

25th October 1993

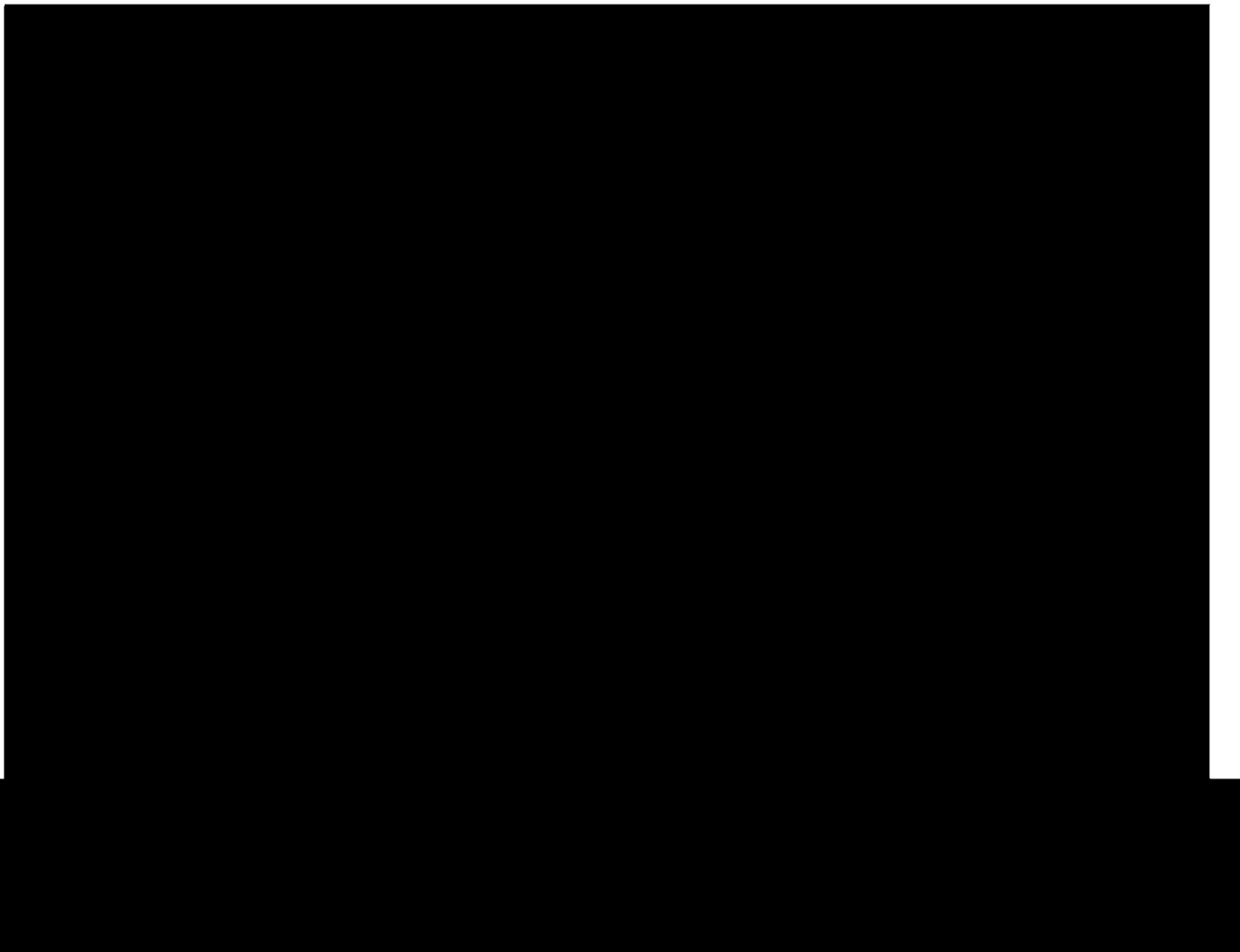
[Redacted]
Department of Psychiatry
Concord Repatriation Hospital
Hospital Road
CONCORD NSW 2139

[Redacted]
25 OCT 1993
MEDICAL DEPT.

Dear [Redacted],

re: PAROXETINE 356 - SUICIDE ATTEMPTS

Over the past few weeks I have been sending further detail about the patients attempting suicide in the above study. Information has been provided for patients [Redacted] [Redacted] In this correspondence I am providing as much detail as I have on file about the other patients.



s22(1)

Patient [REDACTED]

-

A 46 year old woman who committed suicide s47F
s22(1)

The investigator commented that the medication did not have
anytime to act.

Should any further information be received, I will forward it on to you.

Kind regards,

[REDACTED]
Senior Consultant
(Melbourne Office)

cc [REDACTED]
[REDACTED]

FAXED
25/10/93



25th October 1993



18 NOV 1993
MEDICAL DEPT.

Medical Director
SmithKline Beecham
Private Mailbag 34
DANDENONG VIC 3175

Dear [REDACTED]

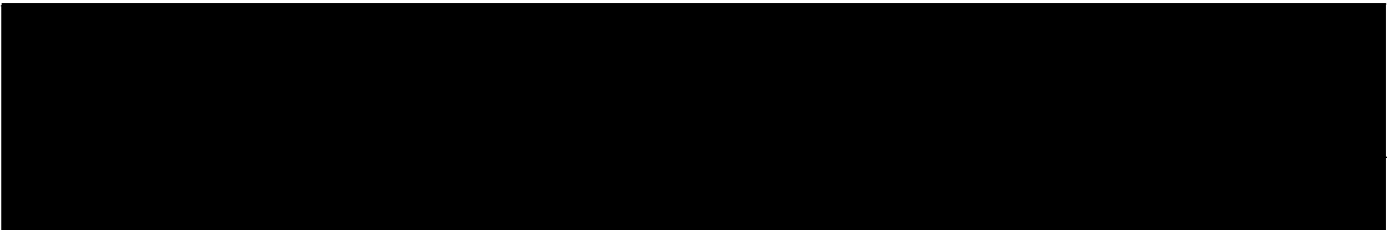
re: **PAROXETINE 356 - SUICIDE ATTEMPTS**

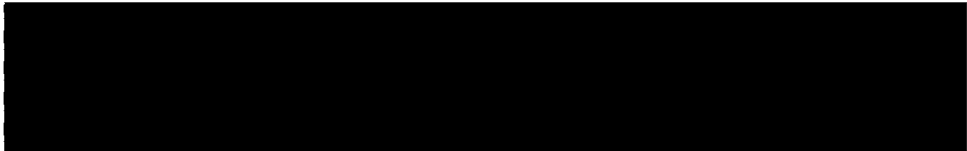
Following our meeting last Thursday, we have tabulated the data held in-house for baseline HAM-D and Baseline HAM-D Item - 3 (Suicide).

The following table shows the result:

	SUICIDE ATTEMPT	NON-SUICIDE
B/LINE HAM-D TOTAL	$\bar{x} = 26.13$ (n=8)	$\bar{x} = 25.55$ (n=54)
B/LINE HAM-D ITEM-3	$\bar{x} = 1.2$ (n=5)	$\bar{x} = 1.64$ (n=14)

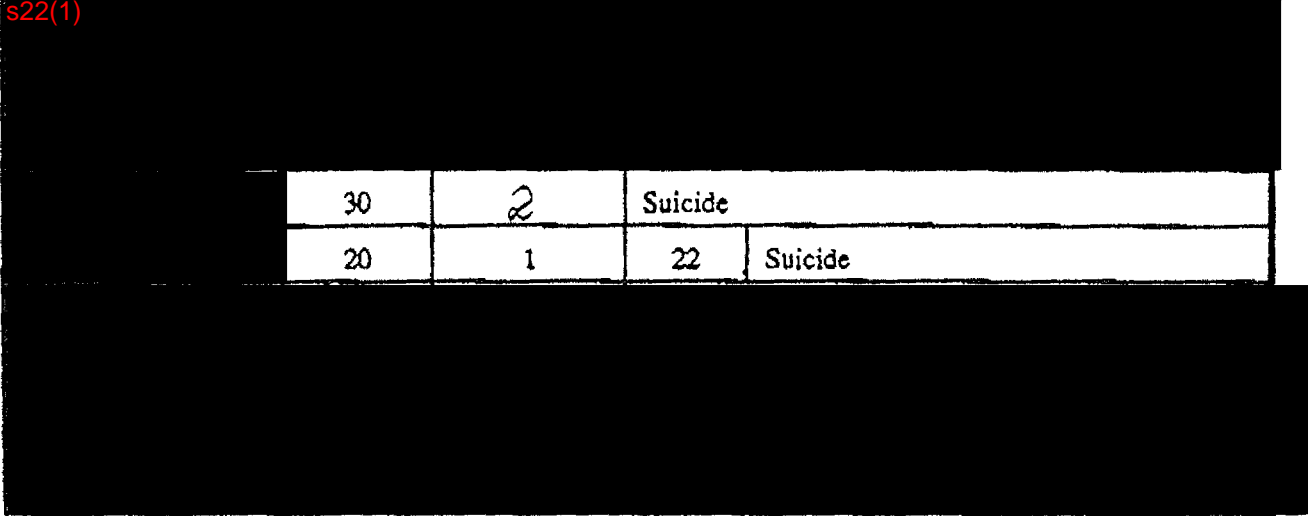
The difference between suicide attempt and non-suicide patients is not significant for B/Line Ham-D scores and item 3 of that b/line score.





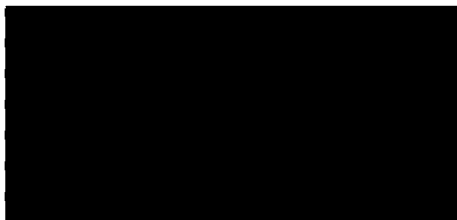
Also tabulated is all the HAM-D scores of the patients attempting suicide.

Centre No	Patient No	B/Line HAM-D	B/LHAM-D Item 3	HAM-D PRIOR SUICIDE ATTEMPT				
				D+7	D+14	D+28	D+42	D+56
s22(1)								
		30	2	Suicide				
		20	1	22	Suicide			



Should you require any further information, please let me know.

Regards,



Senior Consultant
(Melbourne Office)

cc



SB
SmithKline Beecham
Pharmaceuticals

PAROXETINE 356 CLINICAL STUDY MEETING


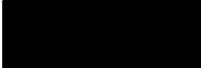


TIME: 6.00 pm
DATE: Friday 26 November 1993
VENUE: Savoy Park Plaza Hotel
630 Little Collins Street
Melbourne

PRESENT:

Chairman:



SmithKline Beecham Australia:

-  - Medical Director
-  - Group Product Manager
-  - Clinical Trial Manager
-  - Product Manager

:



:



Apology:



PAROXETINE 356 CLINICAL STUDY MEETING

Presented by [REDACTED]

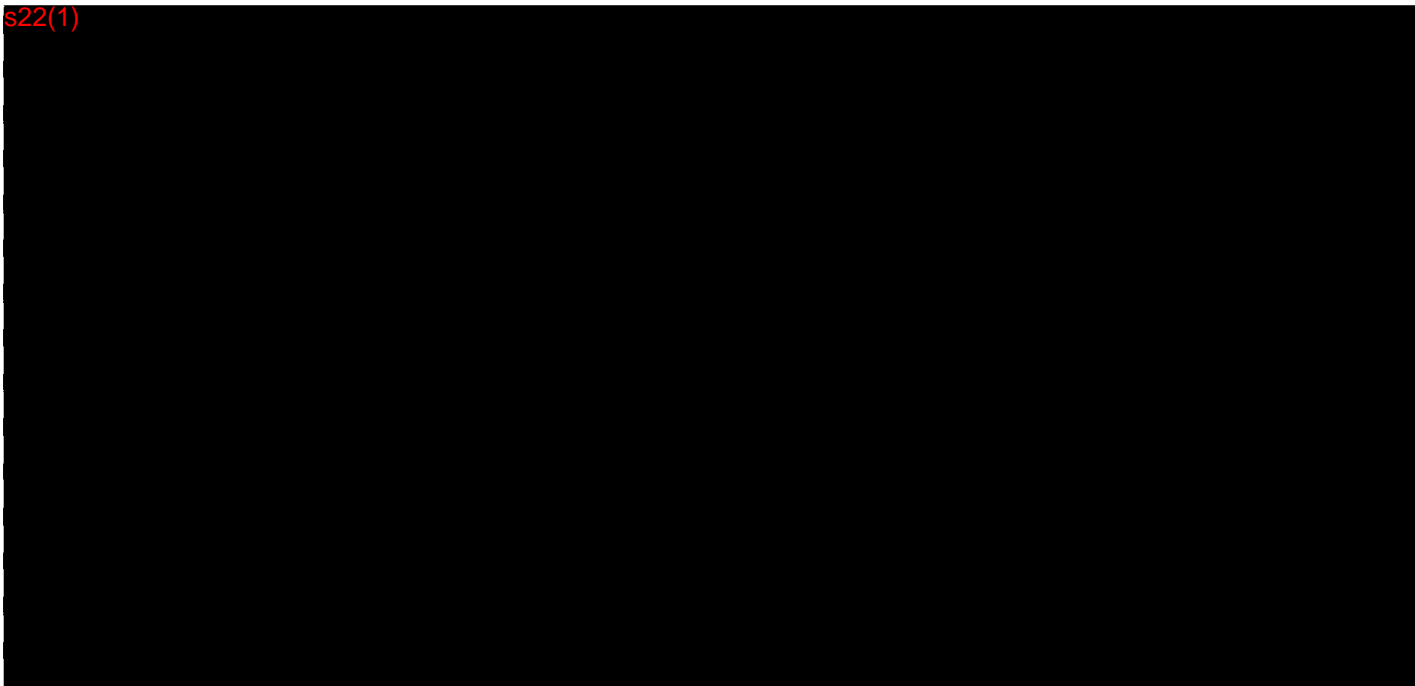
OPENING REMARKS

Dr Sykes explained that the main purpose of the meeting was to discuss the issue of the 9 reported suicide attempts and whether it would be necessary to modify the protocol.

The study remains blind and none of the reported cases have actually been attributed to the study medication.



s22(1)



Patient Number [redacted]

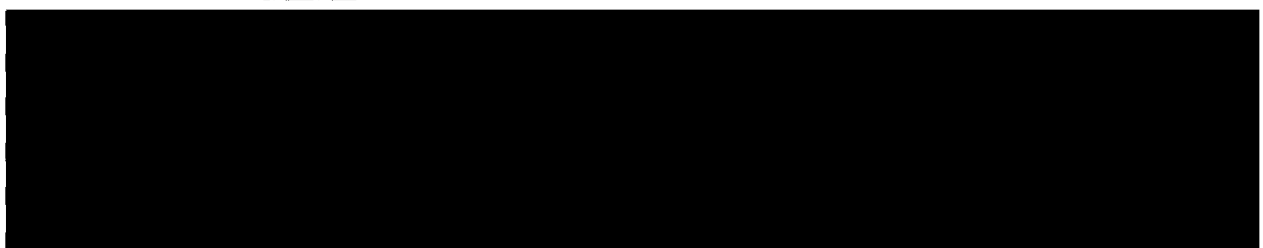


[redacted] the patient s47F [redacted]

Comments:

[redacted] believes the suicide had nothing to do with the drug [redacted]
[redacted]

Patient Number [redacted]



[redacted] herself to death.

Comments:



Pages 9-10 inclusive redacted under section 22(1) of the FOI Act (irrelevant information)

Conclusions

After extensive discussion of the trial protocol, the following decisions were reached:

1. The protocol will remain unchanged.
2. Benzodiazepines may be used for anxiety as well as sleep disturbances.
3. Patients will be selected carefully (NB if seen to be of high suicide risk).

