

Moral, Ethical and Legal Considerations with the Use of Drugs for Performance Maintenance in the Canadian Forces

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ABSTRACT

The operational use of performance maintenance drugs in the Canadian Forces (CF) is influenced by moral, ethical and legal issues. Centrally acting drugs such as methylphenidate, dextroamphetamine, and modafinil, amongst others, have been used in some militaries as a fatigue countermeasure to help military personnel maintain vigilance for prolonged periods of time. The National Defence Act (NDA), The Canadian Human Rights Act (CHRA), The Food and Drugs Act, and the Controlled Drugs and Substances Act (CDSA) are national statutes that are all influential with respect to the potential decision to use performance maintenance drugs in the CF. If these statutes are fully complied with, there would be no legal impediment to the lawful use of medications for the purpose of performance maintenance in the CF. Despite this fact, the use of pharmaceuticals for this purpose is not currently authorized. This lack of approval has been historically on the basis of moral and ethical concerns. A former surgeon general noted in a recent article published in 2007, however, that there may be a role for the use of pharmaceuticals as a military fatigue countermeasure modality under very specific controlled circumstances. The CF has set up a research program at Defence Research and Development Canada (Toronto campus) to take a holistic look at the Fatigue Countermeasures area. This talk will focus on Canadian moral, ethical, and legal issues that influence the prescription of performance maintenance medications for the specific purpose of maintaining wakefulness in the CF.

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The operational use of performance maintenance drugs in the Canadian Forces (CF) is influenced by moral, ethical and legal issues. Centrally acting drugs such as methylphenidate, dextroamphetamine, and modafinil, amongst others, have been used in some militaries as a fatigue countermeasure to help military personnel maintain vigilance for prolonged periods of time. The National Defence Act (NDA), The Canadian Human Rights Act (CHRA), The Food and Drugs Act, and the Controlled Drugs and Substances Act (CDSA) are national statutes that are all influential with respect to the potential decision to use performance maintenance drugs in the CF. If these statutes are fully complied with, there would be no legal impediment to the lawful use of medications for the purpose of performance maintenance in the CF. Despite this fact, the use of pharmaceuticals for this purpose is not currently authorized. This lack of approval has been historically on the basis of moral and ethical concerns. A former surgeon general noted in a recent article published in 2007, however, that there may be a role for the use of pharmaceuticals as a military fatigue countermeasure modality under very specific controlled circumstances. The CF has set up a research program at Defence Research and Development Canada (Toronto campus) to take a holistic look at the Fatigue Countermeasures area. This talk will focus on Canadian moral, ethical, and legal issues that influence the prescription of performance maintenance medications for the specific purpose of maintaining wakefulness in the CF.

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Legal Issues

In the Canadian Forces (CF), there is no legal impediment to the use of lawfully prescribed medications for the purpose of performance maintenance. Prescription of these medications must, however, be in keeping with the direction provided in the National Defence Act (NDA)ⁱ, The Canadian Human Rights Act (CHRA)ⁱⁱ, the Food and Drugs Actⁱⁱⁱ, and the Controlled Drugs and Substances Act (CDSA)^{iv}. Access to these statutes has been facilitated immensely through the internet, with most legislation in the form of acts and associated regulations readily available at <http://laws-lois.justice.gc.ca> to any Canadian citizen. The National Defence Act, specifically, outlines the legal basis for the Canadian Forces (CF). The Act states in Sec 33(1) that all officers and non-commissioned members are at all times liable to perform any lawful duty. This means that members of the CF must be fit to carry out lawful orders at any time, any day of the week. This requirement to be able to carry out a lawful order is considered a bona fide occupational requirement of any CF member. This section of the Act is the basis for the universality of service principle that all members of the CF must satisfy. This universality of service requirement is also enforced in the CHRA paragraph 15(9). Although the CHRA guarantees the rights of all Canadian citizens to life, liberty, security, and the enjoyment of personal property, this paragraph in the CHRA specifically directs that the “Canadian Forces must at all times and under all circumstances perform any functions that they may be required to perform”. It also implies that the CHRA cannot be used as a reason to not comply with a lawful medical recommendation. It also is important in consideration of the implications of refusing to take a medication to maintain wakefulness when medically recommended to do so. Neither the NDA nor the CHRA specifically precludes the use of performance maintenance medications for fatigue countermeasures. The question of the legal use of performance maintenance medications really becomes one of operational necessity in the setting of due diligence. The law prohibits the forceful requirement to take medications for any purpose. The medical recommendation to take medications of this nature must be in an operational setting where all reasonable alternative modalities have been exhausted (i.e. scheduling, circadian adjustment strategies like melatonin and phototherapy, or nutrition like naturally caffeinated beverages). If a member elects to not take a performance maintenance medication in this setting, then from a legal perspective the responsibility would be on him/her to prove that he/she was in fact safe to continue that specific duty. Thus, a member has the legal right to specifically refuse to take a performance maintenance medication, but he/she does not have the right to fall asleep on-duty as a consequence of that refusal. A specific operational example would include the piloting of a single seat armed aircraft, where falling asleep would mean the loss of a national asset, failure to completion a mission, and a risk to the collective safety of the pilot and other CF members and civilians.

In addition to the NDA and CHRA, there is other legislation which impacts on the use of specific performance maintenance pharmacological agents in order to minimize the potential for abuse or misuse. In Canada, there are two major government statutes that deal with pharmaceuticals. These are the Food and Drugs Act, and the Controlled Drugs and Substances Act (CDSA). The Food and Drugs Act sets general guidelines and deals with issues like production standards, labelling, advertisement, safety, and penalties for not abiding with the act. This act has an associated Food and Drug Regulations^v document which identifies all approved pharmaceuticals and in certain cases also includes specific indications for use when there is a risk of abuse. The CDSA deals more specifically with the legal ramifications of illegally using or trafficking in controlled drugs. Most controlled drugs with performance maintenance characteristics would fall under schedule 3 of the Act. CF members' consumption of performance maintenance drugs that are listed as narcotic or controlled drugs or their precursors under the CDSA, and which are not prescribed by a physician in accordance with either that Act or the Food and Drugs Act, would be illegal and not permissible within the CF. The illegal possession of drugs listed in the CDSA are associated with fines as well as possible prison terms. For the controlled amphetamine-type drugs in schedule 3 of the Act, the penalties range from 6 months for possession

to 10 years for trafficking. Interestingly enough, in 2004, about 6% of the Canadian population over the age of 15 years had reported using speed or amphetamines^{vi}.

Health Canada is the federal department that operates the Drug Strategy and Controlled Substances Programme^{vii} in order to regulate controlled substances via the acts and regulations. Since CDSA schedule 3 drugs are prime candidates for misuse, the Food and Drug Regulations part G limits their use to the following indications:

1. in humans:
 - a. narcolepsy,
 - b. hyperkinetic disorders in children,
 - c. mental retardation (minimal brain dysfunction),
 - d. epilepsy,
 - e. parkinsonism, or
 - f. hypotensive states associated with anesthesia; or

2. in animals:
 - a. depression of cardiac and respiratory centres.

Some of these medications have also been used for off-label purposes in palliative care, HIV, and illnesses like MS to counteract the secondary affect of diminished alertness from either the illnesses themselves or their treatments.

The Canadian Forces control routine prescribing by further producing a Drug Benefit Formulary which lists the medications that are available for use in the pharmaceutical care of CF members. This list is approved by the Surgeon General on the recommendation of the CF Pharmacy and Therapeutics Committee^{viii}. Some drugs that have unique value in specific circumstances may be granted a Special Authorization classification, which allows their use to be controlled and audited. The CF also has a specific controlled substance policy 4200-44, which is currently consistent with the CDSA. There is flexibility, however, to allow for prescribing of medications under controlled conditions, if supported by the Surgeon General. This would pertain specifically to the case of the operational use of performance maintenance medications.

There are, however, other pharmaceuticals that are not listed in the CDSA which may have a role in fatigue countermeasures. These other commonly used pharmaceuticals have the potential to increase alertness and include dextroamphetamine (an uncontrolled amphetamine derivative), modafanil, methylphenidate, caffeine, and nicotine. Dextroamphetamine, specifically, has been used by the US Air Force for many years as a fatigue countermeasure in pilots. Modafanil has a far lower potential for abuse and is currently indicated in Canada for use in the management of shift work sleep disorder when taken orally one hour before starting a shift^{ix}. Modafinil's psycho physiological actions likely work by promoting wakefulness instead of a classical amphetamine-like stimulant effect, but have the disadvantage of inducing moderate nausea in susceptible individuals (10 to 15% of the population). Methylphenidate is usually used in Attention Deficit Hyperactivity

Disorder (ADHD) to increase attention. Caffeine itself is the world's most widely used psychoactive drug and by far the most common stimulant with over 80% of North Americans consuming caffeine in various types of beverages on a daily basis. Caffeine is also included in some medications, usually for the purpose of enhancing the effect of the primary ingredient, or reducing a side effect such as drowsiness. Tylenol #3, one of the commonest pain pills prescribed in Canada is a combination of codeine, acetaminophen, and caffeine, where the caffeine component is added for this very purpose. Pure caffeine tablets are also widely available. Nicotine, a common ingredient in tobacco, is used widely throughout the world for its stimulating effects despite the fact that it has an addictive component that has affected millions of people. There would be no legal impediment to using one of these medications not listed in the CDSA for performance maintenance in the CF.

Moral and Ethical Issues

Moral and ethical issues have always played a strong role in public approval in Canada. These issues deal with the determination of right conduct, or the distinction between right and wrong. Moral and ethical issues are largely influenced by partisan agendas and the media, and not by scientific information. Virtually all sovereign nations have at some time in their history administered capital punishment for religious, cultural, and political beliefs. In addition, virtually all have wrongfully executed their accused citizens. Canada is no exception to this rule. The moral & ethical view of Canadian society on the utilization of drugs to either enhance maintenance in athletes, or maintain wakefulness as a fatigue countermeasure in the military is a result of current Canadian cultural fabric. In the past, CF Surgeon Generals have been opposed to the use of performance maintenance medications for fear that they would be used indiscriminately in lieu of other more benign options like better scheduling.

This point of view was relaxed somewhat when the Surgeon General in 2007, BGen Jaeger, published a commentary in the *Aviation, Space and Environmental Medicine Journal* on the ethical use of pharmacological fatigue countermeasures in the US military^x. As surgeon general, her thoughts at the time were reflective of the Canadian Forces health services view point. In this commentary, she outlined her concerns with the lack of publications in the scientific literature on the ethics of military ergogenic enhancement. She also raised the concern that it would be very easy to blur the line between operational necessity and administrative convenience. In her commentary, she was particularly supportive of Dr Russo's work in constructing a decision making framework consisting of 4 essential questions that should be used before the dispensing of fatigue countermeasures pharmaceuticals^{xi}. These were:

1. Is the use truly informed and voluntary;
2. Is the medication safe for use in the individual and operational environment;
3. Is the use consistent with dose and pharmacological function; and
4. Have available non-pharmacological alternatives been fully utilized?

In her paper she was clear that in certain circumstances, with strict controls, that there could be permissive use of what she called 'cogniceuticals' in <Canadian> military operations.

Fatigue Countermeasures Research in Canada

There is no doubt that a holistic approach to fatigue countermeasures is essential for the successful implementation of a program in Canada. The Fatigue Countermeasures umbrella includes a range of modalities which include nutrition, fitness, circadian entrainment, scheduling, and pharmaceuticals to promote awakesness and ensure adequate rest. The fatigue countermeasures of the 1950's are certainly different from the fatigue countermeasures of the 1970's and likewise from the fatigue countermeasures of 2009. Defence Research and Development Canada has conducted research in various components of fatigue countermeasures in the past. These have included research into caffeine gum, melatonin, hypnotics, and circadian desynchronization strategies. Although this research has suggested that there could be an advantage to various strategies, the recommendations of the past have never been formally institutionalized into a clear CF strategy. Recommendations to date have been customized to specific trade or mission requirements.

Through the auspices of the Air & Space Interoperability Council (ASIC) which is made up of UK, US, NZ, and AS, a formal project has been funded to produce an ASIC advisory publication on the wide spectrum of fatigue countermeasures available to commanders in ASIC nations. This publication will form one of the bases for the production of a Commander's Guide to Fatigue Management in Canada. This document will provide a set of guidelines on recognition, hazards, and countermeasures for commanding officers, flight safety officers, and flight surgeons within Canadian legal, moral, and ethical framework.

ⁱ National Defence Act, <http://laws-lois.justice.gc.ca>

ⁱⁱ Canadian Human Rights Act, <http://laws-lois.justice.gc.ca>

ⁱⁱⁱ Food and Drugs Act, <http://www.hc-sc.gc.ca/fn-an/legislation/acts-lois/fda-lad/index-eng.php>

^{iv} Controlled Drugs and Substances Act, <http://laws.justics.gc.ca/en/c-38.8/index.html>

^v Food and Drug Regulations, Part G, Division 4 Practitioners, <http://laws-lois.justice.gc.ca>

^{vi} Canadian Centre on Substance Abuse, <http://www.ccsa.ca/Eng/Topics/Pages/default.aspx>

^{vii} Drug Strategy and Controlled Substances Programme, <http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hecs-dgsesc/dscsp-psasc/index-eng.php>

^{viii} CF Pharmacy and Therapeutics Committee, <http://hr5.ottawa-hull.mil.ca/health-sante/pd/pol/word/4200-49-eng.doc> (internal to the Canadian Forces)

^{ix} Tarascon Pocket Pharmacopoeia, 23rd edition, Jones and Bartlett Publishers, Sudbury, Massachusetts, 2009

^x Jaeger, H., A Glance at the Tip of a Big Iceberg: Commentary on "Recommendations for the Ethical Use of Pharmacological Fatigue Countermeasures in the U.S. Military, Aviation, Space, and Environmental Medicine, Vol. 78, No. 5, Section 11, May 2007.

^{xi} Russo, M., Recommendations on the Ethical use of Pharmacological Fatigue Countermeasures in the US Military, Aviation, Space, and Environmental Medicine, Vol 78(5, Suppl.), B119-27, May 2007.