HEINONLINE

Citation:
Tara Arschin, Battling Breast Cancer: New York's Laws Are Not Enough, 13 Cardozo J.L. & Gender 579 (2007)

Content downloaded/printed from *HeinOnline*

Thu Feb 7 21:44:38 2019

-- Your use of this HeinOnline PDF indicates your acceptance of HeinOnline's Terms and Conditions of the license agreement available at https://heinonline.org/HOL/License

-- The search text of this PDF is generated from uncorrected OCR text.

-- To obtain permission to use this article beyond the scope of your HeinOnline license, please use:

Copyright Information

Use QR Code reader to send PDF to your smartphone or tablet device

BATTLING BREAST CANCER: NEW YORK'S LAWS ARE NOT ENOUGH

TARA ARSCHIN*

I. INTRODUCTION

A major health care issue for women today is breast cancer. The American Cancer Society estimated that 178,480 women in the United States will be diagnosed with invasive breast cancer in 2007, and 40,460 women within this cohort will die from this cancer.[1] Studies find that there is a one in eight chance that a woman will suffer from invasive breast cancer and a one in thirty-three chance that she will die from breast cancer.[2] As startling as these numbers are, New York State has an even higher rate of breast cancer—both in diagnosed cases and in mortality. In 2001, New York had the second largest number of breast cancer cases and deaths in the country.[3] The New York State Department of Health reported that between 2000 and 2004, there was an annual average of 13847.4 women who were diagnosed with breast cancer and 3011.0 who died.[4] Moreover, New York's breast cancer incidence rate increased in certain areas of the state such as Long Island.[5]

---

* J.D., Benjamin N. Cardozo School of Law, 2007; B.A., Duke University, 2004. I would like to thank my family, Arthur, Sharon, and Dana Arschin, for all of their help and support.

[1] American Cancer Society, *How Many Women Get Breast Cancer?* (2006), http://www.cancer.org/docroot/CRI/content/CRI_2_2_1X_How_many_people_get_breast_cancer_5.asp?sitearea= (last visited Apr. 13, 2007).

[2] *Id.* This Note will focus on breast cancer treatment for women. Although it is estimated that 2,030 men will be diagnosed with invasive breast cancer in 2007, the incidence of breast cancer in women is about 100 times greater than in men. *See* American Cancer Society, *What Are the Key Statistics About Breast Cancer in Men?* (2006), http://www.cancer.org/docroot/CRI/content/CRI_2_4_1X_What_are_the_key_statistics_for_male_breast_cancer_28.asp?sitearea= (last visited Apr. 13, 2007).

[3] New York State Department of Health, *Table 1. Cancer Incidence and Mortality by Gender, All Sites of Cancer, New York State, 1999-2003*, http://www.health.state.ny.us/nysdoh/cancer/nyscr/table1/tb1nys.htm. (last visited Apr. 13, 2007).

[4] *Id.*

[5] *See* National Institutes of Health, *New Statistical Methodology Suggests Elevated Breast Cancer Mortality in Large Parts of Northeastern United States* (1997), *available at* http://www.nih.gov/news/pr/jul97/nci-15.htm.

As the incidence of breast cancer has increased over the last few decades,[6] New York has been very active in propagating legislation to increase breast cancer awareness and prevention initiatives.[7] In recent years, New York has enacted several pieces of legislation concerning different aspects of breast cancer including its treatment—i.e. radiation and chemotherapy—as well as other concerns, such as the overall well-being and comfort of breast cancer patients.[8] These laws include provisions for increasing the duration of hospital stays,[9] the availability of insurance coverage for second opinions by doctors outside their insurance plans,[10] and mandatory insurance coverage for reconstructive breast surgery after a mastectomy.[11]

Despite the advances that New York has made in procuring enhanced treatment rights for breast cancer patients, there is one area in which has it *not* been proactive. New York's passivity involves the arena of breast cancer "experimental treatment."[12] Experimental treatment includes drugs not traditionally prescribed in breast cancer treatment, different dosages, and differing methods of administering the treatment. The debate within the medical field regarding experimental breast cancer treatment surrounds the use of High Dose Chemotherapy and Autologous Bone Marrow Transplantation (HDC-ABMT).

Because of its experimental classification, it is harder for patients to obtain HDC-ABMT treatment. However, clinical trials often provide a venue where sick patients can undergo experimental treatments, including HDC-ABMT. These trials generally commence once there is evidence that a treatment is a potentially efficacious or the optimal treatment for a disease, and are conducted with the patients' safety as their top priority. Clinical trials are therefore an appropriate forum in which patients may seek treatment for breast cancer. Unfortunately, insurance companies do not always provide coverage for such trials, especially when the treatment consists of HDC-ABMT.

This Note will examine the rationale behind denying breast cancer patients who have comprehensive medical insurance coverage for these "experimental" treatments in clinical trials and will argue that New York State should be more

---

[6] *See, e.g.*, Marian Segal, U.S. Food and Drug Administration, *Breast Cancer: Complacency the Enemy of Cure*, (2001), *available at* http://www.fda.gov/bbs/topics/CONSUMER/CON00097.html ("Since the early 1970s, according to the National Cancer Institute, the incidence of breast cancer has increased about 1 percent a year. In 1970, there were about 69,000 newly diagnosed cases, compared with 150,000 in 1990. The number of deaths rose from 30,000 in 1970 to 44,000 in 1990").

[7] *See generally* N.Y. PUB. HEALTH LAW § 2405 (McKinney 1989).

[8] *See generally* N.Y. INS LAW § 3216 (McKinney 1984).

[9] *See* N.Y. INS LAW § § 3216(i)(18)(A), 3221(k)(8)(A) (McKinney 1984) (contains the same language as N.Y. INS LAW § 3216(i)(18)(A) (McKinney 1984), but applies to group insurance policies); N.Y. PUB. HEALTH LAW § 2803-o (McKinney 1997).

[10] *See* N.Y. INS LAW §§ 3216(i)(19)(A), 3221(k)(9)(A) (McKinney 1989).

[11] *See* N.Y. INS LAW §§ 3216(i)(20)(A), 3221(k)(9)(A) (McKinney 1989).

[12] *See* § 3216 (j)(1)(B) ("Ambulatory care in hospital out-patient facilities shall mean services for . . . radiation therapy, and services and medications used for *nonexperimental* cancer chemotherapy and cancer hormone therapy . . . ." (emphasis added)). *See also* § 3221 (l)(3)(B)(i).

proactive in mandating insurance companies to automatically include coverage for experimental treatment through clinical trials in their comprehensive medical insurance plans. The Note will examine state statutory, regulatory, and common laws to illustrate how New York deals with this problem, as well as medical studies and other states' laws in order to reach a viable solution to the problem. Ultimately, this Note will conclude that New York should make an adjustment to its laws, mandating insurance coverage for participation in Phase II and Phase III clinical trials administering experimental treatment, including HDC-AMBT, for the treatment of breast cancer if the patient and her physician believe that it is the most promising course of treatment for her condition.

In March 1997, New York Governor George Pataki released an executive memorandum approving bills which amended New York Insurance Law and Public Health Law to include provisions creating a duty to inform women of their treatment options for breast cancer; mandating insurance companies to cover second opinions for diagnoses, coverage for in-patient medical care, and the coverage for reconstructive surgery following mastectomies. The memorandum emphasizes that the purpose of the bills was to "ensure that a woman and her physician—not an insurance gatekeeper—determine the most appropriate level of care" in the treatment of her breast cancer, and that "certain limits on the care that they receive should not be tolerated."[13] Governor Pataki's language indicates his intent for women to be treated for breast cancer to the best of the medical community's ability. Patients and their doctors should have the right to decide the most appropriate avenue of treatment, be it the standard treatment or experimental treatment via a clinical trial.

II. THE PATHOLOGY OF BREAST CANCER

Breast cancer may take many different forms. The medical community has broken breast cancer down into four different categories, in addition to subcategories, based on the stage of advancement of the disease—the degree to which the cancer has spread in and beyond the breast is usually determinative of the stage. At Stage I, the cancer is not very advanced, less than two centimeters in size, and is confined to the breast.[14] Stage II cancer usually consists of a slightly larger tumor and/or spreading to the lymph nodes.[15] Stage III cancer means that the cancer is in the lymph nodes, has spread to other tissues near the breast, or has spread to areas such as the neck or collarbone.[16] Stage IV breast cancer is the most serious, and is often untreatable.[17] This is also known as metastatic breast cancer,

---

[13] Exec. Mem., *Breast Reconstruction Surgery—Insurance Coverage*, (Mar. 18, 1997) (Governor George Pataki. approving L.1997, ch. 21).

[14] National Cancer Institute, *Breast Cancer: Treatment: Stages of Breast Cancer*, http http://cancernet.nci.nih.gov/cancertopics/pdq/treatment/breast/Patient/page2 (last visited Apr. 15, 2007).

[15] *Id.*

[16] *Id.*

[17] *Id.*

which means that the cancer has spread to the other organs of the body, such as the bones, lungs, liver, or brain.[18]

III. TREATMENT

There are many options in breast cancer treatment. There are four standard approaches which are most commonly used in the treating breast cancer: 1) surgery, which may be administered in a variety of ways. Surgery usually consists of the removal of tissue affected by cancer, in the form of a lumpectomy (removal of the tumor) or a mastectomy (a removal of the breast—the patient may undergo a partial mastectomy, a total mastectomy, or a radical mastectomy, where the entire breast, the chest wall muscles under the breast, and all of the lymph nodes under the arm are removed); 2) radiation, which uses x-rays to destroy the cancer cells or prevent their growth (either externally with an x-ray machine or internally through needles or catheters containing radioactive substances); 3) chemotherapy, which works by either ingesting or injecting drugs which destroy the rapidly dividing cells that cause the cancer; and 4) hormone therapy (which is often used for patients with metastatic breast cancer), which works by blocking certain cancer-promoting hormones.[19]

Adjuvant therapy is treatment that is administered after the cancer has been successfully treated and is no longer clearly present in the body. The purpose of adjuvant therapy is to eliminate the risk of recurrence of the cancer by "destroying any single cancer cells [sic] that may have survived the first line of treatment but are otherwise undetectable."[20] Adjuvant therapy usually is administered through further sessions of chemotherapy.[21]

In addition to these traditional treatments, researchers are exploring new avenues of breast cancer treatment. Novel targeted therapy, which is a treatment that targets "specific features of the cancer cells to fight cancer," is one such treatment. This approach is still considered experimental, and is usually only available in clinical studies.[22]

Another form of treatment that the medical community is pursuing is the use

---

[18] *Id.*

[19] National Cancer Institute, *Breast Cancer: Treatment: Treatment Option Overview*, http://cancernet.nci.nih.gov/cancertopics/pdq/treatment/breast/Patient/page5 (last visited Apr. 15, 2007). (hereafter *Treatment Option Overview*). Another treatment that is becoming more popularly used in conjunction with chemotherapy is monoclonal antibody therapy. It is considered an adjuvant therapy. This treatment uses laboratory-made antibodies which identify substances found in cancer cells or that facilitate the growth of cancer cell, and then kills or inhibits the growth of cancer cells, preventing them from spreading. This method of treatment can also facilitate the use of radiation and chemotherapy by having the antibodies carry the drug or radioactive substances used in these processes. *Id.*

[20] Richard Zmuda & Mary Kay Barton, *Breast Cancer: Your Treatment*, Cancerpage.com, http://www.cancerpage.com/articles/default.asp?id=1&subarea=Your_Treatment (last visited Apr. 15, 2007).

[21] *Id.*

[22] Getbcfacts.com, *Novel Targeted Therapy*, http://www.getbcfacts.com/treatment/novel.asp (last visited Apr. 15, 2007).

of HDC administered in conjunction with stem cell, or bone marrow, transplants. This process works by administering higher doses of chemotherapy and subsequently replacing the destroyed cells with stem cells, which are immature blood cells that were removed from the patient's or a donor's bone marrow and subsequently frozen.[23] There are two kinds of stem cell transplants: ABMT, where the stem cells originate in the patient's own body, and allogenic transplants, where the stem cells come from a donor. Breast cancer patients generally undergo ABMT over allogenic transplants.[24]

Much controversy exists regarding the benefits and effectiveness of the HDC-ABMT combination. This is an area that has been the focus of many studies over the past few years. However, the results have not met the high hopes of the medical community. Studies have found that HDC and stem cell transplants do not always yield significantly more favorable results in breast cancer treatment than do traditional treatments.[25]

Stem cell transplantation allows the patient to receive higher doses of chemotherapy. Chemotherapy is normally administered in limited amounts because of its destructive effects on the patient's bone marrow. Therefore, the theory behind stem cell transplants is that patients can receive higher doses of chemotherapy because healthy stem cells will replace the destroyed bone marrow.[26] The higher doses may also reduce the number of chemotherapy treatments that the patient must undergo, abbreviating the duration of treatment.[27]

Although studies on the efficacy and benefits of HDC-ABMT treatment have not yielded very significant differences than traditional treatments in all breast cancer studies, there are studies that have shown promise in the development of treatment using HDC-ABMT.[28]

IV. CLINICAL TRIALS

A clinical trial is a research study designed to test the treatment, prevention, screening, and diagnosing methods for certain diseases.[29] Clinical trials testing treatment may focus on the safety and efficacy in treating a particular disease or condition. The trials range in size, location, and administration, and are sponsored by either private organizations or the government, especially the National Institute of Health ("NIH").[30]

The trials are conducted in different phases. There are generally four phases

---

[23] *Treatment Option Overview*, *supra* note 19.

[24] *See* Zmuda & Barton, *supra* note 20.

[25] *Treatment Option Overview*, *supra* note 19.

[26] *See* Zmuda & Barton *supra* note 20.

[27] *See* Zervos v. Verizon N.Y. Inc., 277 F.3d 635, 641 (2d Cir. 2002 (Zervos IV).

[28] *Id.* at 647.

[29] National Cancer Institute, *Clinical Trials: Questions and Answers*, http://www.cancer.gov/cancertopics/factsheet/Information/clinical-trials (last visited Apr. 15, 2007).

[30] *Id.*

of a trial. Phase I constitutes the early steps of testing new methodologies in screening, diagnosing, preventing, and treating a disease.[31] These trials are very preliminary and provide the administrators an opportunity to determine how to administer the treatment, the safety risks, and the side effects. Phase I studies are very small, usually only involving between 20 and 80 participants.[32]

Phase II trials commence once the proposed approach has satisfied the Phase I requirements by having shown no especially harmful side effects. These trials are slightly larger than Phase I trials.[33] The Phase II trial is designed to test the efficacy of the proposed treatment as well as to further test the treatment's safety.[34]

Phase III trials involve control groups in which some participants, through a randomization process receive treatment through conventional techniques, while others receive the treatment method under examination.[35] Phase III trials are much larger than Phase I and II trials, and may involve thousands of participants throughout the country.[36] Generally, Phase III trials proceed when there is preliminary evidence that indicates the treatment may be effective.[37] Phase III studies seek to determine relative effectiveness when compared with traditional treatment methods and the overall risk-benefit relationship of the treatment.[38]

Phase IV Trials are not as common as trials in the first three phases. These trials are intended to examine the long-term effects of the treatment and usually take place after the treatment has been approved.[39]

Clinical trials are conducted with the goal of maintaining the highest possible safety standards. There are federal regulations pursuant to the Federal Food, Drug, and Cosmetic Act,[40] which govern how clinical trials are conducted. The regulations seek to ensure that the trials are conducted in a way that promotes safety and accuracy. In order to gain approval to run a clinical trial, the trial's sponsor must submit an Investigational New Drug Application ("IND"), which consists of a number of requirements. One of the most important requirements is continuing communication with an Institutional Review Board ("IRB"). The IRB is responsible for the "initial and continuing review and approval of each of the studies in the proposed clinical investigation" and is to be informed of any proposed changes to the study.[41] The IRB is "... any board, committee, or other

---

[31] In its discussion of clinical trials, this Note will hereinafter only discuss trials concerning treatment of diseases, not prevention, screening, and diagnosis.

[32] *See* ClinicalTrials.gov, *An Introduction to Clinical Trials*, http://www.clinicaltrials.gov/ct/gui/info/whatis#types (last visited Apr. 15, 2007).

[33] *Id.*

[34] *See Clinical Trials: Questions and Answers*, *supra* note 29.

[35] *See id.*

[36] *See An Introduction to Clinical Trials*, *supra* note 32.

[37] *See id.*

[38] *See id.*

[39] *See Clinical Trials: Questions and Answers*, *supra* note 29.

[40] 21 U.S.C. § 321 (2000).

[41] 21 CFR § 312.23 (a)(1)(iv) (2006).

group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects."[42]

In addition to approval by an IRB, a trial must create a protocol, which lays out how the trial will run;[43] it "describes what will be done in the study, how it will be conducted, and why each part of the study is necessary."[44] The protocol must describe "all aspects of the study,"[45] and account for potential changes that may occur in the course of the trial.[46] The protocol is a means for ensuring that all of the doctors and researchers participating in the study follow the same standard and course of treating its participants.[47] These regulations are evidence that the clinical trials are well thought-out and at the Phase II and III levels, there is evidence that the treatment may be quite effective.

IVA. RISKS/BENEFITS OF CLINICAL TRIALS

It is true that there are risks involved with participating in a clinical trial for a treatment. Some of these risks include the danger that the method being tested will not work better than the standard treatment would have, there may be increased or more severe side effects with this new form of treatment, that a randomized trial's participants will not be able to choose which treatment they receive, and participation in a clinical trial may be more time-consuming for the patient than if

---

[42] 21 CFR § 56.102 (g) (2006).

[43] 21 CFR § 312.23(a)(6) (2006).

[44] *Clinical Trials: Questions and Answers*, *supra* note 29.

[45] 21 CFR § 312.23(a)(6)(ii) (2006).

A protocol is required to contain the following, with the specific elements and detail of the protocol reflecting the above distinctions depending on the phase of study:
(a) A statement of the objectives and purpose of the study.
(b) The name and address and a statement of the qualifications (curriculum vitae or other statement of qualifications) of each investigator, and the name of each subinvestigator (e.g., research fellow, resident) working under the supervision of the investigator; the name and address of the research facilities to be used; and the name and address of each reviewing Institutional Review Board.
(c) The criteria for patient selection and for exclusion of patients and an estimate of the number of patients to be studied.
(d) A description of the design of the study, including the kind of control group to be used, if any, and a description of methods to be used to minimize bias on the part of subjects, investigators, and analysts.
(e) The method for determining the dose(s) to be administered, the planned maximum dosage, and the duration of individual patient exposure to the drug.
(f) A description of the observations and measurements to be made to fulfill the objectives of the study.
(g) A description of clinical procedures, laboratory tests, or other measures to be taken to monitor the effects of the drug in human subjects and to minimize risk. 21 CFR § 312.23(a)(6)(iii) (2006).

[46] 21 CFR § 312.23(a)(6)(ii) (2006).

A protocol for a Phase 2 or 3 investigation should be designed in such a way that, if the sponsor anticipates that some deviation from the study design may become necessary as the investigation progresses, alternatives or contingencies to provide for such deviation are built into the protocols at the outset. For example, a protocol for a controlled short-term study might include a plan for an early crossover of nonresponders to an alternative therapy. *See also id.*

[47] *See Clinical Trials: Questions and Answers*, *supra* note 29.

the participant was treated in a traditional setting.[48] However, if during the course of a trial the researchers determine that the treatment is ineffective or the side effects are too severe, they are obligated to terminate that course of treatment. Conversely, if the treatment under investigation is yielding impressive results in terms of its efficacy and safety, the researchers may then provide the successful treatment to the trial participants who were part of the control group and receiving the standard method of treatment.[49]

An additional safeguard for the participants in clinical trials is the idea of informed consent, which is "a process by which people learn the important facts about the clinical trial to help them decide whether to participate."[50] Therefore, the participants are fully aware of the risks and downsides of participating in the trial. The requirement for informed consent in clinical trials is established in federal regulations.[51] In order for the trials' sponsors to ensure that they have conformed to the informed consent requirements, they have to educate the potential trial participants about the purpose of the study, the procedures of the study, the risks and benefits of the treatment being tested, and alternative treatment options.[52] Sponsors need to provide the potential participants with "sufficient opportunity to consider whether or not to participate and... minimize the possibility of coercion or undue influence."[53] Furthermore, if new significant developments occur during the course of the study, the trials' researchers must obtain informed consent from the participants once again, ensuring that the patients have up-to-date knowledge on the dangers of the treatment or changes in the study.[54] The trial's participants are also free to terminate their participation in the study at any time, for any reason.[55]

One negative aspect of clinical trials is that a protocol may only call for a limited number of participants for the study, or participants that fit into a certain category of individuals, therefore restricting the availability and accessibility of the trial. As a result, a trial for a certain procedure may not be available to all who are interested, or it may be difficult for the patient to travel to or access the locale where the investigation is taking place. Nonetheless, although some people may experience difficulty in joining a clinical trial, a lack of accessibility or availability is not a pervasive problem. Clinical trials are relatively accessible and available. The National Cancer Institute—NCI—lists 281 clinical trials that are available for breast cancer treatment.[56] ClinicalTrials.gov–an online service run by the NIH–

---

48 *Id.*

49 *Id.*

50 *Id.*

51 21 CFR § 50.20 (1999).

52 21 CFR § 50.25 (1981).

53 21 CFR § 50.20 (1999).

54 *Clinical Trials: Questions and Answers*, *supra* note 29.

55 *Id.*

56 National Cancer Institute, *Search for Clinical Trials: Advanced Search*, http://www.cancer.gov/search/SearchClinicalTrialsAdvanced.aspx?protocolsearchid=2083419 (last visited Apr. 15, 2007).

lists 716 trials for breast cancer treatment.[57] Furthermore, clinical trials often span the United States—some may involve "hundreds of locations at the same time," taking place in "doctors' offices, cancer centers, other medical centers, community hospitals and clinics, and veterans' and military hospitals...."[58]

One of the most compelling reasons to participate in a clinical trial are the possible benefits that such participation will have on society. Although it is possible that the standard treatment for breast cancer is the best course of treatment for patients at the present time, there is another persuasive reason for allowing participation in clinical trials—the potential benefits that these findings may have both on the individual patient and on society. These trials "may offer the best chance of finding an effective treatment" for patients for whom traditional methods of treatment are inadequate or have already failed.[59]

In spite of the potential benefits, insurance companies are reluctant to pay for treatment administered in clinical trials, to society's detriment. The General Counsel for the Blue Cross Blue Shield Association, Mary Ader, affirms "payment decisions based on technology assessments and/or benefit exclusions may in fact delay the diffusion of technologies eventually found to be medically appropriate" [60] since "[g]iven a choice of possible treatments, providers generally opt for the one that the thirdparty [sic] payer reimburses. Therefore, until the newer technologies are proven safe and effective and hence, reimbursable, providers are reluctant to prescribe them."[61] Moreover, knowledge that they will likely face difficulties or many procedural barriers in obtaining coverage for HDC-ABMT may dissuade patients from pursuing this course of treatment even though it may be the most appropriate.

Furthermore, when a treatment's efficacy is as controversial as HDC-ABMT, because of the required controls and protocols, a clinical trial may be the best forum for administering the treatment. In fact, in *Zervos IV*, the Second Circuit pointed out that the insurance company's medical policy director testified that even though HDC-ABMT may not be the most effective treatment, a "high quality clinical trial" would be an appropriate setting to perform such a treatment,[62] and acknowledged that insurance companies should cover treatment from clinical trials.

---

[57] ClinicalTrials.gov, *Search: "breast cancer treatment"*, http://www.clinicaltrials.gov/ct/search?term=breast+cancer+treatment+ (last visited Feb. 11, 2007).

[58] *Clinical Trials: Questions and Answers*, *supra* note 29.

[59] JANET HEINRICH, NIH CLINICAL TRIALS: VARIOUS FACTORS AFFECT PATIENT PARTICIPATION, GAO/HEHS-99-182, U. S. General Accounting Office, 1 (1999), *available at* http://www.gao.gov/archive/1999/he99182.pdf. (Doctors often recommend HDC-ABMT after traditional treatment has failed.)

[60] Mary Ader, *Access to Investigational Treatments*, 6 HEALTH MATRIX 187, 191 (1996).

[61] *Id.* at n.2.

[62] Zervos IV, 277 F.3d at 641.

V. TYPES OF INSURANCE COVERAGE

Insurance coverage comes in many different packages, some more expansive than others. New York's insurance laws require minimum levels of coverage depending on the classification of the insurance plan.[63] New York State defines "[a]ccident and health insurance" as including "insurance against death or personal injury by accident... sickness, ailment or bodily injury," and disability benefits.[64]

Within the health insurance category, there are several levels of insurance coverage. For example, Basic Hospital, Medical and Surgical Insurance pays a portion of hospital room and board costs as well as other hospital services and supplies, including lab tests, X-rays, and medicine. An important characteristic of this type of insurance is that there are time and money limits on the benefits that a patient can receive. Major medical insurance is health insurance that covers the costs of major illnesses or injuries. It covers most of the expenses incurred by hospital stays, medicine, or treatment. Comprehensive major medical coverage provides the benefits of basic hospital, medical and surgical insurance, and major medical insurance.

In addition to basic medical insurance, many insurance companies offer specified disease insurance, which is insurance that only provides coverage for the treatment of a specific disease, and dread disease insurance, which is similar to life insurance, but the insured receives a stipulated percentage of the benefits upon the diagnosis of certain "dread" diseases.[65] Specified disease insurance is intended to supplement a comprehensive insurance plan. In fact, under New York law, in order to be eligible to purchase specified disease insurance, the insured must at least have basic coverage.[66] Although specified disease insurance is applicable to the discussion of breast cancer experimental treatment coverage, in its arguments for reforming New York's insurance laws, this Note will focus on comprehensive medical insurance plans.

VI. NEW YORK LAW REGARDING COVERAGE OF EXPERIMENTAL TREATMENT

New York law requires that basic hospital[67] and major medical[68] insurance plans provide coverage for "necessary treatment because of sickness or injury for at

---

[63] *See, e.g.*, N.Y. INS LAW § 3216(i)(20)(A) (McKinney 2006) which specifies that the statute mandating coverage for reconstructive surgery following a mastectomy only applies to insurance policies providing "medical, major medical, or similar comprehensive-type coverage."

[64] N.Y. INS LAW § 1113 (a)(3) (McKinney 1984).

[65] The Law of Life and Health Insurance § 6.02, MB (2005).

[66] 11 N.Y.C.R.R. § 52.15 (b)(12) (1998). *See also* Sally Esteb Cureton & Dave Cureton, *Cancer Insurance: Is It Right For You?*, Cancerpage.com, http://www.cancerpage.com/news/article.asp?id=1313 (last visited Apr. 22, 2007) (giving an overview of specified disease insurance).

[67] 11 N.Y.C.R.R. § 52.5 (1982)

[68] 11 N.Y.C.R.R. § 52.7 (1982)

least" radiation and chemotherapy.[69] The language in the New York regulations regarding specified disease insurance for cancer is similar to the language used in the regulations that require hospitals and major medical insurance companies to cover chemotherapy and radiation treatment.[70]

New York also has a provision in its statutes for independent and group insurance. It provides that medical insurance policies must provide coverage for experimental or investigational treatment if such treatment has been approved by an external appeals agent.[71] An external appeals agent is a medical professional who is unaffiliated with any health insurance organization,[72] assigned by the New York State Department of Insurance.[73]

Under New York law, the insured has a right to appeal denials of coverage, both internally—within the insurance company—and externally.[74] If the internal appeals process has been waived or the health plan makes a "final adverse determination" regarding the patient's benefits because it classifies the treatment as experimental or investigational, or not medically necessary, then the insured has a right to an external appeal if their physician has recommended the procedure as the best course of treatment.[75]

The insured's chances of becoming eligible to seek an external review as a result of an unfavorable benefits determination is quite high.[76] However, even at

---

[69] 11 N.Y.C.R.R. § 52.5 (b) (1982). In listing the minimum coverage for major medical insurance, § 52.7 (b) refers to the requirements of § 52.5 (b) for the coverage of chemotherapy and radiation. 11 N.Y.C.R.R. § 52.7 (2005).

[70] 11 N.Y.C.R.R. § 52.15 (c)(6)(b)(1) (2005).

[71] *See* N.Y. INS LAW § 3216 (i)(22) (McKinney 2005) and N.Y. INS LAW § 3221 (k)(12) (McKinney 2005), both providing:

No policy shall exclude coverage of a health care service . . . rendered or proposed to be rendered to an insured on the basis that such service is experimental or investigational, is rendered as part of a clinical trial . . . ,provided that coverage of the patient costs of such service has been recommended for the insured by an external appeal agent upon an appeal . . . . [t]he determination of the external appeal agent shall be binding on the parties. *Id.*

[72] 11 N.Y.C.R.R. § 410.4 (2001).

[73] N.Y. INS LAW § 4914 (1998).

[74] N.Y. INS LAW § 4910 (1998).

[75] The insured can request an external appeal when:

(A)[T]he insured has had coverage of a health care service denied on the basis that such service is experimental or investigational, and such denial has been upheld on appeal . . . or both the plan and the insured have jointly agreed to waive any internal appeal, and
(B) the insured's attending physician has certified that the insured has a life-threatening or disabling condition or disease (a) for which standard health services or procedures have been ineffective or would be medically inappropriate, or (b) for which there does not exist a more beneficial standard health service or procedure covered by the health care plan, or (c) for which there exists a clinical trial, and
(C) the insured's attending physician . . . must have recommended either (a) a health service or procedure . . . that, based on two documents from the available medical and scientific evidence, is likely to be more beneficial to the insured than any covered standard health service or procedure; or (b) a clinical trial for which the insured is eligible. . . . and
(D) the specific health service or procedure recommended by the attending physician would otherwise be covered under the policy except for the health care plan's determination that the health service or procedure is experimental or investigational. N.Y. INS LAW § 4910 (2) (McKinney 1998).

[76] *See* Zervos v. Verizon N.Y., Inc., No. 01 Civ. 685 (GBD), 2001 U.S. Dist. LEXIS 17060 (S.D.N.Y. Oct. 22, 2001), *rev'd, vacated by* 277 F.3d 635 (2d Cir. 2002) (Zervos III) (Defendant health

the external appeals level, a patient cannot be sure that that an agent will decide in his favor,[77] especially since the standards required at that level are difficult to satisfy.[78]

As a result of the process outlined by the New York laws, if a patient wants to contest the insurance company's determination, the path that she will most likely take in her attempt to obtain coverage for experimental treatment will lead to the external appeals process, an unnecessarily time-consuming and costly progression for the patient, in a situation where time and money are very limited. An external appeal process can potentially last up to a little less than three months.[79] That time period includes forty-five days for the patient to initiate the appeal and submit supporting documentation, thirty days for the agent to make a determination, plus additional days if the agent requests additional documents.[80] However, the statute does address the problem of the patients' limited timeframe. It allows for an expedited external appeals process in the event that such a delay in the determination of appropriate coverage would "pose an imminent or serious threat to the health of the insured."[81] This determination must be completed within three days and the patient must be notified the next day, instead of the normal statutory allowance of thirty days.[82]

Although the expedited process is important and does try to address the problems that these patients face, it does not do so adequately because of its very nature. The expedited process, although designed with celerity and efficiency in mind, is simply another *process*—a process the patient should not have to go through at all, whether fast or slow. The patient still needs to submit a request for the external appeal and prepare documentation, and has up to 45 days to do so.[83] This is an extra inconvenience and only serves to add continued uncertainty to the patient's situation. Furthermore, although the decreased wait-time for the decision may be beneficial to the patient, the agent has three days instead of thirty to make this decision. Such a large disparity leads one to question whether the agent can really make an appropriate determination in such an abbreviated time period.

---

insurance company had a consistent policy of denying coverage for HDC and stem cell transplants at the initial request for coverage).

Id. at *32.

[77] In 2004, for example, forty-nine percent of external appeals from insurance company denials of coverage for experimental or investigational treatment were upheld, and between 1999 and 2004, over fifty-five percent of these denials were upheld. In the 1999-2004 time period, there were only twenty-four external appeals for denials clinical trial coverage. Of those, only eleven were overturned. *New York State External Appeals Program: Annual Report*, New York State Insurance Department and New York State Department of Health, 26-27 (2004), *available at* http://www.ins.state.ny.us/extapp/extapp04.pdf. (hereinafter "*External Appeals Report*").

[78] *See* N.Y. INS LAW § 4910 (McKinney 2006).

[79] *See* N.Y. INS LAW § 4914 (McKinney 2006).

[80] *See id.*

[81] *See id.*

[82] *See id.*

[83] *See id.*

The purpose of the external appeals law is for "New York's consumers [to] have access to an objective and timely review of coverage determinations by their HMOs and insurers" and to "ensure[] that health care decisions will be made by patients and their doctors, not by gatekeepers."[84] Former New York Governor Pataki explained that the goal was to "promote access to quality health care" and to "demonstrate[] that New York is continuing to lead the nation in protecting the rights and health of its residents."[85] However, after taking into account the added steps of bureaucracy that an external appeal inevitably brings forth, the actual realization of Governor Pataki's goals is dubious.

If an insurance company has internally determined that coverage for a clinical trial is not appropriate, the patient does not have to seek an external appeal. "The rights and remedies conferred... upon insureds... shall be cumulative and in addition to and not in lieu of any other rights or remedies available under law."[86] Accordingly, a patient may forego the external appeals process and seek a judicial determination of the matter.[87]

Although the patient has the right to skip the external appeals process, it is unlikely that a patient would sacrifice this step. A determination through the external appeals process is administratively binding.[88] More importantly, proceeding through the external appeals process is easier, less costly, and more timely than going to court; hence most patients would rather avoid going to court if they could receive a decision in their favor through the external appeals process. However, breast cancer patients desirous of participating in government-approved Phase II and III clinical trials should not need to utilize the options of an external appeal or courtroom litigation. These steps maintain uncertainty of patients' insurance coverage and place an undue burden on them. Breast cancer patients seeking HDC-ABMT in approved clinical trials should not have to go through this process in hopes of receiving this treatment.

In order to receive coverage for clinical trials, New York law grants the right to an external appeal when there "exists a clinical trial."[89] However, there is no New York law that mandates coverage for clinical trials themselves. The standard for an external appeals agent to grant coverage for a clinical trial requires that the trial is "likely to benefit the insured in the treatment of the insured's condition or disease."[90] This standard, which does not seem to be overly burdensome, still

---

[84] Exec. Mem., *Public Health, Insurance—Contract Terms—External Appeals*, (Aug. 5, 1998) (Governor George Pataki. approving L.1998, ch. 586).

[85] *Id.*

[86] N.Y. INS. LAW § 4907 (McKinney 2007).

[87] Vellios v. IPRO, 765 N.Y.S.2d 222, 225-26 (N.Y. Sup. Ct. 2003).

[88] N.Y. INS. LAW § 4914 (b)(4)(A)(iv) (McKinney 2007).

[89] N.Y. INS. LAW § 4910 (b)(2)(B) (McKinney 2007).

[90] N.Y. INS. LAW § 4914 (b)(4)(B)(ii)(a) (McKinney 2007). The standard for evaluating denials of experimental or investigational treatment is "likely to be more beneficial than any standard treatment or treatments" for the patient's malady. *Id.*

leaves the door open for arbitrariness. The statute does not lay out the exact requirements for granting coverage; but rather it mandates only that a written statement accompanying the decision conclude that the patient is likely to benefit from the trial.[91] Because of the vague standard, the patient's likelihood of prevailing in her external appeal remains uncertain.[92]

A 1999 GAO report on clinical trial participation concluded that "having to seek approval through a [health care provider] plan's review and appeals process and negotiating payment for standard care in a trial may dissuade some patients and physicians from pursuing clinical trial opportunities."[93] Although this conclusion was in reference to the insurance companies' internal processes in determining whether to pay for trial participation, the conclusion certainly applies to New York's external appeals process as well. Creating obstacles and unnecessary impediments through a bureaucratic system will serve to prevent patients who may greatly benefit from treatment through clinical trials from receiving those potentially life-saving benefits.

VII. OTHER STATES' LAWS ARE MORE PROGRESSIVE THAN NEW YORK'S

California, Nevada, Arizona, New Mexico, Louisiana, Missouri, Georgia, Tennessee, North Carolina, Michigan, Ohio, Virginia, West Virginia, Delaware, Connecticut, Maine, Maryland, Massachusetts, New Jersey, New Hampshire, and Vermont all have provisions requiring insurance companies to cover treatment through clinical trials.[94] Most of these states require that either the FDA, NIH, an NIH-sponsored cooperative group or center, the U.S. Department of Defense, the U.S. Department of Veterans' Affairs, or a "qualified non-government research entity" approve the clinical trial.[95] Most of these states provide coverage for approved Phase II and III studies, and at least ten of them cover Phase I trials as well.[96] Massachusetts goes as far as to require only one of these organizations to approve Phase I trials, while for Phase II, III, and IV trials, IRB approval alone is sufficient.[97]

By 1995, seven states had enacted various legislation directing insurance companies to provide coverage for ABMT for breast cancer patients.[98] These

---

91 N.Y. INS. LAW § 4914 (b)(4)(B)(ii) (McKinney 2007).

92 *See External Appeals Report*, *supra* note 77, at 25. In a five year period out of twenty-four external appeals for denials of clinical trial coverage, only eleven were granted. *Id.*

93 HEINRICH, *supra* note 59, at 16.

94 National Cancer Institute, *States That Require Health Plans to Cover Patient Care Costs in Clinical Trials*, http://www.cancer.gov/clinicaltrials/learning/laws-about-clinical-trial-costs (last visited Apr. 22, 2007) (hereafter *Patient Care Costs*).

95 *See, e.g.*, MASS. ANN. LAWS ch. 175 § 110L (c)(2) (LexisNexis 2002).

96 *Patient Care Costs*, *supra* note 94.

97 MASS. ANN. LAWS ch. 175 § 110L (c)(2) (LexisNexis 2002).

98 SARAH F. JAGGER, HEALTH INSURANCE: COVERAGE AUTOLOGOUS BONE MARROW TRANSPLANTATION FOR BREAST CANCER, GAO/HEHS-96-83, U.S. General Accounting Office (1996), *available at* http://www.gao.gov/archive/1996/he96083.pdf.

states are Florida, Georgia, Massachusetts, Minnesota, New Hampshire, Rhode Island, and Virginia.[99] Of these states, only Massachusetts, New Hampshire, and Rhode Island have breast cancer rates above that of the national average.[100] These seven states have laws that are more expansive than those in New York requiring insurance companies to provide more treatment options for breast cancer patients. For example, Massachusetts' law maintains that accident and sickness insurance policies provide coverage for bone marrow transplants for patients diagnosed with metastatic breast cancer.[101] New Hampshire also specifically mandates that insurance companies award "coverage for expenses arising from the treatment of breast cancer by autologous bone marrow transplants according to protocols reviewed and approved by the National Cancer Institute."[102] Florida's law explicitly states that insurance companies may not "exclude coverage for bone marrow transplant procedures... under a policy exclusion for experimental, clinical investigative, educational, or similar procedures contained in any individual or group health insurance policy... that covers treatment for cancer " if the patient's physician has recommended it. It does, however, render the coverage subject to classification as non-experimental by the Florida Agency for Healthcare Administration.[103]

Virginia's law is also generous in its availability of insurance coverage for "dose-intensive chemotherapy/autologous bone marrow transplants or stem cell transplants" for breast cancer patients. The restrictions on this coverage are quite minimal; the procedure is covered so long as it is "performed pursuant to protocols approved by the institutional review board of any United States medical teaching college including, but not limited to, National Cancer Institute."[104] Georgia also specifically requires coverage for the use of bone marrow transplants for the treatment of breast cancer. [105]

While New York requires insurance companies to provide coverage for an experimental treatment such as ABMT if an external appeals agent decides that it is the appropriate treatment, there is no outright requirement to cover this type of therapy.[106] However, even states with lower breast cancer rates than New York express in unambiguous terms that insurance companies must cover ABMT, without forcing patients to go through various administrative procedures in order to obtain that coverage.[107]

---

[99] *Id.*

[100] National Institutes of Health, *supra* note 5.

[101] MASS. ANN. LAWS ch. 175 § 47R (LexisNexis 1996).

[102] N.H. REV. STAT. ANN. § 415:18-c (LexisNexis 1992).

[103] FLA. STAT. § 627.4236 (1992).

[104] VA. CODE ANN. § 38.2-3418.1:1 (1994).

[105] GA. CODE ANN. § 33-29-3.3 (1995).

See also GA. CODE ANN. § 33-30-4.4 (2005) (applying the same law to group or blanket policies).

[106] *See* N.Y. INS LAW § 4910 (McKinney 2006).

[107] *See, e.g.*, VA. CODE ANN. § 38.2-3418.1:1 (1994).

VIII. NEW YORK COMMON LAW ON INSURANCE COVERAGE OF EXPERIMENTAL TREATMENT

The New York courts have addressed the issue of insurance coverage for experimental treatment of breast cancer. In *Zervos III*, the district court determined that the insurance company's external review of the patient's case failed the "arbitrary and capricious" standard.[108] The court noted that certain patient appeal determinations may be examined using a *de novo* standard of determination, in which case the court looks at the record and makes its own determination whether the patient should be denied relief.[109]

The district court held that the external review boards must implement a standard that determines if the treatment has a "proven benefit or [is] generally recognized by the medical community as effective or appropriate."[110] The court noted that the questions that the external reviewers asked were not necessarily relevant to whether the use of HDC-AMBT to treat metastatic breast cancer was of a proven benefit. For example, whether the "recommended treatment plan [is] the *best* treatment available for this patient at this time"[111] was *not* significant in establishing a proven benefit. The court explained that there "is no requirement in the definition of experimental/investigational that a treatment be the 'best treatment.'"[112] The Second Circuit affirmed that the insurance company's policy of awarding coverage for the best treatment was "in effect add[ing] additional language to the policy" and that the "language itself requires only that the treatment be effective—not *more* effective than alternatives.[113] Both the policy's language,[114] and the court's standard are less restrictive on the patient's coverage than that of the actual New York state laws. However, the health insurance company's use of a "more effective alternative" standard in evaluating appeals more closely resembled the New York statutes rather than its own articulated

---

[108] Zervos III, 2001 U.S. Dist. LEXIS 17060 at *44-45.. This case deals with the insurance company's own external review process, not the New York State program as established by N.Y. INS. LAW § 4910 discussed *supra* at note 75.

[109] *Id.* at *13.

[110] *Id.* at *46.

[111] *Id.* at *39 (emphasis added).

[112] *Id.* at *40.

[113] Zervos IV, 277 F.3d at 647 (emphasis in text added). In this decision, the Second Circuit reversed and vacated *Zervos III*, directing the district court to order injunctive relief against the insurance company to provide coverage for HDC and ABMT treatment for the insured. *Id.* at 648.

[114] The policy provided coverage for "medically necessary" treatment and defined that as treatments that "are required for the necessary treatment of Injury, Illness, or pregnancy, as distinct from those which are unnecessary or Experimental/Investigational." The policy defined Experimental/Investigational as "services or supplies which are not of proven benefit for the diagnosis or treatment of the Covered Person's condition, or are not generally recognized by the medical community as effective or appropriate for that condition, as determined by the Claims Administrator." Zervos IV, 277 F.3d at 639.

policy. [115] This outcome illustrates that courts are sympathetic to these patients and try to find in their favor.

Other New York federal court cases have had similar outcomes with respect to granting patients coverage for what may be considered experimental treatment. Like *Zervos*, these cases are often decided in favor of plaintiffs because the courts find that the insurance coverage denials do not adequately correspond with the language in the insurance contracts. In *Kekis v. Blue Cross & Blue Shield, Inc.*, the District Court for the Northern District of New York held that the patient was entitled to coverage for HDC-ABMT for the treatment of her breast cancer.[116] The court noted that chemotherapy was the standard treatment for breast cancer, but evidence was introduced that established a fifty-five to eighty-seven percent chance of women in the plaintiff's position suffering a relapse of the condition after receiving only the standard treatment of chemotherapy. As a result, the plaintiff's physician recommended that she undergo HDC-AMBT treatment.[117] Although the court considered that use and efficacy of HDC-AMBT was highly controversial,[118] the court determined that the plaintiff was entitled to a preliminary injunction granting coverage for treatment consisting of HDC-ABMT.[119]

The plaintiff's insurance company denied authorization for her to participate in a clinical trial providing HDC-AMBT on the grounds that the treatment was experimental and her policy excluded coverage for experimental or investigational treatment.[120] The court determined that the factors the insurance company used in deciding that the treatment was experimental were inconsistent with the language of the policy, and therefore "arbitrary and capricious" since HDC-AMBT could not be said to be without any proven medical value.[121] The court also clarified that testing in a clinical environment did not render a certain course of treatment experimental.[122]

Courts may find insurance companies liable for coverage based on the fact that a conflict of interest may exist. In *Whitney v. Empire Blue Cross & Blue Shield*, the District Court for the Southern District of New York held that the insurance company had acted in an arbitrary and capricious manner in denying the decedent estate coverage for HDC-ABMT in a Phase I clinical trial.[123] The court

---

[115] N.Y. INS. LAW § 4910 (2)(B) (McKinney 2006).

[116] Kekis v. Blue Cross & Blue Shield, Inc., 815 F. Supp. 571 (N.D.N.Y. 1993).

[117] *Id.* at 574. Her physician explained he "[knew] the natural history of a person in her situation and it is totally feasible that a more aggressive approach might benefit her." *Id.* at 576.

[118] *Id.* at 574.

[119] *Id.* at 585.

[120] *Id.* at 575.

The plaintiff's policy defined experimental/investigative as "any service or procedure we do not recognize as accepted medical practice." In order to satisfy that exclusion, the insurance company had to determine that the treatment had no "proven medical value." *Id.* at 579.

[121] Kekis, 815 F. Supp. at 582.

[122] *Id.* at 580.

[123] Whitney v. Empire Blue Cross & Blue Shield, 920 F. Supp. 477, 481 (S.D.N.Y. 1996) *vacated*

agreed with the plaintiff that the insurance company had to contend with a conflict of interest in determining that the treatment was "experimental." It explained,

Empire [the insurance company], in determining Whitney's claim, was subject to the influence of a substantial conflict. Empire is at financial risk if the cost of its claims exceeds the premiums it has collected. The ultimate decision to approve or deny coverage resides in Empire's medical director. Empire was administering claims under a policy it issued and for which it was financially responsible. This is the circumstance under which courts have held repeatedly that the insurance company is operating under an inherent conflict of interest.[124]

The court went on to cite *Brown v. Blue Cross & Blue Shield of Alabama*,[125] emphasizing that the insurance company's "fiduciary role lies in perpetual conflict with its profit-making role as a business." Thus, the insurance company is "exercising discretion over a situation for which it incurs "direct, immediate expense as a result of benefit determinations favorable to plan participants."[126] The court also determined that the language of the policy made it "highly manipulatable" and the criteria that the policy used were "so elastic as to be almost meaningless."[127]

Even though in these cases the insurance companies made determinations that the HDC-AMBT treatment was not covered by the insureds' policies, the courts found a way to conclude that the exclusions in the contracts did not apply in the patients' situations. These are cases in which the courts could have easily decided against the plaintiffs, but instead construed the language so that the patients would receive coverage for treatment using HDC-AMBT. Nevertheless, courts

---

by 106 F.3d 475 (2d Cir. 1997). The patient, diagnosed with metastatic breast cancer and having a prognosis of one month to live, underwent HDC-ABMT treatment. Although she died a few months later, she seemed to respond favorably to the treatment, no longer feeling the pain she had experienced prior to the treatment and living longer than doctors had previously predicted. *Id.* at 480.

124 *Id.* at 484.

125 Brown v. Blue Cross & Blue Shield of Ala., 898 F.2d 1556, 1561 (11th Cir. 1990) *cited in* Whitney, 920 F. Supp. at 484.

126 *Id.*

127 Whitney, 920 F. Supp. at 486. The policy used a discretionary standard to determine whether treatment was experimental or investigational, and therefore not medically necessary. The policy defined experimental/investigational as:

1. not of proven benefit for the particular diagnosis or treatment of the Covered Person's particular condition; or

2. not generally recognized by the medical community as reflected in the published peer-reviewed medical literature as effective or appropriate for the particular diagnosis or treatment of the Covered Person's particular condition.

Id. at 481.

The policy also listed five criteria that the insurance company could use in determining whether the patient should receive coverage. However, the policy included a disclaimer that the company "may" use the criteria and "may in our discretion require that any or all of the criteria be met." *Id.* at 481. The five criterion include FDA approval to use the treatment for that particular condition, medical journal publications demonstrating "definite positive effect on health outcomes," a showing that over time the treatment has led to positive health outcomes, that the new "technology is at least as effective in improving health outcomes as established technology," and that the treatment could be used in a standard medical practice setting. *Id.*

making these decisions are problematic—a judge is not a doctor and is not equipped to decide what a patient's treatment should be; yet in these cases, that is exactly what the judges have done. These judges essentially acted as doctors and making life-altering decisions for the patients before them.

IX. IMPORTANT STUDIES SUPPORTING EXPERIMENTAL BREAST CANCER TREATMENT

Phase II studies, uncontrolled/nonrandomized studies,[128] and preliminary reports conducted in the early 1990s found that breast cancer patients undergoing higher doses of chemotherapy with stem cell transplants produced promising results.[129] This led to the inception of a number of large-scale controlled clinical studies dealing with this method of treatment.[130]

A five-year study of 885 patients found that there was a six percent improvement in the relapse-free survival rates between breast cancer patients receiving HDC and stem cell transplants (65 percent) when compared with patients receiving normal chemotherapy doses (59 percent). Furthermore, the study found a ten percent improvement in the relapse-free survival rates of breast cancer patients with a higher risk of relapse—those who had ten or more cancer-positive axillary lymph nodes. Within different subgroups there were higher relapse-free rates as well among patients under age 40.[131] Patients that had HER2/*neu*-negative tumors,[132] and received the higher doses of chemotherapy yielded an even more significant improvement in relapse-free rates than those treated conventionally.[133]

---

[128] Studies that have a separate control group receiving conventional treatment.

[129] *See* Zervos IV, 277 F.3d at 640, n.3.

The Phase II trials "consistently reported high overall rates of response (combined complete and partial responses), ranging from 73 to 100 percent. Despite a median survival of only 10 to 24 months, 7 to 18 percent of patients in these studies remained free of progressive disease for up to 5 years after the treatment."

Id. citing Edward A. Stadtmauer, M.D., et al., *Conventional-Dose Chemotherapy Compared with High-Dose Chemotherapy Plus Autologous Hematopoietic Stem-Cell Transplantation for Metastatic Breast Cancer*, 342 NEW ENG. J. MED. 1069 (2000). *See also* W.D. Peters, et al., *High-Dose Chemotherapy and Autologous Bone Marrow Support as Consolidation After Standard-Dose Adjuvant Therapy for High-Risk Primary Breast Cancer*, 11 J. CLINICAL ONCOLOGY 1132 (1993) (This non-randomized study was often cited by supporters of HDC-ABMT. The study found that after two and a half years, the relapse-free survival rate of the patients was 72 percent, as compared to 38 to 52 percent relapse-free rates found in similar studies of patients treated with just traditional chemotherapy).

[130] National Cancer Institute, *High-Dose Chemotherapy for Breast Cancer: Clinical Trials Overview*, http://www.cancer.gov/clinicaltrials/developments/high-dose-chemo-overview0401 (last visited Apr. 22, 2007).

[131] Sjoerd Rodenhuis, et al., *High-Dose Chemotherapy with Hematopoietic Stem-Cell Rescue for High-Risk Breast Cancer*, 349(1) NEW ENG. J. MED. 7 (2003), *available at* http://content.nejm.org/cgi/content/full/349/1/7.

[132] HER2/*neu*-positive cancer is when the patient has an "excessive amount of the HER2/*neu* cancer gene protein in and around their cells." Marisa Weiss, *HER2/neu Positive Breast Cancer*, Breastcancer.org, http://www.breastcancer.org/faq_herceptin_her2.html (last visited Apr. 22, 2007).

[133] Rodenhuis, *supra* note 131.

Like the Rodenhuis trial, many other trials being conducted have found results that are encouraging in showing the utility of HDC-ABMT. However, many of these studies are inconclusive or the results are not statistically significant even though the relapse-free survival rates are better for the participants in the experimental group than the control group. One study found that the disparity in the overall survival rates between the control group—those receiving treatment consisting of traditional chemotherapy—and the experimental group—patients who received the same chemotherapy in addition to HDC-AMBT—was not statistically significant. However, the study did find that there was an increase in the time until recurrence for the participants in the experimental group; only forty-five percent of the control group was free of recurrence after six years compared to fifty-five percent of the experimental group.[134] Doctors and medical experts acknowledge that these results, although not definitive in establishing HDC-ABMT as a standard in the treatment of breast cancer, support the inference that use of this method of treatment may be optimal in treatment of certain cases of breast cancer.[135]

X. ACCEPTANCE OF HDC-ABMT AS TREATMENT FOR BREAST CANCER

Although recent clinical studies have not yielded results showing a significant improvement of HDC and ABMT treatment over the traditional course of breast cancer treatment, advocates of HDC-ABMT are quick to point out that "although preliminary results from some transplant trials have been disappointing, they cannot be generalized to all patients and, contrary to the impression created by some reports, [the trials] have not resolved the questions about transplantation."[136]

In *Zervos III*, the insurance company, when initially denying the coverage for HDC-ABMT treatment, noted that the plaintiff was not the model patient to receive this kind of treatment because he had metastatic (Stage IV) breast cancer, which it considered to be incurable and therefore not ideal.[137] However, it acknowledged that breast cancer patients in different circumstances may in fact be eligible to receive the benefits of HDC-ABMT.[138]

---

134 Martin S. Tallman, et al., *Conventional Adjuvant Chemotherapy with or without High-Dose Chemotherapy and Autologous Stem-Cell Transplantation in High-Risk Breast Cancer*, 349(1) NEW ENG. J. MED. 17 (2003), *available at* http://content.nejm.org/cgi/content/full/349/1/17.

135 National Cancer Institute, *High-Dose Chemotherapy with Stem Cell Transplantation: Still No Clear Benefit*, http://www.cancer.gov/clinicaltrials/results/high-dose-chemo0703 (last visited Apr. 22, 2007).

136 National Cancer Institute, *Don't Write Off High-Dose Chemotherapy with Bone Marrow Transplant for Breast Cancer, Experts Say*, http://cancernet.nci.nih.gov/newscenter/hd-chemo (last visited Apr. 22, 2007).

137 Zervos III, 2001 U.S. Dist. LEXIS 17060 at *33-34.

138 *Id.* at *33. The insurance company's doctors explained that this type of treatment worked best in patients younger than age 42 and were in complete remission as a result of the chemotherapy. The patient here met neither of those criteria. However, the insurance company had previously awarded coverage for HDC/ABMT to a patient who had stage II breast cancer, which is less advanced and therefore more likely to be cured. The company also emphasized the fact that the patient they had granted coverage to was involved in a phase III trial, while the plaintiff in this case wanted to take part *Id.* (Phase II trials are more concerned with obtaining preliminary evidence on a drug's efficacy. They

Furthermore, in denying the request, the insurer's doctors stated only that HDC-ABMT treatment is not superior to conventional cancer treatment; they did *not* claim that it was not as effective. They also stressed that the side-effects of the HDC-ABMT treatment were more severe than those of conventional treatment.[139] The court nonetheless dismissed that argument as irrelevant to the case.[140]

Advocates for HDC-ABMT treatment of breast cancer claim that insurance companies simply do not want to pay the costs of this treatment.[141] HDC-ABMT can cost anywhere from $80,000 to $150,000, while conventional chemotherapy treatments range from $15,000 to $40,000.[142] One study recognized increased benefits resulting from ABMT but concluded that the costs in relation to the benefits may be "untenable."[143]

In 1994, the United States Office of Personnel Management ("OPM") put forth a requirement for Federal Employee Health Benefits carriers to "offer benefits for [HDC-ABMT] consistent with current medical practice."[144] In 2000, despite studies that raised doubts regarding HDC-ABMT's effectiveness, the OPM maintained its position that this treatment should be covered—although the decision allows for restrictions on the administration of the treatment, such as restricting it to qualified clinical trials.[145] The affirmation of the decision stressed that "the patient and a qualified physician are in the best position to evaluate and decide upon treatment options."[146]

XI. MEDICARE PRACTICES FOR CLINICAL TRIAL COVERAGE

Pursuant to an executive memorandum which President Clinton released on June 7, 2000, Medicare covers payment for "routine patient care costs... and costs due to medical complications associated with participation in clinical trials."[147]

---

seek to "refine" the research and establish a foundation to proceed with more extensive studies on the drug. Phase III trials involve a much larger number of participants and are undertaken after a Phase 2 trial has demonstrated that the drug may be effective and not high-risk. These trials are generally regarded as lower-risk and more credible). Carol Rados, *Inside Clinical Trials: Testing Medical Products in People*, 37 FDA CONSUMER MAGAZINE (Sept.-Oct. 2003), *available at* http://www.fda.gov/fdac/features/2003/503_trial.html.

[139] Zervos III, 2001 U.S. Dist. LEXIS 17060 at *20

[140] *Id.*

[141] *See* Whitney 920 F. Supp. at 484 *supra* note 123 and accompanying text (discussing the conflict of interests insurance companies face when paying out benefits).

[142] *See* JAGGER *supra* note 98. *See also* Whitney, 920 F. Supp. at 482 (discussing costs of treatment).

[143] B. E. Hillner, et al., *Efficacy and Cost-Effectiveness of Autologous Bone Marrow Transplantation in Metastatic Breast Cancer. Estimates Using Decision Analysis While Awaiting Clinical Trial Results*, 267(15) JAMA 2055 (1992).

[144] *FEHBP: OPMS Policy Guidance for 2001: Hearing Before the Subcomm. on Civil Serv., Comm. on Gov't Reform*, 106th Cong. (2000) (statement of William E. Flynn, III, Assoc. Dir. for Ret. & Ins., Office Of Personnel Management), *available at* http://fehb.opm.gov/testify/2000/Flynn-06-13-00.html. (Hereafter *FEHBP*).

[145] *Id.*

[146] *Id.*

[147] *See Overview*, Centers For Medicare & Medicaid Services, (July 13, 2005),

Medicare has a qualifying process for this coverage, which consists of a panel of representatives from various federal agencies convening to determine whether the trial qualifies for coverage. In order to qualify, the panel must determine that the trial satisfies several conditions, such as a "therapeutic intent" of the study, if the trial is sufficiently designed to address the research question, if there is support to justify the trial, and if the trial is sponsored by a credible organization.[148]

The 1999 GAO report found that most insurance companies' policies "generally exclude coverage for clinical trials," although they often allow for a case-by-case review by the insurers' medical personnel.[149] However, generally, the insurance providers would only cover the "standard, nonexperimental care costs" of trial participation.[150] Determining what is and is not "standard" care often becomes problematic; the line between the two categories is not always clear. Factors such as extra tests or negative reactions to treatment muddle the distinction.[151] As a result, some insurers will pay full patient care costs in order to avoid the burden of having to draw such distinctions.[152] However, the majority of insurance companies negotiate the amount of coverage that they will provide for treatment through a trial, and they generally do this on a case-by-case basis.[153]

XII. COSTS IN CLINICAL TRIALS

Insurance companies also argue that by providing coverage for experimental or investigational treatments, they are in effect paying for medical research and not necessarily medical care. As a result, researchers dealing with deficiencies in research funding will encourage patients to seek coverage for investigational treatments as a way of augmenting their resources.[154]

There are two categories of patient care costs: usual care costs and extra care costs.[155] The usual care costs are costs associated with treatment regardless of whether the patient is a participant in a trial or not—i.e., doctor visits, hospital stays, clinical laboratory tests, and x-rays. Extra care costs are those costs incurred by participation in a trial apart from the usual care costs, and include additional tests that are administered as a result of the trial.[156] These costs are sometimes—

---

http://www.cms.hhs.gov/ClinicalTrialPolicies (quoting President Clinton's executive memorandum).

148 *Medicare Coverage ~ Clinical Trials*, Centers For Medicare & Medicaid Services, (Sept. 2000). *available at* http://www.cms.hhs.gov/ClinicalTrialPolicies/Downloads/finalnationalcoverage.pdf.

149 HEINRICH, *supra* note 59, at 2.

150 *Id.*

151 *Id.* at 8.

152 *Id.* at 9.

153 *Id.*

154 Ader, *supra* note 60, at 187.

155 National Cancer Institute, *Clinical Trials and Insurance Coverage—A Resource Guide, available at* http://www.cancer.gov/clinicaltrials/learning/insurance-coverage/page2 (last visited Apr. 22, 2007).

156 *Id.*

but not always—covered by the trial's sponsor.[157] In general, the insurance companies do not pay for the extra care costs or the research costs associated with the trial.[158]

New York State defines patient costs with respect to clinical trials as including:

[a]ll costs of health services required to provide treatment to the insured according to the design of the trial. Such costs shall not include the costs of any investigational drugs or devices themselves, the cost of any non-health services that might be required for the insured to receive the treatment, the costs of managing the research, or costs which would not be covered under the policy for non-investigational treatments.[159]

Therefore, the insurance company does not usually have to shoulder costs other than those it would normally cover via standard treatment—i.e., extra doctor's visits or diagnostic tests.

Although funding participation in clinical trials for the extra costs may increase the insurance companies' costs in the short run, future long-term costs may decrease because of better technology and increased efficiencies that result from these studies. Ultimately, clinical trials will lead to the "elimination of payment for procedures that the research determined were ineffective, and by the swifter channeling of patients to treatments that the research determined were effective."[160]

Furthermore, creating an automatic approval for experimental breast cancer treatment through clinical trials would eliminate the need to proceed through the external appeals process and would also reduce the amount of insured patients going to court seeking coverage for clinical trial expenses. Thus, litigation costs that the insurance companies accrue would also decrease. It is important to note that when patients take the insurance companies to court, the judges have a tendency to rule in favor of the patient. "When potentially life-saving treatment is at stake, trial courts are likely to rule in favor of the plaintiff. Defendants [the insurance companies] rarely appeal."[161] In spite of the insurance companies' fine-tuning of their contracts in attempts to avert losing in court over technicalities in the contract when patients appeal denials of coverage, "[e]ven the finest of investigational exclusions and decision-making processes will face an uphill battle in court in life-threatening cases where the plan is characterized as asking the court for a death sentence for the subscriber."[162]

---

157 *Id.*

158 HEINRICH, *supra* note 59, at 10.

159 N.Y. INS. LAW § 4914 (4)(B)(v) (McKinney 2006).

160 Ader, *supra* note 60, at 199. Ader cites cochlear implants for children as an example of a medical technology whose benefits were at first uncertain but later shown to be beneficial. *Id.* at 191.

161 *Id.* at 195.

162 *Id.* at 196.

There are many ways to deal with the increased costs brought about by HDC-ABMT coverage including cost and risk sharing by the government with the insurance companies. An example of this is the Blue Cross Blue Shield's joint initiative with the NCI sponsoring the Demonstration Project for HDC-ABMT for breast cancer, in which the NCI contributed about forty million dollars to conduct a series of national Phase III trials studying HDC-ABMT.[163]

Furthermore, even if insurance coverage for HDC-ABMT becomes readily available, most breast cancer patients will most likely still opt for traditional treatment. To justify its policy of requiring coverage for HDC-ABMT, the OPM noted that after the "the number of ABMT procedures for breast cancer covered by federal employees program plans dropped from 88 in 1997 to 40 last year [1999]" even though the treatment was covered by insurance.[164] This is evidence that the availability of coverage for treatment such as HDC-ABMT or other experimental treatments does not necessarily correlate with an increase in physicians prescribing such a course of treatment for their patients. Physicians do not arbitrarily prescribe a certain treatment for the sole reason of its availability; rather, they prescribe the treatment they believe will most benefit their patients. Thus, the low number of breast cancer patients that would decide to undergo HDC-ABMT would not be so substantial as to significantly increase costs to the insurance companies.

Another factor to be taken into consideration is the finding that insurance companies may often unknowingly pay for their insureds' clinical participation. There are patients who submit claims for treatment coverage "without identifying the services as trial-related" when requesting insurance coverage.[165] As a result "insurers may be covering more trial services than they officially approve."[166] In addition, academic health centers often enroll patients in clinical trials, leading to insurance coverage for clinical care that was not necessarily authorized by the insurance company. [167]

Studies have found that the differentials in costs of standard care and clinical trial care may not be that great. The GAO report cited a study by the Mayo Clinic which found that the per capita average cost of care for cancer chemotherapy trial participants after a year of treatment was $24,645 as compared with $23,964 for standard treatments.[168] A 2001 study also found that there is no significant increase in treatment costs for patients in trials as compared with non-participant patients.[169]

---

163 *Id.* at 197.

164 *FEHBP*, *supra* note 144.

165 HEINRICH, *supra* note 59, at 17.

166 *Id.*

167 *Id.* at 9, n.11.

168 *Id.* at 4. However, the study acknowledged that for trials involving bone marrow transplants yielded much more significant differentials in costs. *Id.*

169 *See* National Cancer Institute, *Clinical Trials Appear Not to Drive Up the Cost of Cancer Treatment*, http://www.cancer.gov/clinicaltrials/developments/notcostly0103 (last visited Apr. 22,

Although mandating coverage for HDC-ABMT may result in higher costs to insurance companies, there are many factors that suggest the cost increase may not be significant. These mitigating factors include that a small number of women and their doctors choose this treatment, insurance companies are already unknowingly and knowingly paying for these treatments, and litigation involving coverage tends to be in the patients' favor. Accordingly, insurance companies wind up paying for both the treatment and litigation expenses. Most importantly, costs expended by the insurance companies now to cover this treatment will lead to benefits and improvements in the treatment and technology, which will minimize the future costs.

XIII. CURRENT STANDARDS ARE INAPPROPRIATE

New York's current system is creating cumbersome red-tape for patients. This bureaucratic system leads to unnecessary inefficiencies and expenditures of resources by both the patients and the insurance companies. As a result of an unclear standard in determining which clinical trials administering experimental treatments are covered by insurance companies, both companies and patients alike deal with much more uncertainty, which could be avoided if there was a clear rule allowing for Phase II and Phase III government and IRB-approved clinical trials to receive automatic coverage for at least the standard patient care. Instead, patients and insurance companies continue to squander valuable time and money seeking internal appeals, external appeals, and even federal court decisions ruling in their favor. The Southern District of New York confirmed that "[t]he courts are not the appropriate forum for this debate. Yet the courts are forced to resolve these questions of survival and over-valued treatment,"[170] in spite of the "ultimate inappropriateness of the court as the arbiter of social policy."[171] Moreover, these cases are primarily determined based on contractual language, not on the merits of the disputed treatment's quality or its appropriateness for the patient. Because the judiciary system's demonstrated empathy with and bias towards the patients, "[i]t is more productive for health plans to steer their members into well-conceived clinical trials than into ill-conceived judicial ones."[172]

2007). The study found that there were "only slightly higher patient-care costs associated with treating patients in cancer clinical trials compared to treating similar patients outside of trials." However, the study found that "patients enrolled in trials tended to receive more complex, aggressive initial treatment; were more likely to have recurrent disease; and were more likely to be followed for a longer time" which would inevitably lead to higher costs for patients involved in clinical trials. Therefore, in order to isolate the actual cost differential between trial treatment and non-trial treatment, the study accounted for those factors as well as others (i.e., age, stage of disease, initial treatment received, and treatment outcome) which could create greater disparities in cost of treatment. Consequently, the results of the study yielding no significant difference is based on statistical adjustments of these factors. *Id.*

[170] Whitney 920 F. Supp. at 482.

[171] *Id.* at 483.

[172] Ader, *supra* note 60, at 199.

XIV. PROPOSAL AND CONCLUSION

This Note suggests that New York should only make a slight change to its laws regarding insurance coverage for breast cancer experimental treatment. New York should mandate automatic insurance coverage for Phase II and III clinical trials, including those trials testing HDC-ABMT. However, Phase I and IV trials should remain under the current standard and not be included in the automatic coverage. Phase I trials should be excluded because those trials are primarily designed to determine if the new method is safe, whereas Phase II and especially Phase III trials are based on evidence that the method is potentially as efficacious and safe as the standard treatment methods, if not more so. Phase IV trials should remain under the current standard because those trials usually study long-term effects and are not as concerned with treatment of the disease.

The existing New York laws already include a provision for coverage of experimental treatments when conducted in a clinical trial. In this respect, New York is headed in the right direction. However, the statutory inclusion of a requirement for a patient to successfully go through an external appeals agent or even courtroom litigation to receive coverage for participation in a clinical trial is not adequate. This provision creates an additional burden on patients in need of life-saving medical care. Time is of the utmost importance for these patients, and this requirement creates an unnecessary bureaucracy. Not only is it likely that the patients will have to go through an internal appeals process, but if they do not succeed at that level they will probably have to go through an external appeals process. This process requires more time and resources from the patient, further delaying coverage for the treatment. This system is inefficient in a situation where efficiency is of the utmost importance.

By mandating automatic insurance coverage for participation in Phase II and III clinical trials, the New York legislature could avoid the unnecessary costs involved for the patient and the insurance provider in both the external and internal appeals process, thereby expediting patients' access to treatment. Pre-approving all Phase II and III clinical studies will assure the insurance companies that the studies are safe, high-quality, and the patients participating in the trials have been selected because the doctors and researchers in charge of the trial believe that the particular patient has the best chance of succeeding using the prospective treatment.

Furthermore, clinical trials may provide a treatment that could potentially help a patient or improve her quality of life in ways that standard methods of treatment would not. Coverage for clinical trials will serve to play a role in the advent of improved treatments and technologies, possibly saving lives that would not have been saved but for the trial.

Many states have mandated insurance companies to provide coverage for Phase I, II, III, and IV trials. In order for New York to truly "lead the nation in

protecting the rights and health of its residents,"[173] New York should take action and direct the insurance companies to provide coverage for Phase II and III clinical trials.

[173] Exec. Mem, *supra* note 84.