A Constitutional Right to Experimental Drugs?

This article was written by a law student for the general public.

Introduction

Should experimental drugs for the very ill be made more widely available in Canada? According to the Globe and Mail, experimental drug use is one of the "hottest political (and ethical) issues in health care today."[1] Right now, the *Food and Drug Regulations* restrict experimental drugs from public sale until their safety and effectiveness can be guaranteed through clinical trials authorized by Health Canada.[2] The government's "Special Access Programme – Drugs" can allow the seriously or terminally ill to access experimental drugs if they meet certain conditions, but this access is not guaranteed.[3] For those who cannot get access, could the seriously or terminally ill use the *Charter's* section 7 right to life, liberty and security of the person to get access to unapproved, that is experimental, drugs?

Current Options for the Seriously or Terminally Ill in Canada

Currently, Canadians don't have the right to use drugs that Health Canada has not approved. This means that even the seriously and terminally ill whose lives could be saved by using new, experimental drugs may have to wait for them to be approved for public use.

The government's Special Access Programme (SAP) can allow Canadians with "serious or life-threatening conditions" to access these drugs if traditional treatments have failed, are unsuitable, or are unavailable.[4] However, Health Canada still gives manufacturers the final word on whether to provide early access to these drugs.[5] This means that access can be denied even if a person meets the required conditions. As the program only allows seriously or terminally ill Canadians who meet those conditions to apply, other patients have no further options if traditional treatments are not successful.[6]

Section 7 of the *Charter*

Could the *Food and Drug Regulations* and the SAP, which restricts the use of these potentially life-saving drugs, violate section 7 of the *Charter*, which protects a person's right to life, liberty and security of the person?

In order to determine whether the use of section 7 is possible, the first step is to identify if the right to life, liberty, or security of the person is affected. It appears it might well be. State action that increases the risk of death usually affects the right to life. [7] Preventing access to potentially lifesaving experimental drugs might affect the right to life because it puts the lives of patients with terminal illnesses at risk.

If section 7 *Charter* rights are affected,the second step in determining whether the section

can be used is to consider whether the law affecting those rights is consistent with the principles of fundamental justice. These principles include arbitrariness, overbreadth, and gross disproportionality.[8] In order to determine whether not allowing access to experimental drugs is consistent with the principles of fundamental justice, a court needs to consider the purpose of the law or policy. In this case, the purpose of the *Food and Drug Regulations* prohibiting access is to maintain "standards of composition, strength, potency, purity, [and] quality" of drugs.[9]

When restrictions produce an effect that is too extreme in response to its objective, the law is considered grossly disproportionate.[10] It is probable that it would be considered grossly disproportionate in this case. The quality and safety of experimental drugs might not be guaranteed, but potentially preventing their use even by a person who is terminally ill could be too extreme, as these drugs could save the life of someone who has no other hope for recovery. It is possible that these drugs may have unforeseen side-effects. However, are these potential safety concerns more important than potentially saving the lives of those who will otherwise eventually die from terminal illness?

If a court did find a *Charter* violation to the section 7 right to life, liberty and security of the person, the government could try to justify the law. The government would have to explain why maintaining tight safety and quality standards for drugs is an important objective, and how restricting and, in some cases, preventing experimental drug use is logically connected to that objective. The court would then have to decide whether there are less harmful ways of maintaining these standards and whether that law is a proportionate response to that objective. If the government failed to justify the law, this policy could violate the *Charter*.

Conclusion

Currently, the Special Access Programme includes those who are seriously ill and those who are terminally ill. Establishing a right to use experimental drugs for patients under section 7 of the *Charter* would likely not be successful in cases involving non-terminal illness. While current policy could affect their section 7 rights, there is a clear societal interest in controlling the use of drugs that could produce unpredictable or unmanageable side effects, and possibly death. Restricting and controlling access to these drugs seems logically connected to maintaining overall safety. Although the wider use of experimental drugs could diminish the psychological burden on the seriously ill, current policy might be the least harmful way of managing these safety and effectiveness concerns. It may be easier to establish a section 7 *Charter* claim for those who are terminally ill, as the drugs could save a patient that would otherwise die. Even in such cases, these potential safety risks still raise questions about whether more availability of experimental drugs is an option Canada should explore.

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[1] André Picard, "Do the dying have the right to experimental drugs?", *The Globe and Mail*

(11 May 2015) online: The Globe and Mail <http://www.theglobeandmail.com/> .

[2] *Food and Drug Regulations,* CRC, c 870, s C.08.002 (2015) .

[3] Health Canada, "Special Access Programme – Drugs", online: Health Canada < http://www.hc-sc.gc.ca/> .

[4] *Ibid*.

[5] Picard, *supra* note 1; *Ibid*.

[6] Health Canada, *supra* note 3.

[7] Guy Régimbald & Dwight Newman, *The Law of the Canadian Constitution* (Markham: LexisNexis, 2013) at 626 .

[8] Peter W. Hogg, "The Brilliant Career of Section 7 of the Charter" (2012) 58 The Supreme Court Law Review 201 .

[9] *Food and Drug Regulations, supra* note 2 at s A.01.002.

[10] Peter Hogg, *Constitutional Law of Canada* (Toronto: Thomson Reuters, 2007) at 47-7.