SmithKline Beecham Pharmaceuticals
Regulatory Affairs
FDA CONVERSATION RECORD

Date: October 3, 1990	Time: 10:00 AM
Conversation With:	Martin Brecher, M.D.
Title/Affiliation:	Medical Officer Division of Neuropharmacological Drug Products
Telephone Number:	(301) 443-4020
Regarding	PAROXETINE: Suicide-Ideation and Violence-Ideation; Efficacy Review

SUMMARY OF CONVERSATION:

Dr. Brecher called and initially mentioned that the last submission was fine and he looked forward to receiving the weight gain response. He next said he was calling to inform us of a concern that has arisen about fluoxetine and he is formally requesting that we prepare a response to the same issues. He said that the public press has been widely discussing the relationship between fluoxetine and violence-ideation and suicide-ideation. Although the Division does not see it as a real issue, but rather as a public relations problem, Lilly has been asked to submit a detailed response to the public's concern. He therefore is requesting that we do the same since we have a drug with a similar mechanism of action. He said his request is not based on any concern that has developed from his review of paroxetine, but simply that it is an issue that must be addressed with this group of drugs.

He mentioned that one approach would be to address it from three types of data: 1) completed suicides, 2) acts broadly defined as attempted suicides (down to events as small as scratches on the wrists), 3) ideation. He said we should also address the kinds of things mentioned in the article by Dr. Teicher such as obessional suicidal ideation and worsening of the suicidal ideation. Lilly has used the approach of looking at patients who had a value of 0 or 1 on the Hamilton Suicidal Ideation item and have gone to 3 or 4. They presented the differences between patients on placebo, paroxetine and active controls.

Dr. Brecher said that he is working full time on the review of efficacy and expects to finish by the end of the year (December, 1990). He does not expect to have his time divided on any other drugs. Therefore he would like us to submit this report by the end of November. It does not need to be voluminous (e.g. 10 volumes of data listings) as he does not want to review something that large. It will require certain analyses, should be clearly laid out and should look at the issues in different ways. I mentioned that Dr. Tina Blumhardt was already working on this type of document and asked if she could call him for additional input concerning the document. He said that would be fine. Again, he emphasized that the Division does not think it is an issue, but it needs to be addressed.

He added that he was not calling from his office, but he would call again later as he is accumulating some questions concerning efficacy.

Signed: Thomas E. Donnelly, Jr., Ph.D.

cc. Dr. C. Blumhardt
Mr. W. Bushnell
Ms. E. Donnelly
Dr. G. Dunbar
Dr. C. Fake
Dr. M. Fox
Ms. D. Mackleston
Dr. J. Mannion
Dr. J. O'Connor
Dr. R. L. Powell
Dr. B. Wallin