

**EXHIBIT I**

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MARYLAND  
(NORTHERN DIVISION)

SHAYONNA FEATHERSTONE, et al. \*

Plaintiffs \*

v. \*

Case No. \_\_\_\_\_

KENNEDY KRIEGER INSTITUTE, INC., et al. \*

Defendant. \*

\* \* \* \* \*

**AFFIDAVIT OF CECILIA DAVOLI, M.D.**  
**IN SUPPORT OF NOTICE OF REMOVAL**

I, the undersigned, am over the age of eighteen, am competent to testify and have personal knowledge of the following:

1. I, Cecilia Davoli, M.D. am a physician currently licensed to practice medicine in the State of Maryland. My area of expertise is developmental pediatrics and I am Board Certified in pediatrics and neurodevelopmental disabilities. I am employed by the Kennedy Krieger Institute (“Kennedy Krieger”) and am an Assistant Professor of Pediatrics at the Johns Hopkins University School of Medicine.

2. In the spring of 1993 I became involved with the National Institute of Environmental Health Sciences (“NIEHS”) Study – Treatment of Lead-Exposed Children (“TLC”). My involvement was at Kennedy Krieger with J. Julian Chisolm, M.D. I served as a co-investigator for the portion of the TLC Study conducted at Kennedy Krieger.

3. In my role as co-investigator I have obtained first-hand knowledge regarding activities of the NIEHS and its officers as well as the CDC, related to the design and implementation of the TLC Study.

4. A group consisting of, among others, the NIEHS Project Officer and the Principal Investigators from the Clinical Centers, was charged with responsibility for virtually all aspects of the TLC Study, including, the design and implementation of the protocol, enrollment of Study participants, and follow-up. This group held regular meetings and/or conference calls in fulfillment of that responsibility. Also participating in those meetings and calls were various other individuals from NIEHS and the clinical centers who were involved with this Study. I was one such participant. Those meetings and calls were supervised by the NIEHS Project Officer, Dr. Walter Rogan. Dr. Rogan actively participated in the discussions, and guided the direction of the Steering Committee meetings to ensure that the TLC Study plans developed consistent with NIEHS objectives.

5. During the Steering Committee meetings, there was active discussion from all interested participants. However, the only way for a substantive TLC Study decision to be implemented and become part of the Study, was following review by NIEHS. Each and every decision of the Steering Committee was reviewed by Dr. Rogan prior to or during the process of its implementation. No decision could be final without review by Dr. Rogan and the NIEHS.

6. The NIEHS directly controlled and approved the information provided to the Study participants and their families as well as the information contained in the Informed Consent forms.

7. The NIEHS Project Officer and staff conducted periodic site visits at Kennedy Krieger. These visits were intended to: (1) ensure that Kennedy Krieger was conducting its portion of the Study consistent with the trial protocol; (2) review Study participant charts to ensure compliance with the United States Food and Drug Administration (“FDA”) regulations for investigational new drugs (“IND”); (3) observe Kennedy Krieger’s facilities; and (4) survey the residential houses involved in the Study.

8. NIEHS (Dr. Walter Rogan) held the IND exemption for the Study drug, Succimer. During one of the site visits, Dr. Rogan conducted a quiz to make certain that Kennedy Krieger staff involved in the TLC Study understood the nature of the drug, including its side effects, in order to ensure compliance with NIEHS and FDA reporting requirements.

9. In the TLC Study, the United States Centers for Disease Control and Prevention (“CDC”) conducted the laboratory analysis of all blood lead samples from Study participants. Accordingly, it maintained oversight responsibility for all issues related to drawing blood at the Clinical Centers. The CDC established the protocol used by all Clinical Centers for drawing blood as well as for packaging the blood samples for shipment to the CDC laboratory in Atlanta, Georgia. Prior to the implementation of the TLC Study, the project manager for each clinical site was required to attend CDC training and was then expected to train personnel responsible for obtaining blood samples. This training provided instruction for compliance with the CDC protocol. The CDC conducted site visits to ensure that the Clinical Centers were complying with its blood drawing protocol. The CDC also provided certain of the equipment utilized in drawing the blood samples as well as all of the packaging materials.

10. In order to ensure uniform implementation of the TLC Study protocol, NIEHS required all Clinical Centers to participate in central training sessions to learn NIEHS approved techniques for measuring the height, weight, head circumference and blood pressure of Study participants. These were all values required to be obtained as part of the Study. Further, Central training was provided as to NIEHS approved methods for administering relevant psychometric testing, the results of which would be crucial to analyzing the outcome of the Study.

11. The Principal Investigator at Kennedy Krieger was required to seek approval from NIEHS in order to allocate funds for any purpose that deviated in any way from the contract drafted by NIEHS.

12. Kennedy Krieger was required to obtain IRB approval of the Informed Consent Form to be used in enrolling Study participants. After the local IRB utilized by Kennedy Krieger approved the form, Kennedy Krieger was required to submit that form to the NIEHS IRB for further review. The NIEHS IRB ultimately approved the Informed Consent Form used in the TLC Study.

13. Kennedy Krieger was obligated to follow, and did comply with, strict and comprehensive requirements pursuant to research involving human subjects, imposed by the federal government.

14. Based on my personal involvement and observation of virtually all aspects of the design and implementation of the TLC Study at Kennedy Krieger, there is no question that the federal government, through the NIEHS, FDA and CDC, retained and exercised a very detailed level of control over every aspect of the Study.

I HEREBY DECLARE UNDER THE PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT.

Executed on: 19 April 2007

Cecilia Davoli, M.D.  
Cecilia Davoli, M.D.