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The Medical Use of Cannabis: Recent Developments

by

Gareth Griffith and Marie Swain

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EXECUTIVE SUMMARY

It should be emphasised that this paper does not consider the social/recreational use of cannabis/marijuana and the arguments for and against its legalisation or decriminalisation in this context. The paper's sole concern is with the separate and distinct issue of the medical use of cannabis/marijuana.

In recent months two major reports on the medical use of cannabis/marijuana have been released: the first in November 1998 by the House of Lords Select Committee on Science and Technology, the second in March 1999 by the United States Institute of Medicine. The purpose of this paper is to present an overview of these reports and responses to them, as well as to offer some background to the debate concerning the medical use of cannabis/marijuana in the US and UK.

Debate on the medical use of cannabis/marijuana has also occurred in Australia in recent years and this is discussed, along with a comment on the current legal position in this country, in the last section of the paper.

Further, the reports mentioned above are by no means isolated publications. At least five other major reports have been released in recent years. These additional reports were issued by: the Health Council of the Netherlands; the American Medical Association House of Delegates; the British Medical Association; the US National Institute of Health; and the World Health Organization. The main findings of these reports are also set out in this paper.

1. INTRODUCTION

In recent months two major reports on the medical use of cannabis/marijuana have been released: the first in November 1998 by the House of Lords Select Committee on Science and Technology, the second in March 1999 by the United States Institute of Medicine (IOM). The purpose of this paper is to present an overview of these reports, as well as to offer some background to the debate concerning the medical use of cannabis/marijuana in the US and UK. Note that of the two main reports under discussion in this paper, the IOM report is the more technically detailed in its consideration and review of the available scientific data. It is, in effect, a scientific report produced by scientists.

Another point to make is that these two reports are by no means isolated publications. At least five other major reports have been released in recent years, the main findings of which are set out in a later section of this paper. These additional reports were issued by: the Health Council of the Netherlands; the American Medical Association House of Delegates; the British Medical Association; the US National Institute of Health; and the World Health Organization.

Debate on the medical use of cannabis/marijuana has also occurred in Australia in recent years and this is discussed, along with a comment on the current legal position in this country, in the last section of the paper.

By way of a preface to the paper, a note also needs to be made about the varying terminology used in the House of Lords Select Committee and IOM reports, with one referring to *cannabis* and medical use and the other to *marijuana* and medicine. The policy of this paper in this respect is: (a) to explain the relationship between cannabis and marijuana; (b) wherever reference is made to a particular report, to retain the terminology used therein, so that cannabis is the preferred term when outlining the House of Lords Science and Technology Committee report and marijuana is used in the overview of the Institute of Medicine's work; and (c) to employ the more inclusive term 'cannabis' when discussing the legal situation and general public debate in Australia and beyond. A further preparatory note is also made on the historical and contemporary medical use of cannabis/marijuana.

2. DEFINITIONS AND DISTINCTIONS - CANNABIS AND MARIJUANA

In a previous NSW Parliamentary Library publication the relationship between cannabis and marijuana was explained in these terms:

> Cannabis is an herbaceous plant belonging to the hemp family. There is one species of the plant with two subspecies - *cannabis sativa* and *cannabis indica*. *Cannabis sativa* is a tall, cane-like plant cultivated primarily as a source of hemp fibre. *Cannabis indica* is a shorter, shrubbier variety which is usually the main source of the drug marijuana...hashish and the numerous preparations variously known as pot, grass, dope, and by many other

> colloquial terms.[1]

This is confirmed by the Encyclopaedia Britannica which explains that cannabis contains the two subspecies, *C. sativa* and *C. indica*, 'the former selected for its fibres (the source of hemp) and the latter selected for its high concentration of the compound....THC, a drug that exerts effects on the central nervous system and cardiovascular system'.[2]

The House of Lords Select Committee in its *Report on Cannabis for Medical Purpose* adds that, as a drug of abuse, cannabis 'usually takes the form of herbal cannabis (marijuana), consisting of the dried leaves and female flower heads, or cannabis resin (hashish), the resin secreted by the leaves and flower heads, which may be compressed into blocks'.[3] The report goes on to explain that the family of chemically related 21-carbon alkaloids found uniquely in the cannabis plant are known as cannabinoids (these are the principal active compounds of cannabis). There are more than 60 different cannabinoids; one of these, D9 - tetrahydrocannabinol (THC), is the most abundant and accounts for the intoxicating properties of cannabis.[4] A warning is also posted in the same report to the effect that 'It is important to distinguish the different substances and preparations; for instance, cannabis leaf must be distinguished from cannabis extract, and whole cannabis from THC. It is also important, though not always easy, to distinguish the various possible routes of administration, e.g. by smoking and by mouth'.[5]

The IOM explains that throughout its report:

> marijuana refers to unpurified plant substances, including leaves or flower tops whether consumed by ingestion or smoking. References to 'the effects of marijuana' should be understood to include the composite effects of its various components; that is, the effects of THC, the primary psychoactive ingredient in marijuana, are included among its effects, but not all the effects of marijuana are necessarily due to THC. Cannabinoids are the group of compounds related to THC, whether found in the marijuana plant, in animals, or synthesised in chemistry laboratories.[6]

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1 G Griffith and R Jenkin, *Cannabis: The Contemporary Debate*, NSW Parliamentary Library Background Paper No 1/1994, p 3.

2 'Angiosperms: The Flowering Plants', *The Encyclopaedia Britannica*, 1996 CD Rom version.

3 House of Lords Select Committee on Science and Technology, *Report on Cannabis for Medical Purposes*, 9th Report, HL Paper 151, November 1998, para 3.1 (Henceforth, The House of Lords Report) . The report is available at - http://www.parliament.uk

4 Ibid, para 3.2.

5 Ibid, para 5.1.

6 Institute of Medicine, *Marijuana and Medicine: Assessing the Science Base*, 1999 , ES 2. (Henceforth, The IOM Report) Note that this overview of the report is based on the pre-publication copy available on the Internet at - http://www.nap.edu

3. CANNABIS AND MEDICAL USE - AN HISTORICAL AND CONTEMPORARY NOTE

Medical use of cannabis - historical note: That cannabis has been used across the centuries for medical purposes is not in doubt. Evidence suggests that its medicinal properties were well recognised in ancient China where physicians recommended it for the relief of many complaints, including constipation, gout, malaria and loss of appetite, plus as an aid to childbirth.[7] In Western medicine, the House of Lords Select Committee report, cannabis 'appeared in the Herbal (ie pharmacopoeia) of Dioscorides of about 60 AD, and in all subsequent herbals'. It is noted, too, that cannabis was reintroduced into British medicine in 1842 by Dr W O'Shaughnessy, an army surgeon who had served in India. In Victorian times, the report states, cannabis 'was widely used for a variety of ailments, including muscle spasms, menstrual cramps, rheumatism, and the convulsions of tetanus, rabies and epilepsy; it was also used to promote uterine contractions in childbirth, and as a sedative to induce sleep'.[8] With the development of new and better synthetic drugs in the twentieth century herbal remedies generally fell into disuse. However, cannabis, extract of cannabis and tincture of cannabis remained in the British Pharmaceutical Codex (list of registered and approved drugs) of 1949.[9] They were only removed from the Codex in 1954.[10] In 1973 the use of cannabis for medical purposes was prohibited altogether in the UK.[11]

To this debate, the IOM report adds the observation that marijuana's use as a herbal remedy before the 20th century is well documented. It continues: 'However, modern medicine adheres to different standards from those used in the past. The question is not whether marijuana can be used as an herbal remedy, but rather how this remedy meets today's standards of efficacy and safety'. For the IOM, 'The current debate over medical use of marijuana is essentially a debate over the value of its medical properties relative to the risk posed by its use'.[12]

Contemporary medical use - the IOM report: The IOM reports that there have been no comprehensive studies of the demographies and medical conditions of those using marijuana for medical reasons. Any survey results in this area must therefore be treated as partial and tentative in nature, something which is only to be expected when the practice at issue is itself illegal. With these and other qualifications in mind, it was said that most, but not all, 'people who use marijuana to relieve medical conditions have previously used it recreationally' and that, further to this, it is probable that there are 'relatively fewer

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7 G Griffith and R Jenkin, *Cannabis: The Contemporary Debate*, NSW Parliamentary Library Background Paper No 1/1994, p 4.

8 House of Lords Report, para 2.5.

9 Ibid, para 2.6.

10 G Griffith and R Jenkin, *Cannabis: The Contemporary Debate*, p 4.

11 House of Lords Report, para 2.9.

12 The IOM Report, p 1.8.

recreational marijuana users among cancer patients than among AIDS patients'. The report continues: 'Patients who reported their experience with marijuana at the public workshops said that marijuana provided them with great relief from symptoms associated with disparate diseases and ailments, including AIDS wasting, spasticity from multiple sclerosis, depression, chronic pain, and nausea associated with chemotherapy'.[13] The IOM study noted it was not in a position to evaluate or confirm these diagnoses.

Contemporary medical use - the House of Lords Select Committee report: In some ways this report is more forthcoming, commenting that 'Today in the United Kingdom, medical use of cannabis itself is illegal...but quite widespread'. Thereafter various estimations of usage from such bodies as the British Medical Association (BMA), the UK Alliance for Cannabis Therapeutics and the Multiple Sclerosis Society are presented, with the latter for example stating that a survey found that 1 per cent of people with multiple sclerosis use cannabis, a figure the Society considered an underestimation of the true figure.[14] The report suggests, too, that use of cannabis for medical purposes is 'sometimes connived at by the medical profession', although again the evidence is very sketchy.[15] The BMA, it seems, advises users of cannabis for medical purposes 'to be aware of the risks, to enrol for clinical trials, and to talk to their doctors about new alternative treatments; but they do not advise them to stop'.[16] In any event, the House of Lords Select Committee reported that 'Substantial numbers of patients with various conditions are illegally self-medicating with cannabis and are convinced that they derive medical benefit, although scientific evidence for or against such a conclusion is largely lacking'.[17]

The therapeutic and harmful effects claimed for cannabis: Note can be made of the therapeutic and harmful effects claimed for cannabis and cannabinoids. The claimed therapeutic effects of cannabinoids include:

- the control of nausea/vomiting associated with cancer chemotherapy;
- the control of muscle spasticity (eg, associated with multiple sclerosis, cerebral palsy and spinal chord injuries);
- pain management (eg. analgesic, anti-inflammatory);
- anti-convulsant effects (eg. epilepsy);
- treatment of glaucoma; and
- bronchodilation (asthma treatment).

The claimed harmful effects of cannabis include:

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13 Ibid, p 1.35.

14 House of Lords Report, para 5.2.

15 Ibid, para 5.6.

16 Ibid, para 5.10.

17 Ibid, para 1.3.

- effects on memory, learning and cognition, and higher order cognitive processes;
- short-term cardio-vascular effects;
- long-term risks of bronchial disease and cancers of the aerodigestive tract;
- links with psychotic conditions such as schizophrenia in vulnerable individuals;
- dependency - cannabis fulfills the modern (psychologically based) criteria for a drug dependency; and
- effects on the immune and reproductive systems.[18]

4. CANNABIS FOR MEDICAL PURPOSES - THE HOUSE OF LORDS SELECT COMMITTEE ON SCIENCE AND TECHNOLOGY REPORT

Background to the report: As the report itself acknowledges, the main reason for establishing the inquiry into cannabis and medical use was that 'there are now calls for the law to be changed to permit wider medical use of cannabinoids, and to permit the medical use of cannabis itself'.[19] In 1997 the BMA itself published a report on this issue[20] which, more than any other single factor, prompted the House of Lords Select Committee 'to examine the scientific and medical evidence to determine whether there was a case for relaxing some of the current restrictions on the medical use of cannabis'.[21]

A predictable range of opinion is found on the issue in the current debate in the UK, from those who advocate reform to others who see it as a stalking horse to promote the campaign for the legalisation of cannabis.[22]

Cannabis and the law in the UK: Briefly, for much of the historical detail corresponds with US and Australian experience as outlined in later sections of this paper, in the UK cannabis is regulated under the *Misuse of Drugs Act 1971* and the Misuse of Drugs Regulations 1985. Under the Act cannabis itself and cannabis resin are classified as Class B controlled drugs, while the cannabinoid cannabinol and its derivatives (defined as THC and 3-alkyl homologues thereof) are classified as Class A controlled drugs which attract stiffer penalties. Under the Regulations, cannabis, cannabis resin, and cannabinol and its derivatives (other than dronabinol)[23] appear in Schedule 1, which means that, unlike those

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18 *Cannabis Update*, The Parliamentary Office of Science and Technology (UK), Post Note 113, March 1998, p 3.

19 House of Lords Report, para 5.1.

20 BMA, *Therapeutic Uses of Cannabis*, BMA/Harwood Academic Publishers, 1997.

21 House of Lords Report, para 1.5. The report also considered whether the continued prohibition of recreational use is justified on the basis of the scientific evidence of adverse effects'.

22 Ibid, para 7.28.

23 The House of Lords report comments: 'THC itself (dronabinol...) is licensed as an anti-emetic in the USA, but not in this country. The BMA report recommends that it should be licensed here. This would depend on the manufacturer applying for a licence; in the mean time, doctors may prescribe it on an unlicensed basis at their own risk' (para 5.13). However, while dronabinol is not licenced as an anti-emetic in the UK, it may be prescribed

drugs appearing in Schedule 2, they cannot be administered for medical purposes. These Regulations, as the House of Lords Select Committee report explains, also empower the Home Secretary to licence anyone to produce, possess or supply any controlled drug, including a Schedule 1 drug; to licence cultivation of cannabis plants; and to approve premises for smoking cannabis for research purposes.

Thus, the position in practice in the UK is that cannabis and most of its derivatives may not be used in medicine, and may be possessed for research only under Home Office licence.[24] According to the House of Lords Select Committee report, only two psychoactive cannabinoids, nabilone[25] and dronabinol, may be used for medical purposes. Moreover, two non-psychoactive cannabinoids - cannabidiol and cannabichromene - are not controlled drugs and could, in theory, be prescribed as unlicensed medicines. However, it appears that no one is currently doing so.[26]

For those advocating law reform in this area, their main concern is to transfer cannabis from Schedule 1 to Schedule 2 in the 1985 Regulations, thereby permitting its use under certain conditions for medical purposes.[27] However, as the above discussion has shown, the position is more complicated than that. The House of Lords Committee reports in this respect:

> Unlike cannabis itself, the cannabinoid THC (dronabinol) and its analogue nabilone are already accepted by the Government as having medical value...producing the anomaly that, while cannabis itself is banned as a psychoactive drug, THC, the principal substance which makes it psychoactive, is in legitimate medical use.[28]

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on the named-patient basis defined in the 1985 Regulations. In practice it does not seem to be available as yet in the UK. Dronabinol and its use in the USA and Australia is discussed in a later sections of this paper (pages 16 and 33 respectively).

24 As at November 1998 there seemed to be 22 licences in operation, 20 at universities and two at hospitals. Most are for teaching and testing purposes; only three appear to be for research (para 7.20).

25 Nabilone is an analogue of THC and was licensed in 1982 for prescription-only hospital only use against nausea arising from chemotherapy and unresponsive to other treatment. It is said to be used 'very infrequently' (para 5.11). Note that nabilone is a licensed medicine and not a controlled drug.

26 The 1997 BMA report mentioned earlier was in fact prompted by a resolution in favour of medical use of 'certain additional cannabinoids', passed by the BMA's Annual Representative Meeting in the same year. In particular, the BMA called for the extension of the licenced indications for nabilone, and for the licensing of dronabinol for use in multiple sclerosis and other chronic spastic disorders unresponsive to standard drugs (paras 5.6 and 5.24).

27 The BMA has also recommend that 'The WHO (World Health Organisation) should advise the UN Commission on Narcotic Drugs to reschedule certain cannabinoids under the UN Convention on Psychotropic Substances, as in the case of dronabinol' (which was rescheduled in 1995) (para 7.16).

28 Ibid, para 8.9.

As for the issue of prosecution for the use of cannabis for medical purposes in the UK, the House of Lords report notes that the precise figures are not known. The UK Alliance for Cannabis Therapeutics drew the inquiry's attention to 15 reported cases of people charged with cultivation, possession and/or supply in medical situations since 1996: of the 12 cases where the outcomes were known, one resulted in a sentence of 50 hours community service; in the other 11, either the prosecution was abandoned, the defendant was acquitted, or the sentence was no greater than a conditional discharge.[29] In the meantime the BMA has recommended that, 'While research is under way, police, the courts and other prosecuting authorities should be aware of the medicinal reasons for the unlawful use of cannabis by those suffering from certain medical conditions for whom other drugs have proved ineffective'.[30]

Findings and recommendations - medical use of cannabis: The Committee recognised that there is insufficient evidence to either prove or disprove claims that cannabis has, or has not, medical value of any kind. Nevertheless, it concluded, 'we have received enough anecdotal evidence to convince us that cannabis almost certainly does have genuine medical applications, especially in treating the painful muscular spasms and other symptoms of multiple sclerosis (MS) and in the control of other forms of pain'.[31] On this basis, it recommended that: ***Clinical trials of cannabis for the treatment of MS and chronic pain should be mounted as a matter of urgency. (Emphasis in original)***[32]

Further, while these trials could include trials of smoked cannabis, the Committee recognised the dangers of smoking being used to administer any medicine eventually licensed. For this reason it recommended that: ***Research be promoted into alternative modes of administration (e.g. inhalation, sub-lingual, rectal) which would retain the benefit of rapid absorption offered by smoking, without the adverse effects.***

The Committee also expressed dissatisfaction with Government policy that, only if sufficient evidence in favour of cannabis as a medicine were produced for the Medicines Control Agency to licence it, would the Government amend the relevant Regulations so as to permit cannabis to be prescribed. Under this policy, the Committee said, cannabis would not be made available for medical use for several years, in the meantime leaving many thousands to suffer the very unpleasant symptoms of MS. In light of this, the Committee recommended that: ***The Government should take steps to transfer cannabis and cannabis resin from Schedule 1 to the Misuse of Drugs Regulations to Schedule 2, so as to allow doctors to prescribe an appropriate preparation of cannabis, albeit as an unlicensed medicine and on the named-patient basis, and to allow doctors and pharmacists to supply the drug prescribed.*** This would also allow research without a special license from the

29 Ibid, para 7.2.

30 Ibid, para 7.4.

31 Ibid, para 8.2.

32 Note that the actual recommendations of the House of Lords Committee report and the IOM report are reproduced in this bolded/italicised form.

Home Office.

If adopted, the Committee believed, this alternative policy would make the line against recreational use of cannabis easier to hold. This is because the current approach, by placing those who use cannabis for medical reasons in the front line of the war against drug abuse, makes criminals of people whose intentions are innocent, it adds to the burden of enforcement agencies, and it brings the law into disrepute. Having noted that, in order to move cannabis out of Schedule 1 the Government is required to consult the Advisory Council on the Misuse of Drugs, the Committee went on to recommend that: ***They do so at once, and respond to this report only after receiving and considering the advice of the Council.***

Findings and recommendations - medical use of cannabinoids: As noted, at present in the UK all cannabinoids other than THC (dronabinol) remain in Schedule 1 (the THC analogue, nabilone, is a licensed medicine and not a controlled drug). In order to transfer other cannabinoids from Schedule 1, agreement is required through the World Health Organisation under the 1971 UN Convention on Psychotropic Substances. The Committee was not convinced that any other cannabinoid has a convincing medical value. However, in order to facilitate research, it recommended that: ***The Government should raise the matter of rescheduling the remaining cannabinoids with the WHO in due course.***

Findings - why change the law? Primarily, this was for 'compassionate' reasons; secondarily, because the Committee believed that the law in this area is enforced inconsistently. A further subsidiary advantage would be the boost that law reform would give to research in this field. It was thought, too, that the rescheduling option would prevent persons charged with cannabis offences from claiming medical use as a bogus defence or plea in mitigation. Rather than having to investigate individual medical histories, as at present, the authorities would simply ask to see the prescription.

On the other hand, the report recommended that: ***If doctors are permitted to prescribe cannabis on an unlicensed basis, the medical professional bodies should provide firm guidance on how to do so responsibly; and safeguards must be put in place by the professional regulatory bodies to prevent diversion to improper purposes***. For example, the Committee was of the view that cannabis-based medicines should not be prescribed for persons with, or predisposed towards, schizophrenic illness or cardiovascular conditions; nor, pending further research should they be prescribed for pregnant women.

Findings and recommendations - recreational use: For completeness, the Committee's conclusions on this controversial subject can also be noted. In effect, it recommended that, on the basis of the scientific evidence available to the Select Committee: ***Cannabis and its derivates should continue to be controlled drugs.*** In other words, the argument for legalisation was rejected. In arriving at this conclusion the Select Committee cited the harmful effects of cannabis, including: its adverse psychic effects; its addictive qualities if used regularly; its impairment of cognitive functions during use; its risks for people with cardiovascular conditions; and the possibility that smoking cannabis may increase the risk of cancers to the mouth, throat and lung, and that it may cause similar respiratory disorder

to smoking tobacco. However, the Select Committee also warned that these harms must not be overstated.

The Select Committee's views on the toxic effects of cannabis and cannabinoids are set out at Appendix A. This includes a discussion of the relationship between cannabis and schizophrenia, as well as between cannabis and pregnancy.[33]

Responses to the House of Lords Select Committee Report: Discussed below is the official Government response to the House of Lords Select Committee Report, plus other relevant views and opinions.

(A) Government reply

In a departure from the usual conventions, the Government did not wait for the debate on the report to occur, but rejected the Select Committee recommendations that cannabis should be prescribable by doctors, immediately upon the release of the document on 11 November 1998. With the benefit of being informed by the debate which took place in the House of Lords on 3 December 1998, the Government then issued a formal written response to the entire Report, [34] in which it expressed the following views.

In relation to the first recommendation that *clinical trials of cannabis for the treatment of MS and chronic pain should be mounted as a matter of urgency*, the Government indicated that it would welcome clinical trials into the therapeutic uses of cannabis, and that it was content to leave it to the research community to decide whether cannabis as a whole or individual cannabinoids offer the best prospect. In either event, it would be willing to license medical research and trials involving cannabis or the cannabinoids, subject to the conditions set out in the report.

The Government accepted the second recommendation that *research should be promoted into alternative modes of administration which would retain the benefit of rapid absorption by smoking, without the adverse effects*, and would encourage research in this area among those who are looking to develop cannabis as a medicine.

However, the Government did not agree with the third recommendation that it *should take steps to transfer cannabis and cannabis resin from Schedule 1 to the Misuse of Drugs Regulations to Schedule 2, so as to allow doctors to prescribe an appropriate preparation of cannabis, albeit as an unlicensed medicine and on the named-patient basis, and to allow doctors and pharmacists to supply the drug prescribed*. The Government had expressed its initial concerns about this recommendation at the time of publication of the report and again during the debate on 3 December.

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33 At para 4.11 and paras 4.15-4.16 of Appendix A to this paper respectively.

34 This response was appended to the Second Report of the Select Committee on Science and Technology, *Cannabis: The Scientific and Medical Evidence*, located on the Internet at: http://www.publications.parliament.uk.

Its rationale being that substances contained in Schedule 1 to the Regulations are not generally acknowledged as having any therapeutic value. This Schedule includes cannabis, cannabis resin, and the cannabinoids (save nabilone and dronabinol) as well as substances such as coca leaf, Ecstasy, LSD, and raw opium. The fact that a drug is in Schedule 1 does not mean that it can never be moved to a schedule which imposes lesser controls, and the mechanics by which this can occur are described in the report. Cannabis and cannabis resin (but not the cannabinoids) could be re-scheduled without international agreement, but the Government re-states that the question is that posed in the report, namely, whether they should be.

The Government statement goes on to say that there is a well-established procedure which prospective medicines have to go through in order to ensure their safety, quality and efficacy. The very purpose of having these standards is to try and ensure, so far as is possible, that patients are not given medicines which are of poor quality, unsafe or ineffective. The Government's view is that it would not be proper to allow cannabis to be prescribed by doctors before those characteristics have been scientifically established. According to the Government statement, although the report admits that such a position has not been reached, it nonetheless takes the view that there are compassionate grounds for allowing doctors to prescribe cannabis, including smoked cannabis, even though the Select Committee acknowledged that smoking was dangerous and did not envisage smoking being used to administer any eventually licensed medicine, without the results of trials into the drug being known. The Government's belief is that such a move would be premature.

While being aware that there are people whose conditions are not helped by existing medication, the Government was not persuaded that even on compassionate grounds there was a case for setting aside the controls which exist to protect the public, and allowing doctors to prescribe, even on a named patient basis, raw cannabis with unknown standards of safety, quality and efficacy. An additional concern was that if the prescription of raw cannabis was permitted, as recommended in the report, the current momentum behind research into a suitable medicinal product based on cannabis and the cannabinoids would be checked to the detriment of proper scientific evaluation.

According to the Government statement, it's view that raw cannabis should not be available for medicinal purposes and that further research is required is supported by the British Medical Association and the Royal Pharmaceutical Society.

The Government indicated that it did not seek the advice of the Advisory Council on the Misuse of Drugs as suggested in recommendation four of the report, as it had already decided that the recommendations would not be accepted. Before any change in the law on cannabis, or any other controlled drug, is made, the Council has, under the terms of the Misuse of Drugs Act 1971, to be consulted. However, because the Government was not willing, and therefore was not proposing, to change the law in response to the recommendation, there was no legal obligation for the Council to be consulted. At its 19 November meeting, the Council noted that the Government had already firmly indicated that it would not be willing to amend the law as recommended, and took the view that there was accordingly nothing to be gained by giving detailed consideration to the question.

The fifth recommendation of the report related to *raising the question of rescheduling the remaining cannabinoids with the WHO in due course*. Dronabinol, one of the cannabinoids, is, as the report mentions, already subject to less stringent controls under the 1971 UN Convention on Psychotropic Substances than the other cannabinoids because of its now recognised therapeutic value. Accordingly it is in Schedule 2 rather than Schedule 1 of the Misuse of Drugs Regulations 1985. The Government's position is that if it becomes clear that any of the remaining cannabinoids have therapeutic potential it will seek amendment of the 1971 Convention which would make it possible to place these substances in Schedule 2 of the 1985 Regulations without breach of the Convention.

The sixth recommendation relating to the need for guidelines and safeguards to be put in place by medical professional bodies if doctors are permitted to prescribe cannabis on an unlicensed basis, was not considered necessary as the Government was unwilling to allow cannabis to be prescribed on an unlicensed basis. However, some of the consequences which may flow if the recommendation was implemented were outlined in the Government's statement:

(i) If cannabis could be prescribed on a named patient basis the doctor would, as the report acknowledges, take on him or herself full responsibility not only for the welfare of their patient but also for a person being allowed to possess cannabis. In the case of cannabis the Government does not believe that it would be reasonable to burden doctors with that responsibility.

(ii) If doctors were permitted to prescribe cannabis it could, in the absence of a marketing authorisation (product licence), be prescribed for any ailment which the doctor chose. Doctors would come under enormous pressure from some patients to prescribe cannabis for a variety of conditions. In the face of that pressure, whatever guidance might be given by their professional bodies, without statutory control some doctors would undoubtedly give in and prescribe; other doctors believing in the benefits of cannabis would prescribe it anyway.

(iii) Allowing raw cannabis (which would usually be smoked) as a medicine would seriously blur the distinction between misuse and therapeutic use. It would send confusing messages to the public about the risks of misusing the drug. People caught in possession of unprescribed cannabis by the police would frequently argue that it was for therapeutic purposes and claim that the prescription had been lost. On the other hand, if a medicinal form of the drug were available it would be possible to retain a clear difference between the two forms. The risk of diversion of the medicinal form to the illicit market would be no greater than it is for current medicines which contain controlled drugs, on which there are controls on production, supply and possession.

The Government agreed with the Select Committee's final recommendation that *cannabis and its derivatives should continue to be controlled drugs*.

(B) House of Lords Select Committee response[35]

The Select Committee issued a short second Report responding to the Government's statement. It noted that the main arguments by the Government against the Select Committee recommendations had been considered in the course of the inquiry, and were ones which the Select Committee continued to find unpersuasive.

In relation to the Government's first argument that prohibition protects patients from taking substances of unproven efficacy, quality and safety, the Select Committee stated that it had found enough evidence, albeit largely anecdotal, to convince it that cannabis is efficacious, especially against the symptoms of MS and in the control of pain. As significant numbers of sufferers currently use cannabis, in defiance of the law and without medical supervision or quality control the Select Committee said its recommendation would enable the health professions and the pharmaceutical industry to collaborate to provide appropriate preparations. As for the question of safety, the Select Committee stated that although cannabis is well known to be safe in terms of acute toxicity, it acknowledged that its use does involve risks, from which people currently using it for medical purposes are unprotected. For this reason, the Select Committee recommended that the medical professional bodies should provide guidance on responsible prescribing, to protect at-risk groups and to take account of the dangers of intoxication and addiction.

In relation to the Government's second line of argument that permitting prescription now would reduce the momentum of research, the Select Committee found the evidence indicated the contrary position, namely that research had been held back by the stigma and bureaucracy associated with the status of cannabis as an illegal drug.

The third area of disagreement was in relation to the capability of doctors to deal with patients demanding cannabis for improper purposes. The Select Committee did not agree with the Government's lack of conviction in the medical profession and its regulatory bodies in this regard. It also noted recommendations made in the report in relation to special safeguards against diversion.

In conclusion, the Select Committee stated:

> We regret that the mind of the Government appears to be closed on this issue, and hope that the results of new research now under way may cause them to revisit our recommendations at an early date.

(C) Other responses to the House of Lords Report

The Royal Pharmaceutical Society [36] welcomed the House of Lords call to reschedule

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35 The Second Report of the Select Committee on Science and Technology, *Cannabis: The Scientific and Medical Evidence*, located on the Internet at: http://www.publications.parliament.uk.

36 This information can be found on the Internet at: http://www.rpsgb.org.uk/na058.htm#3

cannabis under the Misuse of Drugs Regulations 1985 so that standardised preparations can be prescribed while research into individual active ingredients is carried out. Commenting on the House of Lords report on November 11, Professor Tony Moffat (the Society's chief scientist) said that the Society believed that the way ahead lay in research into the potential medicinal use of the individual active ingredients of cannabis, cannabinoids, rather than in cannabis itself. 'Cannabis is a pharmacologically dirty substance,' he said. 'When you ingest cannabis, you take in hundreds of compounds, some of which may do harm and some of which may be helpful. What we need to do is isolate the useful cannabinoids and that is why we need more research,' he said.

Responding to the House of Lords Report, the British Medical Association (BMA) backed the call for urgent clinical trials of cannabis for the treatment of multiple sclerosis and pain but warned that crude cannabis is not a suitable medicinal product. [37] It expressed disappointment that the House of Lords report failed to make a clear and consistent distinction between cannabinoids, which are the active constituents of cannabis, and cannabis itself. Crude cannabis has many toxic ingredients, including high levels of tar, fungi and pesticide residues and it is not known which of the 60-plus cannabinoids have therapeutic uses and which may have short or long term adverse effects.

In its statement the BMA refers to the fact that it has argued that people who break the law and use crude cannabis to obtain relief from their symptoms should be treated with compassion. However, according to the BMA, the report's recommendations are contradictory. The report rejects smoking as a suitable method of taking the drug and wants doctors to prescribe an 'appropriate preparation of cannabis', probably an oral capsule. However, in the accompanying press release the House of Lords Select Committee envisages that producing a prescription would be sufficient evidence in defence against a charge of possession of cannabis. In the view of the BMA that clearly implies that patients will continue to use crude cannabis, a route the BMA rejects because of the harmful effects of smoking and the unpredictable nature of its effects.

The BMA opposes the recommendation to transfer cannabis and cannabis resin from Schedule 1 to Schedule 2 of the Misuse of Drugs Act. Instead it recommends that certain cannabinoids should be rescheduled and the regulations made sufficiently flexible to allow clinical trials to proceed urgently. The BMA believes that this route will allow the development of targeted medicines whereas simply prescribing cannabis will not resolve the uncertainty and lack of evidence on its pharmacological effects.

Commenting on the report, Sir William Asscher, Chairman of the BMA's Board of Science and Education said :

> I understand the humanitarian motives which have led the House of Lords Committee to recommend legalising cannabis for medical use but scientifically, I cannot support it. We have good clinical trials starting next year which will compare herbal cannabis with a synthetic cannabinoid and

[37] This information can be found on the Internet at: http://www.bma.org.uk/news/news.htm.

> a placebo and these trials should proceed before any hasty move to change the law. Crude cannabis is a toxic mixture of more than 60 cannabinoids and other ingredients. Prescribing it will not add to our knowledge, it will detract from the development of scientifically based and more beneficial new drugs.

Dr Vivienne Nathanson, BMA Head of Health Policy and Research said :

> Many people with conditions like MS use cannabis to relieve pain and control muscle spasm. However crude cannabis also has the unwanted side effect of loss of concentration which affects your ability to drive and work. The other side effects of cannabis are highly unpredictable, partly because it has more than 400 active ingredients in varying quantities. That is why we strongly believe that the development of new cannabis-based drugs is the better route forward particularly if the drugs are to be used long term for chronic conditions.

5. MARIJUANA AND MEDICINE - THE INSTITUTE OF MEDICINE'S REPORT

Background to the IOM report: In January 1997 the White House Office of National Drug Control Policy (ONDCP) asked the Institute of Medicine (IOM) to conduct a review of the scientific evidence to assess the potential health benefits and risks of marijuana and its constituent cannabinoids. The review, which began in August 1997, culminated with the release in March 1999 of the report, *Marijuana and Medicine: Assessing the Science Base*. It is claimed to represent 'the most thorough analysis to date of the relevant scientific literature'.[38] According to an article in *The New York Times* the significance of the report goes beyond its contribution it the discussion of marijuana's medical uses, for 'it has also opened a debate into marijuana's role as a linchpin of a national policy of zero tolerance toward illicit drugs'.[39]

Marijuana and the law in the US: The Introduction to the IOM report notes the 'changing legal landscape' in the US as far as marijuana is concerned, as well as the arguments in recent years for and against its decriminalisation. Basically, the situation in the US has been that marijuana is an illegal drug. In 1942 it was removed from the US Pharmacopoeia on the ground that it was 'believed to be a harmful and addictive drug that caused psychoses, mental deterioration, and violent behaviour'.[40] Marijuana's current legal status in the US was established in 1970 with the passage of the *Controlled Substances Act*, which divided

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38 ONDCP Media Release, *White House Drug Policy Issues Statement on Institute of Medicine's Report on Marijuana and Medicine*, 17 March 1999 - http://www.whitehouse drug policy.gov/news/press/1999/031799.htm

39 C Wren, 'Report on medical use of marijuana brings new fight on zero tolerance', *The New York Times*, 19 March 1999.

40 The IOM Report, p 1.5.

drugs into five Schedules and placed marijuana in Schedule 1, the category for drugs with high potential for abuse and no accepted medical use. Around the same time, however, with the sharp increase in marijuana use, especially among the young, a movement for the decriminalisation of marijuana started. As the IOM report acknowledges this movement has for the past 25 years been 'closely linked' with the medical marijuana movement which, the report notes, 'has coloured the debate'. A leading advocate in this debate has been the National Organization for the Reform of Marijuana Legislation (NORML) which has argued that marijuana is therapeutic in many serious ailments, and is less toxic and sometimes more effective than conventional medicines. On the other side, those opposing the medical use of marijuana see it as a Trojan Horse, a deceptive tactic used by those advocating the decriminalisation of marijuana.

In any event, in the 1970s eleven US States decriminalised marijuana, although subsequently some of these recriminalised marijuana use in the 1980s and 1990s. A further dimension to the story is that during the 1980s some AIDS patients found that marijuana relieved their symptoms, most dramatically, according to the report, those symptoms 'associated with AIDS wasting'. Prosecutions followed in which those charged with unlawful possession of marijuana claimed the 'medical necessity' defence on the ground that they were using the drug to treat medical conditions. The report comments, 'Although most courts rejected these claims, some accepted them'.[41]

The report goes on to explain that, against this background, voters in California and Arizona in 1996 passed referendums that attempted to legalise the medical use of marijuana under particular conditions. The 1996 California referendum known as Proposition 215 allowed, subject to a physician's recommendation, seriously ill Californians to obtain and use marijuana for medical purposes without criminal prosecution or sanction. Also, under the law, physicians cannot be punished or sanctioned for recommending marijuana to patients who suffer from any illness for which marijuana will provide relief. In Arizona the situation is more complicated. There the 1996 referendum, known as Proposition 200, gave the option to physicians to prescribe controlled substances, including marijuana, to treat the disease or relieve the suffering of seriously or terminally ill patients. However, the referendum was stalled when Arizona legislators voted later that all prescription medications must be approved by the Food and Drug Administration (marijuana is not so approved). A second referendum was passed in November 1998 but, as the report comments, 'this is still at odds with federal law'.[42] Summing up the present legal position in the US, the report states:

> As of [the Northern] summer 1998, eight states - California, Connecticut, Louisiana, New Hampshire, Ohio, Vermont, Virginia and Wisconsin - had laws that permit physicians to prescribe marijuana for medical purposes or to allow a medical necessity defence. In November 1998, five states - Arizona, Alaska, Oregon, Nevada, and Washington - passed medical

41 Ibid, p 1.6. Several relevant cases are discussed in D Heilpern and GL Rayner, 'Drug law and necessity' (1997) 22 *Alternative Law Journal* 188 at 191.

42 The IOM Report, p 1.7.

> marijuana ballot initiatives. The District of Columbia also voted on a medical marijuana initiative, but was barred from counting the votes because an amendment designed to prohibit them from doing so was added to the federal appropriation bill; however, exit polls suggested that a majority of voters had approved the measure.[43]

To this the report adds that public support in the US for patient access to marijuana for medical use appears to be 'substantial', with public opinion polls taken during 1997 and 1998 generally reporting '60-70 percent of respondents in favour of allowing medical use of marijuana'. However, it remains the case that the State referenda passed to permit such use are inconsistent with federal laws regulating marijuana and, as the report notes, 'their implementation raises complex legal questions'.[44]

For the Institute of Medicine, the main point to make was that, despite the level of public interest, the current public discussions of the medical use of marijuana 'have not been well informed by carefully reasoned scientific debate'. In effect, this was its brief when some months after the passage of the California and Arizona marijuana referendums, ONDCP asked the Institute to conduct a scientific review of the medical value of marijuana and its constituent compounds: 'the charge to IOM was to review the medical use of marijuana and the harms and benefits attributed to it...'.[45]

The use of dronabinol in the USA: Marijuana and THC are found in Schedule 1 of the *Controlled Substances Act 1970*, the most restrictive Schedule available. Marijuana is not therefore a legally marketed drug in the US; its only legal use is in research under strictly defined conditions. It seems that cannabinoids found in the marijuana plant are automatically in Schedule 1 until the manufacturer requests and provides justification for rescheduling, a process which is likely to be both difficult and costly.

However, over the past 16 years cannabinoids not found in the marijuana plant have been chemically synthesised.[46] Thus, as the IOM report states, under US law 'Schedule 1 status does not necessarily apply to all cannabinoids'.[47] Indeed, as noted earlier in this paper, one cannabinoid, dronabinol, has approval for marketing in the US, where it is marketed as Marinol. Dronabinol is an oral capsule containing THC in sesame oil. It was approved by the Food and Drug Administration in 1985 for the treatment of nausea and vomiting associated with cancer chemotherapy. In 1992 the marketing of dronabinol for the treatment of anorexia associated with weight loss in patients with AIDS was approved. This second approval only occurred after completion of Phase III studies lasting three years and costing

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43 Ibid.

44 Ibid, p 1.6.

45 Ibid.

46 Ibid, p 2.1.

47 Ibid, p 5.3.

$5 million.[48]

As the IOM report explains, dronabinol is 'synthesized in the laboratory rather than extracted from the plant'. The report continues:

> Its manufacture is complex and expensive because of the numerous steps in the manufacturing process needed for purification. Since dronabinol is highly lipophilic, its poor solubility in aqueous solutions together with its high first-pass metabolism in the liver are responsible for its poor bioavailablity; only 10-20 percent of the original oral dose reaches the systemic circulation. The onset of action is slow, with weak plasma concentrations attained 2-4 hours after dosing. By contrast, inhaled marijuana is rapidly absorbed...Dronabinol's most common adverse events are associated with the central nervous system (CNS): anxiety, confusion, depersonalization, dizziness, euphoria, somnolence, and thinking abnormality.[49]

Since 1985 dronabinol has been found in Schedule II, the second most restrictive category under the *Controlled Substances Act 1970*, which is reserved for medically approved substances with 'high potential for abuse'. More recently Unimed Pharmaceuticals, the manufacturer of Marinol, petitioned the Drug Enforcement Administration (DEA) to reschedule its product from Schedule II to Schedule III, a category reserved for medical substances with some potential for abuse. On 5 November 1998 the DEA announced a proposal to reschedule Marinol as requested, although at the time of writing the IOM report no formal action on the proposal had been taken.[50] The report, which discusses the issues relevant to the marketing of Marinol in some detail, comments further: 'The experience with dronabinol may serve as a bellwether for the regulatory and commercial fate of new cannabinoids being considered for development'.[51]

The IOM Report - three main concerns: The report's three main concerns in evaluating the medical use of marijuana were:

- evaluation of the effects of isolated cannabinoids;
- evaluation of the efficacy of marijuana; and
- evaluation of the health risks associated with the medical use of marijuana.

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48 Ibid, p 5.12. Phase III is the final stage of clinical testing under the process resulted by the Food and Drug Administration. The report sets out this whole process in detail. Also, it notes that the only cannabinoid licensed outside the US is nabilone, which is an analogue of THC available in the UK for the management of nausea and vomiting associated with cancer chemotherapy.

49 Ibid, p 5.13.

50 Ibid, p 5.14.

51 Ibid, p 5.11.

Using the reports executive summary as a guide, an overview of the IOM's findings and recommendations in respect of these three concerns can now be presented.

Effects of isolated cannabinoids - findings and recommendations: The IOM report that great advances have been made in this area by basic science over the last 16 years. For example, it seems that THC exerts its effects by mimicking chemicals that are naturally present in the brain (so-called 'natural cannabinoids') and a key research target over the past decade or so has been to discover these and work out their role. Researchers used 'tagged' cannabinoids to identify potential binding sites in the brain and found one type of receptor (CBI), which was widely distributed throughout the brain and was bound only to THC. This led to the discovery of a natural cannabinoid (anandamide) which uses the CBI site.

Chapter 2 of the IOM report summarises the state of cannabinoid biology, as this is known at present. On this basis, it concluded:

- cannabinoids are likely to have a natural role in pain modulation, control of movement, as well as memory;
- the natural role of cannabinoids in immune systems is likely multifaced and remains unclear;
- the brain develops tolerance to cannabinoids;
- animal research demonstrates the potential for dependence, but this potential is observed under a narrower range of conditions than with benzodiazepine, opiates, cocaine, or nicotine; and
- withdrawal symptoms can be observed in animals, but appear to be mild compared to opiates or benzodiazepine, such as diazepam (Valium).

The report also found that: different cannabinoid receptor types found in the body appear to play different roles in normal human physiology; and that some effects of cannabinoids appear to be independent of those receptors. It also concluded that 'The variety of mechanisms through which cannabinoids can influence human physiology underlies the variety of potential therapeutic uses for drugs that might act selectively in different cannabinoid systems'.[52]

The first recommendation of the IOM report was that: ***Research should continue into the physiological effects of synthetic and plant-derived cannabinoids and the natural function of cannabinoids found in the body. Because different cannabinoids appear to have different effects, cannabinoid research should include, but not be restricted to, effects attributable to THC alone.***

Efficacy of cannabinoid drugs - findings and recommendations: The available data investigated by the IOM indicated a 'potential therapeutic value for cannabinoid drugs, particularly for symptoms such as pain relief, control of nausea and vomiting, and appetite stimulation'. These therapeutic effects are best established, it seems, for THC.

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52 Ibid, p 2.44.

However, the report went on to say that the effects of cannabis on the symptoms studied are generally modest and, in most cases, more effective medications exist. On the other side, people do vary in their responses to medications and there will likely always be a subpopulation of patients who do not respond well to other medications. The report commented, 'The combination of cannabinoid drug effects...suggests that cannabinoids would be moderately well suited for certain conditions, such as chemotherapy-induced nausea and vomiting and AIDS wasting'.[53]

Summarising its findings, the report noted again the potential therapeutic value of cannabinoid drugs, but commented that 'smoked marijuana...is a crude THC delivery system that also delivers harmful substances'. The IOM's second recommendation was that: ***Clinical trials of cannabinoid drugs for symptom management should be conducted with the goal of developing rapid-onset, reliable, and safe delivery systems***. Formulations that can deliver THC rapidly and directly to the circulation include deep lung aerosols, nasal sprays, nasal gels and sublingual preparations. It seems that Phase I clinical studies are underway for the delivery of Marinol by these means.

At the same time the IOM report was not overly confident that cannabinoid-based drugs will become available. It will depend on there being sufficient incentive for private enterprise to develop and market such drugs.

The report also looked at the influence of psychological effects on therapeutic effects where marijuana is concerned. Briefly, its conclusion was that the psychological effects of cannabinoids, such as anxiety reduction, sedation, and euphoria can influence their potential therapeutic value. While those effects are potentially undesirable for certain patients and situations (for example, older patients with no previous marijuana experience), for others the effects are beneficial. Its third recommendation was that: ***Psychological effects of cannabinoids, such as anxiety reduction and sedation, which can influence medical benefits, should be evaluated in clinical trials.***

On the specific issue of marijuana use and schizophrenia, the IOM report noted that the association 'is not well understood'. The report went on to comment that 'The scientific literature indicated general agreement that heavy marijuana use can precipitate schizophrenic episodes, but not that marijuana use can cause the underlying psychotic disorder'.[54] It was also reported that schizophrenics prefer the effects of marijuana over those of alcohol or cocaine, 'which they generally use less often than does the general population'. The reasons for this are unknown, the IOM report explained, 'but it raises the possibility that schizophrenics might obtain some symptomatic relief from moderate marijuana use. But overall, compared with the general population, individuals with schizophrenia or with a family history of schizophrenia are likely to be at greater risk of suffering adverse psychiatric effects from the use of cannabinoids'.[55]

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53 Ibid, ES 4.

54 IOM Report, p 3.28.

55 Ibid.

Risks associated with medical use of marijuana - findings and recommendations: According to the report, 'The most contentious aspect of the medical marijuana debate is not whether marijuana can alleviate particular symptoms, but rather the degree of harm associated with its use'.[56] The report then summarises the harmful effects of marijuana to the individual and, to a lesser extent, to society, noting by the way that the vast majority of data on harmful effects is based on smoked marijuana and that, except for the psychoactive effects attributable to THC, it is not possible to distinguish the drug effects from the effects of inhaling smoke of burning plant material.[57]

The report divides the harmful effects of marijuana into *acute* and *chronic* effects and states that, for most people, the primary adverse effect of acute marijuana use is diminished psychomotor performance. It is inadvisable, the report found, to drive 'any vehicle or potentially dangerous equipment while under the influence of marijuana'.[58] On the other hand, the short-term immunosuppressive effects of marijuana use are not well-established and, if they exist at all, are not likely to preclude a legitimate medical use.[59] The acute side effects of marijuana use, according to the report, 'are within the risks tolerated for many medications'.[60]

The chronic effects of marijuana were said to be of greater concern for medical use and fall into two categories: the effects of chronic smoking, and the effects of THC. Numerous studies suggest that marijuana smoke is an important risk factor in the development of respiratory disease. It was found, in this regard, that marijuana smoke, like tobacco smoke, is 'associated with increased risk of cancer, lung damage, and poor pregnancy outcomes' and that smoked marijuana is 'unlikely to be a safe medication for any chronic medical condition'.[61] The IOM's fourth recommendation was that: ***Studies to define the individual health risks of smoking marijuana should be conducted, particularly among populations in which marijuana use is prevalent.***

A second concern associated with chronic marijuana use is that of dependence on the psychoactive effects of THC and the experiencing of any subsequent withdrawal

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56 Ibid, p 3.1.

57 Ibid, p 3.48.

58 Ibid.

59 The report commented: 'The question that needs to be addressed is whether THC or marijuana is a risk factor for HIV infection, for progression to more severe stages of AIDS, or for opportunistic infection among HIV-positive patients (p 3.43). It had been noted previously that 'The relationship between marijuana smoking and the natural course of AIDS is of particular concern because HIV patients are the largest group who report using marijuana for medical purposes. Marijuana use has been linked to both increased risk of progression to AIDS in HIV-seropositive patients, and to increased mortality in AIDS patients' (p. 3.39).

60 Ibid.

61 Ibid, ES 5.

symptoms.[62] The report commented that 'a distinctive marijuana withdrawal syndrome has been identified, but it is mild and short-lived'. This withdrawal syndrome was also said to be 'mild and subtle compared to the profound syndrome of alcohol or heroin withdrawal'.[63] The syndrome includes restlessness, irritability, mild agitation, insomnia, sleep EEG disturbance, nausea, and cramping.[64] The report suggested that slightly more than 4 percent of the general population were dependent on marijuana at one time in their life.[65] Some users do therefore develop dependence but, in the words of the report, 'they appear less likely to do so than users of other drugs (including alcohol and nicotine)...'.[66] On the issue of the prevalence of marijuana use, it was found that, in 1996, 68.6 million people or 32 percent of the US population over 12 years old had tried marijuana or hashish at least once in their lifetime, but only 5 percent were current users. Marijuana use was found to be most prevalent among 18-25 year olds and to decline sharply after age 34.[67] The report found that a vulnerable subpopulation of marijuana users can develop dependence:

> Adolescents, particularly those with conduct disorders, individuals with psychiatric disorders, or problems with substance abuse appear to be at greater risk for marijuana dependence than the general population.[68]

A further concern identified in the IOM report was with marijuana as a 'gateway' drug to the use of more harmful substances. On this issue, the report found that patterns in progression of drug use from adolescence to adulthood are 'strikingly regular' and concluded that 'In the sense that marijuana use typically precedes rather than follows initiation of other illicit drug use, it is indeed a "gateway" drug'. However, it adds that, because underage smoking and alcohol use typically precede marijuana use, marijuana is not the most common, and is rarely the first, 'gateway' to illicit drug use. The report also notes that marijuana does not appear to be a gateway drug

> to the extent that it is the most significant predictor or even the cause of

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62 Ibid, p 3.5. Withdrawal is defined in the report thus: 'The collective symptoms that occur when the drug is abruptly withdrawn are known as withdrawal syndrome and are often the only evidence of physical dependence'. Physiological dependence is said to be 'diagnosed when there is evidence of either tolerance or withdrawal; it is sometimes, but not always, manifested in substance dependence'.

63 Ibid, p 3.7.

64 Ibid, ES 6.

65 Ibid, p 3.19.

66 Ibid, p 3.20. The IOM report also noted that: 'If marijuana or cannabinoid drugs were approved for therapeutic uses, it would be important to consider the possibility of dependence, particularly for patients in high risk groups for substance dependence. Certain controlled substances that are approved medications produce dependence after long term use. This is, however, a normal part of patient management and does not generally present undue risk to the patient'.

67 Ibid, p 3.11.

68 Ibid, p 3. 48.

> heavy drug abuse; that is, care must be taken not to attribute cause to association. The most consistent predictors of heavy drug use appear to be intensity of marijuana use, and co-occurring psychiatric disorders or a family history of psychopathology including alcoholism.[69]

Thus, it was found that 'There is no conclusive evidence that the drug effects of marijuana are causally linked to the subsequent abuse of other illicit drugs'.[70] The report explained that, whereas the stepping stone hypothesis presumes a predominantly physiological component to drug progression, the gateway theory is a social theory: 'The latter does not suggest that the pharmacological qualities of marijuana make it a risk factor for progression to other drug use. Instead it is the legal status of marijuana that makes it a gateway drug'.[71] The report added the cautionary note that data on drug use progression cannot be assumed to apply to the use of drugs for medical purposes: 'It does not follow from those data that if marijuana were available by prescription for medical use, the pattern of drug use would remain the same as seen in illicit use'.[72]

Finally, the link between medical use and drug abuse was considered, in particular in relation to the concern that sanctioning the medical use of marijuana might increase its use among the general population by, among other things, sending the wrong message to children and teenagers about the harms of marijuana. The question here is not whether marijuana can be both harmful and helpful, but whether the perception of its benefits will increase its abuse. According to the IOM report any answer to that question 'remains conjecture'.[73] It found 'little evidence', for instance, that decriminalisation of marijuana use necessarily leads to a substantial increase in marijuana use;[74] or that the medical use of opiates has resulted in the start of drug addiction in many individuals;[75] or indeed that the medical marijuana debate has altered perceptions among adolescents about the risks of marijuana use.[76] The report concluded:

> Present data on drug use progression neither support nor refute the suggestion that medical availability would increase drug abuse. However, this question is beyond the issues normally considered for medical uses of drugs, and should not be a factor in evaluating the therapeutic potential of marijuana or cannabinoids.[77]

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69 Ibid, p 3.23.

70 Ibid, ES 6.

71 Ibid, p 3.21.

72 Ibid, ES 6.

73 Ibid, p 3.23.

74 Ibid, p 3.25.

75 Ibid, p 3.24.

76 Ibid, p 3.27.

77 Ibid, ES 7.

Use of smoked marijuana - findings and recommendations: Due to the health risks associated with smoking, the IOM report concluded that smoked marijuana should generally not be recommended for long-term medical use. Smoking is a poor drug delivery system, in part because of the harmful substances it delivers to the body, but also because cannabis plants contain a variable mixture of biologically active compounds and cannot, therefore, be expected to provide a precisely defined drug effect. If there is any future in cannabinoid drugs, it lies with agents of more certain, not less certain composition.

However, the report also found that for certain patients, such as the terminally ill or those with debilitating symptoms, the long-term risks associated with smoked marijuana are not of great concern. Also, it was acknowledged that, despite the legal, social and health problems associated with smoking marijuana, it is widely use by certain patient groups, thus raising both safety and efficacy issues. On this basis, the report's fifth recommendation was that: ***Clinical trials of marijuana use for medical purposes should be conducted under the following limited circumstances: trials should involve only short-term marijuana use (less than six months); be conducted in patients with conditions for which there is reasonable expectation of efficacy; be approved by institutional review boards; and collect data about efficacy.***

For the IOM, any future marijuana has as a medicine lies in its isolated components, the cannabinoids and their synthetic derivatives: 'Isolated cannabinoids will provide more reliable effects than crude plant mixtures. Therefore, the purpose of clinical trials of smoked marijuana would not be to develop marijuana as a licensed drug, but such trials could be a first step towards the development of rapid-onset, non-smoked cannabinoid delivery systems'.[78] Moreover, it was acknowledged that until a non-smoked, rapid-onset cannabinoid drug delivery system becomes available, there is no clear alternative for people suffering chronic conditions that might be relieved by smoking marijuana, such as pain or AIDS wasting. One suggestion was that patients with conditions of this kind could, subject to their informed consent, be used in clinical trials as experimental subjects using a harmful drug delivery system, in which their condition is closely monitored and documents under medical supervision, thereby increasing the knowledge base of the risks and benefits of marijuana use under such conditions. Following this line of reasoning, the report's sixth recommendation was as follows:

> ***Short-term use of smoked marijuana (less than six months) for patients with debilitating symptoms (such as intractable pain or vomiting) must meet the following conditions:***
> - ***failure of all approved medications to provide relief has been documented;***
> - ***the symptoms can reasonably be expected to be relieved by rapid onset cannabinoid drugs;***
> - ***such treatment is administered under medical supervision in a manner that allows for assessment of treatment effectiveness;***
> - ***and involves an oversight strategy comparable to an institutional***

78 Ibid, ES 11.

> ***review board process that could provide guidance within 24 hours of a submission by a physician to provide marijuana to a patient for a specified use.***

Responses to the IOM Report: Discussed below is the official Government response to the IOM report, plus other relevant views and opinions.

(A) White House Office of National Drug Control Policy:

A statement was issued by the White House Office of National Drug Control Policy (ONDCP) on 17 March 1999 following the release of the Institute of Medicine's Report, *Marijuana and Medicine: Assessing the Science Base*. [79] The ONDCP pointed out that this Report was in response to a request by it in January 1997 that the Institute of Medicine conduct a review of the scientific evidence for assessing the potential health benefits and risks of marijuana and its constituent cannabinoids.

The ONDCP described the report as representing 'the most thorough analysis to date of the relevant scientific literature. It summarizes recent advances in molecular and behavioural neuroscience, in particular newly elaborated systems of transmitters, receptors, and antagonists, all illuminating the physiological effects of cannabinoids'.

After detailing the six specific recommendations made in the report the ONDCP indicated it would carefully study the recommendations and conclusions contained therein, and that it would continue to rely on the professional judgement of the Secretary of Health and Human Services, the Director of the National Institutes of Health, and the Surgeon General on all issues related to the medical value of marijuana and its constituent cannabinoids.

(B) Other responses to the Institute of Medicine Report

Following the release of the report, a number of experts in the drug field as well as various spokespeople from organisations both for and against the medical use of cannabis have commented on the report's findings. Given the currency of the report, however, it would appear that to date no detailed review or analysis has been submitted to any major medical or scientific journal. Some comments drawn from the general press at the time of the report's release are provided below.

Mike Mitka writing in the *Journal of the American Medical Association* [80] commented thus:

> Advocates for the medical use of marijuana received support recently from Institute of Medicine recommendations that clinical trials and drug development should proceed. But its acceptance into the general population of prescribed drugs appears to be years away - if it happens at all.

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79 This document can be found on the Internet at: http://www.whitehousedrugpolicy.gov.

80 *The Journal of the American Medical Association*, Vol 281 No 16, 28 April 1999, pp 1473-1474.

He then refers to the way in which the report's findings are used by those at opposite ends of the debate to support their particular view on the medical use of marijuana. On the one hand, the ONDCP Director General Barry McCaffrey, referred to the comments made in relation to the harms associated with smoking marijuana, and on the other a spokesperson for the Marijuana Policy Project, said that the report presented ample scientific evidence confirming the benefits of marijuana as medicine.

An article in *The New York Times* [81] also alluded to the way in which the report was being held up by advocates on both sides of the issue as being in their favour. Dr Herbert Kleber, one of 13 experts who reviewed the report for the Institute of Medicine before its release, said it set high standards for justifying the medical use of marijuana. But Dr Kleber, medical director of the National Center on Addiction and Substance Abuse at Columbia University, also called the report 'that kind of thing where people can take sound bites to bolster whatever position they want.' Evidence of this is cited in the article. Opponents such as Dr Robert DuPont, clinical professor of psychiatry at Georgetown University Medical School, was quoted as saying: 'The only issue from a policy point of view is whether smoked marijuana is a viable medicine for the treatment for anything, and the report virtually says no, which is very important. People don't go to their pharmacy and get a prescription for burning leaves.' While Bill Zimmerman, Executive Director of Americans for Medical Rights, reportedly said: 'the release of this Report is the beginning of the process, not the end. It will provoke all kinds of activity across the country.'

In a joint media release [82] Dr Eric Voth, Chairman of the International Drug Strategy Institute commented: 'The results of the Institute of Medicine study clearly highlight the problems of smoking marijuana for medicinal purposes. Marijuana is not medicine, and we should adhere to high standards of both efficacy and safety for medicines'. Sandra Bennett, President of Drug Watch International, a non-profit organisation concerned with effective international policies and strategies which discourage drug use, stated: 'Though it has recently been discovered that nicotine has potential for therapeutic use, no responsible doctor would recommend smoking tobacco in the face of its potential to do harm. Marijuana should be viewed even more harshly.'

6. RECOMMENDATIONS MADE IN OTHER RECENT REPORTS ON THE MEDICAL USE OF MARIJUANA

General recommendations: Recommendations from five recent key reports pertaining to the medical use of marijuana are listed by subject in Appendix D to the IOM report.[83] The content of that Appendix is reproduced here in an edited form.

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81 C Wren, 'Report on Medical Use of Marijuana Brings New Fight on Zero Tolerance', *The New York Times*, 19 March 1999.

82 This document can be located on the Internet at: http://www.estreet.com/orgs/dsi/crude/marijuananotmedicine.

83 Recommendations made on issues outside the scope of the IOM report, such as drug law and scheduling decisions, are not included in the appendix. Also, the House of Lords Select Committee Report was not summarised as it was released too late to be analysed carefully.

The IOM team reviewed the following reports and noted their general recommendations thus:

- **Health Council of the Netherlands**, Standing Committee on Medicine (1996) *Marihuana as medicine*. Rijswikj, the Netherlands: Health Council of the Netherlands. In order to assess the efficacy of marihuana and cannabinoids, the committee studied literature published during the past 25 years. Based on their findings, the committee concluded that there was insufficient evidence to justify the medical use of marijuana.

- Report of the Council on Scientific Affairs(1997) Report to the **American Medical Association (AMA) House of Delegates**. Subject: *Medical Marijuana*. Its general recommendation was that adequate and well-controlled studies of smoked marijuana be conducted in patients who have serious conditions for which preclinical, anecdotal, or controlled evidence suggests possible efficacy, including AIDS wasting syndrome, severe acute or delayed emesis induced by chemotherapy, multiple sclerosis, spinal cord injury, dystonia, and neuropathic pain.

- **British Medical Association** (1997) *Therapeutic uses of cannabis*. Harwood Academic Publishers, United Kingdom. The BMA found that further research is required to establish suitable methods of administration, optimal dosage regimens and routes of administration for the above indications.
- **U.S. National Institutes of Health** (1997) *Workshop on the medical utility of marijuana*. Bethesda, MD: National Institutes of Health. It recommended that, for at least some potential indications, marijuana looks promising enough to recommend that there be new controlled studies done for the following indications: appetite stimulation and wasting, chemotherapy-induced nausea and vomiting, neurological and movement disorders, analgesia, glaucoma. Until studies are done using scientifically acceptable clinical trial design and subjected to appropriate statistical analysis, the question concerning the therapeutic utility of marijuana will likely remain largely unanswered.

- **World Health Organization** (1997) *Cannabis: a health perspective and research agenda*. Its general recommendation was that therapeutic uses of cannabinoids warrant further basic pharmacological and experimental investigation and clinical research into their effectiveness. More research is needed on the basic neuropharmacology of THC and other cannabinoids so that better therapeutic agents can be found.

Specific recommendations according to subject: The IOM report summarised the specific findings of these recent reports thus:[84]

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[84] Note that, according to the pre-publication copy of Appendix D to the IOM report, the Health Council of the Netherlands made no recommendations on any of the specific subjects included in this edited version of that Appendix.

(A) Analgesia

- *AMA House of Delegates*: Controlled evidence does not support the view that THC or smoked marijuana offer clinically effective analgesia without causing significant adverse events when used alone. Preclinical evidence suggests that cannabinoids can potentiate opioid analgesia and that cannabinoids may be effective in animal models of neuropathic pain. Further research into the use of cannabinoids in neuropathic pain is warranted.

- *British Medical Association*: The prescription of nabilone, THC and other cannabinoids should be permitted for patients with intractable pain. Further research is needed into the potential of cannabidiol as an analgesic in chronic, terminal and post-operative pain.

- *National Institutes of Health*: Evaluation of cannabinoids in the management of neuropathic pain, including HIV-associated neuropathy, should be undertaken.

- *World Health Organization:* No recommendations, although the report notes that some newly synthesized cannabinoids are extremely potent analgesics. However, separation of the analgesia and side effects remains to be demonstrated.

(B) Nausea and vomiting

- *AMA House of Delegates*: Research involving THC and smoked marijuana should focus on their possible use in treating delayed nausea and vomiting, and their adjunctive use in patients who respond inadequately to 5-HT_3 antagonists. The use of an inhaled substance has the potential for benefit in ambulatory patients who are experiencing the onset of nausea, and are thus unable to take oral medications.

- *British Medical Association*: Further research is needed on the use of ^{8}-THC as an anti-emetic, the use of cannabidiol in combination with THC, and the relative effectiveness of cannabinoids compared with 5-HT_3 antagonists. Further research is needed in other cases, such as post-operative nausea and vomiting.

- *National Institutes of Health*: Inhaled marijuana merits testing in controlled, double-blind, randomized trials for nausea and vomiting.

- *World Health Organization*: More basic research on the central and peripheral mechanisms of the effects of cannabinoids on gastrointestinal function may improve the ability to alleviate nausea and emesis.

(C) Wasting syndrome and appetite stimulation

- *AMA House of Delegates*: THC is moderately effective in the treatment of AIDS wasting, but its long duration of action and intensity of side effects preclude routine

use. Clinical trials of smoked marijuana as an appetite stimulant in patients with AIDS wasting syndrome were recommended.[85]

- *National Institutes of Health*: There is a need for further research where long term administration of marijuana might be considered for therapeutic purposes...Areas of study for the potential appetite-stimulating properties of marijuana include the cachexia of cancer, HIV/AIDS symptomatology, and other wasting syndromes. Investigations should be designed to assess long-term effects on immunology status, the rate of viral replication, and clinical outcomes in participants as well as weight gain . In therapeutic trials of cachexia, research should attempt to separate out the effect of marijuana on mood versus appetite. Some questions need to be answered in the studies: (1) Does smoking marijuana increase total energy intake in patients with catabolic illness. (2) Does marijuana use alter energy expenditure? (3) Does marijuana use alter body weight, and to what extent? (4) Does marijuana use alter body composition and to what extent?

- *World Health Organization*: No specific recommendation, although the report notes that dronabinol is an effective appetite stimulant for patients with AIDS wasting syndrome.

(D) Muscle spasticity

- *AMA House of Delegates*: Considerably more research is required to identify patients who may benefit from THC or smoked marijuana, and to establish whether responses are primarily subjective in nature. A therapeutic trial of smoked marijuana or THC may be warranted in patients with spasticity who do not derive adequate benefit from available oral medications, prior to their considering intrathecal baclofen therapy or neuroablative procedures.

- *British Medical Association*: A high priority should be given to carefully controlled trials of cannabinoids in patients with chronic spastic disorders which have not responded to other drugs... In the mean time, there is a case for the extension of the indications for nabilone and THC for use in chronic spastic disorders unresponsive to standard drugs.

- *National Institutes of Health*: Few available therapies provide even partial relief for the neuropathic pain that complicates many diseases affecting the central nervous system. Cannabinoid drugs are potentially valuable in these areas, especially if delivered by other than the smoked route. More research is needed.[86]

(E) Movement disorders

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[85] Due to apparent irregularities in the pre-publication copy of the IOM report, this account of the AMA House of Delegates recommendation appears here in an edited form.

[86] The pre-publication copy of the IOM report does not include a relevant entry on this subject for the *WHO*. However, reference to the WHO's views on MS is found under the next subject heading, 'Movement disorders'.

- *AMA House of Delegates*: Considerably more research is required to identify dystonic patients who may benefit from THC or smoked marijuana, and to establish whether responses are primarily subjective in nature.

- *British Medical Association*: The potential of (+)-HU-210 for neurodegenerative disorders should be explored through further research

- *National Institutes of Health*: More studies are needed in movement disorders

- *World Health Organization*: No recommendations, although the report notes that cannabinoids have not yet been proven useful in the treatment of convulsant or movement disorder or in treating multiple sclerosis.

(F) Epilepsy

- *AMA House of Delegates*: No recommendations.

- *British Medical Association*: Trials with cannabidiol (which is non-psychoactive) used to enhance the activity of other drugs in cases not well controlled by other anticonvulsants are needed.
- *National Institutes of Health*: No recommendations.

- *World Health Organization*: No recommendations.

(G) Glaucoma

- *AMA House of Delegates:* Neither smoked marijuana nor THC are viable approaches in the treatment of glaucoma, but research on their mechanism of action may be important in developing new agents that act in an additive or synergistic manner with currently available therapies

- *British Medical Association*: Cannabinoids do not at present look promising for these indications, but much further basic and clinical research is needed to develop and investigate cannabinoids which lower intra ocular pressure, preferably by topical application (e.g. eye drops, inhalant aerosols) without producing unacceptable systemic and central nervous system effects.

- *National Institutes of Health*: Further studies to define the mechanism of action and to determine the efficacy of delta9-tetrahydrocannabinol and marijuana in the treatment of glaucoma are justified.

- *World Health Organization*: No recommendations.

The recommendations of the relevant reports on ‘Psychological harms’ are also considered

in Appendix D.[87] However, only the World Health Organization seems to have dealt with that matter in any detail, recommending that:

> There is a need for controlled studies investigating the relationships between cannabis use, schizophrenia and other serious mental disorders. Insufficient research has been undertaken on the 'amotivational' syndrome which may or may not result from heavy cannabis use. It is not clear that the syndrome exists, even though heavy cannabis use is sometimes associated with reduced motivation to succeed in school and work. New research is needed to show whether the reduced motivation seen in some cannabis users is due to other psychoactive substance use and whether it precedes cannabis use. Further development of cognitive and psychomotor tests for controlled studies that are sensitive to the performance effects of cannabis use and that reflect the complexity of specific daily functions (e.g., driving, learning, reasoning) also need additional research. More research [is needed] in examining the relationship between THC concentrations in blood and other fluids and the degree of behavioural impairment produced.

7. CANNABIS, MEDICINE AND THE LAW IN AUSTRALIA

Cannabis and the law in Australia:[88] After outlining the findings of these reports reference can be made to the legal situation in Australia. As in the US, in the nineteenth century the lines between medical and non-medical use, or between use and abuse, were `indistinctly drawn'.[89] The result was that until 1900 or so there were very few legal controls on the sale or use of drugs in Australia, including cannabis. Over the twentieth-century this situation changed. The *Hague Convention* of 1911-12 and the League of Nations sponsored *Geneva Conventions* of 1925 and 1931 established the framework for Australia's early drug laws.[90] The use of opium, morphine, heroin and cocaine was limited to medical purposes by the *Hague Convention*. The *Geneva Convention* of 1925 added cannabis to the list, requiring, among other things, the prohibition of the non-medical use of `Indian hemp' or cannabis. The Commonwealth in 1926 acted to control cannabis importation under the *Customs Act 1901* and legislation in the various States followed to prohibit the

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87 Other subject areas are also covered in Appendix D to the IOM report, but these are not reproduced here as there appear to be certain irregularities in this part of the pre-publication copy available on the Internet. In particular, the Appendix contains two subheadings 'Physiological harms', with different content appearing under these subheadings.

88 This outline is based on G Griffith and R Jenkin, *Cannabis: The Contemporary Debate*, pp 21-25.

89 D Manderson, *From Mr Sin to Mr Big - A History of Australian Drug Laws*, Melbourne, Oxford University Press, 1993, p 10.

90 *International Opium Convention 1911-12*, The Hague; *International Opium Convention: Agreement Concerning the Suppression of, the Manufacture of, Internal Trade in, and use of, Prepared Opium 1925*, Geneva; *Convention for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs 1931*, Geneva.

unauthorised use of cannabis (Victoria in 1927; South Australia in 1934; New South Wales in 1935; Queensland in 1937; Western Australia in 1950; and Tasmania in 1959). However, it was not until 1956 that the Commonwealth introduced an absolute prohibition on the drug. The point to make is that extracts of cannabis could still be found on Australian pharmacy shelves as late as the 1950s.[91]

Consistent with the general trend in the Western World, cannabis use increased dramatically in Australia in the 1960s. Cannabis arrests rose almost 1000 per cent between 1966 and 1969.[92] Already in the mid-1960s drug laws in all jurisdictions were being overhauled to comply with the obligations incurred under the 1961 United Nations *Single Convention on Narcotic Drugs*.[93] The Convention placed cannabis in Schedule IV alongside heroin and other `particularly dangerous' narcotics. In New South Wales cannabis was proscribed under the 1966 *Poisons Act* as a drug of addiction, whilst remaining a prohibited drug under the *Police Offences (Amendment) Act 1908*, to be treated for the purposes of Part VIA of the Act in the same manner as heroin.[94]

In 1988 Australia became a signatory to the United Nations *Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances* which, amongst other things, requires participating nations to prevent the illicit cultivation of plants containing narcotic or psychotropic substances. The cannabis plant is specifically included.[95] Following the subsequent ratification of that Convention, the Commonwealth passed the *Crimes (Traffic in Narcotic Drugs and Psychotropic Substances) Act 1990* to give effect to the Convention's terms. Cannabis is defined to be a `narcotic drug' under Schedule 2 of the Act (read with section 3).[96] In addition, both cannabis and cannabis resin are deemed to be `narcotic substances' under the Commonwealth *Customs Act 1901* (section 4 read with Schedule VI) and declared a prohibited import and export (section 233B). Cannabis is therefore an illegal drug in Australia, with no exception being made for medical use.

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91 G Griffith and R Jenkin, *Cannabis: The Contemporary Debate*, p 4.

92 Manderson, *From Mr Sin to Mr Big - A History of Australian Drug Laws*, p 144.

93 Ibid, p 136. The Convention is also considered, albeit from a different standpoint, in E Walters, *Marijuana - An Australian Crisis*, 2nd Ed, Moorabbin, Associated Printers, 1993, p 124. The Convention was ratified by Australia in 1967.

94 Cannabis was prohibited under Part IV of the *Poisons Act 1966* where it was treated as a drug of addiction. The *Police Offences (Amendment) Act 1908* was amended by proclamation in 1966, declaring that Part VIA would apply to cannabis in the same manner as it applied to diamorphine (heroin) - *New South Wales Government Gazette* no 77 of 5 August 1966, p 3103.

95 Advisory Committee on Illicit Drugs, *Cannabis and the law in Queensland - a discussion paper*, July 1993, at 27.

96 Included in the Schedule are cannabis, cannabis resin and cannabis oil. The text of the Convention is recited in the Act. Section 2 provides that the Act would only commence after the Convention had entered into force in Australia. The Act was proclaimed to commence on 14 February 1993.

The question as to whether the defence of necessity might apply in Australia to the medical use of cannabis has been raised in an academic context, but to date it does not appear to have been dealt with by the courts.[97]

Law reform - a failed attempt: In 1994 a Private Members Bill sponsored by Mr Michael Moore was introduced into the ACT House of Assembly which, among other things, would have amended the *Drugs of Dependence Act 1989* (ACT) to provide a defence to the offence of possessing a small quantity of cannabis if a medical practitioner engaged in research had certified that the cannabis was being used for research purposes. On 30 November 1994 the proposed new clause was passed.[98] However, on 6 December 1994, before the clause was proclaimed to commence, the then Chief Minister of the ACT, Ms Follett, moved to have the resolution of 30 November rescinded and to remove the relevant clause from the legislation. After lengthy deliberation, which included a proposed re-wording of the clause by the then Leader of the Opposition, Mrs Carnell, the motion to omit the clause was passed.[99]

Subsequently, in 1997 Mr Moore raised the issue of the medical use of cannabis as a Matter of Public Importance in the House of Assembly.[100] In the course of that debate, Mrs Carnell (who was by then the Chief Minister) commented that the subject was also under consideration by the Ministerial Council on Drug Strategy.[101] No action, in the form of proposed legislation or the establishment of a Select Committee, appears to have flowed from this Matter of Public Importance debate.

The use of dronabinol in Australia: A 1997 paper commented that, while cannabis is not currently registered as a therapeutic agent in Australia, the synthetic cannabinoid, Marinol (the trade name under which dronabinol is marketed) is 'available to some 100 people in NSW and a register of prescribing doctors has been established through a special access scheme'.[102] However, according to Dr Julian Gold, Director of the Albion St Clinic, Marinol is no longer used on a prescription basis in NSW, primarily because it proved too costly (around $2,500 - $3,000 per month).[103]

This issue was looked at further in a report prepared by the South Australian Drug and

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97 D Heilpern and GL Rayner, 'Drug law and necessity' (1997) 22 *Alternative Law Journal* 188-191.

98 *ACTPD*, 30 November 1994, p 4340.

99 *ACTPD*, 6 December 1994, pp 4554-4590.

100 *ACTPD*, 17 June 1997, p 1671.

101 *ACTPD*, 17 June, p 1680.

102 M Kyriagis, 'Marijuana - Just What the Doctor Ordered?' (1997) 20 *UNSW Law Journal* 594 at 613. Kyriagis also notes that "Nabilone...is imported under a "special access scheme" but there are no applications pending to register the drug in Australia'.

103 Advice received over the telephone by the authors.

Alcohol Services Council for the Ministerial Council on Drug Strategy in 1998 titled, *Therapeutic Uses of Cannabis*. A survey of members of the Australasian Society of HIV Medicine was undertaken for this purpose, asking their views of dronabinol and cannabis in the management of AIDS-related wasting. It was found that of those doctors who responded to the survey and who had not used dronabinol for their patients, 33 percent gave the high cost of the drug as the reason, a finding which seems to confirm the more recent comments of Dr Julian Gold. However, it seems that some doctors were 'also concerned about the side effects of lethargy and sedation, which seems to be particularly associated with taking the drug orally'.[104]

The South Australian study noted the advantages of synthetic preparations of THC over cannabis itself for therapeutic applications, including that, as pharmaceutical products they are clearly separated from the social use of cannabis and that their oral administration avoids the risks associated with smoking. Nonetheless, the study found that dronabinol had 'Not lived up to expectations'.[105] The survey mentioned above of the members of the Australasian Society of HIV Medicine indicated a preference for drugs with anabolic action to promote weight gain in AIDS-related wasting rather than cannabis.

The South Australian study - general conclusions: More generally the conclusions of the South Australian study were that cannabis is more likely to be of value as an 'adjunct to conventional treatment to improve aspects that are currently resistant to, or inadequately resolved by, conventional treatment'. Bearing in mind issues of cost and the health risks associated with smoked cannabis, the study concluded that the greatest potential for therapeutic use of cannabis appears to lie in three areas:

- as an appetite-stimulant, used in conjunction with drugs with anabolic properties to promote increased lean body mass, good nutrition and exercise;
- the management of neuropathic pain; and
- the quick relief of nausea, for example, that associated with some cancer chemotherapy treatments.[106]

The study was less positive in its findings concerning the use of cannabis in the management of glaucoma and neurological conditions such as multiple sclerosis, concluding that in these instances 'the need for long-term use of high dosages makes it

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104 LR Gowing et al, 'Therapeutic use of cannabis: clarifying the debate' (1998) 17 *Drug and Alcohol Review* 445 at 447. This article summarises the findings of the 1998 report. 72 responses were received in total to the survey. Dronabinol was found to be used by 22 doctors (31 percent), only three of whom said it was their preferred treatment. However, of those 22 doctors, 86 percent said that dronabinol was 'slightly or moderately useful', compared to a figure of 63 percent of the total surveyed. There was a 96 percent awareness rate of dronabinol.

105 Ibid, at 450.

106 Ibid, at 451.

highly doubtful that the benefits can be made to outweigh the potential harms'.[107]

There is certainly sufficient evidence of the therapeutic effect of cannabis to justify further research, the study concluded.

The provisional conclusions of the National Drug Strategy Committee: The above findings can be compared and contrasted with the provisional conclusions of the National Drug Strategy Committee in its 1994 monograph titled, *The Health and Psychological Consequences of Cannabis Use*. In brief, these were as follows:

- there is good evidence for the therapeutic potential of THC as an anti-emetic agent. Although uncertainty exists about the optimal method of dosing and the advantages and disadvantages of different routes of administration, there is sufficient evidence to justify it being made available in pure synthetic form to cancer patients. However, with the development of more effective anti-emetic agents, it remains to be seen how widely used the cannabinoids will be;
- there is reasonable evidence for the potential efficacy of THC in the treatment of glaucoma. Further research is required, but it could be used in controlled cases where patients have been informed of the risks involved;
- there is sufficient suggestive evidence of the potential usefulness of various cannabinoids as analgesic, anti-asthmatic, anti-spasmodic, and anti-convulsant agents to warrant further basic pharmacological and experimental investigation, and perhaps clinical research into their effectiveness.[108]

8. CONCLUSIONS

While the above does not purport to be a comprehensive review of the developments relevant to the subject of cannabis and medical use in Australia, it does show that it is an issue of considerable contemporary interest here. Cannabis and medical use certainly appears to be a live issue internationally at present, as evidenced by the reports discussed in this paper and many others, as well as by such developments as the 3 March 1999 decision of the Canadian Health Minister to authorise clinical trials for medical marijuana, plus the development of appropriate guidelines for its medical use and access to a safe supply of the drug.

The findings reported on the medical use of cannabis in this paper do not point to a single, unequivocal answer on all the questions raised by this complex issue. Perhaps the one agreed conclusion is that the analysis of the medical use of cannabis should be separate to, and distinct from, the issue of its social/recreational use and the many arguments for and against the legalisation or decriminalisation of cannabis in this wider context. There also seems to be general agreement that further research, some of which is already underway,

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107 Ibid.

108 W Hall, *The Health and Psychological Consequences of Cannabis Use*, National Drug Strategy Committee, Monograph No 25, 1994, p 199.

is needed to give more definitive answers to the questions which arise in relation to the claimed therapeutic effects of cannabis and its isolated components, the cannabinoids. For the IOM report, at least, any future cannabis/marijuana has as a medicine lies with the cannabinoids and their synthetic derivatives

Appendix A

Toxic Effects of Cannabis and Cannabinoids: Review of the Evidence
Chapter 4:

House of Lords
Select Committee Report:
Cannabis for Medical Purposes

November 1998

CHAPTER 4:

TOXIC EFFECTS OF CANNABIS AND CANNABINOIDS: REVIEW OF THE EVIDENCE

4.1 The prohibition of the recreational use of cannabis, and some of the doubts about medical use, are based on the presumption that cannabis is harmful to individual and public health. We have tested the strength of that presumption, and this Chapter records what we have found. New research on this subject is constantly coming forward, so this cannot be said to be the last word on it. Although cannabis is not in the premier league of dangerous substances, new research tends to suggest that it may be more hazardous to health than might have been thought only a few years ago (Edwards QQ 21, 27).

4.2 In assessing the adverse effects associated with cannabis use, we have been assisted by a number of detailed recent reviews, including the recent WHO report Cannabis: a health perspective and research agenda (WHO/MSA/PSA/97.4); the Australian National Drug Strategy report The health and psychological consequences of cannabis use (1994) and other documents[9] submitted by Professor Wayne Hall, Executive Director of the Australian National Drug and Alcohol Research Centre in Sydney, and his colleagues; and the recent reviews noted above commissioned by the Department of Health. The evidence submitted to us by the Royal Society and the Royal College of Psychiatrists is also particularly relevant.

Acute (short-term) effects of cannabis

4.3 The acute toxicity of cannabis and the cannabinoids is very low; no-one has ever died as a direct and immediate consequence of recreational or medical use (DH QQ 219-223). Official statistics record two deaths involving cannabis (and no other drug) in 1993, two in 1994 and one in 1995 (HC WA 533, 21 January 1998); but these were due to inhalation of vomit. Animal studies have shown a very large separation (by a factor of more than 10,000) between pharmacologically effective and lethal doses.

4.4 One minor toxic side-effect of taking cannabis which merits attention is the short-term effect on the heart and vascular system. This can lead to significant increases in heart rate and a lowering of the blood pressure (Pertwee Q 299). For this reason patients with a history of angina or other cardiovascular disease could be at risk and should probably be excluded from any clinical trials of cannabis-based medicines.

4.5 The most familiar short-term effect of cannabis is to give a "high" - a state of euphoric intoxication. This is, of course, precisely the effect sought by the recreational user, analogous to the effect of alcohol and sought for similar reasons. We have been told, however, that people who use cannabis for medical purposes regard it as an unwelcome side-effect (Hodges Q 97).

4.6 Intoxication with cannabis leads to a slight impairment of psychomotor and cognitive function, which is important for those driving a vehicle, flying an aircraft

or operating machinery (DH Q 197). The Department of Health rate this as "the major concern from a public health perspective" raised by recreational use (p 46), and Professor Hall considers it the most serious possible short-term consequence of cannabis use, both for the user and for the public (p 222).

4.7 There is some disagreement about how long such impairments persist after taking cannabis: most assume that they last for only a few hours (e.g. Kendall p 266); but Professor Heather Ashton of the University of Newcastle-upon-Tyne, principal author of the BMA report, suggested that subtle cognitive impairments could persist for 24 or even 48 hours or more (Q 72), whereas the DETR say "probably .... 24 hours at most" (Press Notice 94/Transport, 11 February 1998). On the other hand the impairment in driving skills does not appear to be severe, even immediately after taking cannabis, when subjects are tested in a driving simulator. This may be because people intoxicated by cannabis appear to compensate for their impairment by taking fewer risks and driving more slowly, whereas alcohol tends to encourage people to take greater risks and drive more aggressively (POST note 113; cp DH p 240).

4.8 Analysis of blood samples from road traffic fatalities in 1996-97 (the results of the first 15 months of a three year DETR study - Press Notice 94/Transport, 11 February 1998) showed that 8 per cent of the victims were positive for cannabis, including 10 per cent of the victims who were driving. However, it is not clear what figures would have been obtained from a random sample of road users not involved in accidents (DH Q 211); and some of those who tested positive may have taken the cannabis as much as 30 days before, so that the effects would have worn off long since (DH p 240). The interpretation of traffic accident data is further confounded by the fact that 22 per cent of the drivers found to be cannabis-positive also had evidence of alcohol intake; proportions of alcohol-positives among cannabis-positive drivers as high as 75 per cent have been reported in other countries in similar studies. Professor Hall considers cannabis's contribution to danger on the roads to be very small; in his view the major effect of cannabis use on driving may be in amplifying the impairments caused by alcohol (cp Keen Q 42). According to a survey of 1,333 regular cannabis users by the Independent Drug Monitoring Unit (IDMU) in 1994, users who drove reported a level of accidents no higher than the general population; those with the highest accident rates were more likely to be heavier poly-drug users.

4.9 It is difficult to see how cannabis intoxication could be monitored, if its use were permitted. There could be no equivalent of the breathalyser for alcohol, since small amounts of cannabis continue to be released from fat into the blood long after any short-term impairment has worn off (see paragraph 3.5 above).

4.10 A single dose of cannabis for an inexperienced user, or an over-dose for an habitual user, can sometimes induce a variety of intensely unpleasant psychic effects including anxiety, panic, paranoia and feelings of impending doom (BMA p 9, RCPsych p 282). These adverse reactions are sometimes referred to as a "whitey" as the subject may become unusually pallid (Montgomery Q 577). These effects usually persist for only a few hours.

4.11 In some instances cannabis use may lead to a longer-lasting toxic psychosis involving delusions and hallucinations that can be misdiagnosed as schizophrenic illness (Strang Q 239, van der Laan Q512). This is transient and clears up within a few days on termination of drug use; but the habitual user risks developing a more persistent psychosis, and potentially serious consequences (such as action under the Mental Health Acts and complications resulting from the administration of powerful neuroleptic drugs) may follow if an erroneous diagnosis of schizophrenia is made. It is also well established that cannabis can exacerbate the symptoms of those already suffering from schizophrenic illness (Q 239) and may worsen the course of the illness; but there is little evidence that cannabis use can precipitate schizophrenia or other mental illness in those not already predisposed to it (RCPsych p 283).

4.12 These relatively rare adverse psychological effects of cannabis are not considered to represent a serious limitation on the potential medical use of the drug (Strang Q 244), save that patients suffering from schizophrenic illness or other psychoses should be excluded. However they do constitute an issue for public health. According to the Department of Health, cannabis contributes to the extra cost of acute psychiatric services imposed by drug misuse, though this cannot be separately costed (p 46; cp RCPsych p 282). The Royal College of Psychiatrists (p 284) believe that the proportion of users who experience acute adverse mental effects is "significant".

Chronic (long-term) toxicity

4.13 Cannabis can have untoward long-term effects on cognitive performance, i.e. the performance of the brain, particularly in heavy users. These have been reviewed for us by the Royal College of Psychiatrists and the Royal Society. While users may show little or no impairment in simple tests of short-term memory, they show significant impairments in tasks that require more complex manipulation of learned material (so-called "executive" brain functions) (Edwards Q 21). There is some evidence that some impairment in complex cognitive function may persist even after cannabis use is discontinued[10]; but such residual deficits if present are small, and their presence controversial (van Amsterdam Q 494, Hall Q 741). Dr Jan van Amsterdam of the Netherlands National Institute of Public Health and the Environment, who has reviewed the literature on long-term cognitive effects of prolonged heavy use and kindly came to Westminster to tell us his findings, pointed out the practical difficulties of assessing possible residual effects (Q 487). These include the impossibility of obtaining pre-drug baseline values (i.e. measures of the cognitive functioning of the subject before their first use of cannabis), the difficulty of estimating the drug dose taken, the need for a lengthy "wash-out" period after termination of use to allow for the slow elimination of residual cannabis from the body, and the possibility of confusing long-term deficits with withdrawal effects. He felt that many of the published reports on this subject had not taken adequate account of these problems.

4.14 The occurrence of an "amotivational syndrome" in long-term heavy cannabis users, with loss of energy and the will to work, has been postulated. However it is now generally discounted (van Amsterdam Q 503); it is thought to represent nothing

more than ongoing intoxication in frequent users of the drug (RCPsych p 283).

4.15 Animal experiments have shown that cannabinoids cause alterations in both male and female sexual hormones; but there is no evidence that cannabis adversely affects human fertility, or that it causes chromosomal or genetic damage (WHO report ch.7). The consumption of cannabis by pregnant women may, however, lead to significantly shorter gestation and lower birth-weight babies in mothers smoking cannabis six or more times a week (WHO report ch.8; DH p 47). These effects may be due to the inhalation of carbon monoxide in cannabis smoke, which lowers the ability of the blood to carry oxygen to the foetus, rather [sic] to any direct effect of cannabinoids. If so, they are comparable with the effects of smoking tobacco.

4.16 The NHS National Teratology [i.e. foetal abnormality] Information Service advise, "There are a few case reports of malformations following marijuana use in pregnancy. However, there is no conclusive evidence to suggest either an increase in the overall malformation rate or any specific pattern of malformations". Nevertheless, they warn: "We would not recommend the legalisation of cannabis because of the potential fetotoxicity that may occur if it is used in pregnancy" (p 280).

4.17 Most of our witnesses regard the consequences of smoking cannabis as the most important long-term risk associated with cannabis use[11]. Cannabis smoke contains all of the toxic chemicals present in tobacco smoke (apart from nicotine), with greater concentrations of carcinogenic benzanthracenes and benzpyrenes. It has been estimated (BMA p 11) that smoking a cannabis cigarette (containing only herbal cannabis) results in approximately a five-fold greater increase in carboxy-haemoglobin concentration[12], a three-fold greater increase in the amount of tar inhaled, and a retention in the respiratory tract of one third more tar, than smoking a tobacco cigarette. Cannabis resin, the most commonly used form of cannabis in the United Kingdom, is often smoked mixed with tobacco, thus adding the well-documented risks of exposure to tobacco smoke, while complicating the picture for the researcher.

4.18 Regular cannabis smokers suffer from an increased incidence of respiratory disorders, including cough, bronchitis and asthma. Microscopic examination of the cells lining the airways of cannabis smokers has revealed the presence of an inflammatory response and some evidence for what may be pre-cancerous changes. There is as yet no epidemiological evidence for an increased risk of lung cancer (DH p 46, Q 205); but, by analogy with tobacco smoking, such a link may take 25-30 years or more before it becomes evident, and the widespread use of smoked cannabis in Western societies dates only from the 1970s. There are some reports of an increased incidence of cancers of the mouth and throat in young cannabis users[13], but so far these involve only small numbers and no cause and effect relationship has been established. Nevertheless, Professor Hall considers it a "pretty reasonable bet" that heavy users incur a risk of cancer (Q 741); and the risk is considered by some of our witnesses to be sufficiently serious to rule out any approval of long-term medical use of smoked cannabis, and to justify the present prohibition on recreational use.

Tolerance to cannabis

4.19 Tolerance is the phenomenon whereby a regular user of a drug requires more each time to achieve the same effect. It is not an adverse effect in itself; but it may make medical use more difficult, and recreational use more damaging as the user's demand for the drug increases.

4.20 Dr Pertwee told us that both animal and human data show that tolerance can develop on repeated administration of high doses of cannabinoids; tolerance may develop more readily to some effects in animals (e.g. lowering of body temperature) than to others (Q 304). However Clare Hodges[14], a sufferer from MS, said that she had not experienced tolerance to the palliative effects of low doses of cannabis, and had been taking the same dose (9g of herbal cannabis per week, costing about £30 per week, usually smoked) for six years; neither had other medical users reported tolerance in their experience (QQ 117-119; cp LMMSG p 269).

4.21 Whether tolerance develops may therefore depend on how much drug is consumed, and how often. Neil Montgomery, a research journalist currently studying cannabis users through the Department of Social Anthropology at the University of Edinburgh, said that his observations of heavy cannabis users (using more than 28g of cannabis resin per week) suggested that they needed as much as eight times higher doses to achieve the same psychoactive effects as regular users consuming smaller doses of the drug (Q 570). Clear evidence of tolerance has also been reported in volunteers given large doses of THC under laboratory conditions (Pertwee Q 304).

4.22 This conforms with the evidence of Professor Hall, who compared the experience with morphine and related opiate pain-relieving agents during the past 20-30 years, pioneered by Dame Cicely Saunders and the Hospice movement. This has shown that tolerance (and addiction - see below) are not major problems in the medical use of these drugs, although in recreational use they may pose severe problems (Q 120).

Dependence on cannabis

4.23 The repeated use of cannabis or cannabinoids does not result in severe physical withdrawal symptoms when the drug is withdrawn; so many have argued that these drugs are not capable of inducing dependence. Dr Pertwee, and Dr David Kendall of the University of Nottingham (p 267), however, described new evidence from animal studies showing marked signs of withdrawal in animals treated repeatedly with large doses of cannabinoids and then challenged with a newly developed cannabinoid CB1 receptor antagonist (see Box 1) called SR141716A. This has provided the first real evidence for physical dependence and withdrawal symptoms in animals (QQ 308-310).

4.24 The BMA report says that withdrawal symptoms from cannabis in man are mild and short-lived; but in the light of the newer definitions of dependence noted in Box 2 this evidence is inconclusive. Professor Ashton indicated that she felt cannabis to be potentially addictive, and compared the withdrawal symptoms - tremor,

restlessness and insomnia - to those experienced by users of alcohol, sleeping pills or tranquillisers. She had talked to students with quite severe cannabis withdrawal problems (Q 73).

BOX 2: DEFINITIONS OF DEPENDENCE

The consumption of any psychoactive drug, legal or illegal, can be thought of as comprising three stages: use, abuse, and addiction. Each stage is marked by higher levels of drug use and increasingly serious consequences. Abuse and addiction have been defined and redefined by various organisations over the years. The most influential current system of diagnosis is that published by the American Psychiatric Association (DSM-IV, 1994). This uses the term substance dependence instead of addiction, and defines this as a cluster of symptoms indicating that the individual continues to use the substance despite significant substance-related problems. The symptoms may include tolerance (the need to take larger and larger doses of the substance to achieve the desired effect), and physical dependence (an altered physical state induced by the substance which produces physical withdrawal symptoms, such as nausea, vomiting, seizures and headache, when substance use is terminated); but neither of these is necessary or sufficient for the diagnosis of substance dependence. Using DSM-IV, dependence can be defined in some instances entirely in terms of psychological dependence; this differs from earlier thinking on these concepts, which tended to equate addiction with physical dependence. The DSM-IV system also defines substance abuse as a less severe diagnosis, involving a pattern of repeated drug use with adverse consequences but falling short of the criteria for substance dependence.

4.25 Professor Griffith Edwards, a member of the Advisory Council on the Misuse of Drugs[15] (Q 27), said that, using internationally agreed criteria (DSM-IV - see Box 2), there seemed no doubt that some regular cannabis users become dependent, and that they suffer withdrawal symptoms on terminating drug use. According to the WHO report, cannabis dependence is characterised by a loss of control over drug use, cognitive and motivational impairments that interfere with work performance, lowered self-esteem and often depression. Professor Hall wrote, "By popular repute, cannabis is not a drug of dependence because it does not have a clearly defined withdrawal syndrome. There is, however, little doubt that some users who want to stop or cut down their cannabis use find it very difficult to do so, and continue to use cannabis despite the adverse effects that it has on their lives." In oral evidence he added that users who sought treatment for cannabis dependence had typically taken large amounts of cannabis every day for perhaps 15 years or more (Q 745).

4.26 The Institute for the Study of Drug Dependence likewise conclude that, while physical dependence is rare, "Regular users can come to feel a psychological need for the drug or may rely on it as a "social lubricant": it is not unknown for people to use cannabis so frequently that they are almost constantly under the influence"

(p 263).

4.27 One measure of the significance of cannabis dependence is the proportion of users who become dependent. Since cannabis dependence is poorly defined, and the total number of users is unknown, this figure is elusive. Data from a recent study of 200 regular users in Australia[16] suggest that more than 50 per cent of such users may be classified as dependent, although many of these do not consider themselves as dependent. This corresponds with the finding of an American study of 1991, cited by the WHO report, that "about half of those who use cannabis daily will become dependent". According to Professor Hall, "Epidemiological studies suggest that cannabis dependence in the sense of impaired control over use is the most common form of drug dependence after tobacco and alcohol, affecting as many as one in ten of those who ever use the drug" (p 221).

4.28 Neil Montgomery estimates that approximately 5 per cent of regular cannabis users are heavy users, consuming as much as 28g of cannabis resin per week. "These are people who have become dependent on cannabis; they are psychologically addicted to the almost constant consumption of cannabis...Becoming stoned and remaining stoned throughout the day is their prime directive" (Q 554).

4.29 Another measure of the extent of cannabis dependence is the number of people who seek treatment for it. Department of Health figures (1996) show that in 6 per cent of all contacts with regional drug clinics cannabis was the main drug of misuse (Q 27). A similar figure, that cannabis users constitute 7 per cent of all new admissions to drug treatment centres in Australia, was reported recently. Dr Philip Robson[17], who runs a Regional Drug Dependence Unit in Oxford, said that 4.9 per cent of those admitted to his unit cited cannabis as their main drug (Q 462). However he did not regard cannabis as an important drug of addiction: "The drug falls well below the threshold of what would be expected for a dependency-producing drug which has clinical significance...I do not meet people who are prepared to knock over old ladies in the street or burglarise houses or commit other crimes to obtain cannabis". Professor Robbins estimated that at least 2 per cent of regular cannabis users (whom he defined as those using cannabis more than once a week) in the USA are dependent, on the basis of an estimate of 5m users and an official figure of 100,000 on specific treatment for cannabis dependency syndrome (Q 623).

4.30 It has been suggested that US figures may be inflated by people on compulsory treatment, for instance after testing positive at work, who may not in fact be dependent. According to Professor Hall, however, "In Australia ... drug testing is uncommon and there is no cannabis treatment industry. Yet treatment services...have seen an increase in the number of persons seeking help for cannabis" (p 221). He even suggests that the figures may be kept down by the widespread belief that it is not possible to be dependent on cannabis (Q 748).

4.31 Giving up cannabis is widely believed to be relatively easy: according to the Department of Health, "studies report that of those who had ever been daily users only 15 per cent persisted with daily use in their late twenties" (p 45). Most epidemiological studies in Britain and the United States have shown that the illicit

use of cannabis mainly involves people in their late teens and twenties, with relatively few users over the age of 30.

4.32 It has been assumed that young cannabis users give up the habit when they enter their thirties; IDMU (p 236), however, suggest that this pattern may be changing. The British Crime Survey (1996) shows that although the prevalence of cannabis use falls after the age of 30, the greatest proportional increases in the period 1991-1996 were in older age groups, with incidence of past use doubling in the 40-44 age group (from 15 per cent to 30 per cent) and trebling in the 45-59 age group (from 3 per cent to 10 per cent). IDMU conclude that the current relatively low levels of cannabis use in the over-30 age group may reflect a generational and cultural divide, rather than substantial numbers of users giving up.

4.33 It is therefore clear that cannabis causes psychological dependence in some users, and may cause physical dependence in a few. The Department of Health sum up the position thus (p 45, cp Edwards Q 28): "Cannabis is a weakly addictive drug but does induce dependence in a significant minority of regular cannabis users."

NOTES:

9. Including Hall W, Room R and Bondy S, A comparison of the health effects of alcohol, cannabis, tobacco and opiates, in Kallant H, Corrigal W, Hall W and Smart R eds The Health Effects of Cannabis, Addiction Research Foundation, Toronto, 1998; and articles awaiting publication in Addiction (Respiratory risks of cannabis smoking, 1998, 93, 1461), Drug and Alcohol Review, and the Lancet Seminar series (14 November 1998).

10. N Solowij, Cannabis and Cognitive Functioning, Cambridge University Press, 1998.

11. See in particular DH p 46; papers kindly supplied by Professor Donald Tashkin, University of California Los Angeles School of Medicine, and Professor Hall; and Appendix 3, paragraph 8.

12. Carboxy-haemoglobin is formed by the action of carbon monoxide on haemoglobin in the blood. It interferes with the transport of oxygen around the body.

13. E.g. Taylor FM III, Marijuana as a potential respiratory carcinogen: a retrospective analysis of a community hospital population, South. Med. J. 1988, 81, 1213.

14. Miss Hodges is the founder-Director of the UK Alliance for Cannabis Therapeutics (ACT). "Clare Hodges" is a nom de guerre.

15. Professor Edwards is Professor Emeritus of Addiction Behaviour at the Institute of Psychiatry, University of London; past Chairman of the National Addiction Centre; and editor-in-chief of the journal Addiction. The ACMD is established under the Misuse of Drugs Act 1971, to advise the Government.

16. By Dr Wendy Swift, Australian National Drug and Alcohol Research Centre.

17. Consultant psychiatrist, Warneford Hospital; senior clinical lecturer, University of Oxford; author of one of the reviews for the Department of Health referred to in paragraph 1.4.