From: Strober, Michael <mstrober@MEDNET.ucla.edu>

To: James.P.McCafferty@gsk.com <James.P.McCafferty@gsk.com>;
Ryannd@MSX.UPMC.EDU

CC:
Martin Keller (Business Fax) <IMCEAFAX-
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Sally Laden (SallyL@stimedinfo.com) <SallyL@stimedinfo.com>;
Strober, Michael <mstrober@MEDNET.ucla.edu>

Subject: RE: paxil response to juredini article.doc

Date: 11/07/2002 21:57:10 (GMT-05:00)

I am happy to sign the reply. I think our response is, perhaps, too polite,
as the letter to the editor was egregious.
-----Original Message-----
From: James.P.McCafferty@gsk.com [mailto:James.P.McCafferty@gsk.com]
Sent: Thursday, November 07, 2002 7:33 AM
To: Ryannd@MSX.UPMC.EDU
Cc: Martin Keller (Business Fax); Martin Keller (Home Fax);
James.P.McCafferty@gsk.com; Martin Keller (martin_keller@brown.edu); Mike
Strober (mstrober@mednet.ucla.edu); Sally Laden (SallyL@stimedinfo.com)
Subject: Re: paxil response to juredini article.doc

Hi Neil,

I agree with your response to the "overt" issues raised by Drs Jereidinei
and Tomkin. You may also wish to add that the paper specifically addressed
the various limitations of the study design and described the limitations
for the clinical implication of the study results. Also the paper
specifically calls for further study.

I see no benefit in addressing the covert issues.

James P McCafferty
Psychiatry Group
Clinical Development and Medical Affairs
GlaxoSmithKline
Phone: Redacted
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E-Mail: James_P_McCafferty@gsk.com

"Ryan, Neal" <Ryannd@MSX.UPMC.EDU>

Produced By GSK In In Re Paxil, C.P.Ct.PA (On-Drug)

06-Nov-2002 15:30

To: "Martin Keller (Home Fax)" , "Sally Laden (SallyL,
"Mike Strober (mstrober, James.P.McCafferty, "Martin Keller (martin_keller,
"Martin Keller (Business Fax)"

cc:
Subject: paxil response to juredini article.doc

Please critique and get back to me ASAP. I'm traveling thu-fri of this week and then wed-fri of next week so time is tight here.

Neal

DRAFT 01

Mina K. Dulcan, Editor
Journal of the American Academy of Child and Adolescent Psychiatry
Editorial Office
Children's Memorial Hospital
2300 Children's Plaza, #156
Chicago, IL 60614-3394

Re: letter of Drs. Jureidini and Tonkin

Dear Dr. Dulcan,

In response to the letter of Drs. Jereidini and Tonkin commenting on our study of paroxetine in adolescent depression (1), we would first like to address the overt issues that they raise and then respond to a covert argument they made.

It seems that they argue that (a) we were insufficiently clear distinguishing between our primary outcome measures and our secondary outcome measures and (b) our assessment that this study found paroxetine effective was incorrect. We feel that we were quite clear in which were primary outcome measures and which were secondary since this is explicitly and clearly elucidated in the abstract of the paper. Therefore, since our two primary outcome measures did not reach a $p < 0.05$ level of statistical significance, the more complex question that remains is whether or not we fairly interpreted the pattern of significant p values across a range of secondary endpoints as indicating that paroxetine is better than placebo for adolescent depression.

This study was designed at a time when there were no randomized controlled

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