/* This case is reported in 562 N.Y.S.2d 908 (Sup. 1990). In this rather unusual case, a health insurance company is required to cover an "experimental" treatment for HIV. This court finds that although a hospital may for liability purposes label a treatment "experimental" that it must cover the treatment as a one that is accepted, EVEN if not accepted for treatment of a particular disease. That is, if chemotherapy is no-experimental, the fact that it is used for an illness which it is not usually used for does not take it outside of its insurance coverage. A recent $70,000,000 verdict in a California case with an HMO refusing to pay for treatment in a similar factual circumstance, involving breast cancer is a further extension of this ruling. */

Thomas J. Bradley, Plaintiff,

v.

Empire Blue Cross and Blue Shield, Defendant.

Supreme Court, New York County, Individual Assignment part 6.

August 1, 1990

ELLIOT WILK, Judge.

This is an action to compel Empire Blue Cross and Blue Shield to provide insurance coverage to Thomas Bradley for a medical procedure to be performed at Johns Hopkins Hospital in Baltimore, Maryland. Plaintiff has moved to enjoin defendant from refusing coverage. Although the courts are generally disinclined to favor preliminary injunctions which mirror the ultimate relief sought, because of the unique circumstances of this case, it is appropriate that this motion be granted. On the return date of the motion, counsel agreed that the cross motion to dismiss would also be treated as its opposition to Mr. Bradley's motion. An expedited hearing was ordered, at the conclusion of which I make the following findings.

Plaintiff, Thomas J. Bradley, is a 47 year old male who is infected with Human Immunodeficiency Virus (HIV), which is a principal cause of Acquired Immunodeficiency Syndrome (AIDS). As a result, has a dangerously low T-cell lymphocyte count which compromises his immune system which compromises his immune system and exposes him to severe opportunistic infections which afflict

AIDS victims. He has experienced numerous symptoms associated with HIV infection.

Mr. Bradley's treating physician, Dr. James D. Lax, referred him to Dr. H. Kent Holland, who is affiliated with Johns Hopkins Hospital, to evaluate his candidacy for a bone marrow transplant. Both doctors believe Mr. Bradley to be terminally ill.

After a thorough examination of Mr. Bradley's medical and emotional condition and with the approval of the Hospital, Dr. Holland and his staff concluded that Mr. Bradley is a suitable candidate for treatment.

The procedure contemplated by Dr. Holland is the administration of high doses of chemotherapy and whole body radiation to destroy the cells in the bone marrow. Mr. Bradley's immune system will then be reconstituted by the introduction of bone marrow donated by his identical twin brother. After the transplant, to protect donor cells from infection, Mr. Bradley will continue with the antiviral drug AZT, which will be administered intravenously.

The pre-transplant treatment of heavy doses of highly toxic drugs requires that Mr. Bradley be reasonably healthy. Should he develop any of the more severe opportunistic infections associated with AIDS, which could happen at any time, he would become ineligible for this treatment.

The proposed bone marrow transplant is to be followed by long term hospitalization and extensive follow-up with antibiotic treatment, transfusion, parenteral nutrition and monitoring of organs for toxic effects.

Empire Blue Cross and Blue Shield has moved to dismiss the complaint on the ground that the treatment described is outside of the scope of its contractual obligation to Mr. Bradley.

The "Empire Plan" provides that "Blue Cross will not pay for services which are deemed experimental or investigative according to guidelines established jointly for the Empire Plan by the State of New York, Blue Cross and Metropolitan Life Insurance Company." Apparently, the guidelines have never been drawn.

In an affidavit submitted in support of the cross motion, Dr. Arthur Levin, associate medical director of Empire, states that "[a]s an aid in determining whether a new procedure not previously evaluated by the Empire Plan is experimental or investigative in treating a particular diagnosis, Empire uses the

criteria established by the Blue Cross and Blue Shield Association." He concludes that the proposed treatment meets none of the criteria.

Dr. David M. Eddy is a professor at Duke University, who specializes in the evaluation of medical practices. He, too, is affiliated with Empire Blue Cross and Blue Shield. He has done an analysis of the literature concerning the use of high-dose chemotherapy with autologous bone marrow transplant for the treatment of metastatic breast cancer. He is not an oncologist, a hematologist or a bone marrow transplant expert and has no expertise in the treatment of HIV or AIDS infected people. At the hearing, he was unable to provide an opinion about the potential benefits of the treatment proposed by Dr. Holland.

Dr. Eddy, in his affidavit, contends that the proposed treatment is investigative. He states that:

[i]n order to be considered noninvestigational, two tests must be met: (1) there must be evidence that the procedure causes benefit, and (2) there must be evidence that, to patients, the benefits of the procedure outweigh its harms.

According to Dr. Eddy, the first test is met when it is determined that the treatment provides greater improvement in health outcomes than alternative treatments. He recognizes only AZT as an alternative available to Mr. Bradley. He distinguishes ultimate from intermediate health outcomes. He then considers (1) survival, (2) relief of symptoms, (3) prevention of complications, (4) risks of treatment and (5) side effects of treatment such as hair loss, nausea, vomiting, diarrhea and anxiety.

The thrust of Dr. Eddy's testimony was that medical treatment may not be considered non-investigative until controlled studies have shown it to be effective and beneficial. Subjective clinical judgments of practitioners do not determine whether a treatment is investigative. Dr. Eddy maintains that because only six of these procedures have been performed, all by Dr. Holland, the proposed treatment must be viewed as investigative.

Dr. Holland is a well credentialed oncologist, hematologist and bone marrow transplant expert who is a faculty member of Johns Hopkins University School of Medicine and a staff member at Johns Hopkins Hospital. I found his testimony to be clear, informed, insightful and persuasive. He testified that Dr. Eddy's

mechanical definition of "investigative" is inadequate and inappropriate to the facts of this case. I agree.

The testimony made clear that both chemotherapy and bone marrow transplants have a sufficient history to support the medical community's conclusion that they are not investigative treatments. This is true notwithstanding the severe side effects of chemotherapy, the significant risk of death from bone marrow transplants and the uncertainty of the results. The consequences of the absence of these treatments is more certain.

The combination of chemotherapy and bone marrow transplant is also accepted by the medical community and has been used with varying success to treat, among other things, metastatic breast cancer, leukemia and aplastic anemia.

The third component of Dr. Holland's procedure, AZT, has gained wide acceptance in the medical community for the treatment of people infected with HIV and AIDS.

Dr. Holland believes that the chemotherapy, radiation, bone marrow transplant combination will be just as effective in treating Mr. Bradley's immunodeficiency as it has been with non-HIV related medical problems.

The availability of the non-infected bone marrow of Mr. Bradley's twin brother re moves the most serious obstacle to a successful transplant-"graft-versus-host" disease and substantially increases his chance of survival. Although Dr. Holland is no more able to guarantee success or to predict results than are physicians using similar methods to attack other diseases, I find the logic of his analysis, which stands unrefuted, to be compelling. The addition of AZT to the procedure provides another guard against reinfection. Its inclusion does not transform what is already accepted medical protocol into experimental treatment.

The only other witness called was Dr. Robert Geller, a well-credentialed expert in oncology, hematology and bone marrow transplants. He is a member of the faculty of the University of Chicago School of Medicine and is affiliated with the University of Chicago Medical Center. His testimony confirmed that of Dr. Holland. Dr. Geller stated that he expects to be performing similar procedures at the University of Chicago Medical Center within six to twelve months.

Hopkins will require that Mr. Bradley sign a "clinical

investigation consent form" which emphasizes the research aspect of the procedure. A similar consent form is required in every bone marrow transplant procedure. The defensive and cautionary language of the form is, no doubt, the bar's contribution to the defense of potential medical malpractice litigation. I do not believe that the form accurately characterizes the nature of the treatment and I have given little weight to it.

In this motion for a preliminary injunction, Mr. Bradley must demonstrate a likelihood of success on the merits, irreparable harm in the absence of the injunction and a balancing of the equities in his favor. W T. Grant Company v. Srogi, 52 N.Y.2d 496, 517, 438 N.Y.S.2d 761, 420 N.E.2d 953 (1981). The likelihood of success is strong, the irreparable harm is, unfortunately, obvious, and the equities lie in his favor. Accordingly, the motion for injunctive relief is granted and Empire is directed to discontinue its refusal to approve payment for the hospitalization costs associated with Mr. Bradley's bone marrow transplant at Johns Hopkins Hospital and is directed to notify Hopkins forthwith that it will cover this procedure. Empire's cross motion to dismiss is denied.