

Letters

EPA Review of Lead Study

I would like to comment on the recent article by Eliot Marshall (*News and Comment*, 25 Nov., p. 906) dealing with the dispute between myself and the Environmental Protection Agency (EPA) review panel headed by Lester Grant.

A subject as important as the effects of lead on the health of children deserves careful scrutiny, and I have welcomed and received close examination of my data by responsible scientists. Although I felt that the panel set up by Grant circumvented the peer review process that EPA had established for the Lead Criteria Document, I welcomed them and gave them unlimited access to my data. Grant and I agreed that I would be given a timely draft copy of their report before its promulgation in order to correct any errors of fact. When the visiting team arrived, on 30 March 1983, I presented them with all of the bound printouts of the study and an index to the data; I also provided them with a meeting room. I met with them for two consecutive days to answer their questions. At their request, certain portions of the printouts were photocopied so that they could work with the data sets individually. At the end of May, when the report had not been sent to me, I called Grant's office to ask for a copy of the draft. I was told it was being worked on and that I would receive a copy as soon as it was ready. I continued to request the draft report at monthly intervals until September without effect. On 30 September, at the same time that a copy was sent to the EPA press in Cincinnati for publication, a copy was sent to me. On first reading, I found at least 12 errors of fact; almost all were biased against the conclusions drawn by my study. By express mail, I informed Grant that, if the erroneous report was not withdrawn, I would insist that a complete errata sheet be sent to every recipient, with an acknowledgment that my original agreement with him had not been fulfilled. The report was withdrawn from the printers.

The report incorrectly assigned dentine lead levels to my groups, incorrectly stated the type of dental tissue analyzed, incorrectly labeled the type of IQ test we employed, and incorrectly cited IQ

scores. Some of these errors were not of major magnitude but were indicative of the care with which the report was assembled and edited. A few errors were serious, however, and questioned the integrity of my data, myself, and my co-workers. I was startled, upon finding these errors, to realize that three which appeared in the draft document had been pointed out earlier by me in written communications to Grant, on multiple occasions.

The report stated that the rate of mistakes my colleagues and I committed in transferring data from the code sheets to the computer was 7 per 1000. The actual rate was lower by an order of magnitude: 7 per 10,000. This error appeared in the report despite the fact that I had brought it to Grant's attention in writing. It was also stated in the report that I did not furnish the distribution of lead levels across excluded subject groups, which suggested that a source of bias could have entered the study at this point. Actually, at Grant's request, I had sent him complete listings of all the dentine lead levels cross-tabulated by exclusionary class. These tabulations, which the report said I had not furnished, were cited in its bibliography!

One member of the panel is quoted by Marshall as saying that "[t]he basis for excluding certain children is still not totally clear." Yet the reasons were delineated in our original paper (1), and the visitors were given copies of the tables listing the excluded subject and the criteria applied. Another panel member stated that, because the computer program "kicked out" cases for which some covariate data was missing, the actual subject number for some of our analyses was less than 158. This is true. It is not true, as he stated, that because the *N* was reduced, the differences may not have been statistically significant. The program we employed (Statistical Package for the Social Sciences) calculated the *P* values on the basis of the number of cases actually analyzed, not the number of cases in the data file.

The most serious criticism of my work was the charge that I may have known the lead classification and outcome scores of my subjects at the time I excluded subjects from the study for rea-

sons such as head injury. Had this been true, an important source of bias could have crept into the subject selection. My associates and I took particular pains to prevent this from happening. The report was incorrect, despite the fact that our blinding procedures had been brought to the attention of Grant and the panel on four occasions, twice in oral presentations and twice in written correspondence. While this statement and the others were withdrawn in the final document, the conclusions drawn from them were allowed to stand.

Finally, Marshall indicates that, according to Grant, I became uncooperative when "problems turned up" and asked all of the reviewers to return all the data before leaving his office. This is simply not true. Grant asked if I would allow them to take the photocopies I had provided them back to North Carolina. I asked him whether their confidentiality would be shielded if I gave them to him. He said they would not. I said that, since these data represented work still in progress, they could not take them from the hospital but they could spend as much time as they wished with the data in Pittsburgh.

Eight days after the panel visited me in Pittsburgh, I received a letter from Grant, in which he wrote:

Thank you for taking time out of a busy schedule to meet last week with myself and members of the expert committee that I have asked to review your studies on association between neurobehavioral effects and low level lead exposures in children. Your assistance in providing an introductory overview of your studies, in making computer printouts of data and statistical analyses results available for inspection by the committee, and in answering questions posed in regard to procedures employed in collecting the data and analyzing the results of your studies was quite helpful and appreciated by us, as was the assistance provided by your secretary during our visit.

It is not clear to me why there is a disparity between these two statements by Grant.

I have never claimed that my work is flawless. Epidemiology in the real world does not permit such hubris. It is, however, more than a little frustrating to see refractory misinterpretations of fact and inference applied to it in the face of repeated efforts at correction.

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References

1. H. L. Needleman *et al.*, *New Engl. J. Med.* 300, 689 (1979); A. Leviton, D. Bellinger, *ibid.* 306, 367 (1982).