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1201 THIRD AVENUE, 40TH FLOOR • SEATTLE, WASHINGTON 98101-3099 • (206) 583-8888

April 8, 1991

Raymond L. Ludwiszewski
Acting Assistant Administrator
for Enforcement
U.S. Environmental Protection Agency
401 M Street S.W.
Washington, DC 20460

Re: -Monsanto Dioxin Studies-

Dear Mr. Ludwiszewski:

I am writing on behalf of my client, Monsanto Company, to urge that the agency's preliminary investigation of allegations challenging the validity of certain dioxin studies funded in whole or in part by Monsanto (hereafter the "investigation") be concluded as quickly as possible. We urge this both because of the lack of substance of the allegations and the wholly inappropriate and damaging public statements made regarding the investigation by an agency employee. To clear the air and resolve this matter, we request a prompt meeting with you and appropriate members of your staff to discuss the issues triggering the investigation and to present our views.

Please understand that our basic frustration with this investigation does not extend to the EPA criminal program's handling of this matter. However, this investigation has become a media event through the unprofessional efforts of a single EPA employee not resident in the criminal program. Specifically, memoranda (Attachments A and B hereto) prepared by this EPA employee detailing many untrue allegations provoking the investigation have been improperly released to the public (see the lengthy "cc" lists attached to the memoranda) and, consequently, have been widely discussed in the lay and scientific press. The agency has been unsuccessful in halting this improper conduct, despite the clear impropriety and the fact that such information releases are highly damaging to Monsanto's reputation. (See, for example, the news articles, Attachment C hereto. See also Attachment D, a letter from Monsanto to EPA expressing concern with earlier public statements of the same employee.)

The agency, having committed legal resources to this investigation, has assumed the duty under Rule 3.6 of the ABA Model Code of Ethics to prevent its employees from making public statements regarding the guilt, innocence, character,

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or credibility of a person or entity being investigated. Until the investigation is completed and the results are made public, the government and its employees have a responsibility to protect those being investigated from unfair "official" public accusations. Unfortunately for my client, that responsibility has not been fulfilled.

What further exacerbates this matter, is that the allegations, when examined, do not justify criminal charges. A discussion of some of the allegations' deficiencies follows.

The Allegations. The assertions causing the initiation of this investigation are primarily those made by a plaintiffs' tort lawyer in litigation against Monsanto (Kemner et al. v. Monsanto) in the early 1980's with respect to a chemical spill in Sturgeon, Missouri. That lawyer, Mr. Rex Carr, is an energetic advocate, well able to manipulate data to the best advantage of his clients. Previous letters to the agency from Monsanto have discussed the improper scientific basis for Mr. Carr's manipulations and related allegations of fraud. (See Attachment E.) We believe that an impartial scientific review will exonerate Monsanto. That is why Monsanto in its letter to EPA of October 1, 1990 (Attachment D), sought a scientific audit by EPA and NIOSH of the studies in question.

Virtually all of the allegations made in the November 15, 1990, EPA employee's memorandum concern matters in the 1960's, 1970's and early 1980's. Monsanto ceased manufacture of the chlorinated chemicals there at issue many years ago. The allegations themselves are not substantively valid; but even if they were, the allegations would not be prosecutable.

Central to the allegations is the assertion that studies done of workers at Monsanto's Nitro, West Virginia, plant were fraudulent and that Monsanto intentionally submitted such studies to EPA, knowing they were fraudulent, to influence the agency improperly in its regulatory decision-making. As shown below, fair examination of the nature, context, and history of these studies demonstrates the fallacy of that assertion.

Of particular relevance to the nature of the conduct associated with the studies are the following facts which demonstrate that there was no criminal conduct:

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- (1) There were several similar studies done by different scientists of essentially the same Monsanto worker population;
- (2) Two of these studies were funded by Monsanto, one was funded partially by Monsanto, and one was funded by a union which financially assisted the efforts of many of its members who were litigating with Monsanto regarding worker health issues;
- (3) The results of all of the studies--including the one funded by the union--were essentially consistent especially with respect to carcinogenicity;
- (4) All of the studies were conducted by eminent scientists, several of whom were not employees of Monsanto;
- (5) The results of the studies here at issue were also substantially the same as many other studies of similar chemical plant worker populations conducted by other scientists having no connection whatsoever with Monsanto.
- (6) The results of the Monsanto studies were also consistent with the government's own studies--called the "Ranch Hand" studies--of Vietnam War veterans allegedly exposed to Agent Orange.
- (7) All of the studies funded in the whole or in part by Monsanto were published in scientific journals and were subjected to or available for peer review¹;
- (8) Monsanto voluntarily has offered to have EPA or NIOSH again subject the studies to a peer review or audit process;
- (9) The criticisms leveled at the studies in the Kemner litigation are those of an aggressive plaintiff's attorney in the context of strongly-contested

¹Peer review is a process by which particular scientific work is reviewed and critiqued by other highly-qualified independent experts.

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litigation with Monsanto; they were not the result of testimony of scientific experts.²

Essentially, a prosecutor would have to establish that several well-regarded scientists engaged in fraudulent conduct in full view of their peers and in concert with specific individuals in Monsanto management and other scientists throughout the world, a proposition that is simply not believable given the context in which the studies were done, the number of different scientists involved, and the consistency of results as between the Monsanto-funded studies

²Plaintiffs provided no expert testimony whatsoever during the three-year Kemner trial which attacked the validity of the Monsanto-funded studies. Instead, plaintiffs' counsel, Rex Carr, given an unusually long leash by the court in cross-examining Monsanto's experts, simply challenged each of the assumptions upon which the studies were based and developed his own theories. His essential thesis was that the studies themselves, when reconfigured into a single study rather than two separate and distinct studies, showed a statistically-significant cancer rate. He reached this erroneous conclusion, reasoning as follows: The Zack/Gaffey mortality study (discussed in the text of this letter, infra) found nine cancer deaths and 49 noncancer deaths among the population studied. Another nine cancer deaths were found in the Zack/Suskind mortality study, along with 23 noncancer deaths. It was asserted by plaintiffs' counsel that the nine cancer deaths found by Zack/Suskind should be added directly to the nine Zack/Gaffey cancer deaths and compared with the 49 noncancer deaths in Zack/Gaffey. Thus, plaintiffs' cancer rate would be 18 out of a total of 67 deaths, which represents a statistically-significant increase over the number of cancer deaths expected. The fallacy in this reasoning is that plaintiffs' counsel completely ignored the 23 noncancer deaths also found in Zack/Suskind. If they are included, the 18 cancers out of the total 90 deaths would not represent a statistically-significant increase over the expected cancer death rate. (See Attachment F which is a photograph of a summary trial exhibit prepared by Monsanto attorneys demonstrating this fallacy.) In short, the reconfiguration of the studies by plaintiffs' counsel improperly ignored a critical group of non-cancer deaths and artificially created an "excess" in mortality through data manipulation.

Moreover, counsel's not-so-subtle manipulation of data as between the two studies constitutes an effort to compare apples and oranges. The study cohort of exposed workers in the Zack/Gaffey study was designed to include only those workers exposed to chronic or low-level contamination for at least one full year.

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and those not funded by Monsanto. A short discussion of the background of the Monsanto-funded studies follows.

Monsanto began manufacturing 2,4,5-Trichlorophenol (2,4,5-T) at its Nitro, West Virginia, plant in 1948. On March 8, 1949, a runaway reaction in an autoclave at the Nitro plant exposed workers to fumes from a chemical mixture. Dioxin in the form of 2,3,7,8 Tetrachlorodibenzo-p-dioxin (2,3,7,8-TCDD) is now believed to have been a contaminant of the chemical mixture to which the workers were exposed. Dioxin is also now known to have been a trace contaminant in the manufacturing process of 2,4,5-T.

The exposed workers were the subject of studies conducted from 1949 until 1955 by the Kettering Institute of the University of Cincinnati College of Medicine under the supervision of Dr. Raymond R. Suskind. (See Attachment G, a copy of a 1979 newspaper article reporting an interview of Dr. Suskind.)

In 1978, after more than a thousand people in Seveso, Italy, had been exposed to a dioxin-related incident similar to the Nitro incident, Dr. Suskind approached Monsanto for the opportunity to do a follow-up study of the Nitro, West Virginia, workers. His purpose was to determine whether any long-term health effects could be identified in workers exposed in the 1949 Nitro accident.

Four studies were done of the Nitro plant workers in the period from 1978 to the early 1980's:

- (1) the "Zack/Suskind" study, a mortality³ study of workers acutely exposed during the 1949 incident which was done under the supervision of Dr. Suskind and funded by Monsanto;

³A "mortality study" is a study of causes of death among a defined group.

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- (2) the "Suskind/Hertzberg" study, a morbidity⁴ study of the potential for long-term health effects of work place exposure to the manufacture of 2,4,5-T which was also done under the supervision of Dr. Suskind and funded in part by Monsanto;
- (3) the "Selikoff/Moses" study, a morbidity study similar to the "Suskind/Hertzberg" study, done under the supervision of Drs. Irving Selikoff and Marian Moses and funded by the Steelworker's Union that represented the Nitro workers; and
- (4) the "Zack/Gaffey" study, a mortality study of workers assigned in the work place over a year or more to the manufacture of 2,4,5-T; this study was done by Monsanto scientists.

Although all four studies sought to identify adverse health effects caused by exposure to dioxin, including cancer, they all reached a similar conclusion regarding cancer--no statistically significant excess in cancer incidence or mortality associated with dioxin exposure was reported. Although not emphasized by plaintiffs' counsel, the similarity in the conclusions of the two morbidity studies bears comments. The morbidity studies were (numbers two and three above): Suskind/Hertzberg (funded by Monsanto) and Selikoff/Moses (funded by the Steelworkers Union whose members were suing Monsanto). The results reached in these two studies, despite their different funding sources and totally different investigative teams, were virtually the same. The only long-term health effect found to be associated with dioxin was chloracne, a non-threatening skin condition similar to teenage acne. A statistically significant increase in cancers associated with dioxin exposure was not observed in either study.

⁴A "morbidity study" is a study of the incidence of disease found among a defined group of persons alive during the period studied.

At trial plaintiffs' counsel in the Kemner case focused his challenge primarily on studies of (1) Zack/Suskind and (4) Zack/Gaffey (discussed in detail within footnote 2). The two mortality studies differed from each other in that Zack/Suskind attempted to study workers exposed to very high or "acute" levels of contaminants in the short-term--i.e., workers exposed in the 1949 autoclave incident--while Zack/Gaffey attempted to study workers assigned to the manufacturing process of 2,4,5-T that were potentially exposed to low levels of contaminants over a long period (at least one year) in the work place. Neither of the mortality studies showed a statistically significant increase in deaths from cancer associated with dioxin exposure. In short, their results were virtually the same with regard to cancer risk as the two morbidity studies.

Thus, simply comparing the results of these four studies, one of which was funded by the union providing financial support for litigation against Monsanto, lends unassailable credence to the proposition that the Monsanto-funded studies were not the product of fraud.

The three studies funded in whole or in part by Monsanto ((1) Zack/Suskind, (2) Suskind/Hertzberg, and (4) Zack/Gaffey) and the Moses/Selikoff study funded by the Steelworkers Union all were published and were subjected to or were available for peer review as a result of their appearance in the following scientific journals:

- (1) Zack and Suskind, "The Mortality Experience of Workers Exposed to Tetrachlorodibenzodioxin in a Trichlorophenol Process Accident," J. Occup. Med. (1980) 22:11-4;
- (2) Suskind and Hertzberg, "Human Health Effects of 2,4,5-T and Its Toxic Contaminants," JAMA (May 11, 1984) 251:2372-80;
- (3) Moses and Selikoff, J. Indus. Med. (1984) 5:161-182; and
- (4) Zack and Gaffey, "A Mortality Study of Workers Employed at the Monsanto Company

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Plant in Nitro, West Virginia," Environ.
Sci. Res. (1983) 26:575-91.

Regarding his independence in undertaking the studies of Monsanto workers, Dr. Suskind responded as follows in the 1979 interview (Attachment G):

All we wanted to make sure of was that Monsanto knew that the design of the experiment and the implementation of the experiment were the responsibility of the University of Cincinnati under my direction, and that they were absolutely not to influence in any way the design or the implementation of it.

With regard to workers' records, Dr. Suskind stated:

We made one of the agreements that Monsanto had to make available to me and to my group all the work records of all the people we were examining. And they did even more than that. They made available all of the work records that we had to choose from. All of their health records from the medical department and all of their compensation records. . . .

The Monsanto-sponsored studies, two of which were supervised by Dr. Suskind, have been in the literature for seven to ten years, have been reviewed on numerous occasions by academics and others, and have not been challenged in a scientific forum. For example, they were cited without criticism in a recent article authored by the National Institute for Occupational Safety and Health (NIOSH) entitled "Cancer Mortality in Workers Exposed to 2,3,7,8-Tetrachlorodibenzo-p-dioxin," N. Engl. J. Med. (1991) 324:212-8 at notes 33, 40, and 41 (hereafter "NIOSH Study"). Moreover, the results of the Monsanto-funded studies have been similar to the results of many other studies done of similar worker populations.⁵

⁵See, e.g., Thiess, Frentzel-Beyme, Link, "Mortality Study of Persons Exposed to Dioxin in a Trichlorophenol-Process Accident that Occurred in

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The NIOSH Study grew out of an effort in the late 1970's to identify and study exposed workers at several U.S. chemical companies that made TCDD-contaminated products. Monsanto cooperated in this effort by supplying substantial information regarding processes and worker history at its Nitro and Krummrich plants. This included data regarding the workers evaluated in the Zack/Suskind and Zack/Gaffey studies mentioned above. Thus, NIOSH had access to all information upon which those studies were based. The recently-reported NIOSH Study cited above is the product of this effort.

In contrast to the scientific approach of researchers undertaking these various studies, counsel in tort cases against Monsanto, including the heralded three and one-half year Kemner trial, have shamelessly manipulated data to support a pre-determined outcome supporting their case theories. Monsanto was sued in the early 1980's by certain townspeople in Sturgeon, Missouri, allegedly exposed to a rail car spill of a product ultimately determined to have been contaminated with a trace amount of TCDD. Despite the fact that EPA, in responding to the spill, had determined that the trace level of dioxin presented no human health hazard, plaintiffs maintained otherwise. In the Kemner lawsuit, the various Nitro worker studies were challenged, as well as how Monsanto dealt with TCDD contamination of its products generally. Plaintiffs' primary strategy--to attack Monsanto's integrity in an effort to deflect the jury's attention from the fact that plaintiffs' claims lacked merit and were contrary to the EPA's own health evaluation--caused plaintiffs' counsel to resort to the tactic of blatantly unscientific and improper manipulation of study data which regrettably has provoked the present investigation.

All of the allegations asserted by Monsanto's accusers in the present investigation were raised publicly by plaintiffs' counsel by 1985 or earlier in that litigation. The EPA employee's memorandum discussed supra which was circulated in November 1990 essentially parrots many of the charges

the BASF AG on November 17, 1953," Am. J. Ind. Med. (1982) 3:179-89; Ott, Olson, Cook, Bond, "Cohort Mortality Study of Chemical Workers with Potential Exposure to the Higher Chlorinated Dioxins," J. Occup. Med. (1987) 29:422-9.

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contained within the plaintiff's appellate brief filed in connection with the appeal of the Kemner case.

In October of 1990, prior to the disclosure of the existence of this investigation but in response to the renewed attack on these studies based upon the time-worn arguments of plaintiffs' counsel in Kemner, Monsanto wrote the agency and requested

. . . an independent audit of the two studies [Zack/Suskind and Zack/Gaffey] followed with a publication by the government in a peer-reviewed journal of the results of that audit.

[Attachment D, p. 2.]

The reason that clearing the air on the propriety of these studies is of continuing importance to Monsanto was further expressed in the letter:

Given the Company's science-based focus, preservation of Monsanto's reputation for performing accurate world-class research is of critical importance to [the Company's] business and research operations. Furthermore, since NIOSH is in the process of issuing study results based, in part, upon the same population involved in the two studies sponsored by Monsanto, it should be important for the government to remove any stigma improperly attached to NIOSH's work

[Id.]

The specific allegations asserted in the EPA employee's memoranda of November 15, 1990, and January 24, 1991, cannot withstand scrutiny or the application of common sense. Since these and other allegations made in the subject memoranda are similarly unfounded, overly strident, and misleading, we would be pleased to discuss them in depth at a meeting with you and your staff.

Because of the insufficient nature of the allegations and repeated and apparently continuing highly improper and damaging public disclosures by an EPA employee, we believe that it is incumbent that the agency conclude this

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investigation forthwith and announce that no basis exists for a criminal charge. We also renew Monsanto's request that a scientific audit of the questioned studies be conducted rather than a criminal investigation, and that Monsanto's name be publicly cleared when justified by that audit.

Again, we would appreciate the opportunity to speak directly to you or appropriate members of your staff regarding the issues raised by this investigation. If you or any of your staff have questions or wish to speak to Monsanto personnel regarding this matter, please contact me directly.

Sincerely yours,


James R. Moore

Enclosure

cc: Pasquale A. Alberico
Howard Berman
Carroll Wills
John West
Kevin Guarino

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4/8/91