REPORT OF THE
SPECIAL ADVISORY COMMISSION ON
MANDATED HEALTH INSURANCE BENEFITS ON

House Bill 539 (1992) Mandated Offer of Coverage for the Treatment of Cancer by Autologous Bone Marrow Transplant

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

HOUSE DOCUMENT NO. 37

COMMONWEALTH OF VIRGINIA
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SENATE OF VIRGINIA

CLARENCE A. HOLLAND
7TH SENATORIAL DISTRICT
VIRGINIA BEACH, MOST OF NORTHWESTERN PART
P.O. BOX 5622
VIRGINIA BEACH, VIRGINIA 23455

December 30, 1992

To: The Honorable L. Douglas Wilder
Governor of Virginia
and
The General Assembly of Virginia

The report contained herein has been prepared pursuant to sections 9-298 and 9-299 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 539 (1992 Session) regarding a proposed mandated offer of coverage for the treatment of cancer by autologous bone marrow transplant.

Respectfully submitted,

Clarence A. Holland, M.D., Chairman
Special Advisory Commission on
Mandated Health Insurance Benefits

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Mandated Health Insurance Benefits

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INTRODUCTION

House Bill 539 was referred to the Special Advisory Commission on Mandated Health Insurance Benefits (Advisory Commission) for evaluation by the House Committee on Corporations, Insurance and Banking during the 1992 session of the General Assembly of Virginia. House Bill 539 is patroned by Delegate David G. Brickley (D-Prince William) and requires that insurers offer and make available coverage for the treatment of cancer by autologous bone marrow transplant.

On May 18, 1992, the Advisory Commission held a public hearing to receive comments from all interested parties regarding House Bill 539. Comments were also received at an April 6, 1992 meeting. Written comments were received from interested parties both before and after the public hearing.

SUMMARY OF THE PROPOSED LEGISLATION

House Bill 539 would add §38.2-3418.2 to the Code of Virginia to require individual or group accident and sickness insurance policies and health service plans and health maintenance organization (HMO) contracts to "offer and make available" coverage for the treatment of cancer by autologous bone marrow transplant (ABMT) when performed pursuant to protocols reviewed and approved by the National Cancer Institute (NCI). The bill requires that deductibles for this coverage under HMO contracts not be greater than for any other health care services and the copayment for the coverage is not to exceed 20%.

The provisions of the bill do not apply to short-term travel, accident only, limited or specified disease policies or short-term renewable policies covering less than six months.

SIMILAR MANDATES IN OTHER STATES

The state of New Hampshire recently passed legislation similar to House Bill 539. The New Hampshire bill was amended to apply only to breast cancer. The bill requires the coverage to be included in health insurance contracts. The legislation will take effect January 1, 1993. No other state has an existing mandate for coverage of ABMT.

The language in House Bill 539, according to a spokesperson with the NCI, would require coverage to be extended to those insureds taking part in ongoing clinical trials utilizing protocols supported by the NCI. The NCI is the federal government's lead agency for research on cancer and is committed to identifying more effective therapies to cure greater numbers of patients. Currently, the NCI has over 100 protocols in its database.

One of the parties involved in the drafting of the New Hampshire legislation suggested that the wording "reviewed and approved by the National Cancer Institute" could be changed to "accepted by the National Cancer Institute" for clarity.

TREATMENT OF CANCER BY AUTOLOGOUS BONE MARROW TRANSPLANT

For a number of years, cancer patients have been treated through the use of chemotherapy. With this treatment, certain types of cancer patients can be cured or put in long-term remission. The chemotherapy drugs kill cancer cells. However, these drugs also kill the patient's bone marrow and therefore, limit the amount of chemotherapy that can be given.

In recent years, cancer centers have addressed this problem by using autologous bone marrow transplantation. Before the patient is given high dose chemotherapy, approximately a quart of bone marrow is removed from the patient's hips. This is called "harvesting" the bone marrow. The bone marrow that is taken from the patient's body is frozen at very low temperatures. After the high dose chemotherapy is administered and has cleared the patient's body, the "harvested" bone marrow is returned to the patient's body and it begins to make the vital blood elements.

Autologous bone marrow transplantation refers to procedures where the recipient is a self-donor as opposed to allogeneic bone marrow transplantation where the marrow comes from another donor.

The use of autologous rather than allogeneic marrow avoids complications such as graft-versus-host disease and immuno-suppression. It also permits treatment of patients who do not have an appropriate HLA (human leukocyte antigen) matched donor.

SAFETY AND EFFECTIVENESS OF ABMT

According to the National Center for Health Services Research and Health Care Technology (NCHSR), clinical trials employing ABMT have demonstrated that its use can successfully rescue some patients and provide complete hematologic recovery. In some cases of Hodgkin's disease, non-Hodgkin's lymphoma, neuroblastoma, and acute leukemia, a number of patients who would not have been expected to survive conventional therapy have achieved long-term survival following ABMT. The clinical trials published to date, however, have not provided definitive evidence of the benefit of ABMT for the treatment of acute leukemia in relapse, chronic granulocytic leukemia, or solid tumors other than neuroblastoma.

The NCHSR (now the Agency for Health Care Policy and Research) is the federal agency that evaluates the safety and

effectiveness of medical technologies being considered for coverage by Medicare and other federally funded programs such as CHAMPUS. NCHSR publication of research findings does not necessarily represent approval or official endorsement by the NCHSR or the U.S. Department of Health and Human Services.

Currently the medical community is divided on the use of ABMT for other types of cancer. There are studies demonstrating the positive use of ABMT 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 advise caution, particularly because of the fact that they consider the mortality rate for the treatment itself to be significant. One of the arguments against the use of ABMT in the treatment of certain types of cancer is that the outcome of many of the studies conducted is 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 ABMT or to compare ABMT to alternative therapies. According to some, duration of disease-free survival following ABMT does not appear to be substantially longer than historical survival without ABMT.

The NCI has begun a study on breast cancer that will include 1,200 women nationally. They will be divided into two groups of 600 each. One group will receive ABMT with high dose chemotherapy and the other half will receive conventional dose chemotherapy. Each group will be documented carefully and evaluated over several years. Blue Cross and Blue Shield of Virginia is one of the participants in the study. According to the NCI, these studies are essential since only through formal, well-performed clinical trials can the effectiveness and toxicity of ABMT in breast cancer patients be determined.

The NCI also advises that bone marrow transplantation is a highly technical and expensive treatment, with costs usually in excess of $200,000, although costs may be as low as $70,000. Costs are incurred outside the hospital as well. Even though the actual hospital stay may be one to two months, patients may need to stay near the treatment center for an additional two to three months for follow-up care.

Statistics from the American Cancer Society estimate that there will be 26,000 new cancer cases in Virginia in 1992 and 12,100 cancer deaths. New cases of breast cancer are projected to total 4,200. Projections for other types of cancers are: lung 4,100, colorectal 3,600, prostate 3,000, uterine 1,000, skin melanoma 750, oral 700, pancreas 600 and leukemia 600. The number of cases for which ABMT will be the recommended course of treatment is not known.

AVAILABILITY OF INSURANCE COVERAGE

Many insurance companies pay for ABMT treatment for some types of cancer, but not for others. When coverage is denied it is usually because the insurer considers ABMT to be experimental or investigative in the treatment of that particular type of cancer.

Although the following list does not imply automatic coverage, a major university hospital has reported that the following insurance companies have paid for ABMT with high dose chemotherapy in patients with breast cancer:

Aetna
Blue Cross & Blue Shield of Alabama
Blue Cross & Blue Shield of New Jersey
Blue Cross & Blue Shield of North Carolina
Blue Cross & Blue Shield of Maine
Blue Cross & Blue Shield of South Carolina
Connecticut General
Equitable
Jefferson Pilot
Metropolitan
New York Life
Provident
Prudential Insurance Company
Travelers

It is important to emphasize that each case was individually reviewed by the group carrier before a decision was made to provide the coverage. It is possible that some insurers appear on the list only because they have paid claims on behalf of self-funded health care plans to which they provide administrative services and not insurance coverage.

In addition, Blue Cross and Blue Shield of Virginia (BCBSVA) testified that it would offer as an endorsement to its group policies coverage for ABMT in the treatment of breast cancer beginning July 1, 1992. The same coverage would be made available to individual policyholders by the end of 1992. The insurer still considers the treatment to be experimental, however, and is only offering the coverage pending the results of the NCI research.

REVIEW CRITERIA

Social Impact

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

Statistics from the American Cancer Society estimate 26,000 new cancer cases in Virginia in 1992 and 12,100 cancer deaths. New cases of breast cancer are projected to total 4,200. Projections for other types of cancers are: lung 4,100, colorectal 3,600, prostate 3,000, uterine 1,000, skin melanoma 750, oral 700, pancreas 600 and leukemia 600. National projections are currently that one out of every nine women will have breast cancer.

The number of cases for which ABMT will be the recommended course of treatment is not known. ABMT is, however, sometimes the recommended treatment for patients with advanced breast cancer. ABMT is also utilized for treatment of Hodgkin's disease, non-Hodgkin's lymphoma, neuroblastoma, and acute leukemia. Clinical trials have also been conducted utilizing ABMT for treatment for acute leukemia in relapse, chronic granulocytic leukemia or solid tumors other than neuroblastoma.

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

Coverage for ABMT varies according to the type of cancer being treated. Some insurers reimburse for ABMT for specific diseases. A few insurers consider treatment of breast cancer by ABMT a covered service, but many consider it to be "experimental" or "investigative" and deny payment.

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.

The expense of ABMT is often prohibitive for many citizens. Nationally costs can be in excess of $200,000, although in Virginia at least one hospital estimates a cost of approximately $70,000. The Health Insurance Association of America estimates the average cost to be $120,000.

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.

In addition to the high cost of treatment, costs are also

incurred outside of the hospital. The inpatient time in the hospital may be one to two months. The patient may need to stay near the treatment site another two or three months for follow up care. The patient and family members must also have funds for these expenses and may also lose earnings during this period of time.

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

The estimate of new cancer cases in Virginia for 1992 is 26,000. The number of cases for which ABMT will be the recommended course of treatment is not known.

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

Demand for coverage exists among those currently in need of this treatment as well as those projected to have a possible need in the future. Public awareness of different medical treatments is usually limited.

Many providers support the request for this type of coverage although not all providers believe ABMT is effective for all types of cancer.

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

No information was received regarding the interest of collective bargaining organizations in negotiating for the inclusion of this coverage.

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.

No health agency findings regarding the social impact of this proposal were presented during this review.

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.

The cost of the proposed coverage is unknown. ABMT treatment currently costs between $70,000 and $200,000. Estimates of the affect of the proposed coverage on the future cost of treatment were not provided by interested parties.

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

It has not been argued that inappropriate use of ABMT will increase if the proposal is enacted. The possible adverse impact of ABMT would logically eliminate the unnecessary use of the procedure. Appropriate use of the procedure would be likely to increase with the availability of insurance coverage.

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

ABMT is an alternative for conventional chemotherapy treatments. Proponents sometimes make the argument that ABMT, although more expensive than one course of traditional treatment, in the long run may be less expensive because subsequent conventional treatments can be avoided that would otherwise be required in the absence of ABMT.

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.

No arguments have been made regarding an increase in the number and types of providers as a result of this proposal.

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.

Insurers generally make the argument that administrative expenses increase whenever a mandate is enacted. Insurers have also made the argument that any increase in the dollar amount of claims paid will be passed on to policyholders. No data has been

furnished to the Advisory Commission from insurers regarding the amount of the anticipated premium change because of the proposal.

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

The total cost of health care may be affected somewhat if policyholders obtain coverage for ABMT. However, a number of individuals obtain funds for the procedure through charities and personal pleas.

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.

Proponents of the mandate make the argument that the medical efficacy of this treatment is established. There are a number of studies that have shown positive results when ABMT is used for a number of diagnoses that insurers still consider to be experimental. Proponents make the argument that any cancer treatment is somewhat experimental because of the difference in individual responses. Proponents also point to the fact that it is the attending physician who makes the recommendation for the procedure and that for some patients it is the only chance for a cure. Proponents also point to the language of the bill which would require coverage for protocols accepted by the National Cancer Institute.

One of the vocal opponents of the mandate takes the position that ABMT for breast cancer does not result in long-term survival or disease free remission that is higher than for those treated with high dose conventional chemotherapy. Opponents of the mandate also mentioned that Medicaid and Medicare do not cover ABMT. Opponents also pointed to the clinical trials currently being sponsored by the National Cancer Institute. Opponents make the point that there is still considerable debate on the safety of high dose chemotherapy with ABMT compared to standard chemotherapy for the treatment of advanced or poor prognosis breast cancer.

Opponents of the mandate took the position that the Commonwealth should not require insurance coverage for a procedure that has not been proven safe and effective. The mandate of coverage for ABMT at this time was compared to requiring coverage for mammograms before they were refined.

Opponents also described the technical assessments that they

conduct before making a decision to include coverage for a particular procedure. Opponents outlined the information that is reviewed and the layers of review that are performed and noted that as new data becomes available, assessments are revised.

One of the major opponents of the mandate summarized the current knowledge of the use of ABMT for breast cancer as having a high initial response rate with unknown durability. The opponent contends that there is no difference in survival or disease-free remission for those treated with high dose or conventional chemotherapy. But, that the up front mortality and morbidity for those undergoing high dose chemotherapy is substantially higher.

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.

The proposed mandate of coverage addresses a medical need and is consistent with the role of health insurance. However, questions of medical efficacy remain.

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

Proponents see the need for the coverage outweighing the potential cost of the benefit. They point to those usually in need of ABMT being women between the ages of 30 and 54. Many of those in need have young children to raise. They acknowledge that every treatment available cannot be paid for every individual. However, they believe that this treatment should not be denied.

Opponents stressed the unproven efficacy of the treatment. In July, 1992, a spokesman for Blue Cross and Blue Shield of Virginia indicated that the cost of their endorsement that would ABMT for breast cancer only, would be $5 per person per month ($60 per year) for groups with 2 to 49 employees. The cost was projected to be less for larger groups.

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

The proposal is a mandated option. However, some proponents have requested that the coverage be required.

A 1986 survey conducted for the State Corporation Commission found that 83% of families that were insured for health care obtained that coverage through employment. In a group setting, the individual insureds do not have the option to select coverage. That decision is made by the group policyholder. Therefore, a mandated option of coverage may not reach many of the citizens who would desire the coverage.

Opponents of mandates make the argument that administrative expenses will not be reduced by "offering" coverage and that insurers are more susceptible to adverse selection with a mandated offering.

RECOMMENDATION

The Special Advisory Commission on Mandated Health Insurance Benefits hereby recommends to the Governor and the General Assembly of Virginia that House Bill 539 (1992) requiring the offer of coverage for the treatment of cancer by autologous bone marrow transplant <u>not</u> be enacted.

CONCLUSION

Although the Advisory Commission recognizes that high dose chemotherapy with autologous bone marrow transplantation results in short-term survival in some cases, concern remains that for many forms of cancer, including breast cancer, such treatment may not be medically efficacious. There is currently no consensus on the use of ABMT for many of the conditions that House Bill 539 would cover..

1992 SESSION

LD2374136

HOUSE BILL NO. 539

Offered January 20, 1992

A BILL to amend and reenact § 38.2-4319 of the Code of Virginia and to amend the Code of Virginia by adding a section numbered 38.2-3418.2.

Patrons—Brickley, Almand, Byrne, Christian, Connally, Darner, Plum and Van Yahres; Senators: Barry, Calhoun, Hawkins, Trumbo and Woods

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Referred to the Committee on Corporations, Insurance and Banking

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Be it enacted by the General Assembly of Virginia:

1. That § 38.2-4319 of the Code of Virginia is amended and reenacted and that the Code of Virginia is amended by adding a section numbered 38.2-3418.2 as follows:

§ 38.2-3418.2. Coverage for bone marrow transplant.—A. Each insurer 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 shall offer and make available coverage under such policy, contract or plan delivered, issued for delivery or renewed in this Commonwealth on and after January 1, 1993, for the treatment of cancer by autologous bone marrow transplants when performed pursuant to protocols reviewed and approved by the National Cancer Institute.

B. Such health care service shall not be subject to any greater deductible than any other health care service provided by the health maintenance organization. The copayment required of the enrollee shall not exceed twenty percent of the charges for such health care service.

C. The provisions of this section shall 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.

§ 38.2-4319. Statutory construction and relationship to other laws.—A. No provisions of this title except this chapter and, insofar as they are not inconsistent with this chapter, §§ 38.2-100, 38.2-200, 38.2-210 through 38.2-213, 38.2-218 through 38.2-225, 38.2-229, 38.2-232, 38.2-316, 38.2-400, 38.2-402 through 38.2-413, 38.2-500 through 38.2-515, 38.2-600 through 38.2-620, Chapter 9 of this title, 38.2-1317 through 38.2-1321, 38.2-1800 through 38.2-1836, 38.2-3401, 38.2-3405, 38.2-3407.1, 38.2-3411.2, 38.2-3418.1, *38.2-3418.2,* 38.2-3419.1, 38.2-3542, and Chapter 53 of this title shall be applicable to any health maintenance organization granted a license under this chapter. This chapter shall not apply to an insurer or health services plan licensed and regulated in conformance with the insurance laws or Chapter 42 of this title except with respect to the activities of its health maintenance organization.

B. Solicitation of enrollees by a licensed health maintenance organization or by its representatives shall not be construed to violate any provisions of law relating to solicitation or advertising by health professionals.

C. A licensed health maintenance organization shall not be deemed to be engaged in the unlawful practice of medicine. All health care providers associated with a health maintenance organization shall be subject to all provisions of law.