Legislative Assembly of Ontario

Assemblée législative de l'Ontario

STANDING COMMITTEE ON SOCIAL POLICY

DILUTED CHEMOTHERAPY DRUGS

2nd Session, 40th Parliament
63 Elizabeth II

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The Honourable Dave Levac, MPP
Speaker of the Legislative Assembly

Sir,

Your Standing Committee on Social Policy has the honour to present its Report and commends it to the House.

Ernie Hardeman, MPP
Chair of the Committee

Queen's Park
April 2014

STANDING COMMITTEE ON SOCIAL POLICY
MEMBERSHIP LIST

2nd Session, 40th Parliament

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** Jane McKenna was replaced by Rod Jackson on October 11, 2013

Christine Elliott, Cindy Forster, and France Gélinas regularly served as substitute members of the Committee.

CONTENTS

LIST OF ABBREVIATIONS

Abbreviation	Organization/Term
CCO	Cancer Care Ontario
CIVA	Central intravenous admixture
GPO	Group purchasing organization
IV	Intravenous
LHIN	Local Health Integration Network
LHSC	London Health Sciences Centre
MHC	Marchese Health Care
MHS	Marchese Hospital Solutions
MOHLTC	Ministry of Health and Long-Term Care
NAPRA	National Association of Pharmacy Regulatory Authorities
OCP	Ontario College of Pharmacists
OHA	Ontario Hospital Association
PRHC	Peterborough Regional Health Centre
R.E.D.	Research, Education and Development Fund
RFP	Request for proposals
SSO	Shared services organization
WRH	Windsor Regional Hospital/Hôtel-Dieu Grace Hospital

INTRODUCTION

The Standing Committee on Social Policy is pleased to present its report on diluted chemotherapy drugs. The report is the culmination of many weeks of hearings, beginning in April 2013 in the aftermath of the discovery that 1,202 patients in Ontario and New Brunswick had received diluted doses of two admixed chemotherapy drugs: gemcitabine and cyclophosphamide.[1] The hearings followed the Committee's passage of an amended motion (see Appendix A) on April 15, 2013.

Key participants in the discovery and in the subsequent response appeared before the Committee in April, May, June, September, and October 2013, some of them more than once. A list of witnesses is found in Appendix B.

BACKGROUND

Medbuy, a national group purchasing organization (GPO), issued a request for proposals (RFP) for pharmaceutical products in 2008. Sterile preparation admixing services were included for the first time. Medbuy members, among them many Ontario hospitals, had encouraged the company to include these services as hospitals were already outsourcing them.[2] The one submission received in response to the admixing portion of the RFP was from Baxter CIVA, which was awarded the contract.[3] Two of the drugs involved were gemcitabine and cyclophosphamide; both were manufactured by Baxter.

With the Baxter contract due to expire in the fall of 2011, Medbuy made a public posting in March of that year announcing that the contract would be renewed. (Baxter was

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[1] Both drugs were received off-site in powder form, then mixed with saline and delivered to hospitals in IV bags. Witnesses used "admixing" and "compounding" to refer to the process used to prepare the drugs for hospital use; the Committee has chosen to use the former. Health Canada's definition of compounding includes the following: "The combining or mixing together of two or more ingredients (of which at least one is a drug or pharmacologically active component) to create a final product in an appropriate form for dosing." See Health Canada, Health Products and Food Branch Inspectorate, *Policy on Manufacturing and Compounding Drug Products in Canada POL-0051* (issued January 26, 2009), p. 7.

[2] The Ontario Hospital Association sent a survey regarding the use of pre-compounded (as opposed to pre-mixed) intravenous (IV) medication purchased from external providers to all Ontario hospitals in April 2013. Its analysis examined the responses of 88 of 129 acute care facilities, representing 94% of acute care beds. Fifty hospitals purchased the medication from external providers. Key reasons for purchasing from external providers included patient safety, Accreditation Canada standards, and occupational health and safety. See Ontario Hospital Association, *Hospital Usage of Pre-Compounded Medications from an External Provider – OHA Survey Results: April 2013*, pp. 1, 3 and 4.

[3] Legislative Assembly, Standing Committee on Social Policy, *Hansard*, 2nd Sess., 40th Parl. (May 6, 2013), p. SP-104 (subsequent references to *Hansard* are, unless otherwise noted, to hearings of this Committee).

thought to be the sole provider of admixing services). Marchese Health Care (MHC) objected, saying that it could also provide such services. Medbuy staff visited a MHC facility, and then reported to Medbuy's pharmacy committee.[4] All were satisfied that MHC could provide admixing services.[5] (The pharmacy committee has about 25 members, many of them directors of pharmacy at their respective hospitals. It is led by Medbuy employees and discussed in greater detail on page 6.)

Because of MHC's challenge, Medbuy was obligated to issue an RFP. During the RFP process, Baxter was asked to provide a list of items that Medbuy member hospitals were purchasing from the company.[6] **This list went to tender and included gemcitabine and cyclophosphamide as non-concentration specific admixtures.**

The deadline for submissions was November 9, 2011. Submissions were received from Baxter, Gentès & Bolduc, and MHC. The RFP included a mandatory requirement that admixing services be supervised by a licensed pharmacist. MHC met this requirement and "warranted" that all of the pharmacists performing admixing services were licensed in Ontario, that it was a pharmacy licensed by the Ontario College of Pharmacists, and that it had consulted with Health Canada about additional requirements for meeting its regulations.[7]

The three submissions were scored against a predetermined set of criteria established by members of Medbuy's pharmacy committee. The criteria were based on four categories: pharmaceutical (maximum 30 points); label (maximum 30 points); financial (maximum 25 points); and business (maximum 15 points). All proponents were required to submit copies of their proposed labels (based on the list provided by Baxter), which were scored, the Standing Committee was told, against "precise label-scoring criteria."[8]

MHC received the highest score and was awarded the contract in the late fall of 2011. Before year-end, the Marchese organization created a new division, Marchese Hospital Solutions (MHS), to handle the Medbuy contract from a location in Mississauga.[9] The contract was signed in February 2012; it included 117 products and was worth $2.6 million. The "overall spend" on gemcitabine and cyclophosphamide was about $10,000.[10]

Under the terms of the contract, gemcitabine and cyclophosphamide were provided to the London Health Sciences Centre (LHSC), the Windsor Regional Hospital/Hôtel-Dieu Grace Hospital (WRH), Lakeridge Health, and a hospital in New Brunswick. The Peterborough Regional Health Centre (PRHC) was not part of the contract but received drugs through the Durham Regional Cancer Centre, part of Lakeridge Health. All facilities began using the MHS product at different points in time, with the PRHC being

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[4] Medbuy told the Committee the facility was in Hamilton. Marchese's president said it was in Kitchener. See *Hansard* (May 6, 2013), p. SP-105; and *Hansard* (April 29, 2013), p. SP-88.
[5] *Hansard* (May 6, 2013), p. SP-104.
[6] *Hansard* (June 4, 2013), p. SP-227.
[7] *Hansard* (May 6, 2013), pp. SP-104 and SP-105.
[8] Ibid.
[9] *Hansard* (May 6, 2013), p. SP-105; and (September 23, 2013), p. SP-272.
[10] *Hansard* (September 23, 2013), p. SP-272.

the last, as shown in the table below.

LOCATION	FIRST USE OF MHS PRODUCT
Windsor Regional Hospital	February 2012[11]
New Brunswick	March 2012[12]
London Health Sciences Centre	March and October 2012[13]
Lakeridge Health	March 12, 2013[14]
Peterborough Regional Health Centre	March 20, 2013[15]

Dilution Discovery

On Tuesday, March 20, 2013, pharmacy assistants at the PRHC began to prepare gemcitabine for a patient's afternoon chemotherapy treatment. The pharmacy's supply of standard multi-patient use bags of admixed chemotherapy drugs from Baxter was depleted; product from MHS, the new supplier, was to be used for the first time.

The assistants noted differences between the two products. Unlike the Baxter bag, the MHS bag required refrigeration. Further examination of the MHS label showed that it did not include the total volume of the bag or the final concentration. A Baxter bag used for an earlier treatment that same day was still available. Its label read: four grams in 100 millilitres; total volume of 105.26 millilitres; gemcitabine 38 milligrams per millilitre. The MHS label indicated four grams in 100 millilitres. The assistants agreed that the final concentration on the MHS bag was unclear and uncertain.[16] In order to comply with a physician's order, they needed to know the specific concentration of the admixture.

The Baxter product had been prepared in an empty Viaflex infusion bag. MHS was using a pre-filled Hospira bag.[17] (The Committee was told that there is a known industry standard that pre-filled IV bags are overfilled to account for evaporation while in storage

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[11] WRH's relationship with MHS began in February 2012. See *Hansard* (April 22, 2013), p. SP-24.
[12] The Saint John Regional Hospital purchased cyclophosphamide "beginning in March 2012." See "Almost 200 New Brunswick patients received diluted doses of chemotherapy," *Canadian Press*, April 3, 2013.
[13] The London Regional Cancer Program began purchasing cyclophosphamide and gemcitabine from MHS on March 1, 2012. The LHSC's in-patient pharmacy began purchasing the two drugs from MHS on October 15, 2012. See *Hansard* (April 29, 2013), p. SP-61.
[14] *Hansard* (April 23, 2013), p. SP-48.
[15] *Hansard* (May 7, 2013), p. SP-128.
[16] Ibid.; and Standing Committee on Social Policy, "Written submission of Lori Webb, Pharmacy Assistant, Peterborough Regional Health Centre," (2013).
[17] Dr. Jake Thiessen, *A Review of the Oncology Under-Dosing Incident: A Report to the Ontario Minister of Health and Long-Term Care* (July 12, 2013), p. 16.

and that “overfill also addresses the issue of volume remaining in IV tubing.”[18])

This lack of clarity resulted in PRHC staff contacting Lakeridge Health and Marchese. When asked if overfill had been taken into account, a Marchese representative said that it had not, leaving PRHC staff to conclude that MHS did not appreciate why concentration was important or how the product was being used.[19]

(The Committee would learn that MHS was preparing the drugs in non-concentration-specific formats with the understanding that each bag would be used for a single patient. Even though the MHS labels were unlike those used by Baxter, the other hospitals were using the bags for multiple patients, as they had done when receiving product from Baxter. They did this under the misapprehension that the drugs had been prepared in concentration-specific formats, even though this was not the case and the label did not give the final concentration.)

In his report, *A Review of the Oncology Under-Dosing Incident*, Dr. Jake Thiessen wrote the following:

> MHS employed a process in the preparation of the bulk reconstituted cyclophosphamide and gemcitabine that failed to compensate adequately for an overfill factor in the supplier’s normal saline bags. On the basis of the MHS labels on the bags . . . , the best estimate is that the average actual cyclophosphamide concentration was 10% lower than that stated on the label. For gemcitabine the average actual concentration was 7% lower than stated on the label.[20]

These findings in Peterborough led to the discovery that 1,202 patients at four hospitals in Ontario (PRHC, Lakeridge Health, WRH, and LHSC) and one in New Brunswick (a hospital in the Horizon Health Network) who had undergone chemotherapy treatment within the previous year, had received diluted doses of gemcitabine and/or cyclophosphamide. The table below shows the number of patients affected at each facility.

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[18] *Hansard* (April 29, 2013), p. SP-81.
[19] *Hansard* (May 27, 2013), p. SP-194.
[20] Thiessen, *A Review of the Oncology Under-Dosing Incident*, p. 1.

LOCATION	NUMBER OF PATIENTS[21]
Windsor Regional Hospital	290
New Brunswick	183
London Health Sciences Centre	691
Lakeridge Health	37
Peterborough Regional Health Centre	1
TOTAL	**1,202**

It was also learned that MHS, the company supplying the two drugs from its facility in Mississauga, was unregulated; neither the federal nor the provincial governments had oversight. To further complicate the issue, the contract for the provision of the two drugs was not between each of the hospitals and MHS, but between MHS's parent company and Medbuy, the GPO contracted by the hospitals.

The Committee wishes to congratulate the pharmacy staff at the PRHC for their thoroughness, attention to detail, and initiative in bringing this matter forward to the relevant authorities. Most importantly, the Committee recognizes the fear and anxiety with which the affected patients and their families have lived since hearing their cancer treatments may have been compromised. It hopes that its comments and recommendations will help ensure that such an incident does not happen again.

COMMITTEE OBSERVATIONS AND RECOMMENDATIONS

Dr. Jake Thiessen's report, *A Review of the Oncology Under-Dosing Incident*, was presented to the Minister of Health and Long-Term Care in July 2013 and released to the public the next month. He made 12 recommendations covering three areas: group purchasing organizations; manufacturing and compounding; and hospitals, clinics, and associated pharmacies. The recommendations appear in Appendix C.

The Committee generally endorses Dr. Thiessen's recommendations. Because it sees its own efforts as complementary to those of Dr. Thiessen, the Committee has focussed its observations and recommendations on issues not specifically mentioned in his report or included in his recommendations. These issues relate to the procurement practices of hospitals; the oversight, monitoring and regulation of non-accredited pharmacies; and other concerns (i.e., labelling, communications, and best practices).

Procurement Practices of Hospitals

Medbuy is a private, share capital corporation and national GPO.[22] It works under contract to health care organizations (e.g., individual hospitals, groups of hospitals and shared services organizations), which make up both its membership and its shareholders.[23]

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[21] Ibid., p. 11.

[22] Medbuy's main competitor is HealthPRO.

[23] A shared service organization (SSO) is "a centralized organization that BPS [broader public sector] institutions join as members to obtain better prices for goods and services

Medbuy has “about 25 full members and probably 75 hospitals.” Some members represent more than one facility.[24] Medbuy’s board of directors is made up of 13 executives from shareholder members, who serve as volunteers, and two independent directors who receive financial compensation.[25] Senior executives representing members also sit on the GPO’s advisory groups, like its pharmacy committee. Standing Committee members listened with skepticism as Medbuy representatives told them that it operates like a not-for-profit in that it does not retain earnings. Any net revenue generated is distributed to members in proportion to what they have spent under Medbuy contracts.[26]

The pharmacy committee has about 25 members who are often directors of pharmacy in their respective hospitals/organizations. The committee is led by Medbuy employees who are also licensed pharmacists. It was this group that developed the scoring criteria for the 2011 RFP and evaluated submissions based on those criteria.[27] **The Standing Committee notes that it was also the pharmacy committee that failed to notice the contract’s lack of clarity with respect to the need for concentration-specific formats for gemcitabine and cyclophosphamide.**

Health care organizations participate in GPOs for a variety of reasons. Those mentioned by witnesses included economies of scale, tighter purchasing practices, higher levels of standardization, and the ability to leverage training for new products and equipment.

While the Committee appreciates these reasons, it has the following concerns about the operation of GPOs: rebates, value adds, the application of provincial legislation, and audits.

REBATES

Witnesses from Medbuy told the Committee that the revenue its activities generate is “rebate revenue.” Many contracts have a rebate structure based on meeting “certain volume thresholds.” If those thresholds are met, additional rebates are secured on behalf of members. The rebates go to Medbuy, which takes what it needs to offset its operating expenses and then distributes the remainder to its members.[28] (Medbuy’s annual budget is in the range of $7 million.[29]) What a member receives is in proportion to what they spend under Medbuy contracts. The Committee was told that in 2012, member spend against Medbuy contracts was $627 million.[30]

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through group purchasing.” See Office of the Auditor General of Ontario, *Annual Report 2009*, p. 202. Examples of SSOs in Ontario’s health sector include Plexxus, Shared Services West, and 3SO.

[24] *Hansard* (September 23, 2013), p. SP-271.

[25] ”Medbuy Briefing Note” attached to email from Medbuy Corporation, London to Clerk, Standing Committee on Social Policy, October 21, 2013.

[26] *Hansard* (May 6, 2013), p. SP-104.

[27] *Hansard* (April 22, 2013), p. SP-29; and *Hansard* (May 6, 2013), p. SP-108. See *Hansard* (May 6, 2013), p. SP-104.

[28] *Hansard* (September 23, 2013), p. SP-273.

[29] Ibid., p. SP-282.

[30] Ibid., p. SP-269.

The Committee requested and received audited financial statements and rebate data from Medbuy, LHSC, WRH, and Lakeridge Health. Some of the latter appear in the table below. While not directly comparable, all are representative of the size of the transactions undertaken by Medbuy on behalf of its members.

ORGANIZATION	2011/12	2012/13
Medbuy[31]		
• Rebates payable[32]	$7,075,696.00	$6,339,395.00
London Health Sciences Centre		
• Pharmaceutical rebates received from Medbuy[33]	1,914,941.00	1,899,165.00
Windsor Regional Hospital		
• Rebates received from Medbuy[34]	462,389.37	409,292.21
Lakeridge Health		
• Rebates received from Medbuy[35]	1,006,199.75	530,048.48

Although appreciative of what was provided, the Committee remains concerned about the lack of transparency with respect to the receipt of rebates and how they are used, by hospitals and by Medbuy alike. Large amounts of public money are involved in these transactions, all of which are conducted without public oversight.

VALUE ADDS

During the course of the hearings, the Committee learned about value-add incentives. The Ministry of Finance defined them as offers by suppliers

[31] Medbuy figures are for the calendar years 2011 and 2012.
[32] Medbuy Corporation, *Financial Statements of Medbuy Corporation Year ended December 31, 2012*, "Balance Sheet." These are rebates paid to all members, not just the three listed in the table. According to footnote 5 in the Statements, rebates payable included $1,163,239 (2011) and $1,104,366 (2012) in research, development and education (R.E.D.) funds. Information in email from Medbuy Corporation to Clerk, Standing Committee on Social Policy, October 21, 2013.
[33] London Health Sciences Centre, "Pharmaceutical Rebates Received from Medbuy Corporation Q1 2011/2012 through Q1 2013/2014." Information in email from LHSC to Clerk, Standing Committee on Social Policy, October 21, 2013.
[34] Windsor Regional Hospital, "Summary of Rebates Received from Medbuy For the Fiscal Years Ending March 31, 2012 and 2013." Information in email from WRH to Clerk, Standing Committee on Social Policy, October 15, 2013.
[35] Information in letter from Lakeridge Health, Oshawa to Clerk, Standing Committee on Social Policy, October 17, 2013.

> over and above the primary goods or services being purchased, with the intent to increase the total value received by the customer.[36]

These incentives are allowed under the Broader Public Sector Procurement Directive, but rules for their use include being "directly relevant and transparently connected" to a procurement.[37] In the case of the Medbuy contract, Marchese's offer included $20,000 for the GPO's Research, Education and Development (R.E.D.) Fund. The Fund allocates money to healthcare industry initiatives, including training for the staff of Member hospitals.[38] Marchese's president told the Committee that the donation was a requirement of the contract but did not know how they came up with the $20,000 figure; she referred to it as a "neutral decision."[39] The Committee interpreted this as meaning a mutual decision made by Marchese and Medbuy.

Medbuy was asked if there was a value-add category included in the scoring process and provided the following response:

> There was at one point. There is no longer, and that's probably been the practice for two or three years. We do not have a separate category of value add.[40]

The Committee examined the 2011 Medbuy RFP for sterile compounding services and the submissions of Marchese's competitors, Baxter and Gentès & Bolduc. The RFP included Schedule B, Value-Added Benefits, which were understood to mean the following:

> Any funds, goods or services provided to the benefit of Participating Medbuy Member(s) which *are not identified as a mandatory submission requirement in this RFP document*. [emphasis added] Value-Added Benefits are related to a particular Product(s) or Service(s) Contract without directly affecting the price(s) of product(s) listed in the submitted Proposal to this RFP. Medbuy encourages Proponents to submit Value-Added Benefits in the form of contributions to the Medbuy Research, Education, and Development (R.E.D.) Fund which will be scored as part of the Business Criteria.[41]

Contrary to what the Committee had heard, value-adds were included in Medbuy's 2011 RFP. They were not a mandatory requirement but were encouraged and included in the score. Like Marchese, Baxter chose to participate in Schedule B; Gentès & Bolduc did not.[42]

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[36] Ministry of Finance, *Broader Public Sector Procurement Directive: Implementation Guidebook* (April 2011), p. 39.
[37] Ibid.
[38] Medbuy, "R.E.D. Fund," n.d.
[39] *Hansard* (June 10, 2013), p. SP-239.
[40] *Hansard* (September 23, 2013), p. SP-273.
[41] Attachment to letter from Gentès & Bolduc, St. Hyacinthe, Quebec, May 31, 2013 to Clerk, Standing Committee on Social Policy.
[42] Ibid., and attachment to letter from Baxter Corporation, Mississauga, May 28, 2013 to

APPLICATION OF PROVINCIAL LEGISLATION

The *Broader Public Sector Accountability Act, 2010* contains rules and accountability standards pertaining to the procurement of goods and services. Medbuy is considered a designated broader public sector organization under the Act because it is controlled by one or more designated broader public sector organizations (e.g., hospitals) and exists solely for the purpose of purchasing goods or services for them.[43] The *Broader Public Sector Procurement Directive*, which applies to designated broader public sector organizations, has many mandatory requirements, one of which is an open competitive process for contracts with a procurement value of $100,000 or more.[44]

The Committee acknowledges that Medbuy is compliant with the *Broader Public Sector Accountability Act, 2010*. It is also aware that Medbuy, as a GPO, is not obligated to adhere to all of the Act's provisions.

EMPLOYEE AND EXECUTIVE SALARIES

Medbuy employs about 50 to 60 people; approximately 20% are licensed health care professionals.[45] While some legislation does apply, Medbuy is not subject to the *Public Sector Salary Disclosure Act, 1996*.[46] This statute requires organizations receiving funding from the province to disclose, on an annual basis, "the names, positions, salaries, and taxable benefits of employees paid $100,000 or more in a calendar year."[47]

Medbuy's CEO was asked how many employees make over $100,000 and told the Committee "perhaps five."[48] In response to a request from the Committee, Medbuy provided staff compensation reports for 2011 and 2012. The report for 2012 contained 60 positions. Some of the titles attached to those positions were listed more than once (e.g., Analyst, Decision Support appeared three times). Individuals holding 17 of these positions made more than $100,000 that year.[49] The Committee is disturbed by the discrepancy between this figure and that provided by the CEO.

AUDITS

The Committee learned that Medbuy can be audited but has not been the subject of what was referred to as "a full-blown audit." Medbuy has provided supporting documentation about specific initiatives when asked to do so by the Broader Public Sector Supply Chain Secretariat of the Ministry of Government Services.[50] The company's annual financial statements are audited but audit results are not made publicly available.[51]

Clerk, Standing Committee on Social Policy.

[43] Ministry of Finance, *Broader Public Sector Procurement Directive: Implementation Guidebook*, p. 1.

[44] Management Board of Cabinet, *Broader Public Sector Procurement Directive* (effective July 1, 2011), p. 8.

[45] *Hansard* (September 23, 2013), p. SP-271.

[46] Ibid., p. SP-280.

[47] Ministry of Finance, "Public Sector Salary Disclosure 2013 (Disclosure for 2012)."

[48] *Hansard* (September 23, 2013), p. SP-280.

[49] "2012 Compensation Report," attached to email from Medbuy Corporation to Clerk, Standing Committee on Social Policy, October 21, 2013.

[50] *Hansard* (May 6, 2013), p. SP-111.

[51] *Hansard* (September 23, 2013), p. SP-280.

In light of the dilution error and the amount of money being spent by hospitals and other health care organizations on drugs through nationally-based GPOs, the Committee believes that there is a need for greater openness and transparency in the way these bodies operate in the province of Ontario and makes the following recommendations.

The Standing Committee on Social Policy recommends that

1. The Ministry of Health and Long-Term Care examine best practices for the procurement and distribution of oncology drugs by provincial cancer centres. Areas to be examined would include, but not be limited to oversight.

2. In order to maintain transparency and accountability, the government of Ontario, through legislative or other means, take those steps necessary to ensure that

- group purchasing organizations and shared services organizations are subject to all aspects of the *Broader Public Sector Accountability Act, 2010*;
- the salaries of employees and executives of group purchasing organizations and shared services organizations are reported under the *Public Sector Salary Disclosure Act, 1996*;
- group purchasing organizations and shared services organizations are subject to audits by the Office of the Auditor General of Ontario;
- public and broader public sector members of group purchasing organizations and shared services organizations pay for the value of procurement services as opposed to a percentage of purchases; and
- rebates and value adds are discontinued.

Oversight, Monitoring, and Regulation of Non-Accredited Pharmacies

Shortly after the public revelation that the gemcitabine and cyclophosphamide admixtures supplied by MHS were diluted, it was learned that the enterprise operated without provincial or federal oversight.

MHC was awarded the contract to supply intravenous admixtures to Medbuy member hospitals, and formed MHS, in late 2011. MHS was created as a separate division to keep the operations of Marchese's hospital admixtures supply business separate from its community-based and home care pharmacies.[52] The Committee was told that Marchese made contact with both Health Canada and the Ontario College of Pharmacists (OCP) in its unsuccessful attempts to find an oversight/regulatory body for MHS.[53]

In the words of a witness from the Ministry of Health and Long-Term Care,

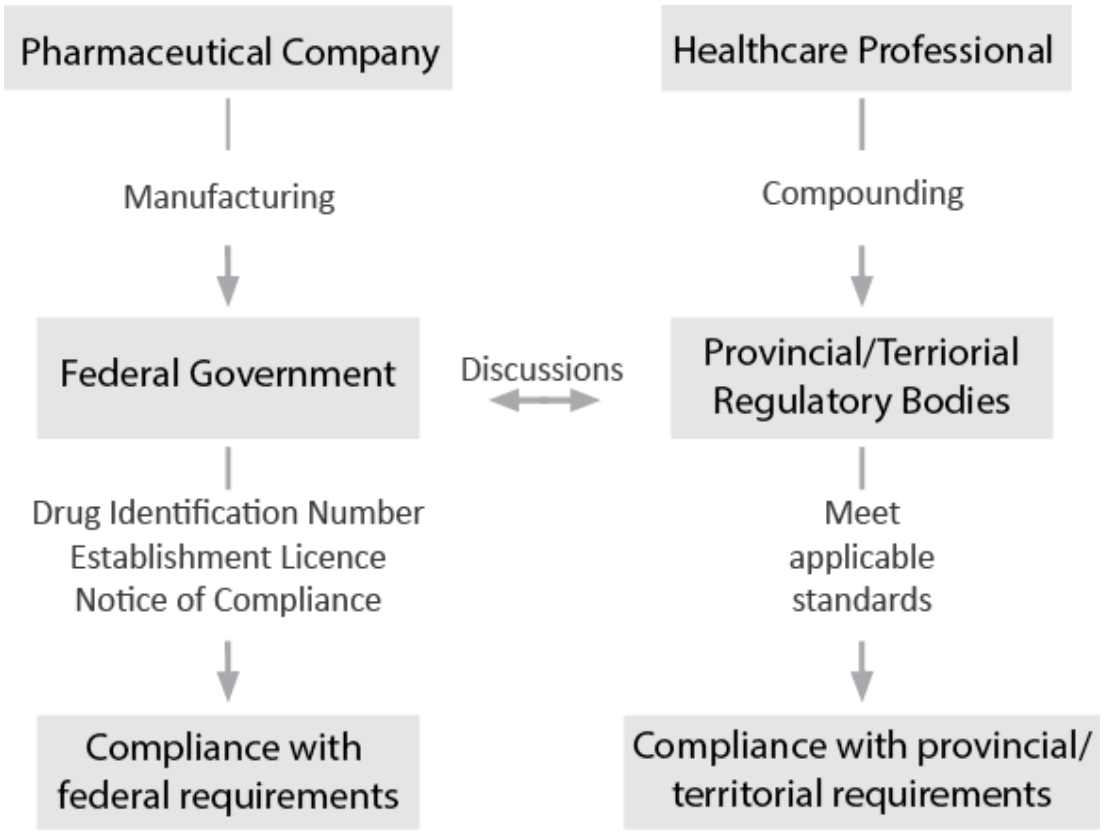
[52] *Hansard* (April 29, 2013), p. SP-80.
[53] The Committee was also told that Baxter, the incumbent provider, was not an accredited pharmacy. See *Hansard* (May 6, 2013), p. SP-109.

> Marchese, the company that mixed and supplied these drugs to the hospitals, fell into a gap between [Health Canada and the Ontario College of Pharmacists]. They were producing these drugs in a facility that was neither a pharmacy nor licensed as a manufacturer. It was a grey area, and consequently, there was no active oversight.[54]

OVERSIGHT AT TIME OF DISCOVERY

The OCP regulates and accredits community pharmacies under the *Drug and Pharmacies Regulation Act*. This Act also specifies that the OCP does not have jurisdiction over hospital pharmacies. Pharmacists and pharmacy technicians, in both community and hospital settings, are regulated by the OCP under the *Pharmacy Act, 1991*.

Health Canada regulates the manufacture, packaging, labelling, and sale of drugs, and licensed drug manufacturers, all under the *Food and Drug Act*. The Act also provides Health Canada with inspection powers in those places where drugs are manufactured, prepared, packaged or stored. Health Canada's *Policy on Manufacturing and Compounding Drug Products in Canada (POL-0051)* includes a diagrammatic representation of provincial and federal jurisdiction over manufacturing and compounding, a re-creation of which appears below.



[54] *Hansard* (April 22, 2013), p. SP-34.

Source: Health Canada, Health Products and Food Branch Inspectorate, *Policy on Manufacturing and Compounding Drug Products in Canada (POL-0051)* (July 30, 2009), p. 4.

PROVINCIAL RESPONSE

Cancer Care Ontario (CCO) issued a press release on April 2, 2013 announcing that patients at four Ontario hospitals who had undergone chemotherapy treatment within the past year had received lower than intended doses of cyclophosphamide and gemcitabine.[55]

The following day, an OCP-appointed investigator and two Health Canada inspectors went to Marchese's Mississauga site. They learned that MHS and an accredited MHC pharmacy occupied the same building. Both entities were visited. MHS had a pharmacist on-site, but the facility was not listed as a pharmacy with the OCP.[56] On April 8 the OCP publicly acknowledged that MHS was not an accredited pharmacy and was outside of its regulatory authority and inspection process. Its investigation proceeded with a focus on the pharmacist, a member of the OCP.[57]

In early April the Ministry of Health and Long-Term Care struck a working group of stakeholders to coordinate a response.[58] It also selected Dr. Jake Thiessen, founding director of the University of Waterloo School of Pharmacy, to lead an independent review of "quality assurance in the province's cancer drug supply chain."[59] His report was released in August.

Later in April the Ministry wrote to businesses it thought might be selling admixed drugs, in order to obtain information about their processes and oversight. Another letter was written to hospitals inquiring about admixing drugs.[60] Over the following weeks, regulatory amendments were introduced requiring hospitals to purchase drugs from regulated suppliers, and expanding the jurisdiction of the OCP to oversee pharmacists and pharmacy technicians in drug preparation premises, including MHS.[61]
The Committee notes that legislation responding to Dr. Thiessen's recommendations was introduced on October 10, 2013. One of its provisions would allow the OCP to accredit and inspect pharmacies in public and private hospitals.

FEDERAL RESPONSE

Health Canada issued an interim direction to companies involved in admixing in mid-April. The direction outlined the conditions under which these activities would be allowed: 1) in a manner that meets federal licensing and manufacturing requirements 2) within a hospital meeting provincial regulatory requirements; or 3) if outside a hospital, under the supervision of a provincially licensed pharmacist.[62] The Committee notes that

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[55] *Hansard* (April 16, 2013), p. 8.
[56] Ibid., pp. SP-15 and SP-18; and *Hansard* (May 6, 2013), p. SP-114.
[57] *Hansard* (May 6, 2013), p. SP-115.
[58] *Hansard* (April 22, 2013), p. SP-34.
[59] Ministry of Health and Long-Term Care, "Dr. Jake Thiessen to Lead Independent Review of Cancer Drug System," *News Release*, April 9, 2013.
[60] *Hansard* (April 22, 2013), pp. SP-34, SP-35 and SP-41.
[61] Ibid., p. SP-35; and *Hansard* (May 27, 2013), p. SP-185.
[62] Health Canada, "Interim Regulatory Oversight of Admixing and Compounding," *News*

Marchese had been admixing under the supervision of a provincially licensed pharmacist.

Following the directive's release, companies performing admixing activities were asked which of the three categories the activity fell under. Health Canada has also worked with provincial and territorial government officials and pharmacist representatives.[63]

The Committee heard that there is significant variation in the way provinces and territories oversee admixing. Members were told that the federal government will continue to exempt what was referred to as "traditional compounding" from its purview, but will focus on activities that appear to be a hybrid between "compounding and manufacturing".[64] It is considering the creation of a new category called commercial compounding-manufacturing, as part of its *Policy on Manufacturing and Compounding Drug Products in Canada (POL-0051)*.[65] The Committee notes that admixing by anyone other than a manufacturer continues to be unregulated.

The Standing Committee on Social Policy recommends that
3. Health Canada act on its intent to create a new category (i.e., commercial compounding-manufacturing) within its *Policy on Manufacturing and Compounding Drug Products in Canada (POL-0051)*.

Other Concerns

LABELLING

During its hearings, hospital representatives told the Committee that Marchese's labelling was considered clearer and more precise than that of its competitors for the Medbuy contract.[66] One of those competitors, Baxter, was told in a debriefing that one of the issues related to its bid was labelling.[67] Members find this discomforting as it was the MHS labelling that first alerted the staff at PRHC to a possible problem with both gemcitabine and cyclophosphamide. The Baxter labels had been used without issue.

In August 2009 CCO issued recommendations related to key components of chemotherapy labelling which focussed on the necessary components and formatting of labels to maximize safe delivery and minimize errors. These guidelines were not designed for admixing facilities. They were intended for the preparation of chemotherapy drugs for individual patients in cancer centres rather than in facilities such as that operated by MHS.[68]

Release, April 19, 2013.
[63] *Hansard* (October 21, 2013), p. SP-316.
[64] Ibid., p. SP-317. A witness from Health Canada described "traditional compounding" as "making a specific dose for a specific patient to meet a specific need." See ibid., p. SP-321.
[65] *Hansard* (October 21, 2013), p. SP-319.
[66] See, for example, *Hansard* (April 23, 2013), p. SP-55; and (April 29, 2013), p. SP-68.
[67] *Hansard* (June 4, 2013), p. SP-225.
[68] *Hansard* (April 16, 2013), p. SP-10; and *Hansard* (April 29, 2013), pp. SP-77 and SP-78.

The Standing Committee on Social Policy recommends that

4. Cancer Care Ontario develop labelling guidelines for the preparation of chemotherapy drugs at provincial admixing facilities like that operated by Marchese Hospital Solutions.
5. The federal government, in consultation with the provinces, consider the introduction of:

- national standards for the labelling of concentration-specific and non-concentration-specific drugs; and
- national standards for the labelling of all admixed (i.e., narcotic, chemotherapy, and epidural) drugs (e.g., single patient use versus multiple patient use).

COMMUNICATIONS

The Medbuy contract saw MHS start to supply members with gemcitabine and cyclophosphamide admixtures in February 2012. MHS's understanding of the contract was that it was required to supply both drugs in non-concentration-specific formats and that each bag would be used for a single patient.[69] As stated earlier in the report, the hospitals were using the bags for multiple patients with the understanding that the drugs were prepared in concentration-specific formats.

The Committee heard that a Marchese pharmacist and a Medbuy manager, who is a pharmacist, had an email exchange in January 2012 regarding the chemotherapy preparations and the attachment of lines or tubes to bags. Marchese asked about the possibility of attaching a line to the bags as a safety precaution.[70] Medbuy replied that it did not expect Marchese to attach lines for the following reason:

> the line set-up is likely different for each member. . . . Members will be putting on a patient specific label in the Pharmacy and can attach a line if desired, at that time.[71]

Marchese took this to mean that Medbuy understood the bags would be used for a single patient.[72]

[69] *Hansard* (June 10, 2013), p. SP-235.
[70] Ibid..
[71] Email 9 (17 Jan. 2012 – 2:54 pm) in package sent by Gowling LaFleur Henderson LLP, Toronto to Clerk, Standing Committee on Social Policy, October 9, 2013.
[72] *Hansard* (June 10, 2013), p. SP-235.

Another email exchange involving the same Marchese and Medbuy staff members, also in January 2012, saw the former write the following:

> a) Lakeridge has indicated their volumes for Gemcitabine 4g/105mL. We were planning on preparing this as 4g/100mL, as listed.[73]

After checking its labels, Medbuy replied as follows:

> the Baxter product was 4g in 105 mL. I don't see any clinical impact from changing the volume but suggest that you decide what your preference is and then discuss with Lakeridge to see if they have any objections.[74]

The Committee believes the above responses were inappropriate and are evidence of a lack of due diligence on the part of health care professionals. It sees these communications as more missed opportunities to catch the need for concentration-specific admixtures and avoid the circumstances of March 20, 2013 and their negative impact on 1,202 patients.

Pharmacists who work with oncology drugs on a regular basis told the Committee that the need to know the precise concentration of these medications was vital as a dose had to be individualized for each patient. An oncologist prescribes a dose that is based on a variety of factors (e.g., patient weight and type of cancer) that are unique to an individual. Concentrations are also adjusted according to a patient's side effects.

The Committee also heard that, according to the product monograph for gemcitabine, in order for a four-gram dose to be used for one standard five-foot-ten patient, that individual would have to weigh over 900 pounds.[75] This information is readily available to any pharmacist.

Four Marchese pharmacists involved in the start-up of the Medbuy contract admitted to having limited experience with oncology drugs. The MHS pharmacist who responded to PRHC's inquiries on March 20 had no practical experience with chemotherapy drugs prior to working at MHS.[76]

BEST PRACTICES

PRHC was one of four Ontario hospitals receiving gemcitabine and cyclophosphamide admixtures as part of Medbuy's contract with MHS. As shown in the table on page 3, it was also the last to start using either product. Three of the other four facilities had been employing MHS products in their treatments for approximately a year.

Committee members are perplexed by the fact that pharmacists and pharmacy assistants/technicians at WRH, LHSC, and Lakeridge Health failed to notice the

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[73] Email 5 (9 Jan 2012 – 5.24 pm) in package sent by Gowling LaFleur Henderson LLP
[74] Email 7 (10 Jan. 2012 – 1:23 pm) in package sent by Gowling LaFleur Henderson LLP.
[75] *Hansard* (June 4, 2013), p. SP-230.
[76] *Hansard* (June 10, 2013), pp. SP-241 and SP-246.

inconsistencies discovered by the staff at PRHC when preparing for the initial use of MHS gemcitabine.

The Committee is concerned about the professional conduct of pharmacists connected to this incident, including those employed by Medbuy and sitting on its pharmacy committee. This concern is so significant that the Committee has written to the Registrar of the Ontario College of Pharmacists (OCP) requesting an investigation. Copies of letters sent by the Committee to the OCP are found in Appendix D.
Accreditation Canada was contacted to determine what if any protocols it had dealing with GPOs and SSOs. In its response, the organization referred to medication management standards and leadership standards. Medical management standards address labelling and monitoring the quality of contracted services. The contents of Accreditation Canada's response are found in Appendix E.

The Standing Committee on Social Policy recommends that
6. Ontario hospitals, and any group purchasing or shared services organizations which obtain medications on their behalf, ensure strict adherence to the relevant standards set by Accreditation Canada.

CONCLUSION

In April 2013 the Standing Committee on Social Policy began its work on the motion found in Appendix A. The scope of that exercise quickly expanded as the Committee learned more about the circumstances leading to the discovery that the gemcitabine and cyclophosphamide provided to five hospitals by Marchese Hospital Solutions were diluted.

Over time, the Committee heard about mistakes and missed opportunities to detect problems with the preparation of the two drugs before they were used by any of the hospitals involved. Members know that the outcomes for all involved would have been much different had the following occurred:

- the members of Medbuy's pharmacy committee noticed the lack of clarity in the list of drugs put out to tender;
- staff at Medbuy and Marchese paid greater heed to the content and context of their email correspondence; and
- the staff at the Windsor, New Brunswick, London, and Lakeridge Health hospitals been as alert as those at the Peterborough Regional Health Centre to the differences between the labels on the Baxter and Marchese products.

The Committee has never lost sight of the effect that this incident has had on the lives of the 1,202 patients, adults and children, who received diluted chemotherapy treatments, as well as their families. It hopes that its recommendations and the responses to them will help to ensure that similar situations are avoided in the future and that the public's faith in the province's health care system is maintained.

CONSOLIDATED LIST OF RECOMMENDATIONS

The Committee requests that those to whom recommendations are directed provide the

Committee Clerk with a written response within 120 calendar days of the tabling of this report with the Speaker of the Legislative Assembly.

The Standing Committee on Social Policy recommends that

1. The Ministry of Health and Long-Term Care examine best practices for the procurement and distribution of oncology drugs by provincial cancer centres. Areas to be examined would include, but not be limited to oversight.

2. In order to maintain transparency and accountability, the government of Ontario, through legislative or other means, take those steps necessary to ensure that

- group purchasing organizations and shared services organizations are subject to all aspects of the *Broader Public Sector Accountability Act, 2010*;
- the salaries of employees and executives of group purchasing organizations and shared services organizations are reported under the *Public Sector Salary Disclosure Act, 1996*;
- group purchasing organizations and shared services organizations are subject to audits by the Office of the Auditor General of Ontario;
- public and broader public sector members of group purchasing organizations and shared services organizations pay for the value of procurement services as opposed to a percentage of purchases; and
- rebates and value adds are discontinued.

3. Health Canada act on its intent to create a new category (i.e., commercial compounding-manufacturing) within its *Policy on Manufacturing and Compounding Drug Products in Canada (POL-0051)*.

4. Cancer Care Ontario develop labelling guidelines for the preparation of chemotherapy drugs at provincial admixing facilities like that operated by Marchese Hospital Solutions.

5. The federal government, in consultation with the provinces, consider the introduction of:

- national standards for the labelling of concentration-specific and non-concentration-specific drugs; and
- national standards for the labelling of all admixed (i.e., narcotic, chemotherapy, and epidural) drugs (e.g., single patient versus multiple patients).

6. Ontario hospitals, and any group purchasing or shared services organizations which obtain medications on their behalf, ensure strict adherence to the relevant standards set by Accreditation Canada.

APPENDIX A

Committee Motion[77]

That pursuant to Standing Order 111(a), the Standing Committee on Social Policy immediately initate a study and investigation regarding recent reports where diluted chemotherapy drugs were administered to patients in Ontario; and, whether or not the Ministry of Health and Long-Term Care effectively exercised its role into the oversight, monitoring and regulation of non-accredited pharmacetuical companies.

That the Committee shall be able to call witnesses under oath as it sees fit to assist in the Committee's investigation and shall produce a report that includes, but is not limited to:

- investigating the apparent lack of oversight, lack of standards and/or absent monitoring for companies like, Marchese Hospital Solutions, by the Minister of Health and Long-Term Care;
- investigating the roles, respectively, of the Ministry of Health and Long-Term Care, the Ontario College of Pharmacists, Health Canada, and any other organizations the Committee might identify in overseeing, providing standards for, and monitoring companies like Marchese Hospital Solutions;
- assessing the adequacy of Ministry of Health's outsourcing strategy, pharmaceutical regulatory regime, guidelines and drug inspection procedures and protocols;
- any impact on the nearly 1,200 cancer patients in Ontario who received a flawed or diluted drug during their cancer treatments;
- whether the steps taken by the government and/or the Ministry and/or the Minister were adequate in responding to this matter;
- what international best practices could have and should have been used to ensure proper checks and balances were and are put in place for companies that produce complex drugs and the hospitals that use those drugs so as to prevent a situation like this from ever happening again.

Notwithstanding the Committee's meeting schedule as ordered by the House, the Committee shall seek permission from the House Leaders and of the House to be permitted to sit to the call of the Chair and to meet notwithstanding prorogation.

[77] *Hansard* (April 15, 2013), pp. SP-4 – SP-5.

APPENDIX B

List of Witnesses and Submissions

ORGANIZATION/INDIVIDUAL	DATE(S) OF APPEARANCE
Baxter Corporation Canada	
• Carol Bentley, Regional Director of Sales • Phil Lynch, Director of Quality • Anne Miao, Director of Pharmacy • Mike Oliver, General Manager	June 4, 2013
Cancer Care Ontario	
• Dr. Michael Sherar, President and CEO	April 16, 2013
• Dr. Carol Sawka, Vice President, Clinical Programs and Quality Initiatives	April 29, 2013
Central East Local Health Integration Network	
• Wayne Gladstone, Chair, Board of Directors • Deborah Hammons, CEO	May 13, 2013
Erie St. Clair Local Health Integration Network	
• Gary Switzer, CEO	May 13, 2013
Health Canada	
• Dr. Supriya Sharma, Senior Medical Adviser, Health Products and Food Branch	October 21, 2013
Lakeridge Health	
• Kevin Empey, President and CEO	April 23, 2013
• Dr. Leta Forbes, Chief and Medical Director, Oncology Program; Quality Lead, Systemic Therapy, Central East LHIN	April 23, 2013
• Nancy Froude, Pharmacist, Durham Regional Cancer Centre	June 3, 2013
• Tom McHugh, Vice President, Clinical Services; Regional Vice President, Cancer Services, Central East LHIN	April 23, 2013
• Leslie Motz, Senior Director, Clinical Services	April 23, 2013

ORGANIZATION/INDIVIDUAL	DATE(S) OF APPEARANCE
London Health Sciences Centre	
• Murray Glendining, Acting CEO; Executive Vice President, Corporate Services and Clinical Support • Sandy Jansen, Director, Pharmacy Services • Neil Johnson, Vice President, Cancer, Renal and Pharmacy Services; Regional Vice President, Cancer Care Ontario • Tony LaRocca, Vice President, Community and Stakeholder Relations • Toby O'Hara, General Manager, Health Care Materials Management Services	April 29, 2013
Marchese Health Care/Marchese Hospital Solutions	
• Janie Bowles-Jordan, Pharmacist, MHC	June 10, 2013
• Kathy Cuerrier, Pharmacist, MHC	June 10, 2013
• Sophia Francis-Pringle, Pharmacist, MHC	June 10, 2013
• Stephanie Gilbreath, Pharmacist, MHC	June 10, 2013
• Kawther Salman, Pharmacist, MHS	June 10, 2013
• Laura Savatteri, Pharmacist, MHC	June 3, 2013
• Roberta Young, Infusion Technician, MHS	June 10, 2013
• Marita Zaffiro, President	April 29, 2013; June 10, 2013
Medbuy Corporation	
• Michael Blanchard, Vice President, Pharmacy, Clinical Services and Business Development	May 6, 2013; September 23, 2013
• Ann Kelterborn, Director, Strategic Sourcing and Member Services, Pharmacy	September 23, 2013
• Kent Nicholson, President and CEO	May 6, 2013; September 23, 2013
• Ron Swartz, Manager, Clinical Services and Patient Safety, Pharmacy	September 23, 2013
Ontario College of Pharmacists	
• Marshall Moleschi, Registrar	April 16, 2013; May 6, 2013

ORGANIZATION/INDIVIDUAL	DATE(S) OF APPEARANCE
Ontario Hospital Association	
• Pat Campbell, President and CEO • Sudha Kutty, Director, Patient Safety, Physician and Professional Issues	May 13, 2013
Ontario Ministry of Health and Long-Term Care	
• Catherine Brown, Assistant Deputy Minister, Health System Accountability and Performance Division	April 22, 2013
• Saäd Rafi, Deputy Minister	April 16, 2013
Peterborough Regional Health Centre	
• Laura Freeman, Vice President, Clinical Services	April 30, 2013
• Sarah Hickey, Pharmacist, Cancer Clinic	May 27, 2013
• Dr. Peter McLaughlin, Chief Medical Officer; Vice President, Clinical and Support Services; Chair, Medical Advisory Committee	April 30, 2013
• Ken Tremblay, President and CEO	April 30, 2013
• Judy Turner, Senior Pharmacy Assistant, Cancer Clinic	May 7, 2013
• Lori Webb, Pharmacy Assistant, Cancer Clinic	Written submission
• Brenda Weir, Director, Emergency, Lab, Diagnostic Imaging and Pharmacy	April 30, 2013
• Craig Woudsma, Pharmacy Assistant, Cancer Clinic	May 7, 2013
South West Local Health Integration Network	
• Michael Barrett, CEO • Jeffrey Low, Chair, Board of Directors	May 14, 2013
Dr. Jake Thiessen	May 27, 2013; September 23, 2013
Windsor Regional Hospital/Hôtel-Dieu Grace Hospital	
• Christine Donaldson, Regional Director, Pharmacy • Dr. Gary Ing, Chief of Staff • David Musyj, President and CEO • Dr. Kenneth Schneider, Chief of Oncology	April 22, 2013

APPENDIX C

Recommendations from Dr. Jake Thiessen's A Review of the Oncology Under-Dosing Incident[78]

Group Purchasing Organizations (GPOs)
1. Notwithstanding the under-dosing incident, the continued use of Group Purchasing Organizations (GPOs) to negotiate vendor product preparation pharmaceutical services shall not be discouraged. However, improvements are needed in the GPO-based processes.
2. Every GPO shall review its procurement process to ensure that risk for patients is considered an essential evaluation and adjudication criterion when considering proposals.
3. Every GPO shall develop and adopt a standardized product and/or service specification description that outlines the requirements for contracted sterile or non-sterile pharmaceutical preparation services.
4. Annually in January, each GPO shall publicize information regarding the contracted pharmaceutical services provided by all its vendors.
5. Marchese Hospital Solutions (MHS) shall review and revise its product preparation processes to ensure that all its products meet the specifications required by professionals in treating patients effectively and safely.
Manufacturing and Compounding
6. The Ontario College of Pharmacists (OCP) (and by extension, the National Association of Pharmacy Regulatory Authorities [NAPRA]) shall work quickly with Health Canada to define best practices and contemporary objective standards for non-sterile and sterile product preparation within a licensed pharmacy.
7. The OCP (and by extension, NAPRA) shall stipulate specialized electronic material records and label requirements for non-sterile and sterile product preparation within a licensed pharmacy.
8. The OCP (and by extension, NAPRA) shall consider a special designation and licence for any licensed pharmacy engaged in large volume non-sterile and sterile product preparation. Such pharmacies shall be inspected annually.
9. The OCP shall specify credentials beyond education and licensing for personnel engaged in non-sterile and sterile product preparation practices within a licensed pharmacy.
10. Health Canada shall license all enterprises that function beyond the product preparation permitted within a licensed pharmacy; that is, all product preparation enterprises not within a licensed pharmacy shall be licensed.
Hospitals, Clinics and Associated Pharmacies
11. The Ontario Hospital Association (OHA) shall conduct a formal review/audit to determine the efficiency and traceability of computer-based clinic and hospital records for

[78] Thiessen, *A Review of the Oncology Under-Dosing Incident*, pp. 2-3.

patients and their treatments, and report the findings to the MOHLTC.
12. The OCP shall license all pharmacies operating within Ontario’s clinics or hospitals.

APPENDIX D

Letters to Ontario College of Pharmacists

October 31, 2013

Marshall Moleschi
Registrar
Ontario College of Pharmacists
483 Huron Street
Toronto, ON M5R 2R4

Dear Dr. Moleschi,

The Standing Committee on Social Policy is currently conducting a study relating to the oversight, monitoring and regulation of non-accredited pharmaceutical companies.

During the hearings the Committee heard testimony from a number of Pharmacists from Marchese Health Care, Medbuy Corporation and the purchasing hospitals involved. The Committee is concerned that the diluted chemotherapy treatments went unnoticed by all of the pharmacists directly involved, for an extended period of time (February 2012-March 2013) without one of them bringing the matter forward.

The Committee has asked me to bring this to the attention of the Ontario College of Pharmacists and for you to launch an investigation.

The Committee would appreciate a report with your decision and findings at your earliest convenience.

On behalf of the Committee, I thank you for your assistance in this matter. If you require any further information, please do not hesitate to contact the Clerk of the Committee, William Short at 416-325-3883 or at william_short@ontla.ola.org.

Sincerely,
Ernie Hardeman, MPP
Chair of the Committee

December 3, 2013

Marshall Moleschi
Registrar
Ontario College of Pharmacists
483 Huron Street
Toronto, ON M5R 2R4

Dear Dr. Moleschi,

Thank you for your letter dated November 14, 2013 in response to the Committee's letter dated October 31, 2013, expressing concern that the diluted chemotherapy treatments went unnoticed by all of the pharmacists directly involved, for an extended period of time without one of them bringing the matter forward.

The Committee would like to follow up and seek clarification on what steps you plan to take not only to address this issue but to ensure it does not happen again. In particular, the Committee asks that you investigate: how this oversight occurred in the first place; why it went on for a long period of time; what are the consequences for such errors; and what changes will be made.

On behalf of the Committee, I thank you for your attention to this matter. If you require further information, please do not hesitate to contact the Clerk of the Committee, Valerie Quioc Lim at 416-325-7352 or at valerie_quioc@ontla.ola.org.

Sincerely,

Ernie Hardeman, MPP
Chair of the Committee

APPENDIX E

Email from Accreditation Canada[79]

Requirements related to contractual relationships with GPOs and SSOs are captured in our Leadership Standards and Medication Management Standards. Below is a summary of the specific requirements in the Standards.

The Medication Management Standards focus on an inter-team approach to prevent and help reduce medication errors and near misses by addressing all aspects of the medication management process, from selection and preparation to administration of the medication and ongoing monitoring of clients. The Standards were recently revised in January 2013 under the guidance of a standards working group consisting of experts in the field from across Canada. The Standards were also circulated to stakeholders for broader feedback prior to release. The revised Standards apply to on-site surveys starting in January 2014.

One of the sections in the Medication Management Standards focuses on "Selecting and Procuring Medications", including the following requirements:

- When selecting medications, the organization examines their packages and labels to identify any potential for confusion (9.1)
- The organization purchases commercially manufactured medications when available to minimize compounding (9.2)
- The pharmacy has a process to identify and resolve problems with medication shipments (9.5)
- The pharmacy has a process to retrieve medications that have been formally recalled or discontinued by Health Canada or the manufacturer (9.6)
- The organization has a process for selecting and procuring medication delivery devices (10.0)
- The organization reports labelling, packaging, and nomenclature problems on medications received from procurement (17.5)

In addition, the Medication Management Standards include the following requirements related to labelling, and monitoring the quality of contracted services:

- The organization labels all compounds and intravenous admixture containers with, at a minimum, information on the name of the medication, base solution, total amount of drug additives, and total volume of solution in the container (17.2)
- Where medication management processes are contracted to external providers, the organization establishes and maintains a contract with each provider that requires consistent levels of quality and adherence to accepted standards of practice (27.2)
- Where medication management processes are contracted to external providers, the organization regularly monitors the quality of services provided (27.3)

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[79] Email from Accreditation Canada , Ottawa to Researcher, Standing Committee on Social Policy, December 16, 2013.

- Further, the Leadership Standards include the following requirements related to selecting and monitoring the quality of contracted services:
- As part of [an] integrated risk management approach, the organization's leaders follow established policies and procedures for selecting and negotiating contracted services.
- Policies and procedures should include - selecting contracted organizations; negotiating the terms of the agreement; signing, reviewing and updating all contracts; and anticipating and addressing risks associated with contracted services.
- As part of [an] integrated risk management approach, the organization's leaders evaluate the quality of contracted services.