

A DEATH-DEFYING LEAP: SECTION 7 *CHARTER* IMPLICATIONS OF THE CANADIAN COUNCIL FOR DONATION AND TRANSPLANTATION'S GUIDELINES FOR THE NEUROLOGICAL DETERMINATION OF DEATH

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Created by a Federal-Provincial/Territorial inter-governmental agreement in 2001, the non-profit Canadian Council for Donation and Transplantation ("CCDT") was mandated to increase Canada's organ and tissue supplies and the viability of organ transplants. The CCDT satisfied this mandate by creating, inter alia, guidelines for the determination of death, before being merged with the Canadian Blood Services ("CBS") in 2008. These brain death guidelines, adopted in some parts of Canada by both policy-makers and practitioners, with possible effects on organ and tissue supplies, substantially redefine the point at which physicians may declare neurological death.

Aspects of this redefinition raise patient safety concerns because they reveal a potential for physicians to declare death significantly earlier, and with greater chance of error, than previous brain death guidelines. For instance, the CCDT recommends that Canada employ a brainstem criterion of death, as used in the United Kingdom. There are concerns that the CCDT recommendations may infringe patients' section 7 rights to life and security of the person under the *Charter*, if government involvement can be shown to permit *Charter* review.

Le Conseil canadien pour le don et la transplantation (CCDT), créé en 2001 par une entente fédérale-provinciale/territoriale, a pour mandat d'augmenter les réserves de tissus et d'organes ainsi que la viabilité des transplantations. Avant sa fusion avec la Société canadienne du sang en 2008, le CCDT a comblé ces exigences entre autres en créant de nouvelles directives sur la fixation des conditions du décès. Ces directives sur la mort cérébrale, adoptées en certains endroits à la fois par des praticiens et les législateurs, redéfinissent substantiellement le moment où les médecins peuvent déclarer une mort cérébrale et pourraient donc avoir des conséquences sur les réserves d'organes et de tissus.

Certains aspects de cette redéfinition soulèvent des inquiétudes quant à la sécurité des patients étant donné la possibilité offerte aux médecins de déclarer une mort considérablement plus tôt, avec un plus grand risque d'erreur, comparativement aux directives précédentes sur la mort cérébrale. Par exemple, le CCDT recommande que le Canada emploie le critère du tronc cérébral comme au Royaume-Uni. Des inquiétudes existent également quant à la possible suffisante violation par ces directives du droit des patients à la vie et à la sécurité garanti par l'article 7 de la

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Citation: Jacquelyn Shaw, "A Death-Defying Leap: Section 7 *Charter* Implications of the Canadian Council for Donation and Transplantation's Guidelines for the Neurological Determination of Death" (2012) 6:1 MJLH 41.

Référence : Jacquelyn Shaw, « A Death-Defying Leap: Section 7 *Charter* Implications of the Canadian Council for Donation and Transplantation's Guidelines for the Neurological Determination of Death » (2012) 6 : 1 RDSM 41.

Despite the CCDT's claims of independent, non-governmental status, the author argues that the CCDT can be shown to be a part of the fabric of government. Alternatively, the CCDT brain death guidelines may also qualify as government activity, in either case permitting *Charter* application. The author argues that, due to their irrational, arbitrary, and disproportionate elements, the CCDT's infringing recommendations do not appear to adequately comply with the principles of fundamental justice. These recommendations seem unlikely to be upheld under section 1 of the *Charter*. Yet, while a *Charter* challenge to the CCDT brain death guidelines appears justified, it may not be feasible. Alternative approaches may be required.

Charte canadienne des droits et libertés si des liens suffisants avec le gouvernement peuvent être établis afin de permettre un examen selon celle-ci.

Malgré les revendications d'indépendance du CCDT, l'auteur soutient qu'il puisse être réputé comme faisant partie de la structure gouvernementale. Autrement, il se peut que les directives du CCDT sur la mort cérébrale puissent également être qualifiées de « gouvernementales », dans les deux cas permettant l'application de la Charte à leur égard. L'auteur soutient qu'en raison de leurs éléments irrationnels, arbitraires et disproportionnés, les recommandations du CCDT contrevenantes ne semblent pas satisfaire aux principes de justice fondamentale. En dernier lieu, ces directives ont peu de chances d'être validées en vertu de l'article 1 de la Charte. Même si une contestation des directives du CCDT fondée sur la Charte semble justifiée, elle pourrait s'avérer impossible, nécessitant par le fait même des solutions alternative

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"No man is an island entire of itself; ... any man's death diminishes me, because I am involved in mankind. And therefore never send to know for whom the bell tolls; it tolls for thee."

- John Donne, 1572-1631

Introduction

The eventuality of death is one of the few certainties in human life. The determination of death requires that physicians employ certain methodologies to test critical functions before declaring a patient to be dead. In Canada, the methodology by which death is declared for organ donation purposes is found in voluntary protocols or guidelines, rather than in primary legislation, such as provincial and territorial human tissue and organ donation statutes. These non-statutory guidelines have historically been defined solely by physician groups, without input from other professions, legislatures, or the public. The most recent such guidelines were created by the Canadian Council for Donation and Transplantation ("CCDT"), an organization established to improve Canada's organ transplantation system, including its relatively low organ donation rates. Claimed to be "a significant, positive advance,"¹ the CCDT guidelines have been included in the Canadian Medical Association's ("CMA") online "Practice Guidelines InfoBase" as the current practice guidelines for the neurological determination of death.

Many experts argue that human biological death involves a continuum of progressive functional losses (e.g. loss of certain organ or nerve functions, including consciousness) spanning the period between birth and complete bodily decay.² In contrast, human legal death is conceptualized as a discrete moment within that continuum, as declared by a physician pursuant to clinical guidelines. Past guidelines have changed incrementally over time, keeping pace with scientific advances. However, analysis of the CCDT guidelines' substance reveals a number of major changes, the scientific justifica-

¹ CCDT, *Severe Brain Injury to Neurological Determination of Death: A Canadian Forum* (2003), online: Trillium Gift of Life Network <www.giftoflife.on.ca/assets/pdfs/1SBINDD_English.pdf> ("Members of the panels came to unanimous agreement on recommendations that mark a significant positive advance on [previously] existing guidelines" at 3) [*SBINDD*].

² See e.g. D Alan Shewmon, "'Brainstem Death,' 'Brain Death' and Death: A Critical Re-Evaluation of the Purported Equivalence" (1998) 14 *Issues L & Med* 125 at 142-43. Others disagree, arguing that biological death is a moment. This paper will adopt the view that human biological death is best described as a functional continuum, with legal death as a point in time within this continuum.

tion for which is unclear. The guidelines have been adopted by a number of large Canadian hospitals, providing some enforceability.³

One guideline change includes the CCDT recommendation that Canadian physicians adopt a brainstem criterion for death. This criterion was previously applied only in the UK, in contrast to the whole-brain criterion, which has been applied in Canada since 1968.⁴ Other concerning changes include weakening or removing some earlier safeguards intended to prevent erroneous (i.e. premature) declarations of brain death. Taken together, such changes may systematically increase the speed with which patients can be declared brain-dead and therefore legally eligible for organ harvest.

This paper explores whether the CCDT guidelines violate the *Canadian Charter of Rights and Freedoms*⁵ and suggests that the guidelines be replaced. Part I provides some context for the discussion. Part II analyses Canadian jurisprudence and the characteristics of the CCDT, and argues that, according to the jurisprudence, the CCDT and its guidelines should be regarded as “government” or “government activity,” respectively, and must therefore comply with the *Charter*. Part III(a) analyses the possible infringement of *Charter* rights by the CCDT guidelines, focussing on section 7 rights to life and security of the person; Part III(b) assesses whether the suspected section 7 deprivations have occurred “in accordance with the principles of fundamental justice”; Part III(c) assesses whether these section 7 infringements might still be upheld under section 1 of the *Charter*, and Part III(d) considers non-*Charter* remedies. Finally, Part IV concludes that the CCDT guidelines may unjustifiably infringe Canadian patients’ section 7

³ This includes major hospitals in Atlantic Canada, Edmonton, and Calgary. See Barrington Research Group, *Canadian Council for Donation and Transplantation (CCDT) Summative Evaluation Final Report* (2006) at 39-40, online: Canadian Blood Services <www.organsandtissues.ca/s/wp-content/uploads/2011/11/Summative_Evaluation_Report.pdf> [*Summative Evaluation*].

⁴ The CCDT’s recommendation would mean that to be declared brain-dead in Canada, only the brainstem (the lower portion of the brain, which controls many reflexes, breathing, and wakefulness), need be shown to be non-functional, in contrast with the earlier requirement to show that both the upper and lower portions of the brain (i.e. the entire brain, including the cortex, which governs conscious thought, memory, personality, voluntary movement, and pain-sensation, as well as the brainstem) are non-functional. The CCDT’s change in criterion is therefore a very significant change.

⁵ Part I of the Constitution Act, 1982, being Schedule B to the *Canada Act 1982* (UK), 1982, c 11 [*Charter*].

rights, suggests that a *Charter* challenge to these guidelines is justified, and discusses possible responses to the guidelines.

I. The CCDT and the Guidelines for the Determination of Death

A. The CCDT

During the 1990s, Canada's federal government became increasingly concerned about the disparity between the organ donation rate, which was low relative to nations such as Spain,⁶ and the increasing number of patients requiring organ transplants in an aging and sedentary society. Unlike many nations, and partly due to Canada's constitutional division of powers, Canada's organ donation system was fragmented, lacking a central coordinating body to oversee it. Between 1996 and 1999, three major nation-wide government reports were produced, providing "the rationale, impetus and structure" for a solution.⁷ A Federal-Provincial/Territorial ("FPT") strategy was

⁶ Health Canada states that "Canada's organ and tissue donation rate is one of the lowest among western industrialized countries. Donation rates have levelled off ... at a time when the need for transplants has increased by 50 per cent" (Health Canada, *Government Response to the Report of the Standing Committee on Health, Organ and Tissue Donation and Transplantation: A Canadian Approach* (September 1999) at 1, online: HC <www.hc-sc.gc.ca/dhp-mps/brgtherap/activit/announce-annonce/govresp_repgouv-eng.php> [Health Canada, *Government Response*]). According to the House of Commons, in 1999, Canada reported 14.4 donors per million population, while countries such as Spain reported rates of 31.5 donors per million population. Reportedly, Spain's donor consent rate doubled in the eight years following the creation of its national OTDT coordinating body, while transplant numbers tripled. See House of Commons, Standing Committee on Health, *Organ Tissue Donation and Transplantation: A Canadian Approach* (3 April 1999) ch 3(A) [1999 Standing Committee Report].

⁷ Three seminal documents provided the rationale for the establishment of the CCDT: the Advisory Committee on Health Services, *Organ and Tissue Donation and Distribution in Canada: A Discussion Document* (1996) [Advisory Committee, *Distribution Discussion Document*]; the 1999 Standing Committee Report, *ibid*; and Health Canada, National Coordinating Committee for Organ and Tissue Donation and Transplantation, *A Coordinated and Comprehensive Donation and Transplantation Strategy for Canada* (18 November 1999) [1999 NCCOTDT Strategy]. The NCCOTDT Strategy in particular provided the targets, means, core functions and support processes for the establishment of an OTDT system coordinated by the CCDT. The content of the 1999 NCCOTDT Strategy was approved by the CDM in September 1999 (*Summative Evaluation, supra* note 3 at 10).

drawn up to create a central coordinating body, the CCDT,⁸ which was staffed with members chosen for their expertise in organ and tissue donation and transplantation (“OTDT”).⁹

Established as a government body in October 2001 by the Conference of Deputy Ministers of Health (“CDM”),¹⁰ the CCDT was tasked, generally, with advising the CDM and, specifically, with creating guidelines, standards, and best practices to improve OTDT and significantly increase Canada’s organ supplies, for CDM approval.¹¹ CCDT directors, authors, and panellists at guideline-creation fora were self-described as “agents of change.”¹² In 2005, the CCDT was incorporated as a non-profit organization, and in 2006 it became a registered charity, operating at arm’s length from government and funded by a Health Canada Contribution Agreement.¹³

⁸ Health Canada, *Interim Funding of the Canadian Council for Donation and Transplantation (CCDT) - Health Canada 2003-05-08* (8 May 2003), online: HC <www.hc-sc.gc.ca/ahc-asc/performance/audit-verif/2004-list/fund-finan-eng.php> [Health Canada, *Interim Funding*].

⁹ Health Canada indicated that “CCDT Board members were selected for their expertise and knowledge of [organ and tissue donation and transplantation]” (*Final Audit Report: Audit of the Management of Contribution Agreements with the Canadian Council for Donation and Transplantation and the Canadian Blood Services*, (September 2009) at 1, online: HC <www.hc-sc.gc.ca/ahc-asc/pubs/_audit-verif/2009-22/index-eng.php> [Health Canada, *Final Audit*]). The CCDT was self-described as an organization “dedicated exclusively to the interests and issues of the organ and tissue donation and transplantation system in Canada” (CCDT, *Collaborate. Support. Enhance: 2006 Annual Report*, (2006) at 17, online: Government of Canada Depository Services Program <dsp-psd.pwgsc.gc.ca/Collection/H1-9-16-2006E.pdf> [CCDT, *2006 Annual Report*]).

¹⁰ Health Canada, *Final Audit*, *ibid* at 1.

¹¹ The CCDT “arose from concerns about the shortage of organs and tissues for transplantation in Canada ... The CCDT was established in October of 2001 as an advisory body to the Federal/Provincial-Territorial Conference of Deputy Ministers of Health (CDM) in its efforts to coordinate activities related to organ and tissue donation and transplantation” (*Summative Evaluation*, *supra* note 3 at 1). As one of the CCDT’s list of nine tasks of its mandate, established 7 June 2001, the CCDT was to “[r]ecommend [OTDT] practice guidelines based on an assessment of best practices” (*ibid* at 12).

¹² *SBINDD*, *supra* note 1 at 1.

¹³ The precise date of the CCDT’s incorporation is unclear: it is listed as 25 February 2005 in Letters Patent; as 1 April 2005 in the CCDT’s Form 3 Annual Summary Report to Industry Canada (19 May 2006); and as 29 April 2005 in the Canada

B. The CCDT Guidelines

In Canada, very little legislation addresses death. In the context of *post mortem* organ and tissue donation, existing legislation stipulates only that death be determined in accordance with “accepted medical practice,”¹⁴ or variants on this phrase. The content of “accepted medical practice” in the context of brain death has traditionally been determined by clinical practice guidelines. Thus, the methodological requirements of brain death declaration appear in guidelines periodically updated by Canadian physician groups.¹⁵ Although voluntary and non-binding by themselves, the CCDT guidelines have served as the template for some Canadian hospitals’ institutional rules for brain death declaration.¹⁶ Through uptake and adoption, the guidelines have acquired enforceability. The CCDT also introduced the guidelines in education sessions for nursing and medical students.¹⁷ There are other suggestions that the guidelines may receive greater uptake due to their seemingly independent, non-governmental origins.¹⁸ As long as the CCDT guidelines

Gazette.

¹⁴ See e.g. *Human Tissue Gift Act*, RSNS 1989, c 215, s 8(1); Bill 121, *Human Organ and Tissue Donation Act*, 2nd Sess, 61st General Assembly, Nova Scotia, 2010, c 36, s 16.

¹⁵ Past guideline-authoring groups included the CMA (1968), the Canadian Congress of Neurological Sciences (1987), and the Canadian Neurocritical Care Group (1999). In 2003, the CCDT acknowledged the 1999 Canadian Neurocritical Care Group guidelines as “broadly reflecting current practices in the declaration of brain death in Canada” (CCDT, *A Review of the Literature on the Determination of Brain Death* (2003) at 13, online: Canadian Blood Services <www.organsandtissues.ca/s/wp-content/uploads/2011/11/Brain-Death-Long-Lit-Review.pdf> [CCDT, Literature Review Brain Death]; 1999 *Standing Committee Report*, *supra* note 6 ch 4).

¹⁶ In Atlantic Canada “*SBINDD* ... recommendations have been adopted by the only two hospitals in the region that do transplants” (*Summative Evaluation*, *supra* note 3 at 40). In Alberta, before the CCDT existed, “[hospitals in] Edmonton and Calgary had different guidelines for [brain death determination]; after the [*SBINDD*] forum ... a consistent [brain death declaration] protocol between both health regions was developed” (*ibid* at 39). The CCDT was headquartered in Edmonton, Alberta after 2005.

¹⁷ *Ibid* at 35.

¹⁸ This seemed to be implied in several reports. According to surveyed OTDT stakeholders, “one of the greatest strengths of the CCDT is the realization by these diverse [OTDT stakeholder] groups that the CCDT is able to provide an objective perspective to discussions since the CCDT is an arm’s length NGO” (CCDT, *CCDT Summative Evaluation* (31 March 2007) at 6, online: Canadian Blood

remain in circulation, they may also provide a foundation upon which to base future, more dramatic changes.¹⁹

It should be noted that physicians must follow some set of guidelines to declare death. Ideally, in light of the physician-patient fiduciary duty, a physician recognizing any set of medical guidelines as risky might wish to select another set of guidelines. However, especially in smaller hospitals, not all physicians declaring death may have a sufficient neurology background to recognize the risks the CCDT guidelines pose. This also assumes that no institutional recommendations exist as to guideline choice, that the physician knows that alternative guidelines exist, and that he or she has no qualms about rejecting recent, “widely endorsed”²⁰ guidelines created by a “national forum of experts.”²¹ Even if these assumptions prove correct, the only brain death guidelines available from the CMA’s online database are the CCDT guidelines; this means that a physician must spend valuable time combing the medical literature for alternative guidelines.

Services <organesettissus.ca/s/wp-content/uploads/2011/11/Summ_Eval_Mngmt_Rsp.pdf> [2007 *CCDT Summative Evaluation*]). The *Summative Evaluation*, *supra* note 3 at 28, 29, reported that “[survey participants] indicated that the CCDT is well placed and well informed on issues, [and] is both objective and inclusive ...” as part of the basis for their conclusions that the CCDT was “doing a good job” in providing initiatives to CDM that had “already been put into practice” and should continue doing so. These responses suggest that past stakeholder receptivity to CCDT recommendations was based, at least partly, on the perception of the CCDT’s objective, arm’s length relationship to government.

¹⁹ The CCDT commented on its guidelines’ lack of enforceability, arguing that the CCDT advisory mandate “needed strengthening to support the implementation of widespread Canadian solutions” (*ibid* at viii, 46). However the CCDT also noted that “[f]uture OTDT policy change is planned. CCDT reports and recommendation are being accessed as an information resource... that various provincial governments are planning in the near future” (*ibid* at 41).

²⁰ The *SBINDD* guidelines are described as “widely endorsed and implemented in Canada,” suggesting some consensus of Canadian medical practitioner opinion supporting their use (CCDT, *Brain Blood Flow in the Neurological Determination of Death Expert Consensus Meeting Report* (2006) at 1, online: Government of Canada <publications.gc.ca/collections/collection_2007/hc-sc/H14-17-2007E.pdf> [*BBFNDD*]).

²¹ SD Shemie et al, “Severe Brain Injury to Neurological Determination of Death: Canadian Forum Recommendations” (2006) 174:6 *Can Med Assoc J* at S1 [*SBINDD 2006*] describes its brain death guidelines as the product of a “national forum of experts,” which may convey a sense of authority that physicians using the guidelines may be reluctant to question.

It should also be clarified that the CCDT guidelines may be applied in declaring brain death in any context, not only those involving organ donors.²² A patient cannot, therefore, necessarily avoid the application of the guidelines simply by exercising a choice not to become a *post mortem* organ donor.²³ The CCDT has described its guidelines as marking “a significant, positive advance on [pre-]existing guidelines.”²⁴ Although previous Canadian brain death guidelines were produced by physician groups and involved minor procedural changes made over time, the CCDT guidelines have made the most substantial changes to brain death declaration procedures.²⁵

The CCDT brain death guidelines were created in a series of four versions. The first CCDT guideline version, created in April 2003 and entitled *Severe Brain Injury to the Neurological Determination of Death (SBINDD)*, was initially disseminated to more than 1,400 healthcare practitioners and policy-makers across Canada over several years following its creation.²⁶ Reported, through this informal dissemination,²⁷ the guidelines achieved some

²² Nothing in the CCDT guidelines prevents their use to declare death in non-donors.

²³ Given the physician-patient “knowledge asymmetry,” patients may not understand the risks posed by the guidelines, nor even know that such guidelines exist. Thus it is unreasonable to ask patients to assume responsibility for avoiding the risks of the guidelines, even if they could somehow do so.

²⁴ *SBINDD*, *supra* note 1 at 3.

²⁵ This article restricts itself to discussing guidelines of Canadian national scope. It is not known and outside the scope of this discussion whether any of the more local or regional organ procurement organizations issuing brain death declaration protocols have attempted similar local changes.

²⁶ *SBINDD*, *supra* note 1. Chronologically, dissemination of the CCDT guidelines was planned to take place via a multiple-phase approach: first via the CCDT advising the CDM; then informal dissemination involving CCDT forum participants and formal dissemination through journal publication, etc. (*ibid* at 25). A similar process was cited elsewhere, involving first a CCDT provision of recommendations to CDM for acceptance and possible FPT policy-maker implementation, then dissemination broadly. “OTDT stakeholders receive either hard or electronic copies of reports, information and reports are posted on the CCDT website, and information is compiled for presentations or journal publications.” (*Summative Evaluation*, *supra* note 3 at 19). Monitoring of adoption was added in late 2004.

²⁷ By 2006 “[a]pproximately 1400 hard copies [of *SBINDD* were] distributed (with a CD ROM included) to Forum Participants, Organ Procurement Organizations, Transplant Program, Health Professional Associations, Non-government Organizations, Critical Care Units across Canada and posted on CCDT website,” and that “[k]nowledge diffusion [of CCDT publications] is occurring through

success in being adopted, “sometimes quite rapidly.”²⁸ Marked tissue supply increases were subsequently reported in some regions, such as Nova Scotia, with smaller national increases observed as well.²⁹ The second guideline version, almost identical to the first, was formally published in March 2006 in the *Canadian Medical Association Journal*.³⁰ This version was also included in the CMA’s online “Clinical Practice Guidelines InfoBase” after July 2006.³¹

informal channels” (*ibid* at 39).

²⁸ *Ibid* at 39. According to the CCDT, the guidelines are also in use in Alberta hospitals and by policy-makers in Ontario, where “CCDT materials are routinely used to prepare Ministry briefs” (at 108). By November 2006, the CCDT reported that its guidelines had “been widely endorsed and implemented in Canada” (*BBFNDD*, *supra* note 20 at 1).

²⁹ Recently, regional increases have included a tripling of Nova Scotia’s tissue supplies in less than three years, soon after adoption of the CCDT guidelines in local transplant hospitals (*Summative Evaluation*, *supra* note 3 at 40). The CCDT claimed credit for this change: “In Nova Scotia, tissue donor numbers have tripled as a result of the work of the CCDT” (*ibid*). The Department of Health in 2005 confirmed this increase, but credited other factors (Nova Scotia Department of Health and Wellness, News Release, “Organ Donation Program Wins National Award” (20 June 2005) online: Government of Nova Scotia <www.gov.ns.ca/news/details.asp?id=20050620004>). It is not stated whether CCDT reports all used the word “tissue” the same way, to differentiate non-organ donations such as blood, skin, cartilage, and bone from whole or partial organs (as in the 1999 NCCOTDT *Strategy*, *supra* note 7 at 8), or whether both organs and non-organs such as blood, skin, cartilage, and bone were included. A smaller national increase in organ availability may have occurred since the CCDT guidelines’ issuance. The CCDT argued in March 2007 that the Canadian Organ Replacement Register had reported, in 2006, a nation-wide increase of 13% in deceased donors, described as “the first [national] increase in five years,” attributed in part to CCDT efforts (2007 *CCDT Summative Evaluation*, *supra* note 18). In contrast, the Canadian Institute for Health Information reported that from 1998-2008 organ supplies rose 28%, of which 9% was due to a decrease in donors (Canadian Institute for Health Information, *Organ Donations Increasing in Canada but not Keeping Pace with Demand*, online: CIHI <www.cihi.ca/CIHI-extportal/internet/en/document/types+of+care/specialized+services/organ+replacements/release_22dec2009> [CIHI, *Keeping Pace with Demand*]).

³⁰ *SBINDD 2006*, *supra* note 21 at S1.

³¹ See Letter of Agreement from Seema Nagpal, Associate Director of Epidemiology, Office for Public Health, CMA, to Kimberly Young, Chief Executive Officer, CCDT, signed 13 July 2006, CCDT <www.ccdt.ca/english/publications/final-pdfs/CMA-CCDT-Agreement.pdf>.

The third guideline version, *Brain Blood Flow in the Neurological Determination of Death (BBFNDD)*, both complements and significantly alters *SBINDD*.³² *BBFNDD* was written in November 2006³³ and posted to the CMA InfoBase with *SBINDD 2006*.³⁴ A final version, *BBFNDD 2008*, was formally published in the *Canadian Journal of Neurological Sciences* in May 2008,³⁵ one month after the CCDT was dissolved as an entity.³⁶ Upon the dissolution of the CCDT, its mandate was transferred to the CBS on 1 April 2008.

The versions of the CCDT guidelines interrelate and may be used simultaneously.³⁷ Their use is concerning because, while previous Canadian brain death guidelines have incorporated minor, incremental changes to keep pace with scientific developments, numerous changes in the CCDT guidelines are far less incremental. Moreover, some appear to contradict established, mainstream scientific thinking on brain death and have possible *Charter* implications.

The role of the CMA and its InfoBase also deserve mention. The CMA is not generally an official standard-setting body; however, in relation to brain death determination, the CMA has acquired some prominence due to historical practice over more than three decades. Since Canada's adoption of brain death as a legal criterion of death in 1968, the CMA has acquired visibility

³² *BBFNDD*, *supra* note 20.

³³ It is not known when *BBFNDD*, copyrighted in February 2007, was posted to the CMA InfoBase. Like *SBINDD*, *BBFNDD* may also have been informally disseminated, via the CMA InfoBase or other means, in the 18 months between its creation and journal publication.

³⁴ *Supra* note 21 (its basic medical recommendations are identical to those of *SBINDD*, *supra* note 1).

³⁵ Sam D Shemie et al, "Brain Blood Flow in the Neurological Determination of Death: Canadian Expert Report" (2008) 35:2 Can J Neurol Sci 140 [*BBFNDD 2008*] (these recommendations were identical to those of *BBFNDD*, *supra* note 20).

³⁶ The CCDT ceased to exist as an entity after 31 March 2008, and was dissolved as a corporation on 22 June 2009, with voluntary revocation of its charitable status occurring on 20 February 2010.

³⁷ Brain death can be declared using only the definition in *SBINDD* (*supra* note 1) or *BBFNDD* (*supra* note 20). However, certain methodological details are provided only in *SBINDD*, relating to pediatric diagnosis, temperature effects, etc., while *BBFNDD* contains added details on brain blood flow testing and some changes relative to *SBINDD* (e.g. treatment of high-dosage barbiturate-affected patients).

and importance with respect to the subject of brain death by issuing, commissioning, approving, and more recently hosting, brain death guidelines on its InfoBase. In 2000, the CMA issued a policy to deliberately move away from issuing or endorsing brain death guidelines. This indicates the CMA's recognition of its long-standing association with Canadian brain death guidelines.³⁸ Therefore, the CMA's dissemination of the CCDT guidelines may be more influential than it at first appears.

Notably, also in 2000, the CMA commenced systematic efforts to disseminate clinical practice guidelines, generally, via its online InfoBase, as part of a CMA "Quality of Care program."³⁹ The CMA stated: "We encourage physicians to use these guidelines for national, provincial, territorial and local guideline initiatives, and in doing so, to promote evidence-based clinical practice and ongoing improvement in the quality of care for Canadians."⁴⁰ Reportedly, the InfoBase was planned as "a one-stop, comprehensive national resource" for guidelines.⁴¹ The CMA's mission in creating the InfoBase was "to 'provide leadership and to promote the highest standard of health and healthcare for Canadians' ... [by] collaborating with other organizations to facilitate and coordinate the clinical practice guideline process in Canada."⁴² One such collaborating organization was the educational body the Royal College of Physicians and Surgeons of Canada. These factors suggest

³⁸ The CMA preferred after 2000 that death determination in the context of OTDT be made "according to widely accepted guidelines established by expert medical groups" (*Organ and Tissue Donation (Update 2000)*, s 7.1, online: <policybase.cma.ca/dbtw-wpd/PolicyPDF/PD00-07.pdf>). The CCDT has been self-described as an expert group that claimed its *SBINDD* guidelines were "widely accepted" (*BBFNDD*, *supra* note 20 at 1).

³⁹ See CMA, "Guidelines for Canadian Clinical Practice: Guidelines" at Foreword, online: CMA <prismadmin.cma.ca/index.php?ci_id=54703&la_id=1 or mdm.ca/cpgsnew/cpgs/gccpg-e.htm> [CMA, "Guidelines"].

⁴⁰ *Ibid.*

⁴¹ B Skidmore, "New and Improved: CMA's Guidelines InfoBase Now at Physicians' Fingertips" (2000) 162:9 Can Med Assoc J 1342 at 1342. InfoBase was intended to be "an alternative source of free clinical practice guidelines to the [CMA] National Guideline Clearinghouse" (Roberta Bronson Fitzpatrick, "CMA InfoBase: Clinical Practice Guidelines" (2008) 27:4 Med Ref Serv Q 419 at 419).

⁴² CMA, "Guidelines", *supra* note 39 at Introduction. The CMA stated that it was "collaborating with other organizations [including the Royal College of Physicians and Surgeons of Canada] to facilitate and coordinate the clinical guideline process in Canada."

that the CCDT guidelines may have a noticeable impact on Canadian medical practice in this area.

C. *Authorization and Creation of the CCDT Guidelines*

It is worth examining the CCDT's brain death guideline-creation process and authority in detail. As per the 1999 National Coordinating Committee for Organ and Tissue Donation and Transplantation ("NCCOTDT") *Strategy*, the CCDT was to "advise ... on overall policy direction, standards and guidelines for the delivery ... of organ and tissue donation and transplantation; to facilitate the development [and] implementation of practice and safety standards."⁴³ Yet reports indicate that the CDM specifically instructed the CCDT to address not only OTDT, but also, as a first priority, brain death determination, a possibility the 1999 Standing Committee had also raised.⁴⁴ In December 2002, "[t]he CDM selected certain priorities from the [CCDT Work-]Plan for the CCDT to address ... essentially putting the work of the other [CCDT] committees on hold."⁴⁵ The CDM's priorities⁴⁶ from the

⁴³ *Supra* note 7 at 23.

⁴⁴ According to authors Robert and Doreen Jackson, "A [deputy minister] possesses only the power that the Minister chooses to delegate [to the deputy minister]." Thus the powers and authority vested in the CDM were delegated to it by the FPT Ministers of Health. They also note that tenure is insecure and that deputy ministers who advise against ministerial policies "risk being viewed as obstacles to the government in pursuit of its partisan political objectives and being removed" (Robert J Jackson & Doreen Jackson, *Politics in Canada: Culture, Institutions, Behaviour and Public Policy*, 3d ed (Scarborough: Prentice-Hall, 1994) at 386.

⁴⁵ *Summative Evaluation*, *supra* note 3 at 20.

⁴⁶ The other priority mentioned was an OTDT social marketing campaign. The CCDT engaged in significant efforts to canvass the organ donation attitudes of indigenous peoples, the general Canadian public, and also health care providers. See e.g. CCDT, *Diverse Communities: Consultation to Explore Peoples' Views on Organ and Tissue Donation*, online: Canadian Blood Services <organesettissus.ca/s/wp-content/uploads/2011/11/Chinese-Cdn-Summary-english.pdf>; CCDT, *Public Awareness and Attitudes on Organ and Tissue Donation and Transplantation Including Donation After Cardiac Death: Final Report*, online: Canadian Blood Services <organesettissus.ca/s/wp-content/uploads/2011/11/Public_Survey_Final_Report.pdf> [CCDT, *Public Awareness Report*]; CCDT, *Health Professional Awareness and Attitudes on Organ and Tissue Donation and Transplantation: Including Donation after Cardiocirculatory Death*, online: Canadian Blood Services <organesettissus.ca/s/wp-content/uploads/2011/11/Survey-Health-Prof.pdf> [CCDT, *Health Professional Survey*].

CCDT's work-plan included addressing the neurological determination of death: "Some components of [the CCDT work-plan] (for example, ... the Neurological Determination of Death component) were approved by the CDM at its December 2002 meeting, and the CCDT was mandated to pursue these initiatives."⁴⁷

The *SBINND* 2003 guidelines were created four months later. They were the CCDT's first guidelines, and they reflected the CDM's prioritization of the neurological determination of death, among other things. Justifying its revision of earlier brain death guidelines and the link to OTDT, the CCDT observed that "consistency and standardization [in brain death determination] will ... enhance the conduct of organ and tissue donation."⁴⁸

Reports reveal that the CCDT was authorized to issue guidelines through a cooperative partnership with the CDM, in which the CCDT provided medical "advice" and the CDM provided the necessary legal approval for the guidelines' dissemination.⁴⁹ The CCDT described a seven-step "advice cycle," the later stages of which included CCDT submission of recommendations to the CDM, CDM approval, guideline dissemination, and uptake monitoring.⁵⁰ CDM approval was described as an integral step in the CCDT's guideline-creation: "The advice is ... forwarded to the CDM for acceptance. It is then distributed to FPT governments for consideration and implementation at the policy level."⁵¹

⁴⁷ *Summative Evaluation*, supra note 3 at 16.

⁴⁸ *SBINDD*, supra note 1 at i.

⁴⁹ The CCDT stressed that its products merely provided advice to the CDM and required CDM approval for the CCDT to disseminate them (*Summative Evaluation*, supra note 3 at 19). This was envisaged in the 1999 NCCOTDT *Strategy*, with the CCDT's duties being to "establish program standards, guidelines and outcome goals for" OTDT initiatives, based on FPT recommendations (supra note 7 at Appendix B-1).

⁵⁰ This was followed in the case of *SBINDD*, at least (*Summative Evaluation*, supra note 3 at 19, 22).

⁵¹ *Ibid* at 19. "The CCDT's mandate is to provide advice to the CDM ... It was then up to the provincial and territorial levels [of government] ... to implement or not the recommendations" (at 11). "[T]he mandate of the [CCDT] is to provide advice to the FPT Conference of Deputy Ministers of Health in support of their efforts to coordinate FPT activities relating to organ and tissue donation and transplantation. The authority to make decisions with respect to organ and tissue donation and transplantation matters shall remain with the FPT governments" (at 12). This

However, even before CDM approval was received, the CCDT guidelines appear to have reflected significant government input. Government officials were required to attend CCDT meetings to provide unspecified input.⁵² The CCDT reported that an unnamed CDM liaison linked the CCDT and the CDM.⁵³ In addition, after 2003, the CCDT chair was a former CDM member.⁵⁴ It is unclear from the available information whether the CDM liai-

arrangement was anticipated in the 1999 NCCOTDT *Strategy*: “[p]olicies, standards and guidelines of national concern will be drafted by the [CCDT] ... for approval by the Ministers of Health” (*supra* note 7 at 26). *SBINND* also lists the plan for dissemination as occurring in two phases, the first involving the CDM, followed by formal and informal dissemination of the guidelines to users (*supra* note 1 at 25).

⁵² *Ex officio* government members attended CCDT meetings during both its government secretariat and non-profit phases, not only permitting government awareness of its activities, but also providing mandatory government input into the creation of the CCDT guidelines. The CCDT’s first set of by-laws, CCDT by-laws No 1, *A By-law Relating Generally to the Transaction of the Business and Affairs of CCDT* (15 October 2001) [CCDT by-laws No 1], stated that, in addition to the 15 CCDT members, there were eight “ex-officio observers” (including FPT government representatives) as non-voting members “entitled to attend [CCDT] meetings,” who could provide written submissions to the CCDT, at the chair’s invitation (s 4). Additional *ex officio* members were added after 2003 (*Summative Evaluation, supra* note 3 at 113). While these members were appointed by government (the provincial and territorial Advisory Committee on Health Services) under CCDT’s by-laws No 1, they were appointed by the CCDT under a third set of by-laws in 2006 (CCDT by-laws No 3, (2 October 2006) [CCDT by-laws No 3]). A 2008 report indicated that Health Canada attended CCDT meetings as *ex officio* members “to brief [CCDT] members on the development and implementation of [OTDT] regulations ... ” (House of Commons, *Standing Committee on Health*, 39th Parl, 2nd Sess, No 15 (4 March 2008) (Kimberly Young) at 6, online: Parliament of Canada <www2.parl.gc.ca/HousePublications/Publication.aspx?DocID=3325761&language=E&mode=1&Parl=39&Sess=2> [2008 *Standing Committee Report*]). As noted elsewhere, Leah Hollins, the CCDT Chair after 2004, was a recent ex-CDM member. An unnamed CDM liaison may have also provided a permanent connection between the CDM and CCDT (CCDT, *2006 Annual Report, supra* note 9 at 4), suggesting the CDM may have been represented at CCDT meetings. This government input was considered mandatory by the CDM (*Summative Evaluation, supra* note 3 at 28). The details of this advice were not described but were reportedly considered important for “credibility” with the CDM.

⁵³ CCDT, *2006 Annual Report, supra* note 9 at 4.

⁵⁴ Ms. Hollins served as British Columbia’s Deputy Minister of Health Services from 1 November 1999 until 27 August 2001 (28 September 2010 email to Jacquelyn

son was the same individual as the CCDT Chair who had recently served on the CDM. There also appears to have been substantial potential for guideline-creation bias through CDM's selection of the CCDT directors for their "expertise and knowledge of OTDT."⁵⁵ Neurologists—whose expertise is vital to the creation of safe guidelines—were conspicuously absent from the selection of CCDT directors.⁵⁶

Neurological expertise is needed to supply details vital to brain death determination, such as information regarding particular drug clearance times, the reliability of certain medical tests, and the safe interpretation of ambiguous results. OTDT expertise alone will not provide the knowledge necessary for the development of brain death guidelines. The government refined the CCDT's board membership, based on its performance observations, through CDM replacement of the CCDT's Chair.⁵⁷ Numerous other directors also left following a recommendation made in a 2003 CDM-commissioned report on CCDT operations by the consultancy KPMG/BearingPoint that the CDM replace directors, but it is unknown whether the CDM deliberately removed any of these other directors.⁵⁸ This governmental shaping of CCDT member-

Shaw from Jennifer Kitching, Reference Librarian, The Legislative Library of British Columbia). This would have made Hollins a CDM member until August 2001. She officially joined the CCDT in January 2004.

⁵⁵ "The Conference [of Deputy Ministers of Health] will select [CCDT] members. The federal Minister of Health will officially appoint the [CCDT] members and designate the Chair." Subject to the discretion of the CDM, members' terms may be renewed (CCDT by-laws No 1, *supra* note 52 s 3.2).

⁵⁶ As determined by reference to the CCDT directors listed in the CCDT application for charitable status in June 2006 [CCDT Charity Application]. While some neurologist non-directors did help to author *SBINDD*, they were a minority (23% in total). Moreover, the directors formulated the questions and discussions, and edited panellists' opinions.

⁵⁷ In October 2003, KPMG/BearingPoint suggested that CDM "re-consider" certain CCDT members and carry out future appointments of the chair and other directors. This recommendation (number 8) was not listed as rejected (*Summative Evaluation*, *supra* note 3 at 112-13). The reported CCDT response to Recommendation 10, which also urged CDM replacement of the chair, was that founding Chair Philip Belitsky resigned and that his replacement, ex-CDM member Leah Hollins, was installed for the term ending 31 March 2007 (*ibid*).

⁵⁸ Overall, 11 of 16 CCDT directors (69%) left, most in the first five years. After the October 2003 KPMG/BearingPoint suggestion that CDM "re-consider" certain CCDT directors and carry out future appointments, 4 of the 16 founding CCDT directors, including Chairman Belitsky, with directors H Ross, Stoyles, and Loertscher, left in late 2003 to early 2004. Four more—Berreza, Craig, Ferre, and S

ship may have helped to produce brain death guidelines more sensitive to OTDT needs than to those of brain-injured patients.

To fully understand the government's influence over the CCDT guidelines' content requires re-visiting the CCDT's origins in the 1990s.⁵⁹ In an effort to establish the future CCDT and to coordinate OTDT improvement, the 1999 Standing Committee on Health recommended that "the federal Minister of Health immediately seek support from the [National Coordinating Committee for Organ and Tissue Donation and Transplantation (NCCOTDT)] and provide it with a small team of Health Canada personnel to initiate action."⁶⁰ Similarly, the Standing Committee recommended "that the CDM establish the [CCDT] to oversee organ and tissue donation and transplantation, [and] to report annually through the CDM to the federal Minister of Health and Parliament."⁶¹ Accordingly, in June 1999, the CDM directed the NCCOTDT to produce a strategy, including "[a] framework for action ... that would result in a sustained systematic approach to increasing the rates of organ and tissue donation and transplantation in Canada."⁶²

Ross had left by the 2005 non-profit conversion date, bringing total departures to half of the original directors. Three more directors—Mohr, Lakey, and Doig—left in 2005-6, after the CCDT became a non-profit. The reasons for most of the turnover were not discussed in CCDT reports.

⁵⁹ The committee initially recommended that the national coordinating body, identical in characteristics to the CCDT, be named the "Canadian Transplant Network" (1999 *Standing Committee Report*, *supra* note 6 ch 3B). In 1995-1996, even before the 1999 *Standing Committee Report*, the Ministers of Health and CDM had begun to take an interest in the issue of OTDT shortages (*Summative Evaluation*, *supra* note 3 at 8; 1999 NCCOTDT *Strategy*, *supra* note 7 at 2-3).

⁶⁰ 1999 *Standing Committee Report*, *supra* note 6 at Recommendation 18.1. The 1999 *Standing Committee Report* strongly urges the strict separation of individual physicians performing brain death determination and those performing transplantation in order to "assure the public intending to donate that their critical care needs will never be jeopardized by the transplantation needs of another individual" (ch 3). It also recommends precisely the opposite regarding staffing the future CCDT with members of existing OTDT organizations (at Recommendation 2.2).

⁶¹ *Summative Evaluation*, *supra* note 3 at 10.

⁶² 1999 NCCOTDT *Strategy*, *supra* note 7 at 4. In setting its principles, goals, and targets in the strategy, the NCCOTDT "considered the goals agreed to by the federal Ministers of Health" of improving Canadians' health, ensuring reasonable access to health benefits, and promoting long-term healthcare system sustainability (*ibid* at 5).

Specific targets and a deadline were required as part of this NCCOTDT strategy. The resulting report urged the swift establishment of the CCDT and set as five-year targets very high, organ-specific increases: 20-95% in the number of transplantable organs and 250% increases for tissues other than organs.⁶³ The CDM approved this plan in September 1999.⁶⁴ Realistically, increases of this magnitude would be impossible without significant amendment of brain death guidelines, particularly since the target increases are for numbers of transplantable organs and, due to disease or damage, not all donated organs can meet transplantation quality standards.⁶⁵ The significant target increases in organs are extremely unlikely to be met through OTDT social marketing campaigns, given the difficulty of altering public behaviours, values, beliefs, and concerns.⁶⁶ Prior to the development of the guide-

⁶³ *Ibid* at 5, 7-8. The 1999 NCCOTDT *Strategy* set as specific goals: 20% more transplantable lungs, 50% more transplantable hearts, 85% more transplantable livers, 95% more transplantable kidneys, and 250% more transplantable tissues (e.g. skin, cartilage, bone, blood, etc) (at 7-8). Target numbers of available organs and tissues would actually have to be much higher to offset the fact that some donated organs are of poor quality by the time they are available for harvest.

⁶⁴ *Ibid* at 4. "In September 1999, the CDM approved the [NCCOTDT] framework for action" (*Summative Evaluation*, *supra* note 3 at 10).

⁶⁵ Therefore, even if modest increases (e.g. 25%) in donor consent were achieved, this would translate to a smaller increase in the number of organs made available. Achieving a very large increase (e.g. 95%) in transplantable organ numbers would require a more dramatic approach such as amending guidelines to declare death earlier in the biological continuum from birth to bodily decay.

⁶⁶ The 1999 *Standing Committee Report*, *supra* note 6 ch 6, concluded as much, stating that "it is the second stage of ... donor identification, management and procurement, where the most significant effect can be made on increasing donor numbers," rather than through the first step of influencing donor intent and choice. However, a CMA submission to the Standing Committee urged that organ donation remain "rooted in the gift philosophy," arguing that "any means or measure to procure organs will tend to be more ethically dubious the more coercive they are and the less they rely on autonomy, personal choice and altruistic giving" (CMA, "State of Organ and Tissue Donation in Canada: Submission to the House of Commons Standing Committee on Health", Brief BR1999-05 (6 March 1999) at 1, online: CMA <policybase.cma.ca/dbtw-wpd/BriefPDF/BR1999-05.pdf>). The CCDT, *Health Professional Survey*, *supra* note 46 at 8, states that even among healthcare professionals, only 68% signed donor cards while 99% claimed to support organ donation. This suggests that awareness may not be the limiting factor.

lines, donation rates had been stagnant for several years.⁶⁷

According to Trillium Gift of Life, as many as eight useable organs and additional tissues (e.g. skin, blood) can be transplanted from a consenting donor, although an average donor yields at least three transplantable organs.⁶⁸ Current technology does not yet permit growing new replacement organs from stem cells. Nor can it salvage the many available but damaged organs to increase the transplantable organ pool.⁶⁹ Therefore, short of requiring mandatory organ donation, social marketing (to encourage growth in donor numbers), and altering brain death guidelines (to increase the proportion of donors eligible for organ harvesting), are the only available means of increasing organ supplies.⁷⁰

With past social marketing efforts having yielded little increase, it seems that a major component of the CDM-approved plan involved significant amendment of previous brain death guidelines. Amending brain death guidelines to allow brain death declaration earlier in the biological continuum offers two means of achieving OTDT targets, through the required “sustained, systematic approach.” First, among the existing pool of brain-injured patients, some of them donors, brain death guideline amendment can increase the proportion of those who may legally be declared brain-dead. Second, such amendment may also increase the proportion of those brain-dead donors who possess transplantation-quality organs.⁷¹ The decision to amend particular guideline details (e.g. replacing whole-brain death with a brainstem criterion) may have been left to CCDT discretion; no evidence exists on the mat-

⁶⁷ *Summative Evaluation*, *supra* note 3 at 9.

⁶⁸ Trillium’s Annual Report for 2009-10 reported an average yield of 3.6 organs per donor, and a targeted goal of 3.75 organs per donor (online: Trillium Gift of Life Network <www.giftoflife.on.ca/pdf/TrilliumAR_09-10_ENG_Spreads.pdf>).

⁶⁹ See Nick Lane, *Power, Sex and Suicide: Mitochondria and the Meaning of Life* (Oxford: Oxford University Press, 2005) at 314.

⁷⁰ These would affect, respectively, the number of donors per million population and the number of organs available per donor.

⁷¹ According to some scholars, the viability of the energy-supplying mitochondria within transplanted organs is vital to transplantation success (Lane, *supra* note 69 at 314). As summarized by Lane, mitochondria become progressively more damaged with patient age due to lack of oxygen, disease or drug side effects. Therefore organs harvested as early as possible in the biological continuum, which suffer less cumulative mitochondrial damage, will normally experience greater transplantation success (*ibid*).

ter. However, it appears clear from the target organ numbers that substantial amendments were impliedly required.

Healthcare sustainability seems to be an enduring concern in the CCDT's history. In documents heralding the CCDT's establishment, sustainability was a recurring theme. A 1999 report accepted the Standing Committee recommendations as "the framework for discussions ... towards the establishment of a sustainable solution for transplantation in Canada."⁷² The CDM then demanded of the NCCOTDT a "sustained, systematic approach" to OTDT improvement. Subsequently, the NCCOTDT's blueprint for CCDT establishment identified healthcare system sustainability as one of its three "over-arching goals," and added that it is "essential that the donation and transplantation system be sustainable for the future."⁷³ The reason may relate to the aging of the baby-boomer generation and anticipated inundation of age-related ill-health. It has been predicted that the over-65 year-old population will double by 2025, expanding the need for hospital beds, staff, replacement organs, and other resources.⁷⁴ There appears to be an implicit belief that OTDT can aid in meeting these needs and achieving sustainability.⁷⁵

Regardless of CCDT content choices, CCDT recommendations were always subject to the requirement of CDM approval before dissemination. As the CDM acted as final arbiter (on behalf of the Federal Minister of Health and Parliament), presumably CCDT guideline drafts could have been denied approval and sent back for correction, thereby shaping the guidelines to fit government priorities. However, given the input from government representatives during the guideline-crafting process, it is unknown whether the CDM ever needed to request guideline corrections before issuing approval.⁷⁶ Early

⁷² Health Canada, *Government Response*, *supra* note 6 at 1.

⁷³ 1999 NCCOTDT *Strategy*, *supra* note 7 at 4-5. The NCCOTDT claimed to have done as the CDM directed by "releas[ing] ... recommendations ... to direct a sustained effort to increase the level of organ and tissue donation and transplantation in Canada" (at A-1).

⁷⁴ See World Health Organization, "50 Facts: Global Health Situation and Trends 1955-2025", online: WHO <www.who.int/whr/1998/media_centre/50facts/en/>.

⁷⁵ See 1999 *Standing Committee Report*, *supra* note 6 ch 3(B)(1)(c). While kidney transplantation may reduce long-term healthcare costs, the issue is complex and no such supporting data exist for other organs.

⁷⁶ However, it is known that the CDM required the CCDT to revise its overall work-plan several times before the CDM would accept the final version in June 2004. See *Summative Evaluation*, *supra* note 3 at 20. Work done prior to that date was high-priority work that the CDM selected and approved for the CCDT.

comments suggest confidence regarding the potential for CCDT recommendations to become medical standards, directly influencing practice. As the Chair asserted in 2003: “A purpose of [the *SBINDD*] forum is to clearly define and standardize ‘accepted medical practice’ [in brain death determination, with the result] intended to be a clear and standardized process for the determination of death.”⁷⁷ *SBINDD* was also intended “[to] provide minimum standards and a code of practice.”⁷⁸

II. Does the Canadian *Charter* Apply to the CCDT Guidelines?

For the purposes of *Charter* review, it must first be determined whether the guidelines fall within the ambit of section 32 or whether their publication by a charitable, non-profit organization renders them purely “private” activity.⁷⁹ Answering this question requires an examination of Canadian jurisprudence and CCDT characteristics.

A. The Law: When Does the *Charter* Apply?

In *Retail, Wholesale and Department Store Union, Local 580 (RWDSU) v Dolphin Delivery Ltd*, a majority of the Supreme Court of Canada, in interpreting section 32, found that the *Charter* does not apply to purely private entities.⁸⁰ Yet, discerning which entities are truly “private” is not always straightforward. In *Slaight Communications Inc v Davidson*, the Supreme Court recognized that an entity, such as a board-appointed adjudicator, need not be a traditional part of government to attract constitutional scrutiny.⁸¹ Of concern in much of the Supreme Court’s section 32 jurisprudence is the po-

⁷⁷ *SBINDD*, *supra* note 1 at 30.

⁷⁸ *Ibid* at i.

⁷⁹ Section 32(1) of the *Charter*, *supra* note 5 states:

This Charter applies

(a) to the Parliament and government of Canada in respect of all matters within the authority of Parliament including all matters relating to the Yukon Territory and Northwest Territories; and

(b) to the legislature and government of each province in respect of all matters within the authority of the legislature of each province.

⁸⁰ [1986] 2 SCR 573 at para 39, 33 DLR (4th) 174, [*Dolphin Delivery*] (“Where ... private party ‘A’ sues private party ‘B’ relying on the common law and where no act of government is relied upon to support the action, the Charter will not apply”).

⁸¹ [1989] 1 SCR 1038 at para 87, 59 DLR (4th) 416, Lamer J (dissenting, but not on this point).

tential for government to delegate powers to bodies described as “independent” and “arm’s length,” which may nonetheless conduct governmental activities. The fear is that such bodies could, by adopting the superficial appearance of private, non-governmental entities, insulate governmental activities from *Charter* review. Justice LaForest, writing for the Court in *Godbout v Longueuil (City of)*, stated:

Were the *Charter* only to apply to those bodies that are institutionally part of government but not to those that are—as a simple matter of fact—governmental in nature (or performing a governmental act), the federal government and the provinces could easily shirk their *Charter* obligations by conferring certain of their powers on other entities and having those entities carry out what are, in reality, governmental activities or policies. In other words, Parliament, the provincial legislatures and the federal and provincial executives could simply create bodies distinct from themselves, vest those bodies with power to perform governmental functions and, thereby, avoid the constraints imposed upon their activities through the operation of the *Charter*. Clearly, this course of action would indirectly narrow the ambit of protection afforded by the *Charter* in a manner that could hardly have been intended ... [I]n view of their fundamental importance, *Charter* rights must be safeguarded from possible attempts to narrow their scope unduly or to circumvent altogether the obligations they engender.⁸²

Accordingly, the Supreme Court has wrestled with the problem of identifying when an entity that appears private and independent may be considered a government entity, for *Charter* review purposes. In *Eldridge v British Columbia (AG)*, the Court held that the *Charter* may apply to an entity on one of two possible bases:

1. First, it may be determined that the entity is itself “government” for the purposes of section 32;⁸³

or:

⁸² [1997] 3 SCR 844 at 48, 152 DLR (4th) 577.

⁸³ The Court stated: “This involves an inquiry into whether the entity whose actions have given rise to the alleged *Charter* breach can, either by its very nature or in virtue of the degree of governmental control exercised over it, properly be characterized as government within the meaning of s 32(1)” ([1997] 3 SCR 624 at para 44, 151 DLR (4th) 577 [*Eldridge*]).

2. an entity may be found to attract Charter scrutiny with respect to a particular activity that can be ascribed to government.⁸⁴

Under the first branch, if an entity is found to be “government,” all of its activities will be considered governmental and therefore subject to the *Charter*, including activities that might ordinarily be considered private. In contrast, under the second branch, only the governmental activity in question will be subject to *Charter* review.

Eldridge involved a hospital that had discontinued funding of sign-language interpretation for deaf patients. The Supreme Court found that the appellant hospital was a private body that the government had chosen to deliver a comprehensive social program on behalf of government.⁸⁵ Accordingly, the program, as delivered by the hospital, was required to conform to the *Charter*.⁸⁶ In a judgment criticized by some, the Court held that there was “a direct and ... precisely defined connection between a specific government policy and the impugned act,”⁸⁷ so that the hospital, despite exercising autonomy with respect to day-to-day operations, was effectively under government control and served as an agent of the government in providing medical services.⁸⁸ However, the Court stated that, in general, the factors identifying a private body as carrying out governmental activity did “not readily admit of *a priori* elucidation.”⁸⁹

The Supreme Court’s most recent treatment of section 32 was the seven-justice majority decision in *Greater Vancouver Transportation Authority v Canadian Federation of Students* in 2009.⁹⁰ The case dealt with the section 32 status of two British Columbia regional transit corporations, BC Transit and Translink, whose policies of refusing to post political advertisements on their buses were found to contravene freedom of expression under section 2(b) of the *Charter*. The Court in *Canadian Federation of Students* con-

⁸⁴ “This demands an investigation not into the nature of the entity whose activity is impugned but rather into the nature of the activity itself. In such cases, one must scrutinize the quality of the act at issue, rather than the quality of the actor” (*ibid* at para 44).

⁸⁵ *Ibid* at para 50.

⁸⁶ *Ibid* at para 51.

⁸⁷ *Ibid*.

⁸⁸ *Ibid*.

⁸⁹ *Ibid* at para 42.

⁹⁰ 2009 SCC 31, [2009] 2 SCR 295 at para 17 [*Canadian Federation of Students*].

firmed that the “control test” remains the relevant legal test for determining government status under section 32 and provided a number of indicia relevant to determining whether the test is met.

Although their factual circumstances differed, the two corporations were both found to be government entities whose activities were subject to the *Charter*. The basis for so classifying the first, BC Transit, was that its enabling legislation designated it as an agent of the government, the entirety of its Board of Directors was appointed by the Lieutenant-Governor in Council, and government had the power to manage BC Transit’s affairs and operations via regulations. Concluding that the provincial government “exercised substantial control over [BC Transit’s] day-to-day affairs,” the Court held that BC Transit was a government agent and could not be said to be operating independently of government.⁹¹

The second corporation, Translink, was found to qualify as “government” on a different basis, not having been legislatively designated an agent of government. Translink’s governmental status derived from a variety of factors, including the Greater Vancouver Regional District’s (“GVRD”) “substantial control over [Translink’s] day-to-day operations” and the GVRD’s power to appoint the “vast majority” (80%) of Translink’s Board of Directors. GVRD was also obliged to ratify Translink’s taxation by-laws, levying by-laws, and overarching transportation plan, with which Translink’s capital and service plans had to be consistent.⁹² Final factors considered by the Supreme Court were Translink’s history and agenda, neither of which had ever been independent of government.⁹³ The Supreme Court agreed that together these indicia met the control test.⁹⁴ The Court also added that, unlike BC Transit, “[to] the extent that the GVRD does not have complete control over Translink, control is shared by the provincial government,”⁹⁵ confirming Translink’s governmental nature.

The Court in *Canadian Federation of Students* commented on governmental practices of creating ostensibly independent, non-governmental organizations, to effect government policy through delegation, without constitutional constraints:

⁹¹ *Ibid.*

⁹² *Ibid* at para 21.

⁹³ *Ibid* at para 20.

⁹⁴ *Ibid.*

⁹⁵ *Ibid.*

government should not be able to shirk its *Charter* obligations by simply conferring its powers on another entity ... The devolution of provincial responsibilities ... cannot therefore be viewed as having created a “*Charter-free*” zone.⁹⁶

Having reviewed key section 32 jurisprudence, the next section considers whether a reviewing court might view the CCDT as attempting to establish a *Charter-free* zone for the creation of clinical guidelines.

B. Applying the Law to the Facts: Does the Charter Apply to the CCDT Guidelines?

Despite the CCDT’s non-profit, charitable status, it remains possible for a court to find that the *Charter* applies to the CCDT guidelines. Applying *Eldridge*, there are two means by which the *Charter* may apply. Through the first test branch, if the CCDT can be shown to qualify as “government,” then all CCDT activities, including the guidelines, will be governmental and therefore subject to *Charter* scrutiny. Alternatively, if the CCDT cannot be shown to be government, then, through the second branch of the *Eldridge* test, the *Charter* may still apply to the guidelines alone, if they can be shown to constitute a form of “government activity” performed by the CCDT.

1. Was the CCDT “Government”?

As noted above, indicia of governmental character include government control over an entity’s day-to-day operations, government appointment (or removal) of those running the organization, and government ratification of the organization’s plans and by-laws, as well as any non-governmental history or agenda the organization may have had. Each factor is considered in turn.

Unlike BC Transit, the CCDT did not display the more obvious indicia of government character, such as legislative designation as an agent of government, nor the stipulation that the Lieutenant-Governor in Council be empowered to manage CCDT affairs and operations by means of regulations. Nonetheless, there does appear to have been evidence of substantial government control over the CCDT.

⁹⁶ *Ibid* at para 22.

Government control over directorial appointments: Evidence suggests there was significant government control over CCDT staff appointment and removal. During the CCDT's initial government phase, the CDM—a government body reporting to the federal Minister of Health and Parliament—appointed 100% of the CCDT's original directors and was initially responsible for renewing the directors' terms.⁹⁷ In October 2006, after the *SBINDD 2006* guidelines had been published,⁹⁸ the CDM relinquished to the CCDT responsibility for directorial appointment and renewal, when the CCDT's by-laws were changed to allow the CCDT to remove, replace, or nominate new directors by 2/3 majority vote.⁹⁹

However, the CCDT's choice in the matter of directors and other appointees may ultimately be argued to reflect the will of those who urged or permitted the CCDT to alter its by-laws, following the first set of by-laws. Notably, in 2003, KPMG/BearingPoint's Recommendation 4 urged the CCDT to alter its original by-laws to be consistent with the proposed FPT CDM *Memorandum of Understanding* and Letter of Agreement.¹⁰⁰ The CCDT "responded" in April 2006 by changing its by-laws "to accommodate requirements of a not-for-profit." Recommendation 4 was not listed among the rejected recommendations, suggesting CDM support for the change. In addition, since the CCDT was converted to a non-profit through Health Canada's support, the CCDT's adoption of its second set of by-laws to allow non-profit functioning appears to have derived ultimately from Health Canada, rather than from the CCDT. Since Health Canada's signing of the Contribution Agreement was conditional on the CCDT satisfying Health Canada's requirements, the contents of the second set of by-laws may be argued to have been directed (or at least permitted) by Health Canada.

⁹⁷ Under CCDT by-laws No 1, *supra* note 52 ss 3.2, 3.3, CCDT members were selected by the CDM and appointed by the Federal Minister of Health, but could be removed before term completion by the CDM.

⁹⁸ The second set of CCDT by-laws was unavailable so its contents are not directly known. However, the KPMG/BearingPoint report suggests that the second set took effect in April 2006 in response to KPMG/BearingPoint's 2003 recommendation that CCDT revise its by-laws for consistency with the FPT *Memorandum of Understanding* and Letter of Agreement (*Summative Evaluation*, *supra* note 3 at 112 (Recommendation 4)).

⁹⁹ CCDT by-laws No 3, *supra* note 52 ss 13, 28, 30. This by-law change appears to have occurred at the CDM's direction (*Summative Evaluation*, *supra* note 3 at 112 (Recommendation 4)).

¹⁰⁰ *Ibid.*

Unfortunately no direct information is available on the content of the second set of by-laws regarding who selected the CCDT directors. No reports indicate who instigated the CCDT's third set of by-laws, in October 2006, which allowed the CCDT to appoint directors, but presumably this third set must also have received Health Canada's approval, as it would have been open to Health Canada to withdraw its Contribution Agreement funds if dissatisfied with the change. The original CCDT by-laws, under which directors were CDM-selected, operated from 2001 until April 2006, covering most of the CCDT's existence, including the period when *SBINDD 2006* was published and the CCDT began non-profit operations. The third set of by-laws took effect around the time *BBFNDD* was written, permitting the CCDT to choose its own directors thereafter. However, no new CCDT directors were added until 2009, well after *BBFNDD 2008* had been published, when several new CCDT directors were appointed from CBS.¹⁰¹

During the CCDT's non-profit phase, it was apparent that government requirements strongly affected the CCDT's membership. For instance, the CCDT stated that "credibility with CDM" was a decisive factor in the selection of CCDT members:

The organization of the CCDT (i.e. involving experts, members of the public and government reps [*sic*]) was deliberately set up so that CCDT would have credibility with the CDM. An organization with only government representatives or with no government representatives would either a) not meet the needs of the transplant providers and community; and/or b) not have credibility with the CDM.¹⁰²

Thus, while a non-profit organization, the CCDT required government representatives in its membership for its recommendations to be approved by the CDM for dissemination. This may explain the appointment of an ex-CDM member as CCDT Chair.¹⁰³ The required governmental presence with-

¹⁰¹ According to the director lists available in the CCDT charitable returns, CBS director Graham Sher and Gale Watson were both appointed as CCDT directors in January 2009.

¹⁰² *Summative Evaluation*, *supra* note 3 at 28.

¹⁰³ According to CCDT by-laws No 1, *supra* note 52, eight "*ex officio* observers," including FPT government representatives, were non-voting members "entitled to attend [CCDT] meetings," but who could only address or provide written submissions to the CCDT at the Chair's invitation (s 4). CCDT by-laws No 3, *supra* note 52 does not state a number, or mention powers of attendance, etc., but

in the CCDT or at its meetings seems to have been intended by the CDM as a means of introducing a governmental perspective into CCDT recommendations. Therefore, even during its independent non-profit phase, the CCDT's Board membership was subject to significant government control.

Removal of certain directors occurred during the government phase. In 2003, the CDM accepted the consulting agency KPMG/BearingPoint's suggestion that the CDM consider for replacement certain CCDT directors, including the existing Chair, Dr. Philip Belitsky, due to CDM "performance expectations."¹⁰⁴ The CCDT's reported response to the recommendation entailed the prompt resignation of Dr. Belitsky, who was replaced in 2004 by British Columbia's ex-Deputy Minister of Health, Ms. Leah Hollins.¹⁰⁵ This CDM-instigated replacement occurred in the initial government phase. Yet, in total, over 60% of the CCDT's original directors were replaced, most in the CCDT's first 5 years, including some in the non-profit period.¹⁰⁶ It is not

allows *ex officio* members to be appointed by the CCDT. Although in 2003, the consulting company KPMG/BearingPoint suggested replacing the CCDT's *ex officio* members with a government/stakeholder liaison group, the CDM chose to retain and expand with "[a]dditional *ex officio* members ... to ensure appropriate and full representation of jurisdictions and stakeholders" (*Summative Evaluation*, *supra* note 3 at 31). Former CCDT CEO Kimberly Young stated that "... as part of their *ex officio* capacity, a representative of Health Canada attended CCDT meetings ..." (2008 *Standing Committee Report*, *supra* note 52).

¹⁰⁴ KPMG/BearingPoint Recommendation 8 (which was not rejected by the CDM or the CCDT) requests "[t]hat the membership (size and required expertise) of the [CCDT] be re-considered. Further that the nomination and appointment processes for the Chair and members be articulated and carried out by the FPT, CDM, more closely aligning overall responsibility and accountability for the effective performance of the CCDT" (*Summative Evaluation*, *supra* note 3 at 112-13). Recommendation 10 (also accepted) was: "That the Chair of the [CCDT] be re-considered given the performance expectations and the required skill sets" (*ibid*).

¹⁰⁵ Notably, the CCDT reported this resignation as its "response" to the CDM's recommendation (*ibid* at 113). Elsewhere, the CCDT simply stated that the CCDT Chair resigned (at 21).

¹⁰⁶ For example, James Mohr left in 2005, after the non-profit conversion, while Dr. Chip Doig resigned in 2006. Leaving dates were deduced from the CCDT and other records. Mohr was listed as a founding director in CCDT by-laws No 1, *supra* note 52 at 8, and he was later a "first director" signatory" in the CCDT's February 2005 application for incorporation as a non-profit (at 1), although his name was mistakenly then replaced on page 2 by a new "first director" (Vivian McAlister). Mohr was not listed as a member after 2005 on team lists such as the CCDT, 2006 *Annual Report*, while McAlister was listed (*supra* note 9 at 2). Dr

known if any other appointments or removals were prompted by the government. Thus, it is unclear if CDM control over individual directorial appointment and removal persisted during the independent non-profit phase.

However, a larger issue may be that ultimately, not only individual directors, but the entire CCDT was “replaced” by another non-profit and charity (the CBS), as the result of a government decision. Despite the CCDT’s apparent successes and its anticipation, in 2006-2007, of a second five-year mandate lasting until 2012, it was dissolved on March 31, 2008.¹⁰⁷ The reason for the transfer to CBS of the CCDT’s mandate, contribution agreement, Chair, and numerous CCDT directors is unclear. CBS’s CEO asserted that the transfer of mandate was “not a function grab by CBS.”¹⁰⁸ Judging by CCDT expectations of a second mandate, the transfer was not a CCDT decision. In fact, the decision to transfer the mandate to CBS was, like so many other decisions regarding the CCDT, probably made by the CDM.¹⁰⁹

Doig was also a founding member who was a signatory “first director” to the CCDT’s February 2005 non-profit application (*ibid* at 2); he was later listed as Chair of the CCDT Donations subcommittee in March 2006 in *SBINDD 2006*, *supra* note 21 at S7, but was not listed as a director in the CCDT Charity Application, *supra* note 56 at 2, or the CCDT, *2006 Annual Report*, *supra* note 9 at 2. Doig reported his resignation from the CCDT in an October 2006 article. See Christopher James Doig, “Is the Canadian Health Care System Ready for Donation After Cardiac Death? A Note of Caution”, 175 (2006) *Can Med Assoc J* 905 at 905.

¹⁰⁷ The CCDT, *2006 Annual Report*, *supra* note 9, states: “we have prepared an exciting and ambitious strategic plan for 2007 to 2012.” In March 2007, the CCDT also recommended continuing in its earlier capacity “in the next five-year period” (2007 *CCDT Summative Evaluation*, *supra* note 18 at 5). The CCDT deferred evaluating long-term effects of its recommendations, to its “next” five-year term (*ibid* at 48). Clearly, in 2006-7 CCDT directors did not believe that their work was nearing completion.

¹⁰⁸ See W Kondro, “National Organ Allocation Mechanism to be Sought” (2008) 179 *Can Med Assoc J* 640 [Kondro, “Allocation Mechanism”].

¹⁰⁹ “In October 2007, the deputy ministers of health for the provinces (except Quebec) and territories agreed in principle to a proposal that CCDT’s functions be transferred to the CBS and that the CBS assume responsibility for Canada’s organ and tissue donation system” (Sonya Norris, Library of Parliament: Parliamentary Information and Research Service, *Organ Donation and Transplantation in Canada*, (Ottawa: 25 June 2009) at 3, online: Library of Parliament <www2.parl.gc.ca/Content/LOP/ResearchPublications/prb0824-e.pdf> [Norris Report]).

Significantly, the CCDT's dissolution indicates that the CDM was, three years into the CCDT's non-profit period, able to compel the CCDT directors to seek revocation of their organization's charitable registration¹¹⁰ and corporate charter.¹¹¹ This seems at odds with the characteristics of an independent, arm's length non-profit. It was also unusual, since the CCDT was a charity with an unused capacity to fundraise to support itself. The CCDT's dissolution after the CDM's decision makes clear that substantial CDM control was maintained over CCDT membership throughout the CCDT's existence.

Government ratification of plans, subsidiary plans, and by-laws: In *Canadian Federation of Students*, Translink was required to create an overall transportation plan for government ratification. Similarly, the CCDT was required to create, for CDM ratification, a long-term work-plan for achieving the NCCOTDT targets. In fact, the CDM reportedly required the CCDT to correct its work-plan several times before accepting it.¹¹² Translink was also to prepare subsidiary plans, consistent with its overarching transportation plan, for government ratification. Somewhat similarly, the government created a subsidiary plan for the CCDT (i.e. a subset of the overall work-plan consisting of components, including the revision of brain death guidelines, selected as immediate CDM priorities), consistent with the overall CCDT work-plan.

The CDM-approved work-plan, and especially the CCDT's CDM-selected priority plan, substantially dictated the day-to-day activities of the CCDT. The priority work of the subsidiary plan required that the CCDT put all its other work-plan activities on hold, except for the tasks of revising brain death guidelines and conducting social marketing. In addition, the

¹¹⁰ The Minister could, under the *Income Tax Act*, RSC 1985, c 1 (5th Supp), ss 149.1(2) or (4.2), have unilaterally revoked the CCDT's charitable status for carrying on non-charitable business or failing to expend its annual funding disbursement quota or for wrong-doing involving gifts and false statements. However, the CCDT's charitable status revocation was recorded as "voluntary," a categorization that is not based on such failures. (Canada Revenue Agency, "Charities Listings", online: CRA <www.cra-arc.gc.ca/chrts-gvng/lstngs/menu-eng.html> [CRA, "Charities Listings"]). Therefore the revocation must have been initiated from within the CCDT.

¹¹¹ Under the *Canada Corporations Act*, RSC 1970, c C-32, s 32(1), a non-profit corporation may surrender its corporate charter if it can prove to the Minister of Industry's satisfaction that it possesses no assets or unresolved debts and that it has given public notice of the planned surrender in the Canada Gazette.

¹¹² See *Summative Evaluation*, *supra* note 3 at 20.

CDM was required to ratify the products of the CCDT's main and subsidiary plans, that is, the guidelines themselves, prior to their dissemination.

Finally, as in *Canadian Federation of Students*, where government was required to ratify the organization's taxation by-laws, there is evidence that the CDM required the CCDT to amend its by-laws on at least one occasion. In 2003, the CDM required that the CCDT update its internal by-laws "to comply with the *Memorandum of Understanding* and letter of agreement."¹¹³ In response, the CCDT updated its by-laws in April 2006, demonstrating government control over CCDT by-law creation during the non-profit period.¹¹⁴ There is no evidence that the CDM later ratified this CCDT choice of by-laws, although Health Canada presumably considered the change to comply with its Contribution Agreement. However, CDM ratification of CCDT work-plans and products certainly occurred, which is consistent with portrayal of the CCDT as a government entity.

Government history and agenda: Another factor considered in *Canadian Federation of Students* was whether Translink had an agenda or history as an entity independent of government. The fact that Translink did not contributed to its classification as a government entity. Unlike Translink, the CCDT had some history of being an entity independent of government, but it also had significant indicia of a government history and agenda. Following intense governmental study of the matter, three major reports were written,¹¹⁵ and a complex, collaborative *Memorandum of Understanding* was arranged by the Canadian government to pre-empt constitutional obstacles to a federal government secretariat operating in the provincial or territorial sphere of healthcare.¹¹⁶ During its initial governmental period, CCDT powers and responsibilities were delegated via the *Memorandum of Understanding*.

Thus, the CCDT functioned during its early history as a governmental secretariat, established to advise the CDM. In total, the CCDT operated as a governmental secretariat for approximately four of its nearly seven years. After the CCDT became a non-profit organization in mid-2005, a Letter of Agreement supplanted the *Memorandum of Understanding*, pursuant to a

¹¹³ *Ibid* at 112. The CDM "accepted" this KPMG/BearingPoint recommendation.

¹¹⁴ *Ibid.*

¹¹⁵ Advisory Committee, *Distribution Discussion Document*, *supra* note 7; 1999 *Standing Committee Report*, *supra* note 6; 1999 *NCCOTDT Strategy*, *supra* note 7.

¹¹⁶ See Health Canada, *Interim Funding*, *supra* note 8.

Health Canada Contribution Agreement.¹¹⁷ However, the CCDT's "basic reporting structure to the CDM remained unchanged" by non-profit incorporation.¹¹⁸

Indicia of the CCDT's government agenda are evident following the 2003 CDM-commissioned formative evaluation of the CCDT's structure and operations, conducted by KPMG/BearingPoint.¹¹⁹ Of KPMG/BearingPoint's 33 recommendations to the CDM,¹²⁰ 88% were followed by the CCDT, while only 12% were rejected based on CDM direction or approval.¹²¹ Notably, some of KPMG/BearingPoint's recommendations were followed even during the CCDT's non-profit phase.¹²²

Rejected suggestions included the recommendation that the CCDT restrict its advice to tissue banking, rather than address donation and transplantation issues more broadly. This recommendation appears to have been rejected due to the CDM's direction and priorities for the CCDT.¹²³

¹¹⁷ Don Parkinson, Health Canada, *Recipient Guide to Health Canada–Contribution Agreements* (2004), online: HC <www.hc-sc.gc.ca/ahc-asc/pubs/_contribution/agreement_accord/index-eng.php> [Health Canada, *Recipient Guide*]. The Guide defines a contribution agreement as "a conditional transfer of funds to an individual, organization or other level of government to reimburse some portion of the costs incurred in carrying out a worthy project that the Government of Canada wishes to support," stressing that under a contribution program, "Health Canada is not purchasing goods or services from a recipient." However, like a contract, "both Health Canada and recipients have responsibilities to ensure that funded projects are completed according to the agreement." A Health Canada program consultant monitors each project to "determine if the activities and expenditures are in line with the agreement and if objectives are being met."

¹¹⁸ *Summative Evaluation*, *supra* note 3 at 119.

¹¹⁹ *Ibid* at 32 (KPMG/BearingPoint's evaluation was made "at the request of the CDM because there were concerns about the role and operations of the CCDT" (*ibid*). The KPMG/BearingPoint recommendations and responses only appear to be available through their reporting in *ibid* at 29-31, 112-115.

¹²⁰ For clarity, none of KPMG/BearingPoint's recommendations dictated the content of clinical guidelines such as *SBINDD* or *BBFNDD*. The recommendations related to aspects of CCDT governance, structure, etc. .

¹²¹ *Ibid* at 31 (There were four recommendations that the CCDT or CDM did not accept that are listed at 31, 112-113).

¹²² For example, the CCDT's adoption of new by-laws in 2006 (CCDT by-laws No 3, *supra* note 52).

¹²³ *Ibid* ("This was not implemented and it was decided that for the remainder of its

KPMG/BearingPoint also recommended that the CCDT remain an unincorporated body, a suggestion that was reportedly rejected by Health Canada.¹²⁴ The CCDT's non-profit incorporation occurred in 2005. Of the other two rejected recommendations, one, involving reducing the number of *ex officio* government attendees, was rejected at the CDM's direction.¹²⁵ The other, which involved the CCDT's subcommittee structure, was postponed until the anticipated renewal of the CCDT's mandate.¹²⁶ The source of that decision was not disclosed.¹²⁷ These factors suggest that the CCDT adhered closely to the CDM's agenda.

As stated elsewhere, the CCDT was not delegated its governmental mandate and authority via an enabling statute. Of note, however, is the existence of CCDT indemnification legislation, enacted in Canada's Yukon Territory in 2002,¹²⁸ seemingly anticipated in the Northwest Territories,¹²⁹ and sug-

first mandate the CCDT would continue to focus on addressing donation and transplantation issues related to perfusable organs" at 31). The CCDT suggests that it alone made the decision to reject, noting that it chose instead to address "transplantation issues related to waitlists and organ allocation" (at 112, Recommendation 1). Yet the CCDT's function was to advise the CDM, on matters of priority to the CDM. KPMG/BearingPoint's recommendation would have conflicted with "priority instructions" that the CDM had selected for the CCDT as its first tasks: "[During the 2001-2004 period], the CDM selected certain priorities from the [CCDT's Work] Plan for the CCDT to address. All of them related to the topic of donation, essentially putting the work of the other committees on hold" (at 20). "Beginning with its first meeting in October of 2001, the [CCDT] ... devoted significant time to development of its work plan ... Some components of it (for example ... the Neurological Determination of Death component) were approved by the CDM at its December 2002 meeting, and the CCDT was mandated to pursue these initiatives" (at 16). To follow KPMG/BearingPoint's recommendation would have conflicted with these CDM priorities, suggesting that the CCDT's rejection of this recommendation was not made independently by the CCDT but was driven by CDM needs.

¹²⁴ *Ibid* at 31, 112. The CCDT or CDM also agreed.

¹²⁵ *Ibid* at 31 (Recommendation 12).

¹²⁶ *Ibid* at 31, Recommendation 16.

¹²⁷ *Ibid*.

¹²⁸ *Canadian Council for Donation and Transplantation Indemnification Act*, RSY 2002, c 24. In November 2001, Hansard cited the reasons supporting the need for indemnifying legislation in the Yukon: "People providing expert advice on health matters can be at risk of having legal action taken against them for the work that they do in good faith and to the best of their abilities"; "It is becoming a frequent and common requirement for governments to ensure that these individuals are not

personally at risk when they accept the responsibility to sit on an advisory group”; “In practical terms, indemnification of the CCDT means the government will pay for the legal expenses, including litigation costs and settlement costs, if legal action is taken against a member of the CCDT for work they have done in good faith for the [CCDT].” However, “the CCDT is required to purchase \$10 million of commercial insurance to draw on first if actions are taken against them. ... In the event that any indemnification would need to be paid out, an agreement is in place among all federal, provincial and territorial governments that will mean that the Yukon [would only pay] just under 0.1 per cent of the total.” (Yukon, Legislative Assembly, *Hansard* 30th Leg 2nd Sess online: Yukon Legislative Assembly <www.hansard.gov.yk.ca/30-legislature/session2/086_Nov_15_2001.html>). The second reading of the Bill passed. According to CBS Annual Reports for 2007-08 and 2008-09, the CBS, as the organization that took over the CCDT’s mandate, made a significant change to its insurance scheme in 2007–2008, which had previously involved a Bermudian captive insurance company, the Canadian Blood Services Insurance Company Ltd, founded in 1998. The company insured the CBS against blood-related losses of up to C\$250 million, of lesser relevance to CCDT matters. See CBS, *Annual Report* 2007-8 at 44, online: CBS <[www.blood.ca/CentreApps/Internet/UW_V502_MainEngine.nsf/resources/Annual+Reports/\\$file/07-08-CBS-Annual-Report-en.pdf](http://www.blood.ca/CentreApps/Internet/UW_V502_MainEngine.nsf/resources/Annual+Reports/$file/07-08-CBS-Annual-Report-en.pdf)>. A significant change was the CBS’ establishment of a second captive insurance company, in British Columbia in May 2006 (at 48). As well as providing additional blood-related coverage (up to \$500 million more), this second insurance company also permitted indemnification of CBS members (who have included some former CCDT directors) against up to \$750 million in non-blood related losses, thus of potential relevance to the CCDT. CBS’ acquisition of this extra insurance coverage caused a net deficit to the CBS of \$8.9 million in 2007–2008 and a projected deficit of \$9.4 million in 2008–2009. Despite possessing this enhanced coverage, further risk assessments, factoring in the CBS’ new OTDT mandate, were commenced in 2007–2008 to assess the adequacy of the two captive insurance companies’ coverage. Reportedly, as of 2007–2008, no major claims had been made under either of the two CBS captive insurance programs (at 44, 45).

¹²⁹In the Northwest Territories, regulations create an exemption for the CCDT from ss 66-67.2 of the *Northwest Territories Financial Administration Act*, RSNWT 1988, c F-4 in *Contract of Indemnification Exemption Regulations*, NWT Reg 018-99. This exemption relates to aspects of indemnifying “an individual not an employee under the Public Service Act who serves at the request of government as a member of a board, agency, committee or council” or an entire “board, agency, committee or council that performs functions on behalf of government,” up to a maximum of \$500,000. The CCDT (along with the CBS and its second captive insurance company) is expressly listed among those to be indemnified (*ibid* s1). Although no indemnification legislation was passed in the Northwest Territories, the regulation suggests planned CCDT indemnification there, as in the Yukon, due

gested (but not pursued) in Canada's other provinces and territories,¹³⁰ for reasons that remain unclear.

Under the only existing CCDT indemnification legislation—that of the Yukon—the federal government agreed to assume financial responsibility for any litigation generated by CCDT “guidance” in that territory, to a maximum of \$10 million. This legislation was passed shortly after the CCDT’s establishment, before guideline-creation had commenced. Though not a statutory grant of governmental authority, such legislation suggests a high level of government support for the CCDT and its activities, through its protection of CCDT directors. None of the previous Canadian clinical groups that created brain death guidelines were protected by indemnifying legislation.

This legislation suggests that the government anticipated the possibility of litigation resulting from the CCDT’s (as yet unwritten) guidelines. It suggests that the government was willing to underwrite possible costs associated with the CCDT guidelines’ operationalization of the government’s plan to address OTDT shortages.¹³¹ This government protection of CCDT members through legislation may strengthen the understanding of the CCDT as animated by a government agenda.

to the CCDT’s performing “functions on behalf of government.”

¹³⁰ As part of an early Contribution Agreement approved (but unsigned) by the Treasury Board Secretariat on 11 April 2002, the [federal] Minister of Health was to “enter into an accord with the provincial and territorial Ministers of Health wherein FPT governments jointly indemnify the members of the [CCDT] and its working groups” (Health Canada, *Interim Funding*, *supra* note 8). However, at that time (2003), the Contribution Agreement was not finalized due to the accord being unsigned. The \$10.8-million Health Canada-CCDT Contribution Agreement was finally signed on 1 April 2005, remaining in effect until 31 March 2008 (Health Canada, *Final Audit*, *supra* note 9 at 1). According to the CCDT, the CDM had recommended in 2003: “[t]hat the CDM conclude a final review of the residual indemnification and determine the necessity for this provision and its inclusion in the FPT Accord. Further, that the CDM pursue the appropriateness of a Memorandum of Understanding and Letter of Agreement that could accomplish the objectives to be accomplished through the FPT Accord, hence replacing the need for the FPT Accord” (*Summative Evaluation*, *supra* note 3 at 112). Reportedly, the issue was addressed, seemingly without need for an FPT Accord, through the CCDT’s acquisition of insurance (*ibid*). No further mention of the CCDT indemnification accord appeared thereafter in Hansard or in provincial and territorial legislation.

¹³¹ Government may be sued in tort for its operational activity, but not for its policy-making (*Neilsen v Kamloops (City of)*, [1984] 2 SCR 2, 10 DLR (4th) 641).

Finally, perhaps the clearest indication of a government agenda was the CCDT's dissolution. As noted, after the CCDT's funding was withdrawn, it was open to the CCDT directors to fundraise, as permitted by the CCDT's charitable status, and to continue functioning as an "independent non-profit." However, after the CDM's agreement to dissolve the CCDT and to withdraw its funding, the CCDT's directors chose to discontinue operations. This suggests that the CCDT had no genuinely independent agenda as a non-profit organization and charity, once its CDM mandate and Health Canada funding were transferred to CBS.

Government control over day-to-day activities: The CCDT appears to have been subject to significant government control in its day-to-day activities. Control appeared to derive from two sources: the CDM (governing the CCDT's activities under its mandate) and, secondarily, Health Canada (governing the CCDT's use of Health Canada funds). The CCDT was subject to significant government monitoring, being required to report annually to the CDM on its activities and progress and subject to regular Health Canada financial audits. It is not known if the CDM liaison or *ex officio* members present at meetings played some role in monitoring CCDT activity. It is plausible that, in addition to injecting a governmental perspective into CCDT activities, the *ex officio* members and CDM liaison might, at least on an informal basis, have reported on CCDT progress to their respective government departments. Certainly nothing seems to have operated to prevent this.

CDM influence was a major theme throughout the CCDT's history and in government preparations prior to CCDT establishment. To recapitulate, following the 1999 Standing Committee's recommendation, the CDM directed the writing of the *1999 NCCOTDT Strategy*, which urged the CCDT's establishment and set the targeted OTDT increases and deadline. The CDM approved these goals and the *NCCOTDT Strategy*'s contents.¹³² Two years later, the CDM created the CCDT "to provide advice to the CDM."¹³³ The CDM suggested all of the CCDT's original board members for federal Ministerial appointment and was initially responsible for member renewal. After calling for a formative evaluation of the CCDT in 2003, to ensure optimal CCDT functioning, the CDM amended CCDT board membership based on performance expectations. The CDM also required that the CCDT respond to

¹³² *Summative Evaluation*, *supra* note 3 at 10.

¹³³ See Health Canada, *Final Audit*, *supra* note 9 at 1; *Summative Evaluation*, *supra* note 3 at 11.

recommendations of the CDM's choosing and reject the remaining recommendations.¹³⁴

Even during the CCDT's non-profit phase, the CDM required government representatives within the CCDT¹³⁵ and a CDM liaison. The two available sets of CCDT by-laws both indicate a requirement that *ex officio* members be sourced from various levels of government. The third set, operating after October 2006, also allowed the appointment of additional non-government *ex officio* members.¹³⁶ It is not known precisely what the content of the second set was on the matter of *ex officio* appointments or whether non-government members could also be included, but by the CCDT's own report in late 2006, government appointees were always required "for credibility with CDM." As noted elsewhere in this article, the content change of the second set of by-laws in April 2006 appears to have been instigated and permitted by government (Health Canada). The change to a third set must presumably also have complied with Health Canada's requirements for the CCDT to continue to qualify for the Contribution Agreement funds.

After the CDM re-considered the original CCDT Chair, he was replaced by a recent former CDM member. Having approved NCCOTDT targets, the CDM approved the CCDT's work-plan to meet these targets, set the CCDT's initial priority tasks, and then monitored CCDT progress via mandatory annual reports. The CDM effectively directed every part of the CCDT's guideline-production "advice cycle," from topic selection through approval¹³⁷ and uptake monitoring.¹³⁸

Finally, the CCDT was dissolved after a CDM agreement to transfer the CCDT's mandate and funding to CBS.¹³⁹ The voluntary revocation of the

¹³⁴ "[T]he CDM ... requested that the CCDT produce ... a response to the [KPMG/BearingPoint] formative evaluation by April 30, 2004" (*ibid* at 20).

¹³⁵ *Ibid* at 28.

¹³⁶ CCDT by-laws No 3, *supra* note 52 s 37.

¹³⁷ The CCDT reported that the *SBINDD* guidelines, at least, were submitted to the CDM for approval, and were subsequently disseminated as "knowledge products" or "consensus recommendations" to users (*Summative Evaluation*, *supra* note 3 at 21, 22, 25).

¹³⁸ *Ibid* at 19.

¹³⁹ According to Health Canada auditors, "dissolution of CCDT was first proposed in 2006" (Health Canada, *Final Audit*, *supra* note 9 at 5). The CDM agreed in principle to dissolve CCDT in October 2007 (Norris Report, *supra* note 109 at 3). Government transferred the CCDT's mandate to the CBS: "In October 2007, the

CCDT's charitable status indicates that the CDM retained sufficient influence over the CCDT's directors to prompt dissolution of the CCDT, in circumstances where loss of Health Canada funding may not have been fatal to the CCDT's continuation. These factors reveal a significant degree of CDM control over CCDT activities, even during the non-profit phase.

In *Canadian Federation of Students*, Translink was compared with universities and hospitals and concluded not to have operated with the same independence.¹⁴⁰ The CCDT members also lacked the academic freedom of funded academics in a university setting, the latter generally being free to choose their subject matter, hypotheses, and to report conclusions that are not pre-determined or influenced by third parties. In contrast, the general outcome of the CCDT guidelines was pre-determined by government: a large "sustained systematic increase" in transplantation-quality organs in a short time-frame, with brain death guidelines effectively specified as the means. After satisfying these government requirements, and after receiving the required input from the *ex officio* government representatives and CDM liaison, little academic freedom may have remained to the CCDT members for guideline-creation.¹⁴¹ Even less may have remained if the CDM required any corrections to guidelines before approving them. Thus, CCDT members' guideline-creation was significantly constrained by government, unlike typical academic freedom in the university context.

Health Canada's influence over CCDT purse strings was another recurrent theme during the CCDT's existence. Reportedly, Health Canada had

Deputy Ministers of Health for the provinces (except Quebec) agreed in principle to a proposal that the CCDT's functions be transferred to Canadian Blood Services (CBS) and that CBS assume responsibility for Canada's organ and tissue donation and transplantation system" (*ibid* at 3). An 8 October 2010 email from the CBS by (former CCDT CEO) Kimberly Young and (former CCDT director) Peter Nickerson also confirmed that the "[CBS] was given a mandate by the federal, provincial and territorial Deputy Ministers of Health (except Quebec) in 2008 to make recommendations on organ and tissue donation and transplantation (OTDT) in Canada," as the CCDT had been mandated previously. Email correspondence of Samantha Hayward (on behalf of Kimberly Young, Executive Director, CBS and Peter Nickerson, Executive Medical Director, CBS) with Jocelyn Downie (8 October 2010) regarding the CBS' Roundtable Discussion at Transplant Atlantic 2010, in Halifax, Nova Scotia, on 13-15 October 2010.

¹⁴⁰ *Canadian Federation of Students*, *supra* note 90 at para 20.

¹⁴¹ It is not clear from any available information whether government dictated the specific content of the CCDT guidelines.

long planned for the CCDT to operate as an “independent, arm’s length” agency.¹⁴² Although reasons for the non-profit conversion were never made known,¹⁴³ reports suggest that the non-profit conversion occurred with Health Canada’s support.¹⁴⁴ Non-profit status must have offered some significant benefit to government, offsetting the considerable time required and financial costs of the conversion,¹⁴⁵ since approximately 39% more Health Canada funding was needed during the CCDT’s non-profit phase to replace government resources.¹⁴⁶ In addition, the CCDT’s conversion to charitable

¹⁴² The CCDT reported: “Since its inception, it has been the intention that the CCDT would assume operations under a [Health Canada] contribution agreement as an independent and ‘arm’s length’ organization” (*Summative Evaluation*, *supra* note 3 at 15).

¹⁴³ It is also unclear what reason grounded the CCDT’s pursuit of charitable registration in addition to its non-profit status. See CCDT Charity Application, *supra* note 56. In the CCDT 2006 *Annual Report* (authored in November 2006 while the CCDT was a charity), the CCDT described itself as “a national, registered non-profit dedicated exclusively to the interests of the organ and tissue donation and transplantation system in Canada” (*supra* note 9 at 7). While CCDT by-laws No 3, *supra* note 52, required CCDT Directors to “take steps” enabling CCDT receipt of bequests, legacies, gifts, etc., no public fundraising activities were reported on CRA charitable returns (s 35). A single \$25 donation was reported on the CRA return for the 2007-ended fiscal year; returns are listed online and are accessible via the CRA, “Charities Listings”, *supra* note 110.

¹⁴⁴ *Summative Evaluation*, *supra* note 3 at 31. This listed all of KPMG/BearingPoint’s 33 recommendations, noting only four that the CCDT or the CDM did not accept, including Recommendation 3, that the CCDT remain unincorporated. Health Canada disagreed with this KPMG/BearingPoint recommendation and “[i]nstead, the CCDT became an incorporated non-profit and signed a Contribution Agreement with Health Canada in June 2005.”

¹⁴⁵ The CCDT’s new “non-governmental” structure was described by participants and stakeholders as “more effective” than the government structure, although it was not clarified at what it was more effective (*ibid* at 15, 21).

¹⁴⁶ “The major administrative change [of the CCDT to non-profit status] took significant time and energy in terms of hiring staff, locating office space and arranging for services previously provided in-house by Health Canada” (*ibid* at 21). Furthermore, “there were significant increases to ... operating costs associated with the CCDT’s transfer [to non-profit status] related to services that were previously provided in-kind within the government i.e. office space, information technology support, accounting and payroll services, human resources” (*ibid* at 55). Reported CCDT expenditures show that, between the last government year (2004-5) and the first non-profit year (2005-6), CCDT annual costs increased by C\$1,067,190 (i.e. 39%) (*ibid*).

status imposed some major disadvantages.¹⁴⁷ Thus, the CCDT's non-profit and charity status must have offered some compelling, balancing advantage, for which Health Canada was willing to spend more and risk temporarily slowing CCDT progress. One advantage suggested was that, as a non-profit, the CCDT's apparent objectivity and independence from government gave it greater credibility with practitioners, potentially enhancing uptake of the CCDT's guidelines.¹⁴⁸

Health Canada exercised financial control over the CCDT during its non-profit phase by funding the CCDT through the Contribution Agreement.¹⁴⁹ This arrangement allowed government to terminate the Agreement and reduce or remove the CCDT's funding at will. It seems unusual for a Contribution Agreement not to require a partial contribution from the recipient organization itself, yet this was the case, leaving the CCDT more dependent on its government funding.¹⁵⁰ Notably, the CCDT was not provided with an unconditional grant of funds to spend as it pleased, but with a conditional grant for the specific purpose of addressing certain "worthy project[s] the Government of Canada wishes to support."¹⁵¹ Evidence shows detailed Health Canada monitoring and control over the CCDT's day-to-day spending decisions.

¹⁴⁷ Charitable status restricted the activities in which the CCDT could legally engage, since Canadian charities are prohibited, under the federal *Income Tax Act*, RSC 1985, c 1, 5th Supp from pursuing, on more than an incidental basis, "political" (i.e. legislative or policy-oriented) activities (Canada Revenue Agency, "Policy Statement: Political Activities", CPS-022, 2 September 2003, at 6.1-6.2, online: CRA <www.cra-arc.gc.ca/chrts-gvng/chrts/pley/cps/cps-022-eng.html>).

¹⁴⁸ 2007 *CCDT Summative Evaluation*, *supra* note 18 at 5.

¹⁴⁹ *Summative Evaluation*, *supra* note 3 at 12.

¹⁵⁰ This sole funding conflicts with the now-archived Treasury Board Secretariat "Policy on Transfer Payments" governing Contribution Agreements, operating during the relevant time period (from 2000 until late 2008). Under s 7.13.2 of the Policy, there was an expectation that a funding recipient would contribute some of its own funds towards the total project costs; s 7.13.1 stated that, before approving a contribution over \$100,000 for a project, the potential recipient must submit a statement indicating its other sources of possible funding. Finally, under ss 7.8.2, 7.8.3, there was also an expectation that the government's contribution funding would be repaid by the recipient organization, although non-profit corporations unable to generate the necessary revenues for repayment could be exempted. See Treasury Board of Canada Secretariat, *Archived [2008-10-01] - Policy on Transfer Payments*, online: TBS <www.tbs-sct.gc.ca/pol/doc-eng.aspx?id=12257>.

¹⁵¹ Health Canada, *Recipient Guide*, *supra* note 117.

Specifically, the Contribution Agreement funding was subject to terms agreed to in advance, regular interim progress checks during receipt of funds, and a final audit before the release of the last funding instalment to the CCDT.¹⁵² These audits judged overall CCDT compliance with the government Contribution Agreement, and suggest government attempts to control CCDT use of these funds.

Yet, overall, Health Canada may have exercised imperfect control over CCDT spending. Health Canada's regular audits noted instances of apparent CCDT funding misallocation (e.g. CCDT use of funds for overseas travel, and excessive hospitality budgets).¹⁵³ It also failed to prevent CCDT payments made to certain CCDT "members" (elsewhere implied to be directors¹⁵⁴), including large "honoraria,"¹⁵⁵ which the recipients reportedly per-

¹⁵² *Ibid.*

¹⁵³ Despite several financial transgressions noted on the Health Canada, *Final Audit*, *supra* note 9 at 8, the CCDT was described as being in compliance with the Contribution Agreement.

¹⁵⁴ For instance, the CCDT's application for charitable status with the CRA, while the CCDT was a non-profit, provides information that, in combination with other information, implies that CCDT directors were receiving honoraria (CCDT Charity Application, *supra* note 56 at Q18). From as early as 2001 until late 2006, the CCDT by-laws permitted only CCDT directors to receive honoraria and benefits (CCDT by-laws No 1, *supra* note 52 s 3.14; CCDT by-laws No 3, *supra* note 52 s 15). Under s 36 of CCDT by-laws No 3, the CEO was to be the CCDT's "only direct employee." These statements reveal that the honoraria and travel benefits reported as paid in the 2006 charitable application must have gone to CCDT directors, since no other individuals were permitted under CCDT by-laws to receive honoraria (*Summative Evaluation*, *supra* note 3 at 17; Health Canada, *Interim Funding*, *supra* note 8). Previous mention of the "honoraria issue" (although not stated as involving CCDT directors) appeared in 2003 in KPMG/BearingPoint's Recommendation 13, which was reported as having been addressed by the "honorarium policy" Health Canada developed pursuant to the CCDT's 2005 Contribution Agreement (*Summative Evaluation* at 113).

¹⁵⁵ Health Canada, *Interim Funding*, *supra* note 8 at 113 indicated that CCDT "members" received honoraria, and expressed concerns that "[CCDT] members perceive the payment of honoraria as compensation. ... The misunderstanding between honoraria and compensation may also impact Health Canada's [future] arm's length relationship to the [CCDT]." Despite these concerns, Health Canada did not prohibit the awarding of honoraria, but set high "maximum" honorarium limits in the CCDT's Contribution Agreement in 2005 (*ibid.*). While a non-profit, the CCDT also reported in late 2006 that "[CCDT] members are paid honoraria," although it left unclear whether the "members" described included CCDT

ceived as salaried “compensation.” The honorarium issue generated considerable Health Canada concern in the 2003 audit as a threat to the CCDT’s (planned) arms’ length status from government.¹⁵⁶ Yet, despite its concern, Health Canada permitted the CCDT practice of awarding honoraria to continue during the non-profit phase. Presumably, Health Canada could have prevented continuation of this behaviour via the Agreement, but did not, for reasons that remain unclear. Instead, it agreed to very large maximum honorarium amounts in the 2005 Contribution Agreement, seemingly jeopardizing the CCDT’s arm’s length status.¹⁵⁷ Another example of Health Canada’s imperfect control involved the CCDT’s awarding of “severance pay” to its remaining “employees” in 2008.¹⁵⁸ This was considered an avoidable and wasteful expense by Health Canada.

Health Canada concluded in 2009 that the CCDT had satisfied the terms of its Contribution Agreement. Yet, even after the CCDT’s dissolution, Health Canada auditing of CCDT expenses continued and extended to the management of the transfer of CCDT’s assets to CBS.¹⁵⁹ This indicates the persistence of Health Canada’s influence well beyond the CCDT’s initial

directors, forum participants, or others (*ibid* at 17). The CCDT’s charitable status application, made in the non-profit period in 2006, also indicated that CCDT directors continued to receive honoraria (CCDT Charity Application, *supra* note 56). In apparent contradiction, the CRA information returns for this same (2007-ended) time period and thereafter reported that CCDT directors received no compensation by honorarium, salary, or benefits. In this and subsequent years, these same CRA returns reported yearly payment of large honoraria, exceeding C\$119,000 per annum in some years, to unspecified individuals at the CCDT (CRA, “Charities Listings”, *supra* note 110).

¹⁵⁶ See Health Canada, *Recipient Guide*, *supra* note 117 (“[u]nder a ... contribution program, Health Canada is not purchasing goods or services from a recipient.” In light of this, salaried compensation for work performed could conflict with this requirement, while honoraria might not.

¹⁵⁷ See *Summative Evaluation*, *supra* note 3 at 113.

¹⁵⁸ See Health Canada, *Final Audit*, *supra* note 9 at 4-5. Severance pay was seemingly not reported however in the 2009-ended CRA return for the CCDT at line C9, which stated that no expenses were incurred “for the compensation of employees during the [2009-ended] fiscal period” (CRA, “Charities Listings”, *supra* note 110). Therefore the amount of the severance pay remains unknown.

¹⁵⁹ Health Canada, Management Response and Action Plan (MRAP): Audit of the Management of Contribution Agreement with the Canadian Council for Donation and Transplantation and the Canadian Blood Services, (17 December 2009), online: HC <www.hc-sc.gc.ca/ahc-asc/pubs/_audit-verif/2009-22/mrap-rdpa-22-eng.php>.

government phase. To paraphrase what was said of Translink, to the extent that Health Canada may not have exercised 100% control over the CCDT, government control over the CCDT was shared with the CDM, which exercised much more extensive control over CCDT operations.¹⁶⁰ Together, these factors suggest that substantial government control was exercised over the CCDT's day-to-day activities, by both the CDM and Health Canada.

Based on these indicia, it seems that there was substantial governmental control over the CCDT. On one hand, the CCDT may not have been an agent of government, as was BC Transit, designated by legislation and subject to regulations governing its affairs. On the other hand, the CCDT appears to have been subject to sufficient governmental control to characterize it as a government entity, not unlike Translink in *Canadian Federation of Students*. Government appointment and removal of members, government ratification of CCDT plans and work products, government control over day-to-day activities, and the CCDT's seeming lack of an agenda independent of government all suggest that the CCDT may qualify as "government." Thus, the CCDT may satisfy the first branch of the *Eldridge* test, as a part of the "fabric of government," making all of the CCDT's activities subject to the *Charter*.

A recent Ontario lower court decision, *Canadian Blood Services v Freeman*, examined whether the *Charter* applied to the activities of the CBS, the organization that eventually took over the CCDT's mandate.¹⁶¹ *Freeman* involved an HIV-negative, homosexual man who argued that he had been discriminated against under section 15 of the *Charter* by being rejected as a potential blood donor. However, Mr. Freeman's argument failed when the court concluded that, based on a lack of governmental control over the CBS, the CBS was a private corporation to which the *Charter* was inapplicable.¹⁶²

Although there are similarities between the CBS and the CCDT,¹⁶³ CBS may be distinguished in several important respects from the CCDT. First, the

¹⁶⁰ *Canadian Federation of Students*, *supra* note 90 at para 20.

¹⁶¹ 2010 ONSC 4885, 217 CRR (2d) 153 [*Freeman*].

¹⁶² *Ibid* at para 343 (the critical factor was the lack of governmental control built into CBS' governance framework).

¹⁶³ *Ibid* at para 305. Both the CCDT and the CBS were independent non-profit organizations and charities which claimed to operate at arms' length to government. Both were created via FPT Memoranda of Understanding, and the government was the sole funding source. No enabling legislation was ever created for either organization, although for the CBS (but not the CCDT) such legislation

Freeman court emphasized the importance of the original *Memorandum of Understanding* which, from the beginning, created the CBS as a non-profit intended to operate at arm's length from government.¹⁶⁴ In contrast, the CCDT was first created as a government secretariat and was only years later converted to an "arm's length" non-profit, suggesting a more governmental history and character.

Second, *Freeman* emphasized that the ministerial right to remove CBS members was never exercised, implying that the requisite "government control" over the CBS was not in evidence: "Although there is a mechanism whereby the Ministers of Health ... can remove one or all of the [CBS] Board members, this has never happened."¹⁶⁵ In contrast, during the government phase, the CCDT Chair (and possibly some of the other directors) was re-considered for replacement by the CDM and the Chair was replaced, followed by government replacement of the entire CCDT with the CBS.

Third, evidence suggests that, unlike at the CBS, the "arm's length" relationship between government and the CCDT may have been flawed (e.g. by honorarium payments that reportedly raised independence concerns but which may have continued).¹⁶⁶ Fourth, the impugned act in *Freeman* was the application of an existing Health Canada screening policy, rejecting Mr. Freeman as a donor. The court concluded that, in rejecting him, the CBS was not "performing a particular government policy or program" sufficient to make CBS "government." In contrast, the impugned CCDT activity was the drafting of guidelines dangerous to some patients. That is, the CCDT did not simply mechanically apply an existing government instrument but created one at government direction, with government-specified subject matter, form, and results, to operationalize a government plan. This may be more likely to qualify as "performing a particular government policy or program." Taken together, these factors suggest that the CCDT had significantly greater governmental character than the CBS. In addition, it remains to be seen how the *Freeman* case may fare upon appeal.

was recommended. According to the court, the CBS' Board of Directors was staffed by provincial government ministers, while at the CCDT, this is not known to have been the case.

¹⁶⁴ Compare *ibid* at para 353.

¹⁶⁵ *Ibid*.

¹⁶⁶ See also *ibid* at para 371.

In 2010, a report by the Professional Institute of the Public Service Commission of Canada expressed concern over the vast scale of the federal government's contracting out services that could be "more effectively and cheaply provided in house," creating, in effect, a "shadow public service."¹⁶⁷ In line with this trend, the CCDT's non-profit status may have effectively disguised the governmental source of its brain death guidelines, while, in the process, perhaps enhancing their uptake.

2. Are the CCDT Guidelines "Government Activity"?

Were the preceding argument to fail, the CCDT guidelines might still attract *Charter* review by satisfying the second branch of the *Eldridge* test. By satisfying this branch, the CCDT guidelines, though not the CCDT's other activities, would constitute "government activity" for the purposes of the *Charter*. Such an argument might succeed, if an express delegation of governmental legislative authority to the CCDT can be identified. This possibility is explored below.

The second branch of the test laid out in *Eldridge* has been employed less often than the first and therefore offers fewer jurisprudential examples. Unfortunately, the Court in *Eldridge* provided few indicia to guide the identification of activities as governmental in nature.¹⁶⁸ A relatively recent case that proceeded on the basis of the second branch is *Sagen v Vancouver Olympic Organizing Committee for the 2010 Olympic and Paralympic Winter Games*.¹⁶⁹ In that case, the court found that an International Olympic Committee decision not to include women's ski jumping as an Olympic event, where the events were staged by the Vancouver Olympic Organizing Committee, was not a governmental activity to which the *Charter* applies.

In so finding, the court reiterated that performance of a public function is insufficient to bring an activity within the ambit of the *Charter*. Instead, the

¹⁶⁷ Professional Institute of the Public Service Commission of Canada, "The Shadow Public Service: Number of Outsourced Employees Explodes" (2010) 36:4 Communications Magazine, online: PIPSC <www.pipsc.ca/portal/page/portal/website/news/magazine/autumn2010/8>.

¹⁶⁸ However, the Court noted what would not identify such activity: "the mere fact that an entity performs a public function or that an activity may be described as public in nature will not be sufficient to bring it within the purview of government" (*Eldridge*, *supra* note 83 at para 43). Instead, governmental activity must involve carrying out a government policy or program.

¹⁶⁹ 2009 BCCA 522, 313 DLR (4th) 393.

Sagen court suggested that “it is necessary to look not only at the activities or function of the entity itself but also to the nature or function of the specific act or decision of the entity that is said to infringe a *Charter* right.”¹⁷⁰ On this basis, the Committee’s decision not to include women’s ski jumping did not qualify as government activity. Although the Vancouver Olympic Organizing Committee was a non-governmental body controlled in minute detail in its day-to-day activities, it was controlled by another private body, with no governmental influence over events or the practical staging of the events.¹⁷¹ To be said to engage in government activity, a body must be carrying out a government policy or program, and there must be evidence of, or the potential for, governmental control.

In comparison, the government funded the CCDT and delegated the authority to create OTDT guidelines through a *Memorandum of Understanding* and Letter of Agreement, the content of which may be deduced from other reports. The CCDT’s OTDT guideline creation activities (including brain death guideline revision) were specifically envisaged in the Standing Committee report, while OTDT-related guideline-creation was planned in the NCCOTDT blueprint. The CCDT’s nine-point mandate, drawn up under the Health Canada Contribution Agreement, included drafting practice guidelines and advising the CDM on the creation of guidelines, standards, and best practices for OTDT improvement.¹⁷² In addition, the CDM identified brain

¹⁷⁰ *Ibid* at para 49.

¹⁷¹ *Ibid* at paras 15, 45, 65.

¹⁷² According to the 2006 *Summative Evaluation*, *supra* note 3 at 12 [emphasis added]: “the CCDT Terms of Reference (June 7 2001) identified the following nine tasks:

1. Provide advice on a coordinated FPT strategy on organ and tissue donation and transplantation as well as advice on the development of high quality provincial/ territorial strategies;
2. Provide advice on, and a forum for, members to discuss opportunities for the *enhancement of standards, clinical practice guidelines and best practices*;
3. Provide a forum for members to discuss issues including: information sharing; provincial/ territorial initiatives related to donation and transplantation; and ethical issues related to donation and transplantation;
4. Consult with relevant health care organizations as required for the purposes of formulating advice only;
5. *Recommend practice guidelines based on an assessment of best practices*;

death determination guidelines as one of the CCDT's two priorities in the CCDT work-plan. The CDM and Health Canada appear to have significantly contributed to the resulting guidelines, both by participating at CCDT meetings and by approving the resulting guidelines. After dissemination, the CDM also maintained an interest in the guidelines' fate within Canada's medical community, requiring the CCDT to monitor guideline uptake.¹⁷³ These indicia suggest that the CCDT, in amending brain death guidelines pursuant to the CDM's instructions, carried out a government policy or program. As previously discussed, the CCDT was controlled in its day-to-day operations in minute detail by the CDM. The guidelines may, therefore, be found to qualify as "governmental activity."

In creating its guidelines, the CCDT exercised government powers delegated through the *Memorandum of Understanding*. The products of delegated governmental legislative activity may be subject to the *Charter*, as noted in *Dolphin Delivery*:

It would seem that the *Charter* would apply to many forms of delegated legislation, regulations, orders-in-council, possibly municipal bylaws, and bylaws and regulations of other creatures of Parliament and the Legislatures. It is not suggested that this list is exhaustive.¹⁷⁴

Thus the CCDT guidelines might be considered subordinate legislation, aiding in the interpretation of primary legislation.¹⁷⁵ Subordinate legislation

6. Provide advice on program and system linkages and interoperability with respect to: information management systems; and educational resources for interdisciplinary professionals involved in donation and transplantation processes;

7. Provide advice on social marketing strategies and their implementation;

8. Monitor, for the purposes of providing advice in accordance with its mandate only, the implementation of a FPT strategy and identify areas of emerging interests; and

9. Monitor, for the purposes of providing advice in accordance with its mandate only, donation and transplant outcomes, both quantitative and qualitative, measured against international and the Canadian experience; and on the outcomes of the FPT strategy, measured against target goals established by the provinces/territories."

¹⁷³ Summative Evaluation, *ibid* at 19.

¹⁷⁴ *Dolphin Delivery*, *supra* note 80 at para 39.

¹⁷⁵ See David Philip Jones & Anne S de Villars, *Principles of Administrative Law*, 5th

represents a growing segment of legislative activity, not all of which receives full Parliamentary scrutiny.¹⁷⁶ This has led some to comment that: “some legislative enactments should be regarded as so important that they should be debated openly in Parliament before enactment, [and] ... should not be contained in subordinate legislation.”¹⁷⁷ The CCDT guidelines add much-needed flesh to the bones of the provincial and territorial tissue gift statutes, by spelling out the procedures for death determination. Yet, when should such soft law, that is, guidelines and policies, be considered legislative activity or law for *Charter* purposes, and when should it be viewed merely as an administrative aid to statutory interpretation?

The question has received somewhat ambiguous Supreme Court treatment to date.¹⁷⁸ Much of the legislative/administrative distinction has turned on whether the soft law in question was binding in nature: legislative activity is indicated by binding guidelines, while administrative activity is suggested by voluntary guidelines. Based on this and other indicia, the Supreme Court in *Little Sisters* refused to recognize a manual of guidelines, used by Customs officers in decisions regarding allegedly obscene gay and lesbian artistic materials, as “law” for *Charter* remediation purposes. Instead, the Court

ed (Toronto: Carswell, 2009) at 104-05. Subordinate legislation may encompass: “ordinances, regulations, rules, codes, by-laws, ... directives and policies,” and “Parliament or a legislature may authorize virtually anyone to make subordinate legislation.” Conceivably, guidelines aiding in the interpretation of statutes, such as the CCDT guidelines, might also fit within this category (Jackson & Jackson, *supra* note 44 at 325). The authors note that “[d]elegated [or subordinate] legislation constitutes a large and ever-increasing proportion of all government legislative decisions.”

¹⁷⁶ *Ibid* (“an enormous volume of [subordinate] legislation (much of it technical) is ... not subjected to the full parliamentary legislative process” at 325).

¹⁷⁷ Jones & de Villars, *supra* note 175 at 108–09.

¹⁷⁸ See Gerald Heckman, “Judicial Review of Soft Law Instruments” (2010) 52 Sup Ct L Rev (2d) 52 at 56-57. As Heckman notes, in past SCC cases such as *Eldridge*, *supra* note 83 and *New Brunswick (Minister of Health and Community Services) v G(J)*, [1999] 3 SCR 46, 177 DLR (4th) 124 [*JG* cited to SCR], as well as *Canadian Federation of Students*, *supra* note 90 at para 72, such policies were held to be “law,” to which the *Charter* applied, while in other cases, such as *Little Sisters Book and Art Emporium v Canada (Minister of Justice)*, 2000 SCC 69, [2000] 2 SCR 1120 [*Little Sisters*], such soft law was deemed to be purely “administrative” guidance. Some authors question how meaningful a distinction there is between administrative policies and legislative policies having the same effect. See e.g. Gerald Heckman, “Judicial Review of Soft Law Instruments” (2010) 52 Sup Ct L Rev (2d) 52 at 57.

held these guidelines to be merely administrative aids for statutory interpretation.¹⁷⁹

Later, the Court in *Canadian Federation of Students* clarified that “non-law” administrative aids are those intended for internal use by a decision maker and are usually accessible only within the government entity applying them, rather than being made publicly available.¹⁸⁰ The Court noted that such guidelines are often informal in nature, requiring no express statutory authority for their creation, and are not intended to establish individual rights, obligations, or entitlements. Conversely, legislative government policies, authorized by statute, contain a general norm or standard intended to be binding, and are “sufficiently accessible and precise.”¹⁸¹

The CCDT guidelines exhibit features from both sides of the administrative/legislative dichotomy. First, although they assist in interpreting statutes, the CCDT guidelines were not authorized by statute, as the CCDT had no enabling statute. Any guideline-making authority appears to have been delegated by the *Memorandum of Understanding*. In addition, while the guidelines contain general norms and standards, they are voluntary, absent uptake by healthcare institutions capable of enforcing them. As noted above, the guidelines have been adopted by hospitals in Alberta and Atlantic Canada.

On the issue of sufficient accessibility and precision, the CCDT guidelines appear to be more precise than the vague comparative manual at issue in *Little Sisters*.¹⁸² They resemble, instead, the policies addressed in *Canadian Federation of Students*. Similar to administrative guidelines, however, the CCDT guidelines could be said to be employed for internal use or “indoor management” purposes. Unlike the administrative guidelines in *Little Sisters*, however, which were only used within the government agency that created them, the CCDT guidelines are used only outside the organization that created them, in healthcare settings.

In contrast to the guidelines in *Little Sisters*, the CCDT guidelines are available to the general public—either online via the CMA InfoBase or via government or through the published medical literature. This seems more

¹⁷⁹ *Little Sisters*, *ibid* at para 85.

¹⁸⁰ *Canadian Federation of Students*, *supra* note 90 at para 63.

¹⁸¹ *Ibid*.

¹⁸² *Little Sisters*, *supra* note 178 (the manual was described as “a rough and ready border screening procedure” at para 80).

akin to the situation in *Canadian Federation of Students*, where the guidelines were accessible to any member of the general public who cared to inquire. However, the argument that the CCDT guidelines are publicly accessible assumes that members of the public have sufficient knowledge of health-care and medical science to locate and understand the guidelines. In practice, these considerations limit the guidelines' public accessibility.

Finally, there is the question as to whether the CCDT guidelines establish individual rights, obligations or entitlements. Unlike purely administrative guidelines, the CCDT guidelines do not per se create patient rights but do have an effect on patients' rights and entitlements at a particular point in the biological continuum from birth to bodily decay. Upon a physician's declaration of a patient's death, the patient ceases to possess legal rights (e.g. to own property, make decisions), the patient's succession or estate opens, and the patient is thereafter considered simply a cadaver.¹⁸³ In Canada, the brain death guidelines that preceded those of the CCDT established a patient's legal rights as (potentially) extending to a later point in the biological continuum than under the CCDT guidelines. Arguably, the CCDT guidelines deal with individual rights, obligations or entitlements, establishing the point at which they divest within the biological continuum of functions, but it is not clear whether this will favour characterizing the guidelines as "law."

It remains for a reviewing court to decide how best to characterize the CCDT guidelines within the spectrum of governmental soft law activity. The implications for remedies of a finding that the guidelines are administrative rather than subordinate legislation or legislative rules is revisited in a later section.

Whether or not the guidelines can be shown to qualify as law remains in some doubt. However, it is probable that even if the CCDT itself cannot be shown to be governmental, the CCDT guidelines could qualify as government activity under the second branch of the *Eldridge* test, and attract *Charter* scrutiny. Additional support for the proposition that the CCDT guidelines constitute government activity may be derived from the federal government's recognition of the CCDT guidelines as Government of Canada publications. The federal government's electronic library of "current and archived Government of Canada publications," the Depository Services Program, lists the

¹⁸³ A human corpse is, however, accorded more respectful treatment than other inanimate matter.

CCDT guidelines and makes them “available to the Canadian public.”¹⁸⁴ Specifically, the *SBINDD* guidelines (created while the CCDT was a government body) and the *BBFNDD* guidelines (created while the CCDT was a non-profit) are listed as “Government of Canada Publications,” attributed to Health Canada.¹⁸⁵ This supports the characterization of the CCDT guidelines as government activity.

III. *Charter* Rights Infringements Under the CCDT Guidelines

A. *Are Charter Rights Infringed by the CCDT Guidelines?*

Having concluded that the CCDT guidelines are probably susceptible to *Charter* scrutiny, the next issue is whether the guidelines risk infringing *Charter* rights. Since the different versions of the guidelines interact and may be in use simultaneously, all invite discussion. A number of *Charter* rights may be infringed by the CCDT guidelines. For instance, the right to freedom of conscience and religion under section 2(a) may be infringed due to the lack of opportunities for expression of religious beliefs regarding the declaration of death under the guidelines.¹⁸⁶ There may also be an infringement of a patients’ section 12 right not to be subjected to cruel and unusual treatment or punishment, since some CCDT recommendations could lead to patients

¹⁸⁴ Government of Canada, “Terms Of Reference Of The Depository Services Program Library Advisory Committee (DSP-LAC)”, online: Depository Services Program <publications.gc.ca/site/eng/depositoryLibraries/dsp-lac/termsOfReference.html> (DSP acts as the Government of Canada’s information safety net, collecting current and archival government publications and making them widely available to the Canadian public).

¹⁸⁵ *SBINDD*, *supra* note 1, and *BBFNDD*, *supra* note 20, were identical in content to *SBINDD 2006*, *supra* note 21, and *BBFNDD 2008*, *supra* note 35, respectively, the latter two being published in academic journals. The DSP’s listing of *SBINDD* suggests that *SBINDD 2006* is also the product of government, based on the shared content. The DSP also lists several CCDT Annual Reports, including one written in late 2006, while the CCDT was a non-profit and charity, as “Government of Canada Publications,” adding weight to earlier arguments that the CCDT itself was government.

¹⁸⁶ See Samantha Weyrauch, “Acceptance of Whole-Brain Death Criteria for Determination of Death: A Comparative Analysis of the United States and Japan” (1999) 17:1 UCLA Pac Basin LJ 91 at 119-22 (for religious reasons, many traditional Buddhist, Shinto, and Confucian followers may not accept brain death as death, preferring a cardiopulmonary criterion).

with reversible conditions being declared dead and subjected to organ harvesting.¹⁸⁷

While any of the above arguments could potentially ground a *Charter* challenge to the guidelines, this paper will focus on the argument that aspects of the CCDT guidelines infringe section 7 of the *Charter*: the “right to life, liberty and security of the person, and the right not to be deprived thereof except in accordance with principles of fundamental justice.” Case law suggests that, for constitutional protection to be triggered under section 7, there must be governmental interference with an “interest of fundamental importance”¹⁸⁸ to an individual, generating a “serious and profound effect” on him.¹⁸⁹ To qualify as an infringement, state interference must also have occurred in a way that is inconsistent with the “principles of fundamental justice.” The procedural entitlements these principles might entail are discussed below.

In general, to trigger protection of the right to security of the person, there must have been a governmental restriction or compulsion of individual choices of a “fundamentally intimate and personal nature.”¹⁹⁰ As the Supreme Court ruled in *Blencoe v British Columbia (Human Rights Commission)*, a section 7 deprivation must affect more than mere reputation, dignity,

¹⁸⁷ It does not seem to be possible to advance an argument based on *Charter*, *supra* note 5, s 15 equality rights (e.g. of inter-regional equality) regarding the CCDT guidelines’ effects (e.g. the use of a brainstem criterion under the CCDT guidelines, versus use of a whole-brain criterion by those not adopting CCDT guidelines: see *SBINDD*). Here, the inequality (i.e. some patients being declared dead based on such factors as a brainstem criterion while others are declared dead using a whole-brain criterion) is “external” to the law itself, resulting from private activity by physicians or hospitals in choosing to adopt or reject the CCDT guidelines. This may preclude an argument that the guidelines deny equal legal benefit, protection, or equality before and under the law via s 15(1): “Every individual is equal before and under the law and has the right to the equal protection and equal benefit of the law without discrimination and, in particular, without discrimination based on race, national or ethnic origin, colour, religion, sex, age or mental or physical disability.” However, this inequality may contribute to the “manifest unfairness” of the CCDT guidelines’ operation, as discussed later.

¹⁸⁸ *Blencoe v British Columbia (Human Rights Commission)*, 2000 SCC 44 at para 82, [2000] 2 SCR 307 [*Blencoe*].

¹⁸⁹ *Ibid* at para 81.

¹⁹⁰ *Ibid* at para 83 (“It is only ... exceptional cases where the state interferes in profoundly intimate and personal choices that ... could trigger the s 7 security of the person interest”).

anxiety or stigma.¹⁹¹ Such deprivation may occur either through physical or psychological means, according to *Rodriguez v British Columbia (AG)*:

Section 7 is ... implicated when the State restricts individuals' security of the person by interfering with, or removing from them control over, their physical or mental integrity ... There is no question, then, that personal autonomy, ... control over one's physical and psychological integrity, and basic human dignity are encompassed within security of the person ...¹⁹²

Threats to security of the person may have a prospective quality. Mere exposure to, or the risk of, security of the person violations can trigger protection.¹⁹³ Nonetheless, David Mullan writes that there exists "a very narrow window of opportunity for operation of s.7," in which "it will take very extreme circumstances to trigger s.7 protection through the security of the person route."¹⁹⁴ So what then has qualified as an "extreme circumstance" sufficient to trigger security of the person protection in past jurisprudence? In *Morgentaler*, the Supreme Court held that requiring a woman to seek a (potentially non-existent) committee's permission to terminate her unwanted pregnancy constituted a profound interference with physical and psychological security of the person.¹⁹⁵ In the influential Ontario Court of Appeal deci-

¹⁹¹ *Ibid* at para 81.

¹⁹² According to the majority in *Rodriguez v British Columbia (AG)*, [1993] 3 SCR 519 at 588, 82 BCLR (2d) 273 [*Rodriguez*], quoting Justice Lamer's judgment in the earlier case of *Reference re ss 193 and 195.1(1)(c) of the Criminal Code (Man)*, [1990] 1 SCR 1123 at para 68, 4 WWR 481.

¹⁹³ See *Singh v Canada (Minister of Employment and Immigration)*, [1985] 1 SCR 177, 17 DLR (4th) 422 [*Singh* cited to SCR] ("security of the person' must encompass freedom from the threat of physical punishment or suffering as well as freedom from such punishment itself" at 207). See also *R v Morgentaler*, [1988] 1 SCR 30, 44 DLR (4th) 385 [*Morgentaler* cited to SCR] (Justice Wilson reiterated the same view, clarifying that "... the fact of exposure [to the security of the person threat] is enough to violate security of the person" at 162).

¹⁹⁴ David J Mullan, *Administrative Law* (Toronto: Irwin Law, 2001) at 200-01.

¹⁹⁵ *Morgentaler*, *supra* note 193 at 56, 65. Chief Justice Dickson stated: "The case-law leads me to the conclusion that state interference with bodily integrity and serious state-imposed psychological stress, at least in the criminal law context, constitute a breach of security of the person. It is not necessary in this case to determine whether the right extends further, to protect ... interests unrelated to criminal justice" (*ibid*). Since *Morgentaler*, other SCC cases have revealed that state-imposed physical and psychological stress can also trigger s 7 security of the person protection in non-criminal contexts, e.g. in immigration, and child

sion in *Fleming v Reid*, forcing involuntarily admitted, mentally ill patients to endure unwanted psychoactive drugs contrary to their competent advance directives, was similarly found to infringe security of the person.¹⁹⁶ In *New Brunswick (Minister of Health and Community Services) v JG*, a state procedure brought against an unrepresented litigant, for her children's removal, was deemed by the Supreme Court a "gross intrusion" into parental autonomy, triggering protection for the parent's psychological security of the person rights.¹⁹⁷ Proceedings for the removal from Canada of individuals who face potentially life-threatening consequences have also triggered security of the person protection.¹⁹⁸

The government-created CCDT guidelines appear to generate significant state interference with the "fundamentally intimate and personal" interest of brain-injured patients in avoiding the premature declaration of death. Inevitably, the point at which death is declared has profound physical and psychological implications for a patient, and deep emotional, spiritual, and cultural ramifications for family and friends. A premature declaration of death therefore seems to have the requisite "serious and profound effect" on a patient by interfering with "interests of fundamental importance" to the patient. These interests include a patient's interest in not being subjected to physical or psy-

protection. As stated in *Blencoe*, *supra* note 188 at para 45: "there is no longer any doubt that s 7 of the *Charter* is not confined to the penal context."

¹⁹⁶ (1991), 82 DLR (4th) 298, 4 OR (3d) 74 (CA) [*Fleming* cited to DLR]. The court stated: "The common law right to bodily integrity and personal autonomy is so entrenched in traditions of our law as to be ranked as fundamental and deserving of the highest order of protection. Indeed, ... the common law right to determine what shall be done with one's own body and the constitutional right to security of the person, both of which are founded on the belief in the dignity and autonomy of each individual, can be treated as coextensive" (at 312). See also *Starson v Swayze*, 2003 SCC 32 at para 75, 1 SCR 722 (a majority of the SCC mentioned the *Fleming* result with some approval, stating: "The right to refuse unwanted medical treatment is fundamental to a person's dignity and autonomy").

¹⁹⁷ *JG*, *supra* note 178 at 78.

¹⁹⁸ See e.g. *United States of America v Burns*, 2001 SCC 7 at para 59, 1 SCR 283 [*Burns*] (state proceedings to extradite two individuals accused of murder to a country employing the death penalty were found to affect liberty and security of the person rights). See also *Suresh v Canada (Minister of Citizenship and Immigration)*, 2002 SCC 1 at para 129, 1 SCR 3 [*Suresh*] (the Court held that deporting a refugee to face a substantial risk of torture infringed his s 7 life, liberty and security of the person rights, subject to exceptions reflecting a need to balance this interest against concern for Canadian security).

chological suffering, in having his bodily integrity respected, and in retaining the legal status of a living member of the human community, at least for as long as those patients assessed under earlier guidelines. These important section 7 interests, with which the CCDT guidelines may interfere, exceed *Blencoe's de minimus* threshold.

Although numerous aspects of the CCDT guidelines may infringe patients' section 7 rights, only selected examples with serious potential effects will be discussed here in depth.¹⁹⁹ These examples are the CCDT's imposition of a brainstem criterion of death; the CCDT's change in the treatment of barbiturate-intoxicated patients; the simplification of testing for high-risk patients; and the removal of recommended wait times in testing. The first example makes it possible to declare some deaths significantly earlier than under previous brain death guidelines, while the other listed examples increase the risk of a premature, "false positive" declaration of death. All of these changes make it possible to systematically hasten the declaration of death, which is the point at which consenting donors become eligible for organ harvesting.

The brainstem criterion of death: The first concerning recommendation is the CCDT's imposition of a brainstem criterion of death. This requires that only the brainstem—that is, the lower part of the brain responsible for breath-

¹⁹⁹ Additional and no less significant section 7 concerns exist with other CCDT guideline recommendations. For instance, tests for brain death were originally divided into (non-technical) "clinical" and (technical) "supplemental" or "confirmatory" tests, the latter being in addition to the clinical tests. However, the CCDT guidelines have increased the reliance placed on non-clinical tests. *BBFNDD 2008*, *supra* note 35 states that ancillary testing is the response "required when there are factors confounding" assessment (at 143). In the past, with potentially transient confounding factors, the affected patient was not to be tested until the confounding factor had resolved or been corrected; this no longer appears to be required by the guidelines. While *BBFNDD 2008* reiterates that in brain death assessment "clinical criteria have primacy" (at 141), and that "[n]eurological determination of death remains principally and fundamentally a clinical determination" (at 143), it clarifies that "the term 'ancillary' should be understood as an alternative to the clinical determination, that otherwise, for any reason, cannot be conducted" (at 142). Since technical tests can now seemingly replace clinical tests for any reason, in theory, under very extreme circumstances, technical tests could become the sole criterion used to determine death. The CCDT also specified a particular type of brain blood flow testing, as discussed later in this paper.

ing,²⁰⁰ wakefulness²⁰¹ and certain other reflexes—need be shown to be permanently non-functional for brain death to be declared. Significantly, the CCDT’s criterion contains no requirement for non-functionality of the brain’s cortex, responsible for conscious awareness, voluntary movement, sensation (e.g. pain), and communication.²⁰² In contrast, the whole-brain criterion of death, recommended in Canadian guidelines since 1968, requires that not only the brainstem, but also the cortex, be shown to be permanently non-functional. Thus, the brainstem criterion requires demonstration of far less brain damage before death may be declared. Accordingly, under a brainstem criterion, some deaths could be declared considerably earlier than under a whole-brain criterion.²⁰³

All versions of the CCDT guidelines recommend a brainstem death criterion. In *SBINDD 2006*, this was phrased as “the irreversible loss of the capacity for consciousness combined with the irreversible loss of all brainstem functions ... including the capacity to breathe.”²⁰⁴ This may be interpreted as producing a brainstem criterion because consciousness is understood to comprise two components: wakefulness (controlled by a functioning brainstem)

²⁰⁰ See Allan Siegel & Hreday N Sapru, *Essential Neuroscience* (New York: Lippincott Williams & Wilkins, 2006) at 403 (the “pre-Bötzing complex” within the ventral respiratory group of neurons of the brainstem is the structure thought to trigger breathing rhythms).

²⁰¹ See S Laureys et al, “Coma” in Robert Stickgold & Matthew Walker, eds, *The Neuroscience of Sleep*, (London: Academic Press, 2009) 146 (“Consciousness is a multifaceted concept that has two dimensions: arousal or wakefulness (i.e., the level of consciousness), and awareness (i.e., the content of consciousness)” at 146).

²⁰² See MF Bear, BW Connors & MA Paradiso, *Neuroscience: Exploring the Brain*, 3d ed (New York: Lippincott, Williams & Wilkins, 2007) at 185.

²⁰³ See *Singh*, *supra* note 193 at 207 (the mere risk of exposure to security of the person threats may be sufficient for *Charter* protection). See also the reasons of Wilson J in *Morgentaler*, *supra* note 193 at 162. How much earlier death could be declared would depend on the nature of the patient’s other injuries and the life support (e.g. ventilator support) provided to him. However, potentially, if damage to the cortex (and to the patient’s body) are nil or minimal, but the brainstem is totally destroyed, the patient could seemingly be declared dead months to years earlier under a brainstem criterion than under a whole-brain criterion.

²⁰⁴ *Supra* note 21 at S3. In contrast, the “whole-brain” death criterion requires permanent loss of function of the entire brain including, but not limited to, the brainstem.

and awareness (generated by a functioning cortex).²⁰⁵ Thus, the “irreversible loss of the capacity for consciousness” may be the product of either loss of cortical function (loss of “awareness”) or loss of brainstem function (loss of “wakefulness”). Under the CCDT guidelines, the minimum brain damage that may prompt a declaration of death is brainstem destruction.

SBINDD 2006 adds the confirmatory detail that “spinal reflexes and motor responses confined to spinal distribution may persist” in brain death.²⁰⁶ Here, the words “motor responses” can refer neither to spinal motor reflexes (since these are mentioned separately), nor to brainstem motor reflexes (since the brainstem must be dead), and must, it seems, therefore refer to *cortical* motor responses. Thus, voluntary motor activity, generated by the cortex and affecting spinal distribution—that is, affecting the entire body—is allowed to persist in the CCDT’s version of brain death, indicating a brainstem criterion of death. Notably, *BBFNDD*’s definition of neurological death contains no details regarding the presence or absence of cortical function, also indicating that it refers to a brainstem death criterion.

CCDT authors have confirmed in medical literature that a brainstem criterion was the intended result.²⁰⁷ Since all CCDT guideline versions recommend a brainstem criterion, and since the CCDT reportedly did an effective job of achieving some informal adoption of the guidelines well before their journal publication, a brainstem criterion may be in some use in Canada. Although the guidelines’ adoption was described by 2006 as only “checker-board,”²⁰⁸ this in itself suggests a potential for serious unfairness in brain

²⁰⁵ See Laureys et al, *supra* note 201 at 146.

²⁰⁶ *Supra* note 21 at S2.

²⁰⁷ See G Bryan Young et al, “Brief Review: The Role of Ancillary Tests in the Neurological Determination of Death” (2006) 53:6 Can J Anaesth 620 at 622. “In Canada we accept the clinical criteria for brain death (essentially brainstem death) ... [a]ll of the clinical criteria for brain death are met with irreversible, total destruction of the brainstem. This is confirmed in the recently adopted [CCDT] Canadian guidelines for the neurological determination of death” (*ibid* at 620-21). Misleadingly, elsewhere, the CCDT has claimed that Canada’s brain death criterion is an amalgam of both whole-brain and brainstem criteria. For instance, *BBFNDD* argues that the CCDT definition of brain death “include[s] both the whole brain death concepts as well as ... brainstem death” (*supra* note 20 at 6). Compare *SBINDD*, *supra* note 1 at 30: “Distinctions between brainstem death and whole-brain death are unclear in Canada.”

²⁰⁸ Wayne Kondro, “Fragmented Organ Donation Programs Hinder Progress” (2006) 175 Can Med Assoc J 1043 at 1044 [Kondro, “Fragmented Organ Donation”].

death declaration, since some regions of Canada may use a brainstem criterion, while others retain a whole-brain criterion.

To date, only the UK has employed a brainstem criterion of death. Almost all other nations employ a whole-brain criterion. Brain death expert James Bernat has clarified the reason the US President's Commission (of which he was a co-author) rejected brainstem death:

the brainstem formulation [of death] does not require commensurate damage to the [cortex]. It therefore leaves open the possibility of misdiagnosis of death because of a pathological process that appears to destroy brainstem activities but that permits some form of residual conscious awareness that cannot easily be detected. It thus lacks the fail-safe feature of whole-brain death.²⁰⁹

In other words, in Bernat's view, and as noted by the CCDT in a literature review it provided to *SBINDD* participants, under a brainstem criterion there remains a possibility that a patient declared brainstem-dead might only be in a "super locked-in" state.²¹⁰ Such a patient would be totally paralyzed and unable to communicate but, due to a functional cortex, might still possess "some form of residual conscious awareness."

The concept of a super locked-in state is a slightly more extreme form of the well-known neurological diagnosis, the "locked-in state."²¹¹ Patients who are locked-in—such as Jean-Dominique Bauby, the author of *The Diving Bell and the Butterfly*²¹²—are almost totally paralyzed due to brainstem damage, except for some residual voluntary movement, usually involving the eyes.²¹³ If known to caregivers, this movement ability can allow the affected patient to communicate, by blinking, for example. Due to a functional cortex, locked-in patients can experience normal cortical functions, including cogni-

²⁰⁹ James L. Bernat, "The Whole-Brain Concept of Death Remains Optimal Public Policy" (2006) 34 *JL Med & Ethics* 35 at 39.

²¹⁰ CCDT, *Literature Review Brain Death*, *supra* note 15 at 6.

²¹¹ Also termed "cerebromedullospinal disconnection."

²¹² Jean-Dominique Bauby, *The Diving-Bell and the Butterfly*, translated by Jeremy Leggatt (London: Harper Perennial, 2008).

²¹³ The anterior part of the pons is the brainstem structure damaged in locked-in syndrome.

tion and pain-sensitivity.²¹⁴ In Bernat's predicted super locked-in state, such a patient would experience a total paralysis of voluntary movement.

While the CCDT has argued that a super locked-in state can be discounted as a purely theoretical construct,²¹⁵ evidence suggests otherwise.²¹⁶ Among ordinary locked-in patients, residual movement abilities may fade over time, eventually creating the total paralysis of a super locked-in state.²¹⁷ If such paralysis occurs in a severe brainstem injury, the patient may be rendered unconscious and unable to breathe, permitting a diagnosis of brainstem death. Yet, while the brainstem injury may eliminate the patient's wakefulness, rendering him unconscious, without cortical destruction, it may not eliminate his awareness (e.g. of pain).²¹⁸ Such a patient, with an intact cortex, could be aware and sensate, though unconscious and paralyzed. Reportedly, some brainstem-dead patients may display cardiovascular and hormonal

²¹⁴ See Peter McCullagh, *Conscious in a Vegetative State? A Critique of the PVS Concept* (London: Kluwer Academic Publishers, 2004) at 6.

²¹⁵ CCDT, *Literature Review Brain Death*, *supra* note 15 at 7.

²¹⁶ McCullagh, *supra* note 214 at 156. The CCDT's claim is contradicted by McCullagh's reference to a 1979 study, which identified 12 patients in a super locked-in state (termed a "total locked-in" state by McCullagh, describing the same state of complete paralysis) (*ibid*). McCullagh also argues that even the incompletely paralyzed "locked-in" syndrome is challenging to diagnose, being easily mistaken for the (unconscious) persistent vegetative state (at 157). See also Damian Cruse et al, "Bedside Detection of Awareness in the Vegetative State: A Cohort Study" (2011) 378 *Lancet* 2088 (among vegetative state patients previously understood to be permanently lacking awareness (and intermittently awake), 19% were actually found to be aware and responsive to verbal instructions, and thus possibly locked in, rather than in a persistent vegetative state). In addition, numerous reports exist of conscious, locked-in patients having been misdiagnosed for years as persistent vegetative state patients. See "Julia Tavalaro, 68: Poet and Author Noted for Defying Severe Paralysis", *Los Angeles Times* (21 December 2003), online: [Los Angeles Times <articles.latimes.com>](http://articles.latimes.com); Kate Connolly, "Trapped In His Own Body for 23 years—the Coma Victim who Screamed Unheard", *The Guardian* (23 November 2009), online: [Guardian Unlimited <www.guardian.co.uk>](http://www.guardian.co.uk). Therefore, it would seem entirely possible for super locked-in patients, if they exist, to be similarly misdiagnosed.

²¹⁷ See McCullagh, *supra* note 214 at 157.

²¹⁸ Since, as noted earlier, "consciousness" comprises both "wakefulness," due to the brainstem's reticular ascending activating system, and "awareness," due to the cortex, a human being may lose consciousness through damage to either (or both) structures, causing loss of either (or both) of these two components of consciousness.

stress responses suggestive of pain during unanaesthetised organ harvesting; however, this remains unsettled.²¹⁹ The possibility that a patient with a destroyed brainstem might simply be in a super locked-in state may therefore not be an easily discounted theoretical concern. In fact, the CCDT appears to acknowledge this state as a realistic possibility in *BBFNDD*'s fifth recommendation, which seems to imply that such patients cannot be declared neurologically dead.²²⁰ It is not clear that Canadians would welcome the CCDT's sudden shift to a brainstem criterion of death. According to a 2005 CCDT survey, 71% of Canada's public does not believe that "whole brain-dead" patients are truly dead, so as many Canadians might object to the more radical brainstem criterion's application to themselves or their loved ones.²²¹ It is unclear whether a causal relationship exists between the belief that brain death is not death and chronically low Canadian organ donor rates.²²² If one exists,

²¹⁹ See Shewmon, *supra* note 2 at 139; Mohamed M Ghoneim, ed, *Awareness During Anesthesia*, (Oxford: Butterworth Heinemann Boston, 2001) at 78 (in surgery on living patients, changes in heart rate, blood pressure, sweating or tear production are considered by some to signal when a patient is inadequately anesthetized and aware of pain, despite being unconscious (i.e. non-wakeful)); P J Young & B F Matta, "Anaesthesia for Organ Donation in the Brainstem-Dead—Why Bother?" (2000) 55 *Anaesthesia* 105 at 106 (however, it is not known whether similar observations during organ harvest in some brainstem-dead donors might indicate pain. Some authors therefore recommend anaesthesia for brainstem-dead donors out of caution); B Poulton & M Garfield, "The Implications of Anaesthetizing the Brainstem Dead" (2000) 55 *Anaesthesia* 695 (the authors suggest that the practice of anaesthetizing the brainstem-dead remains controversial).

²²⁰ *Supra* note 20 at 6. A "key consideration" in Recommendation 5 is that "[in] cases of complete and irreversible loss of brainstem function due to mechanisms other than terminal elevation of intracranial pressure [e.g. brainstem stroke], ... brain blood flow to [cortical] regions may be present thus negating the determination of death by neurological criteria" (*ibid*). This passage recognizes that, in some cases of brainstem destruction, brain blood flow to the cortex may continue to maintain cortical neural function. Such "complete" brainstem damage, including the pons, could generate a "locked-in" or "super locked-in" state, in which the patient's cortical functions (e.g. pain awareness) could be normal. Significantly, Recommendation 5 acknowledges that such a patient should not be declared brain-dead, despite satisfying all elements of *BBFNDD*'s definition of neurological death.

²²¹ See CCDT, *Public Awareness Report*, *supra* note 46 at 8, 33.

²²² *Ibid*. This 2005 CCDT public survey suggested public suspicion (among 71% of those surveyed) that brain death is not actually death, and (in 22%) that organs may be acquired through premature brain death declaration. The possible link between the significant level of disbelief in brain death as death and low organ

were the public to learn of the CCDT's shift to a criterion that permits earlier declaration of death, low donation rates might be further depressed.

The CCDT's recommendation of a brainstem death criterion marks a major shift from the whole-brain criterion, employed since 1968, and stands in stark contrast to the incremental changes made to Canada's brain death guidelines in preceding decades. It would be illuminating to know why the CCDT felt that a brainstem criterion, which has been adopted by only one other nation, was justifiable. The CCDT provided no satisfactory explanation, leaving room only for speculation.²²³ In a 2003 literature review preceding the guidelines, the CCDT merely claimed that "the similarities between the two models of [brain death] determination [i.e. the brainstem and whole-brain criteria] appear more striking than the differences."²²⁴ This implies that the functions of the human cortex—associated with consciousness, thought, voluntary actions, pain perception, memory, and personality—are of negligible importance in assessing the life of a human being. Some Canadians might disagree.

Certain concerns raised in this paper were mentioned by the CCDT prior to its creation of the guidelines, though they were not resolved. For instance, in 2003, the CCDT noted the need to correct, exclude, or wait for confounding factors to dissipate before declaring death.²²⁵ It recommended, however,

donor rates was not explored. If such a link exists, this may mean that major alterations in how early brain death can be declared could, if discovered, further weaken public trust in both declarations of brain death and the ethics of organ procurement, thereby reducing donation rates.

²²³ See CCDT, *Literature Review Brain Death*, *supra* note 15 at 7. One hint may lie in the CCDT's quoting of brain-death architect James Bernat: "the criteria for brain death may ultimately move in the direction of accepting a brainstem formulation [of death] ... this shift in criteria might be facilitated by the development of new medical technologies capable of isolating brainstem activities." The quotation was not supported by a citation, making it difficult to verify. However, Bernat's other writings staunchly defended the whole-brain criterion, based on the concern regarding detecting super locked-in patients. This suggests that Bernat's comment regarding a future change in criterion was probably contingent on the development of technologies able to make this distinction, —which has not occurred to date.

²²⁴ *Ibid* at 25.

²²⁵ *Ibid* at 16-17. Regarding hypothermia or drug intoxication, the CCDT noted that "[c]onfounding clinical conditions such as hypothermia, drug intoxication or drug therapy must be either treated, excluded or allowed to dissipate before [neurological determination of death]" (CCDT, *Executive Summary: A Review of the Literature on the Determination of Brain Death* (Edmonton: CCDT, 2003),

proceeding despite these factors.²²⁶ In addition, in *BBFNDD*, the CCDT appeared to acknowledge the potential for inappropriately declaring dead a patient with an isolated brainstem injury. Despite this potential, the CCDT did not withdraw its earlier support for a brainstem criterion. It gave no reasons for proceeding despite such concerns.

Another CCDT claim was that, unlike the CCDT guidelines,²²⁷ previous brain death guidelines had not been evidence-based.²²⁸ This claim is disingenuous, however, as the evidence must be able to demonstrate that particular brain death guidelines are effective (i.e. they incorrectly declare few dead patients to be “alive”) and safe (i.e. they declare as “dead” only those who are dead). Such evidence is extremely elusive. In terms of objective data, only two relatively small studies exist correlating brain death with cardiac death.²²⁹ Thus the CCDT guidelines are no more evidence-based than earlier guidelines; in fact, they are arguably less so, since they conflict with well-

online: CCDT <www.organsandtissues.ca/s/wp-content/uploads/2011/11/Brain-Death-Short-Lit-Review.pdf> [CCDT, *Short Review*]). Nonetheless, that same year, *SBINDD* allowed brain death testing without requiring confounding conditions to be treated, excluded or to dissipate, as long as a technological test is done, to compensate for the confounder’s interference with clinical testing.

²²⁶ See *SBINDD 2006*, *supra* note 21 at Recommendation A6 (it recommended performing a technical test in such cases, but these tests might be affected by the confounding variable too).

²²⁷ See CCDT, *Short Review*, *supra* note 225 at 3 (“A key objective of the [*SBINDD*] forum ... is to develop an evidence-based, ‘made-in-Canada’ guideline for the diagnosis of brain death”).

²²⁸ *Ibid* at 4-6 lists areas where evidence is lacking: “there is no literature to suggest evidence that evaluation by two physicians is preferable or superior to that of a single clinician”; “a literature review could not establish a firm basis for recommended [wait] interval times”; “there is no scientific corroboration for [a 24-hour wait period between tests in hypoxic-ischemic brain injuries]”; “no evidence-based source for any particular temperature threshold recommendation could be identified”; “there is little if any evidence to support many of the age-related recommendations.” See also *SBINDD*, *supra* note 1 at 7: “the current evidence base for the [earlier] [brain death] guidelines is inadequate.”

²²⁹ See National Institutes of Neurological and Communicative Disorders and Stroke, “An Appraisal of the Criteria of Cerebral Death” (1977) 237 *JAMA* 982-86; US President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Defining Death: Medical, Legal and Ethical Issues in the Determination of Death* (Washington, DC: Government Printing Office, 1981).

established scientific evidence regarding confounding factors, as discussed below.

With no completely satisfactory explanation being put forth, it is unclear why the CCDT felt that the move to a brainstem criterion was appropriate. The fact remains that the brainstem criterion makes it possible to declare brain death in a patient potentially weeks, or more, sooner than under a whole-brain criterion. By making many more organs available sooner, and in a more transplantable state, the brainstem criterion would have offered greater potential for CCDT targets to be achieved. While unpalatable, this explanation satisfies Occam's razor as the simplest hypothesis consistent with known information.

A brainstem criterion could declare dead some patients who are only super locked-in. With damaged brainstems, but intact cortices, such patients might retain pain-awareness, but could be declared brain-dead under CCDT standards, making them eligible for (unanaesthetised) organ harvesting. The CCDT's recommendation of a brainstem criterion may therefore infringe patients' rights to life and to physical and psychological security of the person.²³⁰

Barbiturate-affected patients: The second concern involves two aspects of the CCDT's brain death assessment of barbiturate-intoxicated patients. In earlier guidelines, barbiturate intoxication at any dosage was considered a confounder (i.e. a factor preventing an accurate diagnosis of brain death) requiring postponement of brain death testing. This was due to the potential for barbiturate intoxication to mimic brain death in several ways: barbiturate intoxication may result in coma, blunted neurological responses, and extremely shallow breathing, although these symptoms may be completely reversible with the passage of time. Under earlier guidelines, developed since 1968, a lengthy wait period (potentially of several days) was required for barbiturate clearance from the patient's system, before attempting a brain death assessment.²³¹

²³⁰ See Sam Shemie et al, "Organ Donor Management in Canada: Recommendations of the Forum of Medical Management to Optimize Donor Organ Potential" (2006) 174:6 Can Med Assoc J S13 (the CCDT's 2006 companion practice guideline on organ donor management—"Medical Management for Donor Organ Potential"—does not recommend anesthesia in organ harvesting).

²³¹ See Canadian Congress of Neurological Sciences, *A CMA Position: Guidelines for the Diagnosis of Brain Death* (1987) 136:2 Can Med Assoc J 200A at 200B (for

The CCDT recommendation in *SBINDD* appears to retain the classification of barbiturates as a confounder to be avoided at higher doses (i.e. in “significant intoxications”), but it abandons it at the lower (i.e. “therapeutic”) dosages of “anti-convulsants, sedatives, and analgesics.”²³² Clinically, barbiturates are used as all three.²³³ This recommendation implies that lower barbiturate doses will no longer be considered to confound brain death diagnosis. Adding confusion, elsewhere in *SBINDD*, a “Key Consideration” suggests that, even at higher dosages, barbiturate intoxication may no longer confound brain death declaration, as long as brain blood flow is tested.²³⁴

Problems exist with the recommendation that patients with low, therapeutic dosages of barbiturates be treated differently than those given high dosages. First, with barbiturates, specifically, there may be difficulty in defining what constitutes a therapeutic dose. As drugs, barbiturates have a particularly narrow therapeutic-to-toxic ratio, meaning that the dosage difference between a therapeutic dose and a life-threatening overdose may be small.²³⁵ The relative effect of any barbiturate also depends on the particular barbiturate, on other drugs in the patient’s system, on the patient’s age and size, and on concurrent medical conditions, making characterization of a therapeutic dose a highly individual matter.²³⁶

The level of barbiturate (and other interacting drugs) in a patient’s system may also be unknown. While the abuse of barbiturates as recreational drugs has declined in recent decades, it may be making a comeback among

example, the 1987 “Guidelines for the diagnosis of brain death” specify that “[d]rug intoxication (particularly of barbiturates, sedatives and hypnotics) ... must be excluded” for the brain’s loss of function to be considered irreversible).

²³² *SBINDD 2006*, *supra* note 21 at S3, Recommendation A7.

²³³ See R M Schears, “Barbiturates” in Judith Tintinalli et al, eds, *Tintinalli’s Emergency Medicine: A Comprehensive Study Guide* (New York: McGraw-Hill, 2011) at Introduction.

²³⁴ *Supra* note 1 at 14 (a “Key Consideration” in Recommendation A.6 states: “Existing evidence, although not firmly established, suggests that ... under the circumstances of high dose barbiturate therapy ... brain death can be confirmed by the demonstration of absent intracranial blood flow”).

²³⁵ Also termed its “therapeutic index” or “therapeutic ratio.” See Susan Coupey, “Barbiturates” (1997) 18:8 *Pediatrics in Review* 260 (“Barbiturates are dangerous drugs with a narrow therapeutic index between the dose required for sedation and the dose that will cause coma and death” at 260).

²³⁶ Schears, *supra* note 233 at Pharmacology.

younger substance abusers.²³⁷ Reportedly, some may use barbiturates in combination with (or to mask symptoms of) simultaneous stimulant use.²³⁸ Barbiturates have also been taken in overdose by suicidal individuals, producing an unknown dosage in the patient's system. These factors can make it difficult to determine what dosage of barbiturates exists in a given patient.

This CCDT recommendation is also noteworthy in the context of brain death testing, since barbiturates are commonly used therapeutically (but in high doses) to treat traumatic brain injury, induce therapeutic coma, lower brain metabolism, protect brain tissues from hypoxic damage, and reduce intracranial pressure.²³⁹ Such usage blurs the distinction between higher doses and therapeutic doses. This CCDT recommendation might therefore affect a significant proportion of traumatic brain injury patients assessed for brain death.

SBINDD's recommendations regarding barbiturates are also troubling because, by permitting testing while this confounder is present, a physician may mistakenly and prematurely declare a patient dead. *BBFNDD* added a further change: it not only permitted testing high-dose barbiturate patients, but it also simplified the brain death assessment process for these patients. *BBFNDD*'s Recommendation 9 stipulates that, if a barbiturate-treated patient has a flat electroencephalogram (EEG) trace, no apnoea test of breathing is required, unless "there is uncertainty surrounding the depth or level of barbiturate-induced coma."²⁴⁰ However, it is only by means of an apnoea test that "uncertainty"²⁴¹ regarding the depth of a patient's coma can be identified, in-

²³⁷ Coupey, *supra* note 235 at 260.

²³⁸ *Ibid.*

²³⁹ See Mary Ann Liebert, "The Use of Barbiturates in the Control of Intracranial Hypertension" (1996) 13:11 *Journal of Neurotrauma* 711 at 711. But see J C Orban & C Ichai, "Hierarchical Strategy for Treating Elevated Intracranial Pressure in Severe Traumatic Brain Injury" (2007) 26 *Annales françaises d'anesthésie et de réanimation* 440 at 440 (some now argue that barbiturates are not the optimal treatment for raised intracranial pressure).

²⁴⁰ See *BBFNDD*, *supra* note 20 at 8.

²⁴¹ Comatose patients' symptoms may outwardly appear somewhat similar. Apnoea testing is therefore essential to determining whether a patient's coma is so profound that the Pre-Bötzinger complex within the brainstem is totally non-functional, qualifying the patient as being (at least) brainstem-dead. Recommendation 9 omits the one vital test by which to assess this (*ibid.*).

roducing the element of a Catch-22 into the recommendation.²⁴²

This change in the treatment of barbiturate patients also conflicts with the repeated CCDT assertion, in both *BBFNDD* and *SBINDD*, that EEG is an unreliable indicator of brain death.²⁴³ It is known that barbiturate treatment of brain injuries, specifically, may temporarily produce a flat-line EEG,²⁴⁴ broadening Recommendation 9's application. Recommendation 9 also contradicts the earlier *SBINDD 2006* "Key Consideration" that in high-dose barbiturate patients, a brain blood flow test is required for death declaration. An EEG tests brain electrical activity, rather than brain blood flow.²⁴⁵

²⁴² In Recommendation 9, the default rule is that all flat-EEG, high-barbiturate patients are exempt from apnea testing unless the precondition of uncertainty regarding coma depth is present. The Recommendation incorrectly implies that some certainty of brain death exists in most flat-EEG, high-barbiturate patients. However, uncertainty as to coma depth (i.e. uncertainty as to whether a coma is so deep it qualifies as brain death) can only be established by doing an apnea test, since this test is the only way to establish whether brainstem breathing reflexes persist. Because uncertainty actually exists, an apnea test should always be done in these patients, yet this approach would render Recommendation 9 meaningless. If physicians do not know there is any uncertainty, the default rule of no apnea testing will operate automatically, so that uncertainty about coma depth is never established and so on. By creating a requirement to justify testing, instead of a requirement to test, Recommendation 9 effectively ensures that flat-EEG, high-barbiturate patient will not have to undergo apnea testing.

²⁴³ *Ibid* at 1. These same guidelines advise that EEG is "no longer supported" as a reliable indicator of brain death. The CCDT recommendation against reliance on EEG appears in *SBINDD*, *supra* note 1 at 32, 35, 37. CCDT co-authors state that the EEG "is vulnerable to confounders" and "may be flat or iso-electric in massive barbiturate overdose or deep anesthesia, conditions that are completely reversible. Thus there is a "double dissociation" in that EEG activity may be absent without brain death, either from surviving sub-cortical neurons or completely reversible conditions (false positives) and ... present in patients who meet the criteria for brain death (false negatives) ... At best EEG is mildly confirmatory [of brain death], at worst it is misleading or irrelevant." (Young et al, *supra* note 207 at 622. See also *SBINDD 2006*, *supra* note 21 at S9 (regarding the confounders: "The EEG is significantly affected by hypothermia, drug administration, and metabolic disturbances, thus diminishing its clinical utility").

²⁴⁴ See David D'Argenio, *Advanced Methods of Pharmacokinetic and Pharmacodynamic Systems*, vol 1 (New York: Plenum Press, 1991) at 80-81.

²⁴⁵ Yet even were a brain blood flow test required, this test too could be confounded by barbiturates. Brain blood flow (as measured by the proxy of brain glucose metabolism) may be reduced by 47%-67% by barbiturates. See McCullagh, *supra*

In *BBFNDD*, the CCDT effectively recommends replacing evidence from a reliable but time-consuming clinical test (the apnoea test) with a technological test (the EEG) that the CCDT itself repeatedly declares unreliable. Significantly, no prior set of Canadian guidelines has created exemptions from apnoea testing,²⁴⁶ since this test is an important indicator of brainstem reflex functioning. This functioning is acknowledged by the CCDT as an essential component of *BBFNDD*'s definition of death.²⁴⁷ Omitting the apnoea test leaves no way to assess breathing function. The CCDT's simplified assessment carries a risk of premature declaration of death, as patients may simply be suffering from reversible barbiturate reactions.²⁴⁸ This CCDT change may therefore again infringe patients' section 7 rights to life and security of the person.

"High-risk" patients: Another CCDT recommendation specifically targets the most vulnerable brain-injured patients. According to *BBFNDD*'s Recommendation 8,²⁴⁹ patients at "excessive risk" of death due to their hemodynamic or respiratory instability warrant different treatment in testing. As with the concern detailed above, this treatment involves a simplified test that omits apnoea testing. Specifically, Recommendation 8 advises replacing the apnoea test with an ancillary test²⁵⁰ for brain blood flow—CT angiography—if

note 214 at 122.

²⁴⁶ Recommendation 8 in *BBFNDD*, *supra* note 20 at 8 also recommended omission of apnoea testing for one other patient group, patients who are extremely frail and unstable in terms of their respiratory or hemodynamic status.

²⁴⁷ *Ibid* at 11.

²⁴⁸ This guideline therefore creates a significant risk of false positive diagnoses of brain death. Barbiturates may produce reversible symptoms, much like brain death: respiratory depression, central nervous system depression, reduced cardiac output, and lack of temperature regulation, resulting in a cold, apnoeic patient with low blood pressure, who appears neurologically unresponsive (Schears, *supra* note 233 at Clinical Features, Treatment).

²⁴⁹ *BBFNDD 2008*, *supra* note 35 at 144.

²⁵⁰ The CCDT favoured a particular type of ancillary test assessing "brain blood flow" to brain tissues. There are two possible such tests: tests which record the flow of blood in major blood vessels within the brain (i.e. CT and 4-vessel angiography) and tests of actual "perfusion" of brain tissues with blood (HMPAO or radionuclide scintigraphy). Although in theory, both tests should assess how much blood continues to nourish brain tissues, in reality, brain perfusion tests are more sensitive at detecting whether viable brain tissue actually remains. This is because even when the (tested) major blood vessels are devoid of blood flow, some flow may persist through abnormal blood vessel connections ("collateral linkages") in

the declaring physician believes the apnoea test poses “excessive risk” due to a patient’s respiratory or hemodynamic instability. There are several problems with this. One problem is that the brain blood flow testing through CT angiography could itself pose a risk of causing death in patients. Brain blood flow testing, using CT angiography as the CCDT recommends, involves injected contrast chemicals that may damage organs, possibly triggering an unstable patient’s death.²⁵¹

Yet brain blood flow tests cannot substitute for apnoea testing. As noted earlier, apnoea testing is the only way to test a key element of (either brainstem or whole-brain) death: the brainstem’s breathing reflex.²⁵² If a decision has been made to assess an unstable patient for brain death, his instability

the brain, continuing to nourish brain tissues. “The presence of tissue perfusion/uptake in the absence of demonstrable brain blood flow may arise in the remote circumstance of unexpected collateral blood flow, or flow detection below the lower limits of [the CT angiography] test” (see *BBFNDD*, *supra* note 20 at 3). CT angiography also poses some risks of tissue damage due to contrast media, while scintigraphy poses no comparable risks. See Manraj K S Heran, Navraj S Heran & Sam D Shemie, “A Review of Ancillary Tests in Evaluating Brain Death” (2008) 35 Can J Neurol Sci 409 at 414. While the CCDT states that CT angiography and scintigraphy are “rated equally,” elsewhere it makes clear that CT angiography, the less sensitive and more damaging test for viable brain tissue, is given priority (*BBFNDD*, *supra* note 20 at 4). Without explanation, the CCDT states that: “CT angiography is recommended as a preferred test” (*ibid*). This point was directly contradicted by a CCDT-commissioned paper to which *BBFNDD* specifically refers readers for guidance (*ibid*), which concluded that: “[Among] the preferred ancillary [tests], ... HMPAO ... radionuclide angiography [is] considered the first-line study. When this is not available or is equivocal, 4-vessel angiography ... can be performed” (Manraj Kanwal Singh Heran & Navraj Singh Heran, “Potential Ancillary Tests in the Evaluation of Brain Death: The Value of Cerebral Blood Flow Assessment” (10 October 2006) at 11, online: Canadian Blood Services <www.organsandtissues.ca/s/wp-content/uploads/2011/11/Potential-Ancillary-Tests.pdf>). Similarly, CCDT forum Chair Sam Shemie and the above authors stated in another paper that: “[o]ther options [than CT angiography] are preferred,” for reasons of patient safety in testing and transportation, expertise, cost and availability (Heran, Heran & Shemie at 414). Thus, *BBFNDD* preferentially recommends use of the less sensitive, more indirect and more harmful procedure for assessing the blood supply to brain tissues.

²⁵¹ *Ibid*.

²⁵² See Siegel & Sapru, *supra* note 200 (the Pre-Bötzinger complex within the brainstem is thought to be responsible for producing this reflex).

seems insufficient reason to replace apnoea testing²⁵³ with brain blood flow testing.²⁵⁴ Without apnoea testing, blood flow tests may erroneously declare some patients dead using evidence of interrupted blood flow. Brain blood flow may initially be absent during testing, due to brain swelling, suggesting “brain death” but could later resume, as swelling subsides. A brain blood flow test would provide no direct indication of whether the brainstem reflex that triggers breathing remains functional. If it remains functional but untested, the patient is not, by the CCDT’s own definition, brainstem-dead. Such a patient with restored brain blood flow and (untested but) intact brainstem breathing reflexes could be in a persistent vegetative state.

Performing only a brain blood flow test and no apnoea test on very frail patients might over-assess the number of patients declared “brain-dead” and thereby infringe their rights to life and security of the person. While the wording “excessive risk” in Recommendation 8 suggests concern for patients’ safety, its potential effects suggest the reverse.

Wait time removal: The final concern involves the CCDT’s removal of recommended wait times between re-testing. Traditionally, brain death assessments have required two sequential tests of a patient’s responsiveness. The CCDT now makes it possible for two doctors to simultaneously assess and immediately declare a patient dead, with no intervening wait period. *SBINDD 2006* added the confusing suggestion that if “sequential” testing by a single physician is performed, patients should be recorded as dead when the first test indicates death, rather than awaiting a second result.²⁵⁵ This recommendation would effectively make a second, sequential test superfluous,

²⁵³ Yet Ari R Joffe et al, “A 10-Month-Old Infant With Reversible Findings of Brain Death” (2009) 41 *Pediatric Neurology* 378 at 379, warned of the risk that apnoea testing might also kill a very frail or unstable patient. However, having defined “neurological death” to require evidence of lack of breathing reflexes, as the CCDT has done (*BBFNDD*, *supra* note 20 at 11), it seems that a physician’s only choice should be to either wait for the patient to stabilize or deteriorate further, or to perform the apnoea test as an essential test of brainstem functioning. Replacing the apnoea test with a test of other patient characteristics is not an acceptable alternative.

²⁵⁴ Both of these tests take time to perform and require transporting the patient to the imaging department where angiography is performed. Transportation may also pose risks to unstable patients. See *SBINDD*, *supra* note 1 at 31.

²⁵⁵ *SBINDD 2006*, *supra* note 21 at S10. Only babies under 30 days old are required to be repeat-tested at a different time (S4).

since life support could be withdrawn and organs legally harvested after the first test suggests brain death.²⁵⁶

This CCDT recommendation significantly changes the established procedure for determining death, which has always included an assessment of the irreversibility of a patient's condition. Under prior guidelines, irreversibility was estimated (albeit imperfectly) by requiring re-testing after wait periods of (originally) at least 24 hours, or under later guidelines, as few as two hours. Unfortunately, simultaneous re-testing without wait periods, or accepting the first test suggesting death, prevents detection of transient, reversible conditions that mimic brain death, such as hypothermia (discussed below) or drug effects.

Some argue that, for certain brain trauma patients, initial loss of brain blood flow and neurological unresponsiveness may spontaneously resolve after 48 hours.²⁵⁷ Patients with other neurological conditions, such as Alzheimer's disease, may exhibit cyclic symptoms, again suggesting a need for multiple, sequential tests. As Jennett noted "[a]n important safeguard against mistakenly suspecting brain death is to allow enough time to elapse [in brain death testing]."²⁵⁸ The CCDT's recommendations mean that the irreversibility of a patient's condition is not actually assessed. Thus, some patients could be incorrectly declared dead due to the CCDT's removal of recommended wait times. In contrast, sequential assessments, separated by a wait period, may find some patients alive upon a second test.

The CCDT's founding director Sam Shemie's comments regarding a recent brain death misdiagnosis in Edmonton, Alberta, appear to illustrate this very problem.²⁵⁹ This misdiagnosis appears to have occurred with the use by

²⁵⁶ In such cases, the requirement to declare brain death would seem to be reduced to a single test by a single physician, with no wait period in the testing. This could hasten the declaration of death, making organs available from donors hours or days earlier than previously.

²⁵⁷ Coimbra argues that when some minor flow remains, "suppressed neurological functions remain recoverable ... for up to 48h ... This phenomenon is known as ischemic penumbra" (CG Coimbra, "Implications of Ischemic Penumbra for the Diagnosis of Brain Death" (1999) 32 *Brazilian Journal of Medical and Biological Research* 1479 at 1480).

²⁵⁸ B Jennett, "Brain Death" (1981) 53:11 *British Journal of Anaesthesia* 1111 at 1117.

²⁵⁹ T Blackwell, "Theory on Life Support: Debate Grows Over When Brain Dead Really Means Dead", *National Post* (4 February 2010) online: NP

two paediatric intensivists of the CCDT guidelines, which had been adopted by the hospital, on a 10 month-old baby.²⁶⁰ As permitted by *SBINDD 2006*, only one brain death determination test was performed simultaneously by the two physicians before death was declared.²⁶¹ Ironically, given the CCDT's role in removing wait times, Shemie stated that, had 24-hour wait times been employed by the declaring physicians, permitting reversal of the alleged confounding factor of the infant patient's hypothermia, this misdiagnosis could have been avoided.²⁶²

<www.nationalpost.com> [Blackwell, "Life Support"]; Joffe et al, *supra* note 253 at 378-79.

²⁶⁰ The CCDT reported in 2006 that Edmonton hospitals had made changes to their institutional rules based on the CCDT guidelines. See *Summative Evaluation*, *supra* note 3 at 39, 42. Physicians at Stollery Children's Hospital where the baby died implied that the CCDT guidelines were employed in the case: "[The baby] fulfilled all criteria for brain death according to the [*SBINDD 2006*] recommendations" and "According to [*SBINDD*] Canadian consensus guidelines, this first examination was compatible with brain death" (Joffe et al, *supra*, note 253 at 378-79).

²⁶¹ As permitted by Recommendations A9 and B1 of *SBINDD*, *supra* note 1.

²⁶² "Dr. Shemie, however, said that ... [t]he problem was that the baby was subjected to 24 hours of hypothermia ... which can also mimic brain death. Had the doctors waited another 24 hours before testing for brain death to avoid that 'confounding factor,' there would have been no [misdiagnosis], he [Shemie] argued" (Blackwell, "Life Support", *supra* note 259). Yet *SBINDD*, co-authored by Shemie, removed minimum wait time requirements for all patients over 30 days old, requiring 24-hour minimum wait times only for those less than 30 days old (*supra* note 1 at Recommendation A9 at S4). *SBINDD* also recommended that "the legal time of death be marked by the first determination of death" (*ibid* at Recommendation B1, reversed by *BBFNDD*). Hence, under *SBINDD* Recommendations A9 and B1, the 10-month-old baby could legally be declared brain-dead after the first examination, by two physicians testing concurrently (i.e. zero wait time). This appears from Joffe et al, *supra* note 253 to be what occurred. In seeming contrast to Shemie's statement implying that the problem involved an insufficient pre-test warming period to correct the confounding factor of hypothermia, according to Joffe et al (at 378), when first tested, the baby had in fact been re-warmed to 36.2° Celsius (an acceptable non-hypothermic temperature for *SBINDD* Recommendations A3 and A9). Citing the *SBINDD* guidelines, Joffe et al suggested that these guidelines "may require revision for infants, to more clearly define a time interval between examinations and to incorporate consideration of confounding sedative drug effects [e.g. barbiturates]" (at 378). Under *SBINDD*, "therapeutic" barbiturate dosages were not deemed a confounding variable that would either preclude brain death determination

However, in fact, another Edmonton physician, Dr. Ari Joffe, reported no hypothermia, but noted another potentially influential variable: the baby had received a therapeutic dose of the barbiturate phenobarbital—as permitted by the CCDT guidelines but not previous guidelines—just five hours before the misdiagnosis.²⁶³ As recognized by earlier guidelines, the creation of wait times is an important means of addressing confounding factors. Without wait times to address the possibility of reversible conditions, such as hypothermia or barbiturate intoxication, there remains a potential for patients to erroneously be declared dead under the CCDT guidelines. This suggests the possibility of infringement of rights to life and security of the person.

The above CCDT recommendations suggest governmental interference with “matters of a fundamentally intimate and personal nature” in patients’ lives, invoking section 7 of the *Charter*. There appears to be a real possibility that several CCDT recommendations could be found to infringe patients’ rights to life and security of the person. It remains to be determined whether such infringements accord with the principles of fundamental justice.

B. Are the Section 7 Deprivations “In Accordance with the Principles of Fundamental Justice”?

If the suspected section 7 infringements can be shown to have occurred “in accordance with the principles of fundamental justice,” they comply with the *Charter*.²⁶⁴ It must be determined whether this is the case for each of the possible section 7 infringements mentioned above.

(*SBINDD* Recommendation A2) or require an ancillary brain blood flow test to complete the declaration (*SBINDD* Recommendation A6). Thus, according to *SBINDD*, there were no confounding factors, so the baby could be declared brain-dead after the first examination by two physicians, with no minimum re-testing wait time, and no brain blood flow test. This declaration could not have occurred under earlier brain death guidelines. Four hours before the first actual brain death examination, the physicians performed a computed tomography scan on the baby’s head, but it was not reported whether this scan investigated or found brain blood flow; no brain blood flow test was reported closer to the brain death exam although several were done after the baby resumed breathing (*ibid* at 378-79). It appears that the declaring physicians correctly applied *SBINDD*, resulting in a legal declaration of death after the first examination.

²⁶³ *Ibid.*

²⁶⁴ See *Morgentaler*, *supra* note 193 at 56, Dickson CJ & Lamer J (“Parliament could [legitimately] choose to infringe security of the person if it did so in a manner

Just what procedural fairness entitlements the principles of fundamental justice might entail in this context is not entirely clear. The jurisprudence indicates that the procedures required are not fixed and immutable, but determined by the individual context of a case: “[c]ertain procedural protections might be constitutionally mandated in one context but not in another.”²⁶⁵ Procedural fairness expectations under section 7 must also be balanced against fairness and efficiency considerations.²⁶⁶ According to the Supreme Court in *Reference re BC Motor Vehicle Act*, “the principles of fundamental justice are found in the basic tenets and principles, not only of our judicial process, but also of the other components of our legal system.”²⁶⁷ However, the Court stressed that these principles must be “more than vague generalizations as to what our society considers to be ethical or moral [and] capable of being identified with some precision.”²⁶⁸

Regarding the sources of these principles, the *Suresh* Court stated: “The inquiry into the principles of fundamental justice is informed not only by Canadian experience and jurisprudence but also by international law, including *jus cogens*.”²⁶⁹ Justice Wilson, dissenting in *Thomson Newspapers*, adopted the Court’s view in *Motor Vehicle* that sections 8-14 of the *Charter* provide guidance as to the content of the principles of fundamental justice. She believed these sections reflect “presumptions of the common law developed over time” or included in international human rights conventions that contribute to a justice system “based on a belief in ‘the dignity and worth of the human person.’”²⁷⁰

While it is unclear exactly what procedural entitlements a court might require in a challenge to the CCDT guidelines, case law contains indications as

consistent with the principles of fundamental justice”).

²⁶⁵ *R v Lyons*, [1987] 2 SCR 309 at para 85, 61, CR (3d) 1.

²⁶⁶ *R v Jones*, [1986] 2 SCR 284 at para 41, 31, DLR (4th) 569.

²⁶⁷ [1985] 2 SCR 486 at para 64, 24 DLR (4th) 536 [*BC Motor Vehicle Reference*].

²⁶⁸ *Rodriguez*, *supra* note 192 at 591 (according to the majority).

²⁶⁹ *Supra* note 198 at para 46. See also *Burns*, *supra* note 198 (“[International law] takes into account Canada’s international obligations and values as expressed in the various sources of international human rights law—declarations, covenants, conventions, judicial and quasi-judicial decisions of international tribunals, [and] customary norms” at paras 79-81).

²⁷⁰ *Thomson Newspapers Ltd v Canada* (Director of Investigation and Research, Restrictive Trade Practices Commission), [1990] 1 SCR 425 at 462, 67 DLR (4th) 161 [*Thomson Newspapers cited to SCR*].

to what will be considered unacceptable. A line of Supreme Court jurisprudence has indicated repeatedly that arbitrariness or unfairness will not satisfy the principles of fundamental justice. In *Rodriguez*, the Supreme Court suggested that a law or policy that is either arbitrary or unfair will offend the principles of fundamental justice.²⁷¹ Four of the seven justices in *Morgentaler* viewed a “manifestly unfair” law as similarly offensive,²⁷² which the Supreme Court in *Chaoulli* later interpreted as based on arbitrariness.²⁷³

In *R v Malmo-Levine and R v Caine*, in which liberty was at stake, it was argued that “law that is arbitrary or irrational will infringe section 7.”²⁷⁴ Other section 7 rights, to life and security of the person, appear no less important than the right to liberty and warrant similar protection. In *Chaoulli*, the Court specified that, to avoid being arbitrary, the limit on section 7 rights “requires not only a theoretical connection between the limit and the legislative goal, but a real connection on the facts.”²⁷⁵ Thus, where life and security of the person rights are affected, as by the CCDT guidelines, arbitrariness, unfairness, or irrationality may offend fundamental justice.

Proportionality also appears to be essential to fundamental justice. The Supreme Court stated in *Suresh*, a case involving deportation to possible torture, that:

The notion of proportionality is fundamental to our constitutional system. Thus we must ask whether the government’s proposed response is reasonable in relation to the threat. ... [S]ome responses are so extreme that they are *per se* disproportionate to any legitimate government interest ...²⁷⁶

As noted by Justice LaForest in *Thomson Newspapers*, community interests may play a role in shaping the content of fundamental justice when a

²⁷¹ The *Rodriguez* Court stated that “the blanket prohibition on assisted suicide is not arbitrary or unfair. The prohibition relates to the state’s interest in protecting the vulnerable and is reflective of fundamental values at play in our society. Section 241(b) therefore does not infringe s 7 of the Charter” (*supra* note 192 at 522).

²⁷² See *Morgentaler*, *supra* note 193 at 72, 110, 114, 119.

²⁷³ *Chaoulli v Quebec (AG)*, 2005 SCC 35 at paras 132-33, [2005] 1 SCR 791, 254 DLR (4th) 744 [*Chaoulli*] (reasons of McLachlin CJC, Major J, and Bastarache J).

²⁷⁴ 2003 SCC 74 at para 135, [2003] 3 SCR 571.

²⁷⁵ *Chaoulli*, *supra* note 273 at para 131.

²⁷⁶ *Supra* note 198 at para 47.

“just accommodation” is sought, through “delicate balancing” of the interests of individuals and of the state, taking into account the context in which legal measures operate, so as to benefit the community as a whole.²⁷⁷ A similar contextualization occurred in *Burns*, where the co-accused in a US homicide case argued that their unconditional extradition to face the death penalty would “shock the Canadian conscience,” due to their young age and Canadian nationality,²⁷⁸ violating the principles of fundamental justice. The Court agreed:

The “shocks the conscience” language signals the possibility that ... a particular treatment or punishment may sufficiently violate our sense of fundamental justice as to tilt the balance against extradition.²⁷⁹

A similar standard might be applied to the deprivation of section 7 rights generated by the CCDT guidelines. Overall, it appears that a law that is arbitrary, irrational, unfair, or that employs means disproportionate to the law’s ends—shocking the Canadian conscience—may offend fundamental justice.

The first CCDT concern discussed, the recommendation of a brainstem criterion of death, seems highly unlikely to satisfy the principles of fundamental justice, due to disproportionality between the means employed and the ends attained. The CCDT’s admittedly worthy goal was to increase the availability and viability of organs urgently needed by those on transplant wait-lists. In Canada, every year, 10–30% of those awaiting an organ die.²⁸⁰

²⁷⁷ In *Thomson Newspapers*, *supra* note 270 at para 180, LaForest J wrote regarding the content of s 7 that: “A community’s interests is one of the factors that must be taken into account in defining the principles of fundamental justice.” Specifically, he argued that legal practices should “seek to achieve a just accommodation between interests of individuals and those of the state, both of which play a part in assessing whether a particular law violates the principles of fundamental justice,” adding at para 181, that “in assessing whether a measure violates the principles of fundamental justice,” the specific context in which it operates must be kept steadily in mind (para 176). Overall, he suggested that legal measures are the product of a “delicate balancing” of state and individual interests, whereby “the community as a whole benefits” (paras 176, 208).

²⁷⁸ *Burns*, *supra* note 198 at para 17.

²⁷⁹ *Ibid* at para 69.

²⁸⁰ See Sam D Shemie, Christopher Doig & Philip Belitsky, “Advancing Toward a Modern Death: The Path From Severe Brain Injury to Neurological Determination of Death” (2003) 168 Can Med Assoc J 993 at 993. In 2007, only 2188 of 4195 Canadians on organ waitlists, or 52%, received transplants; the relative proportion

With the aging of Canada's population, this demand-supply deficit has continued to grow.

Yet, a government strategy to overcome a 10–30% deficit in Canada's organ supply through a major redefinition of brain death seems an extreme, disproportionate measure, which does not appear to be justified by recent scientific developments. The brainstem criterion of death has been rejected by other nations, including the US, due to its perceived risks. The possibility that a super locked-in organ donor might suffer after being mistakenly declared dead makes this a radical guideline change. In addition, the fact that the lives of both donors and non-donors are at risk of being curtailed by these guidelines also suggests a disproportionate effect. The possible negative effect of the CCDT recommendation on many brain-injured patients seems disproportionate to the benefits gained by organ recipients.²⁸¹ Therefore, the Supreme Court's observation in *Suresh* that "some [means] are so extreme that they are per se disproportionate to any legitimate government interest" also seems a valid criticism of the CCDT's adoption of brainstem death. Applying the standard enunciated in *Burns*, the CCDT's approach to increasing organ donation by radically redefining brain death criteria might well "shock the Canadian conscience," thereby violating the principles of fundamental justice.

According to the Supreme Court in *Chaoulli*, to avoid being arbitrary, a limit must show more than a purely theoretical connection between the impugned limit and the legislative goal, including "a real connection on the facts." Sustainability was an important element of the CCDT's scheme to improve Canada's transplant system. With the health of the baby-boomer generation declining and threatening to place increasing demands on finite healthcare resources, attempts to curb healthcare system costs were needed. The government may have hoped to rein in some costs by improving transplant access. Yet, the link between infringement of section 7 rights and making healthcare sustainable is more imagined than real. Only in kidney disease is transplantation known to reduce subsequent healthcare costs, by obviating

of the other 48%, who either died or continued waiting, was unstated (Kondro, "Allocation Mechanism", *supra* note 108 at 640).

²⁸¹ In fact, "less than 10-15 per cent of ... suitable donors become actual donors"(Adrian W Gelb & Kerri M Robertson, "Anaesthetic Management of the Brain Dead for Organ Donation" (1990) 37 Can J Anaesth 806 at 806). Among willing organ donors, some unmatched or unsuitable organs may also be rejected after donation.

the need for subsequent dialysis.²⁸² For other organs, such as hearts, arguments regarding cost savings lack support.²⁸³ Without “a real connection on the facts” then, the section 7 violation appears to be arbitrary.

Other fairness considerations also suggest that the principles of fundamental justice have not been satisfied. For instance, there has been no public notice of a major change in the death criterion to the donor and patient populations. Moreover, as urgent as the need for transplantable organs may be, it cannot outweigh the importance of the need to respect the lives, dignity, and bodily integrity of patients assessed for brain death. It has been recognized in Canada and internationally that a declaring physician’s primary loyalty and responsibility is to the patient being assessed for death, not the organ recipient.²⁸⁴ To protect patients being assessed for brain death, physician conflicts

²⁸² According to the 1999 *Standing Committee Report*, *supra* note 6 ch 3(B)(1)(c), “\$19,500 for ... hospital costs [is] associated with a kidney transplant versus ... \$50,000 per year for maintaining an individual on dialysis.”

²⁸³ *Ibid.* The report cited one-time transplant costs of “\$111,120 for heart and lung combined or just lung alone, \$82,400 for liver, and \$75,220 for heart” and remarked that “[with respect to these] other types of transplants, witnesses noted that no life-sustaining alternatives equivalent to dialysis exist,” against which to offset these transplantation costs. Costs of re-transplantation, complications, or treatment for the side effects of anti-rejection drugs may also add to the healthcare system costs of transplantation. After transplantation, recipients must pay five hundred dollars per month for anti-rejection drugs for the rest of their lives.

²⁸⁴ The 2006 World Medical Association *Declaration of Geneva* states: “The health of my patient will be my first consideration” (online: WMA <www.wma.net/en/30publications/10policies/g1/index.html>). Notably, dying patients create no special exceptions. The 2006 World Medical Association *Declaration of Venice on Terminal Illness* describes the duty of physicians caring for terminal patients thus: “to protect the best interests of their patients. There shall be no exception to this principle even in the case of incurable disease” (online: WMA <www.wma.net/en/30publications/10policies/i2/>). Thus, even when a patient is terminally ill, his or her interests have primacy over physician or third-party interests. The 2006 WMA *Statement on Human Organ Donation and Transplantation* also declares: “The primary obligation of physicians is to their individual patients, whether they are potential donors or recipients of transplanted organs ... Nevertheless ... the physician’s responsibility for the well-being of a patient who needs a transplant does not justify unethical or illegal procurement of organs” (online: WMA <www.wma.net/en/30publications/10policies/t7/>). The 2006 WMA *Declaration of Venice*, Principle 1, emphasizes that a physician declaring death in these patients should maintain the primary focus on the dying patient’s best interests rather than on secondary interests (such as organ donation). Also confirming the primacy of the needs of the patient being assessed for death,

of interest with organ transplantation are expressly disallowed in Canadian tissue gift legislation.²⁸⁵ Hastening the declaration of death in severely disabled patients who are unable to speak for themselves, in order to supply others with organs, would reverse this priority and instrumentalize donors as raw materials for the benefit of others. This is inconsistent with respect for the dignity and worth of the human person.

Notably, for four of the Supreme Court justices in *Morgentaler*, one factor that contributed to the striking down of the anti-abortion law was the recognition that “[u]nfair functioning of the law could be caused by external factors which do not relate to the law itself.”²⁸⁶ In *Morgentaler*, pregnant women experienced difficulty in accessing abortions, in part due to hospitals’ failure to create therapeutic abortion committees. The resulting inequality of access was judged “manifestly unfair” to Canadian women.

Similarly, some report an incomplete or “checkerboard” adoption of the CCDT guidelines among Canadian hospitals and jurisdictions.²⁸⁷ This generates the inequitable result that, in some Canadian regions or hospitals, use of the CCDT’s brainstem criterion of death may be required, while in others, a whole-brain criterion might still be used.²⁸⁸ As in *Morgentaler*, external factors, rather than the law itself, have created this gross regional disparity in access to appropriate medical treatment, contributing to the “manifest unfair-

over the needs of would-be organ recipients, the 2006 WMA *Declaration of Sydney on the Determination of Death and the Recovery of Organs* requires death to be declared by a physician who is not in a conflict of interest through involvement in transplanting that patient’s organs (online: <www.wma.net/en/30publications/10policies/d2/index.html>).

²⁸⁵ With the exception of the Northwest Territories and Nunavut, Canada’s provincial tissue gift acts expressly disallow physicians associated with an organ’s transplant from declaring a donor’s death. For example, Nova Scotia’s *Human Tissue Gift Act*, *supra* note 14, s 8(2) states: “No physician who has had any association with the proposed [organ] recipient that might influence his judgment, shall take any part in the determination of the fact of death of the [organ] donor.”

²⁸⁶ *Morgentaler*, *supra* note 193 at 65.

²⁸⁷ See Kondro, “Fragmented Organ Donation”, *supra* note 208; *Summative Evaluation*, *supra* note 3 at viii, para 3 (reported that by late 2006, adoption of CCDT guidelines had occurred in a piecemeal fashion, i.e. “practitioner by practitioner, organization by organization and province by province,” rather than on the desired national scale).

²⁸⁸ For example, in Atlantic Canada, all the hospitals that perform transplants have reportedly adopted the CCDT guidelines (*ibid* at 40, 42).

ness” of the CCDT guidelines’ operation, and offending principles of fundamental justice.

The second concern discussed also seems unlikely to satisfy fundamental justice requirements. The CCDT recommendation affects barbiturate-intoxicated patients, which may form a large segment of those assessed for brain death, including many traumatic brain injury patients, some recreational drug users, accidental overdose victims, those who have attempted suicide, and others. Under *BBFNDD*, these patients may not only undergo brain death assessment while affected by barbiturates (which previously confounded testing), but they may also now undergo a significantly simplified test for brain death.²⁸⁹ In this simplified process, no apnoea test is done for some and an EEG, labeled as unreliable elsewhere in the CCDT guidelines, may replace the CCDT’s earlier recommendation of a brain blood flow test. With the exception of high-risk patients, discussed above, no other patients are assessed in this way. From a patient-safety perspective, the recommendation suggests irrationality and unfairness, implying that it violates the principles of fundamental justice.

This recommendation also appears scientifically arbitrary. Under *BBFNDD*, barbiturate-intoxicated patients are given a significantly different, much simpler assessment than all other patients, without clear, scientific reason. The treatment of barbiturate patients also differs markedly between earlier (*SBINDD*) and later (*BBFNDD*) guidelines, again without reference to a scientific basis for the change.²⁹⁰ According to current medical literature, barbiturates can create reversible, death-like states at dosages that may qualify as therapeutic. Thus, barbiturate-intoxicated patients require greater safeguards in death determination to prevent misdiagnoses. The CCDT’s recommendation therefore seems to be an arbitrary change, lacking scientific support, and contradicting claims that the CCDT guidelines are evidence-based.²⁹¹ While this CCDT recommendation may not affect all patients as-

²⁸⁹ *SBINDD* versions of the CCDT guidelines contain no such recommendations to exclude apnoea testing.

²⁹⁰ See *BBFNDD*, *supra* note 20 at 8. Testing of high-dose, barbiturate-affected patients (and use of a simplified brain death assessment with no apnoea test) was allowed only in the *BBFNDD* versions of the CCDT guidelines, but not in the earlier *SBINDD* guidelines, which only permitted testing with low or therapeutic barbiturate dosages and required an apnoea test for all patients.

²⁹¹ The 1999 NCCOTDT *Strategy* stated its commitment to “evidence-based decision-making” in its plan to improve Canadian OTDT through CCDT efforts (*supra* note 7 at 6). As justification for replacing earlier Canadian brain death guidelines

sessed for brain death, based on the frequency of barbiturate use in head injury and other patients, it may affect a significant proportion. The guidelines' apparent willingness to subject this sub-group of Canadian patients to less thorough testing, possibly to increase organ supply, seems sufficient to "shock the Canadian conscience."

A similar concern attends the third issue discussed. This recommendation specifically targets the most vulnerable patients assessed for brain death: those so frail that brain death tests alone might kill them. Out of concern for their frailty and respect for their lives and dignity, it might be expected that the guidelines would recommend delaying testing in these patients, to await their stabilization or natural demise. Instead, the CCDT recommends simplifying the brain death assessment. This recommendation does not appear to be supported by existing medical knowledge. Since the simplified test may kill or over-assess the death rate in this patient group, this recommendation appears irrational, unfair, and scientifically arbitrary. As with the previous recommendation regarding barbiturate-treated patients, the CCDT's apparent willingness to subject such a vulnerable group of patients to a less rigorous standard of assessment does not suggest respect for patients' dignity and worth. The recommendation therefore appears to violate the principles of fundamental justice.

The final concern involves the effective removal of recommended wait times. This recommendation fails to consider the existence of reversible death-like states, such as hypothermia, which must be excluded before a diagnosis of brain death is medically justified. As noted above, some physicians also believe that, for up to 48 hours after brain trauma, a temporary "ischemic penumbra" may exist in the brain, due to raised intra-cranial pressure limiting brain blood flow. This may be clinically indistinguishable from brain death, but is reversible, making recovery possible for some. Without wait times, such cases cannot be detected.

with the CCDT guidelines, the CCDT argued that previous Canadian brain death guidelines were not evidence-based, thereby implying that its guidelines would be. See CCDT, *Literature Review Brain Death*, *supra* note 15 at iii, 12, 15-16, 19, 25. However, a CCDT survey respondent revealed a low opinion of the CCDT guidelines' evidence basis: "organ donation doesn't have a lot of high level of evidence, medically speaking ... [so] we have to live with expert opinion ... That's one of the problems that critics of the CCDT have, that most of what's been produced is expert panel recommendations—there is not a lot of science or high level of evidence behind those recommendations ... the level of evidence is low" (*Summative Evaluation*, *supra* note 3 at 43).

Wait-time removal leaves the vital irreversibility component of death untested, making declaration of death medically unjustified. An element of irrationality is also introduced by the recommendation to declare death based on the first sequential test result. Early in the CCDTs history, it was declared that the CCDT would be sensitive to the need to protect the safety and the best interests of patients being assessed.²⁹² However, if an important part of diagnostic confidence requires “allowing sufficient time to elapse” before declaration of death, then recommendations discouraging physicians from allowing for such time appear to abandon patient safety considerations. This CCDT suggestion also appears to defy scientific support and rationality, violating fundamental justice.

In summary, on grounds of arbitrariness, irrationality, unfairness, disproportionality, and a standard shocking to the Canadian conscience, each of the section 7 deprivations discussed in the preceding section appears to violate the principles of fundamental justice, suggesting infringement of section 7.

C. Could the Suspected Section 7 Infringements be Justified under Section 1 of the Charter?

Section 1 of the *Charter* allows a prima facie infringing state activity to be upheld on public policy grounds, as a “reasonable limit, prescribed by law and demonstrably justified in a free and democratic society.” Unlike the demonstration of a section 7 deprivation, the burden of proof of justification

²⁹² In 2001, Federal Health Minister Allan Rock, upon unveiling the plan to increase organ donation through CCDT efforts, stated: “Our priority is to protect the health and safety of all Canadians” (“Canadian government launches \$20 million, 5-year plan to increase donors”, *Transplant News* (12 May 2001), online: All Business <www.allbusiness.com/health-care-social-assistance/ambulatory-health-services/783295-1.html>). Presumably, he meant to include Canadians tested for death. Similarly, the goals agreed to by the CDM in approving CCDT creation included a commitment “[t]o preserve, protect and improve the health of Canadians” (*Summative Evaluation*, *supra* note 3 at 10). See also *SBINDD*, *supra* note 1 at 7 (“[CCDT] recommendations [for brain death determination] must be in the best interests of patients with severe brain injury”). Kimberly Young, the CCDT’s former CEO also stated: “According to the CCDT vision ... all donation should be compassionate, safe and efficient” (2008 *Standing Committee Report*, *supra* note 52 at 5). Yet in contrast, the 1999 NCCOTDT *Strategy* was committed to “meet the highest quality and safety standards,” but only for “Canadians in need [of transplants]” (*supra* note 7 at 5). Finally, *BBFNDD* stated that it was intended to reflect “the needs of medical practitioners,” rather than patients of either type (*supra* note 20 at 1).

under section 1 falls to the state.²⁹³ The majority of the Court in the *BC Motor Vehicles Reference* argued that it would take “exceptional conditions” such as “natural disasters, the outbreak of war, epidemics and the like” to justify infringement of section 7 rights.²⁹⁴ Two ideas support this view:

First, the rights protected by s. 7 ... are very significant and cannot ordinarily be overridden by competing social interests. Second, rarely will a violation of the principles of fundamental justice ... be upheld as a reasonable limit demonstrably justified in a free and democratic society.²⁹⁵

Mullan notes that, accordingly, “it is difficult to find examples of a section 1 justification actually succeeding” in upholding a section 7 deprivation.²⁹⁶ Yet for greater certainty, the CCDT guidelines must be examined for the possibility that some of the above infringements might be upheld under section 1. The legal test by which this question is answered is the *Oakes* test, which asks: whether the *Charter* infringement involved a goal that was “pressing and substantial”; whether the claimed infringement was “rationally connected” with that goal; whether the infringement impaired “as little as possible” the right infringed; and, finally, whether the means used were proportionate to the ends sought by the infringing activity.²⁹⁷ A failure at any branch of the *Oakes* test means that the impugned government activity cannot be saved under section 1.

Under the first branch of the *Oakes* test, the goal of the CCDT guidelines was to improve Canada’s relatively dismal rate of organ donation in order to save more lives, an objective that does appear pressing and substantial. As noted earlier, 10-30% of those on Canadian wait lists die while awaiting a transplant. In Canada’s increasingly aging, obese, and sedentary society, the need for transplantable organs is likely to grow. With a transplant, many patients can live longer, more comfortable and fulfilling lives. These facts warrant concern and attention.

²⁹³ This was noted by the majority in *R v Mills*, [1999] 3 SCR 668 at para 66, 180 DLR (4th) 1.

²⁹⁴ *BC Motor Vehicle Reference*, *supra* note 267 at para 85.

²⁹⁵ *JG*, *supra* note 178 at 92.

²⁹⁶ Mullan, *supra* note 194 at 205.

²⁹⁷ The test first appeared in *R v Oakes*, [1986] 1 SCR 103 at 138–39, 26 DLR (4th) 200. It was later amended, the modified result appearing in *R v Laba*, [1994] 3 SCR 965 at 1006, 120 DLR (4th) 175 [*Laba*].

With donation rates hovering around 14 donors per million population, some have described Canadian organ donation as being “in crisis.”²⁹⁸ Yet, is this crisis equivalent to the outbreak of war, an epidemic, or a natural disaster? Canada’s federal government clearly thought that increasing organ donation was both important and urgent.²⁹⁹ The 1999 NCCOTDT blueprint for CCDT establishment suggested that the content of guidelines to be drafted by the CCDT was of “national concern.”³⁰⁰ Following Parliamentary discussions from 1995-1999, improving organ donation was deemed such a high priority as to warrant a *Memorandum of Understanding* among all levels of government to overcome constitutional obstacles. Though the government may not have perceived donation rates as equivalent to such extreme threats as war or epidemic, it is likely that the CCDT guidelines would pass as sufficiently pressing and substantial for the purposes of the first branch of the *Oakes* test.

²⁹⁸ Various reports noted “the donation crisis” of the late 1990s in Canada. See e.g. 1999 NCCOTDT *Strategy*, *supra* note 7 at 3; *Summative Evaluation*, *supra* note 3 at 9. While donation rates have increased slightly each year, these small increases are outpaced by growth in Canada’s population and in rates of organ transplant needs. According to Health Canada, *Government Response*, *supra* note 6, “[d]onation rates have leveled off at 14.5 [donors per million] at a time when the need for transplants has increased by 50 per cent.” In the US, despite much higher donation rates of 21 per million, a 2006 report suggests that organ shortages are so severe that “it is important to explore any scientifically credible and ethically acceptable proposal that might increase the organ supply. This may, of necessity, require a reexamination of the sources of organs and strategies for their acquisition that were rejected in the past at a time when the crisis was less acute” (James F Childress & Catharyn T Liverman, eds, *Organ Donation: Opportunities for Action* (Washington, DC: National Academies Press, 2006) at 141).

²⁹⁹ The 1999 *Standing Committee Report*, *supra* note 6 ch 6 stated that “Canada is currently facing a serious situation with respect to organ and tissue donation and transplantation. ... [E]xtremely low donor numbers have resulted in ever-expanding waiting lists.” The same report mentions the “need for immediate action,” requiring the committee to work “at an accelerated pace” (ch 1). While such wording suggests urgency, it implies nothing so extreme as that required to deal with war, the outbreak of epidemics, or natural disaster.

³⁰⁰ 1999 NCCOTDT *Strategy*, *supra* note 7 at 26. However, in the 1999 *Standing Committee Report*, there was no mention of “national concern” or “national emergency” as a constitutional basis for the proposed federal plan to address the OTDT crisis by creating the CCDT (*supra* note 6 ch 2(E)(1)). The *Report* mentioned only the federal government’s “general powers ... criminal law, spending, and peace, order and good government,” and “the need for a national perspective” (ch 3).

The second branch of the *Oakes* test asks whether the goal in question was “rationally connected” to the impugned action. Here, the action taken in response to the goal described above was the CCDT’s creation of a set of guidelines that redefine the point at which brain death can be declared. Is there a rational connection between the issuance of the guidelines, and the goal of increasing national organ donation rates and viability? Clearly, there is a rational connection because the declaration of brain death marks the point at which it becomes legal to harvest a consenting patient’s organs and tissues.³⁰¹ The earlier brain death can be declared, the sooner organs can be harvested, and the more successful a transplant may be. As stated in a paper co-authored by the CCDT forum chair and a *BBFNDD* contributor, “[e]arlier determination of brain death may ... allow for avoidance of protracted stays in the ICU, and potentially expedite organ donation before tissue viability becomes a concern.”³⁰²

Past efforts to increase donor rates through marketing and education have consistently failed to meet the growing Canadian demand for transplantable organs. Unfortunately, approaches based on donor choice and autonomy face resistance due to strongly held religious or personal values, and possibly due to public fears by some of a conflict of interest between organ donation and death declaration.³⁰³ Under the CCDT approach, some deaths could be declared significantly earlier than under previous guidelines, making a greater number of viable organs available sooner.³⁰⁴ This suggests a rational connection between the CCDT guidelines’ infringement on brain-injured patients’ section 7 rights and the goal of increasing organ supplies.

³⁰¹ Most of the organs harvested for transplant in Canada in 2009 were from brain-dead donors. In 2006 some Canadian provinces began harvesting from “donation after cardiac death” donors. However, these amounted to fewer than 10% of organs harvested for transplant in 2008. See CIHI, *Keeping Pace with Demand*, *supra* note 29.

³⁰² Heran, Heran & Shemie, *supra* note 250 at 411.

³⁰³ According to a 2005 CCDT survey of Canadian public attitudes to OTDT, nearly one-quarter of those surveyed (22%) believed that doctors might declare death prematurely to obtain organs. Although not a majority opinion, this nevertheless indicates the presence of some public concern (CCDT, *Public Awareness Report*, *supra* note 46 at 7).

³⁰⁴ This is especially the case with the use of a brainstem criterion of death, where death might be declared months or years sooner than under a whole-brain criterion. The other CCDT recommendations might allow patients to be declared dead hours or days sooner than under past guidelines.

The connection, though rational, is not without complications. The CCDT's approach might backfire if it became publicly known that the CCDT had dramatically altered the criteria for brain death declaration with the goal of increasing organ supplies. This could negatively affect public trust in organ donation, possibly causing organ donor consent rates to drop. Some also speculate that if organs did become significantly more available, physicians might simply relax current eligibility requirements and offer transplants to less sick patients.³⁰⁵ Thus, the organ demand-supply gap might still persist. Despite this difficulty, it is probable that the CCDT brain death guidelines would still pass as "rationally connected" to the government objective of improving both organ supply and transplant viability.

Under the third branch of the *Oakes* test, can it be said that the CCDT brain death guidelines have impaired patients' security of the person rights only minimally? Such a finding seems highly unlikely. The CCDT might argue that these guideline changes are minimally impairing since they declare dead some severely neurologically damaged people—many of them close to death—only slightly sooner than previous guidelines. Wayne Kondro, in 2006, also reported that brain death accounts for just 1.4% of Canadian deaths.³⁰⁶ In terms of the numbers affected by the guidelines, then, altering brain death guidelines to permit an earlier declaration of death might seem to constitute a minimal encroachment on the rights to life or security of the person.³⁰⁷ Yet, this view breeds disrespect for patients with severe disabilities who are assessed for death. It also ignores the fact that the CCDT recommendations infringe a fundamental, highly-valued, and sensitive right in Canadian society.

In *Fleming*, the Ontario Court of Appeal stated that the right to bodily integrity, which the court deemed co-extensive with the section 7 right to security of the person, is "ranked as fundamental and deserving of the highest order of protection," based on "the belief in the dignity and autonomy of each individual."³⁰⁸ This right is of such overriding importance in Canadian society that even infringing actions with a beneficent or therapeutic intent—such as

³⁰⁵ See Childress & Liverman, *supra* note 298 ("the patients who would gain access to transplantation as a result of an increased organ supply may differ systematically from patients who currently receive a transplant" at 34).

³⁰⁶ Kondro, "Fragmented Organ Donation", *supra* note 208 at 1044.

³⁰⁷ Prior Canadian guidelines were altered to declare patients dead slightly sooner (e.g. reducing wait times from 24 to 2 hours, or by allowing spinal reflexes to persist), but these changes were more incremental.

³⁰⁸ *Fleming*, *supra* note 196 at 312.

the administration of psychoactive drugs by medical staff to cure an individual's serious mental illness, as in *Fleming*—may be deemed to unacceptably infringe rights under section 7 of the *Charter* and may not be upheld under section 1. In *Fleming*, the important individual and societal value of curing severe mental illness, such as schizophrenia, did not outweigh the importance of individual security of the person.

It would seem that infringing actions occurring in a medical context with a beneficent, therapeutic intention to cure a third party's serious illness are even less likely to be upheld under section 1 than the infringement at issue in *Fleming*. The individual and societal benefits of providing more people with viable organ transplants, while meritorious, cannot outweigh the importance of life and security of the person to individuals assessed for brain death. The CCDT brain death guidelines apply to all patients assessed for brain death, whether they are consenting organ donors or not, implicating the rights of more individuals than necessary to increase organ supplies. This, too, suggests insufficient tailoring of the section 7 infringement. It therefore seems doubtful that a court would view the CCDT guidelines' impairment of security of the person as "minimal."

For greater certainty, the final branch of the *Oakes* test will also be examined. This branch asks whether the infringement has "deleterious effects which are proportional to both their salutary effects and the importance of the [Parliamentary] objective."³⁰⁹ Here, the objective sought was a sustainable OTDT system that would resolve Canada's organ donation crisis by increasing donation rates to 25 donors per million within 5 years of CCDT establishment, making larger supplies of transplantation-quality organs and tissues available.³¹⁰ The intended salutary effect was that more successful organ transplants might be performed in Canada, providing years of productive, comfortable life to many needy patients each year, with possible, but as yet unclear, economic benefits.

In addition, as the organ donation agency Trillium Gift of Life's website has argued, organ transplants do not just save lives, they save "productive lives."³¹¹ Patients with organ failure represent a significant cost for govern-

³⁰⁹ As expressed by the court in outlining the *Oakes* test, in *Laba*, *supra* note 297 at 1006.

³¹⁰ 1999 NCCOTDT *Strategy*, *supra* note 7 at 7 ("rais[e] donor levels [from 14 donors per million] to 25 [donors per million] in 5 years" *ibid*).

³¹¹ Trillium Gift of Life, "Frequently Asked Questions", online: TGL <www.gift

ments due to welfare and disability payments, as well as home-care and healthcare system costs for hospitalization, drugs, and interim treatments, such as dialysis. Despite its advantages, however, organ transplantation is no panacea. The benefits of organ donation must ultimately be weighed against the high economic and other costs of transplantation surgery, lifelong anti-rejection drugs, re-transplantation, and treatment of serious side-effects, including cancer, graft-versus-host disease, and chronic fatigue. A complete economic cost-benefit assessment of all types of organ transplantation would be extremely complex. Perhaps because of this, no such assessment has been performed in Canada or other industrialized nations.³¹²

In terms of costs, the potential deleterious effects of the guidelines include the very serious possibility of prematurely declaring a patient dead. While this may offer the advantage of shorter and less expensive hospital ICU stays and more numerous and successful organ transplants, these advantages cannot outweigh the incalculable negative effect of premature death on patients and their families. These risks may affect a significant proportion of patients—both donors and non-donors alike—making the range of persons affected by the infringement broader than necessary to achieve Parliamentary goals.³¹³

While the CCDT recommendations may offer major advantages to some in the cost-benefit calculation, these benefits accrue only to individuals in the relatively healthier, and more powerful group (patients awaiting an organ transplant) at a very high cost to the more vulnerable group (the severely disabled who are assessed for brain death). While both groups are vulnerable, those awaiting organs are less so in that they can typically communicate their wishes and defend their interests. Here, the benefits of greater organ availability for a more dominant group should not lead a court to discount the guidelines' harsh effect on more vulnerable, brain-injured patients.

Nor is it clear that Parliament's goal is achievable simply by increasing organ supplies, since an increased organ supply might simply increase trans-

offlife.on.ca/en/faq.htm> at "How does donation help other people?"

³¹² In Canada, each kidney donation may save \$104,000 per patient in dialysis and other healthcare costs over a twenty-year period. See James F Whiting et al, "Cost-Effectiveness of Organ Donation: Evaluating Investment into Donor Action and Other Donor Initiatives" (2004) 4 *Am J Transplant* 569 at 569. However, it is less clear whether there are cost savings associated with other organ transplants.

³¹³ The guidelines may be applied to declare the death of any patient, whether a donor or not.

plant recommendations to overly frail patients, increasing costs but producing no real gains in these patients' lifespans. The erosion of safeguards encourages disrespect for the lives of severely disabled individuals and could also negatively affect public trust in organ donation if it becomes publicly known.

After weighing these deleterious and salutary effects in the context of the federal government's objective, the proportionality required under the final branch of the *Oakes* test appears to be lacking. The potential negative effect of the CCDT guidelines on the rights of all Canadians—including vulnerable brain-injured individuals—outweighs the societal and individual benefits to be gained from increased organ availability. To conclude, it seems unlikely that the impugned CCDT recommendations could be saved under section 1 of the *Charter* as a reasonable governmental policy choice. If the recommendations are found to be contrary to the *Charter*, a court must strike the guidelines down, according to section 52(1) of the *Constitution*.³¹⁴ However, if, as discussed previously, the guidelines are administrative aids to statutory interpretation this course of action may not be open to a court.³¹⁵

D. Alternative Legal and Disciplinary Responses to the CCDT Guidelines

If the CCDT guidelines cannot be characterized as law for the purposes of section 52, the guidelines could be remedied on a case-by-case basis under section 24 of the *Charter*. Of concern is the fact that a section 24 case-by-case approach leaves the CCDT guidelines “on the books,” where they can continue to affect patients for years to come.³¹⁶ This approach would also be unfortunate, because of the difficulty of finding a suitable plaintiff to challenge the guidelines: a plaintiff who has been misdiagnosed as brain-dead, who is known to have been diagnosed under the CCDT guidelines (or under hospital guidelines based on them), and who has also survived the subsequent withdrawal of life support (or evaded organ harvesting). In addition, the plaintiff (or the plaintiff's family) must be willing to undertake legal ac-

³¹⁴ being Schedule B to the *Canada Act, 1982* (UK), 1982, c 11 s 52(1).

³¹⁵ While unlikely, the CCDT guidelines possess some features that might characterize them as “law” that would enable them to be struck down as inconsistent with the Constitution and therefore “of no force and effect.”

³¹⁶ It is, however, possible that a successful s 24 ruling might have a chilling effect on future physician use of the CCDT guidelines, if the results of the ruling were widely known to physicians.

tion despite the major cost and effort involved.³¹⁷ Finding such a plaintiff poses an enormous obstacle to case-by-case challenge under section 24. A potential challenger might however, exist in the family of the Alberta baby discussed earlier.³¹⁸

Because of the difficulties posed by section 24, several alternative legal responses to the CCDT guidelines' use or dissemination warrant comment. Several potential legal approaches may apply to physicians who applied or disseminated the CCDT guidelines, including the civil law of negligence and College disciplinary penalties.

The civil remedy based on the tort of negligence faces numerous obstacles. First, if a patient is mistakenly declared dead under the CCDT guidelines and is later found to be alive (with a clinical outcome similar to that upon admission), it may be difficult to prove that there is a harm to be compensated through tort: the patient may already be in much the same position as before the misdiagnosis. In other cases, it could be difficult to show causation of the patient's injury, or later death, by the earlier brain death misdiagnosis and the associated temporary withdrawal of care. Finally, patients whose misdiagnoses are never discovered, and who succumbed to treatment cessation or organ harvest, clearly cannot bring an action to recover in negligence.³¹⁹

Not all physicians who declare brain death may be neurologists, so non-neurologists must also be considered. In the US, at least, many hospitals al-

³¹⁷ To date, two other Canadian patients are known to have survived brain death misdiagnoses (one of them long-term). However, these survivors did not pursue a remedy in court and so details such as the guidelines used are unknown. See Tom Blackwell, "Who says Doctors Know Best? Families do not Have Final say in Pulling Plug", *National Post* (11 December 2006).

³¹⁸ Had the Edmonton hospital operated according to prior (CNCG) guidelines, the baby would not have been tested so shortly after barbiturate administration (which the CNCG strictly excluded). In addition, for an infant, a full 24-hour wait period would have been required between tests, and given his hypoxic aetiology, a wait period of over 24 hours would have been possible. Thus the baby's life support and aggressive care would have continued during the 15 hours he was believed dead, which might have led to his survival.

³¹⁹ Neither patients nor their families can bring an action because none will have knowledge that there was ever a misdiagnosis. Even physicians may remain unaware of a misdiagnosis, if organs are harvested or life support withdrawn before signs of life (e.g. breathing attempts) reappear.

low non-neurologists and junior physicians to declare brain death,³²⁰ so this group may be sizable. In a negligence action, a non-neurologist would be held to the standard of a reasonable medical practitioner of his or her type, whose behaviour was “in accordance with the conduct of a prudent and diligent doctor in the same circumstances.”³²¹ However, courts do not possess detailed medical expertise; to construct the relevant standard of care and assess whether a physician’s behaviour complied with reasonable medical expectations, a court may defer to indicia of the norms of professional practice.³²² These norms might include the CMA InfoBase guidelines that produced the harm, leading a court to find no liability.³²³ Due to their dissemination by the CMA and their adoption by some hospitals, the CCDT guidelines might be viewed by a court as an element of standard medical practice, the complexity and scientific content of which are beyond the ordinary understanding and experience of a judge and jury.

³²⁰ See David J Powner, Michael MS Hernandez & Terry E Rives, “Variability Among Hospital Policies for Determining Brain Death in Adults” (2004) 32:6 Crit Care Med 1284 at 1285 (no neurologist was required by 62% of 140 US hospitals studied). Similarly, in a second study, “a surprisingly low rate of involvement of neurologists or neurosurgeons” was the reality in brain death determinations at 41 top US hospitals (David M Greer et al, “Variability of Brain Death Determination Guidelines in Leading US Neurologic Institutions” (2008) 70 Neurology 284 at 287).

³²¹ *ter Neuzen v Korn*, [1995] 3 SCR 674 at para 33, 127 DLR (4th) 577 [*ter Neuzen*]. Thus a family physician would be held to the standard of a reasonably prudent and diligent family physician.

³²² “It is generally accepted that when a doctor acts in accordance with a recognized and respectable practice of the profession, he or she will not be found to be negligent. This is because courts do not ordinarily have the expertise to tell professionals that they are not behaving appropriately in their field ... [T]he medical profession is assumed to have adopted procedures which are in the best interests of patients and are not inherently negligent” (*ibid* at para 38). Yet the court noted that “there are certain situations where [a] standard practice itself may be found to be negligent. However, this will only be the case where a standard practice is ‘fraught with obvious risks’ such that anyone is capable of finding it negligent ... ” (at para 41).

³²³ The Supreme Court held that “where a procedure involves difficult or uncertain questions of medical treatment or complex, scientific or highly technical matters that are beyond the ordinary experience and understanding of a judge and jury, it will not be open to find a standard medical practice negligent” (*ter Neuzen*, *supra* note 321 at para 51). Where the CCDT guidelines’ adoption is presently only “checkerboard” and there is evidence of some variability in practice, it is unclear if the CCDT guidelines qualify as standard practice.

Given the complex neurological content of the guidelines, it may be unreasonable for a court to expect non-neurologists to recognize the flaws in the CCDT guidelines and reject their use. It is only if the guidelines are “fraught with obvious risks” that even a layperson can understand that this would be expected. Brain death tests involve difficult, highly technical knowledge, with which even non-specialist physicians may be unfamiliar. Without this specialized knowledge, physicians are likely to rely on the guidelines. A non-neurologist’s use of the guidelines may therefore neither produce a finding of civil liability in negligence, nor meet the higher evidentiary standard of criminal negligence.³²⁴ A complaint could, however, be initiated against a physician by a member of the public to trigger a College disciplinary hearing.³²⁵

In the case of the misdiagnosed Edmonton baby mentioned earlier, death was declared by two paediatric intensivists. These specialist physicians, who are not usually neurologists, are trained in intensive care of the critically ill. The intensivists here applied the CCDT guidelines correctly in regard to concurrent testing by two physicians, with no minimum wait interval, as permitted by *SBINDD* for all patients over 30 days old,³²⁶ and they declared death after the first examination, as recommended by *SBINDD*.³²⁷ Although a computed tomography test was done four hours before the first brain death test, it was not reported if brain blood flow was part of this test. However, based on *SBINDD* stipulations, no ancillary blood flow test was required since no confounding factors (such as hypothermia) existed.³²⁸ The boy’s therapeutic intoxication with barbiturates and sedatives was not considered by *SBINDD* to be a confounding factor precluding diagnosis or requiring ancillary blood flow testing.³²⁹ Overall, given the boy’s serious initial injury, it is unclear whether he would have lived but for the application of the *SBINDD* guidelines and the ensuing 15 hours without aggressive medical intervention. Because they simply followed guidelines that were not fraught with obvious

³²⁴ *Criminal Code*, RSC 1985, c C-46, ss 219, 220.

³²⁵ *Medical Act*, SNS 1995-96, c 10, s 48 allows a complaint to be made to the College by “any official body corporate or organization” or “any other person.”

³²⁶ *SBINDD*, *supra* note 1 at Recommendation A9.

³²⁷ *Ibid* at Recommendation B1.

³²⁸ Joffe et al, *supra* note 253 at 378 reported a core temperature of 36.2° Celsius when the baby was first tested; *SBINDD* neonatal temperature requirements required the patient be at least 36° Celsius when tested, while requirements for those over 1 year of age were 34°C (*SBINDD*, *supra* note 1 at Recommendations A3, A9).

³²⁹ *Ibid* at Recommendations A2, A6.

risks, it appears that no liability in negligence should apply to the two intensivists who applied the guidelines in declaring the baby's death.

In contrast, neurologists applying the guidelines would be held to the higher standard of the "reasonable specialist" in neurology. Like all physicians, neurologists owe a fiduciary duty to safeguard the lives of the patients they assess for brain death, putting these patients' welfare above the interests of those awaiting organs. It would seem that a reasonable neurologist could be expected to note the guidelines' inconsistencies and risks, and to reject them as dangerous for patients in their care. However, although a reasonable neurologist should recognize that the CCDT guidelines are flawed and risky, the *ter Neuzen* test will not give rise to liability if the risks are not obvious to a layperson, which seems doubtful, or if the CCDT guidelines are considered standard practice, which also remains uncertain.³³⁰ Accordingly, it is unclear how a court may rule in a hypothetical future case involving neurologists. Conceivably, if the guidelines are not deemed "standard practice," employing them might leave a neurologist vulnerable to a finding of civil liability in negligence.

The CMA actively promotes the use of its InfoBase guidelines by Canadian physicians to further "ongoing improvement in the quality of care for Canadians." Reportedly, the InfoBase was planned as a "comprehensive, one-stop source" of guidelines for physicians.³³¹ Based on the number of patients potentially affected, one might predict the potential for civil liability among CMA decision makers who chose to disseminate the CCDT guidelines to users via the InfoBase.³³² At the moment, however, this remains unclear.

³³⁰ See *Flora v Ontario Health Insurance Plan*, 2008 ONCA 538, 295 DLR (4th) 309, a case seeking reimbursement for out-of-country medical expenses involving the interpretation of a standard in a regulation. The court concluded that evidence of medical procedure as practised in the jurisdiction (of the reimbursement decision) was the appropriate standard to be adopted. In contrast, the CCDT guidelines do not yet represent medicine as practised in Canada; adoption is sporadic and the CCDT earlier noted in 2003 that the CNEG guidelines reflected Canadian medical practice (CCDT, *Literature Review Brain Death*, *supra* note 15).

³³¹ Becky Skidmore, "New and Improved: CMA's Guidelines InfoBase Now at Physicians' Fingertips" (2000) 162:9 Can Med Assoc J 1342 at 1342.

³³² As noted earlier, the CMA issued a policy in 2000 to move away from issuing brain death guidelines specifically, preferring to subsequently "defer to affiliated societies" on the matter of brain death. This deferral was facilitated by the CMA's

Considering the CMA's objectives to improve quality of care for human lives, the CMA set surprisingly low criteria for InfoBase inclusion. A CMA InfoBase authors' Guideline, created collaboratively with the Royal College of Physicians and Surgeons to assist InfoBase authors, recommended, *inter alia*, that authors cite their evidentiary basis, its strength and date, and consider ethical issues throughout the guideline creation process.³³³ These seem to be reasonable, minimal core standards that all clinical guidelines should satisfy before being applied to patients. Yet, surprisingly, in contrast to the InfoBase authors' *Guideline*, the CMA InfoBase "inclusion criteria"³³⁴ do not require such minimal ethical and scientific standards. This suggests a kind of wilful blindness to InfoBase guideline content by the CMA.

Instead, the only InfoBase inclusion criterion of a scientific nature is the need for "evidence" of "a literature search" during the guideline-creation process. This is an exceedingly low standard that most health-related organizations would be hard-pressed to fail, making it likely that almost any guidelines submitted to the CMA InfoBase would be considered acceptable. This seems at odds with the InfoBase objective "to provide leadership and to promote the highest standard of health and healthcare for Canadians."³³⁵

Unfortunately, the CCDT guidelines may be part of a broader trend in clinical practice guidelines. Recent authors have lamented the lack of a Canadian source of clinical practice guidelines free from potential conflicting

June 2006 agreement with the CCDT to disseminate its guidelines.

³³³ CMA, *Guidelines for Canadian Clinical Practice*, online: CMA <prismadmin.cma.ca/index.php?ci_id=54703&la_id=1>. Thus there was no requirement to show a scientific basis for any part of the CCDT guidelines, nor to consider ethical matters such as conflicts of interest. Guideline 1 also stipulates that "the goal of clinical practice guidelines should be to improve the quality of health care," while Guideline 7 recommends that practice guidelines "should be developed in collaboration with representatives of those groups who will be affected ... including patients." The CMA appears to have trusted guideline authors to submit safe, ethical, evidence-based guidelines.

³³⁴ The CMA InfoBase's inclusion criteria are: "... be produced in Canada by a medical or health organization, professional society, government agency or expert panel ... ; have been developed or reviewed in the last five years; and have evidence that a literature search was performed during guideline development", CMA, "Submit a Guideline", online: CMA <prismadmin.cma.ca/index.php?ci_id=54685&la_id=1>.

³³⁵ CMA, "Guidelines", *supra* note 39 at Introduction.

interests, such as pharmaceutical company commercial interests.³³⁶ As illustrated in the CCDT's case, conflicting interests may put patient safety at risk. The CMA's undemanding standard for InfoBase inclusion facilitates this trend. Overall, the CMA's passive stance towards ensuring the scientific and ethical merits of its guidelines stands in sharp contrast to its active encouragement of InfoBase use as a means to high-quality, evidence-based care. These observations demand resolution.

Potential College disciplinary penalties may include consequences to licensing or practice. Such consequences may prompt future CMA decision makers to consider more carefully their inclusion criteria and the practice guidelines they disseminate. A final option involves the College disciplinary committee's ability to craft "such other disposition as it deems appropriate."³³⁷ Here, the College could require the withdrawal of CCDT guidelines from the InfoBase and their replacement with earlier, safer guidelines, such as the 1999 Canadian Neurocritical Care Group guidelines, which are more consistent with scientific knowledge on brain death and free from the risk of damaging conflicts of interest.

Conclusion

The determination of death is an issue of fundamental importance to all Canadians. In addition to having direct implications for organ donation and transplantation, the accurate determination of death by the appropriate clinical and technical procedures is a key component of law, associated with many important social conventions and legal decisions in the lives of Canadians. It is important that changes in the guidelines for brain death determination reflect changes in scientific knowledge. It is equally essential that such guidelines respect the *Charter*.

This article has considered whether the *Charter* might be applied to the recent CCDT brain death guidelines, and, if so, whether these guidelines might survive *Charter* scrutiny. As a government agency to which the *Charter* applies, or as a body that performed governmental activity, the CCDT pursued a novel and creative approach to correcting Canada's intractable low

³³⁶ See e.g. Roger Collier, "The Centralized Approach to Guidelines Development" (2011) 183 Can Med Assoc J 299 at 299; Roger Collier, "Clinical Guideline Writers Often Conflicted" (2011) 183 Can Med Assoc J E139 at E139; Roger Collier, "Clinical Practice Guidelines as Marketing Tools" (2011) 183 Can Med Assoc J E141 at E141.

³³⁷ *Medical Act*, *supra* note 325 at s66(2)(e)(i)(G).

organ donation rates. It did so by substantially redefining aspects of the brain death assessment process recommended to Canadian physicians. Some benefits may have flowed from this approach in the form of major regional increases and modest national increases in donor organ and tissue supplies. Nova Scotia, for example, reported a tripling of tissue donations between 2001 and 2005, which the CCDT claimed was due to local adoption of its guidelines.

Although the government may have had valid concerns regarding low organ donation and healthcare sustainability, its attempts at a solution were pursued in an inappropriately one-sided manner. No attempts were made to canvas opinion (especially from the patients, families, and healthcare providers most affected) regarding a possible redefinition of brain death. This is unacceptable in light of historical commitments to ensuring that donor interests have primacy over recipient interests. Public notice of the CCDT changes was not made, even after the fact, which is surprising in light of the magnitude of the changes. There were also no attempts to engage with the public to assess how changes to brain death definitions (proposed by OTDT professionals with conflicting interests) may affect, and perhaps erode, trust in organ donation. Nor were there efforts to assess whether performing a greater number of expensive organ transplants—other than kidney transplants—is capable of generating long-term cost-savings and greater healthcare sustainability.

Unfortunately, the CCDT's recommendations not only dramatically redefined the criterion by which brain death is declared, allowing death to be declared significantly earlier than under past guidelines, but have also removed or weakened important methodological safeguards used in declaring death. While physicians declaring death owe a fiduciary duty to protect the patients they assess, their workplace rules, if based on the CCDT guidelines, may confuse and conflict with this duty. The CCDT changes potentially jeopardize the lives of patients assessed for brain death, infringing rights to life and security of the person under section 7 of the *Charter*. In so doing, they show fundamental disrespect for and instrumentalization of those with neurological injuries. Despite the possible societal benefits to be derived from the guidelines, their infringing recommendations should not be upheld under section 1 of the *Charter*.

The CCDT guidelines appear susceptible to a future *Charter* challenge. It remains to be seen, however, how a court might rule. Striking down the guidelines—though desirable—may not be an option. Yet, if left to stand, future guidelines may build upon the CCDT's foundation, by recommending

still more dramatic changes and further erosion of the rights of patients at their most vulnerable. These serious effects demand immediate replacement of the guidelines. Health Minister Allan Rock, while unveiling the CCDT-based plan to increase organ supplies, stated the following in 2001: “Our priority is to protect the health and safety of all Canadians.”³³⁸ Accordingly, efforts are needed to make brain death guidelines protective of rights to life and security of the person of those undergoing brain death testing. Future brain death determination guidelines must respect the *Charter* as the supreme law protecting *all* those living on Canadian soil, regardless of how close they may appear to death.

³³⁸ Transplant News “Canadian government launches \$20 million, 5-year plan to increase donors” (12 May 2001), online: Transplant News <www.trannews.com>.