AUSTRALIAN MEDICAL ASSOCIATION
ABN 37 008 426 793

T | 61 2 6270 5400
F | 61 2 6270 5499
E | ama@ama.com.au
W | www.ama.com.au

42 Macquarie St Barton ACT 2600
PO Box 6090 Kingston ACT 2604

10/19

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Ms Julie Dennett
Committee Secretary
Standing Committee on Legal and Constitutional Affairs
PO Box 6100
Parliament House
Canberra ACT 2600

Dear Ms Dennett

Attached is the Australian Medical Association's (AMA) submission to the *Inquiry into Patent Amendment (Human Genes and Biological Materials) Bill 2010.*

Sincerely

Dr Andrew Pesce
President

AMA Submission to the Standing Committee on Legal and Constitutional Affairs'
Inquiry into Patent Amendment (Human Genes and Biological Materials) Bill 2010

Thank you for providing the Australian Medical Association (AMA) with the opportunity to make a submission to the Senate's *Inquiry into Patent Amendment (Human Genes and Biological Materials) Bill 2010.*

The AMA anticipates research into the human genome will have a profound impact on the future delivery of health care. Genetic testing, in particular, is expected to play an increasingly important role in the ability to prevent, diagnose, manage, and treat many human diseases.

The AMA recognises the complexity in balancing the need to encourage investment in research whilst having appropriate regulatory safeguards to ensure that the opportunity of and access to genetic testing and related technologies is reasonable and equitable. Notwithstanding, the AMA's position on gene patents states that the holding of patents should not infringe the principle that the human genome is the common heritage of humanity. Further, gene patents should not present an obstacle to the prevention, diagnosis, management, and treatment of disease (*AMA Position Statement on Human Genetic Issues. 1998. Revised 2000. Revised 2002).* In other words, gene patents should not compromise health care by preventing or obstructing medical practitioners and patients from accessing genetic tests and related technologies.

The AMA recognises that the purpose of the Bill, as outlined in the Explanatory Memorandum, is to:

> *Advance medical and scientific research and the diagnosis, treatment and cure of human illness and disease by enabling doctors, clinicians and medical and scientific researchers to gain free and unfettered access to biological materials, however made, that are identical or substantially identical to such materials as they exist in nature.*

This is highly commendable. Allowing doctors, clinicians, and researchers free and unfettered access to such biological materials has the very real potential to facilitate greater, more competitive research into the development of genetic technologies. This would benefit patients, health care professionals, and the broader health care system by allowing more equitable access to a wider range of genetic tests and related technologies.

Whilst the AMA supports the purpose of the Bill, we acknowledge that views on how the *Patents Act 1990* should be amended to achieve this may vary. It's critical to ensure that the Bill does not inadvertently undermine or obstruct otherwise acceptable patentable inventions lest it inadvertently compromise investment in research.

We strongly recommend that the Committee hold further face-to-face consultations with health care professionals, relevant researchers, consumers, and business/industry as to how the Bill should be worded to achieve this aim.

Whilst we support research into the human genome, we recognise the range of complex ethical issues that arise as a consequence. Human genetic research must be conducted under appropriate ethical guidelines and in secure environments according to recognised international standards. In accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research (2007),* the AMA affirms the principle that there should be fair distribution of the benefits of participation in genetic research and fair access to the benefits of genetic research.

Concurrently with research, resources should be directed to the consideration of these issues, and to community education regarding the benefits and risks of the application of genetic research.

Further, as we develop more innovative genetic technologies, we must provide resources to develop and train the health workforce to understand and apply these technologies in the delivery of health care.

We look forward to the Committee's recommendations regarding the Inquiry.