

STURGEON LITIGATION

FROM THE FILES OF

D. Bishop

THIS FILE HAS BEEN REVIEWED BY

LINDA SHAPIRO

FOR:

- Documents describing the presence or potential presence of dioxin in Monsanto products.
- Documents referring to the toxicity of any Isomer of dioxins.
- Documents referring to the toxicity of any Chlorophenol or Chlorophenol product.
- Documents referring to health effects as they relate to the above.

DATE

4/22/85

Monsanto Backgrounder

MONSANTO'S RESPONSE TO NITRO
PLAINTIFFS' OPENING STATEMENT

MONSANTO COMPANY / ST. LOUIS, MO.

June 25, 1984

The Nitro lawsuit involves basically two issues. The first deals with the question of causation, i.e., did the plaintiffs suffer extensive and lasting damage to their health from exposure to dioxin and other chemicals in the Monsanto workplace? The second issue goes to the allegation that the company deliberately intended to injure its Nitro Plant employees.

To the question of causation, Monsanto will stress the following facts:

- The 1949 Incident

On March 8, 1949, about six months after the plant's 2,4,5-T production unit started up, a violent reaction and decomposition occurred when temperature and pressure within an autoclave became excessive. A relief valve opened, venting the contents of the autoclave into the atmosphere and the building-- exposing those present and those subsequently involved in the cleanup operation to the vented materials.

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In response to this unexpected incident, which occurred over 35 years ago, the company moved swiftly to provide independent medical examinations at company expense.

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These examinations were conducted by highly regarded private physicians.

Monsanto's concern and desire to understand what happened and what caused the health problems experienced by some employees immediately following this incident were further evidenced by the company's efforts to seek out and fund independent outside testing of the autoclave residue and the end products of the process.

- Monsanto's On-going Worker Safety Program

Monsanto will introduce substantial evidence during the trial which will show the company's continual emphasis on curtailing workplace exposure to chloracne-causing substances in the manufacturing process. To further enhance employee safety, state-of-the-art design changes were implemented in the 2,4,5-T process and safety programs were made more stringent. A new plant was constructed in 1963, incorporating modern, effective engineering controls. Monsanto's efforts to improve ventilation and curtail airborne exposure continued long after the new plant went into operation. In fact, the company nearly doubled the size of the ventilation system installed in the building.

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- Nitro Plant Health Studies

Altogether, some 400 Monsanto employees worked in the Nitro plant's 2,4,5-T production unit at one time or another during the 21 years the plant manufactured this product.

In the late 1970s, a major industrial accident in Seveso, Italy, followed shortly thereafter by the emergence of the Agent Orange controversy, focused new and growing worldwide concerns on questions regarding the potential human health effects of exposure to dioxin.

Because of these collective factors, in mid-1978, Monsanto announced that it was funding a series of health studies of its Nitro workforce and that the results would be made public upon completion of the research. We did this for two reasons:

First -- we felt we owed our employees and ourselves the most complete health evaluation possible using the latest medical techniques.

Second, this Nitro Plant work group, exposed to 2,4,5-T for sustained periods of time 10 to 30 years ago, represented the best opportunity thus far, anywhere in the world, to study the chronic effects, if any, of exposure to dioxin. Thus, we felt these studies could provide meaningful information to the medical community and, more importantly,

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to those people who may have been exposed to dioxin, anywhere in the world.

All three of these studies have been completed and published in the peer-reviewed scientific literature. Two of these studies (mortality studies) reported the cause of death of former employees. The other study (a morbidity study) focused on the health status of current and former employees who are still living.

The morbidity study was jointly funded by Monsanto and the National Institute of Environmental Health Sciences (NIEHS), a branch of the U.S. Department of Health and Human Services. It was conducted by Raymond A. Suskind, M.D., and his medical team from the Institute of Environmental Health, University of Cincinnati Medical Center.

The uniform conclusions of these studies are summarized as follows:

1. There is no increase in mortality in the Nitro workers as a result of exposure to 2,4,5-T, either from the 1949 autoclave incident or from long-term exposure to the ordinary process of producing 2,4,5-T.
2. There are no long-term health effects that could be statistically associated with employment in

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the 2,4,5-T unit, other than chloracne. A possible association between 2,4,5-T employment and an increase in the history of GI tract ulcers was noted by Dr. Suskind. This apparent excess is currently being further evaluated. However, Dr. Suskind reported that he found no clinical evidence to suggest that exposure from the 2,4,5-T process is associated with an increase of cardiovascular disease, hepatic disease, renal damage, central nervous system or peripheral nerve problems, reproductive problems or birth defects. The conclusions reached by Dr. Suskind are essentially identical to those noted by Drs. Moses and Selikoff in a separate study of the Nitro work force which was funded by the United Steel Workers of America. This union represents the plant's hourly employees, and is helping to finance the plaintiffs' lawsuit.

The conclusions reached in these four separate Nitro health studies are consistent with those detailed in recently published health studies of Vietnam veterans and other individuals exposed to 2,4,5-T and dioxin.

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It is important to note that these conclusions are further shared and will be articulated during the trial by several well-recognized international experts who are involved in the scientific study of herbicides and dioxin. These world authorities include

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Dr. Bo Holmstedt of the Karolinska Institute of Sweden; Dr. Edward Smuckler, Chairman, Department of Pathology, University of California at San Francisco; Dr. Wayland Jackson Hayes, Professor Emeritus of Toxicology, Vanderbilt University Medical School, and Dr. Raymond A. Suskind, Director, Institute of Environmental Health, University of Cincinnati Medical Center.

The seven plaintiffs in this lawsuit were recently examined by medical specialists at West Virginia University's Medical School. These examinations, which will be described in detail at trial, indicate that the health status of each of the plaintiffs is essentially normal for individuals of their respective ages and lifestyles. The one problem which stands out, and which has been noted in previous health studies, is that of chloracne. This condition, while showing substantial improvement over the years, still persists in some of the plaintiffs involved in the 1949 incident. Six of the seven plaintiffs have chloracne and two have recovered from previous cases of bladder cancer.

Thus, Monsanto's Nitro Plant work force has become one of the most medically-studied industrial populations in the world. The consistent findings of these

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investigations clearly show that chloracne is the only significant, long-term health effect that this work force has experienced from exposure to dioxin.

Despite this, and despite the fact that Monsanto never received a single customer complaint regarding health problems in the 21 years that 2,4,5-T was manufactured and sold, the company continues, even today, 15 years after it ceased production, to utilize the best available resources, both medical and scientific, to address the dioxin issue.

- Para Amino Biphenyl (PAB)

Monsanto's historical concern for the safety of its Nitro plant employees is further evidenced by its initiation of a health monitoring program to detect bladder cancers from PAB exposure. This program was initiated well in advance of the appearance in the scientific literature of any research suggesting an association between PAB exposure and bladder cancer. In fact, Monsanto was responsible, on its own volition, for all early U.S. research and publication on this subject. The company's voluntary departure from the business of producing Ajone C/Santoflex B (in which PAB was used) in 1955, is also reflective of Monsanto's early-on commitment to employee safety. The company repeatedly declined to sell its know-how to make

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this product to other companies out of its concern for the safety of other workforces, as well.

Regarding the allegation that Monsanto deliberately intended to injure its workers, the company will introduce evidence that clearly shows the company's historical concern for the health and welfare of its employees.

- For example, in response to claims that the company delayed the institution of its PAB program, the company will show that:
 1. The way Monsanto decisively moved to swiftly deal with the PAB problem was and still is a model of social responsiveness, even measured by today's more rigid standards. These actions were taken voluntarily.
 2. Monsanto responded quickly to this emerging problem before PAB's cancer-causing potential had been reported in the scientific literature.
 3. As soon as Monsanto confirmed an extremely limited number of cases of this relatively rare cancer in workers handling PAB, the company moved to eliminate all exposure to this chemical. At the same time, the company instituted a crash research project to confirm its suspicion that PAB could cause cancer.
 4. Notwithstanding the fact that the company was unable to find a suitable replacement for PAB and well before its human cancer-causing potential was confirmed,

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Monsanto's medical department determined that the potential risk to the workers' health and welfare was unacceptable and that the most responsible course of action was to cease production and exit the business. That decision was swiftly implemented.

In summary, the company-funded PAB program, developed some 30 years ago and maintained even to this day, continues to serve as a model of a responsible, forward-thinking company's actions to safeguard the health and welfare of its workers.

- Plaintiffs contend that Monsanto knew a contaminant was present in the 2,4,5-T process that could cause chloracne prior to the 1949 autoclave incident. Apparently this charge is based on the assertion that at least one case of chloracne occurred before the incident.
 1. The autoclave incident happened only six months after the initial start up of the manufacturing process. The problems associated with plant start up and the ensuing autoclave incident obscured any attempt to focus on the possibility that chloracne could result from routine operations of this facility until sometime in 1952.
 2. The company will stress that the chloracne observed in the 1949 incident was widespread and relatively severe compared to the mild cases that were

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occasionally encountered during normal 2,4,5,-T operations.

3. Early efforts by widely-respected independent researchers, recommended to Monsanto by the U.S. Public Health Service, failed to isolate and identify the contaminant.
4. Therefore, clearly the company did not engage in any coverup, either deliberate or inadvertent. The point is that there was nothing to cover up, i.e., no serious problems from routine operations existed then, nor have any surfaced since production ceased.
- Plaintiffs state that Monsanto kept from its Nitro employees information concerning the health risks associated with dioxin and other chemicals to which they were exposed and failed to institute adequate training and safety programs to protect its workers.

The company will respond to this allegation as follows:

1. Monsanto will emphasize that, to this day, it does not believe its employees were ever exposed to a by-product which has caused any long-term health problems other than chloracne. The aforementioned medical studies bear this out.
2. Monsanto will show that it instituted many training programs to inform its Nitro workers of safety hazards

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and risks attendant with working in the 2,4,5,-T process.

3. Monsanto's historical safety programs have advised, educated and warned its employees of the human health risks possible from working with a wide variety of toxic chemicals. These safety programs and the related, long-standing industrial hygiene program in place at the Nitro plant, were and are designed to assure worker safety on a daily basis.
4. As the public debate on dioxin continues, it is clear that there was and still is very little information of a consensus scientific nature that Monsanto could have shared with its employees with regard to long-term human health risks. Attempts to extrapolate data from animal experiments have repeatedly failed to show that man has experienced the problems observed in animal tests.
5. We will further point out that when we departed the 2,4,5-T business in 1969, most of the animal studies, now available, had not yet been done.

We submit that the dissemination of animal data which is clearly at odds with the substantial body of documented human evidence and the endorsement implicit in disseminating it -- fully five to ten years after we ceased production -- would have been scientifically and socially irresponsible.

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The tragic consequences that can result from blind reliance on animal data were never more painfully evident than following the 1976 incident in Seveso, Italy. Several pregnant women, who had been exposed to dioxin during the industrial accident there, elected to have voluntary abortions because they feared their babies would be born with birth defects. These women acted on the advice of well-meaning but misguided physicians whose opinions were based solely on sketchy animal data. History has proven that the incidence of birth defects in children born to women, exposed to dioxin in and around Seveso, has been no greater than for the country as a whole.

Monsanto will elaborate on these points and others during its opening statement, tentatively scheduled for Friday, June 22, and will present its detailed and compelling evidence as the trial proceeds.

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