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Affidavit of David Garabrant, MD, MPH

Regarding Kelvin Khieu, et al., v Age Refining, Inc., et al.

March 19, 2010

BEFORE ME, the undersigned authority did personally appear David H. Garabrant, M.D., M.P.H., M.S., F.A.C.O.E.M., F.A.C.P.M., who upon being by me first duly sworn, did depose and say as follows:

1. My name is David H. Garabrant, M.D., M.P.H., M.S., F.A.C.O.E.M., F.A.C.P.M. I am over 21 years of age and I am competent to make this affidavit. The facts contained in this affidavit are true and correct and within my personal knowledge.

2. I am a licensed physician specializing in occupational medicine. I am board certified in both occupational medicine and internal medicine. I am qualified as a specialist in the fields of occupational medicine and internal medicine and in the field of epidemiology, especially as it relates to the study of diseases related to exposures to chemical agents. I am Emeritus Professor of Occupational Medicine and Epidemiology at the University of Michigan School of Public Health, and I also hold an appointment as Emeritus Associate Professor in the Department of Emergency Medicine, University of Michigan School of Medicine. I am engaged full-time in research in occupational epidemiology, the training and education of physicians and graduate students in occupational health, and in the clinical practice of occupational medicine.

3. I received my undergraduate degree with high honors in chemical engineering from Tufts University, Medford, Massachusetts in 1972. I received my M.D. degree from

Tufts University School of Medicine, Boston, in 1976. From 1976-77, I served as an intern in internal medicine at Georgetown University Hospital in Washington, D.C. and from 1977-78, I served as a fellow in medical ambulatory care at that same institution. From 1978-80, I served as a resident in occupational medicine at the Harvard School of Public Health, Boston, and received the Master of Public Health degree in 1979 and the Master of Science in Physiology degree in 1980 from that institution. From 1980-81, I served as senior resident in internal medicine at University Hospital, Boston.

4. Upon completion of my training in 1981, I joined the faculty of the University of Southern California School of Medicine, where I was engaged in research in occupational cancer epidemiology and in the practice of occupational medicine until 1988, when I joined the faculty of the University of Michigan. While I have been on the faculty of the University of Michigan, I have served as Director of Occupational Medicine (1988-94), head of the Occupational Health Program (1992-95), Director of the Center for Occupational Health and Safety Engineering (1990-95), Director of the Occupational & Environmental Epidemiology program (2001-2007), and Founding Director of the Risk Science Center (2003-present). My research has focused for the past 25 years on the long term health effects of chemicals on humans and I have published over 200 research articles, book chapters, and abstracts related to this area. A copy of my curriculum vitae is attached.

5. I have served on the Editorial Board of the Journal of Occupational Medicine and currently serve as a reviewer of scientific papers for a number of other journals, including Environmental Health Perspectives, Journal of the National Cancer

Institute, Cancer Causes and Control, Cancer Epidemiology Biomarkers and Prevention, American Journal of Epidemiology, and Cancer Research. I was appointed to membership on the Safety and Occupational Health Study Section of the National Institutes of Health (NIH) in 1992 and served on that Study Section until 1996, having been appointed by Secretary of HHS Donna Shalala as Chair for the 1995-96 year. In that position I served as a peer-reviewer of research proposals for the NIH. I am a Fellow of the American College of Occupational and Environmental Medicine (FACOEM) and a Fellow the American College of Preventive Medicine (FACPM). I am currently a member of a number of professional organizations, including the Society for Epidemiologic Research, the International Epidemiological Association, the Society for Risk Analysis, and the American College of Occupational and Environmental Medicine. I received the Excellence in Research Award from the University of Michigan School of Public Health in 2006 and the Research Excellence Award from the Risk Science Center at the University of Michigan School of Public Health in 2007.

6. I have read the deposition of Steven D. Gore, M.D., dated March 2, 2010 and attached exhibits. I have been asked to provide opinions to a reasonable degree of scientific certainty on the extent to which Dr. Gore has appropriately used reliable scientific methods to make claims about disease causation in this case. It is my understanding that Dr. Gore claims Mr. Khieu's acute myeloid leukemia (AML) was caused by his exposure to products made by Berryman and Rust-Oleum.

7. I conclude that Dr. Gore's opinions cannot be viewed as scientifically reliable or relevant to the facts of the Khieu case for the following reasons.

8. Dr. Gore has failed to consider relevant scientific evidence regarding the relationship between benzene exposure and risk of AML. He has chosen to consider (see Gore exhibit 8) only the subset of evidence that is favorable to his opinions (Hayes et al. 1997;Adegoke et al. 2003;Glass et al. 2003;Glass et al. 2005;Glass et al. 2000;Glass et al. 2006;Patel et al. 2004). He fails to consider an even larger body of reliable scientific evidence that does not support his opinions (Australian Institute of Petroleum et al. 2007;Bloemen et al. 2004;Bond et al. 1986;Collins et al. 2003;Consonni et al. 1999;Costantini et al. 2003;Guenel et al. 2002;Paxton et al. 1994b;Paxton et al. 1994a;Rushton and Romaniuk 1997;Schnatter 2004;Schnatter et al. 1996a;Schnatter et al. 1996b;Schnatter et al. 1996c;Tsai et al. 1983;Wong and Raabe 1995;Wong et al. 2009;Rinsky et al. 1987). The methods of causal inference require that Dr. Gore systematically collect, summarize, and analyze the results of scientific studies in order to make reliable conclusions about disease causation. He has not done so. Because of this deficiency, Dr. Gore's claims regarding general causation are biased and unreliable.

9. Dr. Gore has reached his opinion that Mr. Khieu's AML was caused by exposure to benzene-related products without any knowledge of the amount of benzene exposure Mr. Khieu received from using either Berryman or Rust-Oleum products. As Dr. Gore acknowledges, the risk of AML is related to the amount of benzene exposure. So, while Dr. Gore agrees that AML risk is related to benzene dose, he has no knowledge of Mr. Khieu's dose. Without any foundation he concludes Mr. Khieu's exposure was adequate to cause his AML. This conclusion is not based on scientific reasoning. It is guesswork that has no valid scientific basis and has no connection to

the facts of this case. Because of this deficiency, Dr. Gore's claims regarding specific causation are unreliable.

10. Dr. Gore has failed to consider the substantial body of scientific evidence that shows there is a clear temporal relationship between benzene exposure and risk of AML (Finkelstein 2000;Glass et al. 2004;Hayes et al. 1997;Richardson 2008;Schnatter et al. 1996c;Silver et al. 2002;Wong et al. 2009). These studies show that benzene exposures more than 15 years prior to the diagnosis of AML play no role in its causation. There are no studies to the contrary. Dr. Gore fails to consider this critical issue and simply concludes that benzene exposure irrespective of when it occurred caused Mr. Khieu's AML. Dr. Gore has made no attempt to determine when Mr. Khieu's alleged benzene exposure occurred or how much exposure he had in various time periods prior to diagnosis. He has not considered whether Mr. Khieu's exposures to various benzene-related products occurred during the period when they might have played a causal role or whether they occurred during periods when they were of no etiologic relevance. Dr. Gore's opinions have no connection to the facts of this case. Because of this deficiency, Dr. Gore's claims regarding specific causation are unreliable.

11. Dr. Gore's methods do not allow him to reach his conclusions. Dr. Gore (at page 88 of his deposition) selects a dose-response relationship from the Rinsky paper (Rinsky et al. 2002) (Gore deposition exhibit 12) that shows a 2.3% increase in risk of leukemia for each ppm-year of benzene exposure. He fails to mention that Rinsky also provides an alternative estimate of dose-response that is equally reliable. The alternative dose-response estimate is a 0.52% increase in risk of leukemia for each ppm-year of

benzene exposure (see table V of Rinsky). Dr. Gore provides no justification for choosing either value and has simply chosen the value that shows the biggest risk which is most favorable to his opinions. This sort of picking and choosing of results is inherently unscientific and leads to biased conclusions.

12. The Rinsky value of a 2.3% increase in risk of leukemia per ppm-year means that Mr. Khieu must have had at least 43.5 ppm-years of exposure in order to double his risk of leukemia. (In other words, 2.3% x 43.5 ppm-years = 100% increased risk, or a doubling of risk.) Since Dr. Gore has no idea how much benzene Mr. Khieu was exposed to, he has no idea how much increased risk resulted from his exposure. Lacking this, Dr. Gore cannot say that Mr. Khieu's AML was more likely than not caused by benzene. If, in fact, Mr. Khieu had only 0.1 ppm-years of exposure to benzene, Dr. Gore's method would lead to a conclusion of a 0.23% increase in risk, certainly not enough to conclude this more likely than not caused his AML.

13. Using Dr. Gore's method and Rinsky's equally reliable value of a 0.52% increase in risk of leukemia for each ppm-year of benzene exposure leads to a conclusion that Mr. Khieu would have to have had 192 ppm-years of benzene exposure in order to double his risk of leukemia (0.52% x 192 ppm-years = 100%). Thus, Dr. Gore's method dictates that only under the circumstance where Mr. Khieu had at least 43 to 192 ppm-years of benzene exposure can he say that Mr. Khieu's AML was more likely than not caused by benzene exposure. Since Dr. Gore has no idea how much exposure Mr. Khieu had, he can reach no such conclusion. Because of this deficiency, Dr. Gore's claims regarding specific causation are unreliable.

14. The scientific literature, when collected, summarized, and analyzed carefully indicates that AML has been causally associated with cumulative benzene exposures at and above 40-200 ppm-years (Hayes et al. 1997;Adegoke et al. 2003;Glass et al. 2003;Glass et al. 2005;Glass et al. 2000;Glass et al. 2006;Patel et al. 2004;Australian Institute of Petroleum et al. 2007;Bloemen et al. 2004;Bond et al. 1986;Collins et al. 2003;Consonni et al. 1999;Costantini et al. 2003;Guenel et al. 2002;Paxton et al. 1994b;Paxton et al. 1994a;Rushton and Romaniuk 1997;Schnatter 2004;Schnatter et al. 1996a;Schnatter et al. 1996b;Schnatter et al. 1996c;Tsai et al. 1983;Wong and Raabe 1995;Wong et al. 2009;Rinsky et al. 1987). Furthermore, there are numerous studies of humans exposed to benzene at cumulative exposures below 40 ppm-yrs that show no increased risk of AML. The epidemiologic literature, when analyzed properly and when including all relevant studies, does not support a conclusion that benzene exposures below 40 ppm-yrs place people at increased risk of AML. The scientific literature, when collected, summarized, and analyzed carefully also indicates that benzene exposures more than 15 years prior to diagnosis play no role in the causation of AML (Finkelstein 2000;Glass et al. 2004;Hayes et al. 1997;Richardson 2008;Schnatter et al. 1996c;Silver et al. 2002;Wong et al. 2009).

15. I conclude that Dr. Gore's opinions regarding general causation and specific causation lack sufficient scientific support to be considered reliable in the scientific community. Dr. Gore demonstrates a fundamental lack of knowledge of the scientific literature and of the methods for making claims about general causation. His methods for making specific causation claims are flawed and demonstrate logical contradictions. His conclusions have no basis in the facts of this case, do not rest on a reliable

foundation, and are not relevant to the issues at hand. Because of the lack of scientific methodology and lack of relevance to the facts of this case, his claims regarding the role of benzene exposure in the causation of Mr. Khieu's AML should be considered invalid and unreliable.

FURTHER AFFIANT SAITH NOT: This 19th day of March, 2010

David H. Garabrant, M.D., M.P.H., M.S., F.A.C.O.E.M., F.A.C.P.M.

Sworn to and subscribed before me on this the 19th day of March, 2010.

Notary Public, State of Michigan

My Commission Expires: 12/25/2013

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