

New South Wales

Human Tissue Amendment (Trafficking in Human Organs) Bill 2016

Explanatory note

This explanatory note relates to this Bill as introduced into Parliament.

Overview of Bill

The objects of this Bill are:

- (a) to increase the penalty for commercial trading in human organs and other human tissue, and
- (b) to create offences relating to the use of organs and other tissue taken from people without their consent, and
- (c) to impose a duty on registered health practitioners to report any reasonable belief they have that a patient or other person has received an organ or tissue that was commercially traded or taken without appropriate consent.

Outline of provisions

Clause 1 sets out the name (also called the short title) of the proposed Act.

Clause 2 provides for the commencement of the proposed Act on the date of assent to the proposed Act.

Schedule 1 Amendment of Human Tissue Act 1983 No 164

Schedule 1 [1] and [2] update the long title of the *Human Tissue Act 1983* as a consequence of the changes proposed to be made to that Act, which deal with the unlawful removal and use of tissue from living people (whereas the long title currently refers only to the removal of tissue from deceased people).

Schedule 1 [3]–[7] and [9] update references to the holder of an office and to a Ministry.

Schedule 1 [8] substitutes Part 6 to insert the following provisions creating offences relating to trading in, removal, use and transplantation of tissue:

Part 6 Offences relating to trading in, removal, use and transplantation of tissue

Division 1 Preliminary

Proposed section 32 defines words and expressions used in the proposed Part. A *commercial transplant arrangement* is defined as a contract or arrangement under which any person agrees, for valuable consideration, whether given or to be given to any such person or to any other person, to the sale or supply of any tissue from any such person's body or from the body of any other person, whether before or after that person's death or the death of that other person.

Proposed section 32A explains what the term *appropriate consent* means in the proposed Part. In relation to situations where tissue is removed from a person outside New South Wales, the term is defined so as to give effect to the laws of some other countries that allow for the next of kin of a deceased person to grant consent on the person's behalf and to laws of other countries that have an "opt-out" consent scheme, where a deceased person is treated as if he or she has consented to donating tissue unless the person specifically stated during his or her lifetime that he or she did not consent. The provision also makes it clear that prisoners and other detained persons cannot give appropriate consent.

Proposed section 32B makes it clear that offences under the proposed Part extend, in some circumstances, to conduct that occurs outside New South Wales.

Division 2 Offences relating to trading in tissue

Proposed section 32C makes it an offence to enter into, or offer to enter into or promote, a commercial transplant arrangement, to knowingly provide any services under a commercial transplant arrangement, to knowingly accept any benefit under a commercial transplant arrangement or to consent to the transplantation to a person of tissue removed under a commercial transplant arrangement. The section does not apply to arrangements relating to blood, semen, hair, or any other tissue prescribed by the regulations, where the tissue is provided under a program regulated by a hospital or government-approved organisation. (Proposed section 32E (b) provides that the proposed Division does not apply to such arrangements if they provide only for the reimbursement of any expenses necessarily incurred by the person from whom the tissue is to be removed in relation to the removal of tissue in accordance with the Act.)

Proposed section 32D creates an aggravated offence if the relevant commercial transplant arrangement relates to the sale or supply of an amount of tissue the taking of which from the body of a person would reasonably be expected to kill, or threaten the life of, the person, or to the sale or supply of a vital organ.

Proposed section 32E creates certain exemptions from the offences created by the proposed Division.

Proposed section 32F provides that contracts or arrangements entered into in contravention of proposed Division 2 are void.

Proposed section 32G provides for the Minister to approve certain contracts or arrangements.

Division 3 Offences relating to removal of tissue without consent

Proposed section 32H makes it an offence to remove tissue from the body of another person (whether living or deceased) without the appropriate consent.

Proposed section 32I creates an aggravated offence of removing an amount of tissue the taking of which from the body of a person would reasonably be expected to kill, or threaten the life of, the person, or removing a vital organ, without the appropriate consent.

Proposed section 32J creates certain exemptions from the offences created by the proposed Division.

Division 4 Offences relating to use of tissue removed without consent

Proposed section 32K makes it an offence to use any tissue that is removed from the body of a living person in the course of medical, dental or surgical treatment for any purpose, knowing that appropriate consent was not given. It will also be an offence to use any tissue that is removed from the body of a deceased person, in any circumstances, for any purpose, knowing that appropriate consent was not given.

Proposed section 32L creates an aggravated offence of using an amount of tissue the taking of which from the body of a person would reasonably be expected to kill, or threaten the life of, the person, or a vital organ, knowing that appropriate consent was not given.

Proposed section 32M makes it an offence for a person to consent to the use of any tissue removed from the body of another person for the purpose of its transplantation into the body of the person if the tissue was removed from the body of the other person without the appropriate consent and the person to whom it is transplanted knows of, or is reckless as to, that lack of consent.

Proposed section 32N creates an aggravated offence of consenting to being transplanted with an amount of tissue the taking of which from the body of a person would reasonably be expected to kill, or threaten the life of, the person, or with a vital organ, without the appropriate consent, if the person to whom it is transplanted knows of, or is reckless as to, that lack of consent.

Division 5 Mandatory reporting by registered health practitioners

Proposed section 320 imposes a duty on registered health practitioners to report any reasonable belief they have that a patient has received an organ or tissue that was commercially traded or taken without appropriate consent.

Proposed section 32P provides legal protection for registered health practitioners who make such mandatory reports.

Schedule 1 [10] omits existing offences that are replaced by the proposed offences.

Schedule 1 [11] transfers an existing offence (formerly set out in section 32 (1)).

Schedule 1 [12] makes a consequential amendment to a cross-reference.

Schedule 1 [13] provides that the aggravated offences created by the proposed Act are to be dealt with as indictable offences. The remaining offences are to be dealt with summarily before the Local Court.

Schedule 1 [14] provides for the making of savings or transitional regulations consequent on the amendment of the *Human Tissue Act 1983*.

Schedule 2 Amendment of Health Practitioner Regulation (Adoption of National Law) Act 2009 No 86

Schedule 2 makes it unsatisfactory professional conduct for a registered health practitioner to breach the duty to report a reasonable belief that human organs or human tissue have been obtained under a commercial transplant arrangement or taken from people without their consent.



New South Wales

Human Tissue Amendment (Trafficking in Human Organs) Bill 2016

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Human Tissue Amendment (Trafficking in Human Organs) Bill 2016

No , 2016

A Bill for

An Act to amend the *Human Tissue Act 1983* to make further provision with respect to the commercial or non-consensual trading of human organs and other human tissue; and for related purposes.

| The Legislature of New South Wales enacts: | | | | | |
|--|--|---|--|--|--|
| 1 | Name of Act | 2 | | | |
| | This Act is the Human Tissue Amendment (Trafficking in Human Organs) Act 2016. | 3 | | | |
| 2 | Commencement | 4 | | | |
| | This Act commences on the date of assent to this Act | ŗ | | | |

| Scł | nedule 1 | Amendment of Human Tissue Act 1983 No 164 | 1 |
|-----|----------------------------|---|----------|
| [1] | Long title | | 2 |
| | Insert "and | use" after "removal". | 3 |
| [2] | Long title | | 4 |
| | Insert "livin | g or" before "deceased" where firstly occurring. | 5 |
| [3] | Section 4 D | Definitions | 6 |
| | Omit the de | finition of <i>Director-General</i> from section 4 (1). | 7 |
| | Insert in alp | habetical order: | 8 |
| | | Secretary means the Secretary of the Ministry of Health. | 9 |
| [4] | Section 4 (| 1), definition of "governing body" | 10 |
| | Omit "Direc | ctor-General" from paragraph (b) (iii). Insert instead "Secretary". | 11 |
| [5] | Sections 4 33J (1), (3) | (7) (b), 21C (1) and (5), 21Z (2) (b), 27A, 33A (2), 33I (2), (3) and (7) (b), and (5) and 37A (2)–(6) | 12 13 |
| | Omit "Direc | ctor-General" wherever occurring. Insert instead "Secretary". | 14 |
| [6] | Section 5 D | Designated officers and designated specialists | 15 |
| | Omit "of the | e Department of Health" from section 5 (2) (a). | 16 |
| [7] | Sections 27 | 7 (1A) (a) and 39 (1A) (c) | 17 |
| | Omit "Direc | ctor-General of the Department of Health" wherever occurring. | 18 |
| | Insert instea | d "Secretary". | 19 |
| [8] | Part 6 | | 20 |
| | Omit the Pa | rt. Insert instead: | 21 |
| | Part 6 | Offences relating to trading in, removal, use and transplantation of tissue | 22 23 |
| | Division ' | 1 Preliminary | 24 |
| | 32 Defin | itions | 25 |
| | | In this Part: | 26 |
| | | appropriate consent—see section 32A. | 27 |
| | | commercial transplant arrangement means a contract or arrangement under which any person agrees, for valuable consideration, whether given or to be | 28 29 |
| | | given to any such person or to any other person, to the sale or supply of any | 30 |
| | | tissue from any such person's body or from the body of any other person, whether before or after that person's death or the death of that other person. | 31 32 |
| | | vital organ means an organ that a person cannot survive without, or one of a | 33 |
| | | pair of organs that a person cannot survive without, and includes any of the following: | 34 35 |
| | | (a) heart, | 36 |
| | | (b) lung, | 37 |

32A

| | (c) | kidne | ey, | 1 | |
|-----|--|---|---|--|--|
| | (d) | liver, | | 2 | |
| | (e) | panci | reas. | 3 | |
| Mea | ning o | f "app | ropriate consent" | 4 | |
| (1) | In th | is Part: | | 5 | |
| , , | <i>appropriate consent</i> , in relation to the removal of tissue, or the removal of tissue and its use for a particular purpose, means: | | | | |
| | (a) | Wale autho | e case of tissue of a person that is removed or used in New South es—a consent or authority that is, under this Act, sufficient ority for the tissue to be removed from the person or to be removed the person and used for that particular purpose, or | 8 9 10 11 | |
| | (b) | | e case of tissue of a person that is removed or used outside New h Wales: | 12 13 | |
| | | (i) | the consent of the person from whom the tissue is removed to the removal of the tissue or to the removal of the tissue and its use for that particular purpose, or | 14 15 16 | |
| | | (ii) | if the person from whom the tissue is removed is a minor or otherwise lacks capacity to consent—the consent of the parent or guardian of the person to the removal of the tissue or to the removal of the tissue and its use for that particular purpose, or | 17 18 19 20 | |
| | | (iii) | if the person from whom the tissue is removed is deceased and the laws of the place of death allow for the removal of tissue with the consent of the next of kin of the deceased person—the consent of a senior available next of kin to the removal of the tissue or to the removal of the tissue and its use for that particular purpose, or | 21 22 23 24 25 | |
| | | (iv) | if the person from whom the tissue is removed is deceased and the laws of the place of death provide that a deceased person is taken to have given consent to the removal or use of the person's tissue unless the person has, during the person's lifetime, specifically indicated that he or she does not give consent—the presumed consent of the person arising from failure of the person during the person's lifetime to specifically indicate that he or she does not give consent to the removal of the tissue or to the removal of the tissue and its use for that particular purpose. | 26 27 28 29 30 31 32 33 | |
| (2) | Despite subsection (1): | | | | |
| | (a) | other a hos | e person from whom the tissue is removed is imprisoned or wise detained by a police force or government (whether in a gaol, pital or elsewhere), or was so imprisoned or detained immediately the he or she died, then the person cannot give appropriate consent, | 36 37 38 39 40 | |
| | (b) | one ponly lifeting | e place of death of the person from whom the tissue is removed is prescribed by the regulations, consent will not be presumed and consent expressed by the person himself or herself during his or her me, or the consent of a senior available next of kin, is <i>appropriate ent</i> for the purposes of this Part. | 41 42 43 44 45 | |
| (3) | | regulations may create exceptions to the operation of paragraph (b) (iv) of definition of <i>appropriate consent</i> in subsection (1). | | | |

| 32B | Offences extend to conduct that occurs outside New South Wales | | | 1 |
|-----|--|------------------------|--|----------------------------|
| | | the c | hout limiting the application of Part 1A of the <i>Crimes Act 1900</i> , a person mits an offence under this Part even if one or more of the acts constituting offence occurs outside New South Wales and the person who does the acts stituting the offence, or the person from whom the relevant tissue is oved, is ordinarily resident in New South Wales. | 2 3 4 5 6 |
| Div | ision | 2 | Offences relating to trading in tissue | 7 |
| 32C | Offe | nce of | f trading in tissue | 8 |
| | (1) | A pe | erson must not: | 9 |
| | | (a) | enter into, or offer to enter into or promote, a commercial transplant arrangement, or | 10 11 |
| | | (b) | knowingly provide any services (including medical services) under a commercial transplant arrangement, or | 12 13 |
| | | (c) | knowingly accept any benefit under a commercial transplant arrangement, or | 14 15 |
| | | (d) | consent to the transplantation to the person of tissue removed from the body of another person under a commercial transplant arrangement. | 16 17 |
| | | Max | ximum penalty: 40 penalty units or imprisonment for 6 months, or both. | 18 |
| | (2) | bloo that | s section does not apply to commercial transplant arrangements relating to od, semen, hair, or any other tissue prescribed by the regulations, where tissue is provided under a program regulated by a hospital or ernment-approved organisation. | 19 20 21 22 |
| | (3) | to the | the purposes of this section, a person who consents to the transplantation he person of tissue removed from the body of another person under a mercial transplant arrangement is taken to have accepted a benefit under commercial transplant arrangement. | 23 24 25 26 |
| 32D | Agg | ravate | ed offence of trading in tissue | 27 |
| | (1) | offei | erson commits an offence under this section if the person commits an nce under section 32C and the commercial transplant arrangement cerned relates to the sale or supply of: | 28 29 30 |
| | | (a) | an amount of tissue the taking of which from the body of a person would reasonably be expected to kill, or threaten the life of, the person, or | 31 32 |
| | | (b) | a vital organ. | 33 |
| | | Max | ximum penalty: imprisonment for 25 years. | 34 |
| | (2) | satis that not g | on the trial of a person for an offence under this section, the jury is not sfied that the person is guilty of the offence but is satisfied on the evidence the person is guilty of an offence under section 32C, it may find the person guilty of the offence charged but guilty of an offence under section 32C, the person is liable to punishment accordingly. | 35 36 37 38 39 |
| 32E | Exe | mptior | ns | 40 |
| | | This | Division does not apply to or in respect of: | 41 |
| | | (a) | the sale or supply of tissue if the tissue has been subjected to processing or treatment and the sale or supply is made for the purpose of enabling the tissue to be used for therapeutic, medical or scientific purposes, or | 42 43 44 |

| | | (b) | a contract or arrangement providing only for the reimbursement of any expenses necessarily incurred by the person from whom the tissue is to be removed in relation to the removal of tissue in accordance with this Act. | 1 2 3 4 |
|--------------|-------------------|--------------------------|--|----------------------------|
| 32F | Con | tracts | or arrangements in breach of certain provisions void | 5 |
| | | A co | ontract or arrangement entered into in contravention of this Division is | 6 7 |
| 32G | Mini | ster m | nay approve contracts or arrangements | 8 |
| | (1) | so, the | e Minister considers it desirable by reason of special circumstances to do he Minister may, by instrument in writing, approve the entering into of a ract or arrangement that would, but for the approval, be void by virtue of Division. | 9 10 11 12 |
| | (2) | | Division does not apply to or in respect of a contract or arrangement red into in accordance with such an approval. | 13 14 |
| Div | ision | 3 | Offences relating to removal of tissue without consent | 15 |
| dona remo | tion of val of ti | tissue ssue (i | prohibits the removal of tissue without consent. Part 2 of this Act regulates the (which includes organs) by living persons with consent. Part 4 regulates the including organs) after death, where the deceased person had, during his or her r her consent to that removal. | 16 17 18 19 |
| 32H | Offe | nce of | f unlawful removal of tissue | 20 |
| | | livi̇̀n | erson must not remove tissue from the body of any other person (whether ag or deceased) without the appropriate consent. imum penalty: 40 penalty units or imprisonment for 6 months, or both. | 21 22 23 |
| 201 | _ | | | |
| 32I | | | ed offence of unlawful removal of tissue | 24 |
| | (1) | | erson commits an offence under this section if the person commits an nee under section 32H and the offence involves removing: | 25 26 |
| | | (a) | an amount of tissue from the body of a living person that would reasonably be expected to kill or threaten the life of the person, or | 27 28 |
| | | (b) | an amount of tissue from the body of a deceased person that would, if the person were alive, reasonably be expected to kill or threaten the life of the person, or | 29 30 31 |
| | | (c) | a vital organ. | 32 |
| | | Max | imum penalty: imprisonment for 25 years. | 33 |
| | (2) | satis that t not g | n the trial of a person for an offence under this section, the jury is not fied that the person is guilty of the offence but is satisfied on the evidence the person is guilty of an offence under section 32H, it may find the person guilty of the offence charged but guilty of an offence under section 32H, the person is liable to punishment accordingly. | 34 35 36 37 38 |
| 32J | Offe | nces o | do not apply to conduct authorised by law | 39 |
| | | This unde | Division does not apply to or in respect of anything authorised by or er: | 40 41 |
| | | (a) | the Coroners Act 2009, or | 42 |
| | | (b) | the Anatomy Act 1977, or | 43 |
| | | (c) | any other law. | 44 |

| Division 4 | | | Offences relating to use of tissue removed without consent | 1 2 |
|------------|--|---------------------------|---|----------------------------|
| 32K | Offence of use of tissue removed without consent | | | 3 |
| | | A pe | rson must not: | 4 |
| | | (a) | use any tissue that is removed from the body of a living person in the course of medical, dental or surgical treatment carried out in the interests of the health of the person for any purpose (other than for the purposes of treating the person), knowing that appropriate consent was not given for the removal and use, or | 5 6 7 8 |
| | | (b) | use any tissue that is removed from the body of a deceased person, in any circumstances, for any purpose, knowing that appropriate consent was not given for the removal and use. | 10 11 12 |
| | | Max | imum penalty: 40 penalty units or imprisonment for 6 months, or both. | 13 |
| 32L | Aggı | ravate | d offence of use of tissue removed without consent | 14 |
| | (1) | A pe | erson commits an offence under this section if the person commits an acce under section 32K and the offence involves the use of: | 15 16 |
| | | (a) | an amount of tissue removed from the body of a living person that would reasonably be expected to kill or threaten the life of the person, or | 17 18 |
| | | (b) | an amount of tissue removed from the body of a deceased person that would, if the person were alive, reasonably be expected to kill or threaten the life of the person, or | 19 20 21 |
| | | (c) | a vital organ. | 22 |
| | | Max | imum penalty: imprisonment for 25 years. | 23 |
| | (2) | satist that t not g | In the trial of a person for an offence under this section, the jury is not fied that the person is guilty of the offence but is satisfied on the evidence the person is guilty of an offence under section 32K, it may find the person guilty of the offence charged but guilty of an offence under section 32K, the person is liable to punishment accordingly. | 24 25 26 27 28 |
| 32M | Offence of unlawfully receiving for transplantation tissue removed without consent | | | 29 30 |
| | | anoth | rson must not consent to the use of any tissue removed from the body of her person (whether living or deceased) for the purpose of its plantation to the body of the person if: | 31 32 33 |
| | | (a) | the tissue was removed from the body of the other person without the appropriate consent to the removal and use, and | 34 35 |
| | | (b) | the person to whom it is transplanted knows of, or is reckless as to, that lack of consent. | 36 37 |
| | | Max | imum penalty: 40 penalty units or imprisonment for 6 months, or both. | 38 |
| 32N | Aggravated offence of unlawfully receiving for transplantation tissue removed without consent | | | 39 40 |
| | (1) A person commits an offence under this section if the person commits offence under section 32M and that offence involves the use transplantation of: | | nce under section 32M and that offence involves the use for | 41 42 43 |
| | | (a) | an amount of tissue removed from the body of a living person that would reasonably be expected to kill or threaten the life of the person, or | 44 45 |

| | | (b) | an amount of tissue removed from the body of a deceased person that would, if the person were alive, reasonably be expected to kill or threaten the life of the person, or | 1 2 3 | | | |
|------|-------|---|--|------------------------|--|--|--|
| | | (c) | a vital organ. | 4 | | | |
| | | Maximum penalty: imprisonment for 25 years. | | | | | |
| | (2) | satist that perso | In the trial of a person for an offence under this section, the jury is not fied that the person is guilty of the offence but is satisfied on the evidence the person is guilty of an offence under section 32M, it may find the on not guilty of the offence charged but guilty of an offence under on 32M, and the person is liable to punishment accordingly. | 6 7 8 9 10 | | | |
| Divi | ision | 5 | Mandatory reporting by registered health practitioners | 11 | | | |
| 320 | Man | datory | reporting by registered health practitioners | 12 | | | |
| | (1) | if he trans | gistered health practitioner has a duty to provide a report to the Secretary or she has a reasonable belief that a patient or other person has been planted with or received tissue that was removed from the body of her person (whether living or deceased): | 13 14 15 16 | | | |
| | | (a) | under a commercial transplant arrangement, or | 17 | | | |
| | | (b) | without the appropriate consent to the removal or to its use in that patient or other person. | 18 19 | | | |
| | (2) | | gistered health practitioner is only under such a duty if that reasonable f arises during the course of or from the health practitioner's work. | 20 21 | | | |
| | (3) | That | report must: | 22 | | | |
| | | (a) | be provided as soon as practicable and in the manner required by the regulations, and | 23 24 | | | |
| | | (b) | include the name, or a description, of the patient or other person, and the grounds for the registered health practitioner forming that reasonable belief. | 25 26 27 | | | |
| | (4) | In th | is Division: | 28 | | | |
| | | Pract | stered health practitioner means a person registered under the Health titioner Regulation National Law to practise a health profession (within neaning of that Law), other than as a student. | 29 30 31 | | | |
| 32P | Prot | ection | of registered health practitioners who make reports | 32 | | | |
| | | | registered health practitioner makes a report in good faith to the Secretary ex section 32O: | 33 34 | | | |
| | | (a) | the making of the report does not constitute a breach of professional etiquette or ethics or a departure from accepted standards of professional conduct, and | 35 36 37 | | | |
| | | (b) | no liability for defamation is incurred because of the report, and | 38 | | | |
| | | (c) | the making of the report does not constitute a ground for any civil proceedings, including proceedings for malicious prosecution or for conspiracy or for breach of any duty of confidentiality, and | 39 40 41 | | | |
| | | (d) | the registered health practitioner is not subject to any criminal liability in relation to the making of the report. | 42 43 | | | |

| [9] | Sect | ions 3 | 3A Appointment of inspectors | 1 | |
|------|-----------------------------------|---------|--|----------------------------|--|
| | | | ctor-General may appoint any officer of the Department of Health, or any person rector-General" from section 33A (1). | 2 | |
| | | | ad "Secretary may appoint any officer of the Ministry of Health, or any person cretary". | 4 5 | |
| [10] | Sect | ion 36 | Offences | 6 | |
| | Omit | section | on 36 (1) and (1A). | 7 | |
| [11] | Sect | ion 36 | (2B) | 8 | |
| | Inser | t after | section 36 (2A): | 9 | |
| | | (2B) | A person must not enter into, or offer to enter into, a contract or arrangement under which any person agrees, for valuable consideration, whether given or to be given to any such person or to any other person, to the post-mortem examination of any person's body after that person's death or the body of any other person after the death of that other person. Maximum penalty: 40 penalty units or imprisonment for 6 months, or both. | 10 11 12 13 14 | |
| F401 | 0 1 | 00 | | | |
| [12] | | ion 36 | ` ' | 16 | |
| | Omit | "(1)," | · | 17 | |
| [13] | Sect | ion 38 | | 18 | |
| | Omit the section. Insert instead: | | | | |
| | 38 | Proc | eedings for offences | 20 | |
| | | (1) | Proceedings for an offence under this Act or the regulations are to be dealt with summarily before the Local Court. | 21 22 | |
| | | (2) | Despite subsection (1), an offence under section 32D, 32I, 32L or 32N is to be dealt with as an indictable offence. | 23 24 | |
| [14] | Sche | dule ' | 1 Savings, transitional and other provisions | 25 | |
| | Omit | claus | e 1 (1). Insert instead: | 26 | |
| | | (1) | The regulations may contain provisions of a savings or transitional nature consequent on the enactment of any Act that amends this Act. | 27 28 | |

Amendment of Health Practitioner Regulation Schedule 2 1 (Adoption of National Law) Act 2009 No 86 2 Schedule 1 Modification of Health Practitioner Regulation National Law 3 Insert after section 139B (1) (e) in Schedule 1 [13]: 4 Failure to report tissue traded or transplanted illegally 5 Failing to report having a reasonable belief (arising during the 6 course of or from the registered health practitioner's work) that a 7 patient or other person has been transplanted with or received 8 tissue that was removed from the body of another person 9 (whether living or deceased) under a commercial transplant 10 arrangement, or without the appropriate consent to the removal 11 and use in that patient or other person (within the meaning of the 12 Human Tissue Act 1983). 13