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Senator Gary Humphries
Chair, Community Affairs Committee
Australian Senate
CANBERRA

Via email to: community.affairs@aph.gov.au

Legislative responses to recommendations of the reports of the Legislation Review Committee on the *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002*

The NHMRC is pleased to make this submission to the Senate Community Affairs Committee. Thank you to agreeing to a slight extension for lodging this submission.

Firstly, I would like to provide the NHMRC submission to the Legislation Review Committee (Lockhart Committee) (Attachment A) and the final NHMRC discussion paper on the biological definition of human embryo (Attachment B).

Secondly, the submission below covers five main themes:

1. Background information relevant to the Committee's considerations
2. The significance of the changed governance arrangements for the NHMRC.
3. The administrative (non-legislative) recommendations of the Lockhart Review.
4. Implications for the NHMRC of the proposed legislative responses that the Committee has under consideration.
5. Other commentary.

The NHMRC notes that two bills have been tabled in the Senate outlining legislative responses to the Lockhart Review. On the understanding that Senator Stott-Despoja and Senator Webber provided an exposure draft of their bill and Senator Patterson intends tabling the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Bill 2006* for debate, relevant parts of the discussion below cite Senator Patterson's Bill, rather than the former.

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1. Background

On 5 April 2002, the Council of Australian Governments (COAG) agreed to introduce nationally consistent legislation to ban human cloning and other unacceptable practices and regulate research involving human embryos that had been created for ART treatment but were no longer required for treatment ("excess ART embryos"). COAG also decided that the NHMRC would be responsible for administering the new national regulatory framework.

The legislation currently under review was developed in consultation with State and Territory governments and a range of experts in all States and Territories. The Commonwealth *Research Involving Human Embryos Act 2002* (RIHEA) and *Prohibition of Human Cloning Act 2002* (PHCA) received Royal Assent on 19 December 2002. Subsequently, in accordance with the terms of an intergovernmental agreement, all States and Territories (with the exception of the Northern Territory) have passed corresponding legislation.

Following the passage of the human cloning and embryo research legislation in December 2002, the NHMRC has implemented the strong regulatory framework expected by governments and the community, including the licensing of research involving excess assisted reproductive technology (ART) embryos and appropriate monitoring and compliance arrangements.

The RIHEA establishes the Embryo Research Licensing Committee (the Licensing Committee) as a Principal Committee of the NHMRC. Within the NHMRC, which is responsible for implementing and administering the provisions of these acts, the Licensing Committee is responsible for considering licensing applications and overseeing NHMRC monitoring and compliance activities relevant to the legislation.

In addition to the Licensing Committee, the Australian Health Ethics Committee is responsible for advising the Council on ethical issues relating to health, developing and giving the Council guidelines for the conduct of medical research involving humans and performing other functions as the Minister determines. AHEC has had a long involvement with issues related to the RIHEA and PHCA. These include the development of the *Ethical guidelines on Assisted Reproductive Technology* (1996) and its successor, the *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research* (2004) (2004 ART guidelines), the 1998 report to the Minister for Health on human cloning, and the *National statement on ethical conduct in research involving humans* (1999) (National Statement).

Applications for licences to use excess ART embryos in research must first be assessed and approved by a Human Research Ethics Committee (HREC) that is constituted in accordance with, and acting in compliance with, the National Statement. The Licensing Committee must also have regard to the National Statement and the 2004 ART guidelines in deciding whether to issue a licence, as well as the assessment of the HREC. Finally, the 2004 ART Guidelines define how proper consent must be obtained before any embryo can be used in licensed research.

2. New Governance Arrangements for the NHMRC

On 1 July 2006, the legislative and administrative framework under which the NHMRC operates changed significantly. Amendments to the *National Health and Medical Research Council Act 1992* (NHMRC Act) came into operation, establishing the NHMRC as a prescribed agency for the purposes of the *Financial Management and Accountability Act* and as a statutory agency for the purposes of the *Public Service Act 1999*.

The NHMRC's new governance arrangements include appointment of a Chief Executive Officer (CEO) as the agency head, with direct accountability to the Minister for Health and Ageing. They also included the appointment of a new Council and Principal Committees, and the transfer of staff to the new agency. The new arrangements include a Management Advisory Committee that will assist the CEO on building stronger relationships with external organisations.

The NHMRC remains within the Health and Ageing portfolio and continues to provide the Australian Government with independent expert advice on important health issues; on the allocation of government funding for health and medical research; and on ethical issues in health and research involving humans.

The NHMRC's core business remains unchanged by the governance changes.

3. Administrative Recommendations of the Lockhart Review

The Prime Minister's press release of 23 June 2006 in relation to the "Lockhart Review" indicated Government support for recommendations from the Lockhart Review for administrative improvements that will help reduce red tape in the licensing process and provide further support to the regulatory scheme by enhancing the NHMRC guidelines.

In the CEO's Statement of Intent, which responded to the Minister for Health and Ageing's Statement of Expectations, the NHMRC indicated to the Minister that the NHMRC intends to develop and implement a program for reviewing and enhancing relevant guidelines and providing administrative improvements in the licensing process under the *Research Involving Human Embryos Act 2002*.

4. Implications for the NHMRC of proposed legislation

Consistent application of laws across States and Territories

The NHMRC is responsible for administering the nationally consistent framework established by the Commonwealth RIHEA and the PHCA and corresponding State and Territory legislation. If Commonwealth, State or Territory legislation were to be amended, without corresponding amendments to legislation in other jurisdictions, this would raise the possibility that there would be inconsistency in the prohibitions and

licensing scope between the Commonwealth legislative framework and the existing laws in the States and Territories.

Such inconsistency may create administrative and logistical problems for the NHMRC and difficulties for institutions and commercial enterprises operating across jurisdictions.

Resource implications of proposed changes to the regulatory environment

If the regulatory framework for the licensing of research involving human embryos is amended as recommended by the Lockhart Review, then there may be administrative and resourcing implications for the NHMRC. For example:

- Assessment and inspection requirements
  The proposed expansion of the scope of the licensing and monitoring framework will significantly increase the work load for the NHMRC (in particular its Licensing Committee) in assessing an increased number of applications and monitoring compliance with the new requirements.

- Appropriate expertise
  The NHMRC notes that while additional expertise may be required to inform Licensing Committee consideration of licence applications resulting from expansion in the scope of the licensing provisions, the Lockhart Review did not recommend changing the expertise or membership of the Licensing Committee. The NHMRC also notes that the Explanatory Memorandum to the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Bill 2006* explains that membership of the Licensing Committee is expressed relatively broadly and that the CEO of the NHMRC has the capacity to appoint working committees under the *National Health and Medical Research Council Act 1992*.

5. Other matters

- In relation to the proposed definition of human embryo in legislation under consideration by the Committee, in December 2005 the National Health and Medical Research Council released the final report of the Biological Definition of Human Embryo Working Party as a discussion paper. The definition of "human embryo" provided in that discussion paper (Attachment B) was not endorsed by the NHMRC.

- The proposed definition of *'unsuitable for implantation'* (Schedule 2, Item 4) requires the NHMRC to develop objective criteria to define those embryos that are unsuitable for implantation in the form of new guidelines issued under the NHMRC Act. However the Lockhart Review Report (Recommendations 20-22, 30 refer) did not recommend that the NHMRC develop such guidelines.

- The NHMRC questions whether the requirement that the Minister must report to parliament the reasons for the vacancy on the Committee if this is longer than 3 months (Schedule 2, S14) is too short. The RIHEA prescribes a detailed consultation process involving firstly a call for nominations from jurisdictions and prescribed bodies, followed by 2 stages of consultation with jurisdictions. It is unlikely that this process could be completed within 3 months.

I would be happy to expand on any of the above points should you wish me to appear before the Committee at one of your public hearings.

Yours sincerely

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Chief Executive Officer

5 October 2006