UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

VINCENT B. ODENWALLER, Plaintiff,	)	Hon. Richard A. Enslen
vs.	)	File No. K86-283-CA4
AETNA LIFE INSURANCE COMPANY, a Connecticut Corporation, Defendant.	)	

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OPINION OF ARBITRATOR

FACTS AND BACKGROUND

This lawsuit has been filed by Plaintiff to recover from the Defendant certain sums of money which he expended on behalf of his deceased wife for cancer treatments. The Defendant is the fiduciary of an employee benefit plan providing certain medical expense benefits to employees of the Tandy Corporation and their dependents. The Plaintiff was, at the time relevant to this action, an employee of the Tandy Corporation and he and his deceased wife were beneficiaries of the above policy.

The policy in question provided that:

> "Covered medical expenses are the reasonable charges which an employee is required to pay for---services and supplies received by a covered family member for the necessary treatment of any non-occupational injury or non-occupational disease."

The same policy excluded coverage for care, treatment, or services which were not necessary for the treatment of the injury or disease concerned.

The Plaintiff's wife was diagnosed in 1982 as suffering from Stage 4 breast cancer. Upon diagnosis, she underwent surgery to remove tumors from her breast and surrounding lymph nodes. She was also referred to Dr. Raymond S. Lord, an oncologist, for further evaluation and possible treatment. The patient had a pre-existing asthmatic condition, as well as early osteoporosis as a result of prior steroid therapy. As a result, Dr. Lord ruled out radiation therapy. However, because the patient was estrogen positive, he recommended that she undergo hormonal therapy with a drug called Tamoxifen. The patient sought a second opinion from a physician in the State of New York. That physician recommended an oophorectomy. Because of the conflicting opinions, the patient's case was submitted to the tumor board at Bronson Hospital in Kalamazoo. That Board did not make any specific recommendations, and it was eventually decided by the patient and her physician that she would undergo the Tamoxifen therapy.

Such therapy was begun in November of 1982 and was continued until April of 1983. Unfortunately, the hormonal therapy apparently did not arrest or control the patient's disease process.

As a result, the patient was recommended a chemotherapy regimen. Such therapy began in May of 1983 and, according to the objective evidence, apparently provided some palliative relief.

However, the therapy proved to be intolerable to the patient for a variety of reasons. After consultation with her oncologist the patient decided to terminate the chemotherapy. Instead, she enrolled in a treatment program sponsored by the Immunology Researching Centre (IRC) located in the Bahamas. The specific therapy involved is called immuno-augmentive therapy (IAT). After examination and evaluation the patient was admitted to the IRC's program and in the fall of 1983 began undergoing a course of IAT treatment regimen. By the spring of 1984 the patient's condition had deteriorated and those treatments were discontinued. She died several months later.

The Defendant, as the fiduciary of the above-mentioned employee benefit plan, has refused to pay for the medical expenses incurred by the patient while she was undergoing IAT.

It was the Defendant's position that the IAT therapy was not "necessary treatment". The Defendant has adopted its own definition of "necessary treatment" as meaning that which is "broadly accepted professionally as essential to the treatment of the disease or injury". The Defendant contends that IAT therapy is not broadly accepted professionally and accordingly is not covered by the above-mentioned insurance plan.

DISCUSSION

The basic question presented here is whether the Defendant's decision to deny coverage was arbitrary or capricious. If its definition of "necessary treatment" is rational or consistent with the plain language of the policy, then its decision will not

be deemed arbitrary, even if other equally or even more logical interpretations are possible. In order to be deemed arbitrary, the Defendant's decision must be founded upon considerations in conflict with the intention expressed in the language of the policy, or upon evidence wholly unsupportive of its ultimate decision.

Here, the Defendant has construed the term "necessary treatment" to mean treatment "broadly accepted professional which is essential to treatment of the disease". Since it is conceded that the IAT treatments received by the Plaintiff's decedent are not broadly accepted professionally (at least in the country) Defendant's denial of the claim would appear proper if Defendant's interpretation of the policy is rational or consistent with the language of the policy.

Plaintiff, however, contends that the Defendant's interpretation is not dispositive.

First, the Plaintiff questions, factually, whether the Defendant's interpretation was promulgated in a Summary Plan Description as authorized by ERISA. Plaintiff also questions whether the Defendant's interpretation, even if promulgated appropriately, was provided to him before the claim in the present case was incurred.

Second, Plaintiff contends that Defendant's interpretation is not rationally related to the intent of the plan, as defined by its express language.

Finally, Plaintiff asserts that Defendant's action was arbitrary because no one ever determined that the treatments were

"unnecessary". Rather, according to the Plaintiff, the only determination made was that the treatments were not "generally accepted professionally". In essence, Plaintiff contends that the determination which was made was founded upon an improper basis.

Plaintiff's factual challenge to the policy interpretation can be disposed of quite easily. Though he questions whether the summary booklet containing the fiduciary's interpretation was a planned description authorized under ERISA, he has presented no evidence on the subject. Defendant, on the other hand, vigorously asserts that the interpretive language was contained in a summary plan description and has offered (though it was not available at hearing) to produce the document. This arbitrator is persuaded that at trial the Defendant will be able to satisfactorily demonstrate that the descriptive language was part of the required summary plan description.

Likewise, there is no evidence that the Defendant failed to provide the Plaintiff with the summary plan description before this claim arose. Indeed, the Plaintiff has acknowledged that it was possible that he receive the booklet before the claim arose.

Thus, I find that the definition of "necessary treatment" as set forth by the Defendant was part of a required summary plan description which was timely delivered to the Plaintiff. As such, it serves as the fiduciary's "official" interpretation of the plan's meaning.

The next question, however, is not so easily disposed of: Is the fiduciary's interpretation rational and consistent with the language of the policy?

In my view the term "necessary" implies something that is required, is mandated, or is a pre-requisite for some desired result. Necessity does not depend, logically, upon the general acceptability of a particular course of action, or upon its popularity, or even upon its respectability. Rather, something is "necessary" where the action must be taken in order to achieve an intended goal.

However, there must be some logical connection between the pre-requisite action and the intended result. An act can be necessary only if there exists some realistic possibility that the goal or desired result may occur if the act is undertaken.

Given this view, the fiduciary's definition, which limits "necessary treatments" only to those which are "broadly acceptable professionally", contravenes what appears to me to be the plain and unambiguous meaning of the word "necessary".[1] Moreover, the rationality of the interpretation is questionable. It is possible to imagine situations occurring of extreme emergency, where a physician resorts to heroic, untested and unproved treatment in order to save a life in imminent peril.

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[1] Of course, the policy itself could have limited coverage to only "acceptable" treatments. Had that language been utilized, there would be little dispute here. However, given the unmodified and unrestricted use of the word "necessary" in the policy, one has no choice but to apply its ordinary and literal meaning.

Under the fiduciary's interpretation, such lifesaving treatment would be deemed "unnecessary" because it was not "broadly accepted", even though the physician succeeded in salvaging his patient. This is neither logical nor rational.

For these reasons, I determine that the fiduciary's own interpretation of the meaning of this policy provision cannot be given effect. It follows from this that the fiduciary's denial of this claim was arbitrary, since the denial was based upon the irrational and improper standard of review.[2]

Having reached this conclusion, it now becomes my duty to develop within Federal law concepts an appropriate standard for determining whether given medical treatment is "necessary". In so doing, I understand that I may take into account State law decisions as interpretive aids for the meaning of the word "necessary". However, State common law principles governing contract construction are not applicable. Thus, such well known rules as construing ambiguous terms strictly against the draftsman, or construing insuring agreements so as to provide coverage whenever possible, will have no bearing on this decision.

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[2]It appears from the evidence that the fiduciary never really answered the question of whether the treatments were "necessary". Instead, the fiduciary found the treatment had not gained "broad acceptance within the profession". While this finding was clearly supported by the evidence gathered by the fiduciary, it does not address what, in my judgment, is the appropriate standard for reviewing the claim. The real standard is whether or not the treatments were necessary--that is whether the treatments were rationally related as a pre-requisite to an intended or desired result.

It seems to me that the following elements must exist in order to establish that medical treatment is "necessary":

1. The existence of an underlying illness, disease, or injury must be established with a reasonable degree of medical probability, and

2. There must be an evaluation of the patient as to the efficacy of the particular treatment strategy as well as an evaluation of the various alternate treatment possibilities,[3] and

3. There must exist a demonstrable possibility that the treatment will achieve the intended goal,[4] or

4. Where, under the current state of medical arts it cannot be demonstrated that treatment may be effective, treatment may nevertheless be "necessary" if, by its methodology or pedagogy, its efficacy might be demonstrated in the future.[5]

These four elements, it seems to me, serve as a logical framework within which to analyze whether a given medical

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[3]Even in cases of extreme emergency, some consideration, however brief, must be given to the available possible alternate treatments.

[4]Simply stated, hopeless treatment by definition is unnecessary. Treatment which cannot possibly affect a desired result should be withheld.

[5]Experimental medicine, conducted under clinically and scientifically accepted principles, with appropriate drafted protocol, is not only necessary, but vital to the advancement of the medical arts. To hold that such experimental medicine is necessary to the advancement of medical science, but is unnecessary to the patient because its efficacy cannot be proved is illogical.

treatment is necessary, and indeed whether this particular treatment was necessary.

1. Was a diagnosis of an underlying illness disease or injury made with a reasonable degree of medical probability? Yes. It is undisputed that the patient was diagnosed as having Stage 4 breast cancer.

2. Was the patient evaluated with various treatment modalities in mind? Yes. She was evaluated by a number of physicians and several strategies were developed. At first she was tried on hormonal therapy. This failed by objective measurement. She was then started on chemotherapy. This therapy apparently had some palliative effect on the patient. However, due to the side effects which the patient found intolerable the therapy was abandoned. In this, I can find no fault. Whenever treatment becomes intolerable, a patient has ever right to discontinue the treatment and seek other alternative treatments.

Before beginning IAT, the patient was evaluated by Dr. McPhee of the IRC. He learned that the patient was diagnosed as having Stage 4 breast cancer by an "approved hospital outside the Bahamas". He also learned that hormonal therapy had failed and the chemotherapy was intolerable. He examined the patient, performed x-rays, blood tests and an "immuno-competency test" on the patient to determine whether she was a good candidate for IAT therapy. Accordingly, I find that an appropriate evaluation of the patient was performed before the IAT therapy was commenced.

3. Did there exist a demonstrable possibility that the treatment selected (IAT) would achieve a cure or palliation of

the Plaintiff's illness? No. Despite the claims made by its proponents, the clear weight of the evidence demonstrates that IAT has not yet been shown to be an effective cancer treatment. Indeed, its lack of broad acceptance underscores the fact that, as of now, no study has even suggested that the therapy in question has any effectiveness. It is, to say the least, a controversial treatment strategy which its own advocates admit is currently outside the norm.

4. Even though not yet demonstrably effective, is the methodology or pedagogy of IAT therapy such that one can say that its efficacy might possibly be demonstrated sometime in the future? Here, in my opinion, is the key issue in this case. Is it possible that the IRC might, in the coming years, demonstrate that the IAT has some beneficial effect on cancer patients? Is this treatment program designed in such a fashion that medical science, if not the individual patient, will benefit from knowledge accumulated through scientific and clinical monitoring? Does IRC's program represent that type of ongoing research, experimentation or study which may ultimately add to the body of scientific and medical knowledge?

Unfortunately, based upon the evidence before me, it appears that the answer is no.

It does not appear that this therapeutic program is conducted under a carefully drafted experimental protocol. There are no "double blind" comparisons or trials. There is no systematic follow-up on patients who have received IAT. The precise mechanism by which immuno-augmentive therapy works, or is

suppose to work, is either not well understood or not well explained. While its theory seems plausible (e.g. augmenting the body's own immune defenses with immunological by-products of healthy donors) there appears to be little if any ongoing laboratory experimentation to test this theory. The immuno competency test has not been duplicated by any independent researchers. The components of the therapeutic injections have not been independently verified. Indeed, it is admitted that the National Cancer Institute asserts that IAT serum does not contain what is proponents claim.

Based upon the record before me, it does not appear that the IRC is conducting a therapeutic program which is reasonably designed or intended to add to the general body of scientific knowledge. Nor does it appear that the program, as maintained by the IRC, will be capable of eventually establishing (or disproving) the efficacy of IAT as a weapon in the war against cancer. Since the effectiveness of the therapy is unknown, and since it appears that its effectiveness will remain unknowable under the IRC program as it is presently designed, I cannot find that the treatments in question were "necessary".

OTHER ISSUES

1. Did the therapy in this case provide actual palliation of the patient's illness?

The Plaintiff asserts that the IAT treatment was necessary because it, in fact, proved to be effective. There appears to be two problems with this position. First, I am not certain that it

is proper to determine the "necessity" of a particular treatment through a retrospective review of the effects of actual treatment upon an actual patient. Defendant directs me to authority suggesting that review of a fiduciary's decision is limited to the information available to the fiduciary at the time the decision was made.

Moreover, as Defendant suggests, requiring the fiduciary to withhold its decision on the necessity of treatment until after the effects of a treatment in a given case can be fully assessed might well prove to be impossibly burdensome.

Finally, Plaintiff's suggestion is a two-edged sword. If treatment which initially appears to be totally unrelated to the illness can be later termed "necessary" because of its apparent success, then treatment which appears totally appropriate initially might later be deemed "unnecessary" if the patient fails to respond. For example, in this case was the hormonal therapy unnecessary simply because it failed?

But putting these questions aside, a second and more significant problem exists with the Plaintiff's position. The evidence does not persuade me that the IAT treatments were, in fact effective here. Plaintiff contends that the patient lived longer than the average patient with a similar disease process. That might be true. But it might well be attributable to factors other than IAT. Plaintiff claims that the patient's weight was well stabilized. Again, however, this may or may not have been as a result of the IAT therapy, and it may or may not have had any significance on the palliation of the patient's disease.

During the period in which the patient was undergoing IAT, radiographic evidence demonstrated an inexorable growth in the number and sizes of metastatic tumors.

In short, it is certainly unclear to me that the IAT treatment had any effect on the well-being of the patient. Thus, even if it is proper to review the actual results of treatment in determining whether the treatment is "necessary", the results here are equivocal at best.

2. Has the fiduciary been inconsistent in its application of this policy provision?

Initially, it appeared from some of the materials submitted that the fiduciary had, in some cases, granted coverage to other individuals who received IAT therapy, while denying such coverage here. If such facts were true, then the fiduciary's actions would clearly appear to be arbitrary and capricious. However, as the facts were more fully developed it does not appear that the fiduciary has been inconsistent. In one case, an employee of Western Michigan University was granted coverage under a self-funded plan administered by this fiduciary. However, it appears that the fiduciary initially denied the claim and that the employer, under the plan provision, nevertheless decided to grant coverage. In one other case, there may have been a payment made for IAT therapy by mistake. However, it appears that the fiduciary simply made an error in its administration of the particular plan. Accordingly, it does not appear from the evidence presented at arbitration that the fiduciary has acted in

an inconsistent manner when applying this particular policy provision in other cases.

SUMMARY

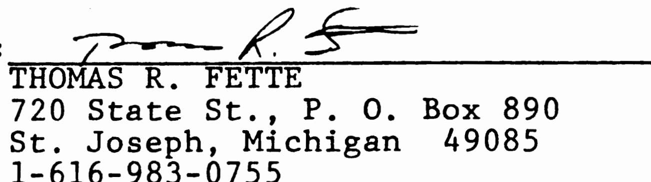
The insuring agreement provided coverage for "necessary" medical expenses. It excluded coverage for "unnecessary" expenses. The fiduciary interpreted this policy provision to mean treatments which were "broadly accepted professionally" would be deemed necessary treatments. I believe that this interpretation is in conflict with the plain and ordinary meaning of the word "necessary", and also that this interpretation inevitably leads to illogical results. Accordingly, I find that the fiduciary's denial of this claim was based upon arbitrary considerations.

In assessing whether the particular treatments in this case were "necessary" however, it does not appear that there is a demonstrable connection between the type of therapy undertaken, and the eventual goal of eradication or palliation of the disease. Nor does it appear that the type of program conducted by IRC is designed in such a fashion that the efficacy of treatment may eventually be proved or disproved.

Therefore, I cannot find that treatments in this case were "necessary" within the meaning of the policy issued to the Plaintiff and I am thus denying the Plaintiff's claim.

Dated: FETTE, DUMKE & PASSARO, P.C.

May 14, 1987 By:



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