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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

IN RE "AGENT ORANGE" PRODUCT LIABILITY LITIGATION	MDL No. 381 (JBW) Civil Action Nos. 79-747 82-778 82-785 82-1141 82-299 82-779 82-788 82-1753 82-767 82-780 82-855 82-1850 82-771 82-781 82-856 82-2594 82-777 82-782 82-1140 83-907

THE UNITED STATES' REPLY TO PLAINTIFFS' OPPOSITION TO THE UNITED STATES' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

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THE UNITED STATES' REPLY TO PLAINTIFFS' OPPOSITION TO THE UNITED STATES' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

I. INTRODUCTION

Plaintiffs' Memorandum In Opposition To The United States' Motion To Dismiss Or, In The Alternative, For Summary Judgment [hereinafter, Opp. Memo.], confirms that plaintiffs can offer no proof that it is more likely than not that a serviceman's exposure to Agent Orange in Vietnam caused injuries to his wife or offspring. Plaintiffs' solution to what they describe as the "burden problem" is for the Court to eliminate the burden of proof altogether, or to "lower the burden to one of showing causation by proof of what is possible or conceivable". Opp. Memo. at 20. Plaintiffs conclude that while proof of cause-in-fact is an "impossibly Draconian burden" here, a full trial is nevertheless appropriate in order to "expose" the various "complex policy issues" which lie at the heart of the causation "controversy." Opp. Memo. at 1, 18, 36. This is hardly a legitimate basis to permit a case otherwise devoid of a triable issue of fact to proceed to trial.

Plaintiffs' action should be dismissed in accordance with the Rules and with established precedent.

II. PLAINTIFFS' OPPOSITION TO THE UNITED STATES' MOTION DOES NOT FULFILL THE REQUIREMENTS OF RULE 56(e)

The Advisory Committee on Rule 56(e) explains that "[t]he very mission of the summary judgment procedure is to pierce the pleadings and to assess the proof in order to see whether there is a genuine need for a trial." Notes of Advisory Committee on Rule 56(e); 6 MOORE'S FEDERAL PRACTICE, ¶ 56.22[2] at 2821 (2d ed. 1966). If, indeed, evidence exists to support plaintiffs' long-standing and heretofore conclusory allegations concerning genetic causation, Rule 56(e) required plaintiffs to come forward with it. The Second Circuit has consistently held:

> A party opposing a motion for summary judgment simply cannot make a secret of his evidence until the trial, for in doing so he risks the possibility that there will be no trial. A summary judgment is intended to "smoke out" the facts so that the judge can decide if anything remains to be tried. [Citations omitted].

Donnelly v. Guion, 467 F.2d 290, 293 (2d Cir. 1972).[1/] Plaintiffs have not done so. Instead, plaintiffs advance pale arguments as to why Dr. Stein's affidavit should be rejected;

1/ See also Quinn v. Syracuse Model Neighborhood Corp., 613 F.2d 438 (2d Cir. 1980), SEC v. Research Automation Corp., 585 F.2d 31, 33, 45 (2d Cir. 1978); American Manufacturers Mutual Insurance Co. v. American Broadcasting-Paramount Theatres, Inc., 388 F.2d 272, 279 (2d Cir. 1967), aff'd after remand, 446 F.2d 1131 (1971), cert. denied, 404 U.S. 1063 (1972); Gatling v. Atlantic Richfield Co., 577 F.2d 185, 187-88 (2d Cir. 1978), cert. denied, 439 U.S. 868 (1979).

why summary judgment is inappropriate in a negligence suit or where causation is at issue; why the CDC, Ranch Hand, and Australian studies should be deemed inadmissible or irrelevant; why the United States should bear the burden of proving that Agent Orange "in fact did not cause" genetic injury; why their burden of proof should be reduced to proof of what is "possible or conceivable;" why they "strongly feel" they can present evidence of "but for" causation; and why, after five years of litigation, they should be allowed additional discovery. As demonstrated in the following sections, this will not suffice to create triable issues of fact where none exist.

A. Plaintiffs' Challenge To The Affidavit Of Dr. Zena Stein Is Without Merit.

Plaintiffs state throughout their Opposition Memorandum that "[t]he sole support for the government Motion is the affidavit of Zena A. Stein." Opp. Memo. at 4, 7, 22, 31, 41. As plaintiffs are well aware, such is not the case.2/ Indeed, even if it were so, the United States would be no less entitled to

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2/ Plaintiffs ignore the considerable record of this litigation which directly bears upon the United States' Motion. For example, the United States' Motion is based upon the absence of proof of causation in the depositions of plaintiffs' experts: Drs. Legator, Levin, Hatch, Silbergeld, Barsotti and Hay. It is also based upon the deposition testimony of Dr. George Lathrop, upon the CDC, Ranch Hand and Australian studies, and upon the various submissions of the defendant manufacturers concerning genetic causation.

summary judgment, and it would not establish plaintiffs' suit as a viable cause of action.[3/]

Plaintiffs offer what purports to be a critical assessment of Dr. Stein's qualifications and of her findings. Instead, plaintiffs deliver a series of ill-considered and inconsequential observations which underscore the merits of the United States' Motion. For example, plainiffs state that Dr. Stein provides "no specific indication of training in the epidemicology (sic) of environmental exposures," and that plaintiffs "don't know what Stein's pertinent qualifications are, what her knowledge is, what she bases her opinion on." Opp. Memo. at 7 and 11. Apart from the fact that Dr. Stein's Affidavit and curriculum vitae attached thereto (Exhibit 1 to the United States' Summary Judgment Memorandum [hereinafter, Sum.J.Memo.]) establishes that she is eminently qualified to render an opinion concerning genetic causation,[4/] plaintiffs' expert Dr. Maureen C. Hatch, whose

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3/ Since the plaintiffs have failed to put forth <u>any</u> evidence which would support a reasonable inference of causation-in-fact, the United States' entitlement to summary judgment has been established with or without Dr. Stein's affidavit, the CDC study, the Ranch Hand study, the Australian study and the evidence previously submitted by the defendant chemical companies and specifically incorporated by the United States' Motion for Summary Judgment. Where, as here, the plaintiffs lack any evidence sufficient to warrant a verdict in their favor, summary judgment in favor of the United States is appropriate even in the absence of an offering of proof of no causation.

4/ The subjects upon which Dr. Stein has published include: "Epidemiologic Detection of Low Dose Effects on the Developing Fetus," "Epidemiologic Studies of Environmental Exposures in Human Reproduction," "Environmental Influences on Rats of Chromosomal Anomalies in Spontaneous Abortions," "Health Effects of Occupational Hazards to Reproductive Failure Assessment,"

[Footnote continued on next page]

testimony is offered by the plaintiffs in opposition to the United States' Motion, confirms Dr. Stein's qualifications:

> Q. When do you plan on making a decision as to whether or not you will give testimony on whether or not these birth defects have been caused by Agent Orange?
>
> A. Certainly not until after I've had a chance to thoroughly review all the relevant records and perhaps I would want to discuss this with some of my own colleagues before deciding whether this was an appropriate role for me.
>
> Q. Would you identify the colleagues with whom you would consult?
>
> A. They would be senior members of my department like Dr. Zena Stein . . . .

Deposition of Maureen C. Hatch, March 21, 1984 at 131. * * *

> Q. Do you recall any others to whom you circulated "Herbicide Exposure and Reproduction, An Overview" by Constable and Hatch?
>
> A. I gave a copy to Dr. Zena Stein at the Division of Epidemiology at Columbia University. . . who is my mentor. . . .

Id. at 209-211.

> Q. So your understanding of biology and cytogenetics is self-taught essentially?
>
> A. Self-taught in terms of my reading but, under the tutelage of some very fine minds, I think, trained in those disciplines.

4/ [continued from previous page]

"Epidemiologic Considerations in Assessing Health Effects at Toxic Waste Sites," "Epidemiologic Outcomes Following Genotoxic Exposures," "Chemical and Physical Exposures of Parents: Effects on Human Reproduction and Offspring." Exhibit 2 to Sum.J.Memo. Dr. Stein was also called upon to provide evidence to the Australian Royal Commission concerning the use and effects of chemical agents on Australian personnel in Vietnam. Exhibit 1 to Sum.J.Memo.

Q. Who are those individuals?

A. Dr. Zena Stein . . . .

Id. at 257. See also pp. 327-328, 411-412. Thus, it is clear that Dr. Stein is competent to testify to the matters contained in her affidavit. Dr. Stein's findings are based on specific studies which are of a type reasonably relied upon by other experts in this field. Dr. Stein concludes that "no laboratory nor epidemiologic evidence exists at this time that is sufficient to a reasonable degree of certainty or probability, to link embryonal deaths or birth defects to paternal exposure to herbicides while in service in Vietnam." Plaintiffs have failed to come forward with facts which could create a genuine issue concerning any of Dr. Stein's conclusions.

B. Negligence Actions Are Not Immune To Summary Judgment Disposition

Plaintiffs are wrong to assume that summary judgment is not appropriate in negligence actions. Haugen v. United States, 492 F. Supp. 398, 400 (E.D.N.Y.), aff'd. 646 F.2d 560 (2d Cir. 1980) ("[I]t is the court's view that summary judgment in the federal defendants' favor is appropriate notwithstanding that the complaint sounds in negligence".); Morton v. Abbott Laboratories, 538 F. Supp. 593, 595 (M.D. Fla. 1982)("By their motions for summary judgment, defendants attack the element of causation. This use of the summary judgment mechanism is entirely appropriate."). Summary judgment in favor of the defendant should be granted in those cases in which there is no genuine issue as to any fact

that is crucial to plaintiff's cause of action so that as a matter of law he cannot recover. See Wright, Miller & Kane, FEDERAL PRACTICE AND PROCEDURE: CIVIL 2d § 2729. Thus, for example, judgment under Rule 56 has been found appropriate on the issue of causation. 5/ Since the affidavits, depositions and

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5/ The following is a sample of federal district court cases in which summary judgment was granted for the defendants on the issue of causation: Collins v. American Optometric Assoc., 693 F.2d 636 (7th Cir. 1982); Morton v. Abbott Laboratories, 538 F. Supp. 593 (M.D. Fla. 1982); Haworth v. Mosher, 395 F.2d 566 (10th Cir. 1968); Phillip v. Sam Finley, Inc., 270 F.Supp. 292 (W.D. Va. 1967); Stevens v. Barnard, III, 512 F.2d 876 (10th Cir. 1975); Simpson v. Hurst Performance, Inc., 437 F. Supp. 445 (M.D. N.C. 1977), aff'd without opinion, 588 F.2d 1351 (4th Cir. 1978); McKnight v. N.M. Paterson & Sons, 286 F.2d 250 (6th Cir. 1960); Shelton v. Brewer, 209 F. Supp. 275 (E.D. La. 1962); Haas v. United States, 492 F.Supp. 755 (D.Mass. 1980); Foecker v. Allis-Chalmers, 366 F.Supp. 1352 (E.D. Pa. 1973); Bulliner v. General Motors Corp., 54 F.R.D. 479 (E.D. N.C. 1971); Crum v. Continental Oil Co., 471 F.2d 784 (5th Cir. 1973); Berry v. Atlantic Coast Line RR., 273 F.2d 572 (4th Cir. 1960); cert. denied, 362 U.S. 976 (1960); Algar v. Yellow Cab Co., 255 F.2d 538 (D.C. Cir. 1958); Vogt v. General Telephone Company of the Southwest, 413 F. Supp. 4 (E.D. Okla. 1975); McQuade v. Arnett, 558 F. Supp. 11 (W.D. Okla., 1982); Timothy v. United States, No. C-80-0045A (D. Utah, July 6, 1983); McCarthy v. United States, No. 83-1287 (D.N.J., September 13, 1984). Summary judgment in favor of the defendant United States has been granted in numerous swine flu vaccine cases specifically on the issue of causation: Frederick v. United States, No. 80-1645 (D.Md., October 23, 1984); Spencer v. United States, No. 81-3162 (S.D.W.Va., May 30, 1984); Kress v. United States, 587 F. Supp. 397 (E.D. Pa. 1984); Barlow v. United States, No. 80-70682 (July 23, 1983); Doniszewski v. United States, No. 80-C-1923 (N.D. Ill. March 31, 1983); Kelley v. United States, No. 80-X1610-S (N.D. Ala. April 18, 1983); Melton v. United States, No. 79-0150-P (W.D. Ky. July 25, 1983); Barney v. United States, No. C 1-80-571 (S.D. Ohio, June 19, 1982); Edwards v. United States, No. C-80-3243 (N.D. Ca. February 19, 1982); Golbinec v. United States, No. C80-213 (N.D. Ohio, September 1, 1982); Erbec v. United States, No. C-1-80-327 (S.D. Ohio, March 25, 1982); Lerman v. United States, No. C-1-80-330

[Footnote continued on next page]

exhibits before the Court on this motion, do not yield any evidence sufficient to establish the existence of a triable issue of fact regarding genetic causation, summary judgment is entirely appropriate.

C. The CDC, Ranch Hand and Australian Studies Are Admissible and Relevant.

Plaintiffs contend that the CDC, Ranch Hand and Australian studies are inadmissible and irrelevant. Plaintiffs base the alleged inadmissibility of the studies upon their belief that "there is not even any reference that the studies or the reports of them are authoritative as required by the Rule." Opp. Memo. at 23-24. Plaintiffs base their conclusion that the studies are irrelevant upon the fact that the studies cannot be "accepted as conclusive disproof of causation." Opp. Memo. at 25.

First, assuming arguendo that the studies contain hearsay, they are nevertheless admissible not only under the learned treatise exception, but also several other exceptions to the rule against hearsay. Under Fed.R.Evid. 803(8)(C), the following are not excluded as hearsay:

5/ [Footnote continued from previous page]

(S.D. Ohio, March 5, 1982); Taylor v. United States, No. 80-17-CIV-5 (E.D. N.C., December 17, 1982); Webb v. United States, No. 79-4070 (N.D. Iowa, June 29, 1982); Elsworth v. United States, No. 78-2553 (D. N.J., March 4, 1981); Peoples v. United States, No. 79-X-0979-S (N.D. Ala., March 31, 1981); Shores v. United States, No. 78-X-0780-S (N.D. Ala., April 21, 1981); Wilson v. United States, No. 79-2929 (E.D. Pa., December 22, 1981); Stephens v. United States, No. 80-6-0100-W (N.D. Ala., November 23, 1981). Slip Opinions attached hereto as Exhibit 1.

> Records, reports, statements, or data compilations, in any form, of public offices or agencies, setting forth . . . factual findings resulting from an investigation made pursuant to authority granted by law, unless the sources of information or other circumstances indicate lack of trustworthiness.

These three studies are clearly such public reports admissible into evidence. See also Fed.R.Evid. 803(6) and (24). These studies constitute reports and statements of government agencies resulting from an investigation made pursuant to authority granted by law, setting forth factual findings,6/ and there are no circumstances indicating its lack of trustworthiness. In fact, "[i]n considering whether a factual report is sufficiently reliable to be admitted under Rule 803(8)(C), we start from the premise that such reports of investigations are presumed to be reliable." In re Japanese Electronics Products, 723 F.2d 238, 265 (3d Cir. 1983).

A number of decisions in suits against vaginal tampon manufacturers to recover for the contraction of Toxic Shock Syndrome ("TSS") are instructive. In Kehm v. Proctor & Gamble Co., 724 F.2d 613 (8th Cir. 1983), the Court of Appeals for the Eighth Circuit affirmed the district court's admission, under Rule 803(8)(C), of three epidemiologic studies by the CDC, and state health agencies concerning the relationship between tampon use

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6/ "Factual findings" include evaluation data. See Advisory Committee Note to Rule 803(8)(C); Litton Systems, Inc. v. AT&T Co., 700 F.2d 785, 818 (2d Cir. 1983), cert. denied, 104 S.Ct. 984 (1984)(FCC decisions regarding AT&T's tariffs, which concluded such tariffs were "unreasonable," are admissible under Rule 803(8)(C)).

and incidence of TSS. The appellate court rejected defendant's argument that their inability to cross-examine the sources interviewed for the studies rendered the studies untrustworthy. 724 F.2d at 618-19.

Similarly, in Wolf v. Proctor & Gamble Co., 555 F. Supp. 613 (D. N.J. 1982), the Court invoked Fed.R.Evid. 803(8)(C) to admit into evidence the TSS case control studies by the CDC. The Court found that studies based on diagnostic opinion were "factual findings" within the meaning of the Rule and that such studies were inherently trustworthy:

> [T]he motivation for accuracy in a record prepared by a public health official concerning outbreaks of serious disease within an area committed to his charge is obvious. A brand of expertise sufficient to insure accuracy may be assumed. . . .

555 F. Supp. at 625, quoting Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1288 (5th Cir.), cert. denied, 419 U.S. 1094 (1974).

More recently, the Fourth Circuit ruled that a district court's refusal to admit TSS epidemiological studies carried out by the CDC and various health agencies constituted reversible error. Ellis v. International Playtex, Inc., No. 83-1275 (4th Cir., September 25, 1984) (to be published at 745 F.2d 292) (See, Exhibit 1).

Second, these studies may be relied upon by expert witnesses, such as Dr. Stein, under Fed.R.Evid. 703. That Rule states:

> The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to him at or before the hearing.

> If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.

This rule specifically permits an expert to rely on a study performed by another. See, e.g. In re Air Crash in Bali, 684 F.2d 1301, 1314-15 (9th Cir. 1982); Bauman v. Centrex Corp., 611 F.2d 1115, 1120 (5th Cir. 1980); Boumholser v. Amex Coal Co., 630 F.2d 550, 553 (7th Cir. 1980).

In her sworn affidavit, Dr. Stein states that "these epidemiological studies are of a type reasonably relied upon by epidemiologists for the formation of their opinions and conclusions. I rely upon them in support of the matters which I have set forth in this affidavit." Plaintiffs offer no testimony or expert opinion to refute Dr. Stein's findings.

Finally, plaintiffs suggest that summary judgment cannot issue because these studies do not conclusively establish lack of causation. Opp. Memo. at 25. Plaintiffs' statement of the United States' burden under Rule 56 is plain wrong. Furthermore, they proffer no medical or scientific method to link a specific incident of their birth defects to paternal exposure to phenoxy herbicides. Plaintiffs do not dispute the fact that no epidemiological evidence substantiates or even corroborates plaintiffs' contentions, or that the CDC, Ranch Hand and Australian studies found that one's status as a Vietnam War veteran does not render it more likely than not that the birth defects of his subsequently

conceived offspring was induced by his exposure to phenoxy herbicides in Vietnam. In response to the United States' Motion, plaintiffs have pointed to nothing in the record which would create a triable issue of material fact. Nothing is offered to substantiate their speculation that paternal exposure to Agent Orange -- and not any other stimulus which causes infants to be born with defects -- caused their injuries.

D. Proof that Agent Orange In Fact Did Not Cause Genetic Injury Is Unnecessary

Plaintiffs contend that, in order for the United States to prevail upon its Motion for Summary Judgment, it "must establish that in fact Agent Orange did not cause the injuries of the plaintiffs and could not have done so." Opp. Memo. at 5. Plaintiffs further submit that, for the purpose of summary judgment, "[t]he question . . . is not what plaintiffs can or cannot prove." Id. Not surprisingly, plaintiffs do not offer a single case to support either proposition.

Plaintiffs ability to prove that it is more likely than not that a serviceman's exposure to Agent Orange in Vietnam caused injuries to his wife or offspring is obviously crucial to plaintiffs' case. The United States' Motion, which was made and amply supported as provided in Rule 56, argues that there can be no genuine dispute that plaintiffs cannot prove this crucial element of their case, so that as a matter of law they cannot recover. Whether Agent Orange could have "conceivably" caused plaintiffs' alleged injuries (which plaintiffs have not shown by

any scientifically recognized method) is, quite simply, irrelevant.

E. Plaintiffs' Burden Elimination/Reduction Argument Is Unfounded.

The relative merits of plaintiffs' contention that their burden of proof of causation be eliminated altogether, or reduced to "proof of what is possible or conceivable," is reflected in the complete lack of legal authority supporting their position. Plaintiffs' perceived need to advance such an argument is indicative of the low quality of plaintiffs' proof concerning genetic causation.

Plaintiffs proffer a number of arguments in support of burden elimination or reduction.7/ For example, plaintiffs aver that, "[i]t is not seriously disputed that the government's use of dioxin-contaminated Agent Orange in Vietnam created a risk of harm to the plaintiffs," and that "plaintiffs are suffering harms or injuries as a result of conditions, illnesses, and for diseases which have been demonstrated by the medical/scientific literature to be the same or to be the type of harms caused by exposure to dioxin." Opp. Memo. at 21. Plaintiffs' counsel cannot, in earnest, suggest that this statement is an expression of his best "knowledge, information and belief formed after reasonable inquiry",

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7/ Plaintiffs have already presented their arguments in support of "burden shifting" in their Memorandum in Opposition to the United States Motion to Dismiss and at oral argument. This Court found that since the level of plaintiffs' proof "is around zero," burden shifting, even if appropriate, would not assist plaintiffs case. Tr. Hearing, October 11, 1984 at 76-77. For similar reasons, plaintiffs' request that their burden be "reduced" to the "substantial factor" test would hardly enhance plaintiffs' case. See Prosser and Keeton, The Law of Torts, § 41 at 265 (5th ed. 1984).

and is "well grounded in fact."8/ Fed.R.Civ.P. 11. 9/ The total void in plaintiffs' proof obviates the need to consider plaintiffs' alternative reasons for burden elimination or reduction.

In sum, plaintiffs' proof of what is "possible or conceivable" is irrelevant to the disposition of the United States' Motion.

III. PLAINTIFFS' PROOF DOES NOT CREATE A GENUINE ISSUE OF MATERIAL FACT

After many long years of discovery, and despite the voluminous scientific and medical literature which has focused upon the

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8/ For this reason, plaintiffs' reference to Allen v. United States, 588 F. Supp. 247 (D.Utah 1984)(appeal pending) is entirely misplaced. Even Judge Jenkins insisted that plaintiffs must first establish a "rational, reasonably exclusive relationship between defendants' conduct . . . and each claimant's asserted injury," 588 F. Supp. at 414. It was plaintiffs' burden to demonstrate such a "strong factual connection" before burden shifting would even be considered. 588 F. Supp. at 411. No such relationship or connection exists here.

Plaintiffs' reliance on Stubbs v. City of Rochester, 226 N.Y. 516, 526, 124 N.E. 137, 140 (1979)(Opp. Memo at 20) is similarly misplaced. They inaccurately construe Stubbs as holding that a one-sixth (16-17%) increased incidence of typhoid cases following water contamination constituted "reasonable certainty" of causation. In fact, the case involved a six-fold (600%) increased incidence during the months of water contamination, as contrasted with the background incidence of the disease during the months when no contamination was apparent. Also, the toxin in Stubbs was a known cause of typhoid, whereas Agent Orange is not a known cause of male-mediated birth defects. Moreover, the Stubbs court indicated that even the 600% increased incidence of typhoid would not foreclose a trier of fact from rendering a verdict in favor of the alleged tortfeasor. Id. at 40.

9/ Plaintiffs' counsel make absurd accusations of "reprehensible" and "akin to criminal" conduct on the part of the United States, in support of their meritless burden elimination and reduction argument. Opp. Memo. at 15. Counsel did not have the slightest colorable basis for making such accusations. Similarly, plaintiffs' suggestion that the United States uniquely possesses information concerning causes of adverse reproductive outcomes and effects of phenoxy herbicides is specious.

etiology of adverse reproductive outcomes and the health effects of phenoxy herbicides and their components, plaintiffs have been unable to point to even a single study or medical article which substantiates the proposition that they were caused to suffer miscarriages or birth defects as a result of the exposure of male servicemen to Agent Orange in Vietnam. 10/ Perhaps appreciating the weakness of their burden elimination/reduction arguments, they introduce what is incredibly characterized as proof of "but for" causation.

Plaintiffs cite only deposition fragments from six individuals whom they named as expert witnesses and unsigned affidavits purportedly submitted by two of those witnesses. Before scrutinizing each of these deposition segments and "affidavit" statements,11/ it would be useful to focus upon the requirements of Fed.R.Civ.P. 56(e) and Fed.R.Evid. 703. Rule 56(e) provides, in pertinent part, as follows:

> Supporting and opposing affidavits shall be made on personal knowledge, shall set forth such facts as would be admissible in evidence, and shall show affirmatively

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10/ See e.g., deposition of Alvin Young, Apr. 20, 1984, at 386-388 and Young dep. Exhibit 13, introduced at p. 346 (attached hereto as Exhibits 2 and 2A respectively).

11/ Both "affidavits" are unsigned and therefore do not constitute affidavits within the meaning of Fed.R.Civ.P. 56(e). They should not be considered by the Court for that reason alone. Furthermore, the tardy submission of the Levin "Affidavit" as well as the suggestions in plaintiffs' attorney Neil R. Peterson's November 21, 1984 letter that the "affidavit" did not emanate from Dr. Levin but from counsel justifies the Court in striking the Levin "Affidavit."

> that the affiant is competent to testify to the matters stated therein. . . . The court may permit affidavits to be supplemented or opposed by depositions. . . .
>
> When a motion for summary judgment is made and supported as provided in this rule, an adverse party may not rest upon the mere allegations or denials of his pleading, but his response, by affidavits or as otherwise provided in this rule, must set forth specific facts showing that there is a genuine issue for trial. If he does not so respond, summary judgment, if appropriate, shall be entered against him. [Emphasis supplied].

Thus, the deposition segments and affidavits upon which plaintiffs rely must not only constitute expressions of expert opinion, but must set forth the basic facts upon which the experts rely and affirmatively show that the experts are competent to testify to the matters stated therein. The Second Circuit recognized in Donnelly v. Guion, supra, 467 F.2d 290, a case cited by plaintiffs, that a party opposing summary judgment may not simply rely upon an affidavit which fails to state the underlying factual bases or reasons upon which the conclusions or opinions contained within the affidavit are premised. An affidavit must provide a "reasonable ground" for its conclusions so "as to satisfy the Judge that those are facts which make it reasonable" that a party shall be allowed to raise those matters at trial. Wallingford v. Directors of the Mutual Society, 5 A.C. 685, 704 (1880)(Lord Blackburn), appearing in B.L. Shientag, "Summary Judgment," 4 Fordham Law Rev. 186, 207-208 (1935).

Expert witnesses often rely upon facts outside their personal knowledge, i.e., hearsay. Under Fed.R.Evid. 703, an expert

may not rely upon hearsay for the formation of his opinions unless that hearsay is "of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject." The Advisory Committee has noted that not all opinion testimony by an expert witness is admissible:

> Facts or data upon which expert opinion are based may, under the rule, be derived from three possible sources. The first is the first hand observation of the witness, with opinions based thereon traditionally allowed. A treating physician affords an example. . . . The second source, presentation at the trial, also reflects existing practice. The technique may be the familiar hypothetical question or having the expert attend the trial and hear the testimony establishing the facts. . . . The third source comtemplated by the rule consists of presentation of data to the expert outside of court and other than by his own perception. . . . [N]otice should be taken that the rule requires that the facts or data "be of a type reasonably relied upon by experts in the particular field."

Notes of Advisory Committee on Proposed Rules, Fed.R.Evid. 703. As discussed below, the affidavits and deposition testimony submitted by plaintiffs in opposition to summary judgment fail to meet these threshold requirements for the viability of expert opinion testimony.

A. Plaintiffs' Proof Suffers From Common Fundamental Defects.

Grasping for any morsel of evidence to create the aura of a genuine factual controversy, plaintiffs tout twenty-three deposition segments and the two unsigned "affidavits." Measured against

the threshold requirements for all affidavits and expert testimony, plaintiffs' evidence is incurably deficient.

First, plaintiffs submit two unsigned documents which they erroneously refer to as "affidavits." Affidavits must be signed, and absent signature they have no legal significance. Fed.R.Civ.P. 56(e). See also, Fed.R.Civ.P. 11. Unsworn statements cannot be considered on a Motion for Summary Judgment. Adickes v. S.H. Kress & Company, 398 U.S. 144, 154 (1970); Schwartz v. Compagnie General Transportation, 405 F.2d 270, 273 and n.1 (2d Cir. 1968). Consequently, plaintiffs' two so-called "affidavits" are in fact not affidavits and should not be considered by this Court.12/

Second, the "affidavits" suffer from the fundamental and fatal defect that they do not derive from the alleged affiants' personal knowledge [See, e.g. Applegate v. Top Associates, Inc., supra, 425 F.2d 92, 96-97; Brady v. Hearst Corp, 281 F.Supp. 637, 642 (D. Mass 1968)] or set forth the affiants' credentials and qualifications with such specificity as would qualify them as expert witnesses under Fed.R.Evid. 702 and 703.

Third, the "affidavits" disobey the time-honored dictate that they "condescend upon the particulars," rather than simply pronounce general conclusions. Wallingford v. Directors of the

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12/ Nor are the two "affidavits" rehabilitated by the unsworn hearsay representations of plaintiffs' counsel that the alleged affiants have agreed to subscribe to all statements contained within the unsigned "affidavits." Statements by attorneys have no probative value on a motion for summary judgment. Mercantile National Bank At Dallas v. Franklin Life Ins. Co., 248 F.2d 57, 59 (5th Cir. 1967).

Mutual Society, supra, 5 A.C. 685, 704. They do not fall within the outer limits set by the Second Circuit in Applegate v. Top Associates, Inc., 425 F.2d 92, 96-97 (2d Cir. 1970):

> We admit to having been fascinated and intrigued by this tale, which could only be matched by an Ian Fleming novel. To avoid summary judgment, however, a plaintiff must do more than whet the curiosity of the court; He must support vague accusation and surmise with concrete particulars. . . . To prevent the exchange of affidavits on a motion for summary judgment from degenerating into mere elaboration of conclusory pleadings, Rule 56(e) requires 'supporting and opposing affidavits (to) be made on personal knowledge (and to) set forth such facts as would be admissable in evidence.' Applegate, however, has submitted an affidavit grounded on suspicion, and bound together with rumor and hearsay. He has provided the court with characters and plot line for a novel of intrigue rather than the concrete particulars which would entitle him to to a trial. [Emphasis supplied].

The plaintiffs' deposition fragments are fraught with similar defects, including the failure to formally provide the Court with the referenced testimony, and thus making it part of the record; failure to qualify the witnesses as experts under Fed.R.Evid. 702; failure to divulge the basic facts and reasons upon which the purported experts' testimony is based; and failure to demonstrate that the witnesses' opinions are expressed with sufficient probative certainty and based on material of a type reasonably relied upon by experts in their fields. See Fed.R.Evid. 703. Assuming, arguendo, that all of plaintiffs' items are technically valid and admissible, they nevertheless fail to

present a genuine factual 13/ issue under Rule 56, of "more likely than not" causation, as will be discussed in the context of the overall deposition testimony rendered by each of the six witnesses and the unsigned "affidavits" attributed to two of them.

Finally, it should be noted that ten of the twenty-three deposition segments refer solely to either the Jordan family or Kerry Ryan, none of whom are plaintiffs in any of the instant actions. Therefore, no testimony regarding these individuals is sufficient to create a genuine issue of fact precluding summary judgment against the plaintiffs. Furthermore, even assuming the addition of the Jordans or Ryans as party plaintiffs in the instant actions, the testimony which plaintiffs offer from each witness is not sufficient to preclude summary judgment.

B. Each Item Of Proof Submitted By Plaintiffs Is Inadequate

An analysis of the material submitted by plaintiffs in the name of each witness reveals that plaintiffs have foresaken their Fed.R.Civ.P. 56(e) burden to demonstrate "more likely than not" causation.

13/ Plaintiffs' reliance upon Sartor v. Natural Gas Corp., 321 U.S. 620 (1944) (Op. Memo. at 3) is misplaced as it does not support the proposition for which it is cited, but is specific only to issues pertaining to damages where the prior language of Fed.R.Civ.P. 56 expressly disfavors summary judgment. Id. at 623. Moreover, no genuine issue of dispute as to "more likely than not" causation exists here. Questions of credibility as to the United States' evidence -- even if they are genuine -- are irrelevant where, as here, plaintiffs have no evidence which would support a judgment in their favor.

1. Maureen Hatch

Perhaps plaintiffs' foremost expert is Dr. Maureen Hatch. Her testimony is cited for the propositions that Agent Orange exposure to males is associated with increased birth defects in humans, that a modest to moderate increase in birth defects has occurred in children of male veterans exposed to Agent Orange, and that Agent Orange exposure appears to have a causal association with congenital malformations in the offspring of exposed fathers. See Opp. Memo. at p. 30 and Hatch deposition at pp. 134, 139, and 418-419.

At no point does Dr. Hatch testify that Agent Orange caused the wives or offspring of exposed servicemen to experience adverse reproductive outcomes of any type. The limited deposition segments which the plaintiffs have offered are taken completely out of context. Even Dr. Hatch's sporadic allusions to an "association" are not based upon material of a type reasonably relied upon by experts in her field, as required by Fed.R.Evid. 703. Nor, as required by Fed.R.Civ.P. 56(e), does she set forth the threshold facts which underlie her suggestions that an "association" may exist.

The three deposition segments selected by plaintiffs cannot be viewed in isolation. They must be considered in light of the entire testimony. The notion that plaintiffs have presented a genuine issue of fact for trial is completely disspelled by the following testimony rendered by Dr. Hatch:

(a) The word "association" does not equate either with "inference" or "cause." (p. 35)

(b) Dr. Hatch has not analyzed the Ranch Hand study data on reproductive effects following exposure to Agent Orange. (pp. 41-42)

(c) Dr. Hatch is not yet convinced that there is a positive association between birth defects and exposure to Agent Orange. (p. 51)

(d) Dr. Hatch can say only that she "think[s]" that there is an association between parental exposure to Agent Orange and birth defects in offspring and that this association "may" be causal. She is not convinced that there is a positive causal relationship between exposure to Agent Orange and birth defects. (p. 54)

(e) "I'm not convinced without further evidence that there was a causal relationship between Agent Orange and neonatal deaths." (p. 57)

(f) Kerry Ryan's birth defects "may have followed the father's exposure to Agent Orange." (p. 87) Dr. Hatch is presently unable to render a professional opinion as to the etiology of the birth defects of the Jordans and Kerry Ryan. (pp. 90-91) Her findings as to the Jordan and Ryan children are "preliminary." (p. 99)

(g) The comparison of Kerry Ryan's birth defects with those occurring in Vietnam is not sufficient for Dr. Hatch to causally attribute Kerry Ryan's birth defects to her father's exposure to Agent Orange in Vietnam. (p. 101).

(h) Dr. Hatch does not yet know if she will testify as to causation in the instances of Kerry Ryan or the Jordan children. While the Ranch Hand evidence will cause her to reconsider, she will first discuss the matter with her colleagues, such as Dr. Zena Stein. (pp. 130-131).

(i) An "association" can exist without there being a "causal relationship." (pp. 141-142) There can even be "strong associations without a causal connection . . . . " (p. 141) Dr. Hatch really does not know whether Agent Orange causes birth defects in humans through male exposure. (p. 142)

(j) The causation of birth defects in humans as a result of exposure of males to chemical compounds is a "possibility." (p. 179)

(k) There is really nothing more than theory to support the proposition today that human male exposure to chemicals causes chromosome lesions. (p. 188)

(l) Dr. Hatch knows of no support for the proposition that gene mutations are caused by human male exposure to chemicals. (p. 190)

(m) Even if Agent Orange causes perinatal deaths or spontaneous abortions, this still would not allow one to say that Agent Orange would necessarily cause birth defects. (p. 194)

(n) It is fair to say that presently there is no evidence to show that male exposure to chemicals causes altered sperm resulting in birth defects. (pp. 199-200) Dr. Hatch knows of no evidence showing chemical exposure leading directly to altered semen quality leading in turn to adverse reproductive outcomes. (p. 200) Nor does Dr. Hatch know of any evidence to support the proposition that male chemical exposure can result in the transference of toxic substances through seminal fluid to an embryo in humans. (p. 200)

(o) There is no direct evidence as to the existence of biological mechanisms for male mediated birth defects in humans. (pp. 201-202) Dr. Hatch comments that there are four theories as to how male exposure in humans to Agent Orange might cause birth defects, but states that there is no support for any of those theories and no direct evidence as to the mechanisms involved under these four theories. (p. 202) Nor is she aware of any other theories which might be invoked. (p. 202)

(p) Dr. Hatch is unaware of "any acceptable evidence" of the transmission of dioxin teratogenicity "through the male." (pp. 345-346)

(q) There is no evidence of molar pregnancies in humans induced by male herbicide exposure. (pp. 467-468)

(r) It is not clear whether Dr. Hatch will testify as to causation regarding either the Jordans or Kerry Ryan; Dr. Hatch will not testify regarding the adverse reproductive outcomes of other families or other individuals. (pp. 481-486)

Finally, plaintiffs' position on causation is further undermined by the exhibits which accompany Dr. Hatch's deposition. See e.g., Exhibit 6 (acceptable evidence of dioxin reproductive toxicity in animals through the male is unknown; studies regarding reproductive effects of Agent Orange are inconclusive); Exhibit 4, p. 2, (there is not yet solid evidence that paternal exposure to a chemical or physical agent can result in congenital malformations in humans); Exhibit 7, p. 4 (exposure of human males to a chemical agent has not been associated with anomalies in offspring; even exposure of male animals to Agent Orange or its components has not produced an anomaly in an animal offspring). The deposition of Dr. Hatch demonstrates only that plaintiffs' proof of causation is non-existent and therefore summary judgment should be granted in favor of the United States.

2. Alan Scott Levin

None of the five deposition fragments plaintiffs offer from immunologist Dr. Levin is sufficient to create a genuine issue of fact regarding the existence of probable causation.

Four of the five deposition segments (nos. 5-8) are irrelevant altogether as they refer exclusively to the Jordan family, and to no plaintiffs in the instant litigation. The fifth segment, stating that "male mediated birth defects are produced by male mediated transmissible defects," [see no. 22 in Opp. Memo. at 30], is unintelligible and adds nothing to their causation arguments.

Despite plaintiffs' representations to the contrary, Dr. Levin does not testify that "[t]he birth defects of the Jordan children are causally related to the Agent Orange exposure of Dan Jordan". See no. 5 in Opp. Memo. at 29. He states only that their birth defects "in some way related to their father's exposure to herbicides in Vietnam." See Levin dep., at 481. Furthermore, Dr. Levin does not express even this vague opinion to a reasonable degree of medical or scientific probability or certainty. Additionally, he provides no foundation for his opinion, nor states that his opinion is based on material of the type that is reasonably relied upon by experts in his field. In short, his testimony does not fulfill the requirements of Fed.R.Civ.P. Rule 56(e) and Fed.R.Evid. 703.

Equally spurious are Dr. Levin's opinions regarding the etiology of the alleged miscarriage of Donna Jordan. See nos. 6-7 in Opp. Memo. at 29. Dr. Levin was unable to answer any questions regarding when this alleged miscarriage occurred or even in fact whether it occurred at all. See Levin dep. at 531. Dr. Levin did not learn of a miscarriage by Donna

Jordan from any medical records or even from anyone within the Jordan family, but rather through communications with counsel for plaintiffs. See Levin dep. at 534-543. He admits that as a competent medical practitioner he would be unwilling to give advice in a case under oath as to a specific plaintiff having had an abortion when he had never seen a medical record indicating that an abortion had occurred. Id. at 543. Dr. Levin simply assumed that Donna Jordan had a miscarriage or spontaneous abortion as a result of her husband's exposure to Agent Orange. Id. at 544. While he confesses that his opinion is based on the information provided to him by plaintiffs' counsel, he nevertheless volunteers that this is not the normal manner in which he forms opinions. Id. at 544-545. Even plaintiffs cannot believe that this constitutes information of a type reasonably relied upon by experts; hence, it is not admissible under Fed.R.Evid. 703.

Additionally, Dr. Levin's stresses that he actually needs further information in order to form an opinion as to the cause of Donna Jordan's alleged miscarriage. Id. at 547-548. He will require access to the medical records in order to formulate and express a final medical opinion. Id. at 548. Comments by plaintiffs' attorneys constitute his only source for information regarding the existence of Donna Jordan's purported pregnancy. Id. at 549-551. He has never seen any medical records relating to the miscarriage or pregnancy of Mrs. Jordan. Id. at 552. He merely assumes that her purported miscarriage was caused by

her husband's alleged toxic exposure. Id. at 553. Finally, when asked "was her pregnancy and miscarriage related to her husband's exposure," Dr. Levin simply responds: "I will answer that in the final form when I see the records." Id. at 554-555. He properly states that he is unwilling as a medical expert to base his opinion on what lawyers tell him. Id. at 555. Consequently, any remarks offered by Dr. Levin thus far do not constitute the expression of professional medical opinions. They present nothing more than inadmissible speculation.

Even Dr. Levin's comments regarding the etiology of the birth defects of the Jordan children are unaccompanied by any underlying facts or substantiating data. His soundings constitute nothing more than unsupported conclusions no different in quality than those rejected by the Second Circuit in Donnelly v. Guion, supra, 467 F.2d 290, 293. His testimony is not couched in terms of reasonable medical certainty or probability. Nor does he claim reliance on any material of a type which is reasonably relied upon by experts in the field of adverse reproductive outcomes. His testimony is not sufficient to oppose summary judgment in accordance with Fed.R.Civ.P. 56(e).

Moreover, the unsigned document which plaintiffs style "Affidavit of Alan S. Levin, M.D.," apart from its threshold inadmissibility,14/ adds nothing to the deposition testimony. Under close analysis, its probative value dissolves, leaving nothing upon which plaintiffs may rely:

14/ See footnote 11, supra, and accompanying text.

(a) The "affidavit" altogether avoids references to "paternal" exposure as a means for inducing adverse reproductive outcomes, and concentrates instead on "parental" exposures and those affecting the female "ovum." See ¶¶ 8 and 9. It fails to demonstrate how exposure of a male to a chemical or compound causes adverse reproductive outcomes in the mate or offspring of that male.

(b) The "affidavit" discusses genetic effects only in terms of possibilities, as clearly demonstrated by the fifteen references in ¶ 9 to "may," "can," and "if," as well as the context in which those words are used.

(c) In specifically discussing 2,3,7,8 TCDD in ¶ 9, the "affidavit" summarily states, without evidentiary support or explanation, that TCDD "can be involved" in any of three mechanisms of damage to protein: infers that TCDD can cause protein damage; opines, without proof, that DNA rearrangement proteins can be damaged, and hypothesizes that the induction of birth defects in the progeny of the host is a possible outcome. Aside from the fact that the "affidavit" ignores the requirements of Fed.R.Evid. 703 and Fed.R.Civ.P. 56(e) by failing to demonstrate reliance upon underlying facts and information of a type reasonably relied upon by experts in the field, it also provides absolutely no evidence that:

1) Agent Orange caused damage to proteins in exposed male servicemen;

2) the damaged proteins included DNA rearrangement proteins in the germ line; or

3) the damage to DNA rearrangement proteins in the germ line caused the progeny of the exposed servicemen to suffer birth defects.

(d) The "affidavit" points only to the Air Force Ranch Hand study to support the notion that there is an increased incidence of birth defects in offspring of servicemen exposed to Agent Orange. See ¶ 10. This assumption is refuted both by the Ranch Hand study itself and by the deposition of its lead author George D. Lathrop.15/ Furthermore, ¶ 10 speaks only of an "association," rather than a causal relationship. The chasm between even a statistically significant association and a causal association is often wide, requiring as many as ten steps to derive the latter from the former.16/ As plaintiffs lack even a statistical association, they have not taken the first step to establishing causation.

(e) The "affidavit's" incredible claim that "I have obtained and reviewed the medical records and detailed medical histories of the plaintiffs" [see ¶ 11] betrays the fact that Dr. Levin has not, as the "affidavit" falsely suggests, reviewed the medical records and detailed medical histories of all of the hundreds of persons named as plaintiffs in the instant actions. Equally suspect is the "affidavit's" claim that "[w]e have performed immunologic tests on the plaintiffs." The identity of the persons to whom the affidavit refers as plaintiffs in ¶¶ 11, 12, and 14 is shrouded in mystery. Dr. Levin's deposition references to the Jordans and the Ryans,17/ non-plaintiffs in the instant actions, infers that these might be the "plaintiffs" to whom his deposition refers. The "affidavit's" wholesale references to "plaintiffs," which refer neither to the entire group of plaintiffs nor to specific

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15/ See subsection (5), infra, for discussion of the Ranch Hand evidence and the Lathrop deposition.

16/ Black, B. and Lilienfeld, D., "Epidemiological Proof in Toxic Tort Litigation," 52 Fordham L.Rev. 732, 762-764 (1984).

17/ See nos. 5-8 in Opp. Memo at 29.

plaintiffs, can only leave the Court and the United States to speculate as to whom the "affidavit" refers. Consequently, it is not probative, and the "affidavit's" final comments regarding the alleged relationship between Agent Orange and birth defects in "plaintiffs" become a nullity.

(f) The "affidavit's" comment that "tests" performed on unidentified "plaintiffs" are "consistant with" [sic] immune dysregulation caused by exposure to 2,3,7,8 TCDD [see ¶ 12] is a non-sequitur. Allegations of consistency in this context are superfluous. The "affidavit" fails to state whether the test results are "inconsistent" with immune dysregulation caused by all other exposures. Thus, consistency is not probative, and fails to infer causation. 18/

(g) The "affidavit's" equivocal and unsubstantiated remark that the cause of damage to cells in the immune system is "similar" to damage to germ line cells [see ¶ 13] provides no proof of "more probable than not" causation.

(h) The "affidavit's" conclusions regarding causation [see ¶ 14] do not logically follow from its preceeding remarks, and is contradicted even by the Ranch Hand evidence upon which it so heavily relies. While the "affidavit" makes fleeting reference to "extensive medical and scientific literature," it provides not even a single citation to any articles which have established that the exposure of males to phenoxy herbicides, or any chemicals for that matter, have caused them to father children with birth defects.

18/ The consistency of two events does not suggest a causal connection. For example, the occurrence of hangnails and nosebleeds is not mutually exclusive. One may have either, neither, or both. The appearance of both a nosebleed and a hangnail in the same individual is totally consistent. Yet neither causes the other. Nor do the two result from a common cause.

(i) The "affidavit" surprisingly claims that Dr. Levin has actually "cared for and evaluated" patients with "birth defects caused by parental exposures to halogenated hydrocarbons including dioxanes substantially equivalent to 2,3,7,8 TCDD." See ¶ 8. However, he offers no proof, and appears to have failed to responsibly report these novel and unprecedented medical findings to the medical and scientific community by way of letters to medical journals or submission of a comprehensive study, or any other manner.

The weakness of both the Levin deposition fragments and "affidavit" reveals that the instant actions are ripe for summary judgment.

3. Deborah A. Barsotti

Dr. Barsotti's testimony was first cited for the proposition that "reproductive dysfunction is associated with dioxin exposure in humans and animals." See Plaintiffs' Opp. Memo. at 29. This testimony creates no genuine issue of fact. It is not specific to Agent Orange. Nor does it pertain to male mediated birth defects or miscarriages. Nor is an association equivalent to causation. The only male effects which are discussed by Dr. Barsotti are decreased libido, sexual activity, and spermatogenesis in the exposed male, not his offspring. Barsotti dep. at 196-197.

Dr. Barsotti does not raise genuine issues of fact regarding the adverse reproductive outcomes of the wives and children of exposed servicemen. Consequently, Dr. Barsotti's second point, that "reproductive dysfunction in humans is increased by dioxin exposure" [Plaintiffs' Opp. Memo. at 30], has nothing to do

with the subject matter of the United States' Motion for Summary Judgment. Furthermore, Dr. Barsotti's peripheral references to an EPA study in Alsea County, Oregon regarding spontaneous abortions alludes merely to unpublished material which is not specific to male-mediated adverse reproductive outcomes; has not been submittted to this Court; has not been shown to be acceptable within any elements of the scientific community; and therefore, is irrelevant.

In short, Dr. Barsotti's testimony is defective under both Fed.R.Civ.P. 56(e) and Fed.R.Evid 703, and therefore does not interpose a basis for denying summary judgment.

4. Alastair Hay

Plaintiffs select only two propositions from the testimony of Dr. Hay. See Opp. Memo. at 30. The first proposition 19/ pertains only to the alleged birth defects of Kerry Ryan, who makes no claims against the United States. Futhermore, Dr. Hay's testimony is not rendered to a reasonable degree of medical or scientific certainty or probability, and fails to divulge either the basic facts or the underlying rationale for his opinion. It therefore amounts to nothing more than a speculative conclusion of a quality which is insufficient to withstand summary judgment under the requirements of Fed.R.Civ.P. 56(e) and Donnelly v. Guion, supra, 467 F.2d 290.

19/ See no. 16 in Op. Memo at 30.

Dr. Hay next suggests that "dioxin is probably responsible for untoward pregnancy outcomes and birth defects." See Opp. Memo. at 30. This factually unsubstantiated suggestion is insufficient to present a genuine issue of fact for trial. Nor is Dr. Hay's speculative opinion expressed to a reasonable degree of medical or scientific certainty or probability. Moreover, the opinion's dubious probative value is compounded by its nonspecificity either to a particular individual, or to an identifiable group of individuals. Finally, Dr. Hay concedes that he would need to know the precise level of exposure before giving an opinion with reference to any individual. Hay dep. at 513. As he has not yet expressed or substantiated such an opinion his testimony leaves unfulfilled plaintiffs' burden under Fed.R.Civ.P. 56(e).

5. Ellen Kovner Silbergeld

Plaintiffs rely upon Dr. Silbergeld's deposition to causally relate the adverse reproductive outcomes of only the non-plaintiff Jordan family to Agent Orange. Plaintiffs' counsel overlook the fact that their claims of injury to the Jordans present no issue in the instant litigation. See nos. 9-10 in Opp. Memo. at 20-30. The referenced testimony does not causally attribute to Agent Orange the miscarriages or birth defects of any of the instant plaintiffs or even those of the wives or offspring of Vietnam veterans generally. Consequently, Dr. Silbergeld's remarks create no genuine issue of fact.

Nor does Dr. Silbergeld directly testify, as plaintiffs' counsel represent, that "Donna Jordan's miscarriage 20/ was caused by Dan Jordan's Agent Orange exposure." Opp. Memo. at 29. Rather, she confesses only that she "thinks" it was caused by Dan Jordan's purported exposure. Silbergeld dep. at 284-285. Her testimony lacks reasonable medical or scientific certainty or probability and is therefore not probative. Nor does she base her opinion either on facts or data of a type reasonably relied upon by experts in her field. She affirms that her opinion is based only on Mr. Jordan's prior presence in Vietnam, the existence of two other untoward reproductive events in the Jordan family, and the purported consistency of the Jordan family's reproductive events with "animal toxicology" which she previously discussed in deposition. Neither that discussion nor the studies to which she alludes document any instances of male-mediated birth defects or miscarriages occurring in any animal models as a result of Agent Orange or dioxin exposure. Nor does Dr. Silbergeld document any instances of adverse reproductive outcomes being induced in humans by male exposure to dioxin or Agent Orange. Her opinions plainly enjoy no discernible factual basis which would justify an inference of causation. They are not premised upon any supporting material, and would not permit a reasonable person to conclude

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20/ As even Dr. Silbergeld would concede, adverse reproductive events are quite common and ordinarily occur in the absence of toxic exposures. Up to "sixty percent (60%)" of pregnancies end in miscarriage before term. See Silbergeld dep. at 282-283.

that Agent Orange caused the injuries which plaintiffs attribute to it. 21/

Dr. Silbergeld's conjecture regarding the cause of the birth defects in the Jordan children is equally baseless and at best only preliminary. She concedes that until she reviews their genetic history and the drugs to which their mother was exposed, which she has not yet done, she is unable to render an opinion regarding the etiology of their birth defects. See Silbergeld dep. at 313.

Finally, Dr. Silbergeld's cavalier references to "gonado toxicity and hormonal dysfunction" in conjunction with "TCDD reception" [see no. 23 in Opp. Memo. at 30] create no genuine issue of fact. Her testimony alludes only to possibilities, and is neither rendered with reasonable certainty or probability nor supported by facts or material of a type reasonably relied upon by experts in her field. See Silbergeld dep. at 210, 222-223.

The unexecuted document entitled "Affidavit of Ellen K. Silbergeld," aside from being in flagrant violation of the requirements of Fed.R.Civ. Pro. 56(e) and therefore inadmissible,

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21/ The standard for evaluating a motion for summary judgment is analogous to that attending a motion for directed verdict. See American Manufacturers Mutual Insurance Co., American Broadcasting-Paramount Pictures, 388 F.2d 272, 279 (1967), aff'd after remand, 446 F.2d 1131 (1971), cert. denied, 404 U S. 1063 (1972). See also, Sartor v. Arkansas Natural Gas Corp., 321 U.S. 620 (1944)(cited in Opp. Memo. at 4). The motion should be granted where the evidence produced by a plaintiff would not warrant a verdict in his favor.

adds nothing to plaintiffs' case. The purported "affidavit" is noteworthy for what it fails to accomplish. It does not identify any particular plaintiffs or even any identifiable groups of plaintiffs who allegedly suffered miscarriages or birth defects as a result of the exposure of their husbands or fathers respectively to Agent Orange in Vietnam. Even if it were technically sufficient and all of its statements were well documented by facts and by material of a type which is reasonably relied by experts, the "affidavit" would not authorize a trier of fact to reasonably conclude that the birth defect or miscarriage of any particular plaintiff, or even of any identifiable group of plaintiffs, was probably caused by alleged exposure of male servicemen to Agent Orange in Vietnam. Therefore, it raises no genuine issue of fact under Fed.R.Civ.P. 56 and provides no basis for denial of summary judgment.

While the Silbergeld "Affidavit" does not merit an extended analysis, there are several points for which responsive comments may be enlightening. First, the "affidavit's" peculiar reliance on the Ranch Hand study for the notion that Agent Orange causes diseases and effects of the type alleged by plaintiffs is altogether bizarre and outrightly contradicted both by the study itself and the deposition of George D. Lathrop, its lead author. In its Executive Summary, the study concludes:

> [T]here is insufficient evidence to support a cause and effect relationship between herbicide exposure and adverse

> health in the Ranch Hand Group at this time. . . . In full context, the baseline study results should be viewed as reassuring to Ranch Handers and to their families at this time.

See Exhibit 5 at iii, attached to the Memorandum In Support Of The United States' Motion To Dismiss, Or In The Alternative, For Summary Judgment [hereinafter "Sum.J.Memo."]. The Ranch Hand data concerning "fertility and reproductive results are preliminary at this time as they are based largely upon subjective self reports that await full medical record or a child birth certificate verification." Id. at ii. Consequently, questionnaire data derived from persons who believe they have injuries and perceived them to have been caused by Agent Orange exposure could hardly be deemed to be material of a type reasonably relied upon by experts in causally attributing minor birth defects of a subjective nature to Agent Orange exposure. Significantly, in spite of the obvious biases inherent in a questionnaire reporting system, the Ranch Hand study found no significant differences between cases and controls in the incidence of severe or moderate birth defects, miscarriages, stillbirths, induced abortions, premature births, live births, learning disabilities, or infant deaths. Id. at ii. Moreover, all fertility and reproductive findings in the Ranch Hand group showed inconsistent relationships to the herbicide exposure index. Id. at ii. The Ranch Hand study raises no genuine issue of fact regarding the cause of the plaintiffs' injuries.

Dr. Lathrop's testimony22/ also shatters the illusion that the Ranch Hand study supports plaintiffs:

> . . . [A]ll fertility and reproductive analyses are judged highly preliminary at this time because they have not fully been verified by medical record and/or birth certificate verifications . . . . [T]he results reported herein for the most part rely upon subjective self-reports from the respondents, both Ranch Handers and comparisons and their spouses. Such responses can be influenced significantly by a variety of biases.
>
> . . . Basically we determined that there were no differences in birth defects between the Ranch Hander comparison group for severe birth defects, that is those birth defects classified as life threatening.
>
> For the category of moderate birth defects defined as those birth defects requiring constant medical care, there was also no difference detected between the Ranch Hand and comparison group.
>
> With respect to minor birth defects, 23/ however, there was a marked and highly significant difference between the Ranch Hand group and the comparison group with the Rand Handers reporting more minor birth defects than the comparison group.

22/ For reference to Dr. Lathrop's qualifications, See Lathrop deposition at 8-17 (April 4, 1984) (attached hereto as Exhibit 3). [Deposition continues on April 6, 1984].

23/ Dr. Lathrop discusses what is meant by "minor" birth defects:

> . . . There are a series of birth defects that appear in the ICD 9 Code and are defined as birth defects not requiring any medical care whatsoever. For example they include the following conditions: Birth tags, birth marks, hyperpigmentation, neonatal jaundice lasting less than one week, forceps marks found at delivery, port wine stains and so forth. Most studies would not have reported these birth defects whatsoever in the analysis of overall birth defects because of their exceedingly minor nature.

Lathrop dep. at 195-196.

> . . . [T]his is a spurious finding based upon a maldistribution of one category of birth defects.

Lathrop dep. at 194-196 [Emphasis supplied].

As to the so-called positive associations within Ranch Hand to which the "affidavit" alludes, Dr. Lathrop stresses that birth and death certificate review is absolutely required to validate the information. Id. at 199-200.

Dr. Lathrop unequivocably states that the Ranch Hand study does not establish in any way that exposure to Agent Orange by the Ranch Hand personnel in Vietnam caused any adverse birth outcomes in their children,24/ and further explains:

> While certain and clear differences were noted with respect to Ranch Hand and comparison group we must refer to the issue of biologic plausibility in the issue of cause and effect. It is specifically noted that there is not one example in the medical literature in any respect, or animal literature, that cites an increase in birth defects or abnormal birth defect outcomes by virtue of singular exposure to the male member of the pair.

Id. at 203. [Emphasis supplied].

Even more appalling is the purported Silbergeld "affidavit's" wholly misplaced and misleading reliance upon the testimony of Dr. Fiona Juliet Stanley before the Australian Royal Commission, which in fact refutes the "affidavit's" suggestion and supports

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24/ See also Lathrop dep. at 205-207, where the Ranch Hand study author rejects the notion that the study would allow one to reasonably conclude that the exposure of American servicemen to Agent Orange "could" have caused adverse birth outcomes.

the position of the United States that plaintiffs lack proof of causation.25/ See ¶9. At the outset, Dr. Stanley notes that the various causation hypotheses are "very unlikely" and "biologically are implausible." See Transcript of Proceedings Before the Royal Commission On The Use And Effects of Chemical Agents On Australian Personnel In Vietnam (testimony of Dr. Stanley), at 4328-4329 (Sept. 3, 1984) [attached hereto as Exhibit 4, and hereinafter referred to as "Stanley"]. In fact, she rejects the notion that Agent Orange exposure in Vietnam increases the likelihood of servicemen fathering children with birth defects. Stanley at 4356. See also Stanley at 4353. She further notes:

> . . . [T]here is no human chemical material mutagen yet demonstrated in any study that is in the literature.

Stanley at 4337.

Third, the "affidavit's" musings regarding the Seveso data are merely conclusory and fail to reveal the facts upon which they supposedly derive. In accordance with the Second Circuit's holding in Donnelly v. Guion, supra, 467 F.2d 290, its conclusions are therefore deficient and may not be deemed viable as an affidavit opposing summary judgment.

Finally, the "affidavit" is replete with other errors, deficiencies and shortcomings:

25/ For the convenience of the Court, the entire transcript of Dr. Stanley's testimony is attached as Exhibit 4.

(a) The "affidavit" refers in ¶ 5 to the consistency of Seveso data with both the CDC and Ranch Hand studies. Yet, the so-called Seveso data and unpublished Bisanti paper are not produced by plaintiffs. The "affidavit" therefore lacks a factual basis insofar as it refers to Seveso in ¶¶ 5-7. Moreover, the published reports regarding the Seveso incident, including that authored by the Bisanti group, fails to causally relate birth defects, miscarriages, or chromosome anomalies to the TCDD exposure which occurred there. See G. Reggiani, "Acute Human Exposure To TCDD In Seveso Italy," 6 Jrnl. Toxicol. & Env. Health 27-43 (1980); E. Homberger, G. Reggiani, et al., "The Seveso Accident: Its Nature, Extent, And Consequences," 22 Ann. Occup. Hyg. 327-367 (1979); L. Bisanti, F. Bonetti, et al., "Experience Of The Accident Of Seveso," Reprint from the Proceedings of the 6th ETS Conference, (Akademiai Kiaco, Budapest 1979)(attached hereto as Exhibits 5 through 7 respectively).

(b) The "affidavit" admits that the Seveso data is based on "insufficient numbers," [see ¶ 6] and consequently does not constitute material of a type which may be reasonably relied upon by experts in formulating an opinion that a causal relationship exists.

(c) The "affidavit" erroneously states that the CDC study, which focused on only major birth anomalies,26/ reported an increased incidence in "minor malformations (including hemangiomas)." [emphasis supplied]. See ¶ 5.

(d) The "affidavit" inaccurately concludes that the Ranch Hand study reported an increased incidence of spina bifida and cleft palate. See ¶ 5. 27/

26/ The CDC study examined 96 groups of only major birth defects. See Exhibit 3, pp. 1, 2, 10, attached to Sum.J.Memo.

27/ The CDC study does not accept the notion that its data supports an inference of a causal relationship between Agent Orange exposure and either spina bifida or cleft palate. See Exhibit 3, pp. 64-67, attached to Sum.J.Memo.

(e) The "affidavit" claim that the CDC study reported an increased incidence of neo-natal deaths is inaccurate. See ¶ 7.

(f) The "affidavit's" allegation that the CDC study "did not detail" its results with reference to those families having more than one child with birth defects is incorrect. Compare ¶ 7 with Exhibit 3, p. 53, attached to Sum.J.Memo. The CDC study concludes that the risks to exposed servicemen for fathering several birth defect babies was "negative" and "nonsignificant." See Exhibit 3, p. 53, attached to Sum.J.Memo.

(g) While the "affidavit" focuses on isolated "statistically significant" CDC findings, it is oblivious to the fact that five percent (5%) of the tests conducted in the course of an epidemiological study would ordinarily yield "significant differences even when there are no differences . . ." See CDC Study, at p. 63, attached as Exhibit 3 to Sum.J.Memo.

(h) The "affidavit" self-contradicts its ultimate conclusion. In ¶ 10, it states that "it can be said 28/ that the two major U.S. studies of Vietnam veterans document and add to the growing body of knowledge that dioxin exposure can and did cause adverse reproductive outcomes." Yet in ¶12 it emphasizes that "the absence" "of refined exposure data" with which "cause and effect relationships can be elucidated clearly."

6. Marvin S. Legator

Dr. Legator's seven deposition segments [see nos. 1-3 and 18-21 in Opp. Memo. at 28, 30] do not enhance plaintiffs' case.

28/ Dr. Silbergeld refrains, apparently, from herself saying this.

¶ 1: The notion of consistency adds nothing. Birth defects may be "consistent with" many things, including attending baseball games, speaking French or riding on motorcycles. Yet the fact that these events are not mutually exclusive with the occurrence of birth defects does not mean they cause birth defects. Futhermore, the witness' reference to toxic exposure is not specific either to male mediated effects, humans, or Agent Orange or its deriviatives.

¶ 2: The Ryan and Jordan children are not plaintiffs in this action. Nor does the witness attribute their alleged injuries to Agent Orange. He remarks only as to "what I would hopefully say." Legator depo. at 288-289. He also concedes that he did not review the Ryan and Jordan children's medical records, he is not a doctor of medicine, and he would not be familiar with many of the medical diagnostic terms. Legator dep. at 285. Furthermore, he admits awareness of the Jordan family's pre-Agent Orange exposure history of congenital malformations. Id. at 288-289. Yet he neither accounts for this history nor discredits it as evidence of a genetic predisposition toward birth defects independent of chemical exposure.

¶ 3: Aside from its irrelevance to any plaintiff in this litigation, this deposition segment refers only to the possibility of what "could" worsen any genetic predisposition of the Jordan children. It is not probative even as to the cause of the non-plaintiff children's alleged injuries.

¶ 18: This speculative, unsubstantiated comment that " . . . [t]he ah locus of the chromosome in man is a target site for TCDD," [Opp. Memo. at 30] is altogether irrelevant and offers no proof of "more probable than not" causation.

¶ 19: The referenced comment as to Ranch Hand study furnishing "evidence in support of mutagenic and birth defect effects from Agent Orange" [Opp. Memo. at 30] is at

variance with the deposition material which plaintiffs' Memorandum cites. The witness remarks merely that he finds that preliminary Ranch Hand data, which he has had little time to even look at and upon which he bases no opinions, "scares" and "bothers" him "a little bit." Legator dep. at 138-139. In any event, Dr. Legator's initial frightened response to the Ranch Hand data should easily be allayed by the full study and the deposition of its author Dr. Lathrop.29/ See subsection (5), supra.

¶ 20: The witness admits that the referenced comments, which enjoy no more than a theoretical basis, constitute only a "possible interpretation" as to what "one can envision."

¶ 21: Despite plaintiffs' representation to the contrary, Dr. Legator does not testify that "[t]here is evidence of male mediated birth defects from Agent Orange." Aside from failing to specify who suffered such defects and what types of defects occurred, Dr. Legator discusses the occurrence of such defects only in the context of non-probative conceivabilities and possibilities.

In short, Dr. Legator's testimony is entitled to no weight.

IV. PLAINTIFFS' APPLICATION FOR RELIEF PURSUANT TO RULE 56(f) IS UNWARRANTED

Plaintiffs' counsel have often touted their preparedness for trial of the very causation issue which is the subject of the United States' Motion. Indeed, only recently plaintiffs' counsel sought the award of a fee "multiplier" in recognition of their accomplishments, including their averred ability to withstand a

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29/ Not having examined the Ranch Hand data himself, Dr. Legator concedes that he is left to rely upon the conclusions of the study's authors. Legator dep. at 142-143.

motion for a directed verdict.30/ Tr. Hearing before the Honorable Jack B. Weinstein, Chief Judge, October 1, 1984, at 51-71. Thus, an application for relief pursuant to Rule 56(f) would hardly seem warranted. Nevertheless, plaintiffs' counsel represents 31/ that additional discovery is necessary in order to "demonstrate the shortcomings" of Dr. Stein's affidavit, and the CDC, Ranch Hand and Australian studies. Opp. Memo. at 41.

Rule 56(f) states:

> . . . [S]hould it appear from the affidavits of a party opposing the motion that he cannot for reasons stated present by affidavit facts essential to justify his opposition, the Court may refuse the application for judgment or may order a continuance to permit affidavits to be obtained or depositions to be taken or discovery to be had or may make such other order as is just. [Emphasis added].

Understandably, a party seeking relief pursuant to Rule 56(f) is required to set forth specific reasons why they are unable to produce affidavits opposing summary judgment, as required by Rule 56(e). Otherwise, Rule 56(f) could be used as a "backdoor defense" to any test of the merits of plaintiffs' claims, undermining the very purpose of the summary judgment procedure. See 6 MOORE'S FEDERAL PRACTICE, ¶ 56.24; Waldron v. British Petroleum Co., 38 F.R.D. 170 (S.D.N.Y. 1965), aff'd. 361 F.2d 671 (2d Cir. 1966).

30/ Plaintiffs' counsel applied for and obtained an opportunity to demonstrate the high state of their preparedness in order to justify a fee multiplier. Tr. Hearing, October 1, 1984 at 72.

31/ Plaintiffs' counsel's "affidavit" certifying the need for such additional discovery, as required by Rule 56(f), consists of an unsworn two sentence footnote at page 41. See also Fed.R.Civ.P. 11.

Plaintiffs have set forth no such reasons. Instead, they have offered what purport to be two affidavits, although unsigned, 32/ in opposition to the United States' Motion, demonstrating that invocation of Rule 56(f) is plainly unnecessary.

Plaintiffs' stated purpose for additional discovery provides yet another reason to deny their request. Plaintiffs' opportunity to depose Dr. Stein, or to depose anyone associated with one or all of the three major birth defect studies, will not take plaintiffs' causation case beyond one of mere suspicion or gossamer inferences drawn from the mere sequence of events. A "demonstration" of the so-called "shortcomings" of Dr. Stein's affidavit, and of the three birth defect studies, will not alter the fact that, after five years of litigation, plaintiffs can offer no sufficient proof of causation. Plaintiffs' application for additional discovery should be denied. 33/

32/ Plaintiffs do not contend that the Silbergeld and Levin affidavits are inadequate in any way. Therefore, the Court can assume that plaintiffs' submittal of these technically deficient and substantively inconsequential affidavits is unrelated to plaintiff's application for relief under Rule 56(f).

33/ Plaintiffs further suggest that they were somehow limited in their ability to conduct "causation" discovery against the United States. Opp. Memo. at 40. Apart from the fact that the United States is hardly the sole repository for causation relevant documents, plaintiffs' contention is utter nonsense. During the past five years of litigation, plaintiffs have had unbridled access to material relevant to the causation issue, from both within and outside of government. The United States has produced literally tens of thousands of pages of causation-relevant documents, including the medical records of all servicemen whose names appear on the Agent Orange Registry, literature searches and dozens of relevant studies. The United States has also produced dozens of causation-relevant witnesses, including Dr. George Lathop, one of the principal authors of the Ranch Hand Study. Plaintiffs' attempt to blame the United States for the nonexistence of causation proof will not revive their case.

IV. CONCLUSION

For the foregoing reasons, and those set forth in the prior submissions, the United States' Motion to Dismiss Or, In The Alternative, For Summary Judgment should be granted.

Respectfully submitted,

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