



Human Tissue and Anatomy Legislation Amendment

Bill.

Second Reading

The Hon. MICHAEL COSTA (Minister for Transport Services, Minister for the Hunter, and Minister Assisting the Minister for Natural Resources (Forests)) [4.53 p.m.]: I move:

That this bill be now read a second time.

I seek leave to have the second reading speech incorporated in *Hansard*.

Leave granted.

During the spring sitting of Parliament last year the Government introduced the Human Tissue and Anatomy Amendment Bill 2002. The bill received unanimous support in the other place but, owing to the pressures of last session's legislative program, did not proceed in this House and consequently lapsed. That bill was the outcome of a lengthy consultation process as the legislation dealt with matters of great sensitivity and concern to the community.

As part of the consultation process the 2002 bill's predecessor, the Human Tissue Amendment Bill 2001, was introduced into Parliament the year before and allowed to lie on the table to provide an opportunity for public comment.

Shortly afterwards the report on the "Inquiry Into Matters Arising from the Post-Mortem and Anatomical Examination Practices of the NSW Institute of Forensic Medicine" - the Glebe Morgue - was published.

The report, prepared by Mr Bret Walker SC, contains a number of recommendations relating to the legislation that currently governs the use of human tissue and the conduct of anatomical examinations.

Consequent upon the submissions received in relation to the Human Tissue Amendment Bill and the recommendations in the Walker report, the Government prepared revised legislation in the form of the Human Tissue and Anatomy Legislation Amendment Bill 2002. The Human Tissue and Anatomy Amendment Bill 2003, which is now before you, is substantively the same as the lapsed 2002 bill.

The underlying purpose of the proposed legislation is to ensure that public confidence in the conduct of post-mortem examinations and the use of human tissue in New South Wales is maintained. To this end, the bill provides for amendments to the Human Tissue Act 1983, the Anatomy Act 1977 and the Coroners Act 1980.

The main features of the proposed legislation provide for the following:

Tissue removed during medical, surgical or dental procedures, or for the purposes of a post-mortem examination, is not to be used for other purposes without written consent;

All non-coronial post-mortem examinations are to be carried out in accordance with the wishes of the deceased or their senior available next of kin;

It will be unlawful to use tissue removed from a body during a non-coronial post-mortem examination for any other purpose without written consent;

The purpose for which a coronial post-mortem examination may be conducted is to be clarified;

In the conduct of any post-mortem or anatomical examination, regard must be had to the dignity of the deceased person;

More effective provisions covering the prohibition in the trade in human tissue and the enforcement of this and other provisions under the Human Tissue Act generally; and

The making of regulations to deal with human tissue collections in an accountable manner.

For the information of honourable members I would now like to provide some further background to the proposed legislation and to discuss the amendments in greater detail.

The law in New South Wales allows for two kinds of post-mortem examinations. A post-mortem examination may be ordered under the Coroners Act to assist a coroner in investigating a death. Owing to the nature of the Coroner's jurisdiction, the consent of the next of kin to perform the post-mortem is not required.

Nevertheless, there are provisions in the Coroners Act that allow next of kin to object to a coronial post-mortem examination. The majority of post-mortem examinations undertaken in New South Wales are ordered by a coroner.

The second kind of post-mortem examination is one that is authorised under the Human Tissue Act. Such a post-mortem examination can be authorised where the deceased expressed a wish or consented to such a procedure during their lifetime.

Where the deceased did not express any views, the Act sets out two different sets of rules as to when a post-mortem examination may take place. If the body of the deceased is not at a hospital, a post-mortem examination can only be authorised by a senior available next of kin. If there is no next of kin to consent to the procedure, no post-mortem may be undertaken.

On the other hand, if the body is at a hospital and no next of kin can be located, a post-mortem examination can be authorised by a designated officer of the hospital.

These two sets of rules are inconsistent with each other. The bill amends these rules to ensure that, where the deceased expressed no views about a post-mortem examination during his or her lifetime, a senior next of kin must be consulted. Where there is no next of kin available, a post-mortem examination will not be able to take place. The amendment ensures that consent is always obtained for a non-coronial post-mortem examination, regardless of whether or not the body is at a hospital.

A similar anomaly exists under the Act in respect of tissue donation. The bill amends the relevant provisions so that tissue may only be removed for donation according to the written consent or wish of the deceased, given whilst alive, or where a senior next of kin gives written consent, irrespective of whether the deceased's body is at a hospital or elsewhere.

Another area of reform introduced by the bill relates to how tissue that is removed during a post-mortem examination may be used. At present, section 31 of the Human Tissue Act allows tissue that is removed during any post-mortem examination to be used for other therapeutic, medical or scientific purposes. The consent of the deceased or their next of kin is not required for these other uses.

"Tissue" is defined in the Act as an organ or any part of the human body. In the past, this provision has led to tissue, such as hearts and lungs, which are removed as part of a post-mortem examination, being used for research. In some cases, such organs and tissue have been kept in hospital tissue collections. Families have often been unaware that bodies released to them after post-mortem examination have had organs or tissue missing from them.

This practice has caused great distress for some families, especially for those whose cultural or religious beliefs require the burial of the whole body intact. It is a particular issue in coronial post-mortem examinations, where the next of kin do not have a role in consenting to the post-mortem examination itself.

The proposed bill also addresses cultural sensitivities by allowing a next of kin of a deceased person to authorise another person to exercise his or her functions under the legislation.

The proposed provision recognises the kinship and other familial relationships that exist in cultural groups such as the Aboriginal and Torres Strait Islander cultures. For example, in the case of a death of an Aboriginal person or a Torres Strait Islander, the powers and duties of the senior next of kin would traditionally be exercisable by the designated culturally appropriate person of the family, extended family, clan or tribe to which the deceased person belonged. By allowing consent to be delegated, the bill provides a means of addressing these important cultural differences.

The provisions in the Human Tissue Act, which currently allow tissue to be used for other purposes without consent, are based on the recommendations of the Australian Law Reform Commission in its 1977 report on human tissue transplants.

The Law Reform Commission recommended that body parts removed during post-mortem examinations should be available for use for other therapeutic, medical and scientific purposes.

However, it is clear that the community no longer considers it appropriate that tissue removed during post-mortem examinations may be used for medical research or other scientific or therapeutic purposes, without the need for consent. The bill will render such a practice unlawful.

The bill inserts new provisions in the Act which state that an authority to use tissue removed during a post-mortem examination for other purposes may only be given if the deceased consented in writing whilst alive. Alternatively, if the deceased did not indicate their wishes whilst alive, or the deceased was a child, their senior available next of kin may consent in writing. However, no such consent may be given if the designated officer is aware, after making reasonable inquiries that the deceased person had objected to the use of their tissue.

An authority to use the tissue must be given by a "designated officer" who is a person appointed under the Act to authorise the use of human tissue obtained through donation or from a post-mortem examination. Where the death is in the jurisdiction of a coroner, the coroner's consent will also be required.

A person giving consent to the use of tissue may limit that consent as they see fit. For example, they may limit the use of tissue to one particular research project.

Under the proposed legislation, the requirement to obtain written consent will also be extended to tissue removed from a living person during medical, dental or surgical treatment. It is anomalous that consent is required for the use of tissue removed after death, but not for tissue removed or expelled in the course of medical, dental or surgical treatment.

Thus, the use of such tissue for therapeutic, medical or scientific purposes will be permitted if the patient, or if the patient has died, the senior available next of kin, has given consent in writing to the use of the tissue for that purpose.

However, a general exception has been included in the legislation with respect to persons for whom the Minister administering the Children and Young Persons (Care and Protection) Act has parental responsibility. After consultation with the Minister for Community Services, the view was taken that children and young persons who are under the Minister's care should not be subject to the provisions of the legislation enabling consent to be given to the use of their tissue.

For the purposes of consistency, the bill also amends the Human Tissue Act to require consent for the removal of tissue from a deceased person and its use for transplantation or other therapeutic, medical or scientific purposes to be in writing or by other prescribed means. The reason it may be necessary to have consent recorded by means other than writing, in the case of donation for transplantation, is because of the time constraints on the retrieval of viable human tissue. For example, in respect of potential cornea donation there is only a short window after death during which the tissue remains medically viable for retrieval. In many instances tissue banks have advised that it is necessary to discuss prospective donation with and obtain the consent of the deceased's family by telephone, as they are not present on hospital premises to provide their consent immediately in writing.

Accordingly consensually recorded verbal consent, or other means of equivalent record to that of written consent, can be prescribed. This will ensure there is no reduction in the availability of tissue for donation whilst adhering to the principle of requiring clearly documented consent to tissue removal.

The bill renders it an offence to use tissue removed during a medical dental or surgical procedure, from the body of a deceased person, or during a post-mortem examination, unless an authority has been given for its use under the Act. It is also unlawful to use tissue outside the terms of the authority.

The proposed legislation provides for two exceptions in respect of the requirement for consent for the use of tissue removed from a deceased person or during the course of therapeutic, medical or scientific procedures.

First, no consent will be required for the retention and therapeutic, medical or scientific use of small samples of any tissue that is lawfully removed from the body of a person (whether living or deceased) and retained in the form of a tissue block or slide. An exception in these terms has also been included in the proposed amendments to the Anatomy Act and the Coroners Act.

The retention of such material is essential in assisting in determining the manner and cause of death under the Coroners Act. The Walker Report also noted the strong justification for the indefinite retention of tissue blocks and slides without specific consent requirements to allow for their use in teaching and research.

The second exception allows for the retention of tissue for a prescribed period for the purpose of obtaining a written authority under the Human Tissue Act for the use of the tissue for therapeutic, medical or scientific purposes. This exception is designed to enable tissue removed in certain circumstances, such as emergency surgery, to be retained until the wishes of the person from whom the tissue was removed, or, if the person dies, their senior available next of kin can be ascertained.

The proposed bill also provides for improved enforcement powers. The updated and improved enforcement provisions will assist in monitoring compliance with the legislation generally. More particularly, these new powers are generally aimed at ensuring that the prohibition on the trade in human tissue contained in section 32 (1) of the Act can be appropriately investigated and enforced.

Section 32 (1) provides that it is an offence to enter into a contract or arrangement under which any person agrees, for valuable consideration, to the sale or supply of tissue from a person either living or deceased, or to the post-mortem examination of any person after death. Section 32 has been updated to ensure that it not only captures any contract or arrangement that might breach section 32 (1) but also captures an *offer* to enter into such an arrangement.

The Act provides for an exception regarding the prohibition on contracting for the sale or supply of human tissue. This exception allows for the sale and supply of therapeutic goods, which contain human tissue.

At present, this exception applies only to goods that are to be used "in accordance with the direction of a medical practitioner". Since this provision was enacted, a number of therapeutic goods have been developed which contain processed human tissue, but are not necessarily used "in accordance with the directions of a medical practitioner".

These include serological tests for certain human diseases (which contain human serum), cell feeder lines for culturing viruses, and other scientific and therapeutic goods.

These products, which are regulated by the Commonwealth Therapeutic Goods Administration, may be used by persons such as laboratory scientists and researchers, rather than in accordance with the directions of a medical practitioner. The bill therefore also updates the current exception to take such therapeutic goods into account.

The further matter addressed by the bill is that of human tissue collections. The Chief Health Officer's audit of human tissue collections indicated that much stored tissue is unidentified. This makes it difficult for comprehensive audits of tissue collections to be undertaken.

The bill addresses this issue by inserting new regulation making powers into the Act. This will allow regulations to be made regarding record keeping for tissue collections, or use of tissue under the Act. Regulations may also be made for the forwarding of such information to the Director-General of the Department of Health. This will allow the Department to properly monitor human tissue collections.

The bill before the House also amends the Anatomy Act 1977. Consistent with the proposed amendments to the Human Tissue Act, the legislation introduces a requirement for written consent by the deceased prior to their death, or by the senior available next of kin, for the use of a body for anatomical examination.

A number of other amendments have been included in the bill by way of updating and clarifying the operation of the Act.

The Walker report took the view that the current provisions of the Anatomy Act only allow for the dissection of bodies. This means that bodies donated under the Anatomy Act cannot be used for the purposes of other medical or scientific research, such as teaching or practising surgical techniques.

A new definition of "anatomical examination" has therefore been included in order to make it clear that such examination includes the use of the body for medical and scientific purposes. A reference to medical or scientific purposes includes educational purposes connected with medicine or science. This will ensure bodies donated under the Act will be able to be used for such purposes as instructing students studying medicine. The bill also introduces a provision stating that, in the conduct of an anatomical examination, regard is to be had to the dignity of the deceased. The bill provides for the inclusion of a similar provision in both the Human Tissue and Coroners Acts.

The comment might be made that neither anatomical examinations nor post-mortems are, of themselves, inherently dignified procedures. However, it is considered important that there be some acknowledgement by way of general principle that the process surrounding these procedures should reflect the ongoing dignity that should be accorded to any person between the time of their death and burial or cremation.

Presently, a licensee may retain a body that has been donated under the Anatomy Act indefinitely, provided an authority to do so is given by an inspector, as required. However, in keeping with the principle propounded in the Walker report that regard is to be had to the dignity of the deceased, it is proposed that a maximum period of 8 years be set for the retention of bodies donated under the legislation.

Specific provision has been made for the permanent retention of tissue where express written consent has been given by the deceased prior to death. Where no consent has been given and the wishes of the deceased in this respect are unknown, the senior available next of kin may consent. However, as previously noted, no consent is

required for the retention of tissue in the form of tissue blocks and slides.

The Anatomy Act currently makes provision for the transfer of bodies between institutions licensed under the Act. However, the legislation is silent regarding the transfer of tissue between licensees.

The proposed bill allows for the transfer of human tissue from a body that is in the possession of a licensed institution to another holder of a license, an authorised officer of a hospital, or a person approved by the Director General for use for medical or scientific purposes. Such transfer will not be permitted where it is contrary to the authority given by the deceased or the next of kin.

This amendment will ensure that activities, such as the practice of surgical procedures on particular tissue or body parts, can be conducted at hospitals and licensed facilities. Provision is made in the bill requiring the licensee to have arrangements in place for the return of the tissue, unless it has been wholly or substantially destroyed in the process.

Finally, the proposed legislation amends the Coroners Act in a number of respects.

The bill clarifies that the purpose of a coronial post-mortem is to assist in the investigation of the manner and cause of death, the time and place of death or the identity of the deceased.

I am sure honourable members will agree that it is imperative that the proper administration of the justice system not be impeded. To this end, provision has also been made in the bill to allow tissue from a coronial post-mortem examination to be used for the Coroner's investigation of a death.

Tissue so removed may also be used for the investigation of any offence, or in any offence proceedings. The provision is essential to ensure that forensic evidence is preserved for the proper investigation of a person's death by the Coroner, and for the proper investigation and prosecution of crime.

The new provision in the bill also allows small samples of bodily fluids, such as blood, to be retained from a coronial post-mortem examination. Small samples of skin, hair and nails may also be kept.

Other small samples of tissue may only be kept where a Coroner makes a direction in a particular case. The direction is required to be made in writing, so that a record of the retention exists. Such a direction may not be made as a general practice, but only in a particular case.

The small samples of tissue that are retained under this provision can only be used for certain purposes. These are as follows:

- the exercise of a coroner's functions;
- the investigation of an offence;
- for use in legal proceedings;
- for any use that is authorised by the deceased or their next of kin under the Human Tissue Act; and
- a purpose prescribed by the regulations.

The ability to prescribe further purposes for the use of such tissue samples is necessary to deal with contingencies that may arise in the future. For example, a particular Government Inquiry or a Royal Commission may require such samples to be re-examined for the purposes of its inquiry.

The capacity to retain these small samples of tissue is necessary to ensure that the coronial system and the justice system continue to function effectively. For example, retained samples of tissue may be used in cases of unsolved deaths. New evidence may come to light several years later, and retained tissue samples may be needed in the re-investigation of the death.

As previously noted, tissue slides and blocks may be retained and used for any therapeutic, medical or scientific purpose. Honourable members will appreciate that the retention of these small samples of tissue is necessary to preserve important interests of society, being the proper investigation of suspicious or unusual deaths and the proper administration of the criminal justice system.

The Government is committed to ensuring that the interests of individuals and the community regarding the use of human tissue from deceased persons are respected. It is also committed to ensuring the proper and effective administration of the justice system.

The Human Tissue and Anatomy Legislation Amendment Bill represents an appropriate balance between:

- the community's expectations concerning the dignified and respectful treatment of deceased persons, the right of individuals, or their families on their behalf, to determine how their bodies should be used, the interests of justice; and
- the need for ongoing medical and scientific research, teaching and inquiry.

I commend the bill to the House.

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