

Bailey v. Blue Cross Blue Shield of Virginia (1994)

In 1994, the Eastern Virginia District court case *Bailey v. Blue Cross Blue Shield of Virginia* established that insurance companies could not deny coverage for experimental stem cell therapy treatments. The plaintiff, Mary Bailey, was diagnosed with advanced stage breast cancer and sought treatment involving high-dose chemotherapy and an advanced stem cell treatment, which was a novelty at the time. Stem cells are cells that have the potential to develop into several different types of cells in the body. The defendant was the health insurance company Blue Cross Blue Shield, which denied coverage for Bailey's treatment. The district court sided with Bailey and ordered that BCBS could not deny coverage for her specific treatment. While *Bailey v. Blue Cross Blue Shield of Virginia* resulted in Bailey receiving compensation for her treatment, it also increased national awareness of stem cell therapy with chemotherapy.

The case represents a contract dispute between Bailey and Blue Cross Blue Shield, hereafter referred to as BCBS. In the contract, under the list of therapeutic services they would cover for cancer treatment, the health insurance company included chemotherapy and radiation therapy. However, BCBS outlined a list of treatments they would not cover. In Bailey's case, her physicians wanted to try peripheral stem cell rescue, which involves the extraction of a patient's own stem cells before chemotherapy that the doctors use later to replenish healthy cells destroyed during chemotherapy. Specifically, BCBS's contract explicitly stated it would not cover stem cell rescue with high dose chemotherapy or radiation. In the court case, the court considered the word "with" important because the ambiguous wording could lead to different interpretations of their policy.

Bailey's legal team argued that the exclusion of stem cell rescue "with" chemotherapy did not mean that chemotherapy alone was not covered by BCBS. Her legal team consisted of lawyer Timothy G. Clancy from Clancy, Cummings, Hatchett, Moschel & Patric in Hampton, Virginia, and lawyer Robert E. Hoskins from Foster & Foster in Greenville, South Carolina. The legal team for BCBS included lawyers Richard J. Cromwell, Thomas E. Spahn, and Robert W. McFarland from McGuire, Woods, Battle & Boothe in Norfolk, Virginia, and Jeanette D. Rogers who was a member of the BCBS legal counsel in Richmond, Virginia. Since Bailey's treatment involved both chemotherapy and stem cell rescue, her legal team argued that the insurance company should have paid for the chemotherapy part of her treatment instead of denying both the chemotherapy and stem cell rescue parts of her treatment.

The historical context of experimental treatments at the time played an important role in restrictive policies of BCBS. Many clinical scientists doubted the efficacy of stem cell rescue, since there was a lack of data that supported the benefits of stem cell rescue at the time. During high-dose chemotherapy and bone marrow transplant, or HDC-ABMT, a physician extracts a patient's bone marrow stem cells and later uses them to replenish the patient's cells after chemotherapy. Those tend to be the cells which make up a person's immune system. Physician Edward Staudtmauer and colleagues reported the results of a major randomized controlled trial of HDC-ABMT for the treatment of breast cancer. The results showed that patients who received HDC-ABMT did not survive more than those who received standard-dose chemotherapy, which supported the findings of previous published randomized trials. In addition to its experimental nature, the treatments were also expensive for insurance companies to cover. Bailey's experimental treatment would have cost around 80,000 US dollars. The lack of supporting clinical evidence at the time combined with a high cost of treatment meant that health insurance companies such as BCBS denied coverage of such treatments in their contracts.

Physicians diagnosed Bailey with breast cancer in 1990. In 1994, Bailey's cancer spread to other

areas of her body, becoming an advanced stage of breast cancer. Bailey's oncologist, Thomas Alberico, recommended a treatment of high-dose chemotherapy, or HDC, with peripheral stem cell rescue, or PSCR, for her best chance of survival. Bailey had undergone the standard chemotherapy, which, when unsuccessful, leads to high-dose chemotherapy, and began the HDC/PSCR treatment on 26 September 1994.

Bailey carried a BCBS insurance plan through Bailey Enterprises. Bailey's husband, Byron Bailey, testified that Response Technologies, the provider of the treatment, informed him that the cost of HDC and PSCR would be between 90,000 and 100,000 US dollars. On 23 June 1994, Response Technologies wrote to BCBS on behalf of Bailey and sought coverage for HDC with PSCR. On 24 June 1994, BCBS denied the request, stating that the proposed treatment was not covered under the company's contract with Bailey.

Bailey began her chemotherapy treatment in May 1994. Even though BCBS denied coverage for her requested treatment plan on 24 June 1994, Bailey continued to seek medical treatment. Her treatment included HDC, radiation treatment, PSCR, and hospitalization. She eventually filed the case to gain coverage to the treatments without having to pay for them out of pocket. On 28 September 1994, the Court initially issued an order that prevented BCBS from denying coverage for the high dose chemotherapy and radiation treatment. The case was taken to court without a trial, hearing, or oral argument.

In the legal brief, Bailey's legal team examined BCBS's health insurance contract and argued that a person could interpret the clause that stated, "with" high dose chemotherapy, in multiple ways. BCBS interpreted it to mean that the stem cell rescue and all high-dose chemotherapy are administered as part of a single treatment plan, and therefore the whole plan, including the HDC, is excluded. Bailey argued that someone could also interpret the clause to mean that stem cell rescue is excluded only when administered with HDC. That interpretation would mean that HDC, which is specifically covered under the policy, would not be excluded by BCBS under its policy. BCBS's policy explicitly covers chemotherapy under its therapy services, but Bailey claimed it is unclear whether the exclusion clearly applies to the HDC. The plaintiff cited a written statement from oncologist Elizabeth Harden, who said all the phases and procedures involved in Bailey's treatment are related to each other. Though a physician administers the treatment plan with the ultimate goal of curing Bailey's condition, each of the phases are separate and distinct phases of treatment. In addition, Harden states that the treatment which is intended to possibly cure Bailey is the HDC aspect of the treatment, whereas the peripheral stem cell rescue is only a minor, supportive procedure involved in Bailey's overall treatment plan.

The main argument in *Bailey v. Blue Cross Blue Shield of Virginia* holds that there is nothing ambiguous about the exclusion in the policy. BCBS put forth several arguments in its legal brief presented to the district court. First, BCBS cites *Brand Distributors, Inc. v. Insurance Company of North America*, as a case that determined when a word can be ambiguous. That definition of ambiguous was only when the meaning is uncertain to those who have examined the context of the entire agreement and are of competent skill and information about the practices and terminology of the business. BCBS asserts there is only one reasonable interpretation of the language in the policy. BCBS interprets the word "with" as synonymous with the word "and." In choosing to view the words "with" and "and" as synonymous, BCBS relies on the "nature of the procedure" to reinforce its conclusion. BCBS then goes on to state that since Bailey herself acknowledges that HDC/PSCR is a single procedure with a number of components and case law states that HDC/PSCR is one unified treatment plan, that "with" and "and" are synonymous.

According to District Judge Joseph Calvitt Clarke Jr., the question was whether BCBS clearly excluded the HDC. BCBS acknowledged that Bailey was theoretically correct that the health insurance policy exclusion could be read in two ways. However, BCBS asserted that Bailey's interpretation was not reasonable and therefore did not create an ambiguity. The judge explained that the case *Doe v. Group Hospitalization* set a precedent, stating that ambiguous terms in an insurance policy are to be construed in favor of coverage and against the insurance company. Ultimately, the district court found BCBS's reasoning unpersuasive. The Court found that the Defendant, BCBS, did not clearly exclude the HDC in its policy, which also had ambiguous verbiage that the insured party could misconstrue.

Bailey v. Blue Cross Blue Shield of Virginia occurred during a time when views held by US insurance companies and courts on experimental procedures were shifting. Physicians prescribed HDC-ABMT, which fell in the same category as Bailey's requested stem cell treatment, in the 1990s for breast cancer more than for any other disease. As a result of Bailey v. Blue Cross Blue Shield of Virginia and other similar healthcare cases, the Food and Drug Administration implemented its cancer drug initiative in 1996 to provide patients with increased access to experimental cancer medicines. In addition, the US Office of Personnel Management, otherwise known as the OPM, which serves as the government's chief human resources agency, decided to mandate coverage of HDC-ABMT for all federal employees. Because the OPM opted to mandate coverage outside the context of randomized clinical trials, private health plans found it unjustifiable to continue to limit their coverage to clinical trials only.

Over time, health insurance companies have moved to provide unconditional coverage for high-dose chemotherapy and advanced stem cell treatment. For terminally ill patients and their physicians and advocates, HDC-ABMT is a last chance intervention offered to those who have not responded to conventional treatment options. According to Michelle Mello and Troyen Brennan, professors at the Harvard School of Public Health in Boston, Massachusetts, Bailey v. Blue Cross Blue Shield of Virginia and similar cases represent what they call a lesson to be learned. They state that lawmakers will set coverage policies when considering the efficacy and cost-effectiveness of a treatment but change their minds when faced with the case of the terminally ill-patient. Until that contrast is resolved, Mello and Brennan argue there will likely be more coverage disputes over experimental treatments.

Sources

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