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TO: R.D. SNEE

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CHEMICALS AND PIGMENTS DEPARTMENT

February 3, 1983

R. D. SNEE
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I have reviewed the letter you propose to send to the editor of "Environmental Science & Technology" in rebuttal to a letter the editor received from Dr. Bert Brunekneef commenting on your article "Development of an Air Quality Standard for Lead from Community Studies".

We have no objection to the publication of your letter. Thank you for the opportunity to review it.

D. R. DIGGS
MARKETING MANAGER - ANTIKNOCKS

DRD:bhj

RESPONSE TO DR. BRUNEKREEF'S COMMENTS ON
DEVELOPING AN AIR QUALITY STANDARD FOR LEAD

The quantitative determination of an air quality standard for lead is an important and complicated issue which has not been given adequate attention. Dr. Brunekreef accurately summarizes my proposed approach (1) and raises some important issues. I will discuss his concerns in the order in which he raised them. It will be apparent that I do not agree with some of his views.

We must keep in mind at the outset that there are two key elements under discussion: the statistical methodology used to develop the air quality standard and the data base used to derive the estimated distribution of blood lead values and the blood lead-air lead relationship used in the procedure. Changes in the latter require only a recomputation while disagreements over the former require a reformulation of the statistical model used. The proper formulation is critical because it can only result after we have an understanding of the system we are trying to regulate.

a. As I pointed out (1), the methodology I proposed will work for any "acceptable" (ie, safe) level of blood lead. I chose the biological guideline proposed by Zielhuis (2) which calls for 50, 90, and 98 percent of the population at risk to have blood lead levels less than 20, 30 and 35 μg/dl, respectively. As I noted, in the case of children, the guideline distribution (99.5 percentile of 30 μg/dl) proposed by the United States Environmental Protection Agency (EPA) can also be used (3). Other guidelines may be appropriate. If the guideline (ie, acceptable distribution of blood lead levels) changes in the future, then the air quality standard will need to be reevaluated.

   The question of safety factors is, for the most part, a societal (policy) judgment outside the methodology used to calculate the standard. Margins of safety can be incorporated. It seems reasonable to assume, however, that any "acceptable" blood lead level contains a margin of safety.

As discussed later, the procedure described in (1) is conservative, thereby providing an additional margin of safety, because the distribution of true blood lead values is broadened by blood lead measurement error, plus any variation due to the inability to accurately measure an individual's air lead exposure.

We must be careful in developing air quality standards to keep the scientific considerations separate from the societal (ie, political) judgments. The calculations should be based on best estimates (ie, average values) of the various inputs. Policy makers can promulgate a standard that is lower than the value calculated from the best available data and scientific knowledge if they feel that such action is necessary. If done in this manner, this action is clearly recognized as a societal judgment made outside of scientific considerations. Incorporating societal judgments within the scientific analysis (eg, the use of upper confidence limits rather than best estimates of model inputs) creates confusion and reduces the effectiveness of the standard setting process because it is not clear to all parties which decisions are based on scientific knowledge and which are based on societal judgments.

The approach proposed in (1) is conservative because the distribution of observed blood lead values used contains measurement error which was not taken into account by the modeling procedure. It is a fundamental principal that an observed blood lead value for a given individual is equal to the true blood lead level plus measurement error due to sampling variation and analytical error.

Observed Blood Lead = (True Blood Lead) + (Measurement Error)

Blood lead measurement error, therefore, broadens the distribution of observed blood lead values compared to the distribution of true values

(4). This produces a lower air quality standard than would occur if the standard were computed on a true value basis by taking the measurement error into account. Lucas (4) found that 50 percent, or more, of the total variation in blood lead measurements can be due to measurement error. Statistical procedures to properly account for measurement error are discussed by Lucas (4) and Hahn (5). These techniques can be used to further refine the methodology described in (1).

b. Dr. Brunekreef properly points out that it is necessary to take all sources of lead exposure into account when setting an air quality standard and notes that soil and dust are important sources of lead for children. Lead exposure from sources other than the air is an integral part of my proposed procedure (1) and that used by the EPA (3). Improvements are needed in this regard and should be incorporated as new data on the other pathways become available.

Lead in dust and dirt comes from many sources including house paint, soil lead, previous air lead levels, and current air lead levels. The linear correlation coefficient between air lead and soil and dust lead is not large, however, being, in general, less than 0.5 (6, 7) and sometimes close to zero (8). Quantitative modeling of these relationships is an important area for further research, but the data available do not suggest a correlation strong enough to justify the use of air lead as an indicator variable.

In my procedure (1) lead exposure from nonair lead sources is accounted for by the distribution of observed blood lead values used to derive the standard. The distribution used is that for a population at a fixed air lead level. The spread in this distribution represents person-to-person variation due to lead exposure from other sources as well as measurement error. In the Azar Study (6), the inability to model the contribution to blood lead from pathways other than air shows up as variation in the

blood lead measurements around the fitted curve. In the Tepper-Levin Study (7), lead exposure from other pathways also resulted in a larger within-group variation. In both of these instances, lead exposure from other pathways increases the variation in observed blood lead levels, thereby broadening the distribution. As noted earlier, a broader distribution produces lower values for the resulting air quality standard.

Lead exposure from soil and dust was incorporated in the air quality standard developed by the EPA (3). They assumed that at a zero air lead level, a child's blood lead level would average 12 µg/dl due to all sources of lead exposure except from the air. They then determined that an air lead level of 1.5 $\mu g/m^3$ would result in a geometric mean blood lead of 15 µg/dl which is consistent with the blood lead guideline of 30 µg/dl for the 99.5 percentile of the distribution. The EPA assumed that blood lead values follow a lognormal distribution with a geometric standard deviation of 1.3.

In any study the inability to unbiasedly sample each individual's air lead exposure also broadens the distribution of blood lead values at a fixed air lead level. This is particularly true in stationary sampler studies, such as that conducted by Tepper and Levin (7), in which a person's lead exposure is approximated by a single air sampler situated in the area in which the person lives or works.

An extreme case is population sampling studies, such as the NHANES II Study (11), in which air lead measurements are not made. In these studies, the distribution of observed blood lead values contains variation due to different air lead exposures as well as lead exposure from other pathways. The variation in the NHANES II Study, due to the 64 sampling locations, as well as any time trends which occurred during the four-year study 1976-80, further broadens the observed blood lead distributions. The use of distributions, such as those developed in the NHANES II Study, will result in a conservative air lead standard due to the broader distribution of blood lead levels.

Dr. Brunekreef claims, without documentation or reference to other papers, that the blood lead-air lead slope is greater than 1 and may be as large as 3. The basis for this conjecture is unclear, for an exhaustive study of the literature shows slopes ranging from approximately 1 to 2 with an overall average value between 1.0 and 1.4 (12). The determination of the appropriate slope is critical to the determination of the standard. It is, however, an input to my proposed methodology and is independent of the methodology. The standard could be derived using a variety of slopes if appropriate.

c. I do not share Dr. Brunekreef's concern about the age of the data base used in my calculations. The studies of Azar, et al, and Tepper and Levin (7) are, today, generally considered to be the best available prospective epidemiologic studies of the relationship between blood lead and air lead. The critical items are the distribution of observed blood lead levels, as estimated by the Tepper and Levin (7) study, and the blood lead-air lead relationship, as estimated by Azar, et al, (9,13) and a linear model with a slope of 1. These inputs to the air quality standard calculations apply equally well to today's population. Blood lead levels in the general population are lower now than they were when these two studies were conducted for several reasons, including the decrease in the lead content of our food and water supply, the reduction in the number of houses with leaded paint, and the declining use of lead in gasoline. These changes should have no effect on the relationship between blood lead and air lead and can only lessen the spread of the within-population distribution. It is certainly appropriate to reevaluate the standard in the future and redo the calculations as new data become available, suggesting that such calculations are appropriate.

Dr. Brunekreef also raises concerns about the effects of variations in population groups. Contrary to his statement, the methodology assumes a distribution for the population at highest risk and not a nationwide

distribution. It should also be recognized that differences present in the population due to culture, sex, race, etc, will broaden the distribution of observed blood lead levels. Lead exposure problems may require different forms of management for different populations; however, there is only one air quality standard. The baseline will be determined by the regulatory agencies and is an input to the methodology described in (1).

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