It is a crime in Canada to assist another person in ending her own life. As a result, people who are grievously and irremediably ill cannot seek a physician’s assistance in dying and may be condemned to a life of severe and intolerable suffering. A person facing this prospect has two options: she can take her own life prematurely, often by violent or dangerous means, or she can suffer until she dies from natural causes. The choice is cruel.

The opening paragraph of the landmark decision in Carter v. Canada (Attorney General) [Carter] succinctly outlines the “cruel” choice faced by many Canadians near the end of their lives. In a unanimous decision, the Supreme Court of Canada struck down Canada’s Criminal Code provisions prohibiting physician-assisted suicide, paving the way for individuals to choose the means and timing of their death. The decision is highly controversial and is likely to be a hot topic for the remainder of 2015 as Parliament decides whether to implement new legislation to govern assisted suicide or to do nothing and leave a legislative void.
In 1993, the \textit{Carter} decision was foreshadowed in \textit{Rodriguez v. British Columbia (Attorney General)} \cite{Rodriguez}. In \textit{Rodriguez}, the Supreme Court split 5:4, with Beverly McLachlin, Canada’s current Chief Justice, writing a strong dissent in favour of allowing physician-assisted suicide. Justice Sopinka, for the majority, rejected the right to die as an element of “the right to life, liberty and security of the person” under s. 7 of the \textit{Canadian Charter of Rights and Freedoms}. Instead, Sopinka J. reasoned that respect for human dignity was not a principle of fundamental justice that could trump society’s conception of the sanctity of life.

The court’s ruling in \textit{Carter} has been lauded in some circles as “compassionate”. \cite{compassionate} Critics, however, are disappointed that the court has placed individual autonomy above society’s interest in the sanctity of human life. \cite{safety} The coalitions formed on both sides of the argument in anticipation of \textit{Carter} are not treating the court’s decision as the last word. Groups opposed to assisted suicide have already called on the Federal Government to draft legislation that imposes “stringent safeguards” on the use of physician-assisted suicide. \cite{stringent}

Both camps were waiting for the Court of Appeal’s decision in \textit{Bentley v. Maplewood Seniors Care Society} \cite{Bentley}. \cite{Bentley} The \textit{Bentley} decision affirms that absent a clear directive that complies with statutory formalities, the court will be extremely cautious in its evaluation of a person’s wish to be allowed to die after they have lost the capacity to make that decision for themselves.

In the wake decisions like \textit{Carter} and \textit{Bentley}, what are the arguments for and against physician-assisted suicide and the withdrawal of care at the end of life? Here, we propose to touch on a few of the arguments briefly.
One of the most significant arguments in discussions about end-of-life care is the risks to vulnerable populations. These groups fall generally into two categories: (1) disabled individuals and (2) individuals who have diminished or no mental capacity. At the trial level in *Carter*, Justice Smith found that “it was feasible for properly qualified and experienced physicians to reliably assess patient competence and voluntariness, and that coercion, undue influence, and ambivalence could all be reliably assessed as part of that process”. She cited numerous empirical studies that showed there was no evidence to justify the concern of abuse to these vulnerable populations.

Another major argument is that there remains no consensus, either amongst the Canadian public or amongst the medical profession, that assisted suicide is ethically defensible. Those opposed to assisted suicide have argued that human life is intrinsically valuable. Permitting assisted suicide would move doctors away from a traditionally accepted goal of preserving life at all costs and would give doctors discretion over their patients that would threaten existing norms with respect to consent and personal autonomy of patients. The public opinion evidence provided at the *Carter* trial, however, shows that majority of Canadians are in favour of doctor-assisted suicide in certain scenarios. Further, there are other end-of-life medical treatments that are lawful and viewed as ethically acceptable, such as refraining from treatment or administering palliative sedation. Supporters of physician-assisted suicide say that the ethical distinction between passive versus active assisted dying is arbitrary.

A related issue is whether doctors will be required to participate in an end-of-life treatment, even if they have a moral objection. This applies both to the withdrawal of care, such as in the case of *Bentley*, and to physician-assisted suicide cases, such as in *Carter*. This question remains an unanswered question at law. The court in *Carter* did not get into the details of how assisted suicide treatments should be administered. Parallels may be drawn between this issue and the issue of administering gay marriage. In 2011, the Saskatchewan Court of Appeal held that provincial marriage commissioners could not invoke freedom of religion to refuse to marry gay couples. Will the courts similarly require doctors working in publicly funded hospitals to help a patient die, even if it is contrary to their faith?

There are certainly other issues that give rise to debate: Is it really necessary to repeal s. 241, when it still serves a deterrent purpose for non-physicians who are counselling suicide? What of the costs of such programs: Will physician-assisted suicide be considered treatment that is covered under health care plans, or will it be an electable treatment that costs additional money? Would such a distinction create a situation of discriminatory access? Is someone who has a mental illness truly competent to consent to physician-assisted suicide? Is a life insurance policy going to pay out upon an assisted suicide? Is there any merit to a “floodgates” argument that the rate of suicides will increase? What are the statistics with respect to suicide rates in jurisdictions where assisted suicide has been decriminalized?

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7. Supra note 1, para. 106.

**HEALTH CANADA PUBLISHES DRAFT GUIDELINES INTERPRETING VANESSA’S LAW**

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Significant amendments to the Food and Drugs Act [FDA],¹ commonly referred to as Vanessa’s Law, became law in November 2014. Many of those amendments will likely be accompanied by amendments to the Food and Drug Regulations² in due course. In the interim, Health Canada issued draft guidelines for interpreting some of the amendments to the FDA (the “Draft Guidelines”). Although Health Canada states that the Draft Guidelines are already in use, feedback from stakeholders in respect of the Draft Guidelines is important, as the finalized version of the Draft Guidelines will likely influence the development of future amendments to the Food and Drug Regulations.

The recent amendments to the FDA include a variety of changes in respect of therapeutic products (e.g., prescription and non-prescription drugs; medical devices; blood and blood products; and vaccines; but exclude natural health products) and include granting the Minister of Health

- the power to require information, tests, or studies,
- the power to require a label change/package modification,
- the power to require a recall of an unsafe therapeutic product,
- the ability to disclose information in certain circumstances, and
- the power to apply tougher consequences for those who do not comply with the FDA and regulations.

In addition, the amendments also require mandatory reporting of serious ADRs and medical device incidents by healthcare institutions.

As a result, the amendments have a wide-ranging and significant impact on all entities in the drug and medical device supply chain.

The Draft Guidelines are directed to establishing principles to guide all decisions made by Health Canada—particularly, in respect of (1) providing
factors in relation the Minister’s ability to make use of the new powers as well as (2) determining to whom these powers apply. The Draft Guidelines are significant and unusual in that they set out the process for Health Canada to follow when applying the new powers under the *FDA*.

By way of illustration, new s. 21.1(1) of the *FDA* provides as follows:

21.1 (1) If the Minister believes that a therapeutic product may present a serious risk of injury to human health, the Minister may order a person to provide the Minister with information that is in the person’s control and that the Minister believes is necessary to determine whether the product presents such a risk.

The Draft Guidelines provide greater detail in respect of, for example, (1) the threshold required for the Minister to use this power, and (2) where the source of the information lies (e.g., pre- or post-market studies, such as clinical trial applications, additional studies submitted as part of terms and conditions place on a market authorization, serious ADR reporting from manufacturers, patients or healthcare institutions, and reports in the medical literature).

Although the term *serious risk* is not defined in the *FDA*, the Draft Guidelines provide some non-exhaustive elements that should be considered in assessing whether a therapeutic product presents a serious risk of injury to human health (e.g., the seriousness of the adverse health consequence, the vulnerability of the patient population, such as the elderly or children, and the extent and impact of the population’s exposure).

The Draft Guidelines further elaborate that new s. 21.1(1) of the *FDA* cannot be used by the Minister to order a person to create new information, such as conducting new analyses or studies, or to seek out information from another source.

The Draft Guidelines also set out the process in respect of the Minister issuing an order under the amendments to the *FDA*. For example, although the Minister is not obliged to, the Draft Guidelines indicate that the Minister should, prior to issuing an order, notify the person believed to have information in their control, and provide the person with a reasonable opportunity to respond (e.g., allow the person an opportunity to correct an error in fact, dispute the case against him, or voluntarily comply with the notification).

Similar guidance to that set out above, in respect of new section 21.1(1) of the *FDA*, is included in the Draft Guidelines in respect of (1) the Minister’s ability to disclose confidential business information about a therapeutic product (i.e., new section 21.1(2) and (3) of the *FDA*); (2) the Minister’s ability to order a label change or package modification (i.e., new s. 21.2 of the *FDA*); and the Minister’s ability to order a recall of a therapeutic product (i.e., new s. 21.3 of the *FDA*).

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2 C.R.C., c. 870.
On March 3, 2015, the British Columbia Court of Appeal dismissed the appeal in Bentley v. Maplewood Seniors Care Society, upholding the chambers judge’s decision.¹

The only issue on appeal was whether or not the chambers judge had erred in failing to make a declaration that the “prompting” of Mrs. Bentley to eat or drink by touching her lips with a spoon or glass constitutes a battery. The appellants did not appeal the chambers judge’s other central findings in the case: that neither of Mrs. Bentley’s written statements of wishes were sufficiently clear; that Mrs. Bentley was indeed consenting to the act of being fed; and, finally, his interpretation that the relevant legislation required her caregivers to continue to offer her food and liquids and did not permit substitute decision-makers to consent to the withdrawal of personal care such as oral feeding that would lead to her death.

Justice Newbury (with Justice Lowry and Justice Chiasson concurring) summarized all the relevant findings of the chambers judge and held that he had found at various points throughout his reasons that (1) Mrs. Bentley is consenting to being given food and water and (2) that meant there was no battery:

In law, such consent is a complete defence to the very technical battery that might otherwise exist. This consent arises in the present, rather than in any previous written instruction, and as we have seen, Mrs. Bentley’s previous written directives were not effective as a consent to the withdrawal of food and water.

The respondents made it clear that if and when Mrs. Bentley refuses feeding by keeping her mouth closed, they would respect that decision and would not seek to intervene by medical means such as tube feeding. The distinction relied on by the chambers judge was that such medical interventions were clearly “health care” measures that Mrs. Bentley or her substitute decision maker could refuse in advance, while oral feeding was “personal care” that she could not.

The other ground of appeal was whether the chambers judge had improperly placed an onus on the petitioners to prove a lack of consent. The court found that the chambers judge appropriately applied the presumption present in both statute and tort law that unless the contrary is demonstrated, an adult is presumed to be capable of making decisions. At the hearing before the chambers judge, the petitioners did not successfully rebut this presumption.³ The chambers judge preferred the expert opinions and other evidence submitted by the respondents that Mrs. Bentley was exercising some choice in accepting oral feeding and was not merely acting in a reflexive manner.

The Court acknowledged in the decision that Alzheimer’s is a terrible disease and that Mrs. Bentley has a loving family who are trying to honour her wishes. The court went on to recognize that it is a very difficult situation in which her family finds themselves.

[However] it is a grave thing […] to ask or instruct caregivers to stand by and watch a patient starve to death. It should come as no surprise that a court of law will be
assiduous in seeking to ascertain and give effect to the wishes of the patient in the “here and now”, even in the face of prior directives, whether clear or not [emphasis in original].

The court specifically commented that this finding is consistent with the Supreme Court of Canada’s recent decision of Carter v. Canada (Attorney General) to the effect that when assisted suicide is legalized, it must be conditional on the clear consent of a capable patient.

The Court of Appeal did make the following comments of interest to those trying to plan for the future:

If nothing else, [the chambers judge’s] analysis shows that persons who wish to make provision for their care and decision-making in their declining years should not only record their wishes clearly, but also obtain legal advice as to what exactly can be accomplished by so-called “living wills”, representation agreements, advance directives and related appointments. The Legislature has prescribed extensive substantive and formal requirements relating to each of these in order to protect not only the person in care but also her caregivers. Assuming compliance with the Charter, it is not open to a court of law to suspend or ignore such requirements.

Finally, the court noted that the constitutional challenges to the applicable legislative provisions had not yet been argued, as the parties had agreed to adjourn that portion of the petition. It remains to be seen whether those challenges will be pursued.

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2 Ibid., para. 14.
3 Ibid., para. 17.
4 Ibid., para. 18.
6 Supra note 1, para. 18.
7 Ibid., para. 6.
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