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To be Argued by:
ANDREW L. FREY

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 FOR DEFENDANTS-APPELLEES ON THE GOVERNMENT CONTRACTOR DEFENSE

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DEFENDANTS-APPELLEES' RULE 26.1
CORPORATE DISCLOSURE STATEMENT

In accordance with Rule 26.1 of the Federal Rules of Appellate Procedure, Defendants-Appellees hereby state:

Monsanto Company. Monsanto Company has no publicly owned parent corporation, and no publicly held corporation owns more than 10 percent of Monsanto's stock.

The Dow Chemical Company. The Dow Chemical Company has no parent corporations and no publicly held company owns 10 percent or more of its stock.

Occidental Chemical Corporation. Occidental Chemical Corporation, the successor by merger to Diamond Shamrock Chemicals Company (which was known prior to September 1, 1983 as Diamond Shamrock Corporation), is an indirect, wholly-owned subsidiary of Occidental Petroleum Corporation, a publicly held company.

Valero Corporation. Valero Corporation, the successor by merger to Ultramar Diamond Shamrock Corporation, has no parent corporation. Barclays Global Investors, N.A. owns more than 10% of its stock.

Maxus Energy Corporation. Maxus Energy Corporation is an indirect, wholly-owned subsidiary of YPF S.A. ("YPF"). Approximately 99 percent of YPF's stock is owned by Repsol YPF S.A. ("Repsol YPF"). Repsol YPF is

publicly held, and the shares of YPF stock not owned by Repsol YPF are also publicly held.

Tierra Solutions, Inc. Tierra Solutions, Inc., formerly known as Chemical Land Holdings, Inc., is an indirect, wholly-owned subsidiary of YPF S.A. ("YPF"). Approximately 99% of YPF's stock is owned by Repsol YPF S.A. ("Repsol YPF"). Repsol YPF is publicly held, and the shares of YPF stock not owned by Repsol YPF are also publicly held.

Hercules Incorporated. Hercules Incorporated has no parent corporations, and no publicly held company owns 10 percent or more of its stock.

Uniroyal, Inc. Uniroyal, Inc. is a dissolved corporation.

C.D.U. Holdings, Inc. C.D.U. Holdings, Inc. is a dissolved corporation.

Uniroyal Chemical Co. Uniroyal Chemical Corp. is wholly owned by the Crompton Corporation, a publicly held company.

T H Agriculture & Nutrition Company, Inc.; Thompson-Hayward Chemical Co.; and Harcros Chemical, Inc. T H Agriculture & Nutrition Company, Inc. (now know as T H Agriculture & Nutrition L.L.C.) is a wholly-owned subsidiary of Philips Electronics North America Corporation, formerly known as North American Philips Corporation. Philips Electronics North America Corporation is an indirect wholly-owned subsidiary of Koninklijke Philips Electronic N.V., a publicly held corporation based in the Netherlands. Thompson-

Hayward Chemical Co. was a former subsidiary of North American Philips Corp., which no longer exists. These assets of Thompson Hayward Chemical Co. were purchased by Harcros Chemical Inc., which is a completely separate entity from Philips Electronics North America Corporation.

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COMM. TO REVIEW THE HEALTH EFFECTS IN VIETNAM VETERANS OF EXPOSURE TO HERBICIDES, INST. OF MEDICINE OF THE NAT'L ACADS., VETERANS & AGENT ORANGE: UPDATE 2002 (Nat'l Acad. Press 2003).....4

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PRELIMINARY STATEMENT

The appeals currently before the Court represent the latest iteration in a case that has already lasted well over two decades. Nineteen years ago, this Court affirmed Judge Weinstein's ruling that Agent Orange claims filed by Vietnam veterans and their families who had opted out of a 1984 class settlement were barred by the government contractor defense. In so holding, the Court observed that "[t]he plaintiffs had a final ***and in our view impossible***, hurdle to surmount, namely the military contractor defense." *In re "Agent Orange" Prod. Liab. Litig.*, 818 F.2d 145, 173 (2d Cir. 1987) (emphasis added).

Today, the Court is presented with Judge Weinstein's dismissal, again on the basis of the government contractor defense, of Agent Orange lawsuits by Vietnam veterans and their families who claim not to be bound by that settlement. In the interim, nothing has changed — the plaintiffs today rely on virtually the same factual record developed through exhaustive discovery over 20 years ago, and the law remains the same in all material respects. In fact, since this Court's opt-out decision, the Fifth and Federal Circuits have concurred that claims brought against Agent Orange manufacturers are barred by the defense. See *Miller* v. *Diamond Shamrock Co.*, 275 F.3d 414 (5th Cir. 2001); *Hercules Inc.* v. *United States*, 24 F.3d 188, 198 (Fed. Cir. 1994), aff'd on other grounds, 516 U.S. 417 (1996). After the Supreme Court upheld the government contractor defense in *Boyle* v. *United*

Technologies Corp., 487 U.S. 500 (1988), this Court once again confirmed the probable applicability of the defense to the facts of this case. *In re "Agent Orange" Prod. Liab. Litig. (Ivy)*, 996 F.2d 1425, 1436 (2d Cir. 1993).

The story began in the early 1960s, when the United States' efforts to assist the South Vietnamese government in resisting the communist insurgency faced two serious problems on the ground. First, Viet Cong ambushes from concealed jungle locations were undermining the effectiveness of the South Vietnamese military and resulting in high casualties (and would before long begin to produce significant numbers of American casualties as well). And second, it was very difficult to locate and disrupt the Viet Cong's supply lines from North Vietnam because they were hidden in dense vegetation. Accordingly, in 1962, in part at the urging of the South Vietnamese government, President Kennedy approved implementation of a strategy of large-scale defoliation in key areas. Government scientists carefully studied health risks that might accompany the use of defoliants for military purposes and concluded that they were safe for these uses. The President determined that the benefits of defoliation substantially exceeded both the health risks and the political risks.

While most of the defendants already produced herbicides for civilian agricultural use in diluted form, government scientists found those products ineffective for the contemplated military uses. Accordingly, these scientists

evaluated various herbicide formulations in order to determine which would best meet the needs of the U.S. and South Vietnamese military. Having identified for itself the specific herbicides and formulations that would be most effective for military purposes, the government ordered those herbicides from the defendants, prescribing the chemical composition, concentrations, and packaging that the manufacturers were required to employ. To ensure adequate supplies as the defoliation effort intensified, the government issued rated orders to the defendants, followed by mandatory directives that effectively commandeered the entire domestic production capacity for Agent Orange.[1]

The government knew (i) that the defoliants it was ordering contained trace amounts of dioxin, (ii) that workers exposed to dioxin during the production of 2,4,5-T — one of the components of Agent Orange — had experienced certain health effects, mainly a skin condition known as chloracne, and (iii) that dioxin was hazardous in pure form. After conducting its own toxicological research and non-public studies, however, and possessed of all relevant information known to the manufacturers, the government concluded that the contemplated use of

[1] While there were several different formulations used, each named after a different color, the bulk of the herbicide produced for use in Vietnam was Agent Orange. We here refer to all the herbicides collectively as "Agent Orange," unless the context requires differentiation.

defoliants in Vietnam would be safe. That conclusion was eminently reasonable, as this Court has observed. See 818 F.2d at 193 (stating that Agent Orange contained only "trace elements of dioxin" and that the "precise hazard of the herbicide, if any, was thus a matter of speculation at the time of its use"). Indeed, this Court found that decades later, in 1987, there was still no basis for a different conclusion: "Even today, the weight of present scientific evidence does not establish that Agent Orange injured personnel in Vietnam." *Id.* at 190. It reiterated that conclusion in 1993: "Notwithstanding the legal and scientific developments of the past nine years, the [plaintiffs'] chances of recovery are nearly as speculative today as they were at the time of settlement." *Ivy*, 996 F.2d at 1437. Nor has any persuasive evidence of causation emerged since then.[2]

---

[2] Even today, the scientific evidence does not establish that Agent Orange injured Vietnam veterans. In 2003, a committee of the Institute of Medicine of the National Academy of Sciences, which was requested by the Secretary of Veterans Affairs to evaluate the health effects of exposure to Agent Orange in Vietnam, failed to find any causal link between Agent Orange exposure and health harm. See COMM. TO REVIEW THE HEALTH EFFECTS IN VIETNAM VETERANS OF EXPOSURE TO HERBICIDES, INST. OF MEDICINE OF THE NAT'L ACADS., VETERANS & AGENT ORANGE: UPDATE 2002 at 8 (Nat'l Acad. Press 2003). See also Alvin L. Young *et al., Assessing Possible Exposures of Ground Troops To Agent Orange During the Vietnam War: The Use of Contemporary Military Records*, 11 ENVTL. SCI. & POLLUTION RESEARCH 349 (2004), *available at* http://dx.doi.org/10.1065/espr2004.10.221; Alvin L. Young *et al., Environmental Fate and Bioavailability of Agent Orange and Its Associated Dioxin During the Vietnam War*, 11 ENVTL. SCI. & POLLUTION RESEARCH 359 (2004), *available at* (cont'd)

COUNTER-STATEMENT OF THE ISSUES PRESENTED

1. Whether the government contractor defense protects manufacturers of military defoliants against a claim based on the presence of dioxin contamination in a government-specified product, where military officials ordered the product with knowledge of the presence of the dioxin, after studying it and concluding that it presented no material health risk.

2. Whether the 1984 global settlement of the class action by veterans who were exposed to Agent Orange during the Vietnam War bars suit by veterans whose illnesses did not manifest until after 1994.

STATEMENT OF THE CASE

Plaintiffs in these appeals claim that they were injured as a result of exposure to Agent Orange in Vietnam, or, in one case (*Garncarz*), in Korea. They allege claims for strict products liability in tort, including design defect, failure-to-warn, and manufacturing defect; breach of implied warranty; and negligence,

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(… cont'd)

http://dx.doi.org/10.1065/espr2004.10.222; Cole *et al.*, Dioxin and Cancer: A Critical Review, 38 REG. TOXICOLOGY & PHARMACOLOGY 378-88 (2003).

The affidavit of Dimitrios Trichopoulos, Jack S. Mandel, Philip S. Guzelian, Michael Newton, and Alvin L. Young, a group of preeminent scientists, refutes any claim that the evidence available today supports a scientific conclusion that Agent Orange caused injury to personnel in Vietnam. 1/22/2004 Trichopoulos *et al.* Aff. (A1204-25).

fraud, and misrepresentation. Plaintiffs seek compensatory and punitive damages. All of the claims center on the presence of trace amounts of the contaminant 2,3,7,8-tetrachlorodibenzo para dioxin ("dioxin") in Agent Orange, a circumstance that was known to and considered by the government, in light of all the existing information as to the possible hazard it posed, when it ordered and reordered Agent Orange.

The current suits involve plaintiffs who differ from members of the 1984 class only in that they allege injuries that manifested after the 1994 deadline for claims for cash payments from the settlement fund. The suits were brought in various state and federal courts, beginning in 1998. Defendants removed the state cases to federal court, and the Panel on Multi-District Litigation transferred all of the cases to the Eastern District of New York, where they were consolidated before Judge Weinstein, who had presided over the 1984 settlement. Judge Weinstein ruled that the All Writs Act established federal jurisdiction over the *Isaacson* case, which had been removed from New Jersey state court, and then dismissed the pending cases on the ground that they presented an impermissible collateral attack on the 1984 settlement.

On appeal, this Court affirmed the finding of federal jurisdiction but reversed the dismissal, holding that Isaacson and Stephenson were not bound by the class settlement because "both learned of their allegedly Agent Orange-related

injuries only after the 1984 settlement fund had expired in 1994." *Stephenson* v. *Dow Chem. Co.*, 273 F.3d 249, 256-57, 260-61 (2d Cir. 2001). An equally divided Supreme Court affirmed this Court's ruling as to dismissal but vacated and remanded the *Isaacson* decision as to jurisdiction for reconsideration in light of *Syngenta Crop Protection, Inc.* v. *Henson*, 537 U.S. 28 (2002), which held that the All Writs Act is not an independent basis for subject matter jurisdiction. *Dow Chem. Co.* v. *Stephenson*, 539 U.S. 111 (2003) (per curiam). This Court in turn remanded to the district court. 346 F.3d 19 (2d Cir. 2003).

In February, 2004, Judge Weinstein denied Isaacson's motion to remand to state court, finding federal jurisdiction under the Federal Officer Removal Statute, 28 U.S.C. § 1442(a)(1). *Isaacson* v. *Dow Chem. Co.*, 304 F. Supp. 2d 442 (E.D.N.Y. 2004). At the same time, he granted defendants' motion for summary judgment on the basis of the government contractor defense but stayed the decision to allow six months of additional discovery. *Isaacson* v. *Dow Chem. Co.*, 304 F. Supp. 2d 404 (E.D.N.Y. 2004).

With respect to plaintiffs' design defect claim, the district court held that "[e]ach element of the Government Contractor Defense has been established" because no reasonable juror could fail to find that:

> 1) The government approved precise specifications for the Agent Orange as set forth in contracts with various administrative agencies and divisions of the Armed Forces. These differed substantially from

> "off-the-shelf" products the defendants were producing for their civilian markets.
>
> 2) The Agent Orange delivered by defendants conformed to these government specifications. This was verified by close checks through government inspectors.
>
> 3) The government knew substantially more about possible dangers of Agent Orange as it intended to, and did, use it than did any or all of the defendants combined.

304 F. Supp. 2d. at 441. In addition, the district court found that "the government was aware of alternative manufacturing processes that might potentially mitigate the presence of dioxin in Agent Orange," but, because of "its quest for maximum production of Agent Orange as a tool of war," the government "failed to specify another production process." *Id.* at 442.

With respect to plaintiffs' "failure-to-warn" claims, the district court likewise held that "[e]ach element of the Government Contractor Defense has been established" because no reasonable juror could fail to find:

> 1) The government had control over the markings, including possible product warnings. It forbade the placement of warnings on the barrels.
>
> 2) The Agent Orange delivered by defendants conformed to the government order that there be no product warnings on the Agent Orange. This was verified by close checks by government inspectors.
>
> 3) The government knew substantially more about possible dangers of Agent Orange as it intended to, and did, use it than did any or all of the defendants combined.

Id. at 441-42.

Finally, the district court concluded: "Having found that the Agent Orange produced by defendants conformed to the government's precise specifications, the manufacturing defect claim cannot stand." *Id*. at 442.

In November, 2004, Judge Weinstein denied plaintiffs' first motion for reconsideration of the grant of summary judgment and reaffirmed his February opinion. *Isaacson* v. *Dow Chem. Co.*, 344 F. Supp. 2d 873 (E.D.N.Y. 2004). The court noted that "[a]ll available relevant files were made available [to plaintiffs, and t]he court and the magistrate judge gave plaintiffs full assistance" in conducting additional discovery. *Id.* at 874. Judge Weinstein's "conclusion remain[ed] unshaken" that the government contractor defense applied. *Ibid.*

The United States filed a Statement of Interest in January 2005 agreeing that defendants meet the *Boyle* test and that plaintiffs' claims are barred by the government contractor defense. Statement of Interest of the United States at 1, n.2 and 50 *et seq*. In March, 2005, Judge Weinstein denied plaintiffs' further motion to reconsider and entered judgment in favor of defendants. *Anderson* v. *Dow Chem. Co.*, MDL No. 381, 2005 WL 483416 (E.D.N.Y. Mar. 2, 2005). These appeals followed.

COUNTER-STATEMENT OF FACTS[3]

Background

The plaintiffs in this case allege that the chemical defoliants used by the U.S. military during the Vietnam War to reduce the cover available for ambushing U.S. and allied troops and to reveal enemy supply routes caused illness, several decades later, in American servicemen who allegedly were exposed to those chemicals. The defoliants in question, including Agent Orange, were the subject of intensive research and development by military scientists over three decades. When President Kennedy approved a full-scale defoliation campaign, he also ordered the military to investigate the safety of Agent Orange as it would be used in Vietnam. Despite the government's knowledge that Agent Orange was contaminated with a chemical called dioxin, which was believed to be highly toxic, the government concluded that the defoliant, which contained only trace amounts of dioxin, was not harmful to humans. Indeed, the military was so committed to the program that

[3] This Statement of Facts is formulated with due regard for the standard of review, which, with respect to the grant of summary judgment on the basis of the government contractor defense, requires disputed facts to be viewed in the light most favorable to the plaintiffs. The historical facts underlying the application of the government contractor defense in this case are generally undisputed, though there is certainly disagreement over the legal implications of those facts.

in March, 1967, it effectively compelled the chemical manufacturers to produce defoliants in order to ensure an uninterrupted and sufficient supply.

The manufacturers had for many years marketed herbicides containing 2,4-dichlorophenoxyacetic acid (2,4-D) and 2,4,5-trichlorophenoxyacetic acid (2,4,5-T), the active ingredients in Agent Orange, with an excellent safety record when used as directed. The government's formulation, however, was different from — and substantially more concentrated than — herbicides the manufacturers had previously produced. In addition, the volume of defoliant applied by the Air Force in Vietnam was much greater than what government regulations allowed with regard to the domestic uses for which the defendants' commercial products were designed. As Judge Weinstein concluded, the evidence was clear that the government knew at least as much as the companies did about the dangers to production workers associated with the manufacture of defoliants containing 2,4,5-T; moreover, its access to non-public, government-commissioned research guaranteed that it knew far more than the manufacturers about any potential hazards of Agent Orange, especially under the unique conditions in which it was used in Vietnam.

General William Westmoreland, the commander of American forces in Vietnam from 1964 to 1968, testified that Agent Orange fully met expectations — it was an "effective weapon" in "a rather unique battlefield environment" and was

used "to accomplish our military mission." Westmoreland Tr. 31-32, 35 (A2096-98).[4] This Court likewise concluded in its 1987 decision that "[t]he use of Agent Orange in Vietnam was believed necessary to deny enemy forces the benefits of jungle concealment along transportation and power lines and near friendly base areas. Its success as a herbicide saved many, perhaps thousands of, lives." 818 F.2d at 192-93. The priority the government placed on achieving those military objectives and protecting the lives of American servicemen easily overrode wholly speculative concerns regarding possible hazards. Dr. John Foster, Director of the Defense Directorate of Research and Engineering, stressed:

> One thing I think is very important to make clear, there was a war going on. We were losing a lot of people from the most incredibly clever and insidious mechanisms. Men walking down trails with heavy foliage all around would be shot at close range by people whom they couldn't see. We had aircraft overhead who simply could not see the trails below them, so we had a lot of forces, and yet they were terribly vulnerable to just a few people hidden in the jungle growth.
>
> In that situation, the overriding interest was to see whether or not the science and technology that was available could be applied to get rid of some of this cover.

Foster Tr. 23-24 (A1673-74).

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[4] Unless otherwise noted, citations to deposition transcripts appear in the Appendix to the 10/27/2004 Affidavit of William A. Krohley.

Summary of Plaintiffs' Principal Factual Assertions

Plaintiffs contend that the defendants sold their commercial herbicides to an unsuspecting government that had no knowledge of the alleged risks the products posed. Specifically, they claim that

- Agent Orange and other defoliants ordered by the military for use in Vietnam were standard, off-the-shelf products available to American farmers (Bauer Br. 12-23; Stephenson Br. 17-19);
- The government exercised little discretion in designing the defoliants; in fact, the defendants themselves controlled the procurement process (Bauer Br. 38-39);
- An alternative manufacturing process, developed by C.H. Boehringer Co., reduced the level of dioxin in 2,4,5-T, but the defendants did not adopt this process because it would have slowed production and increased costs substantially (Bauer Br. 53-55);
- Defendants conspired to hide their knowledge of dioxin and its effects from military officials (Stephenson Br. 32-35); and
- The government was unaware until late in the war that the defoliants were contaminated with dioxin, and when it learned of that contamination, it terminated the defoliation campaign (Anderson Br. 2).

As we will now show, none of these assertions finds any support in the record. Plaintiffs have failed to create a genuine issue of material fact on any point germane to the availability of the government contractor defense.

The Government's Herbicide Research and Development Prior to the Vietnam War

Military scientists at the Crops Division of the Army Chemical Corps Biological Laboratories at Fort Detrick first identified the herbicidal properties of

2,4-D and 2,4,5-T during World War II. See 1983 Hercules Summary Judgment Br., Ex. 2 at 18-19 (A18-19). According to an Army report, "[t]he earliest and possibly the most outstanding contribution [of the Crops Division] was the pioneering work on synthetic plant hormones as herbicides that led to the selection and development of [2,4-D] and [2,4,5-T]." *Id.* at 18 (A18).

Although this research was highly classified during the war, military scientists published their findings in 1946 and continued their research on the efficacy, toxicity, and means of dissemination of various forms of 2,4-D and 2,4,5-T. According to a history published at Fort Detrick, the Detrick researchers helped give birth to the modern herbicide industry:

> In the postwar period, the Camp Detrick group that was studying plant-growth-regulator-type herbicides was the foremost group in the world engaged in this type of activity. Release of the information to the public after World War II caused revolutionary changes in weed control practices throughout the world and resulted in the development of many new industries and a new body of scientific literature.

1983 Hercules Summary Judgment Br., Ex. 2 at 19 (A19). These researchers made great strides toward the design of the defoliants used during the 1960s. "By 1951, it had been determined that the vegetation-control agents of choice would be n-butyl 2,4-D, n-butyl 2,4,5-T, and mixtures of the two." 1983 Hercules Summary Judgment Br., Ex. 3 at 8 (A611). Those were the same chemicals the military would later spray over Vietnam.

The Army's efforts during the 1950s also included research into methods of disseminating defoliants and their effectiveness at meeting the uniquely military objective of improving visibility in combat zones. In the spring of 1951, the Crops Division conducted field tests to assess the feasibility of dispensing undiluted 2,4-D and 2,4,5-T from military cargo planes and bombers. The Crops Division also studied the distribution of herbicide droplets to determine the area that could be effectively treated by a single aircraft. In 1952, the military conducted tests using a prototype large-capacity spray system; this system was the precursor to the Hourglass-MC-1, the first spray system used in Vietnam. 1983 Hercules Summary Judgment Br., Ex. 2 at 25 (A25). This preparation "laid the ground work for the defoliation systems [subsequently used] in Vietnam" (*id.* at 23 (A23)) and proved the effectiveness of aerial spraying in improving visibility for military operations. 10/27/2004 Krohley Aff., Ex. 3 at 6 (A2143).

The Military's Decision to Use Defoliants in Vietnam

1. The Threat Posed by Poor Visibility in Combat Zones

By the early 1960s, the U.S.-supported government in Saigon was facing a growing communist guerrilla movement. The Viet Cong took advantage of the cover offered by Vietnam's dense jungles to ambush and elude detection by allied forces both on the ground and in the air. As a Department of Defense report warned:

> Jungle, roadside, and swamp vegetation offer areas of concealment to terrorists in Free Vietnam, allowing them to establish bases hidden from aerial observation, and to ambush friendly traffic along roads and waterways. Defoliating the vegetation or killing it could improve the observation of such areas.

11/10/2003 Krohley Aff., Ex. 5 at 4 (A734).

In June, 1961, the U.S. Military Assistance Command — Vietnam ("MACV") received an "urgent request from the highest level of the Republic of Vietnam" to evaluate the feasibility of a defoliation strategy. See 10/27/2004 Krohley Aff., Ex. 4, Sect. III-A at 2 (A2274). MACV forwarded this request to the Advanced Research Projects Agency ("ARPA"), an agency within the Department of Defense responsible for investigating innovative and high-risk applications of technology to military operations. That month, ARPA initiated an urgent program to evaluate the feasibility of defoliating tropical vegetation in Vietnam. *Ibid*.

2. The Government's Decision That A Mixture Of 2,4-D and 2,4,5-T Would Be the Most Effective Defoliant for Use in Vietnam

a. The ARPA Research Program

The research phase of ARPA's program, testing the effectiveness of various chemicals in defoliating Vietnamese forests, began in July, 1961 under the direction of Dr. James Brown of the Army Biological Laboratories at Fort Detrick. Dr. Brown traveled to Vietnam to conduct field tests, but his efforts were constrained by his inability to acquire the desired herbicides quickly. The "chemicals of choice," "2,4-D and 2,4,5-T ***[,] could not be obtained on the

open market and less active commercial substitutes were procured." 11/10/2003 Defs.' Supp. Br. in Opp. to Motion to Remand, Ex. 1 at 9 (A612). Dr. Brown also judged commercial spray equipment "inadequate" because it "served to prohibit application of desired amounts of the dilute chemicals." *Ibid*.

When Dr. Brown returned, his report acknowledged that, in addition to "the urgency that this effort be of assistance to South Vietnam," "other factors had to be considered, such as availability in large quantity, costs, and ***known or proven safety in regard to their toxicity to humans*** and animals if a scale-up of spray use should be required." 10/27/2004 Krohley Aff., Ex. 5 at 9 (A738) (emphasis added). He recommended that "appropriate formulations of 2,4-D and 2,4,5-T be exploited for immediate use." *Id.* at 4, 37 (A734, A765). As explained in a later report, Dr. Brown's conclusion was that, "with suitable spray systems and the more potent chemicals of choice (n-butyl 2,4-D and 2,4,5-T), militarily significant defoliation could be accomplished in Vietnam." 11/10/2003 Defs.' Supp. Br. in Opp. to Motion to Remand, Ex. 1 at 9 (A612).

From August 1961 to June 1963, military scientists screened 1,410 chemical compounds, identifying 37 active defoliants and 29 active herbicides in testing on woody plants. 11/10/2003 Defs.' Supp. Br. in Opp. to Motion to Remand, Ex. 5 at 3 (A772). The consensus of personnel at Fort Detrick was that a 50/50 mixture of 2,4-D and 2,4,5-T would be most effective. Minarik Tr. 18-19, 48 (A1867-69).

They believed that those compounds "were the best materials to do the job" (1983 Dow Summary Judgment Br., Ex. 50 (Minarik Tr.) at 52 (A1870)) and "the least toxic herbicides anyone could ever utilize" for defoliation. 1983 Dow Summary Judgment Br., Ex. 66 (Minarik Tr.) at 53-54 (A1870a-70b). This mixture later became known as Agent Orange. Minarik Tr. 48 (A1869). The Crops Division also concluded that a spray volume of three gallons per acre was necessary to penetrate the dense, multi-layer jungle canopy in Vietnam. Delmore Tr. 60-61 (A1614-15).

The 50/50 formulation was designed to achieve uniquely military objectives. A 1963 report from the Institute for Defense Analysis ("IDA") of the Department of Defense explained the differences between commercial and military uses of herbicides:

> In the domestic application of herbicides where there is an emphasis on selectivity of action and economy, agents are used in quite dilute solutions. This allows for fairly precise control of the rate of delivery. By contrast, in military employment, where rapidity and non-specificity of action call for extremely high dose rates of active agent and where the method of delivery by air is costly, it is important that a maximum effectiveness per unit volume be achieved.

11/10/2003 Defs.' Supp. Br. in Opp. to Motion to Remand, Ex. 7 (1/29/1992 Gordon Aff.), Ex. B at 16-17 (A402-403).

b. The Institute for Defense Analysis

The IDA also evaluated defoliants for use in Vietnam. In late 1962, IDA reported to ARPA on the "state-of-the-art" chemical methods for controlling vegetation for military purposes. 1983 Hercules Summary Judgment Br., Ex. 10 at 1 (A35) ("Introduction"). The report stated that herbicides such as 2,4-D and 2,4,5-T were safe when used commercially in "quite dilute solutions." 2/13/1992 Gordon Aff., Ex. B at 16-17 (A402-403). The IDA recognized that the mixtures suggested for use in Vietnam were stronger than the commercial formulations. *Ibid*. But in light of the exigent circumstances, it specifically endorsed the military's intended non-conformance with "the high safety standards required by the Food and Drug Administration for commercial agriculture." 1983 Hercules Summary Judgment Br., Ex. 10 at 9 (A43).

An appended section to the IDA report entitled "Toxicological Considerations" also addressed the anticipated high-volume use of defoliants by the military and the potential consequences:

> In the military environment, the hazards may be increased in that personnel may be less experienced in handling chemicals and under pressure to act quickly. ***Also, military requirements dictate the application of over-kill concentrations (1 lbs/acre) with possible toxicological or cosmetic effects on the exposed population and their domestic animals.***

> *** Two groups of chemicals which are particularly noteworthy for their undesirable effects are the nitro- and chlorophenols.[5] The former may bring on heart disturbances and blindness by cataract formation, while the latter cause respiratory and skin irritation.
>
> While it would be unwise to set any arbitrary toxicity limits for a military agent, a convenient rule of thumb is that any agent in commercial use, unless otherwise noted, may be used safely in military operations when applied with those precautions which are normal to commercial practices.

2/13/1992 Gordon Aff., Ex. B at 13 (A401) (emphasis added).

Nevertheless, despite the concerns identified by the IDA and the knowledge throughout the military's scientific arms and the public health establishment of the toxicity of dioxin and its presence in 2,4,5-T, the government determined that "extremely high dose rates" of undiluted herbicides were required for effective military use, and it proceeded accordingly. *Id.* at 16-17 (A402-403).

3. The Development of Procurement Specifications for Defoliants

a. The Contract Specifications

Having selected a 50/50 mixture of 2,4-D and 2,4,5-T and a three gallon per acre dispersal rate as the optimum solution, the military drew up formal product specifications to begin procurement of the defoliant, now code-named "Agent Orange." The Crops Division at Fort Detrick had already developed some

[5] 2,4-D and 2,4,5-T are chlorophenols.

procurement specifications for 2,4-D and 2,4,5-T as early as March 1953, and the Vietnam-era specifications evolved from that base of knowledge. 1983 Dow Summary Judgment Br., Ex. 11 at 164 (A71).

Anthony Sinclitico, Chief of the Department of Defense's Specifications Division from August 1957 to September 1965, testified that the military followed its usual procedures in drawing up Agent Orange specifications.

> Q. Could you describe the process that was involved in the development of a specification for herbicides?
>
> A. The process for developing a herbicide specification was no different than any other specification that we may be developing for any other military material that may require being purchased by the services. ***
>
> * * *
>
> Q. What was done with the comments by the industrial manufacturers?
>
> A. They were reviewed, and depending upon the project engineers, again, who had the final say in the specification, they would determine whether or not the comments were applicable or not and on that basis, on some occasions we would go back to industry to get more information or data that may be required before we changed the specification.

Sinclitico Tr. 17, 25-26 (A1956, A1964-65). After describing the specification process in detail, Sinclitico was asked:

> Q. In developing the specification for Agent Orange, did you follow the same procedures that you described for the development of the specifications for 2,4-D and 2,4,5-T?

> A. We followed the same procedures that we would follow on the preparation of any specification for any item. All the procedures were the same.

Sinclitico Tr. 54 (A1978).

After Fort Detrick produced the "basic specifications," personnel at the Army's Edgewood Arsenal in Maryland reviewed those "specifications in terms of their compatibility with large-scale production." Stone Tr. 63 (A2021). In 1963, the Army Munitions Command promulgated Military Specifications MIL-H-51147(MU), "Herbicide 2,4-dichlorophenoxy-acetate" and MIL-H-51148(MU), "Herbicide 2,4,5-trichlorophenoxyacetate." 10/27/2004 Krohley Aff., Exs. 6-11 (A2299-2334). These specifications were used as the basis for the military's procurement of Agent Orange. Fredericks Tr. 21-24, 68-71.

The specifications called for mixtures that were very different from the herbicides being produced for commercial use. Defendants' commercial products contained 2,4-D and 2,4,5-T, diluted by substantial amounts of inert ingredients. 2/13/1992 Gordon Aff. ¶ 4 (A393). Agent Orange, in contrast, contained the active ingredients 2,4-D and 2,4,5-T in unprecedented concentrations, with virtually no inert ingredients. *In re "Agent Orange" Prod. Liab. Litig.*, 597 F. Supp. 740, 848 (E.D.N.Y. 1984). An Army report emphasized the hazards this specification implied and warned that Agent Orange and other military defoliants should not be used in civilian environments.

> It should be noted that the materials described in [the July 1963 military specifications for 2,4-D and 2,4,5-T], because of their military use, were of a much higher concentration than materials that are normally used in domestic agricultural and industrial operations. It should also be noted that each of these military specifications contains a paragraph cautioning that the materials procured under these documents must not be diverted to domestic use and that for domestic applications the material should be procured under [a different federal specification].

11/10/2003 Defs.' Supp. Br. in Opp. to Motion to Remand, Ex. 7 (1/29/1992 Gordon Aff.), Ex. B at 2 (A407).

b. The Government Precluded the Manufacturers From Placing Warnings on Drums of Agent Orange.

The government specifically identified the markings that would appear on drums of Agent Orange, and it barred the manufacturers from adding warnings. By contrast, when marketed for domestic use, Defendants' 2,4,5-T and 2,4-D products were accompanied by detailed warnings, typically including cautions against contact with eyes, skin or clothing and against inhaling of mist, as well as general warnings to read the entire label and to follow directions and precautions carefully. See, *e.g.*, 2/8/2005 Heck Aff., Ex. B (3/28/1980 Frawley Aff.) ¶ 10 and Ex. B (to Frawley Aff.) (A2621-22). No such markings were permitted by the government on Agent Orange, even though it was used at much higher concentrations and applied at heavier rates than the domestic versions. See *Isaacson*, 304 F. Supp. 2d at 429-31.

4. Operation Ranch Hand

In 1961, the Joint Chiefs recommended the initiation of defoliation operations to Secretary of Defense Robert McNamara, who, along with Secretary of State Dean Rusk, concurred. President Kennedy gave final clearance in a National Security Action Memorandum dated November 30, 1961. 10/27/2004 Krohley Aff., Ex. 3 at 16-22 (A2148-51). The defoliation program continued until 1970.

In January 1962, while the ARPA research at Fort Detrick was still ongoing, the U.S. Air Force began the operational phase of the defoliation program in South Vietnam under the code name "Ranch Hand." 10/27/2004 Krohley Aff., Ex. 3 at 9-22 (A2144-51); *id.* at Ex. 4, Section III-A at 2 (A2274). The program initially used a mixture of 50% normal butyl ester of 2,4-D, 30% normal butyl ester of 2,4,5-T, and 20% isobutyl ester of 2,4,5-T. This first mixture was code-named "Agent Purple." 10/27/2004 Krohley Aff., Ex. 3 at 199 (A2238).

The Government's Investigation of Potential Health Hazards Associated With Defoliants

1. On President Kennedy's Orders, an Edgewood Arsenal Task Force Evaluated the Toxicity of Agent Purple.

President Kennedy ordered that the military evaluate the safety of 2,4-D and 2,4,5-T as they were to be used in Vietnam. General Delmore, the commanding officer at Edgewood Arsenal, asked Dr. Bernard McNamara, whom he identified

as "one of the best [toxicologists] in the country," to undertake that task. Delmore Tr. 39-40 (A1608-09).[6]

Dr. McNamara assembled and supervised a task force at the Army Chemical Corps Chemical Warfare Laboratories, which were located at Edgewood Arsenal. Whereas Fort Detrick personnel and the IDA had primarily focused on the ***efficacy*** of various defoliants, the Edgewood task force was responsible for investigating the potential ***toxicity*** of Agent Purple. The scientists reviewed the published literature concerning the toxicity of 2,4-D and 2,4,5-T; obtained unpublished information, including information from other government agencies; and performed their own toxicological studies. The Edgewood task force possessed all the knowledge about these compounds that was available at that time, including the fact that dioxin was associated with the 2,4,5-T production process and that it was known to cause chloracne in production workers. It concluded that the military's defoliation campaign posed no material health risks to those who would be exposed to the herbicides in Vietnam.

Plaintiffs offer no evidence to contradict the district court's finding that "[e]arly in the 1960's, Edgewood personnel, on orders from the White House, investigated the toxicity and potential danger of 2,4,5-T and 2,4-D, thoroughly

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[6] Dr. McNamara was not deposed in MDL No. 381 because he was deceased.

reviewing the existing literature and data" (304 F. Supp. 2d at 427), and indeed that finding is amply supported by the record. Nor do they challenge the finding that the Edgewood evaluation was requested by President Kennedy. See Herrero Tr. 27–28 (A1708-09). Indeed, they barely mention Edgewood, simply stating in passing that "the government held meetings to consider whether [2,4-D and 2,4,5-T] met the 'non-toxic' requirement." Stephenson Br. 45. Plaintiffs ignore the literature searches and toxicity testing performed by the task force when they assert that the task force and PSAC "heavily rel[ied] on the commercial record." Stephenson Br. 45. This breezy dismissal of the Edgewood project is belied by the undisputed record.

a. The Edgewood Task Force Thoroughly Researched the Potential Toxicity of Herbicides for Military Use.

The Edgewood task force embarked on an in-depth study of the existing scientific literature and conducted its own toxicity testing. Its conclusion was that Agent Purple, a composite of 2,4-D and 2,4,5-T, was not toxic at levels to which humans would be exposed in Vietnam.

i. The Task Force's Review of the Scientific Literature and the Government's Proprietary, Unpublished Data

Plaintiffs state that "those involved in the selection of the various Agents believed they were using commercial herbicides which were not toxic to humans or animals." Stephenson Br. 44; see also Bauer Br. 20. While it is certainly true

that the commercial herbicides had an outstanding safety record when used as directed, the government did not simple-mindedly believe that it was "using commercial herbicides"; the government's own specifications called for a compound that was far more concentrated than anything the defendants sold commercially. Moreover, the scientists' belief that Agent Orange was safe did not rest entirely on the safety record of defendants' commercial herbicides. To the contrary, the Edgewood scientists engaged in an extended analysis of the scientific data available to them — which was far more information about the health risks associated with Agent Orange use in Vietnam than the manufacturers had.

The Edgewood scientists did review, as a starting point, the available scientific literature, as well as the Department of Agriculture's records showing an absence of any complaints from commercial users. 10/27/2004 Krohley Aff., Ex. 32 at App. A (A2373); Morthland Tr. 50 (A1890). Dr. Morthland "recall[ed] specifically that the Department of Agriculture had not had a complaint over the 15 years since they had certified ["the two compounds under consideration," 2,4-D and 2,4,5-T] for use on field crops." Morthland Tr. 47, 50 (A1889-90).

But the review was hardly confined to those records. Plaintiffs allege that "in the 1960s, the Government had no central repository of toxicology information" and that, in general, "toxicology information held by Government agencies was not readily shared." Stephenson Br. 48. This statement is

conclusively belied by the record: the Edgewood task force canvassed government agencies to find relevant toxicological information about 2,4-D and 2,4,5-T. Dr. McNamara and Dr. Virgil Johnson reviewed the confidential central toxicity files of the Department of Agriculture (Leary Tr. 41-46 (A1800-05)) and Dr. McNamara visited the Occupational Health division of the Public Health Service, which had published relevant information. Osheroff Tr. 78-79 (A1906-07). In addition, the Industrial Liaison Office at Edgewood developed and updated a large body of literature references, including citations to articles identifying dioxin as a chloracnegen (*i.e.*, a substance that causes or promotes chloracne) formed in the production of 2,4,5-T. 10/27/2004 Krohley Aff., Ex. 28, 30 (A2345-49, A2350-65). Finally, Dr. McNamara was aware of a confidential military report at Edgewood concerning dioxin, which referred to an article describing cases of chloracne in workers engaged in the manufacture of 2,4,5-trichlorophenol, an intermediary in the production of 2,4,5-T. Vocci Tr. 191-93 (A2089-91).

ii. The Task Force's Own Empirical Studies

In addition to its comprehensive review of "the medical literature and unpublished data of various research laboratories" (10/27/2004 Krohley Aff., Ex. 32 at 2 (A2368)), the Edgewood task force performed its own toxicity tests. The first study evaluated the acute effects of Agent Purple, including its impact on liver function, in rats, rabbits, and dogs. 2/4/2005 Caley Decl., Ex. 13 (Vocci Tr.) at 91,

95-100, 107 (A2587-94); *id.*, Ex. 16 (A2610) (Vocci Dep. Ex. 2).[7] A second was a sub-acute study designed "to determine whether or not the compound is accumulating in the body in any way." *id.*, Ex. 13 (Vocci Tr.) at 126-130 (A2599-2603); *id.*, Ex. 17 (A2611) (Vocci Dep. Ex. 4). The lethal dose levels established by these tests later factored into Edgewood's conclusion, as discussed below, that Agent Purple was not toxic at the levels at which humans were likely to be exposed in Vietnam. There has never been any suggestion that Agent Orange contained more dioxin than Agent Purple; indeed, plaintiffs asserted below, and Judge Weinstein found, that Agent Purple had "a much ***higher*** dioxin content than 'Agent Orange.'" Plaintiffs' Motion 64 (emphasis added).

All of these data were evaluated "in light of actual use of these materials as military herbicides in Vietnam." 10/27/2004 Krohley Aff., Ex. 32 at 3 (A2368). That is especially significant because this use differed significantly from domestic use. Active ingredients made up at least 95% of the military herbicides by volume. By contrast, domestic weed-killers contained as much as 45% inactive ingredient and were further greatly diluted in water or other liquids before use. The government took into account this difference in concentration. As noted above, in

[7] "Very high high dose levels" were administered, and the scientists focused on the liver as "the target organ that might be involved." 2/4/2005 Caley Decl., Ex. 13 (Vocci Tr.) at 119-20 (A2597-98).

its January 1963 report to the Department of Defense, the IDA recognized that while phenoxy herbicides were safe as used domestically:

> In the military environment, the hazards may be increased in that personnel may be less experienced in handling chemicals and under pressure to act quickly. Also, military requirements dictate the application of over-kill concentrations (lbs/acre) with possible toxicological or cosmetic effects on the exposed population and their domestic animals.

2/13/1992 Gordon Aff., Ex. B at 13 (A401).

iii. The Task Force's Review of Public Health Service Information About the Hazards Associated With Herbicide Use

By the early 1960s, the Division of Occupational Health of the Bureau of State Services of the Public Health Service had considerable knowledge about health effects associated with the manufacture of 2,4,5-T. Dr. Louis Schwartz, Medical Director of the Public Health Service, was the founder of occupational dermatology in the United States. Possick Tr. 57-58 (A1913-14); Birmingham Tr. 199, 202 (A1599-60). Dr. Schwartz had "vast experience" with occupational chloracne by the early 1940s and was a leading expert on the subject. Birmingham Tr. 199, 202 (A1599-60).

On May 8, 1949, Dr. Schwartz and his colleague Dr. Donald Birmingham visited Monsanto's 2,4,5-T plant in Nitro, West Virginia, to investigate an explosion and subsequent cases of chloracne and other worker health problems. Birmingham Tr. 205-206 (A1561-62). In 1963, Dr. Birmingham, accompanied by

Marcus Key, the Assistant Director of the Dermatology Section of the USPHS Occupational Health Division, visited Diamond Alkali's 2,4,5-T plant in Newark, New Jersey to investigate cases of chloracne and porphyria (a liver disorder). Key Tr. 83, 148 (A1771-72). The report they sent to the New Jersey Department of Health, (10/27/2004 Krohley Aff., Ex. 42 (A472-80)), described the chemical process for the manufacture of 2,4,5-T and discussed dioxin as a contaminant in that process. Key Tr. 233-34 (A1782-83); 1983 Dow Summary Judgment Br., Ex. 100 (A2345-49). Dr. Birmingham also wrote a number of scientific articles during the 1950s and 1960s addressing the development of chloracne among chemical plant workers in connection with production of tricholorophenol and/or 2,4,5-T. 10/27/2004 Krohley Aff., Exs. 40-42 (A2440a-40f, A73-86, A472-80).

USPHS's work on 2,4,5-T continued, and by the early 1960s the agency was aware that dioxin was the chloracnegen in 2,4,5-T. See Key Tr. 102-103 (A1771a-71b); 1983 Hercules Summary Judgment Br., Ex. 50 (A65a-65e); 2/7/2005 Gordon Aff., Ex. 11 (A2612-15). Dr. Herbert E. Stokinger, the Chief Toxicologist in the Public Health Service's Division of Occupational Health, testified that by the mid-1960s, if not earlier, the role of dioxin in the etiology of chloracne "was getting to be common knowledge when we met in the American Industrial Hygiene Association meetings during that period. You know, it just became common knowledge." Stokinger Tr. 102, 108-09 (A2009, A2012-13). "Oh, it generally

came to the attention of people that are interested that the impurity was this TCDD." *Id.* at102 (A2009). "Yes, the impurity was tetrachlorodibenzo-paradioxin." *Ibid.* Dr. Stokinger also testified that in 1965 or 1966, Dr. V.K. Rowe of Dow told him of chloracne in Dow workers exposed to dioxin. *Id.* at 77 (A2017a).

All of this information was shared with Edgewood. The Public Health Service maintained a liaison office in the same building as the Crops Division at Fort Detrick throughout the late 1950s and 1960s. That office served Army Chemical Corps personnel at both Fort Detrick and Edgewood. Osheroff Tr. 14-16, 19-20 (A1900, A1902-1904). As a result of these connections, the Edgewood task force had access to all of the information that the Public Health Service had — much of which was published — about occupational chloracne associated with the manufacture of 2,4,5-trichlorophenol and 2,4,5-T, including the experiences of Monsanto and Diamond. In addition, Drs. Key and Birmingham delivered several lectures on occupational diseases of the skin to Army medical officers and toxicologists at the invitation of the Army Environmental Health Agency. Key Tr. 45-48 (A1766-69); Birmingham Tr. 103, 106, 109-10, 251 (A1546-49, A1564). Dr. Birmingham also believed he discussed 2,4,5-T as a chloracnegen in lectures delivered at Edgewood after 1949. Birmingham Tr. 251 (A1564).

Thus, plaintiffs' unsupported assertion that Public Health Service personnel "did not even know the government was spraying 2,4,5-T in Vietnam" (Stephenson Br. 52), even if true, misses the point. The Public Health Service shared information with the Edgewood scientists, and it was Edgewood that was responsible for evaluating the toxicity of 2,4-D, 2,4,5-T, and Agent Purple as the military intended to use them in Vietnam.

b. The Edgewood Scientists Were Aware of the Links Among Dioxin, 2,4,5-T, and Chloracne and Liver Damage.

Even prior to President Kennedy's specific request for information regarding the toxicity of defoliants approved for use in Vietnam, Dr. McNamara and others at Edgewood were well aware both that the manufacture of 2,4,5-trichlorophenol was associated with chloracne and that dioxin was the responsible chloracnegen. 10/27/2004 Krohley Aff., Ex. 24 (A2343-44); Jandorf Tr. 95-96 (A1755-56).

Edgewood's first knowledge of dioxin, initially as an unidentified substance, was derived from chemical weapons screening in the early 1950s. 10/27/2004 Krohley Aff., Exs. 16-19 (A413-43, A2342d-42f); Sultan Tr. 87-88 (A2039-40); Jandorf Tr. 243 (A1761). The Army Chemical Corps's Chemical Warfare Laboratories learned of the 1949 explosion at Monsanto's Nitro, West Virginia, 2,4,5-T plant and asked Monsanto for scrapings from the explosion for use in

testing the then-unidentified chemical as a potential chemical warfare agent. PA3372.[8]

Edgewood again encountered the substance, this time identified as dioxin, in a trip report prepared by Dr. Friedrich Hoffmann, Chief of the Agents Research Branch at Edgewood. Dr. Hoffmann traveled to a conference of industrial hygienists and toxicologists in Europe in 1959, where it was suggested that trace amounts of dioxin in a wood preservative had caused several deaths from liver failure among workers. The scientists he met gave him citations to the literature on dioxin. 10/27/2004 Krohley Aff., Ex. 21 at 1 (A2342g); *id*., Ex. 22 (A2342aa). Dr. Hoffmann's report, which summarized that literature, was distributed widely, and the potential toxicity of dioxin thereby became "common knowledge" at Edgewood. 10/27/2004 Krohley Aff., Ex. 24 (A2343-44); Horton Tr. 63-64 (A1742-43); Jandorf Tr. 86-87 (A1752-53); Summerson Tr. 45 (A2024); Simmons Tr. 101 (A1929); Sultan Tr. 81 (A2036); Sim Tr. 41-43 (A1939-41).

Edgewood personnel were also aware of the link between dioxin and chloracne in the specific context of 2,4,5-T production. The literature Dr. Hoffmann was given during his trip included a 1957 article, written by German scientists J. Kimmig and K.H. Schulz, identifying dioxin as a possible

[8] "PA" citations are to the plaintiffs' combined appendix.

chloracnegenic byproduct of the manufacture of trichlorophenol. 10/27/2004 Krohley Aff., Ex. 23 (A2342ak-42ao). Knowledge of dioxin and chloracne spread throughout Edgewood shortly after Dr. Hoffmann's trip. Simmons Tr. 123 (A1934); Jandorf Tr. 85-86, 144 (A1751-52, A1760); Sultan Tr. 59 (A2029). In June 1970, Dr. Bernard Jandorf, then Chief of the Army Chemical Research Laboratory, wrote to the Director of the Laboratories, stating that his group had "been acquainted with the high toxicity of dioxin since the 1950s (Dr. Hoffmann)." 10/27/2004 Krohley Aff., Ex. 24 (A2343-44). Dr. Jandorf testified that the Edgewood personnel who had this knowledge included, among others, himself, Dr. Witten, and Dr. McNamara. Jandorf Tr. 95-96 (A1755-56).

It is thus beyond dispute that top government scientists at Edgewood became aware of the connections among dioxin, chloracne, and 2,4,5-trichlorophenol by the late 1950s. Plaintiffs respond to this evidence by citing testimony indicating that there were some people at Edgewood who were not aware of some or all of this information.[9] Stephenson Br. 42-43. Nonetheless, undisputed documentary and testimonial evidence makes clear that key people at Edgewood, including Dr. McNamara, Dr. Sultan, Dr. Witten, Dr. Simmons, and Dr. Jandorf, ***did*** have this

[9] Many of the individuals whose testimony plaintiffs cite were not, in fact, Edgewood scientists. Although General Delmore, for example, was in command of Edgewood, he was not a scientist.

knowledge even before President Kennedy requested that Dr. McNamara's Edgewood task force evaluate the toxicity of 2,4-D, 2,4,5-T, and Agent Purple.

Plaintiffs further state that "the Army Chemical Warfare people evaluated dioxin in isolation and not as a contaminant of 2,4,5-T during the 1950s and were completely separate from the Crops Division at Fort Detrick." Stephenson Br. 52-53. This statement is correct in a narrow sense — the effects of dioxin as a trace contaminant are of necessity markedly less pronounced than its effects in pure form — but it ignores completely Edgewood's activities during the ***1960s***, when it evaluated Agent Purple and advised the President's Science Advisory Committee ("PSAC") of its results.

Although the Army believed that dioxin itself was dangerous, at least to production workers, it concluded that Agent Purple, which contained only trace amounts of dioxin, was safe. The Army viewed dioxin as a concern only for manufacturers, whose workers might receive occupational exposures to 2,4,5-trichlorophenol. Dr. Henry Wills, Chief of the Physiology Division in the Medical Research Laboratory at Edgewood, testified that although he knew that 2,4,5-trichlorophenol was an intermediary used to produce 2,4,5-T (Wills Tr. 96 (A2128)) and had been aware of the association between chloracne and the manufacture of 2,4,5-trichlorophenol since the early 1950s (*id.* at 95-96, 158

(A2127-28, A2131)), this connection was not important in evaluating the toxicity of herbicides for use in Vietnam:

> A: For the purposes of the meeting, it was not a significant fact. It's a significant fact for the manufacturer, but not for the Army.
>
> Q: Why do you answer that way, doctor?
>
> A: Well, the Army's purpose is to protect its own personnel who would not be involved in the manufacture.

Id. at 97-98 (A2129-30).

c. Based on the Edgewood Task Force's Studies and the Information Obtained From the Public Health Service, the Military Concluded That the Use of 2,4-D and 2,4,5-T in Vietnam Would Not Present a Health Hazard.

On April 26, 1963, a meeting was held at Edgewood to discuss the results of the group's toxicity research. The minutes of this meeting set forth the agenda:

> [T]hose in attendance would be familiarized with the actual use of certain herbicides in Viet Nam during the past two years. *** [A] sought-for end of the meeting was a general statement about dose levels and hazards to health of man and domestic animals from 2,4-D and 2,4,5-T based on the medical literature and unpublished data of various research laboratories. The Committee was asked to evaluate the toxicity of the mixture known as "Purple." *** The Chairman further stated that the Committee should also review this information in light of ***actual use of these materials as military herbicides in Vietnam*** and comment as to whether health hazards were engendered by such operational use.

10/27/2004 Krohley Aff., Ex. 32 at 3 (A2368) (emphasis added). In addition to the 20 participants listed in the minutes, there were 50-60 observers present. Wills Tr. 67-68 (A2125-26).

The meeting began with a discussion of laboratory toxicology results. Dr. McNamara presented data on the toxicity of 2,4,5-T and 2,4-D to various animal species, concluding that the chemicals possessed a low order of toxicity. Morthland Tr. 53, 55 (A1892-93). McNamara reviewed data on the LD 50 and LD 1 values[10] for 2,4-D and 2,4,5-T in rats, guinea pigs, and mice and stated that, as far as humans were concerned, the "doses which might produce one death in a population of 10,000 are considerably higher than the maximum dose (30 mg/kg of body weight) which could have been delivered in the Viet Nam operations." 10/27/2004 Krohley Aff., Ex. 32 at App. C and table 2 (A2379). In addition, Dr. McNamara presented a summary of the available data from ongoing studies of both acute and chronic toxicity of Agent Purple being performed at Edgewood Arsenal. He concluded that based on the available information "it is very unlikely that 'Purple' would produce any fatalities as used in the operations in Viet Nam." 10/27/2004 Krohley Aff., Ex. 32 at App. C (A2377). Dr. Morthland of the Army Research Office, who was also present at the meeting, testified that chronic toxicity studies performed by Dr. McNamara were in line with the "standards of

[10] "LD 50" is the "lethal dose" required to kill fifty percent of a large population of animals. "LD 1" is a dose that would kill one percent of the population. Vocci Tr. 100 (A2078).

the day" in that they "were carried on for up through 90 days, which in a small animal is quite a chronic period [of] exposure." Morthland Tr. 55 (A1893).

Colonel Frank L. Bauer, Director of Medical Research at Edgewood, agreed with Dr. McNamara's conclusion. He described his team's evaluation of the "possible skin fallout dose [*i.e.*, the amount an individual could expect to receive on his skin as a result of aerial spraying] to man of herbicides as they were used in Viet Nam," and noted that the anticipated dose received by the "standard man" would be well below the best estimates for human toxicity. Morthland Tr. 47, 53 (A1889, 1892); 10/27/2004 Krohley Aff., Ex. 32 (A2366-80).

The group also reviewed data from the history of herbicide use and production. Dr. Warren Shaw reported that records of the Department of Agriculture ("USDA") showed that during the 15 years in which 2,4-D and 2,4,5-T had been used extensively in the United States, the USDA had not received a single complaint of injury to livestock, wildlife, or soils in connection with their use in the field or in research. 10/27/2004 Krohley Aff., Ex. 32 at App. A (A2372-73); Morthland Tr. 50 (A1890). (As noted above, Dr. McNamara and Dr. Virgil Johnson had visited the USDA to review its "Central Toxicity Files" concerning 2,4-D and 2,4,5-T. Leary Tr. 41 (A1800).) Dr. Charles Minarik, Chief of the Crops Division at Fort Detrick, described "incidents of total body splash exposures in manufacturing plants and in operations in Viet Nam" and commented that "in

spite of long periods of exposure to these compounds there were no effects noticed in the workers." 10/27/2004 Krohley Aff., Ex. 32 at 4 (A2369).

Manufacturer representatives also presented data at the Edgewood meeting. Dr. V.K. Rowe of Dow made a presentation during which he discussed the available toxicity data. 10/27/2004 Krohley Aff., Ex. 32 at 5 (A2370). Dr. R.J. Otten of Amchem Products discussed his experience with the use of herbicides in field applications and noted that even though "thousands of people were involved in these operations, skin sensitization was the maximum effect produced." Even that effect was observed in probably only "one out of a thousand persons." *Ibid.*[11]

Based upon the data reviewed and presented, the Committee concluded:

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[11] Plaintiffs once again distort the record when they imply that Dow misrepresented its knowledge at the meeting because "Dow was asked to provide toxicological background" and "[t]he words 'dioxin' and 'chloracne' do not even appear in any minutes of the 1963 meetings." Stephenson Br. 45. Plaintiffs point to no evidence, however, that Dow knew in 1963 of the presence of dioxin in 2,4,5-T. As shown below, the record is clear that Dow disclosed occupational problems and discoveries to the government: to PSAC (Wiesner Tr. 21-33 (A2106-2108); MacDonald Tr. 10-15, 23-26 (A1814-24)); to Dr. Stokinger of the Public Health Service (2/4/2005 Caley Decl., Ex. 11 (Stokinger Tr.) at 77 (A2017a)); to Jane Lewis, the Department of Commerce official involved in procuring Agent Orange (Lewis Tr. 65 (A1809d)); and to the Army Corps of Engineers, the Air Force, and Edgewood in connection with the military's project to develop a facility for the manufacture of Agent Orange. 10/27/2004 Krohley Aff., Exs. 45-47 (A2443-49); Anderson Tr. 25 (A1494). At the time of the April 1963 meeting, Edgewood personnel knew that dioxin was the chloracnegen created in 2,4,5-trichlorophenol manufacture, and only they had access to the secret Hoffmann Trip Report.

> [I]n summary and after careful review of toxicological data related to 2,4-D and 2,4,5-T plus the knowledge as to the manner [in which] these materials have been used for defoliation in military situations in Southeast Asia, the Committee concluded that ***no health hazard is or was involved to man or domestic animals from the amounts or manner these materials were used in the aforementioned exercise***.

10/27/2004 Krohley Aff., Ex. 32 at 5 (A2370) (emphasis added).

d. Plaintiffs Ignore the Central Role of the Edgewood Task Force.

The Edgewood task force played a critical role in addressing President Kennedy's question regarding the toxicity of 2,4-D and 2,4,5-T, both by comprehensively reviewing available information and by carrying out new studies. Nonetheless, in an effort to downplay the government's extensive knowledge, plaintiffs say virtually nothing about the Edgewood task force and do not even mention Dr. McNamara. Instead, plaintiffs discuss — in the context of toxicology research — Dr. James Brown of ARPA and the five person interagency team that ARPA sent to Edgewood to evaluate defoliation operations, which included General Delmore and Dr. Charles Minarik. See Stephenson Br. 43-45. This approach to the undisputed record is highly misleading. ARPA, along with the Crops Division at Fort Detrick, was concerned with the ***effectiveness*** of various herbicides and mechanical details such as the design of spray equipment. It was the Army Chemical Corps at Edgewood, with its extensive prior knowledge of dioxin, that was responsible for reporting to PSAC regarding ***toxicity***.

2. The Edgewood Task Force Reported Its Findings Directly to the President's Science Advisory Committee.

PSAC was an organization within the White House whose chief responsibility was "to provide advice to the President" (McRae Tr. 27 (A1833)) on a "wide variety of national and military problems." Dubridge Tr. 27 (A1620); see also Buckley Tr. 59 (A1567). PSAC was assisted by the President's Office of Science and Technology (McRae Tr. 12-13 (A1830-31)) and chaired by the President's Science Advisor. Dubridge Tr. 28 (A1621). Consistent with President Kennedy's request, the Edgewood task force reported its findings directly to PSAC for its review and concurrence.

On May 9, 1963, less than two weeks after the meeting at Edgewood to discuss and evaluate the toxicity of 2,4-D and 2,4,5-T, representatives of the Army Chemical Corps briefed PSAC on the "Possible Health Hazard of Phenoxyacetates as Related to Defoliation Operations in Vietnam." 10/27/2004 Krohley Aff., Ex. 33 (A2381-2440); Gardner Tr. 61 (A1697). The agenda for the briefing indicates that presentations were made by General Delmore and by Dr. McNamara and others who had made presentations at the earlier Edgewood meeting. 10/27/2004 Krohley Aff., Ex. 33 (A2381-2440). The summary of the briefing states that PSAC was informed of the estimated possible dose of Agent Purple to which a man in an area of maximum contamination during two days of spraying would be exposed, the toxicity of the herbicides, and the "outstanding safety records" of

these compounds over more than 15 years of extensive use. *Id.* at 2-3, 6 (A2383-84, A2437); Morthland Tr. 50-51 (A1890-91). PSAC was then informed of the conclusion reached at Edgewood Arsenal: that "no hazard to health was incurred as a result of the quantity or the method of use in that operation" (i.e., "the use of phenoxyacetates in Vietnam"). 10/27/2004 Krohley Aff., Ex. 33 at 4 (A2385); Morthland Tr. 51 (A1891).

Plaintiffs attempt to separate the knowledge held by Edgewood and PSAC, on the one hand, from that held by the lower-level government officials who were responsible for procuring Agent Orange, on the other. Thus, plaintiffs assert that "PSAC was never formally charged with evaluating the defoliation program and did not get involved in any procurement or contracting decisions." Stephenson Br. 52. This assertion misses the point. President Kennedy ordered an evaluation of the toxicity of the herbicides. That order resulted in the work done by Dr. McNamara's Edgewood task force and culminated in the April 26, 1963 meeting at Edgewood. The results of that meeting were reported to PSAC, whose function was to distill the scientific evidence and advise President Kennedy. He, in turn, was ultimately responsible for the decision to use Agent Orange in Vietnam.

3. Members of PSAC Had Also Learned From Other Sources That Dioxin Was a Contaminant in 2,4,5-T.

There can be no dispute that members of PSAC knew during the period when Agent Orange was being used in Vietnam that dioxin was a contaminant in

2,4,5-T. Dr. Jerome Wiesner, a member of PSAC from approximately 1958 to 1966, testified that he learned of dioxin as a contaminant in 2,4,5-T from a representative of Dow in a discussion following a meeting of the PSAC Panel on the Use of Pesticides. Wiesner Tr. 22-23 (A2107-08). He testified that the Panel examined 2,4-D and 2,4,5-T and that "[t]here seemed to be rather general agreement that these were safe chemicals to use under the proper use conditions." *Id*. at 24 (A2109).

Dr. Gordon J. MacDonald, a member of PSAC from 1965 to 1969, testified that the issue of "the use of herbicides and the presence of dioxin in the herbicides" was discussed in the spring of 1965 by a PSAC subgroup that was focused on "biological chemical warfare." MacDonald Tr. 12 (A1816). Dr. Vincent McRae, a member of the Office of Science and Technology, was also present. Members of the group believed that "the evidence was fragmentary and inconclusive, but that it was a subject that deserved continuing attention." *Id*. at 15 (A1819).

Dr. Donald F. Hornig, the chairman of PSAC, confirmed Dr. MacDonald's testimony. He testified that in the "mid-sixties," he learned that dioxin was "an impurity in 2,4,5-T" that resulted from "the manufacturing process." Hornig Tr. 87, 93-94 (A1716, A1719-20). He further knew that 2,4,5-T was a component of Agent Orange, which gave him cause "to be concerned" about "[w]hat the magnitude of the toxicological effects might be and what the magnitude of the

exposures might be." *Id.* at 89 (A1718). "There was a generalized concern for the health of both the Vietnamese population and the exposed Americans." *Id.* at 134 (A1723). Even in light of this "generalized concern," and recognizing that dioxin might present a potential human health risk (*id.* at 89 (A1718)), Dr. Hornig, distinguishing between dioxin and Agent Orange, concluded there was no "reason to feel that there was a health hazard associated with" Agent Orange in Vietnam. *Id.* at 88 (A1717). As Dr. Hornig testified, "[i]f we had considered that there was a significant, and I emphasize the word significant, hazard, we would have responded" — *i.e.*, notified the President. *Id.* at 135 (A1724).

Dr. Vincent McRae, who was a technical assistant in the White House Office of Science and Technology from 1962 through 1972, confirmed the testimony of these members of PSAC. McRae Tr. 12 (A1830). Dr. McRae's responsibilities included biological and chemical warfare policy issues that might be of concern to the President. *Id*. at 20 (A1832). He testified that in 1966 or 1967 a member of PSAC told him that dioxin was formed in the manufacture of 2,4,5-T. *Id*. at 53-54, 110-11 (A1834-35, A1838-39). He also recalled that this matter was discussed by the full PSAC. *Id*. at 55-56 (A1836-37).

Thus, members of PSAC were fully aware that Agent Orange contained dioxin and evaluated the hazard it posed.[12]

4. At PSAC's Recommendation, the Government Sponsored the Bionetics Study, Which Assessed the Long-Term Health Effects of Exposure to Various Pesticides and Herbicides.

In the spring of 1963, PSAC sent a report to President Kennedy entitled "Use of Pesticides,"[13] including 2,4,5-T. The report, which was focused primarily

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[12] Although they do not do so in their opening appellate briefs, in the court below plaintiffs cited testimony by certain PSAC members who did not recall dioxin or the Vietnam defoliation program having been discussed in PSAC. Such no-recollection evidence does not create a genuine issue of material fact. Moreover, the testimony cited by plaintiffs included that of individuals (John Wilder Tukey and Paul Doty) who were no longer members of PSAC in 1965, when Dr. MacDonald testified that such a discussion occurred.

Plaintiffs' principal attack on Dr. MacDonald's testimony rested on their characterization of testimony from another PSAC member, Dr. Melvin Calvin, one of the individuals Dr. MacDonald identified as taking part in the discussions, as refuting the testimony of MacDonald. However, Dr. Calvin merely testified to a lack of recollection about these matters. See, *e.g.*, 2/4/2005 Caley Decl., Ex. 1 (Calvin Tr.) at 90, 92-93, 98, 101, 118, 128-31 (A2582q-82z). Indeed, Special Master Sol Schreiber had Dr. Calvin clarify his testimony:

> Let me ask you, Doctor, to clarify the record. Is it your testimony that you never discussed herbicides with PSAC members to the best of your recollection or you don't remember ever discussing it?
>
> THE WITNESS: I don't remember.

Id. at 147. In short, Dr. Calvin's testimony does not contradict that of Dr. MacDonald.

on civilian uses and was not motivated by the military use of herbicides, pointed out the absence of information regarding long-term effects of pesticide use on humans, animals, and the environment. 10/27/2004 Krohley Aff., Ex. 34 at 4, 9 (A449, A451). The report cautioned that, while the acute toxic effects of the chemicals were well-known, the government should implement studies "to insure that continued exposures to small amounts of these chemicals in our environment will not be harmful over long periods of time." 10/27/2004 Krohley Aff., Ex. 34 at 2 (Introduction) (A448). On May 15, 1963, President Kennedy ordered government agencies to implement PSAC's recommendations as to domestic pesticide and herbicide use. 10/27/2004 Krohley Aff., Ex. 34 at iii (A445).

The PSAC report became the impetus for a government study conducted from 1963 through 1969 by the Bionetics Research Laboratories. This study, which first became available to the manufacturers when it was made public in 1969, provided the first suggestion of potential long-term dangers associated with exposure to 2,4,5-T in test animals exposed to large quantities of that compound: It reported teratogenicity (causation of birth defects) in test animals exposed to

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(… cont'd)

[13] In this context, the term "pesticides" includes herbicides. See 10/27/2004 Krohley Aff., Ex. 34 at 4-5 (A449).

large doses of the compound. 1983 Dow Summary Judgment Br., Ex. 148 (A129-279).

The National Cancer Institute ("NCI") contracted with Bionetics Research Laboratories for a study of possible carcinogenic, teratogenic, and mutagenic effects of a number of widely used compounds, including 2,4,5-T. 1983 Dow Summary Judgment Br., Ex. 149 (A1500-25). By 1963, NCI knew of the presence of dioxin in 2,4,5-T and its association with chloracne and liver toxicity. 1983 Dow Summary Judgment Br., Exs. 149-50 (A1500-25).[14] The Bionetics Study was an unprecedented departure from previous studies of pesticides in that it investigated the possible ***long-term*** effects of exposure. *Ibid.*[15]

Early results of the Bionetics study suggested the possibility of birth defects in animals that had been exposed to massive doses of 2,4,5-T, and those results

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[14] 2,4,5-T was included in the Bionetics Study not because of industrial health problems in its manufacture, the known dioxin contaminant, or its use in Vietnam, but "[b]ecause of [its] considerable widespread use, predominantly." Baker Tr. 55 (A1509). See also *id.* at 56-57 (A1510-11); Fishbein Tr. 48, 158 (A1668d-68e).

[15] Dr. Kenneth M. Endicott, Director of NCI, announced that the Bionetics Study was prompted by PSAC's recommendation that studies on "[c]hronic effects on organs of both immature and adult animals" should be carried out. 10/27/2004 Krohley Aff., Ex. 34 at 21 (A457). That recommendation demonstrates that when the military reported its evaluation of the toxicity of 2,4,-D, 2,4,5-T, and Agent Purple to PSAC in May 1963, PSAC was well aware of the absence of any studies — by government or industry — of the long-term effects of chemicals such as 2,4,5-T.

were disseminated within the government (but not to the manufacturers) well before the study's official release in the late fall of 1969. Dr. Jessie Steinfeld, Surgeon General of the United States, later testified before a Senate Subcommittee that the first indication of teratogenic effects of 2,4,5-T in test animals had emerged in June, 1966. 10/27/2004 Krohley Aff., Ex. 36 at 178 (A466). Dr. Diane Courtney, who headed the teratogenicity portion of the Bionetics Study (Courtney Tr. 20-21 (A1572-73)), briefed Dr. Steinfeld on the initial results of the study immediately prior to Steinfeld's testimony before the Subcommittee. *Id.* at 110, 117-19 (A1587-90). Dr. Courtney testified at her own deposition in July, 1982 that although she could no longer remember precisely when the first indications of teratogenicity appeared, 2,4,5-T gave some indication of teratogenic effects "certainly" by September, 1966. *Id.* at 66 (A1579).

Senior NCI personnel, including Dr. Richard Bates, the NCI Project Officer on the Bionetics study, reviewed interim progress reports. 10/27/2004 Krohley Aff., Ex. 62 (A499-592); Courtney Tr. 46-47 (A1574-75); Bates Tr. 50 (A1525*l*). Both Dr. Courtney and Dr. Bates testified that progress reports informed NCI of indications that 2,4,5-T might be teratogenic. Bates Tr. 15-17, 64-67 (A1525a-25c, A1525m-25p); 1983 Dow Summary Judgment Br., Exs. 151-52 (A279a-282); Courtney Tr. 69-70 (A1580-81). Dr. Courtney discussed her teratology work on a routine basis with Dr. Arthur Pallotta, her supervisor at NCI, and Dr. Pallotta met

regularly with representatives of NCI to discuss the study. Courtney Tr. 72, 77-78 (A1582, A1584-85).

In September, 1968, Bionetics delivered the completed study, which included the finding of teratogenicity in lab animals, to NCI. 10/27/2004 Krohley Aff., Ex. 36 at 179 (A466). The results were quickly disseminated throughout the government, including the Department of Defense and the President's Office of Science and Technology. In October, 1968, the study was provided to Dr. Garth Fitzhugh, a toxicologist at the FDA. *Ibid.*; Fitzhugh Tr. 79 (A1632). In February, 1969, the results were also made known to Dr. Minarik and others at Fort Detrick and to other representatives of government agencies, including the Department of Defense. Bates Tr. 27-34, 85-86, 114-15 (A1525d-25k, A1525q-25r); Minarik Tr. 136-43 (A1871-78); 1983 Dow Summary Judgment Br., Ex. 154 (A295-300). Minarik also discussed the Bionetics findings at a February 19, 1969 meeting of the Federal Committee on Pest Control that was attended by representatives of the Department of Defense. 1983 Dow Summary Judgment Br., Ex. 155 (A301-11). According to Dr. Steinfeld, extensive analyses of the Bionetics data continued throughout most of 1969. 10/27/2004 Krohley Aff., Ex. 36 at 179 (A466). The Bionetics study was made public in October, 1969.

5. The Air Force's Environmental Health Laboratory Performed Independent Studies Concerning 2,4,5-T During the Relevant Time Frame.

Prior to 1965, the Air Force's Environmental Health Laboratory also studied the effects of 2,4,5-T. Melvin Tr. 24-26, 30, 101-102 (A1849-51, A1854, A1859-60). The studies included evaluation of the effects of herbicides "on air bases [and] personnel living or working on those bases, people in nearby areas." *Id.* at 30 (A1854). The Environmental Health Laboratory was part of the Air Force Logistics Command (*id.* at 21 (A1848)), the same Air Force Command that was responsible for the inventory management of herbicides, including Agent Orange. Shead Tr. 11-14 (A1919-22). That laboratory also bore "worldwide" responsibility for the evaluation and study of environmental problems for the entire Air Force. Melvin Tr. 21, 29 (A1848, A1853).

The Air Force's study was led by Dr. Walter W. Melvin, Jr. Prior to the study, Dr. Melvin knew that dioxin was a byproduct of the 2,4,5-T manufacturing process and that it was associated with the development of chloracne in plant workers. *Id.* at 32-33, 102 (A1855-56, A1860). He was familiar with the accident at Nitro, West Virginia, having learned about it in the mid-1950s as a graduate student at the University of Cincinnati, when Dr. Donald Birmingham of the U.S. Public Health Service Facility in Cincinnati lectured on the subject in Melvin's class on occupational dermatology. *Id*. at 12-13 (A1844-45).

6. The Army and Navy Had Additional Knowledge.

In the summer of 1966, the Office of the Army Surgeon General requested toxicity information on 2,4,5-T from the National Academy of Sciences ("NAS"), an independent organization chartered by Congress and funded by the federal government. 10/27/2004 Krohley Aff., Ex. 56 (A2509). The Navy's Bureau of Medicine and Surgery also requested such information from NAS at the same time. *Ibid*.

By letters dated July 26, 1966, and August 31, 1966, NAS responded to the Navy and Army inquiries, respectively. 10/27/2004 Krohley Aff., Exs. 57, 58 (A118-23, A2509b-09d). Both of these letters stated that 2,4,5-T was toxic if ingested orally and warned of possible chloracne problems. *Ibid*. The letter to the Navy also stated that "[p]orphyria and chloracne have been clinically associated with related compounds as described in the enclosed article by Bleiberg." *Id.*, Ex. 57 at 3 (A120). The Bleiberg article, *Industrially Acquired Porphyria*, 09 ARCH. DERM. 793-91 (June 1964), discussed cases of porphyria and chloracne in Diamond's 2,4,5-T manufacturing plant. 10/27/2004 Krohley Aff., Ex. 43 (A2441-42).

The Government's Reaction to the Threat of Defoliant Shortages

1. The Defense Production Act and DO-Rated Orders

By the mid-1960s, the military's increasing need for large amounts of Agent Orange, which the chemical companies were unable to satisfy because of limited manufacturing capacity, became a matter of concern at the highest levels. Major General Allen T. Stanwix-Hay, Assistant Secretary of Defense for Installation and Logistics, briefed the Secretary of Defense daily on materiel requirements, including herbicide needs. Stanwix-Hay Tr. 24-25, 35-48, 52-54, 92-94 (A1983-2004). According to General Stanwix-Hay, this high level of review was consistent with the importance placed on the defoliant component of the government's munitions arsenal for Southeast Asia and its significance to the war effort, as confirmed at a meeting with General Westmoreland and his staff. *Ibid.*

One response to the looming shortfall was the invocation of the government's extraordinary powers under the Defense Production Act of 1950 ("DPA"), Pub. L. No. 81-774, 64 Stat. 798 (codified at 50 U.S.C. § 2061 *et seq*.). The Act granted the President extensive powers to compel production of war materiel by "requir[ing] acceptance and performance of such contracts or orders *** by any person he finds to be capable of their performance." 50 U.S.C. § 2071(a). The President delegated the bulk of his authority under the Act to the Secretary of Commerce (Exec. Order No. 10161, 15 Fed. Reg. 6105 (Sept. 9,

1950)); the Business and Defense Services Administration ("BDSA") exercised these powers from 1953 through 1970. 18 Fed. Reg. 6503 (Oct. 10, 1953); Dept. Org. Order 40-1A (Sept. 15, 1970).

BDSA Regulation 2 established a system of "rated orders." 32A C.F.R. Ch. VI § 10 (BDSA 1967) (11/10/2003 Defs.' Supp. Br. in Opp. to Remand, Ex. 10). The regulation required that "[e]very order bearing a rating must be accepted and filled regardless of existing contracts and orders except as provided in this section." Section 16 provided: "Every person shall comply with each mandatory order and directive issued to him by [BDSA]." Section 27 made violations of BDSA Regulation 2 a crime punishable by fine or imprisonment. 11/10/2003 Defs.' Supp. Br. in Opp. to Remand, Ex. 10 at 90 (A910) (§ 27).

When a shortage of Agent Orange developed in 1966 despite the use of rated orders, the government initiated even stronger measures to meet anticipated military requirements for Agent Orange, shifting procurement to an "emergency basis." See 11/10/2003 Defs.' Supp. Br. in Opp. to Remand, Ex. 12 (12/12/1991 Gordon Aff.) at Exs. B, F (A377-80); 10/27/2004 Krohley Aff., Ex. 3 at 133 (A2205). The impetus for this shift came directly from military commanders in Vietnam. As Judge Weinstein wrote:

> In December 1966, the Military Assistance Command, Vietnam ("MACV") advised the Commander-In-Chief, Pacific ("CINCPAC") that the United States' projected shortage of Agent Orange was of immediate operational concern to MACV, that the value of herbicide

> operations in Vietnam had been proved, and that a failure to obtain needed supplies would cause an unacceptable impact on military operations. MACV accordingly requested that the United States investigate the possibility of plant expansion or diversion of product from commercial uses to bolster supplies.

Isaacson, 304 F. Supp. 2d at 425; see also 11/10/2003 Defs.' Supp. Br. in Opp. to Remand, Ex. 12 (12/12/1991 Gordon Aff.) ¶ 13 and Ex. F (to Gordon Aff.) (A920, A379-80).

On March 29, 1967, Farris Bryant, the Director of the Office of Emergency Planning of the Executive Office of the President, wrote Secretary of Defense Robert McNamara:

> In accordance with your request, the Administrator, Business and Defense Services Administration, is currently instituting procedures to insure that the entire output of the chemical 2,4,5-T, which is the limiting component in the production of "Orange," will be used on military orders.

11/10/2003 Defs.' Supp. Br. in Opp. to Remand, Ex. 16 at 1 (A965).

By letter dated March 24, 1967, the BDSA directed defendants "to accelerate the delivery of your existing DO rated orders for the defoliant 'Orange.'" 10/27/2004 Krohley Aff., Ex. 65 (A2571). The letter further stated: "This action is taken pursuant to Section 101 of the Defense Production Act of 1950, as amended." *Ibid*. The BDSA directive to Dow, for example, noted that Dow's "capacity for the production of 'Orange'" was 93,000 gallons per month as of April 3, 1967, and ordered Dow to deliver that entire capacity to the military.

Ibid. On March 29, 1967, Dow notified sales personnel and customers nationwide that no commercial 2,4,5-T herbicides would be available "for at least the balance of 1967" due to "military direct orders for the entire United States 2,4,5-T capacity." 1/22/2004 Defs.' Supp. Reply Br. in Opp. to Remand, Ex. 4 (A1326). See also 2/4/2005 Gordon Aff., Ex. 14.

A Commerce Department official informed Edwin Upton of Thompson-Hayward of the exceptional nature of this action: "this was the first time the entire production of a chemical had been taken by the military. The matter was discussed and resolved finally by an executive order of the White House." 1/22/2004 Defs.' Supp. Reply Br. in Opp. to Remand, Ex. 3 at 3 (A1325). The government told Upton that his company "would be required by law to divert [its] entire production *** to the military," and that "Lt. Col. Hinson would negotiate a contract with Thompson-Hayward." *Ibid*.

In the case of Diamond, the government interceded to help it expand its Newark plant:

> In February 1967, the Department of Commerce provided Diamond a "DO-D4" priority rating to obtain equipment and material needed for the Newark Plant expansion. *** Representatives of the Defense General Supply Center actively interceded on behalf of Diamond to assist in obtaining equipment needed for the Plant expansion.
>
> In April 1967, the Department of Commerce telephoned the Operations Manager of Diamond's Agricultural Chemicals Division, to relay "serious concern about the delay in starting up the converted D facilities to produce T Acid." In May 1967, the BDSA assured

> Diamond that it would assist in obtaining any 2,4-D needed by Diamond while awaiting installation of its new 2,4-D equipment. The BDSA also directed that if Diamond completed its Plant expansion earlier than anticipated, and therefore achieved higher rates of 2,4,5-T production, all of it must be formulated into 'Orange' and shipped to the Department of Defense pursuant to Section 101 of the Defense Production Act.

Isaacson, 304 F. Supp. 2d at 425-26; see also 11/10/2003 Gordon Aff., Exs. 14, 23-24 (A381, A973a-75).

2. The Government's Proposed Plant at Weldon Spring.

Another result of the government's alarm over potential defoliant shortages was its decision in 1966 to plan for the construction of a government-operated herbicide manufacturing facility at an Atomic Energy Commission plant in Weldon Spring, Missouri. Eckhaus Tr. 67 (A1636). Although the project was ultimately cancelled, during the planning stages the government — including Edgewood Arsenal representatives — acquired even more knowledge regarding techniques used to manufacture 2,4,5-T and the problems of dioxin contamination and chloracne.

Robert Cox, Section Chief for Production Engineering at Edgewood and one of the first to be involved in the project, testified that in "December of 1966 we received instructions to try to find out how Agent Orange was made because the Army had somewhat committed itself to produce it in its own plants." Cox Tr. 45 (A1595). Within weeks, Cox visited Monsanto's Nitro, West Virginia plant and

learned of the chloracne problem. *Id.* at 70-71 (A1597-98). And Mark Jefferies, an Army Chemical Engineer assigned to Edgewood Arsenal's Weapons Development and Engineering Lab, circulated a memo dated February 20, 1968 to the "Edgewood Arsenal Staff at WSCP" (Weldon Spring Chemical Plant) specifically addressed to the subject of dioxin in order "to supply you with as much information about the stated subject as possible." 10/27/2004 Krohley Aff., Ex. 55 (A491). The memo diagrams 2,3,7,8-TCDD, explains how and where dioxin is formed in the 2,4,5-T manufacturing process, and discusses its potential toxicity. Sigmund Eckhaus of Edgewood was also told, during a visit to Diamond's Newark plant, of that manufacturer's problems with chloracne, a condition with which he was already "familiar." Eckhaus Tr. 177-78 (A1647a-47b).

The chemical manufacturers also provided the government with extensive information during the project regarding 2,4,5-T. For example, in an April 26, 1967 letter to H.G. Fredericks, Deputy Director of Procurement and Production at Edgewood Arsenal, Dow discussed the chloracne hazard; "methods to detect" dioxin content; and a process that had been developed by C.H. Boehringer, a German chemical company, to reduce dioxin levels. Dow offered to consider making this "knowhow" available for the government's use (1/21/2004 Krohley Supp. Aff., Ex. B (A1194-1203)), but the government expressed no interest in Dow's proposal.

In a set of letters to several government officials, all dated September 26, 1967, Dow stated its reasons for not bidding on the project, including that:

> The Chlor-Acne problem associated with the manufacture of Trichlorophenol could not be solved without first receiving permission from a European Chemical Manufacturer.
>
> The Chlor-Acne problem is one of Human Health which Dow has had to combat in the design of its own plants at its Midland operations.

10/27/2004 Krohley Aff., Ex. 45 at 2 (A2444); *id.*, Ex. 46 at 2 (A2446); *id.*, Ex. 47 at 2 (A2449). (The same language appears in each letter.)[16]

Ultimately, the Stearns-Roger Corporation joined with Thompson Chemical Company to form a joint venture, known as T-S-R, to develop the Weldon Spring facility. 10/27/2004 Krohley Aff., Exs. 49-50 (A1384-1401, A2449a-49g). Stearns-Roger files provide further evidence of the extensive knowledge of dioxin among military personnel working on the project. An Engineering Status Report includes the following recommendations under the heading "Health Considerations":

> 1. In the production of TCP, a compound known as dioxen [*sic*] is formed, which causes Chloracne. The formation of the dioxen [*sic*] is

[16] Dow had previously informed Edgewood by letter dated April 20, 1967, in response to an earlier solicitation, that a "serious potential health hazard to production workers is involved in the production of 2,4,5-T." 10/27/2004 Krohley Aff., Ex. 48 at 3 (A485).

> generally controlled by the temperature of the TCP reaction in the autoclave. Montrochem's experience indicates that dioxen [*sic*] is not formed if the temperature is held below 160°C. However, John Angel has experienced the operators contracting Chloracne even though the 160°C temperature conditions were maintained.
>
> 2. Montrochem recommended that T-S-R contact the C. H. Boeringer [*sic*] Company of Ingelhein, Germany, for advice in the control of the dioxen [*sic*]. This company has developed a gas chromatograph test procedure for the finding of dioxen [*sic*] in the process streams.

10/27/2004 Krohley Aff., Ex. 49 at 15 (A1399). There is no evidence that the military ever followed up on this recommendation.

Another document, entitled "2,4,5-Trichlorophenol (TCP) Process," states:

> The autoclave reaction temperature is important since it affects the formation of 2,3,7,8 tetrachlorodibenzo-p-dioxin (hereinafter called dioxin). This dioxin is the main cause of chloracne, liver damage, etc., as has been experienced at most manufacturers of TCP (See accompanying "Safety Problems in the Manufacture of 2,4,5-Trichlorphenol"). Dioxin has been found to kill rabbits by feeding them .00005 gms/kg of body weight.

10/27/2004 Krohley Aff., Ex. 51 at 2 (A2451).[17]

The Edgewood Arsenal chemical officers responsible for the Weldon Spring plant understood that dioxin could be expected to be present in varying amounts at

[17] The document entitled "Safety Problems in the Manufacture of 2,4,5-Trichlorophenol" chronicled incidents of chloracne experienced by various trichlorophenol manufacturers. 10/27/2004 Krohley Aff., Ex. 52 (A2454-55).

every point in the process.[18] As General Hebbeler's testimony that Dow's warnings about dioxin "wouldn't trigger a great concern" makes clear, however, the government decided that dioxin was relevant only to the safety of production workers. Hebbeler Tr. 89 (A1703).

Termination of the Defoliation Campaign

Plaintiffs contend that the government learned in 1969, from Dow, that Agent Orange contained dioxin and that "[a]fter the Government found out about the dioxin contamination, it stopped purchasing Agent Orange and burned the remaining stock at sea" out of concern for the health of those exposed to the herbicide. Anderson Br. 2. That confabulation lacks foundation in the record. To the contrary: as we have shown, the government had known at least since the Hoffmann Trip Report in ***1959*** that 2,4,5-T contained dioxin, it knew far more than defendants did about the associated risks, and it had determined that Agent Orange

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[18] Plaintiffs attempt to minimize the significance of the knowledge of the three Edgewood Arsenal personnel assigned to the Weldon Spring project that dioxin could be formed in the 2,4,5-T production process. Plaintiffs erroneously imply that Bushey, Cox and Jefferies were personnel of the Army Corps of Engineers: "[T]he three Weldon Spring engineers in Denver didn't even disclose their knowledge to their own superiors in the Army Corps of Engineers, much less to the officials in charge of the crops division who selected Agent Orange." Stephenson Br. 53. In fact, they were Edgewood personnel. Not only that, but, as Cox testified, they were stationed at Edgewood and met with Stearns-Roger personnel both at Edgewood and in Denver. 2/4/2005 Caley Decl., Ex. 2 (Cox. Tr.) at 38, 45, 68 (A1594-96).

was safe. The government curtailed the program when it ***released to the public*** the results of the Bionetics study. Unlike the manufacturers — which received this information at the same time as the general public — the government possessed Bionetics' preliminary findings for several years before the final results were released. Thus, the district court clearly was correct that the termination of the herbicide program was based on information "available only to the government." *Isaacson*, 304 F. Supp. 2d at 429.

The government released the final results of the Bionetics study to the public on October 29, 1969. The announcement stated that "off-spring of mice and rats given relatively large oral doses of the herbicide during the early stages of pregnancy showed a higher than expected number of deformities," but emphasized that "it seems improbable that any person could receive harmful amounts of this chemical from any of the existing uses of 2,4,5-T," including the use of Agent Orange in Vietnam. Nevertheless, the government announced that the Department of Defense would henceforth limit Agent Orange use to "areas remote from population." 10/27/2004 Krohley Aff., Ex. 63 at 1-2 (A2509h-09i).

The Bionetics study, an animal study which its authors recognized could not be extrapolated to humans, was the first indication of long-term or latent health effects associated with exposure to 2,4,5-T. Plaintiffs do not claim that the manufacturers received that information before the general public. The

government, by contrast, had been receiving preliminary results from Bionetics indicating teratogenicity at least since 1966 and held the final report for 13 months before releasing it.

Dr. John Foster, then Director of the Defense Directorate of Research and Engineering, advised Secretary of Defense Laird in April 1970 that the continued use of herbicides such as Agent Orange could cause adverse public reaction. 10/27/2004 Krohley Aff., Ex. 3 at 166 (A2222). Foster recommended that the use of Agent Orange be suspended pending further evaluation. *Ibid.* The Secretary of Defense accepted Foster's recommendation, and the use of Agent Orange was suspended on April 15, 1970. *Ibid.* The military protested strongly. Kissinger Tr. 32-33 (A1792-93); Westmoreland Tr. 98-100 (A2099-2101).

The temporary ban on the use of Agent Orange in Vietnam was ultimately made permanent in December 1970, again over the objections of the Joint Chiefs of Staff. 10/27/2004 Krohley Aff., Ex. 3 at 167, 173-75 (A2222, A2225-26). This decision by the Nixon administration was strongly motivated by political considerations; the administration weighed the military's views as to the importance of defoliation to save American lives in Vietnam against what it perceived as countervailing matters of domestic and international policy. *Id.* at 157-75 (A2217-26). At his deposition, Dr. Foster reiterated that the use of Agent Orange was terminated "because of political concerns that were arising." Foster

Tr. 77-78 (A1676-77). And Dr. Henry Kissinger, who was National Security Advisor at the time, later stated the obvious when he testified that, with respect to the defoliation program:

> [T]he Military certainly felt strongly about the fact that there was a military benefit. We had to weigh it against the overall foreign and domestic policy we were considering, and so we decided to overrule the Military without necessarily questioning their military judgment.

Kissinger Tr. 33 (A1793).

SUMMARY OF ARGUMENT

I.

A. Continuing a saga that began a quarter of a century ago, the Agent Orange litigation has returned once more to this Court. On this appeal, the Court has occasion for the third time to address the question whether there are triable issues regarding the application of the government contractor defense to claims of injury from exposure to Agent Orange during the Vietnam War. Twice before, on records virtually identical to that in the present round of cases, the district court has found the defense applicable and this Court has endorsed that conclusion, calling the defense an "impossible hurdle" and a "serious obstacle[]" to recovery. There is no basis to change that view now.

B. As delineated by the Supreme Court, the government contractor defense bars state tort suits against government contractors for products (1) made pursuant to reasonably precise specifications that were approved by the government, (2) that

complied with those specifications, and (3) as to which the contractor warned the government of dangers known to the contractor but not to the government.

1. The defendant manufacturers in this case produced defoliants for the military pursuant to contracts that precisely specified both particular chemical herbicides (2,4-D and 2,4,5-T) and the exact mixtures (Agent Orange, Agent Purple, etc.) in which the military wanted them. Contrary to plaintiffs' principal assertion, the availability of the government contractor defense is not defeated by the claim that there was no specification pertaining to dioxin. There would of course have been no affirmative specification for dioxin, since the substance was a minute contaminant that did not contribute to the effectiveness of the herbicide. But the government, knowing that dioxin was a byproduct of existing techniques used by the contractors for manufacturing the herbicide 2,4,5-T, nevertheless specified that particular herbicide as a major component of Agent Orange, chose not to impose any limit on dioxin levels, and continued to reorder and use Agent Orange throughout the 1960s.

The record makes clear that the military need for the defoliants was pressing and the perceived toxicity risks for those exposed to trace amounts of dioxin were minimal. Based on its own thorough toxicological evaluation of the safety of Agent Orange, which it knew contained 2,4,5-T and thus some level of dioxin, the military proceeded to use it in Vietnam in unprecedented concentrations.

Moreover, though it was aware of both the dioxin contamination and the availability of manufacturing techniques that would reduce dioxin levels, the government did not at any point adopt specifications that would have limited allowable dioxin levels. General James A. Hebbeler, who was heavily involved in the Weldon Spring project, in which the government planned to manufacture Agent Orange itself, testified that the presence of dioxin in herbicides "wouldn't trigger a great concern *** [because] [t]his is a production problem." Hebbeler Tr. 89 (A1703).

Plaintiffs ask this Court to adopt a wholly unprecedented rule that the government contractor defense is unavailable where the contract is silent as to the alleged defect (here, the presence of trace amounts of dioxin) — ***even where the government specifically considered that feature of the product and determined that the product was nevertheless safe for its intended use.*** Such a rule would substantially narrow the defense, because it is rare that the government will enumerate in the contract every precaution that it has considered and decided to forego. As a result, "[c]osts of procurement would escalate ***. Contractors would find insurance difficult or impossible to procure, and bankruptcies might occur among companies supplying products essential to national security. Firms would take steps to avoid entering into government contracts ***." *In re "Agent Orange" Prod. Liab. Litig.*, 818 F.2d at 191. In sum, the contracting process

would become longer, more expensive, and far riskier for the contractor — precisely the outcome that the government contractor defense is intended to prevent.

2. The uncontroverted evidence demonstrates, and the plaintiffs largely concede, that the Agent Orange produced by the defendants fully complied with the government's specifications.

3. Finally, as to the manufacturers' warning obligation under the third prong of the *Boyle* test, the record shows that there were no material dangers known to the manufacturers but not to the United States. There were certain known — but, to the government, irrelevant — health hazards to Agent Orange production workers, primarily chloracne; warnings about these hazards were in fact conveyed to the government, which was already aware of them but persisted in an unaltered course of purchase and use of Agent Orange. (Significantly, none of the plaintiffs claims injury of the sort that was known to be associated with the production of 2,4,5-T at the time it was being produced and used, and indeed plaintiffs have not offered proof that a single case of chloracne was reported during the war among those exposed to Agent Orange in Vietnam.)

Plaintiffs have mustered no evidence that would allow a jury to find that, at the time the government was ordering and reordering Agent Orange, the manufacturers knew of ***any*** potential hazards that were not already known to the

United States. Indeed, as this Court has held, there was no evidence even decades after the war had ended that the alleged hazards are anything but speculative. The defendants could not have told the government that which was unknowable even decades later.

It is also clear that the government possessed far more information about any hazards associated with Agent Orange than did defendants. It was the government that knew of the Hoffmann trip report's account of the apparent dangers of dioxin and of the early results of the Bionetics Study. It was government personnel at Edgewood Arsenal who conducted the toxicity studies of herbicides as they were to be applied in Vietnam, passing their findings and conclusions along to the President's Science Advisory Committee. None of these were disclosed to the manufacturers.

II.

The global class action settlement in 1984 purported to foreclose any future litigation by class members based on their exposure to Agent Orange in Vietnam. This Court nevertheless held in 2001 that veterans who became ill after 1994 had not been adequately represented in the original class action and could not be bound by the settlement. The Supreme Court affirmed by an equally divided Court. Defendants maintain that the decision allowing further litigation of veterans' Agent

Orange claims was erroneous and reserve the right to pursue the issue before this Court en banc or the Supreme Court.

ARGUMENT

In *Boyle* v. *United Technologies Corp.*, 487 U.S. 500 (1988), the Supreme Court recognized the government contractor defense, under which contractors are not liable under state tort law for injuries arising from products manufactured for the government according to its specifications. The defense protects from liability contractors who have implemented discretionary government decisions to take risks that state law may condemn in the consumer sphere. The defense thereby prevents plaintiffs from circumventing the discretionary function exception of the Federal Tort Claims Act by suing contractors for acts as to which the government is immune from suit. Because contractors would pass expected liability costs back to the government through higher prices — or, worse, simply refuse to manufacture products that might subject them to liability — suits against contractors for government decisions would undermine that exception. See *id.* at 511-12.

This Court has emphasized the importance of the government contractor defense in this very context, observing that because the government has immunity, "[t]he military contractor thus faces the great exposure of being the sole 'deep pocket' available. The chemical companies found it prudent to pay $180 million

[in the *Agent Orange* settlement] notwithstanding the weakness of the plaintiffs' case." *In re "Agent Orange" Prod. Liab. Litig.*, 818 F.2d at 191-92. If contractors pass these sorts of costs on to the government — as they inevitably will — such suits will wholly "frustrate[] the objective of the discretionary function exception." *Grispo* v. *Eagle-Picher Indus., Inc.*, 897 F.2d 626, 628-29 (2d Cir. 1990).

Boyle requires contractors to satisfy three requirements:

> Liability for design defects in military equipment cannot be imposed, pursuant to state law, when (1) the United States approved reasonably precise specifications; (2) the equipment conformed to those specifications; and (3) the supplier warned the United States about the dangers in the use of the equipment that were known to the supplier but not to the United States.

Boyle, 487 U.S. at 512. The Court went on to explain the rationale for this test:

> The first two of these conditions assure that the suit is within the area where the policy of the "discretionary function" would be frustrated — *i.e.*, they assure that the design feature in question was ***considered by a Government officer***, and not merely by the contractor itself. The third condition is necessary because, in its absence, the displacement of state tort law would create some incentive for the manufacturer to withhold knowledge of risks, since conveying that knowledge might disrupt the contract but withholding it would produce no liability.

Ibid. (emphasis added).

The concerns that drove *Boyle* are unmistakably implicated in this case. As this Court has observed, it is particularly imperative that the government retain discretion in decisions relating to military equipment and weaponry. See *Grispo*,

897 F.2d at 628 (2d Cir. 1990). It is in the military context that the balance between government discretion and the interests underlying consumer product liability law tilts most strongly in favor of protecting governmental discretion. Thus, the Eleventh Circuit, ruling on a peacetime military design defect claim, explained the broad application of the *Boyle* rule:

> The pilots and crews of military aircraft willingly embrace the risks that they assume by volunteering to serve our country. They are not the "military doubles of civilian motorists," *Tozer*, 792 F.2d at 407, or ordinary purchasers of consumer products. The Supreme Court's adoption of the government contractor defense recognizes that one of these risks is the operation of equipment in which safety concerns have been balanced against cost and performance. With respect to consumer goods, state tort law may hold manufacturers liable where such a balance is found unreasonable. In the sensitive area of federal military procurement, however, the balance is not one for state tort law to strike. Although the defense may sometimes seem harsh in its operation, ***it is a necessary consequence of the incompatibility of modern products liability law and the exigencies of national defense***.

Harduvel v. *Gen. Dynamics Corp.*, 878 F.2d 1311, 1322 (11th Cir. 1989) (emphasis added). That is why the *Boyle* Court "considered the Government's selection of design of military equipment a paradigmatic policy decision that the discretionary function exception shields from the type of judicial 'second-guessing' which would come from the ordinary operation of state tort law." *Grispo*, 897 F.2d at 628.

The government, which had the power to draft young men and subject them to combat in Vietnam, also had the discretion to use Agent Orange to combat the

extreme, immediate risks posed to allied troops by Vietnam's dangerous terrain, notwithstanding any purely speculative adverse health effects. This decision involved precisely the type of contextual policy judgment that the discretionary function exception protects. See *In re "Agent Orange Prod. Liab. Litig.*, 818 F.2d at 174 ("the military contractor defense shields defendant contractors from liability where the hazard is wholly speculative"). The facts outlined above demonstrate beyond question that the decision to use Agent Orange "involve[d] not merely engineering analysis but judgment as to the balancing of many technical, military, and even social considerations, including specifically the trade-off between greater safety and greater combat effectiveness," a process that is insulated from judicial "second-guessing." *Boyle*, 487 U.S. at 511. As this Court has written:

> Agent Orange was a product whose use required a balancing of the risk to friendly personnel against potential military advantage. That balance was the ***exclusive responsibility*** of military professionals and their civilian superiors. The responsibility of the chemical companies was solely to advise the government of hazards known to them of which the government was unaware so that the balance of risk against advantage was informed.

818 F.2d at 192 (emphasis added). In this case, "[t]he United States armed forces accepted the dangers it was aware of because, from a military point of view, the benefits in potential savings of the lives of members of our armed forces and those of our allies outweighed the possible risks." *Isaacson*, 304 F. Supp. 2d at 430.

That decision is the paradigm of government discretion and may not be second-guessed by a court.

STANDARD OF REVIEW

"Summary judgment is appropriate when after viewing all the facts in the record in a light most favorable to the non-moving party, there is no genuine issue of material fact present, so that 'the moving party is entitled to judgment as a matter of law.'" *Forsyth* v. *Fed'n Employment & Guidance Serv.*, 409 F.3d 565 (2d Cir. 2005) (quoting FED. R. CIV. P. 56(c)). A district court's grant of summary judgment is reviewed *de novo*. *Sherman* v. *Mamaroneck Union Free Sch. Dist.*, 340 F.3d 87, 92 (2d Cir. 2003).

This Court has already noted, in another product liability class action managed by Judge Weinstein, the propriety of summary judgment in mass tort litigation. See *In re Brooklyn Navy Yard Asbestos Litig.*, 971 F.2d 831, 840 (2d Cir. 1992) ("We are mindful, moreover, of the difficulties faced by a trial court in managing a complex, multi-plaintiff, multi-defendant mass tort litigation. While the corresponding desirability of streamlining litigation cannot justify dismissing valid claims, it does suggest the particular appropriateness of taking advantage of

the summary judgment mechanism to dispose of claims that, although adequately pleaded, must fail as a matter of law.").[19]

I. SUMMARY JUDGMENT WAS PROPERLY GRANTED ON THE BASIS OF THE GOVERNMENT CONTRACTOR DEFENSE

A, The Applicability of the Government Contractor Defense to Agent Orange Has Been Repeatedly Upheld by This and Other Courts.

The federal courts have been consistent in upholding application of the government contractor defense to Agent Orange contractors. This Court has twice held, on essentially the same MDL-381 record as is presented today, that the present defendants are entitled to summary judgment on the basis of the government contractor defense. In 1987, it upheld the grant of summary judgment

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[19] In his discussion of the standard of review, plaintiff Stephenson cites two Supreme Court cases in a misleading manner. First, he states that "even in *** *Boyle*, the Supreme Court still did not deny plaintiffs the right to trial by jury." Stephenson Br. 9. What this statement conveniently ignores is that the jury trial had already occurred before the case reached the Supreme Court; the Court did, however, say that if the Fourth Circuit reversed the jury verdict because no reasonable jury could have failed to find the government contractor defense proven — the same inquiry as on summary judgment — the ruling would be sound. 487 U.S. at 503, 514. Second, and even more mystifyingly, Stephenson cites *Matsushita Elec. Indus. Co.* v. *Zenith Radio Corp.*, 475 U.S. 574, 587-88 (1986), for the proposition that "*Boyle* is a fact-intensive inquiry not susceptible to summary judgment." Stephenson Br. 9. *Matsushita*, an antitrust case decided two years before *Boyle*, ***upheld*** summary judgment for defendants on a similarly prodigious record, explaining that "if the factual context renders respondents' claim implausible *** respondents must come forward with more persuasive evidence to support their claim than would otherwise be necessary." 475 U.S. at 587.

against veteran plaintiffs — identically situated to the plaintiffs in these cases — who had opted out of the 1984 settlement. See *In re "Agent Orange" Prod. Liab. Litig.*, 818 F.2d at 194. And in 1993, in another suit brought by absent class members, this Court reaffirmed the fairness of the settlement, in part based on the probable applicability of the government contractor defense. See *Ivy*, 996 F.2d 1425. The Fifth Circuit has likewise ruled against civilian plaintiffs alleging the same injuries from Agent Orange. *Miller*, 275 F.3d at 419.[20] The Federal Circuit too has stated unconditionally that the defense is available to Agent Orange manufacturers. *Hercules*, 24 F.3d at 198.

1. In 1984, after massive discovery that thoroughly developed all pertinent facts, the district court approved a global class settlement that purported to cover all present or future Agent Orange claims of veterans and their spouses, parents,

[20] Because the government contractor defense would deny recovery against the defendants for their production of military defoliants on the basis of any legal theory, this Court should also deny plaintiffs' request to prolong this litigation further by amending their complaint to add unspecified new claims. Stephenson Br. 56. This Court should also deny their request to impose additional costs on defendants by conducting yet more discovery, also unspecified. Isaacson Br. 51-55. The record from MDL-381, to which the plaintiffs (with assistance from the defendants, the district court, and Magistrate Judge Azrack) had full access, is, as this Court is aware, vast and comprehensive. See, *e.g.*, 1/15/2004 Aiosa Aff.; 1/15/2004 Whitney Aff.; 3/18/2004 Judge Weinstein Hearing Tr. 8; 3/2/2004 Judge Azrack Hearing Tr. 22; 3/9/2004 letter from Brock to Judge Weinstein.

and children born to them before 1984. *In re "Agent Orange" Prod. Liab. Litig.*, 100 F.R.D. 718, 729 (E.D.N.Y. 1983).

This Court affirmed the fundamental fairness of the settlement. 818 F.2d 145 (2d Cir. 1987). At the outset, the Court expressed its view that

> It is human nature for persons who face cancer in themselves or serious birth defects in their children to search for the causes of these personal tragedies. Well-publicized allegations about Agent Orange have led many such veterans and their families to believe that the herbicide is the source of their current grief. ***
>
> When the case is viewed as legal action for personal injury sounding in tort, however — and we are bound by our oaths to so view it — the most noticeable fact is the pervasive factual and legal doubt that surrounds the plaintiffs' claims. Indeed the clear weight of scientific evidence casts grave doubt on the capacity of Agent Orange to injure human beings. Epidemiological 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.

Addressing that legal action, the Court noted its "belie[f] *** that the [plaintiffs' lawyers] had good reason to view this case as having only nuisance value" and went on to limn the "various weaknesses of plaintiffs' case" (*id.* at 171), including causation (*id.* at 171-73), the difficulty of proving exposure (*id.* at 173), unfavorable state law on liability (*ibid.*), statutes of limitations (*ibid.*), and the "impossib[ility of] attribut[ing] the exposure of an individual to Agent Orange to the product of a particular company." *Ibid.*

Most significantly for present purposes, the Court then noted "a final and in our view impossible, hurdle to surmount, namely the military contractor defense." *Ibid.* That conclusion was based on a determination that "a reasonable trier of fact would have to have found that *** the government had as much knowledge as the defendants of the dangers of dioxin, then relating largely to chloracne and a rare liver disease." It also rested on the principle that "the military contractor defense shields defendant contractors from liability where the hazard is wholly speculative." *Id.* at 173-74. Above all, the Court held,

> [i]t would be anomalous for a company to be held liable by a state or federal court for selling a product ordered by the federal government, particularly when the company could not control the use of that product. Moreover, military activities involve high stakes, and common concepts of risk averseness are of no relevance. To expose private companies generally to lawsuits for injuries arising out of deliberately risky activities of the military would greatly impair the procurement process and perhaps national security itself.

818 F.2d at 150.

2. Next began a long series of lawsuits by class members who sought to escape the settlement. First came those who opted out before the settlement. Judge Weinstein granted summary judgment against them on the basis of the government contractor defense. He found that the government had as much or more knowledge as the defendants "about possible adverse health effects of Agent Orange as it was used in Vietnam" and that it was "clear that the government would have concluded that the beneficial saving of American soldiers' lives by

defoliating the Vietnamese jungles far outweighed any minimal risks to our own or allied troops posed by exposure to Agent Orange." *In re "Agent Orange" Prod. Liab. Litig.*, 611 F. Supp. 1223, 1263-64 (E.D.N.Y. 1985).[21]

On appeal, this Court upheld the application of the government contractor defense. See *In re "Agent Orange" Prod. Liab. Litig.*, 818 F.2d 187. The Court "agree[d] with the district court that the information possessed by the government at pertinent times was as great as, or greater than, that possessed by the chemical companies" (*id.* at 190), and observed that the "precise hazard of the herbicide, if any, was *** a matter of speculation at the time of its use." *Id.* at 193. Like Judge Weinstein, this Court recognized the weakness of the plaintiffs' case on causation: "We add a further reason for affirming the grant of summary judgment based on the military contractor defense. Even today, the weight of present scientific evidence does not establish that Agent Orange injured personnel in Vietnam, even with regard to chloracne and liver damage." *Ibid*. And it found that even if the

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[21] Judge Weinstein also noted that the plaintiffs had failed to prove causation: "[Y]ears of discovery and tens of millions of dollars spent by the government and others on research has not yielded any competent evidence indicating a genuine issue of fact about causation." 611 F. Supp. at 1260. In a related case, decided two months later, Judge Weinstein stated that "The epidemiologic studies and affidavits relied upon by defendants make clear that no rational jury could conclude that exposure to Agent Orange caused [plaintiff's] illness and death." *In re "Agent Orange" Prod. Liab. Litig. (Lilley)*, 611 F. Supp. 1267, 1284 (E.D.N.Y. 1985).

government had been privy to all of the data available decades later, that information would not have changed its discretionary decision to use Agent Orange in Vietnam: "The fact that the epidemiological studies do not exclude the possibility of harm in isolated or unusual cases or in future cases is of no moment because ***it does not constitute evidence material to the military decisions in question.***" *Id.* at 194 (emphasis added).

Plaintiffs assert that *Boyle* somehow negated this Court's 1987 decision. See Stephenson Br. 15-16. They rely on dictum in *Grispo*, 897 F.2d at 635, where this Court suggested in passing that "the more exacting standard a military contractor must satisfy after *Boyle* to establish the military contractor defense *** limit[s] the value of the facts of *Agent Orange* as a benchmark in a failure-to-warn action for satisfaction of the military contractor defense after *Boyle*." We respectfully submit that, as Judge Weinstein observed (*Isaacson*, 304 F. Supp. 2d at 439), the *Grispo* panel misapprehended both the facts of this case and the basis for the 1987 opinions. For example, the *Grispo* majority assumed that the Agent Orange specifications "were silent as to warnings" (897 F.2d at 634), but that supposition is unambiguously refuted by the record. See pp. 23 *supra*; pp. 85-86 *infra*. And it misconstrued the breadth of this Court's Agent Orange opinion, which stated that "under ***any*** formulation" of the defense, the manufacturers of Agent Orange were entitled to its protection. 818 F.2d at 192. This Court is not

bound by dictum in *Grispo* speculating, in the wholly different context of end-user warnings, on the application of the government contractor defense to Agent Orange, nor is that opinion persuasive in that regard. As the Supreme Court recently reiterated, "we are not bound to follow our dicta in a prior case in which the point now at issue was not fully debated." *Central Va. Cmty. Coll*. v. *Katz*, 126 S. Ct. 990, 996 (2006).

3. This Court again noted the probable applicability of the government contractor defense in a post-*Boyle*, post-*Grispo* Agent Orange decision, *Ivy* v. *Diamond Shamrock Chemicals Co*. There, the plaintiffs appealed Judge Weinstein's decision that the settlement barred claims by veterans whose injuries manifested after the settlement. *Ryan* v. *Dow Chem. Co.*, 781 F. Supp. 902 (E.D.N.Y. 1991). This Court affirmed. *Ivy*, 996 F.2d at 1428.

In that opinion, the Court also reaffirmed the fairness of the settlement, pointing out that "serious obstacles to recovery remain," most importantly the government contractor defense:

> It is clear from the chemical companies' contracts with the Government that the government specified Agent Orange's ingredients in great detail. There also is documentary evidence tending to show that the Government strictly prescribed the markings on Agent Orange barrels, and prohibited all extraneous label information, including warnings. Finally, there is evidence that the Government's knowledge of the hazards of Agent Orange and dioxin was at least as great as that of the chemical companies, making it unlikely that there were "dangers *** that were known to the suppliers but not to the United States," of which the suppliers should

> have warned. In sum, although the availability of the government contract defense might not be a foregone conclusion, there is a reasonable probability that it would apply, barring any recovery by the plaintiffs.

Id. at 1436 (citation omitted).[22]

4. Other courts have agreed that the government contractor defense applies. The Federal Circuit rejected a manufacturer's claim that the government should indemnify it for payments made in the Agent Orange settlement, finding that "there can be no serious doubt that had the class action Agent Orange litigation proceeded to termination, no liability would have been imposed" because of the government contractor defense. *Hercules*, 24 F.3d at 200. In yet another post-*Boyle* decision, the Fifth Circuit likewise ruled against civilian plaintiffs alleging the same injuries from Agent Orange. *Miller*, 275 F.3d at 419. The facts as to the government

[22] The Court further noted that "the crucial issue of 'general causation,' *i.e.*, whether any injuries are attributable to Agent Orange, remains unsettled. As one 1992 commentator noted, reviewing the scientific literature: 'To 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.' *** Notwithstanding the legal and scientific developments of the past nine years, the chances of recovery are nearly as speculative today as they were at the time of settlement." *Id.* at 1436-37 (citation omitted). The Court also recognized that, contrary to the *Grispo* court's assumption, the government forbade any warnings on the drums of Agent Orange. *Id.* at 1436.

contractor defense were identical to those in this litigation.[23] The court quoted this Court's opinion upholding the 1984 settlement: "'Subjecting military contractors to full tort liability would inject the judicial branch into political and military decisions that are beyond its constitutional authority and institutional competence.'" *Id.* at 418-19 (quoting *In re "Agent Orange" Prod. Liab. Litig.*, 818 F.2d at 191).

B. The Record Indisputably Establishes That All Three Prongs of the Boyle Test are Satisfied.

The unanimity of the federal courts on this issue is not surprising. The record developed over the nearly three-decade history of this case makes it abundantly clear that all three prongs of the *Boyle* test are satisfied. The government created Agent Orange and developed each of its components (2,4-D and 2,4,5-T). It ordered the manufacturers to produce the defoliant according to its specifications and knew "substantially more about possible dangers of Agent

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[23] Plaintiff Stephenson exclaims that "[t]he entire plaintiffs' record on appeal [in *Miller*] consisted of a single affidavit from Admiral Zumwalt!" Stephenson Br. 22 (citing 275 F.3d at 422 n.4). This is false; note 3, which plaintiff presumably intended to cite, states that "[i]t is upon this affidavit alone that the plaintiff's [*sic*] ***distinguish the present action***" from this Court's 1987 decision. 275 F.3d at 421 n.3 (citing "Record on Appeal at Vol. III, 316 n. 1"). The text explains that "[t]he factual record before this Court presents the same relevant facts that were before the Second Circuit" — *i.e.*, the MDL-381 record. *Id.* at 421.

Orange as it intended to, and did, use it than did any or all of the defendants combined." *Isaacson*, 304 F. Supp. 2d at 441.

Plaintiffs contend, incorrectly, that even if all three *Boyle* prongs are satisfied, there is an independent and additional prerequisite to *Boyle*'s applicability: a conflict between state law and the federal contract. Because the government did not expressly specify dioxin in the Agent Orange it purchased, plaintiffs assert that a state law requirement to eliminate it would not conflict with the government's interest. In *Lewis* v. *Babcock Industries, Inc.*, 985 F.2d 83 (2d Cir. 1993), this Court rejected that very argument and explained that the three-prong *Boyle* test itself determines whether such a conflict exists. *Id.* at 86. As we next discuss, the record below fully satisfies the first *Boyle* prong. Accordingly, the requisite conflict between state tort law and the federal contract has been established.

1. The Government's Specifications Were More Than Reasonably Precise.

The first two prongs of the Boyle test "assure that the suit is within the area where the policy of the 'discretionary function' would be frustrated — *i.e.*, they assure that the design feature in question was considered by a Government officer, and not merely by the contractor itself." See *Boyle*, 500 U.S. at 512. Thus, the question is whether the alleged design flaw reflects the discretionary judgment of the government or solely that of the contractor. See *Butler* v. *Ingalls Shipbuilding,*

Inc., 89 F.3d 582 (9th Cir. 1996); *Stout* v. *Borg-Warner Corp.*, 933 F.2d 331, 336 (5th Cir. 1991); *In re Aircraft Crash Litig.*, 752 F. Supp. 1326, 1333-34 (S.D. Ohio 1990), aff'd, 935 F.2d 269 (6th Cir. 1991).

a. The Specifications Were Precise.

i. The Contracts Specified Agent Orange's Ingredients in Great Detail.

The government's procurement specifications for defoliants used in Vietnam left the manufacturers with little latitude. The specifications for 2,4-D and 2,4,5-T identified not only the ratio of chemical agents in each mixture and the maximum level of impurities, but also the precise esters (*e.g.*, "normal butyl" ester) that would comprise each molecule. For each mixture, the specifications also dictated the amount of acid equivalent as a percentage of total volume; the amount of undissolved matter; the free acid content; the solubility; the specific gravity; and the moisture content.

The specification for 2,4,5-T, for example, required:

> 1. Scope
>
> 1.1 This specification covers one type of herbicide consisting of 95 percent normal-butyl 2.4.5-trichlorophenoxyacetate (2,4,5-T), molecular weight 311.60.
>
> * * *
>
> 3. Requirements
>
> 3.1 Material

> 3.1.1 Composition. The composition of the herbicide shall be normal- butyl 2.4.5-trichlorophenoxyacetate.
>
> 3.1.2 Appearance. The herbicide shall be a clear reddish-brown viscous liquid or reddish-brown solid.
>
> 3.2 Total acid equivalent. The total acid equivalent of the herbicide shall be not less than 80 nor more than 82 percent when tested as specified in 4.5.1.
>
> 3.3 Free acid. The free acid content of the herbicide shall not be greater than 1.0 percent when tested as specified in 4.5.2.
>
> 3.4 Undissolved matter. The herbicide shall be completely soluble, and shall show no evidence of undissolved matter when tested as specified in 4.5.3.
>
> 3.5 Moisture content. The moisture content of the herbicide shall not be greater than 0.2 percent when tested as specified in 4.5.4.
>
> 3.6 Specific gravity. The specific gravity of the herbicide shall be not less than 1.321 nor more than 1.345 at 25°/15.56°C when tested as specified in 4.5.5.

10/27/2004 Krohley Aff, Ex. 11 (A2329-34).

Every court to have considered the issue has agreed that the defoliant specifications were precise. In *Miller*, the Fifth Circuit described the "exacting specifications" for both Agent Orange and its component chemicals, and concluded that they were "more than reasonably precise." 275 F.3d at 419.[24] This Court

[24] Plaintiffs contended below that some contracts, including those for Agents Green, Pink and Purple, did not reference the military specifications for 2,4-D and 2,4,5-T cited in *Miller* and, therefore, were not reasonably precise. However, the Agent Green, Pink and Purple contracts all indisputably specify what the (cont'd)

likewise stated, in reaffirming the fairness of the 1984 settlement, that "[i]t is clear from the chemical companies' contracts with the Government that the Government specified Agent Orange's ingredients in great detail." *Ivy*, 996 F.2d at 1436. See also *Hercules Inc.* v. *United States*, 516 U.S. 417, 419-20 (1996) ("The military prescribed the formula and detailed specifications for manufacture.").

(… cont'd)

government was buying and, thus, contain specifications. Moreover, the specifications in these early contracts were also "reasonably precise." For example, one early Agent Purple contract specified:

> BUTYL ESTERS OF 2,4-D and 2,4,5-T unformulated consisting of the following components:
>
> 50% Normal Butyl 2,4-D by weight.
>
> 30% Normal Butyl 2,4,5-T by weight.
>
> 20% Isobutyl 2,4,5-T by weight.
>
> Minimum Ester Content 97.5%
>
> Freeze Point 0˚ C. Max.
>
> 580 Pounds per drum in
>
> 55 gallon metal drum

Thus, as the district court stated, "The Contracts set forth or incorporated by reference detailed specifications." *Isaacson*, 304 F. Supp. 2d at 424.

ii. The Contracts Prescribed the Labeling of the Drums and Precluded Additional End-User Warnings.

The contracts also prescribed the packaging and labeling of each container of defoliant, and they prohibited the manufacturers from placing any warnings on the drums. 11/10/2003 Brock Aff.; Fenner Tr. 54-55. See also *Hercules*, 516 U.S. at 418-20 ("The contracts *** instructed the suppliers to mark the drums containing the herbicide with a 3 inch orange band with '[n]o further identification as to conten[t].'").

Plaintiffs' contention that the government would have allowed additional warnings finds no support in the record. Plaintiffs concede that language in many contracts that were executed later in the war expressly prohibited additional warnings, mandating "no further identification as to contents." 10/31/2004 Cuker Aff. at 10-11 (A2574b-74c). What plaintiffs miss is that all of the parties to all of the contracts — both the manufacturers and the government — understood that this language simply memorialized the understanding that had been in place all along: that the precise contractual specifications of the markings to appear on the drums implicitly barred any additional markings.

This is confirmed by the unrebutted testimony of witnesses from both defendants and the government. In paragraph 8 of his Mar. 28, 1980 affidavit, John P. Frawley, formerly Director of Toxicology for Hercules, stated:

> The Government also inspected the labeling of the drums in which "Agent Orange" was shipped. Nothing but what the Government specified was allowed to be placed on the drums. This consisted of various product, batch and shipment information stenciled onto the drums' tops and sides by a silk screen method. The only other labeling permitted was a three inch orange stripe around the center of the drum. No warning was placed on the containers, and none was permitted by the contract specifications.

2/8/2005 Heck Aff., Ex. B at 5-6 (¶ 8) (A2620). See also Fenner Tr. 54-55 (A1664-65).

The government's intent is also clear from the following directive dated April 5, 1967:

> Marking: Identification and marking shall be restricted to the following:
>
> One orange band, 3 inches wide encircling the drum at the center line; lot number, Gross Wt., Net Wt., Cube.
>
> No other markings or identification shall be used.

10/27/2004 Krohley Aff., Ex. 15 (A2342b).

b. The Fact That the Specifications Did Not Mention Dioxin Is Irrelevant.

In the face of these detailed specifications, plaintiffs contend that the manufacturers are nevertheless not entitled to the protection of the government contractor defense because the contracts "did not mention dioxin [and] contained NO detail which had any effect on dioxin content." Stephenson Br. 20. They further argue that the manufacturers should have used the Boehringer manufacturing process, which allegedly would have produced Agent Orange

without detectible levels of dioxin. They claim that the government's specifications did not ***preclude*** the use of that process, and that the manufacturers' decisions not to adopt it are therefore not protected by the defense.[25] That argument, however, is contrary to both the factual record and the law.

It is beyond dispute that the government knew that dioxin was a contaminant generated in the process of manufacturing 2,4,5-T. It determined, however, that a defoliant composed of 50 percent 2,4,5-T sprayed undiluted did not pose a health hazard. It is likewise beyond dispute that the government learned that the manufacturing process affected the amount of dioxin[26] but nevertheless continued to insist on immediate production from all manufacturers at full capacity.[27] See pp.

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[25] Plaintiff Isaacson mentions (Br. 47-48) that one of his experts testified that defendants did not follow the "state of the art" in 2,4,5-T manufacturing and therefore violated state law. Isaacson does not explain why this assertion is material. Making a federal defense contingent on showing the absence of liability under state law would defeat its purpose of protecting contractors who would otherwise be liable.

[26] Plaintiff Bauer's claim that the government "had no knowledge whatsoever of how to produce 2,4,5-T" (Bauer Br. 51) is misleading. It may be true that the government did not have "specific knowledge" regarding the production of 2,4,5-T. PA6877 (quoted in Bauer Br. 51). But after the Weldon Spring project it not only knew how to produce 2,4,5-T, but it also knew that dioxin was formed during the production process, and it knew that changing the process could affect the level of dioxin in the product. See p. 56-58 *supra*.

[27] This consideration is fatal to plaintiffs' contention that the government contractor defense does not apply to "manufacturing defects." Properly understood, a manufacturing defect is a failure of an individual item to live up to (cont'd)

55-59 *supra*. Moreover, the government manifested its satisfaction with the defendants' products by repeatedly reordering them — to the extent of requisitioning the entire domestic supply.[28]

Defendants' position on this point is straightforward and reflects the views expressed by this and other courts, as discussed above. When the government's specifications, though otherwise highly detailed, do not expressly address the subject matter of the alleged defect, the government contractor defense is nevertheless satisfied if the government is aware of the condition constituting the alleged defect and of means to mitigate that condition but nevertheless orders and reorders the product without ever incorporating a specification that would control

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(… cont'd)

the intended design. Thus, such a claim presents the same issues as the second prong of the government contractor defense. See *Harduvel*, 878 F.2d at 1321 ("To say that a product failed to conform to specifications is just another way of saying that it was defectively manufactured."); *Zinck* v. *ITT Corp.*, 690 F. Supp. 1331, 1338 (S.D.N.Y. 1988) ("For the same reasons that ITT satisfied the second prong of the government contractor defense, plaintiffs cannot prevail on their claim of manufacturing defect."). Judge Weinstein properly found that the government's knowledge that the contractors used processes that produced dioxin, combined with its decision not to specify an alternative process, necessarily constituted approval of defendants' manufacturing techniques. See *Isaacson*, 304 F. Supp. 2d at 438, 442.

[28] Plaintiffs present an expert affidavit from Dr. Harry Ensley, who recites plaintiffs' argument regarding the absence of a dioxin specification and then offers the unsupported legal conclusion that that alleged deficiency renders the contracts not reasonably precise. See Isaacson Br. 48 (citing Ensley Aff. ¶ 25, PA3957). Obviously, this presents no ***factual*** dispute for a jury.

the existence or extent of the supposed defect. Any other conclusion would frustrate the purpose of the government contractor defense, placing the manufacturer in an untenable position by forcing it to retool processes that are acceptable to the government. The application of this principle has especial force here because of the government's own study of the safety of the product and its judgment that Agent Orange was in fact safe for its intended use.

i. The Risk of Dioxin Exposure Was Inherent in the Specifications for, and the Government's Use of, Agent Orange.

Whatever risks Agent Orange may have presented were inherent in the government's specifications. In the 1960s, it was impossible to synthesize 2,4,5-TCP, a precursor to 2,4,5-T, without creating dioxin as a byproduct. See 1/22/2004 Defs.' Supp. Reply Br. in Opp. to Remand, Ex. 9 at 28 note (A1377); Agency for Toxic Substances and Disease Registry, Chlorophenols § 4.1 (July 1999), *available at* www.atsdr.cdc.gov/toxprofiles/tp107.html (A593-97).[29]

[29] The EPA made official pronouncements to this effect beginning in 1979. See, *e.g.*, EPA Notice of the Denial of Applications for Federal Registration of Intrastate Pesticide Products Containing 2,4,5-T, 15 Fed. Reg. 2,899 (Jan. 15, 1980) (TCDD is an "inadvertent but unavoidable contaminant of 2,4,5-T"); EPA Final Determination Concerning the Rebuttable Presumptions Against Registration for Certain Uses of Pesticide Products Containing 2,4,5-T and Silvex and Notice of Intent to Hold a Hearing, 44 Fed. Reg. 72,323 (Dec. 13, 1979) (TCDD an "unavoidable contaminant"); EPA Decision and Emergency Order Suspending Registrations for Certain Uses in 2,4,5-T and Silvex, 44 Fed. Reg. 15,874 n.1 (cont'd)

Indeed, the government's own proposed production of defoliants would, like that of defendants, have entailed some dioxin contamination — the safety manuals and waste disposal procedures drafted for the Weldon Spring project assumed the presence of dioxin and warned that "Although Operating Temperatures Are Controlled To Prevent Its Formation, Dioxin May be Present." See 1/22/2004 Defs.' Supp. Reply Br. in Opp. to Remand, Ex. 11 (A1384-1401); 10/27/2004 Krohley Aff., Ex. 54 (A2497-2509). Even the Boehringer process did not completely avoid dioxin formation. See 11/2/2004 Smoger Aff., Ex. E-22 (PA5639-40); 11/30/1983 Dow Alt. Liability Br., Exs. 2-3 (A375-76).

In light of these circumstances, plaintiffs' arcane discussion of whether the government specified "what" the defoliants were or "how" they were to be produced (Bauer Br. 42-43) is of no consequence. The implication appears to be that because the government specified the end product rather than the manufacturing process, the first prong of the *Boyle* test is not met. This argument rests entirely on the affidavit of Ralph C. Nash, a retired law professor. Professor Nash, however, did not state that the specifications were not reasonably precise.

(… cont'd)

(March 15, 1979) (TCDD produced as byproduct of "current methods" of manufacturing 2,4,5-T, and although manufacturers attempt to remove this contaminant it cannot be completely removed).

Rather, after a lengthy discourse on the typology of procurement specifications, Nash concluded that the Agent Orange specifications "describe the physical characteristics of the material to be delivered to the Government." PA6994-95. As we have discussed, those physical characteristics could not have been achieved without producing dioxin as a byproduct. There is thus no merit to the plaintiffs' contention that the specifications were imprecise because "they did nothing more than" specify the chemical composition of the defoliants. Bauer Br. 42.

For these reasons, the Fifth Circuit concluded in *Miller* v. *Diamond Shamrock Co.* that

> Agent Orange could not have been made according to the government's specifications without including dioxin, because the government specifically requested that Agent Orange be made with 2, 4, 5-T. *** The alleged defect was the inclusion of dioxin in Agent Orange. ***Dioxin was included because 2,4,5-T was included.***

275 F.3d at 420-21 (emphasis added).

Any risks that might be associated with dioxin, moreover, were magnified by the government's decision to spray the herbicide in "a much higher concentration than materials that are normally used in domestic agricultural and industrial operations." 2/13/92 Gordon Aff., Ex. C at 2 (A407); see also *id.*, Ex. B at 16-17 (A402-403). The military recognized as early as 1963 that its use of overkill concentrations increased the risks of "toxicological or cosmetic effects on the exposed population." *Id.*, Ex. B at 13 (A401). It nonetheless proceeded with

its strategy of heavy spraying for two reasons. First, the purpose of the campaign was to increase visibility in dense jungle — not to kill weeds, the normal use of herbicide. Second, the government wanted to minimize pilots' exposure to heavy ground fire, which they sought to accomplish by spraying more herbicide on each aerial run and thereby limiting the number of runs. This clearly was a discretionary decision for which the manufacturers cannot be held liable.

ii. The Government's Specifications Reflected a Reasoned Judgment That Agent Orange Was Both Safe and Militarily Necessary.

1. The specifications for Agent Orange reflected crucial policy judgments of military and other executive branch decisionmakers. There can be no factual dispute that those individuals consciously considered the urgent military need to defoliate strategically important areas and thereby protect American and allied troops. They also took into account the health effects associated with the defoliants, which were known to contain trace amounts of dioxin, concluding that the defoliants promised great military benefits and were safe as they were to be used in Vietnam. The silence of the specifications as to dioxin must be considered in the context of the government's conclusion that although dioxin itself was toxic, Agent Orange, which contained only ***trace*** levels of dioxin, was nevertheless safe.

For example, John Foster testified that "in spite of the fact that we were overwhelmingly convinced we were doing the right thing to save lives, there were

a few people in the U.S. community, scientific community, who were concerned about these long-term effects, and under the pressure of the war in Vietnam, I do recall that we did what I felt was a very open-handed, even approach to dealing with this matter. *** I'm absolutely convinced we were doing the right thing." Foster Tr. 24-25 (A1674-75). An Institute for Defense Analysis report to ARPA likewise demonstrates that the government did not view suggestions of long-term health risks as warranting serious concern:

> Since any agent will, in most areas, be used once, or at most a few times, it is not necessary to conform to the high safety standards required by the Food and Drug Administration for commercial agriculture.

1983 Hercules Summary Judgment Br., Ex. 10 at 9 (A43).

Thus, in specifying defoliants, "[t]he United States armed forces accepted the dangers it was aware of because, from a military point of view, the benefits in potential savings of the lives of our armed forces and those of our allies outweighed the possible risks." *Isaacson*, 304 F. Supp. 2d at 430. While the plaintiffs urge a single-minded focus on dioxin levels, the government examined not only the health effects of the herbicides themselves but also many other factors, as is characteristic of discretionary decisions of the political branches. The government's election not to tinker with the production process was part of this exercise of discretion.

In light of these necessary tradeoffs, Judge Weinstein correctly concluded:

> [T]he government was aware of alternative manufacturing processes that might potentially mitigate the presence of dioxin in Agent Orange. In its quest for maximum production of Agent Orange as a tool of war, the government's benign connivance failed to specify another production process, sanctioning defendants' use of the then-existing technology, leading inexorably to some dioxin in Agent Orange.

Id., 304 F. Supp. 2d at 442. See also *In re "Agent Orange" Prod. Liab. Litig.*, 611 F. Supp. at 1263-64, aff'd, 818 F.2d 187 (2d Cir. 1987) ("The information available makes it clear that the government would have concluded that the beneficial saving of American soldiers' lives by defoliating the Vietnamese jungles far outweighed any minimal risks to our own or allied troops posed by exposure to Agent Orange. Such a governmental decision falls within the discretionary function exception to liability under the Federal Tort Claims Act.") It is precisely that decision to ignore trace levels of dioxin that plaintiffs challenge in this litigation.

2. Plaintiffs' heavy reliance on the availability of the specific process used by the C.H. Boehringer Co. (Bauer Br. 51-60; Stephenson Br. 7-8, 25-26) is misplaced. Even after both Dow and the government's consultants on the Weldon Spring project brought the Boehringer process to the government's attention, the government did not suggest — much less specify — that the manufacturers use it or otherwise limit dioxin levels. In light of the government's extensive knowledge and its power to change the specification at any time to require lower dioxin levels,

a different manufacturing process, or both, the absence of such a specification must be taken to be a discretionary government decision, not a careless omission.

Plaintiffs' whole theory of the case is that defendants decided not to shift to a manufacturing process that would have reduced dioxin below measurable levels because such a process would impose "slow production rates" and would be "much more expensive" than the processes already in place. See Bauer Br. 54. According to plaintiffs, state tort law required the use of that slower, more expensive process. That theory demonstrates exactly why the government contractor defense is applicable here. The defense is grounded in the concern that, if contractors are subjected to state tort liability arising from discretionary decisions of the government, they will pass along to the government the costs associated with complying with state law. See *Boyle*, 487 U.S. at 507 ("The imposition of liability on Government contractors will directly affect the terms of Government contracts: either the contractor will decline to manufacture the design specified by the Government, or it will raise its price. Either way, the interests of the United States will be directly affected."). Here, the plaintiffs contend that state law — but not the government's specifications — required a process that would have raised costs and reduced the supply of herbicide available to the military. It is clear that such a claim is barred.

3. Such high-level government decisions to adopt a particular strategy imply a discretionary acceptance of any safety/performance tradeoffs known to inhere in that strategy. In *Harduvel*, the Eleventh Circuit found that the military's decision to proceed with an "all-electric" fighter jet (as opposed to a model using hydraulic controls) implied its acceptance of the dangers of wire chafing caused by exposing large amounts of electric wiring to extreme temperatures and vibrations. The government was aware of the risks associated with chafing; accordingly, its acceptance of a design in which chafing was an inherent risk was a discretionary decision for which the contractor could not be held liable. "If a defect is one inherent in the product or system that the government has approved, it will be covered by the defense." 878 F.2d at 1317. Here, the government, after the most extensive research and scientific testing that had been conducted by anyone up to that point, determined that the intended use of Agent Orange in Vietnam was safe and that such use was imperative for military purposes. Surely that determination is at least as worthy of the label "discretionary" as the decision in *Harduvel*.

Furthermore, where, as here, the government decides that a particular product is safe, it is presumed as a matter of law that it would not have chosen to pay — or wait — for a product that incorporated additional safety measures. See, *e.g.*, *Glassco* v. *Miller Equip. Co.*, 966 F.2d 641, 643 (11th Cir. 1992) ("[w]hile it is clear that the government would not have objected to the use of leather that was

somewhat wider or somewhat thicker, a common sense construction of the specifications makes it clear that a discretionary decision was made that the designated width and thickness were adequate, and that the government did not consider it appropriate to pay for wider or thicker leather"); *Stout*, 933 F.2d at 336 (approval without safety feature constituted discretionary action); *Nicholson* v. *United Techs. Corp.*, 697 F. Supp. 598, 603-604 (D. Conn. 1988) (contractor not required to include every imaginable safety device where specifications do not clearly require them); *Ramey* v. *Martin-Baker Aircraft Co.*, 656 F. Supp. 984, 999 (D. Md. 1987) ("[W]hen the government designs a product or approves a design of a product which calls for some physical safeguards but not others, the government contractor is not held liable for the safeguards not provided for in the specifications."). In short, the government need not affirmatively state that it wants the contractor to forego additional measures, such as use of the Boehringer process; the knowledgeable omission of those precautions from the specification necessarily implies a discretionary government decision not to include them.

It would be unreasonable to require that the contract specify the particular characteristic alleged to be defective where the defect alleged is one of omission, and the evidence shows that the government knowledgeably omitted a specification on the subject. And while omitted specifications do not constitute contractual duties, that does not make them any less an exercise of government

discretion. *Cf. Miller*, 275 F.3d at 420 ("[I]t is unclear why the government would remain silent with respect to dioxin if the government wished to forbid its inclusion. An express prohibition would have been much more effective.").

A rule imposing a requirement that any alleged defect must have been addressed explicitly in the specifications would frustrate the policies that the government contractor defense is designed to serve. Such a rule would make the contracting process lengthier and more expensive, because the contractor would seek to induce the government to reject explicitly every safety precaution that it has considered and decided not to include. This Court has outlined the consequences of thus limiting or abrogating the government contractor defense:

> As long as the government is aware of known hazards, the decision to take the risk is made by the government, and it would be destructive of the procurement process and thereby detrimental to national security itself to hold manufacturers liable for injuries caused by the military's use of their products. Costs of procurement would escalate ***. Contractors would find insurance difficult or impossible to procure, and bankruptcies might occur among companies supplying products essential to national security. Firms would take steps to avoid entering into government contracts ***. The effect on procurement would be particularly acute where claims of toxic exposure might be made and the number of potential claimants would be impossible to determine.

In re "Agent Orange" Prod. Liab. Litig., 818 F.2d at 191.

4. Many courts have held that a defendant satisfies the government contractor defense where the specification was silent on the alleged defect. See *Wilson* v. *Boeing Co.*, 655 F. Supp. 766, 773 (E.D. Pa. 1987) (rejecting

requirement of "discussions or negotiations regarding the inclusion or exclusion of the specific design deficiency alleged in this case" and finding it "sufficient for the contractor to show *** that the overall detailed specification was established or approved by the government"); *Maguire* v. *Hughes Aircraft Corp.*, 725 F. Supp. 821, 823-24 (D.N.J. 1989) (same); *Stout*, 933 F.2d at 335 (barring recovery even though "the initial fan specifications prepared by the Army did not include or prohibit the installation of a safety device"); *Crespo* v. *Unisys Corp.*, No. 94-2339 (WGB), 1996 WL 875565, at *10 (D.N.J. Jun. 21, 1996) (rejecting argument that specifications must "expressly negate the possibility of modifications to the design that could have prevented the alleged injuries"); *In re Aircraft Crash Litig.*, 752 F. Supp. at 1351 (finding it "sufficient that the Air Force negotiated and approved the Detail Specification for the aircraft as a whole" though it did not mandate specific defects).

By contrast, there are no cases endorsing plaintiffs' position. The decisions they cite (see Bauer Br. 20-22) are readily distinguishable. *Strickland* v. *Royal Lubricant Co.*, 911 F. Supp. 1460 (M.D. Ala. 1995), held that the silence of relatively vague specifications raised a factual issue where the specifications could have been met by a different, less toxic, chemical. See *id.* at 1467. Here, because the government precisely specified the *n*-butyl ester of 2,4,5-T, substitution of a different herbicide would have violated the specifications. Moreover, unlike in

Strickland, and of especial significance, the government here reordered the product in huge quantities for nearly a decade with full knowledge of the alleged defect. See *infra* pp. 100-104. In *Snell* v. *Bell Helicopter Textron, Inc.*, 107 F.3d 744 (9th Cir. 1997), "there were no discussions with the government" about the critical element. *Id.* at 748. In this case, by contrast, the government was well aware, as a result both of discussions with the contractors and its own extensive research, of the dioxin issue. *Ritch* v. *A.M. General Corp.*, No. 93-451-SD, 1996 WL 310297 (D.N.H. Mar. 28, 1996) merely stands for the proposition that government involvement in product ***design*** does not establish government discretion over ***warning labels***. See *id.* at *9. And finally, *Barron* v. *Martin-Marietta Corp.*, 868 F. Supp. 1203 (N.D. Cal. 1994), concluded that whether the government approved the alleged defects was a fact in dispute, because the court was "uncertain[] *** what in particular those defects were." *Id.* at 1205 n.2.

iii. As a Matter of Law, the Government's Use and Reordering of Defoliants Known to Contain Dioxin Constitutes a Reasonably Precise Specification of Dioxin.

The government did not simply buy one shipment of dioxin-contaminated defoliant from the defendants. It ordered Agent Orange and several variant mixtures for years, at times taking the industry's entire output. The government reordered the defoliants, moreover, with full knowledge that dioxin was present and that manufacturing processes existed that could reduce dioxin levels. Against

such a history, plaintiffs' argument that the absence of a "dioxin specification" rendered the contracts imprecise (see Stephenson Br. 20-25) is legally untenable.

This Court and others have held that "when the Government reorder[s] the specific [product], with knowledge of its alleged design defect, the Government approve[s] reasonably precise specifications for that product such that the manufacturer qualifies for the military contractor defense for any defects in the design of that product." *Lewis*, 985 F.2d at 89. *Lewis* involved a corrosion hazard in a steel cable, which occasionally resulted in catastrophic failure of the ejection module of F-111-F jet fighters. The Air Force nevertheless reordered the defective cable, rather than specifying an available, non-defective alternative. It addressed the problem by changing the maintenance manual and replacing the existing cables with new ones of identical design. *Id.* at 89. This Court, stating that "[t]he Air Force exercised its discretion" in doing so, ruled that "it is not our role to second-guess the Air Force's judgment." *Ibid.* The Court noted that, as in *Boyle*, liability would lead the contractor "to raise the price of the replacement cables *** [, a] reaction [that] would frustrate the policy underlying the FTCA's discretionary function exception by placing the cost of the Government's discretionary decisions on the Government itself when it contracts for a product." *Ibid.*

This decision is in accord with the rulings of other courts. See *Harduvel*, 878 F.2d at 1318 ("Moreover, with full knowledge of the chafing problem in the

design of the aircraft, the Air Force has continued since 1979 to purchase the F-16 as a primary combat fighter plane."); *Dowd* v. *Textron, Inc.*, 792 F.2d 409, 412 (4th Cir. 1986) ("The length and breadth of the Army's experience with the 540 rotor system — and its decision to continue using it — amply establish government approval of the alleged design defects"); *Haltiwanger* v. *Unisys Corp.*, 949 F. Supp. 898, 904 (D.D.C. 1996) ("long-term use of a given design often indicates de facto acceptance of the design and thus constitutes approval for purposes of the *Boyle* test").

The record in this case amply demonstrates that the government, knowing that alternative manufacturing processes could reduce dioxin levels, not only reordered Agent Orange — it commandeered U.S. industry's entire capacity for 2,4,5-T to ensure a steady supply of its chosen formulation. The facts on government control through the use of DO-rated orders under the Defense Production Act are set out at pp. 51-55 *supra* and at Remand Br. 8-14. The government ordered defendants to accelerate production because it considered an aggressive defoliation campaign essential to the achievement of military objectives and the safety of American troops. Farris Bryant, Director of the Office of Emergency Planning in the Executive Office of the President, writing to Defense Secretary Robert McNamara, approved the Commerce Department's recommendation "that all possible production of 'Orange' and its critical

components be directed to the filling of military requirements" and noted that the BDSA "is currently instituting procedures to insure that the entire output of the chemical 2, 4, 5-T *** will be used on military orders." 11/10/2003 Defs.' Supp. Br. in Opp. to Remand, Ex. 16 at 1 (A965).

The government also worked to increase production by redirecting supplies of tetrachlorobenzene, an indispensable precursor to 2,4,5-T, to the contractors. See 2/4/2005 Gordon Aff., Ex. 7 (Goldman Tr.) at 75 (A2580); 11/10/2003 Defs.' Supp. Br. in Opp. to Remand, Ex. 12 (12/12/1991 Gordon Aff.) at Exs. M-U (to Gordon Aff.) (A381-91). The government even looked into opening its own manufacturing facility to produce Agent Orange. See p. 55-59 *supra*. It did so with full knowledge that 2,4,5-T contained dioxin and also with knowledge that the Boehringer process or other techniques might reduce dioxin levels. See p. 56-58 *supra*. If, as this and other courts have held, simply placing another order with knowledge of an alleged defect constitutes approval of reasonably precise specification, the government's actions here overwhelmingly compel that conclusion.

In sum, the government ordered Agent Orange as produced by defendants' existing manufacturing processes with knowledge of dioxin and the possible hazards it posed. The "precise hazard of the herbicide, if any, was *** a matter of speculation at the time of its use," as this Court held in its 1987 *Agent Orange*

decision. 818 F.2d at 193. The government's decision to use Agent Orange in Vietnam — based on its determination that it was an effective weapon of war with potential but acceptable risks — was a fully informed discretionary act which shields defendants from liability in these cases.

c. The Other Objections That Plaintiffs Raise Are Not Relevant to the Precision of Government Specifications.

Boyle requires that "the United States ***approved*** reasonably precise specifications," a condition intended to "assure that the design feature in question was ***considered*** by a Government officer." 487 U.S. at 512 (emphasis added). The plaintiffs nowhere allege that the government did not approve the defoliant specifications. Nonetheless, as they do in the remand brief, they attempt to obscure the obvious applicability of straightforward language by proffering legally irrelevant and factually spurious objections to the procurement process.

i. The Claim That Defendants Controlled the Specifications Process Is Both Irrelevant and Unsupported.

First, plaintiffs argue that the manufacturers controlled the procurement process, prepared the specifications themselves, and decided to leave out any mention of dioxin. From this faulty factual premise, plaintiffs ask this Court to infer that the authorship of the specifications renders the specifications imprecise. Bauer Br. 38-39.

This assertion is both legally and factually erroneous. A contractor's participation in the process of developing specifications is not even relevant under *Boyle*. Interaction between buyer and seller is typical of negotiations for custom-designed products, and it would be most inimical to the government's interests to chill that interaction. In this case, it was a productive way for the government to ensure that the defoliants, while carefully specified, were technically feasible and did not incorporate unrealistic tolerance ranges, and that all parties understood how compliance with each specification would be measured (for example, by weight or volume). *Boyle* held that the discretionary function is implicated where the "feature in question is ***considered*** by a Government officer." *Boyle*, 487 U.S. at 512 (emphasis added). It did not impose any limitation based on who first suggests it.

Boyle itself involved active contractor participation in the design. See *Boyle* v. *United Techs. Corp.*, 792 F.2d 413, 414 (4th Cir. 1986) ("Sikorsky and the Navy worked together to prepare detailed specifications for the CH-53 helicopter. One of Sikorsky's program engineering managers for the CH-53 described in some detail the back-and-forth discussions between Sikorsky and the Navy"), vacated, 487 U.S. 500 (1988). In *Harduvel*, the Eleventh Circuit also found precisely this sort of collaborative "back and forth" between the government and contractors to indicate government approval of the product design. 878 F.2d at 1320 ("In sum,

the design of the F-16 was a result of 'continuous back and forth' between the Air Force and General Dynamics"); see also *Wilson* v. *Boeing Co.*, 655 F. Supp. at 772.

Boyle, moreover, specifically rejected an Eleventh Circuit rule that limited the defense to cases where "the contractor did not participate, or participated only minimally, in the design." 487 U.S. at 513 (citing *Shaw* v. *Grumman Aerospace Corp.*, 778 F.2d 736, 746 (11th Cir. 1985)). The Court explained that the *Shaw* rule

> is not a rule designed to protect the federal interest embodied in the 'discretionary function' exemption. The design ultimately selected may well reflect a significant policy judgment by Government officials whether or not the contractor rather than those officials developed the design. In addition, it does not seem to us sound policy to penalize, and thus deter, active contractor participation in the design process.

Ibid. See also *Carley* v. *Wheeled Coach*, 991 F.2d 1117, 1125 (3d Cir. 1993) ("[I]t is necessary only that the government approve, rather than create, the specifications."); *Oliver* v. *Oshkosh Truck Corp.*, 911 F. Supp. 1161, 1173-74 (E.D. Wis.) (allowing defense where contractor had "total design responsibility"), aff'd, 96 F.3d 992 (7th Cir. 1996); *In re Aircraft Crash Litig.*, 752 F. Supp. at 1341; *Zinck*, 690 F. Supp. at 1336.

In any event, no jury could accept plaintiffs' argument as a factual matter. The government decided what it wanted long before defendants became involved.

See *In re "Agent Orange" Prod. Liab. Litig.*, 597 F. Supp. at 848 ("the government 'invented' Agent Orange"). According to a report from Fort Detrick, "[b]y 1951 it had been determined that the vegetation-control agents of choice would be: n-butyl 2,4-D, n-butyl 2,4,5-T, and mixtures of the two." 11/10/2003 Defs.' Supp. Br. in Opp. to Remand, Ex. 1 at 8 (A611). By 1961, the consensus of researchers at the Edgewood Arsenal was that a mixture of equal portions of *n*-butyl 2,4-D and *n*-butyl 2,4,5-T should be employed in Vietnam. Minarik Tr. 18-19 (A1867-68). It was this decision to use 2,4,5-T — a choice that even plaintiffs concede was made by the government — that ensured the presence of dioxin in Agent Orange. This Court should reject plaintiffs' efforts to obscure this plain fact by suggesting that the government's willingness to accommodate certain technical requirements of the contractors means that the government did not approve precise specifications.

Plaintiffs cite several record sources in an attempt to show that the "manufacturers prepared the details of the specifications." Bauer Br. 39-41. These sources depict collaboration between military personnel and contractors in drafting the specifications (see, *e.g.*, PA6659), but they do not support the inference that "[t]he Army asked Defendants to write the specifications." Bauer Br. 39. In fact, the memo Bauer cites (Br. 39) from C.H. Russell of Monsanto recounts the author's ***failure*** to persuade the Army to accept one of his proposed changes. See

PA6659. See also PA6662 (Army "said the requested change was impossible at this time"). Other cited sources show the chemical companies proposing changes to the specifications (PA5846-26, PA5846-89), requesting clarifications, and making technical corrections. PA5846-44, PA5713.[30] None indicates contractor control over the specification process, and most importantly, none of the changes alleged to have been made at the contractors' suggestion relates in any way to the level of dioxin in the final product.[31]

ii. The Purported "Off-The-Shelf" Nature of Agent Orange Does Not Bar Application of the Government Contractor Defense.

Next, the plaintiffs argue that the government did not approve reasonably precise specifications for Agent Orange because the product was supposedly available "off-the-shelf." Bauer Br. 12-23; Stephenson Br. 17-19. Plaintiffs' contention is simply wrong — Agent Orange was not an "off-the-shelf" product

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[30] Bauer also cites PA5813-24, an irrelevant page from a brief in an earlier iteration of this litigation. Bauer does not provide an appendix cite for the "January 1968 Dow Correspondence." Bauer Br. 41.

[31] Plaintiffs also present deposition testimony from Graydon Holdeman that they claim shows that "Dow didn't even need to change its already existing internal specifications for 2,4,5-T in order to sell Agent Orange." Bauer Br. at 24. That Dow already made an ingredient that ***conformed*** to the government specification is no basis for inferring that Dow ***wrote*** the specification. Furthermore, Agent Orange — not 2,4,5-T — was the product the government ordered, and there is no suggestion that any manufacturer had a preexisting internal specification for Agent Orange.

and would have been illegal as a commercial herbicide — and is of no legal relevance.

1. The fact that some components of a product are commercially available does not void the government contractor defense, even where the components themselves are the source of the alleged defect. See *Niemann* v. *McDonnell Douglas Corp.*, 721 F. Supp. 1019, 1023 (S.D. Ill. 1989) (availability of asbestos strip does not make aircraft a stock product). Because almost any custom-designed product could be broken down into generic component parts, such a standard would eviscerate the defense. See *Miller*, 275 F.3d at 419-20. This point is particularly relevant where, as here, the alleged defect is a trace contaminant, and the government decided to use the product in a far more concentrated form than similar products had been used commercially — a decision that substantially elevated the amount of contaminant to which plaintiffs allegedly were exposed. *Cf. Grispo*, 897 F.2d at 638-39 (Minor, J., concurring) ("Agent Orange itself was composed of stock items, but the Government prescription of how those items should be combined and packaged was the key to the military contractor defense."). In such a case, the contractor would not "have factored the costs of ordinary tort liability into the price of their goods." Stephenson Br. 18 (quoting, without quotation marks, *In re Hawaii Fed. Asbestos Cases*, 960 F.2d 806, 811 (9th Cir. 1992)).

Finally, even if Agent Orange itself had been available in local hardware stores, it is simply not the case that "this 'off-the-shelf limitation' is a new, fourth element of the military contractor defense." *Miller*, 275 F.3d at 419-20 (describing the argument as "absurd"). The cases plaintiffs cite on this point all involve products whose design the government did not even consider. *Hawaii Asbestos* involved the sale of asbestos-containing insulation as a finished product, not a component part. The Ninth Circuit observed that "the military constituted a ***relatively insignificant purchaser*** of products that were primarily designed for applications by private industry." *Hawaii Asbestos*, 960 F.2d at 812 (emphasis added).

In this case, by contrast, the Department of Defense was the ***sole*** consumer of the defoliant it specified, and, at the time of peak demand, it took over the ***entire domestic production*** of 2,4,5-T. The case is thus wholly unlike *Jackson* v. *Deft, Inc.*, which explained that "[a]n ordinary consumer product purchased by the armed forces, such as a can of beans, does not qualify" for the defense, nor do products for which "the military is only one outlet in a ***larger market***." 223 Cal. App. 3d 1305, 1318-19 (Cal. Ct. App. 1990) (internal quotation omitted) (emphasis

in original).[32] As for *Ammend* v. *BioPort, Inc.*, it apparently involved vaccines bought literally off-the-shelf — the plaintiffs alleged that the products were "purchased pursuant to contracts ***devoid of specifications***." 322 F. Supp. 2d 848, 878 (W.D. Mich. 2004) (emphasis added).

2. Plaintiffs' claim that Agent Orange was an off-the-shelf product, even though it was custom-designed for exclusive military use, is in any event untenable. See *Miller*, 275 F.3d at 420 (finding absence of genuine factual dispute on this point). Based on the appendix citations they provide, it appears that plaintiffs wish this Court to conclude that because certain formulations of 2,4-D and 2,4,5-T were commercially available in the 1950s, the military defoliants used in Vietnam were "off-the-shelf" products. Stephenson Br. 17. The commercial availability of components of a custom-designed defoliant does not, of course, make the composite "off-the-shelf." In fact, Agent Orange was never available,

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[32] *Jackson* did not hold that the government contractor defense is always a jury question where a product has dual civilian and military uses, as suggested by Stephenson. Br. 18. To the contrary, it rejected the "extreme position" that "military equipment means a product made exclusively for military use with no commercial purpose." 223 Cal. App. 3d at 1319. The case was sent to the jury only because the California court seemed to think, erroneously, that *Boyle* applies only to "military equipment," and it perceived a fact question as to whether paint qualified. *Ibid.*

before or after the war, for domestic use.[33] Indeed, such sale would not even have been legal, because Agent Orange was not registered under FIFRA, a prerequisite to domestic sale. 11/10/2003 Defs.' Supp. Br. in Opp. to Remand, Ex. 7 (2/13/92 Gordon Aff.) ¶ 10 (A396); *Isaacson*, 304 F. Supp. 2d at 430. Moreover, Agent Orange was used in an entirely different manner from commercial weed-killers. The commercial formulations were far less concentrated, were to be substantially diluted before use, and were applied at a much lower volume than the military version; it is undisputed that they were safe when used as directed — labels on commercial herbicides warned against inhalation and contact with skin. See 10/27/2004 Krohley Aff., Ex. 32 at App. A (A2373); Morthland Tr. 50 (A1890) (noting absence of a single complaint to the U.S. Department of Agriculture from commercial users in the history of commercial sale).

The plaintiffs' claim that Agent Orange was readily available on the commercial market stands in stark contrast to contemporaneous statements of

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[33] Plaintiff Bauer erroneously cites the deposition of James King, a Diamond sales manager, for the claim that Diamond sold "the same product in the exact mixture and composition" as Agent Orange. Bauer Br. 24. But what King actually said was that Diamond sold "a phenoxy herbicide containing 2,4,5-T." PA6279. The military defoliants were unlike anything that Diamond had produced for commercial use — they were not registered under FIFRA, did not carry labels, were devoid of any substantial quantity of inert ingredients, and were sprayed without dilution. See 11/10/2003 Defs.' Supp. Br. in Opp. to Remand, Ex. 7 (2/13/92 Gordon Aff.) ¶¶ 3-7, 10, 11 (A393-97).

government scientists, who expressed their frustration that "[t]he n-butyl 2,4-D and 2,4,5-T chemicals could not be obtained on the open market," forcing them to employ "less active commercial substitutes" for field testing. 11/10/2003 Defs.' Supp. Br. in Opp. to Remand, Ex. 1 at 9 (A612). These substitutes were less active because commercial herbicides all contained a large fraction of inert ingredients. 11/10/2003 Defs.' Supp. Br. in Opp. to Remand, Ex. 7 (2/13/92 Gordon Aff.) ¶¶ 3-6 (A393-94). Such diluted concentrations were adequate for domestic use as a weed-killer but not effective to strip the leaves off trees and bushes in a thick, multi-layered tropical jungle and to destroy Viet Cong food sources. Admiral Moorer explained to Defense Secretary Laird that "[t]here is no direct parallel between tactical herbicide operations in Vietnam and the use of herbicides in the continental United States (CONUS) as the objectives of their use are entirely different." 1983 Dow Summary Judgment Br., Ex. 168 at 1 (A369). Agent Orange also required special spray equipment; as a result of its higher concentration, it was too viscous for use with civilian equipment. See 1/22/2004 Defs.' Supp. Reply Br. in Opp. to Remand, Ex. 1 (Shaw Tr.) (A1319-20). Finally, the commercial versions contained detailed warning labels and directions for use, which the military forbade. 11/10/2003 Defs.' Supp. Br. in Opp. to Remand, Ex. 7 (2/13/92 Gordon Aff.) ¶¶ 5, 11 (A394, A396-97).

Plaintiffs' statement that "defendants *** held the patents on the herbicides" (Stephenson Br. 17) is incorrect. Dow did not patent Agent Purple; rather, it patented a method of preventing 2,4,5-T from crystallizing at moderate temperatures by adding iso-butyl esters of 2,4,5-T to the government's preferred *n*-butyl esters and suggested this method when the government faced problems with Agent Green crystallizing in flight.[34] (Later defoliants, including Orange, did not employ the Dow method because they remained liquid at the relevant temperatures.) This knowledge may have been useful to the government, but that does not convert every defoliant the government ordered — including the vast majority that did not use the patented process — into "off-the-shelf" products. In fact, the same government memo that discusses the patent states the understanding of Dr. "Minarik [of Fort Detrick, who] believed that Pink and Purple were never commercially produced." 1/22/2004 Defs.' Supp. Reply Br. in Opp. to Remand, Ex. 2 at 1 (A1321).

The allegation that "[t]he [a]gents at [i]ssue" in this litigation were patented is even more preposterous. Bauer Br. 14. The patents plaintiffs cite are for

[34] A proper understanding of the patent also dispels any confusion in the letter of the government patent lawyer discussed at Bauer Br. 45. The letter attributes the problem not to any inherent ambiguity in the specifications, but to an error by a government contracting officer, showing that the confusion described in the letter was limited to a single contract. See PA3858. And any ambiguity, of course, had nothing to do with dioxin levels.

formulations or compounds of 2,4-D and/or 2,4,5-T, but none is a patent for 2,4-D or 2,4,5-T itself, and certainly none is for any of the specific combinations and concentrations in the "Agents" that the military specified. The fact that the government began its design process by working from chemicals that it already knew to be effective herbicides, rather than by inventing new ones from scratch, cannot defeat the government contractor defense.

2. Agent Orange Met the Government's Specifications.

The second prong of the *Boyle* test requires the contractor to prove that the product complied with the government's specifications. Only one appellant raises a challenge relevant to this prong. Plaintiff Anderson argues that because "[t]here is nothing in the contracts that specifies the inclusion of any dioxin," the defoliants did not meet specifications and were not "fit to use." Anderson Br. 16-17. This inference is ridiculous, and the conclusion is demonstrably false.

As discussed at pp. 89–92 *supra*, the presence of trace amounts of dioxin was inherent in the specifications for Agent Orange. The government was well aware of this and was not troubled by it. William Fenner, a contracting officer with the Materials Branch of the Directorate of Procurement and Production, Defense General Supply Agency, testified that if a contractor had provided a product that failed to comply with the specifications, the government would have declined payment. 1983 Dow Summary Judgment Br., Ex. 29 at 94-95 (A1666-

67). To his knowledge, that never happened. *Id.* at 95 (A1667). In any event, the presence of a known contaminant not specifically mentioned in the specifications cannot, standing alone, establish non-conformance.

3. The Defendants Met Their Duty to Warn the Government of "Dangers *** That Were Known to the Supplier But Not to the United States."

The final *Boyle* prong requires that "the supplier warned the United States about the dangers in the use of the equipment that were known to the supplier but not to the United States." *Boyle*, 487 U.S. at 512. This prong is intended to remove any "incentive for the manufacturer to withhold knowledge of risks." *Ibid.* This requirement was not violated in any respect: there were no relevant dangers known to the manufacturers; there were in fact warnings to the government of such (irrelevant to the government) dangers as were known; and the government knew more about the health dangers to persons exposed to Agent Orange as it was applied in Vietnam than did the manufacturers.[35]

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[35] Plaintiffs cite two cases for the proposition that the question of relative knowledge about risks associated with Agent Orange is not amenable to summary judgment. See Stephenson Br. 47. Both of those cases, however, involved claims brought by manufacturers against the government under the "superior knowledge doctrine," which allows recovery of "unexpected increased costs of performance of a contract if the ***Government***, at the time the contract was formed, had superior knowledge regarding difficulties in production which were not apparent and were ***not otherwise known by the contractor***." *Hercules Inc.* v. *United States*, 25 Cl. Ct. 616, 622 (1992) (emphasis added); see also *William T. Thompson Co.* v. *United* (cont'd)

a. The Contractors Repeatedly Warned the Military of Production Hazards.

Plaintiffs point to evidence showing that defendants knew about dioxin in 2,4,5-T and the possible risk to production workers. But that evidence does not concern any of the long-term health risks alleged in this case — and plaintiffs have presented no evidence suggesting that the manufacturers had any knowledge of those risks. See Stephenson Br. 29-47. Indeed, plaintiffs' own expert, Dr. Laura Welch, testified that between 1975 and 1985 — years after Agent Orange production had ceased — "there was insufficient data to evaluate fully the human health effects of such herbicide exposure." 1/22/2004 Defs.' Supp. Reply Br. in Opp. to Remand, Ex. 5 at 3 ¶ 8 (A1332). With the exception of chloracne, a condition not suffered by any of the plaintiffs, "the data available for human

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(… cont'd)

States, 26 Cl. Ct. 17, 24 (1992), both aff'd *sub nom. Hercules Inc.* v. *United States*, 24 F.3d 188 (Fed. Cir. 1994). The courts held that there remained issues of material fact in those cases as to whether the government knew more than the defendants did about the alleged risks of Agent Orange. *Hercules*, 25 Cl. Ct. at 622; *Thompson*, 26 Cl. Ct. at 24. Those findings, of course, shed no light as to whether there is an issue of fact about whether the ***contractors*** knew more than the ***government*** did. Moreover, on appeal in *Hercules*, the Federal Circuit, as noted above, denied recovery to the manufacturers precisely because the government contractor defense — the theory relevant to this case — ***would*** have been available to them. See *Hercules*, 24 F.3d at 198.

effects left the question as to whether there were such health effects inconclusive." *Ibid.*

Because of this lack of evidence, and especially in light of the fact that the third *Boyle* prong addresses facts "known" to the defendants, the conclusion of this Court in 1987 that "chemical companies *** could not have breached a duty to inform the government of hazards years earlier" (*In re "Agent Orange" Prod. Liab. Litig.*, 818 F.2d at 190) is no less true today. See also *ibid.* ("Even today, the weight of present scientific evidence does not establish that Agent Orange injured personnel in Vietnam, even with regard to chloracne and liver damage"); *id.* at 193 ("The most relevant question [in the 1960s] was, 'What will Agent Orange do to friendly personnel exposed to it?' The epidemiological studies ask the latter question in hindsight and answer, 'Nothing harmful so far as can be told'"). See also *Miller*, 275 F.3d at 421; *Hercules*, 24 F.3d at 198.

Nor is there any genuine issue of material fact as to the risks of which defendants ***were*** aware, even apart from their immateriality to the government's decision to purchase and use Agent Orange. It is clear that the manufacturers repeatedly informed the government of those hazards. Plaintiffs rely primarily on (i) deposition testimony from the 1980s, in which individual employees of various defendant companies state that they do not recall ***personally*** warning the government of dioxin, and (ii) internal memos expressing concerns about possible

domestic regulation of commercial herbicides. This evidence is insufficient to raise an issue of fact, in light of the substantial direct evidence that the manufacturers ***did*** warn the military — the branch of government that was using Agent Orange — and that the government already had that knowledge and more.

The record amply demonstrates the contractors' specific warnings to the government. The labels on domestically available herbicides warned of skin irritation; the military reviewed those labels and decided to forbid the defendants from placing them on the drums of herbicide that they produced for the government. See *supra* section I.B.1.A.ii. When Dow learned of the Weldon Spring project, moreover, it advised Edgewood Arsenal and representatives from the Office of the Secretary of Defense on four separate occasions of the association of chloracne with the 2,4,5-T manufacturing process. See 1983 Dow Summary Judgment Br., Exs. 120, 121, 122, 124 (A87-103).

In addition:

- Dr. Jerome Wiesner, a member of PSAC from approximately 1958 to 1966, testified that in a discussion following a meeting of the PSAC Panel on the Use of Pesticides, a Dow representative discussed the issue of a trace chemical called dioxin which could be produced during the 2,4,5-T manufacturing process. Wiesner Tr. 21-33 (A2106-2118).
- Dr. Herbert E. Stokinger, the Chief Toxicologist in the Public Health Service's Division of Occupational Health, testified that in 1965 or 1966, V.K. Rowe of Dow told him of a chloracne problem at Dow. Stokinger Tr. 77 (A2017a).

- Jane Lewis, of the Department of Commerce, who was involved in the procurement of Agent Orange for the military during the period between 1966 and 1968, testified that during that period an employee of Dow "informed me that Dow had a problem in its plant with chloracne." Lewis Tr. 65 (A1809d). She further testified that "the company had investigated the problem and had determined that it was caused by dioxin." *Ibid*.

- In addition, when medical organizations within the Army and Navy requested information from the National Academy of Sciences ("NAS") in the summer of 1966 about the toxicity of 2,4,5-T and 2,4-D, the NAS contacted Dow, which supplied such information, including information about chloracne and porphyria. 10/27/2004 Krohley Aff., Exs. 56-58 (A2509a-09i).

The military decided that these warnings had no relevance to deployment decisions. General Hebbeler testified that the information in the Dow letter "wouldn't trigger a great concern *** [because] [t]his is a production problem." Hebbeler Tr. 89 (A1703). Dr. Henry Wills, Chief of the Physiology Division in the Medical Research Laboratory at Edgewood, echoed this thought: the association between dioxin and chloracne "was not a significant fact. It's a significant fact for the manufacturer, but not for the Army. *** [T]he Army's purpose is to protect its own personnel who would not be involved in the manufacture." Wills Tr. 97-98 (A2129-30). When the government began planning its own production, the record makes clear that the defendants ***did*** warn of production risks. See pp. 57 *supra*.

These warnings — as to which plaintiffs present no contrary evidence — fully satisfy the third *Boyle* prong. The testimony of a few employees that they do

not ***personally*** recall giving warnings does not come close to establishing a jury question on this point, as it is hardly necessary that every knowledgeable person in a company personally relay warnings. Moreover, defendants made these warnings at the appropriate time. When the government indicated that it would become involved in production, they actively warned the government of production risks. Of course, the government already knew of those risks, even without warnings from the manufacturers, based on its own investigations beginning in the 1940s. See *supra* pp. 24-51.

b. The Government Knew More Than Defendants About the Potential Dangers of Agent Orange As It Was Used in Vietnam.

Regardless of what the defendants knew, the government contractor defense applies unless those facts were ***not known*** to the government. Here, the record leaves it beyond dispute that the government knew more, particularly with regard to the potential dangers of Agent Orange ***as it was used in Vietnam***. This Court has said as much. In 1987, this Court found that defendants satisfied even a more stringent pre-*Boyle* standard requiring that defendants warn of hazards of which they should have known as well as those of which they actually knew. *In re "Agent Orange" Prod. Liab. Litig.*, 818 F.2d at 190 ("We agree with the district

court that the information possessed by the government at pertinent times was as great as, or greater than, that possessed by the chemical companies").[36]

Plaintiffs' lengthy discussions of defendants' knowledge (Stephenson Br. 29-41; Anderson Br. 4-7) boil down simply to knowledge of chloracne and some liver disease among workers involved in the production of trichlorophenol (and other chlorophenols), identification (in 1965) of dioxin as the chloracnagen, and knowledge that dioxin would also be present in 2,4,5-T and Agent Orange. The government knew all of this, and more. Plaintiffs devote most of their attention to

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[36] The plaintiffs offer no evidence on relative knowledge that has not already been presented to this Court, with the exception of an affidavit from a single witness, Janet Weiss, who was hired simply to sift through and evaluate the record evidence. Dr. Weiss's assertions, discussed at Isaacson Br. 49-51, do not create an issue of material fact as to relative knowledge. To begin with, her affidavit is inadmissible. Dr. Weiss is an expert on "chemicals in the workplace"; her conclusions regarding the government's knowledge of dioxin risks do not apply her expertise, notwithstanding her bald assertion to the contrary. Weiss Dec. ¶ 10. Those conclusions, therefore, are not admissible under FED. R. EVID. 702.

In any event, Dr. Weiss's statements are also inadmissible because she merely supplants counsel in arguing plaintiffs' case. See *Lippe* v. *Bairnco Corp.*, 288 B.R. 678, 688 (S.D.N.Y. 2003); *LinkCo, Inc.* v. *Fujitsu Ltd.*, No. 00 Civ. 7242(SAS), 2002 WL 1585551, at *2 (S.D.N.Y. July 16, 2002).

Finally, Dr. Weiss's supposed expert conclusion is so devoid of reference to — and in fact flatly inconsistent with — the relevant facts that her affidavit alone cannot generate a jury question. (We also note that the second sentence ascribed to the Weiss affidavit by the Isaacson Br. (beginning "By contrast") does not appear in the affidavit itself. Compare Isaacson Br. 49 with Weiss Dec., PA3972-76.)

Dow (Stephenson Br. 30-37), but as we have shown, not only did the government know everything Dow knew, but Dow disclosed what it knew to the government.

Plaintiffs also focus on knowledge Monsanto obtained as the result of an accident in its manufacturing operations in 1949. Stephenson Br. 37-39. This incident and its effects on Monsanto workers were, however, investigated by the Public Health Service, which published an article by Dr. Donald Birmingham in 1959 addressing the Monsanto accident. Plaintiffs also quote a report from Monsanto's medical director that states, "Very conceivably, [dioxin] can be a potent carcinogen." *Id.* at 34. This statement is, on its face, pure speculation, and the Bionetics Report did not find 2,4,5-T to be carcinogenic.

Similarly, plaintiffs refer to Diamond's experience with "chloracne and liver problems in its workforce, including a major industrial incident." Stephenson Br. 39-40. However, Drs. Birmingham and Key of the Public Health Service investigated cases of chloracne and liver disease among Diamond workers, and an article on the subject by Dr. Joseph Bleiberg was published in 1964.[37]

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[37] Plaintiffs also refer to production incidents involving Thompson Chemical Company (Stephenson Br. 40), but this company is no longer in operation and is not a party to these actions. (It was a different company from Thompson Hayward Chemical Co., which is a party.)

Finally, plaintiffs refer to testing by Hercules of 2,4,5-T on rabbits, showing that it could produce chloracne (folliculitis) and liver damage (Stephenson Br. 40-41), but the government knew of chloracne and liver damage.

Plaintiffs similarly refer to statements to the effect that dioxin was "one of the most toxic materials known." Stephenson Br. 41. But the government referred to dioxin in similar terms. For example, the 1959 Hoffmann trip report describes "startling information regarding the toxicity" of dioxin, including speculation that it "caused the death of several workers" in a plant that made a wood preservative. Mr. Vocci of Edgewood testified that Edgewood screened dioxin as a potential chemical warfare agent but concluded it was "extremely toxic" or "too toxic" to be of interest. Vocci Tr. 184 (A2088). Finally, plaintiffs' citation to a few government documents that refer to Agent Orange without mentioning dioxin (see Anderson Br. 7-8) obviously does not create a material issue of fact in the light of the overwhelming evidence of government knowledge of the presence of minute quantities of dioxin in Agent Orange and of dioxin's connection to chloracne.

Agencies including the Army Chemical Corps at Edgewood Arsenal, the President's Science Advisory Committee, the Air Force Environmental Health Laboratory, the Army Surgeon General, the Navy Bureau of Medicine and Surgery, the National Cancer Institute, the U.S. Public Health Service, and the National Academy of Sciences studied potential health hazards associated with either Agent Orange or its component herbicides. The government also commissioned an unprecedented study by Bionetics Research Laboratories of the long-term effects of pesticides, including 2,4,5-T. All of this extensive research

establishes the government's knowledge of any dangers associated with Agent Orange; there can be no genuine dispute of material fact on this point. Of equal importance is the fact that the most significant research on the health effects of defoliants was conducted by the government and was non-public; in particular, the defendants did not receive the Bionetics report until it was released to the public in late 1969, and the defoliation campaign ended almost immediately thereafter. The defendants did not learn of the secret Hoffmann trip report until it was produced in this litigation. See pp. 33-34 *supra*.

Boyle imposes a duty to warn only of "dangers *** known to the supplier ***but not to the United States***." *Boyle*, 487 U.S. at 512.[38] Given the extensive government knowledge about the effect of highly concentrated defoliants in Vietnam, there was no such duty here. See *Lewis*, 985 F.2d at 89-90 ("There is no requirement that appellees inform the Air Force of dangers already known to the Air Force"); *Ramey* v. *Martin-Baker Aircraft Co.*, 874 F.2d 946 (4th Cir. 1989); *Stout*, 933 F.2d at 336-37.

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[38] Plaintiffs ignore this key limitation in their discussion of *Trevino* v. *General Dynamics Corp.*, 865 F.2d 1474, 1482 (5th Cir. 1989) (cited in Stephenson Br. 50). *Trevino* concluded that "[a]fter *Boyle*, a government contractor only has the duty to warn the government of dangers of which it has knowledge but the government does not." *Id.* at 1487.

In asserting that *Boyle* requires contractors to tell the government what the government already knows, plaintiffs ignore the clear language of *Boyle* and misconstrue the case law. *Densberger* v. *United Technologies Corp.*, 297 F.3d 66 (2d Cir. 2002), does not require contractors to warn "*even if those risks were already known to the government,* as long as the contractor was unaware that the government had the information," as Stephenson claims. Br. 51 (emphasis in original). In *Densberger*, this Court speculated that a jury might find causation based on a failure to warn of a danger of which the government already knew. 297 F.3d at 73 n.9 ("UTC's warning might have led the army to say, 'Gee, if this danger (of which we're already aware) is important enough so that UTC decided to warn us of it, we'd better let the pilots know about it too.'"). This statement was made in regard to a jury charge on the issue of negligence, not the government contractor defense. In the latter context, the Supreme Court has left no doubt that contractors must warn only of "the dangers *** that were known to the supplier but not to the United States." *Boyle*, 487 U.S. at 512. *Carley* v. *Wheeled Coach*, 991 F.2d 1117 (3d Cir. 1993), held that the district court could not take ***judicial notice*** of the government's knowledge. Without judicial notice to rely on, the contractor argued "that its satisfaction of the first two prongs of the defense also satisfies the third prong"; it was that argument that the court rejected. *Id.* at 1127.

The plaintiffs most seriously mangle the holding of *Gonzalez* v. *Digital Equipment Corp.*, 8 F. Supp. 2d 194 (E.D.N.Y. 1998), a product liability case brought by an ordinary consumer, in which the court held a manufacturer to an expert standard of care. See *id.* at 198. That case says nothing about the duty to warn under *Boyle*.

c. The Court Need Not Stretch the Law of Imputation of Knowledge to Find the Third Prong Satisfied in This Case.

Plaintiffs contend that "Defendants Attempt To Overcome the Gross Disparity in Knowledge by Imputing the Knowledge of Others in Distant Departments to the Actual Contracting and Specifying Officers." Stephenson Br. 52. Ignoring the massive evidence in the record of pervasive government knowledge, plaintiffs repeatedly assert that "the people who selected, procured, and contracted with the Defendants for 2,4,5-T" (Stephenson Br. 52; see also Bauer Br. 37-38) did not have such knowledge. Thus, plaintiffs accuse the district court of "ignor[ing] the contracting officials' ignorance of information that was rudimentary to the chemical companies, and, instead, strain[ing] to impute knowledge to them by concentrating on others with whom they had little or no contact." Stephenson Br. 53. Plaintiffs further assert that "Defendants proffered a complicated web of circumstantial evidence consisting of fragmentary knowledge

in the hands of government personnel, none of whom were involved in either the selection of Defendants' products or their contract specifications." Bauer Br. 60.

Plaintiffs simply have it wrong. The individuals who decided to use Agent Orange in Vietnam were at the highest levels of government, including the President. See *In re "Agent Orange" Prod. Liab. Litig.*, 818 F.2d. at 198 ("The ultimate policy decision to use Agent Orange was made by President Kennedy."). Top government officials were advised by the military that the use of Agent Orange would save American lives. At the request of President Kennedy, the military concluded, based on an extensive investigation by its top scientists, that Agent Orange, as the military intended to use it in Vietnam, would not harm those exposed to it. PSAC's world-class scientists concurred in that assessment. The contracting officers were merely implementing this high-level strategic decision. Given that the scientists who studied the matter, including those who advised the President, were aware that Agent Orange contained dioxin and concluded that it was safe, the knowledge of contracting officers is not controlling.

Finally, plaintiffs contend that the warning prong may not be satisfied by imputing the knowledge of "Distant Departments" to the contracting officers. See Stephenson Br. 52. The government knowledge on which defendants rely was passed directly from the Edgewood scientists who conducted the research to President's top science advisors; the relationship was hardly distant. Moreover,

imputation of knowledge among government agencies is appropriate where, as here, that knowledge pervades the government.

As Judge Weinstein pointed out in an earlier phase of this litigation, the Restatement (Second) of Agency allows imputation of an agent's knowledge to the principal when the agent has a duty to transmit the information to the principal. *In re "Agent Orange" Prod. Liab. Litig.*, 597 F. Supp. 740, 796 (E.D.N.Y. 1984) (quoting RESTATEMENT (SECOND) OF AGENCY § 272). Thus, the knowledge of government scientists, as the government's agents, is imputed to the government as a whole, and, in particular, the knowledge of military herbicide researchers is imputed to the Department of Defense in the context of decisions about the use of defoliants. The court went on to find the requisite relationship as to knowledge of Agent Orange's alleged hazards. *Ibid.*

The Fifth Circuit also concluded that imputation is appropriate where knowledge is as widespread within the government as it was in this case. See *Miller*, 275 F.3d at 422-23 (finding "pervasive institutional knowledge" within "United States Public Health Service, the Army Chemical Corps Chemical Warfare Laboratories, the President's Science Advisory Committee, the National Academy of Sciences, the Office of the Army Surgeon General, the Navy's Bureau of Medicine and Surgery, and the Advanced Research Project Agency of the Department of Defense"). Of course, such imputation is not necessary in this case,

because the Edgewood scientists not only bore a ***duty*** to inform their superiors; documentary evidence proves that they did so ***in fact***.

The cases plaintiffs cite in this context involve inter-agency relationships and types of information wholly unlike those at issue here. The defendant in *Mason* v. *Texaco, Inc.*, 741 F. Supp. 1472 (D. Kan. 1990), for example, asked the court to impute knowledge to the Coast Guard "simply because the Coast Guard's manager of industrial hygiene was a member of" an association of government hygienists and thereby had access to certain documents. Stephenson Br. 54. By contrast, the present defendants do not rely on the government's mere access to information, but rather on its undisputed actual knowledge, which resulted from studies undertaken to answer the precise question of whether defoliants used in Vietnam posed a health risk to exposed military personnel and civilians. Edgewood personnel, for example, not only had access to the USDA's Central Toxicity Files; deposition and documentary evidence proves that they did in fact review those files.[39]

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[39] *Bateson-Stolte, Inc.* v. *United States*, 172 F. Supp. 454 (Ct. Cl. 1959), is likewise inapposite. There, a contractor sued the Army Corps of Engineers for failing to notify it that the Atomic Energy Commission ("AEC") was building a facility in the area. That development drained the local labor supply, raising the contractor's labor costs after it had bid on the Corps contract. *Id.* at 455. The Court of Claims declined to hold the Corps of Engineers liable for failing to notify the contractor of the AEC's project. *Id*. at 457.

Defendants' imputation argument, to the extent it is necessary at all, does not simply assume that every single government agency knew everything that any other agency did, but rather that closely linked officers engaged in a mutual venture to assess the potential toxicity of Agent Orange shared information in which there was a common interest. When the government orders its agencies to study a problem related to a specific product, the government has knowledge of the results of those studies — that inference is especially reasonable where the product in question is the linchpin of a major military campaign and has received attention from a host of officers ranging from the President on down.[40]

4. Summary Judgment Is Appropriate Notwithstanding That a Small Number of Contracts Remain Missing

Plaintiff Bauer argues that summary judgment is inappropriate as to the small number of contracts that the defendants have not been able to locate decades after their signing. Bauer Br. 41-42. As Judge Weinstein noted, "[t]his is to be expected in this by now ancient case. It does not matter since the contracts and other documents are repetitive and redundant. The product of each of the manufacturers was mixed and expended in such a way that makes it impossible to

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[40] *United States* v. *Weinstein*, 1990 U.S. Dist. LEXIS 61 (E.D.N.Y.), cited at Stephenson Br. 55, provides a good example of the opposite type of product. There, the court refused to impute to the Coast Guard the knowledge that the Department of Defense had, after inspection, rejected a particular shipment of chemical protective suits.

now determine whose Agent Orange actually touched which plaintiff when, if at all." *Isaacson*, 304 F. Supp. 2d at 426.

These missing contracts do not create any issue of material fact. It would be ludicrous to conclude that, while every other shipment of defoliant was produced and sold pursuant to contracts that incorporated detailed specifications, defendants manufactured these few shipments according to their own whim, without direction from the government. Moreover, to survive summary judgment on those shipments alone, the *Bauer* plaintiffs, none of whom served in Vietnam until 1967, would have to prove causation of harm from defoliants made pursuant to those particular contracts, none of which, in Dow's case for example, was signed after 1965. See Bauer Br. 43. They have made no effort to even suggest such causation. As such, this Court should affirm the grant of summary judgment as to all shipments. Accord *Skyline Air Serv., Inc.* v. *G.L. Capps Co.*, 916 F.2d 977, 979 (5th Cir. 1990) (affirming summary judgment on government contractor defense for unproduced contract); *Smith* v. *Xerox Corp.*, 866 F.2d 135, 137-38 (5th Cir. 1989) (same).

II. THESE SUITS ARE FORECLOSED BY THE 1984 CLASS ACTION SETTLEMENT.

The 1984 Agent Orange class action settlement covered "those persons who were in the United States, New Zealand or Australian Armed Forces at any time from 1961 to 1972 who were injured while in or near Vietnam by exposure to

Agent Orange or other phenoxy herbicides." *In re "Agent Orange" Prod. Liab. Litig.*, 100 F.R.D. 718, 729 (E.D.N.Y. 1983). The class "specifically include[d] persons" — such as the current plaintiffs — "who ha[d] not yet manifested injury" at the time of the settlement. *In re "Agent Orange" Prod. Liab. Litig.*, 597 F. Supp. at 865; see also *Ryan*, 781 F. Supp. at 920 (holding plaintiffs with later-manifested injuries bound by settlement), aff'd *sub nom. Ivy* v. *Diamond Shamrock Chem. Co.*, 996 F.2d 1425 (2d Cir. 1993). This Court held, however, that veterans whose injuries did not manifest themselves until 1995 or later had not been adequately represented by class counsel and were not foreclosed by the settlement from pursuing their claims in independent litigation. *Stephenson* v. *Dow Chem. Co.*, 273 F.3d 249 (2d Cir. 2001). The Supreme Court, in a non-precedential ruling, affirmed by an equally divided Court. *Dow Chem. Co.* v. *Stephenson*, 539 U.S. 111 (2003).

Defendants continue to maintain the position that all veteran claims are barred by the settlement. We recognize that this panel is bound by the ruling of the earlier panel, but we reserve the right to seek reconsideration of that ruling before the en banc Court or the Supreme Court.

CONCLUSION

For all of the foregoing reasons, this Court should affirm the order below granting summary judgment in these cases.

May 10, 2006

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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a)(7)(C), I hereby certify that this brief was produced in Times New Roman (a proportionally-spaced typeface), 14-point type and contains 32,533 words (based on the Microsoft Word word processing system word count function). This Court granted leave to file an oversized brief of up to 33,000 words.

I further certify that the electronic copy of this brief filed with the Court is identical in all respects except the signature to the hard copy filed with the Court, and that a virus check was performed on the electronic version using the Norton Anti-Virus software program.

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UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

In re "Agent Orange" Product Liability Litigation	:	**MDL No. 381**
	:	Nos. 05-1760-CV; 05-1693-CV; 05-1694-CV; 05-1695-CV; 05-1696-CV; 05-1698-CV; 05-1700-CV; 05-1737-CV; 05-1771-CV; 05-1810-CV; 05-1813-CV; 05-1820-CV; 05-2450-CV; 05-2451-CV; 05-1817-CV
	:	

CERTIFICATE OF SERVICE

I, Andrew L. Frey, a member of the Bar of this Court, hereby certify that on Wednesday, May 10, 2006, I caused to be served upon each counsel of record for Appellants two copies of the Brief for Defendants-Appellees on the Government Contractor Defense via first-class mail to the addresses that appear on the following service list.

I further caused the document to be served today via electronic mail on each counsel of record for Appellants who has a functioning e-mail address, as identified in the following service list.

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