

the Royal Navy (19) reported cases of mesothelioma among shipyard workers at the Royal Navy dockyard in Devonport, in trades which did not directly involve worker exposure to asbestos, but in which there had been occasional opportunity for exposure merely by virtue of working in the same area. This original finding has been widely confirmed and numerous cases of mesothelioma have since been reported in former shipyard workers (Whitwell and Hawcliffe, 1970 (50)); McEwan et al. 1970 (37)); Stumphius, 1971 (46); Greenberg and Davies, 1974, (16). Studies of populations of current shipyard workers have shown much radiological evidence of asbestos abnormalities among workers in trades only indirectly exposed to asbestos in the yards (Sheers and Templeton, 1968 (44); Fletcher, 1972, (18)).

Further, evidence has indicated that asbestos also acts as a lung carcinogen at levels much below those which will produce asbestosis. Two surveys of shipyard workers who had X-ray evidence of pleural plaques, but generally not of pulmonary fibrosis, showed a 2.5-fold excess risk of death from lung cancer and high risk of mesothelioma (Fletcher, 1972 (18); Edge, 1975 (8)). In a study of the mortality experience of a large U.S. asbestos products manufacturing facility, it was found that workers in low dust areas, with a minimum risk of death from asbestosis, had the same high risk of death from various cancers as workers in dustier areas (Nicholson, 1975, (35)).

It is extremely difficult, if not impossible, to document brief exposures reported to have occurred 20 or more years before the onset of symptoms. To determine the type and extent of non-occupational exposure, the investigator must generally rely on relatives or persons other than the exposed patient for exposure history.

Much of the foregoing information on asbestos-related diseases was prepared by the Occupational Safety and Health Administration (OSHA) and published at 40 FR 47651, October 9, 1975, "Occupational Exposure to Asbestos" has been helpful in preparing this proposal (6)).

CONSUMER EXPOSURE

Reports of the hazard, or potential for hazard, from exposure to asbestos resulting from use of asbestos-containing consumer products are very limited. The only known quantitative study of asbestos levels in products regulated by this Commission was reported by Rohl, et al (1975 (36)), of asbestos fiber concentrations measured during the use of consumer speckling patching and taping compounds. This study indicated that airborne fiber concentrations, exceeding the interim OSHA allowable excursion exposure level, were detected during application and cleanup operations. Fibers were detected in adjacent rooms during mixing operations and it was reported that . . . significant concentrations of asbestos remained suspended and could pervade living quarters for a considerable

duration of time . . . The authors suggest that the use of speckling and other patching compounds (in mixing, and sanding and cleanup operations) may expose the user and other members of the household to . . . significant concentrations of asbestos."

Asbestos in the household presents a great risk due to the presence in the household of persons, such as children, who may be particularly vulnerable to carcinogens. It is generally observed that, because of the long latency period, exposure to inhalable asbestos in the home can be life-shortening for children. In this connection, Dr. Paul Kotin of the Johns-Manville Company, stated to an OSHA Advisory Committee that in his laboratory experience, cancer can be most readily induced in the young (14). This point was further clarified at a briefing before the Commission on June 9, 1977 during which Dr. Kotin stated his belief that the young are doubly vulnerable to carcinogens—first, because of a long lifetime ahead and secondly because young children grow at a more rapid rate than adolescents. Thus, he explained, "A rapidly dividing cell, a cell which has a turnover time shorter when compared to another cell, is perhaps more likely to be subject to the action of a carcinogen."

The Commission concludes that exposure to asbestos from either patching compounds or artificial emberizing materials presents an unreasonable risk of injury sufficient that either product standing alone should be banned. The Commission also notes that consumers are exposed to asbestos from sources other than the products proposed for banning. The asbestos fibers are present in the general environment has been demonstrated by studies such as those by Huff (21); Solikoff, and Harwood (38). Consumers who are exposed to asbestos fibers from artificial embers and ash and patching compounds thus receive additional doses of asbestos and can be presumed to face a greater risk than members of the population who are not so exposed, and a greater cumulative risk than if no asbestos were present in the general environment.

A bibliography of additional scientific and medical literature reviewed by the Commission is noted below and an annotated bibliography is available for review in the Office of the Secretary.

"THRESHOLD" LIMIT

Because of the variability of individual response to carcinogens and other factors, the concept of a "no effect" or "threshold level" of exposure may have little real significance on the basis of existing knowledge. While some level, below which exposure to a carcinogen does not cause cancer, may conceivably exist for any one individual, other individuals may have cancer induced by doses so low as to be effectively zero (38).

In the Proceedings of the Nineteenth Meeting of the Interagency Collaborative Group on Environmental Carcinogenesis devoted to Threshold Evaluated held at the National Institute on August

14, 1975 (23), Dr. H. P. Kraybill, Chairman, states that:

Investigators in the field of carcinogenesis have doubted the existence of a threshold for a carcinogen or at least have maintained that there are no acceptable procedures for assessment of a safe-dose for a carcinogen (i.e. threshold). Thus, it has been concluded that it is not feasible to prove or disprove the presence or absence of a threshold-dose through downward extrapolation from the dose-response curve in regions of detectably significant dosage. The conservatism in this direction is prompted by certain realizations as to the self-replicating nature of the cancer cell, the possible existence of irreversible effects, the aspects of lasting alteration induced by a tumor-producing event, the perpetuation of the neoplastic lesion after the original inducer has disappeared from the milieu, and finally, the possibility of cancer induction from a mutation in a somatic cell.

These theoretical concepts have a bearing on the asbestos issue, particularly as the question of the existence, or nonexistence, of a threshold level of carcinogenic effect. A "no effect" level theoretically may exist, but it has not been demonstrated. Therefore, there is no known threshold level below which exposure to respirable free-form asbestos would be considered safe.

OTHER FEDERAL AGENCY ACTIONS TO REGULATE EXPOSURE TO ASBESTOS

The Occupational Safety and Health Administration of the Department of Labor (OSHA), the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) each has a responsibility to regulate exposure to asbestos.

OSHA regulates exposure to asbestos by workers in all industrial and commercial settings except agriculture. The regulation (29 CFR 1910.1001) states that the 8-hour time-weighted average airborne concentrations of asbestos fibers to which any employee may be exposed shall not exceed two fibers, longer than 5 micrometers, per cubic centimeter of air. In 1975, OSHA proposed an amendment to lower exposure to 5 fibers per cubic centimeter of breathing air. An OSHA proposal to regulate exposure by workers in the building construction industries is expected to be ready for publication within the next few months.

FDA has banned the use of asbestos in filters used in the formulation of parenteral drugs (21 CFR 311.40(j)) and, prior to the establishment of the Consumer Product Safety Commission, banned the use of asbestos in fabric used for general wearing apparel. (16 CFR 1500.17(a) (7)).

EPA regulates asbestos which is released into the air and into the water. These regulations (40 CFR 61, 427, 436) do not set standards for allowable amounts of asbestos in the breathing air but rather minimize or eliminate emissions from industrial locations. These regulations specifically prohibit the presence of asbestos in emissions from plants manufacturing materials for use in building roadways and in manufacturing items such as cloth, textiles, cement, fireproofing and friction products, paper, felt, floor materials, paints, adhesives,