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From the Biological Secretary and Vice-President Professor DJ Read FRS

27 May 2004
Our ref: 14/04

Dear Dr McLaren

Response to the Medical Research Council consultations on the Use of Human Stem Cell Lines and the Code of Practice for the UK Stem Cell Bank

Please find enclosed the Royal Society's response to your consultations, which has been produced with Professor Richard Gardner FRS (University of Oxford), Chair of the Royal Society's Ad hoc Working Group on Stem Cells and Cloning. The Royal Society takes an active role in policy discussions on the use of stem cells and therapeutic cloning in research, and we welcome the invitation to engage in this consultation.

The Royal Society has produced several statements on stem cell research and therapeutic cloning. In particular, in our evidence to the Chief Medical Officer's Expert Group on therapeutic cloning in March 2000 we recommended the formation of a working group to examine the feasibility of establishing frozen banks for various categories of stem cells. The Chief Medical Officer, in his August 2000 report, subsequently carried this recommendation forward leading to the establishment of the UK Stem Cell Bank.

The Royal Society supports the establishment of Codes of Practice for the UK Stem Cell Bank, and views these as essential to ensure best practice and transparency in research. We believe the interim Codes of Practice are comprehensive and cover many key issues addressed in our previous reports which we enclose for your information. However, one area of concern to the Society is the inadequate coverage given to the quality control of stem cell lines. Quality control is of great importance for both basic research and potential clinical applications to assure stem cells are prepared under assured conditions. We recommend concise coverage of quality control should be addressed in the Codes of Practice and a separate Annexe covering specific details of adequate quality control be added to give clear guidance to the research community.

The Society welcomes the framework outlined in the Use of Human Stem Cell Lines Codes of Practice to ensure transparent and open practice to the highest standards. However, one issue

of concern is the confused treatment of the area of consent making it difficult to clearly define what the important issues are. This is particularly relevant in light of the new Human Tissue Bill that is currently making its way through Parliament. The Bill will, in its current form, impact on the consent process for new, and possibly existing, collections.

The Society believes the underlying principle of the Codes of Practice should be to avoid making research too restrictive such that future research programmes are not hampered by restrictive and stifling codes. The principles behind the Codes of Practice are a positive move as part of this wider debate.

As outlined above, the Society supports the principles of both Codes of Practice but believes that both documents should be restructured to give a straightforward outline of issues relating to the many facets of the Codes. In their current form too much detail is included in the main body of the Codes rather than consigning it to the appropriate annexes. We recommend that both Codes would benefit from streamlining so that researchers in the field can easily navigate them and refer to the relevant details as their needs dictate. This would help relieve the administrative pressures of unnecessarily lengthy documentation and bureaucracy that is starting to have a detrimental affect on the very researchers that Codes are written to help.

In summary, the Society is supportive of this positive move towards clear codes for the operation of the UK Stem Cell Bank and for researchers using Stem Cell Lines but recommend that issues highlighted above be addressed to reduce pressure on the research community.

Please do not hesitate to contact us if you require any further information.

Yours sincerely

David J Read