

9036 Jeffery Road
Great Falls, Va. 22066
April 12, 1977

Mr. Joseph Padgett
U.S. Environmental Protection
Agency
Office of Air Quality Planning and
Standards MD-12
Research Triangle Park, North Carolina 27711

Dear Mr. Padgett:

I have been asked to also send you the enclosed statement concerning my analyses of Dr. Robert A. Kehoe's lead balance studies in humans, which I recently sent to Mr. James Smith of the Criteria of Special Studies Office of EPA at Triangle Park..

Please direct any questions you have to me at my address as indicated.

Sincerely yours,

Stanley B. Gross, Ph.D.
(703/759-9311)

cc: ✓ Dr. Robert A. Kehoe
Dr. Gary Ter Haar
Mr. James Smith

enclosure

KE 000015

9036 Jeffery Road
Great Falls, Va. 22066

April 11, 1977

Mr. James R. Smith
Criteria of Special Studies Office
Health Effects Research Lab MD-52
Environmental Protection Agency
Triangle Park, North Carolina 27711

Dear Mr. Smith:

I have been asked to send to you the enclosed statement concerning my analyses of Dr. Robert A. Kehoe's lead balance studies in humans. This data should be useful to the Environmental Protection Agency's considerations in setting the National Ambient Air Quality Standard for Lead.

Sincerely yours,

Stanley B. Gross

Stanley B. Gross, Ph.D.

(703/759-9311)

Dr. Robert A. Kehoe
cc: Dr. Gary Ter Haar

enclosure

KE 0000455

STATEMENT
relating to the
National Ambient Air Quality Standard for Lead
April 11, 1977

by
Stanley B. Gross, Ph.D.
9036 Jeffery Road
Great Falls, Virginia 22066

presented to
Criteria of Special Studies Office
Health Effects Research Laboratory MD-52
Environmental Protection Agency
Triangle Park, North Carolina 27711

I am representing Dr. Robert A. Kehoe of the Department
of Environmental Health of the University of Cincinnati
and the Ethyl Corporation of Baton Rouge, Louisiana.

I am a toxicologist and I have been completing the
data processing on Dr. Kehoe's lead balance studies in
human subjects. Dr. Kehoe began these experiments in
1934 and continued them until 1972. Sixteen individuals
were studied under normal conditions and under conditions
of lead supplementation in their diets or in the air they
were breathing for a total of more than 21,000 days of
measured exposure to lead.

A considerable amount of Dr. Kehoe's data have
already been published; however, the data from several
of his experiments have not. My task over the past
two and a half years has been to compile the bulk of
Dr. Kehoe's data for the purpose of my own analysis and to
publish the data from those experiments which have not

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yet been published. In contrast to Dr. Kehoe's previous reports, I have applied computer techniques to present the data and to analyze them statistically. I am currently working on a monograph which will contain the results of my analyses. The monograph should be completed in the next three months. When it is completed, a summary of my findings will be submitted for publication in one of the scientific journals. Part of my findings has already been presented at the 1975 Annual Meeting of the Society of Toxicology in Atlanta.

The purpose of this statement is to present a very brief summary of some of the results of my work on Dr. Kehoe's data as they pertain to EPA's concerns in setting a National Ambient Air Quality Standard for Lead. A copy of the computer tape containing the data can be made available to EPA for the cost of duplicating the tape.

Methods. All of the subjects were followed throughout these experiments by a physician other than Dr. Kehoe by periodic histories, physical examinations and laboratory studies including hematology, urinalyses and chemical analyses of their blood and urine in order to insure that each subject experienced no harmful effects due to their experimental exposures. There were a total

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of 102 periods of study for the 16 subjects. Throughout all of these periods, each subject collected daily samples of his or her diet, feces and urine which were analyzed for lead. Blood samples were obtained on an approximate weekly basis and were also analyzed for lead.

Each subject was initially observed during a control period (ranging up to 602 days) in order to obtain baseline data on the subject's natural exposure to lead. The control periods, in the case of the inhalation experiments, were followed ^{by} with one or more periods during which time the subjects worked in special inhalation chambers ^{equipped} with devices for generating and monitoring aerosols of lead. The individuals remained in ^{one or another of} these chambers for periods of 2 to 13 hours per day, from every other day to 6 days per week, in periods (ranging ^{up} to 772 days). The chamber concentrations ^{or lead were maintained at} ranged from 10 to 150 micrograms ~~of lead~~ per cubic meter, corresponding to 24 hour adjusted exposure rates of 0.6 to 35.9 micrograms of lead per cubic meter.

The lead aerosols in the chamber had median count diameters of 0.11 to 1.20 micrometers. The periods of exposure ^{periods of observation (ranging up to 866 days)} were followed by post-exposure periods, ^{in the case of} (except in one subject) ~~(ranging up to 866 days)~~ during which time the subjects were followed as they returned ~~to normal status.~~

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Summary Findings. It should be emphasized that none of the ^{subjected to respiratory exposure} ~~inhalation~~ subjects experienced any harmful effects, ~~due to their exposures.~~ The highest adjusted ^{levels of} ~~concentration~~ ^{of lead} ~~exposure rates~~ were approximately 30 micrograms per cubic meter ^{per} for periods of 364 ^{days} ~~and~~ 616 days, ^{on the part of} ~~for~~ subject FC; 628 days ^{in the case of} ~~for~~ subject MOB; 330 days, ^{in the case of} ~~for~~ subject MB; and ^{at a rate of} ~~at a rate of~~ approximately 36 micrograms of lead per cubic meter of 112 days ^{in the case of} ~~for~~ subject LD. In none of these subjects did the mean blood lead concentrations ^{of any of} ~~of any of~~ these subjects exceed 40 micrograms per deciliter, except for one, subject JOS, whose highest mean blood lead was 46 micrograms per deciliter. The ^{level} ~~urine levels~~ ^(concentration of lead in the urine of these subjects) in response to ^{these respiratory} ~~these inhalation~~ exposures ^{to lead} did not exceed ^{the value} ~~the~~ mean of 86 micrograms per day.

There was ^{degree} ~~a~~ considerable amount of variation in ^{the} ~~concentration of lead~~ ^{was observed} in the blood and ~~urinary lead levels seen~~ throughout the experimental periods which were apparently in response to spontaneous changes of the subject's dietary lead ^{intake} ~~levels~~. This phenomena tended to obscure the dose-response effects seen in the blood and urine ^{at} ~~lower~~ levels of exposure. Thus in adjusted ^{levels of ingestion of lead} ~~exposures~~ up to 20 micrograms of lead per (cubic meter) the ^{changes in} ~~changes in~~ blood and ^{urinary} ~~lead levels~~ ~~were~~ correlated only with changes in ^{the} ~~the~~ dietary lead. It was not until the adjusted concentrations ~~used~~ exceeded 70 micrograms of lead

This part of the discussion is not clear. It even misled me.

RAF
By this part is meant the material between the horizontal lines (one on this page and

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per (cubic meter) [?] that the blood and urine ^{respected to} reflected the increases in airborne exposures. By means of visual estimates of linear regression lines throughout the data points, the increases in blood, urine, and feces were 0.38 micrograms per 100 grams, 0.88 micrograms and 2.50 micrograms per day, respectively, for each microgram per cubic meter increase in airborne lead.

It was also interesting to note ~~the control~~ ^{in the control periods} ~~period~~ mean blood lead concentration ~~for~~ the 16 subjects ^{in their control periods} tended to decrease statistically throughout the years of these experiments (1934-1970). This decrease in blood lead concentration was (statistically) associated, with a decrease in dietary lead, but ^{to some extent,} may also have responded to the decreases in the amount of lead in the Cincinnati air observed by others. (This I consider quite unlikely since

the influence of the severity of the respiratory exposure, within the limits involved here, were obviously so slight in proportion to the elementary exposure.)

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