

**ASSISTIVE DEVICES IN CANADA:**  
**ENSURING INCLUSION AND INDEPENDENCE**

ARCH DISABILITY LAW CENTRE  
Toronto, Ontario

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## EXECUTIVE SUMMARY

Access to assistive devices is essential for persons with disabilities to participate fully in work, social and community life. Persons with disabilities must be assured availability of a broad range of safe, reliable and affordable assistive devices that meet their individual needs. The ability to make choices in this regard is fundamental to their dignity.

Disability supports, including assistive devices, have been a key priority for the disability community. At the same time, high levels of unmet needs in relation to assistive devices have been documented. On this basis, and the concerns expressed by persons with disabilities to ARCH, ARCH undertook this project to research and analyze the legal, political and program contexts that govern how assistive devices are regulated in Canada. The project both describes the current landscape and suggests options for change.

Assistive devices include specialized aids and devices that enable persons with disabilities to carry out their everyday activities. These include wheelchairs, hearing aids, adaptive computer technologies, prostheses and ventilators, to name a few. Some forms of information and communications technology and medical devices may be considered “assistive devices”.

The report is grounded, in part, on information ARCH obtained through consultations undertaken in 2007 with those who have a direct interest in assistive devices, including persons with disabilities, their family members, disability organizations, vendors, service providers and government officials.

The goals of the project are twofold: It is aimed to assist persons with disabilities to advocate for themselves and others. It is also intended to provide essential and comprehensive information and suggestions for reform to ground the development of policy in a way that is responsive to the concerns of those who use and work with assistive devices.

The project is divided into four parts:

- Part I details issues identified as important to consumers of assistive devices.
- Part II clarifies the political and legal landscape that governs the sale, use, importation, safety and labelling of assistive devices in Canada. It describes various funding programs for assistive devices within the federal, provincial and territorial jurisdictions.
- Part III outlines additional avenues of redress for consumers who experience problems with their assistive devices. It examines the potential application of product liability law and consumer protection legislation to assistive devices.
- Part IV highlights, from a consumer perspective, the barriers and obstacles that impede the availability and use of assistive devices. It also offers law reform and

policy approaches for the regulation of assistive devices in a manner that maximizes their accessibility and safety.

The project uncovered the following:

- There are multiple funding programs for assistive devices, both federal and provincial/territorial, throughout Canada. There are significant differences between them. Inadequate funding is a reality.
- A complex set of regulations exist which, while covering some aspects of assistive devices, leave many other important aspects unregulated.
- Various types of civil claims may be available to consumers who wish to seek redress for their harm associated with assistive devices. However, there are uncertainties in their specific application to assistive devices.
- A range of approaches is necessary to respond to the gaps this project identified.

ARCH calls on all levels of government to demonstrate their commitment to ensuring that consumers of assistive devices enjoy full participation in society. The effort must be coordinated between governments. The Government of Canada must work with provincial and territorial governments to establish consistent and comprehensive funding programs that make assistive devices available to all who need them and to ensure that all necessary regulations are in place, enforced and effective. The effort must be responsive to the perspectives of the disability community.

The issue of regulation of assistive devices is particularly important at a time when the assistive device industry is changing very quickly, and there is a risk of technologies being developed and regulated in a way that can further marginalize persons with disabilities. Technological developments - if designed effectively at the outset in accordance with universal design principles - have the potential to increase the participation of persons with disabilities in many aspects of Canadian life.

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## **FOREWORD**

This is an ambitious project. And, given its broad scope, we consider it a work in progress. Because ARCH is an Ontario based organization, we have a greater familiarity with the Ontario context. Therefore, this project focuses disproportionately on Ontario, although we have briefly outlined the context for the regulation of assistive devices in the rest of Canada as well. There is a need for further research, including with respect to national and provincial programs that provide assistive devices to persons with disabilities.

We welcome feedback from everyone, especially from advocates outside of Ontario. If you have a comment, please email Theresa Sciberras, Program Assistant at: [scibert@lao.on.ca](mailto:scibert@lao.on.ca).

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## **INTRODUCTION**

### **I. About ARCH Disability Law Centre**

ARCH Disability Law Centre (ARCH) is a specialty legal aid clinic dedicated to advancing the equality rights of persons with disabilities. ARCH represents persons with disabilities in test case litigation, provides summary legal advice and also engages in public legal education and law reform activities. As part of our mandate, ARCH hears concerns from persons with disabilities relating to assistive devices in Ontario and Canada. Please see <http://www.archdisabilitylaw.ca> for more information about ARCH.

### **II. Goals of the Project**

The focus of this project is consistent with a key issue identified by the disability community — supports for daily living. Our focus is on assistive devices, a subset of supports. Without access to safe assistive devices that meet their disability related needs, persons with disabilities will continue to face barriers and be excluded from full participation in work, social and community life. This project aims to provide essential information about the consumer experience and legal context relating to assistive devices. It does so in four ways:

- Part I details the issues identified as important to consumers of assistive devices. For instance, persons with disabilities rely on a wide variety of assistive devices to assist with daily living and to increase quality of life. A consumer must be able to exercise choice, including over the particular assistive device that best meets her particular disability-related needs. Those assistive devices must be safe, reliable and available.
- Part II clarifies the political and legal landscape that governs how assistive devices in Canada. The regulatory regimes that govern the multitude of important assistive devices are exceedingly complex. It investigates, among other topics, Canadian safety standards, labelling requirements and international trade obligations in the context of importing assistive devices.
- Part III outlines legal and other avenues of redress for consumers who experience problems with their assistive devices.
- Part IV offers law reform and policy approaches for the regulation of assistive devices in a manner that maximizes their accessibility and safety.

This information is intended to assist persons with disabilities to advocate for themselves and others. It is also anticipated that it will assist the development and implementation of effective policy.

### **III. Breadth of the Project**

Given that ARCH is an Ontario agency with a provincial mandate, this project focuses on Ontario and federal frameworks. We are conscious of the fact that the laws and

programs in other provinces and the territories are of equal importance and that we have offered only brief attention to them.

This project addresses the broad category of assistive devices. While it includes information about medical devices such as pacemakers and x-ray machines, it does not focus on them. This project does not address issues relevant to pharmaceutical products, transportation services, service animals or attendant services, although these products and services are clearly very important to the independence and inclusion of persons with disabilities.

Research has been conducted from a cross-disability perspective. Accordingly, it represents the experiences of the diverse group of people who have been defined as having a disability. Additionally, it is important to be aware that there may be differences of experience among specific disability groups. ARCH emphasizes the importance of bringing together the perspectives of various disability communities, in order that they support each other.

#### **IV. Methodology**

In the first phase of the project, a scoping study on the law, policy and politics governing assistive devices in Canada was undertaken. This study identified issues important to persons with disabilities, service providers, and other key players. The scoping study included a review of the literature and a brief overview of the regulatory schema governing assistive technologies. The researchers also conducted 17 consultations of about 1 hour each with persons with disabilities and other key players, mostly from Ontario. These consultations with key stakeholders were carried out over two months in early spring of 2007.

In the second phase of the research, we undertook to focus in detail on issues that arose from the scoping study. We conducted 11 in-depth interviews with key players in the industry including vendors, family members, industry representatives and people from relevant government offices. The consultations were carried out in spring 2007.

The structure of both sets of consultations was flexible. Where they could not be conducted in person, consultations were conducted by telephone. Given that the interviews were not intended to represent a random sample, interviewees were selected to represent a broad range of views about the regulation of assistive devices in Canada. The content of interviews identified the broad set of problems and concerns of persons with disabilities, their families, service providers, governments and industry representatives.

We conducted exhaustive legal and policy research with respect to the regulation of medical and assistive devices including: tax treatment, import restrictions, safety standards, labelling requirements and industry development. In undertaking the legal research, we reviewed secondary legal texts, including textbooks, scholarly articles and

chapters. We relied heavily on policy documents published by various levels of government. Relevant caselaw and statutory material was also reviewed.

ARCH staff hear concerns about the availability and the safety of assistive devices from persons who have a disability. Our experience with these issues is based on our contacts with persons with disabilities themselves, their families and support people, advocates and community groups. ARCH staff has provided advice as part of our summary advice and referral service to consumers of assistive devices. As part of this research, we conducted a review of calls received by ARCH staff to our telephone summary advice and referral service.

## **V. Language and Perceptions**

For the disability community, the meaning and use of the terms “consumer” and “client” is very significant. The term “consumer” suggests that a person exerts choice and control over the type and quality of assistive devices that they access. The term “client” is considered by some to be connotative of a passive recipient of service, and not a part of a dynamic and supportive relationship. Accordingly, we have chosen to use the term “consumers” of assistive devices throughout this project. As is highlighted later, it is noteworthy that “consumers” of assistive devices often do not have the same adequate choice and control as “consumers” of generic consumer products.

It is intended that this project provide information to consumers of assistive devices, and is focused on persons with disabilities who are consumers of assistive devices. Not all persons with disabilities use assistive devices. Conversely, not all consumers of assistive devices identify as persons with disabilities.

Herein, we employ a broad understanding of the term “disability”, as set out in the Ontario *Human Rights Code*<sup>1</sup> and the *Accessibility for Ontarians with Disabilities Act, 2005*.<sup>2</sup> We include “conditions” that may typically not be considered a “disability”. Thus the perspective of the consumer who has a medical condition, which is not considered a disability, is included in this report.

Language plays a central role in shaping perceptions about persons with disabilities. Language must be respectful, credible and consistent with current thinking in the disability community.<sup>3</sup> For example, it is preferential to put the person first; “persons with disabilities” is more appropriate than “the disabled”. Also, the term “disability” is a more respectful term than “handicap”. References that cause guilt, a sense of

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<sup>1</sup> R.S.O. 1990, c. H-19, s.10(1).

<sup>2</sup> S.O. 2005, c. 11.

<sup>3</sup> Human Resources and Social Development Canada, *A Way with Words and Images: Suggestions for the Portrayal of Persons with Disabilities* (Ottawa: Her Majesty the Queen in Right of Canada, 2002), online: HRSDC, <[http://www.hrsdc.gc.ca/en/hip/odi/documents/wayWithWords/00\\_toc.shtml](http://www.hrsdc.gc.ca/en/hip/odi/documents/wayWithWords/00_toc.shtml)>.

hopelessness or pity must be avoided, such as referring to someone as “suffering from” or “afflicted with” a disability.

## **VI. Universal Design**

Both legal and policy law-makers have long recognized that the principles of universal design are critical to achieving full participation for persons with disabilities in society. Universal design is the philosophy that all environments, including built structures, technological systems and policies, should be designed to be usable by the broadest possible range of people. Universal design is rooted in the principles of equality and citizenship and seeks to foster social participation for diverse populations by maximizing accessibility.

The Supreme Court of Canada has identified the need to “fine-tune” society to ensure that policies, practices and structures do not exclude persons with disabilities.<sup>4</sup> The Ontario Human Rights Commission (“OHRC”) uses the terms “inclusive design” and “universal design” interchangeably, and states that inclusive design is the approach that is most respectful to persons with disabilities.<sup>5</sup> Full inclusion upfront, without after-the-fact adaptation or retrofitting, is the goal of universal design.

The *Convention on the Rights of Persons with Disabilities*, recently adopted by the United Nations on December 13, 2006, assigns a prominent role to the principle of universal design and expressly integrates this concept as the guiding philosophy for the delivery of services. The *Convention* was opened for signature on March 30, 2007, and received the highest number of signatories to a UN Convention in history on its opening day.<sup>6</sup> Canada is a signatory to the *Convention*.

“Universal design” means the design of products, environments, programmes and services to be usable by all people, to the greatest extent possible, without the need for adaptation or specialized design. **“Universal design” shall not exclude assistive devices for particular groups of persons with disabilities where this is needed.**<sup>7</sup>

This definition explicitly recognizes that there will be times when assistive devices will

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<sup>4</sup> *Eaton v. Brant County Board of Education*, [1997] 1 S.C.R. 241. See also *British Columbia (Superintendent of Motor Vehicles) v. British Columbia (Council of Human Rights)*, [1999] 3 S.C.R. 868.

<sup>5</sup> Ontario, Ontario Human Rights Commission, *Policy and Guidelines on Disability and the Duty to Accommodate* (Toronto: OHRC, 2000) at 15.

<sup>6</sup> United Nations Enable, *Convention on the Rights of Persons with Disabilities and Optional Protocol* online: UN Enable, <<http://www.un.org/esa/socdev/enable/conventioninfo.htm>> (last accessed: 20 June 2007).

<sup>7</sup> *Ibid.* at Article 2 – Definitions [emphasis added].

be needed even when universal design has been utilized. This general recognition of the significance of assistive devices is included elsewhere in the *Convention*. Article 4 (General Obligations) of the *Convention* provides that parties must undertake to ensure and promote the full realization of all human rights and fundamental freedoms for all persons with disabilities, including:

(g) To undertake or promote research and development of, and to promote the availability and use of new technologies, including **information and communications technologies, mobility aids, devices and assistive technologies**, suitable for persons with disabilities, giving priority to technologies at an affordable cost.<sup>8</sup>

Article 9 (Accessibility) of the *Convention* provides that parties take steps to enable persons with disabilities to live independently and participate fully in all aspects of life, to equal access to the physical environment, to transportation, to information and communications, including information and communications technologies and systems, and to other facilities and services. These measures must:

(h) Promote the design, development, production and distribution of accessible **information and communications technologies** and systems at an early stage, so that these technologies and systems become accessible at minimum cost.<sup>9</sup>

Article 20 (Personal Mobility) of the *Convention* sets out that parties will ensure personal mobility with the greatest possible independence for persons with disabilities, including by:

(b) Facilitating access by persons with disabilities to quality mobility aids, devices, assistive technologies and forms of live assistance and intermediaries, including by making them available at affordable cost;

...

(d) Encouraging entities that produce mobility aids, devices and assistive technologies to take into account all aspects of mobility for persons with disabilities.<sup>10</sup>

The issue of regulation is particularly important at a time when the industry is changing very quickly, and there is a risk of technologies being developed and regulated in a way that can further marginalize persons with disabilities. Technological developments - if designed effectively at the outset in accordance with universal design principles - have

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<sup>8</sup> *Ibid.* at Article 4 – General obligations [emphasis added].

<sup>9</sup> *Ibid.* at Article 9 – Accessibility [emphasis added].

<sup>10</sup> *Ibid.* at Article 20 – Personal mobility.

the potential to increase the participation of persons with disabilities in many aspects of Canadian life.

## **PART ONE – CONSUMER PERSPECTIVES**

This project is centered on the perspectives of persons with disabilities. As such, this Part undertakes to examine the experiences of persons with disabilities' use of assistive devices in Canada. This Part does not purport to be an exhaustive review of all barriers and obstacles, but instead it highlights the issues important to persons with disabilities.

### **I. High Levels of Unmet Need**

In *Building an Inclusive and Accessible Canada: Supporting People with Disabilities*,<sup>11</sup> the Council of Canadians with Disabilities (CCD) and the Canadian Association for Community Living (CACL) identified disability supports as a key priority. They assert that two thirds of the adult persons with disabilities lack one or more of the educational, workplace, aids, home modification or other supports they need. The lack of these supports results in poverty, unemployment and exclusion from workplaces, schools and communities. They define disability supports to include any good, service or environmental adaptation that assists persons with disabilities and their families to overcome barriers they face in carrying out daily living activities at each stage of their lives and in participating and being recognized as full citizens, in the social, economic, political and cultural life of the community.<sup>12</sup>

According to Statistics Canada, 1.6 million people with disabilities aged 15 and over (out of 3.4 million Canadians) were in need of assistive aids and devices in 2001.<sup>13</sup> Of those, 29% used some equipment but needed more, and 10% did not have any of the equipment that they needed.<sup>14</sup> The more severe the disability, the more respondents reported having unmet needs for specialized equipment. For instance, 33% for those with severe limitations and 50% for those with very severe limitations used some assistive aids but needed more.<sup>15</sup>

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<sup>11</sup> Council of Canadians with Disabilities and the Canadian Association for Community Living, *Building an Inclusive and Accessible Canada: Supporting People with Disabilities*, online: CCD, <<http://www.ccdonline.ca/publications/accessible%20Canada.html>> (date accessed: 28 June 28, 2007).

<sup>12</sup> See Roeher Institute, *Striking a New Balance: Proposal for a Joint Federal-Provincial/Territorial Disability Supports Investment Initiative* (Toronto: Roeher Institute, 2001).

<sup>13</sup> *Ibid.*

<sup>14</sup> Statistics Canada, *Participation and Activity Limitation Survey: Disability Supports in Canada*, (Ottawa: Government of Canada, 2001) at 6, online: HRSDC, <<http://www.statcan.ca/english/freepub/89-580-XIE/aids.htm>> (last modified: 25 March 2003).

<sup>15</sup> *Ibid.*

## **II. Issues Identified by Consumers: Summary of Consultation Findings**

Interviews conducted at two stages of the project identified issues important to consumers of assistive devices, their family members, and disability advocacy organizations. These issues serve as touchstones throughout this project.

Interviewees agreed that assistive devices are essential to the full participation of persons with disabilities in work, social and community life. Ensuring the availability of assistive devices allows persons with disabilities to get a job, go to school and enjoy the opportunities that persons without disabilities expect. Without the availability of assistive devices, persons with disabilities will continue to face barriers, and be subject to the overlapping processes of exclusion, stigma and marginalization.

An essential first step to full inclusion is to ensure that assistive devices are reliable and safe. ARCH has received reports of assistive devices that have led to serious injury of persons with disabilities. Consumers also expressed concerns about provincial funding programs that do not cover the cost of repairs to assistive devices. When unable to repair malfunctioning devices, persons with disabilities are forced to rely on unsafe assistive devices or none at all.

The lack of full funding for assistive devices particularly impacts persons with disabilities, as they are more likely to experience financial hardship. Most programs that fund assistive devices do not cover the entire cost of the assistive device; the consumer must pay some portion of the cost. Without appropriate levels of funding, persons with disabilities may be forced to do without the assistive device. Furthermore, consumers of provincial funding programs with waiting lists may experience delays in accessing essential assistive devices.

Choice is fundamental to consumers of assistive devices. Each person with a disability has particular abilities and, therefore, different needs for assistive devices. A variety of assistive devices must be made available. As a consumer's disability-related needs change over time, so will her need for particular types of assistive devices. Consumers report frustration with respect to the lack of choice regarding i) the limited selection of assistive devices that meet their disability related needs and ii) the limited number of suppliers or vendors of assistive devices. For example, clients of Ontario's Assistive Devices Program are unable to freely select which assistive device would best meet their disability-related needs in an open market. Instead, they must select from a closed list of eligible devices. Any reforms to the assistive devices industry must address and enhance the availability of choice, including different products that serve the same or similar disability related needs.

Persons with disabilities express the importance of being involved in the selection and design of devices, aware that such participation will lead to more practical design that meets their individual needs. Problems were identified when countries that export assistive devices to Canada have different standards than we do. For example, larger mobility devices designed in the United States that respond to American standards may

be too large to navigate doorways and bathrooms in Canada, where building requirements are less stringent.

Consumers face significant informational hurdles in accessing the assistive devices that they need. They report that programs providing funding for assistive devices are bureaucratic, confusing, and require significant self-advocacy skills. In addition, assistive devices are regulated by an overwhelming system that spans across various levels of government. In a marketplace of increasingly complex technologies, customers, especially persons with disabilities that affect their cognition, may require training on the effective and safe use of assistive devices.

## **PART TWO – THE CURRENT REGULATION OF ASSISTIVE DEVICES IN CANADA**

This Part examines the legal and political context that governs assistive devices in Canada. It outlines the rules and regulations that address assistive devices in Canada.

### **I. Categorizing Devices**

For the purposes of this project there are three types of devices/supports: i) medical devices, ii) assistive devices and iii) information and communication technology (ICT). The categorization of a product depends on the purpose of the categorization. Not all assistive devices are treated in the same way. In some cases, it is difficult to distinguish assistive device categories from generic consumer goods. While a particular product, such as voice recognition software, may meet a disability-related need for one person, it can also be used by busy executives for dictating reports. This makes categorization more complicated: *individualized* consideration is required.

There is much overlap between the schema that regulate medical and assistive devices. Some “medical devices” – as set out by the *Food and Drugs Act* and the *Medical Device Regulations* – are also considered “assistive devices” for the purposes of provincial funding programs. The extent of the cross-over is dependent on the purposes of the categorization. Furthermore, some ICT products may be considered either medical devices or assistive devices.

Each section in Part I will address the particular requirements for classification, including the identity of the decision-maker and the consequences of the device designation.

#### **i. Medical Devices**

The term “medical device” covers a wide range of health or medical instruments used in the treatment, mitigation, diagnosis or prevention of a medical condition. A definition of medical device is found in section 2 of the *Food and Drugs Act*.

"device" means any article, instrument, apparatus or contrivance, including any component, part or accessory thereof, manufactured, sold or represented for use in

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
  - (b) restoring, correcting or modifying a body function or the body structure of human beings or animals,
  - (c) the diagnosis of pregnancy in human beings or animals,
- or

(d) the care of human beings or animals during pregnancy and after birth of the offspring, including care of the offspring,

and includes a contraceptive device but does not include a drug;<sup>16</sup>

A medical device is also defined by the *Medical Device Regulations* to the *Act*,

"medical device" means a device within the meaning of the *Act*, but does not include any device that is intended for use in relation to animals.<sup>17</sup>

In Canada, certain devices have to be licenced as medical devices prior to being sold. Examples of medical devices for the purposes of the *Regulations* are found on Health Canada's website at <http://www.mdall.ca>, which includes a listing of active and archived product licences. In order to determine which devices require a licence, medical devices are further subcategorized into Classes I, II, III and IV devices on the basis of the risk associated with their use. Class I represents the lowest risk while Class IV represents the highest risk.<sup>18</sup> Criteria for classification include: invasiveness, length of invasiveness, body system exposed to the device, whether or not the device relies on a source of energy, whether the device diagnoses or is therapeutic, and whether or not the device delivers energy to the patient.<sup>19</sup>

## **ii. Assistive Devices**

Assistive devices are a subset of the larger category of "disability supports", a term that is often used by the disability community. The Roeher Institute defines disability supports as any good, service or environmental adaptation that assists persons with disabilities and their families to overcome barriers they face in carrying out daily living activities at each stage of their lives and in participating and being recognized as full citizens, in the social, economic, political and cultural life of the community.<sup>20</sup>

While medical devices may be considered as a narrow subset of devices, assistive devices are more broadly defined. Assistive devices are not necessarily medical

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<sup>16</sup> *Food and Drugs Act*, R.S.C. 1985, c. F-27 at s. 2 [hereinafter "Act"].

<sup>17</sup> *Medical Device Regulations*, S.O.R., 98-282. at s. 1 [hereinafter "Regulations"].

<sup>18</sup> *Ibid.* at s. 6.

<sup>19</sup> Industry Canada, *Canadian Medical Devices Industry Chapter 2: Canadian Requirements*, online: Industry Canada Website, <<http://strategis.ic.gc.ca/epic/site/md-am.nsf/en/hi00038e.html>> (last accessed: 29 May 2007).

<sup>20</sup> Roeher Institute, *A Study of Personal Supports in Ontario* (Toronto: Roeher Institute, 1992), as cited by Council of Canadians with Disabilities and the Canadian Association of Community Living, *Building an Inclusive and Accessible Canada: Supporting People with Disabilities*, online: CCD, [www.ccdonline.ca](http://www.ccdonline.ca) (last accessed: 22 June 2007) at 2.

devices and many of them are not regulated under the *Food and Drugs Act* or the *Medical Device Regulations*. Statistics Canada defines assistive devices as follows:

Assistive aids and devices include all specialized aids, devices or services that **enable people with disabilities to carry out their everyday activities**, such as making it easier for them to get around (wheelchair, hand or arm support), or helping them to hear, see or speak (hearing aid, Braille reading materials, keyboard device for communicating). However, assistive aids do not include glasses and contact lenses, since these are commonly used visual aids, and most people who use them report not having activity limitations caused by their visual problems.<sup>21</sup>

Assistive devices focus on the quality of life of persons with disabilities, and on inclusion in work, community and social life. Rather than “fixing” the disability, assistive devices enable persons with disabilities to live more independently. Indeed, persons with disabilities who use assistive devices may not have active involvement with the medical profession.

### **iii. Information and Communication Technologies**

Information and communication technologies (ICT) compose a burgeoning industry, and include adaptive computer technologies, Braille printers, portable note taking devices, screen reading software, and GPS technology. The consulting agency, Inclusive Technologies, offers many exciting examples of mainstream information and communication technologies that can increase accessibility with little or no additional cost.<sup>22</sup> Their website continues:

ICT includes computers, software, copiers, phone systems, websites and more: every product or service that is used to create, manage or store or communicate information in almost any form....Most ICT products have some usability and accessibility features, if only by accident. Unfortunately many ICT products also have unintended barriers to people with disabilities.<sup>23</sup>

It is not always clear how ICTs used by persons with disabilities are classified and, as such, how they are regulated. ICTs used by persons with disabilities may be classified as medical devices or assistive devices. Other ICTs will not be considered either medical or assistive devices, but rather as general consumer products. Without diminishing the importance of their regulation, ICT devices which are not considered to be medical or assistive devices are beyond the scope of this project. ARCH has been

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<sup>21</sup> *Supra* at note 14.

<sup>22</sup> *Inclusive Technologies*, online: Inclusive Technologies Website <<http://www.inclusive.com>> (date accessed: 26 June 2007).

<sup>23</sup> *Ibid.*

working on the issues of accessible telecommunications for persons with disabilities.<sup>24</sup> However, this area of telecommunications regulation is too expansive to be carefully considered in this project.

Technology has revolutionized daily life for everyone, including persons with disabilities. Excitingly, technology can better enable persons with disabilities to carry out their everyday activities. Intelligent technologies may enable older adults to safely remain in their homes through the use of, for example, personal emergency response systems that can detect when a resident has fallen.<sup>25</sup> Additionally, the use of artificial intelligence can promote independence for persons who may experience memory loss or confusion.

ICTs promise vast improvements in the quality of life for persons with disabilities. However, this promise will only be fulfilled where these devices are accessible to persons with disabilities. The ICT industry is changing very quickly. If technologies are not designed in accordance with the principles of universal design, they can create new barriers and further marginalize persons with disabilities.<sup>26</sup> In addition, many ICTs are often not covered by provincial funding programs, and the cost of such products can be prohibitive. ICTs also raise additional issues regarding intellectual property and copyright law.

#### **iv. The Categorization of Assistive Devices and Conceptualization of Disability**

Throughout this project, it is important to consider how the categorization of devices reflects how “disability” is conceptualized. Some critics have expressed the view that assistive devices have been largely defined using medical categories. In their 2004 commentary, Deborah Steinstra and others made the following comment about the international trade regimes that govern access to assistive devices by women with disabilities:

Medical professionals have become gatekeepers for accessing assistive devices, even when they have no expertise in the area. Those who are most knowledgeable about their own needs, the consumers, are prevented from obtaining their own devices, unless they are willing and able to incur the related expenses.<sup>27</sup>

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<sup>24</sup> Please see < [www.archdisabilitylaw.ca](http://www.archdisabilitylaw.ca) > for more information about ARCH’s work.

<sup>25</sup> See, for example, *Toronto Rehab*, online: <<http://www.torontorehab.com>> (date accessed: 26 June 2007).

<sup>26</sup> D. Stienstra, J. Watzke and G. Birch, “A Three-Way Dance: The Global Public Good and Accessibility in Information Technologies” (2007) 23 *Information Society* 149. “It has been both a liberating tool that provides increased access to information as well as a creator of new or additional barriers to accessing information and the benefits of an information society.” at 151.

<sup>27</sup> D. Steinstra, C. Watters, H. Grant, H. Huang and L. Troschuck, *Women with Disabilities: Accessing Trade* (Ottawa: Industry Canada, July 2004) at 37, online: Status

The “social model of disability” views disability as caused by barriers which exclude persons with a disability from involvement and participation. The theory of “social handicapping” proposes that a person may have no functional limitations other than those created by prejudice, stigma and stereotype.<sup>28</sup> The social model analysis de-emphasizes the value of a medical diagnosis, shifting the focus to the significant role of the social environment in “handicapping” individuals. This stands in contrast to the “medical model” which identifies disability as a physiological impairment and aspires to “cure” the disorder. To the extent that categorization of assistive devices relies heavily evaluations by medical professionals, it entrenches the medical model of disability. The social model of disability asserts that persons with disabilities, rather than professionals, should be allowed to describe what they need.

## **II. Overlapping Jurisdictions: Federal, Provincial and Territorial Responsibilities for the Regulation of Assistive Devices**

The regulation of assistive devices is governed by various institutions including government, crown corporations, independent commissions, tribunals and voluntary associations. This section addresses jurisdictional issues in the regulation of assistive devices. It describes the mandates and the (inter-related) roles of the most significant of these bodies, including Industry Canada, Health and Safety Canada, the provinces and Canadian manufacturers.

Canada’s federal, provincial and territorial governments have the power to make laws with respect to different aspects of Canadian life. The rules outlining the various powers of the different levels of government flow from sections 91 and 92 of the *Constitution Act, 1867*,<sup>29</sup> the interpretations placed on it over time by the Courts, and also by agreement of the governments in certain circumstances. In general, the federal government enjoys exclusive jurisdiction over the areas of “Money and Banking”, “International Trade”, “Telecommunications and Broadcasting” and “Border Security”, among others. Provincial governments are responsible for the areas of “Health Care” and “Social Assistance and Social Services”, among others. Areas of shared jurisdiction include “Industry”, “Transportation Infrastructure” and “Public Health”. Action in these areas of shared jurisdiction may require special attention and demand a collaborative approach.<sup>30</sup> See Appendix A for a description of the division of

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of Women Canada <[http://www.swc-cfc.gc.ca/pubs/pubspr/0662367391/index\\_e.html](http://www.swc-cfc.gc.ca/pubs/pubspr/0662367391/index_e.html)> (last modified: 13 December 2004).

<sup>28</sup> See generally J. Bickenbach, *Physical Disability and Social Policy* (Toronto: University of Toronto Press, 1993).

<sup>29</sup> *Constitution Act, 1867* (U.K.), 30 &31 Vict., c. 3, reprinted in R.S.C. 1985, App. II, No. 5. at ss. 91 and 92.

<sup>30</sup> P. Gordon, *A Federal Disability Act: Opportunities and Challenges*. (October 2006) A Paper commissioned by the Council of Canadians with Disabilities and Canadian Association for Community Living at 6.

responsibilities reproduced from a 2006 document released by the federal government entitled “Restoring Fiscal Balance in Canada: Focusing on Priorities”.

### **i. Federal Government**

The federal government provides financial support to provincial and territorial governments through the Canada Health Transfer (CHT) and the Canada Social Transfer (CST), which support specific policy areas such as health care, post-secondary education, social assistance and social services, and early childhood development and childcare.

**Industry Canada** is a federal department headed by the Minister of Industry, and established by the *Department of Industry Act*.<sup>31</sup> The Department aims to improve conditions for investment, improve innovation performance and increase Canada's share of global trade.<sup>32</sup> For example, the department works with the Department of Foreign Affairs and International Trade to encourage foreign companies to invest in Canada.<sup>33</sup> Industry Canada participates in standards-setting forums, such as the International Organization for Standardization, to ensure that Canada's standards are compatible with those of other countries.<sup>34</sup> Industry Canada is responsible for consumer protection legislation, including the *Consumer Packaging and Labelling Act*. Industry Canada is also responsible for Telecommunications legislation.<sup>35</sup> The Terminal Attachment Program Advisory Committee (TAPAC) is a consultative committee chaired by Industry Canada to discuss technical and administrative requirements applicable to the terminal attachment program for products such as telephones, facsimile machines and modems.

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<sup>31</sup> S.C. 1995, c. 1.

<sup>32</sup> Industry Canada, *Mandate*, online: Industry Canada Website <<http://www.ic.gc.ca/cmb/welcomeic.nsf/ICPages/Mandate>> (last modified: 11 December 2006).

<sup>33</sup> *Industry Canada*, online: Industry Canada Website <<http://www.ic.gc.ca/cmb/welcomeic.nsf/ICPages/InternationalIntro>> (last modified: 13 April 2007).

<sup>34</sup> *Ibid.*

<sup>35</sup> Industry Canada, *International Profile*, online: Industry Canada Website: <<http://www.ic.gc.ca/cmb/welcomeic.nsf/ICPages/Menu-e>> (last modified: 22 June 2007). The department's mission is to foster a growing competitive, knowledge-based Canadian economy. The department works with Canadians throughout the economy and in all parts of the country to improve conditions for investment, improve Canada's innovation performance, increase Canada's share of global trade and build a fair, efficient and competitive marketplace. Program areas include developing industry and technology capability, fostering scientific research, setting telecommunications policy, promoting investment and trade, promoting tourism and small business development, and setting rules and services that support the effective operation of the marketplace.”

The **Assistive Devices Industry Office (ADIO)** of Industry Canada aims to assist Canadian businesses in developing assistive products through the provision of strategic information.<sup>36</sup> Despite being a small office, ADIO undertakes activities in three broad areas. First, it encourages the development and promotion of accessibility standards, by for example, having developed an Accessible Procurement Toolkit. Second, it develops statistics on the Canadian Assistive Technology sector. Third, it acts as an industry liaison with international organization as well as other government and non government bodies.

**Health Canada** administers the *Health Care Act*,<sup>37</sup> and acts as a funder through the federal government's Canada Health Transfer. It is a federal department that, among other responsibilities, regulates and approves the use of products including medical devices.<sup>38</sup> Health Canada's Therapeutic Products Directorate (TPD) is the federal regulatory authority for the sale of medical devices in Canada.<sup>39</sup> Health Canada reviews medical devices to assess their safety, effectiveness and quality before being authorized for sale in Canada. Health Canada's Health Products and Food Branch Inspectorate (HPFBI) is responsible for compliance monitoring, and compliance verification and investigation.

The **Office for Disability Issues (ODI)** is an agency of the Department of Human Resources and Social Development Canada. It is a focal point within the Government of Canada for disability related issues. The ODI also provides funding to eligible non-profit organizations working to meet the social development needs of persons with disabilities. It administers the Opportunities Fund for Persons with Disabilities, which helps eligible persons with disabilities to prepare for, obtain and keep employment or self-employment. It is responsible for developing knowledge and research on disability-related issues, which inform policy and program development and build awareness.

The **Common Look and Feel (CLF)** Standards for the Internet were approved by Treasury Board ministers on December 7, 2006. The CLF standards ensure all departmental and government agency websites are accessible to people with disabilities, meeting the World Wide Web Consortium's Web Content Accessibility Guidelines.<sup>40</sup> The CLF standards combine a standard page layout with a strict HTML

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<sup>36</sup> Industry Canada, *ADIO*, online: ADIO Homepage <<http://www.at-links.gc.ca/as/as031e.asp>> (date accessed: 26 June 2007).

<sup>37</sup> *Canada Health Act*, R.S., 1985, c. C-6.

<sup>38</sup> Health Canada, *About Mission, Values, Activities*, online: Health Canada Website <[http://www.hc-sc.gc.ca/ahc-asc/activit/about-apropos/index\\_e.html](http://www.hc-sc.gc.ca/ahc-asc/activit/about-apropos/index_e.html)> (last modified: 29 November 2005).

<sup>39</sup> Health Canada, *Drug and Health Products*, online: Health Canada Website <[http://www.hc-sc.gc.ca/dhp-mps/prodpharma/index\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/index_e.html)> (last modified: 23 April 2007).

<sup>40</sup> Web Accessibility Initiative, *Highlights* online: Web Accessibility Website <<http://www.w3.org/WAI/>> (last modified: 18 June 2007).

coding syntax. The goal is easy-to-use websites that can be accessed by all users, regardless of assistive technologies.<sup>41</sup>

## **ii. Provincial and Territorial Governments**

Provincial and territorial governments are responsible for, amongst other things, the delivery of health services, community and social services and education and development services. Provinces and territories have different approaches to providing assistive devices to insured residents. Some provinces and territories have no particular program dedicated to providing assistive devices, or have a series of scattered programs. For instance, Alberta, Ontario, Saskatchewan, Quebec and Prince Edward Island have specific programs covering a variety of assistive devices. See Section 2.III(ii) for further details about the programs.

Roles and responsibilities for Canada's health care system are shared between the federal and provincial-territorial governments. Generally, provincial and territorial governments are responsible for the management, organization and delivery of health services. The Ontario Ministry of Health and Long Term Care is responsible for administering the health care system and providing services to the Ontario public. It also regulates hospitals and nursing homes, operates psychiatric hospitals and medical laboratories, and co-ordinates emergency health services. Ministries of health in other provinces have roughly the same organization. The ministry also administers the Assistive Devices Program (ADP), which financially assists Ontario residents with long term physical disabilities to obtain assistive devices.

## **iii. Access to Assistive Devices by Aboriginal Communities**

This section will briefly explore the complex question of which level of government exercises jurisdiction over health care, including the provision of assistive devices, to aboriginal communities in Canada. The complexity arises from the fact that responsibility for aboriginal health services is shared between federal, provincial and territorial governments, and Aboriginal organizations.<sup>42</sup> Various factors, such as whether or not an Aboriginal person has "status" and whether or not they live in a First Nations or Inuit community determine which level of government will ultimately be responsible for the provision of health and social services.<sup>43</sup> As such, the delivery of health care services for Aboriginal peoples is a matter of ongoing negotiation between federal, territorial, provincial and aboriginal governments and groups.

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<sup>41</sup> See Treasury Board of Canada Secretariat, *Common Look and Feel for the Internet*, online: Treasury Board of Canada Secretariat <[http://www.tbs-sct.gc.ca/clf-nsi/index\\_e.asp](http://www.tbs-sct.gc.ca/clf-nsi/index_e.asp)> (last modified: 5 January 2007) for more information.

<sup>42</sup> Canada, Health Canada, *Canada's Health Care System*, (Ottawa: Health Canada, 2005) at 1.

<sup>43</sup> Dr. Doug Durst and Mary Bluechardt, "Aboriginal People with Disabilities: A Vacuum in Public Policy" (January 2004) Issue 6, The Saskatchewan Institute of Public Policy Briefing Note at 1.

### a. Services Provided at the Federal Level

The federal government provides direct delivery of health care services to First Nations people with status and Inuit people. This federal jurisdiction stems from Section 91(24) of the *Constitution Act, 1867*, which provides the federal government with constitutional authority over “Indians, and Lands reserved for the Indians.”<sup>44</sup> The federal government provides treatment and public health services in remote areas and public health services in non-isolated First Nations communities through the First Nations and Inuit Health Branch (FNIHB) of Health Canada.<sup>45</sup> The FNIHB delivers public health services to aboriginal people with status, such as health promotion, immunization, dental health, and drug and alcohol prevention programs. The FNIHB also “works with other branches and departments to address disability issues for aboriginal peoples.”<sup>46</sup>

Health Canada's Non-Insured Health Benefits (NIHB) Program is available to First Nations people with status and Inuit people, regardless of where in Canada they reside.<sup>47</sup> The NIHB Program provides funding for, among other things, a specified range of drugs, dental care, vision care, medical supplies and equipment, and medical transportation for eligible First Nations people and Inuit.<sup>48</sup> Additionally, the Adult Care program of Health Canada provides at home care for First Nations persons with disabilities, including homemaking services, foster care and institutional care.<sup>49</sup>

### b. Services Provided at the Provincial/Territorial Level

As mentioned above, the federal government is largely responsible for funding the delivery of health care services to First Nations people living on reserves and to the

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<sup>44</sup> *Supra* note 29 at s. 91(24). Section 91(24) does not apply to non-status Indians or Métis communities.

<sup>45</sup> Indian and Northern Affairs Canada, *Status*, online: Indian and Northern Affairs Canada Website <[http://www.ainc-inac.gc.ca/pr/pub/ywtk/index\\_e.html#hcca](http://www.ainc-inac.gc.ca/pr/pub/ywtk/index_e.html#hcca)> (last modified: 23 April 2004).

<sup>46</sup> Canada, *Advancing the Inclusion of People with Disabilities: a Government of Canada Report*, (Ottawa: Government of Canada, 2006) at 76.

<sup>47</sup> Health Canada, *Non-Insured Health Benefits Program Information Booklet*, (Ottawa: Health Canada, 2003) online: Health Canada, <[http://www.hc-sc.gc.ca/fnih-spni/alt\\_formats/fnihb-dgspni/pdf/pubs/nihb-ssna/2003\\_booklet\\_livret\\_info\\_e.pdf](http://www.hc-sc.gc.ca/fnih-spni/alt_formats/fnihb-dgspni/pdf/pubs/nihb-ssna/2003_booklet_livret_info_e.pdf)> (date accessed: 28 June, 2007).

<sup>48</sup> Health Canada, *Health Canada Website, First Nations and Inuit Health, Non-Insured Health Benefits Program*, online: <[http://www.hc-sc.gc.ca/fnih-spni/nihb-ssna/index\\_e.html](http://www.hc-sc.gc.ca/fnih-spni/nihb-ssna/index_e.html)> (last modified: 10 May 2007).

<sup>49</sup> Service Canada, *Services for Aboriginal Peoples*, online: Service Canada website, <<http://www.servicecanada.gc.ca/en/audiences/aboriginal/health.shtm>> (last modified: 22 November 2006).

Inuit, and has shifted the responsibility for off-reserve delivery to the provinces.<sup>50</sup> Therefore, the provision of health care services to non-status aboriginal people, including persons not residing on reserves falls under provincial jurisdiction. The establishment of Aboriginal health programs in this context is dependent on provincial funding. However, provincial governments have rarely diverted sufficient resources to Aboriginal-specific programs or to Aboriginal groups to develop comprehensive primary care centers.<sup>51</sup> Exceptions include Ontario, British Columbia and Manitoba, which have all provided funding to Aboriginal health centers in urban areas.<sup>52</sup> For instance, Ontario's Aboriginal Healing and Wellness Strategy provides aboriginal-specific programming through Aboriginal Health Access Centers, located both on and off reserve.<sup>53</sup>

In the territories, the Federal government was traditionally responsible for the provision of health services to the entire territorial population, including aboriginal communities. As a result, when the territorial governments were given responsibility for the delivery of health services, this applied to the territorial population as a whole. The only programs that remained under federal authority were those without a provincial counterpart, such as the Non-Insured Health Benefits program.<sup>54</sup>

### c. Services Provided by Aboriginal Governments

Aboriginal health systems, while independently administered, continue to receive funding from the federal and in some cases provincial governments.<sup>55</sup> Originally the federal government was directly responsible for the administration and delivery of all health services in aboriginal communities.<sup>56</sup> However, where possible, Canada's First Nations generally desired to provide their own services.<sup>57</sup> In 1988, the federal government established a program to facilitate the transfer of responsibility for

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<sup>50</sup> Commission on the Future of Health Care in Canada, *Constitutional Jurisdiction over Health and Health Care Services in Canada: Discussion Paper no. 12* by Howard Leeson (Ottawa: Commission on the Future of Health Care in Canada, 2002) at 8, online: Health Canada <[http://www.hc-sc.gc.ca/english/pdf/romanow/pdfs/12\\_Leeson\\_E.pdf](http://www.hc-sc.gc.ca/english/pdf/romanow/pdfs/12_Leeson_E.pdf)> (date accessed: 28 June 28, 2007).

<sup>51</sup> Laurel Lemchuk-Favel and Richard Jock, "Aboriginal Health Systems in Canada: Nine Case Studies" (January 2004) 1 *Journal of Aboriginal Health* 28 at 37, online: NAHO <[http://www.naho.ca/english/pdf/journal\\_p28-51.pdf](http://www.naho.ca/english/pdf/journal_p28-51.pdf)> (date accessed: 28 June, 2007).

<sup>52</sup> *Ibid.*

<sup>53</sup> See the Aboriginal Health and Wellness Strategy's website at <<http://www.ahwsontario.ca>>.

<sup>54</sup> *Supra* note 51 at 37.

<sup>55</sup> *Ibid.* at 42.

<sup>56</sup> *Ibid.* at 40.

<sup>57</sup> *Supra* note 50 at 8.

aboriginal health programs from Health Canada to Aboriginal communities.<sup>58</sup> Financing for these services is provided by contribution and contract arrangements. As a result, aboriginal peoples in Canada are assuming an ever increasing amount of control over social service programs, including disability services in their communities.<sup>59</sup>

#### d. Ongoing Jurisdictional Issues

The jurisdictional issues associated with accessing health care services are a serious concern for aboriginal persons. Confusion over the question of which government or department provides what service poses a significant barrier to accessing health care services.<sup>60</sup> There is ongoing debate about the federal and provincial responsibility regarding services for Métis and other non-status Aboriginal groups.<sup>61</sup> Some First Nations communities have characterized the obligations of the federal government to fund health services as a treaty right.<sup>62</sup> The Saskatchewan Court of Appeal rejected such an argument in *R. v. Swimmer*.<sup>63</sup> The Manitoba Court of Appeal made a similar finding in *Manitoba Hospital Commission v. Klein and Spence*.<sup>64</sup>

### **III. Federal, Provincial and Territorial Programs that Support Access to Assistive Devices**

This section outlines government programs that provide support to persons with disabilities in accessing assistive devices. Funding can come from various sources including federal programs, provincial programs specific to assistive devices, other government programs, and charitable organizations. We have received overwhelming reports from the disability community that funding is an essential element in accessing assistive devices. Without access to funding sources for assistive devices, persons with disabilities will not be able to fully exercise their rights of participation and citizenship in work, social and community life.

#### **i. Federal Programs**

**Veterans Affairs Canada** (VAC) provides access to a range of health benefits to qualified veterans, Canadian Forces members and RCMP personnel. Eligibility

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<sup>58</sup> Martha Jackman, "Constitutional Jurisdiction over Health in Canada" (2000) 8 Health Law Journal 95 at para. 23. Medical Services Branch started to work towards transferring control of health services to First Nations and Inuit communities and organizations in the mid-1980's through the Strategic Policy, Planning and Analysis Directorate.

<sup>59</sup> *Supra* note 43 at 1.

<sup>60</sup> *Ibid.* at 6.

<sup>61</sup> *Supra* note 58 at para. 9.

<sup>62</sup> *Ibid.* at para. 20.

<sup>63</sup> *R. v. Swimmer*, [1971] 1 W.W.R. 756 (Sask. C.A.).

<sup>64</sup> *Manitoba Hospital Commission v. Klein and Spence* (1969), 70 W.W.R. 79 (Man. C.A.).

guidelines are complex, and eligibility is assessed by VAC staff.<sup>65</sup> VAC's **Aids for Daily Living** program provides devices and accessories, such as walking aids and bathroom aids, designed to assist the activities of daily living. This program also covers necessary repairs. Medical equipment is provided from a recycled stock or purchased new if there is nothing available within the recycled inventory.<sup>66</sup> Further information on the Aids for Daily Living Program, including eligibility requirements, is available via the Veteran's Affairs website at: <http://www.vac-acc.gc.ca/clients/sub.cfm?source=services/poc/poc1>.

**Service Canada** operates the Literature for the Blind service which offers postage-free delivery for media used by persons who are blind including tapes, CDs, records and other matter impressed with Braille.<sup>67</sup>

Administered through the Canada Mortgage and Housing Corporation, the **Residential Rehabilitation Assistance Program (RRAP)** for Persons with Disabilities offers forgivable loans to homeowners and landlords to undertake accessibility work to modify dwellings occupied or intended for occupancy by low-income persons with disabilities, including condominiums.<sup>68</sup> Funding is available to landlords and homeowners who demonstrate specified economic criteria. For homeowners, assistance is provided for the total cost of the modifications up to the maximum loan amount for the area. Homeowners must agree to continue to own and occupy the home for the term of the loan. For more information see: [http://www.cmhc-schl.gc.ca/en/co/prfinas/prfinas\\_003.cfm](http://www.cmhc-schl.gc.ca/en/co/prfinas/prfinas_003.cfm).

## **ii. Provincial and Territorial Programs**

This section briefly summarizes the wide range of provincial and territorial funding programs for assistive devices. Because ARCH is an Ontario based organization, we have a greater familiarity with the Ontario context. Although this project focuses on Ontario, we have briefly outlined the context for the regulation of assistive devices in the rest of Canada. This list does not purport to be exhaustive. We welcome feedback and additions from everyone, especially from advocates outside of Ontario.

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<sup>65</sup> Veterans Affairs Canada, *Services and Benefits*, online: Veterans Affairs Canada <<http://www.vac-acc.gc.ca/clients/sub.cfm?source=Services/benefits/content>> (last modified: 6 November 2006).

<sup>66</sup> The Provincial Equipment and Assistive Devices Committee (PEADC), *Equipment and Assistive Devices Programs Available to British Columbians, October 2004*, online: PEADC Website <[www.nsdrc.org/AttachedFiles/EquipmentProgramOct2004.pdf](http://www.nsdrc.org/AttachedFiles/EquipmentProgramOct2004.pdf)> (date accessed: 26 June 2007).

<sup>67</sup> Service Canada, *Literature for the Blind*, online: Service Canada <[http://www.servicecanada.gc.ca/en/goc/literature\\_blind.shtml](http://www.servicecanada.gc.ca/en/goc/literature_blind.shtml)> (last modified: 8 September, 2006).

<sup>68</sup> City of Oshawa, *Residential Rehabilitation Program*, online: Oshawa <[http://www.oshawa.ca/mun\\_res/assist2.asp](http://www.oshawa.ca/mun_res/assist2.asp)> (date accessed: 29 June 2007).

### a. Newfoundland and Labrador

Various **Disability Related Programs and Services** are delivered by the six regional Health and Community Services/Integrated Boards in the province. For instance, The **Special Assistance Program** is a provincial program that provides basic supportive services to assist financially eligible clients in the community with activities of daily living. The benefits include access to health supplies, oxygen, orthotics and equipment.

The **Provincial Home Support Program** serves persons with disability related needs including adults, older adults and children. Funding is allocated to individuals to obtain homemakers, home support workers, attendants and other support required to enable them to remain in their homes and communities. Adults with disabilities who require home support services are also entitled to receive a **Flat Rate Allowance** to a maximum of \$125 per month to cover personal expenses not usually provided for in regular monthly funding. Funding may be available to cover the costs of minor expenses to enable a person with disabilities to make their home environment accessible or to make minor furniture or appliance repairs. Information on these Disability Related Programs and Services can be obtained at: <http://www.health.gov.nl.ca/health/divisions/pgmpolicy/default.htm#homesupport>.

### b. Nova Scotia

A person who has privately purchased a passenger vehicle or light truck or van may apply for a rebate of the **Nova Scotia Sales Tax** to a maximum of \$3,000 in two cases. First, the rebate applies where the applicant is a person with a disability that affects the use of both legs and has a valid Nova Scotia motor vehicle licence. The applicant must use the vehicle primarily for personal transportation, and the vehicle must be the only vehicle registered under the applicant's name. The rebate also applies where the vehicle is equipped with a lift to enable wheelchairs to enter and leave the vehicle, and is used primarily for the transportation of a person with a disability that affects the use of both legs. The vehicle must not be operated for profit or commercial gain, and be the only vehicle registered under the applicant's name.<sup>69</sup> Information on this program can be obtained at: <http://www.gov.ns.ca/snsmr/pdf/taxcomm/guide2006R2.pdf>.

### c. Prince Edward Island

PEI's **Disability Supports Program** offers financial assistance and case planning assistance to residents who have a physical, intellectual, or neurological disability. Based on individual assessments, the program contributes to the cost of bathroom aids, prosthetic devices, visual aids, wheelchairs and other devices. Prince Edward Island's program is the most recent and requires a contribution by the person with a disability or

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<sup>69</sup> Nova Scotia, *Tax Information Guide 2006R2* (Nova Scotia: Service Nova Scotia and Municipal Relations, 2006), online: Service Nova Scotia and Municipal Relations <<http://www.gov.ns.ca/snsmr/pdf/taxcomm/guide2006R2.pdf>> (date accessed: 26 June 2007).

the family to the cost of the devices. Further information is available via the program website at: <http://www.gov.pe.ca/hss/peidsp>.

*d. New Brunswick*

New Brunswick's **Health Services Program** covers certain basic items not ordinarily covered including wheelchairs, bathroom aids, patient lifts, walkers, repairs, replacement parts, hearing aids, orthopedic items, ostomy supplies, prosthetic items, oxygen and other respiratory equipment. The program is available to clients who receive social assistance and their dependants; individuals who have special health needs and qualify for extended health care; and children with special needs where the family demonstrates financial need. Information on the program can be accessed at: <http://www.gnb.ca/0048/english/equipment.htm>.

The **Vehicle Tax Reimbursement Program** is administered by the Ministry of Finance. It offers a refund of the 8% provincial portion of the Harmonized Sales Tax or 15% Provincial Vehicle Tax on private sale transactions of specially equipped vehicles. The vehicle must have a device to enable a wheelchair or scooter to enter or exit, or have auxiliary driving controls. Information on this program can be obtained at: <http://www.gnb.ca/0017/Seniors/SeniorsGuide-e.pdf>.

The **Seniors Rehabilitation Equipment Program** is funded by the Department of Health and Community Services but administered by the Canadian Red Cross. It provides standard and specialized equipment, including mobility equipment, on loan to older adults in order to maintain their ability to remain in the community. It is available to nursing home residents over the age of 65. Information on this program can be obtained at: <http://www.gnb.ca/0017/Seniors/SeniorsGuide-e.pdf>.

The **Federal Provincial Repair Program** provides assistance for modifications to low-income housing in order to improve accessibility for occupants with disabilities. Financial assistance through this program is by way of a repayable loan; however a portion may be forgivable depending on income scale and the amount of required repairs. More information on this program can be obtained at: <http://www.gnb.ca/0017/Seniors/SeniorsGuide-e.pdf>.

The **Vehicle Retrofit Program** provides assistance towards a percentage of the cost of eligible accessibility features for a new or existing vehicle up to a maximum amount of \$8000. This grant is renewable every ten years for individuals or five years for organizations and covers features such as, wheelchair lifts and ramps, hand controls, steering devices and left foot gas pedals, wheelchair restraint systems, and special needs seating among others. Further information can be obtained at: <http://www.gnb.ca/0017/Seniors/SeniorsGuide-e.pdf>.

e. Quebec

The Régie de l'Assurance Maladie's **Hearing Devices program** provides hearing aids to persons who are Deaf, deafened or hard of hearing. The Program covers the purchase and replacement cost of a hearing aid or assistive listening devices.<sup>70</sup> Coverage varies by age and level of hearing loss. Further information on this program can be obtained at: [http://www.ramq.gouv.qc.ca/en/citoyens/assurancemaladie/serv\\_couv\\_queb/aides\\_auditives\\_pq.shtml](http://www.ramq.gouv.qc.ca/en/citoyens/assurancemaladie/serv_couv_queb/aides_auditives_pq.shtml).

The Régie de l'Assurance Maladie's **Visual Devices program** provides visual devices available on loan to persons who are Blind or low-vision in order to enable them to read, write or move about in unfamiliar surroundings. Visual devices made available on loan include reading aids such as tape recorders, closed circuit television systems, optical systems and calculators; writing aids such as conventional typewriters and braille; and mobility aids such as white canes and electronic obstacle detectors.<sup>71</sup> Further information on this program can be obtained at: [http://www.ramq.gouv.qc.ca/en/citoyens/assurancemaladie/serv\\_couv\\_queb/aides\\_visuelles\\_pq.shtml](http://www.ramq.gouv.qc.ca/en/citoyens/assurancemaladie/serv_couv_queb/aides_visuelles_pq.shtml).

The Régie de l'Assurance Maladie's **Ostomy Appliances program** provides Ostomy appliances to persons insured under the Quebec Health Insurance Plan who have undergone a permanent colostomy, ileostomy or urostomy. Persons eligible for the program are entitled, for each ostomy undergone, to an amount of \$700 to cover most of the cost of the ostomy appliances (bags and other products) they need. Every year thereafter, on the anniversary date of the operation, eligible persons receive an amount of \$700, for each ostomy, to cover the cost of replacing the ostomy appliances.<sup>72</sup> More information about this program including how to apply can be obtained at: [http://www.ramq.gouv.qc.ca/en/publications/documents/depliantscitoyens/depl\\_stomie\\_n.pdf](http://www.ramq.gouv.qc.ca/en/publications/documents/depliantscitoyens/depl_stomie_n.pdf).

The Régie de l'Assurance Maladie's **Devices that Compensate for Physical Deficiencies** program provides for the purchase, adjustment, replacement, repair and, in certain cases, adaptation of walking aids, standing aids, locomotor assists and orthotics/prosthetics. The program is available to persons insured under the Quebec Health Insurance Plan who have a physical disability and meet the program's eligibility

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<sup>70</sup> Hear-It, *Canada*, online: Hear-It Website <<http://www.hear-it.org/page.dsp?page=1258>> (date accessed: 26 June 2007).

<sup>71</sup> Montreal Association for the Blind, *MAB Programs and Services – Provincial Aids and Devices Program*, online: Montreal Association for the Blind Website <[http://www.mab.ca/en/services/t\\_provincial.html](http://www.mab.ca/en/services/t_provincial.html)> (last modified: 10 April 2001).

<sup>72</sup> Quebec, *Régie de l'assurance maladie: Ostomy Appliances Program* (Quebec: Direction des communications, 2006), online: Régie de l'assurance maladie <[http://www.ramq.gouv.qc.ca/en/publications/documents/depliantscitoyens/depl\\_stomie\\_n.pdf](http://www.ramq.gouv.qc.ca/en/publications/documents/depliantscitoyens/depl_stomie_n.pdf)> (date accessed : 26 June 2007).

requirements.<sup>73</sup> More information on this program can be obtained at: [http://www.ramq.gouv.qc.ca/en/citoyens/assurancemaladie/serv\\_couv\\_queb/app\\_def\\_phys\\_sc.shtml](http://www.ramq.gouv.qc.ca/en/citoyens/assurancemaladie/serv_couv_queb/app_def_phys_sc.shtml).

The Régie de l'Assurance Maladie administers the **External Breastforms program**. The program is available to women insured under the Quebec Health Insurance Plan who have undergone a total or radical mastectomy, and for women age 14 and over who have a total absence of breast formation.<sup>74</sup> A total of \$200 is provided for each breast through the program, payable every two years. More information on this program can be obtained at: [http://www.ramq.gouv.qc.ca/en/publications/documents/depliantscitoyens/depl\\_mammaires\\_en.pdf](http://www.ramq.gouv.qc.ca/en/publications/documents/depliantscitoyens/depl_mammaires_en.pdf).

Régie de l'Assurance Maladie administers the **Ocular Protheses program**, which offers a reimbursement for the cost of purchasing or replacing an ocular prosthesis (artificial eye) once per five-year period. It also provides a yearly allowance for the repair and maintenance of the prosthesis. The program is available to any person insured under the Quebec Health Insurance Plan who requires an ocular prosthesis.<sup>75</sup> More information on this program can be obtained at: <http://www.ramq.gouv.qc.ca/en/publications/documents/depliantscitoyens/protocul.pdf>.

Further information on assistive devices programs offered in Quebec may be available through the following websites:

- La Régie de l'assurance maladie du Québec : <http://www.ramq.gouv.qc.ca/>
- Office des personnes handicapées du Québec : <http://www.ophq.gouv.qc.ca/index.htm>
- Santé et Services Sociaux : <http://www.msss.gouv.qc.ca/index.php>
- Cophan : <http://www.cophan.org/>

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<sup>73</sup> Régie de l'assurance maladie, *Health Insurance : Services Covered in Quebec* (Quebec : Gouvernement du Québec, 2006), online: Régie de l'assurance maladie Website

<[http://www.ramq.gouv.qc.ca/en/citoyens/assurancemaladie/serv\\_couv\\_queb/app\\_def\\_phys\\_sc.shtml](http://www.ramq.gouv.qc.ca/en/citoyens/assurancemaladie/serv_couv_queb/app_def_phys_sc.shtml)> (last modified : 26 April 2006).

<sup>74</sup> Quebec, *Régie de l'assurance maladie : External Breastforms Program* (Quebec: Direction des communications, 2005), online: Régie de l'assurance maladie <[http://www.ramq.gouv.qc.ca/en/publications/documents/depliantscitoyens/depl\\_mammaires\\_en.pdf](http://www.ramq.gouv.qc.ca/en/publications/documents/depliantscitoyens/depl_mammaires_en.pdf)> (date accessed : 26 June 2007).

<sup>75</sup> Quebec, *Régie de l'assurance maladie : Ocular Protheses Program* (Quebec: Direction des communications, 2003) online: Régie de l'assurance maladie <<http://www.ramq.gouv.qc.ca/en/publications/documents/depliantscitoyens/protocul.pdf>> (date accessed : 26 June 2007).

#### f. Ontario

The **Assistive Devices Program (ADP)** is administered by the Ministry of Health and Long-Term Care. The ADP provides financial assistance to persons with physical disabilities to purchase assistive devices and supplies. Most devices must be authorized by a qualified health care professional registered with the program. The ADP covers more than 8000 pieces of equipment and supplies including diabetes supplies, mobility devices, prosthetics, hearing devices, TTYs, respiratory equipment and ventilators. Depending on the specific device, the ADP will cover 75% of the cost, pay a fixed amount or pay annual grants to the consumer. Recipients of social assistance may receive 100% funding of the ADP-listed price, a fixed amount, or other amounts as set out in the *Policies and Procedures Manual*.<sup>76</sup> See Appendix B for further detail about the ADP.

#### g. Manitoba

The **Breast Prosthesis Program** administered by Manitoba Health offers breast prostheses and surgical brassieres. Persons who have had a single mastectomy may claim two prostheses every four years and two surgical brassieres every year. More information is available at: <http://www.gov.mb.ca/health/mhsip/breast.html>.

The **Eyeglasses Program** administered by Manitoba Health, provides eyeglasses to all Manitoba residents over the age of 65. Program details can be found at: <http://www.gov.mb.ca/health/mhsip/eyeglasses.html>.

Manitoba Health's **Hearing Aid Program** provides hearing aids (analog or digital; ear moulds and ear impressions) to Manitoba residents under the age of 18 who require a hearing aid, as prescribed by an otolaryngologist or audiologist. Additional information can be viewed at: <http://www.gov.mb.ca/health/mhsip/hearingaid.html>.

The **Orthopaedic Shoes Program** is governed by Manitoba Health. It provides orthopaedic shoes (stock or custom made) to all Manitoba residents under 18 years of age. Information regarding the program can be found at: <http://www.gov.mb.ca/health/mhsip/orthoshoes.html>.

Manitoba Health's **Prosthetic Eye/Infant Contact Lens Program** offers prosthetic eyes and infant contact lenses (single or bilateral) to all Manitoba residents who require artificial eyes or cosmetic shells as prescribed by a physician, or corrective contact lenses as prescribed by a medical practitioner. Manitoba Health will provide one lens

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<sup>76</sup> Ministry of Health and Longterm Care, *Policies and Procedures Manual for the Assistive Devices Program* (Toronto: Ontario Ministry of Health and Longterm Care, December 2006) at s.610, online: Ontario Ministry of Health and Longterm Care <[http://www.health.gov.on.ca/english/providers/pub/adp/policymanual\\_06.pdf](http://www.health.gov.on.ca/english/providers/pub/adp/policymanual_06.pdf)> (date accessed: 28 June, 2007).

per eye, per infant. For further details on the program see: [http://www.gov.mb.ca/health/mhsip/prosthetic\\_eye.html](http://www.gov.mb.ca/health/mhsip/prosthetic_eye.html).

Manitoba Health's **Prosthetic and Orthotic Program** provides limb and spinal orthotic or prosthetic devices and services to all Manitoba residents who require them, as prescribed by a medical practitioner. Information can be viewed at: <http://www.gov.mb.ca/health/mhsip/prosthetic.html>.

The **Telecommunications Program** of Manitoba Health offers telecommunications equipment, including TTYs and pagers, to all Manitoba residents who are Deaf, deafened, hard of hearing or have disabilities that impact their speech making ability. This amounts to an 80% allowable rebate, available every five years. More information is available online at: <http://www.gov.mb.ca/health/mhsip/telecommunications.html>.

#### *h. Saskatchewan*

The Ministry of Health administers the **Saskatchewan Aids to Independent Living Program (SAIL)**. SAIL provides benefits to people whose long term disabilities or illnesses leave them unable to function fully with the aim of assisting people in leading more independent and active lifestyles. SAIL provides benefits for orthotic appliances, prosthetic appliances, mobility aids, environmental aids, respiratory equipment and home oxygen and related equipment. Eligibility is based on specific medical criteria and on assessed long-term need. In addition to these regular program benefits, extended coverage is provided under SAIL to beneficiaries with specific disabilities under the following programs:

- The **Paraplegia Program** of the Ministry of Health provides financing for certain drugs, incontinence supplies, specialized rehabilitation equipment, hand controls, ramps and wheelchair lifts.
- The Ministry of Health's **Ostomy Program** provides reimbursement for ostomy supplies.
- SAIL provides funding to CNIB for the **Aids to the Blind Program**, which offers Braille watches, talking calculators and low-vision eyewear.

Further information on all of the above listed SAIL programs can be obtained at: [http://www.health.gov.sk.ca/ps\\_sail.html](http://www.health.gov.sk.ca/ps_sail.html).

#### *i. Alberta*

**Alberta Aids to Daily Living (AADL)** is governed by the Ministry of Health and Wellness. AADL provides benefits to Albertans with long-term disabilities, chronic illnesses or terminal illnesses in order to maintain their independence by providing financial assistance to buy medical equipment and supplies including: back supports, bathing and toileting equipment, hearing aids, hospital beds, incontinence supplies, injection supplies, patient lifters, mastectomy prostheses, ostomy supplies, oxygen, orthotic braces, prosthetic devices, respiratory equipment, specialized seating devices,

wheelchair cushions, wheelchairs, and walkers. An assessment by a health care professional determines eligible equipment and supplies. Albertans are required to pay 25% of the benefit cost to a maximum of \$500 per individual or family per year. Low-income Albertans and persons receiving income assistance are not required to pay the cost-share portion.<sup>77</sup> The program is available to Alberta residents with a valid personal health care number who have a chronic disability (six months or more). However, AADL benefits may not be available to those who are eligible to receive comparable benefits from another source.<sup>78</sup> More information on this program can be obtained at: <http://www.seniors.gov.ab.ca/AADL/index.asp>.

#### *j. British Columbia*

The B.C. **Adult Services Program** is funded by the provincial government for the purpose of providing special technology services to post-secondary students or employees with a disability. The aim of the program is to reduce the barriers experienced by persons with disabilities in reaching their educational and vocational goals. The program operates a loan bank of adaptive technology, which eligible students and employees can access through referring agents.<sup>79</sup>

The **Supports for Daily Living – Employment and Assistance Program** operated by the Ministry of Human Resources provides services and support to persons with disabilities who wish to volunteer, work or be self employed. In order to qualify for the program an individual must, among other requirements, obtain a medical practitioner's prescription, undergo an assessment from an occupational or physical therapist that confirms the need for the equipment or device requested, and be determined to possess no available resources from which to pay the cost of the health supplement. Equipment and devices that may be provided under the program include wheelchairs, personal motorized mobility devices, canes, crutches and walkers, hearing aids, positioning devices, and breathing devices.<sup>80</sup> More information can be obtained at: <http://www.eia.gov.bc.ca/PUBLICAT/bcea/pwd.htm>.

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<sup>77</sup> Alberta, *Alberta Aids to Daily Living (AADL)* (Alberta: Government of Alberta, 2002), online: Alberta Government Website <<http://www.seniors.gov.ab.ca/AADL/index.asp>> (date accessed: 26 June 2007).

<sup>78</sup> Alberta, *Alberta Aids to Daily Living (AADL): Eligibility for Benefits and Available Benefits* (Alberta: Government of Alberta, 2002), online: Alberta Government Website <[http://www.seniors.gov.ab.ca/AADL/benefit\\_eligibility/index.asp](http://www.seniors.gov.ab.ca/AADL/benefit_eligibility/index.asp)> (date accessed: 26 June 2007).

<sup>79</sup> National Educational Association of Disabled Students (NEADS), *British Columbia Adult Services Program*, online: NEADS Website <[http://www.neads.ca/movingon/en/funding/funding\\_west\\_04.php](http://www.neads.ca/movingon/en/funding/funding_west_04.php)> (date accessed: 26 June 2007).

<sup>80</sup> The Provincial Equipment and Assistive Devices Committee (PEADC), *Equipment and Assistive Devices Programs Available to British Columbians* (British Columbia: PEADC, October 2004).

The B.C. **Palliative Benefits Program** provides support in order to enable individuals in the end stage of a life threatening disease to remain at home by covering the cost of medication, medical supplies and equipment. Equipment and supplies covered under the program include mobility aids, transfer aids, hospital beds and mattresses, bathing aids, and incontinence supplies.<sup>81</sup> Further information on this program can be obtained at: <http://www.health.gov.bc.ca/pharme/outgoing/palliative.html>.

The BC Ministry of Children and Family Development operates the **At Home Program**, which assists parents with some of the extraordinary costs of caring for a child with severe disabilities at home. Basic medical benefits provided include dental/orthodontic and optical benefits, hearing aids, medical equipment, medical supplies, pharmacare, orthotics and splints.<sup>82</sup> More information on the At Home Program can be obtained via the Ministry of Children and Family Development website at: [http://www.mcf.gov.bc.ca/at\\_home](http://www.mcf.gov.bc.ca/at_home).

#### k. Nunavut

The **Non-Insured Health Benefits Program** (NIHB) is administered by the government of Nunavut on behalf of the Federal government and covers prescription drugs, dental treatment, vision care, medical supplies and prostheses, and a number of other incidental services for Inuit and First Nations peoples with status. Further information on the NIHB program can be obtained at: [http://www.hc-sc.gc.ca/fnih-spni/nihb-ssna/index\\_e.html](http://www.hc-sc.gc.ca/fnih-spni/nihb-ssna/index_e.html).<sup>83</sup>

The **Extended Health Benefits** program is a supplement to the Nunavut Health Care Plan to assist individuals with health related costs not otherwise covered. This program was developed with the intention of providing similar benefits to non-aboriginal persons as offered by the Federal Government's NIHB program to Inuit and First Nations.<sup>84</sup>

#### l. Yukon

The **Chronic Disease and Disability Benefits Program** provides benefits to Yukon residents with disabilities up to the age of 65.<sup>85</sup> The program does not include persons with disabilities such as poor vision or hearing deficits, except significant hearing loss in

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<sup>81</sup> *Ibid.*

<sup>82</sup> *Ibid.*

<sup>83</sup> The NIHB program is also discussed at Section 2.II(iii).

<sup>84</sup> Nunavut, *Department of Health and Social Services: Business Plan 2003-2004*, online: Department of Health and Social Services <<http://www.gov.nu.ca/Nunavut/English/budget/2003/bp/hss.pdf>> (date accessed: 26 June 2007).

<sup>85</sup> Aboriginal people with status receive benefits under the Federal Non-Insured Benefits Program. More information on this program is available at <[http://www.hc-sc.gc.ca/fnih-spni/pubs/nihb-ssna/2005\\_rpt/index\\_e.html](http://www.hc-sc.gc.ca/fnih-spni/pubs/nihb-ssna/2005_rpt/index_e.html)> (last modified: 2 October 2006) at Section 2.II(iii).

children under 16 years of age. Financial assistance is provided for prescription drugs, medical surgical supplies, medical equipment, food supplements or prostheses that are medically required as recommended by a physician or a community health nurse. Applications for benefits are normally made before a purchase is made. Items covered include: body supports, prosthetic garments, osmotic supplies, glucose test kits, oxygen supply, bandages, respiratory equipment, manually operated hospital beds, manually operated wheelchairs, walking aids, grab bars and support rails, commodes and glucometers. Other equipment or devices that are medically necessary may be covered at the discretion of the Director of the Program. Further information on the Chronic Disease and Disability Benefits Program can be obtained at: [http://www.hss.gov.yk.ca/programs/insured\\_hearing/chronic\\_disease](http://www.hss.gov.yk.ca/programs/insured_hearing/chronic_disease).

Extended Health Benefits under the **Pharmacare Program** are available to Yukon residents at least 65 years of age or aged 60 and married to a living Yukon resident who is at least 65 years of age. Benefits include partial or total coverage for devices including: walking aids, hand inhalers, artificial eyes and limbs, respiratory equipment, commodes and manual wheelchairs. One hearing aid or a replacement hearing aid is allowed per four-year period. Repair and adjustment of hearing aids is allowed once every six months. Batteries are not covered. More information on this program can be obtained at: [http://www.hss.gov.yk.ca/programs/insured\\_hearing/pharmacare](http://www.hss.gov.yk.ca/programs/insured_hearing/pharmacare).

#### *m. Northwest Territories*

The Government of the Northwest Territories (NWT) provides **Extended Health Benefits** to Non-Native and Metis residents. Permanent residents in the NWT who are non-Native or Métis are eligible for the program.<sup>86</sup> Coverage may include: ostomy appliances, dietary aids and supplements, incontinence and catheter supplies, oxygen and specialized oxygen equipment, orthotic devices, self-administered injection supplies, prosthetic appliances, permanent prosthetics, hearing aids, bliss boards, mobility aids, toileting aids, patient lifters, grab bars. Other equipment or devices that are medically necessary may be covered (on a case by case basis) at the discretion of the Department of Health and Social Services and is subject to prior approval. Information on this program can be obtained at: [http://www.hlthss.gov.nt.ca/Features/Programs and Services/ehb/default.asp](http://www.hlthss.gov.nt.ca/Features/Programs_and_Services/ehb/default.asp).

The **Seniors Benefit Program** provides Extended Health Benefits to Métis and Non-Native residents who are 60 years of age and older. Medical Supplies and Equipment covered include: body supports, prosthetic garments, ostomy supplies, syringes and glucose test kits, oxygen supply, artificial limbs, synthetic orthopedic body parts, body braces, hearing aids (up to \$500 every 5 years), respiratory equipment, manually operated wheelchairs, walking aids, grab bars and support rails, commodes and

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<sup>86</sup> A list of specified diseases can be obtained at: [http://www.hlthss.gov.nt.ca/Features/Programs and Services/specified\\_diseases/coverage/ehb\\_for\\_specified\\_diseases\\_coverage\\_conditions\\_covered.asp](http://www.hlthss.gov.nt.ca/Features/Programs_and_Services/specified_diseases/coverage/ehb_for_specified_diseases_coverage_conditions_covered.asp) (last modified: 8 November 2006).

glucometers. Other equipment or devices that are medically necessary may be covered (on a case by case basis) at the discretion of the Department of Health and Social Services and is subject to prior approval. Information on this program can be obtained at:

[http://www.hlthss.gov.nt.ca/Features/Programs\\_and\\_Services/seniors\\_benefit/default.asp](http://www.hlthss.gov.nt.ca/Features/Programs_and_Services/seniors_benefit/default.asp).

The NWT is the only jurisdiction in Canada that provides a supplementary health benefits program specifically for indigenous Métis residents. The **Métis Health Benefits (MHB) Program** provides additional health benefits similar to Non-Insured Health Benefits, but at a coverage level of 100%. Alberta Blue Cross administers the Métis Supplies and Equipment Program on behalf of the Government of the NWT. Eligible devices are the same as those covered by Health Canada's Non-Insured Health Benefits Program.<sup>87</sup> Information on this program can be obtained at: [http://www.hlthss.gov.nt.ca/Features/Programs\\_and\\_Services/Metis/default.asp](http://www.hlthss.gov.nt.ca/Features/Programs_and_Services/Metis/default.asp).

### **iii. Other Funding Sources**

Given the restrictions of provincial government programs, consumers must often look to non-government sources of funding for assistance in paying their portion of the cost of a device, or for assistance for payment of devices that are not covered by government funding programs. Different sources may be available, depending on the consumer's residence. For instance, persons with a disability may seek coverage by private insurance if they are eligible. Applicants to some funding programs may be required to demonstrate that their income falls below specified financial criteria, potentially leaving out consumers earning above those levels.

#### **a. Charitable and Service Organizations**

**Charitable organizations** such as, the Rotary Club, the Royal Canadian Legion, the Kiwanis and the Lions Club may provide financial assistance. Check the yellow pages for local contact information. **Service organizations**, including Muscular Dystrophy Canada, March of Dimes and the Easter Seals Society, may act as transfer agencies providing assistive devices in Canada. Check the yellow pages for contact information.

As an example, the **Canadian National Institute for the Blind (CNIB)** is one of the country's largest suppliers of assistive devices for persons who are blind or low vision. The CNIB provides assistance with ADP applications, but does not normally provide funding directly to consumers. However, in Manitoba, the **Aids to the Blind** program of the Canadian National Institute for the Blind (CNIB) provides brailled watches and tape recorders to Manitoba residents who are blind or low vision.

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<sup>87</sup> NIHB medical supplies and equipment listing is available at: [http://www.hc-sc.gc.ca/fnih-spni/nihb-ssna/provide-fournir/med-equip/criter/index\\_e.html#list](http://www.hc-sc.gc.ca/fnih-spni/nihb-ssna/provide-fournir/med-equip/criter/index_e.html#list) (last modified: 20 March 2006).

Manitoba's **Community Wheelchair Program** is run by the Society for Manitobans with Disabilities (SMD). It offers regular or motorized wheelchairs and other mobility devices based on medical need as assessed by a physician. Further information on this program can be obtained at: <http://www.smd.mb.ca/default.aspx?tabid=46>.

The **Canadian Hearing Society** (CHS) provides a wide range of services to persons who are Deaf, deafened and hard of hearing. The CHS's **Hearing Aid Program** dispenses and fits hearing aids to persons of all ages. The CHS also offers a full range of assistive devices for sale including TTYs, alerting/signalling devices, FM systems and amplifiers. More information on the various other programs and services offered by the CHS can be obtained at: <http://www.chs.ca/services/index.html>.<sup>88</sup>

**Muscular Dystrophy Canada's** equipment loan program provides basic medical equipment, on loan, from a stock of recycled devices such as scooters, manual and electric wheelchairs, and hospital beds. Some funding assistance may be available for the purchase of new equipment. Equipment provided includes mobility devices and modifications, seating and positioning devices, orthopedic devices and bathroom equipment. It is important to note that Muscular Dystrophy Canada's equipment loan programs are managed regionally, and consequently there may be differences between regions and provinces. More information on the Equipment Loan Program can be obtained via Muscular Dystrophy Canada's website at: <http://www.muscle.ca/content/index.php?id=98>.

The **Multiple Sclerosis Society of Canada** offers funding for equipment purchase and permanent loan. However funding programs vary from province to province. To be eligible, clients must have the recommendation of a medical professional supporting the need for the equipment, and limited or non-existent eligibility for other programs.<sup>89</sup> Information can be obtained from the MS Society of Canada website at: <http://www.mssociety.ca/en/help/services.htm#equip>.

The **Canadian Red Cross** offers several Health Equipment Loan Programs. These programs vary across the country according to types of health and medical equipment provided, length of loan, access procedures, and type of service. The Canadian Red Cross offers health equipment loan programs in British Columbia, Alberta, Ontario, New Brunswick, Prince Edward Island, Nova Scotia, and Newfoundland and Labrador. For detailed information on the various Health Equipment Loan Programs offered in specific regions throughout the country please consult the Canadian Red Cross website at: <http://www.redcross.ca/article.asp?id=015828&tid=001>.

The **March of Dimes** operates a number of programs to assist consumers of assistive devices and potential consumers of assistive devices in Ontario:

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<sup>88</sup> You can contact the CHS's Technical Devices department at its national, toll-free number: TTY 1-(800) 537 6030; Voice 1-(800) 465 4327.

<sup>89</sup> *Supra* note 66.

- The Ontario March of Dimes is a source of funding for the client's share of the cost of an assistive device purchased through the Assistive Devices Program. The March of Dimes also provides funding for the repairs and maintenance of assistive devices.
- Larger devices such as ceiling track lift systems, automatic door openers and stair glide systems are funded through the **Home & Vehicle Modification Program** (HVMP), operated by the Ontario March of Dimes, and funded by the Ministry of Community and Social Services. The HVMP provides grants for modifications such as: vehicle hand controls, foot controls, lifts, safety devices, specialized seating for a child, installation of wheel-in showers and wall grab bars. The maximum contribution for a home or a vehicle modification is \$15,000. It is important to note that funding for this program is very limited. For more information see: [http://www.marchofdimes.ca/dimes/people\\_with\\_disabilities\\_caregivers/programs\\_and\\_services/hvmp/hvmp.htm](http://www.marchofdimes.ca/dimes/people_with_disabilities_caregivers/programs_and_services/hvmp/hvmp.htm).
- The **Recycled Rental Equipment Program** provides short or long-term rentals of mobility equipment and devices such as manual and electric wheelchairs, crutches, scooters, walkers, ramps, lifting equipment, bath aids, and home aids. The program is open to any Ontario resident in need of an assistive device, regardless of age or income level. Fees vary depending on the item being rented.
- The **Design Ability Program** employs volunteers with skills such as woodworking, metalworking, plastic molding/shaping, or electronics and engineering. These volunteers work with individuals requiring assistance to find solutions to barriers faced by persons with disabilities by creating unique products or adapting existing devices in order to create simple and inexpensive design solutions that are not available on the open market.

*b. General Ontario Programs not Targeted to Assistive Devices*

In addition, there are other provincial programs that provide limited access to support services, although not principally mandated to provide assistive devices. Although the following examples are Ontario based, there are similar programs in other provinces. Given that ARCH has an Ontario mandate, our expertise is with Ontario-based programs.

There also exist **municipal initiatives** such as the Hardship Fund in the City of Toronto.<sup>90</sup> For instance, Toronto Community Housing may provide funding for renovations, including a ceiling pole.

Ontario's Ministry of Community and Social Services may provide financial aid to recipients of social assistance. For example, the **Ontario Disability Support Program**

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<sup>90</sup> Toronto, *Hardship Fund Policy* (Toronto: City of Toronto, 2006) online: <http://www.toronto.ca/socialservices/Policy/HardshipFund.htm> (date accessed: 26 June 2007).

(ODSP) is designed to assist persons with disabilities who are in financial need. Benefits include: wheelchair/mobility device repair and batteries, hearing aids, eyeglasses, diabetic supplies, ostomy supplies, and a service animal allowance. ODSP will cover the recipient's portion of the cost of a device covered by Ontario's Assistive Devices Program (ADP). Eligibility for ODSP income support benefits is limited to Ontario residents who meet the financial qualifications, and have a continuous or recurrent disability that is expected to last one year or more. Further information about ODSP can be obtained via the Ontario Ministry of Community and Social Services website at: <http://www.mcsc.gov.on.ca/mcss/english/pillars/social/programs/odsp.htm>.

Also in Ontario, the **Assistance for Children with Severe Disabilities** (ACSD) program provides assistance to parents to assist with some of the extra costs of caring for a child who has a disability. Financial assistance ranges from \$25 to \$400 per month depending on the family's gross annual income and the number of other children in the family. The program may help parents with costs related to special shoes and clothing, wheelchair repairs, and hearing aid batteries, for example.<sup>91</sup> Further information can be obtained at: <http://www.children.gov.on.ca/CS/en/programs/SpecialNeeds/assistanceforChildrenwithSevereDisabilities.htm>.

In Ontario, the **Workplace Safety and Insurance Board** (WSIB) may fund the purchase of assistive devices required as a result of a work-related injury.<sup>92</sup> The types of devices and special needs that WSIB insurance benefits will cover include: wheelchairs, artificial limbs, hearing aids, dentures, canes and orthopedic mattresses. In the case of a serious permanent disability, WSIB insurance benefits can pay for home renovations such as the alteration of a car or van. A consumer should seek WSIB approval before buying any of the above listed devices as each device has its own eligibility criteria. WSIB may require a detailed explanation from a health practitioner before approving payment for assistive devices. Information on the various programs and benefits offered by the WSIB can be obtained at: <http://www.wsib.on.ca/wsib/wsibsite.nsf/public/WSIBBenefits>.

In Ontario, **Community Care Access Centres** (CCAC) offer a wide range of community based health services such as in-home professional health care services, support services and case management. Section 11(1) of the *Long Term Care Act* requires the CCAC's to provide, or ensure the provision of, community support services including "providing prescribed equipment, supplies or other goods" prescribed as mandatory by the Lieutenant Governor in Council.<sup>93</sup> The CCAC provides case

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<sup>91</sup> Ontario, *Ministry of Children and Youth Services: Assistance for Children with Severe Disabilities* (Ontario: Queen's Printer for Ontario, 2003), online: Ministry of Children and Youth Services  
<<http://www.children.gov.on.ca/CS/en/programs/SpecialNeeds/assistanceforChildrenwithSevereDisabilities.htm>> (last modified: 31 May 2007).

<sup>92</sup> *Workplace Safety and Insurance Act*, S.O. 1997, c 16, s. 33(1).

<sup>93</sup> *Long Term Care Act*, S.O. 1994, c. 26, ss. 2(4), 11(1).

management services which, in consultation with the client, assesses individual needs for personal support and services. The CCAC Case Manager arranges for medical supplies (e.g. dressings, intravenous supplies) through contracted medical suppliers, for clients who need supplies for nursing treatment. The CCAC Case Manager arranges for rental of a limited range of medical equipment, through contracted equipment suppliers.<sup>94</sup>

#### **IV. Regulating the Safety of Assistive Devices**

This section explores the regulation of product safety by Health Canada and the reporting requirements for vendors and manufacturers of medical devices as set out by the *Medical Device Regulations*. It also addresses the regulation of product safety by the Assistive Devices Program in Ontario.

##### **i. Standards that Apply to Medical and Assistive Devices**

This section explores how product standards may protect users of assistive devices in Canada: how standards are developed in Canada; whether they are mandatory or voluntary; and what enforcement mechanisms currently exist.

###### **a. Canadian Standards Association**

The Canadian Standards Association (CSA) is a not-for-profit association that develops voluntary standards across many industrial sectors. The CSA has published more than 2000 standards. Standards may include product design requirements, test methods or recommended practices. They are developed by committees composed of volunteer members, including business representatives, regulatory bodies, scientists, labour representatives, and consumer groups. Standards are reviewed at least every five years in order to reflect the latest developments in technology and the current realities of the marketplace.<sup>95</sup>

The CSA has developed standards about specific health and safety products, including cardiovascular implants (CAN/CSA-ISO 5840-98) and electrical aids for persons with physical disabilities (Z323.3.1 -1982). In 2003, the CSA adopted the International Organization for Standardization's standard, *Medical Devices - Quality management systems - Requirements for Regulatory Purposes*. It has been adopted in Canada as CAN/CSA-ISO 13485:2003 and 13488:2003.

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<sup>94</sup> Ontario Association of Community Care Access Centers, online: Community Care Access Centre Website <<http://www.ccac-ont.ca>> (date accessed: 26 June 2007).

<sup>95</sup> Canadian Standards Association, *Standards Development* (Canada: Canadian Standards Association 2007), online: Canadian Standards Association Website <<http://www.csa.ca/standards/Default.asp?language=english>> (date accessed: 26 June 2007).

Standards are usually voluntary. The CSA is not a government organization and does not have the power to make a standard mandatory. Even if a standard is not mandatory, many organizations choose to comply in order to demonstrate their commitment to safety.

There are instances where CSA approval is required. First, CSA approval is required for ADP product eligibility. A product's manufacturer or distributor must apply to the ADP program in order for a device to be listed as eligible for funding, confirming that the device meets CSA standards.<sup>96</sup> Secondly, the *Medical Devices Regulations* require Class II medical devices to be manufactured under CAN/CSA ISO 13488, and Class III and IV medical devices to be designed and manufactured under CAN/CSA ISO 13485. See Section 2.IV.ii, below, for more detail about these requirements as set out in the *Medical Device Regulations* to the *Food and Drugs Act*.

#### b. Standards Council of Canada

The Standards Council of Canada is Canada's member body of the International Organization for Standardization (ISO).<sup>97</sup> As described in the *Standards Council of Canada Act*, the Standards Council has the mandate to coordinate and oversee the efforts of the National Standards System.<sup>98</sup> The National Standards System is a network of people and organizations including testing laboratories, certification bodies and standards development organizations like the CSA. It includes a variety of organizations and individuals involved in voluntary standards development, promotion, and implementation in Canada. Once a new standard has been developed, by for example the CSA, it is evaluated by the Standards Council of Canada to see if it meets the criteria of the National Standards System.

The Standards Council of Canada has accredited CSA as one of four nationally accredited standards development organizations. Accreditation of a standards development organization is the formal recognition of their competence to develop standards. Other standards development organizations include the Canadian General Standards Board, Underwriters Laboratories of Canada and the Bureau de normalization du Québec.

#### c. International Organization for Standardization and the International Electro-technical Commission

The International Organization for Standardization (ISO) is a network of national standards bodies representing approximately 140 countries. Founded in 1947, the organization produces world-wide industrial and commercial standards. The ISO works with member countries to develop standards that will improve design, performance,

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<sup>96</sup> *Supra* note 76.

<sup>97</sup> Standards Council of Canada, *Standards in Focus*, online: Standards Council of Canada Website <<http://www.scc.ca/en/index.shtml>> (date accessed: 26 June 2007).

<sup>98</sup> *Standards Council of Canada Act*, R.S.C. 1985, c. S-16.

safety, and other considerations. The ISO addresses standardization in all fields except electrical and electronic engineering.

The International Electro-technical Commission (IEC) is a worldwide organization that prepares and publishes international standards for electrical, electronic and telecommunication technologies. There are approximately 200 governmental and non-governmental organizations that work with IEC, representing more than 50 member countries. The CSA works with IEC to develop standards.

#### d. The Ontario Electrical Safety Code

Most provinces require electrical products to be certified.<sup>99</sup> In 1927, the CSA first developed a *Canadian Electrical Code*. It is primarily a technical document and it is prescriptive in approach. The *Code* describes the standards for electrical installations in detail.<sup>100</sup> The Ontario legislature adopted the *Canadian Electrical Code* with some specific Ontario amendments as the *Ontario Electrical Safety Code* (OESC).<sup>101</sup> There is similar legislation in other provinces and territories.<sup>102</sup>

While the OESC does not apply to an electric assistive device itself, the OESC does apply to the battery or the battery charging equipment. In the case of an electric wheelchair, the OESC applies to the charger which is cord-and-plug connected to an electrical installation.<sup>103</sup> If the charging equipment is "on-board" the wheelchair, then the wheelchair is required to bear a recognized electrical approval marking.<sup>104</sup> If the charging equipment is not part of the chair, then the chair is not required to bear a

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<sup>99</sup> O. Reg. 164/99, s. 2. "Electrical Safety Code" to *Electricity Act*, 1998: Every act or omission in connection with the generation, transmission, distribution, retail or use of electricity in Ontario must be done or made in compliance with the Electrical Safety Code.

<sup>100</sup> Electrical Safety Authority, *Government and Regulations: The Ontario Electrical Safety Code*, online: Electrical Safety Authority Website <[http://www.esainspection.net/Corporate/gr\\_004.php?s=8](http://www.esainspection.net/Corporate/gr_004.php?s=8)> (date accessed: 26 June 2007).

<sup>101</sup> *Ontario Electrical Safety Code*, O. Reg. 10/02 to the *Electricity Act*, 1998. The OESC is a regulation to the *Electricity Act*.

<sup>102</sup> There is similar legislation in British Columbia, Alberta, Saskatchewan, Manitoba, New Brunswick, Nova Scotia and Newfoundland. See for example, in British Columbia, the *Electrical Safety Regulation* B.C. Reg. 100/2004 to the *Electrical Safety Act* s. 20, which adopts the *Canadian Electrical Code* as the *B.C. Electrical Code*.

<sup>103</sup> OESC, *supra* note 101. The OESC defines "electrical equipment" as any device "capable of being used in or for, the generation, transformation, transmission, distribution, supply, or utilization of electric power or energy" and is capable "to serve or perform any particular purpose or function when connected to an electrical installation".

<sup>104</sup> *Ibid.* OESC Rule 2-022 states that no person shall advertise, display, offer for sale, connect to a source of electrical power, or use any electrical equipment unless it has been approved in accordance with Rule 2-024.

recognized marking, but the charging equipment is required to bear a recognized marking.<sup>105</sup>

e. Accessibility for Ontarians with Disabilities Act

The *Accessibility for Ontarians with Disabilities Act* (AODA) is provincial legislation with the goal of creating an accessible Ontario by 2025 through the identification and removal of barriers and the prevention of the erection of barriers. It establishes a system for the creation of accessibility standards in the areas of “goods, services, facilities, accommodation, employment, buildings, structures and premises or such other things as may be prescribed”.<sup>106</sup> Although the AODA includes goods in this list, to date the Ontario Government has not indicated any plans to create a standard that addresses such things as the design, manufacture, production, labelling, distribution, or the requirement for accessible information and training related to goods. Rather, it has or will be working on standards with respect to customer service, transportation, information and communication, the built environment and employment.<sup>107</sup>

One significant goal of an accessibility standard with respect to goods, is that it should reinforce the principles of universal design and provide for their introduction over time into the design and manufacture of goods used by everyone.<sup>108</sup> When goods are designed from a universal or inclusive use perspective, then many people with disabilities will be able to use them and not be so reliant on assistive devices that are designed for the specific use of people with disabilities. An accessibility standard with respect to goods would also address issues of labelling, alternate format, and appropriate training.

There is no harmonization of standards between the United States and Canada, so assistive technology acquired in one country can not be easily used in the other. For instance, most wheelchairs available in Canada are American-made and fit standards of the *Americans with Disabilities Act* (ADA).<sup>109</sup> Title III of the ADA requires the removal of architectural barriers in existing facilities of “public accommodation” where “readily achievable.” Section 4.13 of the *Americans with Disabilities Act Accessibility Guidelines* provides standards about the size of doorways, through which larger wheelchairs can

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<sup>105</sup> *Ibid.* OESC Rule 2-024 recognizes certification organizations accredited by the Standards Council of Canada to approve electrical equipment. Only equipment bearing a recognized mark is approved.

<sup>106</sup> AODA, *supra* note 2 at s.6(6)(a).

<sup>107</sup> Ontario, *Ministry of Community and Social Services: Accessibility for Ontarians with Disabilities* (Ontario: Queen’s Printer for Ontario, 2005), online: Ministry of Community and Social Services <<http://www.mcscs.gov.on.ca/mcss/english/pillars/accessibilityOntario/>> (last modified: 29 May 2007).

<sup>108</sup> See Introduction, Section VI “Universal Design” above.

<sup>109</sup> *Americans With Disabilities Act*, Pub. L. No. 101-336, 104 Stat. 327 (1990). (codified at 42 U.S.C. § 12101 et seq.).

fit.<sup>110</sup> Canada's AODA standards are not as stringent, and larger American-made wheelchairs can not fit through many doorways in Canada.

## **ii. Obligations under the Medical Devices Regulations**

Health Canada states that the goal of the *Medical Device Regulations* is to ensure that "medical devices distributed in Canada are safe, effective, and meet quality standards".<sup>111</sup> In this respect, the Therapeutic Products Directorate of Health Canada undertakes pre-market reviews of the safety of medical devices through device licensing which require quality system certification as well as establishment licensing of importers and distributors. Compliance with device and establishment licensing requirements ensure that companies would be able to adequately identify or take appropriate corrective action regarding unsafe or ineffective devices. The Therapeutic Products Directorate is also responsible for post-market surveillance of adverse effects after licensing, including monitoring complaints about medical devices sold in Canada.

### **a. Overview of the Medical Device Regulations to the Food and Drugs Act**

The *Food and Drugs Act* provides that no person shall sell any device that when used according to the directions may cause injury to the user.<sup>112</sup> Most devices must meet the safety and effectiveness requirements set out in sections 10 to 20 of the *Medical Devices Regulations*.<sup>113</sup> The safety requirements provide for measures that include:

- the design and manufacture of the device;
- the degree of acceptable risks weighed against the benefits;
- the performance of the device;
- protection against deterioration of the device's characteristics and performance;
- compatibility of materials used in the device's manufacture;
- minimizing the risk from reasonably foreseeable hazards (flammability; explosions; contamination; chemicals; microbial residue; radiation; electrical, mechanical or thermal hazards; and fluid leakages);
- appropriately controlled sterilization processes;
- compatibility with all other parts of the system with which it interacts;

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<sup>110</sup> *Americans With Disabilities Act Accessibility Guidelines* ("ADAAG") found in the Code of Federal Regulations at 28 C.F.R., Part 36, Appendix "A." s. 4.13.

<sup>111</sup> Canada, *Health Canada : Guidance for the Labelling of Medical Devices under Section 21 to 23 of the Medical Devices Regulation June 12, 2004 Letter* (Canada: Health Canada, 2004), online: Health Canada Website <[http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/lab/etiq\\_dv10\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/lab/etiq_dv10_e.html)> (last modified: 15 July 2004).

<sup>112</sup> *Supra* note 16 at s.19.

<sup>113</sup> However, devices that are custom-made, imported or sold for special access, or used for investigational testing on human subjects are regulated pursuant to sections 69-78 and sections 79-88 of the *Medical Device Regulations*.

- validation of software, where software is involved.<sup>114</sup>

The term “medical device” covers a wide range of health or medical instruments used in the treatment, mitigation, diagnosis or prevention of a medical condition. A definition of medical device is found in section 2 of the *Food and Drugs Act*,<sup>115</sup> and further referenced in its *Medical Devices Regulations* (the “*Regulations*”).<sup>116</sup> The *Regulations* apply to the sale, advertising and importing of medical devices, other than the importation for personal use.<sup>117</sup> The *Regulations* apply to all medical devices except those that are custom made,<sup>118</sup> imported for special access,<sup>119</sup> or used for investigational testing on human subjects; there are separate provisions which apply to these devices.<sup>120</sup>

Classification of a particular device into Class I, II, III or IV is made by reference to the sixteen Rules set out in Schedule 1 of the *Regulations*. Canada’s Therapeutic Products Directorate, the agency that regulates medical devices, has produced a publication entitled “Guidance for the Risk-Based Classification System” as well as the “Keyword

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<sup>114</sup> Industry Canada, *Canadian Medical Devices Industry: Chapter 2: Canadian Requirements*, online: Industry Canada – Strategis <<http://strategis.ic.gc.ca/epic/site/md-am.nsf/en/hi00038e.html>> (last modified: 9 January 2007).

<sup>115</sup> A medical device is defined by reference to the definition of “device” from the *Food and Drugs Act*, R.S.C. 1985, c. F-27 (the “*Act*”): “device means any article, instrument, apparatus or contrivance, including any component, part or accessory thereof, manufactured, sold or represented for use in:

(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals; (b) restoring, correcting or modifying a body function or the body structure of human beings or animals; (c) the diagnosis of pregnancy in human beings or animals; or (d) the care of human beings or animals during pregnancy and at and after birth of the offspring, including care of the offspring; and includes a contraceptive device but does not include a drug.”

<sup>116</sup> *Supra* note 17. A medical device is also defined by the *Regulations*: ““medical device” means a device within the meaning of the *Act*, but does not include any device that is intended for use in relation to animals.”

<sup>117</sup> *Ibid.* at s. 2.

<sup>118</sup> *Ibid.* at s. 1: A “custom-made device” means a medical device, other than a mass-produced medical device, that (a) is manufactured in accordance with a health care professional’s written direction giving its design characteristics; (b) differs from medical devices generally available for sale or from a dispenser; and (c) is (i) for the sole use of a particular patient of that professional, or (ii) for use by that professional to meet special needs arising in the course of his or her practice.

<sup>119</sup> *Ibid.* at s. 69(2). Special access means access to a medical device for emergency use or if conventional therapies have failed, are unavailable or are unsuitable.

<sup>120</sup> Industry Canada, “Canadian Medical Devices Industry, Chapter 2: Canadian Requirements”. Online: Industry Canada <[strategis.ic.gc.ca/epic/site/md-am.nsf/en/hi00038e.html](http://strategis.ic.gc.ca/epic/site/md-am.nsf/en/hi00038e.html)> (date accessed: 29 May 2007).

Index to Assist Manufacturers in Verifying the Class of Medical Devices,”<sup>121</sup> in order to assist manufacturers in classifying their devices. The more invasive a device, the higher the Class; hence, a vaginal stent is Class II, a urethral stent is Class III, and a cardiovascular stent is Class IV. By way of example, canes, walkers, and wheelchairs (motorized or manual) are Class I devices. Hearing aids are Class II devices, with the exception of an implanted bone-conduction hearing aid, which would be a Class III device. An artificial larynx which is battery powered is a Class II device, but a prosthetic larynx is a Class III device. Manufacturers are responsible for assessing their devices for the purpose of determining the class, subject to verification by Health Canada.<sup>122</sup> If a medical device can fit in more than one class, the higher class applies.<sup>123</sup>

### b. Device Licences

Manufacturers of Class II, III, and IV devices must obtain a device licence before importing, selling or advertising the device in Canada. Class II, III, and IV devices cannot be advertised for sale unless the manufacturer holds such a licence or the advertisement is placed only in a catalogue with a clear warning that the device may not have been licenced in accordance with Canadian law.

While Class I devices, including wheelchairs, do not have to be licenced, they must still meet the safety and effectiveness requirements.<sup>124</sup> Health Canada retains the power to request information from the manufacturer to demonstrate the product’s safety or effectiveness if she believes on reasonable grounds that the device might not meet those requirements. If that belief is verified (or the information is not provided by the manufacturer) Health Canada can order the sale of that Class I device be stopped.<sup>125</sup>

The requirements for a device licence differ based on the Class of device. All licence applications require basic information including: the name of the device, class of the device, name and address of the manufacturer, and the identifier of the device.<sup>126</sup> The additional information required for a device licence depends on the device’s Class. By way of example, a Class II device licence application requires, among other things, an attestation by a senior officer that the manufacturer has objective evidence of the

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<sup>121</sup> Both documents are available at: Health Canada, *Guidance Documents*, online: Health Canada <[http://hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/index\\_e.html](http://hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/index_e.html)> (date accessed: 29 May 2007).

<sup>122</sup> Therapeutic Products Program, *Medical Devices Bulletin*, (Ottawa: Health Canada, Spring Summer 1998) at 3, online: <<http://dsp-psd.pwgsc.gc.ca/Collection/H12-39-4-1E.pdf>> (last accessed 28 June 2007). The program states: “Classifications assigned by the manufacturer will be reviewed by the staff at the Therapeutic Products Program of the Health Canada.”

<sup>123</sup> *Supra* note 17 at s. 7.

<sup>124</sup> *Ibid.* at subsection 9(1).

<sup>125</sup> *Ibid.* at s. 25.

<sup>126</sup> *Ibid.* at subsection 32(1).

device's safety and effectiveness.<sup>127</sup> A Class III device licence application requires, among other things, a list of the standards complied with in the design and manufacture of the device to ensure that the safety and effectiveness requirements are met.<sup>128</sup> A Class IV device licence application requires, among other things, a risk assessment and an analysis and evaluation of risk reduction measures taken to satisfy the safety and effectiveness requirements.<sup>129</sup> In addition, an application for a device licence for any of a Class II, III, or IV device must be accompanied by a copy of the quality management system certificate.<sup>130</sup> The manufacturer must inform Health Canada on an annual basis that the information in the licence application is still accurate or the licence may be cancelled.<sup>131</sup>

In certain circumstances, foreign manufacturers may not have to submit information beyond the basic name and address and identifier information if their application is accompanied by a certificate of compliance and supporting summary report from the foreign regulatory authority certifying that the medical device meets the safety and effectiveness requirements of the country where that authority is recognized by Health Canada.<sup>132</sup>

Even when the manufacturer submits the statutorily required information, Health Canada retains the authority to request more information, and/or samples, if it cannot be satisfied of the device's compliance with the safety and effectiveness requirements.<sup>133</sup> Health Canada can issue a licence subject to terms and conditions (specifically providing for tests to be performed on the device and the results to be made available to Health Canada).<sup>134</sup> Health Canada may refuse to issue a licence on certain grounds and has the power to suspend them as well.<sup>135</sup> A device licence can also be suspended, with or without granting the licensee an opportunity to be heard in respect of the suspension depending on the hazard that is presented by the device.<sup>136</sup>

### c. Establishment Licences

Anyone wishing to sell or import a medical device, including Class I devices, must hold a medical device establishment licence ("MDEL"). Class I devices do not require a device licence although importers/distributors of these devices are required to have an

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<sup>127</sup> *Ibid.* at para 32(2)(c).

<sup>128</sup> *Ibid.* at para 32(3)(d).

<sup>129</sup> *Ibid.* at para 32(4)(d).

<sup>130</sup> A quality management system certificate certifies that the manufacture of the device satisfies CAN/CSA-ISO 13485:03.

<sup>131</sup> *Supra* note 17 at section 43.

<sup>132</sup> *Ibid.* at s. 33.

<sup>133</sup> *Ibid.* at s. 35 .

<sup>134</sup> *Ibid.* at s. 36(2).

<sup>135</sup> *Ibid.* at ss. 38, 40.

<sup>136</sup> *Ibid.* at s. 41. See also Therapeutic Products Program, *Medical Devices Bulletin*, Spring Summer 1998 at 4.

Establishment Licence.<sup>137</sup> Issuance of the establishment licence is contingent upon attestations from the manufacturer that recall, mandatory problem reporting, and complaint handling procedures are in place, and that proper distribution records are maintained. MDELs expire on December 31<sup>st</sup> of each year.<sup>138</sup>

Health Canada must refuse to issue an MDEL if there are reasonable grounds to believe that licensing the device would constitute a risk to the health or safety of patients, users or other persons.<sup>139</sup> If Health Canada refuses to issue an MDEL, the applicant will be notified in writing and given an opportunity to be heard.<sup>140</sup> Furthermore, an MDEL can be suspended in certain circumstances.<sup>141</sup>

The Health Products and Food Branch Inspectorate conducts on-site inspections of Canadian companies with MDELs to determine their compliance with the *Act* and *Regulations*.<sup>142</sup> In general, the primary focus of inspections is to assess compliance with sections of the *Regulations*, such as complaint handling, recalls, and mandatory problem reporting as these sections are not assessed through other mechanisms.<sup>143</sup> The Inspection Program applies to medical device manufacturers, importers and distributors subject to establishment licensing as well as manufacturers of class I devices who are not subject to establishment licensing.<sup>144</sup> Any other party subject to the *Act* and the *Regulations*, or a company holding a CAN/CSA-ISO 13485/88 certificate under CMDCAS, may also be inspected if there is an indication of noncompliance or suspected noncompliance.<sup>145</sup> In most cases, the company is given prior notice of the inspection.<sup>146</sup> Typically, the company will be expected to respond to non-compliances and comments within 30 calendar days of receiving the inspector's final report.<sup>147</sup>

#### d. Quality Management System Certificates

The *Regulations* require medical device manufacturers to use a quality management system certificate as evidence of compliance with the appropriate regulatory quality

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<sup>137</sup> Industry Canada, "Canadian Medical Devices Industry Chapter 2: Canadian Requirements", online: Industry Canada, [http://strategis.ic.gc.ca/epic/site/md-am.nsf/en/hi00038e.html#\\_1\\_64](http://strategis.ic.gc.ca/epic/site/md-am.nsf/en/hi00038e.html#_1_64) (last accessed June 19, 2007).

<sup>138</sup> *Ibid.* at s. 46(2).

<sup>139</sup> *Ibid.* at s. 47(2).

<sup>140</sup> *Ibid.* at s. 47(3).

<sup>141</sup> *Ibid.* at s. 49.

<sup>142</sup> Health Products and Food Branch Inspectorate "Guidance on the Medical Device Inspection Programme," <[http://www.hc-sc.gc.ca/dhp-mpps/compli-conform/info-prod/md-im/index\\_e.html](http://www.hc-sc.gc.ca/dhp-mpps/compli-conform/info-prod/md-im/index_e.html)> (last modified: 17 August 2006).

<sup>143</sup> *Ibid.*

<sup>144</sup> *Ibid.*

<sup>145</sup> *Ibid.*

<sup>146</sup> *Ibid.* at 5.

<sup>147</sup> *Ibid.*

system requirement.<sup>148</sup> The *Regulations* require Class II medical devices to be manufactured and Classes III and IV medical devices to be designed and manufactured under CAN/CSA ISO 13485:03.<sup>149</sup> There are no such requirements for Class I devices. Quality system certificates must be issued by special third party auditing organizations identified as Canadian Medical Devices Conformity Assessment System (CMDCAS) recognized registrars.<sup>150</sup> Guidance documents provide information to registrars recognized by Health Canada on how to perform ISO 13485:2003 quality management system audits.<sup>151</sup>

In the case of imported assistive devices, Health Canada reviews medical devices to assess their safety, effectiveness and quality before being authorized for sale in Canada.<sup>152</sup> Foreign manufacturers applying for a medical device licence do not require CMDCAS certification. Instead, a foreign applicant must demonstrate that it is governed by a regulatory authority in the country of origin, and submit a certificate of compliance that certifies that the medical device meets the safety and effectiveness requirements.<sup>153</sup>

#### e. Records Retention and Reporting Requirements

The manufacturer is responsible for keeping “objective evidence” that the device meets the safety requirements set out above.<sup>154</sup> For instance, distribution records for each device must be maintained by the manufacturer, importer and distributor.<sup>155</sup> The

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<sup>148</sup> *Supra* note 17 at s. 32(2), s. 32(3) and 32(4).

<sup>149</sup> *Ibid.* See also Health Canada, “Quality Systems ISO 13485”, online: Health Canada <[http://www.hc-sc.gc.ca/dhp-mps/md-im/qualsys/index\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/md-im/qualsys/index_e.html)> (last accessed: 29 May 2007).

<sup>150</sup> *Ibid.* at s. 33.

<sup>151</sup> Health Canada, *Guidance Document GD210*, online: Health Canada <[http://www.hc-sc.gc.ca/dhp-mps/alt\\_formats/hpfb-dgpsa/pdf/md-im/cmdcas\\_scecim\\_audit13485\\_2\\_e.pdf](http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/md-im/cmdcas_scecim_audit13485_2_e.pdf)> (date accessed: 29 May 2007). Health Canada provides guidance documents relating to medical devices, including one on the use of recognized standards for safety and effectiveness at: <[http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/index\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/index_e.html)> (last modified: 19 February 2007).

<sup>152</sup> Health Canada, *Activities of the Therapeutic Products Directorate*, online: Health Canada <[http://www.hc-sc.gc.ca/dhp-mps/md-im/activit/index\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/md-im/activit/index_e.html)> (date accessed: 29 May 2007).

<sup>153</sup> *Supra* note 17 at s. 34 (1).

<sup>154</sup> *Ibid.* at s. 9(2). Section 1 of the *Regulations* defines “Objective Evidence” as follows: “Objective evidence” means information that can be proved true, based on facts obtained through observation, measurement, testing or other means, as set out in the definition “objective evidence” in section 2.19 of International Organization for Standardization standard ISO 8402:1994, *Quality management and quality assurance - Vocabulary*, as amended from time to time.

<sup>155</sup> *Ibid.* at s. 52.

records must contain sufficient information to allow a complete and rapid withdrawal of the device from the market.<sup>156</sup> Records must be retained for the estimated life of the device, but not less than two years after the device was dispatched from the manufacturer.<sup>157</sup>

Pursuant to the *Regulation's* Mandatory Problem Reporting provisions and subject to certain conditions, manufacturers and importers of devices must make preliminary and final reports to Health Canada concerning any incident involving a device that is sold in Canada where the device has failed or deteriorated or there were inadequacies in the labelling or directions for use, which has led to (or could have led to) a death or serious deterioration of health.<sup>158</sup> Sections 59 to 61.1 of the *Regulations* set out the types of incidents to be reported, time frames for reporting and content for the preliminary and final reports, including actions taken to prevent the incident from recurring.<sup>159</sup>

Before undertaking the recall of a device, both the manufacturer and the importer must provide Health Canada with detailed information described by the *Regulations*.<sup>160</sup> After such a recall, the manufacturer and the importer must report to Health Canada the results of the recall as well as the action taken to prevent a recurrence of the problem, and each must maintain records related to the recall.

#### f. Complaints about the Safety of Assistive Devices

Health Canada has the power to designate inspectors to ensure compliance with the *Food and Drugs Act* and *Regulations*.<sup>161</sup> Health Canada's Health Products and Food Branch Inspectorate (HPFBI) is responsible for compliance monitoring, and compliance verification and investigation, supported by establishment licensing of drugs and medical devices, and laboratory analysis.<sup>162</sup> Consumers may make a complaint about

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<sup>156</sup> *Ibid.* at s. 53.

<sup>157</sup> *Ibid.* at s. 55.

<sup>158</sup> *Ibid.* at s. 59.

<sup>159</sup> Further information on mandatory problem reporting can be found in the draft guidance document entitled "Mandatory and Voluntary Problem Reporting for Medical Devices," available on the Inspectorate web site: <[http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/mavprfmd-rioevraim\\_tc-tm\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/mavprfmd-rioevraim_tc-tm_e.html)> (last modified: 22 April 2002).

<sup>160</sup> *Supra* note 17 at ss. 57 and 58. Sections 57 and 58 of the *Regulations* provide that the manufacturer, importer and distributor must each maintain records of any reported problems relating to the performance characteristics or safety of the device, including any consumer complaints, received after the device was first sold in Canada.

<sup>161</sup> For more information see HPFBI website at: <[http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/hpfi-ipsa/index\\_e.html](http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/hpfi-ipsa/index_e.html)>.

<sup>162</sup> See Health Canada, *Medical Device Compliance and Enforcement Directive POL-0045* online: Health Canada, <[http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/md-im/pol\\_45\\_tc-tm\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/md-im/pol_45_tc-tm_e.html)> (last accessed: 29 June 2007). See also Health Canada, *Compliance and Enforcement Policy POL-0001 V.2*, online: Health Canada,

product safety to HPFBI.<sup>163</sup> Complaints should be submitted in writing, whenever possible, to the HPFBI provincial office.<sup>164</sup> Relevant information, along with the health product in question and its packaging, should be forwarded to the HPFBI provincial office. Details should include:

- any contact made with the company or store;
- trade name/common name of the health product, list of ingredients;
- Device Licence Number if applicable and known;
- catalogue number, lot number, expiry date, etc;
- copies of labels of the product in question;
- price lists or order forms or flyers which show the name of the company and product in question;
- invoices, receipts, etc. showing the date of sale, if of interest for the compliance verification;
- advertising or promotional material; if taken from newspapers or magazines, the name of the newspaper or magazine and the date on which it appeared;
- any other information which would assist the Inspectorate in verifying the complaint;
- the complainant's contact information.<sup>165</sup>

After notifying the complainant that the complaint was received, the HPFBI reviews complaints to determine if the nature of the complaint falls within its jurisdiction. Complaints involving incidents considered a higher risk will be dealt with first.<sup>166</sup> As part of the review procedures, inspectors have the power to enter premises where devices are manufactured, prepared, preserved, packaged or stored, as well as the power of search and seizure. Persons in charge of the premises entered must give the inspector all reasonable assistance and furnish her with any information that is reasonably required.<sup>167</sup>

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<[http://www.hc-sc.gc.ca/dhp-mpps/compli-conform/gmp-bpf/pol/pol\\_1\\_tc-tm\\_e.html](http://www.hc-sc.gc.ca/dhp-mpps/compli-conform/gmp-bpf/pol/pol_1_tc-tm_e.html)> (last accessed: 28 June 2007).

<sup>163</sup> See here for more information: Health Canada, *Program Reporting*, online: Health Canada, <[http://www.hc-sc.gc.ca/dhp-mpps/compli-conform/prob-report-rapport/index\\_e.html](http://www.hc-sc.gc.ca/dhp-mpps/compli-conform/prob-report-rapport/index_e.html)> (last modified: 1 February 2006).

<sup>164</sup> The HPFBI may be reached toll free at 1-800-267-9675.

<sup>165</sup> Health Canada, *Health Products and Food Branch Inspectorate – Guidance Document – How to Submit a Consumer Complaint Guide -0044* at 3-4, online: Health Canada < [http://www.hc-sc.gc.ca/dhp-mpps/compli-conform/prob-report-rapport/gui-44\\_consumer\\_complaint-plainte\\_consommateur\\_e.html#3](http://www.hc-sc.gc.ca/dhp-mpps/compli-conform/prob-report-rapport/gui-44_consumer_complaint-plainte_consommateur_e.html#3)> (last modified: 20 January 2006).

<sup>166</sup> *Ibid.*

<sup>167</sup> *Ibid.*

The HPFBI will inform the complainant if the complaint will result in enforcement action.<sup>168</sup> If a company does not take the necessary action, the HPFBI may take enforcement actions appropriate to the identified health risk. For example, for Class III and IV devices without device licences, Health Canada will issue a note to stop importation and sale to any importers or distributors in Canada.<sup>169</sup> An Inspector may, when appropriate, monitor the actions taken by the responsible agent until the completion of the compliance verification

Contravention of any of the provisions of the *Act* or *Regulations* is an offence. A person is liable on summary conviction for a first offence to a fine that is no greater than \$500 or to imprisonment for a term not longer than three months or to both. A person is liable for a subsequent offence to a fine not greater than \$1000 or to imprisonment for no longer than six months or to both. Any person that is convicted on indictment may be liable to a fine no greater than \$5000 or to imprisonment for a term that is no longer than 3 years.<sup>170</sup> The amount is seemingly low when compared to the severity of the offence.

### **iii. Other Safety Regulations**

The Consumer Product Safety Bureau and Regional Product Safety Offices of Health Canada may be contacted for information about children's products, candles, lighters, matches, smoke detectors, carbon monoxide detectors, charcoal, decor products, furniture, carpets, construction and renovation products, garden products, household chemicals, cookware products, dishes and glassware products, second-hand products, and recreational and sports product.

## **V. Access to Product Information**

This section examines the accessibility of product information to consumers of assistive devices, including labelling requirements and advertising restrictions.

### **i. Labelling**

If an assistive device is classified as a medical device for the purposes of the *Food and Drug Act*, there are regulations about labelling in the *Medical Device Regulations*. If a product is classified as a general consumer good, then the *Consumer Packaging and Labelling Act* applies. Significantly, there are no regulations about labelling products for their accessibility features under any of the above statutes.

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<sup>168</sup> *Ibid.*

<sup>169</sup> Health Canada, *Medical Device Compliance and Enforcement Directive* (Canada: Health Canada, 11 February 2004), online: Health Canada <[http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/md-im/pol\\_45\\_tc-tm\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/md-im/pol_45_tc-tm_e.html)> (last modified: 11 February 2004).

<sup>170</sup> *Supra* note 16 at s. 31.

### a. Medical Device Regulations

If a product is a medical device, then the *Act* and the *Medical Device Regulations* apply. Pursuant to section 21 of the *Regulations*, one may not import or sell a device unless the device has a label, in legible, permanent and prominent lettering and in easily comprehensible terms, setting out the following information:

- the name of the device;
- the name and address of the manufacturer;
- the identifier of the device (i.e. a unique series of letters or numbers or a bar code that is assigned to a medical device by the manufacturer and that identifies it and distinguishes it from similar devices);
- in the case of a Class III or IV device, the control number;
- if the contents are not readily apparent, an indication of what the package contains;
- the word “Sterile”, if the device is sold in sterile condition;
- the expiry date of the device, if the device has one, to be determined by the manufacturer on the basis of the component with the shortest projected useful life;
- unless self-evident to the intended user, the medical conditions, purposes and uses for which the device is manufactured, sold or represented, including the performance specifications of the device if those specifications are necessary for proper use;
- the directions for use, if required; and
- Any special storage conditions.<sup>171</sup>

Where a product is for sale to the general public, the labelling information must be available to the consumer at the time of sale. The *Regulations* specify that most of the above information must be printed in both English and French when the devices are offered to the general public.<sup>172</sup> Where the devices are not for general sale, the information must be in a minimum of English or French and instructions in the other official language must be available at the customer’s request within a reasonable time period.<sup>173</sup> There are no provisions requiring alternate formats (Braille, large print, audio version, other languages etc.) for labels.

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<sup>171</sup> Health Canada, *Guidance for the Labelling of Medical Devices under Section 21 to 23 of the Medical Devices Regulations*, online: Health Canada <[http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/labl\\_etiq\\_dv10\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/labl_etiq_dv10_e.html)> (last modified: 15 July 2004).

<sup>172</sup> *Supra* note 17 at s. 23(3).

<sup>173</sup> *Ibid.* at s. 23(2).

Consumers can make a complaint regarding inadequacy or errors in labelling of medical devices to Health Canada's Health Products and Food Branch Inspectorate. Anyone who purchases, uses or maintains the devices can report a problem.<sup>174</sup>

### b. Consumer Packaging and Labelling Act

Most goods produced domestically or imported into Canada require consumer package labelling. The Competition Bureau administers the packaging and labelling of many products.<sup>175</sup> The *Consumer Packaging and Labelling Act (CPLA)* governs the packaging, labelling, sale, importation and advertising of prepackaged and certain other products. The *CPLA* prohibits false or misleading representations and requires that products bear accurate and meaningful labelling information to help consumers make informed purchasing decisions. The regulations to the *CPLA* specify the manner and location in which the following statements must appear: product identity, product net quantity and the dealer's name and principal place of business.

The *CPLA* applies "to any article that is or may be the subject of trade or commerce but does not include land or any interest therein".<sup>176</sup> Section 3(2) specifies the *CPLA* does not apply in the case of a medical device or drug under the *Food and Drugs Act*.<sup>177</sup> As such, the *CPLA* may apply where an assistive device is not a medical device for the purposes of the *Food and Drugs Act*.

### c. Other Labelling Requirements

Additional requirements about product packaging and labelling may be found in provincial statutes. For example, bilingual labelling requirements are found not only in federal statutes, but also in the *Québec Charter of the French Language*.<sup>178</sup> Furthermore, the Canadian Food Inspection Agency also has labelling requirements.<sup>179</sup> The *Textile Labelling Act* regulates the labelling of consumer textile articles. The

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<sup>174</sup> Health Canada, *Medical Device Problem Reporting by Healthcare Facilities, Medical Professionals and Device Users*, online: Health Canada Website <[http://www.hc-sc.gc.ca/dhp-mps/alt\\_formats/hpfb-dgpsa/pdf/compli-conform/md\\_prob\\_rep\\_rap\\_incident\\_im\\_e.pdf](http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/compli-conform/md_prob_rep_rap_incident_im_e.pdf)> (date accessed: 28 June 28, 2007).

<sup>175</sup> Competition Bureau Canada, *Law and Litigation*, online: Competition Bureau Canada <<http://www.competitionbureau.gc.ca/internet/index.cfm?itemID=148&lq=e>> (date accessed: 26 June 2007).

<sup>176</sup> *Consumer Packaging and Labelling Act*, R.S. 1985, c. C-38. at s. 2(1).

<sup>177</sup> See Section 2.1.i, above, about categorizing devices, for the precise definition from the *Food and Drugs Act*.

<sup>178</sup> *Charter of the French Language*, R.S.Q. c. C-11 at ss. 51, 52, 54, 58.

<sup>179</sup> Canada, *Canadian Food Inspection Agency: 2003 Guide to Food Labelling and Advertising* (Ottawa: Canadian Food Inspection Agency, 2003), online: Canadian Food Inspection Agency Website <<http://www.inspection.gc.ca/english/fssa/labeti/guide/toce.shtml>> (last modified: 10 May 2007).

regulations to the *Customs Tariff* also require the marking of certain imported goods with their country of origin.<sup>180</sup> Also, specific labelling requirements for stuffed articles are found in certain provinces, including Ontario.<sup>181</sup>

## **ii. Direct to Consumer Advertising of Assistive Devices**

The advertising of drugs or devices aimed directly at the public is prohibited in Canada, although Health Canada has held consultations about relaxing these restrictions since 1996. The *Food and Drugs Act* prohibits advertisement to the general public of devices as a treatment, preventative or cure for an enumerated list of conditions and diseases. Section 3(1) of the Act provides:

3. (1) No person shall advertise any food, drug, cosmetic **or device** to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A.

(2) No person shall sell any food, drug, cosmetic or device  
a. that is represented by label, or  
b. that the person advertises to the general public

as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A.<sup>182</sup>

Schedule A of the *Food and Drugs Act* lists a number of conditions for which treatments, preventatives, or cures cannot be advertised or sold to the general public.<sup>183</sup> It lists 40 conditions including alcoholism, arthritis, asthma, cancer, epilepsy, heart disease, obesity, and sexual impotence.<sup>184</sup> There are additional restrictions to the advertising of prescription drugs that do not apply to medical devices.<sup>185</sup> In addition,

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<sup>180</sup> See *Marking of Imported Goods Regulations* (SOR/94-10); *Determination of Country of Origin for the Purposes of Marking Goods (NAFTA Countries) Regulations* (SOR/94-23); *Determination of Country of Origin for the Purpose of Marking Goods (Non-NAFTA Countries) Regulations* (SOR/94-16).

<sup>181</sup> *Upholstered and Stuffed Articles Act* R.S.O. 1990, c. U-4. More research must be undertaken to confirm whether these requirements apply in the case of assistive devices such as ergonomically designed pillows.

<sup>182</sup> *Supra* note 16 at s.3.1 [emphasis added].

<sup>183</sup> *Ibid.*

<sup>184</sup> Health Canada, *Legislative Renewal: Issue Paper*, online: Health Canada Website <[http://www.hc-sc.gc.ca/ahc-asc/pubs/legren/schedule-annexe-a\\_e.html](http://www.hc-sc.gc.ca/ahc-asc/pubs/legren/schedule-annexe-a_e.html)> (last modified: 1 October 2004).

<sup>185</sup> *Food and Drug Regulations* (C.R.C., c. 870). Section C.01.044 provides: "(1) Where a person advertises to the general public a *Schedule F* Drug, the person shall

Section 20 of the *Act* forbids labelling, packaging selling or advertising a device in a false, misleading or deceptive manner. It is noteworthy that these rules do not apply to assistive devices that are not classified as medical devices.<sup>186</sup>

Some advocate that consumer directed advertising may promote health awareness and choice for consumers of assistive devices. Advertising can empower consumers, helping to put them in charge of their own health care by providing necessary background information.<sup>187</sup> Opponents claim that relaxed guidelines will lead to increased pressure on health care professionals by patients, increased marketing costs leading to increasing costs to the consumer, and the manipulation of vulnerable consumers by advertising. The direct advertising of prescription drugs is the subject of litigation at the Ontario Superior Court of Justice.<sup>188</sup>

### **iii. Training on the Use of Medical and Assistive Devices**

It is clearly important that consumers with disabilities are trained on the safe use of assistive devices. Vendors conduct most of the training on the use of medical and/or assistive devices. Consumers expressed concern that the training that manufacturers provide is not accessible. Many manufacturers do not provide product information or manuals in multiple accessible formats. Help lines offered by manufacturers do not always include TTY lines.<sup>189</sup>

Despite its obvious importance, there are no laws or regulations that require that consumers be trained on the safe and effective use of assistive devices. In order to remedy this gap, there are some peer programs where persons with disabilities can share information about assistive devices. An example of such an informal program includes <http://www.wheelchairjunkie.com>.

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not make any representation other than with respect to the brand name, proper name, common name, price and quantity of the drug.”

<sup>186</sup> A medical device is defined by reference to the definition of “device” from the *Food and Drugs Act*, R.S.C. 1985, c. F-27, s. 2. See Section 1.1.i above.

<sup>187</sup> Rhonda Shirreff, “For Them to Know and You to Find Out: Challenging Restrictions on Direct-to-Consumer Advertising of Contraceptive drugs and Devices” (2000) 58 U.T. Fac. Law Review 121. at para 2.

<sup>188</sup>E. Hansen, “CanWest Challenges Restriction on Direct to Consumer Ads”, ARCH Alert (18 June 2007), online: ARCH Website <<http://www.archdisabilitylaw.ca/publications/archAlert/index.asp>> (last modified: 20 June 2007). In December of 2005, CanWest MediaWorks Inc. (CanWest) launched a Charter challenge against restrictions on the advertising of prescription drugs contained in the *Food and Drugs Act*. In its application, CanWest asserts that the FDA restrictions on advertising of prescription drugs limit their freedom of expression. The Ontario Superior Court of Justice recently granted leave to intervene to a coalition comprised of Canadian health and consumer groups and unions.

<sup>189</sup> The authors attempted to telephone a major international manufacturer of assistive devices and were advised that there was no TTY service available.

There are particular accessibility concerns about training persons with developmental disabilities and persons with mental health issues on the use of assistive devices, especially where they occur concurrently with other disabilities. In their 2007 commentary, Steinstra and others found that the lack of appropriate training is a “critical barrier” for persons with developmental disabilities in the use of Information and Communication Technologies (ICTs).<sup>190</sup>

## **VI. The Movement of Assistive Devices across International Borders**

This section examines the requirements relating to the importation of medical and assistive devices into Canada. In general, these are the same requirements that apply to the importation of all products as there are few rules that specifically regulate the importation of medical and assistive devices. This section will consider the perspectives of both a company importing a product for commercial use, and an individual importing a product for personal use. Most importers are corporations, although increasingly individuals are importing products across borders via sales via the internet. While there are restrictions to the movement of products inter-provincially, they are not addressed in this project.<sup>191</sup>

The procedures for importing assistive devices may seem complex, and may overwhelm individual importers. However, the rules that govern the tariff treatment of imported products are important to consumers of assistive devices, since they can, for example, affect the device’s price.

### **i. Trade Liberalization, Generally**

Since trade liberalization in recent years, there has been a significant increase in the import of assistive devices into Canada.<sup>192</sup> Few manufacturers of assistive devices are Canadian and, as a result, there is very little competition between suppliers. Data demonstrates that Canadians rely heavily on the import of assistive devices, suggesting

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<sup>190</sup> D. Stienstra, J. Watzke and G. Birch, “A Three-Way Dance: The Global Public Good and Accessibility in Information Technologies” (2007) 23 *Information Society* 149 at 151.

<sup>191</sup> In 1994, the premiers and the Prime Minister signed the *Agreement on Internal Trade (AIT)* which came into effect on July 1, 1995. The Agreement aimed to reduce barriers to the movement of persons, goods, services and investments within Canada. Signed in 2006, the *BC-Alberta Trade, Investment and Labour Mobility Agreement (TILMA)* took effect on April 1, 2007. TILMA expands AIT to include other sectors (including energy), and its dispute resolution mechanism is made enforceable. It is not clear how TILMA will affect consumers of assistive devices.

<sup>192</sup> *Supra* note 27 at figs 4 and 5b.

a relatively inefficient domestic industry.<sup>193</sup> Most assistive devices undoubtedly come from the US, although many assistive devices come from outside of North America.<sup>194</sup>

Canada has entered into free trade agreements with other countries to reduce or eliminate tariffs on products. At the multilateral level, Canada is a signatory to the General Agreement on Tariffs and Trade (GATT) and a member of the World Trade Organization. Through successive multilateral rounds of trade negotiations, Canada has reduced its general duty rates on goods imported into Canada. In addition Canada is a signatory to several free trade agreements (FTAs), including the North American Free Trade Agreement (NAFTA) with the United States and Mexico, the Canada-Chile FTA, the Canada-Israel FTA and the Canada-Costa Rica FTA. Goods produced in and imported from countries with which Canada has FTAs may generally be imported into Canada at preferential duty rates provided the exporter provides the Canadian importer with a certificate of origin.

Trade liberalization promises increased international trade, with the gradual elimination of trade barriers including customs tariffs. By increasing competitiveness and efficiency, proponents argued that liberalized trade would lead to lower prices for consumers. On the other hand, critics have found that, for women with disabilities, trade liberalization led to a further erosion of their already marginalized status in Canadian society.<sup>195</sup> For instance, increased reliance on the private sector has led to the reduction in support for public programs.<sup>196</sup>

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<sup>193</sup> *Supra* note 27 at 12 and 13. “The Canadian industry is dominated by a large number of small firms: in 1999, there were some 800 establishments employing 2275 people in the medical equipment and supplies manufacturing industry [citation]. Larger American and European firms appear to enjoy a significant competitive advantage over their Canadian counterparts. This may be due to progressive legislative measures, such as the Americans with Disabilities Act (1990), that have allowed American firms to develop the expertise and innovate capacity that cede to them a “first” mover advantage. Without similar government support for the Canadian industry, domestic firms are likely to continue to lag behind their international competitors in terms of innovation and product development.”

<sup>194</sup> *Ibid.* at 11. “The value of Canada’s imports [of assistive devices] rose rapidly from \$1.3 billion to nearly \$3.0 billion [between 1992 and 2001]. Imports from both the United States and the rest of the world grew significantly; however imports from the rest of the world increased the fastest in percentage terms.”

<sup>195</sup> *Ibid.* at 4. “For women with disabilities, Canada’s entry into trade agreements has meant a further erosion of their already marginalized status in Canadian society.”

<sup>196</sup> *Ibid.* at 37. The authors continue, “Women with disabilities have failed to benefit from the liberalization of trade with the United States over the past decade. Rather, their lives have become more difficult as a result of the liberalization of trade. For some women with disabilities, the changes that have resulted from trade have been ones that affect their survival.”

## **ii. Tariff Classification**

Each item imported into Canada is assigned a 10 digit tariff classification number. The tariff classification numbers can be determined by consulting Schedule I to the *Customs Tariff* online.<sup>197</sup> Canada uses the international Harmonized Commodity Description and Coding System (HS) as the basis for its classification system for imported goods. The first six digits are standardized for all countries using the HS.

Many medical devices fall under the tariff heading “90.18 – Instruments and Appliances used in the medical, surgical and dental sciences.” In addition, wheelchairs correspond to heading 8713, mechano-therapy appliances, such as artificial respiratory equipment, correspond to heading 9019-20, and orthopedic appliances (artificial joints and prostheses) correspond to heading 9021. It is important to note that many other products that meet disability related needs are not included in these categories.

## **iii. Tariff Treatment**

Products imported into Canada may be subject to duty payments. The duty rates vary widely according to the type of goods and the country of origin. As noted above, the tariff classification number determines the rate of duty payable. Goods imported into Canada may be subject to one of twelve separate tariff treatments, established as the result of trade agreements. For instance, there are preferential or reduced rates of duty based on free trade agreements, such as NAFTA. Under NAFTA, many traditional assistive devices enjoy a 0% rate of duty, including hearing aids and wheelchairs.

Excise duties are imposed under the *Excise Act*, on spirits, wine, and tobacco products made in Canada.<sup>198</sup> Excise duties are also levied on certain petroleum products, heavy automobiles and air conditioners designed for automobiles.<sup>199</sup> Excise duties are typically not applied to assistive devices.

## **iv. Importing Non-Commercial Goods for Personal Use**

Persons with disabilities may be frustrated by the poor selection of assistive devices in Canada. Furthermore, what is available in Canada may be prohibitively expensive. They may feel forced to order an assistive device directly from outside the country.

Goods imported for personal use are generally subject to duties. If a consumer imports goods worth \$20 or less for her personal use by courier, they are exempt from duties

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<sup>197</sup> Canada Border Services Agency, *Customs Tariff*, online: Canada Border Services Agency Website <[http://www.cbsa.gc.ca/general/publications/customs\\_tariff-e.html](http://www.cbsa.gc.ca/general/publications/customs_tariff-e.html)> (last modified: 30 May 2007).

<sup>198</sup> *Excise Act, 2001* (2002. c.22).

<sup>199</sup> *Ibid.*

under the *Courier Imports Remission Order*.<sup>200</sup> In addition, there is no duty imposed for “gifts” worth less than \$60.<sup>201</sup> When items are imported by mail, Canada Post is authorized to charge the recipient a \$5 handling fee for the collection and remittance of duty and taxes.<sup>202</sup> Individual importers should also be aware that the *Customs Act* grants CBSA the authority to open any mail that weighs more than 30 grams.<sup>203</sup>

It is important to note that buying medical devices over the internet may pose serious health risks. For instance, a medical device purchased over the internet may not have the required device licence, may have been recalled due to safety concerns, or improperly stored.<sup>204</sup> See Section 2.IV.ii for more information about the safety of medical devices.

## **v. Customs Clearance**

Importers generally hire customs brokers to prepare required customs documentation and arrange payment of import duties and taxes owing to the Crown. The broker acts as a middle man between the importer and the government on about 80 per cent of import transactions.<sup>205</sup> A broker makes it easier for individuals and firms to comply with complex government legislation, and makes it easier for the government to encourage and obtain compliance.<sup>206</sup> For instance, customs brokers make the decisions about the tariff classification of imported products. They are bound by the *Customs Tariff*.<sup>207</sup> The Canada Border Security Agency (CBSA) has the authority to audit that classification. All customs brokers must be licenced.<sup>208</sup>

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<sup>200</sup> CBSA, *Memorandum D8-2-16, Courier Imports Remission* (Ottawa: CBSA, 2001), online: CBSA <<http://www.cbsa-asfc.gc.ca/E/pub/cm/d8-2-16/d8-2-16-e.html>> (last accessed: 29 June 2007). See also *Courier Imports Remission Order*, SI/85-185.

<sup>201</sup> CBSA, *Importing Non-Commercial Goods by Mail*, online: Canada Border Services Agency Website <<http://www.cbsa-asfc.gc.ca/E/pub/cp/rc4051/rc4051-e.html>> (last modified: 9 November 2006). Note: you can not get a gift from a business.

<sup>202</sup> Canada Post, *Customs requirements*, online: Canada Post Website <<http://www.canadapost.ca/tools/pg/manual/PGcustoms-e.asp>> (last modified: 16 April 2007).

<sup>203</sup> *Customs Act*, 1985, c.1 (2<sup>nd</sup> Supp.).

<sup>204</sup> Health Canada, *Its Your Health: Buying Medical Devices over the Internet* (Ottawa: Health Canada, 2006), online: Health Canada Website <[http://www.hc-sc.gc.ca/iyh-vsv/med/med\\_mat\\_e.html](http://www.hc-sc.gc.ca/iyh-vsv/med/med_mat_e.html)> (date accessed: 25 June 2007).

<sup>205</sup> Canadian Society of Customs Brokers, *Publications: Fact Sheet*, online: Canadian Society of Customs Brokers Website <[http://www.cscb.ca/070/pb\\_fs01\\_e.html](http://www.cscb.ca/070/pb_fs01_e.html)> (last modified 26 July 2006).

<sup>206</sup> *Ibid.*

<sup>207</sup> Schedule I to the *Customs Act*.

<sup>208</sup> Canada Border Services Agency, *Memorandum D1-8-1: Licensing of Customs Brokers* (Ottawa: Canada Border Services Agency, 26 March 1993), online: CBSA <<http://www.cbsa-asfc.gc.ca/E/pub/cm/d1-8-1/d1-8-1-e.html>> (last accessed: 7 June 2007).

Individual importers can hire customs brokers for assistance with importing assistive devices. It should be noted that many companies will not work with individual importers, instead only working for companies importing goods. Larger courier companies do, nevertheless, act as brokers for individual importers. However, larger couriers, such as FedEx or UPS, provide customs brokerage services to individuals. There is typically a fee attached to this service.

The Canadian Society for Customs Brokers provides no information about the role of brokers in importing assistive devices on its website.<sup>209</sup>

#### **vi. Health Canada**

Importers must verify if any of the products they are importing are a medical device. Under the *Medical Device Regulations* to the *Food and Drugs Act*, importers of medical devices will be required to obtain an establishment licence, report serious incidents involving the devices they import, maintain distribution records, and establish written procedures regarding investigating incidents and recalling defective devices from the market. See Section 2.IV.ii for more information about these requirements.

Health Canada has a long-standing agreement with CBSA to request importers of medical devices or their brokers to submit an additional copy of a customs invoice to Health Canada with their release papers. The Therapeutic Products Program (TPP) has the opportunity to review this documentation for surveillance purposes. The TPP has the authority to issue an "Import Alert" whereby the TPP advises customs officials that the imported device may be in violation of the *Regulations*.

#### **vii. Complaints about Tariff Classification**

If an individual consumer is dissatisfied by the tax treatment of an assistive device, she may apply for a reassessment, either before payment (Form E14) or after payment (Form B2G).<sup>210</sup>

Individuals and importers may appeal a decision of the CBSA regarding tariff classification to the Canadian International Trade Tribunal (CITT). The CITT is the main quasi-judicial institution with authority to hear appeals relating to the tariff classification and value for duty of goods under the *Customs Act*.<sup>211</sup> It is governed by the *Canadian*

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<sup>209</sup> See the Canadian Society for Customs Brokers website at <<http://www.cscb.ca>> (last modified: 26 June 2007).

<sup>210</sup> Canada Border Services Agency, *Importing Non-Commercial Goods by Mail*; online CBSA, <<http://www.cbsa-asfc.gc.ca/E/pub/cp/rc4051/rc4051-e.html#P017>> (last accessed: 7 June 2007).

<sup>211</sup> Canadian International Trade Tribunal, *Mandate*, online: Canadian International Trade Tribunal Website <[http://www.citt-tcce.gc.ca/mandate/index\\_e.asp](http://www.citt-tcce.gc.ca/mandate/index_e.asp)> (last modified: 4 February 2004).

*International Trade Tribunal Act*.<sup>212</sup> Before bringing an appeal to the CITT, an individual importer should ensure that she follows up with each request from the CBSA.<sup>213</sup> More information about disputing a decision of the CBSA may be found in Memo D11-6-7 “Importers’ Dispute Resolution Process for Origin, Tariff Classification and Value for Duty of Imported Goods”.<sup>214</sup>

## **VII. Tax Treatment of Assistive Devices**

This section explores the tax treatment of assistive devices at the federal, provincial and territorial levels. The tax treatment of an assistive device depends in large part on whether it will also be classified as a “medical device” according to the *Medical Device Regulations* of the *Food and Drugs Act*.

### **i. Goods and Services Tax**

Goods and Services Tax (GST) is payable on most goods at the time of importation under Part IX, Division III, of the *Excise Tax Act*.<sup>215</sup> Since 2006, it is charged at a rate of 6%. Some products such as prescription drugs, medical devices and assistive devices are non-taxable. Non-taxable items are listed under Schedule VII of the *Excise Tax Act*.<sup>216</sup> Part II of Schedule VI lists “medical and assistive devices” as GST exempt.<sup>217</sup> In order to qualify for GST-exemption, confirmation may be required that the device is an assistive device. For instance, section 30 of Part II of Schedule VI to the *Excise Tax Act* requires that the Canadian National Institute for the Blind confirm that an article is specially designed for the use of persons who are blind in order for to qualify as GST-exempt.<sup>218</sup> The *GST/HST Memorandum 4.2* provides an alphabetical list of medical devices and assistive devices that are GST exempt.<sup>219</sup>

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<sup>212</sup> *Canadian International Trade Tribunal Act*, R.S.C. 1985, c. 47 (4th Supp.). See also *Canadian International Trade Tribunal Rules*, S.O.R./91-499.

<sup>213</sup> Canadian International Trade Tribunal, *Information on Appeals*, online: Canadian International Trade Tribunal Website <[http://www.citt-tcce.gc.ca/publicat/apel\\_e.asp](http://www.citt-tcce.gc.ca/publicat/apel_e.asp)> (last accessed: 7 June 2007).

<sup>214</sup> Canadian Border Services Agency, *Publications: Memorandum D11-6-7*, online: Canadian Border Services Agency <<http://www.cbsa-asfc.gc.ca/E/pub/cm/d11-6-7/d11-6-7-02-e.html>> (last modified: 20 February 2003).

<sup>215</sup> *Excise Tax Act*, R.S. 1985, c. E-15, Part IX, Division III.

<sup>216</sup> *Ibid.*

<sup>217</sup> *Ibid.* at ss 12, 14, 27.

<sup>218</sup> *Ibid.* See Schedule VI, Part II, at s. 30.

<sup>219</sup> Canada Revenue Agency, *GST/HST Memoranda Series: 4-2 Medical Assistive Devices*, online: Canada Revenue Agency Website <<http://www.cra-arc.gc.ca/E/pub/gm/4-2r/4-2r-e.html>> (last modified: 6 August 2002).

## **ii. Provincial and Territorial Taxes**

Some assistive devices are exempt from provincial or territorial sales taxes. In Ontario, for instance, equipment designed solely for the use of persons with disabilities is exempt from provincial sales tax in Ontario.<sup>220</sup> Exempt items in Ontario include wheelchair lifts, bath equipment, crutches, communication aids such as TTYs as well as hand controls designed to assist drivers who have a physical disability.<sup>221</sup>

The Canada Border Services Agency (CBSA) has agreements with some provinces and territories that allow it to collect provincial and territorial taxes.<sup>222</sup> For instance, the CBSA collects provincial sales taxes (PST) on behalf of Ontario, Saskatchewan, and both PST and provincial tobacco taxes on behalf of BC, Manitoba and Quebec. The CBSA collects tobacco taxes on behalf of Alberta.<sup>223</sup> The HST is collected by the CBSA, which then remits the HST amounts to New Brunswick, Newfoundland, and Nova Scotia.<sup>224</sup>

## **iii. Other Tax Implications for Persons with Disabilities, including Income Tax Provisions**

The Government of Canada, through the Canada Revenue Agency (CRA) provides relief to persons with disabilities in three forms: the Disability Tax Credit (DTC), the Disability Supports Deduction, and the Medical Expense Tax Credit. The rules governing the availability of these forms of tax relief are complex, and it is important to seek advice from a lawyer or accountant. For more information about these programs and other programs available to persons with disabilities see [www.ccra-adrc.gc.ca/disability](http://www.ccra-adrc.gc.ca/disability).

The **Disability Tax Credit** (DTC) is a non-refundable credit available to taxpayers with disabilities who have a disability that is “severe” and “prolonged”.<sup>225</sup> The credit reduces

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<sup>220</sup> *Retail Sales Tax Act*, R.S.O. 1990, c. R-31 at s. 7(1)(34).

<sup>221</sup> Ontario, *RST Guide: Exempt Items for People with Physical Disabilities* (Ontario: Ministry of Revenue, July 2001), online: Ministry of Revenue Website <<http://www.rev.gov.on.ca/english/guides/rst/802.html>> (last modified: 30 May 2007).

<sup>222</sup> Canadian Border Services Agency, *I Declare: A Guide for Residents of Canada Returning to Canada*, online: Canadian Border Services Agency Website <<http://www.cbsa-asfc.gc.ca/E/pub/cp/rc4044/rc4044-e.html>> (last modified: 20 September 2006).

<sup>223</sup> CBSA, *Importing Non-Commercial Goods by Mail*, online: <<http://www.cbsa-asfc.gc.ca/E/pub/cp/rc4051/rc4051-e.html>> (last modified: 9 November 2006).

<sup>224</sup> The Harmonized Sales Tax (HST) combines the Goods and Services Tax (GST) and certain Provincial Sales Taxes (PST) into a single, blended, sales tax. Currently, there is a 14% HST in the provinces of New Brunswick, Newfoundland, and Nova Scotia.

<sup>225</sup> Canadian Revenue Agency, “Line 316 - Disability Amount”, online: CRA, <<http://www.cra-arc.gc.ca/tax/individuals/topics/income->

the amount of income tax that a person with a disability might otherwise have to pay. Where a person who is eligible for the DTC cannot use it, either at all or in part, because she or he has little or no tax to pay, the DTC may be used by a supporting person.

The **Disability Supports Deduction** allows a person with a disability to deduct certain disability supports expenses incurred in order to work, go to school, or undertake paid work. Allowable expenses include, but are not limited to, Bliss symbol boards, Braille note takers, Braille printers, optical scanners, teletypewriters and voice recognition software.<sup>226</sup>

The **Medical Expense Tax Credit** recognizes the effect of above-average medical expenses on an individual's ability to pay tax. Taxpayers may claim the medical expenses that they or their spouses incur, as well as, in certain circumstances, expenses incurred by specified dependant relatives. The list of eligible medical expenses is regularly reviewed. Eligible medical expenses include, but are not limited to, wheelchairs, wigs, bathroom aids, breast prostheses, crutches, spinal braces, and vehicle modifications.<sup>227</sup>

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[tax/return/completing/deductions/lines300-350/316/menu-e.html](http://www.cra-arc.gc.ca/tax/return/completing/deductions/lines300-350/316/menu-e.html)> (date accessed: 30 May 2007).

<sup>226</sup> For an exhaustive list of eligible devices see online: Canadian Revenue Services Website <<http://www.cra-arc.gc.ca/tax/individuals/topics/income-tax/return/completing/deductions/lines206-236/215/eligible-e.html>> (last modified: 2 January 2007).

<sup>227</sup> For an expansive list see CRA, "IT519, Medical Expense and Disability Tax Credits and Attendant Care Expense Deduction", online: CRA Website <<http://www.cra-arc.gc.ca/E/pub/tp/it519r2-consolid/README.html>> (last modified: 21 March 2003).

### **PART THREE – OTHER AVENUES OF REDRESS FOR CONSUMERS**

This Part outlines additional tools that consumers of assistive devices may use to resolve their complaints about assistive devices. Included here is a scenario which illustrates the magnitude of the impact that a malfunctioning assistive device can have on a person's life and the complexities of using the legal system in an attempt to redress the problem.

Jennifer has a disability that affects her ability to walk. Over time she has tried various types of walkers, wheelchairs and scooters to determine which one makes it easiest for her to carry out all of her daily activities, including travelling outside on roads and sidewalks, going to restaurants, going to work and moving easily in her home. She finds a particular style of scooter that best meets her needs. However, the scooter is very expensive and she earns a limited salary. She cannot afford to purchase the scooter and applies to the provincial government funding program for assistance to do so. The program tells her that she needs an assessment from a health professional to be eligible and that she must purchase the scooter from ABC Health Care. She goes through all steps of the program application process and ultimately gets the scooter. The provincial program paid 75% of its cost and she paid the remaining 25%. The program's policy states that she is only eligible for a replacement scooter every five years and that it will not assist with the cost of repairs.

A year after she got the scooter, she was crossing a busy street and the scooter came to a sudden halt. The scooter would not move at all no matter what she tried. She could not get out of the scooter because of the paralysis she experiences in both legs. As a result, a car hit her and she sustained a broken arm. Three pedestrians quickly came to her rescue, she was rushed to hospital and was unable to work for three weeks.

Now that Jennifer's scooter is unusable, Jennifer cannot leave her home at all as she is not able to move without an assistive device. She is unable to perform most of her daily activities, such as going grocery shopping, to the bank, to work and out for social activities. At the same time, she cannot afford to pay for the repairs to her scooter or to rent a replacement. The provincial funding program will not pay for repairs or provide a replacement scooter for another four years.

Jennifer, and most consumers of assistive devices, would ask themselves the following questions:

- What legal action can Jennifer take to compensate her for her damages and get a repaired or new scooter?
- Whose responsibility is it to fix or replace the scooter?
- Can Jennifer take legal action even if most of the cost of the scooter was paid for by the provincial government?

- What is the nature of the legal relationships between the manufacturer, retailer, government funder and Jennifer?

These are examples of the important issues that many consumers of assistive devices face at some point during their lifetimes. This part does not attempt to provide answers to them. It does, however, suggest areas of law and avenues of redress that consumers may explore, such as products liability claims and statutory regimes that regulate the sale and purchase of goods.

### **I. Factors to Consider Before Filing a Civil Claim**

Consumers of assistive devices may consider commencing civil actions pursuant to product liability regimes as well as pursuant to provincial and territorial consumer protection legislation. It must be emphasized that consumers should seek a legal opinion before proceeding with a civil claim.<sup>228</sup> The information provided herein is for information purposes only.

As is always the case when seeking legal recourse, before launching a civil claim, a potential consumer-plaintiff must consider both the benefits and possible consequences that may be the result of any judicial decision. Chief among these considerations are time and money. Seeking compensation through the judicial system is both a lengthy and costly proposition. A potential plaintiff must also consider the financial risks associated with the legal system. This is particularly the case in Ontario due to the presence of a fee shifting system whereby the unsuccessful party is responsible for paying a portion of the successful party's legal fees.

The Ministry of the Attorney General has published a guide "An Introduction to Civil Cases in the Superior Court of Justice" in order to provide consumers with basic information about civil cases in Ontario courts.<sup>229</sup> In Ontario, the Superior Court of Justice hears most civil suits, including those addressing product liability and consumer protection legislation. Typically the Superior Court of Justice hears civil cases over \$25,000, although provided the claim exceeds \$10,000, there is nothing jurisdictionally to stop a claim from being commenced in the Superior Court. Consumers of assistive devices may also be able to commence their civil claims in a provincial or territorial small claims court. Small claims courts usually have simplified rules and procedures for

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<sup>228</sup> If a consumer wishes to retain a lawyer in Ontario, she may contact the Lawyer Referral Service operated by the Law Society of Upper Canada. Please note that there is a fixed charge of six dollars for each telephone call to use this service. The Lawyer Referral Service will provide a name of a lawyer who practices in the relevant area of law and will provide a half-hour free consultation. From Ontario, the telephone number for the service is 1-900-565-4577.

<sup>229</sup> Ministry of the Attorney General, *An Introduction to Civil Cases in the Superior Court of Justice* (Toronto: Queens Printer, 2006), online: Ontario <<http://www.attorneygeneral.jus.gov.on.ca/english/courts/civil/intro2civilcasesinscj.asp>> (last accessed: 20 June 2007).

non-represented claimants. The Ontario Small Claims Court (a branch of the Superior Court) deals with civil disputes of a monetary value up to \$10,000, including claims for damages for personal injuries.

When considering whether or not to file a civil claim, it is important that consumers be aware of any relevant limitations legislation. Ontario's *Limitations Act*, for example, provides for a general two year limitation on the filing of any claim, starting on the day on which the claim was discovered.<sup>230</sup> However, there are exceptions. Consumers should consult with legal counsel in order to ensure that a potential claim will be permitted under the relevant limitations legislation in their respective jurisdiction.

## **II. Product Liability Litigation**

### *Product Liability in the Context of Assistive Devices*

Consumers who suffer harm or injury caused by an assistive device may choose to seek compensation through the court system by filing a product liability claim. Product liability refers to the "liability of manufacturers and sellers to buyers and others for damages suffered because of defects in the goods manufactured or sold."<sup>231</sup> This brief overview of product liability will attempt to explain the basic concepts underlying Canadian product liability law, as well as address specific areas and issues that are of particular relevance to assistive devices.<sup>232</sup>

The purpose of this section is to illustrate the potential application and use of product liability law to address consumer concerns about injuries and harm they experience relating to their use of assistive devices. As such, this report does not fully explore all aspects of the expansive, complex topic of product liability law. What follows is a cursory overview of product liability law and how it may apply in the context of assistive devices.

While for the purposes of this report, the various causes of action available to consumers considering a product liability claim were dealt with separately. In practice, any or all of the above listed causes of action are available to be used by consumers in a single product liability claim.

A recent Alberta decision, *Park v. B & B Electronics*<sup>233</sup> illustrates the applicability of the various aspects of product liability law to assistive devices. A person described as a

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<sup>230</sup> S.O. 2002, c. 24, Sched. B

<sup>231</sup> Daphne A. Dukelow and Betsy Nuse, *The Dictionary of Canadian Law (2<sup>nd</sup> Ed.)*, (Toronto: Thompson Canada, 1995) at 959.

<sup>232</sup> While we were unable to find many cases dealing specifically with products liability in relation to assistive devices, due to the scope and complexity of such a search, and the variety of assistive devices in the marketplace there may well be more case law on this particular subject. ARCH welcomes any input into this ongoing area of research.

<sup>233</sup> *Park v. B & B Electronics Ltd.*, [2003] A.J. No. 873.

partial quadriplegic purchased an assistive driving system which was designed to meet the needs of his disability. He was injured in a motor vehicle accident when the driving system malfunctioned and subsequently sued both the manufacturer, and the installer of the assistive driving system, as well as a radio installation company. In *Park*, negligent design, the duty to warn, and the learned intermediary rule, were all relevant considerations. This case illustrates that a person who is injured from the use of an assistive device may sue more than one party and that the various types of products liability arguments may all be relevant in a single case.

To place this analysis in context, it is important to note that we found only one product liability case that dealt specifically with an assistive device.<sup>234</sup> However, due to the wide variety and number of assistive devices, there may well be more cases. Interestingly, we were able to find substantially more cases in the context of medical devices.<sup>235</sup>

### *Product Liability: Basic Concepts*

A product liability claim can be filed in tort for negligence, or for breach of warranty. Claims for negligent manufacture involve products “that cause harm when, because of some error in production, the goods fail to conform to their intended, and presumably adequate, specifications,”<sup>236</sup> including where important bolts on a wheelchair are not properly tightened. On the other hand, claims for negligent design involve products that “are manufactured properly but are unduly dangerous because of the way in which they were designed in the first place,”<sup>237</sup> including where brakes on a motorized wheelchair are not designed to be strong enough to properly stop the chair when it is operated on an incline.

### **i. Requirements of a Products Liability Claim in Tort**

It has long been established that a manufacturer owes a duty of care to its ultimate consumers.<sup>238</sup> However, it is not only manufacturers that can be held liable in the case of product defects. Liability can attach to, among others, retailers, repairers, installers, importers, wholesalers, distributors or inspectors, so long as it can be shown that their negligence was responsible for the defect, and ultimately the harm suffered by the Plaintiff/consumer.<sup>239</sup>

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<sup>234</sup> *Ibid.* at para. 124.

<sup>235</sup> See for example, *Hollis v. Dow Corning Corp.*, [1995] 4 S.C.R. 634, and *Karagiannis v. Toronto Hospital*, [2001] O.J. No. 48 (Q.L.) (S.C.J.).

<sup>236</sup> Jamie Cassels and Craig Jones, *The Law of Large Scale Claims : Product Liability, Mass Torts and Complex Litigation in Canada* (Toronto: Irwin Law 2005) at 32.

<sup>237</sup> *Ibid.*

<sup>238</sup> *Donahue v. Stevenson* [1932] AC 562 (H.L.).

<sup>239</sup> S.M. Waddams, *Products Liability 4<sup>th</sup> ed.* (Toronto: Carswell, Thompson Professional Publishing, 2002) at 14.

In a products liability claim in tort for negligence, the Plaintiff/consumer is generally required to prove the following:

- i) the Defendant owed a legal duty of care to the Plaintiff in respect of a product;
- ii) the product was defective;
- iii) the Defendant was negligent in failing to meet the requisite standard of care;
- iv) the defect caused the Plaintiff's injuries; and
- v) the Plaintiff suffered damage as a result of the Defendant's negligence.<sup>240</sup>

## **ii. The Duty to Warn**

Another class of product liability claim based in negligence centers on the duty of the manufacturer to adequately warn consumers regarding the reasonably foreseeable risks associated with the use and reasonably foreseeable misuse of its product.<sup>241</sup> Given that consumers have identified the general lack of consumer information about assistive devices, the manufacturer's duty to warn may take on added importance in this context.<sup>242</sup>

The Supreme Court of Canada addressed this issue in *Hollis v. Dow Corning Corp.*, stating that the duty to warn "serves to correct the knowledge imbalance between manufacturers and consumers by alerting consumers to any dangers and allowing them to make informed decisions concerning the safe use of the product."<sup>243</sup> In duty to warn cases, there may not be an issue of a manufacturing or design defect. However, there will be certain risks associated with the use of the product of which the consumer must be made aware.<sup>244</sup>

In cases where injury or damage occurs through the use of a product, a determination that the manufacturer's warning was insufficient requires the court to determine whether or not the risk which ultimately led to the Plaintiff's harm was reasonably foreseeable. The court must then determine whether the risk in question merited a more comprehensive warning, and whether or not that warning would have prevented the harm to the plaintiff. Finally, the court must consider whether or not the defendant was negligent in failing to provide the more comprehensive warning.<sup>245</sup>

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<sup>240</sup> *Park v. B & B Electronics Ltd.*, [2003] A.J. No. 873 at para. 10, citing Lewis Klar et al., *Remedies in Tort, Vol 3.* (Toronto: Carswell, Thompson Professional Publishing, 1987, 2002) c. 20 at para. 8.

<sup>241</sup> L.G. Theall et al., *Product Liability: Canadian Law and Practice* (Aurora: Canada Law Book, 2001) at L3:10.

<sup>242</sup> See Section 2.V(ii) for further information on Direct to Consumer Advertising of Assistive Devices and its effects on consumer information.

<sup>243</sup> *Hollis v. Dow Corning Corp.* [1995] 4 S.C.R. 634 at para. 21.

<sup>244</sup> *Supra* note 236 at 48.

<sup>245</sup> *Supra* note 241 at L3:10.10.

In *Hollis v. Dow Corning Corp.*, the Supreme Court of Canada stated with respect to a manufacturer's duty to warn:<sup>246</sup>

The nature and scope of the manufacturer's duty to warn varies with the level of danger entailed by the ordinary use of the product. Where significant dangers are entailed by the ordinary use of a product, it will rarely be sufficient for manufacturers to give general warnings concerning those dangers; **the warnings must be sufficiently detailed to give the consumer a full indication of each of the specific dangers arising from the use of the product.**<sup>247</sup>

In the context of assistive devices then, one can envision the duty to warn applying in relation to products such as electric lifts or motorized scooters that pose an inherent safety risk to consumers. The nature and scope of the duty will vary depending on the level of danger of the particular assistive device. Where injuries occur as a result of an assistive device that was neither negligently designed nor negligently manufactured, inadequate warnings may nonetheless give rise to a cause of action.

The manufacturer's duty to warn is an ongoing one that continues to operate after the product leaves the chain of manufacture and distribution. For example, should a manufacturer become aware of a danger associated with a particular product, simply warning new consumers of the danger would not be sufficient. Consumers who had previously purchased the product would also have to be made aware of this newfound danger.

#### *An Exception to the Rule - The Learned Intermediary*

The learned intermediary rule can act as an exception to the manufacturer's duty to warn. Where the product is subject to inspection by, or used under the supervision of an expert, "the manufacturer can discharge its duty to warn by informing this 'learned intermediary' of the risks associated with the product."<sup>248</sup> The rule is of general application, though it may have particular relevance with respect to assistive devices. This is so because of the common involvement of professionals, such as doctors, occupational therapists, physiotherapists and audiologists in the use of assistive devices.

The learned intermediary rule does not relieve the manufacturer of the duty to warn the consumer, it allows the manufacturer to fulfill its duty to the consumer by providing the

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<sup>246</sup> For another leading Canadian case on the duty to warn see *Buchan v. Ortho Pharmaceutical (Canada) Ltd.* (1986) 54 O.R. (2d) 92 (C.A.).

<sup>247</sup> *Supra* note 243 at para 22 [emphasis added].

<sup>248</sup> *Supra* note 236 at 59.

relevant information to the learned intermediary.<sup>249</sup> However, there are debates in the law as to how far, and to whom this rule applies.

### **iii. Product Liability Claims for Breach of Warranty**

While products liability claims most commonly deal with issues of negligence, claims can also be made for breach of warranty.<sup>250</sup> It is essential that consumers take into consideration whether or not a claim can be filed for breach of warranty in addition to any claim that may exist in negligence.<sup>251</sup> In breach of warranty cases, the plaintiff need not demonstrate that the defect was a result of the defendant's negligence; rather, the mere fact of a breach of warranty gives rise to liability.<sup>252</sup>

Claims for breach of warranty are less common than negligence claims because of the fact that a contractual relationship must exist between the parties. A contractual relationship can arise through a contract of sale, as a result of an express warranty provided by the manufacturer to the consumer/plaintiff, or an implied warranty under provincial sale of goods legislation.<sup>253</sup> For more detailed information concerning implied warranties, see Section 3.III(i)(b).

### **iv. Assistive Devices Acquired with the Assistance of Government Funding Programs: Impact on Civil Suits**

As described above in Section 2.III, there are several government programs throughout Canada which provide individuals in need of assistive devices with funding assistance. In some circumstances the individual pays only a portion of the cost of the assistive device and in others, the government pays the entire cost and the individual essentially acquires it for free. The question that arises is what impact the government's involvement has on a civil suit in which the assistive device that they funded results in harm to the consumer. How does the fact that the consumer has not paid for the device affect the claim and any potential government involvement in the suit? While it is beyond the scope of this project to investigate this issue, it is one that will likely need to be explored in any product liability suit in which government funding is involved.

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<sup>249</sup> *Supra* note 241 at L3:40.

<sup>250</sup> Daphne A. Dukelow and Betsy Nuse, *The Dictionary of Canadian Law: Second Edition* (Toronto: Thopson Canada Ltd., 1995) at 1340. A warranty is defined as "an agreement with reference to goods which are the subject of a contract of sale, but collateral to the main purpose of such contract, the breach of which gives rise to a claim for damages, but not a right to reject the goods and treat the contract as repudiated."

<sup>251</sup> *Supra* note 241 at L1:40.30.

<sup>252</sup> *Ibid.*

<sup>253</sup> All of the provinces and territories with the exception of Quebec and British Columbia have enacted sale of goods legislation.

## **v. Intersection between Products Liability Law and the Regulatory Context**

This project highlights the complexity in the application of product liability law to the regulatory context of assistive devices. While there are specific areas in which regulations apply to assistive devices, there is no comprehensive regulatory scheme for assistive devices and there are aspects of assistive devices which are not regulated at all. Additionally, there are some requirements which are mandatory, being set out in legislation and others which are voluntary. The following questions arise:

- Does meeting a regulatory or industry standard affect liability in a civil suit?
- Is there any responsibility on government to properly regulate assistive devices?

We have not undertaken a legal analysis relating to these issues but highlight them as potentially relevant to consumers who choose to pursue a civil suit. Legal writers and jurisprudence have commented on the effect that a manufacturer's compliance with regulatory standards and/or industry standards and practice might have on liability.<sup>254</sup> There is also legal writing on whether or not a government regulator will be found liable for injuries caused by products under its regulatory authority.<sup>255</sup>

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<sup>254</sup> *Supra* note 241 at L2:30.10.2(c). While in some cases manufacturers may still be found negligent where they have met the applicable government regulations or prevailing industry standards, "there is a heavy onus on a plaintiff or claimant to show that in following the standards set by government regulation or an industry standard, the [manufacturer was] nevertheless negligent." Statutory compliance may require a defence to negligence if the statute required the very design, manufacture, or labelling that is claimed to be negligent, see *Ryan v. Victoria (City)*, [1999] 1 S.C.R. 201. However, generally statutory/regulatory compliance is not a defence to negligence, and its value as evidence will vary from case to case, see *R v. Saskatchewan Wheat Pool*, [1983] 1 S.C.R. 205.

<sup>255</sup> *Ibid.* at L5:100.10. The role of government can be separated into distinct policy and operational spheres. In its policy sphere, the government regulatory agency establishes product standards, many of which relate to safety. In its operational sphere the government conducts inspections, issues licenses, and imposes sanctions for failing to comply with relevant regulations. If the activity falls under the policy sphere, it is unlikely that any liability will attach to the government as courts are reticent "to impose liability on government regulators for failing to exercise or badly exercising their policy-making powers." On the other hand, government regulators may be held liable for negligently conducting their operational duties. However, recent medical products liability cases suggest that regulators owe no duty of care to individual consumers even in their operational roles. See for example, *Klein v. American Medical Systems Inc.*, [2006] O.J. No. 5181 (Div. Ct.) (QL) and *Wuttunce v. Merck Frosst Canada Ltd.*, [2007] S.J. No. 7 (Q.B.) (QL).

### **III. Regimes Governing the Sale and Purchase of Goods**

This section examines various statutory and regulatory regimes across the provinces and territories that govern the conditions that regulate the sale and purchase of goods. These regimes may be of use in situations when the seller delivers an inferior quality or insufficient quantity of goods. This section outlines the recourses that are available when contract stipulations or conditions are not met. In particular, it outlines how consumer protection legislation may apply to consumers of assistive devices.<sup>256</sup>

As ARCH has a provincial mandate, most of the information included in this section is Ontario-specific. Other provinces and territories may have analogous consumer protection legislation. For instance, most of the provinces and territories have enacted consumer protection legislation.

#### **i. Sale of Goods Act, R.S.O. 1990**

The *Sale of Goods Act* (“SOGA”) codifies portions of the common law of contract with respect to sales of goods including personal property other than things in action or money.<sup>257</sup> The SOGA establishes general rules relating to the formation of contracts: capacity of parties to contract; form of the contract; determination of price; and conditions and warranties.

In addition, the SOGA also sets out general rules for performance and enforcement of such contracts, including terms regarding: the time when title to the goods passes to the buyer; seller’s and buyer’s obligations and rights; part performance of the contract; cancellation of the contract; rights of the unpaid seller against the goods; resale of the goods by the buyer or seller; and remedies for breach of the contract.

It must be clearly noted that the SOGA is not traditional consumer-protection law. The SOGA is more properly considered part of commercial-contract law; it provides remedies to both sellers and buyers. Moreover, unlike traditional consumer-protection statutes<sup>258</sup> The SOGA provisions can be contracted out of in several ways, including, expressly, by the course of dealing between the parties, or by usage.<sup>259</sup> However, as discussed below, the *Consumer Protection Act, 2002* prohibits the negation or variance of the implied conditions and warranties set out in SOGA with respect to consumer agreements.

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<sup>256</sup> While we were unable to find many cases dealing specifically with consumer protection law in relation to assistive devices, due to the scope and complexity of such a search, and the variety of assistive devices in the marketplace there may well be more case law on this particular subject. ARCH welcomes any input into this ongoing area of research.

<sup>257</sup> *Sale of Goods Act*, R.S.O. 1990, c. S.1 [hereinafter “SOGA”].

<sup>258</sup> *Consumer Protection Act, 2002*, S.O. 2002, c. 20, Sch. A, or the *Residential Tenancies Act*, 2006, S.O. 2006, c. 17.

<sup>259</sup> *Supra* note 257 at s. 53.

Below, certain portions of the SOGA which might be of particular interest to consumers of accessible devices are highlighted. It is not the purpose of this section to summarize the SOGA as a whole.

a. Capacity to Contract of Persons with “Mental Incapacity”

The SOGA confirms that the capacity to enter into a contract of sale is governed by the general law regarding capacity to enter contracts and transfer property. However, section 3 creates an exception to this rule that may impact persons with cognitive, developmental, or mental health disabilities. Specifically, this section provides that despite a “mental incapacity” which would render a person incompetent to contract, where goods that are “necessaries” are sold and delivered to such a person, that person shall pay a reasonable price for those goods. “Necessaries” are defined as: goods suitable to the conditions in life of the minor or other person and to his or her actual requirements at the time of the sale and delivery.<sup>260</sup> It seems possible that some assistive devices may fall into this category and as such, the general rules relating to capacity to contract may potentially not operate. Legal database searches have not revealed significant judicial consideration of this provision.

b. Implied Conditions and Warranties

The SOGA sets out a number of implied conditions and warranties relating to title in goods, fitness for purpose, and defects. It must be remembered that the statutory conditions and warranties can be contracted out of, and in addition, that an express warranty or condition which is inconsistent with a statutory one negatives that statutory warranty or condition.<sup>261</sup> While it is somewhat of an oversimplification, the distinction between a warranty and a condition relates to the remedies available for a breach of either one. Typically, a breach of a warranty only gives rise to a claim for damages, whereas a breach of a condition creates a right to treat the contract as repudiated (i.e. to reject the goods) and/or claim for damages.

The SOGA indicates that there is an implied condition giving the seller the right to sell the goods and implied warranties that the buyer will enjoy quiet possession of the goods, and that the goods will be free from any encumbrances of which the buyer is not made aware.<sup>262</sup>

Where goods are sold by description, there is an implied condition that the goods will correspond to the description.<sup>263</sup> Generally, if goods purchased in a sale by description do not correspond to that description, the buyer can reject them without penalty.

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<sup>260</sup> *Ibid.* at s. 3(2).

<sup>261</sup> *Ibid.* at s. 15(4). Remember that these conditions and warranties cannot be overridden in the case of a consumer agreement under the *Consumer Protection Act*.

<sup>262</sup> *Ibid.* at s. 13.

<sup>263</sup> *Ibid.* at s.14.

There are limited implied conditions as to quality or fitness for a particular purpose of the goods.<sup>264</sup> First, where the buyer makes known to the seller the particular purpose for which the good is needed so as to show reliance on the seller's skill or judgment, there is an implied condition that the goods will be reasonably fit for that purpose. This condition is not implied where the good in question is a specified good sold under its patent or trade name. Second, where goods are bought "by description" (i.e. sight unseen) from a seller who deals in goods of that description (regardless of whether the seller is the manufacturer), there is an implied condition that the goods will be of merchantable quality. This condition does not apply if the buyer had the opportunity to examine the goods where the defects should have been discovered on examination. Third, an implied condition or warranty as to quality or fitness for a particular purpose may be annexed by the usage of trade.

For instance, in *Long v. Baxter*, the Ontario Supreme Court found that, pursuant to the *Sale of Goods Act, 1950*, there was an implied condition that the goods were to be reasonably fit for the purpose for which that a hearing aid was required, as the plaintiff had made known to the defendant.<sup>265</sup>

Where there is a "sale by sample" (i.e. where the buyer examines a sample good and orders in bulk), there are implied conditions that the bulk will correspond with the sample in quality; that the buyer will have a reasonable opportunity to compare the bulk to the sample; and, that the goods will be free from any defect rendering them unmerchantable that would not be apparent on reasonable examination of the sample.<sup>266</sup>

### c. Additional Provisions on Buyers' Rights

There are further provisions confirming that a buyer shall have an opportunity to examine the goods to ensure they are in conformity with the contract before accepting them<sup>267</sup> as well as provisions confirming the buyer's right to maintain an action for non-delivery<sup>268</sup> and/or for breach of warranty or condition.<sup>269</sup>

## **ii. Consumer Protection Act, R.S.O 2002**

The *Consumer Protection Act, 2002*, S.O. 2002, c. 30 ("CPA") brought together and updated six previously existing consumer protection laws: the *Business Practices Act*, the *Consumer Protection Act*, the *Consumer Protection Bureau Act*, the *Loan Brokers Act*, the *Motor Vehicle Repair Act* and the *Prepaid Services Act*. The CPA and the

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<sup>264</sup> *Ibid.* at s. 15.

<sup>265</sup> *Long v. Baxter (c.o.b Beltone Hearing Service)*, [1959] O.J. No. 43.

<sup>266</sup> *Supra* note 257 at s. 16.

<sup>267</sup> *Ibid.* at s. 33.

<sup>268</sup> *Ibid.* at s. 49.

<sup>269</sup> *Ibid.* at s. 51.

regulations came into force in 2005. The Ministry of Government Services is responsible for the CPA.<sup>270</sup> From the Ministry of Government Services website, consumers can also link to the Consumer Protection Branch which assists consumers with filing formal complaints under the CPA where a resolution has not been reached with the seller directly.<sup>271</sup>

The CPA applies to “consumer agreements” if either the consumer or the business is in Ontario. A “consumer” is defined as an individual acting for personal, family or household purposes and does not include a person who is acting for business purposes.<sup>272</sup> The CPA applies with respect to goods and services. A “consumer agreement” is a contract between a consumer and a supplier for goods or services in exchange for payment.

The CPA deals generally with consumer rights and warranties, unfair practices, advance fees, credit agreements and leases (but not of real estate). The CPA also sets out requirements for specific goods/services such as motor vehicle repairs, time shares, loan brokering and credit repair, leasing, and gyms.

The CPA also addresses 4 specific types of consumer agreements, setting out requirements (such as “cooling off”, or cancellation periods) for each:

- Direct contracts: contracts negotiated or concluded away from the place of business, e.g., door-to-door sales.
- Internet contracts: contracts entered into on the Internet, e.g., a website where consumers place online orders.
- Remote contracts: contracts entered into when the business and the consumer are not present together, e.g., by phone, fax or mail.
- Future performance contracts: contracts where delivery, performance or payment in full is not made when the consumer enters the agreement, e.g., fitness clubs.

The substantive and procedural rights enshrined in the CPA cannot be waived, even expressly.<sup>273</sup> The CPA prohibits: limiting a consumer’s right to pursue a court action via an arbitration clause<sup>274</sup> and clauses prohibiting class actions.<sup>275</sup> Further, the CPA contains an “anti-avoidance” clause that requires a court to consider the substance of the contract over the form in order to ensure that businesses do not find a way to

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<sup>270</sup> The Ministry of Government Services outlines the key portions of the CPA on its website at: <<http://www.gov.on.ca/MGS/en/ConsProt/050451.html>>.

<sup>271</sup> In this section we use the term consumer broadly, and is not restricted to consumers of assistive devices.

<sup>272</sup> More research would be required to determine if the CPA would apply where the payer was a government organization, like the Assistive Devices Program in Ontario.

<sup>273</sup> *Supra* note 258 at s. 7(1).

<sup>274</sup> *Ibid.* at s. 7(2).

<sup>275</sup> *Ibid.* at s. 8(1).

contract out of the CPA.<sup>276</sup> Any ambiguity in a consumer agreement will be interpreted in favour of the consumer.<sup>277</sup>

As above, this section is not intended to fully review the CPA. It is meant to provide an introduction of sections which may be of interest to consumers of assistive devices.

### a. Warranties on Goods and Services

The CPA provides that retailers are obliged to give minimum warranties known as deemed warranties that the services supplied under a consumer agreement are of a reasonable quality.<sup>278</sup> As to goods, the CPA indicates that the implied warranties and conditions set out in SOGA also apply in respect of goods which are leased, traded, or otherwise provided under a consumer agreement<sup>279</sup> and that the SOGA implied warranties and conditions cannot be waived or varied in the case of consumer agreements.<sup>280</sup>

### b. Preventing Unfair Practices

The CPA prohibits unfair practices,<sup>281</sup> making a false, misleading or deceptive representation is an unfair practice.<sup>282</sup> It outlines some examples of “false, misleading or deceptive” representations, for example, a representation that the goods have approvals or uses that the goods do not have.<sup>283</sup> The CPA also deems an “unconscionable representation” to be an unfair practice. In determining whether a representation was unconscionable, the existence of a consumer’s disability which the person making the representation knew (or ought to have known) would impede that consumer’s ability to protect his or her interests may be taken into account.<sup>284</sup>

The CPA provides remedies for consumers where a supplier has engaged in unfair practices, including a right of rescission or to sue in damages.<sup>285</sup> Where it is impossible to return the goods concerned, a consumer can recover damages and/ or the difference between her payment and the actual value of the goods or services.<sup>286</sup>

An example of an “unfair practice” from Saskatchewan raises issues particular to consumers of assistive devices. In *Guillet v. Clark*, the Small Claims Division of the

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<sup>276</sup> *Ibid.* at s. 3.

<sup>277</sup> *Ibid.* at s. 11.

<sup>278</sup> *Ibid.* at s. 9(1).

<sup>279</sup> *Ibid.* at s. 9(2).

<sup>280</sup> *Ibid.* at s. 9(3).

<sup>281</sup> *Ibid.* at s. 17(1).

<sup>282</sup> *Ibid.* at s. 14(1).

<sup>283</sup> *Ibid.* at s. 14(2).

<sup>284</sup> *Ibid.* at s. 15(2)(a).

<sup>285</sup> *Ibid.* at s. 18.

<sup>286</sup> *Ibid.* at s. 18(2).

Saskatchewan Provincial Court ordered a refund to an elderly consumer of a hearing aid, pursuant to Saskatchewan's *Consumer Protection Act*. The Court found that the consumer misled by the defendant's failure to determine if the hearing aid was appropriate and necessary. The Justice found that this transaction "was unique and required vigilance and protection for consumers", given that there existed a serious power and knowledge imbalance between the parties.<sup>287</sup>

### c. Additional Protections

The CPA also: provides consumers the right to cancel contracts where delivery of the goods or services is late (by at least 30 days);<sup>288</sup> prohibits repossession of goods without leave of the court where a consumer has paid two-thirds or more of the total payment due;<sup>289</sup> and, provides "cooling-off" periods for internet, remote and direct contracts (ranging from 7-10 days from the date the consumer receives a written copy of the agreement) which allow the consumer to cancel the contract.<sup>290</sup> It is important to note that there is a one year limitation period for claims pursuant to section 18 of the CPA, rather than the general two year limitation period for most civil actions.

## **IV. Other Avenues of Redress**

The section reviews ways in which consumers of assistive devices may seek redress outside of the court system. These less-formal avenues typically require fewer resources than civil actions commenced pursuant to product liability regimes as well as pursuant to provincial and territorial consumer protection legislation.

### **i. Better Business Bureau**

The Canadian Council of Better Business Bureaus is comprised of 18 local Better Business Bureaus (BBB) in all provinces.<sup>291</sup> Better Business Bureaus are self governing organizations established by the local business community. A consumer can find her local BBB office by visiting the Canadian Council of Better Business Bureaus website at <http://www.ccbbb.ca>.

A BBB office handles general consumer complaints including, among others, misleading advertising, improper selling practices, and non-delivery of goods or services. The complaint must involve a consumer-to-business or business-to-business transaction of more than \$20 that relates to the advertisement or sale of a product or service. The BBB will not accept complaints about government services, including presumably the Assistive Devices Program in Ontario. The BBB will also refuse complaints involving allegations of discrimination, allegations of violation of statutory/constitutional rights, and

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<sup>287</sup> *Guillet v. Clark (c.o.b. Cleartone Hearing Centre)*, [2004] S.J. No. 826.

<sup>288</sup> *Supra* note 258 at s.26.

<sup>289</sup> *Ibid.* at s.25.

<sup>290</sup> *Ibid.* at ss.40, 43, 47.

<sup>291</sup> There are no BBB offices located in Canada's three territories.

the professional services of health care professionals, or matters which are or have previously been the subject of litigation between the parties.<sup>292</sup> A complaint to the BBB may be useful for a consumer of an assistive device where the device is defective or a vendor refuses to honour a warranty. It is also applicable to complaints about public safety, not otherwise handled by Health Canada, and instances where the consumer receives poor customer service, or is subject to false advertising.

Historically, over 70% of complaints through the BBB are resolved. In some cases, BBB mediation or arbitration may be offered to assist in resolution.<sup>293</sup> Complaints are usually closed within 30 calendar days.<sup>294</sup> The BBB encourages consumers to attempt to resolve complaints directly with the company, although a local BBB will not reject a complaint if a consumer has not taken this step. While there is no form for filing complaints, the complaints process includes the following steps:

- Complaints should be forwarded in writing to the local BBB, most often the Bureau where the company is located.
- The BBB will not process anonymous complaints.
- The complaint must be from an individual, or their authorized representative. Authorized representatives include lawyers and guardians who are filing on behalf of minor children, the elderly, or persons with disabilities.
- The complaint will be forwarded to the company within two business days.
- The company will be asked to respond within 14 days, and if a response is not received, a second request will be made.
- The complainant will be notified of the company's response when the BBB receives it (or notified that BBB received no response).
- The results are set out in a Reputation Report which is publicly available, including online. The BBB maintains reliability reports on millions of businesses.
- While there is no explicit requirement for the provision of documents in alternate formats, the BBB will assist a consumer with a complaint on an ad-hoc basis upon demonstration of a disability related need.

A search of the complaints filed to the Better Business Bureau serving Mid-Western and Southern Ontario revealed three businesses received complaints from consumers of assistive devices, for a total of nine complaints, in the last 36 months.<sup>295</sup>

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<sup>292</sup> Council of Better Business Bureaus, *Before you Begin Filing Your Complaint* (2006): online: CBBB <<https://odr.bbb.org/odrweb/public/GetStarted.aspx>> (date accessed: 20 June 2007).

<sup>293</sup> *Ibid.*

<sup>294</sup> *Ibid.*

<sup>295</sup> See <<http://www.bbbmwo.ca>> for more information, including a listing of all complaints received by the Better Business Bureau in the area.

## **ii. Provincial Ombudsman Offices**

Consumers of assistive devices can make complaints about individual or systemic problems relating to Ontario government services to the Ontario Ombudsman. There are analogous bodies in other provinces and territories.<sup>296</sup>

The Ombudsman's powers and authorities are contained in the *Ombudsman Act*.<sup>297</sup> Ontario's Ombudsman is an Officer of the Provincial Legislature who is independent of the government and political parties. The Ombudsman's job is to ensure the accountability of government through effective oversight of the administration of government services in Ontario. The Ombudsman is generally an office of last resort; consumers should first try to resolve the problem by using other complaint and appeal procedures. Generally, the Ombudsman will not investigate a complaint which is more than 12 months old. Complaints can be made in writing, by email, phone, fax, or online.<sup>298</sup> All complaints made to the Ombudsman are confidential.

## **iii. Ontario Human Rights Code**

If a consumer of assistive devices feels that she has been subject to discrimination, including on the basis of disability, she may make a complaint pursuant to the Ontario *Human Rights Code* ("Code").<sup>299</sup> The *Code* is a provincial law that gives everybody equal rights and opportunities without discrimination in specific areas such as jobs, housing and services. The *Code's* goal is to prevent discrimination and harassment because of race, colour, sex, disability and age, to name some of the sixteen grounds. The *Code* applies to accessing services, employment, and housing.

When the *Human Rights Code Amendment Act*<sup>300</sup>, comes into effect, the Human Rights Tribunal of Ontario will be responsible for processing human rights complaints under the Ontario *Human Rights Code*. Although this is an Ontario specific institution, there are analogous bodies federally, and in other provinces and territories.<sup>301</sup>

The 1995 decision of *Ontario (Human Rights Commission) and Roberts v. Ontario (Ministry of Health) (No. 2)* is an example of the experience of discrimination by

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<sup>296</sup> For more information, see the British Columbia Ombudsman's website at <<http://www.ombud.gov.bc.ca>>. See also the Forum of Canadian Ombudsman at <<http://www.ombudsmanforum.ca>>.

<sup>297</sup> *Ombudsman Act*, R.S.O. 1990, c. O.6.

<sup>298</sup> For more information on filing a complaint with the Ontario Ombudsman please see <<http://www.ombudsman.on.ca/how.aspx?langID=1>>.

<sup>299</sup> *Human Rights Code*, R.S.O. 1990, c. H.19.

<sup>300</sup> *Human Rights Code Amendment Act*, R.S.O. 2006 c. 30.

<sup>301</sup> See the University of Ottawa's website for a list of Human Rights Commissions across the country at: <[http://www.uottawa.ca/hrrec/links/sitescan\\_e.html](http://www.uottawa.ca/hrrec/links/sitescan_e.html)>.

consumers of assistive devices.<sup>302</sup> The case involved a 71 year-old man who was legally blind and applied for financial assistance from Ontario's Assistive Devices Program to buy a device that would enable him to read. Given that such assistance was only provided to those under the age of 18, the man filed a complaint based on age. The Court of Appeal found that the age restriction for assistance was indeed discriminatory.

## **V. Consumer Protection Organizations**

Consumers who have concerns about the sale, use, maintenance or safety of an assistive device may consider contacting one of the following consumer protection organizations. It is important to note that these organizations are not disability-specific organizations, and may not have knowledge about issues particular to consumers of assistive devices.

The **Canadian Consumer Information Gateway** is an information service maintained by the federal government's Office of Consumer Affairs of Industry Canada.<sup>303</sup> The website includes information on programs and services offered by many federal departments and agencies, provincial and territorial ministries, and non-governmental organizations. It offers clear guidance to consumers about making complaints through a variety of processes. For instance, templates allowing consumers to quickly write letters to their local Better Business Bureau are provided.

The **Public Interest Advocacy Centre** (PIAC) is a non-profit organization that provides legal and research services on behalf of consumer interests, and, in particular, vulnerable consumer interests, concerning the provision of important public services.<sup>304</sup>

The **Consumers' Association of Canada** (CAC) is an independent, not-for-profit, volunteer-based, charitable organization.<sup>305</sup> The CAC is mandated to inform and educate consumers on marketplace issues, to advocate for consumers with government and industry, and work with government and industry to solve marketplace problems. CAC focuses its work in the areas of food, health, trade, standards, financial services, communications industries and other marketplace issues.

The **Consumers Council of Canada** is an independent, non-profit organization, working with consumers, corporations and governments to promote consumers' rights and responsibilities.<sup>306</sup> While the Consumers' Council will not assist the filing of

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<sup>302</sup> *Ontario (Human Rights Commission) v. Ontario (1994)*, 117 D.L.R. (4<sup>th</sup>) 297.

<sup>303</sup> See the Office of Consumer Affairs' website at <<http://consumerinformation.ca>>.

<sup>304</sup> For more information about the Public Interest Advocacy Centre, please see <[http://www.piac.ca/information/what\\_we\\_do](http://www.piac.ca/information/what_we_do)> (last accessed 20 July 2007>.

<sup>305</sup> For more information about the Consumers Association of Canada, please see <<http://www.consumer.ca>>.

<sup>306</sup> For more information on the Consumers' Council of Canada <<http://www.consumerscouncil.com>>.

complaints directly, the organization does include information about effective advocacy on its website.

## **PART FOUR – IDENTIFYING BARRIERS AND OPTIONS FOR CHANGE**

This Part suggests options for change based on the barriers experienced by consumers of assistive devices. It presents some considerations for the better regulation and provision of assistive devices. In particular, it offers law reform and policy approaches to ensuring the accessibility, reliability, effectiveness and safety of assistive devices for persons with disabilities.

### **I. The Consumer Experience**

This section highlights, from a consumer perspective, the obstacles that impede the availability of safe assistive devices. Our thoughts and conclusions are based on consultations with key stakeholders, legal research, and the experience of ARCH staff over time. The importance of this issue has been outlined by the Council of Canadians with Disabilities and Canadian Association for Community Living as follows:

Exclusion and a lack of access to disability supports perpetuate the poverty of people with disabilities and their families. The result is isolation, increased vulnerability, and limited opportunity for Canadians with disabilities to participate and be valued as full citizens...<sup>307</sup>

#### **i. Jurisdictional Confusion**

There are different levels of government, ministries, departments, agencies and organizations that support and regulate assistive devices. For instance, various bodies are responsible for the development, importation, licensing, accessibility, safety and availability of goods and products. There are complex and overlapping regulatory regimes. This “quagmire of bureaucracy” can be overwhelming to persons forced to navigate the system, including persons with disabilities. Also complicating is that different provinces and territories have different funding regimes and, as a result, there is uneven access to assistive devices by consumers across the country.

#### **ii. Restrictive Provincial Funding Regimes**

The breadth and scope of provincial funding programs is a major barrier to accessing assistive devices. According to Statistics Canada, among persons with disabilities aged 15 and over who had unmet needs for assistive aids, nearly one in two (48%) cited the high cost of the equipment as the reason why they did not have it.<sup>308</sup> Most programs

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<sup>307</sup> Council of Canadians with Disabilities and the Canadian Association for Community Living, *Building an Inclusive and Accessible Canada: Supporting People with Disabilities* at 6, online: CCD, < <http://www.ccdonline.ca/publications/accessible%20Canada.htm>>).

<sup>308</sup> Statistics Canada, *Participation and Activity Limitation Survey: Disability Supports in Canada*, (Ottawa: Government of Canada, 2001) at 6, online: HRSDC, < http://

that fund assistive devices do not cover the entire cost of the assistive device. Instead, the consumer must pay some portion of the cost. For example, Ontario's Assistive Devices Program (ADP) covers 75% of the cost of most assistive devices and the consumer bears the other 25% of the cost. In the case of an electronic wheelchair, for example, where the cost of the assistive device is great, the consumer's portion can be prohibitively high. In addition, some vendors require payment up front from consumers for their portion of the payment. Furthermore, the cost of repairing assistive devices is not covered by all funding programs. The lack of full funding particularly impacts persons with disabilities, who are vulnerable to the effects of poverty.<sup>309</sup>

### **iii. Limited Availability of Assistive Devices**

Consumers with disabilities report frustration with the limited availability of Canadian-made assistive devices. Very few manufacturers are Canadian and as a result, there is very little competition between suppliers.<sup>310</sup> Data demonstrates that Canada relies heavily on the import of assistive devices, and exports of assistive devices are limited. This reflects an inefficient domestic industry.<sup>311</sup> It may be that potential investors in the assistive devices industry perceive the market as prohibitively small. However, Canadian consumers report high satisfaction with assistive devices imported from New Zealand. Despite the fact that New Zealand has an even smaller domestic market, its industry has apparently been able to respond effectively to the need.

We are presently experiencing very fast paced technological change, which has an impact on people with disabilities and people without disabilities alike. Given the speed of technological development, particularly with respect to information and communication technologies (ICTs), the issue of effective regulation is particularly important. There is a great possibility that well-designed products that incorporate the principles of universal design can open doors for people with disabilities and provide for

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<http://www.statcan.ca/english/freepub/89-580-XIE/aids.htm>> (last accessed: 27 June 2007).

<sup>309</sup> Federal/Provincial/Territorial Ministers Responsible for Social Services, *In Unison: A Canadian Approach to Disability Issues* (Ottawa: Human Resources Development Canada, 2000), online: Social Union <[http://socialunion.gc.ca/pwd/unison/unison\\_\\_e.html](http://socialunion.gc.ca/pwd/unison/unison__e.html)> (last accessed: 29 June 2007).

<sup>310</sup> *Supra* note 27 at 12 and 13. The authors state: "The Canadian industry is dominated by a large number of small firms: in 1999, there were some 800 establishments employing 2275 people in the medical equipment and supplies manufacturing industry [citation]. Larger American and European firms appear to enjoy a significant competitive advantage over their Canadian counterparts. This may be due to progressive legislative measures, such as the *Americans with Disabilities Act* (1990), that have allowed American firms to develop the expertise and innovate capacity that cede to them a "first" mover advantage. Without similar government support for the Canadian industry, domestic firms are likely to continue to lag behind their international competitors in terms of innovation and product development."

<sup>311</sup> *Ibid.*

more inclusive communities. On the other hand, when new product design pays no attention to the requirements of people with disabilities or the rapidly aging population, there is a great risk of excluding and further marginalizing persons with disabilities.<sup>312</sup>

Consumers frustrated with the poor choice of domestic assistive devices feel forced to import from outside the country. However, unless the imported device is classified as a medical device, it may not be recognized as free from duty. Not all assistive devices used by persons with disabilities are considered “medical devices” for the purposes of the *Medical Device Regulations*. There are not separate commodity classification codes for assistive technology; instead, assistive technology is included with other products. For instance, accessible weight training systems are included in the same categories (and subject to the same customs and duties) as non-accessible weight training systems.<sup>313</sup>

Consumers report that imported devices may not be compatible with other Canadian-made devices, or may not otherwise be used effectively in Canada. For example, American-made mobility devices that meet American standards may be too large to navigate doorways and bathrooms in Canada, where building requirements are less stringent.

#### **iv. Inadequate Consumer Choice**

In a wealthy, free-market economy such as Canada’s, consumers generally expect there to be a range and choice of products. In contrast, the experience of persons with disabilities with respect to their assistive devices is quite different: choice is limited in many ways.

Consumer choice with respect to both products and vendors is limited through provincially funded and charitable organization and/or service provider programs. Most provincial funding programs produce lists of the assistive devices which are eligible for funding. However, there are many devices that, although needed by persons with disabilities, are not included on such lists. The lists of devices eligible for provincial funding are often out of date, and do not keep up with new technologies. Consumers therefore, may be prohibited from choosing a newer, safer product because it has not yet been added to the list of acceptable products eligible for provincial funding.

Provincial programs may also require that consumers purchase assistive devices from a designated list of vendors. Furthermore, provincial programs may require that

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<sup>312</sup> A. D’Aubin, “Working for Barrier Removal in the ICT Area: Creating a More Accessible and Inclusive Canada” (2007) 23 *Information Society* 193. The author states at 195: “Many ICT users with disabilities find themselves always playing catch-up – waiting for adaptive technology to become available that enables them to use the ICT that people without disabilities are using.”

<sup>313</sup> *Customs Tariff 2007*, SOR/2006-167 (23 June 2006). See Tariff Classification Code 9506.91.90.

consumers purchase specialized devices through central equipment pools. For instance, in Ontario, Shoppers HomeHealthCare is the only authorized vendor to provide high technology wheelchairs to ADP clients.<sup>314</sup> This lack of choice is seriously concerning to the disability community.

#### **v. Poor Regulation and Lack of Legal Clarity Regarding the Safety of Assistive Devices**

Persons with disabilities rely on various types of equipment and devices to meet their needs. However, Health Canada only regulates those devices determined to be “medical devices”. There are many products that are not so classified, including emerging technologies. Manufacturers of devices not classified as medical devices are not required to meet Canadian Standards Association (CSA) standards, nor do they have reporting or licensing obligations. That is, CSA approval is not required if the device is not a “medical device” for the purpose of the *Medical Device Regulations*. Further, while Class I medical devices, including wheelchairs, must still meet the safety, effectiveness and labelling requirements, they do not require device licences. In effect, then, CSA approval is also not required where the assistive device is a Class I medical device.

Not only is there inadequate regulation at the outset, procedure in the case of a product failure is also highly problematic. This is particularly so when the individual has acquired or borrowed the device through a provincially funded program, a charitable organization or a service provider. The program may not cover the costs of repair, potentially leading to the continued use of products that are below a safely functioning level, if the user cannot afford the repair costs.

Where the potential for litigation acts as a control on the design and manufacture of products, product liability law can help to ensure product safety. However, given that consumers of assistive devices experience barriers to pursuing litigation (as set out in Section 3.I above), we can speculate that this market-monitoring effect may be much weaker. Section 3.II highlighted that ordinary legal principles of product liability become complex, for example, where the consumer acquires the assistive device involving a third party donors or funders, including provincial funding programs. The complexity and uncertainty in such cases increases the cost of legal action and acts as a significant barrier to consumers pursuing such claims.

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<sup>314</sup> Ministry of Health and Long Term Care, “Central Equipment Pool for High Technology Wheelchairs” in *ADP Today Newsletter* (June 2003), online: Ministry of Health and Long Term Care <[http://www.health.gov.on.ca/english/providers/program/adp/nletter/nl\\_0603.html](http://www.health.gov.on.ca/english/providers/program/adp/nletter/nl_0603.html)> (last accessed: 30 May 2007).

## **vi. Limited Access to Product Information**

Consumers face significant informational hurdles regarding assistive devices. Consumers may require training on the safe use of assistive devices, especially in a marketplace of increasingly complex technologies. Training is sometimes provided by the vendor, a manufacturer's telephone help line, in-store product information or through on-line guides and print manuals. However, no one is obliged to provide such training. Vendors do not always provide consumers with opportunities to test devices before purchase.

Even where it is provided, training is often not provided in accessible formats. In particular, manufacturers are not required to provide product information or manuals in accessible formats. Help lines offered by manufacturers often do not include TTY accessibility. As a result, consumers are forced to rely on informal networks to access information on the safe use of assistive devices.<sup>315</sup>

Products that are not "medical devices" for the purpose of the *Food and Drugs Act* are not regulated for labelling by the *Medical Device Regulations*. Instead, their labels are regulated by the less-stringent *Consumer Packaging and Labelling Act*. Furthermore, neither the *Medical Device Regulations* nor the *Consumer Packaging and Labelling Act* requires that labels be in an accessible format.

Furthermore, even for devices covered by the *Medical Device Regulations* or the *Consumer Packaging and Labelling Act*, there are no labelling requirements for the accessibility features of a product. Before purchasing a product, a consumer may require information about the accessibility features of a device, such as its compatibility with other assistive devices, as in the case of a hearing aid compatible cell phone. Indeed, the lack of information regarding potential accessibility features is recognized as an omission that should be corrected for all products on the consumer market, not only for assistive devices.

In addition, there is very little advertising of assistive devices and so, to the extent that advertising provides useful product information, this avenue is not generally available.

## **II. Looking Forward: Options for Providing Safe Assistive Devices in Canada**

A key goal for Canadian society and of the various governments in Canada is to work towards the full participation of persons with disabilities in work, social and community life. This requires the provision of a full range of supports for persons with disabilities. This project has investigated the current situation with respect to the supports known as assistive devices. We have highlighted key issues identified by consumers. We have also researched the legal, political and program contexts that govern how assistive devices are regulated in Canada.

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<sup>315</sup> As an example, see <<http://www.wheelchairjunkie.com>>.

In this section, we offer a series of options and steps that may go some way to ensuring the achievement of the full participation of persons with disabilities more possible. We briefly identify areas for further consideration, consultation, action and legislation.

### **i. Leadership at the National Level**

If the federal government shows a strong resolve to take the lead, much can be done to address the problems of availability, choice, safety and general regulation of assistive devices in Canada. The effort must be coordinated between governments and be responsive to the perspectives of the disability community. The Government of Canada must work with provincial and territorial governments to establish consistent and comprehensive funding programs that make assistive devices available to all who need them and to ensure that all necessary regulations are in place, enforced, and effective. Also at the federal level, the coordination of disability-related strategies across departments is critical to the effective implementation of these goals. Particular attention must be paid to the delivery and funding of assistive devices to aboriginal communities in Canada, on and off reserves, after thorough consultation with the community.

### **ii. Increased Funding to the Provinces and Territories**

Fiscal limitations at the provincial and territorial levels need to be addressed in order to increase the availability of assistive devices to persons with disabilities. Leadership at the federal level will be clearly demonstrated if the federal government provides significant financial transfers to provincial and territorial programs for disability supports, including assistive devices.

### **iii. Federal Taxation and Incentives for the Domestic Assistive Devices Sector**

Federal taxation rules for individuals must support the acquisition of assistive devices by persons with disabilities. At the industry level, tax incentives and other supports for the design and manufacture in Canada of assistive devices with respect to both traditional and new technologies, must be pursued. Industry Canada should take the lead in supporting a Canadian industry, applying renewed energy to the innovation of accessible technologies in the domestic sector. Particularly in the emerging ICT industry, manufacturers must be encouraged or required to consider the principles of “universal design” and “accessibility by design”.

One idea proposed by consumers of assistive devices is that there should be a central mechanism for consumers to rate or score assistive devices. This information would then be available to other people with disabilities seeking current and informed consumers’ opinions about particular products. This may also encourage competition amongst vendors and manufacturers and enhance product development.

#### **iv. Importing Assistive Devices into Canada**

Given the greater range of products available in other countries, Canadians with disabilities sometimes import assistive devices themselves. An examination of our importing rules, including tariff treatments, should be undertaken to simplify the rules and to eradicate any costs associated with importation that the consumer must pay. All assistive devices used by persons with disabilities should be exempt from duty, brokerage fees and tax.<sup>316</sup> Assistive devices are not frivolous purchases but rather are essential to the individual's daily living.

The Canada Border Services Agency (CBSA) should consider the benefits of creating a registry of people who receive the disability tax credit and use that registry to approve duty-free status related to each person with a disability.<sup>317</sup> The CBSA should consider creating separate commodity classification codes for assistive devices for the *Customs Tariff*.<sup>318</sup> Additionally, the CBSA should consider creating an accessible, user-friendly Web site and fact sheets on importing assistive devices.

#### **v. Safety of Assistive Devices**

Comprehensive, well-understood and well-enforced federal regulations with respect to the safety of assistive devices are essential. Their development may need to be a joint project of the Departments of Industry and Health. Gaps in licensing and enforcement should be addressed. At the very least, the *Medical Device Regulations* should require more stringent regulations for the safety of assistive devices, including those that are not considered to be "medical devices". For instance, the government should consider mandatory inspections of assistive devices, including medical devices.

#### **vi. Disability Legislation at the Federal, Provincial and Territorial Level**

Effective disability legislation is required at the federal, provincial and territorial levels. Such legislation can be the vehicle for barrier removal in the public and private sectors. It may, for instance, set out how accessibility standards will be created and enforced.<sup>319</sup> A disability statute can set out the requirements for effective and comprehensive regulatory standards with respect to all aspects of assistive devices. In the alternative, a disability statute could set out the expectation that such standards will be developed and enforced under other more specific legislation.

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<sup>316</sup> *Supra* note 27.

<sup>317</sup> *Ibid.*

<sup>318</sup> *Ibid.*

<sup>319</sup> P. Gordon, *A Federal Disability Act: Opportunities and Challenges* (Toronto: CCD, October 2006) at 2, online: CCD < <http://www.ccdonline.ca/publications/FDA.html>>.

## **vii. Minimize the Complexity of the Regulation of “Medical Devices” and “Assistive Devices”**

Rules, requirements and obligations must be streamlined to ensure product safety and availability, as well as to ensure that consumers understand the processes. As this project demonstrates, the current context for assistive devices is highly complex, unclear and appears to have developed over time in a hodge-podge fashion. The goal should be to provide regulation and programs in a way that is both effective and readily understandable.

We suggest that the current regime be reviewed to determine if it is the most effective way to provide for the regulation of assistive devices. It is possible that assistive devices should have their own federal statute, one which recognizes the essential and supportive (rather than medical) role they play. The current regulation of medical devices is complex and difficult to navigate. It is not easily understood by consumers of medical devices. The regulation of medical devices, in part at least, is directed towards the well-being of Canadians and, as such, it should be much more ‘user-friendly’.

## **viii. Consumer Information about Assistive Devices**

It is essential that consumers be provided with enough product information to exercise real choice in the market of assistive devices. For instance, consumers require information about how a device will meet their disability related needs. As such, all product information and labelling must be available in accessible formats. In addition, training on the safe use of assistive devices is especially important in a marketplace of increasingly complex technologies. Additionally, training must be provided in accessible formats.

The federal government should also consider amending the *Food and Drugs Act* and its *Medical Devices Regulations* to require manufacturers to include information about a product’s accessibility features on the package, including compatibility with other assistive devices, as in the case of a hearing aid compatible cell phone.

## **ix. Best Practices at the Program Level**

The barriers faced by clients of programs that fund the purchase of assistive devices must be addressed through legislative reform, policy renewal or administrative development. Ideally, provincial and territorial programs funding the purchase of assistive devices would have the following key features:

- The program must cover the cost of repairs of and maintenance of assistive devices.
- Clients must be able to renew equipment as often as their disability related needs change.

- The assessment of the needs for assistive devices must focus on inclusion and independence, rather than an understanding of impairment that focuses on dependence and passivity.
- Clients must be able to exercise choice over the type of assistive device, and where they can purchase the device.
- Where appropriate, the program must cover the full cost of the device. Where a portion of the purchase price is borne by the client, there must be financial assistance available to clients who require it.
- Access to funding must be timely.
- If product lists are maintained they must be broad, offer choice and keep up to date with new technological development.
- The program must be free from discrimination.

This list is not exhaustive and only serves as a starting point. Further consultation with the disability community and other stakeholders is required.

Currently, most programs which deliver assistive devices to people with disabilities maintain lists of approved products. The range of choice for consumers is thus severely limited by the program design itself. The program becomes subject to the lobbying of manufacturers and vendors, and there is an implicit assumption that the ‘program knows best’, or at least better than the consumer. It may be that an array of programs is the most suitable solution in order to provide for the variety of different consumer needs and abilities. It may be appropriate to consider alternative models for the funding of assistive devices. One such model would provide for a more open market where the individual receives funding for the product within a given price range but has more choice in the selection of the product. The system could look more like the Direct Funding Program administered by the Centre for Independent Living in Toronto where funding is allocated to adults with physical disabilities to become employers of their own attendants. In the same vein, consumers could receive authentication from a health care provider to enable them to purchase the device they need, whether it is on a list or not. Allowing consumers to choose the assistive devices that best suit their disability related needs would maximize consumer control and choice. It may also lead to more product innovation and development. In our view, this idea should be investigated and consumers should be consulted before implementation.

## **x. Review of Consumer Protection Legislation and Common Law**

At the provincial legislative levels, consumer protection laws, both statutory and in the common law, should be reviewed with respect to the issues raised in this project. Persons requiring assistive devices should be made aware of their legal options at the time that they acquire the device. The uncertainty with respect to the law of product liability where the assistive device is acquired by a third party funder or supplier, including provincial funding programs, must be addressed from a law reform perspective.

## **xi. Reliance on Consumer Perspectives**

The creation of a system that is based on the fundamental values of full citizenship is essential, and as such, reform to the system must reflect the perspectives of persons with disabilities. All legislation, services, policies and programs must be evaluated through a “lens of discrimination”, carefully assessing their impact on persons with disabilities. Special attention must be paid to the individual experience of discrimination.<sup>320</sup> Intersectional discrimination arises out of the combination of various oppressions, which, together, produce something unique and distinct from any one form of discrimination standing alone.<sup>321</sup> Evidence indicates that members of racialized groups who have disabilities<sup>322</sup> and women with disabilities<sup>323</sup> experience distinctive forms of discrimination. Particular attention must be paid to the barriers experienced by consumers of assistive devices from aboriginal communities.

Traditionally, persons with disabilities have not had a voice in the development of the policies and programs which affect them. Integrating diverse perspectives ensures equity, fosters partnerships and builds buy-in from the community. It is crucial that any reform to legislation, policy, programs and services reflect the perspectives of persons with disabilities. Responsible levels of government must obtain broad feedback from stakeholders, including persons with disabilities, and the consultation must be accessible to persons with disabilities.

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<sup>320</sup> Nitya Iyer, “Categorical Denials: Equality Rights and the Shaping of Social Identity” 19 Queen’s Law Journal 179.

<sup>321</sup> Ontario Human Rights Commission (OHRC), *An Intersectional Approach to Discrimination* (Toronto: Queens Printer, 2001), online: OHRC, <  
[http://www.ohrc.on.ca/english/consultations/intersectionality-discussion-paper\\_1.shtml](http://www.ohrc.on.ca/english/consultations/intersectionality-discussion-paper_1.shtml)  
>.

<sup>322</sup> OHRC *Intersection Approach*, *supra* note 321. Persons of colour with disabilities face challenges beyond those faced by other persons with disabilities with respect to access to housing and employment.

<sup>323</sup> Fiona Sampson, “Globalization and the Inequality of Women with Disabilities” (2003) 2 Journal of Law and Equality 16 at 19. Women with disabilities are especially vulnerable to the experience of unemployment and poverty.

## **APPENDIX A: Current Roles and Responsibilities in Canada**

Reproduced from Government of Canada, *Restoring Fiscal Balance in Canada: Focussing on Priorities* (Ottawa: Ministry of Finance, 2006).

	Federal	Provincial
Money and banking	√	
International and interprovincial trade	√	
Airlines and railways	√	
Telecommunications and broadcasting	√	
Foreign affairs/international assistance	√	
Defence and veterans affairs	√	
Border security	√	
Employment insurance	√	
Criminal law	√	
Fiscal Equalization	√	
Indirect taxation	√	
Direct taxation	√	√
Pensions and income support	√	√
Aboriginal peoples	√	√
Immigration	√	√
Agriculture	√	√
Industry	√	√
Environment	√	√
Policing	√	√
Transportation infrastructure	√	√
Housing	√	√
Post-secondary education, training and research	√	√
Public health	√	√
Primary and secondary education		√
Health care		√
Municipal institutions		√
Social assistance and social services		√
Natural resources		√
Administration of justice		√

## **APPENDIX B: Ontario's Assistive Device Program**

Given that ARCH has a provincial mandate, this report includes additional detail about the Assistive Devices Program (ADP) in Ontario. For the purposes of this project, we have used the ADP as an example of provincial funding programs. This is especially appropriate given that ADP is considered to be the most extensive of the provincial programs, covering more than 8,000 assistive devices. Despite its comprehensiveness, consumers in Ontario have reported negative experiences with the program's operation to ARCH.

The ADP is administered by the Ministry of Health and Long-Term Care ("Ministry of Health"). Its purpose is to financially assist persons with physical disabilities in the purchase of assistive devices and supplies. The Ministry of Health's authority to administer the ADP emanates from subsection 6(1)(4) of the *Ministry of Health and Long-Term Care Act*.<sup>324</sup>

The governing policy of the Assistive Devices Program is the *Policies and Procedures Manual*. The Ministry of Health expects all parties to adhere to the Policy Manual, found on the Ministry of Health web site. It is a comprehensive document, dealing with a host of issues such as eligibility criteria, the application process for funding, vendor and authorizer policies, and contact personnel. There are device-specific manuals that contain more detailed information concerning a specific category of equipment. These manuals are also available on the Ministry of Health web site.

### **I. The ADP Application Process**

Most device requests must be authorized by a qualified health care professional registered with the program. In most device categories, an authorizer assesses the specific needs of the person and prescribes appropriate equipment or supplies. In some device categories, such as adult hearing aids or prosthetic devices, the authorizer is also the vendor. Registered authorizers work in hospitals, home care agencies or private practice. Authorizers charge for their assessments, a cost which is not covered by the ADP program.

There are several application forms in use for applying to ADP. The general form used for many device categories is the Equipment/Supply Authorization ("ESA") form. A customized form is used when applying for the following device categories: oxygen, wheelchairs, positioning and ambulation aids, hearing devices, conventional limbs and breast prostheses. Application forms are available on the Ministry of Health's web site

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<sup>324</sup> R.S.O. 1990, c. M.26 at s. 6(1)(4). Subsection 6(1)(4) states: "6(1) It is the function of the Minister and he or she has the power to carry out the following duties: ... 4. To enter into agreements for the provision of health services and equipment required therefore and for the payment of remuneration for such health services on a basis other than fee for service."

at: [http://www.health.gov.on.ca/english/public/forms/form\\_menus/adp\\_fm.html](http://www.health.gov.on.ca/english/public/forms/form_menus/adp_fm.html). They are also available through a registered authorizer or a registered vendor, or by calling the Ministry of Health Infoline at 1-800-268-1154 or 1-800-387-5559 (TTY).

Instructions for completing the applications are found in the device-specific manuals or the fact sheets. All application forms must first be completed by the consumer, and then by the authorizer or vendor before they are submitted to ADP. ADP requires that the original application form be submitted, either by hand or by mail; photocopies or facsimiles are not acceptable. The client is required to obtain the device within one year of the assessment date.<sup>325</sup>

## **II. ADP Product Eligibility**

The ADP covers more than 8000 pieces of equipment and supplies. More detail about devices that are eligible for funding are set out in the device-specific manuals available at: [http://www.health.gov.on.ca/english/providers/pub/pub\\_menus/pub\\_adp.html](http://www.health.gov.on.ca/english/providers/pub/pub_menus/pub_adp.html). Section 105.05 of the Policy Manual categorizes eligible equipment as follows:

- Diabetes Supplies (Needles and Syringes for Seniors, Insulin Pumps and Supplies for Children and Youth).
- Mobility (Wheelchair, Positioning, Seating and Ambulation Aids)
- Prosthetics and Orthotics (Prosthetic Devices, Orthotics, Pressure Modification Devices; Ostomy Supplies).
- Sensory (Hearing Devices; Visual Aids; Communication Aids; TTY, Cochlear Implant External Processors, Bone Anchored Hearing Aids external processors)
- Medical Supplies (Respiratory Equipment and Supplies; Enteral Feeding and Supplies; Ventilators; Home Oxygen).

The ADP requires that the device be obtained from a registered vendor, unless otherwise provided for in the device-specific manual. Vendors who are registered with the ADP must be located in Ontario, although there are a few vendors who operate in neighbouring provinces. Section 3 of the Policy Manual sets the application process for a vendor to be registered to sell products covered by the ADP program.

Section 1005 of the Policy Manual sets out how new devices are deemed eligible for ADP funding. Manufacturers or distributors should inform the ADP program that they wish to have a new device listed by ADP. The device must fit into one of the device categories. If the device does not fit within a device category, the product can not be listed with ADP.<sup>326</sup> In order to be considered for listing the manufacturer must have a permanent location/distributor in Ontario. Canadian Standards Association (CSA)

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<sup>325</sup> *Supra* note 76 at s. 1100.02. See also Ministry of Health and Long Term Care, "Approval Letters – Expiry Date" (June 2003) *ADP Today Newsletter*, online: MOHLTC, <[http://www.health.gov.on.ca/english/providers/program/adp/nletter/nl\\_0603.html#wchairs](http://www.health.gov.on.ca/english/providers/program/adp/nletter/nl_0603.html#wchairs)> (last accessed: 27 May 2007).

<sup>326</sup> *Ibid.* at s. 1005.02.

approval is required for a product to be covered by the ADP program.<sup>327</sup> See Section 2.IV(i) for more information about CSA standards that apply to assistive devices.

### **III. Eligibility Criteria for ADP Benefits**

Eligibility criteria are set out by both the Policy Manual and device-specific manuals. Section 600 of the Policy Manual provides the ‘basic criteria’ to be considered in order to benefit from the ADP. In order to be eligible for ADP funding, the Policy Manual states that the applicant must be an Ontario resident, have a valid Ontario Health Insurance Plan card and have a physical disability of six months or more. The ADP excludes persons with a primary diagnosis of a learning disability, persons on Workers’ Compensation, persons entitled to coverage under the Veterans Treatment regulations, and persons requiring assistive devices exclusively for sports, work or school.<sup>328</sup>

### **IV. Expenses Covered by ADP**

The device-specific manuals set out the funding structure applicable to the device category in question. Depending on the device category and specific device, the ADP can cover 75% of the cost, pay a fixed amount or pay annual grants to the consumer. Recipients of social assistance may receive 100% funding of the ADP-listed price, a fixed amount, or other amounts as set out in the Policy Manual.<sup>329</sup>

Usually, the client pays her share of the cost at the time of purchase and ADP is billed for the balance by the vendor.<sup>330</sup> The ADP sets the price for most eligible products. The price for a product should be the manufacturer’s unit cost to the vendor plus a reasonable rate of return (up to 33 1/3 percent).<sup>331</sup> ADP reviews prices every 2 years.<sup>332</sup> In recent history, some vendors marked up the cost of wheelchairs. As a result, ADP clients were required to pay more for their share. It is now the case that the ADP program sets the prices. Vendors must not charge more than the established price.

There are several equipment pools where ADP clients must access specialized equipment. There are pools for ventilator equipment, communication devices and visual aids. In addition, the Central Equipment Pool (CEP) provides recycled high technology wheelchairs at a discounted price. All eligible individuals who want ADP funding assistance for power wheelchairs that includes power dynamic tilt and/or recline must apply through the CEP. The CEP is currently managed by Shoppers HomeHealthCare.

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<sup>327</sup> *Ibid.* at s. 1005.04. Section 1005.04 provides that “On receipt of the completed Manufacturers/Distributor Application Form the Program ensures the manufacturer/distributor has provided documentation such as CSA approval...”

<sup>328</sup> *Ibid.* at s. 600.02.

<sup>329</sup> *Ibid.* at s. 610.

<sup>330</sup> *Ibid.* at s. 930. Section 930 provides that “Payment is made directly to the Vendor either by cheque or by direct deposit.”

<sup>331</sup> *Ibid.* at s. 1015.07.

<sup>332</sup> *Ibid.* at s.1015.02.

Only the CEP is authorized to provide service and modifications to CEP wheelchairs.<sup>333</sup> Some members of the disability community have expressed serious concern about the lack of choice of vendors offered to consumers of high end wheelchairs.

## **V. The Safety of Assistive Devices Covered by the ADP**

The ADP may remove a listed device where Health Canada has recalled the product because of safety problems.<sup>334</sup> The vendor can not supply an authorized device that had been previously used or any component that has been previously used.<sup>335</sup> Additionally, a vendor may refuse to provide an unsafe device to an ADP client. Section 570.00 of the ADP Manual states:

Where, in the reasonable opinion of the vendor, a client may be endangered by the provision of an authorized device, the vendor may refuse to provide the device to the client.<sup>336</sup>

The Program Manual provides that Canadian Standards Association (CSA) Approval is required for a product to be covered by the ADP program.<sup>337</sup> All ADP devices must meet CSA standards. Applications by manufacturers to include a product as ADP eligible requires a list of standards complied with in the design/manufacture of the device to ensure that the safety and effectiveness requirements are met. See Section 2.IV(i) for more information about CSA standards that apply to medical and assistive devices.

The ADP program requires all eligible devices to have a warranty issued by the manufacturer.<sup>338</sup> Where the registered vendor custom–makes the device for the client, the vendor will provide the client with a written warranty.<sup>339</sup> Where a client obtains equipment from a central equipment pool, a warranty is issued by the pool. There are no explicit rules about the content or the breadth of the warranty.

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<sup>333</sup> Ministry of Health and Long Term Care, “Central Equipment Pool for High Technology Wheelchairs” in *ADP Today Newsletter* (June 2003), online: Ministry of Health and Long Term Care <[http://www.health.gov.on.ca/english/providers/program/adp/nletter/nl\\_0603.html](http://www.health.gov.on.ca/english/providers/program/adp/nletter/nl_0603.html)> (last accessed: 30 May 2007).

<sup>334</sup> *Policy Manual*, *supra* note 76 at s. 1010.01.

<sup>335</sup> *Ibid.* at s. 1000.04.

<sup>336</sup> *Ibid.* at s. 570.00.

<sup>337</sup> *Ibid.* at s. 1005.04. The section provides, “[o]n receipt of the completed Manufacturers/Distributor Application Form the Program ensures the manufactures/distributor has provided documentation such as CSA approval...”

<sup>338</sup> *Ibid.* at s. 575.00. The section provides, “[t]he registered vendor must provide the client with the manufacturers warranty at the time of providing the device to the client”.

<sup>339</sup> *Ibid.* at s. 575.01. The section provides, “[t]he terms of these warranties are described in the device specific manuals or vendor agreements.”

The ADP program does not cover the cost of repair or replacement during repair.<sup>340</sup> The ADP client, under normal circumstances, owns the device, and is responsible for the device. The client must deal directly with the manufacturer if the device is faulty. ADP clients may purchase service agreements from the vendor or the manufacturer, depending on the circumstances. As an exception, the Central Equipment Pool (CEP) provides repairs to high technology wheelchairs free of charge to CEP clients.

The ADP program may, however, cover the cost of the replacement of a device over a certain time period.<sup>341</sup> The renewal date is calculated for each device, and identifies how long the device should, in most cases, remain in good repair through normal use.

## **VI. Consumer Perspectives of ADP**

However, the ADP is the most extensive of all provincial programs in Canada.<sup>342</sup> Nevertheless, ADP clients face substantial barriers including the following:

- The ADP is particularly bureaucratic and requires much self-advocacy to navigate. One consumer interviewee noted that it is not a consumer-oriented organization.
- The ADP does not cover the cost of repairs.
- There is a waiting period of about 3 months to get an assistive device through ADP.
- There are many devices which, although needed by persons with disabilities, are not covered by ADP. The list of devices eligible for ADP funding is out of date, and does not keep up with new technologies.
- ADP funding is restricted to persons with physical disabilities requiring the use of an assistive device for six months or longer. The applicant must have a primary diagnosis other than a learning disorder.<sup>343</sup>
- ADP does not pay for batteries for power wheelchairs.<sup>344</sup>
- Most of the time, ADP only covers 75% of the cost of the assistive device. Some vendors require payment up front from consumers for their portion of

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<sup>340</sup> *Ibid.* at s. 580. The section provides, “[t]he program does not contribute toward the cost of repairs of purchased devices under any circumstances. The liability for the cost of repairs within the warranty period will depend on the terms of the warranty. The cost of repairs after the warranty period expires is the liability of the client.”

<sup>341</sup> *Ibid.* at s. 1020.

<sup>342</sup> *Supra* note 27 at 13.

<sup>343</sup> *Supra* note 76 at s. 600.02. The ADP excludes persons with a primary diagnosis of a learning disability, persons on Workers’ Compensation, persons entitled to coverage under the Veterans Treatment regulations, and persons requiring assistive devices exclusively for sports, work or school.

<sup>344</sup> Ministry of Health and Long-Term Care, “ADP Mobility Devices”, online: MOHLTC, <<http://www.health.gov.on.ca/english/public/pub/adp/mobility.html>> (last accessed: 29 June 2007).

- the payment. This can be particularly hard for persons with disabilities, who are particularly vulnerable to the effects of poverty.
- ADP does not cover the cost of a replacement device, during repair for example. It is left up to the vendors and the consumer to negotiate a rental for the assistive device. Consumers are at a significant disadvantage during the bargaining process.
  - It has been reported that some vendors encourage consumers to purchase the services of on-site authorizers, in order to will improve that chances that the request to ADP will be granted.
  - Customers must access some specialized devices only through equipment pools. For instance, only the CEP is authorized to provide high technology wheelchairs, including service and modifications to ADP clients.<sup>345</sup>

## **VII. Complaints Process**

There is no appeal process for denials of funding set out in the legislation, regulation, or the Policy Manual. Section 830 of the Policy Manual addresses the denial of funding as follows:

All applications are processed, approved or rejected, according to the rules in each device-specific manual category. [...] If the application is complete, accurate, and conforms to the rules of the respective device-specific manual and the client is eligible, the application is approved. [...] If the application is not complete, not accurate, or does not conform to the rules of the device manuals, the application is rejected.<sup>346</sup>

Although not set out in legislation or policy, the Ministry of Health and Long Term Care advises that individuals who are denied funding follow the following process: they should inquire as to the reasons for the denial. Application Denial Inquiries should be sent to the Claims Assessment Clerk.<sup>347</sup> The applicant should then submit in writing the reasons why they think that they are eligible.<sup>348</sup> The Program Coordinator has the authority and decision-making power to review and decide on such a request. The Claims Assessment Clerk's role is to process information but not to make decisions regarding the reassessment of applications.

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<sup>345</sup> *ADP Today Newsletter*, *supra* note 333.

<sup>346</sup> *Supra* note 76 at s. 830.

<sup>347</sup> R. Lattanzio and L. Kerzner, "Assistive Devices Program" in *A Disability Law Primer: A Continuing Education Program for Ontario Lawyers* (Toronto: ARCH, 2003), online: ARCH  
<[http://www.archdisabilitylaw.ca/publications/disorders/A73\\_2003\\_002616/07\\_assistive\\_devices/index.asp](http://www.archdisabilitylaw.ca/publications/disorders/A73_2003_002616/07_assistive_devices/index.asp)> (30 May 2007).

<sup>348</sup> *Ibid.*

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