From: James P McCafferty/DEV/PHRD/SB_PLC

To: SallyL@stimedinfo.com

Subject: Final Suggestions to the Adolescent Paper

Date: 07/21/1999 16:43:01 (GMT-05:00)

Sally,

Because the number of patients with serious AEs reported for the paroxetine group (11/93, 12%) is high vis a vis the placebo group (2/87, 2%), additional text may be necessary for prospective. I would provide some definition of an SAE, and also state that the serious events, with few exceptions, were psychiatric in nature(as opposed to physical). We should also describe what events led to hospitalization (n.b. 7 paxil patients not 6). Some suggested text below.

Serious adverse effects occurred in 11 patients in the paroxetine group, 5 in the imipramine group, and 2 in the placebo group. An event was defined as serious if it resulted in hospitalization, was associated with suicidal gestures such as overdose, or was described by the treating physician as serious. The serious adverse effects in the paroxetine group consisted of headache during down-titration (1 patient), and various psychiatric events (10 patients): worsening depression (2), emotional lability (eg, suicidal ideation/gestures, overdoses; 5), conduct problems or hostility (eg, aggressiveness, behavioral disturbance in school; 2), and mania (1). Of these, worsening depression, emotional lability, headache, and hostility were considered related or possibly related to treatment. Six patients were hospitalized, and 6 were withdrawn from the study.

Replace last sentence with the following:
Hospitalization was ordered for seven of the paroxetine patients. This included both patients with worsening depression, 2/5 patients who reported suicidal ideation/gestures, both patients with conduct problems and the single patient reported to be euphoric. Five of the 11 paroxetine patients with serious events completed 8 weeks of treatment.