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To Whom It May Concern:

RE: 1. VINYL CHLORIDE. (CAS No. 75-01-4)

This communication is an FYI report on a new case of hepatic Angiosarcoma in a vinyl chloride worker exposed approximately 40 years ago. This individual has been newly diagnosed within the last year, and we have recently become aware of this fact. Outlined below is background information on the issue of vinyl chloride exposure and hepatic hemangiosarcoma. The University of Louisville Industrial Surveillance program has been following a cohort of vinyl chloride exposed individuals since the 1970's. We are currently working with Zeon and provide recommendations to them.

1. Introduction

BF Goodrich began operating a chemical plant in Louisville, Kentucky in the early 1940's. The plant included several discrete manufacturing facilities. Over time, commencing with the sale of the elastomer facility to Zeon Chemical in 1989, BF Goodrich sold its Louisville plant operations to other companies, including Zeon, Noveon (Lubrizol), and Geon (PolyOne). Many BF Goodrich employees were retained by the new owners of the different facilities to assure the continuity of the operations.

Background

In the early 1970's a relationship between excessive exposure to vinyl chloride and Hepatic Angiosarcoma was discovered among employees of BF Goodrich. Between the 1970's and 2000 there were 24 cases reported at the BF Goodrich plant in Louisville, Kentucky and 3 cases reported at the BF Goodrich plant in Avon Lake, Ohio. There was one additional case associated with the BF Goodrich Louisville operations that was reported in 2004. As a result of the health issues related to workplace exposure to vinyl chloride a Health Surveillance program was established by the University of Louisville with sponsorship from BF Goodrich. The program has continued to operate but now Zeon Chemicals is the only company from the BF Goodrich successors to continue sponsorship

This report has been written because of the new findings of 1 Hepatic Angiosarcoma case among the monitored group of former BF Goodrich Louisville employees within this year, plus 2 unconfirmed cases relayed to us by a local surgeon, and 1 additional case that is being verified by medical records. There have been 2 additional confirmed Angiosarcoma cases at the Avon Lake plant since 2010, to our knowledge, although we do not track these cases.

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Objectives

The objectives of this report are to identify a change in the latency period for the development of Angiosarcoma from vinyl chloride exposure and discuss those individuals who are still potentially at risk of developing Angiosarcoma as well as to provide recommendations for possible surveillance utilizing new diagnostic techniques that were not available in the 1970's.

Scope

This report addresses the 343 past employees of the original BF Goodrich Company that have Vinyl Chloride exposure and are potentially at risk for developing Angiosarcoma because of their prior work exposure.

2. Methodology

The medical surveillance program was implemented to follow "high risk" individuals. Individuals were identified as being at "High Risk" because of the following criteria: **1.** They currently or previously held a position that involved Vinyl Chloride exposure, and that job title was known to be one that was in a high exposure area (examples include: a Poly Cleaner, Helper, Chemical Operator). **2.** The employee had a high CERM (Cumulative Rank Exposure Month). This is a ranking method used to evaluate exposure levels to chemicals in the plant. As a note, in our experience, no employee has ever developed Angiosarcoma with a cumulative CERM level lower than 500. Thus, employees on this list had CERM values higher than 500, unless they also fell into multiple other categories which increased their risk. **3.** The employee was hired and worked during the "peak" exposure time frame of the 1960s-1970s before OSHA regulations lowered the daily exposure limits. **4.** The employee had findings during the initial screening program at the plant that identified that individual as being at risk (i.e. liver scan, liver biopsy, etc.) **5.** The employee was a Pallet Plant Worker, which meant that during the initial screening program at the BF Goodrich plant there was some reason this employee was identified as being at risk and removed from the exposure site.

3. Findings

After relating the company rosters to work histories and the various lists mentioned above, as well as the death database to identify persons already deceased, we identified 343 former BFG employees still potentially at risk for developing Angiosarcoma. It is our understanding that 31 of those individuals were subsequently employed by Zeon Chemicals LP.

Our findings indicate that there are still some employees at risk for developing Angiosarcoma and there is an unexpectedly long latency period for the disease development. Although we do not anticipate that there are a large number of undiagnosed cases at this time, it may be appropriate to undertake surveillance testing of at risk individuals.

4. Conclusions

The main conclusion that can be drawn at this point is that Angiosarcoma is not necessarily a disease of the past as previously postulated. We estimate the latency period to be as long as 40 years or more at this point. This challenges some of the widely-held fundamental concepts concerning mechanisms of developing Angiosarcoma. It is important to note that Zeon has

been proactive in maintaining the surveillance program since the late 1980's. Although other companies with legacy BF Goodrich employees previously participated in the surveillance program, Zeon is the only company still actively involved in the program. It is also important to point out that Zeon acquired the elastomers facility that was owned and operated by BF Goodrich. The elastomers facility operation does not involve use or production of vinyl chloride and Zeon never used or produced vinyl chloride. The surveillance program has been continued, in part, to address "legacy" worker exposure from BF Goodrich.

5. Recommendations

As noted previously, routine liver blood tests and older imaging was ineffective at diagnosing Angiosarcoma. AASLD guidelines recommend hepatic ultrasound every 6 months for the early detection of hepatocellular carcinoma in patients with cirrhosis/other at risk patients. We would recommend that at risk workers have surveillance hepatic ultrasounds every 6 months (similar to screening for hepatocellular carcinoma).

We are actively pursuing novel biomarkers for Angiosarcoma and will provide any new information as it develops.

Thus, we are informing the EPA that the latency period for hepatic hemangiosarcoma from vinyl chloride exposure may be much longer than previously thought.

Should you have any questions, please contact me.

Sincerely,



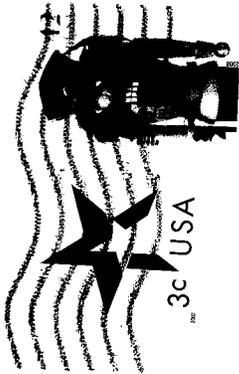
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