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AFFIDAVIT OF ELLEN K. SILBERGELD

Comes now Dr. Ellen K. Silbergeld who states as follows under penalty of perjury:

1. In this Agent Orange litigation, I have previously had the following involvement. I have prepared and reviewed an expert summary which was filed with the Court concerning the substance of my proposed testimony and certain supplements thereto. I have given a deposition in New York City on March 18 and 19, 1984. I have also prepared a 13 page affidavit which was an exhibit to Opt-Out Plaintiffs' Opposition to Defendants' Motion to Dismiss, or in the Alternative, for Summary Judgment. I wish to incorporate those statements, testimony and affidavit by reference. The matters set forth therein are all true and correct to the best of my personal knowledge.

2. I understand that the primary focus of the government's motion to dismiss is in the area of reproductive toxicity. This is my particular field of specialization as a scientist, and I have devoted substantial professional time and effort in the area of the reproductive toxicity of polycyclic halogenated hydrocarbons, of which dioxin is a member.

3. Epidemiological/statistical evidence is related to the understanding of facts in the case of an individual to the extent that it can be demonstrated that the individual shares the characteristics (and exposures) of the epidemiological group (cohort) for which the statistical evidence was derived. This is the case in all issues of medicine and science, and hence all such issues share this common characteristic.

4. The criteria first enunciated by Bradford Hill for determining the acceptability of epidemiological data are (1) replication, (2) strength of association, (3) temporal relationship, (4) specificity, and (5) biological plausibility. Using these criteria as guides, it can be posited, based upon the data known and available to date, that Agent Orange causes the diseases and effects alleged by plaintiffs, particularly with respect to birth defects.

5. In the area of replicability, there are as yet relatively few studies. However, it is worth noting that data from Seveso (Bisanti, in press) are consistent with the CDC 1984 study and with the Ranch Hand study. All three studies report increases in certain birth defects, notably minor malformations (including hemangiomas), spina bifida, and cleft palate. The Australian study is not apparently consistent with these findings; however, there was no attempt by the Australian study to determine likelihood or intensity of dose, so that it is very likely (based upon information from the Royal Commission) that unexposed veterans were included in the exposed group. This would render any conclusions reached by the Donovon study suspect and weak. There also appears to be an excess of neonatal deaths reported in both the Ranch Hand, CDC, and Serveso data.

6. In the area of strength of association, there is not presently a great deal of reliable information due to the absence of quantifiable exposure data. In the occupational studies, there is insufficient evidence as to dose, incomplete collection of subjects (Dow study), or insufficient numbers (Czech study; Seveso; Nitro

study). Strength of association is usually demonstrated as a function of dose response relationships. There is some qualitative evidence for dose response in the CDC study, but the absence of quantifiable exposure data is a definite obstacle here.

7. In the area of temporal relationship, there is again little data, but, what data there is from the Ranch Hand study, from the CDC study and from some of the Seveso data are consistent with temporal logic. The Ranch Hand II study looked at some veterans before and after Southeast Asian service. In this group, it could be seen that there was an increase in the incidence of several male-mediated reproductive effects, including anomalies. The Seveso study has also reported an increase in hemangiomas after the explosion, an increase which has now been reversed after the passage of additional time. (Bisanti). The CDC study remarked, but did not detial, that in exposed veterans' families, there was a much higher incidence of more than one child with a birth defect.

8. In the area of specificity, there exists some of the strongest reproductive toxicity data, although it has not been appreciated. No study has found that Agent Orange or dioxin exposure in other circumstances increases the rate of all birth defects or all types of reproductive toxicity. Instead, the positive studies (noted above) have found increases in only a few types of defects. This is strongly suggestive of specificity and of a specific toxic agent.

9. In the area of biological plausibility, there is substantial evidence for male-mediated birth defects, miscarriages, toxic

exposures, and other unfavorable outcomes expressed in children. Dr. F. Stanley's statement for the Austrailian Royal Commission discusses such hypotheses in considerable detail. These include (1) gametotoxic effects, (2) genetic effects, and (3) secretion of dioxin in seminal fluid. While this latter possibility is dismissed by Dr. Stein in her affidavit, it is known that lead can be secreted in seminal fluid, and Robaire's group at McGill is studying the effects of seminal fluid cytostatic drugs on pregnancy outcome. One of the positive findings of the CDC study is of particular importance here: the increase in childhood cancer in children of the exposed veterans. Male exposures (occupational) have been demonstrated to be associated with increases in childhood cancers (Kantor, and others). To my knowledge, no other study has looked for childhood cancer specifically, although in Ranch Hand II the causes of neonatal deaths are not described, the similarity between it and the CDC study in this regard is striking.

10. Thus, looking purely at epidemiologic criteria, it can be said that the two major United States studies of Vietnam veterans document and add to the growing body of knowledge that dioxin exposure can and did cause adverse reproductive outcomes. It is true that there are gaps in our knowledge, but those gaps do not present obstacles to the formulation of reasonably-based scientific opinions on causation. The major gaps are in the areas of strength of association and temporal relationship. The reasons for this, I address below.

11. As I noted above, there are frustrating gaps in our scientific knowledge of the reproductive toxicity of dioxin. Those gaps are due to the failure to determine, monitor and record for posterity the amount of exposure of individual veterans at the time of exposure. The gaps are also due to the failure to test the exposed servicemen for the presence of dioxin or its effects in their bodies at and/or shortly after the time of their exposure, the failure to keep meaningful medical records of post exposure symptoms, signs, conditions, illnesses and diseases, and the failure to test the Agent Orange product in animals and other lower forms of life prior to spraying.

12. Those failures to obtain and record pertinent data doomed scientific analysis to uncertainty and inconclusiveness in large part. It is only by testing epidemiologically for specific outcomes based upon refined exposure data that cause and effect relationships can be elucidated clearly. The absence of such data here, however, does not prevent the formulation of reliable, validly-based scientific opinion as to causation; it only makes the testing of such hypotheses and the interpretation of available data more difficult.

13. Nonetheless, the fact remains that there is reasonable scientific data available upon which to formulate a valid opinion that dioxin was the cause of adverse reproductive outcomes in children of servicemen exposed to it in Vietnam.

Ellen K. Silbergeld*
ELLEN K. SILBERGELD

*Dr. Silbergeld is presently out of the country as this affidavit is typed in final form (11/14). It was read to her in its entirety on the evening of 11/13 and she approved it. The original will be sent to her for signature and delivery to the Court upon her return to this country.