# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

WILLIAM WHITE, et al.,

:

Plaintiffs,

:

V.

: Civil Action No. 79-1426 (JR)

:

R. JAMES NICHOLSON, Secretary of :

Veterans Affairs,

:

Defendant.

#### **MEMORANDUM**

This case, pending in this Court since 1979, concerns an Agent Orange Program Guide that was issued by the Veteran's Administration in 1978 and remained in effect until 1985.

Plaintiffs' contention is that the VA adopted the AOPG in violation of the notice and comment requirements of the Administrative Procedure Act, 5 U.S.C. § 553, and the publication requirement of the Freedom of Information Act, 5 U.S.C. § 552(a)(1). Because I have concluded that the AOPG did not announce a binding, substantive rule, summary judgment will be granted to the defendant.

# Background

#### A. Regulatory Framework

Although the statutory and regulatory framework has changed over the nearly three decades in which this suit has been pending, the basic entitlement of veterans to benefits for service-connected disabilities has not. The VA regulation setting out "principles relating to service connection" is found

at 38 C.F.R. § 3.303 and has been in effect without substantive change since 1961. Section 3.303(a) provides that service connection can be established in two ways, 1) through "the application of statutory presumptions", or 2) by "affirmatively showing inception or aggravation [of a disease or injury] during service[.]" The first route is known as presumptive service connection and the second as direct service connection. At the time this suit was filed, disabilities stemming from a defined and limited number of conditions, including leukemia, Hodgkin's disease, and malignant tumors, were presumptively service connected if diagnosed within a year after active service. U.S.C. § 312 (1979) (amended by P.L. 102-83, § 5(a), 105 Stat. 406 (1991), and transferred to 38 U.S.C. § 1112). For enumerated diseases diagnosed more than a year after the end of active service, and for all other diseases that were not the subject of a statutory presumption, Section 3.303(d) provided that "[s]ervice connection may be granted for any disease diagnosed after discharge, when all the evidence, including that pertinent to service, establishes that the disease was incurred in service." See also 38 C.F.R. § 3.304 (listing direct service connection requirements). Reasonable doubt was resolved in favor of the veteran, but, under regulations that were in effect during the same period as the AOPG, "the claimant [was] required to submit evidence sufficient to justify a belief in a fair and

impartial mind that his claim is well grounded." 38 C.F.R. \$ 3.102 (1984).

#### B. History of Agent Orange Compensation

The Agent Orange Program Guide, in effect from

April 17, 1978, until September 25, 1985, was issued by the VA,

without public notice or comment, as a one-page amendment to the

VA's Compensation and Pension Program Guide (PG 21-1), a resource

designed for use by agency adjudicators. [Dkt. 33]. The forward

to PG 21-1, written in 1963, states: "It should be understood

that program guides are non-directive and non-policymaking. They

are obviously superseded by instructions, technical bulletins,

regulations, or other authoritative issues at variance[] on the

same subject matter." [Dkt. 26, Ex. 1]. The relevant portion of

the AOPG, titled "Rating Practices and Procedures - Disability 
Vietnam Defoliant Exposure," states:

Claims for service-connected disability benefits are being received from veterans who claim disability incurred through or aggravated by exposure to defoliants used during the Vietnam War.

Except for a skin condition known as chloracne, there are presently no firm data to incriminate the herbicides as causative agents of any other known category of disease or chronic symptom. However, a contaminant Dioxin, found in small quantities in defoliants is toxic.

No special procedures will be initiated for these claims. Instead, each case will receive a thorough development of all available evidence. This will include a request to both the veteran and the service department to furnish verification of exposure to herbicides, the extent and durations thereof and the dates on which such exposure occurred.

All other required development will be done concurrently with the request for verification of exposure to defoliants, and each case will be extended the same consideration given any other claim for service connection.

[Dkt. 23, Ex. A]. These provisions for "rating practices and procedures," in plaintiffs' submission, amounted to the announcement of a rule that required VA adjudicators to deny Agent Orange claims for diseases other than chloracne. Their argument focuses on a single sentence - "Except for a skin condition known as chloracne, there are presently no firm data to incriminate the herbicides as causative agents of any other known category of disease or chronic symptom" - and on the fact that, while the AOPG was in effect, agency adjudicators denied every single Agent Orange-related claim that was for a disease or condition other than chloracne. [Dkt. 27 at 6].

Plaintiffs' suit had been pending here for nearly five years when Congress enacted the Veterans' Dioxin and Radiation Exposure Compensation Standards Act, Pub. L. No. 98-542, 98 Stat. 2725 (Oct. 24, 1984) ("Dioxin Act"). That statute required the VA to create an advisory committee of scientists, and, after receiving the committee's advice, to promulgate regulations based on "sound scientific and medical evidence" identifying diseases

that should be deemed presumptively service connected. 38 U.S.C. § 354(3)(1984). Pursuant to the Dioxin Act, on August 26, 1985, the VA promulgated a final regulation that went into effect in September 1985. 50 Fed. Reg. 34,452, 34,458 (Aug. 26, 1985) (codified at 38 C.F.R. § 3.311a (1985)). In that regulation, the VA authorized presumptive service connection only for chloracne. See Williams v. Principi, 15 Vet. App. 189, 192 (2001) (discussing history of Agent Orange compensation). In 1989, the U.S. District Court for the Northern District of California invalidated the regulation, holding the VA had acted contrary to the Dioxin Act in requiring more evidence than statistical correlation to establish the causal relationship needed for a disease to be the subject of presumptive service connection. Nehmer v. United States Veterans Admin., 712 F. Supp. 1404, 1418 (N.D. Cal. 1989). The Nehmer litigation, brought as a class action, required the VA to conduct a new rulemaking and voided all denials issued from 1985 until 1989 that had been based on the invalidated regulation.

In 1991, Congress disbanded the VA's internal scientific advisory committee and instead required the VA to work with the National Academy of Sciences in promulgating new Agent Orange regulations. See 38 U.S.C. § 1116(b). Since then, the VA has issued many liberalizing regulations that presumptively

service connect numerous diseases to Agent Orange exposure. See  $38 \text{ C.F.R.} \S 3.309 \text{ (e)}$  .

#### C. Procedural History

The complaint in this case was filed on May 31, 1979. On August 31, 1979, the plaintiffs filed a motion for class certification, and, on December 3, 1979, they filed a motion for summary judgment. Later that month, on December 28, the government moved for judgment on the pleadings. Oral argument was heard in February 1980. In 1984, following passage of the Dioxin Act, the government filed a motion to dismiss the case as moot. All four motions remain unresolved. The case was reassigned to me on October 25, 2007.

The parties have long acknowledged that the withdrawal of the AOPG in 1985 mooted plaintiffs' primary request that the Court order the VA to conduct a public rulemaking on Agent Orange-related disability. Based on their contention that the AOPG was issued in violation of FOIA's publication requirement and the APA's notice and comment provisions, plaintiffs still seek class certification and an order voiding Agent Orange denials issued by the VA from April 1978 until September 1985.

In the numerous rounds of supplemental briefing that have taken place, the government has submitted and relied on materials outside of the pleadings, including decisions of the Board of Veterans Appeals and a number of declarations. The

government's Rule 12(c) motion for judgment on the pleadings is accordingly treated as a motion for summary judgment. See Fed. R. Civ. P. 12(d); Yates v. District of Columbia, 324 F.3d 724, 725 (D.C. Cir. 2003).

## <u>Analysis</u>

# A. Requirements for Notice and Comment Rulemaking

"Under 5 U.S.C. § 553, an agency seeking to promulgate a rule must first provide the public with notice of, and an opportunity to comment upon, a proposed version of it." Chamber of Commerce v. U.S. Dept. of Labor, 174 F.3d 206, 211 (D.C. Cir. 1999). Such rules must be published in the federal register pursuant to the Freedom of Information Act. 5 U.S.C. § 552(a)(1). Notice and comment rulemaking is not required for "rules of agency . . . procedure" and "general statements of policy." 5 U.S.C. § 553(b)(3)(A).<sup>2</sup>

<sup>&</sup>lt;sup>1</sup> Rule 12(d) may be read as requiring advance notice of a court's intention to treat a motion filed under Rule 12(c) as a motion under Rule 56. The "instant" motion was filed 28 years ago, however, and I find that the parties have been given "reasonable opportunity to present all the material that is pertinent to the motion."

Policy statements "must either be published in the federal register or made available for public inspection and copying."

<u>Building Indus. Ass'n v. Babbitt</u>, 979 F. Supp. 893, 904-05

(D.D.C. 1997) (citing 5 U.S.C. §§ 552(a)(1)(D) and (a)(2)(B)).

The AOPG was indexed and made available for public inspection and copying. [Dkt. 40, Ex. 4]. It was also distributed to all congressionally-chartered and VA-recognized veterans' service organizations. [Dkt. 16, Ex. 1].

The government's position is that the AOPG "was not a substantive rule subject to the rulemaking requirements of the APA." [Dkt. 33 at 1]. It maintains that the AOPG, including what the plaintiffs' characterize as its 'nothing-but-chloracne' statement, was "informational, designed to inform agency employees of the existing state of factual knowledge and, to a lesser extent, the state of the law." [Dkt. 22 at 24]. All the Program Guide did, according to the government, was "advise[] the agency adjudicative personnel that, except for chloracne, the state of medical knowledge does not permit a general assumption that exposure to herbicides may result in disabilities many years later." Id. at 25.

In much of their briefing, the plaintiffs characterize the defendants' position as arguing that the Program Guide "amounts to a procedural rule." [Dkt. 52 at n.2]. Framing the issue in that way has some interest value, but it assumes the answer to the real question presented here, which is whether the Program Guide is, or contains, a rule at all. (If it is a rule, or contains one, there is nothing procedural about it. See

<sup>3 &</sup>quot;Substantive rules are ones which grant rights, impose obligations, or produce other significant effects on private interests." American Hospital Assoc. v. Bowen, 834 F.2d 1037, 1045 (D.C. Cir. 1987). A procedural rule "does not itself 'alter the rights or interest of parties, although it may alter the manner in which the parties present themselves or their viewpoints to the agency.'" Chamber of Commerce v. U.S. Dep't of Labor, 174 F.3d 206, 211 (D.C. Cir. 1999) (quoting Batterton v. Marshall, 648 F.2d 694, 707 (D.C. Cir. 1980)).

<u>Batterton</u>, 648 F.2d at 707 (explaining that procedural rules deal with the manner in which agencies "organiz[e] their internal operations").)

The AOPG's pronouncement on chloracne was either a substantive rule or a general statement of policy. "The primary distinction between a substantive rule - really any rule - and a general statement of policy [] turns on whether an agency intends to bind itself to a particular legal position." Syncor Int'l Corp. v. Shalala, 127 F.3d 90, 97 (D.C. Cir. 1997). The Court of Appeals has elaborated on the distinction as follows:

The critical distinction between a substantive rule and a general statement of policy is the different practical effect that these two types of pronouncements have in subsequent proceedings. . . A properly adopted substantive rule establishes a standard of conduct which has the force of law. . . .

A general statement of policy, on the other hand, does not establish a "binding norm." It is not finally determinative of the issues or rights to which it is addressed. . . . A policy statement announces the agency's tentative intentions for the future.

Pac. Gas & Elec. Co. v. Fed. Power Comm'n, 506 F.2d 33, 38 (D.C. Cir. 1974). So long as an agency pronouncement "leaves the administrator free to exercise his informed discretion," it will not be "deemed a binding regulation merely because it may have some substantive impact[.]" Panhandle Producers & Royalty Owners

Ass'n v. Economic Regulatory Admin., 822 F.2d 1105, 1110 (D.C. Cir. 1987) (internal citation and quotation marks omitted).

There is no simple "axiom to distinguish between regulations and general statements of policy." Brock v.

Cathedral Bluffs Shale Oil Co., 796 F.2d 533, 536-37 (D.C. Cir. 1986). At the outset, courts are to give "some, albeit 'not overwhelming,' deference to an agency's characterization of its statement." Cmty. Nutrition Inst. v. Young, 818 F.2d 943, 946 (D.C. Cir. 1987) (quoting Brock, 796 F.2d at 537). Far more important, however, is "the language actually used by the agency." Id.

## B. Did the AOPG Establish a Substantive Rule?

Neither the language nor the context of the AOPG suggests that it was intended to establish a binding rule of decision. The sentence that plaintiffs rely upon contains no directive language indicative of a binding norm. It is tentative and self-qualifying: that there are "presently no firm data" does not bind agency adjudicators to take a particular position in each case before them, but instead allows for evolution in the state of medical understanding on Agent Orange and disease causation. The next sentence seems to anticipate such developments: "However, a contaminant Dioxin, found in small quantities in defoliants is toxic." The paragraphs that follow

make clear that, on its face, the text of the rule did not change the substantive framework for demonstrating service connection:

No special procedures will be initiated for these claims. Instead, each case will receive a thorough development of all available evidence. This will include a request to both the veteran and the service department to furnish verification of exposure to herbicides, the extent and duration thereof and the dates on which such exposure occurred.

All other required development will be done concurrently with the request for verification of exposure to defoliants, and each case will be extended the same consideration given any other claim for service connection.

The Guide closes by encouraging adjudicators to flag close cases rather than deny them outright. Its final sentence reads: "There should be no hesitancy in submitting cases, appearing to have merit, but not meeting current criteria for service connection, to the Compensation and Pension Service for advisory opinion."

If this case turned only on the language of the Program Guide and its context (appearing as the two-hundred and fifty-ninth insert to a "non-directive and non-policymaking" manual), the result here would be indisputable. On its face, the Program Guide does not establish a binding, automatic rule of decision.

Compare Appalachian Power Co. v. EPA, 208 F.3d 1015, 1023 (D.C. Cir. 2000) ("[T]he entire Guidance, from beginning to end . . . reads like a ukase. It commands, it requires, it orders, it dictates.").

The language of the Program Guide does not end the inquiry, however, because "an agency pronouncement will be considered binding as a practical matter if it either appears on its face to be binding, or is applied by the agency in a way that indicates it is binding." General Electric Co. v EPA, 290 F.3d 377, 383 (D.C. Cir. 2002) (internal citation omitted); see also Bowen, 834 F.2d at 1057 n.4 (an agency pronouncement "initially classed as a general statement [of policy] is not immunized from subsequent judicial review for conformity with the APA if later developments show the agency to be using it as binding policy"); Cmty. Nutrition, 818 F.2d at 949 (notice-and-comment required because the FDA, "by virtue of its own course of conduct", gave action levels a "present, binding effect"). The passage of time in this case has allowed for the development of a record that raises serious questions about the practical effect that the AOPG had on actual adjudications.

Plaintiffs' position, that the AOPG was void from its inception because of the VA's failure to publish it in the Federal Register and to utilize notice and comment procedures, relies heavily on what they characterize as one-hundred percent conformance to the "rule of the Program Guide." See Dkt. 52 at 3 ("This perfect application of the Program Guide is crucial evidence that the Program Guide is a substantive rule[.]").

Uniformity of outcome alone, however, does not show that the AOPG

was applied as binding. Both sides have submitted a number of decisions by the Board of Veterans Appeals. [Dkt. 45, Dkt. 46, Dkt. 52]. These decisions do not prove that the Board was effectively precluded from finding that a disease other than chloracne was caused by Agent Orange. The decisions generally follow a similar format: in separate sections, the Board lists the claimant's contentions (e.g., the condition(s) for which he seeks benefits), the evidence presented by the claimant, and the applicable "law and regulations." See Dkt. 52, Ex. D, E, & F. But plaintiffs have not submitted a single decision in which the Board cites or directly refers to the AOPG.4

According to the plaintiffs, the binding effect of the Program Guide is demonstrated by the presence of the following language, which they assert is found in the discussion and evaluation section of a large percentage of the decisions that denied service connection:

[T]he Veterans Administration, on its own, as well as by coordinated efforts with other governmental agencies, . . . is undertaking intensive study and review regarding possible health-related effects of reputed exposure to chemical defoliants, including Agent Orange. To date, there is no evidence to link any of the veteran's claimed disorders with reputed exposure to Agent Orange. (Presently, the only known organic disease entity associated

<sup>&</sup>lt;sup>4</sup> Plaintiffs did submit an affidavit stating that in a review of 665 decisions, the Program Guide was referenced by name in 13 of them, see Pls.' Mot. for Sum. Jgmt., Ex. A, but the full context is unknown.

with exposure to chemical defoliants is chloracne . . . However, the veteran's complaints and history of exposure to chemical defoliants have been entered into the Agent Orange Registry Data Base. His interests are, therefore, noted and protected, vis-à-vis Agent Orange allegations; and, should studies conducted by the Veterans Administration or interagency studies conducted outside of the Veterans Administration establish a link between exposure to chemical defoliants and disabilities in the nature of those claimed by the veteran, his claim may be reopened and reevaluated at such future time.

[Dkt. 52, Ex. A at  $\P$  12]. Without a doubt, some of this language - "presently, the only known organic disease entity associated with exposure to chemical defoliants is chloracne" echoes the sentence that plaintiffs focus on in the Program Guide. However, that adjudicators ultimately adopted the position laid out in AOPG does not prove that they were required to do so, regardless of the evidence presented in the case at hand. Plaintiffs do not arque that there are specific decisions in which the claimant presented medical and scientific evidence sufficient to make out direct service connection, only to have that evidence rejected because of the "rule" set out in the Program Guide. Such decisions, had they been put forward, would tend to show that agency adjudicators lacked the ability to exercise their informed discretion. Absent such a showing, there is insufficient basis on which to find that the Program Guide announced a binding rule of decision.

Nor is binding application of the Program Guide by VA adjudicators the only possible explanation for veterans' complete lack of success on Agent Orange claims for diseases other than chloracne from 1979 to 1985. When the AOPG was in effect, veterans making Agent Orange claims could only receive benefits under direct service connection principles, which require a claimant to "establish[] direct actual causation." Combee v. Brown, 34 F.3d 1039, 1044 (Fed. Cir. 1994). In cases of disability from a chronic disease manifested years after the claimant's active service, "[a]ctual causation carries a very difficult burden of proof." Id. at 1042. For Agent Orange claims, that difficulty was compounded by what Congress recognized in 1984 as the "scientific and medical uncertainty" regarding the long-term health effects of dioxin exposure. U.S.C.  $\S$  354(2)(1984). That uncertainty, and the resulting difficulty of establishing actual causation for diseases other than chloracne, was what motivated passage of the Dioxin Act in 1984. See 130 Cong. Rec. 13154-55 (1984) (statement of Sen. Specter) ("The Federal Government has imposed an impossible burden of proof on . . . Vietnam Veterans to establish service connection for their injuries."); 130 Cong. Rec. at 13169 (statement of Sen. Byrd) ("[The Dioxin Act] simply corrects what I understand have been on occasion overly onerous burdens of proof."). The 1984 Act required the VA to conduct a rulemaking

to determine which diseases should <u>thereafter</u> be regarded as presumptively service connected on the basis of a significant statistical correlation. 38 U.S.C. § 354(5) (1984); <u>Nehmer</u>, 712 F. Supp. at 1418. Today, after enactment of the Dioxin Act and subsequent regulations, a veteran may establish that his disability is service-connected to Agent Orange exposure either directly or presumptively. At the time that the AOPG was in effect, the only route open to veterans was direct service connection.

#### Conclusion

The plaintiffs have not shown that the denial of Agent Orange disability claims for diseases other than chloracne resulted from the constraining effect of the Agent Orange Program Guide itself, rather than from the onerous burden of proof that they bore under direct service connection principles. Although the problem took years to be addressed and righted, Congress, the courts, and the VA itself gradually cleared the way for veterans affected by Agent Orange exposure to receive benefits under the far more permissive route of presumptive service connection.

Veterans whose claims were denied while the AOPG was in effect have been free to refile their claims, and to receive forward-looking compensation under liberalizing regulations promulgated since then. 38 U.S.C. § 5110(g); 38 C.F.R. § 3.400. In sum, the statutory and regulatory framework for Agent Orange-related

disability claims has evolved and improved considerably from the time that this case was filed. The Court is unable to grant plaintiffs further relief pursuant to either the APA or to FOIA.

An appropriate order accompanies this memorandum.

JAMES ROBERTSON
United States District Judge