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IN THE DISTRICT COURT OF APPEAL
OF FLORIDA
SECOND DISTRICT

HEALTH OPTIONS, INC.,	)	
	)	
Appellant,	)	
	)	
v.	)	Case No. 2D04-5679
	)	
BETTY A. KABELLER,	)	
	)	
Appellee.	)	
	)	
_____	)	

Opinion filed April 21, 2006.

Appeal from the Circuit Court for
Polk County; J. Michael McCarthy, Judge.

Charles C. Lane of Lau, Lane, Pieper,
Conley & McCreadie, P.A., Tampa,
for Appellant.

Robin Gibson of Gibson, Valenti &
Ashley, P.A., Lake Wales, for Appellee.

SILBERMAN, Judge.

Health Options, Inc., appeals a summary judgment and a final judgment awarding damages in favor of Betty A. Kabeller. Because the trial court erred in its analysis of the provisions of Health Options' group Health Maintenance Organization

(HMO) plan and in resolving an issue of material fact, we reverse and remand for further proceedings.

Ms. Kabeller was covered under an HMO plan for health care services issued by Health Options. In late 2000, she was diagnosed with a "carcinoid tumor in her ileum, metastatic cancer in 5 of 8 lymph nodes, and numerous palpable nodules in her liver." After her oncologist told her that he did not know of any specific treatment for her cancer, Ms. Kabeller investigated her options and learned of a program at the University of Maryland involving TheraSphere treatment. That treatment introduces "a serum-like substance through a needle into a strategic artery." The substance "consists of millions of insoluble microscopic glass beads containing radioactive Yttrium^{90} permanently imbedded within the beads." The treatment purportedly concentrates radiation locally to a tumor and does not damage healthy parts of the body.

According to Ms. Kabeller, her physicians agreed that she could not be successfully treated by surgery, chemotherapy, or traditional radiation therapy and that TheraSphere treatment was her best option. She sought approval from Health Options to pursue the treatment. Health Options refused, asserting that the treatment was excluded from coverage under the plan because it was experimental, investigational, and not medically necessary. Ms. Kabeller decided to obtain the treatment anyway. Then, after exhausting internal and external administrative remedies with respect to Health Options' coverage decision, Ms. Kabeller instituted a civil suit against Health Options to recover the cost of the treatment. Health Options denied liability and raised several affirmative defenses, including that the services for which Ms. Kabeller sought reimbursement were excluded under the plan as experimental or investigational.

Ultimately, Ms. Kabeller filed a motion for summary judgment, arguing that although the plan excludes coverage for experimental or investigational services, an exception to that exclusion applies and, accordingly, her TheraSphere treatment is covered under the plan. The plan excludes coverage for

> **Experimental or Investigational** services except as otherwise covered under the Bone Marrow Transplant provision of the Transplant Services subsection, and except for any drug prescribed for the treatment of cancer that has been approved by the FDA for at least one indication, provided the drug is recognized for treatment of the Covered Person's cancer in a Standard Reference Compendium or recommended for treatment of the Covered Person's cancer in Medical Literature. Drugs prescribed for the treatment of cancer that have not been approved for any indication are excluded. [1]

(Emphasis added.) The emphasized language above is the exception to the exclusion that is at issue here.

Ms. Kabeller argued that the first requirement of the exception had been satisfied, stating "TheraSphere is approved for commercial use by the United States Food and Drug Administration pursuant to approval granted December 10, 1999 under a Humanitarian Use Device Exemption." With respect to the second part of the exception, Ms. Kabeller filed an affidavit by a reference librarian that identified three "peer reviewed national professional journal[s] published in the United States." In addition, she filed three articles from those journals and, as to one article, contended that it established that "TheraSphere treatment is recognized for treatment of liver cancer in Medical Literature."

[1] The plan defines the term "Experimental or Investigational." The definition is contained in the appendix attached to this opinion.

Noting that the earlier internal and administrative reviews of the coverage decision concluded that the exception to the exclusion was inapplicable because TheraSphere is a "device" and not a "drug," Ms. Kabeller argued that the plan does not support such a limitation. She argued that under section 641.31(4), Florida Statutes (2001), "[e]very health maintenance contract, certificate, or member handbook shall clearly state all of the services to which a subscriber is entitled under the contract and must include a clear and understandable statement of any limitations on the services or kinds of services to be provided"; that the plan does not define the terms "device" and "drug"; and that TheraSphere treatment should be covered regardless of whether it is the administration of a drug or the use of a device.

Further, Ms. Kabeller argued that the rules of construction for such contracts require that they be interpreted in favor of greater indemnity. Citing to DaCosta v. General Guaranty Insurance Co. of Florida, 226 So. 2d 104 (Fla. 1969), and Medical Center Health Plan v. Brick, 572 So. 2d 548 (Fla. 1st DCA 1990), she contended that if the plan is susceptible to more than one interpretation, the interpretation providing the greater coverage would prevail. She asserted that in the absence of definitions for the terms "device" and "drug" in the plan, the terms must be given their "plain and ordinary meaning," State Farm Fire & Cas. Ins. Co. of Fla., Inc. v. Deni Assocs., 678 So. 2d 397, 401 (Fla. 4th DCA 1996), or "read in light of the skill and experience of ordinary people," Lindheimer v. St. Paul Fire & Marine Ins. Co., 643 So. 2d 636, 638 (Fla. 3d DCA 1994). She contended that ordinary people would use the word "device" for the bedside mechanism used to inject the treatment and that they would use the word "drug" for the serum-like substance that carries the microscopic

glass beads containing the Yttrium^{90}. Notably, Ms. Kabeller did not present any evidence that TheraSphere treatment is the administration of a drug, and none of the articles that she filed with the trial court describe the treatment as the administration of a drug. Indeed, the articles recognize that the treatment is the administration of radiation therapy, and one article specifically uses the term "device."

Health Options filed its own motion for summary judgment and a supporting affidavit by Scot N. Ackerman, M.D., a board certified radiation oncologist and the chief of the radiation oncology section at a medical center in Jacksonville. Dr. Ackerman stated that TheraSphere is a device and is considered by the FDA to be a device, not a drug. He noted that the FDA approved TheraSphere treatment "for radiation treatment or as a neoadjuvant to surgery or transplantation in patients with unrescectable hepatocellular carcinoma (HCC)." He observed that Ms. Kabeller was not diagnosed with HCC but "was diagnosed with metastatic carcinoid tumor" and that TheraSphere was not approved for use in patients with "metastatic carcinoid tumor." Further, he stated that there was "a consensus of opinion among experts that further studies, research or clinical investigation of TheraSphere was necessary to determine maximum tolerated dosages, toxicity, safety, efficacy, or efficacy as compared with standard means of treatment of Ms. Kabeller's diagnosed condition." He added that TheraSphere had not been proven to be safe and effective to treat individuals with Ms. Kabeller's condition and that "the predominant opinion among experts as expressed in published peer reviewed literature was that further studies were necessary in order to determine safety, toxicity, or effectiveness compared with standard alternatives for TheraSphere treatment for Ms. Kabeller's diagnosed condition."

In its order granting summary judgment, the trial court determined that TheraSphere is a radiation treatment for cancer and that radiation treatments for cancer are covered by the plan. The court considered the exclusion for experimental or investigational services but concluded that the exception eliminated the exclusion in this case, resulting in coverage. The court stated that the plan did not give notice to Ms. Kabeller "that covered radiation treatments would be limited to treatments from a drug and would not include radiation treatments characterized as coming from a device." The court cited to section 641.31(4) and found that the plan did not define the terms "device" or "drug" and did not contain a " 'clear and understandable' statement limiting the covered radiation treatments to substances defined as drugs and excluding substances defined as devices." Later, the court entered a final judgment in Ms. Kabeller's favor for damages, attorney's fees, and costs.

On appeal, Health Options argues that the trial court erred in its analysis of the plan, the impact of section 641.31(4), and the evidence of record. Health Options also argues that Ms. Kabeller did not carry her burden for summary judgment and that the trial court should have entered summary judgment in its favor.

Our standard of review is de novo because we are reviewing a summary judgment involving a question of law, that is, the trial court's legal analysis of the plan provisions. See Major League Baseball v. Morsani, 790 So. 2d 1071, 1074 (Fla. 2001); Smith v. Frontier Commc'ns Int'l, Inc., 805 So. 2d 975, 977 (Fla. 2d DCA 2001); Am. Equity Ins. Co. v. Van Ginhoven, 788 So. 2d 388, 390 (Fla. 5th DCA 2001). In Smith, this court explained:

> Where the interpretation or construction of a written instrument and the legal effect to be drawn from the

> instrument is at issue, the appellate court is not restricted in its ability to reassess the meaning and effect of the instrument, and the appellate court may reach a conclusion contrary to the conclusion of the trial court.

805 So. 2d at 977. In addition, pursuant to Florida Rule of Civil Procedure 1.510(c), a trial court may only grant summary judgment "if the pleadings, depositions, answers to interrogatories, and admissions on file together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." See also Hervey v. Alfonso, 650 So. 2d 644, 645 (Fla. 2d DCA 1995).

The limited evidence contained in the record is that TheraSphere is a device and not a drug. Notwithstanding that evidence, the trial court concluded that the plan did not adequately exclude coverage for devices and, therefore, that the exception to the exclusion, which refers to drugs prescribed for the treatment of cancer that meet certain requirements, applied. In its analysis, the trial court relied heavily on section 641.31(4), which states as follows:

> Every health maintenance contract, certificate, or member handbook shall clearly state all of the services to which a subscriber is entitled under the contract and must include a clear and understandable statement of any limitations on the services or kinds of services to be provided, including any copayment feature or schedule of benefits required by the contract or by any insurer or entity which is underwriting any of the services offered by the health maintenance organization. The contract, certificate, or member handbook shall also state where and in what manner the comprehensive health care services may be obtained.

We cannot agree with the trial court that the plan's lack of definitions for the terms "device" and "drug" violated section 641.31(4) and served to eliminate the exclusion for experimental or investigational services. In Jefferson Insurance Co. of

New York v. Sea World of Florida, Inc., 586 So. 2d 95, 97 (Fla. 5th DCA 1991), the Fifth District stated that "[t]he mere failure to provide a definition for a term involving coverage does not necessarily render the term ambiguous." Courts should not "put a strained and unnatural construction on the terms of a policy in order to create an uncertainty or ambiguity." Id. Instead, "the terms of the contract must be given their everyday meaning and read in light of the skill and experience of ordinary people." Lindheimer v. St. Paul Fire & Marine Ins. Co., 643 So. 2d 636, 638 (Fla. 3d DCA 1994). In Deni Associates of Florida, Inc. v. State Farm Fire & Casualty Insurance Co., 711 So. 2d 1135 (Fla. 1998), the supreme court addressed the lack of definitions for the words "irritant" and "contaminant" in an insurance policy exclusion and concluded that the absence of definitions did not render the policy ambiguous.

Here, the pertinent exclusion is for "Experimental or Investigational services." The term "Experimental or Investigational" is defined in the plan. Among other things, devices and drugs that meet the requirements specified in the definition would be considered experimental or investigational. Such devices and drugs would, by definition, fall within the exclusion unless the exception to the exclusion applies. The exception specifies the circumstances under which a "drug prescribed for the treatment of cancer" would not be considered "Experimental or Investigational."

After reviewing the entire plan, we agree with Health Options' argument that the lack of definitions for the terms "device" and "drug" does not violate section 641.31(4) and does not make the exclusion inapplicable to Ms. Kabeller's claim. Read in context, the plan provides adequate notice as to the services to which a subscriber such as Ms. Kabeller is entitled and the limitations on those services or kinds of

services. Even if some individuals might disagree as to whether TheraSphere is a device or a drug, the possibility of disagreement does not require the conclusion that the plan violates section 641.31(4). Thus, because the trial court's decision largely rested on the erroneous conclusion that the plan violated section 641.31(4), we reverse the summary judgment and the final judgment.

In the summary judgment, the trial court also stated that "whether the exclusion exists or not, the cancer patient exception serves to eliminate the exclusion." This statement was apparently based on the court's view that the articles filed by Ms. Kabeller demonstrated that TheraSphere treatment met the requirements of the exception. However, the trial court did not consider the substance of Dr. Ackerman's affidavit, which specifically outlines why TheraSphere treatment does not meet the requirements of the exception. Instead, the court characterized Dr. Ackerman's affidavit simply as seeking "to establish the validity of the exclusion to the Covered Service."

This characterization is incorrect as Dr. Ackerman's affidavit also states that Ms. Kabeller was not diagnosed with the type of cancer for which the FDA had approved treatment with TheraSphere and that TheraSphere is not a drug recognized for the treatment of Ms. Kabeller's diagnosed condition. Further, two of the articles on which Ms. Kabeller relied address only the treatment of HCC, which is not the type of cancer with which Ms. Kabeller was diagnosed. Thus, the record reflects a genuine issue of material fact, and the trial court erred in entering summary judgment. See Hervey, 650 So. 2d at 645.

Health Options contends that in addition to reversing the summary judgment, we should remand for entry of judgment in its favor. We disagree. The trial

court's decision was based on the lack of definitions in the plan, the conclusion that the plan violated section 641.31(4), and the conclusion that TheraSphere had been recommended for treatment of Ms. Kabeller's cancer. As noted previously, the trial court did not consider the substance of Dr. Ackerman's affidavit and whether either party would be entitled to summary judgment in light of that affidavit or on grounds other than those that the trial court specifically, but erroneously, found to be controlling. Our decision should not be construed as precluding either party from again seeking entry of summary judgment consistent with this opinion, the available evidence, and the applicable law.

Reversed and remanded.

WHATLEY and VILLANTI, JJ., Concur.

APPENDIX

The HMO plan contains the following definition for "Experimental or Investigational":

Experimental or Investigational means any evaluation, treatment, therapy, or device which involves the application, administration or use, of procedures, techniques, equipment, supplies, products, remedies, vaccines, biological products, drugs, pharmaceuticals, or chemical compounds if, as determined solely by HOI:

A. such evaluation, treatment, therapy, or device cannot be lawfully marketed without approval of the United States Food and Drug Administration or the Florida Department of Health and approval for marketing has not, in fact, been given at the time such is furnished to the Covered Person;

B. such evaluation, treatment, therapy, or device is provided pursuant to a written protocol which describes as among its objectives the following: determinations of safety, efficacy, or efficacy in comparison to the standard evaluation, treatment, therapy, or device;

C. such evaluation, treatment, therapy, or device is delivered or should be delivered subject to the approval and supervision of an institutional review board or other entity as required and defined by federal regulations;

D. reliable evidence shows that such evaluation, treatment, therapy, or device is the subject of an ongoing Phase I or II clinical investigation, or the experimental or research arm of a Phase III clinical investigation, or under study to determine: maximum tolerated dosage(s), toxicity, safety, efficacy, or efficacy as compared with the standard means for treatment or diagnosis of the Condition in question;

E. reliable evidence shows that the consensus of opinion among experts is that further studies, research, or clinical investigations are necessary to determine: maximum tolerated dosage(s), toxicity, safety, efficacy, or efficacy as compared with the standard means for treatment or diagnosis of the Condition in question;

F. reliable evidence shows that such evaluation, treatment, therapy, or device has not been proven safe and effective for treatment of the Condition in question, as evidenced in the most recently published

medical literature in the United States, Canada, or Great Britain, using generally accepted scientific, medical, or public health methodologies or statistical practices;

G. there is no consensus among practicing Physicians that the treatment, therapy, or device is safe and effective for the Condition in question; or

H. such evaluation, treatment, therapy, or device is not the standard treatment, therapy, or device utilized by practicing Physicians in treating other patients with the same or similar Condition.

"Reliable evidence" shall mean (as determined by HOI):

A. records maintained by physicians or hospitals rendering care or treatment to the Covered Person or other patients with the same or similar Condition;

B. reports, articles, or written assessments in authoritative medical and scientific literature published in the United States, Canada or Great Britain;

C. published reports, articles, or other literature of the United States Department of Health and Human Services or the United States Public Health Service, including any of the National Institutes of Health, or the United States Office of Technology Assessment;

D. the written protocol or protocols relied upon by the treating physician or institution or the protocols of another physician or institution studying substantially the same evaluation, treatment, therapy, or device;

E. the written informed consent used by the treating physician or institution or by another physician or institution studying substantially the same evaluation, treatment, therapy, or device; or

F. the records (including any reports) of any institutional review board of any institution which has reviewed the evaluation, treatment, therapy, or device for the Condition in question.

NOTE: Services or supplies which are determined by HOI to be Experimental or Investigational are excluded (see Exclusions and Limitations Section). In making benefit determinations, HOI may also rely on the predominant opinion among experts, as expressed in the published authoritative literature, that usage of a particular evaluation, treatment, therapy, or device should be substantially confined to research settings or

that further studies are necessary in order to define safety, toxicity, effectiveness, or effectiveness compared with standard alternatives.