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Verdicts & Settlements In-Depth

Lawyers, Doctors Team Up Over 'Experimental' Care HMO Denied Coverage Of Stomach Treatment

By Geri L. Dreiling

Teamwork between lawyers and doctors was the prescription for victory in a woman's battle with her HMO over "experimental" treatment.

Karen Moses of Kansas City needed a gastric "pacemaker" after her body rejected a pancreas transplant in 2001. When her health plan denied coverage for the device, Moses went to court, armed with the support of her physicians.

She emerged with a permanent injunction issued by Jackson County Circuit Judge Marco Roldan.

"I think the best thing that happened in our case was the persistence and conviction of the treating doctors," said her attorney, Scott Bethune of Davis Bethune & Jones.

"Their written letters were very, very persuasive," said Bethune, who worked on the case pro bono. "It didn't sway the HMO but it did sway the court, I believe."

The decision in *Moses v. Coventry Health Care of Kansas, Inc.*, et al., MLW No. 50666, was handed down on Aug. 2.

Gastric Stimulator

Karen Moses, now 44, was diagnosed with diabetes in 1994. In February 2001, Moses received a pancreas transplant which was rejected by her body six weeks later.

Her chances for a successful transplant were diminished by a condition she suffered known as gastroparesis, which causes a delay in the emptying of the stomach. Symptoms include nausea and vomiting, which made it difficult for her to keep down food and medicine.

The first choice of treatment for gastroparesis involves changing the diet and taking medication, Bethune said. If this treatment fails, the last resort is the implantation a gastric stimulator. The device, which has two electrodes that are implanted in the stomach wall, provides low-dose electrical stimulation to improve the stomach functioning.

Bethune said the device is "very similar to a pacemaker. It stimulates the stomach to help digest food and medication."

Efficient digestion plays an extremely important role in the pancreas transplant process, Bethune said. To reduce the risk of rejection, Moses must take immunosuppressants — but the vomiting caused by the gastroparesis reduces the effectiveness of the medication. And because she could not get enough food in her body, she was in a weakened condition, which also affects a transplant's success rate.

Coverage Denied

After rejection, Moses was referred to Drs. Richard McCallum and Irene Sarosiek at the University of Kansas Medical Center. McCallum, a board-certified gastroenterologist, is the director of the center for the gastrointestinal nerve and muscle function at KUMC. Sarosiek is the center's research director.

After evaluating Moses, the doctors recommended her for the gastric stimulator.

"The credentials of the treating doctor were so impressive," Bethune said. "He was in fact an expert in this area."

Not only was he an expert, Bethune said, McCallum and the center have performed more gastric stimulator implants than any providers in the world. McCallum led a double-blind, placebo controlled study which led the FDA to approve the gastric stimulator device made by Medtronic in 2000 for humanitarian reasons.

Moses had health coverage through her husband's employer, the Internal Revenue Service. Its employee health plan is provided by Coventry Health Care of Kansas.

On July 18, 2003, her doctors wrote to Coventry seeking approval of the purchase of the device and the cost of surgery to implant it. The device itself costs \$12,000, and surgery and hospital expenses cost an additional \$12,000 to \$13,000.

Informing Coventry that the stimulator "has become a generally accepted treatment among practicing physicians for whom all other therapy has failed," McCallum and Sarosiek also included research abstracts with the request.

On July 21, Coventry's medical director, James Utley, denied the coverage request. In support of the denial, he cited the Federal Employees Health Benefit plan brochure which excludes coverage for "experimental or investigational procedures, treatments, drugs or devices." Neither the brochure nor the denial letter contained any reference to how the terms "experimental" or "investigational" are defined.

Two days later, another Coventry medical director, Ron Snyder, denied coverage. However, this denial cited a different coverage exclusion contained in the HMO Plus Membership Handbook. It also did not define experimental or investigational.

Undeterred, Dr. Sarosiek sent a second letter stressing the fact that the therapy was FDA-approved, the procedure was not considered investigational, summarized the center's success with the therapy and stated that Moses was an excellent candidate.

But Coventry once again denied coverage. In a letter written by senior medical director Diana Cokington, the insurance company cited the experimental or investigational exclusion in the membership handbook. It also relied on an abstract prepared by two Coventry nurses which claimed the procedure was experimental. The abstract cited two articles, both written by McCallum, the head of KUMC's program.

Although the denial letters did not define experimental or investigational services, the Federal Employee Health Benefits handbook outlined four criteria: "(1) Any drug not approved for use by the FDA; any drug that is classified as IND (investigational new drug) by the FDA; any drug requiring pre-authorization that is proposed for off-label prescribing; (2) Any health service or product that is subject to Investigational Review Board (IRB) review or approval; (3) Any health service or product that is the subject of a clinical trial that meets criteria for Phase I, Phase II or Phase III as set forth by FDA regulations; (4) Any health product or service that is not considered standard treatment by the medical community, based on clinical evidence reported by peer review medical literature or by generally recognized academic experts."

Moses filed suit against Coventry after the denials in Jackson County Circuit Court. She sought a permanent injunction under state law that would both force Coventry to approve the second pancreas transplant and also cover the implantation of the gastric stimulator device.

"Once this permanent injunction suit was filed," Bethune said, "the HMO agreed to reconsider their

position" with respect to the pancreas transplant. Ultimately, they decided to cover the cost of the re-transplant but they wouldn't cover the gastric stimulator.

Bethune, Randall Brown and Charles McKenzie agreed to handle the injunction suit without charging a fee. However, Bethune notes that they also have a medical negligence claim against the insurance company that is a contingency fee case.

A one-day trial before Jackson County Circuit Judge Marco Roldan was held on May 27. Roldan took the case under advisement and issued a 28-page ruling on Aug. 2.

Preemption

One legal question that came up was whether the Employee Retirement Income Security Act preempted the claim.

Though the question has not been addressed in Missouri courts, Bethune said that "there was some support in other courts that the FEHBA is not completely preempted by ERISA."

And in his ruling, Roldan reviewed the recent U.S. Supreme Court decision in *Aetna Health Inc., et al. v. Avila, et al.*, as well as decisions from several federal district courts throughout the country.

"Numerous other courts interpreting the FEHBA have held that the FEHBA does not completely preempt various state law claims," Roldan wrote. "The Court finds preemption inapplicable."

Turning to the merits of the case, Roldan noted that "when an insurer seeks to avoid coverage under an insurance policy exclusion, the insurer has the burden of proving the applicability of the exclusion."

In this case, Roldan said, Coventry "is attempting to rely upon two different experimental or investigational policy exclusions contained within two different policy plan documents.

"The two exclusions are inconsistent and Exhibit 16, the HMO Plus Membership Handbook, the last exclusion relied upon by Coventry, denominated as the legal agreement between the parties, does not contain a definition of the terms experimental or investigational."

And the insurance company bore the burden of proving that the exclusions apply and that they aren't inconsistent or ambiguous, Roldan said.

"Coventry has not met this burden, and these exclusions are to be strictly construed against Coventry."

'Experimental'

Roldan noted that only one Missouri state court case, *McDaniel v. Blue Cross and Blue Shield of Missouri*, has touched on the experimental or investigational exclusion. However, the court never decided whether a scleroderma treatment was experimental. Instead, the case was disposed in favor of the plaintiff on a procedural issue.

But he said there was federal case law that grapples with the questions raised by the experimental exclusion.

"As is evident from a review of the reported cases," he wrote, "though many insurers rely upon experimental treatment policy exclusions, no commonly accepted definition of 'experimental treatment' exists."

In *Rollo v. Blue Cross/Blue Shield of New Jersey*, a federal district court addressed the experimental exclusion and permanently enjoined the insurance company from refusing to cover a cancer treatment.

Roldan said, "The court in *Rollo*, in permanently enjoining the insurer, stated that while it is reasonable and necessary for an insurer to have an experimental exclusion so members do not have to pay for procedures

which are purely experimental or requested by a 'scientist stirring a magic potion in some laboratory at the top of a mountain with lightning flashing about,' it was clear and beyond dispute that the requested procedure had been standard treatment, and indeed the only treatment available for patients with the discussed medical condition."

Applying the reasoning in Rollo, the court said, "Coventry's medical directors looked only at a tech assessment and consulted no experts in the field, i.e., Dr. McCallum, in coming to their coverage position.

"Coventry put no evidence before the Court which would indicate that the gastric stimulator implantation was experimental or investigational, indeed the only evidence presented was from Dr. McCallum who stated to a reasonable degree of medical certainty that procedure is not experimental or investigational.

"Additionally, even though Dr. McCallum is conducting additional clinical trials on the device and procedure to maximize its efficacy, this does not mean that the procedure is experimental. It only means that Dr. McCallum is trying to make it better," Roldan said.

Policy Language

Turning to the four criteria in the employee handbook, Roldan concluded that none of them applied to the gastric stimulator.

Dr. McCallum testified "to a reasonable degree of medical certainty" that the procedure isn't experimental and that Moses is an ideal candidate.

"Coventry presented no evidence to the contrary," Roldan said, also noting that the Food and Drug Administration had approved the device.

And a provision prohibiting coverage for devices that must first be submitted to an investigational review board was ambiguous, he said.

"It should be noted that the criteria lists 'investigational' review board approval; the IRB at KUMC is called the 'institutional' review board, which may or may not be the same entity that Coventry is referring to," Roldan said.

Moreover, KUMC's institutional review board approved the device several years earlier and the only role it played was to review a patient's informed consent waiver.

The second criterion, Roldan said, "is not applicable."

The third provision states that the service can't be subject to a clinical Phase I, II or III trial.

"Clearly, this language is incomprehensible to a layperson and even a person who is familiar with clinical trials would have trouble interpreting or understanding this criteria.

"Dr. McCallum testified that devices are not classified according [to] the Phase I, II or III classifications within the FDA," Roldan said. "Medical devices, like the gastric stimulator, are not classified as Class I, II or III devices, and are not associated with any clinical trials that may be performed upon them."

The last factor, that the service is not considered standard treatment, also did not apply.

"Dr. McCallum testified to a reasonable degree of medical certainty that this procedure is the standard treatment for patients with gastroparesis similar to [the insured] who have failed all other therapies and treatments that are available."

In addition, Roldan noted that "other medical benefit insurers and other third party payors provide coverage for the gastric stimulator procedure that has been requested."

Bethune said that Moses has now received the gastric stimulator, which has greatly improved her quality of life.

And since the court ruled that the treatment was not experimental, he added that the decision "has the potential to affect other people requesting this very procedure."

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