

Comment on the Bill C-51 Natural Health Products Category

Is the Government Applying a Fair Measurement to Regulate Traditional Chinese Medicine (TCM)?

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The Food and Drug Act has not been revised for 50 years. Without consultations, the government proposed Bill C-51 to amend the Food and Drug Act, which passed the first reading in Canadian Parliament on April 8, 2008 and moved to the second reading on April 28, 2008. The Traditional Chinese Medicine (TCM) community in BC formed a provincial coalition to oppose Bill C-51 on May 21, and on July 15, a national coalition was formed to stop Bill C-51, to address the Amendment to Bill C-51 that dismissed TCM under the Natural Health Product Category. Why does the TCM community want to oppose Bill C-51?

The TCM community respects the government's intention to regulate TCM for the purpose of public safety and hopes that the government will show an equal respect and recognition of traditional culture and the needs of multicultural communities. Like the government, the newly formed coalition, representing the interests of the TCM community, also wants to ensure public health, along with health freedom and the rights of consumers.

Bill C-51, in its present form, does not protect, but prohibits TCM. Bill C-51 requires TCM to live up to the measures for drug standards, which are inappropriate for holistic comprehensive medicines like TCM. According to Bill C-51, safety is determined by benefits that outweigh the risks, and the benefits are determined by efficacy. In turn, according to the Bill, efficacy is determined by clinical trial, which is the wrong measure for use with TCM.

TCM is a comprehensive and rigorous medical system, with a recorded *materia medica*, that differs from that of Western medicine in many ways. Specifically, it is a holistic approach for diagnosis and treatment, with the emphasis on prevention and harmony of body, mind, and spirit.¹ TCM and Western medicine have fundamental differences in their philosophies and conceptual basis, and both medicines need to use their own methods for proving safety.

Briefly, Western medicine emphasizes disease, which is believed to be caused by pathogens, and designs drugs that will target those pathogens to effect a cure. In contrast, TCM emphasizes prevention and restoration, and diseases are believed to be caused by an imbalanced system.

TCM does not believe that all pathogens must be killed, and some may co-exist with the human body. According to TCM, pathogens may grow when one suffers a loss of body vitality or experiences psychological or spiritual despair. Factors, such as internal emotions, external environmental invasion, individual body constitution, and lifestyle (i.e., exercise, diet, work, sex, unexpected events, etc.), can affect the balance of the system and the continuum of health and illness. Medications that are used in TCM are designed to restore the balance by interacting with targets other than pathogens, and the efficacy of the medicines depends on the characteristics of complex mixtures of herbs.²

TCM operates within an open, dynamic system. The diagnosis and treatment process is complicated and in accord with ever-changing conditions. Consequently, a homogeneous patient group in Western medicine may be seen as a heterogeneous group in TCM. For example, a prescription of an herb treatment may require modifications every few days, to manage the changing nature of the conditions. Standardization is not an option.

Typically, TCM uses herbs in combination, with one or more herbs neutralizing the toxic compounds from the other herbs, to achieve a synergistic effect to cure the disease in question:

The principal ingredient of the mixture is a substance that provides the main therapeutic force, and the secondary ingredient enhances or assists the therapeutic action of the first. The rest of the ingredients serve various functions: treating accompanying symptoms, moderating the harshness or toxicity of the primary ingredient, guiding the medicine to the proper organs, or exerting a harmonizing effect.² (p. 192)

How individual herbs might be able to pass “scientific scrutiny” (i.e., clinical trial) represents a challenge for the profession. And how such treatments could be quantitatively researched represents yet another challenge.

Bill C-51 is adapted to the received view of science as being concerned with empirical truth, measurement, and rigor, which strives towards standards of reliability and validity. Bill C-51 also suggests that one set of criteria (i.e., reliability, validity, and trustworthiness) can be applied to all forms of scientific research and that clinical trial can serve as the sole evidence for a treatment’s efficacy.

Only a small number of researchers with backgrounds in complementary and conventional medicine recognize the intrinsic difficulties and limitations of the conventional research methods in assessing the efficacy and safety of TCM.¹ These authorities argue in favor of developing appropriate, rigorous, and systematic evaluation methods to augment Western clinical trials.³ For example, to assess TCM, Whole Systems Research was suggested to be a useful method.

In Whole Systems Research, the goal is to design a system representative of the “real world,” where patient-centered outcomes, patient-practitioner interaction, and diagnosis and treatment

feedback are assessed.⁴ The focus on individualization vs. standardization is a crucial element of the design.⁵ Another aspect of the system includes both Western and TCM diagnoses. The method stems from a neorealist point of view, which interpreted truth as “the extent to which an account accurately represents the social phenomena to which it refers”⁶ which failed to completely capture the essence of TCM in complicated research designs. In any case, the method could be a good start.

Various types of evidence can be used to support TCM, for instance: research evidence, clinical experiences, and patient preference.⁷ The fact that TCM has been clinically tested and well documented for thousands of years should be held accountable. Furthermore, the TCM profession should develop methodologies that fit with its theory and complicated mechanisms, and the government should provide funding for such research.

Whether or not the same structural standards that are used in Western medicine can be applied to TCM should be determined on the basis of fair measurement and whether or not the system of medicine can maintain or improve quality of care. To develop an up-to-date policy for regulation, a responsible government should use methods that are fair, and not simply increase the penalties and powers of inspectors for prosecuting TCM. If the government is lacking the confidence or knowledge to adequately regulate TCM, delegating power to less knowledgeable or inexperienced inspectors is not the best approach.

By using one worldview to oppress and discriminate against another, the government is acting irresponsibly. Bill C-51 is attempting to marginalize TCM, and as a consequence, a new Canadian regulatory system is now needed for applying appropriate and fair criteria for regulating TCM.

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