UNITED STATES COURT OF APPEALS FOR VETERANS CLAIMS

NO. 07-1081

JAMES A. HALCOMB, APPELLANT,

v.

ERIC K. SHINSEKI,
SECRETARY OF VETERANS AFFAIRS, APPELLEE.

On Appeal from the Board of Veterans' Appeals

(Argued April 15, 2009 Decided October 20, 2009)

Zachary M. Stolz, with whom *Landon E. Overby* (non-attorney practitioner), was on the brief, both of Washington, D.C., for the appellant.

Mark M. McNabb, with whom *Paul J. Hutter*, General Counsel; *R. Randall Campbell*, Assistant General Counsel; and *Joan E. Moriarty*, Deputy Assistant General Counsel, were on the brief, all of Washington, D.C., for the appellee.

Before GREENE, *Chief Judge*, and LANCE and DAVIS, *Judges*.

DAVIS, *Judge*: U.S. Army veteran James A. Halcomb appeals through counsel from a December 19, 2006, Board of Veterans' Appeals (Board) decision that denied entitlement to compensation benefits under 38 U.S.C. § 1151 for loss of vision in the left eye. The issue before the Court is whether the appellant has established that VA's care and treatment proximately caused an additional qualifying disability under 38 U.S.C. § 1151(a) and 38 C.F.R. § 3.361 where the only evidence concerning whether VA obtained informed consent prior to the appellant's surgery is a standard form signed by the appellant that does not identify any specific risks that were discussed with him. This Court has jurisdiction to review the Board's decision pursuant to 38 U.S.C. §§ 7252(a) and 7266(a). *See Frankel v. Derwinski*, 1 Vet.App. 23, 25-26 (1990). For the following reasons, the Court will affirm the Board's December 2006 decision.

I. BACKGROUND

On April 10, 2002, the appellant underwent "same day" surgery at the Marion, Illinois, VA Medical Center for removal of a left-eye cataract and lens replacement. After the surgery, he developed endophthalmitis.[1] Later, at St. Louis University Hospital, he underwent a vitreal antibiotic injection of the left eye and a second surgery, known as a "trans para plana victrectomy," to address retinal detachment that was discovered in the course of his treatment. Since these procedures, the veteran has suffered left-eye blindness.

Prior to undergoing his cataract surgery at the VA facility, the appellant signed two documents relating to his permission for the procedures. The first was a form stating that "[t]he nature and purpose of the operation or procedure, possible alternative methods of treatment, the risks involved and the possibility of complications have been fully explained to me." Record (R.) at 426. The other document was a statement typewritten on a VA progress note sheet that read, in relevant part, as follows:

> The relevant aspects of the above stated procedure/treatment, the indications, risks, benefits, and alternatives have been discussed with the patient in understandable language. The patient was given opportunity to ask questions concerning the procedure/treatment. Comprehension of the discussion was indicated, and the patient freely consented to the procedure/treatment without duress or coercion.

R. at 427. Both documents were co-signed by a physician and witnessed by a nurse. Neither document contained any itemization, notations, or further description of what risks or alternatives may have been discussed.

Because his left-eye blindness resulted after the cataracts surgery and subsequent procedures at St. Louis University Hospital, the appellant sought compensation from VA under 38 U.S.C. § 1151(a). In January 2005, a VA regional office (RO) denied that claim. He appealed and in June 2006, the Board remanded the matter for the RO to obtain an opinion as to whether any of appellant's vision loss was due to carelessness, negligence, lack of proper skill, error in judgment, or similar fault of VA in furnishing care during the April 2002 eye surgery. R. at 598. A VA examiner opined

---

[1] "Endophthalmitis" is defined as "inflammation involving the ocular cavities and their adjacent structures." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 627 (31st ed. 2007).

that there was no carelessness, negligence, lack of proper skill, error in judgment, or similar fault of VA in furnishing care, and the RO again denied the appellant's claim for compensation under 38 U.S.C. § 1151(a). The appellant again appealed to the Board.

In the decision here on appeal, the Board denied entitlement to benefits under 38 U.S.C. § 1151(a). Preliminarily, the Board found that both the endophtalmitis and the retinal tears were reasonably foreseeable consequences of the appellant's medical procedures. The Board based its finding on a VA medical examination report that stated that endophthalmitis "is a rare, but not unheard of complication," and that "retinal tears are always a possible complication" in such procedures. R. at 618. The Board further found that "the medical evidence reflects informed consent on the veteran's behalf under 38 C.F.R § 17.32." R. at 10. Relying on the text and content of the consent form, the Board stated that there was no indication that the veteran's consent was not an informed one. This appeal followed.

II. CONTENTIONS OF THE PARTIES

A. The Appellant

The appellant asserts that a generic written consent form fails to comply with the VA regulations on informed consent and establishes negligence per se. He argues that the Board's finding that endophthalmitis and retinal tears were reasonably foreseeable events means that under 38 C.F.R.§ 17.32(c), VA had a duty to specifically inform him of these possible outcomes. The appellant asserts that his VA health care providers failed to tell him of these known risks, that such failure constitutes negligent care under 38 U.S.C. § 1151 and 38 C.F.R. § 3.361(d)(1)(ii), and that this negligence entitles him to VA benefits. *Cf. Ashley v. Derwinski*, 2 Vet.App. 62, 66 (1992) (providing that "the presumption [of official regularity] operates in reverse. If [the action] appears irregular, it is irregular, and the burden shifts to the proponent to show the contrary" (quoting *United States v. Roses Inc.*, 706 F.2d 1563, 1567 (Fed. Cir. 1983))). The alleged failure to inform is based on the fact that these risks were not explicitly mentioned on the face of the consent form, and the consent form is the only evidence on which the Board relied to find informed consent. The appellant maintains that the vague statement on the consent form that the "relevant aspects of the procedure/treatment, the indications, risks, benefits, and alternatives have been discussed," which

does not explicitly list the specific risks of endophthalmitis and retinal tears, does not satisfy the regulation's requirement.

The appellant, however, has pointed to no evidence in the record that he ever alleged that the informed consent discussion was defective in any way. Rather, he states that "in his brief before the Board, he addressed the issues of negligence and reasonable forseeability, both of which are intertwined with the issue of informed consent." Appellant's Supplemental Brief (Supp. Br.) at 1. He further points out that the Board discussed the adequacy of informed consent under 38 C.F.R. § 17.32. *Id.*

B. The Secretary

The Secretary asserts that the appellant's signed consent form is the only evidence in the record bearing on the question. He contends that the governing regulation and statute do not require complete documentation of the informed consent process. Rather, the Secretary insists that 38 C.F.R. § 17.32 requires only that the consent process be "appropriately documented." He proffers that an established interpretation of appropriate documentation is found in the *VHA Handbook* 1004.1, Paragraph 6, which requires, among other things, "[a] statement that relevant aspects of the treatment or procedure including indications, risks, benefits, and alternative options have been discussed with the patient in language the patient understood." *Id.* ¶6(b)(6). Therefore, the Secretary concludes that the informed consent document in this case constitutes appropriate documentation of the informed consent process under 38 C.F.R. § 17.32, deviations from regulatory requirements notwithstanding.[2] The Secretary also contends that the sufficiency of the informed consent process documented in the generic consent form is governed by the presumption of administrative

[2]As the Secretary acknowledges, the informed consent progress note (R. at 427), on which the Board relied as evidence of informed consent, does not conform to the requirements of *VHA Handbook* 1004.1 in several respects. There is no indication of the date or time. There is no indication of the patient's mental status at the time the informed consent information was provided, and the practitioner did not indicate whether the patient had decisionmaking capability.

Moreover, the regulation itself requires the consent discussion to be conducted by "[t]he practitioner who has primary responsibility for the patient or who will perform the particular procedure." 38 C.F.R. § 17.32(c) (2009). The form provides no evidence that this requirement was fulfilled. The signature of the practitioner writing the note is illegible. The form also provides no evidence that there was any discussion of "anticipated results if nothing is done." *Id*. Thus, even if the Secretary were correct that comporting with manual requirements achieves informed consent, this form might have been challenged on several bases.

regularity. He argues that applying this presumption, the adequacy of an appropriately documented informed consent process can be overcome only by submission of clear evidence to the contrary.

III. APPLICABLE LAW

A veteran who believes that he has sustained an additional disability resulting from treatment in a VA facility can seek compensation in two ways. The veteran can submit a claim for benefits under 38 U.S.C. § 1151(a). He may also seek compensation by filing a claim against the government, based on the purported negligence of its employees, including lack of informed consent before surgery, under the Federal Tort Claims Act (FTCA). *See* 38 U.S.C. § 1151(b).

Under 38 U.S.C. § 1151(a), compensation "shall be awarded for a qualifying additional disability in the same manner as if such additional disability were service[ ]connected" if the disability was

(a) . . . not the result of the veteran's willful misconduct and –

> (1) . . . was caused by hospital care, medical or surgical treatment, or examination furnished the veteran under any law administered by the Secretary . . . and the proximate cause of the disability or death was –
>
> (A) carelessness, negligence, lack of proper skill, error in judgment, or similar instance of fault on the part of [VA] in furnishing the hospital care, medical or surgical treatment, or examination; or
>
> (B) an event not reasonably foreseeable.

38 U.S.C. § 1151; *see* Pub. L. No. 104-204, § 422(b)(1), (c), 110 Stat. 2926-27 (1996) (amending section 1151 to incorporate fault requirement and providing that those amendments were made applicable to claims filed on or after October 1, 1997). Thus, to obtain benefits under 38 U.S.C. § 1151(a), a claimant must show: (1) A "qualifying additional disability," (2) actually caused by the treatment furnished by VA, and (3) a proximate or direct cause that is either a fault on the part of VA or an event not reasonably foreseeable. *Id*; 38 C.F.R. § 3.361(c)(1), (d)(1) (2009).

A "qualifying additional disability" is proximately caused by VA medical care, treatment, or examination when the disability results from *either* the carelessness, negligence, lack of proper skill, error in judgment, or similar instance of fault on the part of the Department in furnishing the medical treatment; *or* the disability results from "an event" that is "not reasonably foreseeable." 38 U.S.C.

§ 1151(a); 38 C.F.R. § 3.361(d)(1). To establish that the proximate cause of a disability was the result of carelessness, negligence, lack of proper skill, error in judgment, or similar instance of fault on the part of VA, the claimant must show *either* (1) VA failed to exercise the degree of care that would be expected of a reasonable health care provider; or (2) VA furnished the care, treatment, or examination without the veteran's informed consent. 38 C.F.R. § 3.361(d)(1).

Section 3.361, the VA regulation implementing 38 U.S.C. § 1151(a), advances definitions pertaining to informed consent and reasonably foreseeable events and reads, in relevant part, as follows:

> (1) *Care, treatment, or examination.* To establish that carelessness, negligence, lack of proper skill, error in judgment, or similar instance of fault on VA's part in furnishing hospital care, medical or surgical treatment, or examination proximately caused a veteran's additional disability or death, it must be shown that the hospital care, medical or surgical treatment, or examination caused the veteran's additional disability or death (as explained in paragraph (c) of this section); and
>
> (i) VA failed to exercise the degree of care that would be expected of a reasonable health care provider; or
>
> (ii) VA furnished the hospital care, medical or surgical treatment, or examination without the veteran's . . . informed consent. To determine whether there was informed consent, VA will consider whether the health care providers substantially complied with the requirements of § 17.32 of this chapter. Minor deviations from the requirements of § 17.32 of this chapter that are immaterial under the circumstances of a case will not defeat a finding of informed consent. Consent may be express (i.e., given orally or in writing) or implied under the circumstances specified in § 17.32(b) of this chapter, as in emergency situations.
>
> (2) *Events not reasonably foreseeable.* Whether the proximate cause of a veteran's additional disability or death was an event not reasonably foreseeable is in each claim to be determined based on what a reasonable health care provider would have foreseen. The event need not be completely unforeseeable or unimaginable but must be one that a reasonable health care provider would not have considered to be an ordinary risk of the treatment provided. In determining whether an event was reasonably foreseeable, VA will consider whether the risk of that event was the type of risk that a reasonable health care provider would have disclosed in connection with the informed consent procedures of § 17.32 of this chapter.

38 C.F.R. § 3.361(d); *see also* 69 Fed. Reg. 46,433 (2004). Because VA cited 38 U.S.C. § 1151 as authority for 38 C.F.R. § 3.361, it is apparent the Agency regarded lack of informed consent to be a "similar instance of fault" under that statute.

There is another statute that bears upon the regulatory structure pertaining to informed consent. Subchapter III of title 38, entitled "Protection of Patient Rights," provides that

> [t]he Secretary . . . shall prescribe regulations establishing procedures to ensure that . . . to the maximum extent practicable, *all patient care furnished under this title* shall be carried out only with the *full and informed consent* of the patient . . . .

38 U.S.C. § 7331 (emphasis added). Pertinent regulations require that "[e]xcept as otherwise provided in this section, all patient care furnished under title 38 U.S.C. shall be carried out only with the full and informed consent of the patient or, in appropriate cases, a representative thereof." 38 C.F.R. § 17.32(b).

Concerning the definition of and requirements for informed consent, at the time of the appellant's procedure, 38 C.F.R. § 17.32 provided:

> (c) *General requirements for informed consent.* Informed consent is the freely given consent that follows a careful explanation by the practitioner to the patient . . . of the proposed diagnostic or therapeutic procedure or course of treatment. The practitioner, who has primary responsibility for the patient or who will perform the particular procedure or provide the treatment, must explain in language understandable to the patient . . . [1] the nature of a proposed procedure or treatment; [2] the expected benefits; [3] reasonably foreseeable associated risks, complications or side effects; [4] reasonable and available alternatives; and [5] anticipated results if nothing is done. The patient . . . must be given the opportunity to ask questions, to indicate comprehension of the information provided, and to grant permission freely without coercion.
>
> (d) *Documentation of informed consent.* (1) The informed consent process must be appropriately documented in the medical record. In addition, signature consent is required for all [surgical procedures].

38 C.F.R. § 17.32(c), (d) (2001). That regulation was promulgated to implement 38 U.S.C. §§ 7331 through 7333. The regulation further defined "signature consent" as "[t]he patient's . . . signature on a VA-authorized consent form, *e.g.*, a published numbered VA form (OF 522) or comparable form approved by the local VA facility." 38 C.F.R. § 17.32(a) (2001).

IV. ANALYSIS

The Court is not persuaded by the appellant's argument that he is entitled to VA benefits under 38 U.S.C. § 1151 on the basis that the content of a generic consent form contained in the record establishes that VA was negligent per se. As discussed below, the standard VA consent form does not constitute affirmative evidence of negligence per se. Accordingly, the Court need not resolve the Secretary's arguments concerning the potential evidentiary value of such a form in a case where the adequacy of the consent is in dispute.

A. The Evidence in This Case

Generally, a claimant seeking VA benefits has the burden of presenting evidence supporting his or her claim, albeit with the statutorily mandated assistance of VA. *See* 38 U.S.C. § 5107(a); *Skoczen v. Shinseki*, 564 F.3d 1319 (2009). In this case, it is undisputed that the appellant introduced no evidence below—not even his own lay statements—that the informed consent discussion was defective in any way. Rather, he relies on the absence of a listing of specific disclosed risks on the informed consent form as evidence that VA did not obtain informed consent. He argues that the Board's finding that endophthalmitis and retinal tears were reasonably foreseeable events required their specific disclosure when VA obtained his consent. He contends that the fact that the consent form does not refer to these specific risks raises a presumption that these reasonably foreseeable complications were not discussed, thus contravening the regulatory requirements for informed consent. *See* 38 C.F.R. § 17.32(c) (2009).

We observe that when dealing with similar consent issues, some U.S. district courts, applying state law, have relied heavily on the lack of written documentation of a material risk in the informed consent document to find that informed consent was not obtained. *See Parkins v. United States*, 834 F. Supp. 569, 574 (D. Conn. 1993) (finding most significant evidence showing lack of informed consent to be absence of text in informed consent document discussing paralysis as possible consequence of procedure); *Powers v. United States*, 589 F. Supp. 1084, 1098 (D. Conn. 1984) (finding that consent form, which did not list paralysis as risk of operation "argues powerfully and convincingly for the proposition that the plaintiff was never advised of the material risks inherent in the [procedure].").

B. The Consent Form in the Regulatory Scheme

There are several difficulties, however, that counsel against such an approach in the context of the veterans benefits system. Significantly, to do so would ignore the statutory role of the Secretary in prescribing regulations to carry out statutory directives. "If Congress has explicitly left a gap for the agency to fill, there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation." *Chevron U.S.A., Inc. v. Natural Resources Defense Counsel, Inc.*, 467 U.S. 837, 843 (1984). In this instance, Congress instructed the Secretary to "prescribe regulations establishing procedures to ensure that . . . all patient care furnished under this title shall be carried out only with the full and informed consent of the patient." 38 U.S.C. § 7331. The Secretary responded by implementing a regulation requiring that "the informed consent process must be appropriately documented in the health record." 38 C.F.R. § 17.32(d)(1) (2008).

Moreover, the Secretary's interpretation of his own regulation is entitled to deference where it "reflect[s] the agency's fair and considered judgment on the matter in question." *Auer v. Robbins*, 519 U.S. 452, 462 (1997). The VHA handbook addressing the consent requirements demonstrates that the Department has long regarded the use and completion of consent forms such as VA Form OF-522 as appropriate documentation of the consent process. That view predates the creation of the implementing statute.[3]

---

[3]During the Senate hearings on 38 U.S.C. § 7331, a VA official testified as to the implementation of informed consent referred to in the statute:

> Before a patient has a surgical operation it has long been customary to obtain his signature on some type of document indicating his permission to undergo the outlined procedure. This is not a legal document and does little more than protect the operating team from being charged with assault. In recent years (1973) [VA] has changed this operation permit so that it is now a "Request for Administration of Anesthesia and for Performance of Operations and Other Procedures." In this document, the counseling physician signs his or her name to the statement that he has "counseled this patient as to the nature of the proposed procedures, attendant risks involved and expected results, as described above." It is obviously both impractical and impossible to detail every potential risk involved, and indeed if this were done many patients might well become so frightened that they would decline to accept needed and indicated treatment. Nevertheless, this document has seemed to function well and to my knowledge there have been few if any problems associated with its use over many thousands of operative procedures carried out in the system each year.

Veterans Omnibus Health Care Act of 1976: Hearings Before the Subcomm. on Health and Hospitals of the S. Comm. on Veterans' Affairs, 94th Cong. 596-97 (1976), at 597 (testimony of George A. Higgins, M.D., Chief of the Surgical Service of the Veterans' Administration Hospital, Washington, D.C.). The title of the document referred to in the testimony is that of Optional Form 522.

Thus, both the manual and the legislative history confirm that it is the Agency's considered judgment that the generic, standard form is the best overall approach to accomplishing documentation of the consent process. Although the Court does not entirely follow the Secretary's position with respect to the legal effect of the generic consent form, it will not disturb his judgment that such forms are best suited to the overall needs of VA medical facilities where such surgical procedures are performed. Given that the Secretary's regulations and handbook do not require a detailed recitation of all of the information conveyed in securing informed consent, it cannot be presumed that the appellant's complications were not discussed simply because they were not recorded. Accordingly, the Court is not persuaded by the appellant's reliance upon a negative evidentiary presumption.

In the absence of any evidence in support of the appellant's section 1151–based claim on a theory of negligence per se, his argument fails. The appellant may seek to reopen his claim with new and material evidence that raises specific questions as to the adequacy of the informed consent process, which would have to include his lay assertions that he indeed was not informed of the potential, reasonably foreseeable complications that occurred in his case.

Based on this holding, the Court need not resolve the question of what evidentiary value a generic consent form might have in a case where the claimant introduced other evidence that VA did not obtain informed consent. In this regard, the Court notes that any potential error in the Board's finding that "the medical evidence reflects informed consent on the veteran's behalf under 38 C.F.R § 17.32" (R. at 10) would not have been prejudicial in this case. Should the appellant introduce evidence disputing the issue of consent, the Secretary will need to make a de novo determination on that factual issue when the claim is reopened. The evidentiary significance of the consent form can be fully addressed at that time.

IV. CONCLUSION

Based on the foregoing reasoning, the Court AFFIRMS the Board's December 19, 2006, decision.