side-effects after taking the drug.

In the offices of Hugh James solicitors in Cardiff, Mark Harvey is preparing a legal case against GSK alleging that the company's biggest-selling drug is responsible for destroying the lives of his clients. So far 800 have come forward to join the action.

"Funding for the case is being sorted out at the moment but we're some way off going to court," says Harvey. "We've been making sure that we have gathered enough evidence to make the case and it's now very evident that this is a problem that requires to be looked at. We will be writing letters of claim to the manufacturers in the near future."

Derek Scott, from Dundee, is one of more than two dozen Scots who are involved in Harvey's legal action. The 32-year-old says he was placed on Seroxat three years ago by a university GP to deal with his diagnosed anxiety disorder.

He claims the drug led to him putting on nearly four stones in weight and suffering a range of side-effects, including aggression, tiredness, agitation, concentration difficulties and suicidal thoughts.

Another is something that he calls 'electric shocks in his head'. He says: "They start at the front of my head then spread out to my spine and limbs. When walking I often become disorientated and it is as though my body has a mind of

its own and my legs keep on walking when I want to stop.

"I feel that Seroxat has ruined my life. It got so bad that I had to drop out of the last year of university."

Another 26-year-old Scot involved in the action was prescribed Seroxat in 1999 after going to the doctor as a result of stress. She says that she went from being a top student to a wreck.

"I asked the doctor explicitly if it was addictive and I was told 'no'," she says. "Until I took Seroxat I was getting excellent grades. I got a first class honours degree. Since taking it I have had insomnia and I'm very agitated. It's ruined my life."

"I tried to come off it for about a month but life was unbearable. It was like having flu and I had electric shocks in my head. Now, when I speak to people I completely lose the thread of what I'm saying. My short-term memory is awful. I can't believe how my life has changed."

The woman, from Edinburgh, who asked not to be named, says she can't give up the drug and now must take a daily dose of Seroxat liquid just to make life bearable.

Medawar's online forum is filled with Seroxat users reporting similar experiences. One says: "I've been taking Seroxat for nine months. I stopped taking it 14 days ago... It is 3.30am and I have insomnia. "After two weeks I am distressed

Devastated: Derek Scott claims Seroxat gave him a range of sideeffects including aggression

that I feel the swooshing electrical feeling in my head."

Another writes: "I've been taking Seroxat for five years. When I saw my GP I described the results of a previous attempt to stop-vertigo, mood swings etc. He stated that he had never heard of any withdrawal effects related to the drug! Yet the symptoms of withdrawal are worse than they were before if, as I did the other day, miss a dose. Within 24

'Within 24 hours, after I had missed one of my 2.5 ml doses of Seroxat, I was feeling suicidal'

hours of missing the 2.5ml dose I was feeling suicidal, aggressive, sick, dizzy and exhausted."

An avalanche of complaints about side-effects and withdrawal symptoms has also been forwarded to the Medicines Control Agency (MCA) by

doctors concerned about their patients' symptoms when they have tried to stop taking the drug.

The MCA, the branch of the department of health responsible for regulating medicines in the UK, says the safety of drugs is continually monitored by its 'independent expert advisory body', the Committee on Safety of Medicines (CSM).

However, The Big Issue in Scotland has discovered that more than a quarter of all the CSM's experts have links to GlaxoSmithKline. By searching through

its members' register we found that 11 were employed as advisors or consultants to the company, nine had shares in GSK and 25 had received funding or were involved in research for the drugs giant.

In response, the CSM says that its members 'are required to leave the room' when the committee discusses an issue in which they have an interest, but Medawar does not believe there is enough transparency within the organisation.

Unlike civil servants, members of the committee are not bound by the strict code of conduct that exists to ensure that individuals do not 'misuse their official position'.

"It's a considerable worry," Medawar says. "I don't think there are brown envelopes changing hands but [their links with drugs companies] are much too close to ensure that the public interest shines through.

"Some committee members push the industry line quite hard. In the past, the CSM's expert on Prozac had connections with pharmaceutical companies as long as your arm. It is the culture of closeness and the culture of secrecy that makes these people unaccountable for their actions."

With GSK preparing to fight legal action in both the UK and US, Medawar believes the consequences of losing the cases would be disastrous for the company.

Currently, sales of Seroxat and Paxil amount to 10 per cent of its £6.2 billion total profit in 2001. The year before, sales of the drugs were valued at £1,550 million.

"If the action is successful the effect on GlaxoSmithKline would be devastating," he says. "It would almost certainly ensure the company was taken over by another firm. What they would lose would not only be costs and damages awarded against it, but it would also lose the drug."

But despite the prospect of legal action GlaxoSmithKline says it remains satisfied that Seroxat is safe to use. A spokesman for the company said: "Extensive clinical trials and more than 100 million patient treatments world-wide since 1991 have continued to show Seroxat to be an effective and generally well tolerated treatment for depression and anxiety disorders.

"There has been no reliable scientific evidence from either pre-clinical studies, long term clinical trials or clinical experience, to suggest that Seroxat is addictive, shows dependence or is a drug of abuse."

He added that GlaxoSmithKline monitors the safety of all its products on an ongoing basis, evaluating new data as it becomes available.