

SATURDAY, NOVEMBER 14, 2009

## Paroxetine - The Teratogenic Effect by Bob Fiddaman

Now there's a word, "Teratogenic" - one most of you will be unaware of - one that has caused me considerable confusion over the past few weeks. I shall explain.

The recent GSK vs Kilker case saw files flood the Internet, many of which, if not all, are [featured on this blog](#) and my sister blog, [GlaxoSmithKline Internal Files](#)

What I find astounding is that this word, "Teratogenic" and/or "Teratogen" often appears throughout the Kilker files. A quick search of the word/s simplifies it into laymans terms:

**Teratogenic:** *Able to disturb the growth and development of an embryo or fetus.*

**Teratogen:** *Any agent that can disturb the development of an embryo or fetus. Teratogens may cause a birth defect in the child. Or a teratogen may halt the pregnancy outright. The classes of teratogens include radiation, maternal infections, chemicals, and drugs.*

What has caused me much confusion over the past few weeks is the lack of help I have received trying to find out more about the paroxetine [Paxil, Seroxat] and teratogen link.

The Kilker case files show a link between paroxetine and its teratogenic effect, such a strong link that the jury in that case found that paroxetine was the causation of young Lyam Kilker being born with heart defects.

As a patient/concerned UK citizen I have tried to ask questions regarding this link.

My first port of call was the MHRA. A simple email to the Communications Director asking whether or not paroxetine was a teratogen proved to be less straight forward than I had anticipated. My email could not be passed on to the Head of Pharmacovigilance, Sarah Morgan, at the MHRA as she was on leave. I was told it had been passed on to someone else. Surely, it's a straightforward enough question that wouldn't need such detail to give me a yes or no answer?

Almost 2 weeks have gone by and I've heard nothing.

With that in mind I contacted GlaxoSmithKline - once again, a simple email asking if paroxetine is a teratogenic.

No reply.

Next on my list to seek some form of answer was the [National Poisons Information Service](#). Once again I asked, Is the SSRI antidepressant, paroxetine, brand name Seroxat, teratogenic?

The response I received was baffling to say the least.

*"I am afraid we do not take enquiries from the public. If you are pregnant or thinking of becoming pregnant and are on paroxetine then talk to your GP or midwife who will advise you."*

### **NPIS, Edinburgh**

Okay... still baffled, I next tried Sarah Smith, Senior Pharmacist Pharmacovigilance, [Yellow Card Centre Northern and Yorkshire Regional Drug and Therapeutics Centre](#).

Her reply:

*Unfortunately here at the Yellow Card Centre Northern and Yorkshire we do not handle teratology enquiries. There is a dedicated teratology line for health professionals only listed in the BNF. Should you be a member of the public I suggest you make an appointment to discuss this with your GP.*

Quite odd that such a simple, yet important question, would get three regulatory bodies into a kerfuffle. Even more strange that one is being directed to one's own doctor to get an answer to this question.

So, let's get this clear. A member of the public makes enquiries to the Medicines Regulator, a simple, Is paroxetine a teratogen question is passed around for an answer, an answer that I have still not received.

Next, the pharmaceutical company that manufacture the compound paroxetine [GSK] don't even bother to

reply.

Two other bodies, namely the National Poisons Information Service and the Yellow Card Centre Northern and Yorkshire, tell me that they cannot give me an answer and both refer me to my doctor?

With such a strain on the National Health in the UK one would have thought that doctor's have patient illnesses to tackle rather than someone making an appointment to ask them a question. One has to ask oneself why this information is not publicly available, it is of vital importance that it should be, don't you think?

CALLER: *"Hello, would it be possible to make an appointment with my doctor please?"*

RECEPTIONIST: *"Is it an emergency?"*

CALLER: *"Well, if I have information regarding a drug that is currently on the market and is known to cause birth defects is an emergency then, yes, it is an emergency!"*

If paroxetine [Paxil, Seroxat] IS a teratogen then what on earth is a drug that can harm a fetus doing on the market?

I thought I'd branch out and leave the UK websites, surely a simple question could be answered by other bodies?

The [Illinois Teratogen Information Service \[ITIS\]](#) is one such website.

According to the ITIS, The California Teratogen Information Service performed a prospective cohort study of 101 pregnancies exposed to paroxetine and 195 controls.

They write:

*"The data from this study did not support a significant increase in risk for a congenital malformation. Of note, within the paroxetine group, there was a greater risk for prematurity if used late in pregnancy. However, the paroxetine exposed group also had more exposure to caffeine, tobacco, alcohol and illicit drugs. No difference in the rate of minor malformation, gestational age, or low birth weight was found between the*

*two groups."*

Sadly, this study was performed in June 2001. Quite why it has not been updated remains a mystery... if indeed they think it needs updating.

I wrote Kristen L Dieter, a Genetic Counselor and Coordinator of the Illinois Teratogen Information Service, the following email:

*Dear Kristen,*

*I was wondering, in light of the recent court ruling [GSK v Kilker] if you plan to amend the information given on the ITIS [page](#) - in particular the section headed, ' Birth Outcomes Among Pregnant Women Taking Paroxetine (Paxil®) '*

*The information provided is out of date and Paxil has recently been found to be the causation of Lyam Kilker being born with heart defects.*

*Do you have any plans to a, change the information given on your website or b, make some sort of general announcement about the recent Paxil court ruling?*

*Yours sincerely*

*Bob Fiddaman.*

As yet, no answer!

So, it would appear that this question of whether or not paroxetine is a teratogen appears to be harder to answer than the '*What came first, the chicken or the egg*' question.

The MHRA will no doubt defend their corner by claiming that they [issued a warning](#) to doctors in 2005 regarding paroxetine and birth defects. Was the warning strong enough? Let's take a look at the exact wording.

*"New data from Denmark, Sweden and the US represent a potential signal of an increased risk of congenital*

*malformations following maternal use of paroxetine in the first trimester. However, other epidemiological studies have not supported such an increased risk. All available data are being actively investigated by the Commission on Human Medicines (CHM) and the MHRA and, following our further investigations and discussions within Europe, if necessary new guidance will be issued."*

New data or data that they had never seen before?

It seems very odd that GlaxoSmithKline did not test to see if their drug paroxetine was teratogenic, however, its competitor, Schering Plough did.

The Sloat paper was published in May of this year, and finds that Paxil is a "clear teratogen."

This from the [Kilker trial](#):

*Doctor Sloat's paper demonstrated that Paxil was a clear teratogen, that it was not just an effect of developmental or birth-weight related effect, that it was a direct teratogen, and that there was a spectrum of defects observed in rat embryos at low doses, establishing that it was a very potent teratogen, more teratogenic than cocaine and retinol, clear teratogens in their own right.*

His paper also found teratogenic effects in other SSRIs, not just Paxil.

Let's just take another look at the MHRA warning from 2005.

**Advice to prescribers:**

*Paroxetine should only be used in pregnancy when strictly indicated and only if the benefits for the mother are thought to outweigh the potential risk to the foetus.*

*Until this issue is further investigated, consideration should be given as to whether paroxetine is the most suitable SSRI to be used in pregnant women or those planning to become pregnant.*

*If a decision is made to stop paroxetine treatment, this should be done gradually over a period of several weeks. Abrupt cessation can cause withdrawal symptoms (most commonly dizziness, numbness and tingling,*

*gastrointestinal disturbances, headache, sweating, anxiety and sleep disturbances), which can be severe in some patients.*

**Advice to patients:**

*Women taking paroxetine who want to become pregnant are advised to discuss the balance of risks and benefits of continued treatment with their doctor.*

*Pregnant women who are currently taking paroxetine should not stop their treatment but should discuss their treatment with their doctor or midwife at their next routine appointment.*

There's that benefit/risk being touted again. I can't think of a bigger risk than a child being born with malformations... can you?

Once again, the MHRA are putting the onus on the doctors. Talk to your doctor about the risk/benefits. Talk to your doctor whether or not you should stop your treatment with paroxetine. It's not really '*advice to patients*', more of a cop-out! Do the MHRA think that your average doctor in the UK would have read the "New data from Denmark, Sweden and the US" that they based their warning on?

How on earth can a doctor give a patient the facts when he does not have the facts? It's a shambolic way to run a regulatory system, don't you think?

So what is GlaxoSmithKline's role in all of this?

Well, reading Jane Nieman's deposition from the Kilker trial one would assume that once again they have withheld vital information from both the regulator and patient.

Jane Nieman, a former Glaxo drug-safety executive, told a Pennsylvania jury that Glaxo officials noted in company files they were "almost certain" the drug was related to the problem, the problem being an e-mail from a Paxil user who aborted her fetus because it had a heart defect.

The email in question was sent to GlaxoSmithKline in 2001, 4 years prior to the MHRA issuing a warning to doctors.

We've been here before haven't we folks?

This end I have wrote to the MHRA under the terms of the Freedom of Information Act. [FOI]

I wrote the following on the 30th October, 2009:

----- Original Message -----

*From: fiddaman*

*To: MHRA Information Centre*

*Cc: KENT WOODS ; Gregor, Simon*

*Sent: Friday, October 30, 2009 12:17 PM*

*Subject: FOI Request*

*Dear all,*

*I'd rather get a yes or no answer without having to deem this a FOI request. Alas, the communication between myself and Mr Woods only seems to be one way.*

*My request:*

*Are the MHRA going to launch an investigation into GlaxoSmithKline regarding the suppression of information of Seroxat use for pregnant mothers?*

*You may or may not be aware of the recent ruling in a court of law whereby GlaxoSmithKline were found guilty by a jury of withholding information about Seroxat that led to a child, Lyam Kilker, being born with heart defects.*

*Once again children are being harmed by Glaxo's inability to tell the truth.*

*To recap:*

*Are the MHRA going to launch an investigation into GlaxoSmithKline regarding the suppression of information of Seroxat use for pregnant mothers?*

The MHRA still have time to answer this FOI. I'm pretty certain of what their answer will be but would like to see it just so it's a matter of record.

Amazingly, in 1997, some eight years before the MHRA sent warnings out to doctors regarding the use of GlaxoSmithKline's paroxetine, they, along with the Committee on Safety of Medicines issued Volume 23 Sep 1997 of 'Current Problems in Pharmacovigilance' [See Fig 1] On page three of this particular issue they wrote about drug induced birth defects. The first para reads:

*A teratogen is an agent which causes structural or functional abnormalities in the fetus, or in the child after birth. In the UK, the proportion of spontaneous abortions in clinically recognised pregnancies is 10-20% and of gross malformations is estimated to be about 3%. The cause of most malformations is not known but at least 2-4% are due to drugs or chemicals.*

On **Detecting potential teratogens** they write:

*During development, drugs undergo studies in animals to assess their potential as teratogens. However, lack of a teratogenic effect in animals does not guarantee safety in human pregnancy. Once a drug is marketed, the Yellow Card Scheme is an important method for generating signals which then can be more formally investigated.*

Well, forget the Yellow Card Scheme, they now have an abundance of evidence from the Kilker trial. They have the Sloot paper - remember Dr. Sloot stated: ... *that Paxil was a clear teratogen, that it was not just an effect of developmental or birth-weight related effect, that it was a direct teratogen, and that there was a spectrum of defects observed in rat embryos at low doses, establishing that it was a very potent teratogen, more teratogenic than cocaine and retinol, clear teratogens in their own right.*

It will be interesting to see how my requests unfold, it will also be interesting if I ever get an answer to the question. Is paroxetine a teratogen?

Bob Fiddaman

Fig 1

**Drug-induced birth defects**  
New report of genetic drug-induced birth defects in children's blood

Children's blood samples collected in a national study of the blood in a number of states, including California, have shown a significant increase in the number of children with birth defects, according to a report published in the journal *Journal of the American Medical Association*.

The report, which was based on data from 1980 to 1985, found that the number of children with birth defects had increased by 10 percent over the five-year period. The study also found that the number of children with birth defects had increased by 15 percent over the same period in California.

The study found a significant increase in the number of children with birth defects in California, including the following: Down syndrome, congenital heart disease, cleft lip and palate, cleft palate, and congenital deafness. The study also found that the number of children with birth defects had increased by 10 percent over the five-year period in California.

The study was conducted by the California Department of Health Services, and the results were published in the journal *Journal of the American Medical Association*.

**Read the report**  
The report is available in the journal *Journal of the American Medical Association*, Volume 258, Number 12, June 19, 1985, pages 1685-1688.

**National Yellow Card Information Service**  
This service is available in the United Kingdom and other countries. For more information, contact the National Yellow Card Information Service at 0800 731 6789.

Fid

TUESDAY, NOVEMBER 17, 2009

## GSK Response to Teratogen question - Laughable



Image: e-architect.co.uk

Well, I have kind of seen every trick in the book now...

A few days ago I wrote to GlaxoSmithKline enquiries to ask a simple, yet very important question.

Is paroxetine [Paxil, Seroxat] a teratogen?

To be honest I didn't think they would answer me, and even if they did they would probably direct me to part of their website where one would need a degree in bio-chemistry to fathom out what was written.

I was wrong.

Their response was far more off the wall than the above.

GlaxoSmithKline UK Ltd

Stockley Park West

Uxbridge

Middlesex

UB11 1BT

Tel: +44 (0) 20 8990 9000

Fax: +44 (0) 20 8990 4321

[www.gsk.com](http://www.gsk.com)

IMPORTANT NOTE: PLEASE DO NOT REPLY TO THIS EMAIL AS IT ORIGINATES FROM AN UNATTENDED MAILBOX

Reference Number: REDACTED

Dear Mr Fiddaman,

Thank you for contacting the Medical Information Department at GlaxoSmithKline. As requested please find attached the response to your enquiry regarding our product Seroxat\*(paroxetine).

I apologise, but we have been unable to verify if you are a health care professional. We will be able to assist you with your enquiries if you call our Customer contact Centre on 0800 221441 and select the option for Medical Information or alternatively, if you provide us with a telephone number where we can contact you.

Some information contained in this response may not be included in the approved Summary of Product Characteristics for Seroxat. This response is not intended to offer recommendations for administering this product in a manner inconsistent with its approved labelling in the UK.

Adverse events should be reported. Reporting forms and information can be found at [www.yellowcard.gov.uk](http://www.yellowcard.gov.uk).

Adverse events should also be reported to GlaxoSmithKline on 0800 221 441.

For any further enquiries on our products, please contact our Customer Contact Centre on 0800 221 441.

Yours sincerely,

Medical Information Advisor

GlaxoSmithKline

\*Trademark of GlaxoSmithKline UK Ltd

----

Couple of points here:

\*\*No attachment sent from them - therefore no answer from them.

\*\*Also note that I cannot reply to their email '**IMPORTANT NOTE: PLEASE DO NOT REPLY TO THIS EMAIL AS IT ORIGINATES FROM AN UNATTENDED MAILBOX**'

**GlaxoSmithKline: Transparent as ever!**

Related Link: [Paroxetine - The Teratogenic Effect by Bob Fiddaman](#)

Fid

WEDNESDAY, NOVEMBER 18, 2009

## The GSK Teratogen Plot... Thickens!



Image: [blog.prescriptionaccess.org](http://blog.prescriptionaccess.org)

Bizarre behaviour happening over at the enquiries desk at GlaxoSmithKline. They still have not answered a question I put to them - Is paroxetine a teratogen?

**Teratogen:** *Any agent that can disturb the development of an embryo or fetus. Teratogens may cause a birth defect in the child. Or a teratogen may halt the pregnancy outright. The classes of teratogens include radiation, maternal infections, chemicals, and drugs.*

Following on from [yesterday's answer](#), where they apparently included a response in an attachment to me via email, they, today, wrote the following to me:

*GlaxoSmithKline UK Ltd*

*Stockley Park West*

*Uxbridge*

*Middlesex*

*UB11 1BT*

*Tel: +44 (0) 20 8990 9000*

*Fax: +44 (0) 20 8990 4321*

*[www.gsk.com](http://www.gsk.com)*

*IMPORTANT NOTE: PLEASE DO NOT REPLY TO THIS EMAIL AS IT ORIGINATES FROM AN UNATTENDED MAILBOX*

*Reference Number: REDACTED*

*Dear Mr Fiddaman,*

*Thank you for contacting the Medical Information Department at GlaxoSmithKline for your recent enquiry concerning our product Seroxat\*(paroxetine).*

*Your previous email did not contain an attachment however, we had written as we were unable to verify if you are a health care professional. GlaxoSmithKline works within the guidelines set out in the Code of Practice of the Association of the British Pharmaceutical Industry (ABPI). This does not allow us to provide patients with advice about medicines which are available on prescription because any advice we might give could conflict with that of your own doctor who is in a far better position to advise you. Therefore, to enable GSK to provide you with the most relevant information please can you confirm if you are a health care professional.*

*Some information contained in this response may not be included in the approved Summary of Product Characteristics for Seroxat. This response is not intended to offer recommendations for administering this product in a manner inconsistent with its approved labelling in the UK.*

*Adverse events should be reported. Reporting forms and information can be found at [www.yellowcard.gov.uk](http://www.yellowcard.gov.uk). Adverse events should also be reported to GlaxoSmithKline on 0800 221 441.*

*We will be able to assist you with your enquiries if you call our Customer contact Centre on 0800 221441 and select the option for Medical Information or alternatively, if you provide us with a telephone number where we can contact you.*

*I look forward to hearing from you soon*

*Yours sincerely,*

*Medical Information Advisor*

*GlaxoSmithKline*

*\*Trademark of GlaxoSmithKline UK Ltd*

----

Once again, the email carried the 'advice' - IMPORTANT NOTE: PLEASE DO NOT REPLY TO THIS EMAIL AS IT ORIGINATES FROM AN UNATTENDED MAILBOX.

Strange then, that I replied yesterday using the reply button and they answer me?

Also strange that they should state that my email to them did not contain any attachment - I never said it did!

Quite a poor show if you ask me.

Let's say, for the sake of this rant, that I am a woman who learned two weeks ago that I am pregnant. Around the time of finding I was pregnant, I was prescribed Seroxat - the doctor warned me about the harm it may cause the fetus but told me the benefit of me taking Seroxat outweighed the risk.

I'm then told by a family member that Seroxat is teratogenic. What does that mean? I ask. They tell me and, concerned, I contact the manufacturer of the drug. Surely, there is not another thalidomide medication on the market.

Firstly, the company, GlaxoSmithKline, tell me they have responded with an attachment to an email. Seeing that there is no such attachment, I mail them back, despite the 'advice' within the email that states, IMPORTANT NOTE: PLEASE DO NOT REPLY TO THIS EMAIL AS IT ORIGINATES FROM AN UNATTENDED MAILBOX.

Low and behold, it appears the claim that the email they sent me originates from an unattended mailbox, is not

quite true.

Their second reply is advising me to see and talk to a doctor, the very same doctor that has just told me that the benefit of me taking Seroxat outweighs the risk of my child being born with heart defects.

It seems that GlaxoSmithKline are shirking their responsibility here.

I can just imagine that board meeting:

*"If anyone asks if Seroxat is a teratogen, we shall refer them to a doctor, that way, we are not making any statement of whether it is or it isn't. Let's shift the blame on the doctors"*

Brilliant marketing or wanton neglect?

So, here I am, a woman, I've just learned that I am pregnant. My doctor has wrote a prescription for me because I am feeling depressed. A family member has warned me that Seroxat is teratogenic - I seek more information but the very same company who manufacture and market Seroxat cannot/will not help me.

Furthermore, the UK Medicines Regulator, the MHRA, are ignoring me. They claim that my question to them, [2 weeks ago] is still being dealt with.

In between I contact the National Poisons Information Service. They respond by telling me to ask my doctor if Seroxat is a teratogen.

No problem, I contact the Yellow Card Centre Northern and Yorkshire Regional Drug and Therapeutics Centre. They also tell me to ask my doctor.

Here I am. Pregnant and depressed. Not knowing what choice to make because the manufacturer won't tell me the facts. Not knowing who to turn to any more regarding my concerns over the safety of the life growing inside me.

This, coming from a pharmaceutical company who proudly boast that they are addressing [three key strategic priorities](#): Grow, Deliver, Simplify.

And here's me, wondering whether or not the child inside me will be given the chance to grow. Whether the delivery of my child will come without the words of the mid-wife telling me 'There's complications'. Whether or not the Patient Information Leaflet that accompanies my packet of Seroxat will simplify the risk v benefit that my doctor chose on my behalf.

Maybe GlaxoSmithKline should address three other key strategies. Patients, Care and honesty. Because there is a woman with child here and more than likely somewhere else who is being kept in the dark of whether or not the drug she has been prescribed is a drug that can disturb the development of an embryo or fetus.

Maybe the terotogen link should be announced by GlaxoSmithKline. YES, SEROXAT IS A TERATOGEN AND WE CANNOT SAY FOR SURE WHETHER YOUR CHILD WILL BE BORN WITH HEART DEFECTS.

Then again, with almost 630 cases pending against them in the US Courts regarding children being born with heart defects after the mothers took Seroxat [Paxil in US] they are hardly likely to put human life before anything else on their agenda.

GLAXOSMITHKLINE

DO MORE, FEEL BETTER, LIVE LONGER.

The MHRA have been toying with my question for 13 days. Still no answer.

I have bile in my mouth.

Fid

THURSDAY, NOVEMBER 19, 2009

## Is Seroxat a teratogen. GSK: "discuss your concerns with your doctor"



Image: [blog.prescriptionaccess.org](http://blog.prescriptionaccess.org)

### **Part III of this on-going saga.**

I've had another reply from GlaxoSmithKline regarding the question I put to them last week.

'Is Seroxat a teratogen'?

It appears from their response that my doctor is in a better position to answer my query, despite Glaxo manufacturing the drug?

First, their third email to me: [You will note that they have now removed the 'IMPORTANT NOTE: PLEASE DO NOT REPLY TO THIS EMAIL AS IT ORIGINATES FROM AN UNATTENDED MAILBOX' statement.

GlaxoSmithKline UK Ltd

Stockley Park West

Uxbridge

Middlesex

UB11 1BT

Tel: +44 (0) 20 8990 9000

Fax: +44 (0) 20 8990 4321

www.gsk.com

19th November 2009

Reference Number: REDACTED

Dear Mr Fiddaman

Thank you for contacting the Medical Information Department at GlaxoSmithKline regarding our product Seroxat\* (paroxetine). You asked whether Seroxat is teratogenic.

GlaxoSmithKline works within the guidelines set out in the Code of Practice of the Association of the British Pharmaceutical Industry (ABPI). This does not allow us to provide advice on personal medical matters to individual members of the public so that we do not intervene in the patient / doctor relationship by offering advice which properly should be in the domain of your doctor. We would therefore recommend you discuss your concerns with him or her.

We are, however, able to provide you with information from the UK Summary of Product Characteristics for Seroxat. Should your doctor require additional information regarding the use of Seroxat in pregnancy, we are able to provide this to him or her.

With regards to your question, Section 4.6 (Pregnancy and Lactation) of the UK Summary of Characteristics for Seroxat states the following:

“Some epidemiological studies suggest an increased risk of congenital malformations, particularly cardiovascular (e.g. ventricular and atrial septum defects) associated with the use of paroxetine during the first trimester. The mechanism is unknown. The data suggest that the risk of having an infant with a cardiovascular defect following maternal paroxetine exposure is less than 2/100 compared with an expected rate for such defects of approximately 1/100 in the general population.

Paroxetine should only be used during pregnancy when strictly indicated. The prescribing physician will need to

weigh the option of alternative treatments in women who are pregnant or are planning to become pregnant.”

For further information, the Seroxat UK Summary of Product Characteristics is available at:

<http://emc.medicines.org.uk/>

We would reiterate that your own doctor is in a far better position to advise you and would recommend you discuss your concerns with him or her.

Yours sincerely,

Medical Information Department

GlaxoSmithKline

\*Trademark of GlaxoSmithKline UK Ltd

----

My reply:

Dear Medical Information Dept,

I would prefer a name in future correspondence, I don't think that is too much to ask, do you?

A couple of points before I respond to your email in depth.

Firstly, the original email you sent me, you claimed to have attached a response. Why did you make this claim?

Secondly, on each of the emails [with the exception of your last one] it is written clearly, 'IMPORTANT NOTE: PLEASE DO NOT REPLY TO THIS EMAIL AS IT ORIGINATES FROM AN UNATTENDED MAILBOX' -

If the mailbox was unattended, as you claim, then you would not have responded to me.

Now to your recent response:

Are you asking me to book an appointment with my doctor so I can ask him if paroxetine is a teratogen?

Do you not think this is a drain on NHS resources?

It's basically a simple question that requires a yes or no answer. If I were to enquire as to whether Seroxat was an SSRI would you refer me to my doctor?

It seems very strange that the company who manufacture a product are referring me to a doctor whose knowledge of that product is far less knowledgeable than yours?

The ABPI guideline is:

*GlaxoSmithKline works within the guidelines set out in the Code of Practice of the Association of the British Pharmaceutical Industry (ABPI). This does not allow us to provide advice on personal medical matters to individual members of the public so that we do not intervene in the patient / doctor relationship by offering advice which properly should be in the domain of your doctor. We would therefore recommend you discuss your concerns with him or her.*

I am not seeking advice on a '*personal medical matter*' and am currently not seeing a doctor for any illness, nor am I pregnant - as far as I know, men cannot fall pregnant, though I'm sure sometime soon there will be a miracle pill or vaccine that will put that right.

Forgive me for my flippancy.

Don't you think GlaxoSmithKline have a duty to warn patients as to whether or not one of their products is teratogenic? - If not the patients then maybe the Medicines regulator [MHRA].

Didn't Dr. Sparenborg, a toxicologist, who saw your original rat tests on Paxil [Seroxat] say that GSK needed to conduct further animal studies to account for so many deaths in the original rat studies?

According to trial transcript [9-15-09 Opening Statements](#) - GSK declined to do the additional safety studies due to concern that they would move to the more adverse pregnancy category C while their SSRI competitors would

share category B. This despite GSK scientist Dr. Wier, a teratologist, internally saying Paxil [Seroxat] should always have been a category C due to original animal studies deaths.

Would I be right in saying that All SSRIs except Paxil, are now classified as Category C medications, meaning they should only be used if the potential benefits outweigh the potential risks?

Would I also be correct in saying that since 2005 Paxil [Seroxat] has been classified as a Category D medication in the USA - in other words:

*“Positive evidence of risk-studies in humans,” which means fetal risk has been demonstrated. “Nevertheless, potential benefits from the use of the drug may outweigh the potential risk. For example, the drug may be acceptable if needed in a life threatening situation or serious disease for which safer drugs cannot be used or are ineffective.”*

Source

With the above in mind, do you think I should guide my doctor to the UK Summary of Product Characteristics for Seroxat or maybe guide him to the various testimonies from the recent GSK v Kilker trial. I'm a firm believer in transparency, you see and I think it only fair that my doctor know ALL the facts before prescribing Seroxat to a woman with child. Do you think that's a fair statement to make?

Furthermore, you suggest in your response that *'Should your doctor require additional information regarding the use of Seroxat in pregnancy, we are able to provide this to him or her.'* Will this additional information include any of the above?

Finally, in the last para of your response you write:

*"We would reiterate that your own doctor is in a far better position to advise you and would recommend you discuss your concerns with him or her."*

I find this quite difficult to grasp, seeing as many of your employees have spoken in the media about the benefits

of Seroxat, does GlaxoSmithKline not wish to discuss the risks with me? I already know of the 'benefits', I've read the Patient Information Leaflet.

Judging by your three replies to my initial query, 'Is Seroxat a teratogen', you are saying that my doctor will know the answer to this? Is this your position?

I understand that my in-depth response is rather long and suspect I have raised points that you may not wish to discuss with me.

For the record, I would like a response.

Regards

Bob Fiddaman

SATURDAY, NOVEMBER 21, 2009

## Response From MHRA - "Is Seroxat/Paxil a Teratogen?"



Image: randi.org

I first started writing this blog in 2006. I was basically frustrated at the lack of transparency coming out of the MHRA - My first post pointed to a story from 2004, it was, in essence, an article by Richard Brook giving the reasons as to why he resigned from the Expert Working Group who reviewed the safety of antidepressants.

Brook was then the CEO for the mental health charity, MIND, and he had accused the MHRA of failing in its duty by not acting on data showing that thousands of people were taking unsafe doses of Seroxat.

Brook said: *"On Thursday [last week] the agency at last published information advising that many thousands of men and women in this country may have been taking Seroxat at a dose that was unsafe.*

*"What it failed to mention is that the regulator had the data on which the basis of this decision was made for well over a decade as part of the original licence application.*

*"Despite four major regulatory reviews during this period and considerable consumer reporting and disquiet, the Committee of Safety of Medicines failed either to identify or communicate these key facts. As far as I am aware, the MHRA has not seen fit to acknowledge or address what in my view appears to be extreme negligence."*

The article grabbed my attention so it became my [first post](#) on this blog, I was, at the time, having my own difficulties with the MHRA, which became apparent with my second post, "[YOU CAN RUN ... BUT YOU CAN'T HIDE PROF. WOODS](#)".

For those who don't know, Prof. Woods is the CEO of the MHRA and I had wrote him regarding my concerns over the running of the MHRA and the antidepressant drug, Seroxat. Back then it would have been easier to get a personal response from the Pope as the MHRA were pretty much a closed shop.

Almost four years on and I have corresponded with the MHRA via email, telephone and in person - I even [had my day with Prof. Woods](#) where I raised concerns regarding the difficulties people were facing when withdrawing from SSRi's. I found Prof. Woods to be very charming. Here was a man that I had lambasted many times on this blog and he had the decency to meet with me. For that, he has my respect.

The outcome of that meeting is still on-going. The MHRA have met with Dr. David Healy, something I urged them to do at the meeting. Healy met and put forward his two penneth regarding SSRi withdrawal. [[Minutes of meeting with David Healy](#)]

More recently I have met and corresponded with Simon Gregor, the Director of Communications at the MHRA. Simon wished to seek my views on the MHRA's '[Patient and Public Engagement Strategy](#).' Simon has since met with other patients/advocates to ask for their views. Like Prof. Woods, Simon is a very charming man who listens carefully and appears to show great empathy.

As readers of this blog will know I have, over the past few weeks or so, been trying to ascertain whether or not Seroxat is a teratogen [Any agent that can disturb the development of an embryo or fetus]

The makers of Seroxat, GlaxoSmithKline, won't tell me, they claim:

*"GlaxoSmithKline works within the guidelines set out in the Code of Practice of the Association of the British Pharmaceutical Industry (ABPI). This does not allow us to provide advice on personal medical matters to individual members of the public so that we do not intervene in the patient / doctor relationship by offering advice which properly should be in the domain of your doctor. We would therefore recommend you discuss your concerns with him or her."*

It would appear that this clause is a useful tool for GlaxoSmithKline. If a patient or advocate queries one of their drugs they can pull down the shutters and 'pass the buck' to doctors. The Medical Information Department at GlaxoSmithKline told me, *"We would reiterate that your own doctor is in a far better position to advise you and would recommend you discuss your concerns with him or her."*

Very strange behaviour considering I had previously mentioned to the MHRA that too much onus is put on to doctors regarding SSRi's. See [Notes of a meeting held at MHRA on 2 September 2008](#)

"He [Bob Fiddaman] produced copies of the Patient Information Leaflet (PIL) for Seroxat in which he had **highlighted the 32 places where patients were told to talk with their doctor about various issues**. He felt that too much of an onus was put on doctors, many of whom did not know enough about withdrawal problems and their management."

It would appear that GlaxoSmithKline like to drum home the point of talking to your doctor if you have a problem with one of their products, in this instance, Seroxat!

I have not yet received a definitive answer as to whether Seroxat is a teratogen. Glaxo can't/won't tell me, they guard themselves with the ABPI guidelines.

Before I post the response given to me yesterday from the MHRA over the 'Is Seroxat a teratogen' question, I'd like to point out that the very same guidelines that GlaxoSmithKline use to get out of answering questions about their drugs is supported by the MHRA.

Earlier this year the MHRA joined forces with the Association of the British Pharmaceutical Industry [ABPI] - the same body that protect GlaxoSmithKline from answering direct questions from members of the public, the same body that like to put the onus on doctors rather than the manufacturers of the products.

What I find quite bizarre is the quote from Prof. Woods at this joining of forces:

*"Medicines can bring big benefits, but as with any medical treatment, no medicine is risk-free. By making as much information as possible publicly available, we can help people make informed choices about the medicines they take"*

To coin a phrase, this stuff just writes itself!

Now, I would like the readers of this particular post to bear in mind the above statement of Kent Woods.

Over two weeks ago I wrote to the MHRA, it wasn't a Freedom of Information request, it was just a simple question.

Is Seroxat a teratogen?

Come back later to find out their response.

Fid

SUNDAY, NOVEMBER 22, 2009

## Is Seroxat a Teratogen? : All in 15 Days work



Image: randi.org

It is important, before you continue to read on, that you read the first part of this particular correspondence with the Medicines Healthcare and products Regulatory Agency [MHRA] [HERE](#)

On the 5th of November, 2009 I sent an email to Sarah Morgan, Head of Pharmacovigilance Risk Management, at the MHRA. I also copied in Simon Gregor, Director of Communications at the MHRA. The question was short and sweet, Is paroxetine a teratogen?

**[–noun Biology.**

**a drug or other substance capable of interfering with the development of a fetus, causing birth defects.] [Source](#)**

Never in my wildest dreams did I think that this one simple question would cause such a disarray within the confines of the MHRA. A simple, yet very important question that would take 15 days to answer.

Before their response I'd like to give you a timeline of how the events unfolded.

### **5th November 2009:**

I send an email to Sarah Morgan, Head of Pharmacovigilance Risk Management, at the MHRA. I ask her if paroxetine is a teratogen. I also copy in Simon Gregor, Director of Communications at the MHRA.

**Later that day**

I receive a reply from Simon Gregor telling me that Sarah Morgan '*may be away at the moment*'. Simon tells me he has passed my email on to '*one of her colleagues, and asked them to identify someone else in the team that can reply.*'

**6th November, 2009**

I ask Simon if he has had an answer back yet?

**11th November, 2009**

I remind Simon that I have still not had an answer regarding the paroxetine/teratogen question.

**14th November, 2009**

I email Simon about a different issue but add:

*"Also, could you chase up the paroxetine/teratogen question. I'm quite baffled as to why such a simple question is taking one hell of a time to answer."*

**16th November, 2009**

I email Simon Gregor, Sarah Morgan and Kent Woods the following:

Dear all,

I have gone ahead and wrote my thoughts on the paroxetine/teratogenic link.

[Paroxetine - The Teratogenic Effect by Bob Fiddaman](#)

A simple question I put to the MHRA could not be answered. Other regulatory bodies recommend that I talk to my GP, whilst GlaxoSmithKline cannot even be bothered to answer me.

Now, without the need for me wasting my time with a Freedom Of Information request:

Is paroxetine a teratogen?

Yes or no?

It's a simple question that requires a simple answer.

Regards

Bob Fiddaman

**Same Day**

Simon Gregor answers me with:

Dear Bob

Thanks for this - I know you followed this up with me on Friday, and I have asked for a status update today. I'll let you know as soon as I hear more, but let me reassure you that we are working on an answer to your question.

**Same Day**

I respond with:

Dear Simon,

What is there to work on?

It either is or it isn't?

Your lack of transparency over this is noted. I don't know whether you [MHRA] have to run it by lawyers first?

Imagine, if two weeks ago I was offered paroxetine by my doctor. Imagine if I was unsure about it. Imagine if I was a woman who was pregnant.

Simon, with respect, this is just not good enough. The MHRA have not gave me an answer yet and as you will see from my article nor have GSK or other 'bodies' I asked.

I'm glad I am not a woman who is pregnant.

I am off out for a walk now.

This is poor performance on MHRA's part Simon, very poor.

**Same Day:**

There seems to be some confusion regarding emails sent to and from Simon, he writes:

Dear Bob

I am catching up on emails, and apologies as I don't think I am answering them in the order you sent them.

Re the paroxetine/teratogen question, I emailed you this morning and had asked for a status update. A response is in hand and we aim to have it with you in the next few days.

Re warnings on paroxetine in pregnancy, I have a colleague researching this and again will come back to you as soon as I can.

**17th November, 2009**

I write to both Kent Woods and Simon Gregor with regard to an answer I had received from GlaxoSmithKline, same question, Is Seroxat a teratogen?

**18th November, 2009**

I write the following to Simon Gregor:

Simon,

This is getting beyond a joke now. My request was not under the terms of the FOI Act. It was a simple question that required a yes or no answer.

I would like to know what the MHRA's position is regarding paroxetine and the teratogen link.

Is paroxetine a teratogen?

**19th November, 2009**

Frustrated, disillusioned, I write the following to Simon, MHRA staff and other interested parties.

Dear Simon,

I think it's 14 days since I first asked the MHRA the question, Is paroxetine a teratogen?

If I have not had an answer by the end today then I shall reluctantly pull out of any further communication with you re: Patient and Public Engagement Strategy.

I will however still request information from the MHRA but will use the official FOI Act to do so.

One simple question that seems to have divided a wedge between all the hard work that has gone on to build bridges with myself and other patient advocates and the MHRA.

The question is not difficult, it requires a yes or no answer.

The reluctance of the MHRA to answer leaves me in no doubt that the whole system of adverse drug reporting is a total sham and that the MHRA are NOT doing enough to protect the public from harmful drugs.

No answer by the end of the working day and I shall request it under the FOI terms.

Regards

Bob Fiddaman

\*\*A number of interested [and maybe not so interested] parties have been copied in on this email.

### **Same Day**

I text Simon Gregor and tell him he has an email that I would very much like him to read. Simon texts me back and tells me he is out of the office and won't be able to access his email.

### **November 20th, 2009**

Simon Gregor responds to email I sent yesterday [19/11/09]

Dear Bob

Following our text exchange yesterday, this is just to confirm that I have now had an opportunity to read your email. I can assure you there is no reluctance on our part to answer, and I am sorry if it has seemed that way. A response is being worked on, but in fairness I doubt it will be a one word response - we generally try to provide some background and context to what we say, and that is what colleagues will be working on. When I last checked with colleagues, I was given to understand that the response would be ready about now, so I will ensure that it is sent to you as soon as it is.

### **Same Day**

I reply with:

Simon - is Seroxat an SSRI?

You know that I know the answer.

All I require is a simple yes or no answer to the teratogen question. I don't wish to be directed to such and such a link.

Once you provide me with an answer, I will forward you documents.

Meantime, read this - [Is Seroxat a teratogen. GSK: "discuss your concerns with your doctor"](#)

GlaxoSmithKline are, like you, also giving me the runaround regarding this issue.

I am not an idiot Simon and I don't wish to be treated like one.

You have til 6pm today

### **Later that day**

Finally, the MHRA respond.

That response will be uploaded to this blog later.

Fid

SUNDAY, NOVEMBER 22, 2009

## MHRA Response: Limp-Wristed and Cowardly



Image: thejabberwock.org

So here is the response the MHRA gave me.

I had asked them, Is paroxetine [Seroxat/Paxil] a teratogen?

The opening paragraph sets the tone for the three page answer!

*"The question "Is paroxetine a teratogen?" is not as straight forward as it may appear."*

Not straight forward because it would appear that they [MHRA] don't want it to be that way!

The answer came via email and in a word document. Upon opening the attachment I was greeted with the MHRA logo with the tag line "Safeguarding Public Health"

I am reminded of a couple of lines from the movie Jaws here.

Briefly:

Martin Brody is the new police chief of Amity, an island resort town somewhere in New England. He has a wife named Ellen, and two sons named Michael and Sean. On a Summer morning, Brody is called to the beach, where the mangled body of Summer vacationer Chrissie Watkins has washed ashore. The medical examiner tells Brody that it could have been a shark that killed Watkins. Mayor Larry Vaughn, who is desperate to not

lose the money that will be brought in by 4th of July tourists, wants Brody to say Watkins's death was caused by a motorboat propeller instead of a shark, because the thought of a shark in Amity's waters would drive tourists away from Amity. It looks like Vaughn is a mayor who puts money ahead of people's lives. [\[IMDB\]](#)

Scene One:

Chief Brody is approached by the mother of a child that was killed in the waters of Amity

**Mrs. Kintner:** Chief Brody?

**Brody:** Yes?

[Mrs. Kintner slaps Brody and sobs]

**Mrs. Kintner:** I just found out, that a girl got killed here last week, and you knew it! You knew there was a shark out there! You knew it was dangerous! But you let people go swimming anyway? You knew all those things! But still my boy is dead now. And there's nothing you can do about it. My boy is dead. I wanted you to know that.

[Mrs. Kintner walks away]

Scene Two:

**Mayor Vaughn:** Martin, it's all psychological. You yell barracuda, everybody says, "Huh? What?" You yell shark, we've got a panic on our hands on the Fourth of July.

Scene Three:

**Mayor Vaughn:** I don't think either of one you are familiar with our problems.

**Hooper:** I think that I am familiar with the fact that you are going to ignore this particular problem until it swims up and BITES YOU ON THE ASS!

Here is the limp-wristed response from the MHRA:

*Mr B Fiddaman*

*Via email*

*20 November 2009*

*Dear Mr Fiddaman*

*The question "Is paroxetine a teratogen?" is not as straight forward as it may appear.*

*All medicines are subject to a battery of non-clinical tests which are conducted with the aim of assessing any direct or indirect effect of the medicinal product on reproduction. These tests are defined within European guidelines and are applied to all medicines.*

*These animal reproductive studies did not indicate a direct teratogenic effect for paroxetine prior to licensing. However, the absence of an effect in these animal models does not guarantee an absence of risk in humans.*

*Human pregnancy exposure data always supersedes the animal data if evidence comes to light that the drug may have negative effects on human reproduction in human clinical trials or during the post marketing period. This is one of the reasons that medicines are monitored continuously while they are used in clinical practice and the Yellow Card scheme is a valuable tool in this assessment process.*

*From the available data it is possible to conclude only that paroxetine was not proven to be a teratogen in two animal species studied at the time of licensing but that post marketing epidemiological studies have suggested there is an increased risk of congenital malformations, particularly cardiovascular, in babies born to women taking paroxetine in the first trimester of pregnancy. The latter observation does not prove paroxetine is a direct teratogen by definition or standard toxicological evaluation.*

*Regulatory action is rarely taken based on one case of an adverse event for many reasons but most importantly because there is a background prevalence of all adverse events, including congenital malformations. Congenital cardiac defects are common congenital malformations in the general population with a background prevalence of approximately 7 per 1000 births. Based on an individual case it is not possible to attribute the occurrence of a heart defect to medication exposure.*

*Information about the use of Seroxat in pregnancy has been communicated in a timely manner to prescribers*

*and patients in the UK via updates on the MHRA website, revisions to the Seroxat Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL) and via a Dear Healthcare Professional communication issued by the Commission on Human Medicines (CHM) and MHRA.*

*In December 2005, the MHRA issued communications to patients and healthcare professionals in light of new data from Denmark, Sweden and the US representing a potential signal of an increased risk of congenital malformations following maternal use of paroxetine in the first trimester.*

*All available data was actively investigated by the CHM and the MHRA and, following detailed investigations and discussions within Europe, advice was issued that in women taking paroxetine in the first trimester the risk of birth defects in the newborn may increase from 3% to around 4% for all congenital malformations and from 1% to around 2% for congenital heart malformations.*

*Therefore, if real, any increased risk is small and needs to be considered in the context of the potentially greater risk to the foetus that may result from the mother's depression remaining untreated.*

*All the documents related to the safety of Seroxat in pregnancy can be found at [\[link\]](#)*

*Subsequent to the action take in 2005, the MHRA continued to keep the issue of the safety of use of Seroxat in pregnancy under close review and there was further discussion at a European level. An updated analysis of available data was assessed in the European Union in February 2009. The full details of the metaanalysis are published at [www.gsk.com/media/paroxetine\\_pregnancy.htm](http://www.gsk.com/media/paroxetine_pregnancy.htm)*

*In response to the assessment of this updated analysis, the Seroxat SPC was further updated. The current Seroxat SPC contains the following text in section 4.6 (Pregnancy and Lactation) of the SPC available at [www.emc.medicines.org.uk](http://www.emc.medicines.org.uk)*

*The issue of the safety of use of Seroxat in pregnancy is and will continue to be a priority for the MHRA and we are closely monitoring and evaluating all new data as it comes to light in co-operation with other European authorities. When new data changes the current regulatory position please be assured we will take every action necessary to communicate the information and protect public health.*

*The UK has no current evidence to suggest that the MAH of paroxetine suppressed information about the safety of use of paroxetine during pregnancy. In the meta analysis, all requested information was provided to our knowledge.*

*It is unclear on what basis further investigation of GSK would be made and what the investigation would add to the extensive legal review of the MAH's procedure in relation to providing data.*

*I hope this answers your concerns on this issue.*

Yours sincerely

**Dr Julie Williams**

Acting Group Manager

Pharmacovigilance Risk Management Group

**Coming Soon: Why I no longer wish to have my name associated with the MHRA.**

MONDAY, NOVEMBER 23, 2009

## SEVERING TIES WITH THE MHRA



It seems uncanny that the first ever post on this blog, back in 2006, was to [highlight the failings of the MHRA](#). Over three years has passed since that first post, 3 years, 7 months, and 16 days, 1,326 days, to be exact.

I was quite shocked when I worked this out. I've been writing for that length of time about something I am passionate about. I don't get paid for what I write, quite a lot of man hours put in for voluntary work one would think.

During these 3 years, 7 months, and 16 days the MHRA have investigated the safety and efficacy of Seroxat and other SSRIs/SNRI's. Each time, they have concluded, that the benefits outweigh the risks.

On the 6th March 2008, the MHRA issued a press release, '[GSK investigation concludes](#)'

Part of that statement reads:

*The MHRA has concluded its four year investigation into Glaxosmithkline and its antidepressant drug Seroxat. The investigation focused on whether GSK had failed to inform the MHRA of information it had on the safety of Seroxat in under 18's in a timely manner.*

*The investigation was undertaken with a view to a potential criminal prosecution for breach of drug safety legislation. It was the largest investigation of its kind in the UK, and included the scrutiny of over 1 million pages of evidence.*

*The decision taken by Government Prosecutors, based on the investigation findings and legal advice, is that there is no realistic prospect of a conviction in this case, and that the case should not proceed to criminal*

*prosecution.*

It continued with:

*Professor Kent Woods, MHRA Chief Executive, said: "I remain concerned that GSK could and should have reported this information earlier than they did. All companies have a responsibility to patients, and should report any adverse data signals to us as soon as they discover them. This investigation has revealed important weaknesses in the drug safety legislation in force at the time.*

It is interesting to note that the deflection away from the behaviour of GlaxoSmithKline is directed toward the drug safety legislation in place at that time.

It is also interesting to note that in the four paragraph press release the MHRA choose not to chastise GlaxoSmithKline.

I, along with others, was never happy with the way this investigation was handled and, as with others, I made my feelings clear on this blog and in various other forms of communication with the MHRA. It was, however, something that I and others had anticipated.

The one chance at a criminal prosecution being brought against GlaxoSmithKline, scuppered by an antiquated drug safety legislation. To put it into layman's terms, The MHRA and GlaxoSmithKline had squared up for a fight in the ring. GlaxoSmithKline won on points. There was to be no re-match.

The [response from GSK](#) into the MHRA's conclusion of this 4 year investigation was more like a 'thank you' note if one reads between the lines. It smacked of smugness and a severe lack of conscience.

Both the MHRA and GlaxoSmithKline rode the storm that ensued, "Today's newspaper is tomorrow's fish and chip paper."

Fortunately, the Paxil 329 studies, into which much of the investigation focussed, is [available online](#). Only a fool or pharmaceutical whore would draw to the conclusions that GlaxoSmithKline did nothing wrong.

Jump forward to the year 2009. GlaxoSmithKline under investigation again, not a criminal prosecution but

nonetheless one of vital importance of drug safety and one which the MHRA really needed to keep close tabs on.

3-year-old Lyam Kilker was born with serious heart defects. While pregnant, Kilker's mother took the antidepressant paroxetine [Seroxat/Paxil]. The Jury's decision in this case was that Seroxat/Paxil was the causation of Lyam Kilker being born with heart defects. In other words, Seroxat/Paxil was deemed responsible as the agent that disturbed the development of an embryo or fetus.

A teratogen.

Apparently this one case is not enough for the MHRA to condemn Seroxat to the group of teratogen's. The jury's decision, it appears, is of no concern to the UK Medicine's regulator.

There are approximately a further 630 cases awaiting trial in the US, all claiming that Seroxat was the causation of children being born with heart defects similar to those that Lyam Kilker was born with.

Assuming these cases are heard and won, the MHRA would then have an abundance of evidence at their disposal.

GlaxoSmithKline were ordered to pay the Kilker family \$2.5 million, they have appealed against the decision. Further trauma for the Kilker family lays ahead.

The case files from the Kilker trial are [available online](#). Depositions, cross-examinations, expert witness reports and even a testimony of an ex GlaxoSmithKline Executive all point to the evidence that Seroxat is indeed a clear teratogen.

A new document that was used in the Kilker case was recently handed to me. It's pretty damning for GlaxoSmithKline and also for the MHRA's stance on whether or not Seroxat is a teratogen. [As far as I can ascertain, the MHRA are unsure whether it is or not!]

[Plaintiffs Exhibit 5036](#) in the Kilker trial was a study [Buhimschi & Weiner Medications in Pregnancy and Lactation]

Table 2 from the study lists 'Commonly Prescribed Teratogenic Drugs.

Next to 'Antidepressants' you will find GlaxoSmithKline's drug, paroxetine, known to you and I as Seroxat.

**Table 2. Commonly Prescribed Teratogenic Drugs\***

Drug	FDA Classification <sup>†</sup>
Agents acting on renin-angiotensin system (captopril, lisinopril, enalapril)	C (first trimester) D (second and third trimesters)
Antidepressants (paroxetine)	D
Antiepileptic drugs (valproic acid, carbamazepine, phenytoin)	D
Anxiolytics (diazepam)	D
Alkylating agents (cyclophosphamide)	D
Androgens (danazol)	X
Antimetabolites (methotrexate)	D, X
Carbimazole	D
Coumarin derivatives (warfarin)	X
Estrogens (diethylstilbestrol)	X
Fluconazole	C
Lithium	D
Misoprostol	X
Oral contraceptives	X
Penicillamine	D
Retinoids (isotretinoin)	X
Radioactive iodine (sodium iodide-128)	X
Thalidomide	X

The American equivalent of the MHRA, the FDA, have a class system for their drugs. Paroxetine falls under Class D

Here is what the FDA has to say about Class D drugs:

**"Clear evidence of risk in humans"**

They add

**"Studies, adequate well-controlled or observational, in pregnant women have demonstrated a risk to the fetus"**

Strangely, the FDA, like the MHRA, add:

*"However, the benefits of therapy may outweigh the potential risk"*

Nonetheless, proof that paroxetine is classed as a teratogenic, at least in the United States.

After I had received the MHRA's [limp-wristed response](#) to my 'Is Seroxat a teratogen' question', I sent them this study from Buhimschi & Weiner. I asked them if this conclusion was wrong? I'm not expecting a straight yes or no answer. In fact I'm not really expecting anything back that remotely interests me.

I don't want to waste my time and energy any more with the UK Medicine's regulator. It's obvious to me that they side... and will always side, with the pharmaceutical companies.

This end, I wrote my final thoughts to the MHRA yesterday.

It appears that advocates such as myself are not only fighting against the manufacturers of these drugs, we are also in 'the ring' with the Medicine's regulator's. Hardly a fair fight is it?

Here is the email.

Names from the CC list have been redacted with the exception of Julie Edgington. All will become apparent when you read the email.

----- Original Message -----

From: fiddaman

To: Gregor, Simon

Cc: REDACTED

Sent: Sunday, November 22, 2009 8:11 PM

Subject: MHRA - I am done!

Dear Simon Gregor, and other MHRA staff included in on this email; namely Kent Woods, Alasdair Breckenridge and Sarah Morgan.

You will note from the Cc list I have included some familiar faces, I think all but one of them will be familiar to you.

The 'give2manie' email address is an email that you have probably not come across before. It is the email address of Julie Edgington, an American. Her child, Manie, was born with transposition of the great arteries [TGA].

GA means the aorta and pulmonary arteries in the heart are switched. When a child is born with TGA there is very little oxygen in the blood. The aorta receives the oxygen-poor blood from the right ventricle, but it's carried back to the body without receiving more oxygen. The pulmonary artery receives the oxygen-rich blood from the left ventricle but carries it back to the lungs.

Manie's mother, Julie, took paroxetine whilst she was pregnant.

The reason behind this email and the reason I have included the familiar faces is because I want them all to know where I currently stand with the MHRA.

Your limp-wristed response to my question, Is Seroxat a teratogen, was really the straw that broke the camel's back. You have gone back to your old ways of fence sitting on life threatening issues.

Time and time again you are faced with evidence yet you refuse to acknowledge it. Seroxat IS a teratogen, you know it and so do I... and I imagine the others included on this email do too.

Over the past couple of years the MHRA have opened their doors to Seroxat campaigners, it was a nice gesture but I firmly believe it was merely a token one. Maybe you thought by opening your doors, the problem would simmer - *Keep your friends close, and your enemies closer.*

Simon, you have picked my brains over the past year or so with regard to your yellow card system, a system that is troubled, outdated and, dare I say it, about as useful as a chocolate teapot.

You are very good at what you do Simon, I bear you no malice.

Moving on to your CEO, Kent Woods. Charming man, well he was for the hour meeting I had with him. Since then he has failed to answer any of my emails. Whether he thinks I'm some ruffian from a council estate should not alter the fact that I have some serious complaints that need answering.

He has had plenty of opportunities to correspond with me but has chosen not to. The *'Kent gets hundreds of emails a day'* excuse does not wash with me. Even if he did, does he ignore them all or does he just choose to answer the one's he thinks are important?

Alasdair Breckenridge is big enough to proclaim on national TV that there is nothing wrong with Seroxat, and so I gather at various dinner functions he has attended. Remind me of his role again at the MHRA?

Your recent response regarding the teratogen issue was expected. It was a classic cover your ass answer - in fact I shouldn't really use the word 'answer' as you never actually answered the question did you? [For those included on the email who never saw the answer, it can be found here: [MHRA Response: Limp-Wristed and Cowardly](#)]

The timeline leading up to the MHRA's answer can be read here:

[Is Seroxat a Teratogen? : All in 15 Days work](#)

As you are well aware GlaxoSmithKline were just found guilty by a Jury in the United States. Paxil [Seroxat] was

found to be the cause of the heart defects Lyam Kilker was born with. If a jury can find that Seroxat caused heart defects in a child then I have to ask myself why regulator's can't. Your Chairman being a former employee of GlaxoSmithKline does not really help matters nor does your Head of Licensing, Ian Hudson, another former employee of Glaxo.

You are not protecting the public with regard to Seroxat and other SSRi's. Your stubbornness is staggering. You choose to protect GlaxoSmithKline and anyone who sides with them, is, in my opinion woefully misguided and/or corrupt.

Seroxat IS a teratogen, I should not have to send you the evidence - you should already have it, you are a regulator after all.

I have decided to call it a day with the MHRA. There is no reason for me to correspond with you anymore. I cannot and will not have my name associated with cowards - because that's what you are. There is no direct accusation at individuals here - this is aimed at the MHRA as a whole.

You need to take a good look at yourselves and ask whether or not you are doing enough to protect the public, in particular children. Personally, I don't think you are.

For the other patient/advocates involved with the MHRA on the patient and public engagement (PPE) it is entirely up to you if you wish to continue engaging in talks with the MHRA. My decision is based on my own belief that the MHRA are simply not protecting the public and no matter how many doors they open to patients will not matter a jot because they will never take the side of the likes of myself or young Manie Edgington.

There are a further 630 cases to be heard in the USA regarding children being born with heart defects. The Kilker trial was a landmark case and has set a precedent, the others, I assume, will be settled out of court. No liability. No public record that Seroxat is a teratogen.

Which, will suit the regulators just fine.

I do not want a detailed explanation of the reasons why you could not answer a simple question. My main concern is doctor's in the UK are still prescribing a teratogen - because the MHRA are too limp-wristed to condemn it.

Yours sincerely

Bob Fiddaman

Author of Seroxat Sufferers

<http://fiddaman.blogspot.com>

----

Now, what was the first post on this blog back in 2006?

Fid

**SEROXAT SUFFERERS STAND UP AND BE COUNTED**

Beware of [Obsessive freaks](#) posting as me



Original Image: whitman-ma.gov

*"This petition is to bring criminal charges against GlaxoSmithKline. The medication they made has caused numerous deaths not to mention birth defects. Many babies have died or been born with horrible birth defects caused by the use of Paxil [Seroxat]. Information that Paxil caused birth defects was hidden therefore taking*

*the right to make an informed decision was taken away from Mothers. GlaxoSmithKline needs to be held criminally accountable for their misinformation and blantant lies. It is for all these babies to have justice."*

**SIGN THE PETITION HERE**