





**SmithKline Beecham**  
Pharmaceuticals

To

[Redacted]

Date

26 July 1993

From

cc

[Redacted]

Subject

Protocol 356 - paroxetine vs fluoxetine study

Thank you for your recent fax about the seven serious AE's reported in this study to date.

[Redacted]

Of the 3 patients attempting suicide (patients

[Redacted]

that leaves 2/28 patients attempting suicide

during treatment with study drug which, in my view, is well within the frequency which might be expected in depressed patients entering a clinical study.

[Redacted]

[Redacted]

[Redacted]

Regards

[Redacted]

[Redacted]

FILE NOTE  
MEETING WITH [REDACTED]  
30TH JULY 1993

Paroxetine 356

1. SAEs

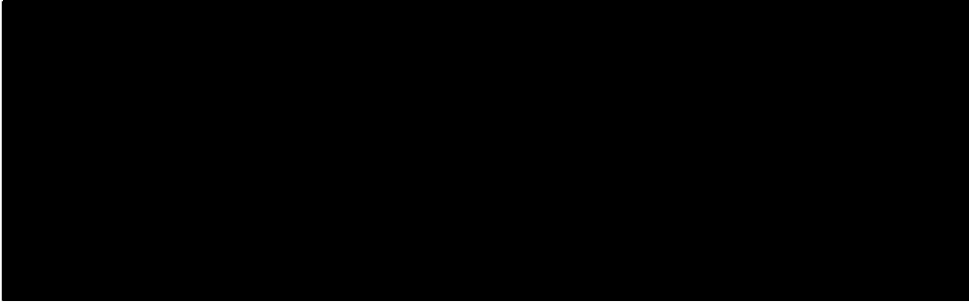
- Based on [REDACTED]'s response investigators were informed by the newsletter only.
- [REDACTED] agrees that formal letters to all investigators are not required.

[REDACTED]

Consultant  
(Melbourne Office)

[REDACTED]





FAX TO:



FAX



FROM:

DATE: 16 August 1993

NO. OF PAGES:

If any pages are omitted or unclear please phone



Dear David,

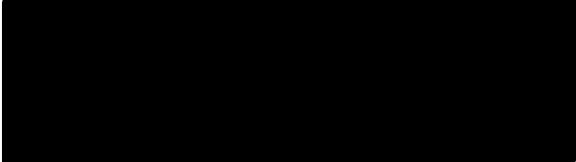
Re: Paroxetine 356

Further to my faxes of August 2 and 11 informing of serious adverse events for patients [redacted] [redacted] [redacted] respectively, I have yet to receive confirmation of receipt.

Please inform whether they have been received.

Kind regards,





TELEPHONE REPORT

Date: 17/8/93

Contact:



Tel No:



IN

OUT

SUBJECT: Paroxetine Suicides -> Requesting company advice.

- SO not in until tomorrow (Wednesday)

→ Ring



rang



to discuss



to

SB UK

take all the information received from tomorrow for her to prepare a statement/report.



TELEPHONE CALL - [REDACTED]  
18/08/93

- [REDACTED] informed [REDACTED] of the phone call from the [REDACTED] IEC.
- [REDACTED] did not believe we should inform the IECs of all SAEs unless there was an alert.
- SS thought we should respond formally to the [REDACTED] IEC and would discuss it with [REDACTED]
- [REDACTED] to discuss further with [REDACTED] tomorrow.
- [REDACTED] thought that the responsibility of reporting all SAEs to IEC should be on [REDACTED]

[REDACTED]

Consultant  
(Melbourne Office)

[REDACTED]

E MAIL

TO: [REDACTED]  
SENIOR CLINICAL RESEARCH MANAGER  
CNSTU  
REIGATE

FROM: [REDACTED]  
CLINICAL RESEARCH MANAGER  
SMITHKLINE BEECHAM  
AUSTRALIA

DATE: 18TH AUGUST 1993

SUBJECT: SUICIDE/IDEATION ON PAROXETINE

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We have had another couple of suicide attempts/deaths in the (356) study vs fluoxetine and a few IECs have requested further information. We have the position paper (Nov '91) which you kindly faxed to us but I wonder if we can have an update from the safety database up to the end of '92 or including '93??

(Also, could you send a hard copy of the position paper.)

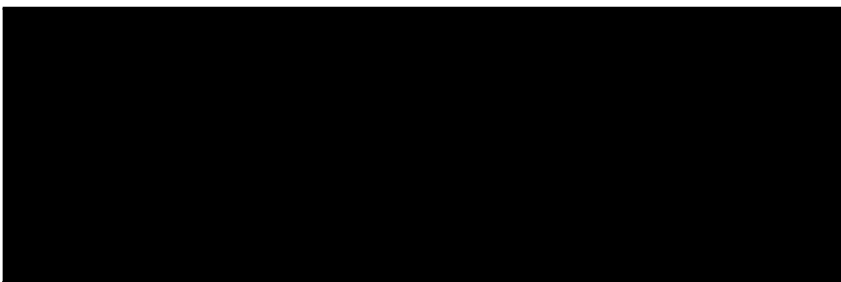
Many thanks.

Regards,

[REDACTED]



FAXED



FAX TO: [redacted] - SB Australia

FAX NO: Auto

FROM: [redacted]

CC: [redacted]

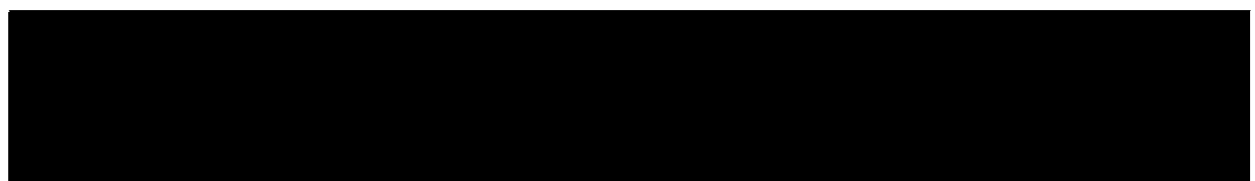
DATE: 24 August 1993

NO. OF PAGES: 3

If any pages are omitted or unclear please phone [redacted]

Dear [redacted]

Re: Paroxetine 356 - Suicide Gestures



[redacted] As yet this has only been received for patient [redacted].



I will be in touch with [redacted] to see how her comments are progressing.

Regards,

*Refer fax  
25/8/93*



Consultant  
(Melbourne Office)

Encl:





TELEPHONE CONTACT - PARAXETINE 356

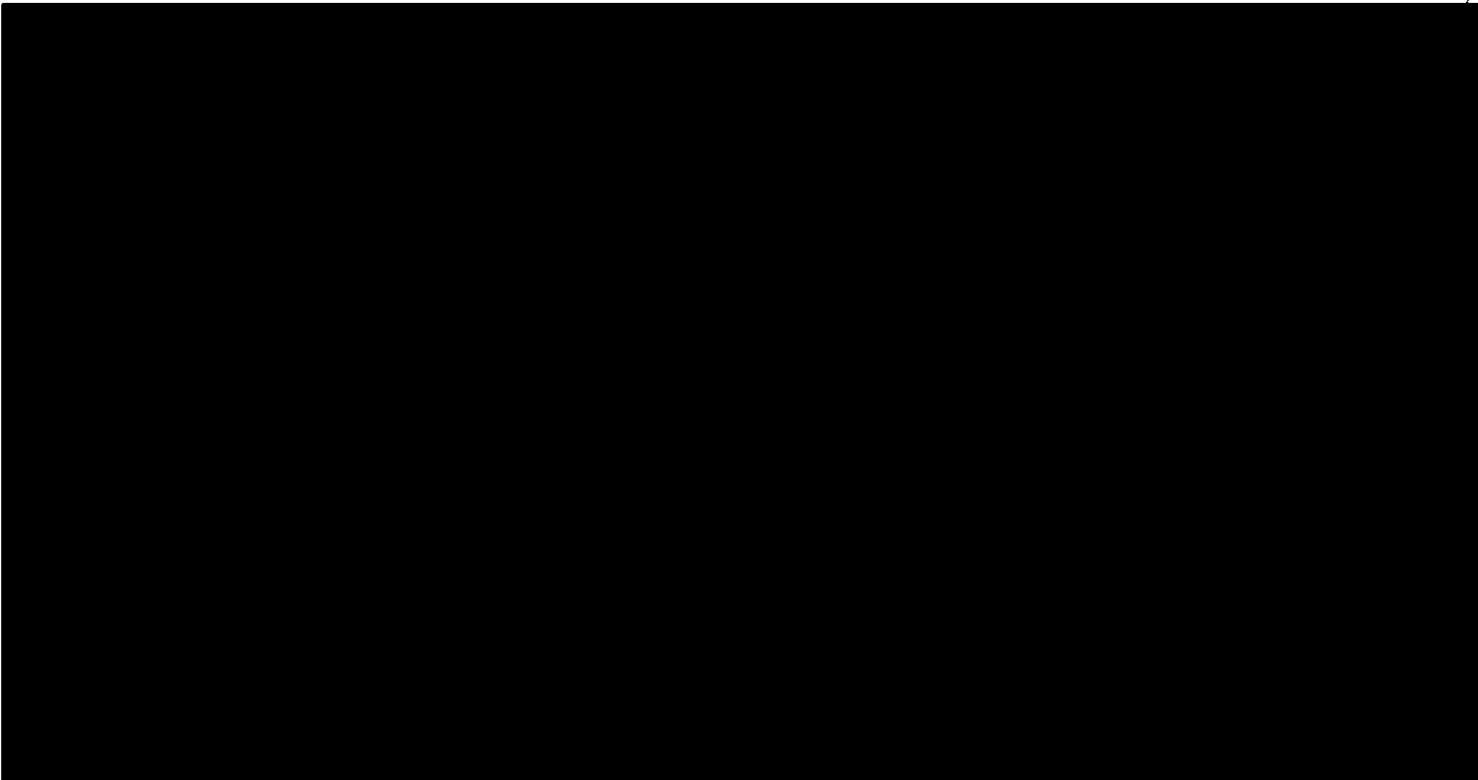
██████ - 2/9/93

- ██████████ apparently rang ████████ very concerned about the suicide attempts in the study.
- ████████ requested as much background information on the patients as possible.
- ████████ to forward the extra letters received from the Doctors regarding the cases. asap.

Discussed with ████████ also ████████ to contact ██████████ to request response from previous fax.

████████████████████  
████████████████████  
████████████████████

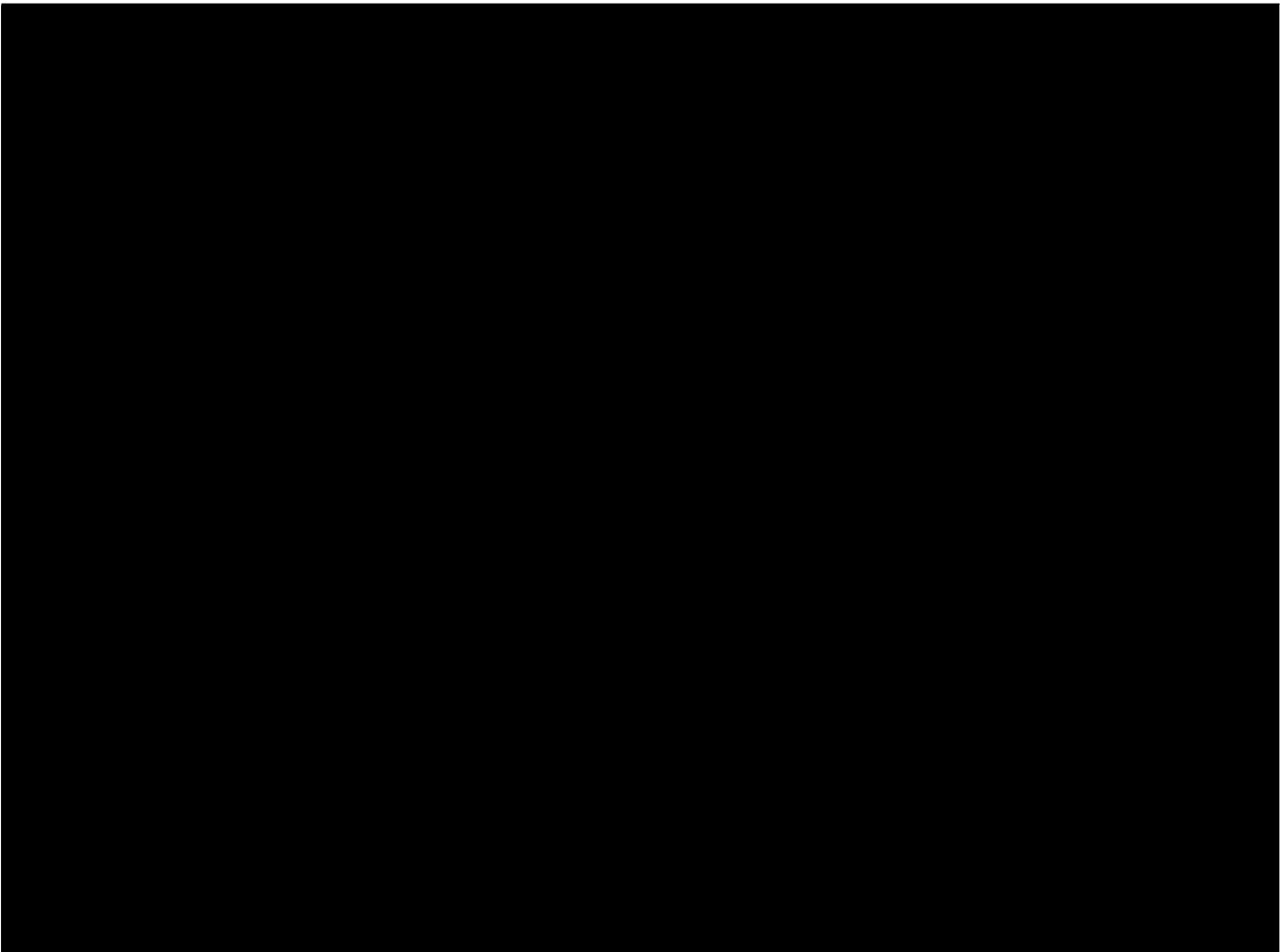




RE:PAROXETINE 356

[REDACTED] Attached is a letter from centre  
[REDACTED] regarding patient [REDACTED] who committed suicide.

As more letters are received I will forward them to you.



(

Pages 14-17 inclusive redacted under section 22(1) of the FOI Act (irrelevant information)