

As a researcher and concerned physician in Brazil, I agree with your evaluation of the crucial role of the Declaration of Helsinki in setting ethical standards for human research. In fact, its ethical framework has become a benchmark in this area and has become, on its own merits, a standard not just of the World Medical Association (WMA) but also for society as a whole.

While we researchers are generally privileged people, many research subjects are among the most vulnerable, living under conditions of deprivation and prone to exploitation. Many trials are performed in extremely poor regions of the world, with the questionable justification that these communities are in urgent need of answers to specific research questions. Such "specific questions" could undoubtedly be answered elsewhere. Furthermore, the vulnerability of these potential research subjects makes it almost impossible for meaningful informed consent to be obtained, and their extreme poverty makes it highly unlikely that the products of the research will be accessible to them. What people in developing countries really need is access to products that have been researched and developed and are in use elsewhere.

In addition to the opposition of the Argentinean and Brazilian medical associations to the changes in paragraph 30 (access to medical care) and the addition of notes of clarification, Brazil also opposed the confused and lax note of clarification to paragraph 29. This note was discussed in a *petit comité* meeting convened by the WMA in September 2001 but was defeated by representatives of the pharmaceutical industry and regulatory agencies and researchers from the United States.

The WMA postponed any modification or note of clarification to paragraph 30 and established a new working group for this discussion. Although this group is skewed in its representation, 2 of the 5 countries represented are from the developing world (Brazil and South Africa). Brazil's position is clear: any change in the Declaration of Helsinki should be made only if there are compelling reasons to do so. And in this un-

equal world, we argue that any modification should be in the direction of making the ethical obligations of providing adequate access to medical care even more stringent, to be applied to every trial involving a human being, wherever such a trial is performed.

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Reference

1. Dismantling the Helsinki Declaration [editorial]. *CMAJ* 2003;169(10):997.

Having represented the Canadian Medical Association (CMA) at the WMA meeting in Helsinki in September 2003, I must take issue with the allegations contained in your editorial and in a report on the debate surrounding paragraph 30 of the Helsinki Declaration.^{1,2}

As I told your reporter, the CMA supports paragraph 30. It is unfortunate for you to suggest that the opponents of paragraph 30 were "abetted" by any silence on the part of the CMA. On the contrary, I personally intervened twice during the formal discussion at the WMA ethics committee in Helsinki to reiterate our support. Moreover, the CMA Secretary General and I intervened frequently and forcefully behind the scenes. That the CMA also supports the necessary efforts of the working group to build consensus behind paragraph 30 should not be misconstrued as weakening our traditional belief in our ethical obligation to help study participants obtain access to a treatment that has been proven beneficial upon completion of a clinical trial.

It is indeed unfortunate that the CMA's record on a matter of such importance has been needlessly called into question. I trust this sets the record straight.

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References

1. Dismantling the Helsinki Declaration [editorial]. *CMAJ* 2003;169(10):997.
2. Helsinki Declaration revisited over concerns about human subjects. *CMAJ* 2003;169(10):1066.

A titre de représentant de l'Association médicale canadienne à l'assemblée de l'Association médicale mondiale (AMM) à Helsinki en septembre dernier, je me dois de contester les allégations de votre éditorial et la représentation que vous faites du débat entourant le paragraphe 30 de la Déclaration d'Helsinki^{1,2}.

Ainsi que je l'ai expliqué à votre reporter, l'AMC appuie le paragraphe 30. Il est malheureux que vous ayez laissé entendre que l'opposition au paragraphe 30 aurait été «facilitée» par un silence de la part de l'AMC. Au contraire, je suis intervenu personnellement deux fois au cours des discussions officielles du comité d'éthique de l'AMM à Helsinki pour réitérer notre appui. De plus, le secrétaire général de l'AMC et moi-même sommes intervenus énergiquement en ce sens en coulisse, à de nombreuses reprises. Le fait que l'AMC appuie également les efforts du groupe de travail pour faire le consensus autour du paragraphe 30 ne devrait pas être faussement interprété comme un affaiblissement de la conviction que nous avons toujours eue de notre obligation éthique d'aider les personnes participant à des études à obtenir après l'essai clinique un traitement se révélant bénéfique.

Il est en vérité tout à fait malheureux que la position de l'AMC dans un dossier d'une telle importance ait été inutilement remise en question. J'espère que la présente lettre dissipera les doutes à cet égard.

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Références

1. Affaiblir la Déclaration d'Helsinki [éditorial]. *JAMC* 2003;169(10):999.
2. Helsinki Declaration revisited over concerns about human subjects. *JAMC* 2003;169(10):1066.