



CABINET DIRECTIVE

*The following is a Copy of a Directive
passed by Cabinet at a Meeting held on
2005/11/04*

MC2005-0442

HCS2005-037. TBM2005-284.

The submission of the Minister of Health and Community Services respecting New Treatment Therapies for Cancer Patients was considered.

The following direction was provided:

1) The Minister of Health and Community Services is authorized to:

- i) add the drug Herceptin to the provincial systemic therapy formulary to treat 40 patients in the early stages of breast cancer per year, commencing November 2005;
 - ii) reallocate up to \$1,030,000 in 2005/06 from the 2004 First Ministers (FMM) Health Accord one-time savings to treat 20 new patients and a backlog of 20 patients this year; and
 - iii) bring forward the \$7,340,000 balance of the total budget request to introduce new treatment therapy for other cancer patients for consideration by Government during the 2006/07 budget process; and
- 2) Approval is given for the Department's 2006/07 budget to be increased by \$3,030,000 (\$2,030,000 – base, \$1,000,000 – one time) to treat 40 new patients in the early stages of breast cancer in 2006-07 and to complete the treatments for the patients started in November 2005.

Deputy Clerk of the Executive Council

HCS/DM
TB/Secretary
AG
Deputy Clerk
File

HCS2005-037
TBM2005-284

New Treatment Therapies for Cancer Patients

**Summary of
Proposal**

The Department is seeking approval of the following:

- 1) To add the drug Herceptin to the provincial systemic therapy formulary to treat 40 patients in the early stages of breast cancer per year, commencing November 2005.
- 2) To reallocate up to \$1,030,000 in 2005-06 from FMM one-time savings to treat 20 new patients and a backlog of 20 patients. This approval requires an increase in the Department's 2006-07 budget by \$3,030,000 (\$2,030,000 base, \$1,000,000 one-time) for 40 new patients per year and to complete the treatments for the patients started in November 2005.
- 3) To bring forward the \$7,340,000 balance of the total budget request to introduce new treatment therapy for other cancer patients for consideration by Government during the 2006-07 budget process.

**Committee
Recommendation**

The Board recommended to the Executive Council that this proposal be approved.

Secretariat Comment

1. The Provincial Systemic Therapy Program is administered by the Eastern Regional Integrated Health Authority and is responsible for the introduction and utilization of intravenous systemic therapy drugs for all cancer patients in the province. The current budget for this Program is \$6.3 million and Eastern Health has requested an additional \$9,370,000 annually to fund new treatment therapies for 370 patients with breast cancer, colorectal cancer and multiple myeloma. (See summary attached to Cabinet paper). New treatment therapies are available for targeted cancer patients and are being used across the country but are not available in this Province.
2. The request from Eastern Health also notes that for 2006-07 a further 20% will be required on the existing budget of \$6.3 million in order to keep pace with inflationary costs and growth in caseload and duration of treatments. The impact of this change will be in the order of \$1.26 million and will be part of the Department's budget submission.
3. The Department is proposing initially to address the provision of treatment therapies for patients in the early stages of breast cancer versus other types of cancer patients as there is pressure from breast cancer patients and oncologists to introduce Herceptin for those in the early stages of the disease. Recent clinical trials in the United States have shown a significant benefit in terms of disease free survival and overall survival with the addition of Herceptin for one year in breast cancer patients who are tested as being HER2 overexpressors. The Federal Drug Administration in the United States has approved the use of this drug in early stage breast cancer patients (July 2005) and a notice of compliance has been filed with Health Canada. The annual cost of \$2,030,000 is expected to cover 40 patients (\$2 million) and the associated laboratory work (\$30,000). It is noted that all jurisdictions with the exception of New Brunswick, have introduced coverage for Herceptin for early stage breast cancer patients this year.
4. As for the other therapies being proposed, the Department would like to undertake further analysis of the proposal given its financial significance and in consideration of overall 2006-07 budget priorities. It should be noted that the submission indicates that Newfoundland and Labrador has the highest incidence of, and mortality from, colorectal cancer in Canada. Oncologists consider the current treatment regimen obsolete in North America. While the present supply of oncologists is relatively stable, there have been previous difficulties in recruiting and retaining oncologists in the past. Oncologists may

choose to pursue employment opportunities elsewhere where new cancer therapies are supported. In fact, one of the oncologists who specializes in treating colorectal cancer has recently indicated he will be leaving the province.

5. The Department advises it is able to identify sufficient one-time cashflow savings from FFM Accord funding to provide the additional funds for this recommendation in 2005-06 of \$1,030,000. Approval of this proposal will result in a total requirement of \$3,030,000 in 2006-07 to cover a cash flow requirement of \$1,000,000 in 2006-07 to complete the treatment of the first 40 patients and funding of \$2,030,000 to begin treatment of another 40 persons. Annual costs thereafter will revert back to \$2,030,000.
6. Budgeting Division agrees that the Department be given some opportunity to undertake some further analysis of the total proposal in view of its other budgetary pressures. The submission notes there may be some additional infrastructure costs should the overall proposal be approved. This also requires some further analysis by the Department but preliminary information would indicate some additional modifications to the laboratory area may be required to install things such as fume hoods where the medications are prepared. The Department will assess the full impact of these items for the 2006-07 budget and may be able to accommodate any additional capital costs from within its ongoing allocations for this purpose.

Action Required**Approve the Treasury Board recommendation.**

BC/SM

November 2, 2005



GOVERNMENT OF
NEWFOUNDLAND
AND LABRADOR

Executive Council

SECRET

Attach to:

HCS2005-037

TBM2005-284

TREASURY BOARD Recommendation to Cabinet

Title:

New Treatment Therapies for Cancer Patients

TREASURY BOARD RECOMMENDATION

The Board recommended to the Executive Council that this proposal be approved.

November 1, 2005

TREASURY BOARD COMMENT

	For Approval	Approved As Is	Approved as Noted	Revise/Resubmit
Signature	JMorris			
Date	October 28, 2005			

PROPOSAL

The proposal (HCS 2005-037) dated October 24, 2005 of the Honourable Minister of Health and Community Services, relating to new treatment therapies for cancer patients.

The Department is seeking approval of the following:

- 1) To add the drug Herceptin to the provincial systemic therapy formulary to treat 40 patients in the early stages of breast cancer per year, commencing November 2005.
- 2) To reallocate up to \$1,030,000 in 2005-06 from FMM one-time savings to treat 20 new patients and a backlog of 20 patients. This approval requires an increase in the Department's 2006-07 budget by \$3,030,000 (\$2,030,000 base, \$1,000,000 one-time) for 40 new patients per year and to complete the treatments for the patients started in November 2005.
- 3) To bring forward the \$7,340,000 balance of the total budget request to introduce new treatment therapy for other cancer patients for consideration by Government during the 2006-07 budget process.

BACKGROUND

The Provincial Systemic Therapy Program is administered by the Eastern Regional Integrated Health Authority and is responsible for the introduction and utilization of intravenous systemic therapy drugs for all cancer patients in the province. The current budget for this Program is \$6.3 million and Eastern Health has requested an additional \$9,370,000 annually to fund new treatment therapies for 370 patients with breast cancer, colorectal cancer and multiple myeloma. (See summary attached.) New treatment therapies are available for targeted cancer patients and are being used across the country but are not available in this Province.

The request from Eastern Health also notes that for 2006-07 a further 20% will be required on the existing budget of \$6.3 million in order to keep pace with inflationary costs and growth in caseload and duration of treatments. The impact of this change will be in the order of \$1.26 million and will be part of the Department's budget submission.

The Department is proposing initially to address the provision of treatment therapies for patients in the early stages of breast cancer versus other types of cancer patients as there is pressure from breast cancer patients and oncologists to introduce Herceptin for those in the early stages of the disease. Recent clinical trials in the United States have shown a significant benefit in terms of disease free survival and overall survival with the addition of Herceptin for one year in breast cancer patients who are tested as being HER2 overexpressors. The Federal Drug Administration in the United States has approved the

use of this drug in early stage breast cancer patients (July 2005) and a notice of compliance has been filed with Health Canada. The annual cost of \$2,030,000 is expected to cover 40 patients (\$2 million) and the associated laboratory work (\$30,000). It is noted that all jurisdictions with the exception of New Brunswick, have introduced coverage for Herceptin for early stage breast cancer patients this year.

As for the other therapies being proposed, the Department would like to undertake further analysis of the proposal given its financial significance and in consideration of overall 2006-07 budget priorities. It should be noted that the submission indicates that Newfoundland and Labrador has the highest incidence of, and mortality from, colorectal cancer in Canada. Oncologists consider the current treatment regimen obsolete in North America. While the present supply of oncologists is relatively stable, there have been previous difficulties in recruiting and retaining oncologists in the past. Oncologists may choose to pursue employment opportunities elsewhere where new cancer therapies are supported. In fact, one of the oncologists who specializes in treating colorectal cancer has recently indicated he will be leaving the province.

ANALYSIS

The Department advises it is able to identify sufficient one-time cashflow savings from FFM Accord funding to provide the additional funds for this recommendation in 2005-06 of \$1,030,000. Approval of this proposal will result in a total requirement of \$3,030,000 in 2006-07 to cover a cash flow requirement of \$1,000,000 in 2006-07 to complete the treatment of the first 40 patients and funding of \$2,030,000 to begin treatment of another 40 persons. Annual costs thereafter will revert back to \$2,030,000.

Budgeting Division agrees that the Department be given some opportunity to undertake some further analysis of the total proposal in view of its other budgetary pressures. The submission notes there may be some additional infrastructure costs should the overall proposal be approved. This also requires some further analysis by the Department but preliminary information would indicate some additional modifications to the laboratory area may be required to install things such as fume hoods where the medications are prepared. The Department will assess the full impact of these items for the 2006-07 budget and may be able to accommodate any additional capital costs from within its ongoing allocations for this purpose.

RECOMMENDATION

It is recommended the following Minute be issued:

The Board recommended to Executive Council that this proposal be approved.

Summary of Proposed Treatments – Provincial Systemic Therapy Program

Treatment and Intent	Treatment Regimen	# patients annually	Annual Cost (Drug cost only)	# patients 2005-06	Additional funding 2005-06	Funding 2006-07
Adjuvant Breast Cancer	Herceptin	40	\$2,000,000	40	\$1,030,000	\$3,030,000
Adjuvant Colorectal Cancer	FOLFOX-4	180	\$4,300,000	83	\$2,000,000	\$4,300,000
Adjuvant Colorectal Cancer	Capecitabine	45	\$ 260,000	22	\$ 130,000	\$ 260,000
1 st line Metastatic Colorectal Cancer	Bevacizumab (Avastin)	95	\$2,430,000	23	\$ 600,000	\$2,430,000
Multiple Myeloma	Bortezomib (Velcade)	10	\$ 350,000	5	\$ 175,000	\$ 350,000
TOTALS*		370	\$9,340,000	173	\$3,935,000	\$10,370,000

- Note 1 – The request from Eastern had also included a request for a treatment regimen covering Cetuximab (Erbix) for 2nd line Metastatic Colorectal Cancer for 36 additional patients annually at a cost of \$1 million for a total proposal of \$10,340,000 covering a total of 406 patients. This item was removed from the proposal due to delays being experienced in the clinical trials for this drug.
- Note 2 – An additional \$30,000 is included in the Department's proposal to cover Laboratory work in 2005-06.

FILE COPY

CONFIDENTIAL**MEMORANDUM TO EXECUTIVE COUNCIL**

Executive Council

*Forward to TB
Oct 27/05
J***TITLE**

OCT 27 2005

New Treatment Therapies for Cancer Patients

RECEIVED**ISSUE**

Whether to introduce new treatment therapies to targeted cancer patients in Newfoundland and Labrador.

RECOMMENDATIONS

It is recommended that the Minister of Health and Community Services be authorized to:

1. add the drug Herceptin to the provincial systemic therapy formulary to treat 40 patients in the early stages of breast cancer per year, commencing November 2005.
2. reallocate up to \$1,030,000 in 2005/06 from FMM one-time savings to treat 20 new patients and a backlog of 20 patients this year. This approval requires an increase in the Department's 2006/07 budget by \$3,030,000 (\$2,030,000 – base, \$1,000,000 – one time) for 40 new patients per year and to complete the treatments for the patients started in November this year.
3. bring forward the \$7,340,000 balance of the total budget request to introduce new treatment therapy for other cancer patients for consideration by Government during the 2006/07 budget process.

BACKGROUND

The Provincial Systemic Therapy Program is administered by the Eastern Regional Integrated Health Authority. It is responsible for the introduction of and utilization of intravenous systemic therapy drugs for all cancer patients in the province. The total systemic therapy budget is approximately \$6.3 million. Eastern Health has submitted a request for an additional \$9,370,000 annually to fund new treatment therapies for 370 patients with breast cancer, colorectal cancer and multiple myeloma (see attached letter). This proposed additional expenditure is a result of new treatment therapies for targeted cancer patients due to advances in cancer research. These treatments are becoming the standard of care for cancer patients across Canada but are currently not available in Newfoundland and Labrador. Some of the drugs being proposed will require new laboratory testing and others will require necessary infrastructure to be put in place.

The availability of these drugs in other provinces and the documented benefits of the drugs from clinical trials are resulting in pressure from patients and providers to add new treatment therapies to the provincial systemic drug formulary. For example, Herceptin has been available in all

jurisdictions including Newfoundland and Labrador for the treatment of patients with advanced breast cancer for a number of years. All provinces, except New Brunswick, have started providing coverage for Herceptin for patients in the early stages of breast cancer. Requests to provide Herceptin for early stage breast cancer have already been received from patients and their families. Recently, there has also been increased pressure from oncologists to provide Herceptin to these patients. The estimated annual cost is \$2,000,000 for the systemic therapy treatments and \$30,000 for laboratory testing to serve 40 patients per year, for a total cost of \$2,030,000.

There have also been new advances in treating persons with colorectal cancer and multiple myeloma. The new treatment therapies include FOLFOX-4 and Capecitabine for patients in the early stages of colorectal cancer and a new agent, Bevacizumab, for patients with advanced colorectal cancer. Newfoundland and Labrador has the highest incidence of, and mortality from, colorectal cancer in Canada. According to the oncologists, the current treatment regime used in this province is considered obsolete in North America and there is also some urgency to introduce the new treatment therapies for colorectal cancer. There have also been new advances in the treatment of multiple myeloma with the use of an agent called Bortezomib. The estimated annual cost of these new therapies is \$7,340,000 to serve about 330 patients per year.

It is anticipated that the demand for new systemic therapies will continue to grow based on a number of factors such as an increase in the incidence of cancer, an increase in the number of patients being treated and an increase in the number of new and very costly therapies being approved by Health Canada. In addition to the \$9,370,000 annual funding for new therapies, an annual budget increase of 20% on the previous year's expenditures will be required to manage the ongoing growth in incidence, duration of treatments, and inflationary costs of medications.

ALTERNATIVES

Option 1 - Maintain the Status Quo

New treatment therapies are being approved by the Federal Drug Administration and Health Canada and are becoming the standard of care for patients in the early and late stages of cancer across Canada. Other therapies are awaiting approval by Health Canada. If the status quo is maintained, residents of Newfoundland and Labrador will not receive the most current and beneficial treatment available to cancer patients in other jurisdictions. As other jurisdictions across Canada approve these drugs, there will be added public pressure to provide the new therapies in this province. Due to the high cost of these drugs, most people are not able to pay privately and cannot access these drugs unless they are added to the provincial drug formulary for cancer patients.

Maintaining the status quo will avoid significant additional expenditures (estimated at \$9,370,000 annually) in the health system. However, public demands will likely escalate if the therapies are not approved and some oncologists may choose to pursue employment opportunities in other provinces where new cancer therapies are supported. There is a stable supply of oncologists here now but there has been a lot of difficulty in recruiting and retaining oncologists in the past. If some oncologists leave, the Department anticipates further recruitment

difficulties, resulting in patient treatment delays or transfer of patients to out of province facilities. This alternative is not supported by the Department.

Option 2 – Approve new treatment therapies for patients with breast cancer, colorectal cancer and multiple myeloma

Approving new treatment therapies for patients with breast cancer, colorectal cancer and multiple myeloma will establish a standard of care for these targeted patient populations similar to other jurisdictions in Canada. Providing the \$9,370,000 required will ensure optimum treatment for cancer patients of Newfoundland and Labrador. Patients and their families will be pleased that Government is committed to providing access to the most advanced and beneficial cancer drug treatments available to provincial residents.

An investment of \$9,370,000 annually is significant and represents a 67% increase over the current systemic therapy budget of \$6.3M. Investing this amount of money for cancer drugs will likely limit the dollars that would be available to support new drug therapies for other health problems, e.g., Alzheimers, arthritis, in both the community and institutional settings. The Department wishes to take some additional time to assess this request in the context of the 2006/07 budget priorities. Funding these drugs will also require additional expenditures in laboratory testing and changes in infrastructure. Some of the drugs also require further review and research by Health Canada. Given these factors, this alternative is not supported by the Department at this time.

Option 3 – Approve new treatment therapies for patients in the early stages of breast cancer

There is pressure from breast cancer patients and the oncologists to introduce Herceptin for patients in the early stages of their disease. Recent clinical trials in the United States have shown a significant benefit in terms of disease free survival and overall survival with the addition of Herceptin for one year in breast cancer patients who are HER2 overexpressors. The use of this drug for early stage breast cancer patients was approved by the Federal Drug Administration in the United States in July 2005 and a notice of compliance has been filed with Health Canada. Eastern Health is working with its Atlantic Provinces colleagues to outline the indicators for this treatment. The estimated cost is \$2,030,000 annually for 40 patients.

Breast cancer patients and their families, as well as the oncologists, will be pleased if Government approves funding to support Herceptin for the treatment of early stages of breast cancer. This approval is consistent with other jurisdictions that have provided universal coverage or on a case by case basis. If approval of this therapy for early stage breast cancer patients is not forthcoming, it is likely that lobbying by patients, families and the oncologists will continue. This alternative is supported by the Department.

LEGISLATIVE/REGULATORY CONSIDERATIONS

There are no legal/legislative considerations.

FINANCIAL CONSIDERATIONS

Eastern Health estimates that a base budget adjustment of \$2,030,000 annually is required to treat 40 patients in the early stages of breast cancer for one year with Herceptin. This amount includes \$2,000,000 for the systemic therapy costs and \$30,000 for laboratory testing. The 2005/06 cash flow requirements are estimated at \$1,030,000 for 20 new patients between November 2005 and March 2006 and another potential 20 patients due to the retesting of existing cancer patients who may be able to avail of this treatment. If Herceptin is approved, the 2006/07 costs are estimated at \$3,030,000 as there are carry over costs of \$1,000,000 for the patients starting their treatments in 2005/06. The base funding will be \$2,030,000 commencing in 2007/08 as the patient backlog will have cleared.

There are three possible funding options: (1) special warrant, (2) supplementary supply during the Fall sitting of the House of Assembly, and (3) reallocate up to \$1,000,000 from FMM one-time savings in 2005/06 to treat 40 patients (20 new, 20 backlog) this year. The Department recommends reallocation of FMM one-time savings in 2005/06. If approval is forthcoming, it requires an increase in the Department's 2006/07 budget by \$3,030,000 (\$2,030,000 base, \$1,000,000 one-time) for 40 new patients per year and to complete the treatments for patients started in November 2005.

INTERDEPARTMENTAL CONSIDERATIONS

There are no interdepartmental considerations.

ABORIGINAL CONSIDERATIONS

There are no specific considerations for the aboriginal populations.

INTERGOVERNMENTAL CONSIDERATIONS

There are no intergovernmental considerations.

OTHER JURISDICTIONS

All jurisdictions, except new Brunswick, introduced coverage for Herceptin for early stage breast cancer patients this year.

OTHER CONSULTATIONS

Discussions have been held with Eastern Health officials and the oncologists at the cancer clinic in St. John's on the recent advances in treatment therapies for patients with breast cancer, colorectal cancer and multiple myeloma.

ENVIRONMENTAL CONSIDERATIONS

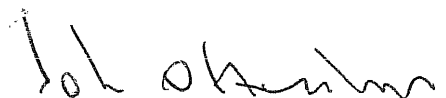
The introduction of additional intravenous systemic therapies may add to the biomedical waste disposal stream in the province.

GENDER ANALYSIS

The primary beneficiaries of Herceptin for early stage breast cancer are women. There is a small number of men who contract breast cancer who can also avail of the benefits from Herceptin. The new therapies for colorectal cancer and multiple myeloma will provide benefits for all cancer patients deemed appropriate to access these drugs by the oncologists.

COMMUNICATIONS AND CONSULTATIONS PLAN

A Communications Plan is included as Annex II.



JOHN OTTENHEIMER, Q.C., M.H.A.

Minister

Department of Health and Community Services

October 26, 2005

Attachments:

Annex I – Letters from Eastern Health

Annex II – Communications Plan

Eastern HEALTH

CODE #		EXE-3215	
C.C. 1.	CJ	4.	
2.	EH	5.	
3.		6.	
REGISTRY		<input checked="" type="checkbox"/>	

26 July 2005

Mr. John Abbott, Deputy Minister
Department of Health and Community
P.O. Box 8700
St. John's, NL
A1B 4J6

Dear Mr. Abbott:

You will recall from earlier conversations and certainly from extensive media reporting that advances in the treatment of various forms of cancer is resulting in extreme pressure from both patients and providers to introduce new medications to our drug formulary as well as new diagnostic tools. It is clear that all Provinces are facing the same issues and it is becoming evident that many are deciding to allocate the funding required.

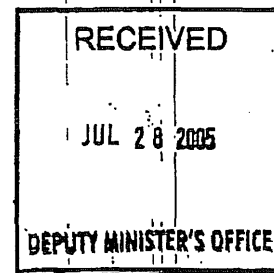
I am attaching correspondence from our clinical experts for your review. The financial implications of keeping in step with the rest of the country are staggering. I would appreciate hearing from you as to how we need to approach this issue.

Sincerely,


George Tilley
President and Chief Executive Officer

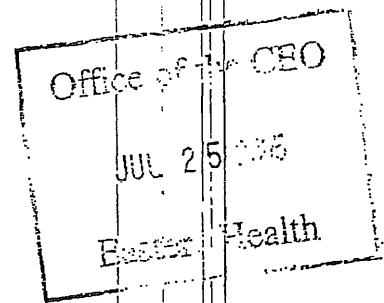
cc. Patricia Pilgrim, COO
Dr. Robert Williams, VP
Beverley Clarke, COO

Attachment



Newfoundland
Cancer Treatment and
Research Foundation

July 25, 2005



Mr. George Tilley
C.E.O.
Eastern Regional Integrated Health Authority
Corporate Office
Waterford Site
Waterford Bridge Road
St. John's, NL A1E 4J8

Dear Mr. Tilley:

RE: ADDITIONAL FUNDING FOR PROVINCIAL SYSTEMIC THERAPY BUDGET

We are writing to request additional funding to our Provincial Systemic Therapy budget. Several recent advances in oncology have led to a change in the adjuvant therapy of breast cancer, adjuvant and metastatic therapy of colorectal cancer and the treatment of multiple myeloma. These advances are the result of the new clinical research in oncology and are becoming the standard of care. This will necessitate an increase in our budget for the 2005-2006 fiscal year to incorporate these new standards into practice for cancer patients of Newfoundland and Labrador. As you are aware, our drug budget for 2005-2006 is approximately \$6.3 million dollars. This represents a \$1 million dollar increase from 2004-2005; however, this amount of funding equals our expenditure for the 2004-2005 year. Cancer centers across the Country anticipate an annual growth in expenditure of approximately 20% per year. This 20% is based on a number of factors, such as, an increase in incidence of cancer, an increase in the number of patients being treated, increased cost of medications, etc. As we have not received an increase in funding over the last three years, we expect the 20% increase on 2004-2005 expenditures to be in range of \$7.5 million dollars. However when we submitted our request for the 2005-2006 budget, this new clinical data was not available and, therefore, this necessitates a request for additional funding.

The first area that requires additional funding is in the adjuvant therapy of breast cancer. Three large randomized clinical trials have reported efficacy data at the American Society of Clinical Oncology (ASCO) meeting in May 2005. These have shown a significant benefit in terms of disease free survival and overall survival with the addition of adjuvant Herceptin for one year in breast cancer patients who are known to be HER2/ *neu* overexpressors. We are in the process of writing a guideline in conjunction with our colleagues in Atlantic Canada that will outline the indications for this treatment. On average, we see 350 new breast cancer patients/year and approximately 15%-20% of those will be HER2/ *neu* overexpressors. Factoring in patients who would not be eligible for this treatment because of age or cardiac toxicity, we are anticipating approximately 40 patients per year. The cost has been estimated to be \$50,000 per patient per year; therefore, we will require an additional \$2,000,000 per year to fund this drug. For the remainder of the 2005-2006 fiscal year, we are requesting an additional \$1,000,000 dollars to pay for adjuvant Herceptin.

In addition, we will now need to test all new breast cancer cases for HER2/ *neu* overexpression using immunohistochemistry. Those patients with an equivocal result will need to go on for confirmatory tests using florescence in situ hybridization (FISH).

Corporate Office

Dr. H. Bliss Murphy
Cancer Centre
St. John's

Regional Programs

Cancer Centre
Central-East
Gander

Cancer Centre
Central-West
Grand Falls-Windton

Cancer Centre
Western Region
Corner Brook

Cancer Centre
Northeastern Region
St. Anthony

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Mr. G. Tilley

Re: Additional Funding for Provincial Systemic Therapy Budget

July 25, 2005

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Currently, the FISH testing is sent out of province. We will also require funding to allow for this testing to be done in an efficient manner and we are asking that this money be given directly to the Cancer Care program to oversee this testing. Collaboration will have to take place with the Pathology program to determine the financial impact of this testing. Unfortunately, we are not able to provide an approximate costing for these procedures at this time. A process is currently underway to determine the financial impact of these additional tests.

The other area in which there has been quite a lot of progress is the treatment of colorectal cancer. New adjuvant therapies are now available for these patients. FOLFOX-4 (Oxaliplatin, 5-FU, folinic acid) chemotherapy that is currently used in the metastatic setting has now been shown in clinical trial to be of benefit in the adjuvant setting for patients with colorectal cancer. Many of our colleagues across the Country are already offering adjuvant FOLFOX-4 chemotherapy to patients as a standard of care and we would like to be able to start offering this treatment in the Fall 2005 once we have the necessary infrastructure available to expand our infusional home chemotherapy program.

On average we see approximately 300 new stage II and III colon cancers patients per year. We will be treating our high-risk stage II and stage III patients with FOLFOX-4 if they are eligible to receive this treatment based on clinical practice guidelines. We anticipate treating 180 patients with this regimen per year. This regimen will cost approximately \$24,000 per patient, therefore, we will require an additional \$4,300,000 dollars per year to fund this treatment. In the 2005-2006 fiscal year we expect to spend \$2,000,000 on the treatment of adjuvant colorectal cancer with adjuvant FOLFOX-4 chemotherapy. However, as previously stated, the utilization of this treatment will depend upon the full implementation of the Home Infusion Program.

The other area of advancement in the treatment of colorectal cancer adjuvantly is the use of oral Capecitabine (Xeloda) for elderly patients. This drug has been shown to be equivalent to 5-FU and folinic acid and much less toxic. Several of our patients treated with intravenous 5-FU and folinic acid chemotherapy develop severe complications necessitating long hospitalizations. Results of recent clinical trials has led to a move in Canada to use oral Capecitabine for these patients instead of bolus intravenous 5-FU and folinic acid. Unfortunately, our Provincial Systemic Therapy Drug Program does not cover oral chemotherapy. This issue MUST be addressed immediately to ensure that we are able to provide our elderly patients with the appropriate adjuvant therapy with oral Capecitabine. We estimate that there will be 45 patients per year at a cost of \$5,770.00 per patient. Annually this will require an additional \$260,000. For the 2005-2006 fiscal year we will require an additional \$130,000 to provide the standard of care with oral Capecitabine for this population as well.

We have previously written to the Government looking for funding for two new agents in the treatment of metastatic colorectal cancer. These include Bevacizumab (Avastin) and Cetuximab (Erbix); Both are used in the treatment of metastatic colorectal cancer. We are anticipating Health Canada approval of both of these drugs in the last quarter of 2005. Previously, we had anticipated that approximately 120 patients per year would be treated with Avastin and 60 patients with Erbix. However, due to expanding clinical evidence on the toxicities of these two agents, we now anticipate 95 patients per year to be treated with Avastin and 36 patients per year to be treated with Erbix. We estimate Avastin will cost the province \$2,430,000 per year and Erbix will cost us \$1,000,000 per year. For the 2005-2006 fiscal year, we will require an additional \$600,000 for Avastin and an additional \$250,000 for Erbix depending on Health Canada's approval of these agents.

There have also been exciting new advances in the treatment of multiple Myeloma with the use of an agent called bortezomib (Velcade). This agent has been reviewed and approved by the HCCSJ and NCTRF

Mr. G. Tilley

Re: Additional Funding for Provincial Systemic Therapy Budget

July 25, 2005

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Pharmacy and Therapeutics committee and it is estimated that approximately 10 patients per year will require treatment. The annual cost of this treatment is approximately \$35,000 per patient. Therefore, we will anticipate an annual cost of approximately \$350,000. Until we gain more clinical experience with using this new agent it is expected that most patient will be treated within the HCCSJ during the first year. The budget impact of this treatment for 2005-2006 will be approximately \$175,000. Currently, hematology drugs given in St. John's are not funded under the Provincial Systemic Therapy Program; however, with the amalgamation of services under Eastern Health this will likely become encompassed under the Provincial Systemic Therapy Program budget.

We think that it is important for us to realize that these increased expenditures are the result of advancements in the care of cancer patients. These treatments have become standard of care across the Country and it is essential that we obtain the necessary funding to ensure optimum treatment for cancer patients of Newfoundland and Labrador. Adjuvant therapy is used to cure cancer patients and, therefore, it is essential that we have this funding to offer the best care to our patients. In total we will require \$10,034,000 annually to fund these new treatments, and an adjustment of \$4,155,000 for the 2005-2006 fiscal year. In addition to this new funding, an annual budget increase of 20% on the previous years expenditures must be built into the budget process to stay current with the ongoing growth in incidence, duration of treatments, and inflationary costs of medications. Appendix I clearly outlines this information in table and graphic format.

We would be more than pleased to meet with you at any time to discuss these further, and we look forward to an opportunity to present this information to your Board and to the Government as needed.

Thank you for your attention to this matter and we look forward to talking to you about this in the new future.

Yours sincerely,

Kara Laing
Kara Laing, M.D., F.R.C.P. (C)

Kara Laing, M.D., F.R.C.P. (C)
Director, Medical Oncology
The Dr. H. Bliss Murphy Cancer Center
Assistant Professor, Faculty of Medicine
Memorial University of Newfoundland

Rick Abbott
Rick Abbott, BSc. Pharm., RPEBC

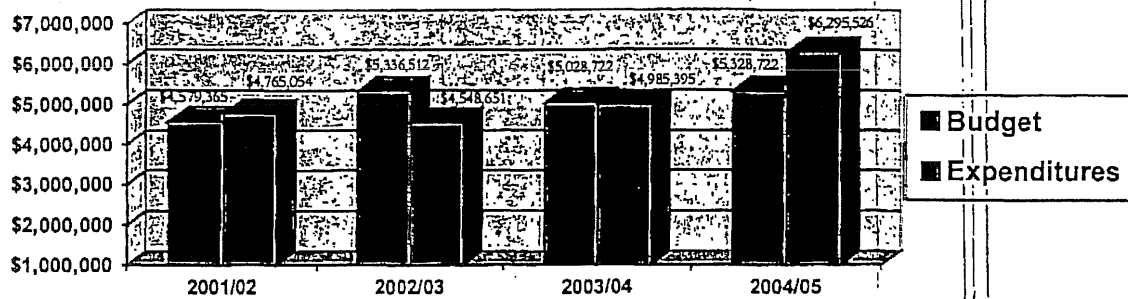
Rick Abbott, BSc. Pharm., RPEBC
Provincial Pharmacy Director
Systemic Therapy

KL/dpr

Cc Mr. G. Butt
Ms. P. Pilgrim
Mr. J. Parsons
Ms. C. Power
Dr. P. Gardiner

Appendix I.

Page 4, July 25, 2005

Graph I: PSTP Budget vs Expenditures, 2001/02 to 2004/05**Table I: Overview of Budget & Expenditures, 2003/04 to 2005/06**

YEAR	Budget	Budget ↑ from Previous Year	Expenditure	Expenditure ↑ fr Previous Year	Projected Deficit
2001/02	\$ 4,579,365	N/A	\$ 4,765,054	N/A	N/A
2002/03	\$ 5,336,112	16%	\$ 4,548,651	(- 4.5%)	N/A
2003/04	\$ 5,028,722	(- 5.8%)	\$ 4,985,395	9.6%	N/A
2004/05	\$ 5,328,722	6%	\$ 6,295,526	26%	N/A
2005/06	\$ 6,368,233	19.5%	*\$ 7,550,000* (Projected)	*20%* (Projected)	(\$ 1,180,000)

**Table II: Overview of Expenditures for New Treatments
In addition to the Current Budget Allocation**

Treatment and Intent	Treatment Regimen	# pts annually	Annual Cost	# pts 05/06	Additional Funding 05/06	Increased Funding 06/07
Adjuvant Breast Cancer	Herceptin	40	\$ 2,000,000	20	\$ 1,000,000	\$ 2,000,000
Adjuvant Colorectal Cancer	FOLFOX-4	180	\$ 4,300,000	83	\$ 2,000,000	\$ 4,300,000
Adjuvant Colorectal Cancer	Capecitabine	45	\$ 260,000	22	\$ 130,000	\$ 260,000
1 st line Metastatic Colorectal Cancer	Bevacizumab (Avastin)	95	\$ 2,430,000	23	\$ 600,000	\$ 2,430,000
2nd line Metastatic Colorectal Cancer	Cetuximab (Erbix)	36	\$ 1,000,000	9	\$ 250,000	\$ 1,000,000
Multiple Myeloma	Bortezomib (Velcade)	10	\$ 350,000	5	\$ 175,000	\$ 350,000
TOTALS		406	\$ 10,340,000	162	\$ 4,155,000	\$ 10,340,000

Less: Cetuximab * 36 1,000,000 9 250,000 1,000,000

Revised Totals: 370 9,340,000 153 3,905,000 9,340,000

* deleted due to delays in clinical trials.

Annex II – Communications Plan

<u>Consulted with:</u> M. Hennessey, HCS J. Abbott, HCS	<u>Date Drafted:</u> October 24, 2005	<u>Anticipated</u> <u>Announcement Date:</u> Late fall
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Communications Analysis**Public Environment**

Advances in cancer research are leading to new and more effective forms of treatment for targeted cancer patients. Some of these treatments are becoming the standard of care for cancer patients across the country but are currently not available in Newfoundland and Labrador. The availability of these drugs in other provinces, along with the documented benefits of the drugs from clinical trials, is resulting in pressure from patients and providers to introduce new medications, including the drug Herceptin, to the Provincial Systemic Therapy (Chemotherapy) Program.

Herceptin, a drug used for the treatment of patients with advanced breast cancer, has been provided in all jurisdictions for a number of years. Currently, all provinces except New Brunswick are now providing coverage for Herceptin for patients in the early stages of breast cancer. Locally, there has been increased pressure from oncologists to provide Herceptin to early stage breast cancer patients in Newfoundland and Labrador.

A recent *Globe and Mail* article (October 19, 2005) touted Herceptin as an effective drug against an aggressive form of early breast cancer in three studies involving thousands of women with early-stage disease, cutting the risk of relapse in half. Herceptin is the first therapeutic antibody approved for the treatment of HER2 positive metastatic breast cancer and is designed to target and block the function of HER2 protein overexpression. Research has shown that HER2 positive breast cancer is a more aggressive disease with a greater likelihood of recurrence, a poorer prognosis, and a decreased chance of survival compared with HER2 negative breast cancer.

Locally, there has been significant recent media attention around inaccurate results from hormone receptor tests for breast cancer patients. Eastern Health became aware of a problem with test results for hormone receptors when a breast cancer patient became ill in spite of testing negative. As a precautionary measure, tissue samples dating back to 1997 are being sent out of the province for retesting at the Mount Sinai hospital in Toronto. Patients who test positive for hormone receptors may be offered Tamoxifen, a drug that interferes with estrogen and progesterone.

There has been significant reaction to the issue. Breast cancer survivor Gerry Rogers, in a recent *Globe and Mail* article, expressed concern over the timing for treatment. "If the case were to be that in fact there was an error in the pathology, then the window of opportunity for the effectiveness of Tamoxifen in my case has kind of passed." Peter Dawe, Director of the Newfoundland and Labrador chapter of the Canadian Cancer Society was quoted as saying that this "has the potential to be a big issue for the province's health-care system and patients... it alters the treatment. You could be having an inadequate treatment based on a test result. There

is a group that has the test result in question and our fear is that they should have received treatment and didn't."

The story has also received national media attention. A recent CBC story (October 20, 2005) titled "Unreliable tests give lesson to all labs" quotes a medical technology expert warning that the lab problem that occurred in Newfoundland and Labrador could be repeated across the country. Given the negative coverage of this story and the resulting lack of confidence among breast cancer patients in the reliability of testing procedures in the province, it is important that Government respond with positive messages about the introduction of Herceptin to the Provincial Systemic Therapy (Chemotherapy) Program.

Strategic Considerations

- Given the timing of ongoing negotiations between physicians and Government, the announcement will be welcomed by the NLMA and oncologists, in particular, and will help to address one of physician's key issues of concern, recruitment and retention. Maintaining the status quo may result in oncologists choosing to pursue employment in other provinces where new cancer therapies are supported.
- Herceptin is already being administered by several other province's in Canada for early breast cancer treatment. A failure to provide the drug in this province may result in criticism that Government is refusing to provide cancer patients with the most current and beneficial treatment possible.
- Given recent media reports about ER/PR testing and the public's resulting loss of confidence in the health system, it is important that Government respond to the needs of breast cancer patients.

Target Audience

- Eastern Regional Integrated Health Authority and other RIHAs
- Oncologists
- Breast cancer patients, survivors and families
- Canadian Cancer Society
- Stakeholders – NLMA, NLNU, NLHBA
- MHAs
- General Public
- Opposition
- Media – local and provincial

Communications Objectives

- To demonstrate government's continued commitment to providing quality health care services to the residents of the province.
- To communicate that Government is cognizant of advances in medical research for cancer patients and is committed to providing cancer patients with the most current and beneficial treatment possible.

Messages

- Government is improving health and community-based services through strategic investments in diagnostic, medical equipment and community supports to care for residents in their communities.
- Through recent Budget investments, we have furthered our Blueprint commitments to reduce the waiting times for diagnostic and treatment procedures; place diagnostic and treatment equipment in regions of the province where it is most needed; and improve timely access to quality health care while ensuring our health system is sustainable into the future.
- Government is cognizant of advances in medical research for cancer patients and is committed to providing cancer patients with the most current and beneficial treatment possible.
- Commencing November 2005, the drug Herceptin will be added to the provincial systemic therapy formulary to treat patients in the early stages of breast cancer. We anticipate that approximately 40 breast cancer patients a year will in the early stages of breast cancer will be administered this drug.
- The estimated annual cost to add the drug to the program is \$2 million for the systemic therapy treatments and \$30,000 for laboratory testing to serve 40 patients per year, for a total cost of \$2,030,000.

The Announcement

A joint news release is recommended between the Department of Health and Community Services and Eastern Health.

Materials required:

- Briefing Note
- Key Messages

Interdepartmental Coordination

- The Department of Health and Community Services will take the lead role on this announcement.

Briefing of MHAs

- MHAs will be briefed accordingly.

Evaluation Criteria

- Monitor public reaction, key stake holders and media reaction.



GOVERNMENT OF
NEWFOUNDLAND AND LABRADOR

Treasury Board
Office of the Minister

27 October 2005

Hon. John Ottenheimer, Q.C., M.H.A.
Minister of Health and Community Services

Dear Colleague:

I refer to your letter of October 21st, 2005 seeking approval to bring forward a Cabinet Submission to address coverage for Herceptin for 40 patients annually at an estimated cost of \$2 million with the request for other new treatment therapies for colorectal cancer and multiple myeloma to be considered as part of your budget submission for 2006-07.

I understand discussions on this matter have been held between our officials and this approach is considered to be acceptable to me.

Yours sincerely,

A handwritten signature in cursive script, reading "Loyola Sullivan".

Loyola Sullivan, MHA
Ferryland District
Minister of Finance and
President of Treasury Board

**SECRET**Attach To: HCS2005-037
TBM2005-284**COMMUNICATIONS AND CONSULTATION BRANCH BRIEFING NOTE****Title:****NEW TREATMENT THERAPIES FOR CANCER PATIENTS****Branch****Comment:**

1. The Communications and Consultations Branch agrees with the communications approach outlined in the appended communications plan, however recommends strengthening the key messages to focus on government's recent investments to enhance cancer services; improve access to chemotherapy and increased funding for new drug treatments.. As noted in the strategic consideration section of the plan, this announcement is a positive counter to the recent media reports regarding inaccurate results around hormone receptor testing.
2. The plan's strategic considerations should note potential outcry from Alzheimer's supporters and the department is asked to consult with the Communications and Consultations Branch on timing of the announcement.
3. The department's roll-out strategy should also include utilizing stakeholder endorsement (i.e. Canadian Cancer Society) in any announcement.

Date: November 1, 2005**Prepared by:** Melony O'Neill**Reviewed by:** Carolyn Chaplin