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Michael A. Parsont, Chief
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United States Nuclear
Regulatory Commission
Washington, D.C. 20555

Dear Dr. Parsont:

This is in response to your letter of March 12, 1981 with respect to publication of a report by Ginevan and Curtiss as a NUREG document by April 30, 1981. There are both technical and legal objections to this report. This is also the broader question: Should federal regulatory agencies use their powers and the taxpayers' dollars to harass persons in the private sector who question the policies of these agencies?

The past reluctance of scientists such as myself to resort to legal redress has largely been due to our commitment to a free discussion of scientific issues even when, as in this instance, NRC's purpose is to "justify" its regulatory policies. Moreover, it may be difficult for a jury to distinguish between an effort to discredit and derogate the work or reputation of an independent scientist (always "in the name of science") and genuine scientific criticism. Fortunately in this instance there is a simple and clear way to make this distinction, a litmus test that a jury can understand.

There is a very serious technical error in the report, an error which makes the analysis and analytic strategy used here both scientifically and statistically invalid. Moreover it is not a highly technical point, it hinges on simple facts about the way the Tri-State survey data was collected. This mistake leaves NRC with two choices. If the purpose is to discredit a critic of NRC regulatory policies (such as the 5 rem per year standards), then NRC will publish the NUREG report as scheduled. On the other hand if this is science, the authors will have to go back to the drawing board.

For this reason I am requesting under the Freedom of Information Act, and for possible legal action, the names of all persons who have participated in the development, approval, or implementation of contract no. W-31-109-ENG-38 and who may be co-defendents in legal action. Please identify the role, federal agency or other institution, and duration of participation of the persons who are named.

Now let me briefly outline the nature of the mistake that was made in the report produced under the above contract and why the subsequent actions of NRC provide a litmus test of NRC motives and intentions. The problem really arises because the authors are remote from the Tri-State data and are using this data without my permission and without access to the source documents that are in my possession. They have made a series of statements about the Tri-State study and about our analyses which are counterfactual.

The report states:

In defining "exposed" versus "unexposed" categories it was decided to separately compare each radiation exposure category to the zero exposure category. This was adopted because we felt it provides a clearer view of the pattern of risk (e.g., does risk increase with increasing dose?) than did the methods used in the original Tri-State study.

Anyone interested in doing a scientific study rather than a hatchet job, anyone who did not presuppose that all of the persons who had previously analyzed the Tri-State were rigging the results, might have asked: Why <u>didn't</u> the previous analysts do the obvious and simple-minded analysis using "zero exposure" as a baseline? Could they possibly have had a good reason for choosing more complicated lines of analysis?

Those close to the data knew that the Tri-State survey was a household interview study with a <u>random sample</u> of the general population and census of leukemia cases. It was not a standard case-control study with "a group of 1370 controls chosen for a similar age and sex distribution" as the report states. A major problem in this household interview study is that the random "control" is almost always alive but the "case" is often dead. Information on health history of a dead "case" may often come from a collateral relative. Hence, "zero exposure" in the leukemia series is a mixture of "zero exposure" and inadequate reporting of exposure. While reported exposures can be verified from hospital records, etc., "zero exposure" cannot. Hence, it is a very bad category to use as a baseline for comparisons. As the relative risks in the tables often show, the "zero exposure" risks (because of the mixture) are often higher than the 1-5 film categories. It was scientifically and statistically a fatal mistake to use "zero exposure" for all the comparisons--a mistake which was avoided by the analysts familiar with the actual study.

In sum: The analysts remote from the actual data fell into pitfall that the previous analysts avoided. The mistake not only invalidates the analysis, it invalidates the strategy used here. It guarantees the negative results because it artifactually obscures any linear (or other) dosageresponse relationships and the power is very poor. If the authors want to deny posi ive results by earlier analysis they must, of course, show that their analysis is valid and more powerful--something this bad mistake rules out entirely.

Hence, the situation here is simple and clear enough for a jury to understand. If this report is intended as a scientific study, then the authors must rethink and redo their entire analysis so as to avoid the fatal pitfall that their predecessors avoided. On the other hand, if NRC has commissioned a hatchet job for the express purpose of discrediting the work and reputation of my colleagues in the Biostatistics Department at Roswell Park Memorial Institute and myself, then of course it will be published as a NUREG document by April 30, 1981.

It is neither better nor worse than the other hatchet jobs that the National Cancer Institute and others in the federal interagency task forces on radiation hazards have carried out. However, it should be good enough to provide a basis for legal action aimed at trying to put a stop to the harassment of private citizens by the federal regulatory agencies.

Very sincerely yours,

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NOTE: You are not authorized to reproduce this letter or to use it for any purpose other than to communicate the critique to the authors.