

MEMORANDUM ON AN INVESTIGATION OF THE POTENTIAL
HAZARD OF THE PERCUTANEOUS ABSORPTION OF A LEAD SALT
EMPLOYED IN THE FORMULATION OF A HAIR DYE

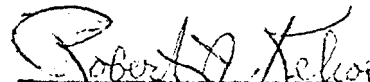
1. The technique of the investigation consists in the provision of a single simplified formulation (attached), which is believed to be representative of those employed in a number of commercial preparations.
2. This formulation is to be used, in accordance with the instructions issued to those who make use of the commercial preparation, by ten human subjects, who have been selected from among the technical assistants, 8 males and 2 females, in the Kettering Laboratory.
3. The subjects have been under general medical supervision of the members of the Clinical staff of the Laboratory, who maintain an occupational health service on behalf of the entire staff of the Laboratory. Through this service, the general status of the health of these subjects is known to the clinicians. In addition, however, according to the general program of the Laboratory, in connection with experiments involving human subjects, such additional laboratory tests as are believed by the Clinical staff to be useful for the purpose of revealing abnormalities of bodily function, will be completed before the experiment is initiated. The health status of the subjects will be reviewed during the experimental regimen and after it has been completed.
4. The subjects will be supervised as to the initial interim and final condition of their hair and scalp by the staff dermatologist, who will see them at regular intervals or at any other indicated time.
5. It is intended that this experiment should demonstrate the occurrence or non-occurrence of the percutaneous absorption of lead, under the experimental conditions, in so far, quantitatively, as such absorption or the lack of it can be demonstrated by the induction or lack of induction of a significant elevation of the rate of the excretion of lead in the urine of the subjects. The concentration of lead in the blood will also be determined before the initiation of the experimental exposure to lead, at certain intervals during the conduct of the experiment, and afterward. It is recognized that any elevation of the lead in the blood which may result from the experimental procedures will come, if at all, after the response in the urinary excretion of lead shall have appeared. However, the observed change, or a lack of change, in the concentration of lead in the blood, if any, will provide useful information concerning the significance of the exposure to lead.
6. Since there are opportunities for the ingestion of lead, through the contamination of the hands (especially) of the experimental subjects, every precaution will be urged upon each individual subject for the avoidance of such opportunities. (Herein lies the principal advantage of employing subjects who are familiar with experimental work of this type, and with the measures of precaution and precision that are required to avoid minute deviations in technique.)

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7. In consonance with the policies of the Laboratory, in connection with human experimentation, the foregoing details, together with other information in this and other written descriptions of the experimental procedures will be supplied to the Committee on Human Experimentation of the Kettering Laboratory, in writing, and will be discussed with the members of this Committee, should they so desire. A report will be made, thereafter, to the Committee representative of the faculty of the College of Medicine of the University of Cincinnati.

Signed:


Robert A. Kehoe, M.D.
Professor Emeritus of
Occupational Medicine

Signed:


Emil A. Pfitzer, Sc.D.
Associate Professor of
Toxicology

Date: July 3, 1967

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SUPPLEMENTARY MEMORANDUM IN RELATION TO THE MEDICAL SUPERVISION OF THE SUBJECTS

(Paragraph 3 of "Memorandum On An Investigation, etc.")

The available information in the medical records of the subjects (members of the service staff of the Kettering Laboratory) is under review from the aspect of its adequacy in portraying the state of health of each individual who has elected to be a subject in this experiment. Wherein any such record is deficient, with respect to the physiological status of a specific person, it will be supplemented by clinical examinations and laboratory tests. In view of the minor stress and negligible hazard anticipated in the experiment, there is no need for more than the common clinical and laboratory tests that can be expected to yield evidence of physical and physiological fitness for the ordinary tasks of life. It is essential, however, that there be no functional disorder that might be expected to impair significantly general metabolic processes or to interfere with the hepatic handling of metals (lead in particular) or the renal excretory processes. The latter is important, in this instance, not so much for the protection of the subjects against the retention of potentially toxic quantities of lead in their bodies, as for the efficiency of the renal excretory apparatus in demonstrating, indirectly, through its response, the occurrence of any slight degree of absorption of lead. Nevertheless, both purposes are served by the assurance of the functional sufficiency of the renal apparatus.

It is expected, in line with the long practice of the Laboratory in similar experiments, that each subject will be interviewed weekly, during the experiment, by a physician answerable, for competence and responsibility, to the Clinical Division and the Director of the Laboratory. The sole function of such physician will be to satisfy himself as to the health and well-being of each subject, not only in the setting of the experiment being conducted, but with respect to his freedom from illness of any type that should disqualify him (her), in the mind of a skilled and prudent physician, for engaging in such an experiment. This physician will not be concerned in any way with the conduct of the experiment. He will conduct such examinations and laboratory tests as may, in his judgment, be required, from time to time, to reveal the state of health of the subjects. He shall have access to the data of the experiment as it is made available by analytical or other procedures. He shall also maintain a record of the observations made on each of the subjects, and of his conclusions or recommendations. He shall communicate, promptly, to the Head of the Clinical Division or the Director of the Laboratory, any decision at which he may arrive concerning the desirability of terminating the experiment or the participation of any or all of the subjects in it.

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