UNITED STATES COURT OF APPEAL FOR VETERANS CLAIMS

No. 19-7165

PAT HATFIELD,

Appellant

v.

ROBERT L. WILKIE,
Secretary of Veterans Affairs,

Appellee.

AMENDED REPLY BRIEF OF THE APPELLANT

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TABLE OF CONTENTS

Table of Authorities ii

Record Before the Agency ..... ~~ii~~iv

Arguments 1

1. The The Board misapplied *McNair v. Shinseki*, 25 Vet. App. 98 (2011) and 38 C.F.R. § 3.361(d)(1) 1

~~1. Board misapplied 38 C.F.R. § 17.32 and *McNair v. Shinseki*, 25 Vet. App. 98 (2011) in finding that the veteran provided informed consent. Notwithstanding these errors, the Board's own findings warrant reversal .....~~

~~3.~~2. In finding that the veteran's death was a reasonably foreseeable even, the Board ~~misconstrued Hatfield's claim~~relied on inadequate VA medical opinions, misinterpreted the favorable medical opinions ~~of record~~, and misapplied 38 C.F.R. § 3.361(d)(2) 9

~~4.~~

~~5.~~3. The Board's finding that there are no pending or unadjudicated issues from the 1980 Board decision is clearly erroneous and not supported by an adequate statement of reasons or bases 13

~~6.~~4. The Board's credibility findings are not supported by an adequate statement of reasons or bases 14

Conclusion 15

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TABLE OF AUTHORITIES

Cases

Acevedo v. Shinseki, 25 Vet. App. 286 (2012) 13

Barr v. Nicholson, 21 Vet. App. 303 (2007) 13

Canterbury v. Spence, 464 F.2d 772 (D.C. Cir 1972) 6, 7

Grassi v. Shinseki, No. 12-2809, Vet. App. LEXIS 1934, *16 (Nov. 22, 2013) 3, 4

Hensley v. West, 212 F.3d 1255 (Fed. Cir. 2000) 12

Hicks v. Brown, 8 Vet. App. 417 (1995) 13

Lancaster v. McDonald, No. 13-1609, Vet. App. LEXIS 1372 (Aug. 7, 2014) 2, 5

McNair v. Shinseki, 25 Vet. App. 98 (2011) 1, 2, 5, 14, 15

MacWhorter v. Derwinski, 2 Vet. App. 133 (1992) 9, 12

Martin v. Occupational Safety & Health Review Comm'n, 499 U.S. 144 (1991) 12

Murphy v. Shulkin, No. 16-1923, Vet. App. LEXIS 1416 (Sept. 29, 2017) 2, 5

Nieves-Rodriguez v. Peake, 22 Vet. App. 295 (2008) 13

Schertz v. Shinseki, 26 Vet. App. 362 (2013) 10

Stefl v. Nicholson, 21 Vet. App. 120 (2007) 13

38 U.S.C. § 4131 (1976) 7, 8

~~38 U.S.C. § 1151 .....~~

Other

Veterans Health Care, 45 Fed. Reg. 6933 (Jan 31, 1980) (final rule) 7, 8

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) .....7, 8~~38~~

~~C.F.R. § 17.32 .....~~

RECORD BEFORE THE AGENCY

R at 2-18 (BVA decision dated October 10, 2019).....2, 3, 5, 6, 11

R at 37-47 (Appellant's post CAVC remand brief to BVA) 13

~~R at 103-05 (BVA decision dated January 23, 2019) .....~~

R at 157-59 (November 2018 VA examination) 11

R at 188-96 (BVA decision dated April 4, 2018) 2, 3, 5, 6

R at 221-25 (January 8, 2018 private examination) 11

~~R at 297-301 (Memorandum Decision dated November 3, 2017) .....~~

R at 698 (Statement in support of claim dated September 27, 2013) 15

~~R at 1190 (Death Certificate) .....~~

~~R at 1435-36 (Letter from Appellant dated September 30, (year illegible)) .....~~

~~R at 1474-78 (August 20, 1980 VA examination) .....~~

~~R at 1520-21 (BVA decision dated January 31, 1980) .....~~

~~R at 1550-51 (May 29, 1979 VA examination) .....~~

~~R at 1587-95 (VA treatment records) .....~~

ARGUMENTS

1. **The Board~~'s~~ misapplied *McNair v. Shinseki*, 25 Vet. App. 98 (2011) and 38 C.F.R. § 3.361(d)(1).**

In her opening brief Hatfield argued that reversal of the Board's decision is warranted because the Board found all elements necessary ~~to~~ for entitlement to benefits under 38 U.S.C. § 1151 and 38 C.F.R. § 3.361. App. Br. at 13-18. ~~Specifically, that the Board held that the veteran suffered an additional disability or death as a result of the VA treatment or procedure and that there is no evidence that the Veteran signed an informed consent, no documentation of any consent, and no indication of informed or signature consent. *Id.*~~ Hatfield further argued that the Board improperly interpreted this Court's holding in *McNair v. Shinseki*, 25 Vet. App. 98 (2011) when it ~~dismissed~~ ignored the complete lack of informed consent or substantial compliance with 38 C.F.R. § 17.32 and concluded that "no reasonable patient would have opted to forego the radiation treatment provided by VA." App. Br. at 13-18.

~~———~~The Secretary responds that the lack of documentation of informed consent does not require reversal of the Board's decision and takes the position that the Court's holding in *McNair* equally applies to situations in which the informed consent process is and is not documented in the record. Sec. Br. at 13-15 (citing nonprecedential decisions in *Lancaster v. McDonald*, No. 13-1609, 2014 U.S. App. Vet. Claims LEXIS 1372 (Aug. 7, 2014) and *Murphy v. Shulkin*, No. 16-1923, 2017 U.S. App. Vet. Claims LEXIS 1416 (Sept. 29, 2017).

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As an initial matter, the Secretary's reliance on the nonprecedential decisions is misplaced. In both cases the record and the claimants' testimony that they provided informed consent showed substantial compliance with 38 C.F.R. § 17.32 such that the absence of the informed consent documentation still required analysis by the Board as to whether a reasonable person in similar circumstances would have undergone the medical treatment at issue even if informed of the foreseeable risks. See *Lancaster*, No. 13-1609 at *2; *Murphy*, No 16-1923 at *1-2. The Secretary over simplifies Hatfield's case as turning on the mere presence or absence of informed consent documentation, but it actually turns on whether there was substantial compliance with section 17.32 as required by 38 C.F.R. § 3.361(d)(1).

Here, the Board's decision on appeal is devoid of any analysis or finding that there was substantial compliance with section 17.32. Instead, the Board acknowledged that there is no documentation of any consent and that . R-16-17, 192. The Board further held that there is no indication of any informed or signature consent. R-16-17, 192 *Id*. Despite these findings, the Board failed to analyze whether there was substantial compliance with section 17.32 to trigger further inquiry as to whether a reasonable person would have proceeded with the radiation treatment. 38 C.F.R. § 3.361; *McNair*, 25 Vet. App. at 105-06.

The Secretary argues that "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." Sec. Br. at 16. However, the fatal flaw in the Secretary's argument is that the Board not

~~only found that "there is no informed consent document of record" and "there is no~~ informed consent. R-16, 17, 192~~. *Id*~~. Nor did the Board cite to any other evidence of record showing any consent or otherwise find substantial compliance with section 17.32.

Contrary to the Secretary's assertion, Hatfield is not arguing that a lack of documentation of informed consent is dispositive, but rather, without evidence of any consent there could not have been substantial compliance with 38 C.F.R. § 17.32 to compare whether any deviation was minor and immaterial. A lack of any consent (informed or otherwise) cannot be dismissed as a minor or immaterial "technical or procedural" error.

The Secretary argues that Hatfield'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 informed consent and requiring the award of compensation." Sec. Br. at 16-17. The Secretary further asserts that Hatfield'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 with the meaning of 38 C.F.R. § 3.361(d)(1)(ii). Sec. Br. at 17. ~~He argues that 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. Sec. Br. at 17.~~

However, Hatfield first notes that this Court has already applied her interpretation in *Grassi* and did not find it to lead to an absurd result. *Grassi v. Shinseki*, No. 12-2809, Vet. App. LEXIS 1934 (Nov. 22, 2013). To the ~~Contrary~~contrary, the Court correctly ~~correctly~~ noted that the Board's broad reading of *McNair* transformed complete failure to attempt to obtain informed consent into an excusable, minor deviation from its own regulatory requirements, which renders meaningless the informed consent requirements of section 17.32 and allows the minor-deviations exception to swallow the general rule that VA must obtain a veteran's informed consent before furnishing hospital care or medical or surgical treatment. *Grassi*, 12-2809 at *18. The Court distinguished the facts in *McNair* in which the VA doctor informed the veteran of some risks of treatment and provided a general informed consent form with Grassi's case in which there is no evidence in the record indicating that VA even attempted to obtain the veteran's informed consent. *Id.* at *20. The Court noted that Grassi's case is not like *McNair* where VA generally followed its own informed consent procedures but did not strictly comply with all of its regulatory requirements; ~~but rather~~instead, VA did not attempt to comply with those requirements at all. *Id*. at *21. The Court concluded that it is unclear how the Board concluded that VA's failure to undertake any effort to obtain Grassi's informed consent constituted substantial compliance with section 17.32. *Id*.

The Secretary also misinterprets Hatfield's argument as imposing 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. Sec. Br. at 19. The Secretary argues that

Hatfield 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. Sec. Br. at 20. The Secretary interprets Hatfield's argument as establishing a "subjective standard" which would place the physician "in jeopardy of the patient's hindsight" because it involves recall of a discussion regarding informed consent that took place over 40 years ago. Sec. Br. at 20.

However, Hatfield is not arguing for a different standard. As noted above, the standard under 38 C.F.R. § 3.361(d)(1) and *McNair*, has always been that an informed consent finding must first consider whether there was substantial compliance with section 17.32 and, if so, then to consider whether any deviations were minor or immaterial. Again, the Secretary's argument centers around the availability of the documentation of informed consent, instead of whether there was substantial compliance with section 17.32. However, the Board has already found that there no indication of informed or signature. R-16, 17, 192. This factual situation is different from all three cases relied on by the Secretary which contained either documentation of consent or testimony from the veteran that he/she provided informed consent, or both. *See McNair, Lancaster*, and *Murphy* supra.

The Secretary next argues that an award of compensation under 38 U.S.C. § 1151 is not warranted without a claimant having to satisfy the causation element required by 38 U.S.C. § 1151. Sec. Br. at 21. Yet, the Board has already held that "the element with respect to the additional disability or death being the result of the VA treatment or procedure is also clearly established." R-15.

Confusingly, when reciting the applicable law, the Secretary conceded that pursuant to 38 C.F.R. § 1151(a) and 38 C.F.R. § 3.361(d), Hatfield "may receive compensation for the qualifying death of the Veteran if 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*." Sec. Br. at 12-13 (emphasis added). In now arguing that to establish causation Hatfield must show that the lack of consent was the proximate cause of the veteran's death, the Secretary misinterprets 38 C.F.R. § 3.361(d)(1). Sec. Br. at 22. The Secretary's argument is undercut by the plain language of 38 C.F.R. § 3.361(d)(1) itself, which states that

> 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

and "VA furnished the hospital care, medical or surgical treatment, or examination without the veteran''s or, in appropriate cases, the veteran'' s representative's informed consent." 38 C.F.R. § 3.361(d)(1). Contrary to the Secretary's assertion, section 3.361(d)(1) describes *how* to establish proximate cause, i.e. by showing that the medical treatment caused the veteran's death and that the medical treatment was furnished without informed consent. *Id.* As noted above, the Board has already determined that the actual causation element has been satisfied. R-15. It has also found that the proximate cause element has been satisfied when it determined that there is no indication of informed or signature consent. R-16, 17, 192.

The Secretary repeatedly emphasizes that *McNair* relied on common law negligence principles (Sec. Br. at 14, 17, 19, 21), but fails to recognize that common law negligence principles provide for physician liability when treatment is rendered without first obtaining informed consent. As noted by the Federal Circuit in *Canterbury v. Spence*, "It is well established that the physician must seek and secure his patient['s] consent before commencing an operation or other course of treatment" and "It is the settled rule that therapy not authorized by the patient may amount to a tort – a common law battery – by the physician." 464 F.2d 772, 782-783 (Fed. Cir. 1972). The Court further held that the physician has long borne a duty, on pain of liability for unauthorized treatment, to make adequate disclosure to the patient.[22] *Id*. at 783.

The Secretary also concedes that 38 C.F.R. § 17.32 was made retroactive to 1976 when it was enacted in 1980 but argues that VA did not intend to impose strict liability on itself for care provided between 1976 and 1980 when failing to comply with the informed consent requirements "in a regulation that did not yet exist." Sec. Br. at 22. However, the VA's own statements in promulgating 38 C.F. R. § 17.34 seem to contradict the Secretary's argument. In promulgating 38 C.F.R. § 17.34 in January 31, 1980 and making it retroactive to October 21, 1976, the VA stated that it has amended its Medical Series of regulations to comply with provisions of the Veterans Omnibus Health Care Act of 1976~~, whose purpose was to improve the quality of hospital care, medical services and nursing home case in VA healthcare facilities, and to make certain technical and conforming amendments to prior laws governing VA medical care~~. 45 Fed. Reg. 6933. Importantly, the Veteran Omnibus Health Care Act of 1976, which was passed on October 21, 1976, provided in relevant part

§ 4131 Informed consent

> The Administrator, upon the recommendation of the Chief Medical Director and pursuant to the provisions of section 4134 of this title, shall prescribe regulations establishing procedures to ensure that all medical and prosthetic research carried out and, 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 or subject or, in appropriate cases, a representative thereof.

38 U.S.C. § 4131.

> 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.'

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.).~~ Again, the Board has already determined that there is no indication of informed or signature consent.

Hatfield also argued that the Board misapplied *McNair* when it outsourced its duty to make a legal determination regarding whether a reasonable person under similar circumstances would have proceeded with treatment~~,~~ to a VA medical examiner who is not competent to opine on legal matters. App. Br. at 17-18. The Secretary did not respond to

this argument. *MacWhorter v. Derwinski*, 2 Vet.App. 133, 135-36 (1992) (Where appellant has presented a legally plausible position and the Secretary has failed to respond to an appellant's arguments, the Court may deem the points raised by appellant and ignored by the Secretary to be conceded.).

In sum, Hatfield asserts that having already found that the veteran suffered an additional disability or death due to the VA treatment at issue and ~~and that the element with respect to the additional disability or death being the result of the VA treatment is also "clearly established," the Board has conceded actual causation of the veteran's death. Additionally, in finding that there was~~ no indication of any informed or signature consent or other evidence of ~~, and failing to make any finding as to whether there was~~ substantial compliance with 38 C.F.R. § 17.32, the Board ~~effectively~~ found all elements necessary for entitlement to the benefits sought. ~~that the proximate cause element for the veterans death has been satisfied.~~ Therefore, reversal of the Board's decision is warranted.

2. In finding that the veteran's death was a reasonably foreseeable event, the Board relied on inadequate VA medical opinions, misinterpreted the favorable medical opinions, and misapplied 38 C.F.R. § 3.361(d)(2).

In her opening brief, Hatfield argued that the Board improperly relied on the 1979 medical opinion because the examination is inadequate. App. Br. at 19-20. Specifically, Hatfield argued that the 1979 examiner did not provide an opinion as to foreseeability, did not provide any rationale for any conclusory statements that could be construed as an opinion regarding foreseeability, and was not based on the complete evidentiary record. *Id.*

Hatfield also argued that the 1980 VA opinion is inadequate because the examiner did not respond to the Board's inquiry regarding foreseeability. App. Br. at 21-23. Hatfield

~~also argued~~asserted that the Board's flawed interpretation of 38 C.F.R. § 3.361(d)(2) limited probative value to the January 2018 favorable medical opinion and that the Board misinterpreted the November 2018 VA opinion and ignored the examiner's favorable opinion regarding foreseeability. App. Br. at 23-25.

Rather than respond to the adequacy of the VA opinions or the Board's interpretation and treatment of the January 2018 and November 2018 opinions, the Secretary responds that Hatfield arguments are based on a misunderstanding of the law and not supported by the evidence of record. Sec. Br. at 23. Specifically, the Secretary argued that Hatfield did not demonstrate that any Board error was prejudicial because the proper inquiry for entitlement to benefits was not the suddenness of the veteran's death but "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." Sec. Br. at 23-24. The Secretary asserts that all the medical opinions of record acknowledge that respiratory, pulmonary, or lung conditions are a foreseeable consequence of radiation for Hodgkin's disease but the severity and suddenness of the Veteran's complications were rare but foreseeable. Sec. Br. at 24. The Secretary further argued that the risk of an event may be reasonably foreseeable by medical standards even if it occurs only in a small percentage of cases and that the consensus of the medical opinions makes it clear that the complications suffered by the Veteran were foreseeable. Sec. Br. at 26.

However, the actual regulatory language does not require an event to be *completely* unforeseeable or unimaginable. 38 C.F.R. § 3.361(d)(2); *Schertz v. Shinseki*, 26 Vet. App.

362, 368-369 (2013) (stating that a treating physician may take the "kitchen sink approach," informing a patient of numerous risks, but such risks might still be considered "not reasonably foreseeable"). It only requires that a reasonable health care provider would not have considered the event to be an ordinary risk of the treatment provided with consideration as to whether the risk of the event was the type of risk that would have been disclosed in connection with the informed consent procedures of 38 C.F.R. § 17.32. *Id*.

There are only two medical opinions of record that adequately address the foreseeability inquiry in context of the informed consent procedures. The November 2018 VA opinion, (which the Board found to be probative) opined that the veteran suffered an "Acute Radiation Reaction" and explained that

> a typical informed consent document would be unlikely to list Acute Radiation Reaction of the lungs as a known complication of treatment. Acute radiation reaction typically relates to skin or gastrointestinal symptomatology, not a progressive terminal pulmonary condition. Such a condition is exceedingly rare and *in this case would have been unexpected and unanticipated.*

R-159.

The January 2018 opinion, also concluded that it is more likely than not that the veteran's death due to the rapid development and progression of radiation pneumonitis was not a foreseeable event. R-15-16, 224. The examiner addressed the informed consent procedures noting that the veteran's treating physicians did not consider the veteran's quick onset severe fatal pulmonary complications as at all likely and that no concern about the potential of fatal radiation pneumonitis was expressed anywhere in the medical record. R-224.

Neither the 1979 nor the 1980 VA opinions adequately addressed the issue of foreseeability let alone with supporting rationale and discussion as to whether a risk of the event was the type of risk that would have been disclosed in connection with the informed consent procedures. Instead, by noting the ~~veteran's~~ suddenness of the veteran's fatal pulmonary reaction was "very unusual" and that the risk of which was "small – probably less than 1%", the 1979 and 1980 statements fell squarely within the regulatory language that an event need not be completely unforeseeable or unimaginable to be considered as reasonably unforeseeable. 38 C.F.R. § 3.361(d)(2). Nor did any of the conclusory statements made by the 1979 and 1980 VA examiners indicate that such a "small" and "very unusual" risk would have been disclosed had the VA treatment providers obtained informed consent.

~~The Secretary argues that the medical opinions of record all agree that the development of pulmonary fibrosis was foreseeable. Sec. Br. at 25-26. However, all of the medical opinions of record, to include the inadequate 1979 and 1980 opinions, differentiate between ordinary pulmonary complications and sudden onset fatal acute radiation reaction as suffered by the veteran.~~

Further, none of the arguments advanced by the Secretary were the basis for the Board's denial. Instead, the Board premised its denial of benefits on its finding that the May 1979, August 1980, and November 2018 VA opinions were the most probative medical evidence of record on the matter of foreseeability. R. at 15-17. Thus, the Secretary's arguments amount to nothing more than post-hoc rationalization. *See Martin v. Occupational Safety & Health Review Comm'n*, 499 U.S. 144, 146 (1991) (holding that

litigating positions are not entitled to judicial deference when they are merely counsel's "post-hoc rationalizations" for agency action and are advanced for the first time on appeal); *see also Hensley v. West*, 212 F.3d 1255, 1263 (Fed. Cir. 2000) (noting "the general rule that appellate tribunals are not appropriate fora for initial fact finding").

The Secretary did not argue that the Board's reliance on these opinions was in accordance with the law but rather that any errors in the Board's reliance on the opinions were nonprejudicial.[1] Yet, this Court has consistently held that the Board's reliance on an inadequate VA medical opinion renders its statement of reasons or bases inadequate and frustrates judicial review. *Acevedo v. Shinseki*, 25 Vet. App. 286, 293 (2012), *Nieves-Rodriguez v. Peake*, 22 Vet. App. 295, 301 (2008); *Stefl v. Nicholson*, 21 Vet. App. 120, 123 (2007); *Barr v. Nicholson*, 21 Vet. App. 303, 311 (2007); *Hicks v. Brown*, 8 Vet. App. 417, 422 (1995). Because the Board improperly relied on inadequate medical opinions and misinterpreted or ignored the favorable opinions of record, its statement of reasons or bases is inadequate. Therefore, remand is warranted.

3. The Board's finding that there are no pending or unadjudicated issues from the 1980 Board decision is clearly erroneous and not supported by an adequate statement of reasons or bases.

In her opening brief Hatfield argued that the Board misconstrued her argument regarding pending or unadjudicated issues from the 1980 Board decision in that the original claim was for the veteran's death, not a disease or injury. App. Br. at 25-26. ~~Hatfield~~

[1] By not responding to Hatfield's arguments regarding the adequacy of the VA opinions and taking the position that any error by the Board was nonprejudicial, the Secretary has essentially conceded that the Board erred in its treatment of 1979, 1980, January 2018, and November 2018 opinions. *MacWhorter*, 2 Vet. App. at 135-36.

~~expressly argued to the Board that "It is the quickness of the Veteran's *death*" that is the~~ 1980 legally denied all potential theories of entitlement to the benefit denied such that no theory would have remained pending and unadjudicated. Sec. Br. at 28.

not asserting that a specific theory remains pending and unadjudicated but rather that her original claim was for compensation under 38 U.S.C. § 1151 (formerly 38 U.S.C. § 351) for the veteran's death not a disease or injury. R-45, 124. In the decision on appeal the Board did not address whether Hatfield's claim for compensation for the veteran's death remained unadjudicated. It only addressed whether any theories regarding compensation for an injury or disease remained pending. R-1466-67). Therefore, remand is necessary.

4. The Board's credibility findings are not supported by an adequate statement of reasons or bases.

Finally, in her opening brief, Hatfield argued that Board erred in rejecting the lay statements of record. App. Br. at 27-28. The Secretary responds that *McNair* established 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). Sec. Br. at 29. The Secretary asserts~~ that Hatfield 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*. ~~,~~ Sec. Br. at 29. ~~*Id.*~~

~~The Secretary further asserts that Hatfield has not attempted to explain how her lay~~ argument. In *McNair*, the veteran contended that she was not informed that she might suffer from neuralgia as a result of the surgery she underwent. 25 Vet. App. at 105. The Board found that the preponderance of the evidence was against the veteran's assertions. *Id.* However, the Court remanded the Board's decision holding, *inter alia*, that the Board did not provide any rationale for its conclusion as to what a reasonable person could assume. *Id.* The Court did not reject McNair's lay assertions ~~as~~ citing an objective test for substantial compliance with 38 C.F.R. § 17.32. *Id.* Instead, the Court acknowledged the Board's requirement to consider the veteran's lay statements regarding informed consent in addition to the informed consent documentation of record and noted the Board's obligations to make credibility determinations. *Id.* at 104-05.

veteran "had no idea that he would die from radiation treatments" and that she and the veteran were told by the treating physician that the radiation treatment administered was a 95 percent cure for Hodgkin's Disease and that the veteran would be able to live a normal life for 15 more years. R-357, 698, 1433, 1499, 1540, 1555-62. The Board cited to no evidence contradicting these lay statements or otherwise showing any informed consent.

As previously argued, the Board failed to make any findings as to whether there was substantial compliance with 38 C.F.R. § 17.32 and in fact, made findings that ~~show~~ show there was no compliance with section 17.32 whatsoever. ~~Importantly, Hatfield notes that t~~The objective test in *McNair* for determining whether there was informed consent ~~to include whether there were any immaterial deviations~~ is based on a reasonable person standard but does not preclude consideration of the lay evidence of record. *McNair*, 25 Vet.

App. at 105-06. Hatfield's lay statements were not intended to show what a ~~What is~~ healthcare provider would have foreseen, but rather that ~~is not what Hatfield's lay~~ aware (i.e. informed by VA medical personnel) that sudden death due to acute radiation reaction was a potential risk associated with radiation treatment as to indicate any informed consent.

CONCLUSION AND RELIEF SOUGHT

As previously argued, Hatfield asserts that the Board's errors require reversal of its decision with an award of benefits under 38 U.S.C. § 1151. ~~Hatfield asserts that given the Board's findings regarding informed consent, the only permissible view of the evidence combined with the proper application of the law warrants reversal of the Board's decision.~~

Respectfully submitted on September 11~~1~~, 2020 by:

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On September 11~~1~~, 2020, a copy of the foregoing Amended Reply Brief for was filed and served via electronic filing for the United States Court of Appeals for Veterans Claims on: Attorney James Drysdale, counsel for Appellee, Secretary of Veterans Affairs at James.Drysdale@va.gov. I certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

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