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Paxil Birth Defect Trial: Battle of the Experts

Tuesday, March 02, 2010 by: Evelyn Pringle, health freedom writer

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(NaturalNews) In the first Paxil birth defect trial that resulted in a \$2.5 million verdict against GlaxoSmithKline in October 2009, the infant, Lyam Kilker, was born with three heart defects; an atrial septal defect, a ventricular septal defect, and an interrupted aortic arch, after his mother took Paxil while pregnant.

Pregnant women cannot participate in clinical trials on drugs due to the risk of harm to the fetus. But after a drug has been on the market for a while, epidemiology studies can review the medical records of women who have taken a new drug while pregnant and the records of women who were not exposed to the drug while pregnant and compare the outcomes of the infants.

The plaintiffs' experts, Doctors Ra-id Abdulla, David Healy, Shira Kramer and Suzanne Parisian, all testified that they believed Paxil (paroxetine) caused Lyam's defects, based in part, on the scientific literature on studies available on Paxil to date.

Battle of the Experts

During her September 15, 2009 opening statement, Glaxo's lead attorney, Chilton Varner, told the jury, the "experts in the case diverge sharply on how they interpret that body of scientific literature."

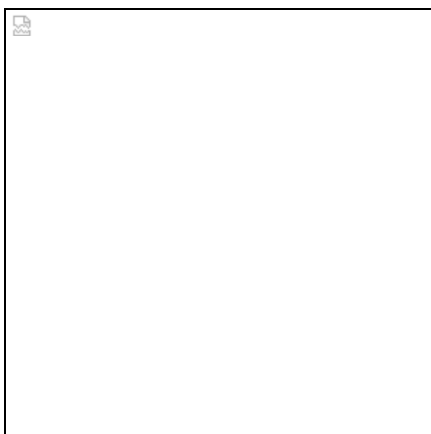
The "plaintiffs' experts say that these scientific studies prove causation, they prove that Paxil causes cardiac defects and IAA," she noted.

"They get there by ... lumping all cardiac defects together and looking at the numbers for cardiac defects as a group," she said, "They also get there by rejecting any application of the tool of statistical significance."

"The plaintiffs' experts will tell you they believe that as long as there is a difference between the two groups, and the Paxil group is higher than the control group, that's enough," Varner told the jury.

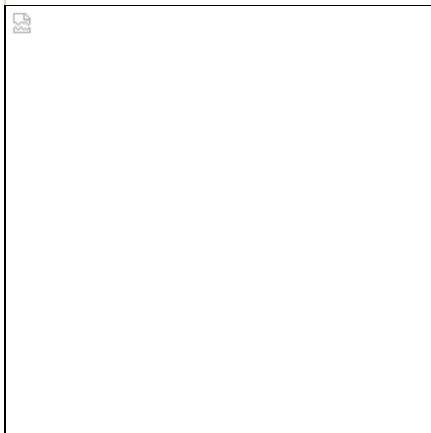
"GSK's experts, on the other hand, are anti-lumping," she said. "They say that you can't lump all heart defects together because they form for different reasons at different times by different processes and that you can't use evidence as to one kind of defect to imply that it also applies to another kind of cardiac defect."

"And GSK's experts will tell you that statistical significance matters," she stated, "that without applying the tool of statistical significance, you have no idea whether the difference between the two groups is real and meaningful or whether it is simply the operation of chance or coincidence."



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Studies Designed to Fail

During his September 15, 2009 opening statement, the family's lead attorney, Sean Tracey, told the jury: "You are going to hear from experts in this case that there are ways to design studies to fail."

"If you truly don't want to know the truth," he said, "very smart people can design studies that won't show you the truth."

Dr Shira Kramer, an epidemiologist, testified as an expert for the plaintiffs. Kramer was asked to explain what is meant by "inclusive by design." It's "a very, very serious problem that has been written about quite a bit," she told the jury.

The reason for "the tremendous amount of concern and literature on this topic," she said, "is many of these studies look like they have been designed to fail."

It's the "deliberate design of epidemiological studies in such a way as to make it, if not impossible, extraordinarily difficult to detect relationship between an exposure and an outcome or a disease," Kramer explained.

In the Paxil studies, many of the "designed characteristics have been such that they would minimize or make it more difficult to detect an increased risk," she said. "And despite that, these studies have shown consistency in showing an increased risk of cardiac malformations associated with first trimester Paroxetine exposure."

"The pressure is always against the ability to detect increased risk in the way these studies are designed," Kramer said. "And, yet, despite that, we are seeing consistently elevated risks associated with Paxil, which is very, very important, very compelling, and very alarming actually."

Kramer described the difference between association and causation as meaning that a single study with a finding of an elevated risk of birth defects would only show an association. "When you have a body of literature which shows through multiple studies consistently elevated findings, then you move from association in one study to causation, that this factor causes the disease," she told the jury.

During closing arguments on October 8, 2009, Tracey told the jury that, "Defense lawyers can't stand the word 'causal.'"

"Causal" is the "kiss of death" for a defense lawyer, he said, because they know that is one of the questions the jury will be asked.

"The second question you are going to be asked," he told the jury, is "Do you find that Michelle David's ingestion of defendant's drug Paxil was a factual cause in bringing about the heart defects?"

Epidemiology 101

While testifying, Kramer explained what is meant by relative risks and confidence intervals. "Our real interest in epidemiology is to measure rates of disease and excess risk," she said. "But we also want to know really how precise is this measure."

"And the precision of this measure is very much tied to the size of the population that you are studying and the number of exposed people," she explained.

"In other words," she said, "if we were to go into a large population and do the same study a hundred times, how many times out of a hundred would we find the same exact answer?"

"It is similar to tossing a coin," she noted. "If you are looking at the proportion of heads and tails in a coin toss, and you toss that coin a thousand times ... you are going to come up with that 50/50 proportion pretty much all the time."

"That's a very precise answer," she pointed out.

"So if you think about it that way," Kramer said, "the larger the sample size, the larger the number of people that you study, the more precise your study estimate of that relative risk is."

"And we estimate the precision of this relative risk by calculating something called confidence interval," she told the jury. "If you were to repeat this study, let's say 95 times out of a hundred, what would that range be?"

For instance, where the relative risk in a study is 2, and they calculate statistically a 95 percent confidence interval with a range of between 1.5 and 2.5, the actual relative risk would fall somewhere in this range. That "means 95 trials out of a hundred would generate results in this range," Kramer stated.

A test that is not statistically significant should not be discarded, she said. The "practice of statistical significance testing has been very much rejected in epidemiology because it was never developed really to study health or biomedical or human health problems."

"This whole issue of rejection of a hypothesis, yes-no answers," she explained, "was created for agricultural and industrial studies, whether or not a certain widget would be produced more efficiently in one production method than another or whether one field is more productive than another in an agricultural setting, these are easy yes-no answers and don't impact human health."

A single-minded focus on significance testing is dangerous from a public health perspective, she said, because "it leads to discarding very important and relevant data and studies."

Glaxo's Own Meta-Analysis

While testifying, Kramer explained that a "meta-analysis is an analysis of all the data that have been generated on a subject, so it's an agglomeration, a statistical analysis of all the data to come up with a summary risk for all of the studies together."

"It's an attempt to overcome the issue of small sample sizes," she said, "so the individual doing the meta-analysis will take all of the studies and will actually combine all of the results into summary statistics so that there is more power and there is some attempt to come up with a summary of all of the data that have been generated to date."

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The famous neuropsychopharmacology expert from Wales, Dr David Healy, also testified for the plaintiffs. During his testimony, the jury was presented with two charts from Glaxo's own website, showing the results of its own internal meta-analysis of the existing epidemiological studies.

The analysis had only been put on the website recently, he noted, maybe last year. One chart showed all birth defects lumped together, or combined, and the other showed cardiac birth defects.

In discussing the chart on combined birth defects, Healy said, "what everybody here needs to see is ... the little dots in the middle of the lines."

If you "look at the pattern of dots there, you will see that of all the studies that have now been done, most of the dots fall on the right-hand side," he noted. "This means that there is an increased risk that Paxil causes birth defects."

"What I want you to look at here ... is the consistency," he told the jury. "The dots are all falling on the right-hand side of the line, which shows an increased risk."

"When GlaxoSmithKline added all this up," Healy said, "you see the dot at the bottom, that is statistically significant."

"They say there is no chance that Paxil is not causing these birth defects. Chance is gone. It is causing the birth defects," he told the jury.

With the chart on cardiac birth defects, "again, you see the patterns of dots are mostly on the right," Healy pointed out.

"What you see here at the end," he said, "shows you a 1.5-fold increase in risk."

This "comes from their Web site," he stated, "I have had no part in trying to generate these data at all."

While testifying, Healy discussed several of the studies in Glaxo's analysis, including the abstract for a presentation given at a conference in 2001, referred to as Unfred, which also had an author named Chambers. The full paper on the study, with Chambers as the author, had never been published but the data was in Glaxo's database.

"These data almost 10 years later," Healy said, "showing a fivefold increased risk in heart defects and a tenfold increased risk in birth defects in general has not been published."

Second Expert Opinion

During her testimony, Kramer also went over Glaxo's meta-analysis and explained what it showed. "GSK determined that the odds ratio for cardiac malformation as a broad class was 1.48," she told the jury. "That is a 48-percent increased risk where they have combined data from all of the studies that they could find to date."

"They also found an odds ratio of 1.67 for septal defects," she said. "That is a 67-percent increased risk of septal defects associated with first trimester Paroxetine exposure for all the studies, for the three studies where there was actually data on septal defects."

"And then for their summary odds ratio for right ventricular outflow tract obstruction defects," she added, "the two case control studies which actually looked at those types of defects they found a summary odds ratio of 2.85."

Most of the studies in the meta-analysis did not break down the cardiac defects into subcategories, Kramer said. "Either because they simply didn't have enough individuals in their studies or they set up their study rules which preclude them from doing so."

It would be inappropriate to conclude that if a specific cardiac defect was not found in these studies that Paxil did not cause it, she said. "It would be very much inappropriate and erroneous to assume that because that subcategory is not mentioned ... that there is no increased risk associated with it."

Kramer also testified about the Wurst study, published only 12 or 13 days before she testified. The "GlaxoSmithKline meta-analysis that we just discussed was not published," she told the jury. The "Wurst study is the published version ... but updated with one additional study."

She was asked whether there was anything new or different in the Wurst study. "Well, the only thing that is different in ... the published version versus unpublished version," she said, "is that they did not publish any subgroupings of cardiac abnormalities, birth defects in the published version."

They only "analyzed and published the summary odds ratio for all cardiac birth defects combined," she noted.

"And that summary odds ratio was very similar to the first one," she said. "It's 1.46. That is a 46-percent increased risk for all cardiac defects combined."

During cross-examination, Glaxo attorney, Todd Davis, told Kramer, "despite every single one of those studies looking at that those different patient populations over different time periods, there is not a single case in any of the studies that you talked about ... that identifies a patient who was exposed to Paroxetine or Paxil who had an IAA..."

He noted that Lyam "was diagnosed with an interrupted aortic arch Type A," and asked Kramer: "Can you -- can you point to the jury in your report where you mention anything about interrupted aortic arch of any kind?"

"I probably didn't because there is no specific study that analyzed that specific defect as a stand alone category," she replied.

Kramer pointed out that "the epidemiological studies that have been conducted never individually analyzed the rates of the risk of interrupted aortic arch Type A associated with first trimester Paxil exposure."

Because it is so very rare, she said, it would be impossible to do given the required sample size of "something over a million" subjects in order to conduct such a study.

"And since no such study was ever done," she told the jury, "you would not expect to find any specific study that would have been able to analyze interrupted aortic arch Type A as a specific subgroup."

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Most of the studies, she said, "just reported on all cardiac malformations as a group and even those that ... did any kind of subgroup analysis restricted them to the most common subgroups."

There were several studies where they restricted any analysis to subgroups where they had at least 200 women whose child suffered a specific birth defect, "which would automatically exclude IAA Type A," she explained.

The Louik paper restricted the analysis to subgroups of 100, she said. But the "Louik study itself very clearly lists IAA as a specific cardiac malformation under conotruncal defects in their appendix where they list specific subgroups that they looked at and considered," Kramer told the jury.

Louik Study

The Louik study was funded by Glaxo and conducted out of the Slone Epidemiology Center For Birth Defects. While Kramer was testifying earlier, Tracey put up a slide entitled, "Louik, et al - GSK involvement," and told her to tell "the jury what GSK's involvement in this study was both publicly and then privately."

Davis objected to this testimony. "There is nothing in Doctor Kramer's expert report that discusses anything about communications with GSK that somehow impacted the Louik study, so there has been no notice to GSK that she would be offering those opinions today," he argued to the judge, while the jury was out of the courtroom.

"Your Honor," Tracey told the judge, "this issue is something that has been percolating for a number of years."

"This information about GSK's involvement and manipulation of the Louik study is something that has recently come to light," Tracey said. "In fact, the deposition of their epidemiologist, Sara Ephross, was taken after ... the deadline for Doctor Kramer's report."

"And, in fact, last week, while we were in trial," he told the judge, "a Federal Court in Boston has ordered the Slone Epidemiology Center and GSK to turn over documents related to their involvement in this study."

"Quite frankly," he said, "the only people prejudiced by this are the plaintiffs, because GSK knows exactly what they did and when they did it, and we have been trying to get this information for some time."

The judge excluded testimony about an email exchange between Dr Louik and Ephross.

But the comments by Louik, not seen by the jury, that appeared in court filings, stated in part: "we did not accept your changes. We are trying to avoid reinforcing the widely held perception that 'statistical significance' is a standard by which to judge the validity of a study finding. Significance is a function of study size, and while a single non-significant result might not be credible, in this case it supports findings from other studies and should not be dismissed for reasons of significance alone."

In the affidavit filed in the Federal Court that ordered the release of the communications between Glaxo and the Slone Center, Louik wrote: "We rejected all of GSK's suggestions that might have served to weaken our findings and conclusions."

"GSK suggested that our 'overall' findings did not support the hypothesis that Paxil increases the risk of cardiac defects," she stated. "We rejected that suggestion as well."

Birth Defect Numbers Halt

When Paxil was first approved in the US, although Glaxo did not list the number of birth defect cases reported on the label, if a doctor contacted the firm wanting information, Glaxo sent out medical information letters with the number of birth defects reported.

Tracey entered three such letters into evidence. The first letter listed 36, the second 42, and the third 64. Then in the late 1990s, instead of including the number of birth defects reported, the letters started only listing the percentages, and after that they went to listing nothing, Tracey told the jury in closing arguments. "It goes from numbers to percentages to nothing."

During the trial, a Doctor Hobbiger testified that Glaxo enacted a policy not to give doctors the numbers because doctors were incapable of putting them into context. "The funny thing about that to me," Tracey told the jury, "is why were the doctors capable of putting the numbers in context when the numbers were low?"

"How did they magically become incapable of rational thought once the numbers became high?," he pointed out.

He noted that a big thing happened in 1998. Glaxo analyzed all the data they had been receiving on Paxil, and the person writing the report made the following finding: "The number of reports we have of women with birth defects is an alarmingly high number. We should not see this number of birth defects. It's four to five times what we would expect to see."

"This is an internal document that nobody has ever seen before, not the FDA, not anyone," Tracey said.

Earlier in the trial, he had showed the jury a letter from 1984, in which the FDA specifically told Glaxo they needed to tell the FDA "whether or not you receive any alarming information either in animal studies or in the human population."

"And in 1998 this is their language, not mine," Tracy told the jury. "The incidence rate of congenital abnormalities as observed in data reported in this document is 13.3 percent."

This is a problem, he said, because the background rate "is 2-1/2 to 4 percent, depending on who you believe."

Birth Defect Info Request Refused

During the trial, the jury learned that in 2001, Glaxo received two emails from a woman specifically asking for any information Glaxo might have on birth outcomes of babies born to mothers who took Paxil.

The woman reported that she had recently gotten married and immediately became pregnant because they wanted lots of children. But when she was six months along, the pregnancy had to be terminated after tests showed the baby had a rare heart defect and would likely not survive to term or survive the necessary open heart surgery to save his life if born alive.

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"To say the least, I was absolutely distraught with this news," the woman said. "I thought this was something that I did ... because I stayed on the Paxil for selfish reasons."

"I wanted to know if you could direct me to any information you might have of any woman that has taken Paxil and still had healthy babies," the woman wrote in late May 2001.

"My husband and I are ready to try again to get pregnant in the next month or two," she said. "I am so nervous."

The woman had been on Paxil for over four years and loved how the drug worked for panic attacks. "I don't want to stop taking my miracle pill," she wrote. "But, then again, if there is a chance that this might hurt or affect the baby, I want to know upfront."

"And I will somehow stop taking it for the time being," she added. "Please contact me as soon as possible. Please don't forget about me."

The woman sent a second email on June 1, 2001, and stated: "This response is in regards to an e-mail that I had sent you previously."

"I was asking to see if you have any or are in the process of any clinical trials for women who are currently on Paxil and pregnant," she said. "I wanted to find out information to see how many women were on Paxil during pregnancy and if they were able to successfully have healthy babies."

"I love the product, and I don't think I could have gotten through my panic attacks without the wonderful help of this miracle drug," she told Glaxo.

"I just want to start to try and get pregnant again soon," she wrote. "I do not want to put my unborn child through anything that would hurt him/her."

"Please, if you do not have this information, where is this information held?" she wrote. "Does anyone do studies like this? Please, any information you may give me would be great."

Glaxo wrote back on June 6, 2001. "We are attaching a copy of our current product information for Paxil. Please review the section on use during pregnancy," the letter read.

"Further questions about your treatment should be directed to the physician, pharmacist or healthcare provider who has the most complete information about your medical condition," they said. "Because patient care is individualised, we encourage patients to direct questions about their medical condition and treatment to their physician."

"We believe that because your physician knows your medical history, he or she is best suited to answer your questions," Glaxo wrote. "Our drug information department is available to answer any questions your physician or pharmacist may have about our products."

Glaxo sent the woman basically a form letter on June 13, 2001, asking for a signature on an authorization to get her medical records, but provided no answers to the woman's questions.

On a Glaxo internal document with the same date, the box "almost certain" was checked for "Relatedness assessment to medication." There is no higher category of certainty that Paxil caused the birth defect than the box checked.

Jane Nieman, a Glaxo employee at the time, was listed as the contact person on a report sent to the FDA. Before trial, Tracey took Nieman's deposition and questioned her about Glaxo's policy for reviewing adverse event reports prior to showing her the documents about the mother who aborted her baby that said it was "almost certain" that Paxil caused the defect.

Portions of the deposition were played for the jury. Before Nieman knew about the "almost certain" document, she testified that when a causality assessment was made a physician was involved and it was a team effort. "I think it is very much a team," she said. "I think that's really how they worked."

"They would look at the case and they would form a medical opinion as to whether there was a possible, probable or no causality," she stated.

Tracey told the jury that Nieman was "stunned" when she saw the document with "almost certain," checked so he asked her whether she was uncomfortable with the fact that the assessment was made. "It was made. It's a fact," she said in the deposition. "I don't feel uncomfortable with it."

Later in the deposition, Nieman claimed she did not know who checked that box. "Somebody from GSK filled that in," she said. "There's a possibility someone made a mistake and checked the box wrong."

During the trial, Glaxo had Doctors, Stephen Hobbiger and Judith Jones, testify that the checked box was definitely a mistake because they don't do causality assessments in the US citing "almost certain," that they only do it that way in France.

During cross-examination, Tracey showed Jones a causality assessment from Canada that had "almost certain," and she said well, maybe they do it that way in Canada. He then showed her one from the US that also had "almost certain."

In the documents sent to the FDA, Glaxo did not include the words "almost certain," according to testimony by Dr Suzanne Parisian, a former FDA official.

Glaxo also never changed the Paxil label after receiving the report and the rules are that a drug company has to change or strengthen the warning on the label, if "they have reasonable evidence of an association with the report for their product and an adverse experience," Parisian explained.

Smoke and Mirrors

Throughout the trial, Glaxo attorneys focused on Lyam's IAA defect and harped on about "statistical significance," when as described above, the studies were designed to ensure that a "statistically significant" increased risk in rare defects would not be detected.

During closing arguments on October 8, 2009, Tracey told the jury he wanted to talk about Glaxo's "obsession" with

ignoring the fact that Lyam had three cardiac defects. "All they want to talk about is this interrupted aortic arch," he pointed out.

The "reason that they want to talk about it so much is because they know this, they're never going to look for this," he told the jury.

"The only ones that would have the money, time and effort to undertake a study of 1.5 million women would be them," Tracey said. "And they know it's never going to get done."

"So they're in a can't lose position if you buy their argument," he told the jury.

"They admit, though," he pointed out, "that they have two cases now in their own database of interrupted aortic arch."

During closing arguments, Tracey recounted how he had put up Glaxo's own meta-analysis from the company's website, with 9 different studies, and "each and every one of them says Paxil increases the risk of heart defects," he pointed out.

"And this is a document that I know pains them," Tracey said. "Because ... the author of their own meta-analysis, Charlie Poole, the author that they hired ..., when he looked at the data privately, privately, outside of courtrooms, he said: This begs the key question. Do we think the best explanation at present is that first trimester paroxetine use increases the birth prevalence of cardiac malformations? I do."

"I do," Poole said. "Outside the courtroom," Tracey told the jury.

"But when this document got published, by the time it went through everybody's hands, by the time the editing was over, that statement disappears," he said. "It is not in the peer-reviewed literature."

In her closing, Varner told the jury, "the final fact that matters is that no regulatory agency or medical organization has ever concluded or said that Paxil causes birth defects. Only plaintiffs' experts have said so and in this courtroom," she said.

In his final summation, Tracy said, "I want to put something to bed that Ms. Varner said immediately, and that's this: Ms. Varner said that no regulatory agency in the world has ever said Paxil is a teratogen."


"That is simply untrue," he told the jury. "This is what the FDA says right here, There is positive evidence of human fetal risk," reading from a letter from the FDA.

He also noted that Paxil's label, under "Teratogenic Effects" states: "Epidemiological studies have shown that infants exposed to first trimester exposure to paroxetine have an increased risk of congenital malformations, particularly heart defects."

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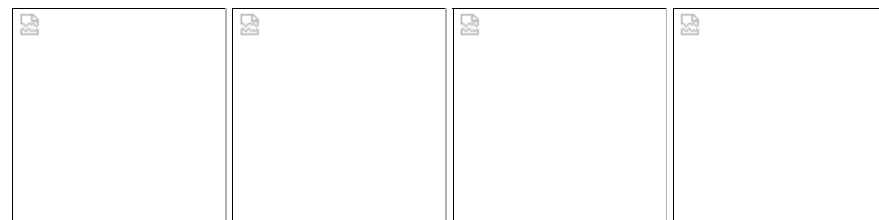


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"http://www.NaturalNews.com/028279_Paxil_birth_defects.html">
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