June 22, 2017

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National Center for Environmental Assessment
U.S. Environmental Protection Agency
3511 Gillespie Avenue
Nashville, TN 37205

Subject: Information Potentially Relevant to the *Toxicological Review of Chloroprene*

Dear Mr. Davis:

I am writing to provide you two reports that are potentially relevant to EPA's 2010 *Toxicological Review of Chloroprene*. The reports explore cancer incidence among several locations in Louisiana, including the Louisiana zip code where the Denka Performance Elastomers LLC neoprene production facility (i.e., the former DuPont Pontchartrain facility) is located. While the cancer incidence evaluations were conducted to investigate concerns about asbestos exposures, they provide insights that may be relevant to any ongoing and future evaluations of the strength of associations between chloroprene and cancer in humans. I provide the full citations for the two reports later in this letter, but first provide background information that helps explain their relevance.

Background

As you are likely aware, EPA has been investigating air quality impacts of chloroprene emissions from the Denka facility located in Reserve, Louisiana. The facility is in St. John the Baptist Parish, which has a population of approximately 45,000 residents. During EPA's evaluation, the Louisiana Tumor Registry provided Parish-level cancer incidence statistics for the years 2004 to 2013 (see: https://www.epa.gov/sites/production/files/2016-06/documents/ldh-tumor-registry-sjbp-2004-2013.pdf). Those statistics show that most cancers have incidence rates in St. John the Baptist Parish that are lower than or comparable to incidence rates for Louisiana. The principal exceptions being stomach cancer and pancreatic cancer, which had incidence rates in St. John the Baptist Parish at least 20 percent higher than the statewide rates.

Some parties have pointed to the Parish-level cancer incidence data as evidence that theoretical cancer risks calculated for chloroprene emitted by the Denka (and formerly DuPont) facility are overstated. However, such arguments do not account for the fact that most Parish residents live relatively far from the Denka facility and therefore have lower chloroprene exposures. More specifically, EPA's Enforcement and Compliance History Online (ECHO) application estimates that only 1,579 Parish residents live within 1 mile of the Denka facility, which is where dispersion modeling analyses have shown facility-related air quality impacts to be greatest. With more than 95 percent of the St. John the Baptist Parish residents living more than 1 mile from the facility, the Parish-level data clearly do not represent the residential populations with the highest

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chloroprene exposures. Moreover, comparisons of the crude incidence rates do not provide insights on how incidence varies by age, sex, or race – factors of interest when evaluating trends in cancer incidence.

Cancer incidence data at finer spatial scales (e.g., at the zip code level or Census tract level) are much more relevant for investigating health outcomes potentially attributed to facility emissions. A colleague of mine has requested such data from the Louisiana Tumor Registry, but the Registry's data release policy only allows for such data to be released in certain circumstances – such as to researchers with institutional review board approvals. Therefore, I unfortunately do not have direct access to the raw cancer incidence data that would be of greatest interest.

Report on Cancer Incidence from 1991-2000

While performing ongoing research on Denka issues, I recently found a report that provides the finer resolution cancer data, which I have not been able to access directly from the Louisiana Tumor Registry. The document is: *Health Statistics Review for Louisiana Communities that Received Asbestos Contaminated Vermiculite from Libby, Montana*. It was prepared by the Louisiana Department of Health and Hospitals under a cooperative agreement with the Agency for Toxic Substances and Disease Registry (ATSDR). The report does not have a date on the front cover, but the electronic file name suggests it was issued in April 2005. The report is online at: https://www.atsdr.cdc.gov/hac/pha/vermiculitehod/vermiculitehcfinal040805.pdf.

This report examines cancer incidence data relevant to four industrial facilities in Louisiana that received and further processed asbestos contaminated vermiculite ore from the Libby mines. The report presents cancer incidence statistics for the four zip codes where the four facilities operated. One of the facilities of interest—Filter Media Company—operated at 578 West 10th Street in Reserve, Louisiana, which is just under 3 miles northwest of the Denka facility and located in zip code 70084.

I want to call your attention to the fact that the report presents age-adjusted standardized incidence ratios (SIRs) for several cancers for the zip code where Denka is located (see Table 3C on page 16 of the document). This zip code has a population of approximately 7,000 residents, and includes the residential area immediately west of Denka. The SIRs are based on Louisiana Tumor Registry data from a 10-year time frame (1991-2000).

As Table 3C shows, the authors found a modest (SIR = 1.233, 95% confidence interval = 1.14-1.38) statistically significant increase in all cancers combined for the entire zip code population and an approximately two-fold (SIR = 2.084, 95% confidence interval = 1.29-3.06) statistically significant increase in lung cancer among black females. The latter observation is particularly intriguing because (a) the population within 1 mile of the Denka facility is 96 percent African-American (according to ECHO) and (b) lung cancer in female mice accounted for the greatest portion of the unit risk factor published in the *Toxicological Review of Chloroprene*. A statistically significant increase in lung cancer incidence was also observed among black males, but to a lesser extent (SIR = 1.489, 95% confidence interval = 1.01-2.06); and a similar pattern of elevated incidence among black females and black males was observed for cancer of combined respiratory organs.

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It is interesting to see how this localized area with a much smaller population has statistically significant increased rates of certain cancers, which were not detected based on the Parish-wide data. Of the four zip codes considered in this analysis, statistically significant increases in lung cancer and respiratory cancers were only observed in the zip code nearest Denka.

Report on Cancer Incidence from 1988-2002

After locating the 2005 report, I found a second report from 2008 that addresses the same topic, but considers cancer incidence data for a different time frame. The document is: *Health Consultation: Cancer Statistics Review for Louisiana Communities that Received Asbestos Containing Vermiculite from Libby, Montana.* This document was also prepared by the Louisiana Department of Health and Hospitals under an ATSDR cooperative agreement and is online at: https://www.atsdr.cdc.gov/HAC/pha/CancerStatisticsforLACommunities/Cancer%20Statistics%20for%20LA%20Communities%20UPDATED%20HC%2012-10-08.pdf.

This report and the 2005 document are similar in that both reports examine cancer incidence for four zip codes based on Louisiana Tumor Registry data. However, the 2008 report presents cancer incidence data for a 15-year time frame (1988-2002) and provides additional statistics with different standardization procedures. Nonetheless, many of the same concerns inferred from the 2005 report are echoed in the 2008 report: an increase in lung cancer incidence among black females that appears to be nearly statistically significant (SIR = 1.56, 95% confidence interval = 0.91-2.50) and an increase in all cancers combined in zip code 70084.

Implications

Of course, inferences of causation cannot be drawn from these cancer incidence data alone, especially in the absence of underlying exposure data. Additionally, the observed increase in lung cancer among blacks could result from many factors, such as environmental exposures to any number of carcinogens (e.g., chloroprene, asbestos[1], chemicals emitted by other nearby industrial facilities), smoking[2], dietary exposures, and genetics. At the very least, the data in these reports can be used to counter arguments that EPA receives about the implications of Parish-wide cancer statistics.

That all being said, it is my hope that awareness of these reports prompts further investigation. The two studies investigate cancer through 2002, and 12 more years of cancer incidence data (2003-2014) are currently available from the Louisiana Tumor Registry. Examination of the more recent data would more fully account for latency effects as the main production operations

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[1] While the Louisiana studies were part of a much larger ATSDR study of former vermiculite processing facilities nationwide, zip code 70084 was the only area that showed statistically significant increases in total cancer incidence and in lung cancer incidence. This observation is gleaned from ATSDR's peer-reviewed publication on its vermiculite research (see: K. Horton, et al., A Review of the Federal Government's Health Activities in Response to Asbestos-Contaminated Ore Found in Libby, Montana, Inhalation Toxicology, 18:925-940; the section on "U.S. Health Statistics Reviews" presents the cancer mortality and cancer incidence evaluations, with other study sites shown in Table 9 [mortality] and Table 10 [incidence] and the Louisiana data presented in the text.)

[2] Data from the Louisiana Environmental Public Health Tracking Network indicate that smoking prevalence among adults in St. John the Baptist Parish is lower than the statewide average, but smoking data are not readily available at finer spatial scales.

at the former DuPont facility did not begin until circa 1970. Additionally, the two reports referenced in this letter only examined certain asbestos-related cancers, and further study could consider a much broader range of cancers.

While it is possible that the cancer incidence data from the two reports identified an unstable trend and cancer incidence has since returned to expected levels, it is also possible that cancer incidence in the neighborhoods of greatest interest remains elevated.

Please do not hesitate to contact me at 781-674-7312 or john.wilhelmi@erg.com if you would like to discuss this further.

Sincerely,

John Wilhelmi
Vice President

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