To: Dr Harvey PS/CMO

From: Dr Susan Turnbull

Date: 24 June 1996

Copies: Dr Metters
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Mr Podger o/r
Miss Mithani
Ms Lockyer
Ms McEwen SolB4
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Ms Phillips o/r
Mr Dunlevy
Ms Ryan SolC3
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Dr Nicholas o/r
Mr Robb

Briefing for UK CMOs Meeting: Hepatitis C

1. In Dr Nicholas' absence on annual leave I have been asked to collate briefing for the following agenda item at the forthcoming UK CMOs meeting 4-5 July:

   Hepatitis C (i) Legal implications
   (ii)Health care workers

2. **Legal implications**
   With thanks to Ms McEwen of SolB4, I attach briefing on two types of claims against the Department of Health arising from hepatitis C infection. Ms McEwen is content for all the information to be circulated to the other CMOs, but suggests

24/06/96

that much of the detail about individual cases may be superfluous for this purpose. I am attaching two versions: **Version A** including plaintiff details and an edited **Version B.**

Executive Board

3. A detailed paper on hepatitis C was discussed at a meeting of the Executive Board on 13/14 June, summarising the complex set of issues raised by this disease, with possible "duty of care" legal ramifications. A copy of the paper is attached (**Annex C**). The **Executive Summary** appears suitable for circulation to the other CMOs, but the entire paper for CMO only to ensure that he is as fully briefed as possible. I understand from the EB secretariat that the Executive Board agreed that measures needed to be taken on the public health perspective, recognising the limits of current knowledge, and that further policy development would be affected by the views of professionals (including possibly SMAC), research findings and other information.

Hepatitis C infected health care workers

4. I attach a brief summary of the current position as pertains to hepatitis C infected health care workers (**Annex D**). This is suitable for circulation to the other CMOs, and this policy position is familiar to all the territorial SMOs who attend meetings of the Advisory Group on Hepatitis and the UK Advisory Panel for Health Care Workers infected with Bloodborne Viruses. Dr Nicholas has a detailed paper in preparation for CMO on the complexities of the current advice about workers who have not transmitted their hepatitis C infection and who currently can continue to perform exposure prone procedures. He will be finalising this and forwarding it to CMO as soon as possible after his return on 1 July. This will refer to the defensibility of a policy which involves "acceptable risk".

Overall summary [CMO may wish to share this with other CMOs]

5. The Secretary of State has a duty of care to four main groups:

i) Those infected as a result of NHS treatment - covered in Ms McEwen's paper.

ii) Those who are health care workers

iii) Those in high risk groups who are more likely to be infected than the general population - such as injecting drug misusers. This includes a duty to provide information on risks -to prevent deterioration on a personal basis, and also to prevent spread of infection.

iv) The general population, in terms of information about public health risks and their expectation that the treatment they receive from health care workers will not expose them to risks which could reasonably and practicably have been avoided.

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Annex C

EB(96)42

CATEGORY B PAPER

Hepatitis C

1. The attached paper summarises the very complex set of issues which this disease raises. We are seeking the Board's views prior to producing, jointly with the wider Department, a submission for Ministers on this topic.

2. It is clear there is no obvious preferred way forward. The key dilemma that we and Ministers face is the conflict between what **may** be desirable public health policy and the capacity of the NHS to deliver. In this situation guidance recommending action which cannot in practice be undertaken could result in more embarrassment for us and Ministers than the current situation where we are criticised for not making such recommendations.

3. There are some areas where more information, if available, could clearly help, particularly about the likely overall effectiveness of the public health campaigns proposed. Also, while what is suggested is not a formal screening programme, to encourage individuals at risk to come forward for testing does have many of the characteristics of such a programme and needs to be evaluated accordingly. We need however to put the issue to Ministers reasonably quickly and will have to therefore rely on existing information alone.

4. There is another set of issues which needs to be explored with colleagues in the public health group namely, how what may be an undischargeable commitment was entered into and what approaches are necessary to prevent this happening again. This is not a question of failure to consult the Executive - we were appropriately involved. Rather there may be a significant discrepancy, even an incompatibility, between some of the criteria used to justify this sort of programme (eg: the "duty of care", the often pressing to need to "take action" in the face of a public health threat, and the need to protect Ministers from even quite remote risks of legal action) with the declared purpose and aims of the NHS and the increasing emphasis given to cost effectiveness as a way in to priority setting. We will pursue this angle in the light of the Board's comments.

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HEPATITIS C.

Executive Summary.

- Hepatitis C (HCV) is a transmissible blood borne virus infection (infectivity similar to HIV but transmitted mainly through drug misusers sharing equipment rather than sexually), which can cause persistent infection and eventually chronic liver failure and liver cancer. Its prevalence is uncertain but could be up to 1% of the population. HCV has important public health implications. **There is a case for issuing guidance on the public health issues to encourage people to come forward for testing and to limit further spread of HCV.**

- The Department is coming under increasing pressure to raise HCV awareness since the licensing of Alpha Interferon (IntFα) a year ago offered a treatment for some patients with HCV (even though only some 25% will respond) and was the main reason why the "Lookback" exercise was set up last year to trace patients infected through blood transfusion in the course of NHS treatment. Ministers have already given commitments to ensure that counselling and, where medically appropriate, treatment are available for such patients.

- There is now a major issue about the number of other infected people who could come forward for testing. The largest potential patient group is current and ex-drug misusers who have shared equipment. The rate at which they come forward will depend to a large extent on what action the Department takes to publicise HCV and its risk factors.

- Increased testing has resource implications for the NHS, in particular, the specialist hepatology service which are seeing increasing numbers of HCV patients. The cost of treatment with alpha interferon (£2-5,000/patient) is already placing a considerable burden on purchasers and the pressure to prescribe Alpha Interferon widely is growing.

- Alpha Interferon is, however, of limited overall clinical and cost effectiveness and its widespread use poses a dilemma. To deny any individual patient, however infected, a trial of a drug that may prevent their developing serious liver damage or even cancer is contentious, and may lay Ministers open to criticism (or even litigation). Conversely, to encourage people to seek treatment at a time when they are asymptomatic and may remain so for decades, during which time more effective treatments are almost certain to be developed, is equally questionable (and costly - potentially up to £51m additional cost in 1997/8). **There is, therefore, also a case for issuing guidance to the NHS on the management of HCV.**

- There is also an issue around PES. Any guidance issued by the Executive which requires or could be taken to encourage the NHS to be more active in the treatment of HCV patients may prejudice the Department's PES position. Ministers will need to be aware of the implications of issuing guidance in relation to PES negotiations.

- **HCV is an important public health issue which poses difficult questions for the Department. The impact of HCV on the NHS depends to a large extent on how**

the Department responds. This paper seeks the Board's views on the key handling issues.

HEPATITIS C (HCV): THE CURRENT POSITION

1. The NHS is faced with dealing with an unknown but potentially significant number of patients infected with Hepatitis C (HCV), a blood borne virus which frequently results in persistent infection which can be transmitted in a similar way to Hepatitis B and HIV. It can cause chronic hepatitis which may lead to cirrhosis and even cancer. However, the development of progressive liver disease may take up to 20 years post infection. The risk and speed of progression may also depend on the HCV genotype and the presence of other risk factors. Establishing precise prevalence figures is difficult although the experience of other developed countries suggests that a considerable number of people are likely to be infected with HCV.

2. There are essentially **two groups of patients**. Some, like haemophiliacs and recipients of blood transfusions (minimum of 7000 cases), have been **infected as a result of NHS treatment**. The other main group is both **current and past injecting drug misusers who have shared equipment**. This latter group, unlike the first, is likely to grow. Sexual transmission is generally thought to be low but can occur (partners are at some risk of infection). Although estimates vary, prevalence is estimated to be between 0.1 and 1% of the population - the **best current estimate is 300,000 people**. By way of comparison, in the US roughly 1.2% of the population are infected. The prevalence in some ethnic groups is said to be much higher.

3. The licensing of Alpha Interferon (January 1995) has provided a potential treatment for patients with HCV who develop active hepatitis. Treatment may prevent some of the 25% who respond from progressing to liver failure or liver cancer. Despite the low success rate, some specialists feel that there is sufficient evidence to show that it is clinically effective to justify prescribing it to all patients who may benefit. The availability of treatment has increased interest in the disease and provided a much stronger incentive than simply preventing transmission, for identifying those infected[1]. It was the main reason why the "Lookback" exercise was set up to identify patients infected through blood transfusion in the course of NHS treatment.

Pressures.

4. Colleagues in the wider Department have alerted the Executive to the current pressures on the Department/NHS to take a more proactive approach to HCV, which are as follows:

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[1] There are some similar considerations to those raised by the more recent licensing of Beta-Interferon for Multiple Sclerosis, e.g. treatment is costly but not effective in many cases, the side effects are at least as bad, and there is pressure from the voluntary sector to encourage those who may benefit to come forward for treatment.

- The Advisory Council on the Misuse of Drugs (the statutory body which advises Government on drug misuse issues) has expressed concern about the potential increase among drug misusers unless clear advice is given about the dangers of HCV and the need for testing. They are equally concerned about the potentially large numbers of ex-drug misusers who may be unaware that they are infected. **The "Clinical Guidelines on Drug Misuse and Dependence" issued to all doctors in 1991 advises testing for HCV and follow-up.** Guidance was also issued to health authorities last year on drug misuse services which referred to the high prevalence of hepatitis C amongst injecting drug users and former injectors. This asked health authorities to review prevention programmes. **With such guidance already issued, it is difficult to counteract pressure from the ACMD for a comprehensive response including measures to prevent spread and provide access to treatment for those who may benefit.**

- The report of the Task Force set up to review the effectiveness of drugs services was published on 1 May. It draws attention to the large numbers of drug misusers infected with Hepatitis C and consequent treatment implications. It recommends that the Department should consider how people who could benefit from treatment should be encouraged to come forward. **More generally, the White Paper, "Tackling Drugs Together" explicitly commits Government, and at local level multi-agency Drugs Action Teams, to develop accessible services and to reduce the health risks and other damage associated with drug misuse.**

- The voluntary organisations are lobbying the Department for additional resources for this group of patients and for publicising how HCV can be prevented and treated.

- There is pressure for compensation from the Haemophilia Society for those infected with hepatitis C through blood products prior to 1985. Approximately 3000 haemophiliacs are thought to be infected who are not covered by the HIV compensation scheme. Ministers have resisted significant political pressure for compensation on the grounds that no negligence was involved but they have given commitments to help, including (in December 1995) investigation of alleged problems of access to alpha interferon. So far the few cases identified have been readily resolved.

- The "Lookback" of blood transfusion recipients infected with hepatitis C prior to the introduction of screening for Hepatitis C in September 1991 has created further pressure. It is likely that approximately 3000 recipients of infected blood who are still alive are likely to be identified by this exercise, and they are currently being traced. Ministers have given assurances that these patients will be tested and, if appropriate, treated.[2] A list of Ministerial and Departmental commitments is appended (Annex A) some of which could be interpreted in a wider context.

- The question of funding for counselling, testing and treatment has also been raised. The cost of Alpha Interferon alone is high (£2-5000 per patient depending on which regimen is used and at what stage it is administered). There is pressure for resources

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[2] Interim Report on the Hepatitis C Look Back Exercise submitted to Ministers on 5th February available on request.

for HCV to be ring-fenced in the way that they were (but are no longer) for HIV.

5. These pressures mean that **not to act** would continue to invite criticism for holding back up-to-date public health advice. It can also be argued that encouraging people to come forward for testing and possibly treatment may decrease the longer term NHS costs. However, any such reductions could be offset by increased costs of monitoring untreated patients[3] or potential savings from the development of cheaper more effective therapies. Trials of newer treatment regimens are already in progress so the value of treating, at present, asymptomatic patients (who may remain so for many years) with a relatively ineffective expensive drug is questionable.

The problem.

6. **From a public health point of view**, there is an obligation to remind health professionals, and people who may have been infected, about HCV and the desirability of counselling and testing. We have so far avoided going down this road because of the resource implications for the NHS. Raising awareness poses undoubted difficulties for the NHS. **The identification of asymptomatic patients by testing, though consistent with policy on HIV, will place increasing pressure on specialist services which are already fully-stretched** (some hepatologists have told us that hepatitis C represents 2/3 of their current workload). If the prevalence of HCV is in line with current estimates there will be medical and nursing manpower demands for increasing service availability, the scale of which has yet to be assessed. However, faced with criticism over the slow progress with the "Lookback", Ministers decided not to speed up detection as the bottleneck would then transfer to hepatology clinics.

7. It can be argued that responding to HCV is just one of many pressures on the acute sector and that giving priority to it is not sound policy. In terms of value for money, there may be better candidates for additional resources. There are so far few cost effectiveness studies either on the prevention of spread of HCV (even if it were possible given that drug misusers in particular tend to disregard advice on HIV which is seen as a bigger threat than HCV), or on the cost effectiveness of treating HCV compared to other interventions (although Alpha Interferon is probably more cost-effective than Beta Interferon, used for treating multiple sclerosis). However, in November 1995, the Standing Group on Health Technology identified, as a top priority, assessment of the effectiveness and cost effectiveness of Alpa Interferon in the early treatment of HCV infection. It will clearly be some time before the results are available. There is already a public perception, as well as a Ministerial commitment, that those infected **through NHS treatment** should be treated if medically appropriate.

8. Distinguishing between people infected through NHS treatment and through other routes such as drug misuse would be contentious. Ministers would be exposed to criticism if it appeared that the Department/NHS was operating a selective policy on testing and/or treatment dependent on the mode of infection (shades of the "deserving" and "undeserving" poor). Pressure groups like the British Liver Trust would rapidly identify any evidence of

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[3] Sheill A, Briggs S, Farrell GC. The cost effectiveness of alpha interferon in the treatment of chronic active hepatitis C. Med J Aust 1994; **160**: 268-72.

a tier approach if Ministers fail to follow the "Tackling Drugs Together" commitment. The only acceptable grounds for refusing treatment would be a medical contraindication. Similarly, appearing to withhold treatment on cost grounds would be politically unacceptable, particularly given the wide range of people who may be at risk (e.g. health care workers, haemophiliacs and people who injected drugs 20 years ago who are only now manifesting signs of liver damage).

9. **The cost of treatment with Alpha Interferon has been estimated as likely to increase by between £9 and 51m[4] in 1997/8 depending on how we approach this. There is already evidence of increased expenditure on Alpha Interferon in the primary as well as the acute sector and this is being monitored.** Although public health priorities must be a prime consideration, any new pressure on the NHS on the potential scale forecast would be a prime candidate to cite in PES. However, if we are to do so, we risk falling over the PES convention that requiring the NHS to respond to new pressures or to extend the range of treatments offered **before resources have been secured**, indicates acceptance that this is affordable within the existing settlement. **There is therefore a potential conflict between the Department's overriding responsibility for public health, compounded by growing lobby pressure for a more proactive approach, and conventional PES tactics.**

10. Finance colleagues advise that because of the present lack of robust prevalence data a quantified pressure for treatment of HCV will not form part of the current PES round. However, the increasing evidence of need and demand for services will be cited as one of the many factors contributing to the high level of pressure on the NHS generally. Finance further advise that where, as in this case, serious public health considerations arise it should be possible, with deft handling in the PES round, for the Department to go some way in the short term to meeting public and patient expectations for a positive response to these demands **and** keep the issue alive in current and future survey negotiations.

Current action.

11. We have already put in hand work to assess the resource implications of HCV[5] and allocated resources (£1m) for research into hepatitis C primarily to clarify its prevalence, natural history, and the clinical effectiveness of treatment. We are supporting the voluntary organisations dealing with hepatitis C (e.g. the British Liver Trust) through Section 64 grants.

12. **We are committed to issuing purchasing guidance on drug treatment services based on the Task Force report which will need to take into account the steps to prevent and treat Hepatitis C.** It may be that we should issue further guidance to inform purchasers about some of the options available so that they have sufficient details on which to base their purchasing decisions. Clinical guidelines along the lines of those issued by SMAC on Beta Interferon may also be helpful. These could focus on which groups of patients should be tested and who is likely to benefit from treatment (taking account of life expectancy, any co-

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[4] Wessex Institute of Public Health, impact of new medical technologies.

[5] EOR paper on the resource implications of HCV available on request.

m dity and current drug misuse which could mitigate against successful treatment). Issuing any guidance, however, implies a new signal about the relative priority to be attached to treatment. Initial soundings of purchasers indicate that, particularly in the current climate of serious strain on the acute services, such guidance is unlikely to be welcome particularly if prescriptive.

Conclusion.

13. HCV is developing into a major issue both on the public health front and because of the potential consequences for NHS expenditure and resources. It is still too early to provide any firm estimates of the scale of the potential demand for services. However, the more proactive the Department on the public health front, the faster the rise in immediate demand for testing, counselling and treatment.

14. HCV is one of a large number of growing pressures that can be identified on the acute services. Our current line is that money is not allocated to support specific treatments and that health authorities need to decide on priorities. Guidance ought to be issued on the public health front and perhaps also to the NHS on the management of the Disease. However, any such guidance could jeopardise any prospect of a successful future PES bid (see paragraph 10).

15. There is strong pressure on the Wider Department to act immediately on the public health front in general and for drug misusers both past and present in particular. Since colleagues first approach to the Executive, we have worked closely with them and consulted widely with experts in the field, ROs and purchasers to clarify the current position. We believe Ministers will have to be consulted about the handling of HCV, including the PES position. Some of the issues raised are clinical (such as the appropriateness of encouraging asymptomatic patients to come forward for testing and the treatment of infected patients with Alpha Interferon).

Options:

16. Essentially the Department is faced with three options:

i. **Do nothing** - questionable in that it could compromise Ministers;

ii. **Do nothing pending further advice from e.g. SMAC and/or the outcome of current research** - possibly defensible;

iii. **Accept the need to embark immediately on measures to increase public and professional awareness** - defensible, but the resulting workload would be an added pressure which some health authorities and Trusts would find it difficult to cope with. It also carries the risk of being presented as another "health scare".

A n proposed

17. What is **not** proposed is any kind of screening programme for HCV; the intention is to fulfil Ministers public health responsibilities and commitments already made by:

i. heightening awareness of HCV and its risks among health professionals and high risk groups;

ii. ensuring that counselling and testing are available for those who come forward as they are for HIV;

iii. providing access to hepatology services (including liver biopsy) for those testing positive;

iv. offering treatment with Alpha Interferon only to those with clear clinical indications.

18. **It is therefore proposed that, subject to the views of the Board, a submission be prepared jointly with colleagues in the Wider Department to inform Ministers about HCV. To help in preparing this, the Board are asked:**

- can the conflict between the public health priorities (and possible long term health and expenditure benefits) and the need to protect the NHS from additional pressures be resolved? In practice can we avoid a (limited) public health initiative when public health is a fundamental Ministerial responsibility?

- how actively should the Department respond to the various pressures for a proactive stance towards HCV (given the existing commitments to the "Lookback" and to drug misusers) in view of the resource implications which the NHS will find it very hard to address?

- should we issue guidance (purchasing and/or clinical) to inform and/or prepare the NHS for dealing with potentially large numbers of HCV patients coming forward for testing/treatment (to ensure that Alpha Interferon is not prescribed inappropriately)?

- is any additional work required to clarify any aspect of HCV that should be put in hand before any action is taken?

- should the help of SMAC be sought in developing clinical guidelines on the use of Alpha Interferon?