

HEALTH AMENDMENT BILL

AS REPORTED FROM THE HEALTH COMMITTEE

COMMENTARY

Recommendation

The Health Committee has examined the Health Amendment Bill and recommends that it be passed with the amendments shown in the bill.

Conduct of the examination

The Health Amendment Bill was referred to the Health Committee on 31 March 1998. The closing date for submissions was 8 May 1998. The committee received and considered five submissions from the Blood Transfusion Trust, the Haemophilia Society of New Zealand Inc. and other interested groups and individuals. The submission of the Blood Transfusion Trust was heard orally. Thirty minutes was spent on the hearing of evidence and consideration took one hour and 40 minutes. Advice was received from the Ministry of Health.

This commentary sets out the details of the committee's consideration of the bill and the major issues addressed by the committee.

Background

The Government has decided to create a unified national blood service, to be called the New Zealand Blood Service (NZBS). The NZBS will provide a nationally co-ordinated service including collection, processing, accreditation and supply of blood products. This approach will replace the existing systems in which Crown health enterprises have each tried to provide such services individually. The NZBS will replace the Blood Transfusion Trust (BTT), a charitable trust established pursuant to section 92 of the Health Amendment Act 1993. Both the NZBS and the BTT are Crown entities for the purposes of the Public Finance Act 1989. The BTT would be abolished by the bill.

Bone marrow has been thought to be part of blood for the purposes of trading restrictions on blood. However, the status of bone marrow is not legally clear and the bill would provide this clarification.

Purpose of the bill

The bill would amend the Health Act 1956 by substituting a new Part 3A relating to trading in human blood and declared human substances. This new Part extends the prohibition on trading in human blood to human bone marrow and declared human substances. The other main purpose of the bill is to disestablish the BTT. The bill empowers the Minister of Health to appoint entities to be responsible for the performance of specified functions in relation to blood and controlled human substances. The NZBS has been established as a Crown health enterprise and it is proposed that it be appointed as the national blood agency.

Committee's consideration and recommended amendments

Commencement date

The bill, as introduced, would come into effect on a date appointed by Order in Council. The BTT expressed concern at the lack of a firm commencement date, stating that this made it impossible to plan effectively for its dissolution. We recommend an amendment to clause 1 (2) to specify that the bill comes into force on the second day after it receives the Royal assent.

Ownership of blood

The BTT recommended that the status of donated blood be clarified and that the bill confirm NZBS' right to deal with blood. We consider that to include provision relating to the ownership of blood would be incompatible with the nature of donated blood as a gift to its recipient rather than to the NZBS. However, we support clarifying the full rights of an appointed entity to deal with blood and recommend that the bill be amended accordingly. A non-legislative measure relating to blood already exists in the fact that donors sign a declaration of understanding when donating blood.

Under the new structure, the NZBS will be responsible for all processes from collection through to the point where the blood is taken from a blood bank for administration to a person. We recommend the insertion of a provision that limits the liability of an entity carrying out blood and controlled human substance functions where an entity acts or does not act in order to carry out its functions appropriately.

The bill requires the NZBS to show respect for blood and controlled human substances as donations.

Accountability for blood services

We were interested in accountability for blood services in light of previous cases of blood transmitting Hepatitis C and HIV and recent concern over Creutzfeldt Jakob Disease. We accept Ministry of Health advice that the Minister of Health will be accountable for blood services. In addition, clear lines of accountability will be established between the Minister and the NZBS. The NZBS has been established as a Crown health enterprise (CHE). The Minister will be responsible for the performance of the NZBS as shareholding Minister and in relation to ensuring that it meets the terms and conditions of its appointment. The board of the NZBS will be accountable to the shareholding Ministers for the performance of the NZBS while the chief executive will be responsible to the board for the operation of the NZBS.

The submissions from the BTT, New Zealand Haemophilia Society Inc., and the DPA (New Zealand) Inc. questioned the use of the CHE model for the NZBS, given the commercial focus of CHEs. However, we consider that the CHE structure is an appropriate one for a number of reasons including:

- the shareholding Ministers have stated that CHEs are no longer required to make a profit;
- CHEs are the current providers of health services and this is the role of the NZBS;
- CHEs are accountable to shareholding Ministers and to Parliament and must undertake public reporting; and
- CHE performance is formally monitored by the Crown Company Monitoring Advisory Unit and reported to the shareholding Ministers.

Trading in blood and charging for blood

The Health Act 1956 prohibits trading in human blood, one's own blood or controlled human substances. The bill inserts an amended definition to the Act to extend the prohibition to include bone marrow from which constituents of blood can be derived. The Act also proscribes the collection of blood or controlled human substances. However, the bill would provide an exemption for entities appointed by the Minister of Health to collect and distribute blood and controlled human substances.

The bill would continue the existing prohibition against charging for the administration of blood and extend it to controlled human substances but authorises the Minister of Health to exempt persons from that prohibition.

Some submissions argued for the removal of the Minister of Health's power to issue exemptions to the prohibitions against trading in blood and charging for blood. However, there may be instances when it may be necessary to charge for blood such as a need to use expensive overseas blood products or in treating an overseas visitor or in autologous blood transfusions where they are not clinically necessary or medically indicated. It may also be necessary to trade in blood to reimburse the reasonable costs to a donor with specific bone marrow type, rare blood types or special plasma attributes. For these reasons, we support the continuance of the exemption provisions.

Dissolution of the BTT

The bill provides for the transfer of the assets and liabilities of the BTT to the NZBS, excluding any contract of services that is binding on the BTT. On the date that the bill comes into force, the BTT would be dissolved and its trustees cease to hold office.

The BTT raised concerns that the trustees may be personally liable for redundancy payments arising as a result of the dissolution of the Trust. We accept Ministry advice that trustees will not be personally liable for redundancy costs because of the current statutory protection of trustees and the fact that they would be acting to implement the new regime. In order to clarify the situation regarding redundancy, we recommend the removal of the exception of employment contracts from the assets and liabilities transferred from the BTT to the NZBS under the bill.

The BTT has expressed a desire to complete its end of year audit and reporting requirements. We therefore recommend that the bill be amended to specify that the trustees may continue to act as trustees specifically for that purpose, by appointment by the NZBS.

The bill provides protection to BTT trustees acting in pursuit of the purposes of the Trust, except in cases of bad faith or lack of reasonable care. However, the BTT has pointed out that this protection would not apply where the trustees act towards the dissolution of the Trust. While it is difficult to imagine that this poses

a significant risk to the trustees, we consider that it would be preferable to remove the risk altogether. We recommend that the bill be amended accordingly.

Appointment of agencies to collect blood

The bill would authorise the Minister of Health to appoint one or more entities to be responsible for collecting and distributing blood and controlled human substances. Currently, the NZBS will be responsible for controlled human substances but this is not its core function and the bill enables alternative arrangements to be made in the future through the appointment of other entities. Some submissions expressed concern at the use of the term 'entity' as being imprecise. The term has a wide legal meaning which we consider to be consistent with our expectations of its use in respect of the NZBS. It describes any body appointed by the Minister to carry out functions specified by the Minister. We are satisfied that the use of 'entity' is appropriate and do not recommend any changes. We note that the bill would require the Minister to present to the House a copy of the appointments and any amendments to them or revocations of them.

KEY TO SYMBOLS USED IN REPRINTED BILL
AS REPORTED FROM A SELECT COMMITTEE

Struck Out (Unanimous)

Subject to this Act,

Text struck out unanimously

New (Unanimous)

Subject to this Act,

Text inserted unanimously

~~(Subject to this Act,)~~

Words struck out unanimously

Subject to this Act,

Words inserted unanimously

HEALTH AMENDMENT

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A BILL INTITULED

An Act to amend the Health Act 1956

BE IT ENACTED by the Parliament of New Zealand as follows:

- 5 **1. Short Title and commencement**—(1) This Act may be cited as the Health Amendment Act 1998, and is part of the Health Act 1956* (“the principal Act”).

*R.S. Vol. 31, p. 467
Amendments: 1994, Nos. 37, 133, 137

Struck Out (Unanimous)

(2) This Act comes into force on a date to be appointed by the Governor-General by Order in Council.

New (Unanimous)

(2) This Act comes into force on the second day after the date on which it receives the Royal assent. 5

PART 1

AMENDMENTS TO PRINCIPAL ACT RELATING TO COLLECTION OF BLOOD

2. Duty to provide information for purposes of blood collection—The principal Act is amended by repealing section 22E, and substituting the following section: 10

“22E. The Minister may, at any time, by notice in writing, require a Crown health enterprise to provide to an entity appointed under **section 92H**, in such manner as the Minister specifies in the notice, such information as is specified in the notice, being health information of the kind referred to in paragraph (d) or paragraph (e) of the definition of that term in section 22B.” 15

3. Part 3A substituted—The principal Act is amended by repealing Part IIIA, and substituting the following Part: 20

“PART 3A

“TRADING IN HUMAN BLOOD AND CONTROLLED HUMAN SUBSTANCE

“92A. **Interpretation**—In this Part, unless the context otherwise requires,— 25

“‘Appointed entity’ means an entity appointed under **section 92H**:

“‘Blood’ means human blood; and—

“(a) Includes the following: 30

“(i) A substance derived from blood:

“(ii) A human organ, or human bone marrow, or human tissue, including the placenta, of a kind that is suitable as a source from which to derive a constituent of blood that may be used therapeutically or in the 35

preparation of a substance for therapeutic use:

“(iii) A constituent of an organ, bone marrow, or tissue described in **subparagraph (ii)**:

5 “(iv) Human haematopoietic stem cells, or a constituent of human haematopoietic stem cells, that may be used therapeutically or in the preparation of a substance for therapeutic use; but

10 “(b) Does not include the following:

“(i) Any substance derived from blood, a human organ, human bone marrow, human tissue, or human haematopoietic stem cells that is intended for use in quality control or as a diagnostic product:

15 “(ii) Any substance containing a fraction of blood, a human organ, human bone marrow, human tissue, or human haematopoietic stem cells that the Governor-General by Order in Council declares not to be blood for the purposes of this Part:

20 “ ‘Controlled human substance’—

“(a) Means—

25 “(i) Human bone marrow (other than human bone marrow referred to in **paragraph (a) (ii)** of the definition of the term ‘blood’ in this section) that may be used therapeutically or in the preparation of a substance for therapeutic use; or

30 “(ii) A constituent of human bone marrow described in **subparagraph (i)**; or

35 “(iii) Any other substance of the human body that may be used therapeutically or in the preparation of a substance for therapeutic use and that the Governor-General by Order in Council declares to be included in this definition; but

“(b) Does not include—

40 “(i) A product derived from any controlled human substance that is intended for use in quality control or as a diagnostic product; or

“(ii) A substance containing a fraction of any controlled human substance that the Governor-General by Order in Council declares not to be a controlled human substance for the purposes of this Part. 5

“92B. **Trading in own blood or controlled human substance prohibited**—(1) No person may require or accept financial or other consideration for the blood or any controlled human substance of that person.

“(2) No person may provide financial or other consideration for the taking of blood or any controlled human substance from the body of a person for administration to another person. 10

“(3) Every person commits an offence and is liable to a fine not exceeding \$1,000 who contravenes **subsection (1)**. 15

“(4) Every person commits an offence and is liable to imprisonment for a term not exceeding 6 months or a fine not exceeding \$5,000 who contravenes **subsection (2)**.

“92C. **Collection of blood or controlled human substance**—(1) No person may take blood or any controlled human substance from the body of a person for the purpose of obtaining that blood or that substance for administration to another person. 20

“(2) Every person commits an offence and is liable to imprisonment for a term not exceeding 6 months or a fine not exceeding \$5,000 who contravenes **subsection (1)**. 25

“(3) **Subsection (1)** does not apply to—

“(a) An appointed entity that is authorised to take blood and controlled human substances from persons; or

“(b) An employee or agent of an appointed entity who is authorised by the entity to take blood or controlled human substances on behalf of the entity, if the entity has the power to authorise employees or agents to do so. 30

“(4) For the purposes of **subsection (3)**, an appointed entity is authorised to take blood and controlled human substances, and has the power to authorise employees and agents of the entity to do so, unless the notice by which the entity is appointed provides otherwise. 35

“(5) Every appointed entity described in **subsection (3) (a)** and every employee or agent described in **subsection (3) (b)** who takes blood or any controlled human substance must give due recognition to the fact that the blood or controlled human substance has been donated. 40

“92D. **Charging for administered blood or controlled human substance**—(1) No person who administers blood or any controlled human substance to another person may require or accept financial or other consideration for that blood or that substance from the person to whom it is administered.

5 “(2) Every person commits an offence and is liable to imprisonment for a term not exceeding 6 months or a fine not exceeding \$5,000 who contravenes **subsection (1)**.

10 “92E. **Exemptions**—(1) The Minister may, in his or her discretion and on such terms and conditions (if any) as the Minister thinks fit, by notice in writing, exempt a person or persons or class of persons from compliance with any or all of the provisions of **sections 92B (1), 92B (2), and 92D (1)**, and may in the same manner vary or revoke any such exemption.

15 “(2) Where a notice is given under **subsection (1)**, the Minister must as soon as practicable after giving the notice, publish in the *Gazette* and present to the House of Representatives a copy of the notice.

20 “92F. **Unauthorised advertising prohibited**—(1) No person may distribute an advertisement relating to the purchase or sale in New Zealand of blood or a controlled human substance.

“ (2) For the purposes of **subsection (1)**, ‘distribute’ means—

25 “(a) To publish or otherwise disseminate, by newspaper, magazine, periodical, book, billboard, radio, television, cinematograph film, or any other means whatever; or

“(b) To exhibit to public view in any premises or place; or

30 “(c) To deposit in any area, yard, garden, or enclosure comprising part of or appurtenant to any premises.

“ (3) Every person commits an offence and is liable to imprisonment for a term not exceeding 3 months or a fine not exceeding \$2,500 who contravenes **subsection (1)**.

35 “92G. **Liability of employers, principals, and directors**—(1) An act done by a person as the employee (‘the employee’) of another person (‘the employer’) is for the purposes of an offence against this Part to be treated as done by the employer as well as by the employee, if—

“ (a) The employer approved of the act; or

40 “ (b) The employer knew that the act was to be done or was being done and failed to take all reasonable steps to prevent it.

“(2) An act done by a person as the agent (‘the agent’) of another person (‘the principal’) is for the purposes of an offence against this Part to be treated as done by the principal as well as by the agent, if—

“(a) The principal approved of the act; or 5

“(b) The principal knew that the act was to be done or was being done and failed to take all reasonable steps to prevent it.

“(3) Where a body corporate is convicted of an offence against this Part, a director of the body corporate is to be treated as having committed the same offence if— 10

“(a) The director approved of the act that constituted the offence; or

“(b) The director knew the offence was to be or was being committed and failed to take all reasonable steps to prevent it. 15

“(4) In **subsection (3)**, the term ‘director’ includes a person who is concerned in the management of a body corporate.

“92H. **Appointed entities to collect and distribute blood and controlled human substances**—(1) The Minister may from time to time, by notice in writing, appoint 1 or more entities to be responsible for the performance of such functions in relation to blood and controlled human substances as are specified in the notice. 20

“(2) An appointment under **subsection (1)** may be subject to such terms and conditions as are specified in the notice appointing the appointee. 25

“(3) The Minister may from time to time, by notice in writing, revoke, vary, or add to—

“(a) Any of the functions for which an appointee is responsible: 30

“(b) Any of the terms or conditions of the appointment.

“(4) The Minister may, at any time, by notice in writing, revoke an appointment made under **subsection (1)**.

“(5) A notice given under this section takes effect on the date specified for the purpose in the notice or, if no date is specified for that purpose, on the day after the date on which it is issued. 35

New (Unanimous)

“(5A) An appointed entity that performs, in accordance with a notice given under this section, any function in relation to blood or a controlled human substance, is entitled to do 40

New (Unanimous)

anything, or refrain from doing anything, that is necessary or desirable for the purpose of performing that function, unless a notice given under this section provides otherwise.

5 “(6) As soon as practicable after the Minister gives a notice under **subsection (1)** or **subsection (3) (a)** or **subsection (4)**, the Minister must—

“(a) Publish a copy of it in the *Gazette*; and

“(b) Present a copy of it to the House of Representatives.

10 “92i. **Exemption from Part II of Commerce Act 1986**—
Nothing in Part II of the Commerce Act 1986 applies to—

“(a) Any contract, arrangement, understanding, or covenant in relation to blood or controlled human substances that—

15 “(i) At the time it is entered into is, or is of a class that is, approved for the purposes of this section by the Governor-General by Order in Council; or

20 “(ii) Is entered into by a person who (at the time it is entered into) is, or is of a class that is, approved for the purposes of this section by the Governor-General by Order in Council; or

“(b) Any act done to give effect to a provision of any contract, arrangement, understanding, or covenant to which **paragraph (a)** applies.”

25 *New (Unanimous)*

“92j. **Protection of appointed entities**—(1) Section 129 applies to any appointed entity, and to any employee or agent of an appointed entity, who, in pursuance or intended pursuance of a provision in a notice given under **section 92h**, does
30 any act, or fails or refuses to do any act, in relation to blood or a controlled human substance.

“(2) For the purpose of applying section 129 in accordance with **subsection (1)**, a provision in a notice given under **section 92h** is to be regarded as a provision of this Act.”

PART 2

PROVISIONS RELATING TO DISSOLUTION OF BLOOD TRANSFUSION TRUST

4. Vesting of assets of blood transfusion trust—(1) In this section and in sections 6, 6A, 6B, and 7, the term “the Trust” means the blood transfusion trust established under section 92J of the principal Act (as in force before the commencement of this Act). 5

(2) On the date that this Act comes into force, the assets and the liabilities of the Trust (*other than assets and liabilities described in subsection (3)*) vest in the Crown health enterprise known as New Zealand Blood Service Limited freed of all trusts affecting those assets or liabilities. 10

Struck Out (Unanimous)

(3) The assets and liabilities vested by subsection (2) do not include any contract of service that is binding on the Trust or on a trustee of the Trust. 15

(4) Sections 6, 8, and 9, and the First Schedule, of the Health Reforms (Transitional Provisions) Act 1993 apply in respect of the vesting of assets and liabilities by subsection (2) as if— 20

- (a) Those assets and liabilities were transferred under section 5 of that Act; and
- (b) The Trust were the transferor and New Zealand Blood Service Limited were the transferee under a proposal approved by an Order in Council made under that section. 25

New (Unanimous)

(4A) Unless in any case the context otherwise requires, every reference to the Trust in any document (other than an enactment) is, after the commencement of this Act, to be read as a reference to New Zealand Blood Service Limited. 30

(5) In this section, unless the context otherwise requires, the terms “assets”, “liabilities”, and “transfer” have the same meaning as they have in section 2 of the Health Reforms (Transitional Provisions) Act 1993. 35

5. Respect for donated blood—(1) New Zealand Blood Service Limited must, in managing any blood or controlled human substance vested in it by section 4, give due recognition to

the fact that the blood or controlled human substance has been donated.

5 (2) In this section, the terms “blood” and “controlled human substance” have the same meaning as they have in **section 92A** of the principal Act.

6. Blood transfusion trust dissolved—(1) On the date that this Act comes into force the Trust is dissolved.

(2) On the date that this Act comes into force every trustee of the Trust ceases to hold office as trustee of the Trust.

10 *New (Unanimous)*

6A. Final report of Trust—(1) Subject to **section 6B**, New Zealand Blood Service Limited (in this section and in **section 6B** referred to as the transferee) must prepare the Trust’s final report within 3 months after the date on which this Act comes into force.

15 (2) The final report referred to in **subsection (1)** consists of—

(a) An annual report setting out the information specified in section 41 of the Public Finance Act 1989 in relation to the Trust’s operations for the period beginning with 1 July 1997 and ending with the close of the day immediately before the commencement of this Act; and

20 (b) The Trust’s financial statements for that period, which must—

25 (i) Set out the information specified in section 41 of the Public Finance Act 1989; and

(ii) Be accompanied by an audit opinion prepared by the Audit Office in accordance with section 43 of that Act.

30 (3) The final report must be signed on behalf of the transferee or by the persons appointed, under **section 6B**, to prepare the report, as the case may require.

(4) As soon as practicable after receiving a copy of the final report, the Minister must present the report to the House of Representatives.

6B. Appointment of persons to discharge reporting obligations—(1) In any case where the transferee is, because of **section 6A** or the operation of **section 4 (2)**, required to prepare a report concerning the Trust, the transferee may, by notice in

New (Unanimous)

writing, appoint 2 persons, eligible to be appointed under **subsection (2)**, to prepare that report.

(2) The following persons are eligible to be appointed under **subsection (1)**:

- (a) Two former trustees of the Trust; or
- (b) One former trustee of the Trust and 1 former executive officer of the Trust.

(3) When a report prepared by persons appointed under **subsection (1)** is presented in properly completed form to the Minister, the obligation of the transferee to prepare the report is discharged.

(4) If in any case a person appointed under **subsection (1)** is, at any time, unable or unwilling to prepare the report required by the appointment, the transferee may—

- (a) Replace that person by appointing another person who is, in the circumstances of the case, eligible to be appointed under **subsection (2)** to prepare the report; or
- (b) Terminate the appointment of both persons appointed to prepare the report and—
 - (i) Appoint 2 other persons who are eligible to be appointed under **subsection (2)** to prepare the report; or
 - (ii) Prepare the report itself.

7. Protection of former trustees—(1) Section 92L of the principal Act (as in force before the commencement of this Act) continues to apply to former trustees of the Trust as if this Act had not been passed.

New (Unanimous)

(2) If, in the period commencing on 31 March 1998 and ending with the close of the day immediately before the commencement of this Act, a former trustee or officer of the Trust did an act, or failed or refused to do an act, in order to prepare for, or assist in, the implementation of this Act, the trustee or officer is under no civil or criminal liability for doing, or failing or refusing to do, the act.

(3) **Subsection (2)** does not exclude the liability of a former trustee or officer of the Trust for doing, or failing or refusing to do, an act in bad faith or without reasonable care.

New (Unanimous)

(4) **Subsection (2)** applies despite any provision in the deed by which the Trust was established.

5 **8. Consequential amendment to Ombudsmen Act 1975**—The Ombudsmen Act 1975 is consequentially amended by omitting from Part II of the First Schedule the item relating to the blood transfusion trust established under section 92J of the Health Act 1956.

10 **9. Consequential amendment to Public Finance Act 1989**—The Public Finance Act 1989 is consequentially amended by omitting from the Fourth, Fifth, and Sixth Schedules the item relating to the blood transfusion trust established under section 92J of the Health Act 1956.

15 **10. Consequential repeals**—The following enactments are consequentially repealed:
 (a) Section 27 of the Health Amendment Act 1993;
 (b) Section 2 of the Health Amendment Act (No. 3) 1994.