Hair Dye Blood Analyses

KE 0013152

N14918

Following a discussion with Dr Lerner, in an attempt to answer the questions raised in the attached memo (some of which were regarded as entirely irrelevant, and far beyond the scope of the duties of the Committee headed by Dr Lerner), the decision was made to have no more communication with the Committee; but rather to propose to Drs. Lindell and Goldman, that the Department of Dermatology take over the project, and obtain, directly, the approval of the College Committee on this issue.

This was agreed upon, as the issue was ended, from the outset of following

MEMORANDUM

TO: Robert A. Kehoe, M.D.

FROM: Committee on Ethics of Human Experimentation

DATE: December 4, 1967

SUBJECT: Potential Hazard in Use of Lead-Containing Hair Dyes

The Committee on Ethics of Human Experimentation has reviewed the information supplied to it with reference to the above proposed experimental clinical study. On the basis of the available information, the Committee cannot forward the protocol to the Director of the Laboratory with an unqualified recommendation for approval. The following represent comments and additional information that is requested. Upon the receipt of this information a further review of the proposal would be made. The order of sequence is not representative of the importance of any of the comments, questions, etc.

1. An amplification of the reasons for conducting the study should be supplied.

2. A more complete review of the pertinent literature that is referred to with regard to percutaneous absorption of lead salts should be supplied.

3. How comparable is the proposed generic formulation to similar products currently on the market?

4. What formulations are currently on the market? What is their general composition? What is the extent of their use?

5. How does the proposed mode and frequency of application compare to that recommended on commercially available products?

6. Could not the goals of the current proposed study be achieved by the use of a readily available commercial product on controlled subjects as well as by the use of a generic formulation?

7. What is the mode of action of the hair dye?

8. Is there any assurance that the FDA will accept the data collected in this experiment as meaningful for a number of currently available formulations? Generally, each new formulation of a compound would be considered as a separate entity. Has the protocol been submitted to FDA for their consideration?

9. It is agreed that it is not possible always to directly extrapolate results obtained in animals to man. However, in the experience of the committee, this is the generally accepted route of experimentation - that is extending from animals into man rather than testing man initially. A further explanation for the reason for not pursuing this generally accepted line of investigation is requested.

10. Primary responsibility for the supervision and safety of the subjects in the experiment must rest with the principal investigator. The subjects must be under the direct supervision of a physician licensed to practice medicine in the state of Ohio. The name and general qualifications of this physician should be stated. The protocol should contain a complete description of the procedures that will be used to assure the safety of the subjects.

11. The subjects should be required to sign an informed consent statement. A copy of this statement should be attached.

12. The proposal suggests using approximately ten subjects. It is recommended that consideration be given to a sequential use of the subjects rather than exposing all subjects to the unknowns of the experiment at one time.

13. The protocol indicates that through the Occupational Health Service of the Laboratory, the general status of the subjects is known to clinicians. It is the understanding of this committee that in the last several years, the Occupational Health Service of the Kettering Laboratory has not included a periodic health evaluation of these individuals and the type of information that would normally have been available in the past has not been available for the past five years. The protocol goes

on to say that the clinical staff will monitor the safety of the experiment. As stated earlier, this is the responsibility of the principal investigator. This responsibility must rest in a named individual.

I, or any member of the committee, will be happy to discuss any of the above with you.

Sidney Lerner

Sidney Lerner, M.D.
Chairman, Committee on Ethics
of Human Experimentation

SL:rms