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Doctor's docket

Benefits notwithstanding: discipline associated with efficacious medical treatment

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Facts

Dr B is an advocate of the use of hyperthermia for palliative cancer treatment. Dr B ran a clinic in California that is one of only 5 or 6 major U.S. institutions that perform hyperthermia. Based in large part on his own research, Dr B claimed that hyperthermia with and without radiation given daily and more often can have beneficial effects, and can also result in lower per-treatment radiation amounts, thus extending the time the patient can receive radiation.

Experts strongly disagreed with Dr B's contentions. They indicate that accepted practice is to use hyperthermia only in conjunction with radiation therapy and not more frequently than once every three days. Furthermore, they argue that hyperthermia does not allow a physician to reduce radiation doses, regardless of whether hyperthermia is used for curative treatment or palliation efforts.

Dr B had two patients, E, a 51 year-old woman with stage IV breast cancer, and J, a 61 year-old man with stage IV colorectal cancer. E had refused all treatment before meeting with Dr B. Without any test results, Dr B considered the tumor to be malignant and believed that E required immediate palliative treatment. Dr B treated E with hyperthermia alone and with hyperthermia and radiation. E suffered skin involvement and pleural effusions, and the tumor resolved 95%. In the 12-week period of full treatment, E received 105 hyperthermia treatments with and without radiation, sometimes more than once/day. However, due to metastatic disease, E died 4 months after treatment began.

J had a previous history of two major surgical resections, but after being diagnosed with terminal disease, refused any additional traditional curative treatment efforts. He went to Dr B, who administered both radiation and hyperthermia. J received 80 radiation treatments over 198 days, with a cumulative dose of 8,015 cGy, which started at 180 cGy/day and were progressively reduced to 50 cGy, accompanied by 162 hyperthermia treatments. After these treatments, J was "free of pain" from two months after treatment until almost a year later, with the tumor having shrunk at least 50%. However, J died due to progressive uremia, anemia, and renal failure ~14 months after first seeing Dr B.

The Medical Board of California initiated administrative proceedings to discipline Dr B for his hyperthermia and radiation palliative treatments. The Board claimed that Dr B departed from the standard of care.

Testifying for the Board were Dr PE, former chair of the Department of Radiation Oncology at a medical school, and Dr PR, a professor of radiation oncology at another medical school. Dr PE indicated that for cancer palliative care, the standard of care never called for the use of hyperthermia alone. Dr PE also noted that administering hyperthermia more frequently than once every 72 hours was also a violation of the standard of care because a tumor develops temporary resistance to any further heat, a phenomenon known as thermotolerance, and hence more frequent treatments are

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ineffective. Dr PE emphasized that he had never seen any peer-reviewed data supporting daily hyperthermia.

Further, Dr PE noted that the standard of care for radiation required daily administration 5 days/week over a period of 6-8 weeks, with each treatment administering 180-200 cGy. Doses longer than 7 weeks with a total dosage of greater than 6,500 cGy and individual doses of less than 180 cGy violated the standard of care.

Dr PR agreed with Dr PE. Dr PR also noted that he was not aware of a single published clinical trial that delivered hyperthermia daily, nor was there any evidence advocating the use of hyperthermia alone without radiation. Dr PR also noted that it would be "totally incorrect to compromise the radiation and lower the amount of daily doses of radiation because you were getting hyperthermia."

Dr B offered three experts in addition to himself. He also had former patients of his testify as to the success of his treatments. His professional experts were Dr S, a director of the Department of Radiation Oncology and Endocurie therapy at a Medical Center; Dr BE, a medical director of radiation oncology at Hospital A; and Dr. C, a biophysicist from Hospital B.

Dr B testified that giving hyperthermia alone was valid to alleviate the patient's pain. He also claimed it negated thermotolerance. However, he could not provide published evidence supporting this claim.

Dr S indicated that hyperthermia was effective in killing cancer cells when given alone, and did not violate the standard of care. However, on further questioning, Dr S also testified that he was not aware of any peer-reviewed journals that supported daily or twice-daily hyperthermia. As well, for his own patients, he used daily hyperthermia only on 5% of his patients and always in conjunction with radiation.

Dr S also testified that there was no real standard for the number of radiation treatments when combined with hyperthermia. He claimed that the dosage of radiation could be decreased from the standard of 180 cGy when administered with hyperthermia. However, he acknowledged that there was no professional literature supporting his theory.

Dr BE indicated that, according to some literature, thermotolerance has not been established such that it would preclude daily hyperthermia treatments. However, Dr BE had not personally administered hyperthermia treatments for the past two years, but when he did, he admitted he would only do so two to three times per week, and he had never used daily treatments himself.

Finally, Dr C disagreed with Dr PR as to scientific evidence of radiation negating thermotolerance. In fact, his position was that he had been advocating daily hyperthermia treatments for 20 years, and that thermotolerance was irrelevant. However, Dr C was not a physician, and he acknowledged that his opinion was in the minority. Further, on questioning, he indicated that palliative cases were not treated with daily hyperthermia at Hospital B.

After the testimony, the Board accused Dr B of grossly negligent, repeatedly negligent, and incompetent treatment of E and J, all constituting unprofessional conduct. Following an administrative hearing, the Administrative Law Judge (ALJ) issued a decision agreeing with the Board. The ALJ concluded that Dr B had violated the standard of care. In closing, the ALJ indicated that:

> [E]ven though [Dr B] deviated from the standard of care in connection with patients [E] and [J], his methods were not necessarily clinically 'incorrect.' Both patients were suffering from metastatic cancer and were terminal when they presented. Under [Dr B's] care, one patient experienced a 95% resolution of the original tumor; the other, a 50% resolution. The weight of the evidence determined the standard of care in [Dr B's] geographic area during the relevant time period, but not the efficacy of [Dr B's] treatment methods. Although the two patients whose care and treatment were the subject of this action did not survive, a great many others have …. It is axiomatic that the standard of care is a fluid concept that shares a symbiotic and inter-dependent relationship with medical progress. Only time will tell whether [Dr B] is a pioneer or a renegade. He deviated from the standard of care in his treatment methods, and for that, his license is disciplined.

The Board then placed Dr B on probation for 5 years.

Dr B sought court review of the Board decision. The trial court found that "there were palliative results. There were helpful results [from Dr B's treatments] …. [However Dr B] deviated from the standard of care in connection with the patients ...." Hence, the trial court adopted the standards of care set forth by the Board's experts, and entered judgment in the Board's favor.

Dr. B appealed again. He claimed that the substantial evidence did not support the trial court's determination that he violated the standard of care, or that there was no applicable standard of care. The Board claimed that the trial court was correct in its assessment and its decision should be affirmed.

Legal analysis

The appellate court affirmed the trial court's decision and held for the Board (Bicher v. Sup. Ct. and Medical Board of California, 2008 WL 542674 (Cal.App. Feb. 29, 2008)).

The appellate court first noted that the facts of the case were not in material dispute. It stated that the legal issue was whether substantial evidence supported the trial court's determination of the appropriate standard of medical care. More specifically, the appellate court was to determine whether there was substantial evidence supporting the trial court's findings, including the formulation of the standard of care.

The Court of Appeals then indicated that the standard of care must be shown by expert testimony. However, the appellate court also noted that it did not need to look for

actual harm to patients in order to sustain the trial court and Board findings of negligence and incompetence.

The appellate court then reviewed the case. It observed that there was a disagreement between Dr B and the Board as to thermotolerance and hyperthermia treatments alone as well as the amount and timing of radiation for curative or palliative treatments. However, it noted that Dr B's expert opinions were theoretical and that most of Dr B's experts themselves did not use hyperthermia alone. Further, their claims were not grounded or supported by the medical literature. On the other hand, the Board's experts clearly testified as to a standard of care in practice that was justified by medical literature. This latter testimony, according to the court, constituted substantial evidence in support of the trial court's formulation as to the standard of care.

The court also addressed Dr B's claims that there was no standard of care, and therefore he could not be faulted for violating a non-existent standard. The court rejected this argument. It noted that:

> Arguing there is no standard of care does not exonerate [Dr B]. Rather, it demonstrates that in treating [E] and [J], [Dr B] failed to exercise 'that reasonable degree of knowledge and skill which is ordinarily possessed and exercised by other members of his profession in similar circumstances.' [i.e., the standard of care.] … The knowledge [Dr B] claims he has and has used is not ordinarily possessed or used by other doctors in similar circumstances. He is the only one. If there is no standard of care applicable to what he did, then his actions were outside the permissible scope of his medical practice.

The Court of Appeals concluded by quoting a treatise on malpractice law:

> [P]ioneering doctors, and countless others, have often had to confront orthodoxy. What by today's lights appears controversial or even heretical may turn out as tomorrow's standard of care. A legal policy, even if it recognizes an element of calculated risk in the delivery of many aspects of health care, can work mischievious results which unduly crimps the innovated spirit so often present in the health care community.
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> From the perspective of the contending attorneys, a finer line usually separates the suspect practitioner from the conventional community …. Indeed the defendant-provider may truly function at the cutting edge. If so, however, ample scientific documentation, typically of recent origin and from one or more reputable sources, will be present to fortify the technique or procedure which has gone awry.

The appellate court held that sufficient scientific evidence and testimony supported the trial court's determination of the standard of care. It noted that "the record discloses 'ample' scientific support of the opinions of the Board's experts; the record does not do the same for the opinions of [Dr B's] experts." It then affirmed the trial court's decision.