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Dr June Raine, Director of
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Dear Dr Raine, [See previous correspondence]

You may or may not have heard that yesterday in Cheyenne, Wyoming a Court found Glaxo SmithKline guilty on several accounts including the count that Paroxetine can cause suicidality, that it specifically did so and contributed to the wrongful death of Don and Rita Schell as well as Deborah and Alyssa Tobin and that the company had been responsible for a failure to test and a failure to warn. You may also be aware of a verdict in the Hawkins case in New South Wales some weeks ago where a Supreme Court Judge made it clear that in his opinion Mr David Hawkins would not have murdered his wife but for the influence of Sertraline.

In the course of my work as an expert witness in Tobin versus SmithKline I got the chance to look at SmithKline's healthy volunteer database in Harlow. Their characterisation of this for you was that: "There were no reports of suicidal thoughts in any of the volunteer studies. There were few reports of 'emotional lability', however these reactions were not found to be related to suicidal thoughts or behaviour. Some volunteers reported anxiety, nervousness and agitation while taking paroxetine, however the most commonly reported adverse events were nausea, diarrhoea, drowsiness and insomnia".

What I found was that approximately 25% of the volunteers in the studies that I reviewed which were all of the healthy volunteer studies done prior to the filing of this drug for registration in the US and in the UK - 34 studies approximately in all. These yielded a 25% agitation, nervousness/akathisia rate. Some of the multiple does studies in healthy volunteers lasting 2-3 weeks yielded an up to 85% withdrawal rate in the volunteers.

All of their healthy volunteer studies were supposed to have been made available to me but not all were. Of the ones that were missing there was trace correspondence left in once indicating that the investigator had never witnessed such a level of problems in a study with healthy volunteers. Another study was a single dose study which in a dose dependent fashion yielded a 75% rate of severe adverse events most of which involved the central nervous system. There were other disturbing indications from one of the other missing studies.

Volunteers who had participated in the programme went on to suicidal acts. The relationship between their intake of paroxetine and later suicidal acts is a matter about which neither you nor SmithKline Beecham should be sanguine.

These studies were for the most part done on company employees. None of the studies bar the missing ones were done by investigators with a background in psychiatry. The investigators were general physicians with a primary interest in gastrointestinal problems who could not have been expected to detect mental problems of this sort that have concerned me and I would have thought should concern you.

My testimony in this case also bore witness to sealed studies and other unreported data. It commented on the Montgomery Baldwin Study which yielded a projected rate of 45 suicide attempts in a group of recurrent brief depressive disordered patients on paroxetine per annum versus 12 on placebo. The figures were not statistically significant in great part one has to suggest because the company had terminated the study early. This termination and subsequent non-publication I would imagine the jury will have found and others will find significant.

Dr Hudson, currently of the MCA, was a witness for SmithKline in this case. He may well be able to give you further details on some of the issues involved. His testimony involved repeated reference to the fact that SmithKline Beecham cannot decide whether their drug had caused problems such as the wrongful death of Don and Rita Schell or Deborah and Alyssa Tobin or the wrongful deaths of many other people whose deaths have been reported to SmithKline even when these reports have been accompanied by the opinions of their treating physicians that the drug had indeed contributed to the problem. Dr Hudson's testimony was that until controlled trials or other similar studies had proven in general that paroxetine could cause such problems that the company could not make decisions on any specific case.

This appears to me a Black Hole defence. It is entirely conceivable that tens of thousands of suicides could disappear into this Black Hole without either SmithKline Beecham, Pfizer or Eli Lilly being called upon to make any judgements as to whether their drug was contributing to the problem. The lack of evidence from randomised controlled trials or epidemiological studies in this context is not evidence of a lack of a problem. It stems explicitly from failures of SmithKline Beecham, Pfizer or Lilly to do the requisite studies. Both David Wheadon and Christine Blumhardt from SmithKline as well as Roger Lane from Pfizer and Charles Beasley from Eli Lilly along with outside experts such as Daniel Casey and John Mann have testified under oath in the course of the last year that there have been no studies undertaken by any of these companies or others that have been designed to test whether the SSRIs could cause a problem. I believe that this will in due course be seen for the extraordinary state of affairs that it is.

I think what will also be clear is that SmithKline Beecham recognised the presence of withdrawal syndromes in their volunteers from the early to mid 1980s. That withdrawal syndromes occurred at a much higher rate than occur on benzodiazepines. Nevertheless they applied for and have received from you and other regulators a licence to claim that their drug is effective in the prophylaxis of depression and these claims have been based on designs which almost certainly are designs better suited to show the presence of a withdrawal syndrome than designs suited to demonstrate prophylaxis in depressive disorders. A great number of people have in recent years been told that when they begin to feel ill on discontinuing treatment that this is the recrudescence of their mood disorder rather than a discontinuation syndrome from their drug. I would imagine that a great many such people and others on their behalf will feel extraordinarily let down and angry when faced with the evidence that I've been faced with.

Yours sincerely

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