Vet. App. No. 19-7165

IN THE UNITED STATES COURT OF APPEALS FOR VETERANS CLAIMS

PAT A. HATFIELD,
Appellant,

v.

ROBERT L. WILKIE,
Secretary of Veterans Affairs,

Appellee.

ON APPEAL FROM THE BOARD OF VETERANS' APPEALS

BRIEF OF THE APPELLEE SECRETARY OF VETERANS AFFAIRS

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	)	
Appellee.	)	

ON APPEAL FROM THE
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BRIEF OF THE APPELLEE SECRETARY OF VETERANS AFFAIRS

I. STATEMENT OF THE ISSUE

Whether this Court should affirm the October 10, 2019, decision of the Board of Veterans' Appeals (Board), which denied Appellant entitlement to Dependency and Indemnity Compensation (DIC) benefits under 38 U.S.C. § 1151 for the cause of the Veteran's death as a result of medical treatment provided by the Department of Veterans Affairs (VA).

II. STATEMENT OF THE CASE

A. Nature of the Case

This appeal contests the October 10, 2019, Board decision, which found that Appellant was not entitled to DIC benefits under 38 U.S.C. § 1151 for the cause of the Veteran's death as a result of medical treatment provided by VA. *See* [Record Before the Agency (R.) at 1-20]. The Court should affirm the Board's decision

because Appellant has not carried her burden of demonstrating that it is clearly erroneous or the product of any prejudicial error.

B. Statement of Relevant Facts and Proceedings Below

The Veteran, Archie A. Hatfield, had qualifying service in the United States Army from March 1944 to May 1945. [R. at 1192 (1192-93)]. He died in January 1979, and his death certificate lists cardiac arrest as the immediate cause of death and radiation-induced pulmonary fibrosis as a condition that gave rise to the immediate cause of death. [R. at 1190 (1190-91)]. Appellant, Pat A. Hatfield, is the Veteran's surviving spouse. *See* [R. at 1014 (1014-15)] (marriage certificate).

At the time of the Veteran's death, he had received radiation treatment at VA for an otherwise fatal diagnosis of stage 2B Hodgkin's lymphoma. *See* [R. at 1595 (1593-95)] (a September 1978 VA discharge summary stating that the Veteran was diagnosed with "Hodgkin's lymphoma . . . staged at 2B," and that he would "be treated with radiation therapy for approximately one month"); *see also* [R. at 162 (160-62)] (a November 2018 medical opinion stating that thoracic Hodgkin's lymphoma "stage 2B is a lethal disorder untreated"); [R. at 1551 (1550-51)] (a May 1979 medial opinion describing the condition as an "otherwise uniformly fatal malignanc[y]"). As a result of the radiation treatment, the Veteran developed a lung condition that contributed to his death. *See* [R. at 785 (780-85)] (a January 1979 autopsy report stating that the Veteran presented in July 1978 with a right lung mass diagnosed as Hodgkin's disease and was provided radiation, which concluded in December 1978, and resulted in progressive respiratory

distress ultimately diagnosed as interstitial pneumonitis with fibrosis consistent with acute radiation reaction).

Appellant filed her initial VA claim in January 1979. [R. at 1609-16]. VA obtained a medical opinion in May 1979, which concluded that there was "no evidence that the [V]eteran's death resulted through carelessness, accident, negligence, lack of proper skill, error in judgment or similar instances of fault on the part of [VA]." [R. at 1551 (1550-51)]. The physician explained that "the pathologic diagnosis of Hodgkin's disease was correct" and "consistent with clinical stage II B." [R. at 1550 (1550-51)]. The physician noted that, "[b]ecause of the large extent of the mass disease in the chest, it was felt that radiation therapy would be necessary to deal with the local bulk disease." [R. at 1551 (1550-51)]. The radiation doses and fields were described as "standard and acceptable treatment," and the physician found "no evidence for deviation from accepted radiotherapy practices." [R. at 1551 (1550-51)]. In addition, the physician stated that "[r]adiation pneumonitis following this type of therapy has a predictable and finite incidence, up to as much as 50% in some series." [R. at 1551 (1550-51)]. However, the physician noted that it was unusual for radiation pneumonitis to have its onset as soon after completion of the therapy as it did in the Veteran's case. [R. at 1551 (1550-51)]. Ultimately, the physician opined that "[s]uch an outcome is always a potential risk when treating otherwise uniformly fatal malignancies with these modalities." [R. at 1551 (1550-51)].

Appellant's claim was denied by the VA Regional Office (RO) in June 1979. [R. at 1547]. In March 1979, Appellant filed a Substantive Appeal in which she stated that "[t]he oncologist told me and my husband there was a 95% cure for [H]odgkins disease with proper treatment. . . . We did not agree on radiation treatments to burn him up." [R. at 1499 (1498-99)].

The Board obtained an independent medical expert opinion in August 1980 from the Head of the Division of Oncology at Albany Medical College. [R. at 1474-79]. The independent expert stated that the treatment plan of radiation therapy followed by chemotherapy was "fully appropriate" for the Veteran. [R. at 1476 (1474-79)]. He explained that the development of pulmonary complications are "an expected risk of radiation therapy," and that the dose of radiation "necessary to control active Hodgkin's disease in the lymph nodes" would "cause pulmonary complications whenever the lung is radiated to this dose." [R. at 1476 (1474-79)]. The independent expert further stated that "the extent of damage . . . varies from being an asymptomatic change . . . to a fatal generalized interstitial pneumonitis," although noting that the risk of a fatal pulmonary reaction was "small—probably less than 1%." [R. at 1476 (1474-79)]. The independent expert concluded by stating that "[g]eneralized fatal radiation pneumonitis is an unusual but well recognized complication of 'mantle' radiation in Hodgkin's disease." [R. at 1478 (1474-79)].

The Board denied Appellant's claim in an October 1980 decision, wherein it found "that the treatment plan implemented in this case was sound, even though

the results were undeniably tragic." [R. at 1465 (1452-68)]. The Board panel, which included a medical member, emphasized "that allowing the [V]eteran's Hodgkin's disease to go untreated would have led to certain death" and found that "[n]o reasonable mode of treatment in such a case is without risk." [R. at 1465 (1452-68)]. The Board acknowledged that the independent medical expert advised that the risk of a fatal pulmonary reaction was very small, but it found that such a reaction was a contemplated possible result of the treatment provided. [R. at 1466 (1452-68)].

Appellant attempted to reopen her claim multiple times over the years, most recently in July 2010. [R. at 1372-83]. The RO issued a rating decision in January 2011 that found that Appellant had not submitted new and material evidence to reopen her previously and finally denied claim. [R. at 1254-56, 1280-83]. Appellant filed a Notice of Disagreement (NOD) with the RO's decision in March 2011, [R. at 1226-27]; the RO issued a Statement of the Case (SOC) in July 2012, [R. at 973-99]; and Appellant perfected her appeal by filing a Substantive Appeal with the Board in August 2012, [R. at 957-58].

The Board issued a decision in July 2016 that found Appellant had not submitted new and material evidence sufficient to reopen her previously denied claim of service connection for the cause of the Veteran's death and had not submitted new and material evidence to reopen her previously-denied claim of entitlement to payment of DIC benefits under 38 U.S.C. § 1151. [R. at 327-46].

Appellant, by and through her current attorney, sought review of the Board's July 2016 decision by this Court, resulting in a memorandum decision by the Court in November 2017 that dismissed the appeal, in part, and remanded, in part. [R. at 297-301]; *see Hatfield v. Shulkin*, No. 16-3332, 2017 U.S. App. Vet. Claims LEXIS 1618 (November 3, 2017). The Court held that, "[b]ecause appellant has presented no arguments on appeal concerning the Board's denial of reopening her late husband's service-connection claim, she is deemed to have abandoned it." [R. at 297 (397-301)]. The Court dismissed Appellant's "appeal regarding the Board's failure to discuss whether the specific lung disease leading to her husband's death [quick-onset fatal lung disease] was unforeseeable," explaining that "this 'foreseeability issue'" was not properly before the Court. [R. at 298, 299 (297-301)].

On remand, Appellant submitted a January 2018 private medical opinion that concluded it was "more likely than not that [the Veteran's] death due to rapid development and progression of bilateral radiation pneumonitis was not a foreseeable event." [R. at 224 (221-25)]. The physician noted that medical literature from 1975 indicated that the risk of such complications to be small and death from it very rare. [R. at 224 (221-25)]. The opinion conceded that "pulmonary complications and some degree of pneumonitis is a known complication of especially Cobalt radiation treatment to the lung," but stated that "severe and fatal pulmonary complications that onset so quickly [are] not common." [R. at 224 (221-25)]. As a result, the physician opined that Appellant's death "was

not a foreseeable event." [R. at 224 (221-25)]. In addition, the physician opined "that there was no consent for this complication," reasoning that "there is no identifiable evidence that [the Veteran] provided informed consent or was presented with information sufficient for an informed consent." [R. at 225 (221-25)]. The physician concluded by stating that "the potential risk of dying within weeks of completing radiation would . . . not normally be included in any informed consent protocol at that time." [R. at 225 (221-25)].

The Board issued a decision in April 2018 that found new and material evidence had been received to reopen Appellant's previously denied claim of entitlement to payment of DIC benefits under 38 U.S.C. § 1151 and remanded that issue on the merits for additional development. [R. at 193 (188-99)]. Appellant sought review of the Board's decision by this Court, resulting in a Joint Motion for Partial Remand (JMPR) to ensure that the Board addressed "Appellant's expressly raised theory that a foreseeability theory of entitlement to DIC under [38 U.S.C.] § 1151 remains pending and unadjudicated." [R. at 67 (64-70)]; *see Hatfield v. Wilkie*, Vet. App. No. 18-1779, Joint Motion for Partial Remand (March 27, 2019).

In November 2018, a VA physician provided an opinion that "[t]here is no question that the treatment provided to the [V]eteran in 1978 was appropriate and the dosage of radiation, 4,000 rads, was not excessive by standards in effect at that time." [R. at 161 (160-62)]. The physician stated that "pulmonary fibrosis is a known complication of radiotherapy," but acknowledged that it rarely progressed rapidly ending in early death as it did in this case. [R. at 162 (160-62)]. On the

issue of informed consent, the physician noted that "the disease process was lethal without treatment, and a patient would have had limited options." [R. at 162 (160-62)]. He explained that, "[t]horacic Hodg[]kin's Lymphoma stage 2B is a lethal disorder untreated" and "with the bulky thoracic tumor he had . . . [h]is lungs would have failed in a relatively short time." [R. at 162 (160-62)]. The physician stated that, "[g]iven this situation, no reasonable patient would opt to forgo the radiation treatment that was proposed to the [V]eteran in 1978." [R. at 162 (160-62)].

The Board issued the decision now on appeal on October 10, 2019. [R. at 1-20]. It found that Appellant was not entitled to DIC benefits under 38 U.S.C. § 1151 for the cause of the Veteran's death as a result of medical treatment provided by VA because (1) the proximate cause of the Veteran's death was not due to carelessness, negligence, lack of proper skill, error in judgment, or similar instance of fault on the part of VA in furnishing hospital care, medical or surgical treatment, or examination, and was not the result of an event not reasonably foreseeable; and (2) although there is no evidence that the Veteran signed an informed consent to radiation treatment and its potential risks, no reasonable patient would have opted to forego the radiation treatment provided by VA. [R. at 5 (1-20)]. In addition, the Board found that Appellant's "theory of foreseeability is not pending (and unadjudicated) from the 1980 Board denial" because "in the October 1980 Board decision finding of facts section, the Board found that '[i]t has not been demonstrated that pulmonary fibrosis (or any other disease or injury present at the time of the [V]eteran's death) was an unforeseen

or untoward event associated with treatment administered at [VA] facilities.'" [R. at 7 (1-20)] (quoting [R. at 1467 (1452-68)]).

III. ARGUMENT

A. Appellant Has Not Carried Her Burden of Demonstrating that the Board's Decision is Clearly Erroneous or the Product of Prejudicial Error

The Court should affirm the Board's October 10, 2019, decision, which found that Appellant was not entitled to DIC benefits under 38 U.S.C. § 1151 for the cause of the Veteran's death as a result of medical treatment provided by VA because that decision is plausibly based on the evidence of record and is not clearly erroneous. *Gilbert v. Derwinski*, 1 Vet.App. 49, 52 (1990). Appellant has not demonstrated that the Board committed prejudicial error so as to warrant any action by the Court other than affirmance. *See Hilkert v. West*, 12 Vet.App. 145, 151 (1999) (en banc) (holding that appellant has the burden of demonstrating error), *aff'd*, 232 F.3d 908 (Fed. Cir. 2000) (table); *see also Shinseki v. Sanders*, 556 U.S. 396, 409-10 (2009) (explaining that the burden of demonstrating prejudice normally falls upon the party attacking the agency's determination).

The Board's factual findings, including its finding of whether a claimant has established a basis for compensation under 38 U.S.C. § 1151, are reviewed by this Court under the "clearly erroneous" standard of review set forth in 38 U.S.C. § 7261(a)(4). *See Look v. Derwinski*, 2 Vet.App. 157, 161-62 (1992). Under the "clearly erroneous" standard, the Court must accept the Board's findings of fact unless firmly convinced, in light of the whole record, that they are mistaken.

Warren v. McDonald, 28 Vet.App. 214, 218 (2016). The standard is not met simply because the Court would have decided matters differently had it been the trier of fact. *Id.* Because, here, there is a plausible basis in the record for the Board's overall conclusion that Appellant is not entitled to DIC benefits under 38 U.S.C. § 1151, the Court should affirm the Board's decision. *See Warren*, 28 Vet.App. at 218; *see also Fears v. Wilkie*, 31 Vet.App. 308, 314 (2019) (explaining that, under the "clearly erroneous" standard, the Board's findings may only be overturned "if there is no plausible basis in the record" for them).

B. Legal Principles Applicable to Appellant's Claim for Compensation Under 38 U.S.C. § 1151

Under 38 U.S.C. § 1151(a), compensation "shall be awarded for a qualifying additional disability or a qualifying death of a [V]eteran in the same manner as if such additional disability or death were service-connected" if not the result of willful misconduct and "(1) the disability or death 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(a); *see* Pub. L. No. 104-204, § 422(b)(1), (c), 110 Stat. 2926-27 (1996) (amending section 1151 to incorporate a fault requirement and providing

that the amendments were made applicable to claims filed on or after October 1, 1997).

The VA regulation implementing 38 U.S.C. § 1151(a) explains that, to obtain benefits, a claimant must show the following: (1) a "qualifying additional disability or qualifying death," (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. 38 C.F.R. § 3.361(c)(1), (d)(1).[1] To establish proximate cause, a claimant must show either that (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).

The regulation explains that, "[t]o 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." 38 C.F.R. § 3.361(d)(1)(ii). Further, the regulation states that "[m]inor 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." 38 C.F.R. § 3.361(d)(1)(ii). The

[1] The provisions of 38 C.F.R. § 3.361 apply to "claims received by VA on or after October 1, 1997," to include "original claims and claims to reopen or otherwise readjudicate a previously claim for benefits under 38 U.S.C. § 1151 or its predecessors." 38 C.F.R. § 3.361(a). Appellant's claim to reopen, which gave rise to the current appeal, was received by VA on July 20, 2010. [R. at 1370-87]. Because the date of receipt of the claim is after October 1, 1997, the provisions of 38 C.F.R. § 3.361 apply.

regulation explains that "[w]hether 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" and states that "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" and "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. 46426, 46433 (Aug. 3, 2004) (final rule promulgating revisions to 38 C.F.R. § 3.361).

Concerning the definition of and requirements for informed consent, 38 C.F.R. § 17.32 provides, in pertinent part, that "[i]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," including "the expected benefits; reasonably foreseeable associated risks, complications or side effects; reasonable and available alternatives; and anticipated results if nothing is done." 38 C.F.R. § 17.32(c). The regulation states that "[t]he informed consent process must be appropriately documented in the medical record." 38 C.F.R. § 17.32(d).

Therefore, as relevant here, Appellant may receive compensation under 38 U.S.C. § 1151(a) for the qualifying death of the Veteran it she demonstrates that his death proximately resulted from negligent VA medical care or similar

instance of fault, which she can demonstrate by a showing that VA did not obtain informed consent, or that his death resulted from an event not reasonably foreseeable. *See* 38 U.S.C. § 1151(a); 38 C.F.R. § 3.361(d)(1)(ii).

C. Appellant's Arguments Do Not Defeat the Board's Finding of Informed Consent

Appellant argues that there is no evidence of record documenting that the Veteran provided informed consent for radiation treatment to treat his Hodgkin's disease in 1978 and, as a result, that she is entitled to compensation under 38 U.S.C. § 1151 and 38 C.F.R. § 3.361(d)(1)(ii). *See* [Appellant's Brief (Br.) at 11-18]. The Board acknowledged that "there is no dispute that there is no informed consent document of record." [R. at 16 (1-20)]. The Court should not be persuaded by Appellant's assertion that a lack of documentation of the Veteran having provided informed consent requires that the Board's decision be reversed and that she be awarded benefits. Appellant's argument is not supported by the text, structure, history, or purpose of 38 U.S.C. § 1151 or 38 C.F.R. § 3.361. [2]

[2] The Secretary asserts that his interpretation of the regulation comports with a plain reading of the regulation using traditional tools of interpretation, as discussed herein, to require that VA consider whether a deviation from the informed consent requirements of 38 C.F.R. § 17.32 is minor and immaterial under the circumstances of a case. Therefore, the "regulation then just means what it means—and the court must give it effect." *Kisor v. Wilkie*, 139 S. Ct. 2400, 2415 (2019). However, should the Court find the regulation to be genuinely ambiguous, deference should be afforded to the Secretary's reasonable interpretation argued herein, which involves the Secretary's substantive expertise in the provision of healthcare, and matters of obtaining informed consent related thereto. *Id.*; *see Auer v. Robbins*, 519 U.S. 452 (1996).

In *McNair v. Shinseki*, the Court considered "the evidentiary effect of . . . a generic consent form when the scope of the advice provided to a patient-turned claimant is contested by the claimant." *McNair v. Shinseki*, 25 Vet.App. 98, 103 (2011). The Secretary argued, and the Court agreed, that 38 C.F.R. § 3.361(d)(1)(ii) should be interpreted to mean that deviations from the informed consent requirements of 38 C.F.R. § 17.32 are minor and immaterial if a reasonable person under the circumstances would have consented to the treatment anyway. *McNair,* 25 Vet.App. at 106. The Court found that "[t]he text of [38 C.F.R.] § 3.361(d)(1)(ii) and its placement in the overall regulatory scheme demonstrate that the term minor deviations includes substantive as well as technical or procedural errors" in the informed consent process. *Id.* The Court also found that the common law understanding upon which 38 C.F.R. § 3.361(d)(1)(ii) is based, and the history of the promulgation of the regulation, also demonstrated that deviations from the informed consent requirements of 38 C.F.R. § 17.32 are minor and immaterial if a reasonable person in similar circumstances would have proceeded with the medical treatment even if informed of the foreseeable risk. *McNair,* 25 Vet.App. at 107; *see* 67 Fed. Reg 76322, 76323 (Dec. 12, 2002) (proposed rule) (stating that Congress established a single "tort-variety negligence" standard that would trigger entitlement to 38 U.S.C. § 1151 benefits); *see also* 69 Fed. Reg. at 46433 (final rule) (explaining that 38 U.S.C. § 1151 reflects ordinary common-law principles of negligence" and that the

provisions of "38 C.F.R. § 3.361(d)(1) are intended merely to restate, more simply and clearly, the standards governing determinations of negligence").

Appellant attempts to limit the Court's holding in *McNair* to the factual situation where the informed consent process is documented in the record, but was of a generic nature without documentation of the specific risk that later lead to additional disability or death. *See* [Br. at 11-18] (relying on nonprecedential authority, *Grassi v. Shinseki*, No. 12-2809, 2013 U.S. App. Vet. Claims LEXIS 1934 (November 22, 2013)). However, the holding of *McNair* is not expressly limited to that factual situation, and the logic of the Court's decision applies equally well in the factual situation where, as here, the informed consent process is not documented in the record. *See, e.g., Lancaster v. McDonald*, No. 13-1609, 2014 U.S. App. Vet. Claims LEXIS 1372 (Aug. 7, 2014) (reasoning by Chief Judge Kasold, who authored the Court's precedent in *McNair*, that "in the absence of an informed consent form, there remains the issue of whether a reasonable person would have undergone the medical procedure even knowing the possible risks associated with the procedure," rejecting an argument for reversal); *see also Murphy v. Shulkin*, No. 16-1923, 2017 U.S. App. Vet. Claims LEXIS 1416 (Sept. 29, 2017) (reasoning by Judge Schoelen that "the absence of an informed consent form is not dispositive," and stating that the Board provided a "proper restatement of the Court's caselaw" in finding that, even in the absence of any consent form, "a reasonable person in similar circumstances would have

proceeded with the medical treatment even if informed of the foreseeable risk" (internal quotations omitted)). [3]

The lack of "documentation" of informed consent does not prove a lack of informed consent under 38 C.F.R. § 17.32 and 38 C.F.R. § 3.361(d)(1)(ii) and does not require the award of compensation under 38 U.S.C § 1151. Appellant's argument for that result would make the absence of a consent form dispositive and preclude any ability of an adjudicator to consider whether a "technical or procedural" error in documenting the informed consent process constitutes a minor and immaterial deviation from the requirements of 38 C.F.R. § 17.32 under the circumstances of the case. *See* [Br. at 11-18]. Such an argument is contrary to the plain language of 38 C.F.R. § 3.361(d)(1)(ii), which states that minor and immaterial deviations from the requirements of 38 C.F.R. § 17.32 will not defeat a finding of informed consent, as well as the Court's decision in *McNair*, which explained that deviations in compliance with the informed consent requirements of 38 C.F.R. § 17.32 contemplated by 38 C.F.R. § 3.361(d)(1)(2) include both "substantive as well as technical or procedural errors." *McNair*, 25 Vet.App. at 106. Appellant's interpretation of the regulation would lead to the absurd result of allowing "substantive" errors to be deemed immaterial, but mandating that all "technical or procedural" errors be deemed material, thus defeating a finding of

[3] In accordance with VET. APP. R. 30(a), these two nonprecedential authorities are cited only for the persuasive value of their logic and reasoning since no clear precedent exists that applies *McNair* in the factual situation where there is no informed consent document contained in the record.

informed consent and requiring the award of compensation. Courts should avoid statutory or regulatory interpretations that lead to absurd results. *See, e.g., McNeill v. United States*, 563 U.S. 816, 822 (2011).

In *McNair*, the Court found that the common law tort negligence principles underlying 38 C.F.R. § 3.361(d)(1) were most consistent with the use of an objective test for determining whether such a deviation in compliance with the informed consent process was minor and immaterial under 38 C.F.R. § 3.361(d)(1). *McNair,* 25 Vet.App. at 107; *see* 67 Fed. Reg at 76323 (proposed rule); 69 Fed. Reg. at 46433 (final rule). The Court explained that "the adjudicator not only must look to the likelihood of an undisclosed risk materializing, but also recognize that some foreseeable risks may be minor when compared to the foreseeable consequences of continuing without undergoing the treatment." *McNair,* 25 Vet.App. at 107. Appellant's interpretation would effectively preclude any consideration of whether there was substantial compliance with the informed consent requirements of 38 C.F.R. § 17.32, to include whether a "technical or procedural" deviation in the documentation of the informed consent process was minor or immaterial within the meaning of 38 C.F.R. § 3.361(d)(1)(ii). However, the objective test set forth in *McNair* should apply equally to determining whether a "technical or procedural" deviation from the requirements of 38 C.F.R. § 17.32 is minor and immaterial as it does in determining whether a "substantive" deviation from the requirements of 38 C.F.R. § 17.32 is minor and immaterial.

The Board correctly found that Applying that test to the circumstances of this case does not defeat a finding of informed consent. The Board found "that no reasonable patient would have opted to forego the radiation treatment provided by VA." [R. at 17-18 (1-20)]. The Board relied on medical opinion evidence that explained that a "lack of treatment of the Veteran's Hodgkin's disease would have led to certain death." [R. at 16 (1-20)]; *see* [R. at 162 (160-62)] (a November 2018 medical opinion stating that thoracic Hodgkin's lymphoma "stage 2B is a lethal disorder untreated"); *see also* [R. at 1551 (1550-51)] (a May 1979 medial opinion describing the condition as an "otherwise uniformly fatal malignanc[y]"). The Board also noted that the November 2018 medical opinion explained that "because the disease process was lethal without treatment . . . a patient would have had limited options" and opined that, "[g]iven this situation, no reasonable patient would opt to forgo the radiation treatment that was proposed to the [V]eteran in 1978." [R. at 162 (160-62)]. [R. at 14 (1-20)] (quoting [R. at 162 (160-62)]). The Board correctly applied the objective test set forth in *McNair* and plausibly found that the potential risks of the Veteran undergoing radiation treatment in 1978 were not outweighed by the foreseeable consequences of continuing without undergoing the treatment, which was "certain death," such that no reasonable person would have forgone the treatment. [R. at 5, 16, 17-18 (1-20)]. From an objective perspective, the lack of documentation of the Veteran's consent to a treatment with the risk of a rare but potentially fatal lung condition should not defeat a finding of informed consent when the risk of not proceeding with treatment was certain death.

The Board's factual findings on this issue are plausibly based on the evidence of record and are not clearly erroneous, and its findings form the factual predicate for concluding that any "technical or procedural" deviation in complying with the documentation of the informed consent process would be minor and immaterial under the 38 C.F.R. § 3.361(d)(1)(2) and would not defeat a finding of informed consent.

The Court should reject Appellant's attempt to limit the holding of *McNair* and impose a different standard for determining whether a "technical or procedural" deviation in complying with the documentation of the informed consent process under 38 C.F.R. § 17.32 was minor or immaterial under the circumstances of this case. In *McNair,* the Court explained that the use of an objective standard, rooted in the common law, "'is fair to the patient because it requires consideration by the factfinder of what a reasonable person with all of the characteristics of the plaintiff would have done under the same circumstances . . . and is likewise fair to the physician-defendant because the physician is not placed in jeopardy of the patient's hindsight.'" *McNair,* 25 Vet.App. at 107 (quoting *Sherwood v. Carter,* 805 P.2d 452, 465 (Idaho 1991)). The Court also noted that "there is no reason to believe that the Secretary intended to apply" a subjective standard to informed-consent determinations, and it further noted the inherent difficulties that imposing a subjective standard would impose on the finder-of-fact as well as a patient who dies and would be foreclosed from any recovery because she could not testify as to what her subjective belief was at the time of the procedure. *Id.* n.1. Appellant

has not explained why a different standard should apply when documentation of the informed consent process is not available than when documentation is available but fails to show that a specific risk was not disclosed. The inherent difficulties in using a subjective standard recognized by the Court in *McNair* would apply equally in either factual situation.

Appellant's argument, if accepted, would place the physician "in jeopardy of the patient's hindsight," which, in this case, involves recall of a discussion regarding informed consent that took place over 40 years ago knowing that the procedure resulted in the Veteran's death. *McNair,* 25 Vet.App. at 107. Appellant acknowledges that at least some discussion of the risks of the Veteran undergoing radiation treatment for Hodgkin's disease took place. *See* [Br. at 27-28] (acknowledging that "she and the [V]eteran were told by the treating physician that the radiation treatment administered was a 95 percent cure for Hodgkin's Disease"); *see* [R. at 1499 (1497-99)] (Appellant's March 1980 statement); *see also* [R. at 1557 (1555-62)] (Appellant's April 1979 statement). Appellant also noted that she and her husband "did not agree on radiation treatments to burn him up." [R. at 1499 (1497-99)]. Inherent in Appellant's statements is that she and the Veteran were informed by a VA oncologist at the time of treatment that there would be a 5% chance that the radiation treatment would not be effective and, in addition, that she and her husband agreed on radiation treatments, although not knowing that the treatments would "burn him up." *See* [R. at 1498, 1499 (1497-99)]. Appellant's March 1980 statement also acknowledged that "my husband is not

living . . . and can not verify what I am going to tell you." [R. at 1498 (1497-99)]; *cf. McNair,* 25 Vet.App. at 107 n.1. (discussing the inherent difficulty of applying a subjective standard to informed-consent determinations, noting specifically the example where a patient dies and is not able to testify as to his or her subjective belief at the time of the procedure). The inherent difficulties in using a subjective standard that were noted in *McNair* are made clear by the facts of this case.

In addition, the Court should not sanction the award of compensation under 38 U.S.C. § 1151 without a claimant having to satisfy the causation element required by 38 U.S.C. § 1151. The history of 38 U.S.C. § 1151, which clearly requires that the VA negligence or fault be the proximate cause of the injury or death, and the Court's holding in *McNair*, which relied on common law negligence principles, both support the view that 38 C.F.R. § 3.361 must be interpreted within the parameters of the statutory causation requirement of 38 U.S.C. § 1151. A different result would imply that VA intended in the regulations to award compensation under 38 U.S.C. § 1151 in some circumstances without causation with respect to the VA act of fault, despite the causation requirement in the statute, based solely on a "technical or procedural" deviation in complying with the informed consent requirements of 38 C.F.R. § 17.32 . VA did not intend that result and did not so indicate in the Federal Register; rather, VA indicated that general tort principles would apply, as *McNair* acknowledged, and those principles include a causation requirement with respect to informed consent**.** *See* 67 Fed. Reg at 76323 (proposed rule); 69 Fed. Reg. at 46433 (final rule).

The structure of the regulation also supports this view. The informed consent requirements fall under the 38 C.F.R. § 3.361(d) subheading for establishing proximate cause. Under 38 C.F.R. § 3.361(d)(1), to establish that VA negligence proximately caused the death, there are two general elements: (1) lack of consent; and (2) causation. Where, as here, the VA fault alleged is in not obtaining informed consent, the lack of consent must be the proximate cause of death under the statute. The objective test set forth by the Court in *McNair* adequately addresses this issue by inquiring whether "a reasonable person in similar circumstances would have proceeded with the medical treatment even if informed of the foreseeable risk." *McNair,* 25 Vet.App. at 107.

As relevant in this case, it should be noted that 38 C.F.R. § 17.32 did not exist prior to 1980 (when its predecessor 38 C.F.R. § 17.34 was promulgated). *See* 45 Fed. Reg. 6933 (Jan 31, 1980) (final rule promulgating 17.34). When, as here, treatment occurred prior to 1980, there was no regulation similar to 38 C.F.R. § 17.32 in place. While VA did make 38 C.F.R. § 17.34 retroactive to 1976 when it was enacted in 1980, it does not follow that VA also intended to impose strict liability on itself for care proved between 1976 and 1980 when failing to comply with the informed consent requirements in a regulation that did not yet exist. The more logical reading is that VA must consider whether there was substantial compliance with the informed consent requirements of 38 C.F.R. § 17.32 by determining whether any deviations are minor and immaterial based on the specific factual circumstances of the case. The objective test set forth by the Court in

McNair adequately addresses this issue. Appellant has not persuasively explained why it should not be applied in this case and has not carried her burden of demonstrating that the Board's application of that test to the circumstances of this case was not plausibly based on the evidence of record or was inconsistent with the requirements of 38 C.F.R. § 3.361(d)(1)(ii). As a result, the Court should affirm the Board's decision.

D. The Board Did Not Clearly Err in Finding that the Proximate Cause of the Veteran's Death Was Not an Event Reasonably Foreseeable

Appellant argues that the Board erred by failing to provide an adequate statement of reasons or bases for finding that the Veteran's sudden death was reasonably foreseeable, and faults the Board for relying on VA, independent, and private medical opinions that, he claims, all fail to adequately address whether the suddenness of the Veteran's death was an event not reasonably foreseeable. [Br. at 19-25]. Appellant's "foreseeability" arguments are based on a misunderstanding of 38 U.S.C. § 1151(a)(1)(B) and 38 C.F.R. § 3.361(d)(2) and are not supported by the evidence of record.

Appellant's focus on whether the suddenness of the Veteran's death was reasonably foreseeable is misplaced because the relevant inquiry under the statute and regulation is whether the Veteran developing pulmonary fibrosis was an event that was reasonably foreseeable as a result of his VA treatment and, if not, whether pulmonary fibrosis was the proximate cause of the Veteran's death. In *Ollis v. Shulkin*, the Federal Circuit explained that a theory of recovery under

§ 1151(a)(1)(B) requires that a claimant "show that the disability or death was proximately caused by the unforeseeable event." *Ollis v. Shulkin*, 857 F.3d. 1338, 1344 (2017). As *Ollis* explained, "even if [the claimant] can satisfy the proximate cause requirement of § 1151(a)(1)(B), the cause requirement of § 1151(a)(1) remains." *Ollis*, 857 F.3d. at 1345. The Federal Circuit emphasized that, when the theory of recovery is based on 38 U.S.C. § 1151(a)(1)(B), the provisions of 38 U.S.C. § 1151(a)(1) require that VA care result in an unforeseeable event and that 38 U.S.C. § 1151(a)(1)(B) then "further requires" that the unforeseeable event proximately cause disability or death. *Ollis*, 857 F.3d. at 1345. Appellant skips a significant analytical step in arguing that the Veteran's death itself was not an event reasonably foreseeable, but his argument still does not establish that death resulting from pulmonary fibrosis was not an event reasonably unforeseeable. *See, e.g.,* [R. at 1478 (1474-79)] (1980 independent expert opinion stating that "[g]eneralized fatal radiation pneumonitis is an unusual but well recognized complication of 'mantle' radiation in Hodgkin's disease").

All the VA, independent, and private opinions of record in this case acknowledge that respiratory, pulmonary, or lung conditions are a foreseeable consequence of radiation for Hodgkin's disease. The consensus is that, although the severity and suddenness of the Veteran's complications were rare, the complications were known and were foreseeable. *See* [R. at 1551 (1550-51)] (May 1979 VA opinion that "[r]adiation pneumonitis following this type of therapy has a predictable and finite incidence, up to as much as 50% in some series . . .

[and] may be fatal" and "although it is very unusual for it to have its onset this soon after completion of therapy . . . [s]uch an outcome is always a potential risk"); [R. at 1476 (1474-79)] (August 1980 independent medical expert opinion noting that the radiation does "necessary to control active Hodgkin's" can cause a "fatal generalized inte[r]stitial pneumonitis" but that "the risk of a fatal pulmonary reaction . . . is small—probably less than 1%"); [R. at 224 (221-25)] (February 2018 private opinion that "pulmonary complications and some degree of pneumonitis is a known complication . . . severe and fatal pulmonary complications that onset so quickly is not common"); [R. at 162 (160-62)] (November 2018 VA opinion that "pulmonary fibrosis is a known complication of radiotherapy" and "can occur as early as 1 to 3 months after treatment" . . . [but] rarely progresses rapidly, ending in an early death as in this case").

The plain wording of 38 C.F.R. § 3.361(d)(2) states that the determination as to whether an event is not reasonably foreseeable is "based on what a reasonable health care provider would have foreseen." *Id.*; *see also Schertz v. Shinseki*, 26 Vet.App. 362, 368 (2013). Here, multiple healthcare providers have indicated that respiratory, pulmonary, or lung conditions, to include pulmonary fibrosis, are a foreseeable consequence of radiation for Hodgkin's disease and can be potentially fatal. *See* [R. at 1551 (1550-51)]; [R. at 1476 (1474-79)]; [R. at 224 (221-25)]; [R. at 162 (160-62)]. No opinion indicates otherwise.

In promulgating 38 C.F.R. § 3.361(d)(2), VA explained that "[t]he risk of an event may be reasonably foreseeable by medical standards even if the event

occurs in only a small percentage of cases." 69 FR at 46430 (final rule). Here, the risk of the Veteran developing pulmonary fibrosis as a result of his VA radiation treatment was not an event reasonably unforeseeable as measured by the applicable "reasonable health care provider" standard. Indeed, given the uniform consensus of VA, independent, and private physicians on this issue over the span of more than four decades, it is clear that the complications that the Veteran suffered were foreseeable. Although the severity and suddenness of the Veteran's death as a result of those complications was rare, it does not support Appellant's legal argument that the respiratory, pulmonary, or lung conditions, to include pulmonary fibrosis, that the Veteran experienced were not reasonably foreseeable or that such complications could be foreseen to be potentially fatal.

Appellant places an undue emphasis on the suddenness of the Veteran's death as an event that was not reasonably foreseeable, but 38 U.S.C. § 1151(a)(1) requires that VA care result in an unforeseeable event and 38 U.S.C. § 1151(a)(1)(B) then "further requires" that the unforeseeable event proximately cause disability or death. *See Ollis*, 857 F.3d. at 1345. Because Appellant has not established that the Veteran's development of pulmonary fibrosis was an event not reasonably foreseeable, or that such a condition could not reasonably be foreseen to potentially result in death, she has not carried her burden of demonstrating any prejudicial Board error in finding that compensation under a "foreseeability" theory pursuant to 38 U.S.C. 1151(a)(1)(B) was not warranted, to

include any procedural duty-to-assist error or substantive error by the Board in its interpretation of the applicable statute and regulation. *See* [Br. at 23-25].

E. The Board Did Not Err in Finding that There Is No Claim Pending and Unadjudicated from 1980

Appellant argues that the Board's October 1980 decision failed to address whether the "quickness of the Veteran's *death*" was an unforeseeable event. [Br. at 26]. She asserts that the issue has remained pending and unadjudicated since her original claim. [Br. at 26]. Appellant argues that the Board's 1980 decision did "not adjudicate whether the veteran's death itself was unforeseeable" but only addressed whether the Veteran "suffered an unforeseeable injury or disease prior to his death." [Br. at 26].

However, the Board's October 1980 decision expressly found that while "the risk of a fatal pulmonary reaction is very small . . . we are unable to say that such a reaction was not a contemplated possible result." [R. at 1466 (1452-68)] (Board panel decision, including a medical member). The Board acknowledged that "the [V]eteran's death in January 1979 was immediately caused by cardiac arrest due to pulmonary fibrosis which was induced by radiation therapy for Hodgkin's disease," but it found that pulmonary fibrosis was not "an unforeseen or untoward event associated with treatment administered at [VA] facilities." [R. at 1467 (1452-68)]. As a result, the Board concluded that the criteria for the award of benefits under 38 U.S.C. 351 (the predecessor to 38 U.S.C. § 1151) had not been met. [R. at 1468 (1452-68)].

The Board correctly determined that "the theory of foreseeability is not pending (and unadjudicated) from the 1980 Board denial" because the issue had been adequately adjudicated. [R. at 7 (1-20)]. The Board also correctly explained that, legally, the Board's denial of entitlement to compensation in October 1980 denied all potential theories of entitlement to the benefit denied such that no theory would have remained pending and unadjudicated. [R. at 7 (1-20)]; *see Bingham v. Nicholson*, 421 F.3d 1346, 1348 (Fed. Cir. 2005) (explaining that the denial of a claim by the Board is a decision as to all potential theories of entitlement, not just those considered and rejected); *see also Robinson v. Mansfield*, 21 Vet. App. 545, 550 (2008) (stating that, in *Bingham*, "the Federal Circuit recognized that separate theories in support of a claim for a particular benefit are not equivalent to separate claims and that a final denial on one theory is a final denial on all theories" (citing *Bingham*, 421 F.3d at 1349)), *aff'd sub nom. Robinson v. Shinseki*, 557 F.3d 1355 (Fed. Cir. 2009). Appellant has not carried her burden of demonstrating any Board error in finding that a theory of entitlement to compensation under 38 U.S.C. § 1151 that was allegedly not addressed by the Board in 1980 would vitiate the finality of the Board's October 1980 decision that denied compensation under that regulation (or its precursor) or constitute a distinct claim that has remained pending and unadjudicated since 1980.

F. The Board Did Not Err in Assessing the Competency of Lay Evidence

Appellant argues that the Board erred by failing to provide an adequate statement of reasons or bases to support its finding that the lay evidence that she

and her sister provided was not competent on the complex issue of whether the Veteran's treatment was appropriate or whether VA negligence proximately caused the Veteran's death. [Br. at 27-28]. Appellant argues that her statements regarding foreseeability and informed consent were competent and credible because she "had no idea [the Veteran] would die from radiation treatments" and that she believed his death "was an unforeseeable event." [Br. at 27].

However, as previously argued, in *McNair*, the Court found that the common law negligence principles cited as the basis for the promulgation of 38 C.F.R. § 3.361(d)(1) were most consistent with an objective test for determining whether a deviation from the informed consent requirements of 38 C.F.R. § 17.32 was minor and immaterial and thus insufficient to show a lack of substantial compliance or to defeat a finding of informed consent under 38 C.F.R. § 3.361(d)(1). Appellant has not explained how her lay testimony, which is based on her subjective view of whether there was informed consent, is relevant to the application of the objective test articulated for such determinations in *McNair*. Moreover, as previously argued, the plain wording of 38 C.F.R. § 3.361(d)(2) states that the determination as to whether an event is not reasonably foreseeable is "based on what a reasonable health care provider would have foreseen." Appellant has not attempted to explain how her lay evidence is competent to opine on the matter of what a reasonable health care provider would have foreseen. *See Hyder v. Derwinski*, 1 Vet.App. 221, 225 (1991) ("Lay hypothesizing, particularly in the absence of any supporting medical authority, serves no constructive purpose and

cannot be considered by this Court."). As such, Appellant has not demonstrated that the Board committed any prejudicial error.

IV. CONCLUSION

In sum, Appellant has not shown that the Board's decision is clearly erroneous or the product of any prejudicial error. *See Hilkert*, 12 Vet.App. at 151; *see also Sanders*, 556 U.S. at 409-10. Because Appellant limited allegations of error to those noted above, she has abandoned any other issues or arguments that she could have raised but did not. *Woehlaert v. Nicholson*, 21 Vet.App. 456, 463 (2007). The Secretary requests that the Court take due account of the rule of prejudicial error wherever applicable in this case. 38 U.S.C. § 7261(b)(2); *Sanders*, 556 U.S. at 409-10. In view of the foregoing, Appellee respectfully requests that the Court affirm the Board's October 10, 2019, decision.

Respectfully submitted,

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