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Brian Wilson*

If it's Reusable Why not Reuse it?
The Reuse of Single Use Medical
Devices

The reprocessing and subsequent reuse of medical devices labelled by the manufacturer as 'single-use only' is a cost cutting strategy employed by many healthcare centres. However, attempting to extend the life of a device labelled as 'single-use only' raises a number of unique concerns surrounding the issue of legal liability, specifically, who should bear responsibility if someone suffers harm as a result of a reprocessed single-use device. Following an overview of the current regulatory environment, the potential tortious liability attaching to those who may be implicated in the reprocessing chain is discussed. Specifically, this paper examines the duty and standard of care owed by regulatory bodies, original manufacturers, third-party reproprocessors, healthcare facilities and care providers in the reuse of devices labelled as 'single-use only'. Finally, by drawing on various international practices the paper concludes by advocating for regulatory reform to better provide proactive oversight in the area of reuse in Canada.

Le retraitement et la réutilisation de dispositifs médicaux étiquetés par leurs fabricants comme étant à usage unique sont une stratégie de réduction des coûts à laquelle ont recours de nombreux centres de soins de santé. Cependant, une tentative de prolonger le cycle de vie d'un dispositif destiné à n'être utilisé qu'une seule fois soulève un certain nombre de préoccupations quant à la responsabilité légale, plus particulièrement, qui est responsable si un patient subit un préjudice en conséquence de la réutilisation d'un dispositif médical à usage unique retransformé? Après avoir donné un aperçu du contexte réglementaire actuel, l'auteur discute de la responsabilité délictuelle potentielle qui incombe aux acteurs de la chaîne de retraitement. Plus précisément, l'article traite du devoir et de la norme de diligence des organismes de réglementation, des fabricants, des tiers qui procèdent au retraitement, des établissements de soins de santé et des fournisseurs de soins dans la réutilisation des dispositifs à usage unique. Enfin, s'inspirant de diverses pratiques qui ont cours à l'étranger, l'auteur conclut par un plaidoyer pour une réforme de la réglementation afin que le secteur de la réutilisation au Canada soit mieux surveillé.

* The author is currently completing his articles at Blake, Cassels & Graydon LLP. He expresses many thanks to Professor Elaine Gibson of the Dalhousie Health Law Institute for her help and guidance with this paper.

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Introduction

The longstanding practice of reusing certain medical devices has received increased attention over the past decade. The concern stems from a phenomenon that originated in the late 1970s and early 1980s with the advent of the single-use medical device (SUD).¹ During that time manufacturers began to produce an increasing number of SUDs in response to consumer demand and the availability of new synthetic (e.g. plastics) technology.² Since then the reprocessing process has grown to include many medical devices marketed as “disposable” or “single use”

1. Health Canada, *Issue Analysis Summary: The Reuse of Single-Use Medical Devices* (Ottawa: Therapeutic Products Directorate, 2005), online: <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/md-im/saprmnd_ias_gcsrmm_raq_2005-06-09-eng.pdf>.

2. Martin S Favero, “Requiem for Reuse of Single-Use Devices in US hospitals” (2001) 22 *Infect Control Hosp Epidemiol* 539.

only. Table one provides a list of some of the most frequently reprocessed items identified as single-use only.³

HOSPITAL DEPARTMENT	SUD
Anaesthesiology	Ventilator circuits
Gastroenterology	Biopsy forceps
Orthopaedics	Blades and Drill bits
Obstetrics/ Gynaecology	Breast Pump kit Vaginal speculums
Cardiology	Angioplasty balloon catheters
Miscellaneous (general instruments)	Oral Airways Clamps ET Tubes

Table 1. Single-use medical devices frequently reprocessed

Given the lack of recognized data on the safety and effectiveness of reuse, it is not surprising that the reprocessing of SUDs has sparked much debate.⁴ Further, this activity seems to be taking place in spite of manufacturers' label instructions warning against reuse, without consistent direction from professional associations or other healthcare stakeholders and in the absence of clear regulatory guidance.⁵ This provides for little consistency between neighbouring hospitals, let alone a provincial or national standard.

Since 1986 three surveys have been conducted on the reuse of SUDs by Canadian acute-care facilities.⁶ The most recent study, completed in 2008, found wide-spread reuse in a significant number of Canadian hospitals. Of 398 hospitals surveyed 28 per cent admitted to reusing SUDs.⁷ While some of the reprocessing was contracted out to licensed reprocessors, 85

3. Health Canada, *Medical Devices Reprocessing Concerns and Recommendations* (Ottawa: Scientific Advisory Panel on Reprocessing of Medical Devices, October 2006), online: <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/md-im/saprmnd_table_gcsrmm_tableau_2006-10-12-13-eng.pdf>; See also David Hailey et al, "Reprocessing of single-use medical devices: Clinical, economic, and health services impact" (Ottawa: Canadian Agency for Drugs and Technologies in Health, 2008).

4. US, General Accounting Office, *Single-Use Medical Devices: Little Available Evidence of Harm from Reuse, but Oversight Warranted* (2000), online: General Accounting Office <<http://www.gao.gov/new.items/he00123.pdf>>.

5. Canadian Healthcare Association, *The Reuse of Single-Use Medical Devices: Guidelines for Healthcare Facilities* (Ottawa: CHA Press, 1996) at 9-10.

6. BA Campbell et al, "Reuse of Disposable Medical Devices in Canadian Hospitals" (1987) 15 Am J Infect Control 196; MA Miller, D Gravel & S Paton, "Reuse of Single-Use Medical Devices in Canadian Acute-Care Healthcare Facilities" (2001) 27:23 Can Commun Dis Rep 193; J Polisena et al, "Reprocessing of Single-Use Medical Devices: National Survey of Canadian Acute-Care Hospitals" (Ottawa: Canadian Agency for Drugs and Technologies in Health, 2008).

7. Polisena, *ibid* at 4.

per cent of the hospitals who admitted to reprocessing said that they did the work themselves.⁸ Among the hospitals practicing reprocessing, 40 per cent self-reported that they do not have written protocols in place for reuse, or any way of determining the number of times that the item has been reused.⁹

While all medical devices pose risks of harm from defects in manufacturing or improper use, the reprocessing of SUDs raises a number of unique concerns. Specifically, who should bear responsibility if someone suffers harm as a result of a reprocessed SUD?

The practice of reusing SUDs is cause for concern for healthcare facilities as well as a host of other entities: the regulatory body responsible for the control and management of SUDs, the original manufacturer of the device, any third-party reproducers of the device, and the care provider who treats the patient. Given the level of reuse activity that has reportedly occurred, and continues to occur, it seems appropriate to consider the legal implications of reuse as it relates to all those involved in the reprocessing chain. Following an overview of the current regulatory framework in Canada, this paper will discuss the potential tortious liability of each entity. More specifically, the focus of this paper will be to examine the 'duty' and the 'standard of care' owed to patients by each of the entities involved in reprocessing. The paper concludes by drawing on current practices from around the world to suggest a regulatory framework to augment the tort system—a solution that aims to provide clarity, guidance and certainty in the area of reuse in Canada.

1. *The current regulatory environment*

The starting point for any discussion on medical device use in Canada is the *Medical Devices Regulations*¹⁰ made pursuant to Canada's *Food and Drugs Act*.¹¹ These statutory instruments prescribe the legal requirements for manufacturers of medical devices and regulate the sale, importation and advertising of these products. Health Canada is responsible for the administration and oversight of the *FDA*.¹² The Bureau of Medical Devices is a directorate of Health Canada's Health Protection Branch and is the principal guardian of the *Medical Devices Regulations*. Its mandate is the

8. *Ibid* at 7.

9. *Ibid* at 6.

10. *Medical Devices Regulations*, SOR/98-282.

11. *Food and Drugs Act*, RSC 1985, c F-27.

12. *Department of National Health and Welfare Act*, RSC 1985, c N-10, as repealed by SC 2006, c 11, s 105. In 1996 the government enacted the *Department of Health Act* which replaced the *Department of National Health and Welfare Act* and gave rise to the Department of Health (Health Canada) in its current form. See *Department of Health Act*, RSC 1996, c 8 H-3.2, s 2.

pre-market investigation, monitoring, approval, testing, and regulation of medical devices, including those imported into Canada. A manufacturer is defined in s. 1 of the *Regulations* as:

...a person who sells a medical device under their own name, or under a trade-mark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf.¹³

Although cleaning and sterilizing devices may be considered a manufacturing activity, merely carrying out the activity does not make the agent a manufacturer within the meaning of the *Regulations*. The *FDA* and its *Regulations* do not lay down requirements on the user of the device since the *Regulations* apply only where the device is sold. Section 2 of the *Regulations* reads:

These *Regulations* apply to

- (a) the sale and advertising for sale of a medical device; and
- (b) the importation of a medical device for sale or for use on individuals, other than importation for personal use.¹⁴

Many consumers assume that since the *Regulations* require manufacturers to provide adequate instructions and warnings for the safe use of their products; that users, in turn, are required to follow those instructions. That is not the case. The *FDA* and its *Regulations* are silent on the use of a device contrary to a manufacturer's instructions.

The Medical Devices Bureau of Health Canada has taken the position that hospitals are not device manufacturers within the meaning of the *Regulations*. This is because hospitals engaged in reuse activity do not sell or distribute devices under their own name or trademark.¹⁵ If hospitals are not manufacturers, then it follows that healthcare facilities which use, maintain and sterilize medical devices are not governed by the *Regulations*. The application of the *Regulations* is, however, less clear where a third party for compensation reprocesses devices belonging to a hospital and then returns them to that facility for reuse.

13. *Supra* note 10, s 1.

14. *Supra* note 10, s 2.

15. Health Canada, *Update on Reprocessing and Reuse of Single-Use Medical Devices*, (Ottawa: Therapeutic Products Directorate, 2007), online: <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pef/md-im/lthsud_md_lahimj_im-eng.pdf>.

In 2005, the National Scientific Advisory Panel on Reprocessing of Medical Devices [Advisory Panel] made recommendations to Health Canada, one of which was to undertake the regulation of SUD reprocessing.¹⁶ The Advisory Panel also provided a list of criteria for device design and materials which could be used to judge the safety of reprocessing particular devices. Health Canada responded by stating that it did not have the authority to regulate the use of medical devices in a clinical environment and, by extension, the reuse of disposables, on the basis that the *Medical Devices Regulations* do not apply to the use of a device *after* its sale.¹⁷

Health Canada asserts that the use and reuse of medical devices is to be controlled by provincial laws and medical licensing bodies pursuant to provincial powers. Constitutionally, provincial jurisdiction over healthcare within a province exists through the provinces general authority over “matters of a local and private nature” in s. 92(16) of the *Constitution Act*, 1867, and over the “management of hospitals” in s. 92(7).¹⁸ Health Canada finds support for its reluctance to champion this issue in section 12 of the *Department of Health Act* which reads:

Nothing in this Act or the regulations authorizes the Minister or any officer or employee of the Department to exercise any jurisdiction or control over any health authority operating under the laws of any province.¹⁹

Thus Health Canada cannot operate within the sphere of provincially mandated services, such as delivery of health care, operation of hospitals, or regulation of the health care professions. The duties of the federal Health Minister, set out in s. 4 (1), are limited to “all matters over which Parliament has jurisdiction relating to the promotion and preservation of the health of the people of Canada not by law assigned to any other department, board or agency of the Government of Canada.”²⁰ Although the delivery of healthcare and the establishment of policies and standards with respect to patient care have traditionally been the responsibility of provincial and territorial health ministers, few of the provinces have yet to enact any legislation affecting the reuse of SUDs.

16. Health Canada, Scientific Advisory Panel on Reprocessing of Medical Devices, *Record of Proceedings*, (Ottawa: Therapeutic Products Directorate, 2005), online: <http://www.hc-sc.gc.ca/dhp-mps/md-im/activit/sci-consult/reproc-retraite/saprmnd_rop_gcsrmm_crd_2005-02-10-eng.php> [Advisory Panel].

17. *Supra* note 15.

18. *Ibid.*

19. *Department of Health Act*, SC 1996, c 8, s 12.

20. *Ibid* at s 4(1).

Quebec

In 1993, the Conseil d'évaluation des technologies de la santé du Québec published guidelines advising that the reuse of cardiac catheters, pacemakers and hemodialyzers did not pose unacceptable risks to patients provided that hospitals had adequate procedures in place to assure quality reuse.²¹ However, in 1997 the Québec Minister of Health and Social Services updated its position by not allowing the reuse of some devices (e.g. cardiac catheters) if the original use was in patients considered vectors for disease transmission.²²

Manitoba

In February 1998, Manitoba banned the reuse of critical care disposables in health care facilities.²³

Northwest Territories

In 2005, the Northwest Territories revised its *Hospital and Health Care Facility Standards Regulations* to require that "a disposable device intended to be used on a patient during a single procedure shall not be used on a patient for more than one procedure and shall not be used on another patient."²⁴ This is the only province or territory to issue a blanket ban on the reuse of all SUDs in Canada.

Ontario

Ontario has issued the most robust set of guidelines. In 2006, the Ontario Ministry of Health and Long Term Care endorsed a guidance document developed by its Provincial Infectious Disease Advisory Committee (PIDAC). Ontario Best Practice Guidelines state that critical and semi-critical medical equipment or devices labelled as single-use must not be reprocessed and reused unless the reprocessing is done by a licensed reprocessor. The Ontario guidelines also suggest that some items like needles should never be reprocessed while they strongly recommend that other devices with small lumens (e.g. catheters) be single-use only. In an effort to manage any legal risk inherent with reuse, the guidelines suggest

21. Conseil d'évaluation des technologies de la santé du Québec (CETS), "The reuse of single-use catheters" by Roger Jacob & Patricia Bentolia (Montreal: The Conseil, 1993).

22. Conseil d'évaluation des technologies de la santé du Québec (CETS), Report CETS 9704 RE, "The reuse of single-use catheter and the risk of transmission of Creutzfeldt-Jakob disease: an update—non-systematic review" (Montreal: The Conseil, 1997).

23. *Supra* note 15.

24. *Hospital and Health Care Facility Standards Regulations*, NWT Reg 036-2005, s 62.

initiating “written policies, extensive testing of reprocessing protocols and strict adherence to quality assurance investigations.”²⁵

British Columbia

British Columbia has a policy that as of January 1, 2008 all health authorities must eliminate the reprocessing and reuse of critical contact single-use devices unless they have been reprocessed by a licensed third-party reprocessor, certified by a national regulatory authority such as Health Canada or the US Food and Drug Administration.²⁶

Alberta

In 2008, Alberta issued a set of standards for single-use medical devices in which it adopted much of the same language and protocols as the Ontario guidelines.²⁷

Other federal and provincial stakeholders have also weighed in on the issue of reprocessing SUDs. The Canadian Healthcare Association published *The Reuse of Single-Use Medical Devices: Guidelines for Healthcare Facilities* in 1996, which addresses the key issues regarding single-use device reuse—cleaning and sterilization protocols, cost justification, liability costs and the patient’s right to information.²⁸ It does not take a position for or against reuse of SUDs, but provides a framework to enable a facility to judge the merits of reuse, and to establish the quality systems necessary to ensure that reprocessed SUDs are safe. In spite of this guidance, in 2008, a Health Canada-sponsored study found that 40 per cent of the hospitals reusing SUDs did not have a system in place to track usage.²⁹

Notwithstanding the lack of a clear regulatory mandate to oversee reprocessing and reuse activity within hospitals, Health Canada continues to face pressure from device manufacturers, hospitals and other healthcare stakeholders to take action to standardize policies on reuse across Canada.

25. Ontario, Provincial Infectious Diseases Advisory Committee (PIDAC), *Best Practices for Cleaning, Disinfection, and Sterilization* (Infection Prevention and Control Subcommittee, 2006), online: <http://www.health.gov.bc.ca/library/publications/year/2007/BPGuidelines_Cleaning_Disinfection_Sterilization_MedicalDevices.pdf>.

26. British Columbia, Ministry of Health Policy Communiqué, *Reprocessing of Medical Devices and Patient Care Equipment* (June 2007).

27. Alberta, *Standards for Single-Use Medical Devices* (16 January 2008), online: <<http://www.health.alberta.ca/documents/IPC-Medical-Device-Cleaning-2008.pdf>>. Note: Since this paper was accepted for publication Alberta amended its standards for SUDs providing that critical and semi-critical medical devices shall not be used.

28. Canadian Healthcare Association, *The Reuse of Single-Use Medical Devices: Guidelines for Healthcare Facilities*, (Ottawa: CHA Press, 1996).

29. Polisen, *supra* note 6 at 6.

II. *Legal consequences of reuse*

There has yet to be a reported Canadian case on the reuse of SUDs in Canada. While we wait for the definitive word on the tortious liability attaching to reuse activities, the jurisprudence to date does provide insight into the potential liability of regulatory bodies, manufacturers, third-party reprocessors, hospitals and healthcare professions. Figure one represents the path an SUD takes in the reprocessing process and, in turn, provides a visual which helps us to understand how various actors are connected to a liability claim relating to SUD reprocessing.

The discussion in this paper will be confined, in the main, to the primary basis of liability—negligence. Specifically, the potential duty and standard of care attaching itself to the following actors will be examined: (a) government regulator; (b) original manufacturer; (c) third-party reprocessor; (d) healthcare facility; and (e) physicians.

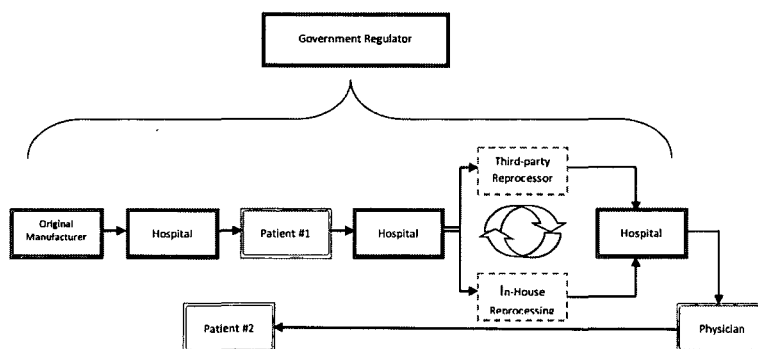


Figure 1. The Path of a Reprocessed Single-Use Device

The first question to consider in an action for negligence is whether the defendant owed the plaintiff a duty of care. In determining whether a duty of care exists the court will apply the two-step *Anns* test as adopted by the Supreme Court in *Kamloops v. Nielsen*.³⁰ The first step focuses on the relationship between the parties. It asks whether the relationship is of sufficient proximity so that the harm that occurred was a reasonably foreseeable consequence of the defendant's act.³¹ A relationship of proximity was described by the Supreme Court of Canada in *Hercules Managements Ltd. v. Ernst & Young*, as one "of such a nature that the defendant may be said to be under an obligation to be mindful of the

30. *City of Kamloops v. Jan Clemmensen Nielsen et al*, [1984] 2 SCR 2 at 10-11.

31. *Donoghue v Stevenson*, [1932] AC 562 (HL) at 580-581; see also *Cooper v Hobart* 2001 SCC 79, [2001] 3 SCR 537 at para 24.

plaintiff's legitimate interests in conducting his or her affairs."³² In *Cooper v. Hobart*, McLachlin C.J. and Major J. stated that determining the closeness of a relationship may involve "looking at expectations, representations, reliance, and the property or other interests involved."³³ These factors help inform whether "it is just and fair having regard to that relationship to impose a duty of care in law upon the defendant."³⁴

The second question is whether the imposition of a duty should be moderated or negated by any policy concerns.³⁵ This stage is not concerned with the relationship between the parties, but rather the effect of recognizing a duty of care on other legal obligations, the legal system and society more generally.³⁶ Finally, if a plaintiff is able to establish that the defendant owes them a duty of care, the plaintiff must then demonstrate that the defendant has breached the standard of care. A defendant's conduct breaches this standard if it creates an unreasonable risk of harm.³⁷

1. *Government regulator*

The parameters of government liability for regulatory negligence continue to evolve. We have moved from a system of complete Crown immunity to one where a government may be held liable in tort.³⁸ But while a duty of care is almost always presumed to exist between a hospital and patient (or physician and patient), in the case of a regulatory body, any potential duty of care must be considered within its statutory context.³⁹ We begin with a survey of the liability of the Crown in tort actions generally.

The Supreme Court of Canada considered a regulator's duty of care to the consumer in *Edwards v. The Law Society of Upper Canada*.⁴⁰ In *Edwards*, the issue was whether the Law Society of Upper Canada (the regulatory body) owed a duty of care to persons who deposit money into a solicitor's trust account. The Supreme Court held that the Law Society owed a duty to the public as a whole, and had an obligation to discharge its mandate having regard for the public's interest. However, no private law duty existed to members of the public who dealt with organizations or persons whose conduct was overseen by the regulator as there was no proximate relationship.⁴¹

32. *Hercules Managements Ltd v Ernst & Young*, [1997] 2 SCR 165 at para 24.

33. *Cooper*, *supra* note 31 at para 34.

34. *Ibid*.

35. *Ibid* at para 37; see generally *Anns v Merton London Borough Council*, [1978] AC 728 (HL).

36. *Cooper*, *ibid* at para 37.

37. *Mustapha v Culligan of Canada Ltd*, 2008 SCC 27, [2008] 2 SCR 114 at para 7.

38. *Crown Liability and Proceedings Act*, RSC 1985, c C-50, s 2(b).

39. *Cooper*, *supra* note 31 at para 43.

40. *Edwards v Law Society of Upper Canada*, 2001 SCC 80, [2001] 3 SCR 562.

41. *Ibid* at para 14.

The Federal Court of Canada has also considered the scope of regulator liability. In *AO Farms Inc v. Canada*⁴² the Court held that the government does not have a proximate relationship to an individual when it makes decisions of a political, social or economic nature. Hugessen J. held that:

The relationship between the government and the governed is not one of individual proximity. Any, perhaps most, government actions are likely to cause harm to some members of the public. This is why government is not an easy matter. Of course, the government owes a duty to the public but it is a duty owed to the public collectively and not individually.⁴³

In *Cooper v Hobart* the Supreme Court noted that even if a prima facie duty of care is found it will be negated where (i) the regulator must make difficult discretionary decisions in the area of public policy; (ii) where liability for the damages flowing from the grant of a license or registration could lead to an indeterminate liability; or (iii) if the imposition of a private duty of care could result in a huge burden to the taxpayer.⁴⁴ The Court's rationale was that policy is the prerogative of the elected legislature and it is inappropriate for courts to second guess the government by imposing liability for the consequences of a particular policy decision.⁴⁵

In the context of medical devices, two decisions from Ontario have grappled with the notion of a private law duty of care owed by Health Canada. In *Klein v. American Medical Systems Inc.*, a woman sued the Federal government on the basis that she suffered harm from a device that was implanted in her body to alleviate female incontinence.⁴⁶ The claimant alleged that Health Canada, in accordance with its authority to regulate medical devices under the *FDA* and its associated *Regulations* was negligent in issuing the manufacturer the license to distribute the product in Canada. The Ontario Divisional Court held that, "any duties imposed by the legislation with respect to the regulation of medical devices by Health Canada are duties owed to the public at large and not to private individuals."⁴⁷ Chapnick J., concluding that the lack of a duty was "plain and obvious,"⁴⁸ commented:

Health Canada is only one player in the complex regulatory and delivery scheme governing medical devices in Canada. It has no direct role in

42. *AO Farms Inc v Canada* (2000), 28 Admin LR (3d) 315 (FC).

43. *Ibid* at para 11.

44. *Cooper*, *supra* note 31 at paras 52-56.

45. *Ibid* at para 38.

46. *Klein v American Medical Systems Inc et al* (2006), 84 OR (3d) 217 (Sup Ct J).

47. *Ibid* at para 31.

48. *Ibid* at para 35.

the commercial transaction or the medical decision-making that leads to individual use. The duties of care toward the patient or consumer are qualitatively different from any public duty owed by Health Canada as the government regulator.⁴⁹

In a second case, *Attis v. Canada (Minister of Health)*, two appellants alleged that they were the recipients of faulty breast implants leading to permanent disabilities.⁵⁰ The appellants claimed that Health Canada undertook to regulate in this area and that it did so negligently. Lang J.A., speaking for the Court, held that when a government decides what laws to enact or how to allocate limited resources for the general good, it has neither a close nor direct relationship with a particular member of the public.⁵¹ The job of the government is to govern and, in the course of doing so, make broad-based policy decisions for the benefit of the public collectively, even if those decisions may not have positive implications for all individuals.⁵² In dismissing the claim against Health Canada, Lang J.A. concluded:

It would severely curtail the government's ability to govern if it were found to have the necessary direct and close relationship to an individual member of the public to support a claim in tort for bad government policy decisions. It is accepted that, if the government fails to make good decisions in these areas, the public will demonstrate its displeasure at election time.⁵³

Health Canada's duty to the public as a whole was emphasized in 1953 when The Minister of National Health and Welfare first introduced the *FDA*. He noted that, "The purpose of the bill of course is *to protect the Canadian people in matters of health* ... The bill is concerned with the prohibition of things that are injurious to health and that are unfit for use, and with the prevention of deception in the manufacture and sale of goods consumed *by the public*."⁵⁴ In most cases, the courts have said that the purpose of this legislative scheme is to facilitate the regulator's authority to use its discretion to act in the public interest, and that the legislative regime does not demonstrate an intent to provide for a private remedy

49. *Ibid* at para 33.

50. *Attis v Canada (Minister of Health)*, 2008 ONCA 660, 93 OR (3d) 35 at para 4.

51. *Ibid* at para 65.

52. *Ibid*.

53. *Ibid*.

54. *House of Commons Debates*, 21 at Parl, 7th Sess, Vol IV (21 April 1953) at 4141 (Hon Paul Martin) [emphasis added].

to individuals.⁵⁵ It is also important to remember that Health Canada's responsibilities extend far beyond the regulation of medical devices. Under the *FDA*, Health Canada regulates among others, food, drugs and cosmetics. As such, imposing liability on Health Canada in the context of medical devices, and more specifically single-use medical devices, could have a far reaching and indeterminate effect on the public purse. In *Attis*, the Court found that such a "spectre of indeterminate liability, negative[s] the imposition of government liability."⁵⁶

It is noteworthy that while courts will not hold regulators liable for policy decisions, they will attach liability to the negligent *execution* of a policy decision (e.g. operational decisions in implementing the policy).⁵⁷ If Health Canada has consciously decided to avoid responsibility to regulate in this area, a failure to govern or prohibit "is a manifest policy decision."⁵⁸ And so, as long as there is no champion of the regulator role, a court is unlikely to assign regulator liability.

2. *Original manufacturer*

Original manufacturers naturally advocate against reuse, ostensibly based on safety concerns. In 2004, the Medical Devices Association of Canada issued a position paper in which they vehemently argued against reuse saying, "reuse carries serious risks" and that "the manufacturer does not guarantee the sterility, functionality or quality of the device after it has been reprocessed."⁵⁹ MEDEC's strong position is undoubtedly influenced by the fact that manufacturers of consumable goods owe a duty of care to the ultimate consumer of that good.⁶⁰ In fact, manufacturers have statutory duties to ensure that devices are fit for their intended use and may face legal liability for preventable manufacturing defects that cause harm to patients. Section 12 of the *Medical Devices Regulations* provides that:

A medical device shall perform as intended by the manufacturer and shall be effective for the medical conditions, purposes and uses for which it is manufactured, sold or represented.⁶¹

Similarly, s. 13 governs the lifespan of a device and states that:

55. *Drady v Canada (Minister of Health)*, 2008 ONCA 659, 300 DLR (4th) 443; see also *Wuttunee et al v Merck Frosst Canada Ltd et al*, 2007 SKQB 29, 291 Sask R 161.

56. *Supra* note 50 at para 77.

57. *Cooper, supra* note 31 at para 38.

58. *Supra* note 50 at para 19 (affirming motions judge ruling).

59. Medical Devices Association of Canada, "Cause for Concern: The Reuse of Single Use Medical Devices," Position Paper, (19 July 2004), online: <http://www.medec.org/webfm_send/894> [MEDEC].

60. *Hollis v Dow Corning Corp.*, [1995] 4 SCR 634 at para 20.

61. *Supra* note 10 at s 12.

During the *projected useful life* of a medical device, its characteristics and performance shall not deteriorate *under normal use* to such a degree that the health or safety of a patient, user or other person is adversely affected.⁶²

A manufacturer's duty encompasses warning consumers of dangers it knows or ought to know are inherent in the product's use. Such a duty is a continuing one, requiring manufacturers to warn not only of dangers known at the time of sale, but also of dangers discovered after the product has been sold and delivered.⁶³ In the case of medical products, the standard of care to be met by manufacturers in ensuring that consumers are properly warned is necessarily high as products that are to be "placed in the body" have a great capacity to cause injury.⁶⁴ All warnings must be reasonably communicated, but are limited to clearly describing any specific dangers that arise from the ordinary use of the product.⁶⁵ Manufacturers discharge this duty through the use of labels, advising that devices are for single use only. Section 21(1) of the *Regulations* outlines this requirement as follows:

No person shall import or sell a medical device unless the device has a label that sets out the following information:

...

(g) *the expiry date of the device*, if the device has one, to be determined by the manufacturer on the basis of the component that has the shortest projected useful life;

(h) 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.⁶⁶

Original manufacturers who label devices as single use rely on that warning to absolve them from responsibility for harm. At least one academic argues that reprocessing amounts to "deviation from product labelling" and "constitutes a superseding, intervening cause and shifts all liability to the reprocessor or re-user."⁶⁷ While it remains for a court of law to either confirm or reject this position, labelling a device as single use is likely to fulfill a manufacturer's informational duty to the consumer by

62. *Ibid* at s 13 [emphasis added].

63. *Hollis*, *supra* note 60.

64. *Ibid* at para 23.

65. *Lambert v Lastoplex Chemicals Co*, [1972] SCR 569 at para 574.

66. *Supra* note 10 at s 21(1) [emphasis added].

67. JM Hogan & TE Colonna, "Products liability implications of reprocessing and reuse of single-use medical devices." (1998) 53 Food & Drug L J 385 at 399.

providing a warning to what is termed a “learned intermediary.” This rule applies where a consumer places primary reliance on the judgment of a “learned intermediary” and not the manufacturer.⁶⁸ In the case of medical devices, it is not practical to have the manufacturer warn every patient. The learned intermediary is the healthcare professional with whom the patient has contact.

The learned intermediary rule is likely to apply to SUDs. It has been applied in cases where a product is highly technical in nature, is intended to be used only under the supervision of experts, and where the nature of the product is such that the consumer cannot not realistically receive a direct warning from the manufacturer before using the product.⁶⁹ The rule requires that the intermediary is “learned,” i.e., fully apprised of the risks associated with the use of the product.⁷⁰ Accordingly, the manufacturer can only be said to have discharged its duty to the consumer when the intermediary’s knowledge approximates that of the manufacturer. In the case of SUDs, a label identifying a device as safe for ‘single use only’ could not convey a clearer message to the intermediary.

Some commentators have suggested that an original manufacturer bears responsibility for the foreseeable misuse of its products. Given the research that shows widespread reuse of SUDs it is arguable that the reprocessing of certain SUDs is foreseeable. While there is some American jurisprudence to support this claim,⁷¹ this has not been the case in Canada. In *Ragoonanan v Imperial Tobacco Canada Ltd*, the Court held that it will examine “the user’s ability to perceive and avoid the risk” and that, “where the risk of injury is not caused by a hidden danger, but an obvious characteristic inherent in the product, and where the exercise of reasonable care by the user can completely avoid the risk, these factors point towards a finding of no liability.”⁷² Similarly, in *Robson v. Ashworth* the Court stated, “the concept of personal responsibility demands that those who knowingly and deliberately misuse a useful thing ought to be aware that the responsibility for that misuse is theirs and not that of the person who gives it to them.”⁷³

68. *Hollis*, *supra* note 60 at para 27.

69. *Ibid* at para 28.

70. *Ibid* at para 29.

71. See *Piper v Bear Med Sys*, 180 Ariz 170 (Az Ct App 1993) (holding a ventilator manufacturer liable for design defect due to reasonably foreseeable misuse by respiratory therapists, who modified an expiratory arm by adding parts when the manufacturer was aware of this process).

72. *Ragoonanan Estate v Imperial Tobacco Canada Ltd* (2000), 51 OR (3d) 603 at para 124 (Sup Ct J).

73. *Robson v Ashworth* (1985), 33 CCLT 229 (Ont Sup Ct HCJ).

3. *Third-party reproprocessors*

A third-party reprocessor is not subject to the *Regulations* provided that it does not sell medical devices under its own name or trademark. A third-party reprocessor might be subject to the *Regulations*, however, if it were to remove the original manufacturer's trademark and rebrand the item as its own or if it resold refurbished medical devices to hospitals other than the one from which they originated.

A third-party reprocessor might not meet the statutory definition of manufacturer, but could nevertheless be liable for negligence. Reprocessors undoubtedly owe a duty of care to patients who will be treated with devices that they have refurbished. A duty of care is imposed when "one who brings himself into a relation with others through an activity which foreseeably exposes them to danger if proper care is not observed, must exercise reasonable care to safeguard them from physical injury."⁷⁴

Reprocessors must ensure that their refurbishing activities are adequate to warrant the proper functioning and cleanliness of devices intended for reuse. As one academic notes, reproprocessors have a duty "to establish and maintain appropriate reprocessing protocols and to ensure that re-use of the device is safe and presents no increased risk of harm or injury to the patient above and beyond those inherent in the original use of the SUD."⁷⁵

While reproprocessors emphasize that devices may be safely reused after an appropriate refurbishing process, a patient who has suffered injury as a result of a reused SUD will undoubtedly allege a breach of the standard of care. Such a claim is likely to turn on the weight given to the departure from the device's 'single-use only' labelling. It will be incumbent upon the reprocessor to demonstrate the reasonableness of such off-label use. It is likely that a court will hold a reprocessor to the same standard of care required by original manufacturers. In *Hollis v. Birch*, the Court suggested that the liability of a manufacturer for a defect in a breast prosthesis was almost absolute because the prosthesis was inherently dangerous as it was designed to be implanted in the human body.⁷⁶ A similar logic can be applied to SUDs. In all cases the reprocessor is aware of the possibility of improper sterilization as well as the seriousness of the consequences of returning a defective device to a healthcare facility. Given that all reprocessed SUDs will come in contact with a patient, it is probable that a court will hold a reprocessor to a very high standard of care.

74. John Fleming, *The Law of Torts*, 7th ed (Sydney: The Law Book Company Ltd, 1987) at 466.

75. EP Wang, "Regulatory and legal implications of reprocessing and reuse of single-use medical devices" (2001) 56 Food & Drug LJ 77 at 93.

76. *Hollis v Birch*, [1990] BCJ No 1059 (Prov. Ct.).

4. Hospitals

The law imposes a clear obligation on hospitals to provide safe systems for the patients to whom they provide services. It is an established principle under Canadian law that hospitals owe a duty of care to patients to provide proper and adequate facilities and equipment so as to reasonably ensure patient safety.⁷⁷ This duty of care naturally extends to the maintenance of these facilities and equipment,⁷⁸ which is likely to include procedures for sterilization and the reuse of SUDs.

The off-label use of reprocessed SUDs, however, does not necessarily constitute a failure to provide an appropriate standard of care for patients.⁷⁹ A hospital will be found to have breached its standard of care if it fails to take reasonable measures to guard against foreseeable risks. In considering a hospital's conduct in the case of SUDs, the court is likely to consider the steps taken by the hospital to ensure that appropriate protocols are developed and followed. Similarly, the court may also consider industry practice by looking at the standards in place at other similar institutions.

Nonetheless, merely conforming to a pervasive practice will not necessarily shield an institution from liability if a court finds the practice, in and of itself, negligent. In *Pitman Estate v. Bain*, the Canadian Red Cross was alleged to be negligent for their failure to adequately screen for HIV infected blood. Lang J. held that, "the court is, of course, free to reject that evidence of custom, if it is of the opinion that the entire industry was negligent in adhering to the particular practice."⁸⁰

A negligence claim will also likely examine the efforts of the hospital to ensure that its employees and medical staff follow hospital policy regarding the reuse of SUDs. Hospitals have been found to have breached the standard of care for failing to adopt adequate measures to ensure that staff followed internal hospital policies.⁸¹ If a hospital can show, however, that reasonable protocols have been developed and followed, the hospital may be able to avoid liability. For example, in *Parragh v. Eagle Ridge Hospital and Health Care Centre* the plaintiff alleged that he had contracted an invasive bacterial infection as a result of negligent sterilization procedures.⁸² Expert testimony established that the hospital

77. *Briffett v Gander & District Hospital Board et al* (1992), 103 Nfld & PEIR 271 (SC (TD)); see also E Picard & G Robertson, *Legal Liability of Doctors and Hospitals in Canada*, 3d ed (Toronto: Carswell Thomson Professional Publishing, 1996) at 379 [Picard].

78. *Cherniwchan v Royal Columbian Hospital* 2005 BCSC 32, 136 ACWS (3d) 762 at para 49.

79. *Pitman Estate v Bain* (1994), 112 DLR (4th) 257 at para 272.

80. *Ibid* at para 261.

81. *Comeau v Saint John Regional Hospital et al*, 2001 NBCA 113, 244 NBR (2d) 201.

82. *Parragh v Eagle Ridge Hospital and Health Care Centre*, 2008 BCSC 1299 at para 6, 170 ACWS (3d) 729.

adopted and rigorously followed the *Recommended Standards, Guidelines, and Position Statements for Registered Nursing Practice*.⁸³ Thus the Court found it had not breached its standard of care.⁸⁴ While the hospital in this case met the requisite standard of care, this is likely to be a significant hurdle for many healthcare facilities given the current practices of limited oversight and few written policies regarding SUDs.⁸⁵

5. *Physicians*

In the vast majority of negligence cases involving a direct doctor-patient relationship, the existence of a duty is usually conceded.⁸⁶ As such, a negligence claim against a physician usually begins with an examination of the physician's standard of care, which is normally that of a reasonable medical practitioner considering all the circumstances. To quote the Court in *Crits v. Sylvester*:

Every medical practitioner must bring to his task a reasonable degree of skill and knowledge and must exercise a reasonable degree of care. He is bound to exercise that degree of care and skill which could reasonably be expected of a normal, prudent practitioner of the same experience and standing, and if he holds himself out as a specialist, a higher degree of skill is required of him than of one who does not profess to be so qualified by special training and ability.⁸⁷

The question is whether a healthcare professional falls below an appropriate standard of care in using reprocessed SUDs. The position is, perhaps, different depending on whether the physician is aware that a specific device has been reprocessed.

The physician does not know a SUD is being used

In this scenario, the first question is whether the physician was negligent in not knowing of the risk, determined by applying the "reasonable doctor" standard.⁸⁸ The Supreme Court of Canada, in *Ter Neuzen v. Korn*, noted that a physician's standard of care "must be judged in light of the knowledge that ought to have been reasonably possessed at the time of the alleged act of negligence."⁸⁹ In assessing whether the physician ought to have known, it is generally accepted that a court will look to the recognized practices

83. *Ibid* at para 61.

84. *Ibid* at paras 61-68.

85. Polisena, *supra* note 6 at 6.

86. See for example *Chasse v. Evenson et al*, 2006 ABQB 342, [2006] 399 AR 121 at para 8.

87. *Crits v. Sylvester*, [1956] OR 132 at 143 (CA), *aff'd* [1956] SCR 991.

88. *Ibid*.

89. *Ter Neuzen v. Korn*, [1995] 3 SCR 674 at para 34.

of the profession.⁹⁰ There are, however, situations where the standard practice itself may be found negligent if the standard practice is “fraught with obvious risks” such that anyone is capable of finding it negligent (regardless of their expertise in the particular area).⁹¹ In this scenario, where the standard practice would be the reuse of devices labelled single-use without informing the physician, it is arguable that such a custom is fraught with such obvious risks that the court would not defer to clinical expertise on the matter.

Despite the recommendations and guidance documents in existence from various healthcare organizations and provincial authorities, all of which recommend that a written reuse policy be in place, it is uncertain as to whether physicians could escape liability by claiming that they do not know they are using a reprocessed SUD. Most “best practice” documents and advisory bulletins are clear in advocating the importance of tracking SUDs throughout their use and reuse.⁹² Practically speaking, given the conflicting reports on the safety of reprocessing SUDs, a court is apt to expect a healthcare professional to know when an SUD device is being used and when one is not.

The jurisprudence suggests that failure to adopt alternative measures even in the face of prevailing practice among practitioners may be found to be negligent.⁹³ In *Anderson v. Chasney*, a physician performed throat surgery on a child.⁹⁴ During the surgery, sponges were used without any tape or strings attached to ensure that none was left in the throat and a nurse was not present to count the number of sponges used. One of the sponges was inadvertently left in the throat, and after the operation the child died of suffocation. At the time, the impugned practice was standard practice in hospitals. Nonetheless, the Court of Appeal held that the surgeon acted negligently. An analogy might be drawn between this case and the practice of physicians not considering the use of SUDs in their practices.

Even if a plaintiff fails to establish that the reuse of a SUD is a plain and obvious risk, a physician may still be found liable. Where a physician has or ought to have knowledge of a particular risk, the standard of care is also raised. The need for greater vigilance in these situations was affirmed in *Rietze v. Bruser*.⁹⁵ In that case, the Court held that the nature of the procedure or the patient’s condition may require the physician to meet

90. *Ibid* at para 33.

91. *Ibid* at para 41.

92. See for example *supra* notes 25-28.

93. *Ter Neuzen*, *supra* note 89 at para 44.

94. *Anderson v Chasney et al*, [1949] 4 DLR 71 (Man CA), *aff’d* [1950] 4 DLR 223 (SCC).

95. *Rietze v Bruser et al*, [1979] 1 WWR 31 (Man QB).

a higher standard of care. Thus, a court may find that a physician ought to know that an SUD is going to be reused because the very nature of reusing SUDs imposes a heightened risk of infection. In turn, a court may impose a higher standard of care on physicians to be more vigilant for such things as infectious disease stemming from the use of a reprocessed SUD. For example, in the context of post-operative care, prescribing drugs to minimize or avert an adverse effect (e.g. infection) stemming from the use of a reprocessed drill bit in a hip replacement, might be the requisite standard of care.

Conversely, there is some jurisprudence to suggest that if physicians are not made aware of certain risks, by no fault of their own, the court will be reluctant to find a breach of the standard of care. In *Kovacich v. St Joseph's Hospital*, a patient contracted a potentially life-threatening *Streptococcus A* infection after surgery.⁹⁶ The hospital's Infection Control Committee had been aware that there were similar incidences occurring in the community but this information was not forwarded to the physicians. The patient plaintiff alleged that had this information been disclosed he would not have had the surgery. The Court held that "there was no reason given the personal knowledge of the two doctors...to disclose the phenomena of *Streptococcus A* infection and necrotizing fasciitis as a risk."⁹⁷

Assessing whether a physician has fallen below the standard of care in not knowing when a SUD is being reused is highly case specific and fact dependent. This speaks to the importance of having a clear system in place so that healthcare providers are mindful of which devices are being reused and any increased risks associated with that reuse. If a court concludes that a reasonable physician would have known of the risk or ought to have known of the risk, the physician will be found to have breached their standard of care for failing to apprise themselves of the risk.

96. *Kovacich v St Joseph's Hospital* (2004), 134 ACWS (3d) 917.

97. *Ibid* at para 143.

*The physician knows that an SUD is being reused but does not disclose this to the patient*⁹⁸

It is well known that, except in very limited circumstances, patients must give their informed consent before any treatment can be lawfully provided to them.⁹⁹ For consent to be legally valid, it must be given voluntarily by a competent person who has been fully informed of the nature of the treatment and its relevant risks and benefits. The primary question is whether the patient has been sufficiently informed of any risks of the procedure which would influence a decision.

The leading Canadian decision with respect to informed consent is *Reibl v. Hughes*.¹⁰⁰ Although a physician is not required to inform a patient of every single risk associated with a procedure, the physician is obligated to disclose any material, special or unusual risks.¹⁰¹ The analysis of what constitutes a material risk includes considerations of the likelihood of the occurrence of a risk and the gravity of the potential consequences. Chief Justice Laskin held in *Reibl* that even if a risk is a mere possibility, it must be disclosed if its occurrence carries serious consequences (e.g. paralysis, death).¹⁰²

Since the decision in *Reibl*, the courts have adopted an expansive view of a patient's reasonable right to know, construing the language of "material, special or unusual risk" liberally.¹⁰³ That is, courts place little emphasis on how the risk is characterized, preferring to focus on whether a reasonable person in the patient's position would want to know.¹⁰⁴

If the physician (or hospital) can establish that there is no increase in the level of risk associated with the reused device, the court should find that it is reasonable to proceed on the basis that there is no need to obtain specific informed consent to the reuse of an SUD.¹⁰⁵ One commentator points out that "[t]he consent process is a communication between the patient and

98. While the duty of disclosure rests primarily with the practitioner who plans to carry out the proposed treatment, there is some case law which suggests the hospitals have an independent, non-delegable duty to ensure that informed consent is obtained from patients prior to medical treatment: see *LaChambre v Nair*, [1989] 2 WWR 749, 74 Sask R 87, (QB). While the non-delegable nature of this duty has been subject to comment (see E Picard & G Robertson, *Legal Liability of Doctors and Hospitals in Canada*, 3d ed (Toronto: Carswell Thomson Professional Publishing, 1996) at 146-47), hospitals should operate on the basis that they have a duty to put systems in place, such as protocols and proper procedures designed to ensure informed consent.

99. *Arndt v Smith*, [1997] 2 SCR 539 at paras 45-55.

100. *Reibl v Hughes*, [1980] 2 SCR 880.

101. *Ibid* at 884.

102. *Ibid* at 885.

103. Picard, *supra* note 77 at 128.

104. *Reibl*, *supra* note 100 at 899.

105. Wang, *supra* note 75 at 95.

physician about the procedure itself, not the instrumentation.”¹⁰⁶ Typically, “surgeons do not confer with patients preoperatively to discuss whether a hook, electrosurgical instrument or a spatula will be used to remove the gallbladder during a laparoscopic cholecystectomy.”¹⁰⁷

Alternatively, it is open to argue that patients entering a healthcare facility have assumptions about the care they are likely to receive—assumptions that undoubtedly include being treated with their own and not some set of refurbished devices. Therefore, it might be possible for a patient to claim that whether the medical equipment to be used in his treatment was reused was of material importance. Some commentators agree that a patient has the right to know if a reprocessed SUD will be used, and that they have a concomitant right to refuse treatment unless a new device is used:

It is safe to assume that most patients prefer the procedure or surgery to be performed with the lowest possible risk. By inference, most patients would not want to increase their risks unnecessarily by allowing reused medical devices to be used on them when that device was not manufactured, marketed or approved for more than a single use.¹⁰⁸

Another academic adds that where a hospital or physician has a policy with respect to reusing devices, patients should be informed of this.¹⁰⁹

In the absence of specific regulations governing the use of reprocessed SUDs, healthcare providers cannot turn to regulatory rules to determine what, if any, information must be disclosed to a patient to meet informed consent requirements. Ultimately, an obligation to disclose reuse activities will depend on several factors some of which will undoubtedly include: (1) the SUD in question; (2) scientific evidence about its reuse; (3) the relative risk associated with reprocessed SUDs in comparison to alternatives; and (4) whether reprocessing and reuse protocols contribute to significant increases in risk to the patient.¹¹⁰ If the evidence indicates an increased risk of harm, healthcare providers may have a legal obligation to disclose this information to a patient before treatment.

106. M Parsons, “The Dilemma Over the Reuse of ‘Single-Use’ Medical Devices: A Risk Manager’s Perspective” (1997) 19:3 *Today’s Surg Nurse* 17 at 18.

107. D Dunn, “Reprocessing Single-use Devices: The Ethical Dilemma” (2002) 75 *AORN J* 989 at 992.

108. D Carey, “Reprocessing and Reusing Single-use Only Medical Devices: Safe Medical Practice or Risky Business?” (2001) 17 *J Contemp Health Law Policy* 657 at 672.

109. B Dickens, “Legal Issues surrounding reuse of Disposable Medical Device: Medical Device Liability New Regulations, New Concerns” in *Proceedings of the Fourth CCOHTA Regional Symposium* (Ottawa: Canadian Coordinating Office for Health Technology Assessment, 1995).

110. Wang, *supra* note 75 at 95. See also Hogan, *supra* note 67 at 398.

III. *The international regulatory environment*

The international position on the reuse of SUDs is generally as varied and muddled as that of Canada. Some countries, however, have developed clear positions respecting the use of SUDs.

1. *United States*

In contrast to Health Canada's position, the United States Food and Drugs Administration has taken the position that hospitals and third-parties engaged in reprocessing SUDs will be subject to all the regulatory requirements currently applicable to original equipment manufacturers including pre-market submission requirements.¹¹¹ All regulatory requirements for these parties were fully implemented (via the *Medical Device User Fee and Modernization Act, 2002*),¹¹² and include a registration and listing scheme for reprocessors, inspections under the *Quality System Regulations*, labelling, adverse event reporting, corrections and removals, pre-market clearance as well as tracking requirements.¹¹³

2. *Australia*

Like the United States, there is a national regulatory framework. It was introduced in 2003 by the Australian Therapeutic Goods Administration. Under this regulatory scheme, when an SUD undergoes reprocessing it is defined as "re-manufactured" for the purpose of reuse, and so the intended purpose and design specifications for the device are considered to be altered from single-use to reusable. The person responsible for undertaking the reprocessing is considered to be a manufacturer and must comply with the therapeutic goods legislation relating to the manufacturing of medical devices.¹¹⁴

3. *United Kingdom*

Although the United Kingdom has not issued a regulatory ban, a strong statement against the practice has been issued by the Medicines and Healthcare products Regulatory Agency (MHRA). An October 2006 bulletin, entitled "Single-use Medical Devices: Implications and Consequences of Reuse" highlights the hazards and risks associated with

111. US, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, *Guidance for Industry and FDA staff: Enforcement Priorities for Single-Use Devices Reprocessed by Third-Parties and Hospitals* (14 August 2000), online: <<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM107164.htm>>.

112. *Medical Device User Fee and Modernization Act*, Pub L No 107-250, 116 Stat 1588 (2002).

113. US Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, *Notice re: Reuse of Single Use Devices*.

114. *Therapeutic Goods Act 1989* (Cth).

reprocessing and reusing single-use medical devices, and outlines the legal issues associated for such actions. The MHRA makes it clear in this document that, “devices designated for ‘single-use’ must not be reused under any circumstances.”¹¹⁵

4. *European Union*

The legal framework for medical devices comprises three Directives; the 1990 Directive on Active Implantable Medical Devices,¹¹⁶ the 1993 Directive Concerning Medical Devices,¹¹⁷ which is the main directive, and the 1998 Directive on In Vitro Diagnostic Medical Devices.¹¹⁸ Use of a device outside its original specifications, however, is not covered by the Directives. This, in turn, leaves no clear guidance with respect to the reuse of single-use devices. In 2003, the European Council published the “Report on the health implications of council directive 93/42/EEC of 14 June 1993 concerning medical devices.” The report acknowledges that the reprocessing of single-use medical devices is not banned by the Directives, but urges member states to take the necessary measures to ensure that single-use devices are not reused “as the reuse of medical devices intended for single-use only poses a risk for patients and hospital staff.”¹¹⁹ Many European countries have, in fact, taken positions with respect to reuse activities.

France, for example, has implemented an outright ban on all reuse activity,¹²⁰ while Germany provides for a strict documentation and validation process for reused SUDs, requiring proof from the reprocessor that the reprocessing procedure is safe for patients, users and other third parties.¹²¹ As well as imposing conditions on the design of SUDs, Sweden requires hospitals to obtain a patient’s informed consent to their use.

115. UK, Department of Health, Device Bulletin DB2006(04), “Single-use Medical Devices: Implications and Consequences of Reuse” (October 2006).

116. EC, *Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices*, [1990] OJ, L 189/1.

117. EC, *Council Directive 93/42/EEC as of 14 June 1993 concerning medical devices*, [1993] OJ, L 169/1.

118. EC, *Directive 98/79/EC of the European Parliament and of the council of 27 October 1998 on in vitro diagnostic medical devices*, [1998] OJ, L 331/1.

119. Eucomed, “Manifesto calling for EU regulation of all reprocessing of single use medical devices: final adoption by Eucomed and five stakeholders in healthcare.” *Press release* (March 2003, Brussels) online: CPME <http://www.cpme.be/news_press.php?id=8>.

120. Journal Officiel de la République Française, Art R 711-1.16.b.

121. MHRA Device Bulletin: Single use medical Devices: Implications and consequences of Reuse - DB2006(4) – October 2006, online: <<http://www.mhra.gov.uk/Publications/Safetyguidance/DeviceBulletins/CON2024995>>.

IV. *A recommended approach*

Without a regulatory regime regarding SUDs that provides standards, compliance provisions, and enforcement penalties, there is only a reactive tort compensation scheme that does not directly ensure the safety of SUDs. I outline three approaches to the current problem of unregulated SUDs and discuss the benefits and difficulties that flow from each alternative.

1. *Option one: Maintain the status quo—encourage provinces and territories to develop their own regulatory solutions*

Health Canada could play a supportive role in helping the provinces and territories devise their own solutions for this issue. Such solutions could involve regulations incorporating mandatory standards. This alternative would be less costly for Health Canada and the provinces would have some autonomy to determine what solution was best-suited to their needs and their existing regulatory systems.

As is already the case, some provinces have chosen to establish or maintain voluntary standards (e.g. guidelines), while others have implemented regulatory standards. This has resulted in SUDs being held to different standards depending on the jurisdiction. Such a piecemeal approach has the potential to create a hodgepodge of jurisprudence spanning the country. Eucomed (European Association of Medical Device Suppliers) notes the importance of having “national policies and legislation on the reprocessing of single-use medical devices by reprocessors, hospitals, original manufacturers and medical practitioners.”¹²² Maintaining a provincial approach to reuse activity affects the health of Canadians by subjecting them to a geographical lottery. Depending on where a patient resides, they may never be subject to reprocessed SUDs, they may be subject to reprocessed SUDs that are required to comply with rigorous standards, or they may be subject to reprocessed SUDs in a province that does not provide any direction on reuse.

2. *Option two: Attempt to ban the reuse of all single-use devices*

In light of the potential health risks posed by the practice, it may be in the best interests of patients for Health Canada to do what several European countries have done, which is prohibit reuse of any device that is labelled by the manufacturer as being intended for single use only. This option would eliminate the need to develop and maintain regulations, safety standards and quality assurance systems for reprocessing single-use devices. Given the serious cost implications associated with having to buy new devices for every procedure, some researchers suggest that Manitoba's

122. *Supra* note 119.

ban on the reuse of just critical care disposables has an estimated cost of an additional four million dollars per year.¹²³ When considering the cost implications, it is important to consider what effects such a ban would have on hospitals if the ban were to be implemented without additional funding. Would a hospital be forced to perform fewer procedures? Where else might the hospital cut funds? The answers to both these questions could have important implications for patients.

3. *Option three: amend the Medical Devices Regulations to include the activities of reprocessors*

While Health Canada may not be able to regulate the *use* of SUDs in the traditional sense, it is open for them to subject reprocessing *activities* in and of themselves to the *Regulations*. I would postulate that the origins of this sovereign power include federal authority under s. 91 of the *British North America Act* in respect of criminal law, trade and commerce, and in the residual power to legislate in the areas of peace, order and good government.

A lengthy constitutional division of powers analysis is beyond the scope of this paper, but support for this contention is briefly outlined. First, the criminal power has been held to extend to those laws that are designed to promote public peace, safety, order, *health* or other legitimate public purpose.¹²⁴ In *Labatt Breweries*, the Court held that a health hazard may ground a criminal prohibition,¹²⁵ while in *R. v. Hydro Quebec*, the Court held that “parliament has for long exercised extensive control over such matters as food and drugs by prohibitions grounded in the criminal law power.”¹²⁶ Second, the federal power to regulate in the area of trade and commerce is said to include matters of “trade affecting the whole dominion.”¹²⁷ The test in determining whether the trade and commerce head applies is whether the issue is “a question of general interest throughout the Dominion.”¹²⁸ The reprocessing, distribution and reuse of SUDs are undoubtedly matters having an impact on the country as a whole, and which can only be dealt with on an integrated national basis. Finally, it has been held that the residual powers of Parliament to legislate in the areas of peace, order and good government (POGG) apply in the context of health.¹²⁹ The POGG

123. Hailey, *supra* note 3.

124. *R v Malmo-Levine; R v Caine*, [2003] 3 SCR 571 at para 122.

125. *Labatt Breweries of Canada Ltd v Attorney General of Canada*, [1980] 1 SCR 914 at 934.

126. *R v Hydro-Quebec*, [1997] 3 SCR 213 at para 131.

127. *Citizens Insurance Company of Canada v Parsons* (1880), 4 SCR 215; see also *Labatt*, *supra* note 125 at 935.

128. *Reference Re the Anti-Inflation Act*, [1976] 2 SCR 373 at 426.

129. *Labatt*, *supra* note 125 at 934.

power is said to apply where the subject matter “goes beyond local or provincial concern and must, from its inherent nature, be of the concern of the Dominion as a whole.”¹³⁰

The importance of having a national policy with respect to the reuse of SUDs is paramount. This is a national concern that cannot realistically be satisfied by cooperative provincial action because the failure of one province to cooperate would carry with it grave consequences for the residents, and any visitors, to that province. The nature of SUD reuse has the necessary national dimension to justify the invocation of national regulations.

As has been done in the United States and Australia, Health Canada should amend the *Medical Devices Regulations* to subject reproprocessors to the same standards as an original manufacturer. Reprocessors should be required to comply with the same quality system requirements, audits, inspections, and the same mandatory problem reporting as the original manufacturer. As a result, this would provide increased safety to patients by ensuring that reprocessing is done according to established standards and regulatory control.

There are two ways to accomplish this objective. The US approach was to enact the *Medical Device User Fee and Modernization Act of 2002* (MDUFMA),¹³¹ which amends sections of the federal *Food, Drug, and Cosmetics Act* (FD&CA) to include definitions for “single use device” and “reprocessed.”¹³² The MDUFMA then adds a section to the FD&CA which reads:

(1) With respect to reprocessed single-use devices for which reports are required under subsection (k):

(A) ... [onus is on reproprocessors to] ensure that the device is substantially equivalent to a predicate device, including validation data, cleaning and sterilization, and functional performance demonstrating that the single-use device will remain substantially equivalent to its predicate device after the maximum number of times the device is reprocessed as intended by the person submitting the premarket notification.¹³³

The MDUFMA also makes it easier for patients and health care professionals to know when they are using a reprocessed device. The labelling requirements necessitate that reprocessed single-use devices prominently and conspicuously bear the statement:

130. *Ibid* at 944-45.

131. *Supra* note 112 § 302(d).

132. *Food, Drug and Cosmetics Act*, Pub L No 107-250, 65 Stat 648 (1951).

133. *Supra* note 112 § 302(b)(o)(1)(A).

Reprocessed device for single use. Reprocessed by [name of manufacturer that reprocessed the device].¹³⁴

This provision is intended to limit any liability attaching to the original manufacturer for a defect or adverse effect resulting from the reuse of SUDs. This seems like a logical place to allocate the legal risks associated with reuse. Canada's Medical Devices Technology Companies (MEDEC) have long advocated for such an approach suggesting that, "they [reprocessors] should be forced to remove the name and any distinguishing trademarks of the original manufacturer from the device and assume full responsibility for the device."¹³⁵

The enactment of a similar labelling provision in Canada would solve some of the informed consent issues mentioned earlier. First, it ensures that healthcare professionals are themselves informed when a device is reused. Second, by having a system in place that requires devices be tested and approved as safe for reuse renders any debate over disclosure unnecessary; any device being reused would, by law, pose no greater risk than their new counter-parts.

While the result of the Australian framework is the same—reprocessors are subject to the same requirements as original manufacturers—they take a more direct approach. The *Therapeutic Goods Act* 1989 has been amended to include those who refurbish medical devices within the meaning of a "manufacturer." Section 41BG reads:

(2) The manufacturer of the device is the person who does one or more of the following using ready-made products:

...

(d) fully refurbishes the device¹³⁶

Both of these approaches are successful in requiring any party who endeavours to reprocess to not only be licensed to do so, but also to demonstrate that their devices are safe for reuse before any of their reprocessed devices are allowed to be used on patients. If a hospital or a third-party can show that they are able to reprocess a single-use device and restore its original specifications without increasing the risk to patient safety, there is no obvious reason to prohibit such an activity. While some may argue that this approach will likely be difficult to implement, it is important to note that it involves little in the way of legislative amendment

134. *Supra* note 112 § 302(a)(1).

135. *Supra* note 59 at 9.

136. *Supra* note 114 at s 41BG.

and could piggy-back the same licensing and compliance enforcement system already in place for original manufacturers.

What is certain is that by subjecting reproprocessors to the same standards as original manufacturers, there is a strong incentive to develop sound reuse practices. Contravention of the *Food and Drugs Act* or the *Medical Devices Regulations* can result in both hefty fines and substantial jail time. In addition, reproprocessors could lose their medical devices license. While one would like to think that the potential to inflict harm would be enough to convince reproprocessors to develop rigorous standards, the reality is that this may not be the case. Without regulation, one might find it more economical to run the risk of having to pay an injured claimant than to implement the testing procedures required to ensure the safety of their reprocessed devices. However, the imposition of jail time or the loss of a license is likely to discourage unsafe practices.

It is important to remember that labelling a device as single use is at the sole discretion of manufacturers; all the label means is that the device has not been tested as safe for reuse. While some medical devices are likely never to be safe for reuse (e.g. needles), there is some suggestion from the American courts that manufacturers often label a device single use solely to (a) avoid the testing costs inherent in labelling a device as safe for multiple uses; (b) to increase revenue by selling more units; and (c) to attempt to avoid liability.¹³⁷ This may mean that many items currently labelled single use could be just as safe as their reusable counterparts. Reprocessors should be encouraged to develop refurbishing schemes that are safe and effective in returning devices to their original forms. It not only helps eliminate biomedical waste, but provides a disincentive to original manufacturers to label a device as single use without it being necessary; if a manufacturer labels devices as single use with the intent to profit on increased sales, they are not likely to cash in on such a tactic if hospitals are prepared to refurbish devices labelled as single use.

Thus while it is likely that an injured patient would have recourse through the tort system, litigation presents many uncertainties and challenges for a potential plaintiff. The implementation of a regulatory system, while not precluding a claim in tort, is a proactive approach that works to lessen the chance of patient injury from improperly reprocessed SUDs by placing a bigger burden on reproprocessors.

137. *United States Surgical Corp v Orris Inc*, 5F, Supp 2d 1201 at 1207 (1998).

Conclusion

Reuse of SUDs has been touted as an important cost-saving strategy in response to escalating healthcare costs, and continues to be common practice in the healthcare community.¹³⁸ Until courts or regulators decide otherwise, many legal questions with respect to this practice remain unanswered. As such, those who are involved in reprocessing devices labelled as “single use only” need to carefully consider the potential for legal liability associated with reuse activities. Similarly, any economic benefits stemming from reuse must be weighed in light of the health risks associated with the reusing of SUDs. While a blanket policy against reuse may be risk adverse, it is not cost effective or practical. Patient risks and institutional liabilities would be best served if Parliament were to amend the *Medical Devices Regulations* to include reprocessing within the definition of manufacturing. By subjecting reproprocessors to the same requirements as an original manufacturer, there will be a structured set of expectations for those involved in the reprocessing practice and national consistency in terms of patient care.

138. Polisen, *supra* note 6.