



To:

mw. M.J.A. van der Hoeven  
Minister van Onderwijs, Cultuur en Wetenschap  
Postbus 16375  
2500 BJ Den Haag

Drs. J.F. Hoogervorst  
Minister van Volksgezondheid, Welzijn en Sport  
Postbus 20350  
2500 EJ Den Haag

Mr. L.J. Brinkhorst  
Minister van Economische Zaken  
Postbus 20101  
2500 EC Den Haag

(Ministers in charge of the BSIK programme)

Prof.dr. J.A. Knottnerus  
President of the Health Council of the Netherlands  
Postbus 16052  
2500 BB Den Haag

Concerning: objection to non-regulated therapies using stem cells

Rotterdam, 15 June 2006

Dear Ms van der Hoeven, Dear Mr Brinkhorst, Hoogervorst, and Knottnerus,

We write with great concern over the cavalier medical attitudes prevailing over the practice of so-called stem cell 'therapies' in The Netherlands (see recent articles in the NRC-Handelsblad). As a group of research scientists involved in the innovative research directive of the BSIK Stem Cells in Development and Disease Consortium, we find the practice of stem cell 'therapy' in many cases unsafe and without merit.

On the basic research level, there is little evidence that injection of umbilical cord blood stem cells into damaged heart (or any other tissue suffering trauma, except blood) has regenerative or therapeutic value. Yet, until recently, a UK-based stem cell therapy company was free to recruit patients in the UK (where such 'therapies' are not allowed) and perform the procedure in the Netherlands at high cost. The so-called 'therapy' has not been subjected to stringent testing through controlled clinical experimental trials. Its safety may be questioned since it involved injecting non-matched donor cord blood into the circulation. National regulation of research on experimental medical procedures provides a sound basis for proving clinical benefit and protection of the patient from adverse side effects. For example, new drugs entering into the clinics are subjected to stringent controlled testing before approval. While we, as scientists, are aware of the commercial and medical promises of stem cell 'therapy', we are also cognisant of the lack of 'proof of principle' in the present use of stem cells. In fact, we are worried that the boldness of the commercial enterprises will have a devastating affect on patient health and on the future positive and sound aspects of stem cell 'therapy'.

At present, in the unregulated commercial setting in the Netherlands, patients are given false hope and are unprotected against potential dangers. Considering that well-informed and internationally recognized basic medical research efforts are ongoing in this country, and that medical practices in hospitals and clinics must be approved by the CCMO, it is time to bring commercial



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enterprises offering stem cell 'therapies' under the same regulatory scrutiny. Stem cell 'therapies' should not be provided by public or private clinics before nationally approved well-controlled experimental trials have been undertaken. Only in this way will the health of the Dutch community be ensured and will we prevent the Netherlands become a refuge for practices not founded upon evidence based medicine.

Sincerely,

The scientist involved in Stem Cells in Development and Disease (BSIK consortium 03038)

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A Dutch version of this text has been sent to the addressees and published as an open letter on the website of the consortium.

cc:

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