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AIR PRODUCTS

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Dr. D. J. Paustenbach
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Dear Dennis:

An outline and an abstract of the forthcoming chapter on vinyl chloride are attached. There may be some revisions to both as the chapter progresses, but this represents my general intentions. Please let me have any thoughts on either.

Very truly yours,

John T. Barr, Manager
Regulatory Response

JTB:pbr
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Enclosure

Outline

# Vinyl Chloride Revisited:

# The Impact of Latency on Quantitative Risk Assessment

John T. Barr

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1. Abstract

The first significant human health concern for exposure to vinyl chloride (VC) appeared about 25 years ago, and its carcinogenicity was discovered about 15 years ago. An enormous amount of laboratory study, epidemiology, and data analysis has been carried out on VC since that time, and extensive regulatory actions have been taken in every developed country. Current occupational or societal exposures are negligible.

Nevertheless, there are continuing regulatory initiatives based on even more "rigorous" quantitative risk analysis, each of which is less relevant to the human condition than the previous versions. All are based on animal data; none make any effort to utilize human data, nor to incorporate biologically sound mechanistic considerations.

The Angio Registry is a unique and extremely valuable source of human data, and contains a detailed history of every known occupational case of angiosarcoma of the liver (ASL), the recognized human response to VC exposure. Analysis of the data of the Registry allows an estimate of both the minimum exposure and the minimum time required to develop the disease. It also aids in understanding the mechanism of the disease, and has been used to predict the number of cases that may be expected to develop.

This analysis leads to the conclusion that there is no measurable risk at current exposures, a position which is supported by the failure to find any cases among the general population.

The VC situation is singular in the rarity of the disease and the ability of the length exposure to be defined quite exactly. A similar treatment of other carcinogens will be more difficult, and, likely, less accurate. Nevertheless, the value of considering all available human data in quantitative risk assessment is apparent, and the principle can be useful in other cases as well.

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