Document 11

[redacted]

[redacted]

4th August, 1993

[redacted]

Chairperson
Ethics Committee
[redacted]

RE: #6/93 PAROXETINE/FLUOXETINE PROTOCOL 29060/356

Dear [redacted],

It is with some concern that I need to report an untoward event which involved patient [redacted] who was participating in this protocol.

The patient presented at [redacted] on [redacted] having [redacted] as part of a suicide gesture.

[redacted]

[redacted]

However, on the 30th June the ward was contacted by the police to say that the patient had committed suicide [redacted]

[redacted]

While there have been suggestions in the literature that the selective serotonin reuptake inhibitor - fluoxetine, increases suicidal behaviour, most recent data suggests that this is not the case. It would appear that patients admitted to psychiatric units tend to have personality disorders which result in more impulsive behaviour and the possible role for these selective serotonin reuptake

inhibitors in facilitating this behaviour is still under scrutiny. Clearly, this is of concern and patients participating in this protocol will be scrutinised even more carefully than occurred with this patient.

Yours sincerely,

[redacted]

SERIOUS ADVERSE EXPERIENCES

Appendix 20B

Information Required for Telephone Reports

A serious adverse experience is one which is life-threatening, temporarily or permanently disabling or requires inpatient hospitalization or prolongation of hospitalization, as well as any occurrence of cancer, congenital anomaly or overdose. According to the SK&F Protocol and Protocol Administrative Document you have agreed to follow, serious adverse experiences must be reported within 24 hours by telephone to SK&F (see the Protocol Administrative Document for complete details.) To assist you in reporting all the required information, this form may be completed before telephoning.

Protocol No. 26090/356 Patient or Document No. [redacted]

Patient Initials or Identification [redacted] Date of Birth [redacted] Day Month Year

Sex FEMALE Race [redacted] Weight [redacted] Height ____

Condition being studied DEPRESSION SK&F Medical Monitor [redacted]

Adverse Experience (AE) COMMITED SUICIDE

Onset Date: [redacted] Year Cleared Date: [redacted] Day Month Year

Severity: ☐ Mild ☐ Moderate ☑ Severe

Did this AE cause.... (Check box if "Yes")
☐ Immediate risk of death ☐ Hospitalization or prolonged hospitalization
☐ Permanent disability ☑ Death

Study drug name/no. FLUOXETINE/PAROXETINE Code/Randomization No. ____

Lot No. ____ Vial/Package description ____

Dates of administration: Start Date [redacted] Stop Date [redacted] Day Month Year

Unit dose [redacted] each [redacted] Frequency/ Infusion time [redacted] Total daily dose [redacted]

Was the code broken? ☐ Yes ☑ No

Was study medication changed because of this event? ☐ No ☐ Decreased ☑ Discontinued

If study medication was decreased or discontinued, did the event resolve? ☐ Yes ☑ No
- If discontinued, was study medication reintroduced? ☐ Yes ☑ No
- If yes, did the AE recur? ☐ Yes ☐ No

Relationship of AE to study medication: ☐ Related ☐ Possibly related ☑ Not related

Probable cause: [redacted]

Other condition: ____

Was the AE treated? ☑ No ☐ Yes (specify) PATIENT DEAD

Comments: [redacted]

FOUND DEAD. APPEARED TO BE SUICIDE

Person who discovered AE [redacted]

Person reporting AE [redacted]

Address

Investigator name

Concomitant Medication

Medication Name	Start Date	Stop Date	Unit Dose	Route	Freq	Total Daily Dose
[redacted]						

Relevant Medical History

Condition	Start Date	End Date
[redacted]		

Relevant Laboratory Values

Parameter	Value	Date or Visit No.	Normal Range	Units
[redacted]				