SENATE STANDING COMMITTEE

FOR THE

SCRUTINY OF BILLS

THIRD REPORT

OF

2002

20 March 2002

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ISSN 0729-6258

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MEMBERS OF THE COMMITTEE

Senator B Cooney (Chairman)
Senator W Crane (Deputy Chairman)
Senator T Crossin
Senator J Ferris
Senator B Mason
Senator A Murray

TERMS OF REFERENCE

Extract from **Standing Order 24**

(1)

(a) At the commencement of each Parliament, a Standing Committee for the Scrutiny of Bills shall be appointed to report, in respect of the clauses of bills introduced into the Senate, and in respect of Acts of the Parliament, whether such bills or Acts, by express words or otherwise:

(i) trespass unduly on personal rights and liberties;

(ii) make rights, liberties or obligations unduly dependent upon insufficiently defined administrative powers;

(iii) make rights, liberties or obligations unduly dependent upon non-reviewable decisions;

(iv) inappropriately delegate legislative powers; or

(v) insufficiently subject the exercise of legislative power to parliamentary scrutiny.

(b) The Committee, for the purpose of reporting upon the clauses of a bill when the bill has been introduced into the Senate, may consider any proposed law or other document or information available to it, notwithstanding that such proposed law, document or information has not been presented to the Senate.

SENATE STANDING COMMITTEE FOR THE SCRUTINY OF BILLS

THIRD REPORT OF 2002

The Committee presents its Third Report of 2002 to the Senate.

The Committee draws the attention of the Senate to clauses of the following bills which contain provisions that the Committee considers may fall within principles 1(a)(i) to 1(a)(v) of Standing Order 24:

Criminal Code Amendment (Anti-hoax and Other Measures) Bill 2002

Therapeutic Goods Amendment Bill (No. 1) 2002

Veterans' Affairs Legislation Amendment (Further Budget 2000 and Other Measures) Bill 2002

Criminal Code Amendment (Anti-hoax and Other Measures) Bill 2002

Introduction

The Committee dealt with this bill in *Alert Digest No. 1 of 2002*, in which it made various comments. The Attorney-General responded to those comments in a letter dated 8 March 2002.

In its *Second Report of 2002*, the Committee sought further advice from the Attorney-General in relation to retrospectivity. The Attorney-General has responded in a letter dated 15 March 2002. A copy of the letter is attached to this report. An extract from the *Second Report* and relevant parts of the Attorney-General's response are discussed below.

Extract from Alert Digest No. 1 of 2002

This bill was introduced into the House of Representatives on 13 February 2002 by the Attorney-General. [Portfolio responsibility: Attorney-General]

The bill proposes to amend:

- the *Criminal Code Act 1995* to add new offences relating to the sending of dangerous, threatening and hoax material through the post or similar services; and
- the *Crimes Act 1914* to replace existing outdated postal offences.

The bill proposes that federal offences cover the use of all postal and other like services, not just Australia Post as at present. The bill also increases the penalties for the offences of sending threatening, dangerous or hoax material through postal and similar services to more appropriate levels which reflect the harm that can be caused by material.

Legislation by press release
Schedule 1

Schedule 1 to this bill proposes to amend the Criminal Code by creating a new offence dealing with the use of the post to send hoax material. These amendments are expressed to commence at 2pm on 16 October 2001, thus retrospectively creating a criminal offence. The justification given for this retrospectivity (as set out in the Explanatory Memorandum) is that this is the time and date at which the Prime Minister publicly announced that he would introduce such provisions.

Notwithstanding the seriousness of the conduct at which this bill is directed, the retrospective creation of a criminal offence is similarly a serious matter. The bill itself is a very clear example of "legislation by press release" – a practice which the Committee has consistently brought to the attention of Senators. As the Committee has previously noted, "the fact that a proposal to legislate has been announced is no justification for treating that proposal as if it were enacted legislation".

The Committee draws Senators' attention to this provision, as it may be considered to trespass unduly on personal rights and liberties, in breach of principle 1(a)(i) of the Committee's terms of reference.

Relevant extract from the response from the Attorney-General dated 8 March 2002

> The Committee observed that the retrospective creation of a criminal offence is a serious matter and further stated that the announcement of a proposal to legislate provides no justification for treating that proposal as if it were enacted legislation. The Government agrees that the retrospective creation of an offence is a serious matter. However, in the case of the new hoax offence there are exceptional circumstances justifying retrospectivity. During October 2001, hoaxes were causing significant concern and disruption. Following the terrorist attacks of 11 September 2001, police investigated over 3000 incidents involving suspicious packages of which over 1000 involved anthrax hoaxes. As a result of these hoaxes, mail centres and offices had to be decontaminated, security measures enhanced and emergency services diverted from other duties. These false alarms cost the community both in terms of unnecessary use of public resources and in terms of increased fear and anxiety.
>
> As stated in the Explanatory Memorandum, it was necessary to ensure that such conduct was adequately deterred in the period before the resumption of Parliament. The Prime Minister's announcement of 16 October 2001 provided this deterrence. The Prime Minister's announcement was in very clear terms, and received immediate, widespread publicity. The amendments operate only from the time of that announcement.

It has been accepted that amendments to taxation law may apply retrospectively where the Government has announced, by press release, its intention to introduce a Bill to amend taxation law, and the Bill is introduced within 6 months after the date of the announcement (Senate Resolution of 8 November 1988). The new hoax offence was introduced within 4 months after the date of the Prime Minister's announcement.

An additional consideration is that there is no circumstance in which the perpetration of a hoax that a dangerous or harmful thing has been sent could be considered a legitimate activity in which a person was entitled to engage pending these amendments. The amendments do not retrospectively abrogate a legitimate right or entitlement. For all these reasons, the retrospective application of these amendments is not considered to contravene fundamental principles of fairness or due process.

The Committee thanks the Attorney-General for this response which acknowledges that the retrospective creation of an offence is a serious matter. Specifically, the Attorney draws attention to the apparently analogous practice of legislation by press release when retrospectively amending taxation law, and states that there are no circumstances in which perpetrating a hoax "could be considered a legitimate activity" and that, therefore, the amendments "do not retrospectively abrogate a legitimate right or entitlement".

The Committee has often expressed concern at the prevalence of 'legislation by press release' in amendments to taxation law. Taxation law is concerned with financial arrangements, and appropriate behaviour in relation to them. Imprecision in the commencement of amendments may have behavioural and financial consequences. Taxation law is essentially regulatory in nature. However, these amendments propose to retrospectively create criminal offences – a much more serious issue when considering the merits of retrospectivity. The practices developed for amending taxation law are not an appropriate precedent for amendments which go to criminal responsibility.

In addition, while it is undeniable that perpetrating a hoax cannot be considered a 'legitimate' activity, what this bill proposes to do is retrospectively declare it to be 'criminal' activity – again, a different, and more serious, issue of principle. Not every 'illegitimate' activity is 'criminal' activity. Declaring something 'illegitimate', and then retrospectively declaring it to be a crime, would seem to establish an unfortunate and undesirable precedent. A crime may be created by a simple announcement. The Committee **asks the Attorney-General** to reconsider these provisions so that, before they become law, they can be adequately scrutinised by both the House of Representatives and the Senate.

For these reasons, the Committee continues to draw Senators' attention to this provision, as it may be considered to trespass unduly on personal rights and liberties, in breach of principle 1(a)(i) of the Committee's terms of reference.

Relevant extract from the response from the Attorney-General dated 15 March 2002

> I wish to reiterate that the terms of the anti-hoax offence and its retrospectivity were very clearly foreshadowed by the Prime Minister on 16 October 2001. The new offence is very similar to the existing Crimes Act 1914 offence, with complete overlap in most circumstances that are likely to arise. I also note that the Prosecution Policy of the Commonwealth, and the public interest test that it incorporates, will apply to any proposed prosecution of this offence.

The Committee thanks the Attorney-General for this further response, but reiterates its concern at the use of retrospectivity in the creation of criminal offences. Ultimately, this is an issue best left for resolution by the Senate. The Committee **seeks the Attorney-General's assurance** that these provisions will not be used as a precedent for the retrospective creation of criminal offences in other circumstances.

Given the seriousness with which it views the retrospective creation of criminal liability, the Committee continues to draw Senators' attention to this provision, as it may be considered to trespass unduly on personal rights and liberties, in breach of principle 1(a)(i) of the Committee's terms of reference.

Creation of criminal offence by regulation
Proposed new subsection 471.15(1)

Clause 6 of Schedule 2 to this bill proposes to insert a new subsection 471.15(1) in the Criminal Code. This will allow for the further definition, by regulation, of those dangerous or harmful substances the posting of which will be an offence. To that extent, this subsection allows for the creation of a criminal offence by Executive Order – in a regulation – rather than by primary legislation, which would be debated in both Houses of the Parliament.

This proposed new provision is apparently in the same form as the existing section 85X of the *Crimes Act 1914*. Nevertheless, the Committee **seeks the Minister's** advice as to why it is appropriate that an offence of such seriousness should be addressed through subordinate, rather than primary, legislation.

The Committee draws Senators' attention to the provision, as it may be considered to delegate legislative powers inappropriately, in breach of principle 1(a)(iv) of the Committee's terms of reference.

Relevant extract from the response from the Attorney-General dated 8 March 2002

> The Committee also sought my advice as to why it is appropriate that proposed subsection 471.15(1), which makes it an offence to cause an explosive or a dangerous or harmful substance to be carried by post, provides for dangerous or harmful substances to be specified in regulations. As stated in the Explanatory Memorandum, it is necessary to have the scope to add items by regulation, because the specific items that are prohibited for posting with Australia Post may change at short notice, including where new types of goods come into existence.
>
> The proposed offence replicates the existing offence in subsection 85X(2) of the *Crimes Act 1914*, which also relies on the prescription of dangerous substances in regulations. The current descriptions of dangerous substances in the regulations are based on the Technical Instructions for the Safe Transport of Dangerous Goods by Air published by the International Civil Aviation Organisation, which are updated every two years. By continuing to allow for the prescription of dangerous substances in regulations, proposed subsection 471.15(1) will enable the list of dangerous substances to be revised quickly to ensure consistency with international standards.
>
> I hope that this information is of assistance to the Committee.

The Committee thanks the Attorney-General for this further response. While mindful of the precedent provided by the existing subsection 85X(2) of the *Crimes Act 1914*, the Committee continues to have concerns where serious criminal offences can be created or modified by regulation.

For this reason, the Committee continues to draw Senators' attention to this provision, as it may be considered to delegate legislative powers inappropriately, in breach of principle 1(a)(iv) of the Committee's terms of reference.

Relevant extract from the response from the Attorney-General dated 15 March 2002

> The provision for proscription under regulation in proposed section 471.15 simply replicates an equivalent provision in the existing section 85X of the Crimes Act 1914. The capacity to proscribe banned substances that are dangerous or harmful is an essential piece of flexibility to deal with changing circumstances. The parameters of the offence are clearly marked out by the 'dangerous or harmful' test in the primary legislation, allowing full Parliamentary scrutiny of the nature of the offence. Regulations made to give effect to the offence would, of course, be disallowable.
>
> If it would assist the Committee to receive a briefing from officers of my Department in relation to the Bill, I would be pleased to facilitate this.

The Committee thanks the Attorney-General for this response. The Committee recognises that proposed new section 471.15 replicates an existing provision in the Crimes Act, and that any regulations which are made to give effect to the offence will be disallowable. However, the Committee continues to have concerns where serious criminal offences can be created or modified by regulation. Ultimately, this is an issue best left for resolution by the Senate.

For this reason, the Committee continues to draw Senators' attention to this provision, as it may be considered to delegate legislative powers inappropriately, in breach of principle 1(a)(iv) of the Committee's terms of reference.

Therapeutic Goods Amendment Bill (No. 1) 2002

Introduction

The Committee dealt with this bill in *Alert Digest No. 2 of 2002*, in which it made various comments. The Parliamentary Secretary to the Minister for Health and Ageing has responded to those comments in a letter dated 19 March 2002. A copy of the letter is attached to this report. An extract from the *Alert Digest* and relevant parts of the Parliamentary Secretary's response are discussed below.

Extract from Alert Digest No. 2 of 2002

This bill was introduced into the House of Representatives on 20 February 2002 by the Parliamentary Secretary to the Minister for Health and Ageing. [Portfolio responsibility: Health and Ageing]

The bill proposes to amend the *Therapeutic Goods Act 1989* to strengthen the Commonwealth's ability to plan for and respond to national emergencies, including acts of bioterrorism that involve the deliberate release of chemical, biological or radiological substances or the emergence of a new, highly contagious disease.

The bill permits the Minister to make a decision, either in the case of an actual emergency or possible emergency, to allow the importation, manufacture or supply of unapproved therapeutic goods such as antibiotics, vaccines and chemical antidotes that are needed to treat large numbers of patients.

The bill also provides for the strengthening of offence provisions and record keeping and reporting requirements in the Act to ensure adequate control over the importation, manufacture and use of such unapproved therapeutic goods.

Non-disallowable declarations
Proposed new subsections 18A(10) and (11)

Item 1 of Schedule 1 to this bill proposes to insert a new section 18A in the *Therapeutic Goods Act 1989*. This new section gives the Minister power to exempt specific therapeutic goods, or a specific class of therapeutic goods, from the registration and listing requirements in the Act in circumstances of a threat to public health.

These registration and listing requirements were presumably included in the Act in the public interest. Where it is proposed that they be bypassed, that same public interest would normally require a cautious approach – for example, in the circumstances of emergency contemplated by the bill perhaps by including measures such as criteria to determine when exemptions should be granted.

Proposed new subsections 18A(10) and (11) require a document containing particulars of the exemption, and any subsequent decision about revoking or varying any conditions of that exemption, to be published in the *Gazette* and tabled in the Parliament. However, the Explanatory Memorandum states that the declaration itself need not be either gazetted or tabled, because "it would not be in the interests of public safety to release every detail of some conditions, such as the location where specific goods are being stored".

The Committee notes that these Ministerial declarations, which allow for the granting of exemptions from the legislation, and which are therefore apparently legislative in character, are not disallowable instruments. The Committee, therefore, **seeks the Minister's advice** as to why these declarations are not subject to Parliamentary scrutiny, and whether any guidelines will be produced to determine when s 18A exemptions are to be granted.

Pending the Minister's response, the Committee draws Senators' attention to these provisions as they may be considered to insufficiently subject the exercise of delegated legislative power to Parliamentary scrutiny, in breach of principle 1(a)(v) of the Committee's terms of reference.

Relevant extract from the response from the Parliamentary Secretary

Thank you for your letter of 14 March 2002 relating to Therapeutic Goods Amendment Bill (No.1) 2002.

In that letter the Committee raised questions about the need to make the decisions of the Minister under proposed section 18A disallowable. These are decisions to allow certain therapeutic goods intended for supply to the general public to "by-pass" the registration and listing requirements. The Committee also raised questions about the strict liability offences in proposed subsections 20(2C) and 30H(3).

Non-disallowable decisions
Proposed new subsections 18A(10) and (11)

The object of the *Therapeutic Goods Act 1989* (the Act) is to provide for the establishment and maintenance of a national system of controls relating to the

quality, safety, efficacy and timely availability of therapeutic goods to be used in Australia. This normally involves the evaluation by the Therapeutic Goods Administration, or assessment against statutory criteria, of goods required by the Act to be registered or listed in the Australian Register of Therapeutic Goods (the Register). However, the Act also makes provision for therapeutic goods to be exempted from the registration and listing requirements in certain circumstances. For example, under the Special Access Scheme seriously ill persons or terminally ill patients can be granted access to goods that have not been assessed or approved for quality, safety or efficacy, where availability to such patients may outweigh the risk of their being supplied with unapproved medicines.

The new provisions in section 18A address unusual circumstances that may not eventuate. That section is concerned with the availability of therapeutic goods that have not been approved for supply in Australia for the treatment of, for example, an outbreak of an uncommon but serious disease including the consequences of an act of bioterrorism. Diseases in mind include anthrax and smallpox. Appropriate response times in relation to certain bioterrorist events may be measured in minutes. The national interest issue to be weighed is whether it is preferable to have no appropriate goods available to treat the Australian public in the event of the kinds of emergency envisaged by the legislation or, whether it is preferable to have appropriate goods available even though those goods have not been evaluated for registration in Australia. It might be borne in mind that, whilst the goods that may be exempted are not registered in Australia, there may be circumstances in which they may have been evaluated and approved for use in other countries. It is also envisaged that goods which are imported and stockpiled may become registered whilst stockpiled. In that event, under proposed subsection 18A(5) the exemption would cease to apply.

Whilst the Minister's powers under section 18A bypass the normal evaluation and registration requirements, the exercise of the power will ensure the availability of therapeutic goods in unusual circumstances where there is a national emergency. In the event of a potential threat, there would be a justifiable expectation that measures be put in place to reduce the risk to the general public.

The Minister's power to exempt goods from the operation of Division 2 of Part 3 of the Act may be described as falling into two different circumstances, as set out below.

In the event of an actual emergency envisaged by new paragraph 18A(2)(b) immediate action is needed and the exemption may have been made and the goods supplied to the public and perhaps used, perhaps before the 5 sitting days within which these instruments are required to be tabled. To make a decision subject to disallowance where the decision would have already been acted upon and the action perhaps completed would not appear to be practical. Parliament will, however, be in a position to scrutinise the decision taken to exempt goods in such circumstances because of the requirement to table such decisions.

In the event of a potential threat, once a decision to stockpile is made, it is expected that events may occur so quickly that disallowance may not affect the import or manufacture of the product. Also, a decision to disallow (which could have the effect of increasing the risk that the Australian public may be without sufficient supplies of therapeutic goods that would be needed in an emergency) would presumably be made on one of two grounds: either the particular goods exempted were inappropriate or that no potential threat exists.

In relation to the particular therapeutic goods that are the subject of the exemption, only a very limited range of goods are known to be suitable in the event of the kind of emergencies currently envisaged. In determining whether or not there is a need to stockpile in anticipation of a potential threat, the Minister has available the advice of his or her Department and State government authorities that have the expertise in dealing with and making judgements about national emergencies, including acts of terrorism. The Department also has access to specialist professional advice about the appropriateness of therapeutic goods that are to be exempted.

Guidelines will be developed in relation to what constitutes a potential threat or an actual emergency. No criteria were included in the legislation in order to allow flexibility in dealing with new threats, such as threats from new diseases or bioterrorist activities that cannot be foreseen at the present time.

The delegation of the Minister's power under proposed paragraph 18A(2)(a) to exempt certain goods to create a preparedness to deal with a potential threat has been restricted to the Secretary of the Department of Health and Ageing. The restriction on delegation in this way imposes limits on who can exercise the power.

It is envisaged that decisions made under the new provisions would be subject to a high level of political and parliamentary scrutiny. It should also be noted that the Minister can impose time limits on exemptions, revoke exemptions and impose additional conditions on exemptions.

The Committee thanks the Parliamentary Secretary for this response.

Strict liability offence
Proposed new subsections 20(2C) and 30H(3)

Among other things, this bill proposes to create a number of new offences. Proposed new subsection 20(2C) creates an offence of importing therapeutic goods subject to a section 18A exemption in breach of a condition of that exemption. Proposed new subsection 20(2D) declares this to be an offence of strict liability.

Similarly, proposed new subsection 30H(3) creates an offence of failing to keep proper records where this is a condition of an exemption under section 18A. Proposed new subsection 30H(4) declares this to be an offence of strict liability.

In each case, the Explanatory Memorandum notes that the bill creates a fault liability offence (with a penalty of 240 penalty units, and with strict liability applying to the element that the goods are exempt goods under section 18A) and an accompanying strict liability offence (with a lower penalty of 60 penalty units). With regard to the proposed section 20(2C) offence, the Explanatory Memorandum states that:

Experience in the past with prosecutions under subsection 20(1) has shown that it is often difficult to secure a conviction because of problems with proving intent. Failure to secure a prosecution has resulted in seized unapproved therapeutic goods having to be returned to an importer … This poses a risk to public health because it is difficult to monitor these returned unapproved goods which could subsequently be released into the market place. The new strict liability offence in subsection 20(2C) is intended to overcome this problem in relation to goods that are the subject of an exemption under section 18A. These goods in particular may pose an even greater threat to public health because they may contain live vaccines that could, in themselves, be used for terrorist activities.

With regard to proposed new subsection 30H(3), the Explanatory Memorandum states that

The two offences, and in particular the high penalty in the first [fault liability offence], recognise the importance of the record keeping requirements. If adequate records are not kept in relation to these goods it will be very difficult to maintain proper control over their supply, handling, use, storage or disposal and there could be a resulting risk to public health if these matters cannot be monitored properly.

The Committee acknowledges that this bill is intended to strengthen the ability of the Commonwealth to respond to national emergencies, such as bio-terrorism, in which there is the potential for large numbers of people to require emergency pharmaceutical treatment. This is an important consideration.

However, with regard to proposed subsection 20(2C) it seems that there might be a danger of criminalising conduct which might otherwise have an innocent explanation (ie importing therapeutic goods while unaware that they are subject to an exemption). If the mischief here is the risk to public health as a result of the possible return to an importer of unapproved therapeutic goods then, arguably, the bill might address this by amending requirements elsewhere in the Act (for example, by providing for the retention of unapproved goods subject to an exemption until approval had been granted).

And with regard to proposed subsection 30H(3), the Explanatory Memorandum does not explain why an offence against this subsection should be an offence of strict liability. The Committee, therefore, **seeks the Minister's advice** as to these matters.

Pending the Minister's response, the Committee draws Senators' attention to these provisions as they may be considered to trespass unduly on personal rights and liberties, in breach of principle 1(a)(i) of the Committee's terms of reference.

Relevant extract from the response from the Parliamentary Secretary

Strict Liability Offence
Proposed new subsection 20(2C)

The Committee is concerned that, with regard to proposed subsection 20(2C), there might be a danger of criminalising conduct which might otherwise have an innocent explanation.

It is unlikely that the kinds of therapeutic goods which are likely to be the subject of an exemption under section 18A could be imported under circumstances where a legitimate importer could be unaware of the regulatory status of the goods. The nature of the goods to be used for their intended purposes is not such that they are readily available for purchase for such use by the general public. Because of the potential for some products, such as smallpox vaccine, to be used in terrorist activities, strict controls are imposed on the goods to ensure that they are not diverted for illegal purposes and that they are imported into Australia strictly for use to meet emergency needs. In fact, worldwide there may be only one or two legitimate manufacturers and suppliers of some of the goods that may be needed.

In the unlikely event that an importer mistakenly imports goods that are the subject of a section 18A exemption, the Criminal Code provides a defence of mistake of fact.

The inclusion of a strict liability provision was also considered the best mechanism for ensuring that goods, imported in breach of a condition of the section18A exemption, could be seized in order to ensure that they did not find their way into the marketplace. The suggestion that amendments might be made to the Act to provide for the retention of the goods by the authorities until an approval has been granted is not consistent with the scheme provided for in section 18A. Goods exempted under section 18A are not approved - they are exempted from the requirement to be entered on the Register. The exemption can be made subject to conditions. Depending on the condition of the exemption applying to the particular goods, there could be situations where it may never be appropriate to release certain seized goods. One example would be where a condition of the exemption required the goods to be sourced from one particular overseas supplier only (because the Minister could only be assured that goods from that particular supplier were likely to be safe, efficacious and of good quality). In such cases goods imported from another supplier may never be released for storage or supply in Australia.

Subsection 30H(3)

The Committee seeks advice on why an offence against proposed subsection 30H(3) should be an offence of strict liability. Keeping track of the exempt goods is considered to be of critical importance because of the nature of the goods that will be the subject of an exemption under proposed section 18A, and the risk that the goods or quantities of the goods could be diverted and used for purposes other than the mischief the goods are intended to address. Apart from ensuring as far as possible that the goods will be appropriately used to maximise their beneficial effect, these goods have not been evaluated for safety or efficacy for their intended use. The extent of their distribution and supply is information that is required to manage properly the use of the products. For this reason, it was considered appropriate that a failure to account by keeping accurate records (which may relate, for example to

amounts in storage and supply) would attract an offence of strict liability. The creation of an offence of strict liability reflects the seriousness with which the obligation to keep records is regarded.

The Committee thanks the Parliamentary Secretary for this response.

Veterans' Affairs Legislation Amendment (Further Budget 2000 and Other Measures) Bill 2002

Introduction

The Committee dealt with this bill in *Alert Digest No. 2 of 2002*, in which it made various comments. The Minister for Veterans' Affairs has responded to those comments in a letter dated 19 March 2002. A copy of the letter is attached to this report. An extract from the *Alert Digest* and relevant parts of the Minister's response are discussed below.

Extract from Alert Digest No. 2 of 2002

This bill was introduced into the House of Representatives on 21 February 2002 by the Minister Assisting the Minister for Defence. [Portfolio responsibility: Veterans' Affairs]

The bill proposes to amend the *Veterans' Entitlements Act 1986* to provide for:

- a more generous treatment for the way in which periodic compensation payments will affect the pension payments received by partners of compensation recipients;
- direct recovery of certain compensation debts from compensation payers and insurers;
- financial assets which are regarded as unrealisable for the purposes of the assets test hardship provisions, to be similarly regarded for the purposes of the income test deeming provisions – the amendments will provide that the actual return on the unrealisable asset will be counted as ordinary income rather than the deemed rate of return;
- the inclusion of small superannuation accounts in definitions relating to assets consequential to the enactment of the *Small Superannuation Accounts Act 1995*;
- streamlining the operation of the income streams rules and limiting the abuse of those rules – these amendments mirror those made to the social security law by the *Family and Community Services Legislation (Simplification and Other Measures) Act 2001* (No. 71 of 2001); and

- the rounding of pensions and income support payments to the nearest cent in line with the rules contained in the *Social Security (Administration) Act 1999*.

Retrospective commencement
Schedule 3, Part 1

By virtue of the table in subclause 2(1), the amendments proposed by Part 1 of Schedule 3 are to commence retrospectively on 1 July 1995. It appears that these amendments, which are consequential to the enactment of the *Small Superannuation Accounts Act 1995*, and which mirror amendments made to social security law, are technical only, as the Explanatory Memorandum indicates that they have no financial impact. Nevertheless, the Committee **seeks the Minister's confirmation** that these retrospective amendments will not adversely affect any person.

Pending the Minister's confirmation, the Committee draws Senators' attention to these provisions as they may be considered to trespass unduly on personal rights and liberties, in breach of principle 1(a)(i) of the Committee's terms of reference.

Relevant extract from the response from the Minister

> In your Alert Digest (No. 2 of 2002) of 13 March 2002, you sought confirmation that the retrospective amendments to be made by Part 1, of Schedule 3 of the Veterans' Affairs Legislation Amendment (Further Budget 2000 and Other Measures) Bill 2002, consequential to the enactment of the *Small Superannuation Accounts Act 1995*, will not adversely affect any person.
>
> I am able to confirm that the proposed amendments do not adversely affect any person and will ensure that persons with small superannuation accounts under the scheme will receive the same asset and income test exemptions that are extended to persons who hold accounts with superannuation and similar funds.

Retrospective commencement
Schedules 1, 2 and 4 and Schedule 3, Part 2

Schedule 1 to this bill makes amendments to provide for "a more generous treatment" for the way in which periodic compensation payments will affect pension payments received by partners of those receiving compensation.

Schedule 2 provides that financial assets regarded as unrealisable for the purposes of the assets test hardship provisions will be similarly regarded for the purposes of the income test deeming provisions.

The amendments included in Schedule 4 are intended to align the rounding rules of the Department of Veterans' Affairs with those under the *Social Security (Administration) Act 1999.*

The amendments included in Part 2 of Schedule 3 are intended to streamline the operation of the income streams rules and limit the abuse of those rules.

By virtue of the table in subclause 2(1), these amendments are to commence retrospectively on 20 September 2001. It appears that these amendments either have no financial impact, or are beneficial to recipients of veterans' benefits. However, this conclusion is not entirely clear from the Explanatory Memorandum. The Committee, therefore, **seeks the Minister's confirmation** that these amendments will not adversely affect any recipients.

Pending the Minister's confirmation, the Committee draws Senators' attention to these provisions as they may be considered to trespass unduly on personal rights and liberties, in breach of principle 1(a)(i) of the Committee's terms of reference.

Relevant extract from the response from the Minister

> Confirmation was also sought that the retrospective amendments to be made by Schedules 1, 2 and 4 and Part 2, of Schedule 3 of the Veterans' Affairs Legislation Amendment (Further Budget 2000 and Other Measures) Bill 2002, will not adversely affect any recipients.
>
> I am able to confirm that the proposed amendments do not adversely affect any person with those amendments in Schedule 1 relating to compensation recovery and in Schedule 2 relating to unrealisable assets being beneficial to all those affected.
>
> The amendments made by Part 2 of Schedule 3 will ensure that the treatment of income streams under the means test will be clear and unambiguous and will correct some anomalies in, and the unintended consequences of, earlier amendments.
>
> The amendments made by Schedule 4 will provide for the rounding of instalments of income support to the nearest cent. Previously instalments were rounded to the nearest 10 cents. While some recipients of income support payments may be marginally affected by a lower instalment other recipients will receive an increased instalment.

The Committee thanks the Minister for this response.

Barney Cooney
Chairman

ATTORNEY-GENERAL
THE HON. DARYL WILLIAMS AM QC MP

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15 MAR 2002
Senate Standing C'ttee
for the Scrutiny of Bills

02/1404 CRJ

15 MAR 2002

Senator Barney Cooney
Chairman
Senate Standing Committee
for the Scrutiny of Bills
Parliament House
Canberra ACT 2600

Dear Senator Cooney

I refer to the Scrutiny of Bills *Alert Digest No. 2 of 2002* in which your Committee expressed concerns about the Criminal Code Amendment (Anti-hoax and Other Measures) Bill 2002.

I wish to reiterate that the terms of the anti-hoax offence and its retrospectivity were very clearly foreshadowed by the Prime Minister on 16 October 2001. The new offence is very similar to the existing *Crimes Act 1914* offence, with complete overlap in most circumstances that are likely to arise. I also note that the Prosecution Policy of the Commonwealth, and the public interest test that it incorporates, will apply to any proposed prosecution of this offence.

The provision for proscription under regulation in proposed section 471.15 simply replicates an equivalent provision in the existing section 85X of the *Crimes Act 1914*. The capacity to proscribe banned substances that are dangerous or harmful is an essential piece of flexibility to deal with changing circumstances. The parameters of the offence are clearly marked out by the 'dangerous or harmful' test in the primary legislation, allowing full Parliamentary scrutiny of the nature of the offence. Regulations made to give effect to the offence would, of course, be disallowable.

If it would assist the Committee to receive a briefing from officers of my Department in relation to the Bill, I would be pleased to facilitate this.

Yours sincerely

Daryl Williams

DARYL WILLIAMS

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THE HON TRISH WORTH MP
Parliamentary Secretary to the Minister for Health and Ageing
Member for Adelaide

Chairman
Senator B Cooney
Standing Committee on Scrutiny of Bills
Parliament House
CANBERRA ACT 2600

Dear Senator Cooney

Thank you for your letter of 14 March 2002 relating to Therapeutic Goods Amendment Bill (No.1) 2002.

In that letter the Committee raised questions about the need to make the decisions of the Minister under proposed section 18A disallowable. These are decisions to allow certain therapeutic goods intended for supply to the general public to "by-pass" the registration and listing requirements. The Committee also raised questions about the strict liability offences in proposed subsections 20(2C) and 30H(3).

Non-disallowable decisions

Proposed new subsections 18A(10) and (11)
The object of the *Therapeutic Goods Act 1989* (the Act) is to provide for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods to be used in Australia. This normally involves the evaluation by the Therapeutic Goods Administration, or assessment against statutory criteria, of goods required by the Act to be registered or listed in the Australian Register of Therapeutic Goods (the Register). However, the Act also makes provision for therapeutic goods to be exempted from the registration and listing requirements in certain circumstances. For example, under the Special Access Scheme seriously ill persons or terminally ill patients can be granted access to goods that have not been assessed or approved for quality, safety or efficacy, where availability to such patients may outweigh the risk of their being supplied with unapproved medicines.

The new provisions in section 18A address unusual circumstances that may not eventuate. That section is concerned with the availability of therapeutic goods that have not been approved for supply in Australia for the treatment of, for example, an outbreak of an uncommon but serious disease including the consequences of an act of bioterrorism. Diseases in mind include anthrax and smallpox. Appropriate response times in relation to certain bioterrorist events may be measured in minutes. The national interest issue to be weighed is whether it is preferable to have no appropriate goods available to treat the Australian public in the event of the kinds of emergency envisaged by the legislation or, whether it is preferable to have appropriate goods

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available even though those goods have not been evaluated for registration in Australia. It might be borne in mind that, whilst the goods that may be exempted are not registered in Australia, there may be circumstances in which they may have been evaluated and approved for use in other countries. It is also envisaged that goods which are imported and stockpiled may become registered whilst stockpiled. In that event, under proposed subsection 18A(5) the exemption would cease to apply.

Whilst the Minister's powers under section 18A bypass the normal evaluation and registration requirements, the exercise of the power will ensure the availability of therapeutic goods in unusual circumstances where there is a national emergency. In the event of a potential threat, there would be a justifiable expectation that measures be put in place to reduce the risk to the general public.

The Minister's power to exempt goods from the operation of Division 2 of Part 3 of the Act may be described as falling into two different circumstances, as set out below.

In the event of an actual emergency envisaged by new paragraph 18A(2)(b) immediate action is needed and the exemption may have been made and the goods supplied to the public and perhaps used, perhaps before the 5 sitting days within which these instruments are required to be tabled. To make a decision subject to disallowance where the decision would have already been acted upon and the action perhaps completed would not appear to be practical. Parliament will, however, be in a position to scrutinise the decision taken to exempt goods in such circumstances because of the requirement to table such decisions.

In the event of a potential threat, once a decision to stockpile is made, it is expected that events may occur so quickly that disallowance may not affect the import or manufacture of the product. Also, a decision to disallow (which could have the effect of increasing the risk that the Australian public may be without sufficient supplies of therapeutic goods that would be needed in an emergency) would presumably be made on one of two grounds: either the particular goods exempted were inappropriate or that no potential threat exists.

In relation to the particular therapeutic goods that are the subject of the exemption, only a very limited range of goods are known to be suitable in the event of the kind of emergencies currently envisaged. In determining whether or not there is a need to stockpile in anticipation of a potential threat, the Minister has available the advice of his or her Department and State government authorities that have the expertise in dealing with and making judgements about national emergencies, including acts of terrorism. The Department also has access to specialist professional advice about the appropriateness of therapeutic goods that are to be exempted.

Guidelines will be developed in relation to what constitutes a potential threat or an actual emergency. No criteria were included in the legislation in order to allow flexibility in dealing with new threats, such as threats from new diseases or bioterrorist activities that cannot be foreseen at the present time.

The delegation of the Minister's power under proposed paragraph 18A(2)(a) to exempt certain goods to create a preparedness to deal with a potential threat has been restricted to the Secretary of the Department of Health and Ageing. The restriction on delegation in this way imposes limits on who can exercise the power.

It is envisaged that decisions made under the new provisions would be subject to a high level of political and parliamentary scrutiny. It should also be noted that the Minister can impose time limits on exemptions, revoke exemptions and impose additional conditions on exemptions.

Strict Liability Offence
Proposed new subsection 20(2C)

The Committee is concerned that, with regard to proposed subsection 20(2C), there might be a danger of criminalising conduct which might otherwise have an innocent explanation.

It is unlikely that the kinds of therapeutic goods which are likely to be the subject of an exemption under section 18A could be imported under circumstances where a legitimate importer could be unaware of the regulatory status of the goods. The nature of the goods to be used for their intended purposes is not such that they are readily available for purchase for such use by the general public. Because of the potential for some products, such as smallpox vaccine, to be used in terrorist activities, strict controls are imposed on the goods to ensure that they are not diverted for illegal purposes and that they are imported into Australia strictly for use to meet emergency needs. In fact, worldwide there may be only one or two legitimate manufacturers and suppliers of some of the goods that may be needed.

In the unlikely event that an importer mistakenly imports goods that are the subject of a section 18A exemption, the Criminal Code provides a defence of mistake of fact.

The inclusion of a strict liability provision was also considered the best mechanism for ensuring that goods, imported in breach of a condition of the section18A exemption, could be seized in order to ensure that they did not find their way into the marketplace. The suggestion that amendments might be made to the Act to provide for the retention of the goods by the authorities until an approval has been granted is not consistent with the scheme provided for in section 18A. Goods exempted under section 18A are not approved - they are exempted from the requirement to be entered on the Register. The exemption can be made subject to conditions. Depending on the condition of the exemption applying to the particular goods, there could be situations where it may never be appropriate to release certain seized goods. One example would be where a condition of the exemption required the goods to be sourced from one particular overseas supplier only (because the Minister could only be assured that goods from that particular supplier were likely to be safe, efficacious and of good quality). In such cases goods imported from another supplier may never be released for storage or supply in Australia.

Subsection 30H(3)
The Committee seeks advice on why an offence against proposed subsection 30H(3) should be an offence of strict liability. Keeping track of the exempt goods is considered to be of critical importance because of the nature of the goods that will be the subject of an exemption under proposed section 18A, and the risk that the goods or quantities of the goods could be diverted and used for purposes other than the mischief the goods are intended to address. Apart from ensuring as far as possible that the goods will be appropriately used to maximise their beneficial effect, these goods have not been evaluated for safety or efficacy for their intended use. The extent of their distribution and supply is information that is required to manage properly the use of the products. For this reason, it was considered appropriate that a failure to account by keeping accurate records (which may relate, for example to amounts in storage and supply) would attract an offence of strict liability. The creation of an offence of strict liability reflects the seriousness with which the obligation to keep records is regarded.

Yours sincerely

Trish Worth

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19 MAR 2002

MINISTER FOR VETERANS' AFFAIRS
MINISTER ASSISTING THE MINISTER FOR DEFENCE

PARLIAMENT HOUSE
CANBERRA ACT 2600

Senator B Cooney
Chairman
Senate Standing Committee for the Scrutiny of Bills
Parliament House
CANBERRA ACT 2600

Dear Senator Cooney

In your Alert Digest (No. 2 of 2002) of 13 March 2002, you sought confirmation that the retrospective amendments to be made by Part 1, of Schedule 3 of the Veterans' Affairs Legislation Amendment (Further Budget 2000 and Other Measures) Bill 2002, consequential to the enactment of the *Small Superannuation Accounts Act 1995*, will not adversely affect any person.

I am able to confirm that the proposed amendments do not adversely affect any person and will ensure that persons with small superannuation accounts under the scheme will receive the same asset and income test exemptions that are extended to persons who hold accounts with superannuation and similar funds.

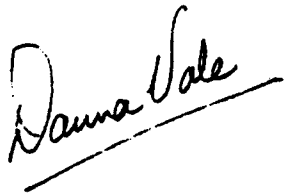
Confirmation was also sought that the retrospective amendments to be made by Schedules 1, 2 and 4 and Part 2, of Schedule 3 of the Veterans' Affairs Legislation Amendment (Further Budget 2000 and Other Measures) Bill 2002, will not adversely affect any recipients.

I am able to confirm that the proposed amendments do not adversely affect any person with those amendments in Schedule 1 relating to compensation recovery and in Schedule 2 relating to unrealisable assets being beneficial to all those affected.

The amendments made by Part 2 of Schedule 3 will ensure that the treatment of income streams under the means test will be clear and unambiguous and will correct some anomalies in, and the unintended consequences of, earlier amendments.

The amendments made by Schedule 4 will provide for the rounding of instalments of income support to the nearest cent. Previously instalments were rounded to the nearest 10 cents. While some recipients of income support payments may be marginally affected by a lower instalment other recipients will receive an increased instalment.

Yours sincerely



DANNA VALE MP

19 MAR 2002