Oncology Issues

ISSN: 1046-3356 (Print) 2573-1777 (Online) Journal homepage: https://www.tandfonline.com/loi/uacc20

Suing Insurers: Litigation over Autologous Bone Marrow Transplants and Breast Cancer

Ted Wieseman

To cite this article: Ted Wieseman (1991) Suing Insurers: Litigation over Autologous Bone Marrow Transplants and Breast Cancer, Oncology Issues, 6:2, 7-12, DOI: 10.1080/10463356.1991.11905027

To link to this article: https://doi.org/10.1080/10463356.1991.11905027

Suing Insurers: Litigation Over Autologous Bone Marrow Transplants And Breast Cancer

By Ted Wieseman

The effectiveness of High-Dose Chemotherapy and Autologous Bone Marrow Transplantation in the treatment of solid tumors, which carries a potential price tag of millions of dollars, has resulted in a flurry of coverage denials by insurers. Such denials have left patients with no recourse except the jurisprudence system. This article discusses the lawsuits, to date, brought against Blue Cross/Blue Shield Plans and Prudential, the results of those suits, and what the future may hold.

Although not all Blue Cross/Blue Shield Plans refuse to cover High Dose Chemotherapy and Autologous Bone Marrow Transplants (HDC/ABMTs), the majority do, particularly for the treatment of solid tumors, such as breast cancer. However, breast cancer patients who have refused to accept the Blues' denial of coverage for HDC/ABMT and filed lawsuits have been successful. Since January 1, 1990, there have been nine court decisions, all lost by insurance companies on the basis of whether HDC/ABMT is experimental. The Blues lost eight times and Prudential once. However, in 1988 and 1989, when oncologists first began recommending HDC/ABMTs for solid tumors, these two insurance companies met with greater success, winning three of the first four HDC/ABMT court cases.

The Early Cases

As stated previously, insurance companies won the first few HDC/ABMT solid tumor cases. Before 1990, few physicians were prepared to testify that the treatment was not experimental. Indeed, in the very first HDC/ABMT court decision, the plaintiff did not even dispute the Blues' determination that the treatment was experimental for Stage IV metastatic breast cancer.[1] Ms. Thomas argued the legal doctrine of "estoppel." That is, Blue Cross/Blue Shield of Alabama (BCBS/AL) should be required to cover her ABMT because: 1) it had already paid for part of the treatment (the harvesting of the bone marrow at Vanderbilt Medical Center); and 2) BCBS/AL had previously covered HDC/ABMT for another breast cancer patient. Judge William B. Hand ruled against Ms. Thomas, holding that it was undisputed that HDC/ABMT was experimental and that BCBS/AL could not be estopped into being held "perpetually liable" to all of its insured plan participants because of a past error.[2]

Two other pre-1990 HDC/ABMT breast cancer cases were won by insurance companies: Blue Cross Blue Shield of Virginia won *Hurowitz v. Blue Cross and Blue Shield of Virginia*[3] and Prudential won *Sweeney v. Gerber Products Co. Medical Benefit Plan*.[4] Both courts rejected the testimony of the treating oncologists that HDC/ABMT was no longer experimental for the treatment of metastatic breast cancer, and both declined to issue preliminary injunctions for advance payment of the costs. In *Sweeney*, the Court also discounted the testimony of Dr. Karel Dicke, who administered the transplant program at the University of Nebraska Medical Center. It ruled that there was "no question that high-dose chemotherapy accompanied by autologous bone marrow transplantation as a treatment for breast cancer remains today a treatment which is in an experimental and investigational stage."[5] *Sweeney*, which was decided on December 20, 1989, was the last HDC/ABMT case won by an insurance carrier.

However, insurance companies did not win all of the early cases. Prudential lost an important case in the federal district court in New Jersey on July 7, 1989. The case, *Dozsa v. Crum & Forster Ins.*,[6] involved a motion for a preliminary injunction to advance funds for an HDC/ABMT for a multiple myeloma patient at Johns Hopkins in Baltimore. Judge Dickinson R. Debevoise issued the preliminary injunction and wrote a long and comprehensive opinion that was to become a harbinger of future cases.

In *Dozsa*, the Prudential health plan covered treatments "commonly and customarily recognized throughout the doctor's profession as appropriate," and which were "neither educational nor experimental in nature."[7] Prudential's witnesses—its Vice President, Dr. David Plocher, and two private oncologists—testified that although the company covered HDC/ABMT for some types of cancers, it classified ABMT for solid tumors, like multiple myeloma, as experimental because: 1) it had not yet been demonstrated safe and effective in Phase III randomized and controlled clinical trials; and 2) there was no "clear consensus in published peer-review medical literature."[8] Prudential relied exclusively on scientific research criteria and presented no testimony from practicing medical oncologists on the definition embodied in the language of the health plan; that is, "commonly and customarily recognized throughout the doctor's profession as appropriate."

However, the plaintiff's treating oncologists in New Jersey and at Johns Hopkins did present such testimony. They told the court that the only treatment for Mr. Dozsa was HDC/ABMT, that he would die in six months without the treatment, that the treatment was "commonly and customarily" recognized, that it was not experimental, and that, regardless of the state of peer-review literature,

Ted Wieseman *is Assistant Public Defender, State of Maryland. The views and opinions expressed in this article are the author's own personal views and opinions and have no connection with his employment with the Public Defender's Office of the State of Maryland.*

In each case, the insurance company disregarded the language of its health plan and asked the court to accept its scientific research definition of "experimental"

HDC/ABMT was accepted and used at major hospital centers in Europe and the United States.[9]

Judge Debevoise ruled that Prudential could not ignore the language of the health plan. He stated that the definition of experimental in the health plan did not look to the opinion of scientists engaged in research; rather, it looked to doctors engaged in the actual practice of medicine—that is, what is "customarily recognized throughout the doctor's profession as appropriate in the treatment of multiple myeloma."[10] The doctors who should make that determination were "those who would work in the field of ABMT treatment and other oncologists who knew about such treatment."[11] Furthermore, Judge Debevoise stated that while lack of consensus in peer-review literature might be "some evidence" of experimental status, it could not be a determining factor because, in cancer therapy, "it takes time for literature to catch up with accepted practice and what doctors are actually doing."[12]

The scenario in *Dozsa* would be replayed in each of the later court decisions in 1990 and 1991. In each case, the insurance company disregarded the language of its health plan and asked the court to accept its scientific research definition of "experimental." In each case, the court rejected that argument and ruled that the insurer was bound by the contractual language in its health plan.

The 1990 Cases

The first 1990 decision on HDC/ABMT was *Rollo v. Blue Cross/Blue Shield of New Jersey*,[13] which was filed for a plaintiff by the same attorney for a plaintiff in the same federal court as in *Dozsa*. The *Rollo* case was a final decision after a trial and involved a different insurer, BCBS/NJ, as well as a different type of cancer, relapsed Wilms' tumor of the kidney.

The case involved an eight-year-old child who, without HDC/ABMT, had only a one-to-two percent chance of surviving for one year. Judge Maryanne Barry began her written opinion with language that probably explains better than any other language or any other legal analysis why the individual judges in all of the 1990–1991 HDC/ABMT cases have ruled against the Blues and Prudential:

> "When the parties were first before me less than six weeks ago, I was called upon to decide whether eight-year-old Tishna Rollo could live or whether she must die; a humbling and sobering decision."[14]

The evidence at the *Rollo* trial showed that the BCBS/NJ contract excluded "investigational or experimental procedures" defined as "not accepted as a standard medical treatment."[15] BCBS/NJ presented one witness, its medical director, Dr. Otto Matheke, whose medical experience had been in general surgery. Similar to the testimony of Dr. Plocher of Prudential in *Dozsa*, Dr. Matheke testified that BCBS defined "experimental" by looking to peer-reviewed literature, BCBS technical evaluations, and the National Blues' Uniform Medical Policy Manual, which classifies treatments and drugs as accepted or experimental on the basis of five technology evaluation criteria (TEC) based on scientific research standards (see the discussion under *Pirozzi, infra*). Under BCBS/NJ policy, Dr. Matheke should have consulted local physicians and inquired of national bodies, like the American Medical Association, but failed to do so.[16]

The plaintiff presented the testimony of his treating pediatric oncologist, and written materials from Dr. Sarah Strandjord of the University of Nebraska where the transplant had been performed, as well as from pediatric oncologists from Philadelphia and London. This testimony established, to the satisfaction of Judge Barry, that HDC/ABMT "is and has been for several years the standard medical treatment for relapsed Wilms' tumor."[17] Judge Barry ruled that BCBS/NJ had "mishandled this claim for coverage."[18] She found

State vs. Federal Court Trials

Two explanatory notes about legal procedures are important to this discussion of HDC/ABMT lawsuits. First, most of the HDC/ABMT lawsuits, to date, were filed in federal rather than state courts. A federal law called the ERISA statute (Employment Retirement Income Security Act, 29 U.S.C. 1001-1461) defines the procedures and rights of employees to challenge denials of benefits under employment pension and benefit plans, including health insurance plans.

Generally, the ERISA statute is favorable to employers and their insurance carriers. Not all HDC/ABMT cases were filed in the federal courts, because the ERISA statute does not apply to state and local government employees, who may file suit in state courts. In general, state insurance laws and procedures are less favorable to insurance companies. For example, in state courts, any ambiguity or uncertainty in the meaning of the language of the insurance benefits plan is construed against the insurance company, because it drafted the language.

Secondly, a substantial number of the HDC/ABMT cases, to date, involved pre-trial hearings on motions for a preliminary injunction, which is an order that requires the insurance company to pay ABMT expenses at the beginning of the case, rather than awaiting the outcome of the trial which, because most courts are so congested, may not occur for one to two years. If an insurance company pays for ABMT preliminarily, and later wins at trial, the plaintiff will be ordered to reimburse the insurance company. To win a preliminary injunction, plaintiffs must satisfy the court that there is a substantial likelihood they will win at trial, that they will suffer irreparable injury if relief is delayed, and that granting early relief is in the public interest. (*E.g., Dozsa v. Crum & Forster Insurance Co.*, 716 F.Supp. 131 [D.N.J. 1989])

that BCBS/NJ had made no effort to determine the merits of the plaintiff's claim and had denied coverage based on the national Uniform Medical Policy Manual and a national TEC evaluation that breast cancer and other solid tumors, not including Wilms' tumor, were experimental.[19]

The next 1990 case lost by the Blues was a Stage IV breast cancer case, *Thomas v. Blue Cross and Blue Shield of Massachusetts*.[20] In this case, a preliminary injunction was issued and BCBS/MA paid for the HDC/ABMT at Duke University. The next breast cancer case, *Pirozzi v. Blue Cross-Blue Shield of Virginia*,[21] which followed two weeks later, was an expedited trial that produced a lengthy opinion by Judge Thomas S. Ellis, III. Judge Ellis held that BCBS/VA would be required to cover an HDC/ABMT for a Stage IV breast cancer patient at Montefiore Hospital in Pittsburgh. The BCBS/VA health plan excluded from coverage:

> "experimental or clinical investigative procedures; services of no scientifically proved medical value; also services not in accordance with generally accepted standards of medical practice."[22]

In *Pirozzi*, BCBS presented only one witness, its medical director, Dr. John Colley, who was not an oncologist, and who testified similarly to Dr. Plocher in *Dozsa* and Dr. Matheke in *Rollo*. Namely, that the company did not deny coverage on the basis of the language of the contract, but on the scientific definition of experimental found in the National Association's December 1988 Uniform Medical Policy Manual and TEC evaluations.[23] The *Pirozzi* opinion spelled out the National Blue's five "technology evaluation criteria" referred to earlier in the *Rollo* case:

1. Is the drug or device approved by the FDA or a government regulatory body?
2. Does the peer-reviewed medical and scientific literature permit BCBS to make conclusions about the procedure's safety and effectiveness?
3. Does available scientific evidence show a net beneficial effect?
4. Is the procedure as safe and as effective as existing alternatives?
5. Can the procedure be expected to satisfy criteria numbers three and four outside the research setting?[24]

Dr. Colley testified that he had seen no evidence since December 1988 to alter the conclusion that HDC/ABMT was experimental for breast cancer. He stated that peer-reviewed literature was inconclusive, HDC/ABMT had not been tested adequately using "so-called Phase III double-blind studies utilizing a placebo or control group," and that the treatment had an unacceptably high mortality rate.[25]

In deciding for the plaintiff in *Pirozzi*, Judge Ellis made an identical ruling to the ones made earlier by the federal judges in *Dozsa*, *Rollo*, and *Cole*. He could not ignore the language of the health plan and rely on scientific criteria that were not written into the definition in the plan, including the absence of Phase III studies.[26]

Judge Ellis looked to the plaintiff's witnesses, her treating oncologist, and Dr. Roy Beveridge, head of the bone marrow transplant unit at Fairfax County Hospital in Virginia. Dr. Beveridge testified that HDC/ABMT was no longer experimental for breast cancer, that it was a medically necessary and effective treatment that offered Ms. Pirozzi the best chance for long-term survival, and that it was an accepted treatment used at most major medical centers in the United States. He also applied the BCBS five "technology evaluation criteria" to the present status of scientific research on HDC/ABMT and, unlike the 1988 Uniform Medical Policy Manual, concluded that it was not experimental.[27]

In June, the Blues lost the fourth case of the year, *Cole v. Blue Cross and Blue Shield of Massachusetts*.[28] This was a testicular cancer case in which the federal court in Massachusetts issued a preliminary injunction that BCBS/MA advance funds for a HDC/ABMT at the Dana-Farber Cancer Institute in Boston. In a short opinion, Judge John J. McNaught ruled for the plaintiff because the doctors at Dana-Farber, "recognized internationally as one of the foremost institutions for diagnosis and treatment of cancer," agreed that ABMT was the "appropriate and only generally accepted treatment" and that, without the treatment, Mr. Cole would probably die within a few months. The judge dismissed a BCBS/MA argument that 91 percent of the testicular cancer patients who receive HDC/ABMT die within the year and, therefore, the cure rate is only nine percent.[29]

In August, the Blues lost an AIDS case in the state courts of New York, *Bradley v. Empire Blue Cross and Blue Shield*.[30] The court issued a preliminary injunction and rejected the BCBS/NY argument that an HDC/Bone Marrow Transplant (from the patient's twin brother—not autologous) at Johns Hopkins in Baltimore was experimental. As in the other cases, BCBS/NY relied on scientific criteria and did not present any oncologists as witnesses. The Court ruled in favor of the plaintiff and his two oncologists from Johns Hopkins and the University of Chicago.

A week later, Prudential lost a declaratory judgment in a Stage IV breast cancer case, *Stewart v. Hewlett-Packard Co.*[31] in the same federal court that had decided the *Pirozzi* case. And, in October, BCBS/MD lost a preliminary injunction in a Stage IV breast cancer case in the state court in Annapolis, MD, *Simmons v Blue Cross-Blue Shield of Maryland*.[32] The plaintiffs in the two cases were represented by the same law firm that had represented Ms. Pirozzi.

Law suffers from the same problem as cancer research; there is a lag between the time cases are decided by judges and the time they are published in case law books

The 1991 Cases

Law suffers from the same problem as cancer research; there is a lag between the time cases are decided by judges and the time they are published in case law books. By 1991 the earlier *Dozsa*, *Pirozzi*, and *Cole* opinions were in the case books, and *Rollo* and other unpublished opinions were available on computerized legal database networks (LEXIS and WESTLAW). As a result, when the Blues lost two final decisions in February 1991, *Reiff v. Blue Cross* and *Blue Shield of Oklahoma*[33] and *Adams v. Blue Cross-Blue Shield of Maryland*,[34] those trials

Judge Garbis rejected BCBS' reliance on scientific research and its five technology criteria. He ruled that the sole issue in the case was the health plan's contractual language

were accompanied by detailed and lengthy opinions. The judges who wrote the *Reiff* and *Adams* opinions referred liberally to the prior cases and used them as points of departure for their own detailed analyses into areas not previously examined.

In *Reiff*, a two-day trial in the federal district court in Tulsa, Judge James O. Ellison ordered BCBS/OK to provide coverage for HDC/ABMT for a Stage IV breast cancer patient at M.D. Anderson in Houston. The BCBS/OK witnesses were its president, whose background was public relations and advertising rather than medicine; its medical director, who was an internist; and Dr. Ronald Poulin, an oncologist retained by a BCBS consulting firm.

As in the other cases, the BCBS witnesses relied on the five technology evaluation criteria, the Uniform Medical Policy Manual (as updated in 1990), and the absence of Phase III controlled trials.[35] However, in this case, BCBS/OK conceded that HDC/ABMT was as effective as any other treatment for metastatic breast cancer and that the published literature now favored the ABMT treatment.[36] The BCBS position in *Reiff* was that it could not be "established how much better HDC/ABMT is than the old treatment."[37]

Judge Ellison rejected BCBS' reliance on scientific criteria as not being part of the contract.[38] The judge found, from the testimony of plaintiff's treating oncologists, Alan Keller in Tulsa and Richard Champlin at M.D. Anderson, as well as from materials in the BCBS files, that HDC/ABMT had become "the treatment for metastatic breast cancer" and had become widely available in hospitals in Tulsa and Oklahoma City.[39]

The protocol at M.D. Anderson was like a Phase III trial except that M.D. Anderson removed the feature of placing randomly selected patients into a control group that did not receive HDC/ABMT, because it was unethical to continue to treat patients under the old methods.[40] The judge appeared to be impressed that the January 1991 *Journal of Clinical Oncology* reported that 80 percent of oncologists surveyed stated that "HDC/ABMT would be the treatment of choice for themselves or their wife or daughter."[41]

Another issue in *Reiff* was the unusual language in the health plan, which appeared to give the company unfettered discretion to decide which treatments were experimental:

> "Experimental/Investigative: Any treatment... which we do not recognize as accepted medical treatment for the condition being treated."[42]

Judge Ellison found that BCBS's apparent discretion was restricted by the law surrounding ERISA and the duties of fiduciaries. BCBS, in its role as administrator of Ms. Reiff's health benefits employment plan, had a conflict of interest in representing the interests of the employee beneficiaries and its own financial interests. Judge Ellison ruled that when a fiduciary has a conflict of interest, its "wrong but apparently reasonable interpretation is arbitrary and capricious if it advances the conflicting interest of the fiduciary at the expense of the... beneficiaries" unless BCBS could show that its interpretation benefitted everyone connected with the plan, employers and employees alike.[43] Since the plaintiff had proved BCBS/OK was wrong in classifying HDC/ABMT as experimental, the court ruled in her favor, and Judge Ellison issued a permanent injunction.

The *Reiff* decision on February 11 was followed two weeks later by the *Adams* case[44], a 41-page opinion written after a seven-day trial in November and December in the federal district court in Baltimore. The attorneys for BCBS/MD and the plaintiffs were the same in *Adams* as in the *Simmons* case (decided in Annapolis in October), as well as in several other cases pending in the state and federal courts in Maryland. BCBS/MD had decided that *Adams* would be its "test case" and decide all of the pending cases.

There were two plaintiffs in *Adams:* Ms. Adams, who was the first and, to date, only plaintiff in a court decision with Stage II/III breast cancer, and Ms. Whittington who had Stage IV breast cancer. Ms. Adams's HDC/ABMT had been performed at Duke during the summer, and Ms. Whittington's was performed at Georgetown during the trial. BCBS/MD presented the live or videotaped testimony of its medical director, four oncologists, and Dr. David Eddy, a medical doctor and biostatistician from Duke University, who had formulated the five technology evaluation criteria and the TEC evaluations on breast cancer for the National BCBS Association.

The plaintiffs presented testimony from eight oncologists and ABMT specialists. The testimony at the trial and the resulting opinion written by Judge Marvin J. Garbis described in great detail the procedures used by the Blues to process claims; the formulation of the TEC Evaluations by the National BCBS Association; the use of HDC/ABMT in the United States and in foreign countries; the presents costs, duration, and mortality rates of the treatment; and the success rates from using the treatment.

Most significant in the *Adams* opinion was Judge Garbis' interpretation of the meaning of the language "accepted medical practice." Like the other judges, Judge Garbis rejected BCBS' reliance on scientific research and the National Association's five technology criteria. He ruled that the sole issue in the case was the contractual language in the BCBS/MD health plan:

> "The terms Experimental and Investigative mean the use of any treatment... not generally acknowledged as accepted medical practice by the suitable specialty practicing in Maryland, as decided by us."[45]

Judge Garbis held that there was no reason for the court to look outside the health plan contract to find the definition of "experimental," because the contract itself defined the term as "not generally acknowledged as accepted medical practice."

> "The exclusion provision in the Blue Cross plan looks specifically to a community of practitioners who use practical criteria in evaluating the acceptability of a treatment. In particular, the contract looks to the standard of practice adopted by local practicing medical oncologists

and not to a community of objective scientific observers as is true of the Blue Cross definition for 'accepted medical practice'..."[46]

Judge Garbis wrote that the term "accepted medical practice" meant the "customary practices among reasonable and prudent physicians—not merely what practitioners judge to be accepted but what they use in treating their own patients."[47] It followed that "accepted medical practice" meant an appropriate treatment that was not malpractice. Judge Garbis summarized the definition of "accepted medical practice" in terms of the legal standards for medical malpractice as:

"an appropriate treatment option offered by the ordinary prudent and reasonable medical oncologist exercising due care for his or her patient."[48]

Applying this definition of "accepted medical practice," Judge Garbis ruled that the plaintiffs' witnesses had established that Maryland-based medical oncologists viewed HDC/ABMT as accepted medical practice for Stages II, III, and IV breast cancer, and that they regularly recommended it for their patients.[49]

BCBS/MD did not present meaningful testimony to counter plaintiff's experts. Only two of the six BCBS witnesses even addressed the accepted medical practices of Maryland oncologists, and they, both Maryland oncologists, testified that, given the appropriate patients, they also would have referred the patients for HDC/ABMT. Dr David Eddy and the BCBS/MD medical director not only disregarded the language of the health plan, but further testified that they "considered it improper to rely on practitioners to determine whether a procedure was experimental."[50] The other two BCBS witnesses were out-or-state oncologists unfamiliar with Maryland medical practices.

Judge Garbis wrote that although it was not necessary to the case, he had reviewed the expert testimony of BCBS's and plaintiffs' witnesses using the BCBS definition of "accepted medical practice," and found that HDC/ABMT satisfied BCBS' "purely scientific criteria."[51] For Stage IV breast cancer, overall survival may be similar for HDC/ABMT and low-dose therapy, but the scientific evidence showed that at any given time, "more women will have lived longer, free of disease, than if they had been treated with low-dose therapy."[52] It was "highly unreasonable for Blue Cross to ignore the benefits of disease-free survival in favor of concentrating only on long-term survival rates." For stage II/III breast cancer, data published by Dr. William Peters of Duke University showed a significantly increased rate of disease-free survival for HDC/ABMT over low-dose therapy.[53] In addition, the BCBS scientific analysis was "seriously flawed."[54]

In agreeing to pay the medical expenses of HDC/ABMTs for 600 women in the trials, the participating Blues have agreed to do nothing more than what the courts have been ordering them to do since December 1989

The Future

The costs of HDC/ABMTs ($100,000 to $200,000 per treatment) remain a heavy concern to insurers and employers. Several local BCBS plans, including New Jersey, Massachusetts, and West Virginia, are financially in "dire straits."[55] However, in many instances, the costs of HDC/ABMTs are merely passed on to employers. Litigation, which probably costs insurers an additional $50,000–$200,000 per case, has not been successful. The strategy of BCBS and Prudential—asking courts to accept a scientific research definition of "experimental" that was not incorporated into the contractual language of the health plans—was unrealistic and doomed to failure. One of the most basic of all legal principles is that in lawsuits over contracts, courts do not look outside the language of the contract.

The National Blue's response to the court losses was announced in a press release on October 29, 1990—three months before the decisions in *Reiff* and *Adams*. It announced that 15 of the 73 state and regional BCBS plans had agreed to participate in a program with the National Cancer Institute (NCI) to fund Phase III randomized clinical trials for HDC/ABMT and breast cancer.[56,57,58] The participating Blues would pay for the expenses of treatment and medical care for 1,200 women with Stage II and Stage IV breast cancer trials at 50 participating hospitals over the next five years. The patients would be randomized into two groups: 600 who would receive HDC/ABMT and 600 who would receive low-dose therapy. The National Association said this program "marked the first time a private health insurer had agreed to pay for studies of experimental medical procedures or treatments."[57] The National Association was praised for its public-spirited support of medical research and experimental trials.[57,58]

The National Blues' has acknowledged that the funding of the NCI trials was in response to the court decisions. The press release announcing the trials said that the Blues had been sued by "more than a dozen people or consumer groups," that the Blues had lost "more than half the suits," and, "if we don't do anything, we will have to' continue to fight this out in the courts."[57]

Apparently, the future policy of the 15 participating BCBS plans would be to offer HDC/ABMT for breast cancer patients only through the NCI trials, where each patient would have a 50–50 chance of being randomized into the HDC/ABMT group rather than into the low-dose control group. Under this plan, the obligation of the participating BCBS plans to fund HDC/ABMTs for breast cancer would be limited to 600 patients in the next five years, which could be a substantial savings given the American Cancer Society statistic that 44,000 women die each year from breast cancer.[58]

The Blues' prospects for success with the NCI trials are uncertain. In agreeing to pay the medical expenses of HDC/ABMTs for 600 women in the trials, the participating Blues have agreed to do nothing more than what the courts have been consistently ordering them to do since December 1989. The chances of the courts' retreating from *Adams, Reiff,* and *Pirozzi* to validate the Blues' plan to use randomized trials to exclude 50 percent of eligible breast cancer patients from HDC/ABMT are questionable. Some hospitals and oncologists have already questioned whether the NCI trials can be conducted, because of ethical problems raised in placing patients in the

control low-dose therapy group when HDC/ABMT has been demonstrated to be a superior treatment.[59,60]

A future possibility would be for the Blues and Prudential to follow a suggestion of Judge Garbis in the *Adams* opinion and change the language of their health insurance plans to allow their medical directors "to unilaterally review the scientific data and make the final determination with regard to whether a procedure was accepted."[61] However, changing the language of health insurance contracts is easier said than done. Insurance companies cannot change the language of their policies without the approval of their state insurance commissions.

Even if the insurance companies were able to change the language of their health plans, and retain absolute discretion to decide which treatments were experimental and which were accepted medical practice, recent case law suggests that the courts might prevent insurers from exercising such broad discretion to deny claims. Recent ERISA cases have borrowed from the law defining the duties of fiduciaries to restrict the discretion of insurance companies administering health insurance plans. As administrators of employees' health plans under ERISA, insurers have fiduciary duties to the employees that restrict their discretion to interpret broad language to deny claims to further their own financial interests.[62,63,64]

Another possible limitation on the discretion of medical insurance companies is a body of case law called the "reasonable expectations" doctrine, which state courts have been developing and applying to insurance contracts and standardized agreements.[65] In our modern society, few written contracts are negotiated between two individuals engaged in arms-length bargaining over specific terms. The majority of contracts are preprinted forms drafted by the insurer or seller that are seldom read in their entirety and, frequently, not even made available to the insurer or purchaser until weeks or months after the agreement has been signed and has taken effect.

Under the "reasonable expectations" principle, state courts have refused to give effect to printed language in insurance and standardized contracts that departs from the objectively reasonable expectations of the parties. For example, in one case where the specific language of a liability policy covered only those burglaries where there was a forced entry into the premises, as evidenced by physical marks or physical damage, the court required the insurance company to cover all burglaries, including those where no marks were left on the exterior of the premises. The court ruled that the printed language in the policy conflicted with both a layman's conception of the crime of burglary as well as the legal definition of the crime.[66] Burglary can be committed by entering the premises through an open window as well as by breaking a closed one.

Judge Garbis's opinion in *Adams*, defining "accepted medical practice" as any appropriate treatment that is not malpractice[67] is consistent with the "reasonable expectation" of participants in health insurance programs. It is not unreasonable for employees who enter a health insurance program to expect the program to cover the treatments recommended by their physicians and recognized as appropriate by the medical community. Stripped of its legal complexities and reduced to its barest terms, the *Adams* opinion was an application of the old adage, "the doctor knows best," which is a popularized expression of the public's perceptions and expectations of the medical profession.

Apparently, some BCBS plans have decided that the best response is no response; they continue to litigate and to lose these cases. The number of patients who have both the knowledge and the financial resources (about $10,000 to $50,000) to undertake a law suit may be small enough to make it less costly for insurance companies to defend and to lose these suits than to pay $100,000 to $200,000 for HDC/ABMTs for all eligible breast cancer patients.

At issue in these cases is who should be making decisions about the availability of new treatments and medical technologies to the public. The decisions should not be left to courts of law which, by necessity, decide only those cases in which patients have the knowledge and means to file lawsuits. Certainly, the decisions should not be left solely to insurance companies that are motivated by financial self-interest. The availability of, and funding for, new medical treatments goes to the heart of the delivery of medical services in this country. The issue is too important to leave by default to ad hoc decisions of courts or to the discretion of insurance companies. ■

REFERENCES:

1. *Thomas v. Gulf Health Plan*, 688 F.Supp 590 [S.D.Ala. 1988])
2. *id.* at 595
3. Cir.Ct.Richmond, filed May 19, 1988
4. 728 F.Supp. 594 (D.Nebr. 1989)
5. *id.* at 597
6. 716 F.Supp.131 (D.N.J. 1989)
7. *id.* at 134
8. *id.* at 135
9. *id.* at 132, 138-139
10. *id.* at 139
11. *ibid*
12. *id.* at 138, 139
13. C.A. 90-597 (D.N.J., filed Mar. 22, 1990
14. *id.* at 2
15. *id.* at 10
16. *id.* at 7-8
17. *id.* at 26
18. *id.* at 29
19. *id.* at 10-14
20. C.A. 90-10831-H (D.Mass., filed Apr. 5, 1990
21. 741 F.Supp.586 (D.E.Va. 1990)
22. *id.* at 588
23. *id.* at 590
24. *id.* at 590-591
25. *id.* at 591
26. *id.* at 593-594
27. *id.* at 591-593
28. 738 F.Supp. 42 (1990)
29. *id.* at 43-44
30. Index No. 15290/90 (N.Y.Co.Sup.Ct., filed Aug. 1, 1990
31. C.A. 90-875-A (E.D.Va., filed Aug. 7, 1990
32. Case No. 3115202 (Cir.Ct.Anne Arundel Co.)
33. Case No. 90-C-1020-E (N.D.Okla., filed Feb. 11, 1991
34. C.A. 90-1730 (D.Md., filed Feb. 27, 1991
35. *Reiff, supra* (slip opinion 6-13)
36. *id.* at 6, 11
37. *id.* at 6
38. *id.* at 22-23
39. *id.* at 6, 134
40. *id.* at 13-14
41. *ibid.*
42. *id.* at 8
43. *id.* at 17-22
44. *Adams, supra*
45. *Adams, supra* (slip opinion 7)
46. *id.* at 18
47. *id.* at 19-20
48. *id.* at 20
49. *id.* at 26-27
50. *id.* at 23, 25-26
51. *id.* at 29
52. *id.* at 32
53. *id.* at 32-33
54. *id.* at 33
55. *Wall Street Journal*, March 8, 1991, A1
56. *Wall Street Journal*, Oct. 30, 1990, B4
57. *New York Times*, Nov. 12, 1990, A1
58. *Washington Post*, Nov. 13, 1990, A1
59. *Reiff, supra* at 13-14
60. *Adams, supra* at 35-36
61. *id.* at 39-40
62. *Brown v. Blue Cross and Blue Shield of Alabama*, 898 F.2d 1556 (11th Cir. 1990)
63. *Reiff, supra* at 17-22
64. *Reilly v. Blue Cross and Blue Shield of Wisconsin*, 846 F.2d 426 (7th Cir.), *cert. denied*, 488 U.S. 856 (1988)
65. *C & J Fertilizer v. Allied Mutual Ins. Co.*, 227 N.W.2d 169 (Iowa 1975); *Reinstatement (Second) Contracts*, Sec. 211
66. *C & J Fertilizer v. Allied Mutual Ins. Co., supra*
67. *Adams, supra* at 20-26