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August 17, 1976

Bruce L. Harrison, Esquire
Capehart & Scatchard, P.A.
217 North Sixth Street
Camden, New Jersey 08102

Re: SPI-VCM/PVC--Birth
Defects, Stillbirths and
Miscarriages

Dear Bruce:

Following up on our telephone conversations last week, the following is the promised compilation of materials relating to the questions of (1) the relationship between vinyl chloride exposure and birth defects in plant communities, and (2) stillbirths and miscarriages among the wives of workers exposed to vinyl chloride monomer.

1. "Oncogenic and Mutagenic Risks in Communities with PVC Production Facilities" by Dr. Peter Infante (then of the Ohio Department of Health). This paper was presented at a conference on occupational carcinogenesis held March 24-27, 1975 in New York sponsored by the N.Y. Academy of Sciences. The paper is in draft form (unfortunately without charts) and, to the best of our knowledge, it has not yet been published in the professional literature. This is our best source on Infante's work on birth defects in the three northern Ohio communities mentioned.

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2. "Vinyl Chloride and Congenital Malformations," as printed in Morbidity and Mortality (July 19, 1976), the weekly newsletter of the federal Center for Disease Control (CDC). This is the best non-industry rebuttal of Infante's work on birth defects, that is, number 1 above.

3. "Congenital Malformations and Vinyl Chloride," as printed in The Lancet, November 29, 1975. This paper is, quite simply, a reprint in letter form of the Morbidity and Mortality piece mentioned above. 

4. "Genetic Risks of Vinyl Chloride" by Infante et al. This is a typewritten draft version of a paper on stillbirths and miscarriages in Pottstown, Pennsylvania that was released in February, 1976.

5. "Genetic Risks of Vinyl Chloride" by Infante et al, as published in The Lancet, April 3, 1976. There are some minor differences between this version and the draft version mentioned above, but they are of little importance.

6. "PVC and Health: A Background Statement." This is, of course, the basic industry position paper on the entire VCM/PVC situation. It contains sections on both the birth defects and stillbirth issues.

7. "PVC and Health: Questions and Answers." This is the most recent industry effort. It has short questions and answers on both the birth defects and stillbirth issues.

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We are informed that there are no other relevant documents on either of these issues. Reportedly, all the news stories and the like to which you may be referred have been based on one or more of these reports.

As to the future, the CDC is conducting a research project on "Defects in Charleston, West Virginia". At this juncture, however, we are uncertain of the status of this project and do not know when a report can be anticipated. If this might be of some use to you, please do not hesitate to let me know so that we can get you a copy at the earliest possible moment.

Finally, of some real concern to the industry is the Infante stillbirth study noted in items 4 and 5 above. The problem is that, although the study is assailable (beginning with research technique) until a more definitive study is conducted we are unable to refute its assertions. Unfortunately, the National Institute of Occupational Safety and Health (NIOSH) for which Infante now works is not expected to launch a second, more complete study of this problem. We are told that they are satisfied with the results of the Pottstown study and, as result, it is up to industry to either launch its own study or convince another government agency to conduct additional research which might refute the Infante data.

Although we have probably supplied you with much more material than you will ultimately need, you will recall that as a result of our last telephone conversation, it was decided that it might be of some use to you to have more than just The Lancet article and our "Background Statement." If there is any more information which you need, please let us know so that we can try to develop it for you. Of course, if you have any questions or comments concerning this letter or any of the enclosed materials, please do not hesitate to contact us.

Cordially yours,

Enclosures

cc: Mr. Ray Abramowitz
bcc: Dr. A. Ross Adams
Mr. Ralph L. Harding, Jr.
Mr. John R. Lawrence
Mr. Matthew M. Swetonic

JEH:cs

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Draft B

Dr. Wayne R. Sorenson
Continental Oil Co.
Ponca City, Oklahoma 74601

Re: Ad Hoc Task Force on PVC Pipe

Dear Wayne:

As you know, Mr. Heckman had to go on a business trip abroad immediately after our meeting with Dr. Angelotti and Mr. Ronk of the Food and Drug Administration on June 16. Consequently, I am reporting for him the results of the meeting that he, Dr. Daniel Dixler and I held to explore FDA's attitudes and recommendations with regard to the jurisdictional question concerning potable water pipe.

The meeting was very informal, open, friendly and I believe we were able to obtain some insight as to the nature of the problem we, and the two concerned agencies, face.

To begin with, we want to let you know that although we sent a copy of our letter ~~addressed~~ to Dr. Angelotti ~~to both men~~ in advance of the meeting, ~~these were~~ retrieved when we left so that there is no formal document in the FDA files. *if was*

Secondly, we came away with the general feeling that if EPA were to take a strong stand and insist that it had complete jurisdiction over potable water distribution systems from source to tap and firmly announced its intention to exercise this jurisdiction, FDA may well cede to it. On the other hand, it is apparent that within the FDA administrative hierarchy there are those who, predictably, argue that FDA can do a better job than EPA in this area, will do a better job, and, therefore, should have jurisdiction over potable water. ~~This group is in no way motivated by the bureaucratic empire building syndrome; they are only motivated by the public good.~~

Based upon our reading between the lines, it would appear that:

1. Within EPA there is a struggle as to whether EPA should assume jurisdiction over all aspects of potable water including direct additives such as disinfecting

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