MEMO

To:

Bradley Hospital IRB Brown University IRB

Butler Hospital IRB

From:

Martin B. Keller, M.D.

Date:

January 30, 1995

Re:

Adverse event in "A Multicenter, Double-blind, Placebo

Controlled Study of Paroxetine and Imipramine in Adolescents

with Unipolar Major Depression"

Patient ALR # 070 ingested 82 Tylenol pills on 1/19/95. She was admitted to St. Ann's Hospital in Fall River and stayed for 3 days. The patient's mother informed the staff at St. Ann's that her daughter was a patient in the study and gave them Douglas Robbins, M.D.'s name, one of the study physicians. No one from St. Ann's contacted Dr. Robbins.

The patient's mother notified ALR's study clinician, Rebecca Šmall, on 1/23/95, who then notified James McCafferty at SmithKline Beecham. Rebecca Small and Douglas Robbins, M.D., met with ALR and her father on 1/27/95. The patient was discontinued from the study. She is now being treated by Harvard Community Health Plan.