

United States Court of Appeals
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued February 2, 1995 Decided April 25, 1995

No. 93-5404

THE AMERICAN LEGION,
APPELLANT

v.

EDWARD DERWINSKI, SECRETARY, DEPARTMENT OF
VETERANS AFFAIRS;
DONNA E. SHALALA, SECRETARY, DEPARTMENT OF HEALTH AND
HUMAN SERVICES;
WILLIAM L. ROPER, M.D., DIRECTOR, CENTERS FOR
DISEASE CONTROL;
VERNON N. HOUK, DIRECTOR, CENTER FOR ENVIRONMENTAL
HEALTH AND INJURY CONTROL CENTER;
UNITED STATES OF AMERICA,
APPELLEES
and Consolidated Case No. 94-5013

VIETNAM VETERANS OF AMERICA;
HAROLD A. BUTLER; CAROL RIDOLFI-DELANEY;
MAREL J. MACKI; BEVERLY NEHMER,
APPELLANTS

v.

EDWARD DERWINSKI, SECRETARY, DEPARTMENT OF
VETERANS AFFAIRS;
DONNA E. SHALALA, SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES;
WILLIAM L. ROPER, M.D., DIRECTOR, CENTERS FOR
DISEASE CONTROL;
VERNON N. HOUK, DIRECTOR, CENTER FOR ENVIRONMENTAL
HEALTH AND INJURY CONTROL CENTER;
UNITED STATES OF AMERICA,
APPELLEES

Appeals from the United States District Court
for the District of Columbia
(90cv1808)

Gershon M. Ratner argued the cause for appellants. With him on the briefs were *Mark A. Venuti* and *Ron Simon*. *Barton F. Stichman* entered an appearance for appellants.

Jonathan R. Siegel, Attorney, United States Department of Justice, argued the cause for appellees.

With him on the brief were *Frank W. Hunger*, Assistant Attorney General, *Eric H. Holder, Jr.*, United States Attorney, and *Robert S. Greenspan*, Attorney, United States Department of Justice.

Before: EDWARDS, *Chief Judge*; RANDOLPH and ROGERS, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* ROGERS.

ROGERS, *Circuit Judge*: The American Legion and others appeal from the grant of summary judgment rejecting their challenge to the decision of the Secretary of Veterans Affairs to abandon a congressionally mandated epidemiological study of the effects of exposure to dioxin, a by-product of Agent Orange and other herbicides, on Vietnam veterans.¹ The district court ruled that the Secretary had acted within his discretion in abandoning the Agent Orange Study, which the Secretary had commissioned the Centers for Disease Control to design and conduct, after determining that sampling problems made it unlikely that the investigation would yield scientifically valid results. *American Legion v. Derwinski*, 827 F. Supp. 805, 812-14 (D.D.C. 1993). Appellants contend that the Secretary erroneously relied on a repealed standard as the basis for abandoning the study and violated the statute by halting the study before submitting a mandated report of health results to Congress; alternatively, they challenge as arbitrary and capricious the Secretary's conclusion that a scientifically valid study was impossible. Finding these contentions unpersuasive, we affirm.

I.

As background to appellants' contentions, we first outline the statute and the Secretary's efforts to implement the statutory directive for an epidemiological study on the effects of exposure to dioxins during the Vietnam conflict.

A. The Statute. In enacting the Veterans' Health Programs Extension and Improvement Act of 1979, Pub. L. No. 96-151, 93 Stat. 1092 (codified as amended at 38 U.S.C. § 219 note (1988)), *reprinted as amended in* 38 U.S.C.A. § 527 note (1991) (the "1979 Act"), Congress sought to determine by means of an epidemiological study the health effects of exposure to Agent Orange and

¹In 1988, Congress redesignated the Veterans Administration as the Department of Veterans Affairs and named the Secretary of Veterans Affairs (previously, the Administrator of Veterans' Affairs) to head the department. Department of Veterans Affairs Act, Pub. L. No. 100-527, 102 Stat. 2635 (1988). We use the current title "Secretary" in this opinion whenever the statute or record refers to the Administrator of Veterans' Affairs.

other herbicides on Vietnam veterans.² *Id.* § 307; *see also* S. REP. NO. 260, 96th Cong., 1st Sess. 36-40 (1979) ("1979 S. REP."), *reprinted in relevant part in* 1979 U.S.C.C.A.N. 1894, 1922-1926. These herbicides, which the United States military used during the Vietnam conflict, contain varying amounts of dioxins—also referred to as TCDD³—which studies have suggested can cause harmful health effects in laboratory animals and consequently led to concern about similar effects in humans.⁴ Congress sought to determine whether Vietnam veterans had suffered such adverse health effects as a result of their military service and, if so, to compensate them for their injuries. *See* 1979 S. REP. at 38-40.

The 1979 Act directed the Secretary to conduct an epidemiological study pursuant to a protocol approved by the director of the congressional Office of Technology Assessment ("OTA"). 1979 Act § 307(a)(2)(A)(i). The statute also required the director of OTA to oversee the conduct of the study and report its oversight activities to the appropriate congressional committees. *Id.* § 307(a)(2). Further, as part of the effort to ensure that the study was "scientifically valid and ... conducted with efficiency and objectivity," the 1979 Act directed the President to coordinate the Secretary's study with any other Federal governmental studies on the effects of dioxins. *Id.* § 307(c). The 1979 Act expressly required, however, that the Secretary continue the study only "for as long after the submission of [his first] report [to Congress on 'the results thus far obtained under the study'] ... as the [Secretary] may determine reasonable in light of the possibility of developing through such study significant new information on the long-term adverse health effects of exposure to dioxins." *Id.* § 307(a)(3), (b)(2).

The 1979 Act initially called for an epidemiological study of veterans who "were exposed to"

²Epidemiology is "a branch of science and medicine [that] uses studies to 'observe the effect of exposure to a single factor upon the incidence of disease in two otherwise identical populations.'" *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 945 (3d Cir. 1990) (quoting Black & Lilienfeld, *Epidemiological Proof in Toxic Tort Litigation*, 52 *Fordham L. Rev.* 732, 755 (1984)); *see also* Affidavit of Dr. Zena A. Stein, proffered by appellants, at 2.

³TCDD stands for 2,3,7,8-Tetrachlorodibenzo-p-Dioxin, a by-product created during the manufacture of certain herbicides.

⁴*See* 1979 S. REP. at 37-39; Health Study Protocol at 4-5.

dioxins during the Vietnam conflict. *Id.* § 307(a)(1) (amended 1981). From the outset, a major obstacle to completion of the study was the identification of veterans, other than "Ranch Hands" who did the actual spraying, who had been exposed to Agent Orange during their service in Vietnam. S. REP. NO. 89, 97th Cong., 1st Sess. 25 (1981) ("1981 S. REP."). To address this problem, Congress amended the statute in 1981 to require a study of veterans' health effects that "may result" from exposure to dioxins. Veterans' Health Care, Training, and Small Business Loan Act of 1981, Pub. L. 97-72 § 401(a)(1), 95 Stat. 1061 (1981) (codified at 38 U.S.C. § 219 note (1988)), *reprinted in* 38 U.S.C.A. § 527 note ("1981 Amendments"). The 1981 Amendments also expanded the scope of the study to examine health effects that may have resulted from other factors in the overall Vietnam experience, "including exposure to other herbicides, chemicals, medications, or environmental hazards or conditions." *Id.* According to the Senate Report, the amendments were intended to "allow the Secretary to begin the study of the health status of these veterans by identifying a population of veterans who served in Vietnam, without first having to determine whether each was, without question, exposed to Agent Orange in Vietnam." 1981 S. REP. at 26.

B. The Health Study Protocol and Pilot Study. Following enactment of the 1981 Amendments, the Secretary entered into a contract with the Centers for Disease Control ("the Center") to design a protocol for the epidemiological investigation. The Center's Health Study Protocol, completed in November 1983, proposed three studies to evaluate the health of Vietnam veterans, one of which was the "Agent Orange" Study, designed to examine the effects of exposure to Agent Orange and other herbicides on veterans' health. *See* United States Department of Health and Human Services, Public Health Service, Centers for Disease Control, Protocol for Epidemiologic Studies of the Health of Vietnam Veterans (November 1983) at 1, 6-9 ("Health Study Protocol").⁵ To isolate the effects of dioxin exposure, the Center needed to distinguish between groups of Vietnam veterans who were similar except for their level of dioxin exposure. *See supra* n.2. The Health Study

⁵The two other studies—the "Vietnam Experience" study, to assess the "possible health effects of the general Vietnam experience," and the "Sarcoma/Lymphoma" or "Selected Cancers" study, to "evaluate the risk of contracting soft tissue sarcoma and lymphoma among Vietnam veterans (and/or those exposed to herbicides)"—have been completed and are not at issue in these appeals.

Protocol proposed to use military records to divide a sample of Vietnam veterans into those who were likely exposed to herbicides in Vietnam and those likely not exposed and then to compare the health of the two cohorts. Health Study Protocol at 6-7, 10-15. The Center planned to review battalion journal files and morning reports to locate companies at various times during the Vietnam conflict and to determine the presence or absence of individuals within the company. Utilizing herbicide usage reports such as aircraft spraying records to estimate the location and timing of herbicide applications, the Center planned to fit veterans into the "likely exposed" or "likely not exposed" cohort "according to the measure of their company's distance in time and space from any herbicide applications." *Id.* at 6. To measure the possible health effects of dioxins, the Center would then compare the medical histories of "likely exposed" and "likely not exposed" veterans based on review of mortality records, health interviews, medical examinations, and laboratory tests. *Id.* at 20-25.

The Health Study Protocol cautioned that certain "obstacles" prevented the Center from adopting the "ideal" design for an Agent Orange cohort study, which would have compared one group free from all exposure to another group subjected to "meaningful" exposure to herbicides. These obstacles included the difficulty of defining "meaningful exposure" and the uncertainty about whether exposed veterans were comparable to unexposed veterans in other characteristics that might affect health. Most significant for purposes of these appeals, the Protocol noted that the "uneven quality" of the military records, including gaps in company records and errors in herbicide usage records, meant that "the categorization of individuals with respect to their potential for herbicide exposure will be uncertain and will forever remain so." *Id.* at 6. The Health Study Protocol concluded that "[s]ince many of the proposed procedures are untested, modification, indeed even a recommendation not to proceed with an Agent Orange Study, may be required..." *Id.* at 11.

The Center's initial review, conducted from 1983 to 1986, confirmed its concern that inadequacies in the military documentation would likely make identification of appropriate cohorts impossible. Informed of these difficulties, OTA advised Congress in September 1985 that if the difficulties in evaluating exposure were not resolved, OTA might conclude that the "it is impossible

to study the effects of Agent Orange." OTA subsequently suggested that the Center postpone any "major new phase" of its Agent Orange Study until it had devised an appropriate means of estimating exposure and recommended that instead of proceeding with the interviews of study subjects scheduled to begin in January 1986, the Center conduct a pilot study to test the methods and results of its initial exposure assessments. Accordingly, the Environmental Support Group of the United States Army and Joint Services developed a pilot study, at the Center's request, to identify "heavily exposed personnel." Completed in mid-1986, the pilot study ranked veterans based on their number of "hits," or opportunities for exposure to Agent Orange; veterans with the largest number of "hits" were classified as those most likely to have faced heavy exposure.⁶

In early 1986, the Agent Orange Working Group ("Working Group"), formed by the President to carry out his responsibilities under the 1979 Act, convened a Science Subpanel on Exposure Assessment ("Science Subpanel") to evaluate the Center's exposure assessment methods and review the results of the pilot study. In a May 26, 1986, letter to the Working Group, the Science Subpanel concluded that two problems jeopardized the Center's Agent Orange Study: first, the potential for "considerable" misclassification because of unit dispersion and incomplete records of spray operations; and second, the fact that the Center's records review showed that most veterans had never been exposed to a "hit," as defined by the Center, and thus "the paucity of clearly exposed combat veterans makes it questionable whether a sufficient number can be assembled to conduct an epidemiological study of the type originally designed." The Science Subpanel noted that recent scientific advances might enable the Center more accurately to identify cohorts of likely exposed and likely unexposed veterans, but that given the problems with current identification methods, "any study of ground troops, which is dependent upon military records for the assessment of exposure to herbicides, [should] not be conducted without an additional method to verify exposure."

C. The TCDD Validation Study. Responding to the recommendations from OTA and the Science Subpanel not to proceed with a military records-based study without some independent

⁶A veteran received a score of one "hit" for each day that his company was located within 2 kilometers of a reported Agent Orange spray line applied within the previous 6 days.

verification, the Center developed a protocol to compare current serum TCDD levels in veterans' blood. Assuming TCDD survived in the blood for several years, the Center postulated that veterans who faced "heavy" exposure could be expected to have higher serum TCDD levels than lesser exposed veterans even twenty years after their exposure to Agent Orange.⁷ The Center used both the pilot study's "hit"-based exposure indices and veterans' self-reported exposure estimates to divide a set of Vietnam veterans into "low hit," "medium hit," and "high hit" subsets and, for comparison, also examined a group of non-Vietnam veterans of the same era.

The results of the TCDD study confirmed the Center's suspicions that neither military records nor self-reporting could adequately differentiate between veterans who were and were not likely exposed to Agent Orange in Vietnam. U.S. Department of Health & Human Services, Centers for Disease Control, Comparison of Serum Levels of 2,3,7,8-Tetrachlorodibenzo-p-Dioxin With Indirect Estimates of Agent Orange Exposure Among Vietnam Veterans: Final Report (August 1987) ("TCDD Report"). The Center found "no meaningful association" between veterans' current TCDD levels and the exposure indices developed through either military records or self-reporting.⁸ *Id.* at 1. Besides failing to validate the use of military records as exposure indicators, the TCDD study reinforced the conclusion that ground troops faced little likelihood of "heavy" exposure to Agent Orange. *Id.* at 2. The Center thus concluded that it could not conduct the cohort Agent Orange Study that it had originally planned:

The findings of this study and the conclusion from the Agent Orange Working Group Science Subpanel report on exposure assessment (June 1986) do not identify any method for using military records or self-reported exposure to distinguish between U.S. Army ground combat troops who were and were not exposed to Agent Orange

⁷Although the Center did not know the precise half-life of TCDD at the time it developed its TCDD protocol, it determined in the course of the study that TCDD has an average half-life of seven years. The half-life of a substance is "the time required by the body, tissue, or organ to metabolize or inactivate half the amount of a substance taken in." F.A. DAVIS, TABER'S CYCLOPEDIA MEDICAL DICTIONARY at 717 (1985).

⁸The Center controlled for differences such as age, race, region of current residence, body mass index, alcohol use, smoking history, and self-reported civilian occupational and home exposure to herbicides. *Id.* at 23. The study also considered the impact of other factors that might lead to study bias—group selection, laboratory error or measurement bias, variability in half-life, selection or participation bias, and sample size—and concluded that none of these factors likely influenced the results. *Id.* at 27-30.

in Vietnam, as would be needed for a cohort study of possible health effects.

Id. at 1.

In a review of the TCDD study, OTA agreed that "a large- scale epidemiological study to look for effects of Agent Orange in ground troops who served in Vietnam" was currently impossible, and cautioned that any future studies "should be narrowly focused on specific, testable hypotheses, and cannot have the aim of generalizability to all or most ground troops." *Id.* at 9. On October 29, 1987, the director of the Center reported to the Secretary the Center's concurrence with OTA and the Working Group that the Agent Orange Study "cannot be conducted" and that the Center had begun "the close-out process" for its Agent Orange Study.

D. The Secretary's decision. In December 1987, the Department of Medicine and Surgery in the Veterans Administration recommended a halt to all further studies of the effects of Agent Orange (other than the Air Force's Ranch Hand study). Because the results of the TCDD report "make it exceedingly unlikely that any method will satisfactorily distinguish between exposed and unexposed Vietnam veterans," the Department of Medicine and Surgery concluded that "a scientifically meaningful epidemiological study of the possible health effects of Agent Orange cannot be conducted."

On February 9, 1988, the Secretary sent the TCDD report, along with correspondence from OTA and the Working Group, to the Chairman of the House Committee on Veterans' Affairs. In a cover letter the Secretary stated that:

Despite our efforts, ... no one has successfully identified a large enough group of Vietnam veterans known to have been exposed to Agent Orange or other herbicides to allow the preparation of a protocol and the conduct of an epidemiological study as required by Public Law 96-151.⁹ I must, therefore, advise you that no scientifically sound study can be undertaken and request that the [Veterans Administration] be relieved of the requirement to do this research. This opinion coincides with that of the Office of Technology Assessment, as expressed in their comments of September 1987, and with the June 3, 1987, comments of the interagency Agent Orange Working Group.

A week later, the Secretary formally notified the Chairman of the decision to discontinue work on the

⁹The Secretary described Ranch Hand veterans as "the sole group of veterans ... available for the successful epidemiological investigation envisaged by the Congress."

Center's Agent Orange Study. On February 19, 1988, in his third annual report to Congress on the status of the Center's three-part Health Study, the Secretary repeated his conclusion that "based on the results of the ... TCDD Validation Study, ... an [Agent Orange Study] cannot be conducted so as to achieve a scientifically sound conclusion regarding the possible adverse health effects of exposure of Vietnam veterans to Agent Orange."¹⁰

Appellants thereafter filed suit, contending that the Secretary unlawfully abandoned the Center's Agent Orange Study based on the wrong legal standard, that the Secretary lacked authority to terminate the Agent Orange Study before submitting a health results report to Congress, and that his decision was contrary to the Administrative Procedure Act, 5 U.S.C. § 706. Following the district court's grant of summary judgment for appellees, appellants filed these consolidated appeals.

II.

In addressing appellants' challenges to the grant of summary judgment in favor of appellees, our review is *de novo*. *Diamond v. Atwood*, 43 F.3d 1538, 1540 (D.C. Cir. 1995); *Shields v. Eli Lilly & Co.*, 895 F.2d 1463, 1466 (D.C. Cir. 1990). Thus, the limited questions before the court are whether the Secretary adopted a "permissible" interpretation of the 1979 and 1981 Acts, *see Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 841-42 (1984), and, if so, whether, as a matter of law, the Secretary's decision in February 1988 to abandon the Center's Agent Orange Study was arbitrary and capricious, an abuse of discretion, or otherwise contrary to law. 5 U.S.C. § 706(2)(A); *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971); *Dr. Pepper/Seven-Up Companies, Inc. v. FTC*, 991 F.2d 859, 862 (D.C. Cir. 1993). In reviewing

¹⁰In accord with the Secretary's recommendation that any allocated but unexpended funds be reallocated to either "the U.S. Air Force's Ranch Hand Study's blood dioxin levels research or other research on Agent Orange and closely related subjects," Congress in 1988 transferred \$3,000,000 of the unexpended funds for blood tests in the Ranch Hand study and \$1,000,000 for "a survey of scientific evidence, studies, and literature" regarding the health effects of possible herbicide exposure in Vietnam, to be conducted by an independent scientific entity under contract with the VA, "pursuant to a law enacted after the date of the enactment of this Act." *See* § 1201 of Pub. L. No. 100-687, 102 Stat. 4105, 4125 (1988). Subsequently, in 1991, Congress authorized the National Academy of Sciences to review and evaluate the available scientific studies regarding the health effects of herbicide exposure and required the Secretary to enact regulations establishing a presumption that any malady correlated with herbicide exposure is service-related. Agent Orange Act of 1991, Pub. L. No. 102-4, 105 Stat. 11 (1991) (codified as amended at 38 U.S.C. § 1116 & note (Supp. IV 1992)).

the Secretary's decision to abandon the study, the court's task is to determine whether the Secretary "examine[d] the relevant data," and made a "rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (internal quotations omitted); *see also Citizens to Preserve Overton Park v. Volpe*, 401 U.S. at 416. Given the nature of the scientific expertise brought to bear on the issue of whether to continue the Center's Agent Orange Study, the court's review is at its most deferential. *Baltimore Gas & Electric Co. v. Natural Resources Defense Council, Inc.*, 462 U.S. 87, 103 (1983).

A. Reporting "results". Appellants contend that the Secretary violated the statute by abandoning the Center's Agent Orange Study before reporting actual health results to Congress. Section 307(b)(2) of the 1979 Act provides:

Not later than twenty-four months after the date of the approval of the protocol ... and annually thereafter, the [Secretary] shall submit to the appropriate committees of the Congress a report containing (A) a description of the *results thus far obtained under the study* conducted pursuant to this subsection, and (B) such comments and recommendations as the [Secretary] considers appropriate in light of such results. [Emphasis added].

Appellants maintain that the word "results" in § 307(b)(2) means substantive health results, and hence, that the Secretary lacked authority to abandon the Center's Agent Orange Study before reporting to Congress the Center's conclusions about adverse health effects of Agent Orange and other herbicides on Vietnam veterans. *See id.* § 307(a)(3) *as amended by* 1981 Amendments § 401(a)(2) (Secretary may discontinue the study "after the submission of the first report under subsection (b)(2)"). The Secretary interprets "results" under § 307(b)(2) to include the progress made thus far to carry out the study and maintains that he fulfilled § 307(b)(2)'s requirement when he provided Congress with a progress report on February 13, 1986.

In reviewing the Secretary's interpretation of § 307(b)(2), we apply the standard of review set forth in *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 841-42 (1984). Because, contrary to appellants' contentions, neither the plain language nor the structure of the statute makes clear Congress' intent to confine "results" to "health results" in mandating reports by the Secretary, the court must defer to the Secretary's interpretation if it "is based on a permissible

construction of the statute." *Id.* The Secretary's interpretation accordingly invokes our deference.¹¹ Because the Secretary's interpretation of "results" is consistent with Congress' use of that term in the statute, *see* 1979 Act § 307(b)(2), and appellants' construction of congressional intent would lead to absurd results, the Secretary's interpretation withstands scrutiny.

The Secretary's interpretation that "results thus far obtained under the study" means the results of the Secretary's efforts pursuant to the statute is not an impermissible construction of § 307(b)(2). The word "results" is hardly a technical term of art, but one of common parlance subject to multiple meanings. Thus, "results" may include conclusions that the Secretary has reached in the course of efforts to carry out the Center's Agent Orange Study and are not, as appellants suggest, necessarily limited to "health results" produced by that study. The "result" of the TCDD study, for example, is the conclusion that current blood serum levels bear no relation to military records-based exposure assessments. The "results" of the pilot study are the index of "hit"-based exposure assessments and the conclusion that most ground troops did not have the opportunity for heavy exposure to Agent Orange. Both studies led, in one sense, to "results ... obtained under the study" since they followed the Secretary's approval of the Health Study Protocol and represented efforts to develop data that would enable the production of scientifically valid epidemiological conclusions.

Put otherwise, an epidemiological study on long-term health effects produces many types of "results" that the Secretary could report to Congress. The fact that the statute requires the Secretary to submit annual reports on the "results thus far obtained under the study" comports with the view that Congress wanted regular progress reports on the results of the Secretary's efforts, whether or not such reports contained substantive health results. *See* 1979 Act § 307(b)(2). Indeed, the Secretary's submission of various reports to Congress between 1986 and 1988 alerted Congress that the development of scientifically valid health results depended on the identification of reliable indices of cohort exposure. The language of § 307(a)(3) also supports the Secretary's interpretation; by

¹¹Although *Chevron* deference would not apply if the Secretary had adopted this interpretation solely for purposes of litigation, *see City of Kansas City, Mo. v. HUD*, 923 F.2d 188, 192 (D.C. Cir. 1991), the interpretation at issue appeared in the Secretary's February 13, 1986, report to Congress, in which he stated: "As required by Section 307 of Public Law 96-151 ... I am sending you and your committee the first status report and its appendices" on the Agent Orange Study.

allowing the Secretary to abandon the study after submission of the first report if he finds it unlikely that the study will yield "significant new information on the long-term health effects of exposure to dioxins," subsection (a)(3) appears to contemplate that the Secretary's first report may not itself contain information on adverse health effects.¹² *Id.* § 307(a)(3).

Appellants' contrary statutory arguments are unpersuasive. First, appellants contend that because the statute requires OTA to submit "updates" on the status of unapproved protocols, *id.* § 307(a)(2)(B)(ii), Congress must have intended "results" under § 307(b)(2) to mean more than a progress report. Although courts generally presume that "Congress acted intentionally and purposely" when particular language in one section of a statute is omitted in another section, *Russello v. United States*, 464 U.S. 16, 23 (1983) (quoting *United States v. Wong Kim Bo*, 472 F.2d 720, 722 (5th Cir. 1972)), the statutory differences between the reporting requirements imposed on OTA and the Secretary are consistent with the Secretary's interpretation of "results." OTA's "updates" on the status of protocol revisions reflect only the status of the Secretary's plans to conduct the study; because the Center's Agent Orange Study has not yet begun, the reports cannot contain its "results." The Secretary's reports, by contrast, reflect information gathered in the process of conducting the study, which can fairly be labeled "results thus far obtained under the study."

Similarly unpersuasive is appellants' second contention that the differences between the Agent Orange statute and a 1983 statute providing for an epidemiological study of the health effects of radiation exposure, Veterans Health Care Amendments of 1983, Pub. L. 98-160 § 601, 97 Stat. 1006-08 (1983) (codified as amended at 38 U.S.C. § 219 note (1988)) (the "1983 Act"), demonstrate

¹²The fact that Congress directed the Secretary to consider various administrative actions based on the "results" reported under § 307(b)(2) does not make his interpretation of "results" unreasonable. *See id.* § 307(b)(2)(B), (b)(3). The statute requires the Secretary to submit "comments and recommendations [that the Secretary] considers appropriate in light of such results," *id.* § 307(b)(2)(B), and to give notice and comment of "actions, *if any*," that the Secretary proposes to take in response to the results. *Id.* § 307(b)(3) (emphasis added). The Secretary fulfilled the requirements of § 307(b)(2)(B) in his first and subsequent progress reports, when he informed Congress of the proposed TCDD study and its results, notified Congress of the Center's Agent Orange Study's abandonment, and recommended that the legislature reallocate unused funds. *See supra* n.10. Subsection (b)(3) makes clear that the Secretary need not recommend *any* "action" based on the study's "results." It is consistent with this subsection for the Secretary to recommend no rulemaking action, given the "result" that the effects of Agent Orange could not presently be ascertained.

that Congress intended to require the Secretary to provide "health results" in his reports pursuant to § 307(b)(2) of the 1979 Act. Although the 1983 Act explicitly gives the Secretary discretion not to conduct a study if he finds a scientifically valid study infeasible, *id.* § 601(a)(1)(B), the fact that the Secretary could not abandon the epidemiological study without developing a protocol and reporting some kind of results does not mean that the "results" reported must be "health results." Nor is the 1983 Act's requirement of reports on "the progress ... and any results" of the radiation study, *id.* § 601(a)(5)(A), inconsistent with interpreting "results" as used in § 307(b)(2) of the 1979 Act to include data and conclusions other than "health results." Absent either a conflict between the 1983 Act and the Secretary's interpretation or a clear contrary meaning of the word "results," we will not read the 1983 Act to preclude the reasonable interpretation adopted by the Secretary. *Compare West Virginia University Hosp., Inc. v. Casey*, 499 U.S. 83, 99-101 (1991).¹³

Indeed, the reasonableness of the Secretary's interpretation is manifest in light of the implausibility of the alternative interpretation proposed by appellants. *See United States v. Wilson*, 112 S. Ct. 1351, 1354 (1992). Under their interpretation, Congress intended to require the Secretary to proceed with the Center's Agent Orange Study and present its "results" to Congress even when the Secretary knew that the inability to identify necessary data would render the results scientifically useless. Not only do the 1981 Amendments and the Secretary's reports to Congress make clear that Congress knew that the underlying data was problematic, but the various reporting requirements in the statute highlight the unreasonableness of appellants' unsupported assumption that Congress intended the Secretary to devote resources to a study that the Secretary, the Center, the congressional OTA, and the President's Working Group had all concluded could not yield the valid scientific results mandated by statute. Other provisions in the statute also suggest that Congress did not intend the Secretary to conduct a study unless it was a scientifically valid one. Congress expressly required the

¹³Finally, while Congress' failure to consider the possibility that the study might not ultimately yield substantive health results cannot form the basis for an interpretation contrary to the plain meaning of a statute, *see West Virginia Univ. Hosp., Inc. v. Casey*, 499 U.S. at 100-01, where the Secretary's interpretation comports with the language of the statute and an alternative interpretation would produce absurd results, the fact that Congress did not specifically consider the issue is irrelevant. *See id.*; *see also Natural Resources Defense Council, Inc. v. EPA*, 725 F.2d 761, 770 (D.C. Cir. 1984).

Secretary to conduct the study pursuant to a protocol approved by the director of OTA. 1979 Act § 307(a)(2)(A)(i). The director of the OTA was to assess scientific validity in his approval or disapproval of the proposed protocol. *Id.* § 307(a)(2)(B)(i). Also, Congress directed the President to monitor the study for the purpose of assuring that the study was scientifically valid. *Id.* § 307(c). Assuming the accuracy of the Secretary's conclusion that a scientifically valid Agent Orange study was infeasible, in the absence of a clear statutory command, the Secretary was not required to proceed with a study that by all indications would not advance scientific knowledge solely to fulfill the obligation to report "results."

Because the language and purpose of the statute support the Secretary's interpretation of "results" as the progress made thus far in the Center's Agent Orange Study, we conclude that the Secretary satisfied his initial reporting obligation under § 307(b)(2) of the 1979 Act when he submitted a report to Congress on February 13, 1986, describing the results of efforts to carry out the epidemiological study.

B. The Standard. Appellants contend that the Secretary acted contrary to law because he decided to abandon the study based on the repealed standard of the 1979 Act (focusing on individual veterans who "were exposed to ... dioxins")¹⁴ instead of the liberalized standard adopted in the 1981 Amendments (examining health effects that "may have resulted from exposure").¹⁵ Appellants rely on the fact that in his February 9, 1988, letter to the Chairman of the House Committee on Veterans' Affairs, the Secretary reported that he had not "successfully identified a large enough group of Vietnam veterans *known to have been exposed* to Agent Orange or other herbicides to allow the preparation of a protocol and the conduct of an epidemiological study as required by Public Law 96-151." They also point to the beginning of the Secretary's letter where he referred to the repealed legal standard in discussing the efforts made under the 1979 Act "[s]ince 1980." Appellants' emphasis on this language, however, overlooks other language in the Secretary's letter that demonstrates that he based his decision on concerns about scientific validity rather than compliance with the pre-1981

¹⁴1979 Act § 307(a)(1) (amended 1981).

¹⁵1981 Amendments § 401(a)(1).

statutory mandate, that the numerous reports before the Secretary recommended abandoning the Center's Agent Orange Study because compliance with the 1981 mandate was not scientifically possible, and that the TCDD study confirmed that military records could not yield adequate exposure indices.

As appellants point out, a reviewing court "must judge the propriety of [agency] action solely by the grounds invoked by the agency." *SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947). It is equally true, however, that "we will uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned." *Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 285-86 (1974). Hence, even if some of the agency's remarks might appear erroneous when read in isolation, the court will uphold agency action that, "[c]onsidered in its entirety," is based on appropriate considerations and otherwise complies with relevant statutes and the Administrative Procedures Act. *District Lodge 64 v. NLRB*, 949 F.2d 441, 446 (D.C. Cir. 1991). Such consideration here indicates that the Secretary did not base his decision on the repealed statutory standard.

First, that the Secretary's decision focused on problems with the cohort study designed pursuant to the 1981 Amendments is evident from his letter's reference to the identification of a large enough *group* of veterans, as distinct from the focus of the original 1979 Act on individuals who had been exposed. The Secretary expressly incorporated by reference a separate statement by the Veterans' Administration's Department of Medicine and Surgery that refers to the 1981 standard and discusses the efforts to "estimate the likelihood" of exposure to Agent Orange. He noted, moreover, at the beginning of his letter that completion of the TCDD study "enabled the V[eterans'] A[dm]inistration] to complete an attempt to determine directly and specifically whether exposure to Agent Orange had an adverse effect on the health of Vietnam veterans," thereby indicating that as addressed in the TCDD study, verification of exposure data remained the important factor under the 1981 standard. In context, therefore, the Secretary's reference to exposure suggests that the inability to distinguish exposure levels among different groups of veterans meant that he could not establish the data base necessary for a scientifically valid study.

Second, the Secretary attached to his February 9, 1988, letter to Congress OTA's September 1987 report and the Working Group's comments of June 3, 1987; both documents recommended abandonment of the Center's Agent Orange Study, not because of an inability to ensure that each study subject was exposed to Agent Orange, but because current identification methods provided no scientifically valid means of differentiating groups of veterans based on the degree of exposure, and thus the long-term health effects of Agent Orange and other herbicides on the study subjects could not be assessed. OTA and the Working Group thus concluded that "no scientifically sound study can be undertaken."

Third, the Secretary also attached to his February 9, 1988, letter to Congress the TCDD validation study, which confirmed that compliance with the 1981 statutory mandate was not feasible because the Center was unable to classify groups of veterans based on their degree of exposure to Agent Orange and other herbicides. The Center compared individual hit scores as well as median TCDD levels by company, by the company in which the veteran spent the most time, and by the company in which the veteran had the most "hits." The Center concluded that neither individuals with higher "hit" scores nor companies with predicted higher levels of exposure had, on average, significantly higher TCDD levels in their blood, and therefore that it could not develop the data base needed for a cohort epidemiological study.

Viewing the Secretary's February 9, 1988, letter together with the documents that he incorporated by reference thus makes clear that notwithstanding the Secretary's reference to the inability to identify veterans "*known to have been exposed*" to Agent Orange and other herbicides, his decision to abandon the Center's Agent Orange Study rested on the inability to identify study cohorts based on the degree of exposure. Although Congress anticipated that the 1981 Amendments would remove the threshold problem of identifying individual veterans who were exposed to Agent Orange, 1981 S. REP. 26, 33, the amendments left in place the requirement that the study yield scientifically valid results. Appellants appear to ignore or underestimate the significance of the fact that even under the 1981 Amendments the epidemiology study depended on exposure data, and that the Center's Agent Orange Study relied on the ability to determine the degree of exposure

experienced by different groups of veterans. Thus, notwithstanding the Secretary's unfortunate choice of some words in his February 9 letter, the references noted by appellants cannot be divorced from the Secretary's references to "a large enough group" and the enclosed statement of the Department of Science and Medicine or fairly understood without regard to the supporting materials on which he relied in making his decision. For these reasons, we conclude that the Secretary did not rely on an improper legal standard in deciding to abandon the Agent Orange epidemiological study.

C. Abandoning the original Agent Orange Study. Because appellants' other challenges fail, the success of their appeals turns on whether, as a matter of law, the Secretary acted arbitrarily and capriciously in determining in February 1988 that a scientifically valid epidemiological study was infeasible. Appellants maintain that the "risk" of misclassification cannot alone make an epidemiological study scientifically invalid and that the Secretary had no evidence to support the conclusion that the degree of misclassification was sufficiently high to make valid scientific results unobtainable.

The statute vests the Secretary with broad discretion to abandon the entire epidemiological study if, after his initial report to Congress, the Secretary determines that the study will yield no useful scientific results.

The study ... shall be continued for as long after the submission of the first report under subsection (b)(2) as the [Secretary] may determine reasonable in light of the possibility of developing through such study significant new information on the long-term adverse health effects of exposure to dioxins.

1979 Act § 307(a)(3) *as amended by* 1981 Amendments § 401(a)(2). Given this broad discretion, the scope of our review of the Secretary's decision to abandon one component of the Health Study Protocol is particularly limited. *See Kreis v. Secretary of Air Force*, 866 F.2d 1508, 1514 (D.C. Cir. 1989) ("[i]t is simply more difficult to say that the Secretary has acted arbitrarily if he is authorized to act 'when he considers it necessary ...' than it is if he is required to act whenever a court determines that certain objective conditions are met") (emphasis in original). Applying this standard, we conclude that the Secretary did not act arbitrarily and capriciously in abandoning the Center's Agent Orange Study after determining, in view of the available reports, studies and recommendations, that it was unlikely to produce scientifically valid conclusions about the long-term effects of exposure

to Agent Orange and other herbicides on Vietnam veterans' health. 1979 Act § 307(a)(3), (c).

The information available to the Secretary indicated that from its inception, the Center's Agent Orange Study was confronted with identification difficulties that persisted through an additional pilot study and completion of the TCDD study. The Center's Health Study Protocol anticipated that its records-based method of exposure assessment might require "modification, indeed even a recommendation not to proceed with an Agent Orange study..." Health Study Protocol at 11. The initial review of military records confirmed the Center's concern that it might not succeed in identifying cohorts of veterans who faced a greater likelihood of exposure to Agent Orange and other herbicides than comparable cohorts of their peers and thus would have no way of distinguishing the health effects of exposure to Agent Orange or other herbicides, as needed for an epidemiological study. The congressional OTA and the President's Working Group supported this assessment. The pilot study, which the Center commissioned to evaluate its exposure assessment methods, highlighted the inexactitude in the military records and revealed not only that unit dispersion and inadequate spray records made classification difficult, but also that most veterans (other than the Ranch Hands) never had the opportunity for significant Agent Orange exposure. The TCDD validation study, in turn, confirmed that the military records-based assessments bore no relationship to current (and therefore past) levels of Agent Orange in veterans' blood. With the evidence suggesting that the military records did not provide accurate exposure indices, and with no evidence that an alternative method existed to identify a sufficient number of veterans who were likely exposed to Agent Orange or other herbicides, the Secretary could reasonably conclude, in concurrence with the Center, OTA, and the Working Group, that the originally planned epidemiological Agent Orange Study was infeasible.

The fact that the TCDD study left open the possibility that military records might accurately identify exposed veterans at low levels of exposure does not alter this conclusion. Because the purpose of the TCDD study was to *validate* the records-based exposure indices, the study, while not ruling out the possibility that military records provided accurate exposure indices at low levels of exposure, did not provide the verification of low-level exposure indices that the Center, OTA, and the Working Group had deemed necessary to justify a cohort study using military records.

Appellants nevertheless fault the Secretary for his failure to determine precisely how much misclassification inheres in the military records. According to appellants, the Science Subpanel implicitly drew a line "on the epidemiological risk continuum" beyond which the degree of misclassification made scientific validity unachievable.¹⁶ They maintain that *Ethyl Corp. v. EPA*, 541 F.2d 1, 38-40 (D.C. Cir. 1976), and other cases require the Secretary to make this line explicit and to support his determination with evidence in the record. *Ethyl*, which involved an agency rule setting a particular numerical value for acceptable blood lead levels, 541 F.2d at 38, offers little guidance here. Whereas *Ethyl* addressed whether the agency had a rational basis for the chosen numerical value, the question in these appeals is whether the Secretary had a rational basis for determining that no known method existed to verify whether the military records-based assessments differentiated between exposed and non-exposed veterans in the way necessary for a cohort study. The TCDD study was designed, in part, to accomplish what appellants charge the Secretary should have done: determine the degree of correlation (and therefore the degree of misclassification) between military records and TCDD exposure. As the TCDD study illustrates, the Secretary has no way of knowing the precise degree of misclassification. The Secretary knows only that inaccuracies and imprecision in the military records make it impossible to determine whether a particular group of veterans is more likely to have been exposed to Agent Orange and other herbicides than a comparable cohort of their peers. That he did not pursue still other alternatives, at best vaguely identified by appellants, does not demonstrate that the Secretary acted unreasonably in concluding in February 1988 that the Center's Agent Orange Study should be abandoned.¹⁷

¹⁶Appellants also rely on a statement in the 1986 Science Subpanel report that it "felt that an additional method to verify exposure is required" as indicating that the Secretary acted on the basis of amorphous "feelings" rather than evidence in the record. The Secretary, however, based his conclusion that an exposure verification method was necessary on more than the Science Subpanel's "feelings." OTA had similarly concluded that, because of misclassification problems, an independent method of exposure assessment or some means of verifying the records-based exposure estimates was needed. In addition, the TCDD study, which post-dated the Science Subpanel report, confirmed that military records did not give reliable estimates of exposure to Agent Orange among ground troops and that most ground troops had never faced meaningful exposure to Agent Orange or other herbicides.

¹⁷Appellants proffer the affidavit of Dr. Zena A. Stein, who states that "[m]isclassification problems, like those at issue in the [Center's] exposure study ... do not necessarily invalidate any

For these reasons we conclude that appellants have failed to show that when the Secretary made his decision, after extensive efforts to identify and classify the data required for an epidemiological study that focused solely on the long-term health effects of dioxin exposure, the Secretary acted unreasonably or contrary to law in abandoning the Center's Agent Orange Study. To the extent that Vietnam veterans as a group faced higher exposure to Agent Orange and other herbicides than other groups of veterans, the Center's Vietnam Experience and Selected Cancers Studies were designed, in part, to detect health effects that may have resulted from such exposure. In addition, the Air Force's Ranch Hands study was examining the one group of veterans who faced heavy exposure to Agent Orange and other herbicides. Based on the data available to the Secretary in February 1988, however, the Secretary could reasonably conclude that it was impossible to identify groups of Vietnam veterans who were similar except for their levels of dioxin exposure, as required for the cohort tests necessary to ascertain the health effects of dioxins through a scientifically valid Agent Orange Study.

Accordingly, because appellants have failed to present a material issue of fact or to demonstrate that appellees were not entitled to judgment as a matter of law as to whether the Secretary's decision was arbitrary, capricious, an abuse of discretion, or otherwise contrary to the law, we affirm the grant of summary judgment to appellees.

justification of the study." Affidavit at 6-7. Dr. Stein, however, concedes that "a valid study must meet a minimum threshold of probability and comparability" between exposed and unexposed cohorts with respect to the fact of exposure, amount and duration of exposure, and other personal characteristics and influences that might affect individuals' health. *Id.* at 2-4. Significantly, Dr. Stein does not criticize the methodology used by the Center in reviewing the military records, and she acknowledges that misclassification might preclude a valid Agent Orange Study if "the misclassification problems were much greater than anticipated and outlined in" the Health Study Protocol. *Id.* at 7.

Nor does appellants' assertion that the National Academy of Sciences has now proposed to conduct an Agent Orange Study based on military records discredit the Secretary's decision, which was made several years before the Academy issued its preliminary proposal. Moreover, in the single page from the proposal that appears in the record, the Academy acknowledges that it "does not know whether the approach it proposes will prove valid or whether new methods will identify a sufficient number of highly exposed Vietnam veterans for an epidemiologic study." National Academy of Sciences, Institute of Medicine, Veterans and Agent Orange: Health Effects of Herbicides Used in Vietnam (1993). This is hardly a criticism of the Secretary's approach, let alone the identification of a fundamental flaw in the studies and conclusions on which the Secretary relied.

