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Dismantling the Helsinki Declaration

Had Moses come down from the mountain with the Ten Commandments bristling with footnotes, his vision of a new moral order might have come to naught. Since 1964, the Helsinki Declaration has been the stone tablet of medical research ethics; if not quite Mosaic in stature, it has exerted a far-reaching and constructive influence on the conduct of research involving human participants.[1] Until 1999 the Declaration remained essentially unchanged, but a more recent compulsion to "clarify" the document threatens to weaken its authority.

Formal ethical guidelines for research did not exist until the Nuremberg trials, in response to Nazi physicians who conducted horrific pseudoscientific medical experiments on concentration camp internees. No one who has seen the evidence of this (films made by the physician "researchers" of the Third Reich can be seen at the United States Holocaust Memorial Museum www.ushmm.org) would wonder that the military tribunal felt compelled to issue a set of principles for research on humans: the Nuremberg Code (http://ohsr.od.nih.gov/nuremberg.php3).

The burgeoning of medical research and the development of new research methods during the 1950s prompted the World Medical Association to develop an expanded code of ethical principles; these were proclaimed by the WMA at their meeting in Helsinki in 1964 (www.wma.net/e/policy/b3.htm). The most notable modifications of the Declaration were made in 2000 in response to new ethical challenges stemming from HIV- and AIDS-related research being conducted in very poor countries. Among these was a new statement (paragraph 30) that, on completion of a clinical trial, study participants should be provided with the "best proven prophylactic, diagnostic and therapeutic methods identified by the study." Under this principle, patients enrolled in a trial of a new antiretroviral therapy, for example, would be assured that at the end of the trial they could continue to receive the drug for the duration of their illness or life. Prior to the revisions of the Declaration in 2000, study participants had no such guarantee. In wealthy countries, continuing access to study interventions are generally assured by the near-universal availability of health care. This is rarely the case in the developing world; thus, the need for a clear statement that places responsibility for providing continuing treatment of study subjects on researchers and their sponsors.

In 2000, paragraph 30 was strongly supported by many medical association members of the WMA, including the CMA. But objections were raised, notably by the US Department of Health and Human Services and multinational pharmaceutical companies, that paragraph 30 would in some contexts impede useful research. In September of this year, a working group of the WMA proposed a "note of clarification" and an "amended version" of paragraph 30. Under the new terms, patients enrolled in a study would receive "whenever possible… the benefits that resulted" and would be given access to any "available" best-proven therapy. Effectively, these "clarifications" nullify the force of paragraph 30. They allow researchers and their sponsors to weasel out of providing continuing care to study subjects wherever administrative, economic or political circumstances create difficulties.

That the proposed changes were not accepted is largely to the credit of the Argentinean and Brazilian medical associations, who spoke out forcefully against the footnotes and against all continuing efforts to weaken the Declaration. However, abetted by the support of national associations such as the British Medical Association and by the silence of some others — including the CMA — the dismantling of Helsinki has not been stopped. A subcommittee will continue to study paragraph 30 (and possibly others) and return for another attempt next year.

Canada, which has played a leading role in developing guidelines for medical research on human subjects,[2] and the CMA, which advocated for paragraph 30 in 2000, should take a strong stand next year and protest any further footnotes to Helsinki. It is the role of research ethics boards to take local circumstances into account when considering a study proposal. Medical associations must not permit special interest groups to turn a universally accepted statement of principles for the conduct of research on humans into a set of "moral concessions that weaken the traditional universality of the Declaration … [and damage] the reputation and trustworthiness of the medical profession."[3] Thou shalt not discontinue effective treatment of study subjects upon termination of the research. Period. — *CMAJ*

References

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2. Law Commission of Canada. The governance of health research involving human subjects. Ottawa: The Commission; 2000.
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