United States Court of Appeals
For the First Circuit

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Nos. 00-2553, 00-2554, 00-2555

EVELYN HEINRICH, on behalf of her husband, GEORGE HEINRICH, and HENRY M. SIENKEWICZ, on behalf of his mother, EILEEN ROSE SIENKEWICZ JR.,

Plaintiffs, Appellants, Cross-Appellees,

ROSEMARY GUALTIERI, on behalf of her father, JOSEPH MAYNE, and WALTER CARL VAN DYKE, Representative of the Estate of WALTER CARMEN VAN DYKE,

Plaintiffs, Appellants,

v.

ELIZABETH DUTTON SWEET and FREDERICK H. GREIN JR., Representatives of the Estate of WILLIAM H. SWEET, M.D., and MASSACHUSETTS GENERAL HOSPITAL,

Defendants, Appellees, Cross-Appellants,

UNITED STATES OF AMERICA,

Defendant, Appellee,

ESTATE OF LEE EDWARD FARR, ASSOCIATED UNIVERSITIES, INC., and MASSACHUSETTS INSTITUTE OF TECHNOLOGY,

Defendants.

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APPEALS FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

[Hon. William G. Young, U.S. District Judge]

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Before

Lynch, Circuit Judge,

Coffin and Cyr, Senior Circuit Judges.

Anthony Z. Roisman with whom John K. McGuire Jr., McGuire & McGuire, P.C., Martin H. Freeman, Freeman & Freeman, P.C., John M. Clifford, Billie P. Garde, and Clifford, Lyons & Garde were on brief for appellants, cross-appellees.

James B. Re with whom Karen W. Salon and Sally & Fitch were on brief for appellees, cross-appellants Elizabeth Dutton Sweet and Frederick H. Grein Jr., Representatives of the Estate of William H. Sweet, M.D.

Joseph L. Doherty Jr. with whom Christopher J. Maley and Martin, Magnuson, McCarthy & Kenney were on brief for appellee, cross-appellant Massachusetts General Hospital.

Robert D. McCallum Jr., Assistant Attorney General Civil Division, with whom J. Patrick Glynn, Director, Torts Branch, David S. Fishback, Assistant Director, Torts Branch, and Burke M. Wong, Trial Attorney, Torts Branch, were on brief for appellee United States.

Pamela P. Heacock, Paul W. Johnson, and Smith & Duggan LLP were on brief for amici curiae Professional Liability Foundation, Ltd., Massachusetts Medical Society, American Medical Association, and American College of Surgeons.

August 27, 2002

LYNCH, Circuit Judge. This is a medical malpractice case, brought in 1995, for the deaths of two Massachusetts General Hospital (MGH) patients in 1961. The plaintiffs sued the doctor and institutions responsible for treating their decedents, Eileen Sienkewicz and George Heinrich, who suffered from a terminal form of brain cancer, with an experimental treatment known as boron neutron capture therapy (BNCT). BNCT proved not to save the lives of Sienkewicz or Heinrich.

The plaintiffs' complaint included eleven causes of action. By the time the case reached trial, there were only three causes of action left. The jury returned a verdict for the plaintiffs on two claims -- negligence and wrongful death -- and found for the defendants on the informed consent claim. The defendants appeal from the negligence and wrongful death verdicts, arguing that there was insufficient evidence.

The plaintiffs also sued the United States government under the Federal Tort Claims Act (FTCA) for its involvement in the experimental BNCT treatment through the Atomic Energy Commission (AEC). The district court determined that the government "cannot be held liable under the [FTCA] for the alleged negligence of the private defendants" and allowed the government's motion for judgment. Heinrich v. Sweet (Heinrich IV), 83 F. Supp. 2d 214, 224 (D. Mass. 2000). The plaintiffs appeal from that judgment and from

the district court's subsequent reduction of the damages award to the plaintiffs.

We affirm the district court's judgment for the United States on the FTCA claim. We vacate the judgment for the plaintiffs on the negligence and wrongful death claims because there was insufficient evidence to meet the plaintiffs' burden of proof, and we direct entry of judgment for the defendants, Dr. Sweet and MGH.

I.

Because there is a challenge to the sufficiency of the evidence, we describe the facts in this case in the light most favorable to the verdicts. Rodowicz v. Mass. Mut. Life Ins. Co., 279 F.3d 36, 39 (1st Cir. 2002).

The events surrounding this case happened over four decades ago. George Heinrich and Eileen Sienkewicz, the plaintiffs' decedents, both suffered from glioblastoma multiforme, the most common, most malignant, and deadliest form of brain cancer, and were both treated by Dr. Sweet at MGH in 1960-61. Both Heinrich and Sienkewicz consented to and participated in medical trials for Boron Neutron Capture Therapy (BNCT) performed by Dr. Sweet at a nuclear reactor facility at the Massachusetts Institute of Technology (MIT). It is these BNCT treatments that are the subject of the malpractice case.

A. Eileen Sienkewicz

Eileen Sienkewicz was admitted to MGH on June 10, 1960, complaining of severe headaches, lethargy, lack of concentration, and disorientation. At the time, she was thirty-nine years old. Dr. Sweet observed her for a few days, and then performed a left parietal-temporal craniotomy on June 13 during which he removed a mass of brain tissue which proved to be a glioblastoma multiforme, a cancerous tumor. Sienkewicz was then discharged from the hospital on June 25.

Over the summer of 1960, she suffered from lethargy, depression, insomnia, and general confusion. She was readmitted to MGH on November 13, 1960, and on November 15 she underwent BNCT, under Dr. Sweet's supervision, at the MIT reactor. At first, her lethargy worsened, but a couple of days later, she began to improve and "became more alert and began to talk again . . . and [was] essentially as responsive as she had been preoperatively." She was discharged again on December 3, 1960.

After her discharge, she continued to feel depressed. She underwent electroshock therapy at a different hospital during the first week of January 1961, her mood improved considerably, and she was "up and about doing her housework at home."

On February 27, 1961, she experienced a headache on the left side, weakness in her right limbs, and difficulty with speech. She was again admitted to MGH and her condition improved inexplicably. She was discharged on March 4, 1961.

Over the summer of 1961, she again became disoriented and depressed. She could not sleep and she experienced nausea and severe headaches. She was readmitted to MGH on August 13, 1961, when a "[brain] scan showed a suspicious area" in the region of the tumor. She was discharged on August 19. But on September 27, she was again admitted to MGH because her condition worsened. She experienced increased headaches, speech difficulties, insomnia, and depression. At the hospital her condition only deteriorated. She was very depressed and disoriented. She eventually lapsed into a coma and died on October 31, 1961, sixteen and a half months after she was first diagnosed with brain cancer.

B. George Heinrich

George Heinrich was admitted to MGH on October 22, 1960. He complained of intermittent severe headaches, nausea, vomiting, drowsiness, and decreased vision. After Heinrich was observed for a few days, Dr. James C. White performed a left temporoparietal craniotomy on October 25 and partially removed a tumor which proved to be a glioblastoma multiforme. Heinrich was given twenty conventional radiation treatments, and his recovery seemed to be going well, but the tumor regrew and he had a second operation on December 15, 1960. Again, Heinrich's condition improved temporarily, but on January 2, 1961, he was readmitted to the hospital because his wound was infected. The infection was treated and subsided.

On January 18, 1961, Heinrich was taken to the MIT nuclear reactor and underwent BNCT. Despite the fact that Heinrich experienced some problems with his surgical wound, "[f]or a short time he again continued to do well." But around February 10, he began to feel very lethargic and disoriented. His condition continued to deteriorate, and a brain scan performed on April 11, 1961, showed "a definite abnormality" in the region of his tumor. By May 15, his condition had so deteriorated that he was transferred to a nursing home, where he died on May 27, 1961, about seven months after he was diagnosed with brain cancer.

C. BNCT

Boron Neutron Capture Therapy was an experimental treatment in the early 1960s for the deadliest form of brain cancer -- glioblastoma multiforme. The various estimates of the expected survival time for a patient with this type of brain cancer in 1960-61 are all measured in months.

BNCT combines chemotherapy with radiation. The theory behind BNCT at that time was that combining "boron-10 and thermal neutrons, each innocuous by itself in the doses used," would produce "a high energy nuclear reaction" that would deliver highly localized radiation to tumor cells to destroy them while largely sparing normal brain tissue. According to the theory, a compound containing boron-10 would be injected into the bloodstream supplying the brain. This compound would be taken up by tumor

tissue but not by normal tissue. The tumor would then be exposed to a neutron beam produced by a nuclear reactor. When the neutron beam interacted with the boron-10, a fission reaction would occur and destroy the surrounding tumor tissue.

BNCT was first attempted at the Brookhaven National Laboratories in 1951 by a team that included Dr. Lee Edward Farr and Dr. Sweet, both neurosurgeons. BNCT was performed on ten patients from 1951-53. The experiments with BNCT at that time proved unsuccessful, and all the patients died of the brain cancer shortly after the therapy, although there was some short-lived improvement in two of the patients. Dr. Sweet and his fellow researchers stopped the experiments and tried to learn from the failure. Three reasons for the failure of the treatment were identified: (1) the radiation dose delivered was too low; (2) the neutrons used had too low penetration; and (3) an optimal boron compound had not yet been found.

Over the next decade, Dr. Sweet and others continued to work on developing BNCT. In 1960-61 clinical trials of BNCT were again performed, this time at MIT's nuclear reactor facility. The AEC supported these trials with funding under a contract with Dr. Sweet, as well as with supplies of boron necessary to conduct the BNCT treatments. Consistent with its general policy of setting out broad objectives and leaving most decisions in the hands of the scientists and institutions who received funding for medical

research, the AEC monitored the trials through written reports and occasional site visits.[1]

The team of doctors and scientists who worked with Dr. Sweet on the BNCT trials at MIT included Dr. Soloway, the principal chemist, Dr. Brownell, the principal physicist, and Dr. Ojemann, a senior resident in neurosurgery at the time. Before Dr. Sweet could proceed with the 1960-61 BNCT trials, he had to get approval from three different medical and administrative committees at MGH. In addition, he had to get the approval of the Biomedical Advisory Committee at MIT, which was comprised of representatives from MIT and three medical schools in the Boston area.

Improvements to BNCT had been made between the trials at Brookhaven and those at MIT. MIT's reactor facility was considered superior to Brookhaven's for three reasons. First, it could deliver a therapeutic dose of neutrons in less time, which was thought to be advantageous because it optimized the level of boron compound in the tumor. Second, a more optimal boron-10 compound was found and used. Finally, at MIT the doctors were able to expose the tumor more directly to the neutron beam because of the placement of the equipment and the operating room.

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[1] While a copy of the particular contract for the MIT trials is not a part of the record, there is no indication that it differed in these respects from other AEC contracts in operation at the time.

A number of patients, all with terminal brain cancer, consented to the BNCT treatments. Sienkewicz was the first patient in this 1960-61 series of BNCT trials, while Heinrich was the sixth patient. Between their two treatments there were four other patients. The second patient was not irradiated because the tumor was too far advanced. The third patient was given the therapy and made a satisfactory recovery, but died of meningitis six weeks later. The fourth patient had recurrences of cancer in other parts of the body and died five months later. The fifth patient showed no improvement and died two months later. All in all, there were nineteen patients in this series of trials.

The doctors were very optimistic about the treatment after seeing its effect on the first patient, Sienkewicz, "who was strikingly improved" after BNCT "to the point that she could manage her own home and children until the last 2½ months of her life." This improvement was known as of December 3, 1960, before Heinrich had his BNCT treatment on January 19, 1961. However, the doctors' "cheerful optimism . . . waned" when they collected the results of the entire study after its conclusion.

After the trials ended in August 1961, Dr. Sweet and other members of his team studied the results. Dr. Sweet, Dr. Ojemann, and two other doctors presented a paper at the 40th annual meeting of the American Association of Neuropathologists in 1964, summarizing the BNCT trials at MIT and analyzing the results. A

revised version of the paper was later published in the Journal of Neuropathology and Experimental Neurology in 1972. In addition, Drs. Soloway, Brownell, Ojemann, and Sweet published an article in 1964 entitled "Boron-Slow Neutron Capture Therapy: Present Status." Sweet and his coauthors concluded that the BNCT trials at MIT failed due to four main "deficiencies," including:

> 1) [Their] lack of appreciation of the full complexity and requirements of our biological systems with regard to the boron compound, specifically to the need to clear it from the cerebral blood stream.
> 2) The inadequacy of the current status of knowledge regarding boron chemistry.
> 3) Insufficient information as to the methods of optimizing the shape of neutron beam for capture therapy.
> 4) The lack of the requisite dosimetric [measuring] equipment.

They also stated that "the theoretical aspects which prompted [their] initial attempts" remained "attractive," and expressed optimism that, after further study in a variety of scientific fields, "[their] therapeutic goal may be within reach."

Since the 1960-61 BNCT trials at MIT, there have been further BNCT trials in other places by other doctors. Most notably, Dr. Hiroshi Hatanaka performed clinical trials in Japan between 1968 and 1989 and achieved a survival rate of up to five years in some of his patients.[2]

The medical doctors most closely involved with the BNCT trials could not, by reason of age and infirmity or death, testify

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[2] The defendants offered additional evidence of ongoing work with BNCT, but the district court excluded that evidence.

at the belated trial. Dr. Farr, who supervised the BNCT trials at Brookhaven, died in 1997. Dr. Sweet died after the trial in January 2001. He did not testify at trial because his age and medical condition had by then rendered him incompetent.

II.

The procedural history of this case is complicated. The plaintiffs first brought the case in the Eastern District of New York on September 21, 1995, as a putative class action on behalf of their decedents. The case was transferred to the District of Massachusetts on August 20, 1997. The complaint, filed on behalf of decedents from the BNCT trials both at Brookhaven in 1951-53 and MIT in 1960-61, included eleven causes of action against all of the parties involved in the BNCT trials: Dr. Sweet; MGH; MIT; Associated Universities, Inc., which operated Brookhaven National Laboratories; the Estate of Dr. Lee Edward Farr, who supervised the BNCT trials at Brookhaven; and the United States government, which was responsible for the AEC.

On April 20, 1999, the district court denied the government's motion to dismiss the FTCA claims on the basis of the statute of limitations. Heinrich v. Sweet (Heinrich I), 44 F. Supp. 2d 408 (D. Mass. 1999).

On April 30, 1999, the district court dismissed plaintiffs' battery, intentional infliction of emotional distress,

strict liability, toxic substances, and crimes against humanity claims. Heinrich v. Sweet (Heinrich II), 49 F. Supp. 2d 27 (D. Mass. 1999).

On August 16, 1999, the district court dismissed the state law claims of plaintiffs whose decedents underwent BNCT at the Brookhaven National Laboratories in New York (Joseph Mayne and Walter Carmen Van Dyke) as untimely under New York law. Heinrich v. Sweet (Heinrich III), 62 F. Supp. 2d 282 (D. Mass. 1999). At the same time, the district court held that the FTCA's independent contractor exception and discretionary function exception did not apply to the case and declined to dismiss plaintiffs' FTCA claims against the United States on either basis. Id. at 321-26. On September 9, 1999, the district court granted summary judgment on the plaintiffs' Bivens claim against all the private defendants.[3]

The jury heard evidence over fifteen days between September 10 and October 7, 1999. At the end of the trial, the court dismissed the fraud and negligent misrepresentation claims on a motion for judgment as a matter of law.

Finally, the jury returned a verdict for defendant MIT on all counts. The jury's verdict form had verdicts for Dr. Sweet and MGH on the same line, as if they were one party, because the

[3] The district court made other rulings permitting plaintiffs' claims to survive the statute of limitations and retroactivity defenses, and ruled for plaintiffs on issues of which statutory scheme applied. Heinrich III, 62 F. Supp. 2d at 304. We have no occasion to pass on whether these rulings were correct.

plaintiffs' theory of liability as to MGH was based exclusively on vicarious liability for Dr. Sweet's actions. The jury returned a verdict for defendants Dr. Sweet and MGH on the informed consent count, and for plaintiffs Heinrich and Sienkewicz on the negligence and wrongful death counts. The jury assessed a total of $3 million in compensatory damages against MGH and Dr. Sweet jointly and severally. The jury also assessed $1.75 million in punitive damages against Dr. Sweet, and $3.25 million against MGH.[4]

Because FTCA claims are heard by a judge rather than a jury, see 28 U.S.C. § 2402, the district court ruled separately on the remaining claims against the federal government on February 9, 2000. Heinrich v. Sweet (Heinrich IV), 83 F. Supp. 2d 214 (D. Mass. 2000). Based on further evidence made available in post-trial proceedings about the AEC's involvement in the BNCT treatments, the court reversed its previous determination, found that the independent contractor exception applied, and ordered judgment for the United States. Id. at 221-24. Because its finding on the independent contractor exception disposed of the FTCA claims, the district court deemed it unnecessary to reach the issue of the discretionary function exception.

Dr. Sweet and MGH filed a motion for a new trial, a renewed motion for judgment as a matter of law, and a motion for

[4] After the trial, on January 5, 2000, the district court denied class certification.

reduction of the jury award. Among the grounds asserted in their motion for judgment as a matter of law was that the evidence did not meet the plaintiffs' burden of proof. The district court rejected the motion for a new trial and the motion for judgment as a matter of law. The district court ruled from the bench that "[t]he evidence is sufficient to support each of the causes of action which were submitted to the jury" but gave no reasons for its ruling. In a written opinion, the district court reduced the jury award because it determined that the jury had been instructed to apply the incorrect Massachusetts wrongful death statute (the 1995 statute instead of the one in effect when the treatments took place). Thus, the award was reduced to $750,000 (joint and several) for the negligence count, and $20,000 from each defendant to each plaintiff for the wrongful death count. Heinrich v. Sweet (Heinrich V), 118 F. Supp. 2d 73, 77-83 (D. Mass. 2000).

III.

The plaintiffs and the defendants appeal from the judgments of the district court. Plaintiffs argue that the jury award for the wrongful death claims should not have been reduced, that they should be awarded prejudgment interest, and that the judgment for the United States on the FTCA claim should be reversed.

Defendants MGH and Dr. Sweet argue that judgment should have been entered in their favor as a matter of law because the

statute of limitations on the plaintiffs' claims had run. In addition, they argue that there was insufficient evidence to support the negligence and wrongful death claims. They argue that the plaintiffs did not show that Dr. Sweet departed from the applicable standard of care or that his actions hastened the decedents' deaths. MGH also argues that it cannot be held liable in light of the state charitable immunity doctrine. The government argues that it cannot be held liable under the FTCA since both the independent contractor exception and the discretionary function exception under that Act apply. The government also asserts that the FTCA's statute of limitations bars plaintiffs' claims against the United States.

Because we agree with the defendants that there was insufficient evidence to support the negligence and wrongful death claims, we do not reach the plaintiffs' arguments about the reduction of the jury award and prejudgment interest. We also do not reach the statute of limitations issues or MGH's charitable immunity argument.

IV.

A. Federal Tort Claims Act

Before proceeding to the underlying negligence and wrongful death claims, we consider whether the FTCA, 28 U.S.C. §§ 1346(b), 2671-80 (2000), waives sovereign immunity so that the United States is susceptible to liability for these causes of

action, whatever their merits. We affirm the district court's judgment for the United States.

The district court concluded that the relationship that the AEC had with Dr. Sweet and MGH was an independent contractor relationship, because the AEC did not exercise "detailed supervision or day-to-day control" over the BNCT treatments. Heinrich IV, 83 F. Supp. 2d at 221-24. This finding required dismissal of the claims under the independent contractor exception to the FTCA, 28 U.S.C. § 2671. See United States v. Orleans, 425 U.S. 807, 816-17 (1976). Rather than directly disputing the district court's characterization of the relationship, plaintiffs object that "the U.S. should be liable for the AEC's failure to follow its policy on human radiation experiments." As plaintiffs summarize it, this policy required a "reasonable basis to believe the experiment would provide therapeutic benefit to the patient."

This argument is unavailing. Plaintiffs derive the purported "policy" from four letters written by AEC officials in 1947 and 1951, none of them about BNCT itself. There is, however, no clear evidence that these letters represented any specific or binding AEC policy. They are individual communications, not necessarily disseminated to anyone but their individual addressees. They contain only broadly-worded statements to the effect that a doctor should not conduct experimental treatments without a "reasonable hope" or an "expectation" of therapeutic benefit. One

of the 1947 letters also emphasized the AEC's "understand[ing]" that "the decision as to the advisability of the treatment will be made by the doctor concerned." The final report of the presidentially-appointed Advisory Committee on Human Radiation Experiments, introduced into evidence by plaintiffs, analyzed the same correspondence and concluded that it did not clearly represent formal policy, with the possible exception of informed consent requirements not at issue here.

Furthermore, even if the letters stated the AEC's policy, that policy would not restrict the AEC's discretion concerning BNCT treatments. The FTCA shields from liability a federal agency's exercise of a "discretionary function." 28 U.S.C. § 2680(a). The plaintiffs' asserted policy requiring a "reasonable basis" to expect "therapeutic benefit" would hardly constrain the AEC's judgment at all. It would be quite different from the narrow, discretion-limiting rule in the case on which plaintiffs rely so heavily, Berkovitz v. United States, 486 U.S. 531 (1988), which concerned the detailed regulatory scheme for licensing and testing of polio vaccines. Rather, these broad parameters leave a host of case-by-case judgments for agency officials to make, each requiring the exercise of discretion and the consideration of the agency's overarching policy goals. This is a classic discretionary function. See United States v. Gaubert, 499 U.S. 315, 327-34 (1991) (regulators' choices in oversight of savings and loan

qualify as discretionary function); Shansky v. United States, 164 F.3d 688, 691 (1st Cir. 1999) (general statement in agency operating manual leaves discretion to individual managers); Irving v. United States, 162 F.3d 154, 162-63 (1st Cir. 1998) (en banc) (guidelines in OSHA inspection manual leave discretion to individual inspectors).

We affirm the district court's holding that the FTCA does not permit suit against the federal government.

B. Sufficiency of the Evidence Against Dr. Sweet and MGH

Defendants Dr. Sweet and MGH challenge the sufficiency of the evidence against them on the negligence and wrongful death claims and argue that the district court should have entered judgment as a matter of law in their favor. The district court, ruling from the bench, denied the motion for judgment as a matter of law based on insufficiency of the evidence without stating its reasons for doing so. We review de novo a district court's denial of a Rule 50 motion for judgment as a matter of law. But "[o]ur review is weighted toward preservation of the jury verdict," Rodowicz, 279 F.3d at 41, and "[w]e must affirm unless the evidence was 'so strongly and overwhelmingly' inconsistent with the verdicts that no reasonable jury could have returned them," Walton v. Nalco Chem. Co., 272 F.3d 13, 23 (1st Cir. 2001) (quoting Negron v. Caleb Brett U.S.A., Inc., 212 F.3d 666, 668 (1st Cir. 2000)).

Massachusetts law governs both the wrongful death and negligence claims.

1. Wrongful Death

Dr. Sweet and MGH argue that because there was no evidence that BNCT hastened the death of either decedent, the district court should have entered judgment as a matter of law in the defendants' favor on the wrongful death claim, and the jury verdict against them on this claim should be vacated.

The district court instructed the jury that in order for the plaintiffs to receive compensatory damages for a wrongful death claim, the defendant had "to shorten the life" of the decedent.[5] The court explained that "if, had there been no . . . procedure, the person would have gone downhill, and would eventually then have died of the disease, but because of the procedure they died earlier, then you can award damages." The plaintiffs did not object to this instruction specifically at the time it was given, and so they have forfeited any potential objection to it on appeal, absent plain error. See Fed. R. Civ. P. 51; Gray v. Genlyte Group, 289 F.3d 128, 133-34 (1st Cir. 2002).

[5] Plaintiffs based their wrongful death claim on both negligence and intentional misconduct. Cf. Necktas v. Gen. Motors Corp., 357 Mass. 546, 259 N.E.2d 234, 236 (1970) ("The right of recovery for death . . . is based either upon negligence or upon a wilful, wanton or reckless act causing death."). The instructions to the jury about wrongful death focused solely on wrongful death as a negligence claim, and we do not understand plaintiffs to pursue an intentional misconduct claim on appeal.

This instruction was not inconsistent with Massachusetts case law.[6] To make out a claim for wrongful death on a negligence theory, a plaintiff must show that the defendant's negligence caused the plaintiff to die prematurely. Harlow v. Chin, 405 Mass. 697, 545 N.E.2d 602, 605 (1989) ("A plaintiff in a medical malpractice action has the burden of proving that the physician's negligence was the proximate cause of the plaintiff's injuries."). Defendants dispute their liability for wrongful death by focusing on this causation element. Under these jury instructions, where the plaintiffs were terminally ill and death was imminent, plaintiffs must show that the defendant's actions hastened death "even though it would have occurred at no very remote date from other causes." Edwards v. Warwick, 317 Mass. 573, 59 N.E.2d 194, 196 (1945); see also Coburn v. Moore, 320 Mass. 116, 68 N.E.2d 5, 10 (1946) (holding that there was "enough to show a causal relation between the negligence of the defendant and the death of the intestate" where the defendant's actions "accelerated [intestate's] death"); Walker v. Gage, 223 Mass. 179, 111 N.E. 766, 767 (1916) (holding that evidence that the accident hastened intestate's death was "enough legally to constitute the accident the proximate cause of his death"). There was not plain error in the instruction that

[6] Because of this jury instruction, issued without objection, we need not reach the issue of whether there are other methods to win compensatory damages for wrongful death under Massachusetts law.

plaintiffs must show that the defendants "shorten[ed] the life" of the decedent.

The necessary "causal connection between the negligence of the defendant, if found, and the plaintiff's injuries . . . is a question that a jury could determine only with the aid of expert opinion." Berardi v. Menicks, 340 Mass. 396, 164 N.E.2d 544, 547 (1960); see also Mitchell v. United States, 141 F.3d 8, 13 (1st Cir. 1998); Harlow, 545 N.E.2d at 605. Plaintiffs argue that the jury's finding that death was hastened by defendant's negligence need not be based on expert testimony if there is any probative evidence at all. Plaintiffs rely on Edwards, 59 N.E.2d at 195-96, where the court permitted consideration of the issue of whether an automobile accident had hastened death. Edwards is inapposite. Contrary to plaintiffs' argument, there was expert medical testimony in Edwards tying the death to the auto accident. Furthermore, in a medical malpractice case in which plaintiff argues that the treatment, not the terminal disease, hastened the death, and all of the expert testimony is that it cannot be said that the treatment hastened the death, a jury is not free to reach a contrary conclusion. Whether such a treatment ultimately hastened a patient's death is not a topic of common experience; it

requires expert testimony.[7] There is no evidence at all in the record that BNCT hastened decedents' deaths.

Plaintiffs' own medical expert, Dr. Larry Junck, a professor of neurology and neuro-oncology, plainly stated that he could not say that BNCT hastened the decedents' deaths:

> I think it would be very difficult for me to say what would have happened had they not received that treatment. That would be just hypothetical and it's just the kind of thing that I would have no basis for saying what would have happened had they not received BNCT and perhaps received some other treatment.

In addition, Dr. Junck responded on cross-examination as follows:

> Q. But you certainly cannot say that the administration of BNCT in any way hastened [Sienkewicz's] death?
> A. That's correct.
> Q. And as to George Heinrich you cannot say that the administration of the BNCT in any way hastened George Heinrich's death; is that correct?
> A. That's correct.

Dr. Junck testified that in the early 1960s the median life expectancy for glioblastoma multiforme patients such as Sienkewicz and Heinrich, from diagnosis to death, without any treatment, was four to six months. He also testified that the life expectancy for a glioblastoma multiforme patient who underwent conventional therapy including conventional radiation was eight to twelve months. Sienkewicz well exceeded this life expectancy as she lived for sixteen and a half months after she was first

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[7] Plaintiffs also argue that such proof may come in documentary form; but the documents they cite do not support their proposition.

diagnosed, and eleven months after she underwent BNCT. Heinrich survived for seven months after he was first diagnosed. Although this is slightly below the median life expectancy for glioblastoma multiforme patients who received conventional therapy, as identified by Dr. Junck, it is not sufficiently below the median to show that Heinrich would have lived longer had he not received BNCT.

In addition, two of defendants' experts also clearly testified that they could not determine that BNCT hastened the decedents' deaths. Dr. Raymond Laws, a professor of neurosurgery and a practicing neurosurgeon, stated that he "found no evidence that the BNCT hastened [Sienkewicz's] demise" or that "[it] hastened [Heinrich's] demise." Dr. Edward G. Koski, an anesthesiologist and Director of Human Research Affairs for Partners Health Care Systems, which includes MGH, stated that "Ms. Sienkewicz appeared to have lived somewhat longer than would have been expected given the nature of her tumor and the usual course of the disease and people in her age group."

In response, plaintiffs attempt to rely on an article entitled "The Longevity of Patients with Glioblastoma Multiforme," published in 1950 in the Journal of Neurosurgery. The article stated that "[t]he average duration from the first symptom to exitus was 17 months." The plaintiffs depend on this assertion to say that both Sienkewicz and Heinrich lived below the life

expectancy and that BNCT hastened their deaths. The very next two sentences in this article read: "However, this average was distorted by the unusual cases to be discussed. The median survival was 8.3 months, a figure that is more indicative of the usual case." Moreover, when Dr. Junck, plaintiffs' expert, himself commented on this portion of the article, he said "the average really isn't telling us as much about what the typical patient did because it's so heavily influenced by two particular people. The median is a figure that describes the patient in the exact middle of the group."

The plaintiffs also rely on the fact that "Dr[]. Sweet . . . as well as other writers . . . concluded that there is no evidence that the BNCT experiments at the MIT reactor in 1960 and 1961 prolonged anyone's life." In an article written by Dr. Sweet and others, published in the Journal of Neuropathology and Experimental Neurology in 1972, the authors stated that BNCT, as utilized in 1961, "offered no advantage over standard methods of therapy already available." Similarly, in an article by Dr. Sweet and others about the "present status" of BNCT, published in 1964, the authors wrote that there was "[o]nly one instance of prolonged improvement," apparently referring to Sienkewicz. There is no doubt that these articles, written by the doctors most closely involved with BNCT, stated that BNCT as performed in 1961 was not a more successful way to treat glioblastoma multiforme than the

conventional treatment available at the time. However, the articles also say nothing about BNCT causing the death of the patients earlier than would otherwise be expected. In fact, in the article published in 1972, the authors say that "[t]he average survival time from the time of diagnosis . . . was roughly the same [as the] average survival for a similar large series treated [in the conventional manner.]"

Taking the evidence in the light most favorable to the verdict, there was no evidence that BNCT hastened the death of Heinrich or Sienkewicz. The evidence was overwhelmingly inconsistent with the verdicts for plaintiffs on their wrongful death claims and is therefore insufficient to uphold those verdicts. Independently, our conclusion that the evidence was not sufficient to support a verdict of negligence, described below, also means that the wrongful death verdict cannot stand.

2. Negligence

Dr. Sweet and MGH challenge the jury's verdict in favor of plaintiffs on the negligence claims. They argue that there was insufficient evidence to show that Dr. Sweet deviated from the applicable standard of care.

To prevail on a negligence claim, a plaintiff must show by a preponderance of the evidence "(1) a legal duty owed by defendant to plaintiff; (2) a breach of that duty; (3) proximate or legal cause; and (4) actual damage or injury." Jorgensen v. Mass.

Port Auth., 905 F.2d 515, 522 (1st Cir. 1990); see also Harlow, 545 N.E.2d at 604-05 ("'To entitle the plaintiff to go to the jury [on a negligence claim] there must be sufficient evidence to warrant a finding (1) of negligence on the defendant's part, and (2) of a causal relationship between the negligence and the plaintiff's injuries.'" (quoting Civitarese v. Gorney, 358 Mass. 652, 266 N.E.2d 668, 671 (1971))).

The defendants argue that there was insufficient evidence at trial to show that Dr. Sweet violated his duty of care to the plaintiffs' decedents by failing to comply with the applicable standard of care.

The Massachusetts Supreme Judicial Court articulated the standard of care for physicians in Brune v. Belinkoff:

> The proper standard is whether the physician, if a general practitioner, has exercised the degree of care and skill of the average qualified practitioner, taking into account the advances in the profession. In applying this standard it is permissible to consider the medical resources available to the physician as one circumstance in determining the skill and care required. Under this standard some allowance is thus made for the type of community in which the physician carries on his practice.
>
> One holding himself out as a specialist should be held to the standard of care and skill of the average member of the profession practising the specialty, taking into account the advances in the profession. And, as in the case of the general practitioner, it is permissible to consider the medical resources available to him.

354 Mass. 102, 235 N.E.2d 793, 798 (1968) (emphasis added) (citations omitted); see also Stepakoff v. Kantar, 393 Mass. 836, 473 N.E.2d 1131, 1135 (1985). The standard of care for medical

doctors is not static or rigid. It is a standard that changes depending on many factors, including a doctor's specialty, the resources available, and the advances of the medical profession at the time of the alleged negligent act. The duty to be measured is the one as of the time of the act. Here, that means November 1960 as to Sienkewicz, and January 1961 as to Heinrich.

In this case, the determination of the standard of care owed by Dr. Sweet to the decedents must be influenced by his specialty, the state of medical practice and advances as of November 1960 and January 1961, and the fact that in treating the decedents he was also conducting medical research for a new treatment. Under the circumstances of this case, where the jury was asked to evaluate the doctor's conduct many years after the events took place, it is especially important that the correct standard of care in place at the time of the treatments be clearly established and used.

Massachusetts law requires that unless "'the negligence and harmful results are sufficiently obvious as to lie within common knowledge,'" such as "a case where there is certainty of a foreign object or dangerous physical organ left in a patient during an operation," the plaintiff must present expert testimony as to the standard of care and its breach. Haggerty v. McCarthy, 344 Mass. 136, 181 N.E.2d 562, 565-66 (1962) (quoting Cyr v. Giesen, 150 Me. 248, 108 A.2d 316, 318 (1954)); see also Collins v. Baron,

392 Mass. 565, 467 N.E.2d 171, 173-74 (1984). This case required such expert testimony. As an alternative or an addition to expert testimony, the plaintiff may also present admissions from the defendant about his fault. Collins, 467 N.E.2d at 173-74. "Testimony concerning conclusory admissions by a malpractice defendant may suffice to sustain a jury's finding of negligence if, from the admission, the jury 'could infer an acknowledgment of all the necessary elements of legal liability.'" Id. (quoting Zimmerman v. Litvich, 297 Mass. 91, 7 N.E.2d 437, 438 (1937)).

Plaintiffs' theory of the case, presented in their closing argument, was that Dr. Sweet knew all along that BNCT had no therapeutic value and that it would harm his patients, but that he nonetheless proceeded with the BNCT trials in the name of the progress of medical research and concealed what he knew about the danger of BNCT from his patients.

Plaintiffs make a several-pronged argument. The first is that before Dr. Sweet used BNCT in treating Heinrich and Sienkewicz, Dr. Sweet had no basis to believe that BNCT would be therapeutic. More specifically, they maintain that Dr. Sweet did not know how much radiation he would give and whether it would help his patients or lead to their deaths. Plaintiffs' theory was that in 1960-61 the defendants should not have proceeded with BNCT when they had not found a boron compound of acceptable toxicity and had not established a way of determining the level of radiation that

was going to the tumor as opposed to normal brain tissue.[8] Plaintiffs also assert that Dr. Sweet knew after he used BNCT on the two patients and before their deaths that BNCT caused substantial loss of function and brain necrosis; the record contains no evidence to show these final assertions.

Plaintiffs presented two medical expert witnesses to support their theory of the case: Dr. Junck, a professor of neurology and neuro-oncology, and Dr. Grodin, an expert on medical ethics. For purposes of this appeal, we assume that the district court did not abuse its discretion in qualifying any of the medical experts to testify, including Dr. Junck and Dr. Grodin.

Plaintiffs' lead expert, Dr. Junck, was not asked to relate his opinion as to whether Dr. Sweet had violated the relevant standard of care. Instead, he was asked, over objection, whether Dr. Sweet, MGH, and MIT had acted "appropriately or inappropriately, responsibly or irresponsibly, in performing human experiments on George Heinrich and Eileen Sienkewicz." In response, Dr. Junck said: "I believe that the evidence indicated that Massachusetts General Hospital and MIT acted inappropriately in relation to performing human experiments on the two persons

[8] No evidence was ever submitted that there was any way of achieving greater clarity about these points other than through human subjects. The evidence in the record is that animal studies were not sufficiently similar.

named." In response to a follow-up question, again allowed over objection, Dr. Junck extended this statement to include Dr. Sweet.

There are several problems with the expert testimony presented by Dr. Junck, plaintiffs' lead expert. The first two concerns are related. First, we think the question put to Dr. Junck was wrong. Its highly suggestive emphasis on acting "responsibly" and its prejudicial reference to "human experimentation" did not concern a standard of care for medical treatment. Second, the form of the question was incorrect and did not lead to the required information. While the standard of care question need not be formulaic and some leeway is allowed, see Bradford v. Baystate Med. Ctr., 415 Mass. 202, 613 N.E.2d 82, 86-87 & n.6 (1993); Nickerson v. Lee, 42 Mass. App. Ct. 106, 674 N.E.2d 1111, 1115 (1997); Rahilly v. North Adams Reg'l Hosp., 36 Mass. App. Ct. 714, 636 N.E.2d 280, 283 n.6 (1994), we think this question was inadequate to tie Dr. Junck's opinion to the standard of care for a specialist like Dr. Sweet in 1960-61. To say that Dr. Sweet was in breach of the standard of care, the jury must know what the standard of care was, see 37 J.R. Nolan & L.J. Sartorio, Massachusetts Practice § 279, at 452 (2d ed. 1989), and neither the question presented to Dr. Junck nor his answer provide this information.

Apart from the incorrect form of the question presented to Dr. Junck, there is a fundamental problem with his opinion: it

was based in an undifferentiated fashion on information, analyses, and publications which became available only after the BNCT treatments had been undertaken and not on the information that was available to Dr. Sweet when he conducted the trials. Dr. Junck relied on articles written about the BNCT trials conducted at MIT after the trials ended (and after Heinrich and Sienkewicz had died). Such articles may sometimes contain probative information about the doctors' state of knowledge before they begin a set a medical trials. This is not the case here. Instead, the articles' pertinent information was learned after the trials, once the doctors had an opportunity to study and analyze them. For example, in March 1962, Dr. Sweet wrote a report to the AEC in which he stated that BNCT destroyed too much normal brain tissue along with the tumor. This report was written with the benefit of hindsight, and does not show what Dr. Sweet and his team knew when they were conducting the trials in 1960-61. Much less does it support the conclusion that Dr. Sweet violated any standard of care in 1960-61. The report is not an admission of negligence. That medical research at times produces results less than hoped for is to be expected. This does not logically lead to the conclusion that the research should not be undertaken. To the extent that Dr. Junck described this report as evidence on which he relied in forming his opinion, it was not evidence about what Dr. Sweet knew at the time of the trials, but about what he learned as a result of the trials.

Furthermore, some of Dr. Junck's opinions rested on particular data or publications that do not support his conclusions and have been mischaracterized by plaintiffs in their briefs to us. We give some examples. In testifying that no acceptable boron compound had been found by the time of the BNCT trials at MIT, Dr. Junck relied on a document in which an AEC representative memorialized his March 30, 1959, meeting with Drs. Sweet, Brownell, and Soloway. The memorandum includes a paragraph about the doctors' discussion of the "brain tumor therapy" research and notes that one of "the major issues at stake" was "the finding of a suitable boron compound which has a low toxicity." However, the document goes on to note that "Dr. Soloway, the biochemist . . . [said] he had received a very promising compound from [another doctor]. . . ." This document is insufficient to show that Dr. Sweet's team's research was so inadequate as to violate the standard of care by the time the BNCT trials took place.[9]

To support his view that Dr. Sweet knew nothing about determining the level of radiation which was going to the tumor as opposed to normal brain tissue, Dr. Junck relied on a letter dated January 31, 1952, written from the Brookhaven National Laboratories to Dr. Sweet's office. The letter stated that the levels of

[9] Plaintiffs also point to a portion of Dr. Junck's testimony in which he said "[t]hey hadn't . . . found a boron compound . . . that was free of a lot of substantial side effects." But this testimony was struck from the record and its citation to us is improper.

radiation that patients had received were not actually known because of the difficulties of measuring them during the treatment. This letter was written while the earlier BNCT trials were taking place at Brookhaven in the early 1950s and seems to relate information about those trials. The letter was relevant, but insufficient to establish that Dr. Sweet knew so little at the time he conducted the BNCT trials at MIT in 1960-61 as to violate the standard of care.

In turn, the testimony of Dr. Grodin, the plaintiffs' medical ethics expert, about BNCT was that

> there was no evidence that there was any benefit, potential benefit to the individual terminally ill subjects and there was significant evidence of harm, cell death due to necrosis, and therefore it was [his] opinion that in weighing the risks against the benefits that the risks outweighed the benefits and therefore . . . the research should not be conducted.

Dr. Grodin's conclusion suffers from the same problems as Dr. Junck's conclusion -- it was not tied to the time period in question,[10] and it depended heavily on information about BNCT that became available to Dr. Sweet and his team only after the completion and analysis of the trials. In addition, the evidence does not support Dr. Grodin's conclusion that the BNCT trials should not have been approved.

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[10] Dr. Grodin's opinion about the boron injection, by contrast, was tied to the 1960-61 time period when the BNCT trials were conducted at MIT.

Dr. Grodin's opinion was based, in part, on a paper presented by Dr. Sweet and others to the American Association of Neuropathologists in 1964, after the events in question and learning from those events. The paper stated that "the cause of death at post mortem examination was cerebral in nature, specifically extensive radiation necrosis to the brain in nine [of fourteen subjects]." Of course, after-the-fact autopsy evidence does not establish what the state of knowledge was at the time of treatment. To the extent that Dr. Grodin relied on this evidence in forming his opinion, his reliance was misplaced. Again, this was not evidence about what Dr. Sweet knew at the time of the trials, but about what he learned as a result of the trials.

In addition, Dr. Grodin's opinion in essence was that the research project should not have been approved. However, he was unaware of the scope of the duties of the various medical committees which reviewed and approved the BNCT research in 1960-61, he was unaware of what materials were before the MIT committee which approved the BNCT trials, and he had no basis to say the committee did not act in good faith. There was not an adequate foundation established for Dr. Grodin to express an opinion that the treatments, approved at the time by numerous relevant committees, violated the standard of care in 1960-61.

Besides the expert testimony, plaintiffs also rely on several documents admitted into evidence to support that testimony

and their theory that Dr. Sweet knew before he conducted the BNCT trials at MIT that they would have no therapeutic value. This claim by plaintiffs is undercut by the fact that Sienkewicz's condition improved dramatically after BNCT, and that this instilled confidence and optimism in Dr. Sweet and his team in the treatment. There were only a few pieces of documentary evidence that contained information on the knowledge about BNCT before 1960-61. None of them show that Dr. Sweet knew before he conducted the BNCT trials that they would have no therapeutic value.

First, there was a 1951 letter from the AEC to Dr. Sweet asking him for more information about BNCT before supplying him with boron 10. The letter asked Dr. Sweet whether BNCT trials had been conducted on animals, and what the dosage of radiation would be. Dr. Sweet responded with his own letter stating that no experiments had been performed on animals because these would not be useful "since the conditions are so different," and that there were no "useful answers" to any of the questions. On its face this is not evidence of negligence. It is also evidence from a decade before the trials in question took place.[11]

[11] There was also the 1952 letter from Brookhaven to Dr. Sweet's office at MGH, discussed previously with regard to Dr. Junck's testimony. Again, this letter, discussing the lack of knowledge about the amount of radiation that patients received during BNCT, pertained to the BNCT studies at Brookhaven and does not say much about the knowledge accumulated by Dr. Sweet and his team almost a decade later.

Second, there was a 1955 article by Dr. Sweet and others published in Cancer that analyzed the results of autopsies of eight BNCT patients at Brookhaven in 1951-52. The article noted that the patients' brains were adversely affected by radiation which may have been caused by BNCT. However, the article was written about the BNCT trials at Brookhaven, which occurred nearly a decade before the BNCT studies in question here. In addition, the evidence at trial was that the MIT facility was superior to the Brookhaven facility and was designed in ways that were meant to address these concerns.

Third, there were two 1959 memoranda by an AEC representative which memorialized his meetings with Dr. Sweet and some members of Dr. Sweet's team. Although the first memorandum, discussed earlier, stated a remaining problem with BNCT, it was also optimistic that a solution to the problem was near. Similarly, the second memorandum of a June 19, 1959, meeting stated that Dr. Sweet had "some rough going" with the BNCT research, but again expressed optimism about the contacts made by Dr. Soloway and how these would help him find a suitable boron compound.

Lastly, there were two articles written in 1954 by Dr. Sweet and others in which the BNCT trials at Brookhaven were analyzed. These articles pointed to the problems with BNCT at the time, but also expressed hope about the further use of BNCT after more exploration and research. They do not support the conclusion

that there was no evidence of any potential benefit to the patients from BNCT in 1960-61.

The plaintiffs also rely on articles and documents written by Dr. Sweet and others on his team after the BNCT trials conducted at MIT, to support the contention that the doctors themselves admitted to wrongdoing, and that these alleged admissions are sufficient to show that Dr. Sweet violated his duty of care to the plaintiffs. For example, in 1964 Dr. Sweet co-authored an article entitled "Boron-Slow Neutron Capture Therapy: Present Status," in which the authors concluded that there were four main "deficiencies" that rendered BNCT not "practicable," and went on to outline those deficiencies. No reasonable reader could view the articles, written after the BNCT trials at MIT ended, based on hindsight, and presented to colleagues in science and medicine for consideration, as admissions of wrongdoing. The articles, rather, are objective academic appraisals of the BNCT trials and their failures. The purpose of medical research and trials is to learn from them and improve medical treatments for diseases, including treatment for the subjects of the trials. There would surely be a chilling effect on research in the medical field and deterrence of important progress in medical treatments if doctors and scientists could not frankly assess the successes and failures of their studies in published academic articles so that others can build on their work and learn from it.

The only correct articulation at trial of the standard of care applicable to Dr. Sweet came from one of the defense experts, Dr. Charles Fager, a neurosurgeon. In response to questions asking him to "tak[e] into consideration the advances in the profession at the time and the resources available to Dr. Sweet at that time . . . for a person practicing within the specialty of neurosurgery at that time," he testified that he had an opinion, given those factors. Within those criteria, which were not the criteria used by plaintiffs' experts, Dr. Fager stated that "Dr. Sweet certainly maintained the acceptable methods of practice of neurosurgery at that time."

Dr. Fager formed his opinion by considering what was known about glioblastoma multiforme and BNCT and its effects in 1960-61, when Dr. Sweet conducted the trials in question. More specifically, he took into account the circumstances surrounding the plaintiffs' BNCT treatments. He stated that Sienkewicz was suffering from a "malignant brain tumor," and that there was a "recurrence of tumor" after Dr. Sweet operated on her. He also said that Heinrich was suffering from "a malignant invasive tumor" and that "[h]e had no hope of survival."

Dr. Koski, the Director of Human Research Affairs for Partners Health Care System (which includes MGH) also provided expert testimony for the defendants. As Director of Human Research Affairs, Dr. Koski has "broad responsibility for oversight of all

human investigation that is conducted within the Partners Health Care System, particularly with respect to protection of human subjects who are participating in research . . . ." Dr. Koski testified that various committees at MGH had reviewed and approved Dr. Sweet's application to conduct the BNCT trials at MIT, including the surgical executive committee, which "consider[ed] issues of treatments and therapies that came up before the [surgery] department"; the general executive committee of the staff, which "is the principal governing committee of the Massachusetts General Hospital"; and the Board of Trustees, which has "the overall responsibility for governance of the hospital." Thus, Dr. Sweet's proposal to conduct BNCT trials in 1960-61 received three levels of administrative review at MGH, and was approved at every level. Furthermore, other evidence indicated that the BNCT trials were also reviewed and approved by the Biomedical Advisory Committee at MIT, which was comprised of representatives from MIT and three area medical schools and whose function was "the review and approval of biomedical experiments . . . at the reactor from the point of view of provision of maximum safety to investigators, patients, or any human beings on whom tracer experiments, diagnosis, or therapy is to be performed." The ten members of the MIT committee -- seven from institutions other than MIT -- had to be unanimous on their vote to approve a research project. Approval by these various committees is very compelling

evidence to show that the BNCT trials complied with the prevalent standard of care at the time. Indeed, Dr. Koski stated that "[i]n [his] opinion, the initiation of the boron neutron capture therapy studies [was] in accordance with the process that was prevailing at the time."

Our discussion above is alone sufficient to vacate the verdict. Nonetheless, we add this additional reasoning on an independent ground. The fact that Dr. Sweet and MGH prevailed on the informed consent claim also is pertinent to the insufficiency of the evidence to show that Dr. Sweet was in breach of his duty of care to his patients.[12] Under the informed consent doctrine in Massachusetts, "a physician owes to his patient the duty to disclose in a reasonable manner all significant medical information that the physician possesses or reasonably should possess that is material to an intelligent decision by the patient whether to undergo a proposed procedure." Harnish v. Children's Hosp. Med. Ctr., 387 Mass. 152, 439 N.E.2d 240, 243 (1982). Thus, a doctor who proposes an experimental course of treatment must not only tell the patient about the treatment and its consequences, but must also

[12] The plaintiffs argue that the trial court instructed that the jury could find informed consent even if Dr. Sweet and MGH did not provide them with material information as to risks and possible benefits. The transcript does not support that reading. The transcript shows that the trial judge was dealing with the different problem of proximate causation -- whether the decedents would have withheld consent but for lack of information -- which the jury needed to consider. We reject the rest of the plaintiffs' argument that Dr. Sweet failed to disclose material information.

inform the patient that he is conducting an experimental treatment and that the patient is part of a study. The doctor must not only tell the patient the known risks of the treatment, as he would in a conventional setting, but must also inform the patient that there may be unknown risks.[13] Cf. Moore v. Regents of Univ. of Cal., 793 P.2d 479, 483 (Cal. 1990) (holding that in obtaining a patient's consent to a procedure, "a physician must disclose personal interests unrelated to the patient's health, whether research or economic, that may affect the physician's professional judgment"); 1 S.E. Pegalis & H.F. Wachsman, American Law of Medical Malpractice 2d §4:1, at 185-86, 189 (1992) ("When human research is being conducted, standards governing disclosure are considerably different from those in the therapeutic setting.").

Defendants argue that if Heinrich and Sienkewicz were adequately informed about the treatment, its experimental nature, and its known risks, and agreed to undergo the treatment nonetheless, then Dr. Sweet and MGH cannot be liable for performing

[13] There are now federal regulations in place which deal specifically with what a doctor must tell a patient to obtain informed consent before that patient can become part of a research study. See 1 M.J. Zaremski & L.S. Goldstein, Medical and Hospital Negligence § 15:10 (1995). In addition, some states also have laws that deal with informed consent in the realm of "therapeutic experimental procedures." See, e.g., Whitlock v. Duke Univ., 637 F. Supp. 1463, 1467-68 (M.D.N.C. 1986).

the very treatment to which the patients agreed.[14] On the facts of this case, we agree with the argument.

While there are surely fact patterns where the defendants' argument would be invalid, this case does not fit within them. This is not an instance in which the doctor fully informs the patient about a certain treatment, but then does something at variance with the described treatment; that would be independently negligent and falls below the standard of care. An example would be if a doctor were to fully inform a patient that he will be performing a certain surgery, and then performs the surgery, but leaves the scalpel in the patient's body. Nor is this a situation where the doctor fully informs the patient about an overtly negligent procedure with no possible benefits to the patient, and then performs that procedure. For example, if a doctor were to inform the patient that he would be performing a certain surgery and that he would be leaving the scalpel in the patient's body after the surgery, even if a patient may have ignorantly agreed to this procedure, the doctor's actions would still fall below the standard of care, constituting negligence.

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[14] Plaintiffs argue that because defendants did not bring to the trial court's attention any alleged inconsistency in the verdict, defendants have waived the claim that the verdicts cannot stand because they are inconsistent. Masure v. Donnelly, 962 F.2d 128, 134 (1st Cir. 1992). However we do not understand defendants to be making an inconsistency argument, per se, but rather to be using the informed consent verdict in their favor as further evidence that there was no evidentiary support for a finding of negligence.

The district court, presumably, was alluding to these situations when it said that informed consent does not "operate[] as a defense to a claim of negligence in Massachusetts." Heinrich V, 118 F. Supp. 2d at 91. These situations do not exist here. There is no evidence to show that the procedure which Dr. Sweet performed was any different from the procedure about which he informed his patients, and there is no evidence to show that what he proposed to his patients was blatantly negligent. The informed consent verdict for the defendants also means that the jury rejected plaintiffs' theory that Dr. Sweet concealed what he knew about the danger of BNCT from the plaintiffs, thus narrowing the plaintiffs' theory to the grounds discussed and rejected earlier.

In summary, the evidence presented at trial to show that Dr. Sweet violated the standard of care had several fatal flaws. The evidence from the plaintiffs' experts that Dr. Sweet did not conform to the applicable standard of care in 1960-61 was wholly inadequate. The evidence was not linked to the state of Dr. Sweet and his team's knowledge at the time the trials took place, and was largely based on articles written by Dr. Sweet and other members of his team about the BNCT trials and their weaknesses after the trials had ended and the authors had compiled and analyzed the data obtained from the trials. In contrast, there was strong evidence from the defendants' experts that Dr. Sweet did act within the standard of care at that time. In addition, the documentary

evidence, including the letters, memoranda, and articles from before 1960, does not show that Dr. Sweet and his team knew that BNCT had no therapeutic value. Furthermore, the BNCT treatments were reviewed and approved by three different committees at MGH and one committee at MIT before they were conducted. Lastly, the defendants' argument is buttressed by the fact that the jury ruled in favor of the defendants on the informed consent claim.

V.

This is a difficult case. What is at stake is the medical treatment of two patients and the professional reputations of individuals and institutions based on services performed over four decades ago. The bar to be surmounted in litigation over current charges of malpractice is a demanding one. That bar cannot be lowered to compensate for absence of relevant experience, fading memory, or lack of documentary evidence. Conclusory opinions, unattached to predicate evidence of existing standards, cannot fairly fill the void.

The district court's judgment for the United States is affirmed. The jury verdict for the plaintiffs on the negligence and wrongful death claims is vacated and we direct entry of judgment for the defendants Dr. Sweet and MGH. No costs are awarded.