05-1760-CV

& 05-1820-CV

United States Court of Appeals
for the Second Circuit

IN RE "AGENT ORANGE" PRODUCT LIABILITY LITIGATION

DANIEL RAYMOND STEPHENSON, SUSAN STEPHENSON, DANIEL ANTHONY STEPHENSON, AND EMILY ELIZABETH STEPHENSON,

Plaintiffs-Appellants,

v.

DOW CHEMICAL COMPANY; MONSANTO COMPANY; HERCULES INC.; OCCIDENTAL CHEMICAL CORPORATION; ULTRAMAR DIAMOND; MAXUS ENERGY CORP.; CHEMICAL LAND HOLDINGS, INC.; T-H AGRICULTURE & NUTRITION CO.; THOMPSON HAYWARD CHEMICAL CO.; HARCROS CHEMICALS, INC.; UNIROYAL, INC.; C.D.U. HOLDING, INC.; AND UNIROYAL CHEMICAL CORP.,

Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

BRIEF OF AMERICAN CHEMISTRY COUNCIL AND CHLORINE CHEMISTRY COUNCIL AS *AMICI CURIAE* IN SUPPORT OF DEFENDANTS-APPELLEES

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February 22, 2006

CORPORATE DISCLOSURE

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, the American Chemistry Council and Chlorine Chemistry Council state as follows:

American Chemistry Council – The American Chemistry Council is the trade association representing U.S. chemical companies. The American Chemistry Council has no publicly owned parent corporation, and no publicly owned corporation owns more than 10% of its stock.

Chlorine Chemistry Council – The Chlorine Chemistry Council is a business council of the American Chemistry Council, representing the manufacturers and users of chlorine and chlorine-related products. The Chlorine Chemistry Council has no publicly owned parent corporation, and no publicly owned corporation owns more than 10% of its stock.

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INTEREST OF AMICI

Amicus the American Chemistry Council is the trade association representing U.S. chemical companies. Amicus the Chlorine Chemistry Council is a business council of the American Chemistry Council, representing the manufacturers and users of chlorine and chlorine-related products.

Amici and their members have a strong interest in ensuring that the federal courts deciding product liability cases have the most accurate and up-to-date scientific information regarding the effects of exposure to chemicals and other products. The American Chemistry Council and the Chlorine Chemistry Council participate regularly in federal court litigation both as a party and as amicus curiae.

In this litigation, amici supporting plaintiffs have filed a brief that the American Chemistry Council and the Chlorine Chemistry Council believe does not describe accurately the available scientific literature about the effects experienced by Vietnam veterans from Agent Orange. *See* Brief of Amici Brian G. Durie, *et al.*, In Support Of Appellants. This brief addresses directly the brief filed by plaintiffs' amici.

This Court previously extended the time for filing this brief to and including February 22, 2006. Counsel for plaintiffs in 05-1820-CV (Gerson H. Smoger) and counsel for plaintiffs in 05-1760-CV (Stephen B. Murray, Jr.), as well as counsel for defendants in both cases (Andrew L. Frey) consented to the filing of this brief.

SUMMARY OF ARGUMENT

Contrary to the arguments of plaintiffs' amici, *see* Brief of Amici Curiae, Brian G. Durie, *et al.* In Support Of Appellants ("Durie Amicus Brief"), there is no scientific consensus that the exposure of Vietnam veterans to Agent Orange has caused soft-tissue sarcoma, non-Hodgkin's lymphoma, multiple myeloma, or any other cancer. The Institute of Medicine Report that plaintiffs' amici tout as proof that Agent Orange causes cancer in veterans in fact expressly disclaims any conclusions as to causation and, moreover, expressly recognizes that "it is impossible to quantify the degree of risk likely to be experienced by veterans because of their exposure to herbicides in Vietnam." *Institute of Medicine*, *Veterans and Agent Orange: Update 2004* at 17 (2005) ("2004 IOM Report"). Indeed, more than thirty years of serious scientific analysis and scores of epidemiological studies of Vietnam veterans have failed to demonstrate even a consistent *association* between exposure to Agent Orange and the cancers plaintiffs here have suffered, much less proof of *causation* of the sort plaintiffs' claims require.

Consistent both with those facts and with more than two decades of decisions from this Court and other federal courts, Judge Weinstein tentatively concluded below that medical science does not support plaintiffs' causation claims, and he thus suggested that plaintiffs' claims would likely fail for lack of

"substantial proof of causality." *In re "Agent Orange" Prod. Liab. Litig.*, 304 F. Supp. 2d 404, 407 (E.D.N.Y. 2004).

Plaintiffs' amici assert here that Judge Weinstein's conclusion is out of step with new evidence they claim demonstrates the requisite causation. This assertion is unfounded. An expert affidavit below surveyed the latest studies and concluded that "the epidemiological and scientific literature on Vietnam veterans and Agent Orange does not establish causation of any disease by Agent Orange even for a veteran with substantial exposure." Affidavit of Dimitrios Trichopoulos, Jack S. Mandel, Philip S. Guzelian, Michael Newton & Alvin L. Young ¶ 35 (dated Jan. 22, 2004) ("Trichopoulos Aff."). Moreover, Judge Weinstein supplemented this evidence with his own reading of the available scientific literature. Indeed, the docket sheet reveals that Judge Weinstein has taken judicial notice of literally hundreds of articles and studies addressing the effects of Agent Orange, and his opinions consistently reflect the careful consideration he has given to these issues.

Contrary to the contentions of plaintiffs' amici, there is little evidence – new or old – that exposure to Agent Orange is even associated with increased risk of disease in Vietnam veterans, and no evidence at all that would support plaintiffs' claims of causation. The amici rely principally on studies examining certain diseases and high levels of exposure to certain chemicals. But these studies are of little relevance to the inquiry at hand – they generally deal with dioxin (or other

substances) rather than Agent Orange; they address segments of the general population (such as workers in industrial plants) rather than Vietnam veterans; they make no effort to distinguish between veterans who served in Vietnam and those who were actually exposed to Agent Orange; and they demonstrate *at most* association rather than causation. Indeed, the most reliable studies in this area refute any causal link such as that hypothesized by plaintiffs' amici.

In short, the available scientific evidence – which Judge Weinstein had before him – demonstrates that Judge Weinstein's observation below was correct. There is no sufficient scientific support for the claims of plaintiffs and other Vietnam veterans that Agent Orange caused the cancers and other diseases that now afflict them.

ARGUMENT

I. JUDGE WEINSTEIN'S PRELIMINARY CAUSATION ANALYSIS WAS WELL-GROUNDED IN PRECEDENT.

The principal focus of Judge Weinstein's opinion was his conclusion that the government contractor defense forecloses plaintiffs' claims. *See In re "Agent Orange" Prod. Liab. Litig.*, 304 F. Supp. 2d 404, 424-42 (E.D.N.Y. 2004). In the course of that opinion, however, Judge Weinstein offered a tentative assessment of plaintiffs' claims that their diseases – principally multiple myeloma and non-Hodgkin's lymphoma – resulted from their exposure to Agent Orange while serving in the U.S. military in Vietnam. Judge Weinstein noted that "[i]n earlier

waves of such suits in the 1970s, 1980s and 1990s, the courts concluded that none of the available evidence would support a finding to a more-probable-than-not standard of causality between exposure to Agent Orange and disease (except for a quickly discoverable and curable form of skin irritation, chloracne)." 304 F. Supp. 2d at 407. He went on to note that "[t]he scientific basis for that conclusion of lack of any substantial proof of causality, either general or specific to individuals, remains much the same." *Id.* (citing *Institute of Medicine, Veterans and Agent Orange: Update 2002* (2003)).

That conclusion is consistent with more than two decades of decisions that have noted the absence of any credible scientific support for the contention that exposure to Agent Orange has caused elevated risks of cancer in Vietnam veterans. This Court first addressed the issue in 1987, when it affirmed Judge Weinstein's certification and settlement of the class actions brought in the initial wave of Agent Orange litigation. *See In re "Agent Orange" Prod. Liab. Litig.*, 818 F.2d 145 (2d Cir. 1987). Writing for a unanimous court, Judge Winter noted that "the clear weight of scientific evidence casts grave doubt on the capacity of Agent Orange to injure human beings," 818 F.2d at 149, and that "[e]pidemiological studies of Vietnam veterans, many of which were undertaken by the United States, Australian, and various state governments, demonstrate no greater incidence of relevant ailments among veterans or their families than among any other group."

818 F.2d at 149; *see also In re "Agent Orange" Prod. Liab. Litig.*, 818 F.2d 187, 193 (2d Cir. 1987) (noting that "epidemiological studies of those very personnel and their families fail to show that Agent Orange was hazardous"). The Court observed that the pertinent question was "'What will Agent Orange do to friendly personnel exposed to it?'" The epidemiological studies provided an answer: "'Nothing harmful so far as can be told.'" *Id.*

This Court revisited the issue in 1993, when it affirmed Judge Weinstein's conclusion that the initial Agent Orange class settlement barred plaintiffs' claims in the so-called "second wave" of Agent Orange litigation. *In re "Agent Orange" Prod. Liab. Litig.*, 996 F.2d 1425 (2d Cir. 1993). Again speaking unanimously, this Court quoted the scientific literature that made clear that "'[t]o date, there has been no conclusive evidence that exposure to Agent Orange is carcinogenic, mutagenic or teratogenic in humans. Furthermore, no deaths attributable solely to exposure to Agent Orange and its dioxin contaminant have been reported.'" 996 F.2d at 1437 (quoting 13B Arthur L. Frank, *Courtroom Medicine: Cancer*, § 25A.00, at 25A-4 (1992)). This Court thus concluded that "despite continuing research, the crucial issue of 'general causation,' *i.e.*, whether any injuries are attributable to Agent Orange, remains unsettled." 996 F.2d at 1436-37. That analysis led this Court to conclude that Agent Orange plaintiffs had only "dim prospects of success." *Id.* at 1437.

This Court's conclusions were based in part on the extensive scientific record that Judge Weinstein had compiled and analyzed. In 1985, for example, Judge Weinstein surveyed the evidence advanced by the plaintiffs. Focusing in particular on epidemiological studies such as those touted now by plaintiffs' amici, Judge Weinstein concluded that "[n]o acceptable study to date of Vietnam veterans and their families concludes that there is a causal connection between exposure to Agent Orange and the serious adverse health effects claimed by plaintiffs." *In re "Agent Orange" Prod. Liab. Litig.*, 611 F. Supp. 1223, 1231 (E.D.N.Y. 1985). Judge Weinstein similarly examined the other evidence – apart from the epidemiological studies – and concluded that it "rests on surmise and inapposite extrapolations from animal studies and industrial accidents." *Id.*

Thus, although Judge Weinstein expressed sympathy for the suffering of Vietnam veterans, *see, e.g.*, *id.* at 1229 (noting that "[p]laintiff Vietnam veterans do suffer" and that "[m]any deserve help from the government"), he concluded that there was simply no "credible evidence of a causal link between exposure to Agent Orange and the various diseases from which [the plaintiffs] are allegedly suffering," *id.*; *see also In re "Agent Orange" Prod. Liab. Litig*., 611 F. Supp. 1396, 1400 (E.D.N.Y. 1985) (noting that "[b]ecause no substantial scientific evidence supports a finding of causal connection between Agent Orange exposure and any specific disease except chloracne, and because of the near impossibility of

proving that any particular plaintiff's condition was caused by Agent Orange, dividing the fund among those with particular diseases is unjustified").

II. JUDGE WEINSTEIN'S PRELIMINARY CAUSATION ANALYSIS WAS INFORMED BY THE MOST UP-TO-DATE SCIENTIFIC EVIDENCE.

In an effort to discredit Judge Weinstein's causation conclusion, plaintiffs' amici launch a series of attacks, including principally the suggestion that the sole support for Judge Weinstein's conclusion was the 2002 IOM Report. *See* Durie Amicus Brief at 7. That is a patent distortion of the record.

For more than two decades Judge Weinstein has actively studied the existing medical data related to Agent Orange and has meticulously disclosed his ongoing efforts to the parties. The docket sheet below reflects more than 150 entries from 1984 through 2005 describing scientific journals and articles relating to Agent Orange and the health consequences of exposure that Judge Weinstein has read and of which he has taken "judicial notice." Throughout the mid-1990s, for example, Judge Weinstein took notice of reports such as the EPA Health Assessment Documents for Tetrachlorodibenzo-p-Dioxin and Related Compounds on 10/21/1994 (docket entry 14679); EPA Review Draft Documents for Public Review for 120 day public review and comment (docket entry 14790); Estimating Exposure to Dioxin-Like Compounds Volume 1 Executive Summary (docket entry 14791); Health Assessment Document for 2,3,7,8 TCDD and Related Compounds

(docket entry 14792); Estimating Exposure to Dioxin Like Compounds, Volume 11, Properties, Sources, Occurrences and Background Exposures (docket entry 14794); and EPA Review Draft Estimating Exposure to Dioxin Like Compounds (docket entry 14795).

More recently, the docket sheet reflects entry after entry of relevant material, including evidence regarding the Air Force Ranch Hand Study (docket entry 16763), issues of Agent Orange Review (*e.g.*, docket entries 16086, 16089, 16841, 16866), reports in the popular press and scientific journals (docket entries 16081, 16083, 16920), and government reports (docket entry 16888).

Nor was that the only causation evidence before Judge Weinstein. Several distinguished scientists submitted an affidavit analyzing (among other things) the existing epidemiological studies, industrial exposure studies, and the "Ranch Hand Study," in addition to analyzing the IOM Report on which plaintiffs' amici rely. *See* Trichopoulos Aff. ¶¶ 18-26.[1] That affidavit concluded that "the epidemiological literature on Vietnam veterans and Agent Orange is extensive and overwhelmingly negative," and that the "epidemiological and scientific literature on Vietnam veterans and Agent Orange does not establish any causation of any disease by Agent Orange even for a veteran with substantial exposure." *Id.* ¶ 35.

[1] The Ranch Hand Study is a comprehensive epidemiological examination of Ranch Hand veterans, who operated the fixed-wing herbicide missions in Vietnam. *See also infra* pages 13, 20-21.

The notion that Judge Weinstein was poorly informed is also at odds with Judge Weinstein's opinions on Agent Orange-related litigation, which confirm his familiarity with the latest research. In *McMillan v. Togus Regional Office*, 294 F. Supp. 2d 305 (E.D.N.Y. 2003), for example, plaintiff had sued the National Academy of Sciences and the Institute of Medicine for allegedly failing to review adequately the scientific evidence regarding the link between Agent Orange and illnesses among Vietnam veterans. In the course of his opinion dismissing plaintiff's suit, Judge Weinstein demonstrated intimate familiarity not only with the IOM Report at issue there (and cited by Judge Weinstein below), *see id.* at 307-14, but also with the "enormous literature on the subject of the health of Vietnam veterans and their progeny," *id.* at 322; *see, e.g.*, *id.* (citing papers from national symposium in connection with Agent Orange Class Assistance Program).

Judge Weinstein's lengthy and scholarly opinion addressing the claims brought by the Vietnam Association for Victims of Agent Orange/Dioxin reflects the same thorough grounding in the relevant scientific literature. *See In re "Agent Orange" Prod. Liab. Litig.*, 373 F. Supp. 2d 7, 19, 22-23, 32 (E.D.N.Y. 2005) (discussing recent scientific articles and explaining why they do not alter the court's conclusions as to lack of proof of exposure or causation). He noted that "[p]roof of causal connection depends primarily upon substantial epidemiological and other scientific data, particularly since some four million Vietnamese are

claimed to have been adversely affected," and that plaintiffs' "[a]necdotal evidence . . . can not suffice to prove cause and effect." *Id.* at 32. Although the case was dismissed on other grounds, Judge Weinstein noted that epidemiological studies regarding Vietnamese plaintiffs are not available "with the richness of demographic and other data published in the United States," and he cited recent articles suggesting that the existing body of epidemiological literature was insufficient. *Id.*

Plaintiffs' amici's remaining attacks on Judge Weinstein also miss the mark. They suggest, for example, that Judge Weinstein ignored "new evidence" of causation. But plaintiffs' amici vastly overstate the "new" scientific information on which they rely. They place heavy emphasis, for example, on the so-called "Hardell studies" conducted initially in "the late 1970s by a group of Scandinavian epidemiologists/oncologists." Durie Amicus Brief at 21; *see id*., at 29 (additional citations to Hardell study). Judge Weinstein, however, examined these studies in depth and expressly noted the flaws in the Hardell studies:

> The parties, and especially plaintiffs, rely on over one hundred epidemiological studies not conducted by government officials and as such not subject to the 803(8)(C) exception. . . . Most of the studies rely on inapposite data and would be excluded under Rules 401 to 403. Some of them on industrial exposure have been recognized as flawed. *See, e.g.*, *Palmer v. Nova Scotia Forest Industries*, 60 N.S.R. (2d) 271, 352-53, 2 D.L.R. (4th) 397 (S.Ct. Nova Scotia, 1983) (Nunn, J.) (refusing to enter injunction against spraying of 2-4-D, 2,4,5-T-

> phenoxy herbicides in part *because expert studies, such as Hardell's, showing alleged adverse health effects were widely recognized as flawed*).

In re "Agent Orange" Product Liability Litigation, 611 F. Supp. at 1241 (emphasis added). Further, a recent comprehensive review article on the evidence relating to the "hypothetical cause-effect relationship" between 2,3,7,8-TCDD and cancer also discounts the Hardell findings because no other investigators could replicate them. *See* Philip Cole, *et al.*, *Dioxin and Cancer: A Critical Review*, 38 Regulatory Toxicology and Pharmacology 378, 383 (2003). In fact, the Cole review article concludes that "[t]he long-term accumulation of negative, weak, and inconsistent findings suggest that TCDD eventually will be recognized as not carcinogenic for humans." *Id* at 378.

Nor is there any merit to the contentions of plaintiffs' amici that "in attempting to justify its own choice of when to terminate the compensation fund at the end of 1994, [Judge Weinstein] grossly underestimates the latency period for cancer." Durie Amicus Brief at 9. While certain cancers may continue to occur after a latency period of thirty to forty years, such cancers almost invariably begin to occur at increased rates within about fifteen years. Judge Weinstein relied on this fact when he noted that "[a]s veterans become older and diseases of their peer non-veteran group are more and more common, it is less and less likely that a connection of the disease for a particular veteran to Agent Orange can be proved to

any substantial degree of probability through epidemiological or other scientific techniques." 304 F. Supp. 2d at 422. As there was still no reliable evidence of increased risk in the mid-1980s, fifteen to twenty-five years after exposure, the court was quite correct to discount the possibility that any "valid claims" would arise for the first time after 1994.

The court's latency analysis has been confirmed, rather than undermined, by the additional passage of time: An ongoing study of the Ranch Hand veterans, one of the groups of Vietnam veterans who suffered the highest exposure to Agent Orange, has shown no marked excess of cancer even now, thirty-five to forty years after the exposure.[2]

In short, it is hard to imagine a district court better positioned than Judge Weinstein to assess the current state of the medical and scientific record regarding the effects of exposure to Agent Orange, or a district court less vulnerable to the accusations of plaintiffs' amici. For nearly three decades, Judge Weinstein has devoted his energies to addressing the massive Agent Orange litigation. *See, e.g.*,

[2] The 2005 report of this study concludes that "the significant associations between herbicide exposure or dioxin levels and the likelihood of developing cancer were seen primarily for Ranch Hand officers and Ranch Hands in the low dioxin category, which were the lower-exposed subgroups, on average. Some of these associations also may have been due to chance or to a lack of adjustment for a factor not considered in these analyses." Air Force Health Study, *An Epidemiologic Investigation of Health Effects in Air Force Personnel Following Exposure to Herbicides – 2002 Follow-up Examination and Results*, Science Application International Corporation at 10-138 (2005).

373 F. Supp. 2d at 23-27 (citing scores of Agent Orange opinions). The suggestion by plaintiffs' amici that Judge Weinstein was ill-informed or that his tentative causation analysis was based on a single IOM Report cannot be taken seriously.

III. THE IOM REPORT CONFIRMS THE ABSENCE OF ANY SCIENTIFIC EVIDENCE SUPPORTING PLAINTIFFS' CLAIMS OF CAUSATION.

The contention of plaintiffs' amici that Judge Weinstein misinterpreted the IOM Report fares no better. As noted, the courts in prior Agent Orange litigation have consistently concluded that "none of the available evidence would support a finding to a more-probable-than-not standard of causality between exposure to Agent Orange and disease (except for a quickly discoverable and curable form of skin irritation, chloracne)." 304 F. Supp. 2d at 407. Citing the 2002 IOM Report, Judge Weinstein concluded in this round of Agent Orange cases that "[t]he scientific basis for that conclusion of lack of any substantial proof of causality, either general or specific to individuals, remains much the same." *Id.*

Even a cursory reading of the IOM Reports confirms Judge Weinstein's understanding of the medical evidence. The most recent IOM Report concludes, for example, that "in general, *it is impossible* to quantify the degree of risk likely to be experienced by veterans because of their exposure to herbicides in Vietnam." 2004 IOM Report at 17 (emphasis added); *see also id.* at 7 (noting that the "lack of adequate data on Vietnam veterans themselves makes it difficult to reach

conclusions about increased risk of disease among Vietnam veterans"). The Report highlights the inadequacy of the current state of the scientific record, decrying "the lack of data on Vietnam veterans, the large uncertainties about the magnitude of potential risk posed by exposure to herbicides in epidemiologic studies, the inadequate control for other important risk factors in many epidemiologic studies, and the uncertainty about the nature and magnitude of exposure to herbicides in Vietnam." *Id.* at 7. Indeed, far from reflecting a "scientific consensus" that Agent Orange has caused cancer in Vietnam veterans, the Report highlights the need "for additional scientific studies to resolve continuing scientific uncertainties about the health effects of the herbicides used in Vietnam and their contaminants." *Id.* at 10. The IOM Report simply cannot be read to reflect a scientific consensus that Agent Orange exposure has caused cancer in Vietnam veterans.

The efforts of plaintiffs' amici to persuade this Court otherwise are fundamentally flawed. To begin with, determinations of scientific causation has never been IOM's mandate. For public policy reasons, Congress created a program of compensation for Vietnam veterans without requiring reliable scientific evidence of the health effects of Agent Orange exposure. Pursuant to the Agent Orange Act of 1991, the IOM was directed to "provide scientific information for the Secretary of Veterans Affairs" to aid in the implementation of the

compensation program. 1994 IOM Report at 227. The IOM's periodic reports – the first was published in 1994, and the IOM has issued updated reports every two years since – have done just that. The IOM, however, has expressly disclaimed any intent to make causation assessments, noting that its "charge was n[ot] to focus on questions of causation," *id*, and explaining that its categorization of diseases was "based on 'statistical association,' not on causality as is common in scientific reviews," *id.* at 246; *see also e.g.*, 1994 IOM Report at 7, 572; 2004 IOM Report at 7 ("As mandated by PL 102-4, the distinctions among categories are based on statistical association, not on causality.").

The attempt of plaintiffs' amici to extract a favorable conclusion about causation from the IOM Reports depends on a sleight of hand. Plaintiffs' amici state that "the Institute of Medicine of the National Academy of Sciences found that the evidence is sufficient to conclude that there is a *positive causal association* between exposure to 'herbicides' and non-Hodgkin's lymphoma." *See* Durie Amicus Brief at 18 (emphasis added). But the use of the term "positive causal association" – a term that the IOM Reports do not use – conflates "association" with "causation." As the Federal Judicial Center's *Reference Manual on Scientific Evidence* explains, however, "an association is not equivalent to causation":

> An association identified in an epidemiologic study may or may not be causal. Assessing whether an association is causal requires an understanding of the strengths and weaknesses of the study's design and implementation, as

> well as a judgment about how the study findings fit with other scientific knowledge.

Reference Manual on Scientific Evidence at 336-337.[3]

A disease thus may be "associated" with Agent Orange, in the sense that it is more prevalent among Vietnam veterans than among others, simply because some aspect of service in the Vietnam War resulted in higher rates of the disease, yet that circumstance may be entirely unrelated to the effects of transitory exposure to Agent Orange. In that case, the existence of an "association" would say nothing reliable about the connection between Agent Orange exposure and disease.[4]

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[3] The peril of conflating association with causation is not unique to the Agent Orange context. In some early epidemiological studies, for example, coffee drinking was associated with lung cancer. However, coffee drinking used to be highly associated with smoking cigarettes, thus smoking was a "confounding" variable. Once smoking was controlled for, the association between coffee drinking and lung cancer disappeared. *See* Junius C. McElveen & Chris Amantea, *Legislating Risk Assessment*, 63 U. CIN. L. REV., 1553, 1581 (1995). In the present case, there are numerous potential confounding causes of disease in troops fighting in difficult and unprecedented circumstances in a tropical jungle environment.

[4] The vast gulf between association and causation has been well established in the context of Agent Orange. As described in *Nehmer v. United States Veterans' Administration*, 712 F. Supp. 1404, 1407-08 (C. D. Cal. 1989), the Veterans Administration ("VA") initially adopted a causation standard to govern eligibility for disability benefits under the Veterans' Dioxin and Radiation Exposure Compensations Standards Act of 1984. Applying that standard, the VA denied more than 31,000 claims for compensation in the first three years of the program. 712 F. Supp. at 1408. That causation standard was declared invalid in *Nehmer*, *see id.* at 1416-20, and was replaced with a standard requiring only a "significant statistical association, *id.* at 1420. Under that more relaxed standard, the VA has granted thousands of claims and is paying hundreds of millions of dollars in Agent Orange benefits.

The distinction between association and causation is particularly significant in the present context because of the congressional mandate to assess only the former. The IOM thus considers the link between chemical exposure and disease to be sufficient when "a positive association has been observed between herbicides and the outcome in studies in which chance, bias, and confounding could be ruled out with reasonable confidence." 2002 IOM Report at 8. "Several small studies that are free of bias and confounding" may be sufficient evidence of an association when the results are "consistent in magnitude and direction," *id.* at 14, even if larger and more reliable studies fail to replicate the small studies and even report results to the contrary.

The Court in *Amorgianos v. National Railroad Passenger Corp.*, 137 F. Supp. 2d 147 (E.D.N.Y. 2001), analyzed similar evidentiary issues and found that, "[e]ven when an appropriately designed study yields evidence of a statistical association. . . . epidemiologists generally do not accept such an association by itself as proof of a causal relationship." *Id.* at 168. Indeed, the court in *Amorgianos* explained that a more rigorous scientific methodology must be applied to establish a causal relation. *See id.* (discussing the nine "Bradford Hill criteria," which "[e]pidemiologists generally look to . . . to determine whether a statistical association is indeed causal"). The IOM analysis is a far cry from the scientific methodology set forth in the guidelines used by epidemiologists to assess

causation, as the IOM itself recognizes. *See, e.g.*, 1996 IOM Report at 5 ("[S]tandard criteria used in epidemiology for assessing causality (Hill, 1971) do not strictly apply.").

Indeed, the best epidemiological studies of Vietnam veterans refute the notion that there is any causal link between elevated levels of cancer and Agent Orange. Both the U.S. Centers for Disease Control and Prevention ("CDC") and the Australian Royal Commission conducted sophisticated studies of troops not directly responsible for herbicide operations. *See* Centers for Disease Control, *Serum 2, 3, 7, 8 -Tetrachlorodibenzo-p-Dioxin Levels in U.S. Army Vietnam-era Veterans*, JAMA 260 (9):1249-1254 (1988) ("CDC 1988"); *Royal Commission on the Use and Effects of Chemical Agents on Australian Personnel in Vietnam*, *Final Report. Vol. 4* (1985) ("Royal Commission 1985"). The CDC tested serum dioxin levels for over 600 combat ground troops who were classified, based on their military records, as likely having high exposure to Agent Orange. (CDC 1988.) The CDC found that their dioxin levels were indistinguishable from the background dioxin levels in veterans who never served in Vietnam. *Id.* These serum dioxin tests were among the first to be conducted when the technology was developed in the mid-1980s, and the lack of any discernable group differences at this time is strong evidence that troops (other than those applying herbicides) were not substantially exposed to Agent Orange. *See* Trichopoulos Aff. ¶¶ 19, 30.

(CDC 1988) These results were similar to another large study of Australian Vietnam veterans performed by the Australian Royal Commission. (Royal Commission 1985) Moreover, although the studies found health effects to be associated with service in Vietnam, most could be ascribed to risk factors for combat soldiers. Other diseases (such as non-Hodgkin's lymphoma) were found in elevated levels, but had no apparent correlation with exposure to Agent Orange, and, indeed, the risk of non-Hodgkin's lymphoma tended to be *lower* in veterans who had served where Agent Orange had been sprayed. *See* Centers for Disease Control, *The Association of Selected Cancers with Service in the U.S. Military in Vietnam*, Archives of Internal Medicine 150:2473-2505 (1990).

The nearly-completed Ranch Hand study reinforces these results. The Ranch Hand study examined veterans who operated the fixed-wing herbicide spraying missions in Vietnam and compared them to veterans who flew the same aircraft but never flew herbicide missions and were not exposed to Agent Orange. Elevated serum levels confirmed that the Ranch Hand group had been exposed to Agent Orange. Logically, if one were to find an increased risk from Agent Orange exposure in any group of Vietnam veterans, it would first show up in the most heavily exposed Ranch Hand group. However, study of the Ranch Hand veterans has not found any cancer-related health effects caused by Agent Orange exposure, *see* Michalek J.E. *et al.*, *The Air Force Health Study: A Summary of Results*,

Organohalogen Compounds 54:396-399 (2001), and the overall mortality rate is similar to the comparison group and statistically significantly lower than the mortality rate expected based on the general population, *see* Akhtar F.Z. *et al.*, *Cancer in U.S. Air Force Veterans of the Vietnam War*, Journal of Occupational and Environmental Medicine 46(2):123-136 (2004) ("Akhtar *et al.* 2004").

It is even less likely that Vietnam veterans generally would experience any elevated risk of cancer, because several factors combined to minimize the exposure to Agent Orange by troops other than those (such as the veterans in the Ranch Hand Study) who were assigned to conduct the spraying.

First, many of the defoliant missions were targeted at areas controlled by enemy forces and thus required fighter escorts and military engagement in advance of spraying to suppress enemy resistance. Mission procedures designed to limit the risk to allied ground troops from friendly fire also minimized the possibility that allied troops would be sprayed directly. *See* Trichopoulos Aff. ¶ 28; *see also* Alvin Young *et al.*, *Assessing Possible Exposures of Ground Troops to Agent Orange During the Vietnam War: The Use of Contemporary Military Records*, Environmental Science & Pollution Research 11: 349-58 (2004).

Second, because of the dense upper foliage in the jungles of Vietnam and photodegradation – the half-life of TCDD in Agent Orange spread on leaves and exposed to natural sunlight is less than six hours – typically less than ten percent

and often as little as one percent of the Agent Orange would penetrate to the ground in a closed canopy forest, further limiting the exposure of allied troops. *See* Trichopoulos Aff. ¶ 29; *see also* Alvin Young *et al.*, *Environmental Fate and Bioavailability of Agent Orange and Its Associated Dioxin During the Vietnam War*, Environmental Science & Pollution Research 11: 359-70 (2004).

Third, the remaining portion of Agent Orange dried almost immediately and, once dried, was difficult to dislodge, making skin absorption unlikely. *Id.*

There is, in short, nothing even approaching a "scientific consensus" that Agent Orange has caused cancers in Vietnam veterans, and nothing in the IOM Report suggests otherwise. As the scientific experts below opined, the Ranch Hand Study and the other studies of Vietnam veterans "effectively rule out the possibility of widespread health effects in Vietnam veterans due to Agent Orange." Trichopoulos Aff. ¶ 24.

IV. THE IOM REPORT DOES NOT FIND EVEN AN ASSOCIATION BETWEEN AGENT ORANGE AND CANCER IN VIETNAM VETERANS.

Even as to association, the conclusions of the IOM Reports generally do not support the position of plaintiffs' amici because most of the studies on which the IOM relies do not involve Agent Orange and Vietnam veterans.

The most recent IOM report acknowledges, for example, that "[m]ost of the evidence on which the findings regarding associations are based . . . comes from

studies of people exposed to TCDD or herbicides in occupational and environmental settings rather than from studies of Vietnam veterans." 2004 IOM Report at 9; *see also* 1994 IOM Report at 247 (same). The IOM Reports also emphasize "the lack of adequate exposure data on Vietnam veterans themselves." 2004 IOM Report at 9; *see also* 1994 IOM Report at 247 (same).

The IOM Reports have consistently recognized that studies of industrial exposure are a poor proxy for studies of Vietnam veterans – the former are based typically on far more extensive occupational and environmental exposure or on exposure to chemicals other than Agent Orange and TCDD. *See* 2004 IOM Report at 17-18 ("The evidence of herbicide exposure among various groups studied suggests that most Vietnam veterans (except those with documented high exposures, such as participants in Operation Ranch Hand) had lower exposure to herbicides and TCDD than did the subjects of many occupational and environmental studies."). The IOM thus has cautioned against aggressively extrapolating from the industrial studies:

> To estimate the magnitude of risk for a particular health outcome among herbicide exposed Vietnam veterans, quantitative information about the dose-time response relationship for each health outcome in humans, information on the extent of herbicide exposure among Vietnam veterans, and estimates of individual exposure are needed. Given the large uncertainties that remain about the magnitude of potential risk from exposure to herbicides in the studies that have been reviewed (Chapters 8-11), the inadequate control for important confounders, and the uncertainty about the nature and magnitude of exposure to herbicides in Vietnam (Chapter 6), none of the ingredients

> necessary for a quantitative risk assessment are available. *Thus, it is not possible for the committee to quantify the degree of risk likely to be experienced by veterans because of their exposure to herbicides in Vietnam.*

1994 IOM Report at 15 (emphasis added); *see also* 2004 IOM Report at 9 ("[Q]uantification of the actual risks experienced by veterans exposed to the compounds of interest during the Vietnam War is not possible.").

The conclusions of the IOM that there is "sufficient evidence" of an association between some herbicide exposure and certain cancers – principally chronic lymphocytic leukemia, soft-tissue sarcoma, non-Hodgkin's lymphoma, and Hodgkin's disease – is thus of limited relevance here.[5] Indeed, an examination of the specific evidence cited demonstrates that the IOM's conclusion that there is "sufficient evidence of an association" between *dioxin* and certain cancers does not demonstrate a similar association for Vietnam veterans exposed to Agent Orange (and is, of course, insufficient to prove causation).

Soft Tissue Sarcoma (STS).

The finding of sufficient evidence with respect to soft-tissue sarcoma is based on occupational and environmental studies whose results are frequently not statistically significant and whose subjects have high levels of exposure to dioxin and, significantly, probable exposure to other chemicals as well. Moreover, the

[5] The IOM Reports also found "sufficient evidence" of association for chloracne, a non-cancerous skin condition that is not the basis of plaintiffs' claims and thus is not addressed further in this brief.

results of those studies are contrary to the numerous studies of Vietnam veterans, some of which are discussed above, which almost uniformly show no statistically significant increase in STS. Thus, even the IOM's statement that "[t]he available data on Vietnam veterans do not permit a conclusion on whether they are at increased risk for STS," 2002 IOM Report at 287; *see also* 2004 IOM Report at 251, minimizes the fact that 20 studies of Vietnam veterans were cited in the 2002 IOM Report, and the vast majority – including the Ranch Hand Study – were negative for increased risk of STS.

Non-Hodgkin's Lymphoma (NHL).

The IOM Reports acknowledge that "the evidence regarding association is drawn from occupational and other studies in which subjects were exposed to a variety of herbicides and herbicide components." 2002 IOM Report at 355. The results reported in many of the studies cited are not statistically significant. As for evidence of increased risk in veterans, the Reports cite a single study of Australian Vietnam veterans as "possibly" indicating an increased risk. That study investigated self-reported health effects and Vietnam service, not Agent Orange or TCDD, and after further investigation of medical records and elimination of over-reporting, the increase largely disappeared. *See* Commonwealth Department of Veterans' Affairs, *Morbidity of Vietnam Veterans: A Study of the Health of*

Australia's Vietnam Veteran Community – Vol. 1: Male Vietnam Veterans Survey and Community Comparison Outcomes (1998).

Other studies suggest that veterans may have an increased risk of non-Hodgkin's lymphoma related to service in Vietnam generally, but this increased risk is not found in those veterans thought to be exposed to Agent Orange. *See, e.g.*, Akhtar *et al.* 2004; Air Force Health Study, *An Epidemiologic Investigation of Health Effects in Air Force Personnel Following Exposure to Herbicides – 1997 Follow-up Examination and Results*, Science Application International Corporation (2000). For example, discussing the latest evidence on NHL incidence in Vietnam veterans, the IOM noted:

> Akhtar *et al.* (2004) describe cancer incidence and mortality in a prospective cohort study of Air Force Operation Ranch Hand Vietnam veterans who sprayed Agent Orange during their service in Southeast Asia. . . No excess of lymphopoietic cancers was noted for the Ranch Hand veterans (10 observed, 11.8 expected; SIR, 0.85; 95% CI, 0.4–1.5). . . .This pattern did not change when the analyses were restricted to veterans whose tours of duty ended between 1966 and 1970, the years when Agent Orange was the predominant herbicide in use in Vietnam.

2004 IOM Report at 311. Once again, the finding that there is evidence of an "association" is not tantamount to showing causation, as the best designed studies of Vietnam veterans do not even suggest an "association," let alone a causal relationship.

Chronic Lymphocytic Leukemia (CLL).

The 2002 IOM Report concluded that there was sufficient evidence of an association with respect to CLL based on six occupational studies of agricultural workers exposed to largely unknown types of "herbicides" and other pesticides and chemicals. Five of the six occupational studies reviewed did not report direct information on herbicide exposure for the CLL cases. No veteran studies were cited, and the Seveso study data on CLL for persons highly exposed to TCDD after an industrial explosion were negative. The finding of an "association" was not made specifically as to Agent Orange, TCDD, or Vietnam veterans. Indeed, the IOM concluded that "[t]he limited data available on Vietnam veterans do not suggest that they are at increased risk for CLL." 2002 IOM Report at 376; *see also* 2004 IOM Report at 337 (stating that "the lack of exposure information on Vietnam veterans precludes quantification of any possible increase in their risk.").

Hodgkin's Disease.

As it did with respect to the diseases discussed above, the 1994 IOM Report concluded that there was sufficient evidence of an association between Hodgkin's Disease and "herbicides" based largely on studies of industrial and agricultural workers whose potential exposures differed substantially from those of Vietnam veterans. 1994 IOM Report at 556-57. Again, many of the cited studies do not report statistically significant results. In contrast, the numerous studies of Vietnam

veterans and Agent Orange that are central to the proper evaluation of causation provide little support for an association between Agent Orange and Hodgkin's Disease, though they are given little weight in the IOM's determination of association. In the latest update, the section on Hodgkin's Disease referred to the Akhtar (2004) study again and stated that "No excess of lymphopoietic cancers was noted for the Ranch Hand veterans." 2004 IOM Report at 318. Consistent with this finding, the latest report summarized that "the lack of exposure information on Vietnam veterans precludes quantification of any possible increase in their risk." *Id.* at 319.

Multiple Myeloma.

The 1994 IOM Report concluded that there was there was *limited* or *suggestive* evidence of an association between exposure to Agent Orange and multiple myeloma. This categorization is satisfied if "at least one high-quality study shows a positive association, but the results of other studies are inconsistent." 2004 IOM Report at 8. This is a much weaker standard than even the watered-down "sufficient evidence" standard discussed above. Significantly, the purported increased risk appears only in occupational and industrial exposure studies, and not in studies of Vietnam veterans. Further, the latest IOM Report acknowledges that the significance of one of the earlier occupational studies that showed an increased risk needs to be re-evaluated as more data have become

available questioning whether the earlier reported risk was due to chance and the small size of the study:

> The study by Swaen et al. (2004) gives additional data on a cohort study that was included in VAO. In the first report on the cohort, the SMR was significantly elevated (8.2; 95% CI; 1.6–23.8), but it was based on 3 deaths. Despite more than doubling the amount of follow-up time, the new report for the cohort does not include any additional cases. The confidence interval for the updated SMR now includes the null value.

More significantly, the results of the latest Ranch Hand study, Akhtar et al. (2004), demonstrates that no increased risk of multiple myeloma has been found in the most highly exposed Vietnam veterans.

CONCLUSION

Contrary to the contentions of plaintiffs' amici, there is no "scientific consensus" that Vietnam veterans are suffering from diseases *caused* by Agent Orange. Indeed, the best designed epidemiological studies refute that notion. Judge Weinstein was thus entirely correct that "none of the available evidence would support a finding to a more-probable-than-not standard of causality between exposure to Agent Orange and disease" and that plaintiffs' claims would likely fail for "lack of any substantial proof of causality."

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CERTIFICATE OF COMPLIANCE WITH FED. R. APP. P. 32(A)(7)(B)

I hereby certify that this brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 6873 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

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CERTIFICATE OF SERVICE

Pursuant to Fed. R. App. P. 25(d), I certify that on February 22, 2006, I served the foregoing Brief Of American Chemistry Council And Chlorine Chemistry Council As *Amici Curiae* In Support Of Defendants-Appellees by sending two copies via first-class mail to the parties that appear on the attached service list.

I further certify that on February 22, 2006, I caused the document to be served via electronic mail on each counsel of record who has a functioning e-mail address, as identified in the following service list.

I further certify that on this 22d day of February 2006, I filed the foregoing Brief Of American Chemistry Council And Chlorine Chemistry Council As *Amici Curiae* In Support Of Defendants-Appellees by dispatching the original and ten copies of it to a third-party commercial carrier for overnight delivery to the Clerk of the Court.

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