



11 OCT 1993
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2nd September, 1993



Secretary,
Research Ethics Committee,
Eastern Sydney Area Health Service,
PRINCE OF WALES HOSPITAL

Dear 

RE: A DOUBLE-BLIND MULTICENTRE STUDY COMPARING
PAROXETINE AND FLUOXETINE IN THE TREATMENT
OF PATIENTS WITH MAJOR DEPRESSIVE DISORDER
REF. NO. 92/131

I pass on for your information correspondence just received from Smith Kline Beecham - the sponsors of the above study. The letter indicates that there have been seven suicide attempts including two deaths in the first 63 patients included in this Australian multicentre study. The company are quite appropriately notifying the investigators of this current situation and have requested that these be submitted to the respective Ethics Committees.

My feeling about this report is that it means we should keep a very close eye on the ongoing suicide attempt rates in this study. I have previously examined the literature concerning adverse effects of fluoxetine and paroxetine and am happy from the data (now involving thousands of patients on both drugs) that there is no evidence that either increase the suicide rate or ideation in depressed patients. Both drugs have been marketed in many countries around the world. Fluoxetine has been on the market in the U.S. since 1987 and despite a scare one year or two ago the FDA concluded that there was no evidence that this drug increases suicidal ideation. Paroxetine has now been on the market in the U.S. for about eight months.

In response to this information I have asked the company to update these figures each month so that we can closely monitor any progress. My feeling is that this is a chance accumulation of suicide attempts in the early phase of the

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study and the figures will approach more normally expected results as the study progresses. However, monthly monitoring will be necessary to keep us happy that this is in fact the case. I have also requested the company to arrange for a breaking of the code so that we can see if one of the study drugs is responsible.

[REDACTED] we will be commencing the study in the next few weeks. I am certain that we are not exposing our patients to any risk and that this will turn out to be a chance, but unfortunate, accumulation of suicides in the early phase of the study. I will keep the Ethics Committee informed of any further correspondence received.

Regards,
Yours sincerely,

[REDACTED]
Associate Professor, School of Psychiatry

cc: [REDACTED]

