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PRIVILEGED AND CONFIDENTIAL
ATTORNEY-CLIENT COMMUNICATION

MEMORANDUM FOR THE VINYL CHLORIDE PANEL

Re: Options for Addressing ATSDR Test Rule

At the end of the conference call on October 31, I was asked to provide a paper that would identify the options available to the manufacturers of vinyl chloride represented on the Vinyl Chloride Panel to address the testing requirements that the Environmental Protection Agency (EPA) has indicated it will propose for vinyl chloride as part of the Agency for Toxic Substances and Disease Registry (ATSDR) test rule. 59 Fed. Reg. 49934 (Sept. 30, 1994). These are guideline tests of reproductive, developmental, and neuro-toxicity, all by the inhalation route. The EPA notice invites manufacturers and processors of vinyl chloride to develop and submit testing proposals to EPA. If no testing proposal is made, or if there is failure to conclude the negotiation of an Enforceable Consent Agreement, EPA intends to proceed with rulemaking to require the identified tests.

The genesis of the September 30 EPA notice is the final priority data needs for 38 priority hazardous substances, including vinyl chloride, identified by ATSDR several years ago. 57 Fed. Reg. 54150 (Nov. 16, 1992). At that time, ATSDR identified a multi-generation reproductive toxicity study as a Group A data need and a two-species developmental toxicity study as a Group B data need, along with certain other studies, all by the inhalation route. More recently, ATSDR solicited voluntary research for these chemicals and indicated that the reproductive and developmental toxicity studies had been referred to EPA for

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addition to its master testing list, the first step in test rule development under Section 4 of the Toxic Substances Control Act (TSCA). 59 Fed. Reg. 11434 (March 10, 1994). ATSDR did not identify a neurotoxicity study as a data need. According to Has Shah, this study was added to the list in the September 30 notice at the request of the EPA Air Office.

The three basic options available to the Vinyl Chloride Panel to address this situation are briefly described below.

Option 1 - Do Nothing

There is no obligation to respond to the EPA solicitation of testing proposals. If the Panel believes that there is no scientific basis for ATSDR's identification of the vinyl chloride data needs, and no justification under TSCA for the issuance by EPA of a test rule to fill those data needs (as well as the data need that EPA has added on its own initiative) the Panel need do nothing at this time. EPA will proceed to propose a test rule, which presumably will include the three identified requirements for vinyl chloride. After the test rule is proposed, presumably in the first half of 1995, the Panel will have an opportunity to submit comments supporting its position. Thereafter, EPA will publish a final test rule. Any requirements for vinyl chloride testing imposed by the final test rule will have to be met by the vinyl chloride manufacturers (and processors), absent a successful legal challenge to the final test rule.

The advantage of this approach is that it postpones any testing until EPA has completed the rulemaking process and preserves all options for legal challenge to the final test rule.

There are several risks inherent in this approach. First, it is my understanding that the Panel did not comment to ATSDR when it proposed priority data needs for vinyl chloride in October 1991. It will therefore be difficult to attack the determination by ATSDR that the available data are inadequate to assess reproductive and developmental toxicity via inhalation. This concern does not apply to the newly added neurotoxicity study.

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Second, by foregoing the opportunity to come forward with testing proposals, the Panel effectively assures that any final test rule will require EPA guideline studies. By negotiating with ATSDR and/or EPA at this time to meet the identified data needs, the Panel would have some flexibility to deviate from guidelines (which are not yet final in any event for reproductive and developmental toxicity) and to be more creative both in the conduct and the timing of the studies that are likely ultimately to be required.

Third, by taking this approach the Panel would almost certainly be setting the stage for a disagreement with EPA over what test data are needed for vinyl chloride that could only be resolved by a judicial challenge to the final test rule. The success of any such challenge would depend upon a number of factors that we have not reviewed, including whether vinyl chloride enters the environment in substantial quantities and whether there is or may be substantial human exposure to vinyl chloride, as well as the adequacy of existing data. It is safe to say, however, that previous challenges to test rules on these grounds have not often been successful.

Finally, Has believes there is also the possibility that, in the course of rulemaking, EPA might decide to expand the requirements to include additional testing.

Option 2 - Work With ATSDR To Address
The Data Needs It Initially Identified

If the Panel believes that there is some scientific justification for ATSDR's conclusion that additional data are needed to assess the reproductive and developmental toxicity of vinyl chloride to individuals exposed by inhalation, it may wish to work with ATSDR to develop a testing program to meet these requirements. While, as indicated above, ATSDR solicited such testing proposals in March 1994, and EPA may believe that ATSDR terminated its voluntary testing program on September 30, when EPA published its notice, it appears that ATSDR would still be interested in receiving proposals for voluntary testing. If so, and if the Panel were to make a concerted effort to promote such a voluntary testing program with ATSDR, including meeting on an

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expedited basis with ATSDR officials and scientific staff, it might be possible to obtain ATSDR's support in communicating to EPA that the neurotoxicity study added to the list by EPA is not necessary. Whether EPA would decide to require the neurotoxicity study by test rule then might depend upon the extent to which the EPA Air Office feels strongly that such data are needed for some regulatory purpose.

The advantages of this option are that the Panel would have greater influence over the protocols for the reproductive and developmental toxicity studies, and that it may be possible to persuade ATSDR to accept a time line that would stretch out the testing costs over additional years. If ATSDR could convince EPA that these two studies meet all its data needs and that vinyl chloride should be dropped from the test rule, this would be a significant additional advantage.

The disadvantage, obviously, is that the Panel would be committing to a testing program with a cost in the neighborhood of \$1 million and with indeterminate results. In any event, however, it seems likely that a final test rule would include these requirements.

Option 3 - Notify EPA Of Interest In
Developing A Testing Proposal To
Cover All Three Studies

If the Panel believes that reproductive and developmental toxicity are indeed data needs for vinyl chloride, and that in addition there would be advantages in conducting a neurotoxicity study under a protocol agreed in advance with EPA, the Panel may wish to provide a proposal for voluntary testing directly to EPA. This would be consistent with the statement in the notice that testing proposals "should cover all identified data needs of a substance . . . in order to be considered for Enforceable Consent Agreement (ECA) negotiation." Even if it is not possible to develop such a proposal by November 29, the notice makes clear that EPA will extend the deadline upon a showing of good faith efforts to develop a proposal.

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The advantages of this approach are that it would resolve the major testing requirements for vinyl chloride that have been identified by ATSDR and EPA at this time and provide an opportunity to influence both the conduct and timing of the studies.

The disadvantage of this approach is that it would increase the cost over Option 2 by several hundred thousand dollars, the cost of conducting an inhalation neurotoxicity study. In addition, obviously, it is not possible to predict the outcome of such a study in advance. As with Option 2, on the other hand, it seems likely that absent some action by the Panel a neurotoxicity study will be required in any event by the final test rule.

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I look forward to discussing the options with you on the Monday morning conference call.

Caffey Norman
W. Caffey Norman, III

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