# Exhibit 17

*University of Maryland School of Medicine*

*Department of Epidemiology & Preventive Medicine*
*Baltimore MD 21201*
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FAX TRANSMISSION COVER SHEET

*Date:* *January 2, 1996*

*To:* *Merrill Brophy*

*Fax:* *550-8365*

*Re:* *IRB response*

*Sender:* *Judith D. Rubin, MD, MPH*

*YOU SHOULD RECEIVE 3 PAGE(S), INCLUDING THIS COVER SHEET. IF YOU DO NOT RECEIVE ALL THE PAGES, PLEASE CALL 410-706-2864.*

Hi Merrill-

Happy New Year!

Attached is the IRB letter and my response for your files.

Thanks.

Judy

CONFIDENTIAL

UNIVERSITY OF MARYLAND
AT BALTIMORE
INSTITUTIONAL REVIEW BOARD

655 W. Baltimore St.
BRB 14-016

Baltimore, MD
21201-1559

Date: 12/12/95

From: Institutional Review Board (Assurance Number M1174-01NR)

To: JUDITH RUBIN, MD,MPH
Dept: PEDIATRICS/EPIDEMIOLOGY
Address: ROOM 132E, HOWARD HALL

Re: "TREATMENT OF LEAD-EXPOSED CHILDREN (TLC) TRIAL"

The official record of this protocol includes the following information:
IRB Number: 1195011
Expiration: 12/08/98
PI: RUBIN, JUDITH

The Institutional Review Board met on December 8, 1995 and reviewed your protocol. However, the following information must be provided before final approval can be given. Please submit one copy of the requested information January 2, 1996 so that the IRB can evaluate your response at its next meeting.

- Although this trial is well designed and well justified, we are concerned that this trial is still ongoing after several years in operation. Since there is an untreated control group, we would like you to present us with data that would justify continuing the trial with an untreated group. Please provide us with preliminary data and data analysis that would suggest that there is no information yet available to state that succimer treatment is not effective in reducing low lead levels.

- We also would like you to submit any toxicity data collected at this or other study site so we can evaluate the risk section of your consent form.

If you have any questions, please contact the Office for Research Subjects by email (ORS@schmed01) or by telephone (410.706.5037).

1 pt @ KKI
diarrhea → stopped drug → challenge → recurrence of diarrhea Did not unblend the pt.

Robert R. Conley, MD
Chairman, IRB

School of Medicine

UNIVERSITY OF MARYLAND
AT BALTIMORE

DEPARTMENT OF EPIDEMIOLOGY AND PREVENTIVE MEDICINE

January 2, 1996

CONFIDENTIAL

Robert R. Conley, M.D.
Chairman, IRB
14-016 BRB

Dear Dr. Conley:

**Re: Toxicity of Lead-Exposed Children (TLC) Trial - IRB Number 1195011**

I am writing in reply to the points raised in your letter of December 12. I have discussed the IRB concerns and outlined this response with the other TLC co-investigators at the Kennedy-Krieger Institute and Johns Hopkins School of Medicine.

Length of the trial. Following a one-year planning period, enrollment of study subjects began in August, 1994. Therefore, the length of the trial to date is just over 15 months. As outlined in the protocol, the major endpoint (outcome measure) is neurodevelopmental status 36 months after randomization. There is at present no new information that would preclude continuing the trial with an untreated group. Succimer continues to be labeled only for blood lead levels $\geq$ 45 micrograms/dl, higher than the range of blood leads in TLC subjects (considerably higher in most cases). Furthermore, there have been no controlled studies of succimer that confirm long-term benefit to patients.

Toxicity data. There have been no serious adverse events in the TLC trial thus far. Approximately 100 subjects have been randomized at the three Baltimore sites. Of these, only one child has been withdrawn from study drug because of side effects. In this case (a Kennedy-Krieger patient), the child developed diarrhea on drug; the drug was stopped and resumed a few days later, at which time the diarrhea recurred and so the drug was discontinued. This occurrence was not considered to be serious and did not result in unblinding of the child's treatment status. No serious adverse events related to drug administration have been reported to us from the other clinical centers.

The status of the study was reviewed by the Data Safety Monitoring Committee in December 1995, at which time they decided to continue the trial. Please let me know if there are additional concerns about this study.

Yours truly,

Judith D. Rubin

Judith D. Rubin, M.D., M.P.H.
Associate Professor

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