ABSTRACT

This article explores the criteria for catastrophic impairment with respect to mental and behavioural functioning as defined by the Ontario Statutory Accident Benefit Schedule (the “SABS”) in s. 2(1.1)(g). It reviews the relevant areas of the SABS, along with key arbitrations and court rulings. This article also explores Designated Assessment Centre (“DAC”) guidelines and conventions as applied to determination of catastrophic mental and behavioural impairment. It concludes with a perspective from rehabilitation psychology, utilizing the framework and approaches offered in the American Medical Association’s Guides to the Evaluation of Permanent Impairment, fourth edition, 1993 (the “AMA Guides”), and offers a comparison with these other sources.

THE SABS

The Ontario Statutory Accident Benefit Schedule (the “SABS”) is remedial in nature and intended to protect consumers, supporting the intention of returning motor vehicle accident victims to their pre-accident functioning. Healthcare benefits covered under the SABS include attendant care, medical and rehabilitation expenses, income replacement, and housekeeping expenses. The SABS provides for two tiers of benefits. This two-tier system follows the assumption that, in general, those with more significant impairment levels potentially will require access to a higher level of benefits. When a person meets criteria set out in the SABS for catastrophic
improvement, the second, significantly increased tier of benefits becomes potentially available. The SABS enumerates eight different tests for catastrophic impairment. If any of the tests are met, the person is considered catastrophically impaired. This article concerns itself specifically with the eighth test, defined according to s. 2(1.1)(g) of the SABS as follows:

an impairment that, in accordance with the American Medical Association’s Guides to the Evaluation of Permanent Impairment, 4th edition, 1993, results in a class 4 impairment (marked impairment) or class 5 impairment (extreme impairment) due to mental or behavioural disorder.5

The relevant chapter in the 4th Edition of the AMA Guides is Chapter 14, Mental and Behavioral Disorders.4 Chapter 14 lays out a system for the qualitative rating of mental and behavioural impairment. It describes four functional classes: activities of daily living; social functioning; concentration, persistence and pace (task completion); and deterioration or decompensation in work or work-like settings (adaptation). Clinicians rate impairment in each of these classes qualitatively, using an ordinal scale: none, mild, moderate, marked, and extreme. Differences of opinion exist with respect to how many classes of marked or extreme impairment are required to meet the SABS g test for catastrophic impairment, as the wording of the test is open to interpretation.

COURT RULINGS AND FSCO ARBITRATIONS

A number of court rulings and arbitrations address the issue of how many classes of marked or extreme impairment satisfy the SABS g test for catastrophic impairment. Here I review briefly the cases that most directly address this issue, pointing to a single class of marked or extreme impairment as sufficient to satisfy this test.

In the court case of Desbiens v. Mordini, Justice Spiegel notes the following in para. 129 with respect to a single class of marked impairment being sufficient to meet the SABS g test for catastrophic impairment:

In the area of adaptation (deterioration or decompensation in a work-like setting), Dr. Finlayson found that Mr. Desbiens’ impairment fell within a Class 4 (marked impairment) in which the impairment levels “significantly impeded useful functioning”. It is not disputed that it is sufficient for Mr. Desbiens to establish that his impairment in any one of the areas of functioning meets the requirements of clause (g).5

H. and Lombard General Insurance Company of Canada is a FSCO Arbitration heard before Arbitrator Renahan.6 This arbitration notes that Ms. H.’s
DAC assessors found it “unfortunate that Justice Spiegel did not clarify the context of his statement in Desbiens that it was not disputed that one class 4 marked impairment was sufficient to satisfy the definition of ‘catastrophic impairment’ in clause (g)”7. In other words, there is potential ambiguity whether Spiegel J. concludes that only one marked class of function is needed to establish catastrophic impairment, or whether he is simply noting that the parties did not dispute that one class was sufficient for Mr. Desbiens to satisfy the SABS g test. In Ms. H.’s case, Arbitrator Renahan leaves no doubt in his conclusion regarding the number of spheres of marked impairment required to satisfy the SABS g test for catastrophic impairment:

Since she satisfies a marked impairment under one of the aspects of functioning described in (sic) chapter in the Guides dealing with mental and behavioural disorders, she has suffered a catastrophic impairment with the meaning of section 2(1)(g) of the Schedule.8

In a more recent FSCO arbitration, Anna Pastore and Aviva Canada, Arbitrator Nastasi comments at length regarding the issue of how many classes of marked impairment are sufficient to satisfy the SABS g test for catastrophic impairment. She concludes clearly, “I find that one marked impairment is adequate to meet the definition of catastrophic impairment”.10 In coming to this conclusion, she bases her reasoning on the highly interrelated nature of the four functional classes described in Chapter 14 of the Guides, as well as the awareness that each of the classes represents functioning “in a basic and core area of life”.11 She also states, “Given the importance of each area of function the loss of any one alone is significant and adequate to meet the definition of catastrophic impairment. To accept one marked impairment is in line with a remedial approach to the Schedule”.12

DAC GUIDELINES

The SABS provided for a system of Designated Assessment Centres (“DACs”), which an amendment then phased out, effective March 1, 2006. DACs carried out assessments and produced reports under a set of guidelines drafted by The Minister’s Committee on the Designated Assessment Centre System. DAC guidelines addressed catastrophic impairment assessments, and initially provided specific direction with respect to the issue of how many marked or extreme classes of functioning are required to meet SABS g criteria for catastrophic impairment.

In December 1997, FSCO released a CAT DAC Interim Manual (the Interim Guidelines)13 offering the first detailed protocol for assessment of catastrophic impairment. This manual advises the use of a staged assessment with respect to mental and behavioural impairments, looking first at impairment in the domains of activities of daily living, social functioning, and concentration, persistence and pace. The Interim Guidelines indicates that two marked impairments among these classes would meet the definition of catastrophic, and that the claimant would be classified “at (4) Marked overall.”14 The Interim Guidelines further suggests that if only one class is classified as marked, then the assessment would proceed to determine the level of impairment in the fourth class of functioning, adaptation. If the claimant then were also found to have marked impairment with respect to adaptation, they would meet the definition of catastrophic. It is not clear why the Interim Guidelines suggests such a staged approach to the assessment of mental and behavioural impairment. Chapter 14 of the AMA Guides does not support such an approach. Chapter 14 suggests that functioning be assessed with respect to all four classes.

Subsequent DAC guidelines removed the language with respect to a staged assessment of mental and behavioural impairment. They also removed language with respect to how many classes of marked impairment would be required to meet the definition of catastrophic. The April 2002 Catastrophic Impairment Designated Assessment Centre Assessment Guidelines,15 which is the last drafted revision, provides the following language:

Final classification of impairments due to mental and behavioural disorders will take into consideration the four functional domains of ADL; social functioning; concentration, persistence and pace; and, work adaptation, under five levels of severity ranging from no impairment to extreme impairment. The SABS directs that catastrophic impairment is met when an individual reaches marked or extreme impairment (Class IV or Class V impairment) due to mental or behavioural disorder.16

Though the language in the revised Guidelines is unclear with respect to the number of classes of marked impairment required for catastrophic designation, the convention of requiring two classes of marked impairment remained general practice among catastrophic DAC assessors. The original reasoning for the guideline requiring two classes of marked or extreme impairment appears to come directly from an interpretation of a few sentences in Chapter 14 of the 4th edition of the AMA Guides, rather than from a broader psychological perspective on the chapter’s approach to impairment analysis as it is nested in the overall context of the AMA Guides. The relevant passages in Chapter 14 are as follows:

marked: is a level of impairment that significantly impedes useful functioning. Taken alone, a
“marked” impairment would not completely preclude functioning, but together with marked limitation in another class, it might limit useful functioning.17

and:

Marked limitation in two or more spheres would be likely to preclude performing complex tasks without special supports or assistance, such as that provided in a sheltered environment.18

RAISING QUESTIONS

From a psychological perspective, it is not clear that the decision to require two marked or extreme classes (as suggested in the Interim Guidelines) follows sound clinical reasoning. It may also be discriminatory with respect to people suffering mental and behavioural impairments by placing a higher bar to be met for catastrophic impairment than the requirements for physical impairments. For example, a person whose arm is amputated at the shoulder as a result of a motor vehicle accident is assigned a whole person impairment (“WPI”) rating of 60 per cent.19 This rating exceeds the SABS f criterion that requires a whole person impairment rating of 55 per cent or more to be considered catastrophically impaired.20 Assuming a healthy emotional adjustment (no mental or behavioural impairment), loss of the entire arm may “significantly impede useful functioning”, but likely would not “completely preclude functioning.”21 This person would be considered catastrophically impaired according to SABS f. Clinically, it is not clear why such a high bar, completely precluding functioning, was then applied by the Interim Guidelines with respect to the number of mental and behavioural classes of marked or extreme impairment required to be considered catastrophically impaired by SABS g criteria. The remainder of this article explores further a psychological perspective with respect to the number of marked or extreme classes of functioning required for catastrophic impairment.

RE-EXPLORING CHAPTER 14 OF THE AMA GUIDES

The framers of the AMA Guides chapter on mental and behavioural impairments (Chapter 14, 4th edition), turned to the model used by Social Security for disability assessments in the United States. The chapter describes four functional classes. Though they each focus on human functioning through a unique lens, they also overlap considerably. As noted earlier, these four classes are activities of daily living, social functioning, task completion, and adaptation. Each class represents an essential domain of mental and behavioural functioning, or as Arbitrator Nastasi puts it, a basic and core area of life. Because they overlap, any significant impairment in one class likely means some degree of impairment in the other three. Shopping is an activity that illustrates this overlap, as it can be considered in an impairment analysis in the first three functional classes. It is an activity of daily life, and there are social elements involved. It is also a sample of a person’s ability to complete tasks in an uncontrolled environment, requiring concentration and the ability to persist, and can be explored in terms of pace. Cooking is another example of an activity that can be viewed in more than one domain, as it is an activity of daily life and also requires an ability to concentrate, persist and pace in order to complete. There are social elements involved in many activities of daily life, as well as in work and work-like settings. Concentration is an element that is essential to most daily activities, social interactions, and work activities.

Given that the AMA Guides is grounded in a framework for social security disability assessments, it is not surprising that Chapter 14 places a significant focus on adaptation to work or work-like settings, which typically is seen as the most complex domain of human behaviour. Assessment of a person’s ability to function in the first three classes provides useful information in forming an inference about that person’s ability to function in the complex realm of a work or work-like setting. Functioning in a work or work-like setting can be seen to subsume many of the essential elements of functioning in the other three classes.

ASSESSING MENTAL AND BEHAVIOURAL IMPAIRMENTS

Justice MacKinnon points out that, “The Guides were clearly not designed by the AMA for the purpose directed by the Ontario legislature. They must be interpreted in a manner that is contextually consistent with the language of the SABS.”22 That language is remedial in nature, providing a context that assumes a consideration of healthcare needs in the assessment of impairment. Justice Spiegel, in Desbienens v. Mordini, also reminds us of the remedial nature of the legislation, and in particular the emphasis on fairness to recognize the significantly greater healthcare needs of those victims who are catastrophically impaired.23 In other words, impairment determinations are not simply intellectual exercises, as they are nested in the very human context of healthcare needs. Though the AMA Guides may not have been designed to assess treatment or care needs, when assessing psychological impairment a consideration of such needs helps inform more fully an understanding of the severity of mental and behavioural impairments.

Chapter 14 of the AMA Guides provides an outline for assessing mental and behavioural impair-
ments. The approach described in this chapter includes the formulation of a complete multi-axial DSM diagnosis. A multi-axial diagnosis is not complete without a Global Assessment of Function, or GAF. The GAF is often misunderstood and misapplied narrowly as only an assessment of symptom severity, but the scale ranges include ratings for both symptom severity and mental and behavioural functioning. It can be applied specifically to arrive at a solely functional rating. In fact the name of the scale itself (Global Assessment of Function) highlights its use in the assessment of function. As applied to an analysis of mental and behavioural impairments across four classes of functioning, the GAF is useful in providing a global, or overall, indicator of mental and behavioural functioning.

Applying the reasoning used in determining a GAF to analyzing a patient’s level of functional impairment across the four classes described in the AMA Guides chapter on mental and behavioural impairment results in a more holistic understanding of the four classes. The more severe the functional impairments are across the four classes, the lower the patient’s GAF will be. How the GAF might be useful in determining a quantitative WPI with respect to mental and behavioural impairments is not explored here. This article raises the notion of the GAF simply to facilitate understanding of the differences among overall, average and combined approaches to rating.

It is important to understand that the GAF is a global measure, not an average assessment of function. This is an essential distinction. A global or overall approach to the assessment of impairments takes all impairments into account, unlike an averaging approach, and thus helps the clinician to develop more sound treatment and care planning. For example, using an averaging approach to assess a patient with the ability to do self-care on a daily basis, but unable to function in the work place, underestimates the severity of overall impairment, and does not allow for adequate treatment/rehabilitation planning or provision of care.

A parallel example from the physical realm is a patient who has lost his or her entire arm and also has total loss of vision in one eye. A WPI of 60 is applied for the arm being amputated, and a WPI of 24 is applied to the total loss of vision in one eye. An averaging approach applied to separate impairments establishes a WPI for this patient of 42, which clearly underestimates the patient’s overall impairments (the patient with the loss of an arm and an eye ends up with a lower rating than a patient who has only lost an arm). The AMA Guides uses a combining approach to capture better the overall physical impairment when there are two or more separate impairments, resulting in a WPI of 77 in the example above.

It bears stating that Chapter 14 of the AMA Guides applies ordinal rating categories (nil to extreme) to the four classes of functioning. As such, basic statistics informs us we cannot average these ordinal ratings. Further, the domains, as noted earlier, have a significant amount of overlap. As such, again from a statistical perspective, an average of overlapping ordinal ratings is even less meaningful.

The one example provided in Chapter 14 indicates only an overall rating. This is an unfortunate example, as there are two classes rated as markedly impaired, and two classes as moderate, and does not help to clarify what an overall rating means. Despite this shortcoming, the language used is important. The example offers an overall impairment rating. Though an overall rating is often confused with an average, it is actually more consistent with the notion of a global rating, such as the rating provided by a GAF that is fundamental to a multiaxial psychological diagnosis. Nowhere in this chapter nor elsewhere in the AMA Guides, is the notion of overall equated with averaging.

The AMA Guides combines quantitative impairment ratings as a common method for arriving at overall impairment ratings. In the case of the four qualitative classes in Chapter 14, this is statistically meaningless. Further, because of the substantial overlap among classes, it may result in an overestimate of impairment. When we look to other chapters in the AMA Guides for assistance with the issue of an alternative to combining the ratings for the four classes of mental and behavioural impairment, we find the idea of taking the person’s highest impairment rating among a number of overlapping rated areas to stand for the patient’s level of impairment. For example, when rating cerebral impairment, Chapter 4 (The Nervous System), advises:

A patient may have more than one of the types of cerebral dysfunction noted above. The most severe of the first five categories shown above should be used to represent the cerebral impairment.

Clinically, this also is most consistent with the notion that an assessment of impairment points ultimately to a patient’s treatment and care needs, which are underestimated if an average rating is chosen, and overestimated if overlapping categories are combined. It is seen as enough to take the most severe impairment as representative of the overall impairment, as each category represents a significant, or core, aspect of cerebral functioning. However, it should be noted that a person with impairments in multiple classes may well be more impaired and require more services than a person with impairments in only one class. Thus it is meaningful and important to detail all classes of impairment, while being mindful that the class with
the highest level of rated impairment represents only the minimal overall level of impairment that can be counted on as reliably present.

Returning to Chapter 14, we remain faced with determining an approach to overall impairment rating, given four overlapping classes of mental and behavioural functioning that are rated. We already have seen in the AMA Guides that combining is not used in such situations. Also, statistically it makes no sense to apply a combining method to the ordinal ratings on the four classes found in Chapter 14, just as it makes no sense to average them. We are left with the method used elsewhere in the AMA Guides when impairments overlap: choosing the highest level of impairment among these four classes as standing for the patient’s level of impairment, as the patient will exhibit at least that level of impairment, along with whatever levels of impairment are determined in the other classes. If one class is markedly impaired, then useful functioning is, at least, significantly impeded in a basic and core area of life.

The arbitral decision to take one class of marked or extreme impairment as satisfying the SABS g test for catastrophic impairment is most consistent with the approach found in the AMA Guides when two or more impairments overlap. This approach also avoids either overestimating (combining) or underestimating (averaging) a person’s level of mental and behavioural impairment, which is most consistent with the notion of accurately planning for treatment, rehabilitation and care needs, as well as the remedial nature of the SABS. The person’s overall mental and behavioural impairments can be expected to be at least as severe as their highest impairment rating among the four classes, resulting in the most clinically useful and meaningful rating. If the most severely rated class stands for the patient’s overall mental and behavioural impairment, then one marked rating, indicating useful functioning is significantly impeded in at least one core and basic area of life, is sufficient to meet the SABS g test for catastrophic impairment. As such, a rehabilitation perspective in psychology is consistent with the prevailing trend in the arbitrations on the issue of how many classes of marked or extreme impairment are necessary to establish catastrophic impairment with respect to SABS g.

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Effective July 1, 2010, Ontario will eliminate its Provincial Retail Sales Tax ("PST") and harmonize with the federal Goods and Services Tax ("GST") to create a single value-added tax known as Harmonized Sales Tax ("HST").

KEY POINTS

- The HST rate will be 13 per cent (five per cent federal + eight per cent provincial).
- Businesses currently registered for Ontario PST purposes will cease filing PST returns for periods after July 1, 2010.
- The Canada Revenue Agency will audit and administer the HST, meaning businesses will file a single sales tax return — a GST/HST return — with the federal government.

IMPACT ON HOSPITALS AND FOUNDATIONS

Presently, hospitals and other charities such as foundations, pay GST on most of the goods and services that they purchase in the course of their operations, but they only generally pay PST on purchases of tangible personal property, a select number of services and some insurance premiums.

Following harmonization, the HST will generally apply to all of the same property and services that the GST is presently applied to, including most real property, intangible property and services.

For entities engaged entirely in GST-taxable activities, this harmonization will have little negative impact because such entities are entitled to fully recover the HST that they will pay by way of input tax credits.

Hospitals and foundations, on the other hand, are not generally entitled to such input tax credits and instead must rely on the public sector body rebate to recover a portion of their GST expenses.

As with the GST, hospitals and other charities, such foundations will generally pay HST on most of their purchases and will have to rely on new public sector body rebates of the eight per cent provincial component of the HST.

The new rebates are to be paid out to hospitals at a rate of 87 per cent and to other charities and qualifying not-for-profits at a rate of 82 per cent. Accordingly, hospitals will generally recover 83 per cent of the five per cent federal portion of the HST and 87 per cent of the eight per cent provincial portion of the HST. Similarly, charities, such as foundations, will generally recover 50 per cent of the five per cent federal portion of the HST and 82 per cent of the eight per cent provincial portion of the HST.

These rebate figures were designed to approximate the amount of net PST that hospitals and other charities incur so that their net sales tax costs in a given year would not increase. However, until each hospital and foundation looks to its own spending patterns and any upcoming major expenses, it will be impossible to determine whether these rebates are actually tax neutral.

Accordingly, during this period before harmonization takes effect, all Ontario hospitals and their foundations should be reviewing their plans for the next 12 months so that they can take advantage of the time that still remains before harmonization to make those purchases that are not subject to PST presently, but that will become subject to HST.

Some of the more notable goods and services that will become subject to HST but that are not subject to PST include custom software, consulting services, and commercial real property (there is no intention to eliminate Ontario’s Land Transfer Tax upon harmonization).

In conducting such reviews, hospitals and their foundations should be cognizant of the Transition Rules that were announced on October 14, 2009. These Transition Rules will govern the application of the PST and HST for purchases of services and property between now and July 1, 2010, as well as leases and licences that straddle this date.

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A patient is in the intensive care ward. He is suffering from pancreatic cancer, is unresponsive, has great difficulty breathing on his own and will require assisted ventilation in order to survive. The patient has a properly executed power of attorney for personal care (sometimes called an advance directive), naming his best friend as his attorney for personal care and instructing that under no circumstances is he to be connected to a ventilator. The patient had provided his family physician and his friend with a copy of the power of attorney.

The physician consults with the patient’s wife regarding the use of the ventilator and the wife who is terrified that her husband will die, instructs the physician to do everything possible to keep her husband alive. The physician, aware that ethical issues are involved, calls in the hospital’s bioethicist for a consultation. The bioethicist presumes that the wife is the appropriate substitute decision maker, suggests that the rest of the family be consulted to ensure that the decision is supported by all and advises the physician to listen to the wife’s instructions.

The husband is connected to a ventilator, awakes and learns that he will need to be connected to the ventilator for the rest of his life. He sues the physician for the tort of battery and names the bioethicist in the suit on the basis of negligence. His lawyers argued that the bioethicist should have inquired as to whether there was a power of attorney, that she recommended the wrong substitute decision maker and did not ascertain if the patient had expressed prior capable wishes relevant to the use of a ventilator.

INTRODUCTION

Bioethicists are increasingly being hired on or engaged on a case-by-case basis at Canadian hospitals and other healthcare institutions to work with patients, families, healthcare professionals, administrators and researchers in addressing ethically complex healthcare challenges related to a wide range of clinical, organizational and research-related issues. Specific consultations generally center around cases where parties disagree as to the ethically acceptable options. Some common sources of such tension include end-of-life decisions, consent, disclosure, priority setting, and balancing of expected harms and benefits associated with clinical care or research.

Although most bioethicists have completed graduate training in bioethics and are increasingly working as part of the clinical healthcare team, the profession remains unregulated in Canada. There is no title protection for the term “bioethicist”, which means that anyone is permitted to call him or herself a bioethicist and to practise bioethics. There is no mandatory level of education or certification required. There is no specific code of ethics which governs the profession, no regulatory body nor delineation of a scope of practice.

The law regarding the legal liability of bioethicists in their day-to-day work is not yet clear. As well, there is very little case law in Canada pertaining to the standard of care required for unregulated healthcare providers in general. Given that to date, bioethicists have not been successfully sued for ethics consultations — is legal vulnerability a legitimate concern?

While legal claims against bioethicists participating on research ethics boards have been put forward, there has yet to be a full legal action in Canada based on a bioethicist’s professional activities within a healthcare institution. The jurisprudence that is available, however, offers some insight into the potential legal liability that Canadian bioethicists may face in the future and the standard of care that might be applied.

The goal of this article is to provide a current analysis of the major liability issues that bioethicists might face in a negligence suit. It is essentially a wake-up call for bioethicists, those who consult with bioethicists, as well as, those who employ these professionals to consider some of the potential legal consequences stemming from bioethics practice.

RECENT EXPOSURE OF BIOETHICISTS TO LEGAL LIABILITY

In Weiss v. Solomon, a research subject died after undergoing a fluorescein angiography. Interestingly, in addition to finding the principal investigator liable for negligence for failing to emphasize the risks of fluorescein angiography on the consent form and for not being more selective in the choice of partici-
pants, the court found the hospital, through its research ethics board, also liable for those reasons. The finding in Weiss exemplifies how bioethicists who consult on research studies may be found liable in negligence actions. It instructs how the elements of a negligence action may be interpreted and applied with respect to research ethical boards, and by extension, bioethicists who sit on the Boards.

Similarly, in Grimes v. Krieger Institutional Inc., the claimants argued that Krieger Institutional Inc., as the medical researcher, breached its duty of care by failing to: (1) design a study that did not involve placing children at unnecessary risk, (2) fully inform the participants of all the risks, and to (3) inform the participants of the results in a timely manner. The court in this case held, that “informed consent agreements in nontherapeutic research projects … can constitute contracts; and that, under certain circumstances, such research agreements can, as a matter of law, constitute “special relationships” giving rise to duties, out of the breach of which negligence actions can arise”.

In Gelsinger v. Trustees of the University of Pennsylvania, an 18-year-old who volunteered to participate in a corrective gene study, died during the course of the study. A bioethicist was one of the named defendants regarding the action in negligence. Similarly, in Robertson v. McGee, a case involving a research study on a melanoma vaccine, the bioethicist that consulted with the research ethics board was named as a defendant. Although Gelsinger settled for an undisclosed amount, and Robertson was dismissed for lack of subject matter jurisdiction, the naming of the bioethicist in both cases is instructive. It sheds light on the potential liability that bioethicists may face in the future, and specifically, how an action in negligence can be brought against them. Other examples where research ethics boards have been named in actions include: Hamlet v. Genentech, Inc., where the Western Institutional Review Board was named as a defendant, Wade v. Oregon Health and Science University, which listed 12 members of the IRB board as defendants, and Scheer v. Burke, which listed the chairman of the IRB as an individual defendant.

The small number of litigated cases should not lull bioethicists into a false sense of legal security. Given that bioethicists are providing a wide range of services, and are increasingly holding themselves out as health-care professionals, legal action in the near future is quite probable. It has been over 12 years since Gordon Duval’s exploration of liability considerations for clinical bioethicists and over seven years since David Sontag’s consideration of the potential legal liability of individual bioethicists practising in the United States. The current Canadian climate is characterized by the varied and evolving role of bioethicists. Relevant activities include the recent development by the Canadian Bioethics Society (“CBS”) Taskforce on Working Conditions for Bioethicists of the Model Job/Role Description for Bioethicists in Canada, the CBS’ Draft Model Code of Ethics for Bioethicists, the work of Practicing Healthcare Ethicists Exploring Professionalization (“PHEEP”), the University of Toronto Joint Centre for Bioethics CORE Network Working Group on Professionalization/Credentialing of Bioethics, as well as the extensive work being pursued related to potential professionalization by members of the American Society for Bioethics and Humanities (“ASBH”) including the second edition of the Core Competencies for Healthcare Ethics Consultation currently out for consultation. Such activities having created a professional climate warranting an updated legal analysis matched to the current expectations related to the role of bioethicist and the range of activities performed by bioethicists in Canadian healthcare institutions. Recent case law and guidelines provide an overview of the major issues pertaining to the legal vulnerability of Canadian bioethicists.

The relevant documents suggest that bioethicists can no longer rely on a level of ambiguity that may have protected them from liability in the past. While there has yet to be a direct Canadian precedent describing the nature of a bioethicist’s legal responsibilities, or potential legal vulnerability for their institutional work, it is only a matter of time until this issue is brought forward for judicial attention.

THE ROLE OF BIOETHICISTS IN CANADIAN HEALTHCARE INSTITUTIONS

It is an understatement to say that bioethicists working in Canadian healthcare institutions have
varied roles and responsibilities. Not only do these professionals come from a variety of educational disciplines, but the work they actually perform within healthcare institutions is often tailored to their unique expertise and the specific needs of the institution in which they are working. The Model Job/Role Description outlines the range of work that may be taken on by bioethicists in Canada.

- Developing and Managing Ethics Program Infrastructure
- Organizational Ethics Leadership
- Identification of Ethics Issues
- Ethical Consultation
- Policy Development
- Education
- Research Dissemination
- Professional Development

While it is unlikely that any one bioethicist could perform — in a sustainable fashion — all the activities outlined in this document, they represent the range of activities one could reasonably expect a bioethicist to be capable of performing.

The role of the bioethicist is “to provide leadership and support regarding the ethics of clinical care and hospital management. The ethicist works to build capacity for ethical decision-making, promotes a thriving moral community within the hospital to improve patient care, and creates integrated, sustainable and accountable ethics resources from bedside to boardroom.”

It is generally the case that bioethicists have, as a minimum level of education, a Masters or terminal professional degree (e.g. J.D./MD). Practical experience, such as an ethics fellowship, internship or a leadership role on a clinical or research ethics committee is often a component of preparatory training. Finally, bioethicists can be reasonably expected to have the skills and attributes defined in recent publications proposing core competencies in the field.

ELEMENTS OF A NEGLIGENCE ACTION BROUGHT AGAINST A BIOETHICIST IN CANADA

It is very likely that any action against a bioethicist would be based in negligence. Negligence is a broad cause of action that is open to continued growth because its conceptual framework can be applied to new situations and relationships. A claimant must prove four elements for a successful negligence claim. These are: (1) duty of care; (2) a breach in the standard of care; (3) harm suffered by the claimant (material damages); and, (4) sufficient causation between the actions of the defendant (the bioethicist) and the harm suffered by the claimant. These elements would need to be proven in a sequential order, starting with whether a bioethicist owed a duty to the claimant and then moving through the other three elements. If the claimant would be unable to prove any of the four elements, then the bioethicist would not be found liable for negligence against the claimant, and would not have to pay damages. In Donoghue v. Stevenson, Lord Atkin stated, “The rule that you are to love your neighbour becomes in law, you must not injure your neighbour; and the lawyer’s question, Who is my neighbour? receives a restricted reply. You must take reasonable care to avoid acts or omissions which you can reasonably foresee would be likely to injure your neighbour”. Accordingly, the threshold question in any negligence action is determining whether someone is your neighbour, or legally speaking, whether the defendant owes a duty of care to the complainant.

1. DUTY OF CARE

First and foremost, the claimant must demonstrate that the bioethicist owed him/her a legal duty of care. This means that a legal relationship must exist between the bioethicist and the claimant. Cooper v. Hobart is the leading Canadian case on the duty of care. In determining whether to impose a duty of care, the Supreme Court of Canada set out a two-part test. The first part of the test requires both reasonable foreseeability of harm and a relationship of sufficient proximity to make the imposition of a duty of care fair. The second part requires courts to consider overriding policy reasons for negating the duty of care. The classic articulation of which relationships are close enough to satisfy the first part of the test, and attract a duty of care, can be found in Donoghue where the House of Lords identified which persons are legally one’s “neighbours”.

In considering whether bioethicists can be considered to owe a duty of care to patients, Duval noted that there is “little doubt that the patient is a person so closely and directly affected by the consultant’s ethics advice that the consultant ought reasonably to have had the patient in contemplation when giving such advice”. However, there is some debate as to whether the bioethicist’s duty lies with certain individuals such as the doctor, the patient, and others. In most cases, bioethicists will receive “the first call”
from the physician or another member of the healthcare team, as opposed to the family or individual patient. Therefore in the eyes of Donnie Self and Joy Skeel, “if a traditional understanding of consultations in the medical setting is applied to ethics consultations, then clearly the client or recipient of the efforts of a bioethicist is the physician.”38 Andrew Merritt counters this argument by noting that bioethicists should be held to a duty of care in the same way a consulting physician owes a duty of care to the patient — even if the consulting physician never meets directly with the patient.37 He argues that bioethicists owe a duty of care “whenever they are consulted to further the interests of patients”.38 Others believe that the court could also rely upon a fiduciary relationship between the bioethicist and the patient to find a duty of care.39 A fiduciary relationship is described as “one of trust and dependence that, in the medical context, imposes upon the medical practitioner a [set] of particular obligations to the patient — including those of utmost good faith, loyalty, honesty, respect for confidential information, and an obligation to act in the patient’s best interests”.40

Canadian courts seem to be quite comfortable finding that if medical practitioners are holding themselves out as capable of performing a professional task, then they are liable for the consequences resulting from their actions. In Gibbons v. Harris,41 the Alberta Supreme Court, Appellate Division, held that a chiropractor was liable for damages resulting from his failure to correctly diagnose an ailment and his application of the wrong method of treatment.42 At the time, chiropractors were not regulated, yet that did not stop the court from finding that the chiropractor was a medical practitioner.

A medical practitioner, whether he be registered or not, impliedly undertakes that he is possessed of a reasonable amount of knowledge and skill necessary for the performance of any professional task upon which he enters, and any such person who for reward or in the performance of a duty, either through negligence or ignorance, causes injury to a patient, is liable in damages for the consequences resulting therefrom.43

Even more telling, the judge was willing to apply a broader rule to establish a duty to include “all persons professing any special skill”.44

The practice of a profession, art, or calling which, from its nature, demands some special skill, ability and experience, carries with it a representation that the person practising or exercising it possesses, to a reasonable extent, the amount of skill, ability, and experience which it demands. Such a person is liable for injury caused to another to whom he owes a duty to take care, if he fails to possess that amount of skill and experience which is usual in his profession or calling, or if he neglects to use the skill and experience which he possesses or the necessary degree of care demanded or professed.

The line of reasoning provided in Gibbons suggests that a bioethicist working in a clinical setting would be holding him or herself out as someone with a special skill and could therefore be held liable for injury caused to another. The unfounded assumption that since bioethicists have not agreed upon a set of standards they will not be held accountable, seems to be of little relevance in determining whether a duty of care exists. It appears that the courts are very willing to assign responsibility to those who are relying upon a special skill set for financial gain.46 Further, one could argue that a bioethicist’s duty of care extends to anyone engaging the services of the bioethicist, including but not limited to, physicians, patients, nursing practitioners and other hospital staff.

2. Breaching the Standard of Care

The second element a claimant must prove is that the bioethicist has not met the standard of care expected of bioethicists. With general negligence lawsuits, the court would compare the actions of the defendant with those of a “reasonable person” in the defendant’s situation.47 This comparison is described as a standard of care and it represents the benchmark of behaviour the court expects from the party owing a duty of care. If the actions of the bioethicist would be similar to those of a reasonable person in the bioethicist’s position, then the bioethicist could be deemed as having met the standard of care required. On the other hand, if the actions of the bioethicist were to be markedly different from the standard normally expected between the parties, then the court may find that the bioethicist had not met the standard of care required. The courts in Canada have consistently applied a high, and exacting, standard of care for professionals — due to the fact that they purport to have a special skill set that is not shared by the common layperson.48 The standard of care for these individuals is usually determined by the common practices and behaviours of the profession-at-large.

There is much debate as to whether “bioethics” should even be considered a profession.49 Would it be reasonable to say that since there is significant controversy surrounding the prospect of “professionalizing” or regulating the study and practice of bioethics — that bioethicists would not be held to the higher professional standard? In spite of the work of the CBS and ASBH referred to above,50 Sontag’s conclusion is still correct in that there is
still “no universally agreed-upon standard for what skills one needs to possess in order to be qualified to act as a bioethicist”. In fact, some authors have advocated against assigning a specific set of competencies — as forcing rules and procedures would go against the nature of bioethics itself. Giles Scofield has critiqued the current state of bioethics professionalization saying that “due to the substantial and seemingly desirable benefits that come with an occupation becoming a profession, it is odd that the field thinks, talks about itself, and acts as if were already a profession — but that it cannot and will not professionalize itself formally”. He argues that by intentionally keeping the roles of bioethicists vague, “it becomes difficult if not impossible to know what it is not”. In essence, nobody can determine “what [issues] ethics consultants cannot, do not, should not, and will not concern themselves”. Larry Churchill also finds the presentation of the Core Competencies to be quite perplexing. “The report states clearly and emphatically that the listing of core competencies does not constitute an effort at professional standardization, and lists numerous problems with certification … Yet, the tone of the report, its history, and several of its features belie the disclaimers.” While Churchill ultimately argues that increased standardization of practices is distracting bioethicists from asking more probing questions of an existential nature, his work does highlight that there is a disconnect between bioethicists themselves on how to manage expectations from both within and outside the bioethics community. This disconnect may lead the courts to assign a clearer standard if faced with the opportunity.

Some bioethics scholars seek a middle ground by focusing the skill set on procedure, as opposed to the substance of the answer. This approach reflects the reality that there is no obvious “right” or “wrong” answer to many ethical problems. Larry Lowenstein and Jeanne DesBrisy expand on this point: “what is involved in not a lack of skill, so much as an exercise of the healthcare ethicist’s judgment at the relevant time, and the court may be reluctant to say that choosing a certain ethical option was negligent”. Therefore bioethicists might believe that their final decisions would be protected from liability. “If an ethicist acted in good faith, with due care, without malice, and in conformity with thoughtful procedures and thorough investigation of facts, and the conclusions and recommendations were reasonably warranted, then he/she will not be found to have breached her duty to the patient”. But, what constitutes a “thorough investigation” or a “reasonably warranted recommendation”? Bioethicists might be inclined to ignore these standards, as they themselves are having such a hard time defining them.

However recent analysis at the Supreme Court of Canada stipulates that the courts themselves have the power to set a standard to a profession — even if the profession is itself unable or unwilling to do so. In ter Neuzen v. Korn, the Supreme Court of Canada examined the case of a doctor who conducted an artificial insemination procedure during the early 1980s, which resulted in his patient contracting HIV through infected semen harvested from the donor. Specifically, the Court addressed whether the physician could be found negligent, in spite of the fact that he had conformed to the prevailing standard of medical practice that existed in 1985. The Court also recognized that it had the power to determine if a prevailing standard of practice could be found inadequate. First, Justice Sopinka recognized that a profession can set a standard of practice for its members; and that the Court may rely upon this principle of professional deference to determine whether a standard of care has been met. “[C]onformity with common practice will generally exonerate physicians of any complaint of negligence.”

Yet Sopinka J. allowed for the possibility of Court intervention by outlining two exceptions to the general principle of professional deference. The first exception pertains to when the standard itself is negligent: “[t]here are certain situations where the standard practice itself may be found to be negligent. However this will only be where the standard practice is fraught with obvious risks such that anyone is capable of finding it negligent, without the necessity of judging matters requiring diagnostic or clinical expertise”. In the same vein, “if a standard practice fails to adopt obvious and reasonable precautions which are readily apparent to the ordinary finder of fact, then it is no excuse for a practitioner to claim that he or she was merely conforming to such a negligent common practice”.

The second exception, where the Court may intervene regarding a profession’s standard of care, is even more relevant to bioethicists. Justice Sopinka concluded that if the Court finds that there was no recognized practice at the relevant time, then the Court itself will determine the relevant standard of care.

If the alleged act or acts of negligence are such that the jury could reject expert evidence as to standard practice and set the appropriate standard without reliance on expert evidence, then it can do precisely that where the expert evidence fails to establish a standard practice.

[Emphasis added by authors]

In 2002, the Superior Court of Justice of Ontario applied this new power in Carere v. Cressman to set the standard of care for midwives practising in 1985. The case involved a negligence claim against
a midwife who had performed a procedure in 1985 known as "external cephalic version" ("ECV").

The procedure resulted in complications and the child was born with cerebral palsy.

The objective of the Superior Court was to determine if the midwife had breached the standard of care of midwives in 1985 — since it was not appropriate to apply the standard of care of midwives 17 years later in 2002. While the study of midwifery is now regulated across Canada, this was not the case in 1985. Justice Henderson began by expanding the term "medical practitioner" to include midwives and noted that the same concepts could apply to "any healthcare practitioner". Therefore there is a strong likelihood that the following analysis on how to construct a standard of care for a midwife would be highly persuasive when determining how the court would construct a standard of care for a bioethicist.

Justice Henderson began by reviewing the ter Neuzen decision and stipulating several principles. First, he recognized that not only were midwives in Ontario not regulated in 1985, but they were also treated poorly by the mainstream medical community. However, he asserts that this "does not mean that in 1985, in Ontario, Cressman had no standard of care … by holding herself out as a midwife, Cressman must be taken to represent that she had some expertise in the area of prenatal care and birth procedures". He cited a letter sent by Cressman to her client, Carere, in which she set out her qualifications and detailed her experiences with midwifery. Justice Henderson then notes several reasons, many of which could be applicable to present-day bioethicists, which would state that there was no recognized standard of care at the time the injury occurred.

[M]idwives were either operating on their own, or in loose pockets of midwifery. Some were trained and some were not. There was no requirement for particular training. Standards of practice only started to be written down by a midwifery association in 1987, and it was an ongoing process to develop and record these standards. Many of the midwives operated in remote communities. Most were not welcome in hospitals, or by doctors.

In spite of these comments, Henderson J. still felt obliged to determine a standard due to Cressman's "holding out" of possessing a specific skill. It is hard to argue that bioethicists, who have recently become very accepted in hospital settings, typically have a graduate degree in bioethics and are hired specifically as "bioethicists" and have begun to delineate selected core competencies, would not be viewed as holding themselves out as possessing specific skills and hence subject to the same treatment as midwives were in this case.

The court then proceeded to look at several experts to aid in establishing a standard of care for ECVs. These experts were a) a midwife who began practising in Ontario in 1989; b) an obstetrician who also performed ECVs; and, c) a midwife practising in England. The judge found that the midwife from England was a qualified witness in that the procedure for ECVs is generally the same in Canada and in England. The court also accepted the opinion of the obstetrician, in spite of the fact that he was qualified in medicine and not midwifery — "his medical training enhances his ability to describe the nature and risks of the procedure". Finally, the court accepted the testimony of the midwife who began practising midwifery after the date in question. The court declared that "her evidence is useful, even though her expertise is post-1985". It is also interesting to note that the court admitted into evidence Myles Textbook for Midwives, a British textbook that has been used to train midwives for decades. It was used generally by midwives in the 1980s and Cressman admitted that it was the text that she relied upon in her training. Therefore the court found that Myles was an authoritative text on the subject.

After determining that the training qualifications and standards of midwives varied from the lack of regulation, the court officially found no recognized practice for midwives who performed ECVs in Ontario in 1985. Therefore, Henderson J. concluded that "it is for the court to determine the reasonable standard of care expected of a midwife who attempted [an ECV]".

Furthermore, "the assessment of the specific allegations of negligence against Cressman does not require any special diagnostic or clinical skill, but rather requires the use of ordinary common sense". He then proceeded to look at the specific opinions of the experts and the textbook to determine the reasonable standard of care required of any midwife who performed an ECV in Ontario in 1985.

This case demonstrates that even if Canadian bioethicists themselves do not set a standard of care for bioethicists one may very well be constructed by a court in the future. The following sources could provide some assistance in such an endeavour. For instance, Canadian courts could examine bioethics guidelines or policy documents used in Canadian hospitals. The work of the Canadian Bioethics Society, in developing a Model Job/Role Description for bioethicists, as well as the Draft Model Code of Ethics would be quite persuasive. The inventory identified by Françoise Baylis in 1994 is also cited widely in the bioethics community. La Puma and Scheidmayer also identify "fundamental skills" for bioethicists that the court could take into account. They may also rely upon the standards articulated in
the Tri-Council Policy Statement for ethical review of research.

The courts would likely be very willing to look at work from international jurisdictions including the United States. The ASBH Core Competencies for Health Care Ethics Consultation, could be considered a valuable source for describing the reasonable expectations for bioethicists in the context of ethics consultations. Carere also leaves open the possibility for other professionals to espouse as to the standard of care for bioethicists. Individuals such as doctors, nurses or social workers, would be very familiar with the activities of bioethicists and may be called upon to speak to professional norms.

Canadian bioethicists should carefully consider all of these sources, as they would likely form the basis against which a court would evaluate their actions if faced with a negligence suit. It would therefore be imprudent for bioethicists to try to convince themselves that because the industry itself has not formally established a standard of care and is not a regulated profession — that the courts would not fill the gap if given the opportunity.

3. HARM SUFFERED BY THE CLAIMANT

The third element, would require a case-by-case determination. To establish harm the claimant has to have suffered a material injury, and demonstrate proof of damages. If found liable, the bioethicist may be required to compensate the victim for losses. Compensation could include medical bills, lost income and the costs of future care, as well as an award for pain and suffering and the loss of the enjoyment of life. If a tort causes death, the estate and dependants could seek compensation for their losses including the loss of support by dependants.

4. SUFFICIENT CAUSATION BETWEEN THE ACTIONS OF THE BIOETHICIST AND THE HARM SUFFERED BY THE CLAIMANT

Causation is the final element in a negligence suit. Causation is a question of fact that must be determined on a balance of probabilities. Notwithstanding the fact that the defendant had a duty of care to the claimant, breached the required standard of care, and the claimant suffered harm, the claimant must prove that the defendant’s actions actually caused the specified harm.

Causation would be very difficult to determine consistently in the case of bioethicists. One way of framing the issue would be to categorize the different types of consultations or ethics activities based upon the levels of control the bioethicists exert over the final outcome. The first category exerts the most control and occurs when the bioethicist is in the position of issuing a binding decision. It should be noted however, that the first category would almost never describe contemporary ethics consultations or activities in Canadian healthcare institutions. The second category occurs when the bioethicist issues a non-binding recommendation, but convinces the parties to accept his or her proposal. The third category occurs when the bioethicist issues a non-binding recommendation and does not attempt to persuade the parties to adopt it. Finally the last category represents scenarios where the bioethicist’s efforts are limited to facilitating consensus, and he or she refrain from providing any recommendation.

To determine causation, one would have to find that there was both a legal cause and a proximate cause of the injuries. To determine the legal cause, one would ask “but for this negligent act, it is more likely than not that those injuries would not have been suffered by the claimant”. To determine whether a proximate cause exists, one would ask whether the bioethicist could reasonably have foreseen the injuries suffered by the claimant, at the time the advice was given. Liability in negligence will be denied if the connection between the action of the bioethicist and the harm suffered by the claimant is too remote. Generally, it will be sufficient to prove that the type of damage was a possible result of the negligent act.

The but for test would be easily satisfied in the first category, since the binding decision of the bioethicist would have required the person who asked for the consultation to pursue the specific action that ultimately resulted in harm. It would also be quite straightforward to assign proximate cause, as the bioethicist could reasonably have foreseen most of the injuries that the claimant would have suffered.

As for the second category, it could be effectively argued that “convincing” another party to follow a course of action would also satisfy the but for test. Again, the proximate cause could also be satisfied since the bioethicist would likely have been in the position to foresee most injuries that could have been suffered, and would be presumed to have considered these injuries when advocating for one action versus another.

The third category, however, would be less straightforward. Sontag notes that at first glance it may appear that a non-binding recommendation would not satisfy the but for test, since it is the clinician, patient, substitute decision maker, administrator or other person who may have called the consult who makes the final decision. Further, there is no duty to follow the advice of the bioethicist, and he cites several authorities that indicate that physicians have the ultimate responsibility for final treatment decisions.

George Agich however, argues that lay people see bioethicists as having a certain level of moral authority. He worries that this may “place such a heavy
burden on those benefiting from the consultation to follow the non-binding recommendation or come up with very good reasons not to follow the ethics advice”.96 Therefore due to the trust accorded to the bioethicist in the ethics consultation process, “the physician or patient would treat the “nonbinding” recommendation of the clinical ethicist as, “if not binding, at least highly persuasive, in much the same way as a medical consult”.

Also since patients and physicians have their own reasons for not automatically consulting a bioethicist,98 when they do seek a consult they are expecting the bioethicist’s views to play a significant role in the treatment decision.99 Therefore according to Sontag, the but for test would be satisfied — as even non-binding recommendations can passively influence the final decision.100 Proving this however, would be relatively difficult and should not be automatically assumed. Furthermore, the proximate cause would also be subject to as much controversy as the legal cause. Thus, there is potential for a substantial amount of very costly litigation in proving this category.

Activities that would fall under the final category create the least legal vulnerability for bioethicists. If an ethicist merely facilitates a consensus, with the goal of ensuring that the decision reached is ethically acceptable, it would be exceedingly difficult for a claimant to prove causation.101 In essence, according to Sontag, "only if an ethicist allows an ethically impermissible outcome to the consultation, which then causes harm to the patient, can the ethicist’s actions be considered a legal cause of the harm”.102 For this to happen, the bioethicist would have to be grossly negligent and display behaviours that would go completely against common sense and the practice of most bioethicists. In terms of proximate harm, it would be difficult for a claimant to prove that an ethicist, who in good faith tried to foster consensus, would reasonably foresee the damages that would occur from the consensus exercise.

DEALING WITH THE RISKS

It is becoming increasingly probable that bioethicists may be held to a standard of care — even if such a standard is not formally established by the profession itself.

Bioethicists should actively apprise themselves of the latest literature and training pertaining to hospital-based bioethics work, with the mindset that the court could assign these standards and responsibilities to a bioethicist. It would therefore be prudent for a bioethicist to ensure that he or she is always functioning at a standard of care comparable to what would be defensible in the literature. If for whatever reason a bioethicist considers the practices outlined in the literature or guidance documents to be unethical, then the bioethicist should document why this is so and provide alternative standards that they would be able to rely upon if in the position of having to defend a negligence claim. A bioethicist who is employed by a healthcare institution should ensure that he or she is covered by the general errors and omissions insurance policy of the employer. At law, employers are vicariously liable for the actions and omissions of their employees and hence bioethicist-employees would likely be covered for negligence. However independent contractor bioethicists who consult to individuals or organizations should ensure that they obtain appropriate errors and omissions insurance to cover them in the event they are subject to a lawsuit.

BACK TO THE CASE

Consider the case raised at the beginning of this article.

**WAS THERE A DUTY OF CARE?**

The bioethicist employed by the hospital would have known that the patient would be directly affected by her advice and ought reasonably to have had the patient in contemplation when giving such advice. Likely a duty of care would be established.

**WAS THERE A STANDARD OF CARE?** Surely the standard of care for a bioethicist working in a healthcare setting would be to know the relevant consent to treatment legislation, which typically indicates that if a person has executed a power of attorney for personal care, and if that person becomes incapable of making his or her own treatment decisions, the treatment decisions are to be made by the named attorney. In looking at the TCPS and other guidance documents, as well as prevailing legislation in many jurisdictions, a patient’s prior capable wishes are to be adhered to by the substitute decision maker when such wishes are known, and a bioethicist who understands the ethical value of respecting a patient’s autonomous wishes, would be expected to have canvassed the possibility that there was evidence (such as the power of attorney for personal care) of the patient’s previously expressed capable wishes.

**WAS THERE A BREACH OF THE STANDARD OF CARE?** In the facts as given, the bioethicist did not enquire as to whether there was a power of attorney for personal care (and hence her recommendation that the wife act as the substitute decision maker when treatment was inconsistent with relevant law and underlying ethical principles) and did not enquire as to evidence of the patient’s prior capable wishes. These omissions would likely be a breach of the standard of care.

**WAS HARM SUFFERED BY THE CLAIMANT?** Although the claimant survived, the very thing he had indicated he did not want, was imposed upon him — a
lifelong connection to a ventilator. At minimum, there could be a claim for pain and suffering.

Was there sufficient causation between the actions of the bioethicist and the harm suffered by the patient? But for the omissions of the bioethicist (and the physician as well), it is likely that the correct substitute decision maker could have been consulted and the prior capable wishes respected for no ventilator. It could be argued that the bioethicist could reasonably have foreseen that in the absence of ascertaining if there were previously expressed capable wishes, that unwanted treatment might be imposed upon the patient. If the bioethicist had raised the issue of “prior capable wishes” or whether there was a power of attorney for personal care, the physician might not have connected him to a ventilator.

A person who intentionally causes harmful or offensive contact to another is liable for a tort action in battery, even though no actual harm is intended or even occurred. A medical or surgical procedure that takes place against the patient’s wishes or instructions can be viewed as an intentional interference with the body of another without that person’s consent and hence constitute the tort of battery. The sanction of a person’s body is so highly regarded by the law that damages can be awarded to the victim, even though the victim was not hurt and the interference may have been of benefit.

In this case, the physician, the bioethicist and/or the hospital in which the bioethicist works, could face a legal suit in negligence (and battery in the case of the physician). The consulted bioethicist had an obligation to satisfy herself that the person providing the instructions was the legal substitute decision maker. One might even imagine a situation where only the physician is sued and she cross-claims against the bioethicist/hospital for damages.

CONCLUSION

It is the goal of this article to highlight the potential legal vulnerability of bioethicists practising in Canada in an era characterized by significant reflection on the role of bioethicists working in healthcare institutions. Those interested in the role of bioethicists should be aware that, in the context of a legal dispute, the court may still assign a standard of care to bioethicists; notwithstanding the lack of clear standards generated by a professional college or regulatory body. With a court-assigned standard, a bioethicist could be found liable if the court determines that the actions of the bioethicist fell below that standard. Bioethicists must be diligent in the carrying out of their professional activities, and aware of the evolving standards being created by legally relevant case law and policy documents. Legally prudent bioethicists working in Canada should remain abreast of what standards are precipitating in the profession and cognizant of how their actions compare as well as ensure that they have the appropriate insurance coverage in the case of a legal suit.

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The authors wish to extend their special thanks to Jana Lambert for her excellent research assistance.]

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1 Throughout this article, the term “bioethicist” is used to describe those who have specific training in bioethics and who work exclusively in this area. It is specifically referring to those bioethicists who perform clinical, organizational or research ethics consultations in a health-care institution. The term does not include other professionals working in healthcare institutions who may have an interest in bioethics but do not devote their full work time to the pursuit. This article is intended as a general comment about the legal risks associated with working as a bioethicist in a Canadian healthcare institution and should not be considered legal advice. It is strongly recommended that bioethicists consult practising lawyers for individual and independent legal advice tailored to their specific needs.


5 Ibid. at 841.

6 Ibid. at 858.


8 2002 U.S. Dist. Lexis 4072 (Okla.) (“Robertson”).

9 J. Thompson, P. Baird and J. Downie, Report of the Committee of Inquiry on the Case Involving Dr. Nancy Olivieri, the Hospital for Sick Children, the University of Toronto and Apotex Inc. (Toronto:
James Lorimer & Co. Ltd., 2001), online: Canadian Association of University Teachers
10 Medical Research Council of Canada, Natural Sciences and Engineering Research Council of Canada,
11 Supra note 9, Report at 42.
12 No. 03-CVS-1 161 (N.C. Sup. Ct. July 2003), online: Sherman, Silverstein, Kohl, Rose and Podolsky P.A.
14 No. 00375 (Phila County C.P. July 2003), online: Sherman, Silverstein, Kohl, Rose and Podolsky P.A.
20 University of Toronto Joint Centre for Bioethics CORE Network Working Group on Professionalization/Credentialing of Bioethics online:
23 Ibid. at 510.
24 Supra note 17.
25 Ibid.
27 Supra note 17.
28 Ibid.
29 Ibid.
30 Supra note 15 at 271. See generally, Sontag, supra note 16 at 689-694 Theoretically, there are several ways in which a claimant may bring an action against a bioethicist. One example could be through contract law, although this possibility is so unlikely we will not deal with it in this article. Sontag also argues that bioethicists could be held liable for “acting in concert” or “directing or permitting conduct” that would cause harm to the patient. However, if a claimant can prove negligence, then this can also lead to a finding that a bioethicist is liable to these two intentional torts as well. Therefore the rest of this article focuses exclusively on the elements required to prove a negligence claim.
32 Ibid. at 580.
34 Supra note 31 at 580.
35 Supra note 15 at 272.
37 Andrew L. Merritt, “The Tort Liability of Hospital Ethics Committees” (1987) 60 S. Cal. L. Rev. 1239 at 1283. Ibid.
38 Supra note 15 at 272.
41 Ibid. at paras. 28-29.
42 Ibid. at para. 4. 4
43 Justice Stuart goes on to explain a type of special skill, which the authors believe could be analogized to the bioethics context. “I think that the defendant's advertisements
did represent that he possessed special skill and knowledge with regard to human ailments generally, and that representation included in my opinion a representation that he had sufficient special skill and knowledge to enable him to tell what was the matter with a human spine when it was brought to him for treatment, that is, to diagnose its true condition.” See, Ibid. at para. 18.

Ibid. at para. 5.

See for example, Gibbons, ibid. at para. 27, where it is stated, “It seems to me to be intolerable that any person should hold himself out as specially skilled in treating the human spine and should proceed to treat one presented to him without knowing, and without even feeling seriously the responsibility of being able to ascertain, what is really wrong with it”.


Deborah Cummins argues that bioethicists who provide consultations do not yet meet the criteria for professional status. Yet, she argues that most professions do not meet the criteria either. She suggests that instead of a definitive “yes” or “no” to the question of professional status, it is more helpful to envision a continuum of professionalization, and that the bioethics consultation has been moving along a continuum towards greater professional status. See Deborah Cummins, “The Professional Status of Bioethics Consultation” (2002) 23 Theoretical Medicine and Bioethics 19 at 39.


Supra note 16 at 696.


Ibid. at 97.

Ibid. at 97.


Supra note 16.

Supra note 16 at 699.


Ibid.

Ibid. at 696.

Ibid. at 696 and para 41 of QL case.

Ibid. at para. 41.

Ibid. at 701 and para. 51 of QL case.

Ibid. at 700-701 and para. 55 the QL case.

Most hospitals and healthcare-related businesses are brimming with intellectual property ("IP") which may have significant commercial value. Commercialization is a way to capitalize on that value by taking an idea, prototype, invention, etc., and developing and selling it in the form of a commercially viable product. In the current economic climate, maximizing this commercial value is an increasingly important priority for healthcare institutions. With growing operating costs and the difficulties of securing funding, such institutions have an increasing need for "unfettered" funds (e.g., funds which are not allocated for specific functions), such as those which might be earned via IP commercialization.

In this article, we provide a brief review of some of the key elements of commercialization strategies which healthcare institutions and businesses can employ to maximize their return on investment.

**KEY COMMERCIALIZATION ISSUES**

The key commercialization issues essentially revolve around three factors:

1. Identifying and protecting intellectual property rights ("IPRs");
2. Evaluating the commercial potential of IPRs; and
3. Choosing the appropriate route of commercialization.

With respect to obtaining, identifying and protecting IP, it is extremely important for healthcare organizations and hospitals to consider all forms of IPRs. This means focusing not only on patents but also on other IP rights such as copyright, trademarks, trade secrets and confidential information. By focusing on each of these forms of IP protection, institutions will ensure they do not overlook a valuable source of potential revenue generation. For example, while some may focus on the development of new surgical techniques or medicines, there may be some under-capitalized value in a patient intake form developed by hospital administrators or clinicians to aid in the rapid identification of significant medical needs. Such a form may be the subject of copyright protection, which in general will be much cheaper and faster to obtain than patent protection.

In addition, licensing of an institution’s “brand” may also provide much needed revenue. Alternatively, trade secrets or confidentiality may be another way to protect certain types of information (e.g., the formula of a recipe or a food item developed in the institution’s kitchen). In the appropriate context, the trade secret could be licensed for revenue generation.

Once the appropriate IPRs have been identified, it is necessary to determine the IPR “landscape”. Have there been any prior public disclosures by the inventors (possibly negating the ability to obtain patent protection), or has someone else invented or tried to patent the development? With regard to whether the institution even has the right to commercialize the development, does any third party have rights that could restrict the manufacture, use or sale of the development? It is also important to confirm that the healthcare organization or institution owns the IP which has been developed. This process involves making sure that all of the necessary inventors or authors have been properly identified, and that they are required to transfer all the applicable rights to the institution. This process can be more complex where there are a number of different collaborators, each of whom may be an author or inventor. To add a further wrinkle, where such collaborators are affiliated with third parties, these third parties may then have an ownership interest in the development.

Also, there should be an analysis of the development’s commercialization potential. Factors such as current and future market size, and the required expertise to commercialize the development should be considered. For example, does the institution have the necessary expertise internally, or does it need external expertise?

Once an institution decides to commercialize its development, it should also consider which commercialization path would be best for the institution. Generally speaking, there are four possible commercialization models. The four models are explained below and are summarized in the attached figure. It will, however, be understood that various combinations of these models can be applied when commercializing the technology.
The first model is the “DIY” (or Do-It-Yourself) model. This approach is rarely practical for hospitals, since they typically have limited resources available to commercialize IP. With such a model, the hospital will maintain maximum control over the commercialization process. However, there are a number of key proficiencies (such as knowledge of marketing and regulatory approval) that may be required in order for the hospital to successfully commercialize the IP.

The next model is the “cooperation” or “collaboration” model, in which a hospital may work with another entity (i.e., a commercialization partner) through either, for example, a partnership or joint venture to maximize the potential for development. Key aspects of this model will include structuring the relationship, identifying the responsibilities of each of the parties (who does what and when), and addressing ownership (or co-ownership) of IPRs for current and future developments.

The third model is the “licensing” model, in which a hospital will license its IP to another entity who may be better positioned to develop it. The entity may be a related party (e.g., a spin-off or joint venture entity) or an unrelated third party. In a licensing relationship, key issues to address will include: the nature of the licence grant (e.g., exclusive/non-exclusive), the compensation model (e.g., royalties, milestone payments, etc.), ownership of future IP developments, and any restrictions on public disclosure of the technology. In this context, it will be important to appropriately allocate the risk and responsibilities through the licensing agreement. Usually, this is done through various representations and warranties by the parties, and the licensor may be required to indemnify the licensee should there be allegations by third parties of invalidity or infringement. More importantly, it is necessary to confirm that there are no ownership issues for the underlying technology, and that the licensor is actually the owner of the licensed IPR.

Finally, in a “transfer” model, a hospital will try to find an appropriate entity to whom to sell the IPRs. As with the licensing model, this may be a related party (e.g., a spin-off or joint venture entity) or an unrelated party. Here, the key issues may include the form and quantum of compensation, and whether or not there is a licence back. It is important to understand that, even with the transfer model, there will likely still be some risk because the assigning healthcare institution may offer various representations and warranties with respect to the validity, non-infringement and ownership of the IP. Also, the purchaser will likely conduct some form of due diligence concerning the intellectual property, with one of the key aspects being ownership thereof. It will be necessary for the owner of the intellectual property (the healthcare institution) to make sure it addresses any and all issues with respect to ownership prior to any such due diligence process.

For each of the various models noted above, some of the main factors to consider are the degree of con-
control which the institution will have over the commercialization process, the allocation of risk (particularly for the healthcare institution), and the return on investment. The DIY model will afford the hospital the greatest degree of control over commercialization. This control is lower for those healthcare institutions utilizing the cooperative model, and likely lower still in the licensing model. In the transfer model, the hospital’s control over the commercialization process will typically be the lowest.

Not surprisingly, the allocation of risk may generally track the degree of control that the hospital or healthcare institution enjoys. That is, generally speaking, the higher the degree of control, the greater the risk. Similarly, the lower the control, the lower the risk for the healthcare institution. Finally, it is also generally the case that the less control over the commercialization process which is afforded to the hospital, the lower its potential return on investment (“ROI”).

In view of the complexities involved, it is necessary for each healthcare organization to balance its desired control, risk and ROI to identify the best route of commercialization for its valuable intellectual property.

It will be apparent then that commercializing IP requires a multifaceted analysis which takes into account a number of different considerations. Like the old adage which states “the devil is in the details”, it is necessary to fully understand the different considerations so as to obtain the best results for the healthcare organization.

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- FEDERAL AUDITOR GENERAL’S REPORT ON CANADA HEALTH INFOWAY -

Michael R. Whitt, Q.C.,
Bennett Jones LLP

The Auditor General’s Fall 2009 Report, released November 3, 2009, included at Chapter 4 a detailed review of the operations of Canada Health Infoway.

The report notes that Infoway is tasked to deploy $1.6 billion of federal funding to encourage and enhance the prospects of a modernization of health records in Canada by the development and adoption of large-scale electronic health record systems in the various provincial and territorial jurisdictions of Canada. To a very large extent, Infoway received passing grades from the Auditor General.

The Auditor General also noted that six provincial and territorial governments were auditing their respective healthcare modernization efforts, and while some reports had been published, a consolidated report is planned for release to the public in early 2010.

There were some instructive recommendations in the Federal Auditor General’s report:

1. The publicly stated goal of Infoway to have electronic health records systems “available” to 50 per cent of Canadians by 2010 is potentially misleading, given Infoway’s stance that “available” does not necessarily mean “used” or “adopted”. The Auditor General suggested that this be clarified.

2. Some tightening of contracting procedures for goods and services was recommended, although overall, Infoway’s processes were good. Infoway’s contract amendment processes, however, should be tightened up to permit its Board to understand and control amendments which extend the term of tendered contracts or the monetary value of contracts. Infoway’s processes were otherwise acceptable.

3. Although no real problems were identified in the audit, a potential for future problems was identified in the lack of procedural requirements to document internal analyses permitting funds to be released. Infoway has agreed to amend its processes.

4. Although on the surface directed at Infoway, the Auditor General recommended that Infoway obtain the results of provincial system conformance testing and plans to remedy non-conforming sys-
tems from provincial governments it assists, as a condition of further funding. This is an obvious reference to the very real risk of problematic implementation of appropriate vendor selection and conformance testing being carried out by a variety of provincial governments using a variety of different mechanisms (from procurement processes and “standing offers” from vendors, through to technical systems analyses and tests using sample data sets to assure operability and core functionality). It is an industry concern that those regional efforts to select and control vendors have a high risk of generating problems with primary care providers’ acquisition, implementation, and adoption, and do not necessarily end with nationally compatible interoperability (an Infoway goal).

5. Infoway should report annually on the actual adoption of electronic health record systems by healthcare professionals and whether the systems are compliant with national interoperability standards. The Auditor General believes that this will provide Parliament and Canadians with a truer picture of Infoway’s success in achieving its purposes. Infoway has agreed, but with the caveat that adoption is outside of its control, and difficult to measure.

6. Infoway should also report its results achieved compared with its expected results. Again, Infoway has agreed, and has said that that information has been provided in different forms on an unconsolidated basis, but will in future be consolidated.

7. The Auditor General also recommends that the reports of actual versus planned results should be against Infoway’s performance targets on each of its five core systems:

- Registries of providers and patients;
- Diagnostic Imaging systems;
- Drug Information Systems;
- Laboratory Information Systems; and
- Interoperability of Electronic Health Records systems.

8. Health Canada should develop and adopt a better monitoring framework to ensure Infoway is compliant with its funding agreements. Health Canada responded that compliance with this recommendation has been put into place between the close of the audit period and the report.

In all, Canada Health Infoway and its management have been given a favorable report card. This is very encouraging for the industry, as other funding agencies have been the subject of negative audit reports and have generated a public and political backlash, impairing commercial efforts to automate healthcare delivery through new information and communications technologies and systems.

[Editor’s note: A Patent Agent (2001) and a Trademark Agent (1994) in addition to being a lawyer Michael Whitt advises technology-based businesses on commercialization and compliance matters, and on the structure, negotiation and documentation of novel business models, strategies and transactions, particularly regarding intellectual property and information and other technologies. Mr. Whitt has been involved with computer and information technologies for over three decades and advises small, medium and large clients with technology or intellectual property assets and operations. He also assists clients with the protection of personal information and privacy law compliance, policy review and advice, contract terms in IT and other information-handling and information-flow transactions and operations, breach mitigation and notification, and response to regulatory inquiries and demands in private sector and health information matters both provincially and federally.]
Leibowitz, the Chairman of the FTC, referred to reverse payments as "collusive deals" and estimated that the elimination of these payments could save American consumers US$35 billion over ten years. The FTC also addressed the issue in its June 2009 interim report on "authorized generics", which deals with generic drugs sold by a brand pharmaceutical manufacturer. According to the FTC, its initial findings suggest that the prices of prescription drugs are lower when authorized generics are available. The report also suggests that agreements to delay introducing authorized and independent generics can harm consumers by delaying price competition between generic and branded pharmaceuticals.

The FTC has been joined in its stand against reverse payments by the U.S. Department of Justice ("DOJ"). In July 2009, at the request of the 2nd U.S. Circuit Court of Appeals, the U.S. DOJ filed a brief setting out its views on the legality of reverse payments under U.S. antitrust legislation. In its brief, the U.S. DOJ stated that in light of the "anticompetitive potential of reverse payments … it is sufficiently clear that such agreements should be treated as presumptively unlawful under Section 1 of the Sherman Act". However, the DOJ qualified its statement by noting that defendants may rebut this presumption by showing that the payments do not unduly restrain competition. The DOJ also declined to take a position in the underlying case (which involves a challenge by drug purchasers to a settlement between Bayer AG and Barr Pharmaceuticals to keep a generic version of the antibiotic Ciprofloxacin off the market). As a result, it remains to be seen whether the decision of the 2nd Circuit will be influenced by the DOJ's position, particularly given that the Court has previously taken a permissive approach to the legality of such settlements.

Consistent with the FTC's and DOJ's recently stated position regarding reverse payments, the Energy and Commerce subcommittee of the U.S. House of Representatives endorsed legislation in June 2009 that would prohibit "pay-for-delay" patent settlements. The Senate Judiciary Committee is considering similar legislation. The push to introduce such legislation has not been without controversy — particularly in light of the differing decisions from U.S. courts on whether "pay-for-delay" settlements violate U.S. antitrust law.

EUROPEAN UNION

The European Commission has been conducting an inquiry into the pharmaceutical sector for the past year. In November 2008, the Commission conducted "dawn raids" against a number of pharmaceutical companies. In July 2009, the Commission issued its final report and simultaneously announced the initiation of formal proceedings against Servier (a pharmaceutical manufacturer) and five generics manufacturers (Krka, Lupin, Matrix Laboratories Limited, Niche Generics and Teva) on suspicion of conduct contrary to Articles 81 and 82 of the EC Treaty. Among other things, the Commission alleges that Servier abused its dominant position by entering into "reverse payment" settlement agreements with the generics manufacturers in respect of its patented cardiovascular medicine.

The Commission's final report calculates that three billion EUR could have been saved between 2000 and 2007 if generic entry had occurred earlier. The report concludes that there are a number of factors which contribute to the delay of entry by generics including the patent filing strategies of the branded pharmaceutical companies, patent litigation and "pay for delay" settlements. The report recommends significant changes to the existing regulatory framework to improve access to generics, including the establishment of a unified specialized patent litigation system across the European Union and a EU community-wide patent.

Perhaps not surprisingly, the report also recommends that competition law scrutiny of the pharmaceutical sector be intensified in the European Union. On the issue of "reverse payment" settlements specifically, the report notes that the Commission will consider "focused monitoring … of those settlements with a potential to adversely affect European consumers" and that the Commission will initiate enforcement action in appropriate cases (such as the proceedings referred to above).

The Commission's efforts in this area remain ongoing. In a speech on September 29, 2009, the European Competition Commissioner stated that the Commission is "capitalising" on the pharmaceutical sector inquiry by bringing new cases and reiterated the importance of the Commission's efforts to "improve the functioning of this sector". In addition, the Commission confirmed on October 6, 2009 that it had conducted surprise inspections of certain pharmaceutical companies including manufacturers of brand name pharmaceuticals. The inspectors are said to have been looking for evidence of restrictive business practices and/or the abuse of a dominant market position.

CANADA

The Canadian Competition Bureau has also recently examined aspects of the pharmaceutical industry in Canada. Specifically, the Bureau issued a report in 2008 on the state of generic drug competition in Canada. The Bureau suggested in this report that while there is active competition between generic manufacturers in Canada, the resulting cost savings have not been passed on to consumers. In the Bureau's view, the failure to pass on these cost
savings is due to the structure of existing private and public drug plans and the manner in which these plans pay for generic drugs. The Bureau's suggestions for improvements in this area include the adoption of competitive tendering by provincial drug plans and the development of a network of preferred pharmacy providers for private drug plans (where individuals are encouraged to take their prescriptions to be filled at such providers).

"Reverse payment" settlements have yet to be the subject of scrutiny in Canada. However, upcoming amendments to the Competition Act could increase the likelihood of "reverse payments" becoming an issue. In particular, the new per se conspiracy offence, which comes into force in March 2010, may make it easier to prosecute reverse payment settlements in Canada as unlawful agreements between competitors because the Bureau will no longer be required to demonstrate an "undue lessening of competition" in a relevant market. Even if not caught by the per se offence, "reverse payment" settlements could potentially be challenged under a new civil provision to be enacted that authorizes the Bureau to seek remedies from the Competition Tribunal in respect of agreements between competitors that substantially prevent or lessen competition. In addition, given that the Bureau appears to have reinvigorated its enforcement efforts with respect to abuse of dominance (including joint dominance), it is possible that "reverse payment" settlements could be reviewed under the abuse of dominance provisions. With significant new administrative penalties of $10 million now available where an abuse of dominance allegation has been made out, the threat of such enforcement activity carries with it substantial financial risk.

CONCLUSION

The combined effect of the policy, legislative and enforcement initiatives described above is to heighten antitrust scrutiny of the global pharmaceutical industry. As a result, pharmaceutical companies should be sensitive to the fact that their conduct (particularly vis à vis their competitors) might attract interest from antitrust authorities, including in Canada.

[Editor's note: George Addy is the partner who leads the firm's Competition & Foreign Investment Review practice. He focuses on all aspects of competition law, including strategic advice and representation before competition authorities in Canada and abroad dealing with cartels, mergers, acquisitions, joint ventures, abuse of dominance and other reviewable trade practices.

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Health Law in Canada February 2010 Volume 30, No. 3

UNDERSTANDING THE PPP: THE BPS SUPPLY CHAIN GUIDE

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INTRODUCTION

Hospitals’ procurement practices in the past have generally been governed by the Agreement on Internal Trade (the “AIT”). The AIT sought to reduce barriers to the movement of persons, goods, services and investments within Canada, and in doing so provided certain procurement rules for government purchasing. Annex 502.4 (Procurement — Provisions for municipalities, municipal organizations, school boards and publicly-funded academic, health and social service entities) (the “Annex”) is the Annex which specifically applies to hospitals and other publicly-funded health entities.

The Annex, while providing the core parameters for a health sector entity’s procurement policy, leaves many questions unanswered. The BPS Supply Chain Guideline (April 2009) (the “Guideline”), targeted at the “broader public sector” (or “BPS”), helps address those gaps. The Guideline was drafted in response to a March 2008 direction from the Ontario’s Treasury Board of Cabinet that a supply chain guideline be prepared and, as of April 1, 2009, be incorporated into the funding agreements of BPS organizations receiving more than $10 million per fiscal year from the Ministries of Health and Long-Term Care, Education and Training, Colleges and Universities (“In-Scope Recipients”). The Guideline is also mandatory for shared service organizations (“SSOs”) owned or funded by In-Scope Recipients.

The first edition of the Guideline, available as of the date of publication of this article, includes two essential Principles towards the goal of supply chain excellence: a Code of Ethics and a Procurement Policies and Procedures (“PPP”) standard. It is the latter PPP standard — which governs how the organization conducts sourcing, contracting and purchasing activities, including approval segregation and limits, competitive and non-competitive procurement purchasing, contract awarding, conflict of interest and bid protest procedures — which is the focus of this article. We emphasize that the Guideline is an extensive document, and thus we have highlighted below only some of the more significant PPP requirements set out in that Guideline.

Finally, we note that the Guideline has been issued roughly concurrent with the new Management Board of Cabinet Procurement Directive (July 2009) (the “Procurement Directive”). The Procurement Directive applies to two specific groups of entities (“Ministries” and “Other Included Entities”) which generally do not encompass hospitals; however, the content of the Procurement Directive and the Guideline is nevertheless very similar, and — as we indicate below — the Procurement Directive can assist in providing further guidance in the application of the Guideline.

THRESHOLDS FOR COMPETITIVE PROCUREMENTS

The Guideline does appear to raise the level of obligation to competitively procure from that set out in the Annex. We have highlighted below the different thresholds between the Annex, the Guideline, and also — for comparative purpose — the Procurement Directive (Ministries) and the Procurement Directive (Other Included Entities).

<table>
<thead>
<tr>
<th>Type of Service</th>
<th>Annex</th>
<th>Guideline</th>
<th>Procurement Directive (Ministries)</th>
<th>Procurement Directive (Other Included Entities)</th>
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<td>[Consulting] Services</td>
<td>&gt; $100,000 = “tendering process”,</td>
<td>&lt; $100,000 = OC, or at minimum, IC, encouraged</td>
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<td>Goods</td>
<td>&gt; $100,000 = “tendering process”.</td>
<td>&lt; $100,000 = OC, or at minimum, IC, encouraged</td>
<td>&lt; $25,000 = OC, encouraged</td>
<td>&gt; $100,000 = OC</td>
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<tr>
<td>[Non-Consulting] Services</td>
<td>&gt; $100,000 = “tendering process”.</td>
<td>&lt; $100,000 = OC, or at minimum, IC, encouraged</td>
<td>&lt; $25,000 = OC, encouraged</td>
<td>OC encouraged</td>
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<td>&gt; $100,000 = OC</td>
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<tr>
<td>Construction</td>
<td>&gt; $250,000 = “tendering process”.</td>
<td>&lt; $100,000 = OC, or at minimum, IC, encouraged</td>
<td>N/A — Appears to be treated as a service, but inconsistent</td>
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<td>&gt; $100,000 = OC</td>
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1. Agreement on Internal Trade
2. The AIT
3. Annex 502.4 (Procurement — Provisions for municipalities, municipal organizations, school boards and publicly-funded academic, health and social service entities)
4. Annex
5. Management Board of Cabinet Procurement Directive
6. Procurement Directive (Ministries)
7. Procurement Directive (Other Included Entities)
In summary, there are two significant changes of note between the thresholds set out in the AIT and the Guideline. First, the higher threshold for construction which previously existed has been eliminated such that it is now treated the same as any other service.11 Second, the more oblique reference to “tendering process” which was set out in the AIT has been replaced with a more express requirement for, as applicable, an “invitational” or an “open” competitive procurement, in parallel with similar requirements in the Procurement Directive.

Two other differences are also worthy of note. While the standard of obligation is higher for Ministries under the Procurement Directive, the standard of obligation for the BPS is in fact greater than that for Other Included Entities under the Procurement Directive. Further, while the procurement of consulting services is treated as a separate category and therefore clearly of particular concern for the Management Board (again, being reflective of the concerns raised by certain of the recent procurement issues in the Ontario health sector), the Guideline does highlight consulting services as being deserving of special attention.

EXCEPTIONS TO THE THRESHOLDS

As with the Annex and the Procurement Directive, the Guideline sets out certain exceptions to the requirement to competitively procure goods or services — i.e. so to allow for “single”12 or “sole”13 sourcing. Most of these exceptions set out in the Annex, the Guideline and Procurement Directive directly parallel each other. For example, such an exception exists where an unforeseen situation of urgency exists, and the goods/services cannot be obtained by means of a competitive procurement. However, it is noteworthy that, unlike the Annex and the Guideline, the Procurement Directive expressly clarifies that such an unforeseen situation of urgency does not occur where the entity has failed to allow sufficient time to conduct a competitive procurement — in other words, entities will not be permitted, either willfully or through negligence, to “create” such a situation of urgency in order to avoid their obligation to competitively procure.

The Guideline requires that where a BPS organization bypasses the competitive process, formal documentation must be completed to support and justify the decision, which documentation must then be approved by the appropriate authority levels within the organization and may be used as supporting documentation in the case of a competitive dispute.14 The Guideline references a sample non-competitive process bypass template which will be provided in a future version of the Guideline, but has not yet been included. The Procurement Directive is helpful in addressing this current gap in the Guideline: it expressly sets out certain written documentation requirements for each Ministry where the entity elects to make a non-competitive procurement, which include the requirement to document the applicable exception; the rationale for relying on such exception; whether the selected vendor was previously awarded a contract within the past five years for the same or closely-related requirements; a description of the potential pool of vendors that might have responded to competitive procurement; an assessment of all potential vendor complaints and how the entity would respond to those complaints; a description of any alternatives considered; and a description of the impact on the business requirements if the non-competitive procurement were not to be approved. Adopting such a process in a hospital’s procurement policy imposes a helpful discipline each time the hospital relies upon such an exception for a non-competitive procurement.

RESTRICTIONS ON USE OF INFORMATION SOLICITATION DOCUMENTS

The Guideline describes the role of different information-gathering mechanisms, such as Requests for Information (“RFIs”), Requests for Expressions of Interest (“RFEIs”) and Requests for Supplier Qualifications (“RFSQs”), in assisting the BPS organization to plan a fair and cost-effective procurement process, define the requirements for the procurement documents, or identify whether there are qualified and/or interested suppliers.

However, like the Procurement Directive,15 the Guideline emphasizes that RFIs and RFEIs are not competitions meant to result in the award of work, and that therefore, a correctly executed information solicitation process should not result in a legal contract with a proponent. In-Scope Recipients should also note the Guideline requirement that RFIs and RFEIs not ask for proprietary information from suppliers.

BID RESPONSE TIMES

In order to ensure that each bidder receives sufficient time to prepare a reasonable response for the competitive process, purchasing BPS organizations are required to provide suppliers with a minimum response time of 15 calendar days for procurements valued at $100,000 or more.16 Further, the Guidelines advise that BPS organizations consider providing response times longer than 15 days to ensure that suppliers have a reasonable period of time to submit a bid, and that in any case the permitted response time should also take into account the complexity of the procurement and the time needed by the organization to properly disseminate the information. For example, the Procurement Directive requires that Ministries provide vendors with a minimum of 30 calendar days for complex/high risk procurements.
FORM OF CONTRACT

Both the Guideline17 and the Procurement Directive18 require that the final contract with the vendor be finalized using the form of agreement/contract that was released with the procurement document, a requirement which is in any case consistent with existing best practices.

CONCLUSION

Both the Guideline and the Procurement Directive are lengthy and comprehensive documents which we would suggest warrant further study. In addition to setting out the requirements of the new procurement landscape in Ontario, they together provide an invaluable resource for hospitals seeking to develop and implement a new, or update their existing, competitive procurement policy.

[Editor’s note: John Beardwood is engaged in a corporate/commercial practice, with an emphasis on information technology, outsourcing and privacy law-related matters. Mr. Beardwood is regularly listed among the world’s preeminent internet and e-commerce lawyers in Who’s Who Legal — The International Who’s Who of Business Lawyers where, in addition to being referred to as “an authority on outsourcing” in the guide to Internet and E-Commerce Lawyers, he is identified as being both one of the two most highly nominated Canadian lawyers in the guide, and one of the ten “most highly regarded individuals” globally. He is consistently recognized in The Best Lawyers in Canada for information technology law, and highly recommended as an outsourcing practitioner in the PLC Which Lawyer? Yearbook and in the PLC Outsourcing Handbook. His biography is to be included in the Canadian Who’s Who (2010). Mr. Beardwood is a frequent national and international speaker and writer on various technology, outsourcing and privacy law-related topics, and is the co-editor and contributing author of the leading industry text Outsourcing Transactions: A Practical Guide (now in 4th ed.). Mr. Beardwood is Co-Chair of the firm’s National Technology and Intellectual Property Practice Group, Vice-Director of the Privacy and Information Protection Practice Group (Toronto) and Co-Chair of the Outsourcing Practice Group.

1 On July 18, 1994, the First Ministers signed the AIT, which came into effect on July 1, 1995.
2 And to a certain extent the 1997 Ontario-Quebec Procurement Agreement, which regulates trade between Ontario and Quebec to ensure equal access to public sector procurement for the respective local suppliers.
3 As a result of announcements in the 2009 Ontario Budget, it is anticipated that the definition of In-
THE AMENDED CORONERS ACT: 
REGULATING FORENSIC PATHOLOGISTS AND 
A MORE IN-DEPTH CORONER’S INVESTIGATION •

Jennifer Hunter
Miller Thomson LLP

Introduced into the Ontario legislature on October 23, 2008, Bill 115, an Act to amend the Coroners Act, 1990, was carried in its third reading on May 28, 2009, and many of the new provisions have already come into force. In passing the amendments, it is apparent that legislators were primarily seeking to professionalize and reorganize Pediatric Forensic Pathology services in accordance with the recommendations contained in the report of Justice Stephen T. Goudge, which was released on October 1, 2008. The motivation is to improve current and future Pediatric Forensic Pathology services, develop reliable practices, and ultimately restore public confidence in the discipline. The amendments to the Coroners Act, R.S.O. 1990, c. C.37, are, accordingly, aimed at enhancing oversight and accountability, and providing additional quality control measures.

JUSTICE GOUDGE’S INQUIRY INTO PEDIATRIC FORENSIC PATHOLOGY IN ONTARIO

ENHANCING OVERSIGHT AND ACCOUNTABILITY

In its previous form, the Coroners Act did not contemplate the role of pathologists, forensic pathologists, or the regulation and oversight of their profession and work. In his report, Goudge J. stated that the legislative framework was inadequate and he provided recommendations centred on developing the role of a pathologist into an official legislative and operational structure which is consistent with a coroner’s involvement in criminally suspicious deaths.

To achieve the desired level of formality the amended Coroners Act provides for the regulation of forensic pathology. The Act will, for instance, require that all post-mortem investigations performed in connection with a Coroner’s warrant be performed by “pathologists”, a term which is now properly defined and included in the Act. Sections 28 and 29 of the Act are re-enacted to clearly provide for the roles of coroners and pathologists with regard to post-mortem examinations. To improve accountability, the Act now requires pathologists who have performed a post-mortem examination to report the findings from their investigations and analyses to the coroner who issued the warrant, as well as to the Regional Coroner and Chief Forensic Pathologist.

To provide quality assurances for the provision of pathologists’ services under the Act, forensic pathologists must be “authorized” to perform services under the Act and the provision of those services is to be facilitated by the Ontario Forensic Pathology Service (“OFPS”), which is formally established in s. 6 of the Coroners Act. A registry of the forensic pathologists that are authorized is maintained by the Chief Forensic Pathologist who is also responsible for the administration and operation of the OFPS and for supervising and directing authorized pathologists in their provision of services under the Act. The Chief Forensic Pathologist is also responsible for conducting programs of instruction to pathologists and for preparing, publishing and distributing a code of ethics for the guidance of those pathologists.

Although the Goudge Report also suggested the appointment of regional directors for each forensic pathology unit to provide oversight and assume responsibility for the work of their respective units, the Act does not provide for this. However, it would seem possible that regional directors in pathology would be considered by legislators in the future, since the Act does provide for regional coroners.

OVERSIGHT AND COMPLAINTS

The emphasis on enhancing oversight and accountability has also led to the establishment of the Death Investigation Oversight Council, although this provision has not yet come into force. This change arose from Goudge J.’s recommendation to establish a “governing council” whose principal function would involve overseeing the duties of the Chief Coroner and ensuring that the forensic pathology work completed for the Office of the Chief Coroner is satisfactory. The recommendations advised setting out the obligations and responsibilities of the governing council, including oversight, budgetary approval, and the administration of a public complaints process. Accordingly, the provisions of the amended Act provide the Death Investigation Oversight Council with the authority to supervise and advise the Chief Coroner and Chief Forensic Pathologist on matters including financial resource management, strategic planning and accountability. Furthermore, the Chief Coroner and Chief Forensic Pathologist must report to the Oversight Council on such activities. The Council must, in turn, report to the Minister on its activities, including on the advice it has provided.
The new provisions also require the Council to establish a Complaints Committee and the Act now provides the right of persons to make a complaint to the Committee about a coroner, a pathologist or another person with powers or duties under the Act. Complaints will be received in writing but may not deal with coroner decisions with respect to holding, scheduling or conducting an inquest.

CORONERS’ INVESTIGATIONS AND INQUESTS

A significant amendment to the Coroners Act which does not arise from the Goudge report and is not related to forensic pathology involves the clarification, and some might say expansion, of the purpose and scope of a coroner’s investigation. Previously, the stated function of such an investigation was to determine whether holding an inquest was necessary.

Following revision, s. 15(1) of the Act states clearly that a coroner’s investigation is held for the purpose stated above but also to inquire and determine who the deceased was, and when, where, and how the person passed away. Section 15(1) also states that the purpose of a coroner’s investigation includes the collection and analysis of information obtained during the investigation, with a view toward preventing similar deaths. In effect, this amendment makes it clear that where a coroner has determined that an inquest is not necessary, it is expected that he or she will perform the same function as the inquest jury.

Previously, an investigating coroner had no specific authority to address the prevention of further deaths in similar circumstances. In fact, whether a jury might make useful recommendations on the issue was one of the considerations for a coroner in determining whether an inquest was “necessary”.

Now that the issue is to be explicitly addressed during the course of the investigation, it is unknown what effect this will have on the prevalence of non-mandatory inquests.

To enhance accountability, s. 4(1)(d) of the Act, which traditionally only required that the findings and recommendations from coroners’ juries were presented to the appropriate body, has been expanded to further require the Chief Coroner to present the suggestions and results of coroners’ investigations to the appropriate persons, agencies and ministries of government.

Finally, under s. 18(3), the Chief Coroner is required to inform the public about the results of an investigation, should the Chief Coroner reasonably consider it necessary to bring it to their attention, in the interest of public safety.

As noted above, it is not yet known what impact these changes will have on the coroner’s investigation process. However, one possible outcome will be more rigorous investigations, particularly in cases where an inquest is not mandatory since the coroner may be able to achieve the same goals as a jury without expending the same resources. If this turns out to be the case, it will be important for an organization to carefully consider how it will respond to requests for information from the coroner or the police officers who are conducting the investigation.

[Editor’s Note: Jennifer Hunter is an associate practising in the area of health law, including providing representation at coroner inquests. Ms. Hunter would like to thank Melissa Schulman, summer student at Miller Thomson LLP, for her assistance in preparing this article.

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