HUMAN
RIGHTS
COMMISSION

REPORT NO. 11

HUMAN RIGHTS OF THE TERMINALLY ILL

The Right of Terminally Ill Patients to have Access to Heroin for Painkilling Purposes

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Human Rights Commission
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4 March 1985

The Honourable Lionel Bowen, M.P.
Deputy Prime Minister and Attorney-General
Parliament House
Canberra, A.C.T. 2600

Dear Attorney-General,

Pursuant to section 9(1)(a) and (c) of the *Human Rights Commission Act 1981*, we present this report to you following the Human Rights Commission's examination of *The Right of Terminally Ill Patients to have Access to Heroin for Painkilling Purposes.*

Yours sincerely,

Chairman
for and on behalf of the
Human Rights Commission

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THE FUNCTIONS OF THE COMMISSION

Section 9 of the Human Rights Commision Act 1981 reads:

9. (1) The functions of the Commission are—

(a) to examine enactments, and (when requested to do so by the Minister) proposed enactments, for the purpose of ascertaining whether the enactments or proposed enactments are, or would be, inconsistent with or contrary to any human rights, and to report to the Minister the results of any such examination;

(b) to inquire into any act or practice that may be inconsistent with or contrary to any human right, and-

(i) where the Commission considers it appropriate to do so—endeavour to effect a settlement of the matters that gave rise to the inquiry; and

(ii) where the Commission is of the opinion that the act or practice is inconsistent with or contrary to any human right, and the Commission has not considered it appropriate to endeavour to effect a settlement of the matters that gave rise to the inquiry or has endeavoured without success to effect a settlement of those matters—to report to the Minister the results of its inquiry and of any endeavours it has made to effect such a settlement;

(c) on its own initiative or when requested by the Minister, to report to the Minister as to the laws that should be made by the Parliament, or action that should be taken by the Commonwealth, on matters relating to human rights;

(d) when requested by the Minister, to report to the Minister as to the action (if any) that, in the opinion of the Commission, needs to be taken by Australia in order to comply with the provisions of the Covenant, of the Declarations or of any relevant international instrument;

(e) on its own initiative or when requested by the Minister, to examine any relevant international instrument for the purpose of ascertaining whether there are any inconsistencies between that instrument and the Covenant, the Declarations or any other relevant international instrument, and to report to the Minister the results of any such examination;

(f) to promote an understanding and acceptance, and the public discussion, of human rights in Australia and the external Territories;

(g) to undertake research and educational programs, and other programs, on behalf of the Commonwealth for the purpose of promoting human rights and to co-ordinate any such programs undertaken by any other persons or authorities on behalf of the Commonwealth;

(h) to perform—

(0 any functions conferred on the Commission by any other enactment;

(ii) any functions conferred on the Commision pursuant to any arrangement in force under section 11; and

(iii) any functions conferred on the Commission by any State Act or Northern Territory enactment, being functions that are declared by the Minister, by notice published in the Gazette, to be complementary to other functions of

the Commission; and

(j) to do anything incidental or conducive to the performance of any of the preceding functions.

(2) The Commission shall not—

(a) regard an enactment or proposed enactment as being inconsistent with or contrary to any human right for the purposes of paragraph (1)(a) or (b) by reason of a provision of the enactment or proposed enactment that is included solely for the purpose of securing adequate advancement of particular persons or groups of persons in order to enable them to enjoy or exercise human rights equally with other persons; or

(b) regard an act or practice as being inconsistent with or contrary to any human right for the purposes of paragraph (1)(a) or (b) where the act or practice is done or engaged in solely for the purpose referred to in paragraph (a).

(3) For the purpose of the performance of its functions, the Commission may work with and consult appropriate non-governmental organisations.

I. INTRODUCTION

Heroin is an enigma because this relatively simple chemical seems to produce so much harm and yet is capable of doing so much good.'

Background

1. The Human Rights Commission has received representations from a number of people involved in the treatment of terminally ill patients, requesting that heroin be made available for use in the treatment of terminally ill patients.

2. In response to these requests, and in accordance with its general mandate to examine Commonwealth legislation and report on matters relating to human rights, the Commission has undertaken a study of the human rights of terminally ill patients and their right to use heroin for medical purposes.

3. This report addresses the question of terminally ill patients' rights to have access to heroin for painkilling purposes. The report does not consider the issues relating to the availability of heroin in the community and the prescription of heroin through medical practitioners for heroin addicts.

4. The Commission has received correspondence from a number of individuals and organisations supporting the right of terminally ill patients to have access to heroin for painkilling purposes. Others were concerned about the care and treatment of terminally ill patients and the patients' right to decide how they wished to be treated in the terminal stages of their illness. The Commission thanks all those people who made a contribution.

Human Rights

5. Human rights are defined in the Human Rights Commission Act 1981 as the rights and freedoms recognised in the International Covenant on Civil and Political Rights (ICCPR) and in the Declarations of the Rights of the Child, on the Rights of Mentally Retarded Persons and on the Rights of Disabled Persons. This report is therefore focused on the rights defined in these documents. The most relevant articles of the Covenant and Declarations are included in Appendixes 1 and 2.

A. Trebach, *The Heroin Solution, Yale* University Press, New Haven, 1982, ix.

II. ISSUES REGARDING THE MEDICAL USE OF HEROIN FOR TERMINALLY ILL PATIENTS

Significant Issues

6. Terminally ill patients, for example with cancer or leukemia, often go through a dehumanising process over the period of their illness. Special consideration must be given to their needs and rights as individuals. The requirement for adequate pain relief would be one of their most pressing needs. Provision of this relief allows them to die in a more humane and dignified manner.

7. Heroin is probably one of the most feared drugs in terms of its addictive potential. Attitudes towards heroin have always carried with them many of the myths and distortions surrounding the drug. Despite the virtual world-wide prohibition on the use of heroin, the abuse of heroin has not declined and there are widespread problems of heroin dependence.

8. It is estimated that 40-50 per cent of terminally ill cancer patients experience severe pain. Such pain is generally chronic and continuous and does not reduce in degree over time. Anxiety and depression frequently accompany chronic pain and this may aggravate the patient's perceptions of such pain.' Recurring pain is also harder to control.

9. Chronic pain is perhaps the hardest aspect of a terminal illness that a patient has to cope with, as it seems meaningless as well as endless. It is likely to get worse and the pain can occupy the patient's whole attention, isolating that person from the outside world.' As one patient testifies:

> At 1.10 a.m. there is nothing to distract the mind. It concentrates its attention on the unbearable pain which becomes more and more unbearable.'

The fearful anticipation of pain and accompanying anxiety, depression and insomnia may only accentuate the physical component of pain.

10. People suffering from severe pain are more likely to be hospitalised than people whose pain is controlled or who experience little pain. Kingsbury' noted that one of the reasons why pain is not relieved is that some doctors do not fully appreciate that pain is not simply a physical sensation. The sensation of pain will be accompanied by an emotional reaction, and the patient's pain threshold will vary according to his or her mood and morale and the intensity of the pain. Boredom and apathy can also contribute to a patient's suffering. These other factors often are not considered in the care of the dying patient.

11. Specialised care units, such as those found in hospices, are more likely to be successful in relieving pain than hospitals. In St Christopher's hospice in Britain, 99 per cent of the patients obtain pain relief while they are still in a conscious and alert state.' One of the main objectives of a hospice is pain control:

> Pain control aims at that point at which the dying have lost the fear of pain and have attained that level of tolerable suffering which in their eyes constitutes a good trade-off for the alternative of oblivion in the completely drugged state.'

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1 E. Shapiro, 'The Right of Privacy and Heroin Use for Painkilling Purposes by the Terminally III Cancer Patient', (1979) 21 *Arizona Law Review* 41-59.
2 K. Kingsbury, *I want to die at home.* Fraser and Jenkinson, Heidelberg. Victoria. 1980.
3 Personal comment to the Human Rights Commission.
4 Kingsbury, op. cit.
5 ibid.
6 M. Baum and R. C. Baum, *Growing Old. A Societal Perspective,* Prentice Hall Inc., Englewood Cliffs. New Jersey, 1980.

12. Drug therapy is usually the primary means of pain relief. The use of non-narcotic drugs is preferable, but they have limited effectiveness for the treatment of intractable pain. Morphine and heroin are the most potent narcotic drugs available.

13. Heroin is not a `superdrug' that will magically solve the needs of people who face the agony of a painful terminal illness. There is also a need for loving and humane care.' However, where the patient's care involves the administration of drugs to relieve pain, the patient's right to choose the drug which provides him or her with the most effective pain relief must be considered.

Rights of Terminally Ill Patients

14. The central human rights issues which are raised in prohibiting the medical use of heroin to control unrelieved pain are:

(a) whether a patient should have the right to have access to or choose the form of pain relief which is most effective for himself or herself; and
(b) whether the prohibition against the medical use of heroin infringes that right, especially when considering the special needs of terminally ill patients in the treatment of chronic pain.

15. There may be a conflict of interest between the individual and the State when considering the medical use of heroin, especially in relation to public health and safety. However, any restrictions imposed by the State which may infringe an individual's rights can only be justified when there are special, and overriding, reasons for the restrictions.

16. What rights do terminally ill patients have to use heroin to relieve pain unmanageable by other drugs? Robertson' noted that terminally ill patients in America may have a right under the U.S. Constitution to have heroin to relieve pain, although no case has been brought before the court. This may be derived from an extension of the constitutional right to privacy to personal decisions regarding medical care. If a person has the right to refuse medical treatment, he or she may also have the right to choose the treatment which is the most effective in control of chronic pain.

17. The U.S. Supreme Court declared in *Roe v. Wade'* that the right to privacy 'is broad enough to encompass a woman's decision whether or not to terminate her pregnancy'. In *Re Quinlan"*, the New Jersey Supreme Court, discussing the right of an irreversibly comatose patient to refuse treatment, regarded the right to privacy as encompassing a patient's decision to decline medical treatment under certain circumstances. The father, applying on behalf of his daughter who was judged to have little hope of recovery, was authorised to withdraw the extraordinary procedures sustaining her vital processes.

18. The limits of the right to privacy under the U.S. Constitution have not been accurately defined. Shapiro" has discussed this issue in relation to heroin use for terminally ill patients. He suggests that any limitation of a person's fundamental right may be justified if there are 'compelling state interests' in support of the prohibitions against the medical use of heroin. Currently, two principal interests are likely to be raised. The first argument is that it is in the State's interest to prevent addiction to the drug. This is a weak argument when considering patients diagnosed as terminally ill, as addiction would not be relevant. The second argument concerns the control of the illicit use of drugs. The

7 A. S. Trebach, *The Heroin Solution,* Yale University Press, New Haven, 1982.
8 .1. A. Robertson, *The Rights of the Critically Ill,* Bantam Books. Toronto, 1983.
9 *Roe v. Wade,* 410 U.S. Supreme Court 113, 1983.
10 *In Re Quinlan,* 70 N.J. 10. 355A. 2d 647, 1976.
11 Shapiro, op. cit.

State's concern over control may in this case be regarded as a compelling State interest. However, as the distribution of other drugs with a high potential for abuse is regulated, there may be no necessity for a total prohibition against the medical use of heroin by terminally ill patients.

19. Patients have a right to be fully informed about their illness. The Medical Consumers Association of N.S.W. suggests a patient's legal rights include 'the right to a clear, concise explanation in lay person's terms of all proposed procedures and possible alternatives. The explanation should include information about the risk of any side or after effects, problems relating to recuperation and possibility of success, risk of death, and whether such procedures or treatments are of an experimental nature.' Patients should also have a right to refuse any specific treatment, drug, examination or other health care procedures, and must not be subjected to any treatments without their competent and voluntary consent.

20. Although patients do not at present have an inherent legal right to be fully informed about the nature of their illnesses, in certain circumstances a medical practitioner may be held liable for negligence, assault and battery or trespass if he or she has failed to inform the patient or has failed to obtain informed consent.

21. The Commission believes that a patient should be fully informed about the type of drugs or treatment he or she is receiving, possible side effects and any alternative treatments which are available. A patient's request for treatment should be fully considered by the medical profession. Cases in which a patient's requests for a particular drug are ignored because of suspected addiction may be a violation of the patient's rights in the absence of any evidence of addiction.

22. Although Australia does not have provisions similar to those contained in the U.S. Constitution, previously referred to, an argument for the rights of terminally ill patients may be extended from the right to privacy under Article 17 of the International Covenant on Civil and Political Rights (ICCPR). On such an interpretation of the Article, an individual may have the right to his or her own choice of medical treatment.

23. Article 17 states that 'no one shall be subjected to arbitrary or unlawful interference with his privacy, family, home or correspondence'. Scholars have included moments of pain or extreme depression in their list of stivations which pertain to privacy:

> The Article protects every individual on every occasion and in every context in which he requires secrecy or seclusion . . . with regard to his physical being, disposition, moral character or habits, mental or physical health, profession, business, work or intellectual activities.'[2]

Article 17 of the ICCPR only forbids interference with privacy that is 'arbitrary or unlawful'. The Third Committee of the General Assembly chose the word 'arbitrary' because the word has a broader meaning than the word 'illegal' ." Volio' noted that 'arbitrary' in this context not only means contrary to the law, but also means despotic, tyrannical or uncontrolled. 'Arbitrary' therefore means 'illegal' as well as 'incompatible with the principles of justice and human dignity'. An interpretation of arbitrary interference with privacy must take into account the actions of the State in relation to the rights and needs of an individual.

24. The right to privacy must be balanced against society's collective interests. However, as previously argued, the case for the State's interests may not justify a

12 F. Volio, 'Legal Personality, Privacy and the Family', in L. Henkin (ed.), *The International Bill of Rights. The Covenant on Civil and Political Rights,* Columbia University Press, New York, 1981, 195.

13 P. Hannan, 'The Word Arbitrary as used in the Universal Declaration of Rights: 'Illegal' or 'Unjust'?', (1969) 10 *Harvard Law Review* 225-62.

14 Volio, op. cit.

complete prohibition against the medical use of heroin. The most appropriate role of the Government in regulating a dying individual's choice of pain treatment clearly must be balanced against the individual's need under the most intimate and pressing circumstances.

25. A terminally ill patient would undoubtedly be considered a disabled person under the Declaration on the Rights of Disabled Persons. Paragraph 1 states that 'the term "disabled person" means any person unable to ensure by himself or herself, wholly or partly, the necessities of a normal individual and/or social life, as a result of a deficiency, either congenital or not, in his or her physical or mental capacity'.

26. The Declaration and the Covenant do not address the issue of an individual's right to refuse or choose a form of medical treatment. However, disabled persons have the same fundamental rights as their fellow citizens of the same age (paragraph 4). The Commission is of the view that this means that a person's fundamental rights should not be reduced or modified as the result of an illness or disability, and his or her rights should therefore be enjoyed and exercised as far as practicable.

27. Disabled persons have the inherent right to respect for their human dignity, which implies they have a right to a decent life, as normal and full as possible (paragraph 3). It may therefore be argued that a terminally ill patient has the right to choose the most effective form of pain relief. The Commission believes this would allow that person to be treated in a humane and respectful manner, and the right to die with dignity.

28. Paragraph 8 states that disabled persons are entitled to have their special needs taken into consideration at all stages of economic and social planning. Accordingly the Commission suggests that the exceptional need of a terminally ill patient for pain relief would be a case of special need.

29. Disabled persons should be protected against all treatment of a discriminatory, abusive or degrading nature (paragraph 10). The Commission proposes that to refuse a person the choice of the most effective form of pain relief could be considered abusive or degrading to a dying individual experiencing chronic pain.

Medical Use of Heroin in Australia

30. There are twelve signatory countries to the Single Convention on Narcotic Drugs, 1961, that report legal use of heroin. Of these, only the United Kingdom and Belgium have a consumption over 1 kg.'[5] The medical use of heroin in Australia has been prohibited for over thirty years.

31. The importation of heroin was prohibited by the Commonwealth in Australia in 1953, after a recommendation by the World Health Assembly. Following this prohibition, the Australian States, with the exception of Victoria, prohibited the use of heroin and ordered the destruction of existing stocks:

> Heroin is classed as a Schedule Four drug under the Single Convention on Narcotic Drugs, 1961. Parties to the Convention are invited to prohibit production, manufacture, export and import of, trade in and possession or use of heroin, except for amounts that may be necessary for medical and scientific research under the direct supervision and control of the party.'

32. At the time heroin was prohibited, Australia had the highest per capita consumption in the world and there was general abuse through over-prescription of the drug. Since 1974 it has been possible to import small amounts of heroin for scientific

15 Canadian Expert Advisory Committee on the management of severe chronic pain in cancer patients, *Report: Cancer Pain,* September 1984.

16 Royal Commission of Inquiry into Drugs, *Report,* AGPS, Canberra, 1980, C178.

purposes with the express permission of the Commonwealth Director-General of Health. (The use has been confined to samples and standards for forensic purposes.)

33. The Australian Royal Commission of Inquiry into Drugs' in 1980 considered the use of heroin in medical practice. The Commission found that there was interest among some practitioners in relaxing the present prohibition against the use of heroin in medical practice. This interest arose from practitioners' experience before 1953, overseas experience in England, or through consideration of reported clinical trials. There was no clear consensus over the issue.

34. The Royal Commission made three recommendations. Firstly, the Department of Health should monitor overseas clinical trials to establish if it is desirable to conduct clinical trials in Australia. Secondly, no action should be taken to change the present legal controls unless it is clearly established that heroin has significant, unique properties as an analgesic which require its use in specified areas of medical practice and that strict control procedures can be implemented to prevent the diversion of legal heroin to uses outside medical practice.

35. The final recommendation stated that heroin should not be used in the treatment of drug-dependent persons.

36. The question of the medical use of heroin was raised in Parliament in 1981. In reply to a question, the Minister for Health noted that the Australian Health Ministers' Conference in 1980 agreed to the use of heroin for the control of intractable pain in patients suffering terminal carcinoma, conditional on suitable controls being implemented. It was also agreed that the Commonwealth should strictly control the single source of supply. A clinical trial was proposed which was consistent with the recommendations of the Royal Commission of Inquiry into Drugs, 1980. Precise methods of control to prevent the misuse of heroin would be decided by the individual States and Territories within their own legislation. [18]

37. No clinical trials have been conducted in Australia up to 1984. An expert working party of the National Health and Medical Research Council (NH&MRC) was requested by the Australian Health Ministers' Conference, March 1982, to evaluate the relevant literature. The NH&MRC Working Party recommended:

> Heroin has no demonstrable advantage or unique properties in the relief of chronic severe pain, which cannot be obtained through other regimens of pain control, and therefore it should not be reintroduced for clinical use in Australia.'[19]

The NH&MRC endorsed this recommendation, which was subsequently noted by the April 1984 Health Ministers' Conference:[20]

38. Australia is a signatory to two international drug conventions—the Single Convention on Narcotic Drugs, 1961, and the Convention on Psychotropic Substances, 1971—which limit trade and manufacture of narcotic substances. The Single Convention on Narcotic Drugs, 1961, limits the use of heroin (a Schedule 4 drug) to medical and scientific purposes. Further, parties to the Convention are invited to limit the amount of a drug available to that necessary for medical and scientific research if the party considers that the most appropriate means of control. Article 2(5b) of the Single Convention on Narcotic Drugs, 1961, states:

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17 ibid.

18 Australia, House of Representatives, *Debates,* October 1981, 2800. Minister for Health.

19 NH&MRC Working Party on Heroin, 'Summary Record of Meeting in Canberra on 19 September 1983'. Recommendation to Public Health Advisory Committee.

20 Drugs of Dependence Branch, Commonwealth Department of Health. Correspondence to Human Rights Commission, 13 June 1984.

> A Party shall, if in its opinion, the prevailing conditions in its country render it the most appropriate means of protecting public health and welfare, prohibit the production, manufacture, export and import of, trade in, possession or use of any such drug except for amounts which may be necessary for medical and scientific research only, including clinical trials therewith to be conducted under or subject to the direct supervision and control of the party.

The United Kingdom is also a signatory to the Convention and restricts the use of heroin to medical purposes.

39. There is an interest in the medical use of heroin in Australia by practitioners. For example, letters to The Editor in the *Medical Journal of Australie* stated, from the doctors' own experience, heroin was superior to morphine for chronic intractable pain. One doctor noted that quite a number of patients react violently to morphine, but tolerate heroin quite well. Some of the opinions given to the Australian Royal Commission of Inquiry into Drugs reflected these experiences. Overall, there was considerable support for conducting clinical trials within Australia, before legalising heroin for specialised medical use.

40. The Victorian Hospitals' Association suggested that any proposed advantages of the reintroduction of heroin as a pain relief would be outweighed by disadvantages, especially those regarding the cost of manufacture and controls on the supply of heroin to patients."

41. The Australian Medical Association (AMA) released a press statement in February 1979, which said:

> Doctors know that in the great majority of cases pain in cancer can be relieved by other drugs without the use of heroin. This has been confirmed by research in England, where the medical use of heroin is legal.
>
> But the important point is that there are still a small number of cases for which heroin may give relief where all else fails.
>
> The AMA believes that to deny even a small number of patients a drug that may make their last days more bearable is not justified as a means of controlling drug abuse.

The AMA's current position supports their previous press release, and the Association's view is that the ban on the medical use of heroin for the relief of severe persistent pain should be lifted.'

The Medical Debate

42. There is a continuing medical debate over the use of heroin as an analgesic. The evidence is reviewed in Appendix 3. It has not been demonstrated that heroin is a universally superior analgesic for all patients who need pain relief. However, most researchers agree that a small number of patients may benefit from heroin, especially given that it can be injected in smaller quantities. Heroin may therefore provide a range of therapeutic benefits and could provide a superior analgesic for some patients in controlling pain, anxiety and related conditions.

43. The effectiveness of a particular drug will vary according to the patient's condition. Different drugs may be more helpful as symptoms change, and in some cases heroin will have no special advantage. In some cases complete or partial relief may be obtained by the use of such surgical procedures as regional nerve blocks.

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21 (1981) 1 *Medical Journal of Australia* 89-90. Letters to The Editor.
22 Victorian Hospitals Association, Correspondence to Human Rights Commission, 5 February 1985.
23 Australian Medical Association, Correspondence to Human Rights Commission, 21 January 1985.

44. Medical researchers do not understand why patients respond differently to particular narcotics. Kaiko, a leading research pharmacologist, remarked that the management of pain for terminally ill patients may be significantly improved if medical professionals knew how to evaluate pain, choose and change drugs and dosages, and overcome unfounded fears of addiction.[24]

45. Arguments about the possible addictive potential of heroin are not relevant to terminally ill patients. From British government reports, there is a virtual absence of heroin addicts who had originally become addicted under a doctor's care. Reported problems of diversion of the drug from medical use are also virtually non-existent.' Control and distribution of the drug would require the same controls as exist for other narcotic drugs, such as morphine.

46. 'Few personal decisions can be imagined that possess the intimacy or importance of the decision to alleviate chronic pain during the final weeks or months of one's life.'" The Commission believes that in cases where terminally ill patients cannot obtain effective pain relief from other available drugs or treatment, the patient should be allowed, in consultation with his or her doctor, to use heroin.

47. Heroin cannot be regarded as a universal panacea for terminally ill patients. There are many alternative treatments available and the most effective treatment will vary according to the patient's conditions or symptoms. There are, however, some patients who may benefit from the drug, especially those in the final stages of an illness, who require injected medications.

48. The question which the Government should be addressing is not whether heroin is a universally superior drug for all patients but whether carefully controlled medical benefits for some patients suffering the agonies of a terminal illness outweigh the potential harm to society. From the evidence presented, problems of addiction and control do not differ from those which exist for presently used narcotic drugs and hence do not appear to be a determining factor.

Commonwealth Legislation

49. Commonwealth legislation controls export, import and manufacturing of narcotic drugs and to a limited extent prescribing and wholesaling. The relevant Acts are the Customs Act 1901, National Health Act 1953, Narcotic Drugs Act 1967 and Therapeutic Goods Act 1966.

50. The Customs Act 1901 and Customs (Prohibited Imports) Regulations control the import of various drugs. Under the Narcotic Drugs Act 1967 the Minister for Health may grant a licence for the manufacture of narcotic drugs to which the Single Convention on Narcotic Drugs, 1961, applies. The licensee is required to comply with the conditions as specified by the Minister in the licence (subsection 9(4)).

51. The National Health Act 1953 regulates drugs which can be prescribed as pharmaceutical benefits. The Minister may determine the strength, maximum quantity and brand of any medicinal preparation or drug supplied as a pharmaceutical benefit as well as the medical conditions which qualify for the benefit under the Act (sections 85 and 89).

52. The Therapeutic Goods Act 1966 makes provision for the control and use of therapeutic substances (including drugs) within Australia. Importation of goods for

24 B. Bolsen, 'U.S. trials show heroin not superior to morphine'. (1982) 247 *JAMA* 18, 2471.
25 Trebach. op. cit.
26 Shapiro, op. cit.. 42.

therapeutic use is prohibited if the goods do not conform to certain standards as determined by the Minister under the Act. Further, the Minister must approve the interstate trade of goods for therapeutic use, the listing of such goods as pharmaceutical benefits and the supply of these goods to the Commonwealth or a Commonwealth authority.

State Legislation

53. Most State and Territory regulation of narcotic drugs is to be found in the legislation relating to poisons. To ensure that there are comparable restrictions in all jurisdictions, the States and Territories have adopted in a reasonably uniform manner the drugs and poisons schedules formulated by the NH&MRC. A substance included in a particular schedule is subject to the controls which are appropriate to that particular schedule. These controls must be observed by the manufacturer, supplier and user of the drug.

A.C.T. Legislation

54. The A.C.T. uses a more extensive schedule system in listing drugs than the States. Heroin is listed as a Schedule 12 drug under the A.C.T. Poisons and Narcotics Drugs Ordinance 1978. Controls on the manufacture, distribution, authorised possession and prescription of drugs in the A.C.T. are to be found in the Public Health (Prohibited Drugs) Ordinance 1957, Poisons and Dangerous Drugs Ordinance 1933 and Poisons and Narcotic Drugs Ordinance 1978.

Overseas Experience

55. Both the United States and Canadian Governments are reviewing the medical use of heroin. In the United States a proposed new law, the Compassionate Pain Relief Act (HR 5290) was rejected in Congress in September 1984. The law would have made heroin available to cancer patients to control their pain in injected form and only to patients with cancer in situations where conventional analgesics are ineffective or contraindicated. The proposed law received both support and criticism from the medical profession.[27]

56. The Canadian Government, after receiving public petitions, is planning to conduct a clinicial trial which will compare heroin, morphine and hydromophone (Dilaudid) and will involve at least 750 cancer patients over 1984-85. A Gallup poll during July 1984 indicated that 73 per cent of Canadians endorsed the use of heroin for terminally ill patients.

57. The Canadian Report of the Expert Advisory Committee on the Management of Severe Pain (September 1984) recommended that heroin should not be reintroduced into Canada at the present time. It concluded that deficient pain control experienced by cancer patients in Canada was related to lack of knowledge, inappropriate attitudes and inadequate prescriptions of narcotic analgesics. In addition, some pain syndromes exist which are not responsive to narcotic analgesics and for which other therapeutic options must be developed. The report recommended that more highly concentrated and soluble forms of existing narcotic analgesics be developed and priority be given to improved education, training of health professionals and pain management services.

58. Following the introduction of a private members bill (Bill C-213) in the Canadian House of Commons—an Act to amend the Narcotic Control Act to allow heroin to be used

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27 E. N. Brandt, 'Compassionate Pain Relief: Is Heroin the Answer', and M. D. Mondzac, 'In Defense of the Reintroduction of Heroin into Medical Practice and H.R. 5290— The Compassionate Pain Relief Act', (1984) 311 *New England Journal of Medicine* 530-35.

for terminally ill patients and those in intractable pain—the Canadian Government announced its intention to legalise the medical use of heroin. A Government Bill is expected to be introduced in late February or March 1985. The Canadian Medical Association welcomed the announcement and it has ended several years of public campaigning on the matter."

28 Canada. House of Commons. *Debates,* 20 December 1984, Vol. 128 (33), 1st Session of 33rd Parliament, 1424-31.

III. CONCLUSIONS

59. The Commission believes that generally there is a need for improvement in the care and management of pain in terminally ill patients. The majority of patients can receive effective pain relief if they receive proper care and if the current range of analgesics is administered in adequate doses.

60. However, the Commission believes that a small number of terminally ill patients, particularly those suffering from cancer or leukemia, may benefit from the administration of heroin as a painkiller.

61. Current medical evidence suggests that heroin is just as effective as alternative narcotics which are available, and heroin may be more effective for some patients and in particular circumstances. However, no long-term medical study has evaluated the regular administration of injected heroin for cancer patients with chronic pain.

62. Restricted access to heroin for medical purposes is consistent with Australia's obligations as a signatory to the Single Convention on Narcotic Drugs.

63. Normally the patients involved will be in hospitals. However, some will be elsewhere—for example, at home—and it should be practicable to allow strictly controlled administration of heroin to them also.

64. Restrictions and interference with the rights, dignity and self-respect of patients should be minimised. The Commission's view is that any interference with the patients' rights should be consistent with the proper care of patients themselves.

IV. RECOMMENDATIONS

65. The Commission recommends that:

(1) Heroin should be made available to terminally ill patients who cannot obtain effective pain relief through other treatments or drugs.

(2) Heroin should be listed as a pharmaceutical benefit and its administration by or under the immediate supervision of a medical practitioner should be allowed outside hospitals. This would mean that it could be administered to all terminally ill patients who may benefit from the drug.

(3) The Minister for Health should:

(i) take up the matter with the State Ministers for Health;

(ii) in consultation with the States, license the manufacture of a limited quantity of heroin for medical use by terminally ill patients (Narcotic Drugs Ordinance 1967, section 9).

(4) Amendments should be made to A.C.T. Poisons and Narcotic Drugs Ordinance 1967 legislation to make heroin available for terminally ill patients in the A.C.T.

APPENDIX 1

International Covenant on Civil and Political Rights

Article 17

1. No one shall be subjected to arbitrary or unlawful interference with his privacy, family, home or correspondence, nor to unlawful attacks on his honour and reputation.
2. Everyone has the right to the protection of the law against such interference or attacks.

APPENDIX 2

Declaration on the Rights of Disabled Persons
(Relevant Paragraphs)

1. The term 'disabled person' means any person unable to ensure by himself or herself, wholly or partly, the necessities of a normal individual and/or social life, as a result of a deficiency, either congenital or not, in his or her physical or mental capabilities.

2. Disabled persons shall enjoy all the rights set forth in this Declaration. These rights shall be granted to all disabled persons without any exception whatsoever and without distinction or discrimination on the basis of race, colour, sex, language, religion, political or other opinions, national or social origin, state of wealth, birth or any other situation applying either to the disabled person himself or herself or to his or her family.

3. Disabled persons have the inherent right to respect for their human dignity. Disabled persons, whatever the origin, nature and seriousness of their handicaps and disabilities, have the same fundamental rights as their fellow-citizens of the same age which implies first and foremost the right to enjoy a decent life, as normal and full as possible.

4. Disabled persons have the same civil and political rights as other human beings; paragraph 7 of the Declaration on the Rights of Mentally Retarded Persons applies to any possible limitation or suppression of those rights for mentally disabled persons.

8. Disabled persons are entitled to have their special needs taken into consideration at all stages of economic and social planning.

10. Disabled persons shall be protected against all exploitation, all regulations and all treatment of a discriminatory, abusive or degrading nature.

APPENDIX 3

Medical Evidence

Medical Use of Heroin

Heroin (or diacetylmorphine hydrochloride or diamorphine hydrochloride) is a morphine derivative. Heroin has been prescribed for the relief of severe pain, such as occurs in terminal cancer. It also has been used to treat persistent coughs; lung and respiratory diseases; postoperative pain following minor or major surgery; discomfort and anxiety of child birth; anxiety, pain and irregular blood pressure following heart attacks; and burns and other painful injuries. It has been clinically used in the United Kingdom for many years. However, there is a continuing scientific debate regarding the use of heroin in medical treatment and its effectiveness for pain relief.

Morphine and heroin are the most potent narcotic drugs available and they both may be administered in a wide range of oral doses (from 5 to 100 mg every four hours), as well as by injection.

An American drug agency (NIDA) in 1975 described heroin as:

> . . . a highly effective narcotic analgesic, similar in pharmacological action to morphine, although its milligram potency as a pain-killer is three to four times greater than that of morphine. Heroin produces an analgesic effect by a two-fold action on the central nervous system; the pain threshold is elevated and psychological response to pain is altered. Pain may still be recognised as being present, but the individual reacts less emotionally to it.'

It was also added that heroin has the greatest addictive potential of all the opiates. However, at present there is no scientific evidence to support this statement.

St Christopher's hospice in London was a major centre for the evaluation of heroin use in terminal cancer care until the late 1970s. Heroin was the preferred oral medication in advanced cases of cancer, as it avoided some of the most undesirable side effects of morphine, such as nausea, vomiting and mental depression. Morphine also acts as a respiratory depressant, which can cause 'intolerable feelings of suffocation' in some cancer patients, especially if they have lung cancer.' Many terminal cancer patients can be treated successfully with oral morphine. However, tolerance builds up over time, and oral doses eventually become insufficient for patients who are in pain over a period of months.'

Medical Research

Research reported in the early 1960s from Harvard Medical School found that heroin was approximately two to four times as potent as morphine in relieving moderate, severe or very severe postoperative pain during the first 150 minutes after the injection (2.3 mg to 5.2 mg of heroin was needed to match the analgesic potency of 10 mg morphine).

Although a small amount of heroin was needed to produce the same analgesic effect that was obtained with morphine, researchers claimed that there was no convincing evidence that heroin would provide greater relief than other analgesics in cancer patients. Lasagna' noted that the results of controlled studies that used equivalent analgesic doses showed no significant difference between heroin and morphine in their capacity to

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1 A. Trebach. *The Heroin Solution,* Yale University Press, New Haven, 1982, 60.
2 E. L. Shapiro, 'The Right of Privacy and Heroin Use for Painkilling Purposes by the Terminally Ill Cancer Patient', (1979) 21 *Arizona Law Review* 41-59.
3 B. Bo!sem 'U.S. trials show heroin not superior to morphine'. (1982) 247 *JAMA* 18, 2471.
4 L. Lasagna, 'The Clinical Evaluation of Morphine and Its Substitutes as Analgesics', (1964) 16 *Pharmacological Review* 47.

produce analgesia, respiratory depression, and other side effects, or in addictive potential. A later study by some Belfast doctors in 1969 found diamorphine was the only drug to show any significant differences from morphine. In particular, heroin had an earlier onset of action, more marked sedation and relief of apprehension and caused fewer patients to vomit.' However, these studies were not dealing with terminally ill cancer patients suffering from chronic intractable pain.

Trebach° noted that other conclusions could be drawn from these reports. From a patient's point of view, a more powerful drug which has a faster action than currently accepted drugs may be a significant advantage if the individual is suffering from chronic pain.

Although heroin has been widely used in England for cancer care, no rigorously controlled experimental research was conducted until the 1970s. In 1974, Twycross, a research pharmacologist, conducted a study of 500 patients with advanced cancer, 80 per cent of whom were treated with heroin. He found that diamorphine did not lead to impairment of mental faculties, tolerance was not a practical problem and addiction did not seem to occur. Patients were alert and mobile, and some went home for varying lengths of time Daily oral doses of 150 mg of diamorphine did not appear to be incompatible with normal activity. Twycross added that diamorphine could not be considered as a panacea for terminal cancer, but must be used within the context of total patient care. Heroin may be a more humane alternative to morphine.

In Twycross's 1977 controlled trial, 699 patients who entered the hospice over a two-year period were given either morphine or heroin orally. Dosages were increased until the patient was free of pain. The procedure was done on a double-blind basis: neither the patient nor the attending medical staff knew which of the drugs was being used at the particular time. He concluded: . . provided allowance is made for the difference in potency, morphine is a satisfactory substitute for orally administered diamorphine. However, when injections are necessary, the greater solubility of its hydrochloride gives diamorphine an important practical advantage over morphine, especially when large doses are required': If a patient requires high dosage levels, a much greater volume of morphine solution would be required to give the same relief as diamorphine solution. An injection every 3 or 4 hours may cause a great deal of pain and tissue damage to a terminally ill patient.

Twycross also concluded that when diamorphine was given intravenously, it has an earlier onset of action, is more sedating and causes less vomiting than morphine. All these factors are important in the relief of severe acute pain. He later stated that 'when injections are necessary, diamorphine hydrochloride is used at all hospices in Britain' .[8]

It is interesting to note that Twycross has changed his opinion and now states there is no particular advantage in the use of heroin to treat cancer patients, even with the small percentage of patients who need injections.° Twycross considers that North American doctors have not actively campaigned for the legislation of medical heroin because doctors who presently use their narcotics badly will use heroin just as badly, and in practice, patients will be no better off.'° Twycross also commented to the Canadian Expert Advisory Committee on the management of severe pain (1984) that there is not one shred of evidence that heroin is necessary to obtain pain relief in cancer patients." The

5 Trebach. op. cit.
6 ibid.
7 R. G. Twycross. `Choice of Strong Analgesic in Terminal Cancer: Diamorphine or Morphine?', (1977) 3 *Pain* 102-3.
8 R. G. Twycross, `Morphine and Diamorphine in the Terminally III Patient', (1982) 74 *ACTA Anaesthesiol Salad:* supplement 128.
9 Trebach, op. cit.
10 ibid. 73.
11 Canadian Committee of Inquiry on the management of severe chronic pain in cancer patients. *Report: Cancer Pain,* September 1984.

development of a freeze-dried morphine acetate in the U.S. may greatly enhance the solubility of morphine, allowing it to be injected in smaller volumes.

In another recent study, Kaiko et al." studied the mood and side effects of heroin and morphine in 166 cancer patients with postoperative pain. Dosages with equal analgesic effects provided comparable improvements in mood, particularly feelings of peacefulness. Peak moodY improvements occurred earlier after heroin than after morphine, but were less sustained. They concluded that heroin has no apparent unique advantages or disadvantages for the relief of pain with cancer. This study was conducted with postoperative patients with cancer, not with patients in the final stages of a terminal illness.

Lasagna" agreed with the conclusion and further stated that although some patients may be better off with heroin than morphine, or vice versa, the potential problems of storage, theft or diversion for other uses mean the legalisation of heroin for medical use is not socially responsible.

William Beaver, of Georgetown University School of Medicine, Washington, D.C., in the clinical trial in the U.S., commented:

> Most terminal cancer patients with pain can be treated successfully with oral morphine or other narcotic analgesics. However . . . a small subgroup of patients requiring large, intramuscular injections could benefit from heroin because it is more water-soluble as well as more potent than morphine.'[4]

Several factors may contribute to the use of injections. Pain may be so intense that it fails to respond even to large doses of oral morphine and a patient may need to receive medication every three or four hours. Unrelieved nausea and vomiting may prevent the full absorption of oral medication and hence injections may be needed. In the final stages of illness, a patient's increasing debility may make oral administration difficult or impossible. For an emaciated patient with little muscle left, the practice of using a small volume injection is clearly the most humane practice.'

Trebach' summarised the scientific evidence and considers it equivocal and conflicting. No evidence has indicated that heroin is inferior to other medicines. Other evidence supports either the superiority or similarity of heroin to other alternatives. The following are some of his major conclusions.

> Heroin is superior to other medicines for *some* patients in controlling pain, anxiety and related conditions. The effectiveness will vary with patients' conditions and as symptoms change other drugs may be helpful. For many patients with other symptoms (including cancer patients), heroin has no special advantage.
>
> There is no scientific evidence that heroin harms patients or that it is an ineffective medicine. There is evidence that heroin provides a wide range of therapeutic benefits, but it has not been demonstrated that heroin is universally superior to other medicines for all patients who need a narcotic.
>
> Science cannot predict which patients will be helped by heroin. The effect of the drug on an individual needs to be observed over a period of time to determine its effectiveness. Patients' expectations of the impact of a drug will also influence the effect of the drug on the physical and emotional condition of some patients.

Trebach's final conclusion was:

> . . . no scientific justification exists for the continuing legal prohibition of the use of heroin in the treatment of the organically ill and the injured. Indeed, each patient in pain should be eligible

12 R. F. Kaiko et al., 'Analgesic and Mood Effects of Heroin and Morphine in Cancer Pain with Postoperative Pain'. (1981) 304 *New England Journal of Medicine* 1501.
13 L. Lasagna, 'Heroin: A Medical ¯Me Too" '. (1981) 304 New *England Journal of Medicine* 1539.
14 Bolsen, op. cit. 2471.
15 Shapiro. op. cit.
16 Trebach, op. cit.

to receive the drug in order to determine whether it provides particular benefits for him or her at that time.''

Trebach also emphasised that we need more information about doctors' decisions to prescribe heroin in actual practice and about the patients' perceptions of the effectiveness of the drug. These perceptions of how the drug operates in actual practice may be more important than pharmacological findings. Beaver and Kaiko note that one major problem is the failure of physicians to administer medication in adequate doses or frequently enough to provide adequate pain relief.'

Walsh and Saunders wrote a letter describing the British experience with heroin:

> The only objective advantage of heroin is a practical one, for intramuscular injection. We are unaware of any advantages heroin may have over other opiates of comparable solubility, though this matter has not been subjected to controlled study. Current evidence provides no justification for the legislation of heroin.'

However, it has been estimated that 10-19 per cent of cancer patients in a hospice setting may need heroin when the criteria for need are solubility and injection size alone.[2]'

The current medical debate is reflected in response to the proposed Compassionate Pain Relief Act in the United States. Brandt[21] stated that there is no clinical evidence to suggest that doctors need to use heroin to improve their management of severe chronic pain in terminal illness. He argued that heroin is metabolised by the body into morphine and therefore the action of heroin is indistinguishable from morphine. When heroin is administered intraveneously, it is converted to 6-acetylmorphine and morphine. However, the pharmacotinetics of 6-acetylmorphine have never been studied; nor has there been any study of the regular use of parenteral heroin for the treatment of chronic pain."

Brandt[23] further argued that 'there is no dispute over heroin's ability to help control pain; however, with the availability of Dilaudid and now Dilaudid-HP, a highly soluble and a more potent analgesic heroin is superflous'. However, no studies have compared Dilaudid and heroin as an analgesic for the treatment of pain in cancer patients. Mondzac[24] added that because of the well-recognised individual variations in drug tolerance and response to analgesics, Dilaudid-HP is not an acceptable substitute for heroin at the present time.

Most physicians agree that our current approach to pain relief is inadequate and many doctors prescribe inadequate doses of narcotics. Medical professionals should be concerned that each individual patient receives adequate pain relief from the narcotic which that individual responds to best.

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17 ibid. 79.
18 M. Sun, 'Heroin, Morphine found comparable as Painkiller'. (1982) 216 *Science* (4543) 277.
19 T. D. Walsh and C. M. Saunders, 'Heroin and Morphine in Advanced Cancer', (1984) 310 *New England Journal of Medicine* 599.
20 M. D. Mondzac, 'In Defence of the Reintroduction of Heroin into Medical Practice and H.R. 5290 — The Compassionate Pain Relief Act', (1984) 31 I *New England Journal of Medicine* 532-5.
21 E. N. Brandt, 'Compassionate Pain Relief: Is Heroin the Answer', (1984) 311 *New England Journal of Medicine* 530-2.
22 Mondzac, op. cit.
23 Brandt, op. cit. 531.
24 Mondzac, op. cit.