UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
SOLID WASTE AND EMERGENCY RESPONSE

MEMORANDUM

DATE: February 23, 1990

SUBJECT: Newly Revealed Fraud by Monsanto in an Epidemiological Study Used by EPA to Assess Human Health Effects from Dioxins

FROM: Cate Jenkins, Ph.D.
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TO: Raymond C. Loehr, Ph.D.
Chair, Executive Committee
Science Advisory Board (A 101)
Office of the Administrator

On November 28, 1989 you transmitted to the Administrator a review by the Science Advisory Board (SAB)[1] of "A Cancer Risk-Specific Dose Estimate for 2,3,7,8-TCDD."[2] This review concluded that the existing epidemiologic studies were conflicting, and did not provide definitive data on human health effects of dioxins, and thus EPA should continue to utilize animal toxicologic data as a basis for dioxin risk assessments.

A key epidemiological study leading to this conclusion was performed by Monsanto Corporation. This study examined medical records were examined of employees exposed to dioxins from a 1949 explosion of a 2,4,5-trichlorophenol manufacturing process, and

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[1] U.S. EPA, Science Advisory Board, Ad Hoc Dioxin Panel (November 28, 1989) Review of Draft Documents "A Cancer Risk-Specific Dose Estimate for 2,3,7,8-TCDD and "Estimating Exposure to 2,3,7,8-TCDD."

[2] U.S. EPA, Office of Health and Environmental Assessment (June, 1988) A Cancer Risk-Specific Dose Estimate for 2,3,7,8-TCDD,EPA Publication No. EPA/600/6-88/007Aa.

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alleged that the record demonstrated a deliberate course of conduct by Monsanto through "altered" research to prove to the world that the only health consequence of dioxins was the relatively harmless, reversible condition of chloracne. The cross examination of Dr. Roush, Medical Director of Monsanto, was said to clearly establish the fraudulent nature of the cancer mortality study by Dr. Zack, a Monsanto employee, and an "independent" researcher, Dr. Suskind, described as having performed "joint" studies with Monsanto.

An earlier, predecessor study performed by Dr. Zack was alleged to have deliberately and knowingly omitted 5 deaths from the group exposed to dioxins in the 1949 accident, while removing 4 workers who had been exposed and putting these workers in the unexposed group, serving to provide an apparent increase the cancer death rate in the unexposed group. The overall cancer death rate was alleged to have actually been 65% greater in the exposed population, with 143% higher lung cancers, 108% higher genitourinary cancers, 809% higher bladder cancers, and 92% higher lymphatic cancers.

The Monsanto study performed by Dr. Suskind on workers exposed to dioxins in the 1949 accident, published in 1980 in the Journal of the American Medical Association and the same year in the Journal of Occupational Medicine with Dr. Zack as co-author (this was the study was reviewed by EPA), was also alleged to be fraudulent. It was claimed that the actual medical records revealed gross misclassifications and omissions. The correct classification was said to have been 28 cancers in the exposed group compared to only 2 in the unexposed group; Suskind reported 14 cancers in the exposed group and 6 in the unexposed group. In addition, it was alleged that in November of 1955, Dr. Suskind colluded with Monsanto to conceal findings of psychoneuroses in the exposed workers from the Workers Compensation Commission. Dr. Suskind was alleged to have falsely stated that workers' nervous system and liver problems had disappeared by 1953, with the stated intention by Suskind to make the world believe that only a few of the workers continued to have problems. Dr. Suskind was reported as acknowledging to the Court that the world and the scientific community were intended to, and indeed had, relied upon his reports of no adverse cancer effects from human exposures to dioxins.

It is a commonly bandied adage that dioxins have not been demonstrated to have caused cancer in humans, despite documented exposures. Perhaps this may now been seen as yet another "old industry tale" in light of the fraud allegedly committed by Monsanto in conducting its "research" on its workers exposed to dioxins. It could be that other studies on exposed populations are similarly flawed and subject to fraud.

I request that the SAB on it own, or by way of direction to EPA's Office of Research and Development, obtain the full files from the ongoing case against Monsanto to determine whether definitive conclusions may now be drawn regarding the evidence establishing a causal link between dioxins and human cancer in the Monsanto population. I believe that an audit of other dioxin-related human epidemiological studies should be performed, to determine whether misclassification of medical records or other errors has resulted in similarly flawed conclusions. Studies that would be particularly prone to bias would be those performed by any manufacturing firm on its own employees, or in conjunction with an outside researcher, since a positive finding of excess cancer mortality or morbidity would result in the financial liability of that firm.

cc: Donald G. Barnes, Ph.D.
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