



ANU LAW
STUDENTS'
SOCIETY

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**Health Law, Bioethics and Human Rights
2nd Semester 2009**

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Question 1

75.5/100

To: Minister for Health and Aging

Re: Ethical, Legal and Human Rights Concerns regarding s206BA

The draft legislation attempts to legislate into the area of the doctor patient fiduciary relationship.

Fiduciary Obligation of Doctors

In Australia at common law the doctor patient relationship is an established fiduciary relationship, but only for limited purposes. The aim of this is to protect a patient's confidence in their doctor and maintain the fundamental loyalty and integrity of that relationship which facilitates its optimal functioning. *Breen v Williams* is authority for the statement that a fiduciary owes duties to his her beneficiary only in respect of those aspects of the relationship, which exhibit the characteristics of trust, confidence and vulnerability. Generally speaking in Australia these aspects are largely confined to the economic and sexual aspects of the relationship.

In this case the legislation, in specific s206BA may relate to the financial aspects of the doc/patient relationship. In the case of *Moore* from the US a man whose cells had been taken from him by a doctor and used to develop a commercial cell line (HeLa) without the mans consent or knowledge was successfully able to sue the doc and university in question for a right to the financial profits from his cell line.

Furthermore the nature of genetic information – its potential to reveal a lot of very personal information about an individual which has the potential to be misused (insurance co's, government etc) would point to a relationship of trust, confidence and vulnerability between the owner of the genetic material and the holder of genetic information. Thus the legislation appears to act against the very grain of the doctor/patient relationship at common law.

Informed Consent

The legislation seeks to remove legal liability for failure to give informed consent. This may be contentious for a number of reasons:

a. Human Rights

The Nuremburg Code was the first time the primacy of individual consent was enunciated. The code was created in response to the atrocities committed in Nazi Germany in WWII in regard to human experimentation. Following the Nuremburg Code the right to informed consent was enshrined in Art 7 of ICCPR, which is also picked up by s10(2) of the Human Rights Act 2004 (ACT). UNESCO Declaration also references the right to informed consent in Art 5(b). Art 10 of the UNESCO Dec states that no research ...in fields of genetics...should prevail over respect for human rights. Furthermore: Art 11 – practices contrary to Human dignity ...shall not be permitted.

In relation to financial gains from genetic testing the Convention on Human Rights and Biomedicine Art 21: contains a prohibition on financial gain from the human body and its parts. Therefore if s206BA is used to create financial gains (which are the main aim of corporations which the legs refer to) it may breach article 21.

b. Bioethics

The NHMRC published guidelines titled “National Statement on Research Involving Humans” in 1999. These guidelines are accepted as national standards in this area. Any researchers who wish to get NHMRC funding must first have their research approved the Ethics Committee (ICE). This may act as a safeguard to help prevent human rights abuses stemming from s206BA since only corporations which are NHMRC approved are allowed to forgo informed consent.

c. Health Law

In the case of *Rogers v Whitaker* it was established that there is a duty to warn a patient of a material risk inherent in the proposed treatment. It is said to have an objective and subjective limb. This may extend to informing a patient of uses of their DNA – that seem both objectively and subjectively relevant. In the ACT if there is ambiguity in the legislation the courts may refer to the human rights in order to aid interpretation of the Act – Human Rights Act 2004 (ACT). If this legislation were to come before the courts it may be held to be ambiguous because on one hand it says ‘freely’ donated sample, but it may only be ‘free’ if there is fully informed consent – the courts may read down the legislation.

Presenting the Issue to the Public

The minister may wish to point to the ethical guidelines and ethics committee approval requirements as a safeguard for potential abuse, also reference Human Rights Act 2004 (ACT). Furthermore he/she may wish to refer to the benefits to society of genetic research and testing. He/she may also want to emphasise that participation in clinical trials is voluntary.