The Failure to Deliver as Promised

In March 2009, a 63-year-old man was diagnosed with stage IV gastric carcinoma with metastasis to the liver. His treating oncologist gave him a prognosis of about 10 months' life expectancy with chemotherapy. The patient's family searched for alternative treatment options and found a natural alternative treatment center claiming the ability to cure the patient.

The patient and his family decided to defer chemotherapy, and he was admitted to the alternative treatment center for three to four weeks of inpatient care. The treatment consisted of "colonic hydrotherapy," supplements designed to cleanse the body, and a diet restricted to seed milk, vegetable juice, and spinach soup.

After six days, the patient developed severe diarrhea, confusion, and profound weakness. He was taken to a local hospital and admitted with a diagnosis of acute renal failure. Dialysis attempts were unsuccessful, and the man died of respiratory distress secondary to acute renal failure a week later.

The plaintiff claimed that the treatment provided by the defendants was contraindicated and caused acute renal failure, noting that the patient's kidney function had been relatively normal when he entered the treatment facility. The plaintiff claimed that defendant Dr N., a chiropractor, never reviewed any of the decedent's medical records, did not discuss the proposed treatment plan with his treating physicians, and failed to properly monitor the patient's condition, notice his deterioration, and provide timely transfer to a hospital.

The defendant claimed that the treatment given had no adverse effects on the decedent and that the acute renal failure was due to hepatorenal syndrome due to his advanced metastatic liver cancer.

OUTCOME

A $2.5 million verdict was returned. An appeal was pending.

COMMENT

This is a case against a chiropractor, so why discuss it in a journal dedicated to NP and PA practice? Because it involves scope of practice, alternative medicine, the safety of "natural" treatments, and the ethical and legal problems of making unsupportable promises to patients.

Know your scope of practice, and don't overextend. Clinicians trained as specialists (eg, in pediatrics, midwifery, or anesthesia) should use caution departing from that area. Those trained as "generalists" need to be careful as well; even if you were trained in a family practice program, if you are a PA who has worked in dermatology for the past 10 years, think twice about giving treatment or advice to your friend with a neurologic complaint. In the event of a lawsuit, the plaintiff will spend a great deal of time building your resume as an expert in your discipline, only to attack you as inexperienced and unqualified in the case in which you extended yourself.

Here a chiropractor, without ever examining the patient, directed the treatment of a very sick man in an area in which he was not qualified. While chiropractors may claim the ability to treat outside their traditional scope, the jury's verdict in this case proves that they were not persuaded he was right to do so. The chiropractor, Dr N., eventually lost his license, based in part on the false promises he made about his ability to cure patients of "any and all diseases, including cancer, by restoring the body to its natural state ...." This opportunistic preying upon the most ill and vulnerable in our society likely irked the jurors, who returned a substantial award, considering that the patient's short life expectancy was uncontested.

Handle alternative medicine with particular care, because an alternative treatment may not qualify as "medicine" at all. If we define *medicine* as the application of scientific principles to health care, an alternative that is unproven, unstudied, and unknown does not qualify. Rather, it is guesswork—with potentially devastating consequences.

In this case, through his company, the chiropractor based his treatment plan on guesswork that colonic hydrotherapy and severe dietary restrictions would help a patient with stage IV metastatic gastric carcinoma. He was wrong, and the jury concluded that these alternatives injured the patient and hastened his death.

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Certainly, Western medicine has been rightly and fairly criticized for failing to promote wellness through a healthy lifestyle, including diet, exercise, safety, emotional well-being, and stress management. However, when venturing from generally accepted health promotion strategies to a specific recommendation that an alternative agent "is good for" a specific problem, be careful. You may believe lavender oil is an effective antibiotic—but can you prove it?

If you choose lavender oil over a demonstrably effective antibiotic to treat pneumonia, and the patient deteriorates, you will be held accountable. The plaintiff will demand answers, and the jury will await your explanation. Reliance on vague concepts, not generally accepted in the literature (eg, "energy management," detoxifying, unblocking "clogged" nervous systems), will be ridiculed by the plaintiff's experts, and you will be skewered on cross-examination. It is not enough to personally "believe" in the alternative; you must be able to support your treatment decisions through the best evidence possible.

To be fair, this cuts both ways: Some Western medical practices are based on anecdotal evidence with minimal scientific support. There was a time when a corneal abrasion was patched, a fractured clavicle was stabilized with a figure-of-eight dressing, and narcotics were withheld from a suffering patient with acute abdomen because it would "mask signs." Our "Western" system is not immune from the impact of poor research, group-think, dogmas leading to inappropriate practice, and other sources of logical fallacy.

As NPs and PAs, we will be held to a scientific evidentiary standard. The standard of care will be based upon the care a reasonably prudent clinician would deliver in a similar situation. At trial, you will be confronted with a PA or NP on the stand testifying against you regarding what is reasonably prudent, acceptable care. Make sure your actions are scientifically defensible.

Interestingly, the standard for admitting a scientific opinion as expert testimony has changed. In 1923, *Frye v United States*[1] established that, for an expert opinion to be admissible, the testimony had to be based on what is "generally accepted in the scientific community." In 1993, the Supreme Court case *Daubert v Merrell Dow Pharmaceuticals*[2] determined that the opinion need not be "generally accepted" but must be based on scientific method and must be relevant to the case; the judge serves as a "gatekeeper" to be sure the opinions flow from "scientific knowledge."

> *"You must be able to support your treatment decisions through the best evidence possible."*

Medical malpractice cases are based on state law. Some follow Frye, some Daubert. The latter is a more relaxed standard, but even in states following Daubert, an expert witness who purports to testify on an alternative treatment must follow the scientific method. For example, the webpage of the defendant chiropractor's institute (still in business) currently claims that "Heart/Brain Entrainment Therapy balances frequencies of organs/glands/tissues. Everything in the universe resonates at a particular frequency—light, sound, and every cell, organ, gland, and tissue in you."[3]

So, whatever Heart/Brain Entrainment Therapy is, for that theory to be admissible in a Frye jurisdiction it would likely have to be "generally accepted" in the medical community. To be admissible in a Daubert jurisdiction, proponents of the testimony would have to show evidence of a scientific methodology supporting the theory before the jury could hear any testimony about it. In either case, strategically, the defense attorney would likely file a motion to block either certain parts of the testimony or the testimony entirely.

IN SUM

Jurors expect sound scientific methodology supporting medical decisions; use care when selecting treatment for patients. Robustly adopt health promotion and general wellness strategies. However, if you use alternatives directed toward a specific therapy solving a specific problem, use them cautiously and with an awareness that the indication for the therapy should be scientifically defensible. **—DML** **CR**

REFERENCES

1. *Frye v United States*, 293 F. 1013 (D.C. Cir. 1923).
2. *Daubert v Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993).
3. Total Health Institute. Bioelectrical Energy, Quantum Frequency Resonance. www.totalhealthinstitute.com/about. Accessed July 14, 2015.