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Trial Testimony In A Maryland Bone Marrow Transplant Suit

By Marilyn Mannisto Evans

In late February 1991, a United States District Court in Maryland, found in favor of two plaintiffs who were seeking to compel Blue Cross/Blue Shield of Maryland to pay for their bone marrow transplants. The judge's summation of the trial provides an insightful look at the issues—policy language, the definition of experimental, what constitutes accepted medical practice—and the basis for the Court's ruling.

In 1990, two plaintiffs were advised by their physicians that High Dose Chemotherapy Treatment with Autologous Bone Marrow Transplant (HDCT/ABMT) offered the best available treatment for their breast cancers (Stage II/III and Stage IV, respectively). Both women were denied pre-authorization of insurance coverage for the procedure from Blue Cross-Blue Shield of Maryland (BCBS/MD), based upon a policy provision which excluded coverage for "experimental and investigative" treatments. The policy defined "experimental and investigative" as "generally acknowledged... accepted medical practice."

Letters of appeal by the plaintiffs' treating physicians and letters from their attorneys citing recommended oncologic contacts were not responded to. As a result, the women filed suit in a Maryland District Court. Because the health insurance plans under which both plaintiffs were covered were "employee welfare benefit plans," the case was governed by the Employee Retirement Income Security Act of 1974 (ERISA) and, accordingly, the case fell under federal jurisdiction.

Defining Plan Language

During the trial, Blue Cross argued that it could deny coverage for the plaintiffs' HDCT/ABMT treatment because of a provision in its benefit plan which states that "the plan will not pay for services. . . that are experimental or investigative in nature." Furthermore, Blue Cross pointed out that the plan provision defines the term "experimental or investigative" to mean "any treatment. . . not generally acknowledged as accepted medical practice by the suitable medical specialty practicing in Maryland, as decided by us."

First, the court had to determine the "appropriate standard of review" under which to evaluate Blue Cross' interpretation and application of its contractual agreement. In previous denials of benefits challenged in court under ERISA, the courts held that "if the benefit plan in fact grants power to the trustee to construe disputed or doubtful terms, the trustee's interpretation will not be disturbed if reasonable." (*Bruch*, 109 S.Ct. at 954). However, in this specific case, the Court found the plan language far more "vague and ambiguous" than the broad and clear language that previous courts held to confer discretionary authority to plan administrators. The court ruled that the language "as decided by us," did not grant Blue Cross the authority to define the meaning of the phrase "experimental" or "investigative."

Moreover, because of the vagueness of the plan's language, the Court reviewed the Blue Cross decision and plan interpretation under a *de novo* (over again, or anew) standard of review. As a result, Blue Cross had to justify its denial of coverage on the basis that there was not a "consensus of acknowledgement" about the procedure on the part of "practicing Maryland oncologists" at the time the plaintiffs' appeals were denied (April and July 1990).

Defining 'Accepted Medical Practice'

Once the standard of review of contract language was determined, Blue Cross argued that "accepted medical practice" is a "standard practice" which has 1) proven itself through a rigorous process of clinical testing and amassing of scientific evidence, 2) has known risks and benefits, and 3) is a practice not in the process of being tested to gather generalizable knowledge. In an attempt to provide legal support for that definition, Blue Cross relied upon a decision of the United States Court of Appeals for the District of Columbia Circuit Court (*Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), which established that experts can only testify when their testimony relates to a technique that is "generally accepted by the relevant scientific community." *Frye* looks to whether a consensus exists within a community of "objective scientific observers whose livelihood is not intimately connected with the technique."

However, the Court rejected the use of the Frye standard to define "accepted medical practice, stating that "the objective scientific evaluation of a technique for purposes of determining the admissibility of expert testimony in a trial is far different from the practical evaluation of a medical treatment to decide whether it is accepted medical practice. In the first case, scientists are asked to quantify a technique's reliability, predictability, and precision so that a jury can rely upon it to determine facts (i.e., polygraph tests, DNA profiling, or the use of hypnosis in memory restoration).

In the second case, the Court stated, physicians practicing the scientific art of medicine must strike a practical balance between the risks of a particular treatment, the effectiveness of the treatment, and the availability of other options. Therefore, the Court found the Blue Cross definition of "accepted medical practice" based on the *Frye* standard to be "arbitrary and

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capricious," because it was "inconsistent with the language of the plan documents," which looked specifically to a "community of practitioners who use practical criteria in evaluating the acceptability of a treatment." Therefore, the question before the Court remained whether, at the relevant times, "a consensus of Maryland oncologists considered HCDT/ABMT to be an appropriate treatment option offered by the ordinary prudent and reasonable medical oncologist exercising due care for his or her patient."

Blue Cross' Witnesses

Testimony by the corporate Medical Director for Blue Cross-Blue Shield of Maryland revealed that he "did not consult, or consulted minimally, Maryland medical oncologists in arriving at the decision to deny coverage for the plaintiffs' claims." Rather, the Court found that the medical director "relied heavily on a 1988 technical evaluation prepared by the Technical Evaluation Committee (TEC) in association with the National Blue Cross-Blue Shield Association, which found that ABMT used as treatment for breast cancer was experimental." In short, the medical director relied upon Blue Cross' evaluation of scientific data, as well as his own independent review, rather than relying on local, expert medical opinion.

In an effort to prove that ABMT was not yet accepted medical practice at the time of the plaintiffs' applications for coverage, Blue Cross presented six expert witnesses. At trial, a biostatistician hired by Blue Cross to prepare the 1990 National Association Report on the subject of ABMT for breast cancer, testified that HDCT-ABMT was "still experimental, because a number of questions remained unanswered with regard to potential benefits, in particular overall survival rates, as well as potential harm, namely, toxicity rates." He contended that it was "improper [for Blue Cross] to rely on practitioner opinions to determine whether a procedure was experimental; instead, independent Blue Cross analysis of the scientific data was necessary."

This witness also was of the opinion that it was "highly significant that Phase III randomized clinical trials had not yet been completed for HDCT/ABMT, but were in the process of being conducted." Even though he acknowledged that "Phase III studies were not necessary in all cases, pointing to the use of HDCT/ABMT for non-Hodgkins lymphoma as an example of a 'home-run' treatment," he testified that Phase I and II studies for HDCT/ABMT in the treatment of breast cancer had not achieved such "home-run" results. He stated that "significant long-term survival rates in breast cancer patients treated with HDCT/ABMT had not yet been demonstrated, at least not in studies which he considered to be reliable."

Blue Cross also presented several other experts: two practicing Maryland oncologists, an AIDS researcher, and an oncologist practicing in Los Angeles. All of these experts stated that HDCT/ABMT was experimental in April and July of 1990, based on their review of the scientific literature. In particular, these witnesses pointed to questions regarding 1) whether the procedure resulted in long-term survival, 2) toxicity rates, 3) the appropriate combinations of chemotherapy drugs to use, and 4) the effect of using growth factors to stimulate bone marrow replacement after untainted bone marrow has been reinfused.

The two Maryland-based oncologists premised their discussions on a definition of "accepted medical practice" which turned on whether the practice was well-described in the literature, had been tested by many persons, and whether it had produced acceptable toxicity ratios and well-described results. Despite their conclusions, however, both physicians admitted that given the appropriate patient, they too would have referred their patients for treatment with the procedure. The court found that Blue Cross' other experts failed to discuss the views of Maryland oncologists with any degree of specificity.

As a result, the court rejected the opinions of the Blue Cross experts because they based their opinions on a definition of the term, "accepted medical practice," that was inconsistent with the contract language. The court ruled that "instead of focusing testimony on the opinion of members of the Maryland oncological community, the Blue Cross experts concentrated on their own independent evaluations of the scientific data." Furthermore, the court stated that "after reviewing the relevant scientific data, the practicing medical community must make an overall value judgment about whether a treatment is accepted. . . or indeed recommending the treatment as an option.

Plaintiffs' Witnesses

In contrast to the Blue Cross experts, the Court found that the plaintiffs' expert witnesses utilized a practical definition of what constitutes "accepted medical treatment" that was both "consistent with the standard legal definition and consistent with the contract language." The six local oncologists who testified revealed that they had "hundreds of conversations with Maryland oncologists in the process of setting up and operating a bone marrow transplant program," that they could "identify 50 or 60 Maryland oncologists who had referred or discussed patients with regard to using HDCT/ABMT to treat breast cancer," and that it was "generally acknowledged as accepted medical practice" by Maryland oncologists as of April and July of 1990.

The court also found that the testimony of plaintiffs' experts that HDCT/ABMT treatment was in use at many major medical centers around the country "convincing evidence that the treatment had scientifically proven value and was in accordance with generally accepted standards of medical practice."

Scientific Criteria

Although it was not necessary to support the preceding conclusion, the court determined that "even if it were to accept the Blue Cross definition of the term 'accepted medical practice,' which turns on scientific criteria, HDCT/ABMT would satisfy the five scientific criteria developed by Blue Cross' own Technology Evaluation Committee." Those criteria are:

1) The technology must have final approval from the appropriate government regulatory body.
2) The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.
3) The technology must improve the net health outcome.
4) The technology must be as beneficial as any established alternatives.
5) The improvement must be attainable outside the research setting.

Plaintiffs' counsel presented evaluations of HDCT/ABMT for breast cancer which concluded, in July of 1990, that the procedure satisfied all five of the TEC criteria. Moreover, local Maryland oncologists testified that as of April 1990, the procedure satisfied all five of the criteria.

Moreover, the Court found that scientific data provided by the plaintiffs' expert witnesses was "persuasive testimony that at the time Blue Cross decided to deny benefits to the plaintiffs, HDCT/ABMT had already demonstrated dramatic increases in complete and overall response rates... as well as significant improvement in disease-free survival."

Much of the scientific testimony comprised results from clinical trials at Duke Medical Center which demonstrated that 70 percent of women with Stage IV metastatic breast cancer who are treated early in the disease with induction therapy followed by high-dose therapy with bone marrow support had achieved total remission as compared to a 15 to 20 percent complete response rate under standard low-dose therapy alone. Of those women treated with HDCT/ABMT following induction therapy, 25 percent remained disease free at a 3-1/2 year follow-up, versus a 20 percent rate for standard therapy. Therefore, the court noted a "significant benefit in disease-free survival to be gained from using HDCT/ABMT," and considered it "highly unreasonable for Blue Cross to ignore the benefits of disease-free survival in favor of concentrating only on long-term survival rates." The expert witness from Duke also testified that at the time Blue Cross denied coverage to one of the plaintiffs, Duke trials had "demonstrated that after 30 months, 70 percent of the women treated with HDCT/ABMT following adjuvant therapy achieved disease-free survival, compared to a mere 20 percent of women treated with low-dose therapy." In addition, "those women treated with HDCT/ABMT achieved an overall response rate of 80 percent at a follow up of 40 months, compared to 60 percent for women treated with low-dose therapy."

As a result, the court found that "beyond dramatically increased complete response rates and increased disease-free survival rates," women undergoing HDCT/ABMT "spend far less time on therapy than do their counterparts on low-dose therapy." Together, these outcomes convinced the court that the results "may serve to offset whatever increase in toxicity may result from using HDCT/ABMT."

Ongoing Clinical Trials

One of Blue Cross' arguments for insisting that HDCT/ABMT treatments are experimental was based on the fact that "the treatments at issue were to be given on research protocol at teaching hospitals." (During the course of the trial, it was announced that a number of Blue Cross/Blue Shield plans would provide funding for ABMT trials developed by the NCI for breast cancer patients.) However, the Court found that the concern of Blue Cross' expert witnesses over incomplete Phase III studies to be of "no moment." Of significant import to that finding was testimony by plaintiffs' witnesses that "a Phase III random clinical trial would be ethically acceptable only if the treatment was potentially as good as, if not better than, low-dose therapy." In other words, investigators could not ethically conduct randomized clinical trials if HDCT/ABMT was known with any certainty to be less effective than low-dose chemotherapy. Moreover, plaintiffs' witnesses explained that "to make Phase III studies ethically acceptable, researchers have had to offer HDCT/ABMT to those patients who relapse on low-dose therapy, precisely because data demonstrates HDCT/ABMT's superiority." As a result, the court found that because the treatment is being studied "on protocol" does not "alter the fact that at the relevant times Maryland oncologists generally acknowledged the treatment to be accepted medical practice. "Of course," the court stated, "researchers maintain an interest in collecting further information about HDCT/ABMT. However, physicians refer their patients for HDCT/ABMT for the primary purpose of medical treatment, and under the plan definition it is of little consequence that the treatment also provides information to research investigators." Although the court recognized that "questions remain with respect to overall survival," it ruled that "research need not prove a treatment completely curative in order for it to have sufficient merit to be judged an 'accepted medical practice."

The Final Ruling

The court found Blue Cross-Blue Shield's decision to deny coverage for HDCT/ABMT to be "arbitrary and capricious" for two reasons. First, the court found the Blues' interpretation of "accepted medical practice" to be unreasonable because it was inconsistent with the language in the exclusion provision. "Alternatively," the court stated, "accepting Blue Cross' focus on scientific criteria," its decision was unreasonable because it "ran counter to the evidence" before the BCBS/MD medical director.

Second, the court found that "Blue Cross' decision to deny benefits was arbitrary and capricious because "it failed to consider the most relevant aspect of all—the opinion of the Maryland oncological community." The court ruled that "Blue Cross had absolutely no evidence before it with regard to whether Maryland oncologists generally acknowledge HDCT/ABMT to be accepted medical practice." Instead, the medical director for Blue Cross "unilaterally drew his own conclusions, based upon the National Association Report and his own review of the data, that Maryland oncologists could not possibly have considered the treatment to be accepted because, in his opinion, no proof of the treatment's efficacy yet existed."

The court found it "completely unreasonable" for Blue Cross' medical director to have "relied on outside scientific opinion and his own independent review of the literature, while selectively ignoring the professional opinions of Maryland oncologists and plaintiffs' treating physicians." Furthermore, the court ruled that "if Blue Cross had wished the plan administrator to unilaterally review the scientific data and make the final determination with regard to whether a procedure was accepted, it could have drafted its contractual exclusion to reflect that intent." For example, the court cited a review of a Blue Cross benefit plan which excluded treatments "not yet recognized as accepted medical practice by Blue Cross and Blue Shield United. (*Reilly vs. Blue Cross & Blue Shield United of Wisconsin,* 846 F.2d 416 (7th Cir. 1988). "The Blue Cross plan at issue in this case did not contain such a provision," the court noted. "Yet Blue Cross arbitrarily and capriciously acted as if it did."

In conclusion, the court found that Blue Cross' medical director "should have deferred to the opinion of the Maryland oncological community;" if he had "chosen to consult with the doctors listed in the material submitted to him by the plaintiffs, he would have discovered that HDCT/ABMT was generally acknowledged as accepted medical treatment by Maryland oncologists," and that "his failure to consult the very medical experts to which the plan defers is nothing if not unreasonable." For those reasons, the court found in favor of both plaintiffs. ■