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**REGION 8**
**U.S. ENVIRONMENTAL PROTECTION AGENCY**

**BEFORE THE COMMITTEE ON**
**ENVIRONMENT AND PUBLIC WORKS**
**UNITED STATES SENATE**

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Good morning Madame Chairman and members of the Committee. I am Captain Aubrey K. Miller, MD, MPH, a physician in the U.S. Public Health Service and a Senior Medical Officer and Toxicologist for the U.S. Environmental Protection Agency (EPA), Region 8 Office. In addition to my experiences prior to working for the federal government caring for patients suffering from asbestos-related disease as a Board Certified occupational physician., over the last eight years my work has been directly focused on improving our understanding of the health effects associated with asbestos exposure in Libby, Montana. Further, the early activities of my involvement, while employed in the Department of Health and Human Services (DHHS) Region 8 Office, were focused on strengthening the health care infrastructure of the Libby community to better care for those affected by this terrible tragedy. Thank you for the opportunity to discuss EPA's perspective and progress in understanding the current state of the science concerning the human health effects associated with exposure to asbestos.

## DEFINITIONS OF ASBESTOS

Asbestos is a general term for fibrous silicate minerals, including minerals in the amphibole and serpentine classes. A 1971 National Academy of Sciences (NAS) report distinguished the general term "asbestos" and commercial varieties as follows:

> "Asbestos" is a generic term for a number of hydrated silicates that, when crushed or processed, separate into flexible fibers made up of fibrils. [footnote omitted]. Although there are many asbestos minerals, only six are of commercial importance: Chrysotile, a tubular serpentine mineral, accounts for 95% of the world's production; the others, all amphiboles, are amosite, crocidolite, anthophyllite, tremolite, and actinolite. (NAS 1971).

With respect to a definition of asbestos which is most relevant to our current understanding of health effects, the Centers for Disease Control, National Institute for Occupational Safety and Health (NIOSH), in 1990 testimony before the Occupational Safety and Health Administration (OSHA), and reiterated again in 2001, broadened its science-based definition of "asbestos" as a result of concerns about the microscopic identification of the six commercial forms of asbestos minerals. The six minerals can also occur in a non-fibrous (so-called "massive") form. The non-fibrous mineral forms of the six asbestos minerals can be found geologically in the same ore deposits in which the fibrous asbestos minerals occur or in deposits where other commercially exploited minerals are mined (e.g., industrial grade talc). "Cleavage fragments," small mineral shards that are often microscopically indistinguishable from typical asbestos fibers, can be generated from the non-fibrous forms of the asbestos minerals during their handling, crushing, or processing, and these "cleavage fragments" are often microscopically indistinguishable from typical asbestos fibers of the (fibrous) minerals.

The elemental composition of the six asbestos minerals can vary slightly as a result of geological conditions such as pressure, temperature, or proximity of other minerals. Recognizing these variations in elemental composition, NIOSH stated that the six asbestos minerals can be defined by their "solid-solution" mineral series. For example, the mineral series tremolite-ferroactinolite contains the asbestos mineral actinolite. These mineral series are considered solid-solutions in which cations (i.e., sodium, calcium, magnesium, iron, etc.) are replaced by other cations which can affect the elemental composition of the mineral without significantly altering the structure.

NIOSH bases this expanded "asbestos" definition – encompassing the entire solid-solution mineral series for each of the six currently regulated asbestos minerals and including cleavage fragments from the non-fibrous forms of these minerals – on scientific evidence from cellular and animal studies suggesting that dimension, specifically length and diameter, as well as durability, may be more critical factors in causing disease than chemical or elemental composition [CDC 2001]. EPA recognizes that there is considerable controversy regarding the toxicity of fiber-like cleavage fragments, and additional research will help to improve understanding of important health determinants.

**WHERE ASBESTOS OCCURS NATURALLY**

As a natural mineral, serpentine and amphibole deposits may be present as natural outcroppings. The fibers present may exhibit a range of mineral forms and morphologies. There are many communities where these minerals are present in native soils. Community members have been exposed to elevated ambient levels of these materials in outdoor air, to materials brought into the home (e.g., fibrous clays used for interior wall coverings), and during outside activities like farming. Residents in communities exhibit health effects similar to those noted in the occupation cohorts including pleural fibrosis, asbestosis, lung cancer, and mesothelioma. These deposits in some cases include minerals which were commercially mined and milled (chrysotile and crocidolite). In addition, health effects have also been seen in communities that are exposed environmentally to actinolite, tremolite, and erionite. Erionite, which is not asbestos, represents a third class of silicate minerals, zeolites or framework silicates. EPA is currently evaluating sites impacted by natural outcroppings of silicate minerals including actinolite-tremolite, anthopholyte, chrysotile, anthopholyte and erionite.

**HEALTH EFFECTS**

Asbestos has been classified as "carcinogenic to humans" by EPA (1986) and as a "Class A" carcinogen by the World Health Organization. Although mesothelioma and lung cancer are the malignancies most consistently and strongly associated with such fiber exposures, cancers of the gastrointestinal tract (Jarvholm et al. 1984; Kolonel et al. 1985; Sanden, Naslund, & Jarvholm 1985), larynx (Blot et al. 1980; Burch et al. 1981; von Bittersohl 1977; Rubino et al. 1979), pancreas, (Selikoff and Seidman 1981), and ovary (Acheson et al. 1982; Wignall and Fos 1982) have also been identified. A recent review by the National Academy of Sciences Institute of Medicine concluded there was sufficient evidence to infer a causal association for laryngeal cancer; but, the evidence for pharyngeal, stomach and colorectal cancers is only suggestive, not sufficient (NAS 2006).

The noncancerous conditions related to asbestos exposure may be more prevalent than cancer and just as debilitating and lethal. Exposure to asbestos fibers via inhalation is associated with noncancer diseases to the pleura and lungs. The American Thoracic Society (ATS) recently defined nonmalignant asbestos-related disease to include the conditions of interstitial pulmonary fibrosis (asbestosis), benign asbestos-related pleural effusions, pleural fibrosis (both circumscribed fibrosis, or plaques, and diffuse fibrosis), and obstruction of pulmonary airflow

(*ATS Documents* 2004). Rounded atelectasis, a benign form of subpleural lung collapse, has also been associated with asbestos exposure (Terra-Filho et al. 2003). Asbestos diseases have latency periods ranging from a year to several decades, depending on the health endpoint of concern. The latency varies for nonmalignant effects, from approximately a year for pleural effusion to several years for asbestosis (Cugell and Kamp 2004). Once established, asbestos-related nonmalignant interstitial and pleural disorders may remain static or progress in severity in the absence of continued exposure, but they rarely regress (Becklake 1994). Asbestos-related pleural effects are often found in individuals without occupational exposures and even asbestosis has been noted in some communities where materials may have been brought into homes (Luce et al. 2000; Luce et al., 2004; Bernardini et al. 2003; Luo et al. 2003; Baumann et al. 2007; Metintas et al. 2003).

There is a scientific debate concerning the differences in the extent of disease caused by different fiber types and sizes. Some of these differences may be due to the physical and chemical properties of the different fiber types. For example, several studies suggest that amphibole asbestos types (tremolite, amosite, and especially crocidolite) may be more harmful than chrysotile, particularly for mesothelioma. Other data indicate that fiber size dimensions (length and diameter) are important factors for cancer-causing potential. Some data indicate that fibers with lengths greater than 5.0 µm are more likely to cause injury than fibers with lengths less than 2.5 µm. (1 µm is about 1/25,000 of an inch). Additional data indicate that short fibers can contribute to injury. This appears to be true for mesothelioma, lung cancer, and asbestosis. However, fibers thicker than 3.0 µm are of lesser concern, because they appear to have less of a chance for penetrating to the lower regions of the lung. (ATSDR Tox Profile for Asbestos (2001), p. 6.)

Because of this uncertainty, more work needs to be done to understand which of the many forms of asbestos or asbestos-like fibers associated with adverse health effects require additional study. To this end, EPA in engaged in an asbestos toxicology research program.

## EPA'S HEALTH ASSESSMENT ACTIVITIES FOR ASBESTOS AND SILICATE MINERAL FIBERS

EPA's Integrated Risk Information System (IRIS) database provides health assessments and tools for quantitative risk characterization which represent a consensus agency position. The current asbestos assessment was posted on IRIS in 1988 and provides cancer risk estimates based on a meta-analysis of 14 studies of workers exposed to commercial asbestos (primarily chrysotile, amosite, and crocidolite). The risk estimate represents both lung cancer and mesothelioma risk. At that time, EPA discussed many of the complexities regarding the health effects of asbestos, including: mineral form, fiber dimension, and fiber morphology. However, the exposure data available in the epidemiologic literature did not allow for refinement of the cancer risk estimate based on these factors (EPA 1986).

In 1991, the EPA published a Health Assessment on vermiculite, reviewing the studies available at that time on workers exposed to amphibole asbestos-contaminated vermiculite (Libby, MT and the Enoree region of South Carolina). The document concluded that weight of evidence for asbestos-contaminated vermiculite is sufficient to show a causal relationship for increased lung cancer in miners and millers (EPA 1991).

In preparation to update the asbestos health assessment, EPA held several conferences regarding asbestos toxicity, convening national experts on the mechanisms of fiber toxicity: “Asbestos Health Effects Conference” in 2001 and “Mechanisms of Toxicity Workshop” in 2003. In 2004 EPA initiated a health assessment focused on the noncancer effects of asbestos. In February 2006, EPA announced that it would begin a cancer health assessment for asbestos as well. In expectation of updating the cancer assessment, EPA has coordinated with NIOSH to reanalyze historical worker cohorts with state of the art exposure measurements for a key chrysotile study (Dement et al. 1994). EPA is continuing this collaboration and is working with nationally recognized experts from academia to conduct similar reanalysis, using state-of-the-art exposure measurements for key studies of workers exposed to amosite (Levin et al. 1998; Seidman et al. 1986).

As part of its ongoing activities, EPA is developing a set of research projects to assess the dosimetric and toxicologic effects of amphibole fiber-containing vermiculite ore from Libby, Montana. The objective of these projects is to address data gaps and scientific uncertainty for the quantitative characterization of health risks from exposure to the Libby amphibole and other asbestos-form fibers. The research plan for these projects was initiated from the recommendations of a multi-agency meeting in January 2007 and is now being revised in response to external peer review. Funding has been approved and research is anticipated to commence by July 2007. The research involves the following assessment studies:

- Libby Amphibole RfC Development;
- Libby Amphibole Cancer Assessment;

- Fiber Size Distribution in Libby Vermiculite;
- Dosimetry Model Development and Simulation Studies;
- *In Vitro* Dissolution Assays;
- *In Vitro* Toxicity Endpoints;
- Comparative Toxicology In Mice and Rats;
- Inhalation Toxicology In Rats;
- New Epidemiologic Information From Libby, Montana and other cohorts; and
- Interim Risk Methodology For Quantification Of Cancer Risk From Inhalation Exposure to Asbestos.

**EXPOSURE and EXPOSURE MITIGATION**

Over the past several years, EPA conducted research designed to reduce uncertainties in asbestos exposure scenarios. This work was a collaboration among ORD's National Exposure Research Laboratory, National Risk Management Research Laboratory, and National Health and Environmental Effects Research Laboratory. A report addressing the state-of-the-science for various exposure scenarios was completed in 2006. Additionally, a database of exposures, doses, and physical-chemical properties has been developed for more than 40 asbestos fibers. An air sampling study was also completed, as was an analysis of the Comprehensive Soil Method.

Workplace exposure mitigation practices have been in place for decades. To minimize exposure from building demolition, EPA has been working on an alternative to the National Emissions Standards for Hazardous Air Pollutants (NESHAP) method for demolition of buildings containing asbestos. Also, the California Air Resources Board and the Agency for Toxic Substances and Disease Registry (ATSDR) provide advice for limiting exposure to naturally occurring asbestos.

**CLOSING**

EPA will continue its efforts to increase our understanding on the health effects from asbestos and mineral fiber exposure. These efforts by EPA and those of its Federal, state, and local partners will provide needed health effects data and help inform Federal, state, and local decision making on how best to reduce and mitigate potential exposure. I will be pleased to answer any questions that the Committee may have on these issues.

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