CAUSE NO. 91-02496-A

JACKIE LYNN BIFFLE, INDIVIDUALLY AND AS NEXT FRIEND OF JOLIE LYNN BIFFLE, A MINOR AND ON BEHALF OF THE ESTATE OF MICHAEL HAYS BIFFLE, DECEASED; and MICHELLE SELETTE BIFFLE	§	IN THE DISTRICT COURT OF
VS.	§	DALLAS COUNTY, TEXAS
ELI LILLY & COMPANY and DISTA PRODUCTS COMPANY	§	14TH JUDICIAL DISTRICT

DEFENDANTS ELI LILLY AND COMPANY and DISTA PRODUCT COMPANY'S AMENDED AND SUPPLEMENTAL ANSWERS TO PLAINTIFFS' FIRST INTERROGATORIES

Defendants, Eli Lilly and Company and Dista Products Company ("Lilly") offer the following Amended and Supplemental Answers to Plaintiffs' First Interrogatories.

PRELIMINARY STATEMENT

Lilly's Amended and Supplemental Answers are served pursuant to a meeting and agreement of Lilly and Plaintiffs' counsel on August 18, 1992 wherein the parties agreed that Lilly would undertake, in good faith, to amend and supplement certain of its Answers to Plaintiffs' First Interrogatories of September 26, 1991.

Lilly's Amended and Supplemental Answers to Plaintiffs' First Interrogatories are served subject to and without waiving those general and specific objections as set out in Lilly's Answers and Objections, which were served on September 26, 1991, and which are specifically adopted and incorporated herein by reference. These answers are also made subject to and without

PLAINTIFF'S EXHIBIT

waiver of those discovery issues pending before the Supreme Court of Texas and dissemination issues pending before the Texas Court of Appeals. The parties have agreed to preserve the status quo awaiting the decisions of these courts.

(e) The total number of photographs taken during said study, setting forth what each photograph depicts;
(f) The name description and total number of all animals used in said study;
(g) All findings and conclusions made by the defendant from said study; and
(h) Identify, (as per instruction L), the custodian or custodians of all such records.

ANSWER: Not applicable as to animal studies. As to clinical studies, see response number 42 and response number 51.

44. At any time since Prozac was first placed on the market, did the Food and Drug Administration suggest, request or require your company to conduct human studies? If so, for each such study, please state:

(a) Whether the study was suggested, requested or required:
(b) The date the study was suggested, requested or required;
(c) Whether or not said study had been started and, if so, the date it was commenced;
(d) A complete explanation of the nature and purpose of the study;
(e) A complete description of the protocol and guidelines of said study, (if reduced to a writing, please annex same);
(f) The name of the department which is conducting or has conducted said study; and
(g) Identify, (as per instruction L), the custodian or custodians of all records maintained on said study.

ANSWER: Discussions were had between Lilly and the FDA regarding possible data analyses or clinical trial designs which would test whether the Teicher assertions are in fact real. The FDA did not request or require any action from Lilly nor suggest a particular analytical or study approach. The discussions and question as to whether additional studies be done were mooted by the findings of

the FDA Psychopharmacological Drug Advisory Committee on September 20, 1991. No additional studies were conducted.

(a) See above.

(b) These discussions took place between approximately the third quarter of 1990 to the third quarter of 1991.

(c) Not applicable.

(d) Not applicable.

(e) Not applicable.

(f) Not applicable.

(g) Not applicable.

45. With respect to each condition for which defendant has recommended the use of Prozac or manufactured Prozac, identify, (as per instruction L), who under defendant's control had the final responsibility of approving Prozac for that purpose?

ANSWER: See prior response to this interrogatory. No one person had final responsibility for approving the submission of the NDA for Prozac for use in depression. However, R. L. Zerbe, M.D. is a Lilly employee who is knowledgeable about the clinical data included in the NDA.

46. Did the defendant ever come to the conclusion that Prozac was effective in treating depression? If so, describe in detail the tests which defendant relied upon which led to defendant's conclusion that Prozac was effective when treating depression, and identify, (as per instruction M), all documents relating thereto. Please annex photocopies of same.