REPORT OF THE
SPECIAL ADVISORY COMMISSION ON MANDATED
HEALTH INSURANCE BENEFITS

HOUSE BILL 2426 and SENATE BILL 991: REPEALS OF THE MANDATED OFFER OF COVERAGE FOR BONE MARROW TRANSPLANTS OR STEM CELL TRANSPLANTS FOR BREAST CANCER

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

COMMONWEALTH OF VIRGINIA
RICHMOND
2008

January 4, 2008

To: The Honorable Timothy M. Kaine
Governor of Virginia
and
The General Assembly of Virginia

The report contained herein has been prepared pursuant to §§ 2.2-2504 and 2.2-2505 of the Code of Virginia.

This report documents a study conducted by the Special Advisory Commission on Mandated Health Insurance Benefits to assess the social and financial impact and the medical efficacy of House Bill 2426 and Senate Bill 991 regarding proposed repeals of the mandated offer of coverage for bone marrow transplants or stem cell transplants for breast cancer.

Respectfully submitted,

R. Lee Ware, Jr.
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INTRODUCTION

The House Committee on Commerce and Labor referred House Bill 2426 to the Special Advisory Commission on Mandated Health Insurance Benefits (Advisory Commission) during the 2007 Session of the General Assembly. House Bill 2426 was introduced by Delegate Kathy J. Byron.

The Senate Committee on Commerce and Labor referred Senate Bill 991 to the Advisory Commission during the 2007 Session of the General Assembly. Senate Bill 991 was introduced by Senator Harry B. Blevins.

The Advisory Commission held a hearing on July 18, 2007 in Richmond to receive public comments on House Bill 2426 and Senate Bill 991. In addition to the patron, Delegate Kathy J. Byron, a representative of the Virginia Association of Health Plans (VAHP) spoke in favor of the bills. Written comments in support of the bills were provided by the Virginia Breast Cancer Foundation (VBCF) and VAHP. A member of the Advisory Board of Massey Cancer Center who is also cancer survivor spoke against House Bill 2426 and Senate Bill 991. A physician on the staff of the Virginia Commonwealth University (VCU), Massey Cancer Center provided expert testimony at the September 20, 2007 meeting.

The Joint Legislative Audit and Review Commission (JLARC) provided an assessment on the Evaluation of Senate Bill 991 and House Bill 2426: *Repeals of Mandated Offer for Autologous Bone Marrow Transplant or Stem Cell Transplant for Breast Cancer in accordance with sections 2.2-2503 and 30-58.1 of the Code of Virginia.* The report is available on the JLARC website at http://jlarc.state.va.us.

CURRENT REQUIREMENT OF OFFER OF COVERAGE FOR BONE MARROW TRANSPLANT

If enacted, House Bill 2426 would repeal in its entirety § 38.2-3418.1:1 in the Code of Virginia. Senate Bill 991 would amend § 38.2-3418.1:1 in the Code of Virginia by removing the mandated offer of coverage requirement for dose-intensive chemotherapy/autologous bone marrow transplants, but would continue to require companies to offer and make available coverage of stem cell transplants for the treatment of breast cancer.

Section 38.2-3418.1:1 is applicable to individual or group accident and sickness insurance policies providing hospital, medical and surgical, or major medical coverage on an expense-incurred basis; corporations providing individual or group accident and sickness subscription contracts; and health maintenance organizations (HMOs) providing health care plans. The section requires that coverage be made available for the treatment of breast cancer by dose-intensive chemotherapy/autologous bone marrow transplants or stem cell transplants when 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 protocols that have been favorably reviewed and utilized by hematologists or oncologists experienced in dose-intensive chemotherapy/autologous bone marrow transplants or stem cell transplants.

The section requires that copayments for this coverage under policies, contracts or plans should not be greater than for any other coverage, and coverage shall be subject to the same deductible as any other coverage. A different deductible may be offered and made available. The section does not apply to short-term travel, accident-only, limited or specified disease policies, or to short-term nonrenewable policies of not more than six months' duration.

Section 2.2-2818 requires coverage for state employees for the treatment of breast cancer by dose-intensive chemotherapy with autologous bone marrow transplants or stem cell support when performed at a clinical program authorized to provide such therapies as a part of clinical trials sponsored by the National Cancer Institute.

PRIOR REVIEW

During the 1992 Session of the General Assembly, the House Committee on Corporations, Insurance and Banking referred a bill to mandate coverage for bone marrow transplants to the Advisory Commission. House Bill 539 was introduced by Delegate David G. Brickley and would have required insurers to offer and make available coverage for the treatment of cancer by autologous bone marrow transplants. During that time, the Advisory Commission had concerns that the treatment may not have been medically efficacious. The Advisory Commission voted to recommend against the enactment of House Bill 539 (1993 House Document No. 37).

During the 1994 Session of the General Assembly, House Bill 240 was referred to the Advisory Commission for evaluation by the Joint Commission on Health Care. The bill was introduced by Delegate Mary T. Christian and required insurers to offer and make available coverage for the treatment of cancer by dose-intensive chemotherapy and autologous bone marrow transplants or stem cell transplants. At that time, the Advisory Commission recommended the enactment of House Bill 240 with a technical amendment. The amendment clarified that the mandated offer of coverage was to be limited to the treatment of breast cancer. The Advisory Commission recognized the reports of the improved effectiveness of the treatments and the impact a lack of coverage had on Virginia citizens. The Advisory Commission voted to recommend the enactment of House Bill 240. 1995 Senate Document No. 9 stated:

> The medical community was divided on the use of autologous bone marrow transplant for other types of cancer. There were studies that demonstrated the positive use of autologous bone marrow transplant including the *Technology Assessment of High-Dose Chemotherapy and Autologous Bone Marrow Support for Breast Cancer* prepared by

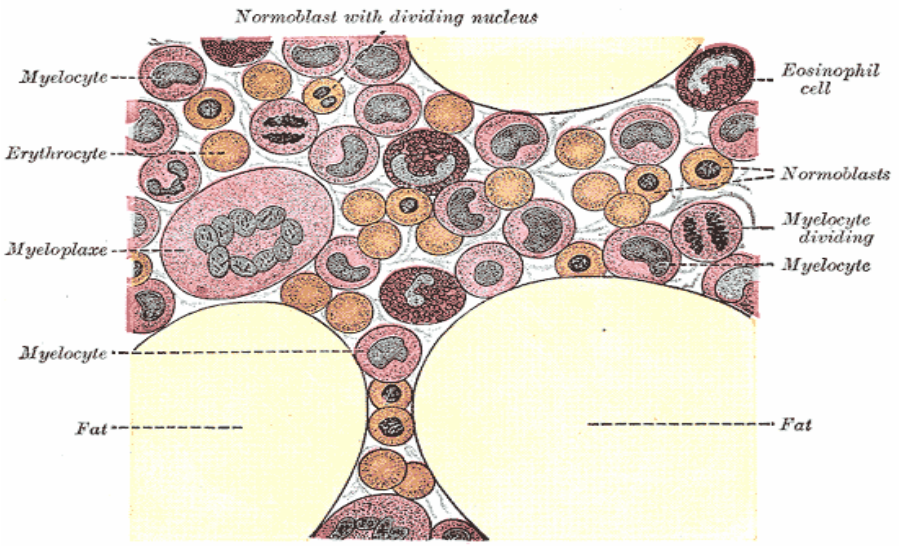
Dr. William P. Peters of Duke University Medical Center, Dr. Marc E. Lippman of Georgetown University Medical Center, Dr. Gianni Bonandonna of Milan, Italy, Dr. Vincent T. DeVita, Jr. of Memorial Sloan Kettering Cancer Center in New York, Dr. James F. Holland of Mount Sinai School of Medicine, and Dr. Gary L. Rosner of Duke University Cancer Center. According to this assessment, the use of high dose chemotherapy and autologous bone marrow support for selected patients with breast cancer should no longer be considered investigational.

However, others in the medical field advised caution particularly because of the fact that they considered the mortality rate for the treatment itself to be significant. One of the arguments against the use of autologous bone marrow transplant in the treatment of certain types of cancer is that the outcome of many of the studies conducted was based on the short follow-up periods. It has been argued that the follow-up periods have not been sufficient to draw conclusions concerning survival following autologous bone marrow transplant or to compare autologous bone marrow transplant to alternative therapies. According to some, duration of disease-free survival following autologous bone marrow transplant does not appear to be substantially longer than historical survival without autologous bone marrow transplants.

The National Cancer Institute, the federal government's lead agency for research on cancer, had begun a study on breast cancer that included 1,200 women nationally. The women were divided into two groups of 600 each. One group received autologous bone marrow transplant with high dose chemotherapy and the other half received conventional dose chemotherapy. Each group was documented carefully and evaluated over several years. According to the National Cancer Institute, these studies were essential since only through formal, well-performed clinical trials can the effectives and toxicity of autologous bone marrow transplant in breast cancer patient would be determined.[1]

Bone Marrow and Stem Cell Transplants

The American Cancer Society (ACS) states that stem cells are blood cells that circulate in our bodies as immature hematopoietic stem cells. Stem cells live in the bone marrow that is the soft, spongy tissue located in the hollow interior of bones where mostly new blood cells are produced. When blood cells mature and leave the bone marrow, they enter the blood stream, known as the peripheral blood stem cells. The ACS states that stem cell transplants are used to refurnish the bone marrow when the cells have been destroyed by disease, chemotherapy, or radiation. [2]



Gray's Anatomy illustration of cells in bone marrow.

The National Cancer Institute (NCI) Fact Sheet, entitled "Bone Marrow Transplantation and Peripheral Blood Stem Cell: Question and Answers" located at website, www.cancer.gov discussed the usage of bone marrow transplantation for cancer treatment:

> Chemotherapy and radiation therapy generally affect cells that divide rapidly. They are used to treat cancer because cancer cells divide more often than most healthy cells. However, because bone marrow cells also divide frequently, high-dose treatments can severely damage or destroy the patient's bone marrow. Without healthy bone marrow, the patient is no longer able to make the blood cells needed to carry oxygen, fight infection, and prevent bleeding. The bone marrow transplantation and peripheral blood stem cell transplantation replace stem cells that were destroyed by treatment. The healthy, transplanted stem cells can restore the bone marrow's ability to produce the blood cells the patient needs. [3]

The Virginia Commonwealth University Massey Cancer Center website, www.massey.vcu.edu/cancer states that stem cells can either be collected from the circulating cells in the peripheral blood system or from the bone marrow:

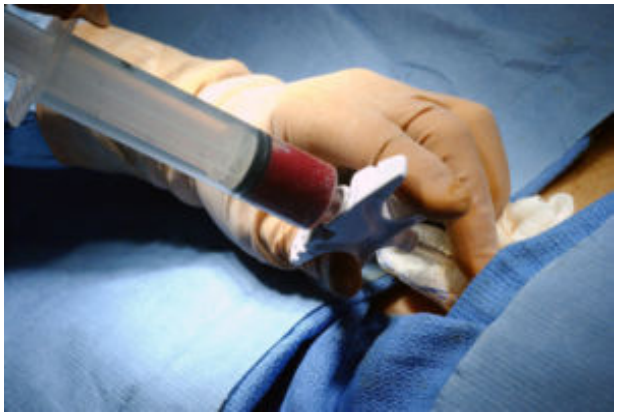
> The goal of a bone marrow transplant is to cure many diseases and types of cancer. When a person's bone marrow has been damaged or destroyed due to a disease or intense treatments or radiation or chemotherapy for cancer, a bone marrow transplant may be needed. A bone marrow transplant can be used to: replace diseased, non-functioning bone marrow with healthy functioning bone marrow (for conditions such as leukemia, severe aplastic anemia, lymphomas, multiple myeloma, immune deficiency disorders, solid-tumor cancers, such as breast or ovarian); replace the bone marrow and restore its normal function after high doses of chemotherapy or radiation are given to treat a malignancy. This

> process is often called “rescue” (for diseases such as lymphoma, neuroblastoma and breast cancer); replace bone marrow with genetically healthy functioning bone marrow to prevent further damage from a genetic disease process (such as Hurler’s syndrome and adrenoleukodystrophy).[4]

The ACS stated that there are three sources of stem cells to use for transplants including, the bone marrow, circulating (peripheral) blood, and umbilical cord blood. Initially, all stem cell transplants performed were bone marrow transplants. However, peripheral blood stem cell transplants are more widespread. Doctors are able to harvest more stem cells from peripheral blood than bone marrow. It was explained that peripheral blood stem cell transplantation is much easier on the donor and that the recipient’s blood count recovers faster than with the bone marrow transplant. The cord blood transplant is the newest source of stem cells. Blood is taken from the placenta and umbilical cord of newborns. Even though the small amount of blood contains a high number of stem cells, the numbers are too low for large adults, and the cord blood transplant is mainly used in small adults and children.[5]

According to the Massey Cancer Center, the only difference between stem cell transplantation and traditional bone marrow transplantation is the method by which the stem cells are removed or harvested from the patient.[6] The Massey Cancer Center explained the process of harvesting stem cells from the bone marrow:

> Bone marrow harvest involved collecting stem cells with a needle placed into the soft center of the bone, the marrow. Most sites used for bone marrow harvesting are located in the hip bones and the sternum. [7]



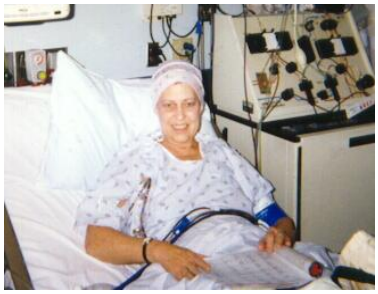
Bone marrow harvest

The Massey Cancer Center explained the process of harvesting stem cells from the blood stream known as apheresis:

> The donor is connected to a special cell separation machine via a needle inserted in the vein. Blood is taken from one vein and is circulated through the machine that removes the stem cells and

returns the remaining blood and plasma back to the donor through another needle inserted into the opposite arm. [8]

In the picture below, a patient receives apheresis to gather the stem cells from her blood. The procedure is a slow process that may take up to several hours in order to collect enough stem cells to ensure a chance of successful engraftment in the recipient.[9]



There are three different types of bone marrow transplants - autologous, allogeneic, and umbilical cord blood transplants:

1. Autologous bone marrow transplant is used when the patients become their own donors, using stem cells from either bone marrow harvest or apheresis (peripheral blood stem cells). The stem cells are removed or harvested before the treatment and then frozen. After patients have received high doses of chemotherapy, the stem cells are thawed and given back to the patients.[10]
2. Allogeneic bone marrow transplant is mainly used when the donor shares the same genetic type as the patient. The stem cells are taken either by bone marrow harvest or apheresis (peripheral blood stem cells from a family member such as a parent, brother or sister.) Syngeneic stem cell transplant is a distinctive type of allogeneic transplant because the donor is an identical twin of the patient with identical tissue types. However, if patients do not have a similar match in their family, they may find a match from a national registry.[11]

Non-myeloablative transplant is the latest type of allogeneic transplant:

> The transplant is used to suppress the immune system just enough to allow donor stem cells to settle in the bone marrow. The new immune cells begin to destroy the cancer cells, in what is known as a "graft-versus-tumor" effect. In this procedure, the patient is given low doses of chemo-not enough to destroy the cancer or all of the bone marrow, but enough to suppress the patient's immune system. Following the chemo the stem cells are infused. Slowly, over the course of months, they take over the bone marrow and replace the patient's own bone marrow cells. These new cells then develop an immune reaction to the cancer and kill off the patient's cancer cells.[12]

3. Umbilical cord blood transplant is used when the stem cells are taken from the placenta and umbilical cord of newborns. The stem cells are tested, counted, frozen, and stored for later use.[13]

SOCIAL IMPACT

The Richmond Times Dispatch article entitled "Breast Cancer and Virginia Women" dated April 12, 2007, reported that between 1998 and 2002, approximately 4,600 women were diagnosed with invasive breast cancer in Virginia. The article noted that between 1998 and 2005, approximately 1,059 women died from breast cancer. It was also reported that between 1998 and 2002, 51% of those cases of breast cancer were diagnosed at a local stage of the disease.[14]

According to the information provided by the Virginia Commonwealth University Massey Cancer Center, during the calendar years 2005 and 2006, there were 107 and 120 bone marrows or stem cell transplants performed at Virginia Commonwealth University Health System (VCUHS), respectively. The transplant program was established in 1988 and performs autologous, allogeneic and cord blood transplants for both adults and children with cancer and other diseases for which transplantation is recommended. Since the opening of the VCUHS bone marrow transplantation program, more than 1,450 transplants have been performed. During the time that clinical trials were underway for testing the treatment of breast cancer with stem cell transplants, VCUHS performed 345 autologous stem cell transplants for women with breast cancer. The transplants were largely conducted between 1991 and 1999. VCUHS noted that 2001 was the last year that a breast cancer patient was treated with autologous stem cell transplant.[15]

A NCI article entitled "High-Dose Chemotherapy for Breast Cancer: History" reviewed on April 12, 2005 (www.cancer.gov/clinicaltrials) discussed the treatment history of women with breast cancer. The article stated that over the past twenty years, over 15,000 women with breast cancer have been treated with a difficult and unproven procedure, high doses of chemotherapy followed by blood cell transplants to replenish the bone marrow damaged by the chemotherapy. During the early 1990s, advocates and women with breast cancer were demanding the treatment. Legislatures in some states responded by requiring insurance companies to pay for the procedure. During the mid 1990s, more women start receiving the treatment for breast cancer than for any other cancer. [16]

The Virginia Cancer Registry (VCR) reported the use of bone marrow transplant procedures or stem cell harvest and infusion during 1990 – 2005*. The following selected therapies were included: [17]

Therapy Frequency		Percent
Bone marrow transplant unspecified type	209	30.8
Bone marrow transplant autologous	131	19.3
Bone marrow transplant allogeneic	139	20.5
Stem cell harvest and infusion	199	29.4
Total	678	100.0

Therapy by Primary Site	Breast	Hematopoetic/Reticuloend Othelial**	Lymph node	Other ***	Total
Bone marrow transplant unspecified type	70	91	28	20	209
Bone marrow transplant autologous	52	56	14	9	131
Bone marrow transplant allogeneic	19	111	8	1	139
Stem cell harvest and infusion	86	71	19	23	199
Total	227	329	69	53	678

* 2005 reporting year is not complete

** Hematopoetic/Reticuloendothelial=Blood, Bone Marrow, and Spleen (Leukemias)

***Other includes Adrenal Gland, Ovary, Stomach, Colon, Bone, Kidney, Liver, Lung & Bronchus, Peritoneum, Respiratory System, Soft Tissue, Testis, Gall Bladder, Brain, Autonomic/Peripheral Nervous System in numbers too small to report.

FINANCIAL IMPACT

Stem cell transplants are very expensive. The total cost for the treatment can be approximately $100,000 or more. According to the ACS, transplants are still considered experimental for a lot of cancers, especially solid tumors.[18]

An article in Health Affairs entitled "The Controversy Over High-Dose Chemotherapy With Autologous Bone Marrow Transplant For Breast Cancer" dated September/October 2001 discussed the lessons for insurance coverage decision making regarding the case of HDC-ABMT. The article reported that approximately 42,680 breast cancer patients were treated with autologous bone marrow transplants between 1990 and 1999. The nation's health insurers spent over $3.4 billion during that ten-year time frame for a treatment that over the long run offered no medical advantage than the standard-dose chemotherapy. These costs of treatment eventually were passed on to the plans' subscribers and taxpayers.[19]

Section 38.2-3419.1 of the Code of Virginia and the State Corporation Commission's Rules Governing the Reporting of Cost and Utilization Data Relating to Mandated Benefits and Mandated Providers (14 VAC 5-190-10) require every insurer, health service plan, and HMO to report to the State

Corporation Commission cost and utilization information for each of the mandated benefits in Sections 38.2-3408 through 38.2-3419, and 38.2-4221 of the Code of Virginia. Report Document Number 289 covered the 2005 calendar year reporting period and provided the following information relating to the costs associated with bone marrow transplants. [20]

Premium Data and Premium Impact

Companies are required to use actual claim experience and other relevant actuarial information to determine the premium impact of each mandated benefit.[21]

To assess the impact of mandated benefit or mandated offers on premiums applicable to individual contracts and group certificates, the companies are required to report the total annual premium that would be charged for what is considered to be a standard health insurance contract and/or group certificate in Virginia. The total annual premium is reported, per unit of coverage, for individual contracts and group certificate, including single and family coverage.[22]

Table 1 and 1(a) below is informative in assessing, on the average, the premium cost of providing coverage for bone marrow transplants, relative to the overall cost of a standard contract, group certificates, and HMOs for single coverage and family coverage in Virginia.[23]

Table 1: Premium Impact on Individual Contracts and Group Certificates		
Individual	Single	Family
Bone Marrow Transplants*	.34%	.47%
Group		
Bone Marrow Transplants*	1.87%	1.76%
Table 1(a): Premium Impact on HMOs Individual Contracts and Group Certificates		
Individual	Single	Family
Bone Marrow Transplants*	.00%	.00%
Group		
Bone Marrow Transplants*	1.38%	.75%

*Mandated offer of coverage

Claim Experience and Financial Impact

Companies are required to report the total claims paid or incurred under individual contracts and group certificates. The average claim cost per contract or certificate is computed by dividing the total claims attributable to the mandated offer by the number of applicable contracts or certificates. The average percent of total claims for a specific mandated offer is computed by dividing the total claim payment associated with the mandated offer by the total claims reported by the insurers and health services plans.[24]

Table 2 below summarizes the claims experience for total claims for individual and group contracts for the three most recent reporting years, 2003, 2004, and 2005. [25]

Table 2 Claims Experience for Average Percent of Total Claims			
Individual	2003	2004	2005
Bone Marrow Transplants*	.01	.60	.56
Group	2003	2004	2005
Bone Marrow Transplants*	.27	.23	.61

*Mandated offer of coverage

Utilization of Services

Companies are required to report the number of visits and the number of days attributable to each mandated benefit for which claims were paid during the reporting period.[26]

Table 3 below represents the average number of visits per certificate for bone marrow transplants and the average number of days per certificate for the treatment. [27]

Table 3: Utilization of Services: Group Coverage		
Group	Average Visits per Certificate	Average Days per Certificate
Bone Marrow Transplants*	.05	.02

*Mandated offer of coverage

MEDICAL EFFICACY

ACS explained some of the advantages and disadvantages of autologous, allogeneic, and syngeneic stem cell transplants. During the autologous stem cell transplant, the patients are getting their own cells back, and there is no risk to the immune system. However, during this procedure, the cancer cells may be harvested along with the stem cells and then put back into a patient's body. ACS stated "doctors sometimes treat the cells first with anticancer drugs or other therapies to reduce the number of cancerous cells that may be present. This is called purging."[28]

ACS noted that during an allogeneic stem cell transplant, the donor stem cells produce their own immune cells that help destroy any cancer cells that remain after high-dose treatment. Another possible advantage is that the donor can often be recalled if needed to donate more stem cells. Stem cells from healthy donors are also free of cancer cells. However, there are some drawbacks to this type of transplant. Graft rejection can occur when the donor cells are destroyed by the patient's immune system before settling in the bone marrow. Another concern is that the donor cells will create new immune cells that attack the patient's body, or the donor stem cells may recognize the patient's cells as foreign territory and turn against their new home. This attack is called graft-versus-host disease. There is also a very small risk of certain infections from the donor cells. With syngeneic stem cell transplant, the donor and the recipient will have identical tissue types, and the graft-versus-host disease is not a concern. However, a drawback to this transplant is that it will not destroy any remaining cancer cells. [29]

According to ACS, a non-myeloablative transplant, which does not require high doses of chemotherapy, is very useful for older patients. However, this procedure may not work well for patients with various diseases. ACS noted that during 2007, this procedure was still relatively new, and long-term outcomes were not yet available.[30]

The NCI article, "High-Dose Chemotherapy for Breast Cancer: History," explained that the majority of patients received the high-dose regimens outside of clinical trials, and, therefore, the success or failure rates of the treatments could not be reliably established. Therefore, during the late 1990s, studies from randomized trials were needed to determine whether women with breast cancer benefited from high-dose therapy with transplants. In early 2000, two studies of clinical trials (Netherlands Cancer Institute and U.S. Intergroup Study) reported that high doses of chemotherapy were no more effective than standard chemotherapy for women with advanced or high-risk breast cancer. [31]

An article in Academy Health, dated January 2005, entitled "Evaluating Promising New Treatments for Life-Threatening Disease: Implications of the High-Dose Chemotherapy/Autologous Bone Marrow Transplantation (HDC/ABMT) Experience for Treating Breast Cancer" discussed three reasons that HDC/ABMT for treating breast cancer spread widely before its effectiveness

was established and the decisions to stop the diffusion. First, a researcher stated:

> Spread was driven by the default system of decision making, demands of desperate patients, advice of treating physicians, reaction to insurance coverage denials, litigation, entrepreneurial oncology, federal and state mandates, and the media. [32]

Second, the researchers explained that conflicting values occurred during the entire evaluation process:

> Patient demands for early access to an experimental therapy, especially by individuals with a life-threatening illness for whom existing therapy is inadequate, must be balanced with society's need to evaluate a procedure's effectiveness and protect the integrity of the evaluation process.[33]

Third, the researchers noted that an institutional deficit existed regarding the evaluation of new interventions, especially when treatments are considered life-savings but extremely expensive:

> A public-private partnership involving the National Institutes of Health, clinical scientists, insurers, and patient representatives to oversee the evaluation of medical procedures as they move from small, single-site, hypothesis-generating Phase 2 studies to large, multi-site, hypothesis-testing Phase 3 randomized clinical trials. [34]

An article entitled "High-Dose Chemotherapy for Breast Cancer: Clinical Trials Overview" posted on the NCI's website reviewed April 12, 2005 compared the effectiveness of the clinical trials of high-dose chemotherapy and blood cell transplants with a standard treatment for various stages of breast cancer. One high-priority trial enrolled 783 patients with stage II or III breast cancer and more than 10 positive lymph nodes. Early results from the clinical trials displayed no difference in survival between patients that had received high-doses therapy and patients that had received intermediate-dose therapy. Another second high-priority trial enrolled 553 patients that had metastatic (spreading to other organs) breast cancer. Based on a random testing of 89 patients that had received the standard chemotherapy and 110 patients with high-dose chemotherapy plus transplant, it was reported that after three years of observing the patients, there were no considerable differences in survival rates or in the progression of the disease to become worse. The researchers noted that infection, vomiting, diarrhea and other side effects were detected more in the group that had received high-dose chemotherapy. [35]

An article entitled "High-Dose Chemotherapy with Stem Cell Transplantation: Still No Clear Benefit" reviewed on the NCI's website on April 12, 2005 examined the benefits of high-dose chemotherapy with stem cell transplantation for women at high risk of a breast cancer relapse. The Netherlands Cancer Institute study consisted of 885 patients of women younger than 56 years old, and the U.S. Intergroup Study consisted of 511 women no

older than 60 years of age. The overall survival rates did not significantly improve for patients receiving high-dose chemotherapy with stem cell transplantation. It was also noted that nine patients died as a result of transplantation complications, and nine patients developed preleukemia or acute myeloid leukemia as a result of receiving high-dose chemotherapy treatments. The author suggested that conventional therapy should remain the standard of care for women with high-risk breast cancer.[36]

According to an article in Health Affairs entitled "Making Policy When The Evidence Is In Dispute," dated January/February 2005, good health policymaking includes deliberation of much more than clinical evidence. The authors discussed one of four recent clinical policy controversies of how debates about the evidence have occurred from predictable differences of opposing parties regarding high-dose chemotherapy and bone marrow transplants for breast cancer. The article explained that experts were promoting this new treatment based only on limited evidence from Phase II trials with no historical evidence. It was noted that there were conflicting views in courts between experts that were in favor of the transplantations and those that questioned their benefits. The article explained that hospitals quickly added this benefit to their alternative treatments and eventually put pressure on legislatures to mandate that insurance companies cover the treatment. The article reported that after an estimated 600 premature deaths, it was determined that ABMT provided no benefit over conventional therapy. The article explained that some patients may have acted on premature evidence because some felt that they had very little to lose. It was explained that less attention was directed towards the risks of the treatment and its adverse effects on their quality of life.[37]

The article in the Health Affairs stated that researchers, policymakers for the health plans, and the National Breast Cancer Coalition (NBCC) have all recognized the need for thoroughly conducted trials with clinical endpoints. After the preliminary reports of disappointing results in the clinical trials for ABMT, NBCC stated:

> Unfortunately, because so many physicians performed this procedure outside of a clinical trial setting, we do not know how effective it is. Had these procedures been performed within a randomized clinical trial we would have had the answer some time ago. The high cost of ineffective therapy was borne by a vulnerable group of patients and the public at large, while the role of politicians mandating individual treatments set a troubling precedent in an era of high-tech medicine and vocal interest groups.[38]

The article, "The Controversy Over High-Dose Chemotherapy With Autologous Bone Marrow Transplant For Breast Cancer," discussed another concern that treatment with HDC-ABMT involves serious burdens for the patients. Symptoms include:

> Acute-onset toxicities (in addition to vomiting and diarrhea) include sepsis, pulmonary failure, veno-occlusive disease, cardiac failure, nephrotoxicity, hemorrhagic cystitis, and cardiac toxicity. Among the chronic sequelae that may ensue are acute myelogenous leukemia or myelo-dysplastic syndrome, bone marrow insufficiency, psychosexual disorders, and heightened vulnerability to opportunistic infections in the first year after treatment. HDC-ABMT also can kill. The recent randomized clinical trials reported treatment-related mortality rates ranging from zero to 7 percent among HDC-ABMT recipients, while the standard-dose control arms of the studies had no such deaths.[39]

The article stated that when health plans started covering HDC-ABMT outside of clinical trials, the interests of the patients and society were not heading in the same direction, and, eventually, clinical trials suffered severely. [40]

CURRENT INDUSTRY PRACTICES

The State Corporation Commission Bureau of Insurance recently surveyed 50 of the top writers of accident and sickness insurance in Virginia regarding each of the bills to be reviewed by the Advisory Commission this year. Forty companies responded by July 23, 2007. Nine of the respondents indicated that they have little or no applicable health insurance business in force in Virginia and, therefore, could not provide the information requested.

Of the 31 respondents that completed the Bureau of Insurance survey, fifteen reported that they would provide coverage for ABMT and stem cell transplants in the absence of a mandate if the transplant was medically necessary and not experimental. Twelve companies reported that they would not provide coverage in the absence of a mandate. The remaining four companies did not respond to the question.

The survey asked the number of claims reported for ABMT or stem cell transplants. Initially, eight companies reported a total of sixty-two claims for ABMT or stem cell transplants for breast cancer during the past five years. The BOI and JLARC staff requested additional information about the claims. Six of the eight insurance companies later reported that 47 of the 62 reported claims for ABMT or stem cell transplants for breast cancer were for treatments of other conditions, performed through clinical trials, or coding errors. The remaining two companies did not provide additional information.

Eight insurers reported cost figures that ranged from $.04 to $ 2.00 per month per individual policy to provide coverage for ABMT. Seven insurers reported cost figures that ranged from $.04 to $ 2.00 per month per individual policy to provide coverage for stem cell transplants. Nine insurers reported cost figures that ranged from $.04 to $16.12 per month per group contract to provide

coverage for ABMT. Eight insurers reported cost figures that ranged from $.04 to $16.12 per month per group contract to provide coverage for stem cell transplants.

Insurers were asked if they currently provide coverage for medically necessary dose-intensive chemotherapy/autologous bone marrow transplants or stem cell transplants for any conditions other than breast cancer. A total of fourteen companies indicated that they would provide coverage for some conditions. The prevalent conditions covered among the companies were multiple myeloma, hodgkins disease, leukemia, lymphomas, neuroblastoma, germ cell neoplasms (testicular and non-testicular), myelodysplastic, aplastic anemia, immunodeficiency disease, thalassemia, and solid tumors. Some companies indicated they provide coverage for other specific conditions of cancer. Three insurers reported an average cost for ABMT and stem cell transplants that ranged from $87,860 to $500,000 per transplant.

Two companies stated that evidence-based medicine has proven that these procedures are not effective in the treatment of breast cancer and are no longer standards of care for this diagnosis.

One company stated that according to medical literature (e.g. Hayes Technology), treatments by ABMT and stem cell transplants are not recommended for the treatment of breast cancer.

SIMILAR LEGISLATION IN OTHER STATES

According to information from the National Insurance Law Service, 9 states have passed some type of legislation requiring coverage for bone marrow transplants. Of those 9 states, Georgia, Missouri, Tennessee, and Virginia require a mandated offer of coverage bone marrow transplants.

Florida provides that insurers or health maintenance organizations shall not exclude coverage for bone marrow transplant procedures recommended by the referring physician and the treating physician under a policy exclusion for experimental, clinical investigative, educational, or similar procedures contained in any individual or group health insurance policy or health maintenance organization contracts if the particular use of the bone marrow transplant procedure is determined to be accepted within the appropriate oncological specialty. Florida requires that coverage of bone marrow transplant procedures must include costs associated with the donor-patient to the same extent and limitations as costs associated with the insured, except the reasonable costs of searching for the donor may be limited to immediate family members and the National Bone Marrow Donor Program.

Georgia requires individual and group accident and sickness insurance plans, policies, or contracts to make available, either as a part of or as an optional endorsement, to all such policies providing major medical insurance

coverage for bone marrow transplants for the treatment of breast cancer and Hodgkin's disease.

Kentucky requires that all insurers issuing individual health insurance policies that provide coverage for treatment of breast cancer by chemotherapy on an expense-incurred basis must also provide coverage for treatment of breast cancer by high-dose chemotherapy with autologous bone marrow transplantation or stem cell transplantation.

Massachusetts requires that health maintenance organization contracts provide coverage for a bone marrow transplant or transplants for persons who have been diagnosed with breast cancer that has progressed to metastatic disease.

Missouri requires an offer of coverage for the treatment of breast cancer by dose-intensive chemotherapy/autologous bone marrow transplants or stem cell transplants when performed pursuant to nationally accepted peer review protocols utilized by breast cancer treatment centers experienced in dose-intensive chemotherapy/autologous bone marrow transplants or stem cell transplants.

New Hampshire requires insurers of group or blanket accident or health insurance providing benefits for medical or hospital expenses to provide to residents and those whose principal place of employment is in the state of New Hampshire coverage for expenses arising from the treatment of breast cancer by autologous bone marrow transplants according to protocols reviewed and approved by the NCI.

New Jersey requires coverage for the treatment of cancer by dose-intensive chemotherapy/autologous bone marrow transplants and peripheral blood stem cell transplants when performed by institutions approved by the NCI or pursuant to protocols consistent with the guidelines of the American Society of Clinical Oncologists.

Tennessee requires coverage for the treatment of cancer by dose-intensive chemotherapy/autologous bone marrow transplants or stem cell transplants for patients or enrollees included in the TennCare program. Insurers proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical, or major medical coverage on an expense-incurred basis; each corporation providing individual or group accident and sickness subscription contracts; and each health maintenance organization providing a health care plan for health care services must offer and make available such coverage.

REVIEW CRITERIA

SOCIAL IMPACT

a. The extent to which the treatment or service is generally utilized by a significant portion of the population.

The Virginia Cancer Registry (VCR) reported the following use of bone marrow transplant procedures or stem cell harvest and infusion during 1990 – 2005*. [41]

Therapy by Primary Site	**Breast**
Bone marrow transplant unspecified type	70
Bone marrow transplant autologous	52
Bone marrow transplant allogeneic	19
Stem cell harvest and infusion	86
Total	227

The Richmond Times Dispatch article entitled "Breast Cancer and Virginia Women," dated April 12, 2007, reported that between 1998 and 2002, approximately 4,600 women were diagnosed with invasive breast cancer in Virginia. The article noted that between 1998 and 2005, approximately 1,059 women died from breast cancer. It was also reported that between 1998 and 2002, 51% of those cases of breast cancers were diagnosed at a local stage of the disease.[42]

The VCUHS transplant program was established in 1988 and performed autologous, allogeneic and cord blood transplantation for both adults and children for the treatment of cancer and other diseases. Since the opening of the VCUHS bone marrow transplantation program, more than 1,450 transplants have been performed. During the time that clinical trials were underway for testing the treatment of breast cancer with stem cell transplant, VCUHS performed 345 autologous stem cell transplants for women with breast cancer. The transplants were largely conducted between 1991 and 1999. VCUHS noted that 2001 was the last year that a breast cancer patient was treated with an autologous stem cell transplant.[43]

b. The extent to which insurance coverage for the treatment or service is already available.

Coverage is currently available because of Virginia's current requirement for a mandated offer of coverage for the treatment of breast cancer by dose-intensive chemotherapy/autologous bone marrow transplants or stem cell transplants. Section 38.2-3418.1:1 requires group accident and sickness insurance policies to offer and make available coverage for the treatment of breast cancer by dose-intensive chemotherapy/autologous bone marrow transplants or stem cell transplants when performed pursuant to protocols approved by the institutional review board of any United States medical teaching

college including, but not limited to, NCI protocols that have been favorably reviewed and utilized by hematologists or oncologists experienced in dose-intensive chemotherapy/autologous bone marrow transplants or stem cell transplants.

Section 2.2-2818 requires coverage for state employees for the treatment of breast cancer by dose-intensive chemotherapy with autologous bone marrow transplants or stem cell support when performed at a clinical program authorized to provide such therapies as a part of clinical trials sponsored by the NCI.

In a 2007 State Corporation Commission Bureau of Insurance survey of the fifty top writers of accident and sickness insurance in Virginia, 31 companies currently writing applicable business in Virginia responded. Of the 31 respondents that completed the Bureau of Insurance survey, fourteen (45%) reported that they would provide coverage for ABMT and stem cell transplants in the absence of a mandate if the transplant was medically necessary and not experimental. Ten companies reported that they would not provide coverage in the absence of a mandate. One company reported coverage for ABMT would continue; however, they would not provide coverage for stem cell transplants in the absence of a mandate. The remaining six companies did not respond to the question.

c. If coverage is not generally available, the extent to which the lack of coverage results in persons being unable to obtain necessary health care treatments.

Coverage is generally available because of the mandated offer of coverage; however, individuals covered under group contracts are unable to obtain this health care treatment if the group policyholder does not accept the coverage.

d. If the coverage is not generally available, the extent to which the lack of coverage results in unreasonable financial hardship on those persons needing treatment.

Coverage is currently available as a mandated offer of coverage for the treatment of breast cancer by dose-intensive chemotherapy/autologous bone marrow transplants or stem cell transplants. Coverage is also available for clinical trials.

Section 38.2-3418.8 in the Code of Virginia requires coverage for clinical trials for treatment studies on cancer. Coverage for patient costs incurred during clinical trials for treatment studies on cancer shall be provided if the treatment is being conducted in a Phase II, Phase III, or Phase IV clinical trial. Such treatment may be provided on a case-by-case basis if the treatment is being provided in a Phase I clinical trial.

If enacted, House Bill 2426 and Senate Bill 991 would repeal the mandated offer of coverage for the treatment of breast cancer by dose-intensive chemotherapy/autologous bone marrow transplants or stem cell transplants and some patients may have to pay for the treatments out of pocket. The ACS stated that stem cell transplants are very expensive, and total costs for the treatment can be approximately $100,000 or more. According to the JLARC assessment, a physician at VCU Medical Center estimated that the procedure would cost between $100,000 and $200,000.[44]

e. The level of public demand for the treatment or service.

The VBCF stated that currently, high-dose chemotherapy with bone marrow transplant or stem cell transplant is not considered the standard of care for breast cancer and the public demand for these treatments is limited.[45]

One opponent provided comments against House Bill 2426 and Senate Bill 991 at the public hearing. A cancer survivor with Stage IV breast cancer who is also a member of the Advisory Board of Massey Cancer Center stated that she was part of the driving force in 1994 that supported the mandated coverage of bone marrow transplants for breast cancer. She testified that during her Stage IV cancer, conventional treatment was unsuccessful, and the only treatment regimen for her cancer was a stem cell transplant. She further stated that stem cell transplants are still being done successfully for breast cancer patients in limited situations, and that a small number of patients can benefit from the transplants.

f. The level of public demand and the level of demand from providers for individual and group insurance coverage of the treatment or service.

No information was received from physicians in support of retaining the mandate. One physician explained that the mandated treatment is no longer used on a routine basis. Coverage is available under clinical trials for those who might benefit from the transplant that are accepted into a trial.

g. The level of interest of collective bargaining organizations in negotiating privately for inclusion of this coverage in group contracts.

The level of interest of collective bargaining organizations in negotiating privately for inclusion of this coverage in group contract is unknown.

h. Any relevant findings of the state health planning agency or the appropriate health system agency relating to the social impact of the mandated benefit.

The Advisory Commission is not aware of any findings of the state health planning agency or health system agency relating to the social impact of treating breast cancer patients with dose-intensive chemotherapy/autologous bone marrow transplants or stem cell transplants.

During the 1992 Session of the General Assembly, the House Committee on Corporations, Insurance and Banking referred a bill to mandate coverage for bone marrow transplants to the Advisory Commission. House Bill 539 was introduced by Delegate David G. Brickley and would have required insurers to offer and make available coverage for the treatment of cancer by autologous bone marrow transplants. During that time, the Advisory Commission had concerns that the treatment may not have been medically efficacious. They voted to recommend against the enactment of House Bill 539 (1993 House Document No. 37).

During the 1994 Session of the General Assembly, House Bill 240 was referred to the Advisory Commission for evaluation by the Joint Commission on Health Care. The bill was introduced by Delegate Mary T. Christian and required insurers to offer and make available coverage for the treatment of cancer by dose-intensive chemotherapy and autologous bone marrow transplants or stem cell transplants. At that time, the Advisory Commission recommended the enactment of House Bill 240 with a technical amendment. The amendment clarified that the mandated offer of coverage was to be limited to the treatment of breast cancer. The Advisory Commission recognized the reports of the improved effectiveness of the treatments and the impact a lack of coverage had on Virginia citizens. They voted to recommend the enactment of House Bill 240 (1995 Senate Document No. 9).[46]

FINANCIAL IMPACT

a. The extent to which the proposed insurance coverage would increase or decrease the cost of treatment or service over the next five years.

No information was provided by proponents or opponents that would indicate that House Bill 2426 or Senate Bill 991 would increase or decrease the cost of treatment over the next five years.

b. The extent to which the proposed insurance coverage might increase the appropriate or inappropriate use of the treatment or service.

The repeal of mandated coverage for autologous bone marrow transplants or stem cell transplants for breast cancer is not expected to increase the appropriate or inappropriate use of treatments. The current use of the treatments is very limited.

The VBCF stated that high dose-intensive chemotherapy with bone marrow transplants or stem cell transplants is not considered a standard of care for breast cancer patients. Autologous bone marrow and stem cell transplants for breast cancer do not need to be mandated for coverage by insurance companies except in the context of clinical trials.[47]

c. The extent to which the mandated treatment or service might serve as an alternative for more expensive or less expensive treatment or service.

The JLARC assessment reported that conventional chemotherapy is the most common alternative to high-dose chemotherapy with autologous bone marrow transplant or stem cell transplant:

> Most of the clinical trials reviewed by JLARC staff compared the outcomes of patients who received that conventional chemotherapy had less severe side effects than high dose chemotherapy with autologous bone marrow transplant or stem cell transplant (HDC-ABMT/SCT) to patients who received conventional therapy, and most of these trials found that all patients had similar outcomes. Conventional chemotherapy also has less severe side effects than HDC-ABMT/SCT and costs three to five times less. [48]

d. The extent to which the insurance coverage may affect the number and types of providers of the mandated treatment or service over the next five years.

It is unlikely that the repeal of the proposed mandate would significantly affect the number and types of providers in the next five years. There are very few, if any, providers in Virginia that offer the treatment.

e. The extent to which insurance coverage might be expected to increase or decrease the administrative expenses of insurance companies and the premium and administrative expenses of policyholders.

Eight insurers reported cost figures that ranged from $.04 to $ 2.00 per month per individual policy to provide coverage for ABMT. Seven insurers reported cost figures that ranged from $.04 to $ 2.00 per month per individual policy to provide coverage for stem cell transplants. Nine insurers reported cost

figures that ranged from $.04 to $16.12 per month per group contract to provide coverage for ABMT. Eight insurers reported cost figures that ranged from $.04 to $16.12 per month per group contract to provide coverage for stem cell transplants.

f. The impact of coverage on the total cost of health care.

The VAHP testified in favor of House Bill 2426 and Senate Bill 991 at the public hearing. They reported that from 1990 to 1999 the nation's health insurers spent $3.4 billion on the treatments of autologous bone marrow transplants and stem cell transplants and over the long run the treatments resulted in no medical benefit over standard dose chemotherapy. [49]

At this time, the use of conventional chemotherapy and other treatments should not increase significantly because very few people are receiving autologous bone marrow or stem cell transplants.

MEDICAL EFFICACY

a. The contribution of the benefit to the quality of patient care and the health status of the population, including the results of any research demonstrating the medical efficacy of the treatment or service compared to alternatives or not providing the treatment or service.

The Cochrane Database of Systematic Review (2005), entitled "High Dose Chemotherapy and Autologous Bone Marrow or Stem Cell Transplantation Versus Conventional Chemotherapy for Women with Early Poor Prognosis Breast Cancer" analyzed the outcomes of survival rates and quality of life that included 2,535 women randomized to receive high-dose chemotherapy and 2,529 women randomized to receive conventional chemotherapy. The researchers selected thirteen randomized controlled trials comparing high-dose chemotherapy with conventional chemotherapy for women with early poor prognosis breast cancer. The high-dose chemotherapy autologous bone marrow or stem cell transplants resulted in a statistically significant benefit in event-free survival for women at three and four years. However, in the overall survival, there was no significant difference between the two groups that received high-dose chemotherapy or conventional therapy. Morbidity was more common and severe in the high-dose chemotherapy group. The authors concluded that there was no sufficient data to support the routine use of high dose chemotherapy autologous bone marrow or stem cell transplant for women with early poor prognosis breast cancer.[50]

The National Breast Cancer Coalition (NBCC)'s "Position Statement on High-Dose Chemotherapy with Bone Marrow Transplant or Stem Cell Support, October 2003" stated that there is no scientific evidence to support the use of

high-dose chemotherapy with bone marrow or stem cell transplant for the treatment of breast cancer. Clinical trials have shown that this procedure is not more effective than standard therapy. NBCC believed that no breast cancer patient should receive high-dose chemotherapy with bone marrow or stem cell transplant unless the patient is participating in a randomized, controlled clinical trial. [51]

The NCI article, "High-Dose Chemotherapy for Breast Cancer: History," explained the majority of patients received the high-dose regimens outside of clinical trials, meaning that the success or failure of the treatments could not be reliably established. During the late 1990s studies from randomized trials were needed to determine whether women with breast cancer benefited from high-dose therapy with transplants. During the early 2000, two studies of clinical trials (Netherlands Cancer Institute and U.S. Intergroup Study) reported that high doses of chemotherapy were no more effective than standard chemotherapy for women with advanced or high-risk breast cancer. [52]

The VAHP testified in favor of House Bill 2426 and Senate Bill 991 at the public hearing. They stated that evidence has proven that autologous bone marrow transplants and stem cell transplants are not effective treatments for breast cancer. VAHP believed that the last treatments of autologous bone marrow transplants and stem cell transplants for breast cancer were performed in 2001; raised concerns that the treatments created more risk, harm, and higher mortality for some patients; and noted that the benefit appears to have no more medical benefit than the standard treatments. VAHP stated that breast cancer patients are getting the standard of care that the community deems appropriate and effective treatment. [53]

VAHP provided written comments in support of House Bill 2426 and Senate Bill 991 regarding coverage for bone marrow transplants:

> Science has proven that this treatment modality is not effective in the management of breast cancer and may even be harmful to patients. The January/February 2005 edition of the respected journal Health Affairs cited mandated coverage of ABMT as an example of the inadvisability of mandating specific medical procedures. ABMT was initially hailed as a breakthough in treating breast cancer, despite only preliminary clinical trials. Evidence-based medicine has displayed that by establishing mandates based on emotion rather than science, the opposite effect of what was originally intended may occur. Extensive clinical trials determined that ABMT may have detrimental effects on the patient in addition to the treatment's inability to successfully treat the cancer. Health plans in Virginia establish their treatment and coverage guidelines using documented scientifically-verified medical protocols. By covering evidence-based procedures, Virginia's health plans seek to ensure that their enrollees receive quality and effective care. [54]

The VBCF provided written comments stating their support for insurance coverage for breast cancer therapies and devices that are evidence-based and cost effective:

> VBCF never endorsed insurance coverage for bone marrow transplants in breast cancer patients outside of randomized, controlled clinical trials because evidence they were more effective than standard therapies did not exist. Because so many bone marrow transplants were done outside of clinical trials it took much longer than it should have to gain the evidence needed to prove bone marrow transplants did not extend lives and were very costly.[55]

The VBCF also stated it would not oppose the repeal of the provision that has required insurers to offer and make available coverage for the treatment of breast cancer by high-dose chemotherapy with bone marrow or stem cell transplants if coverage is available when the patient is participating in a clinical trial.[56]

The JLARC assessment noted that Phase III study results that high dose chemotherapy and the transplants do not provide "any additional benefit to the overall population of breast cancer patients." [57]

b. If the legislation seeks to mandate coverage of an additional class of practitioners:

1) The results of any professionally acceptable research demonstrating the medical results achieved by the additional class of practitioners relative to those already covered.

Not applicable.

2) The methods of the appropriate professional organization that assure clinical proficiency.

Not applicable.

EFFECTS OF BALANCING THE SOCIAL, FINANCIAL AND MEDICAL EFFICACY CONSIDERATIONS

a. The extent to which the benefit addresses a medical or a broader social need and whether it is consistent with the role of health insurance.

Proponents believe that House Bill 2426 and Senate Bill 991 address medical and social needs since high dose-intensive chemotherapy/autologous bone marrow transplants or stem cell transplants are no longer the standard of care for the treatment of breast cancer outside of clinical trials. The benefit is consistent with the role of health insurance.

The JLARC assessment noted that although the current mandate for high-dose chemotherapy with autologous bone marrow transplant or stem cell transplant is consistent with the role of insurance, the need appears to be minimal because it is no longer the standard of care, and has a low demand and utilization rate:

> In the 13 years since the mandate's passage, the treatment approach to breast cancer has dramatically changed, and high-dose chemotherapy with autologous bone marrow transplant or stem cell transplant has been found to provide no additional benefit over other treatment options. These two factors have nearly eliminated the social need for this treatment. Even without this mandate, insurers will still be required to cover this treatment if it is performed as part of a clinical trail, which according to medical experts is the most appropriate setting for this treatment.[58]

b. The extent to which the need for coverage outweighs the costs of mandating the benefit for all policyholders.

VAHP testified in favor of House Bill 2426 and Senate Bill 991 at the public hearing. VAHP reported that from 1990 to 1999, the nation's health insurers spent $3.4 billion on the treatments of autologous bone marrow transplants and stem cell transplants; over the long run, the treatments resulted in no medical benefit over standard dose chemotherapy. [59]

The JLARC assessment stated that even though the cost of treatment for high-dose chemotherapy with autologous bone marrow transplant or stem cell transplant is very high, there is little need for the treatment because medical professionals no longer consider it as a standard of care:

> This keeps the premium cost of the mandate relatively low for policyholders. When treatment is recommend for breast cancer patients, it is provided as part of a clinical trial, according to medical experts. Even without the mandate, these patients would still be able to access this treatment through a clinical trial, and insurance

coverage would be provided due to the separate clinical trials mandate. [60]

c. The extent to which the need for coverage may be solved by mandating the availability of the coverage as an option for policyholders.

Section 38.2-3418.1:1 in the Code of Virginia currently requires health insurers to offer and make available coverage for the treatment of breast cancer by dose-intensive chemotherapy/autologous bone marrow transplants or stem cell transplants.

RECOMMENDATION

The Advisory Commission voted on September 20, 2007 to recommend the enactment of House Bill 2426 (Yes-7, No-2). The members voted unanimously (Yes-9, No-0) to recommend the enactment of Senate Bill 991 and conform it to House Bill 2426.

CONCLUSION

The Advisory Commission believes that based upon the information presented**,** high-dose intensive chemotherapy/autologous bone marrow transplants or stem cell transplants are currently not considered the standard of care for the treatment of breast cancer. The members believe that a mandate is no longer needed. Patients have opportunities to participate in clinical trials to obtain these procedures if their particular condition warrants the treatments and they meet the requirements of a trial because of the mandated coverage of clinical trials in Section 38.2-3418.8.

ENDNOTES

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[2] American Cancer Society, "Bone Marrow and Peripheral Blood Stem Cell Transplants" www.cancer.org 2/26/07.

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[4] Virginia Commonwealth University, Massey Cancer Center, "Bone Marrow Transplantation" www.massey.vcu.edu 3/28/07

[5] American Cancer Society. State Facts and Figures. Virginia County-level Incidence Data 2006. www.cancer.org.

[6] Virginia Commonwealth University, Massey Cancer Center, "Bone Marrow Transplantation" www.massey.vcu.edu 3/28/07

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[15] VCU Health System, Massey Cancer Center. April 5, 2007

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[19] Michelle M. Mello and Troyen A. Brennan, "The Controversy Over High-Dose Chemotherapy With Autologous Bone Marrow Transplant For Breast Cancer," *Health Affairs*, vol. 20-no. 5 September/October 2001.

[20] Report of the State Corporation Commission on the Financial Impact of Mandated Health Insurance Benefits and Providers Pursuant to Section 38.2-3419.1 of the Code of Virginia: 2005 Reporting Period. Report Document No. 289.

[21] Report of the State Corporation Commission on the Financial Impact of Mandated Health Insurance Benefits and Providers Pursuant to Section 38.2-3419.1 of the Code of Virginia: 2005 Reporting Period. Report Document No. 289.

[22] Report of the State Corporation Commission on the Financial Impact of Mandated Health Insurance Benefits and Providers Pursuant to Section 38.2-3419.1 of the Code of Virginia: 2005 Reporting Period. Report Document No. 289.

[23] Report of the State Corporation Commission on the Financial Impact of Mandated Health Insurance Benefits and Providers Pursuant to Section 38.2-3419.1 of the Code of Virginia: 2005 Reporting Period. Report Document No. 289.

[24] Report of the State Corporation Commission on the Financial Impact of Mandated Health Insurance Benefits and Providers Pursuant to Section 38.2-3419.1 of the Code of Virginia: 2005 Reporting Period. Report Document No. 289.

[25] Report of the State Corporation Commission on the Financial Impact of Mandated Health Insurance Benefits and Providers Pursuant to Section 38.2-3419.1 of the Code of Virginia: 2005 Reporting Period. Report Document No. 289.

[26] Report of the State Corporation Commission on the Financial Impact of Mandated Health Insurance Benefits and Providers Pursuant to Section 38.2-3419.1 of the Code of Virginia: 2005 Reporting Period. Report Document No. 289.

[27] Report of the State Corporation Commission on the Financial Impact of Mandated Health Insurance Benefits and Providers Pursuant to Section 38.2-3419.1 of the Code of Virginia: 2005 Reporting Period. Report Document No. 289.

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[45] Virginia Breast Cancer Foundation (VBCF), August 24, 2007.

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[47] Virginia Breast Cancer Foundation (VBCF), August 24, 2007.

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[51] National Breast Cancer Coalition (NBCC), "Position Statement on High-Dose Chemotherapy with Bone Marrow Transplant or Stem Cell Support," October 2003

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[55] Virginia Breast Cancer Foundation (VBCF), August 24, 2007.

[56] Virginia Breast Cancer Foundation (VBCF), August 24, 2007.

[57] Joint Legislative Audit and Review Commission of the Virginia General Assembly, Evaluation of Proposed Mandated Health Insurance Benefits, "Evaluation of SB 991 and HB 2426: Repeals of Mandated Offer for Autologous Bone Marrow Transplant or Stem Cell Transplant for Breast Cancer," September 2007.

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