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UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

IN RE: "AGENT ORANGE" PRODUCT LIABILITY LITIGATION	:	MDL # 381 (JBW)
	:	(Civ. Nos. 79-747, 82-299, 82-767, 82-771, 82-777, 82-778, 82-779, 82-780, 82-781, 82-782, 82-785, 82-788, 82-855, 82-856, 82-1140, 82-1141, 82-1753, 82-1850, 82-2594, 83-907)

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

INTRODUCTION

The Agent Orange case is the antithesis of the type case in which summary judgment is appropriate. Almost every feature which Courts cite when denying summary judgment is present here. Agent Orange is a negligence case in which summary judgment is traditionally not available. 6 Moore's Federal Practice (Second Edition), ¶ 56.15 [1.-0], p. 56-399. More significantly, it involves complex policy issues of great public importance which need the full exploration of trial and, hence, should not be decided on affidavits. _____, ¶56.15 [1.-0], pp. 56-398, 404,

The policy considerations raised by the causation issue and its public importance are bvious. The executive and legislative branches of government have attempted to address this issue. However, they have neither compensated the veterans and their families for their injuries, nor succeeded in allaying their profound fears that their injuries were caused by the veterans' exposure to dioxin-contaminated Agent Orange.

The causation issue continues to be shrouded in great ongoing controversy within the scientific community. The epidemiological studies undertaken in an effort to resolve the causation issue are incomplete. As we will show, those studies which have been completed contain serious deficiencies for which the government is responsible which preclude their results from being used as a basis for granting summary judgment.

Nor does the motion of the United States for summary judgment[1/] satisfy the requirements of Rule 56 of the F.R. Civ.P., and even if it did, it could not now be granted consistent with Rule 56 (f) thereof. Moreover, there are numerous facts and mechanisms which render the application for such relief unwarranted and unsupportable.

THE LAW OF SUMMARY JUDGMENTS

We begin with the threshold concept that the moving papers must affirmatively

> ...show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. [Rule 56(c), F.R. Civ.P.]

This the United States has completely failed to do.

Second, there are certain "boilerplate" principles of law applicable to summary judgment motions which may be briefly summarized as follows:

a. The proponent has the burden of showing by credible evidence of sufficient probative weight, that there is no genuine triable issue of fact. Adickes v. Kress, 398 U.S. 144; Donnelly v. Guion, 467 F.2d 290 (2d Cir. 1972), Moore's Fed. Prac., ¶s 56.15 [1.-00], p. 56-405, 56.16 [3], p. 56-463.

b. Where the evidence on the issue which is

[1/]The United States' references to a motion to dismiss is hallucinatory. Such a motion is addressed only to the pleadings, which here are manifestly adequate, assuming their truth as required by such a motion, to withstand such an onslaught.

the subject of the motion for summary judgment is largely in the hands of the summary judgment proponent, the motion should be denied. Pollar v. Columbia Broadcasting System, 368 U.S. 464 (1962).

c. Where the issue to be resolved on the summary judgment motion depends on expert opinion which is sharply disputed, summary judgment is inappropriate. Sartor v. Arkansas Natural Gas Corp., 321 U.S. 620, (1944).

d. Affidavits supporting a motion for summary judgment may have insufficient probative value to satisfy the burden imposed upon the moving party, if not made on personal knowledge. Moore's Fed. Prac., 56.11(3), p. 56-231; Avery v. Norfolk & Western Ry. Co., 52 F.R.D. 356 (N.D. Ohio 1971). "Affidavits containing mere conclusions have little or no probative value for purposes of a motion for summary judgment." Moore's Fed. Prac., ¶ 56.11, p. 56-242.

e. Any reasonable doubt should be resolved against the movant. Van Brode Milling Co. v. Kravex Mfg. Corp., 21 F.R.D. 246 (E.D. NY 1957).

f. Courts should exercise great caution in granting summary judgments and should guard against depriving a party of a trial upon the merits when a bona fide dispute exists upon any material issue of fact. Minnesota Mining & Mfg. Co. v. Superior Insulating Tape Co., 284 F.2d 478, 483 (8th Cir. 1960).

Some explanation is in order in the facts of this case. Thus, for example, all courts have expressed difficulty with the concept of trial by affidavit, which is what the government proposes

here.[2] as Professor Moore has put it in discussing the leading case of Sartor v. Arkansas Natural Gas Corp., 321 U.S. 620 (1944):

> In Sartor v. Arkansas Natural Gas Corp., a suit to recovery royalties on the basis of market price alleged to be in excess of a 3-cent rate at which plaintiff has been paid, the Court reversed a summary judgment for the defendant. Justice Jackson emphasized the analoguous function of the judge in ruling on the motion to that which he exercises in ruling on a motion for a directed verdict; and noted that defendant's affidavits as to market price were given by interested or biased witnesses and their testimony, if given at trial, would have been for the jury to evaluate and for it to decide whether any and if any what, weight is to be given to their testimony. He stated that Rule 56 "authorizes summary judgment only where the moving party is entitled to judgment as a matter of law, where is it quite clear what the truth is, that no genuine issue remains for trial"; and that
>
> "It may well be that the weight of the evidence would be found on a trial to be with defendant. But it may not withdraw these witnesses from cross-examination, the best method yet devised for testing trustworthiness of testimony. And their credibility and the weight to be given to their opinions is to be determined, after trial, in the regular manner." (Citations omitted.)

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[2]/The sole support for the government motion is the affidavit of Zena A. Stein. (See infra in text for criticism of her affidavit). The vague and omnibus reference of the government in its motion to "the record of this litigation" is manifestly insufficient to put plaintiffs on notice of what they claim therein supports their motion. Be it remembered, the burden of proof here is on the government, not the plaintiffs; and the Federal Rules still have not foresaken their requirement of so-called "notice" pleading. No court should place on the opponent of the motion the onus of calling out what it is, at its peril, that the government thereby seeks to invoke on its behalf from the tens of thousands of pages of pleadings, documents, depositions and the discovery materials contained in "the record of this litigation." If the government is to lazy or recalcitrant to do its job properly, that is not the fault of plaintiffs; but, such a defalcation of duty palpably cannot entitle the government to summary judgment here.

6 Moore, Fed. Prac., ¶56.16 [1.-00], p. 56-402. See also Colby v. Klune, 178 F.2d 876 (2d Cir. 1949) in which Judge Frank held:

> Particularly where, as here, the facts are peculiarly in the knowledge of defendants or their witnesses, should plaintiff have an opportunity to impeach them at a trial; and their demeanor may be the most effective impeachment. [Id., at 874.]

Judge Frank also spoke out against an approach to litigation which wrongly disposed of highly contested matters at the pre-trial stage:

> We hear much of crowded trial dockets as the cause of deplorable delays in the administration of justice. The way to eliminate that congestion is by the appointment of a sufficient number of judges, not by doing injustice by depriving litigants of a fair method of trial. [Id., at 873.]

The reasons for these rules are obvious. They lie rooted in the fact that it is too easy for one party or the other to come forward with a trumped-up, conclusory affidavit, which is at the same time facially plausible and technically defective, and use it to try to alter the burden of proof and prevent that full inquiry which is rightly the hallmark of civil litigation. The plain fact here, in context, is that the government, to succeed on its motion, must establish that in fact Agent orange did not cause the injuries of the plaintiffs and could not have done so. The question here is not what plaintiffs can or cannot prove. Plaintiffs' need "prove" nothing, need show nothing to the Court or the Untied States until the government has shown, based on evidence whose credibility, materiality and strength is not in doubt, that there is no genuine issue as to causation. This it has not done.

Notwithstanding the obvious and articulated invitation by the Court to the government to file this motion, notwithstanding the government's hesitance to do so, and notwithstanding the Court's oft-repeated pre-analysis if not pre-judgment[3/] as to the weakness of the plaintiffs' causation case on birth defects, this Court can do nothing to or about the plaintiff's causation case unless it can do so within the scope and intendment of the Federal Rules of Civil Procedure. The bold-facedness of what the government attempts here at the Court's urging is highlighted by the facts that (1) no similar invitation by the Court was issued to the chemical companies who had just as much to lose as the government does, (2) no similar motion has been made by the government in response to the chemical companies' third-party complaint against it, (3) the court has allowed that third party complaint to go forward on the reproductive issue alone as the sole basis for recovery at the present time, and (4) the settlement with the chemical companies specifically took account of reproductive/birth defect instances in its countenancing a reservation of a portion of the settlement for future claims, with obvious reference to after-born children. It would be a cruel hoax indeed if the claims of the veteran plaintiffs to settlement moneys were dissipated by payment

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[3/]What this Court wrongly views as evidence of the weakness of the plaintiffs' reproductive case cannot substitute for the only legally permissible basis for decision here - that the government has shown beyond the shadow of a doubt that there is absolutely no way in which the plaintiffs oculd recover becasue there is no genuine issue between the plaintiffs and the United States on the issue of causation.

of benefits for reproductive misadventures if, at the same time, there could have been no recovery for such.

THE STEIN AFFIDAVIT

We turn now to the sole demonstrable basis for the government's motion--the affidavit by Zena A. Stein. This affidavit is so defective legally that it can profit the government nothing on this motion.

As to qualifications:

1. Stein derives some of her income from major research projects funded by the United States (NIH).

2. Stein is a consultant for the United States (NIEHS, EPA and NIOSH at least), presumably deriving income therefrom.

3. The affidavit is silent as to what "evidence" Stein gave to the Australian Royal Commission, whether it even involved birth defects, what she said, which side she took in the controversy if she was involved in it, how much work she did, who underwrote any expenses in regard thereto, and how much time she herself spent on doing research and/or reviewing literature on Agent Orange.

4. No publications which, from their title, appertained to Agent Orange.

5. No position which, from its title, involved any Agent Orange responsibilities.

6. No specific indication of training in the epidemicology of environmental exposures.

7. No indication of what specifics other than three studies, she reviewed in formulating her opinions.

8. No showing of any clinical examination or treatment of Agent Orange victims.

As to substance:

1. No statement of personal knowledge vs. information and belief.

2. Conclusory versus being a statement of facts within her knowledge.

3. No definition of "birth defect" and whether her practical experience is mental and/or physical birth defects.

4. What is comprehended by the term medical vs. medical/scientific literature (¶4), since very little is written by medical doctors, including CDC's Erickson who is a dentist by trade.

5. What a "trace contaminant" is and whether her use of the term "trace" somehow conditions her thinking as to the amount of exposure sustained by the plaintiff veterans.

6. When did she "examine" the proposition (¶5), for what purpose, at whose request, at whose cost.

7. What animal, human and general studies has she reviewed. How do plaintiffs counter such abstract generalities?

8. What animal data re phenoxy herbicides did she consider (¶7)? Did the phenoxy herbicides in questin contain TCDD? A dearth of authority implies some. What authority showed positive results. Is the other authority negative or merely neutral to the proposition? What are its strengths and weaknesses. How does that authority square with the increased incidence of embryo deaths in humans from Seveso? Who performed the negative or neutral studies and who financed the research?

9. Define the basis on which animal experimentation furnishes a predictor of human response (¶7). Does predictability have anything to do with dose? Does dose have anything to do with reproductive outcome. What is the mechanism of the effect.

Why is it impossible to postulate no threshold dose for reproductive effects? What is the effect of chronic versus acute exposure on reproductive effects. Does the lipophylic characteristic of TCDD import any concern for predictability or dose-effect relationships. Did the animal studies involve chronic or acute exposures? Does bioaccumulation have any impact on reproductive effect?

10. Why, in the last sentences of ¶ 7, do you seem to distinguish between epidemiologic data as being founded solely on human versus animal observations? Is animal study invalid? If so, why rely on it? If not invalid, is your reference to "dearth" not a matter of conclusion and inference versus fact? Is not this sentence a non-sequitur from what goes before?

11. What level of proof do you want for causal association or cause to be demonstrable?

12. Can you testify, on the basis of the three supposed epidemiologic studies set out in ¶ 8, that Agent Orange, as a matter of reasonable medical/scientific certainty did not cause the reproductive insult in any plaintiff in this litigation?

13. Have you reviewed the medical records of Chad and Michael Jordan or Kerry Ryan in this case? Have you read the depositions of their parents? Do you know how much Agent Orange exposure their fathers had?

14. What are the defects and weakenesses in the three studies to which you refer? Would a layman fully understand the import of those defects and weaknesses or would they require elucidation by expert witnesses in the fields of medicine, science and epidemiology? Are there not some specific positive results in each of the studies? Is or are any one or more of the studies capable of disproving causation of the reproductive insult in any given individual as a matter of absolute certainty?

15. Could fundamental mis-suppositions as to the exposure of those involved in the studies invalidate the results? What is your opinion of the governmental abuse of scientific integrity in manipulating the cohorts in Ranch Hand after the start of the study?

16. What importance do you attach to "statistical significance" as a baseline for predictability? Can multiple tests ever, together, alter the determinants for "statistical significance"? What significance would there be to a finding of cleft palates and spina bifida in animals exposed to dioxin as a teratogen and the same birth defects in humans as a result of paternal exposure. Is is impossible for maternal and paternal exposure to produce the same reproductive defect. Can children acquire birth defects from chromosomal changes in their fathers? Can they "inherit" birth defects from their fathers?

17. Are there any results which are absolutely certain on the basis of the three studies you cite.

18. Is there other birth defect data known from occupational or environmental exposures to dioxin?

19. Is it fair to say that you do not "know" that Vietnam service did not raise the risk of "major" birth defects? Is cleft palate a major defect? Is spina bifida? Is cancer in the offspring? Is excess spontaneous abortions?

20. Is it not true of Ranch Hand that, with a scope so broad, no meaningful data to support a negative can be said to arise as to any individual birth defect? Is it not the function of epidemiology to be as narrowly and precisely focused as possible?

22. Does the fact that imprecise studies do not yet show a causal connection mean that no such connection can ever be shown? If any one of the studies showed a general positive result, could it not be said that that positive result was open to doubt because of the inherent weakness of the study?

23. Is the "evidence" you refer to in ¶ 9 different than the studies in ¶ 8. If so, what is it? What is "consistent" evidence? Does this mean there is some evidence to support a relationship. If so, what is it? Why do you call it inconsistent?

24. Are there any clinical symptoms or chemical tracers (¶ 10) which can indirectly link defects to chemical exposure of the fathers? Are there any?

25. Does the face that you do not know of such symptoms or tracers for the fathers mean they do not exist?

26. What does "reasonable degree of certainty or probability" mean to you?

The list could be longer. There are more questions, more points of doubt, more conundrums, more weaknesses, more omissions, but, at a given point,their explication is like "carrying coals to Newcastle". The point of all this exercise is really quite simple. We simply don't know what Stein's pertinent qualifications are, what her knowledge is, what she bases her opinion on. Her affidavit is living proof of why Moore, in hundreds of pages of textual treatment, does not cite one instance of proving or disproving medical causation by affidavit in a summary judgment proceeding. The fact is that medical causation is an area fraught with nuances which affect the weight and even the admissibility of an opinion. At a minimum, plaintiffs are entitled to depose Stein to flesh out and contradict her affidavit and the conclusions in it.

At best, Stein's affidavit represents her and the government's view of things, a view substantially contradicted by several of plaintiffs' witnesses who testified on discovery by the chemical companies (Silbergeld, Hatch, Codario, Levin, Hay, Legator). See also the affidavits of Dr. Alan Levin and of Dr. Ellen Silbergeld attached hereto. Thus, the best the Stein affidavit does for the United States is to create a conflict. But, a conflict does not, by definition, establish the absence of a genuine issue of material fact.

THE "TEST" OF CAUSATION

This Court has suggested that the applicable causation standard is the "but for" or 51% probability test. However, that test is not a formulation of a neutral factual proposition against which the evidence on the causation issue can be evaluated to determine whether there are genuine disputed issues as to the material facts. On the contrary, the "but for" causation test is in reality a policy sensitive statement which operates here as a built-in bias against recovery. There is no hard and fast rule which requires this Court to apply the "but for" causation standard in preference to the less stringent "substantial factor" test. Delgado, "Beyond Sindell: Relaxation of Cause in Fact Rules for Indeterminate Plaintiffs", 70 Calif. Law Rev. 881 (1982); Malone, "Ruminations on Cause In Fact", 9 Stanford Law Review 60 (1956). Plaintiffs respectfully urge the Court to again review the cited law review articles for the useful insights they present on the causation issue.

Turning to our facts, there are three potential tests applicable here:

> [1] The "but for" test, under which the plaintiff must establish that without defendant's actions the injury would not have occurred, is the most frequently employed test.
>
> [2] A material and contributing factor test, which requires that plaintiff show only that the defendants' conduct contributed to his or her injury, is applied in some jurisdictions of mixed causation.

* * * *

> [3] Courts could also lower the burden of proof where a defendant's action appears especially reprehensible, so as to allow plaintiffs to recover by showing that causation is possible, or conceivable, rather than probable.

[Delgado, supra, 70 Cal. L.R. at 886-7, 897].

However, the but-for test is patently defective. As Malone puts it:

> The essential weakness of the but-for test is the fact that it ignores the irresistable urge of the trier to pass judgment at the same time that he observes. It is an intellectual jacket to which the human mind will not willingly submit. The test was discredited even for philosophical usage by David Hume, its originator. (Citations omitted.)

[9 Stanford L.R. at 66-67]. In support of the "substantial factor" test, Malone states:

> We demand that we be allowed to judge as we observe. Drama has triumphed over syllogism.

[Id., at 89].

Given the latency factor, the multi or mixed causal sources to which plaintiffs' diseases can be attributed and the government's sole responsibility for any deficiencies in the evidence needed to resolve the causation issue[4/], a strong equity and public policy argument exists for the application here of the less stringent "substan-

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[4/]See Plaintiffs' arguments supporting the shifting of the causation burden to the government, set forth in Plaintiff's Memorandum of Points and Authorities in Opposition to the U.S. Motion to Dismiss (dated 10/10/84), pp. 131-192.

tial factor" test. To do so would not require any radical departure from well settled judicial treatment of the causation-in-fact issue.

> "On its face, a simple mechanical formula requiring only a finding of but for causation is in reality a contextual policy sensitive instrument. The commentators, Malone[5], Green[6], Keeton[7], and Prosser[8], purport to find a sliding-scale approach in which courts apply the causation-in-fact requirement with decreasing stringency as the equities or public policies increasingly favor recovery. (70 Calif. L. Rev. at 891).

The Court is not powerless and should not hesitate to apply an appropriate causation standard tailored to the unique circumstances of the Agent Orange case. The record is clear on the government's fault for the use of dioxin-contaminated Agent Orange and the enormous disparity of knowledge on the causation issue between an all-powerful government and the plaintiffs, and the government's negligent conduct which imposed upon it sole responsibility for any deficiencies in the evidence needed to decide the causation issue. By any balancing test which weighs the justice, equity or public policy considerations incident to the causation issue, the plaintiffs should prevail. This Court in determining whether to apply the "but for" or "substantial factor" standards, should select the latter because plaintiffs deserve the benefit of a less stringent burden of proof in

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5/Malone, "Ruminations on Cause-in-Fact", 9 Stanford L. R. 60, 61-64 (1956).
6/Green, "The Causal Relation Issue in Negligence Law", 60 Mich. L.R. 543, 560-561.
7/Keeton, Legal Cause in the Law of Torts, VII 18-20 (1963).
8/Prosser, "Handbook of the Law of Torts", 237 (4th Ed. 1971), at 459.

keeping with the equities favoring plaintiffs.

Such an appropriate resolution here would not even involve the Court in a "reduced burden" analysis. However, here, we submit that the government's conduct meets the reprehensibility test justifying adoption of such a reduced burden standard. We begin with the fact that this Court has given substantial play and weight to the government contractor defense in its Fairness Opinion in this case. This means, perforce, that this Court viewed the government as probably having had as much or more knowledge than the chemical companies. This Court also certified a punitive class action against the manufacturers. Next, we know that the difficulty claimed by the United States to be present in the data which supposedly precludes a showing of causation is a difficulty caused totally by governmental failure to monitor and measure exposure and to test the servicemen at the time of exposure and immediately thereafter.

The fact is that the government has not moved against the plaintiffs on the ground that it was not negligence. What it says for purposes of this motion is that it can be as negligent as the day is long and that it can affirmatively preclude a finding of causation by its deliberate and/or negligent failure to test the product it procured, to monitor exposure, to treat and record reaction data, and to test its servicemen. The very concept is heinous. It is most akin to letting the criminal destroy evidence or obstruct justice. For any court to profess itself powerless to cope with such reprehensible conduct and permit the United States to proclaim that the

fruits of its omissions bar recovery makes a mockery of justice. As Malone states:

> Whenever a court's estimate of the impact of policy upon fact finds its most natural and comfortable expression in terms of quantity, it seems sensible that it should be free to abandon the but-for rule and resort instead to the substantial factor formula.

[9 Stanford L.R., at 96-7.] While Malone spoke of the substantial factor rule, the "reduced burden" standard of Delgado would also be appropriately invoked here.

Finally, the historical evaluation of the tort doctrines of causation casts serious doubt that the economic rationale underlying the "but for" causation test is appropriate in the unique circumstances of the Agent Orange case. The "but for" causation doctrine replaced the earlier doctrine of objective causation whose central legitimating function was corrective justice and the restoration of the status quo that existed before any infringement of a person's right.

> "The idea of vindication of individual rights was intimately connected with the notion of objective causation. Only if it was possible to say objectively that A caused B's injury would courts be able to take money from A and give damages to B without being charged with redistribution. Without objective causation a court might be free to choose among a variety of possible defendants in order to vindicate the plaintiff's claim. If the question of which of several acts "caused" the plaintiff's injury was open to judicial discretion, how could private law stay clear of the dangers of the political uses of law for purposes of redistribution." Morton J. Horwitz, "The Doctrine of Objecjtive Causation; The Politics of Law" ed. David Kairys, Pantheon Books, 1982, 201, 202.

The doctrine of objective causation borrowed from the natural sciences the notion that there were objective "chains of causation" from which judges could scientifically determine which acts in a complicated series of events really "caused" the plaintiffs injury. Horwitz, p. 202. The doctrine recognized the need to establish "proximate" cause as distinguished from remote cause and it sought to classify situations in which separate acts constituted "intervening" or "supervening" causes sufficient to break the "chain" and hold another defendant liable.

> "But, above all, it was necessary to find a single "scientific" cause and thus a single responsible defendant, for any acknowledgement for multiple causation would open the floodgates of judicial discretion." Horwitz, p. 202.

The doctrine of objective causation came under attack in the 1870's. It was disputed that the law could objectively distinguish between "proximate" and "remote" causes in order to assign legal liability in a non-discretionary manner. It was argued that the phrase "chain of causation" embodied a dangerous metaphor; that there was no single objective "proximate" cause, and that the true cause of any event was the whole set of its antecedents taken together. Horwitz, p. 203.

The perception arose that the doctrine of objective causation and its recognition of multiple causation would give judges uncontrolled discretion to infuse their concepts of politics and morality into the law and to impose tort liability upon entrepreneurs and thus inhibit economic growth.

Under the later attack in the 1920's of the school of Legal Realists, the ultimate result of the politics of causation was the replacement of the doctrine of objective causation with the "but for" causation test and its rationale of limiting entrepreneurial liability and promoting economic growth.

> "Without objective causation, the problem of assigning liability has become simple a question of the fairness of the distribution of risks", a concealed half-conscious battle on the question of legislative policy. Liability for injury had become just another cost of doing business, which could be "estimated", insured against, and ultimately included in the price paid by the public", Horwitz, p. 211.

It is clear that at its root, the "but for" causation test is simply a rule of fairness as to the distribution of risks that a Court applies in a given case in accordance with its tort policy preconceptions. It has limited significance in furthering tort law goals. Calabrese, "Concerning Cause and the Law of Torts", 43 U. Chi. L. Rev. 69, (1975).

In the Agent Orange case, there is no compelling "fairness" policy reason justifying application of the "but for" causation test as the burden to be met by the veterans in proving their claims against the government. The facts cry out for a less draconian causation standard.

In summary therefore, in the interests of fairness, justice and equity, the Court should reexamine its inclination to apply the "but for" causation test. The causation issue is so freighted with policy considerations and public policy importance that a full trial record should be developed before the Court determines whether to apply

the "but for" or "substantial factor" test or some alternative less stringent approach similar to those described as means of avoiding the causal problem. Since this a complete important case in which there is a genuine dispute as to what causation standard should be applied as a matter of policy, and since the application of the proper standard itself turns upon the development of a complete evidentiary record, plaintiffs are entitled to an ample opportunity for discovery on the causation issues. Hospital Bldg. Co. v Trustees, Rex Hospital, 425 U.S. 738 (1976). Summary judgment should therefore be denied.

BURDEN AVOIDANCE MECHANISMS

The Court has available to it several mechanisms by which to find that any burden on the plaintiffs has been satisfied. We say "any" burden because we submit, as set out infra, that there is not really or properly any burden on the plaintiffs to establish anything in terms of this motion. Essentially, here the burden is on the United States.

First, while not strictly a burden avoidance mechanism, the Court has available to it, as noted supra, two lowered standards of proof which are available in the facts of this case. On one level, it certainly can apply the "substantial factor" test. Whether this is because there are more than one potential causes of the injury or because this test tracks the vital reality of the judgment process without placing the trier in a mental straight jacket, the result is the same. Moreover, given only that the government's conduct be deemed

reprehensible, the Court could lower the burden to one of showing causation by proof of what is possible or conceivable, rather than the probably standard usually used. 70 Cal. L.R., at 897. Cf. Stubbs v. City of Rochester, 226 N.Y. 516, 526, 124 N.E. 137, 140 (1979), holding that a one-sixth increase in cases of typhoid after the city negligently allowed its water supply to be contaminated was reasonable certainty in the face of many other potential causes of typhoid, causes which the plaintiff could not distinguish. Compare that result ensuing upon a 16% increase in cases, with the "statistically significant" 200% litmus test increase upon which this Court erroneously insists, and this Court's result cannot even be called anachronistic.

Second, the Court could find that exposure to the risk attendant upon dioxin exposure is a harm in and of itself (See 70 Cal. L.R., at 896), thus disregarding any resolution of causation completely, The theory of recovery is akin to that underlying causes for infliction of mental distress. Recovery can be had under this theory for negligent conduct if the contact with and/or exposure to dioxin is treated as an impact, or for reckless disregard of the rights of others in the event that exposure to dioxin is not treated as an impact. We submit that the government's conduct would satisfy either level of proof, although that really is not at issue on this motion.

Third, the Court can avoid a burden-based decision by the use of a presumption. The presumption has its foundation in the FIFRA statute which presumes the Agent Orange herbicide to be a toxic

poison harmful to human health and in the judicial declarations that it is one of the most toxic chemicals known to man.[9] If the presumption is indulged, then plaintiffs have made out a prima facie case at the threshold. Certainly they make out enough of a case thereby to be entitled to go to a jury.[10]

The Court could also shift the burden of proof to the government once risk-creation and harm are shown.[11] It is not seriously disputed that the government's use of dioxin-contaminated Agent Orange in Vietnam created a risk of harm to the plaintiffs. The government's discontinuance of Agent Orange spraying after the Dow Chemical Company letter of June 15, 1970 to Secretary of Defense Melvin Laird is telling evidence of its belief that the spraying created such a risk. Thus, since plaintiffs are suffering harms or injuries as the result of conditions, illnesses and/or diseases which have been demonstrated by the medical/scientific literature to be the same as or to be the type of harms caused by exposure to dioxin, they satisfy the risk-creation/harm standard sufficiently to shift the burden to the givernment to prove that plaintiff's injuries were not caused by their exposure.[12] This approach was recently followed

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[9]/See plaintiffs' arguments regarding FIFRA and the regulatory and judicial history of 2,4,5-T set forth in Plaintiffs' Memorandum of Points and Authorities in Opposition to the United States' Motion to Dismiss (dated 10/10/84) pp. 167-188 (hereinafter Plaintiffs' Memorandum")

[10]/Of course, this assumes there is a burden on the plaintiffs, which there is not. The burden on this Motion, as noted *supra*, is on the United States.

[11]/Plaintiffs' Memorandum, pp. 151-166.

[12]/*Id.*, at pp. 151-166

by the Court in Allen v. United States, 588 F.Supp. 247 (D. Utah, 1984), a decision which this Court has cited with favor on this very issue in its Fairness Opinion. The Allen approach is apparently not new, having also been used in the leading English case of McGhee v. National Coal Board, 3 All E.R. 1009 (1972). See 70 Cal. L.R. at 896-7.

The Court can also avoid the burden problem in causation by estopping the government from denying causation once its negligent conduct and the occurrence of harm are shown.13/ The estoppel is justified not only by the negligent conduct of the United States, but also by its failure to monitor exposure, its failure to treat and record the symptoms of the servicemen, and its failure to test the veterans timely or to test the product before use.

Use of any of these mechanisms could nullify and/or reduce the burden on plaintiffs to permit their action to go forward. In so arguing, two cautions must again be set out. First, the burden here is not on the plaintiffs. Second, the argument assumes the propriety of the Court's statements on causation, an assumption the plaintiffs strenuously contest, as set out below.

THE LEGAL INSUFFICIENCY OF THE GOVERNMENT'S CASE

The only thing specific the government has given this Court is the Stein affidavit and the references therein. This is completely inadequate to serve as a basis for summary jdugment.

13/Plaintiffs' Memorandum, pp. 75 - 76

The Stein affidavit itself is hopelessly inadequate, as set out above, to establish anything. Her affidavit addresses only the generic level of causation, never the matter of proximate cause in an individual case. It is silent as to her meaningfully relevent qualifications. It is without specific reference to literature except in three instances which are considered below. It is conclusory. It does not discuss the merits or demerits of any of those three referenced studies and gives no indicator or analysis of the confidence which can be placed in any of them.

This latter failure is critical. Although the government proffers the articles or reports, they are not admissible in and of themselves. Rule 803(18), F.R. Evid. The reason why is crucial., As the Advisory Committee Notes on the Rule set out:

> ...there is, nevertheless, an additional difficulty in the likelihood that the treatise will be misunderstood and misapplied without expert assistance and supervision. This difficulty is recognized in the cases demonstrating unwillingness to sustain findings relative to disability on the basis of judicially noticed medical texts.14/[Citations omitted.] The rule avoids the danger of misunderstanding and misapplication by limiting the use of treatises as substantive evidence to situations in which an expert is on the stand and available to explain and assist in the application of if declared. The limitation upon receiving the publication itself physicially in evidence, contained in the last sentence, is designed to further this policy. (Emphasis supplied.)

4 Weinstein's Evidence, p. 803-50. There is not even any reference

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14/Yet the government would here preclude causation on the basis of unexplained articles and studies.

that the studies or the reports of them are authoritative as required by the Rule.

Moreover, even without expert analysis, the three specified studies are inadequate to sustain the government's burden.

Thus, so-called Erickson study was designed to be conducted by the Centers for Disease Control, and other units of the United States Government's Department of Health and Human Services, on the basis of "The Protocol for Epidemiological Studies of the Health of Vietnam Veterans", November, 1983.

Attached hereto as Appendix 1 are excerpted references to that Protocol describing the problems and uncertainties which limit the validity of such epidemiological studies. Some of these deficiencies are even acknowledged in the government's August, 1984 study entitled "Vietnam Veterans' Risks for Fathering Babies with Birth Defects" (the so-called Erickson study). This study is summarized in Government's Exhibit 2 and set forth in full in Exhibit 3. The study contained a central flaw which undermined its power to detect increased risks and, hence negated its significance as disproof of causation.

> The power (i.e., ability) of a study to detect increased risks for fathering babies with defects depends on the magnitude of the true risk, the number of cases available, the number of controls available, the rate of the exposure of interest in the control group, and the level of significance chosen. The frequency of the major 'exposure' variable of interest - the proportion of Vietnam veterans among the fathers of babies born without defects was not known at the time the study was designed, but estimated to be 10% to 20% based on information provided by the Atlanta office of the Veternas Administration. (Emphasis supplied.)

Exhibit 2, JAMA, 252:7, p. 904, left to center column.

In order to gain exposure data the Army Agent Orange Task force asked each Vietnam Veteran if he believed he had been exposed to Agent Orange. In order to score their responses, the task force prepared an Exposure Opportunity Index (EOI). However, the study acknowledged:

> The accuracy of Vietnam veterans' self-reports of Agent Orange exposure is unknown, as is the accuracy of the EOI, and it is unlikely that any validation will ever be possible. The records of troop movements and herbicide use that are available today were made for military purposes and not for the purpose of estimating exposure for epidemiologic studies.[15] (Emphasis supplied.)

Id., p. 905, left column. Thus, without accurate and complete exposure data, neither the Erickson nor the Ranch Hand study can be accepted as conclusive disproof of causation. The government alone bears responsibility for this deficiency in the data which it could and should have timely obtained.

In its concluding paragraphs, the authors of the government's Exhibit 2, admit:

> "Although the present study was large, the estimates of Agent Orange exposure that had to be used were probably rather inaccurate. Therefore, the conclusions regarding

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[15] Exhibit 3 (the full report) p. 24 describes the deficiencies in the exposure index as follows:

> It must be emphasized that this index, as it applies to individual veterans, does not necessarily reflect true levels of Agent Orange exposures, and even with respect to opportunities for exposure, its accuracy is unknown. The score assigned to any particular individual is only the panel's considered opinion about the opportunities for exposure an individual may have had. On the basis of records that exist today, it is impossible to assess how well the index reflects true levels of Agent Orange exposure. (Emphasis supplied.)

The Index referred to the Herbs tapes used in Ranch Hand (Ex. 3, p. 23) and this comment likewise impugns the validity of the Ranch Hand results.

possible Agent Orange-associated risks for Vietnam veterans that can be drawn from this study are weak."

The inadequacy of the exposure data relied on by the study is compounded by the fact that 25% of the Vietnam veterans believed that they were exposed, another 25% "don't know", and half believe they were not exposed (Ex. 3, p. 41). The study failed to quantitatively or qualitatively evaluate how significant changes in the above percentages would have affected the study conclusions on causation. The study authors simply admitted that the validity of the Agent Orange Exposure Opportunity Index was unknown, and stated that questions directed to whether particular index scores indicated higher degrees of exposure or greater opportunities for exposure "cannot be answered today, and probably never will be answered." (Ex. 3, p. 59.)

Because of the incompleteness and admitted inaccuracy of the estimates of Agent Orange exposure, the study authors admit that the conclusions stated in Exhibit 3 regarding possible causation are weak.

> The studies of human populations with well-documented exposure to herbicides and/or dioxin have included small numbers of people. Such small studies have only a weak ability to demonstrate even modestly increased risks. Therefore, the fact that none have been demonstrated may reflect the weakness of the studies rather than a true lack of effect. The present study included a relatively large number of people, but the estimates of Agent Orange-associated risks for Vietnam veterans that can be drawn from this study are rather weak. (Emphasis supplied.)

Ex. 3, p. 67. Hence, they cannot be relied on as a basis for granting summary judgment.

Another inherent weakness of the government's CDC and Ranch Hand studies is that they were retrospective case control studies, and were inferior to the prospective cohort epidemiological studies which the government could and should have performed when it first learned in the 1960's (or at least immediately after June 15, 1970), of the possible causal connection between exposure and adverse health effects. Appendix 2 describes the advantages of prospective over retrospective epidemiological studies.

The Australian study, Jan. 1983, Ex. 4, also suffers from the lack of an exposure index:

> After much effort had been expended in attempts to develop an index of exposure to Australian troops to herbicides, it was concluded that no satisfactory index could be developed, and the title of the unit was changed, following the Minister for Veterans' Affairs' public statement of the 15 February 1982, to Australian Veterans Health Studies. The lack of an index of exposure means that conclusions of the study relate to service in Vietnam, and that an increased risk of anomalies, had one been found, could not have been attributed to the herbicide exposure. (Ex. 4, p.1)

This make is impossible to determine the degree of exposure, a significant shortcoming, because:

> While the result that was obtained is persuasive evidence of the lack of effect of Vietnam service and thus of exposure, there as a cause of birth defects, other AVHS investigations have shown that exposure to herbicides was infrequent and probably very low in Australian troops in Vietnam; the study does not exclude possible effects of herbicides in situations of substantial exposure. (Ex. 4, p. 2).

Finally, Ranch Hand itself has been criticized on several bases:

1. Manipulation of cohorts after study has begun.

2. Consequent alteration of statistical significance of certain data, including incidence of cancer figures.

3. So much breadth in an epidemiologic study that its very design precluded picking up increases in individual defects.

Additionally, the Government's own witness, Dr. Philp Landrigan of NIOSH, admitted that a governmental task force had criticized the design of the Ranch Hand study and that the criticisms had not been corrected. Landrigan transcript, p.).

The bottom line is that the Court is legally in no position to accept the minimal showing the government has made here as a proof of anything, let alone as a satisfaction of the government's burden on a motion for summary judgment.

THE PLAINTIFFS' CASE

Compared to the absence of a showing by the United States, plaintiffs can adduce the following proof on causation.

1. Birth defects are consistent with the adverse effects of chemical toxicity (Legator 287/15-25).

2. The most likely cause of the birth defects in the Ryan and Jordan children is chemical toxicity (Legator 286/6-8)

3. Chemical toxicity could worsen any genetic predisposition or outcome in the Jordan children (Legator 288/28-289/5).

4. Agent Orange was the cause of the thumb anomaly, the missing digits and the missing thumb in the Jordan children (Hay 164/4-11).

5. The birth defects of the Jordan children are causally related to the Agent orange exposure of Dan Jordan (Levin 481).

6. Donna Jordan's miscarriage was caused by Dan Jordan's Agent Orange exposure (Levin 531/2-4).

7. Dan Jordan's Agent Orange exposure caused him to have two birth defective children (Levin 613/20-22).

8. The history of minor hand problems in the Jordan family strengthens the concept that Agent Orange brought out the birth defects by bringing out the oncogene (Levin 624-625).

9. Donna Jordan's miscarriage was caused by Dan Jordan's Agent Orange exposure (Silbergeld 284/2-285/16).

10. The Jordan childrens' birth defects were due to their father's Agent Orange exposure (Silbergeld 305/1-8).

11. Reproductive dysfunction is associated with dioxin exposure in humans and animals (Barsotti 194/24-195/1).

12. Reproductive dysfunctions in humans is increased by dioxin exposure (Barsotti 196/4-8, 19-25).

13. There is evidence of Agent Orange exposure to males being associated with increased birth defects in humans (Hatch 134/21-24).

14. There is evidence of a modest to moderate increase in birth defects in children of male veterans exposed to Agent Orange (Hatch 139/4-8).

15. Agent Orange exposure appears to have a causal association with congenital malformations in the offspring of exposed fathers (Hatch 418/21- 419/1).

16. Exposure of Michael Ryan to Agent Orange in Vietnam caused the birth defects in Kerry Ryan (Hay 164/15-18, 166/16-20).

17. The available evidence would suggest that it is probably that dioxin is responsible for untoward pregnancy outcomes and birth defects (Hay 513/9-12).

18. The Ah locus of the chromosome in man is a target site for TCDD (Legator 82/4-6).

19. The Ranch Hand Study furnishes evidence in support of mutagenic and birth defect effects from Agent Orange (Legator 138-140)

20. TCDD induces a genetic lesion in sperm which is carried through spermatogenesis into impregnation and is manifest in progeny through phyical handicaps, neonatal deaths, and minor congenital anomalies (Legator 148/9-22).

21. There is evidence of male mediated birth defects from Agent Orange (Legator 150/154).

22. Male mediated birth defects are produced by male mediated transmissible defects (Levin 614/1-3, 615, 616).

23. Gonado toxicity and hormonal dysfunction involve the TCDD receptor (Ah locus) as a mechanism of toxic action (Silbergeld 209/14-20, 222/3-223/3).

In addition the attached exhibits of Dr. Alan Levin, M.D., and Dr. Ellen Silbergeld, Ph. D., both attest to the biological plausibility of Agent Orange contaminated by dioxin being the cause of birth defects. Dr. Levin speaks to the free radical anolog of Agent Orange to ralation in the causation of birth defects. Dr. Silbergeld speaks to the epidemiological criteria which must be met scientifically and to the import of the absence of data due to the government's failure to create and obtain that data.

Both affidavits, each from a separate perspective demonstrate the scientific validity of the opinions given above by Drs. Legator, Levin, Hatch, Silbergeld, Barsotti and Hay, and why those physicians and scientists can testify as they do on the basis of reasonable medical/scientific probability. In considering the above opinions of plaintiffs' scientists and physicians, the Court should bear in mind that each was elicited through adversarial cross-examination by attorneys for the chemical companies. There is not a consistent, explained, fully-developed presentation of each as there would have been on direct examination. Nonetheless, those opinions, based upon review of the actual representative plaintiff case records and the witnesses' documented knowledge of the breadth of the medical/scientific literature stand in stark contrast to the negative parroting of inconclusive results that forms the basis of the Stein affidavit.

The government plainly has not carried its burden. The showing by the plaintiffs is overwhelming here and, for purposes of this motion, unrefuted and unrefutable by anything the government has offerred. The motion should be denied. No court should substitute its

motion or predeliction of what non-evidence (articles, studies, books) shows for what is before it by way of testimony and evidence. To do otherwise would be to deny plaintiffs their constitutional right of court access.

COMMENTS ON A CASE OF "FIRST IMPRESSION"

This is the first and only Agent Orange litigation involving claims of injury from exposure to Agent Orange. That superficially makes this litigation a matter of first impression. However, in reality, nothing could be further form the truth. This Court should not be misguided by the United States into accepting whole-cloth the argument of the government that, because the scientific evidence is not complete, no cause and effect relationships can be documented in this litigation setting.

We begin with two assumptions which must both be indulged on this motion since the government has not chosen to place them at issue for the nonce:

1. The government was negligent in that it breached a duty of care; and

2. The government failed to test the product before use for its effect on animals or humans, failed to keep accurate exposure records at the time of exposure, failed to monitor and record the health status of exposed individuals on any systematic basis at the time of exposure and immediately thereafter, failed to conduct a prospective epidemiologic study of exposed servicemen and failed to perform vital testing on those servicemen to document the presence and effects of dioxin in their body tissue.

It should be noted that the government could not dispute the second assumption at all. In perspective, it should also be noted that the so-called HERBS types are the only systematic effort ever undertaken by the United States to quantitate the exposure of the servicemen, and that the index of exposure in Ranch Hand, which carries over into the CDC study, is seriously flawed for several reasons:

1. It makes spray estimates based only on mission records, assuming that the coordinates of the mission were actually achieved.

2. It bases exposure indices on group troop movement records on a company or platoon basis, without regard to squads or individuals,

3. It is totally silent as to the length of time groups and/or individuals were in sprayed areas.

4. It takes no account of spraying of perimeters necessarily patrolled by foot soldiers on a daily basis.

5. It takes no account of ground contamination.

6. It takes no account of water contamination.

7. It takes no account of direct spraying.

8. It takes no account of food contamination.

9. It refuses to recognize that direct spraying of base camps occurred while servicemen were present.

10. It takes no account of clothing contamination or the lenth of time servicemen were in that clothing.

11. It takes no account of non-fixed-wing aircraft (helicopter) spraying which was substantial in certain areas.

From the government's point of view, the HERBS tapes are nothing but a belatedly-created set of flights and coordinates which endeavor to lend an air of authenticity to its supposed epidemiologic treatment of dioxin-exposed servicemen from Vietnam. Thus, in very true perspective, the government which seeks to use the "evidence" of its studies to prove a negative here is the selfsame party which prevented the existence of the appropriate data.

Hence, under the circumstances, the government should not be permitted to invoke the non-conclusiveness of its so-called "evidence" as proof of non-causation here. Moreover, at a minimum, the government should not be permitted to use the supposed unavailability of reliable, well-founded data to subtly beguile this Court into thinking that, because the true science of the issue is novel and inconclusive, it can prevail, and that plaintiffs have no evidence of causation.

The same type of argument the United States makes here was clearly and compellingly rejected on both the trial and appellate levels in Ferebee v. Chevron Chemical Co., 522 F.Supp. 1293 (D.D.C. 1982), aff'd 736 F.2d 1529 (D.C. Cir. 1984). Rather than repeat plaintiffs argument of that case, we respectfully refer the Court to our treatment of it and the case of Allen v. United States, 588 F.Supp. 247 (D. Utah 1984) contained in Plaintiffs' Memorandum on Causation, a brief to be filed roughly contemporaneously herewith. Suffice it to say here:

> ...products liability law does not preclude recovery until a "statistically significant" number of people have been injured or until science has had the time and resources to complete sophisticated laboratory studies of the chemical.

736 F.2d at 1535.

This, then, is a case where extant decisional law teaches that there may be a recovery based upon such available, extant scientific evidence of causation as there may be. But this addresses only the permissible use of such extant science. So long as that scientific base, whatever it is, is the type of scientific base reasonably relied upon by scientists in formulating opinions, it may be relied upon by the expert as a basis for opinion. Rule 703, F.R. Evid. Once the opinion is in evidence, what is left is a matter of balancing, a task to be performed by the fact-finder, not the court as a matter of law.

There is nothing new about this analysis. It is as old as the 1919 case of Stubbs v. City of Rochester, supra. Thus, while the science may be "new" due to the dilatoriness of the government, the legal use to which that science may be put is not. Truly then, this is not a case of first impression, legally. That it may be new scientifically is immaterial to the legal issue of causation before this Court.

THE CAUSATION BURDEN

Plaintiffs are concerned that, in some unknown way, several different concepts and/or standards appertaining to causation have

somehow become merged in the Court's mind. The result is that the Court appears to have placed upon plaintiffs in relation to causation an impossibly draconian burden which the Court feels they cannot satisfy to "prove" reproductive misadventures are caused by Agent Orange exposure. Thus, it seems, from the Court's own statements in court and from some of its writing in its opinions, that statistical significance and "more likely than not" have somehow become admixed. The net result appears to have been a requirement that there be proof rising to a 50+% chance of relationship before the Court will even consider the evidence in light of a but-for test. We may well be wrong in our perception; however, if this is what the Court is doing and thinking, we respectfully submit that the Court is wrong. Nonetheless, we feel it important to set out our thinking on the interrelationship of these concepts.

First, we consider statistical significance. This is a term of science, not of law. To be statistically significant, a given result must be judged against a sliding and reciprocal scale of both sample size and obeserved results. Thus, the larger the sample studied, the smaller can be the percentage increase in results which will be said to be statistically significant.16/ In absolute

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16/The relevant criterion is the power of the study. This depends in part on the quality of the exposure data and the numbers tested. Thus if the test and control groups are each 10,000, a very small increase, certainly less than two times, may be statistically significant. If the test involves only 20 per group, much more than a two fold increase would be needed for statistical significance. If exposure data is exquisite, very small changes may be statistically significant. If exposure data is jumbled and poor, a large change may be statistically insignificant. It should be borne in mind here that the government is solely responsible for the lack of valid exposure data. This means, in effect, that the government has prejudicially manipulated the data to prevent a small increase in adverse results from ever being statistically significant.

terms, statistical significance means that there is less than a 5% or 1% chance of the result being due to chance, or, conversely, that there is a 95% or 99% level of confidence that the results are due to the matter being tested. If those levels are achieved, then the hypothesis (e.g., Agent Orange exposure causes birth defects) being tested is deemed true, i.e., proven. In the example, a cause and effect relationship would be established--i.e., Agent Orange exposure caused birth defects. The only legal analog to this is the criminal standard of proof - beyond a reasonable doubt. In the science of statistics, this is defined as the 95% or 99% confidence level.

Second, we consider the standard of proof that will permit a judicial result. Three general ones are commonly accepted for various purposes:

(1) Beyond a reasonable doubt - the criminal standard for finding culpability.

(2) Balance of probabilities, i.e., more likely than not--the civil standard for recovery.

(3) Scintilla of evidence - a sometimes administrative standard used in a negative way - i.e., under the Donnelly amendment, there must not be a scintilla of evidence that a food additive causes cancer in animals or humans.

Here, we obviously deal with the civil standard, under which it is said that all the evidence considered together must convince a jury that the scale tips at least ever so slightly in favor of the plaintiff. This jury criterion for judging evidence can conveniently and mechanistically, but wrongly, be transformed into a 50+% standard. It can also be validated superficially, but again wrongly, by its compatibility with the scientific concept of statistical significance. Tbus, at one sampling level, it can be said that there must be 2 times the adverse outcomes in the test group versus the control group. This readily transposes into a statement that there is then more than a 50% chance of the result being due to an exposure as opposed to some other, perhaps unknown cause.

Science and civil law would thus seem to mesh. But, the concordance is superficial only. As noted above the only legal analog to statistical significance is "beyond a reasonable doubt". Thus, meshing the two, we would be saying that it was beyond a reasonable doubt that the exposure of x to Agent Orange was more likely than not the cause of the birth defect in x's child. This makes it obvious that the scientific term statistical significance is irrelevant to a civil jury's determination of "more likely than not". The statistical significance of a finding is but one factor affecting the weight a jury may accord to particular testimony. It is not a pre-condition of or a threshold for the jury determination of more likely than not.17/

17/See: Silbergeld, "Reappraising Epidemiology: A Response to Mr. Dore", 7 Harv. Envtl. L. Rev. 441, 445 (1983) for a statement of how a scientist validly formulates an opinion on legal cause without statistical significance support.

Finally, we consider the but-for construct mentioned several times by the Court. We submit it is the wrong construct, but more of that in a moment. For our purposes here, but-for is a test construct in light of which expert testimony must be presented. Thus, an expert must testify that as a matter of reasonable medical probability a given result would not have occurred but for X. At the threshold, this construct has nothing necessarily to do with statistical significance. A scientific finding of statistical significance may make it easier for an expert to testify "but-for", but it does not prevent but-for testimony being presented as a result of other scientific factors.[18]/ This construct is not universal, i.e., it may be molded, changed, adapted or disregarded and avoided by the judge to suit the public policy against which the liability of a defendant should be judged. This involves such considerations as risk-spreading, innocence of the victim, reprehensibility of conduct by the defendant, availability of proof, presence of covariables, etc.

Let there be no doubt here. Plaintiffs strongly feel they can present expert "but-for" testimony of sufficient quality and quantity to warrant submitting the issue of reproductive defects to the jury. The above recitation of opinion evidence should make that obvious. However, to the extent the Court perceives any weakness in the testimony because of governmental negligence and misconduct, we submit that the Court would be fully warranted (1) in shifting the burden to the United States, (2) in estopping it from contesting causation or (3) in indulging a statutory presumption of reproductive

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[18]/Ibid.

toxicity against the United States. To the extent that covariables are present, the Court would be warranted in reducing the standard to the substantial factor one set out above and in Plaintiffs' Memorandum on Causation.

In any event, (1) statistical significance, (2) the jury criterion for decision, and (3) the litmus test for expert testimony, are all separate concepts. They have some relationship to each other, albeit not a necessary one in any way. They cannot be used outside their proper spheres and they cannot be meshed and comingled at will to create and impose draconian and impossible burdens of proof on the plaintiffs.

DISCOVERY IS NECESSARY

The motion of the United States for summary judgment cannot be viewed in isolation. From one perspective, it is filed at the very onset of the case against the United States, before the government has even answered the complaint. From another perspective, it is filed long after the onset of the litigation. However, plaintiffs were limited to selecting 15 government witnesses to depose after January, 1984. Moreover, the choices of witnesses made by plaintiffs at that time,when the plaintiffs were pursuing only the chemical companies, were made with an eye toward establishing superior knowledge of dioxin hazards on the part of the chemical companies. Those depositions were not undertaken to test the government witnesses' knowledge of the validity of the scientific literature or their opinions on causa-

tion. Thus, plaintiffs are writing not on a clean discovery slate against the government, but on an absent one.

The sole support for the motion of the United States is the Stein affidavit and three reports. The only way to expose the lack of credentials of the affiant and the mistakes, omissions, misperceptions, and invalid references set forth in the affidavit is by thorough and probing cross examination. The most meaningful way in which to demonstrate the shortcomings of the three reports is by discovery of the authors and ancillary personnel and by exposing through deposition of appropriate personnel the shortcomings in the exposure data which subserves the validity of the statistical results.

In addition, there is extant a question of burden-shifting which appertains to the causation issue. Plaintiffs need discovery of government conduct in broad perspective to lay the framework for a fully-documented argument that burden-shifting is appropriate here.19/

Rule 56(f), F.R. Civ.P., specifically provides that this Court may continue the motion for summary judgment in order to permit plaintiffs to obtain the requisite discovery by deposition. Notwithstanding the urging of the Court that prompted the government to file this motion, Rule 56(f) is bottomed on precepts of justice, and justice here dictates that plaintiffs have a discovery opportunity if the United States is to be allowed to rely upon the inadequate showing

19/The undersigned sets out the matters in the last two paragraphs as being minimum discovery requirements in specific relation to the causation issue herein. He states them as his true and accurate evaluation on the basis of his personal knowledge, information and belief, under penalty of perjury.

it has made.

CONCLUSION

Accordingly, in view of the above, plaintiffs submit that the motion of the United States for summary judgment should be denied.

NEIL R. PETERSON
Greitzer & Locks (Philadelphia)

for:

PLAINTIFFS' MANAGEMENT COMMITTEE
26 Court Street - Suite 304-8
Brooklyn, New York 11242
(212) 330-0900

of Counsel:
Irving Like

The Protocol for Epidemiological Studies of the Health of Vietnam Veterans, November, 1983, being conducted by the Centers for Disease Control (CDC) and other units of the U.S. Department of Health and Human Services (Protocol), describes the studies which are designed to evaluate the health effects of possible exposure to Agent Orange.

The Protocol notes that the task of determining if there is a causal relation between exposure and the diseases suffered by the Vietnam veterans is complicated by problems and uncertainties which arise from the following considerations:

1. The presence of varying or undetermined amounts of dioxin and their unequal distribution in Vietnam (pp. 4, 6)

2. Prior occupational exposure (some of which involved the factories of defendants) had no, or inadequate controls; exposure was usually of unknown magnitude and duration, to what were after mixtures of chemicals and the total number of exposed persons was usually not reported (p.4).

3. Little objective evidence is available regarding the health of Vietnam veterans relative to the health of other men of similar age (p.5).

4. No studies were made that compared the health of men who had seen combat with the health of contemporary men who had not participated in combat. (p. 5).

5. The military records needed to assess exposure were incomplete and full of errors, and unable to define objectively meaningful exposure. Thus, the categorization of individuals with respect to their potential for herbicide exposure "will be uncertain and will forever remain so." (p. 6).

6. Because of the inherent limitations of the records, even the planned cohort studies may suffer from exposure misclassification, imprecision of exposure separation, lack of comparability with respect to other health influencing factors, respondent bias, and problems in analysis and interpretation (p.7).

7. Great difficulty in location of the requisite number of veteran study subjects, which may lead to an underascertainment of deaths and uncertainty as to the causes of death (pp. 18-20).

8. The possibility of confounding factors which may be associated both with health outcomes and with exposure (pp.21,22).

9. Unavailability of important items of information about the study subjects' military service (p.22).

10. The choice of the sample sizes for each cohort of 6,000 for mortality assessment and interview, and 2,000 for examination and laboratory testing had to be arbitrarily chosen, because no good data exists on the expected prevalences of the outcomes postulated to be associated with dioxin exposure in populations similar to the veterans to be studies (p. 26).

11. Of particular concern is the possibility that the records that have to be used to define the first two Agent Orange

study cohorts ("likely exposed" and "likely not exposed") are so incomplete and/or inaccurate that there will be a sizeable amount of random misclassification in respect to herbicide exposure. If this is the case, the statistical power of the studies may be reduced to a significant degree, and the measures of effect will be biased toward the null (p. 27).

12. There is also considerable concern that the Centers for Disease Control will have difficulty in achieving a high rate of participation among those selected for inclusion in the cohort study, thus preventing the reaching of the desired sample size (p. 27).

13. Although it will be desirable to assess study participants and non-participants with respect to differences in health and differences in exposures to health influency factors, this cannot be done for those who were interviewed and those who are not. CDC will have little, if any, health related information about men who will not participate or who are not located (p.28).

14. There may be problems with potential confounding variables which modify the association between various diseases and service in Vietnam (pp. 34, 35).

15. There are additional unavoidable limitations of the CDC proposed studies which will preclude describing the results as "definitive". Apart from the problem of exposure misclassification already described, the studies will have low power for rare diseases and/or low increases in risk or for increases in risk limited to those veterans with prolonged and/or heavy exposure to herbicides or some other harmful factor. Thus, an overall finding of no increase in risk might "hide" a real increase for specific disease categories or special groups of veterans (p. 37).

16. Depending on the results of analysis, the design of the Agent Orange study may present unusual problems of inference which may be the result of exposure misclassification or difference in service experience (pp. 37, 38).

There is clear scientific agreement as to the advantages of a prospective study over a retrospective study as an analytic approach to the etiology of diseases which develop over a long period of time.

Since diseases caused by exposure to toxic substances, such as dioxin-contaminated Agent Orange develop over a long period of time, etiologic study of these conditions requires the analysis of events which occur over time. Two major methods are available for observation studies of etiology-one retrospective, the other prospective. (Mausner & Bahn, Epidemiology, An Introductory Text, W.B. Saunders Co., 1974, p. 313 (hereinafter Epidemiology)).

Retrospective Study

In a retrospective study, people diagnosed as having a disease (cases) are compared with persons who do not have the disease (controls). The purpose is to determine if the two groups differ in proportion of persons who had been exposed to a specific factor or factors.

Such a study is retrospective because it compares cases and controls with regard to the presence of some elemenet in their past experience (Epidemiology, p. 313).

APPENDIX I

Prospective Study

In contrast, a prospective study starts with a group of people (a cohort) all considered to be free of a given disease, but who vary in exposure to a supposed toxic factor. The cohort is followed over time in order to determine differences in the rate at which disease develops in relation to exposure to the factor (Epidemiology, p. 112).

A schematic diagram of the differences in time factor as between retrospective and prospective studies follows:

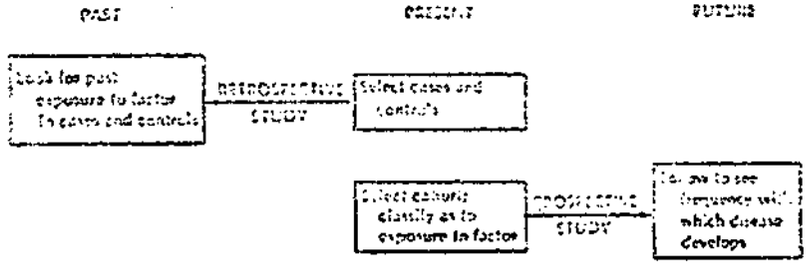

Figure 12-3 Schematic diagram of time factor in epidemiologic studies.

(Source: Epidemiology, p 112)

The essential difference between the retrospective and prospective studies lies not in the time sequence, but rather in the way the study groups are assembled. In retrospective studies, diseased and non-diseased groups (cases and controls) are selected and compared for presence or absence of the antecedent factor. In the instant case, this factor would be dioxin-contaminated herbicides. In prospective studies, the investigator begins with individuals who are free of the disease under

consideration. They are classified by exposure or lack of exposure to the antecedent factor (dioxin-contaminated Orange) and followed for the development of the disease (Epidemiology, p. 313). Retrospective studies have several disadvantages.

The first problem is one of incomplete information, i.e., needed information about past events may not be available from routine records or may be inaccurately recorded. (Epidemiology, p. 319). If information is sought by an interview or questionnaire, the informant (the veteran, in the instant case), may have inadequate information about, or recall of events in the distant past.

Secondly, information supplied by an informant may be biased. At the time of the study, the disease has already been diagnosed in the cases. As a result, informants about cases may have a different recall of past events, than informants for controls. People may be more likely to search for explanations for the disease in the cases and, therefore, may assign more significance to past events. This is known as recall bias.

Thirdly, there may be serious problems associated with the use of the retrospective method, in regard to the selection of an appropriate control group (Epidemiology, p.320).

The selection of controls (in the instant case,

the non-exposed group of veterans), can introduce serious bias. If the disease among the controls is affected (either positively or negatively), by the factor being investigated, a true association may be partially masked or a spurious association found (Epidemiology, p. 320).

The incidence rate of the disease under study usually cannot be derived form a retrospective study because there are no appropriate populations at risk. Because ... the way the study group is assembled, the case and control groups do not represent the total populations exposed and not exposed to the factor (contaminated herbicides). Thus, it may not be possible to calculate the disease incidence rate in person exposed and not exposed to such ... factor (Epidemiology, p. 320).

In prospective studies, several approaches to selection of a cohort are possible. A particular group may be chosen for study because it is accessible, or because its medical records are readily available, or because the group is known to have experienced some particular exposure (Epidemiology, p. 321).

When study group is essentially homogeneous in exposure, comparison can be made with another cohort differing in previous exposure or with rates derived from vital statistics (Epidemiology, p. 321).

A prospective epidemiologic study has distinct

advantages over retrospective studies:

a. In a prospective study, the cohort (the group of soldiers exposed to Agent Orange in Vietnam) would have been classified in relation to each member's exposure before his disease developed. (Epidemiology, p. 320). Therefore, this classification could not be biased by the exposed veteran's knowledge that disease existed. As previously noted, such bias can occur in retrospective studies where the cohort is classified in relation to exposure after the disease developed. Prospective studies permit determination of the magnitude or risk of disease for the populations exposed and not exposed. Therefore, the excess risk due to exposure to a given factor can be calculated directly (Epidemiology, p. 322). There are two major ways of expressing this excess: relative risk and attributable risk. Relative risk is defined as the ratio of the incidence rate of those exposed to a factor to the incidence rate of those not exposed. Attributable risk can be defined as:

1. the extent to which incidence of disease in a group of exposed persons can be attributed to their exposure;

2. the proportion of all cases of the disease in the total population that can be attributed to the exposure

(Epidemiology, p. 322).

b. A second advantage is that prospective studies also permit calculation of disease incidence rates among those exposed and those not exposed. Therefore, the absolute difference in incidence rates between groups (attributable risk) and also the true relative risks can be measured (Epidemiology, pp. 323, 324).

c. Furthermore, prospective studies entail observation of many outcomes, and although they may be designed to detect association of a particular factor with specific disease, they can yield association of that factor with additional disease (Epidemiology, p. 324).

To summarize, therefore, the following table summarizes the comparisons of retrospective and prospective studies (Epidemiology, p. 324).

TABLE 13-5 Retrospective and Prospective Studies: Summary of Advantages and Disadvantages

	Advantages	Disadvantages
Retrospective Study	Relatively inexpensive	Incomplete information
	Smaller number of subjects	Biased recall
	Relatively quick results	Problems of selecting control group and matching variables
	Suitable for rare diseases	Yields only relative risk
Prospective Study	Lack of bias in factor	Possible bias in ascertainment of disease
	Yields incidence rates as well as relative risk	Large numbers of subjects required
	Can yield associations with additional disease as by-product	Long follow-up period
		Problem of attrition
		Changes over time in criteria and methods
		Very costly

It can be readily seen that if the defendants had timely warned the government of all they knew regarding the dioxin problem, the government could have undertaken appropriate prospective epidemiological studies to aid in determining causal connection. Such studies would have employed all of the advantages of prospective studies and could have been designed to avoid its disadvantages. To illustrate, we list each of the disadvantages of prospective studies and the planning that the government would have undertaken to overcome them.

1. Possible bias. Since the group of exposed persons is clarified before disease develops, their knowledge of exposure to dioxin is unlikely to influence ascertainment of the disease (Epidemiology, p. 323).

2. Large number of subjects required and long follow-up period. If the government had acted promptly during the Vietnam war and subsequent to its termination, to identify, monitor and record the exposure of all soldiers, and to also maintain complete medical records of any disease that developed within the group of exposed veterans. The problems which have beset the government in setting up the pending retrospective studies such as inaccurate or incomplete records as to identification of exposed veterans and their subsequent medical history, could have been avoided.

3. Problem of Attrition. The need to follow a cohort over a long period of time can cause the problem of attrition, the loss of members of the cohort group (the exposed veterans) due to lack of interest, migration, or death from other causes. Other difficulties can arise from change in the status of subjects with respect to variables of interest (e.g., changes of area of residence, occupations, etc.), leading to error in classification of exposure (Epidemiology, p. 325).

However, the government had the means and resources through the Veteran's Administration and other governmental agencies to follow the cohort of exposed veterans and to take whatever steps were necessary to avoid such difficulties and to avoid any error in classification of exposure.

4. Changes over time in criteria & methods. The government could also have, with careful planning, prevented any problem resulting from any changes in diagnostic criteria and methods over time affecting the classification of individuals as diseased or not diseased. Since the government could have established and maintained complete exposure and medical records with respect to the exposed veterans during the Vietnam war and post war follow-up period, changes in appropriate diagnostic criteria and methods could be controlled through statistical techniques such as periodic cohort analysis, establishment of sub-groups, analysis of co-variance and refinements, and

control of variables, so as to avoid errors in results.

In fact, had the government acted in a timely manner, it could have instituted a type of study which combines the advantages of both the retrospective and the prospective study designs. This type of study, known as the historical prospective, consists of the identification of a group at some point in the past and analysis of their subsequent morbidity or mortality experience. (Epidemiology, p. 325).

To conduct such a study it must be possible to identify from the records, the membership of some previously existing group. Secondly, it is necessary that the factors of interest had been recorded adequately at that time or can be reconstructed from other sources. Thirdly, it must be possible to obtain the needed information about the outcome (i.e., disease or death) for almost all the cohort. This may be accomplished through routine records maintained by the sponsor of the study, or it may be possible to obtain the necessary follow-up information through death certificates, hospital records, disability pensions, etc. (Epidemiology, p. 325).

The government had the means to initiate the historical/prospective type study. It had the medical records of each soldier. It could have established the methods and procedures for recording exposure to the requisite degree of detail required. And it could, through

VA follow-up, accurately determine the disease outcome of the cohort group exposure.

The government had the means to follow-up and keep track of the medical history of the entire exposed and non-exposed veterans who served during the Vietnam war. It could, for example, have instituted the Agent Orange Registry much earlier and thereby avoided its error and incompleteness which were inevitable given the fact it was established many years after the veterans' exposure in Vietnam.

Had the government acted in a timely manner, it could have examined each exposed soldier from time to time to determine if dioxin was present in his body system. As the Veteran's Administration cautioned in its March 1, 1983 Circular, 10-83-38:

> "It is important that each veteran be fully advised of the limitations of an Agent Orange related examination, that is, what the examination can or cannot reveal as regards the presence of dioxin the body system..."(p. 2).

The inadequacy of such a physical examination performed in the 1980's is obvious. Dioxin could have been present in the body systems of soldiers at a much earlier time after exposure so as to cause injury. But, such dioxin could have been eliminated through bodily functions so as not to be detected by an examination conducted in the 1980's. It could also be stored in fat tissue which is not easily obtainable for testing except through a biopsy procedure which would cause a great deal of pain.

Thus, the absence of dioxin presently in the tissues of veterans does not in and of itself negate the causal connection between exposure and injury if such dioxin was earlier present, and is no longer detectable. The government was in an infinitely better position to evaluate the potential adverse health effects of dioxin in the system of exposed soldiers had it earlier acted to discover the location and quantity of such dioxin in the bodies of the veterans. The government's negligence means that it disregarded this vitally important diagnostic opportunity, and made impossible the attainment of the Agent Orange Registry's prime objective.

The Agent Orange Registry requires all participating veterans to be given blood count, urinalysis, and other laboratory pathology and other diagnostic studies, in conjunction with their physical examinations. Obviously, if a veteran were timely classified in a prospective epidemiological study, the value of early follow-up medical examinations and laboratory studies would be of far greater value than the belated Agent Orange Registry physical examinations and studies performed in the 1980's in conjunction with retrospective studies in which the veterans are part of case-control comparisons.

CERTIFICATE OF SERVICE

NEIL R. PETERSON, ESQUIRE, attorney for plaintiffs hereby certifies that he caused true and correct copies of the foregoing Plaintiffs' Opposition to United States of America's Motion for Summary Judgment, to be served upon all counsel by Federal Express Mail to the United States and by first-class mail to all other counsel.

DATE

NEIL R. PETERSON