BROWN UNIVERSITY Providence, Rhode Island 02912

TO: Dorinda Williams, IRB Staff Assistant

FROM: Martin B. Keller, M.D.

DATE: 10/30/95

Re: **Adverse Event Report** for A Multicenter, Double-Blind, Placebo Controlled Study Of Paroxetine And Impramine In Adolescents With Unipolar Major Depression

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Adverse Event #2: Subject #00057, TRC, Pregnancy

On 12/29/94, parents of subject TRC, called to inform research staff of positive pregnancy test. The study sponsor, Smith Kline Beechum was notified of situation immediately and, as a result, termination taper of medication was agreed upon by study personnel. Termination taper was based on subject non-compliance regarding her original agreement to follow study protocol by appropriately using effective birth control measures. TRC and her mother had known about pregnancy since 12/10/94, but neglected to inform study staff until 12/29. TRC gave birth to a healthy baby approximately 8 weeks ago.

Adverse Event #3: Subject #106, RLA, Psychiatric hospitalization

RLA was hospitalized on 9/15/95 due to becoming very compative with her mother and threatening suicide. Depressive symptoms had decreased significantly several days before this hospitalization. As a result of this improvement in depressive symptomology, study personnel has determined that hospitalization was due to Oppositional Defiant Disorder. Upon entering in-patient treatment at Bradley Hospital it was learned that RLA had not been taking her study medication since her previous study visit. RLA was terminated from the study for non-compliance. This event was appropriately reported to the study sponsor , Smith Kline Beechum, in accordance with study protocol.

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