COMMENTS OF MEDICAL DEPARTMENT ON WALL STREET JOURNAL ARTICLE,

"PERSISTENT PCB's"

The Wall Street Journal article contains nothing new. It is an "update" or review of published and unpublished data, opinions from experts (such as Barry Commoner) and, for the most part, realistic--or at least expected--views of personnel in government agencies.

1. Effects - Animals & Humans

Skin and liver effects have been demonstrated in several species of animals. Similar, but less severe effects may have occurred in humans as a result of accidental industrial exposures, but these have not been well documented. Certainly, there has been no problem in Monsanto.

The only valid and comprehensive study of serious effects in humans relates to the Japanese incident where about 1000 people became ill after consuming ricebran oil contaminated with PCB's.

The referenced study by Kimbrough reporting liver cancer in rats from Aroclor 1260 is in direct contrast to the Monsanto sponsored studies at Industrial Bio-Test Laboratories which found no increased liver cancer incidence in life-time rat studies with Aroclors 1242, 1254, and 1260. (A consultant pathologist for Monsanto will examine the liver tissue slides from the Kimbrough rats the week of October 13 to get an unbiased evaluation of the observed liver damage in that study.)

Reference is made to the recent monkey studies by Allen at the Wisconsin Primate Center. Our toxicologists visited Dr. J. Allen at the University of Wisconsin on September 29, 1975. He has observed effects in monkeys at PCB dosages lower than have been reported previously for other animal species. Female monkeys exhibited more marked effects than males. This sex difference is consistent with earlier observations for rodents in that females were more susceptible than males to the liver effects of PCB's. We believe his observations are valid.

Because of differences in the amounts of food eaten by monkeys and man, a direct comparison of dietary concentrations is not meaningful. Recalculation of Dr. Allen's data shows that his monkeys received 100 µg/kg/day of PCB's. FDA had calculated earlier that 10 µg/kg/day was the lowest dosage which had been estimated to produce effects in man. They estimated that 4 µg/kg/day might be a "safe" level based on the average dose shown to produce effects in man, and adopted 1 µg/kg/day as an acceptable level of intake. Dr. Allen has shown that a dosage 10 times that known to cause effects in man is also harmful to monkeys. We conclude that his data have added to the emotional component of the PCB controversy but not to the interpretation of safety. We

cannot scientifically assess the impact of his findings on the FDA's earlier decision until a "no effect" level has been determined in monkeys, but it does lessen the safety factor formerly based on earlier studies.

2. Extent of Contamination

Monsanto has (rightfully?) relied on government agencies (and others sponsored by the government) to monitor PCB contamination of food, packaging materials, air, water, etc. There have been conflicting reports in the 1970-1975 time period as to whether amounts of contamination have been increasing or decreasing.

The article states, "In many places the accumulation of PCB's in the environment either has exceeded or may soon exceed that of DDT." We believe this is due to a decrease in DDT levels--not an increase in PCB's.

Further, "Oceanographers have found the chemicals far at sea." Qualified government scientists have reported a 40-fold decrease in the Atlantic in the 1972-1974 period. A five-fold decrease in Atlantic plankton was reported for the same period. Data on inland lakes and waterways do not confirm higher levels now than five years ago.

Most importantly, we believe the FDA "market basket surveys" and other studies by FDA have indicated a decrease in PCB contamination of the nation's food supply. One exception may be fish in certain localized areas. In the Northern Great Lakes, the levels in fish are down due to reduction of effluents into tributaries to the lakes. Some increases in the reported levels in fish may be due to a more systematic and comprehensive program of monitoring or analysis.

3. Public Health Implications

The tolerance for concentrations in foods and water will be established by the U. S. Food and Drug Administration. We are not concerned about possible skin exposure nor potential occupational exposures. We believe experience over 40 years and available health record data indicate that these aspects are being controlled adequately.

The fundamental issue from a public health viewpoint is whether contamination of the environment is increasing, is stable, or decreasing. Clearly, if it were going down, there would be no great issue. The evidence would indicate there may, at least, be local increases. If increases are local, they could be controlled locally. If increases are generalized, action required would be dependent on the magnitude of the increase.

Barry Commoner's 20/20 hindsight allows his comment "lack of environmental caution in introducing PCB's amounts to "an absolutely shocking and staggering case history." The fact is that no one--in government, academia, or industry--had his foresight in 1929--nor even 10 years ago in 1965. The lack of environmental caution implies that no thought was given to this subject. As late as 1972 an interdepartmental task force of government agencies called the risk minimal.

The researchers who discovered PCB's in fish in 1966 did so not because "fish at first had been thought to be suffering from DDT intoxication" but because two dedicated Swedish analysts identified PCB's because "unknowns" in the analysis of fish tissues for DDT and its metabolites posed a challenge.

Finally, the article states, "In the absence of standards, most PCB users have been free to pollute waterways, though some regional EPA offices have tried to regulate emissions through permits." If there are PCB users discharging PCB's without a permit, it is because EPA has not been able to function in accordance with the Congressionally mandated program of issuing permits for all industrial discharges. It is not because of lack of any standard.