

CALIFORNIA TESTIMONY

Gary M. Marsh, Ph.D.

April 26, 2007

Good morning (afternoon). My name is Gary Marsh. I am Professor of Biostatistics and Director of the Center for Occupational Biostatistics and Epidemiology at the University of Pittsburgh, Graduate School of Public Health. Since 1978, I have designed and conducted more than 25 occupational epidemiology studies of health effects from various workplace exposures. A major focus of my research has been the evaluation of human health effects from formaldehyde exposure.

Most of the epidemiology evidence for assessing human cancer risk from formaldehyde exposure comes from 3 large cohort studies of industrial workers: one in Britain and 2 in the U.S. by the National Institute for Occupational Safety and Health and the National Cancer Institute or NCI. In 2004, the International Agency for Research on Cancer or IARC reclassified formaldehyde as carcinogenic in humans based largely on evidence from the NCI study that formaldehyde causes nasopharyngeal cancer or NPC. The NCI finding was based on only 8 NPC deaths among exposed workers, an increase of only 2 NPC deaths from IARC's 1995 classification of formaldehyde as a probable carcinogen. Only one NPC death was observed in the other two cohort studies combined. The evidence that formaldehyde causes other cancers, such as leukemia, was deemed non-sufficient by IARC.

Recent literature reviews and several reanalyses of the NCI cohort data conducted by my research group have cast considerable doubt on the validity of NCI's findings and IARC's reclassification. For example, we showed that NCI's findings for NPC were driven entirely by an anomalous finding in 1 of 10 study plants, termed Plant 1. Six of the 8 NPC deaths occurred among exposed workers in this single plant, resulting in a statistically significant 10-fold excess

in NPC, compared with a 35% deficit in NPC deaths among exposed workers in the remaining 9 plants.

We have also conducted an independent and expanded cohort study of Plant 1. We concluded in our latest published report that the anomalous finding for NPC in Plant 1 may be related to previous work in the extensive, local metal industry. These jobs entailed possible exposures to several risk factors for NPC, including sulfuric acid mists, mineral acid, metal dust and heat.

In summary, our reanalyses of the NCI cohort data do not support their suggestion of a causal association with formaldehyde and NPC. I believe that the 2004 decision by IARC to reclassify formaldehyde as a Group 1 substance was premature considering: the small number of NPC deaths, the missing evidence from the British and NIOSH cohort studies, the anomalous finding for NPC in Plant 1, and our new evidence that the NPC risk in the influential Plant 1 may be related to previous work in the metal industry.

Thank you for your time and attention.

###