CHAPTER ONE

INTRODUCTION

1.1 BACKGROUND TO THE REPORT

In May 1997 the Minister for Health, the Hon Dr Andrew Refshauge, asked the Standing Committee on Social Issues to inquire into, and report on, the incidence and impact of Hepatitis C (HCV) in New South Wales. The Terms of Reference sent to the Committee specifically asked it to examine:

- the social and economic impact of Hepatitis C in NSW and the implications for future policy and funding of health and community services;
- the extent of the disease and its aetiology and epidemiology;
- the adequacy of policies, and diagnostic and treatment services with particular attention to strategies for prevention, given current health budget constraints;
- the groups and individuals in the community at increased risk of infection;
- the extent of the infection in specific population groups at risk, and the adequacy of education/prevention and care and treatment services available to them; and
- the risks involved for health care workers and the adequacy of policies and procedures on occupational health and safety.

During the course of the Inquiry, the Committee took evidence from 69 witnesses including some of the nation's most eminent Hepatitis C specialists in addition to experts in drug and alcohol, epidemiology, virology and public health. Evidence was also taken from agencies providing a range of services to those with Hepatitis C along with people who have the disease. Some of the most poignant and moving evidence came from those with HCV as they recounted their first hand experience of dealing with Hepatitis C - the side effects of either the disease itself or the drug therapy, the difficulties in accessing information and understanding general practitioners, and the overwhelming sense of helplessness as their health deteriorated.

The Committee also undertook site visits to three organisations that are involved in managing or supporting those with Hepatitis C: the Kirketon Road Clinic at Kings Cross, the Albion Street Clinic located at Darlinghurst and the headquarters of the NSW Users and AIDS Association (NUAA) at Bondi. During the visit to NUAA the Committee took evidence from a number of people with Hepatitis C.

Submissions were received from 123 individuals and relevant agencies. A very wide range of people with Hepatitis C made submissions including injecting drug users, prisoners, and those who had contracted Hepatitis C through infected blood or blood products. Many of those making submissions asked that the material they provided be treated in confidence. To respect these requests submissions from people with Hepatitis C will be referred to by number rather than name throughout the Report.

As far as the Committee can ascertain, this is the first Parliamentary Committee in Australia to consider the issue of Hepatitis C. Throughout the Inquiry, the Committee received very strong support for its work and numerous witnesses commended the Standing Committee for considering the issue. The Chair of the Australian National Council of AIDS and Related Diseases (ANCARD), for example told the Committee that the Council was:

> *extraordinarily pleased with the establishment of this Committee and hopes that the Committee will have some positive recommendations to help us deal with the questions of Hepatitis C* (Puplick evidence, 7 November 1997).

1.2 PUTTING THIS INQUIRY INTO CONTEXT: PREVIOUS WORK

Throughout the past decade, the issue of Hepatitis C has been considered at both the federal and state level. The following discussion summarises the findings of various taskforces and committees that have attempted to come to terms with this disease and the impact it has both upon individual lives and the health system.

1.2.1 FEDERAL INQUIRIES

- **The Joint National Health and Medical Research Council and Australian Health Ministers' Advisory Council Taskforce: 1993**

In 1993 the Joint National Health and Medical Research Council (NHMRC) and Australian Health Ministers' Advisory Council (AHMAC) Taskforce established a joint Taskforce to report on the epidemiology and natural history of Hepatitis C, and the cost-effectiveness of proposed disease control and treatment protocols. The Taskforce was also requested to examine the use of interferon. At that time the Pharmaceutical Benefits Advisory Committee was in the process of considering an application for the listing of interferon as a pharmaceutical benefit for the treatment of Hepatitis C. It was therefore decided not to duplicate these deliberations and the Terms of Reference were revised accordingly.

The resultant report, *Hepatitis C Epidemiology, Natural History, Control and Treatment*, was endorsed by both the NHMRC and AHMAC the following year. The final report forwarded recommendations in the areas of diagnosis, screening, epidemiology, natural history, Hepatitis C control and management (NHMRC, 1994).

Following acceptance of the report by the NHMRC and the AHMAC, a Commonwealth/State and Territory Implementation Working Group was established by AHMAC to examine the implications of the implementation of the report. AHMAC also extended the sunset clause of the Taskforce to enable further review of the efficacy of interferon in the treatment of Hepatitis C, including clinical indications, dose and duration of therapy and appropriate limitations on prescribing. The second report of

the Taskforce, *Treatment of Chronic Hepatitis C with Interferon*, was accepted by both NHMRC and AHMAC. The report was also considered by the Commonwealth's Pharmaceutical Benefits Advisory Committee (PBAC) which recommended interferon be made available as a pharmaceutical benefit along with a monitoring program for patients on interferon.

- **The National Hepatitis C Action Plan: 1994**

Following the acceptance of the NHMRC-AHMAC Taskforce's report AHMAC established a Commonwealth/State Working Group to examine the implications of the implementation of the report. The Implementation Working Group recognised the need for a nationally coordinated approach and initiated the development of the National Hepatitis C Action Plan. This Plan, which builds on the recommendations of the joint NHMRC/AHMAC report, was endorsed by AHMAC in October 1994.

The Plan has two aims:

- to minimise the transmission of Hepatitis C; and

- to minimise the personal and social impact for those already infected (AHMAC, 1994:i).

A series of recommendations were forwarded in each of four priority areas for action including: epidemiology and surveillance (three recommendations); testing (four recommendations); clinical management (three recommendations); and education and prevention (three recommendations).

In accordance with the National Hepatitis C Action Plan, the Commonwealth has been progressing a national package of measures to address the needs of people with Hepatitis C which includes:

- the development of a nationally coordinated approach to education and prevention working with affected communities to develop and implement a range of national education initiatives consistent with this approach (see Chapter Ten);

- the implementation of a package of education initiatives in identified areas of need including the following:

    - a national needs assessment on education needs of people with Hepatitis C conducted by the Hepatitis C Councils (National Hepatitis C Councils Education Reference Group, 1996);

    - a Hepatitis C program for people with haemophilia conducted by the Haemophilia Foundation of Australia (see Section 9.1.2);

  - a two year education program for general practitioners, to be implemented by the Royal Australian College of General Practitioners (taking into account the NHMRC Guidelines for General Practitioners) (see Section 8.4.1);

  - a national needs assessment for health care workers;

  - education material addressing infection control advice for the tattooing and skin penetration industry (see Section 10.5); and

  - a forum to address injecting drug use;

- incorporation of Hepatitis C messages into campaigns and education strategies under the National HIV/AIDS Strategy and the National Drug Strategy where appropriate;

- the introduction of more stringent requirements for pre-market evaluation and registration of Hepatitis C test kits under the *Therapeutic Goods Act, 1995*;

- a 12 month surveillance study with States and Territories on a pilot study to step up surveillance activities and commission research into the epidemiology of Hepatitis C in Australia - information from this study will inform future education programs for Hepatitis C;

- research into the epidemiology of Hepatitis C; and

- the development of these NHMRC guidelines on detection and management of Hepatitis C (NHMRC, 1997:iii).

The Hepatitis C Council suggested to the Committee that the extent to which strategies proposed in the National Action Plan have been addressed in NSW has been “limited” by a lack of Commonwealth funding for particular areas as well as a lack of agreement around responsibilities for education programs (Hepatitis C Council submission).

In early 1998 the Commonwealth Department of Health and Family Services commissioned a review of the *National Hepatitis C Action Plan* and an associated education document, the *Nationally Coordinated Hepatitis C Education and Prevention Approach* (produced in response to recommendation eleven of the Action Plan and reviewed in Chapter Ten).

The Review will:

1. Present a strategic overview of the HCV epidemic in Australia including:
   a. Estimates of HCV incidence and prevalence in Australia, projections of the long-term sequelae of HCV infection, estimates of present and future

economic cost of HCV to Australia, and a commentary on the social impact of HCV; and

b. Deficiencies in information collection and research capacity in achieving 1 (a); and

c. Priorities for future effort in remedying these deficiencies;

2. Assess the performance of the National HCV Action Plan and the Nationally Coordinated Hepatitis C Education and Prevention Approach in relation to their policies, principles and objectives across its major areas of activity:

- epidemiology and surveillance;
- education and prevention programs;
- testing strategy; and
- patient management counselling and treatment;

3. Identify the strengths and weaknesses of the current national and state level responses to HCV and the opportunities and threats facing these responses. This analysis should include consideration of the national coordination and liaison mechanisms linking Hepatitis C with HIV/AIDS, the National Drugs Strategy and other public health initiatives;

4. Consider and discuss the implications of the changing public health policy context since the National Hepatitis C Action Plan was first developed including:

- the development of the National Public Health Partnership,
- changes to Commonwealth-State relations including the broadbanding of Commonwealth public health program Specific Purpose Payments to State and Territory governments,
- the development and implementation of the Third National HIV/AIDS and Related Diseases Strategy,
- developments in national drugs policy, and
- the development of the National Communicable Diseases Surveillance Strategy; and

5. Recommend strategic directions and priorities for national action on HCV including specification of the essential components of an organised response to HCV at the state and territory level (Commonwealth Department of Health and Family Services, 1998:2-3).

The Committee understands that various organisations are undertaking different components of the review including:

- epidemiological estimates: National Centre in HIV Epidemiology and Clinical Research;
- estimates of present and future economic costs: Alan Shiell, Department of

Public Health, University of Sydney;

- social impact, program history and review of the National Hepatitis C Action Plan implementation: Evaluation and Research Unit, Division of Public Health, Commonwealth Department of Health and Family Services;

- analysis of strengths and weaknesses and opportunities and threats in Australia's response to Hepatitis C: David Lowe Consulting and Mandala Consulting; and

- strategic directions and priorities for national action: David Lowe Consulting and Mandala Consulting.

According to the Review's tender document, it was anticipated the Review would be undertaken over a three month period commencing in March and finishing in June 1998. As of November 1998, the final report had not been released.

The Review's Background Briefing Paper used at the mid-review consultation meeting held in Sydney in July 1998 suggested that the final report would identify five key challenges that emerged from the Review's analysis of the strengths and weaknesses of the current national and state level response to HCV and the opportunities and threats facing these responses. The challenges identified include:

1. reducing transmission of Hepatitis C;

2. improving care and support for people living with Hepatitis C;

3. getting the research right;

4. extending partnerships; and

5. clarifying structures, roles and responsibilities (David Lowe Consulting and Mandala Consulting, 1998:15).

The Hepatitis C Council suggested to the Committee that the Review is:

> *expected to show some areas of need have begun to be met, [but] it will almost certainly show that the great bulk of prevention work and much needed improvements to care, support and treatment services remain to be done* (Loveday evidence, 30 March 1998).

The Committee understands that, following the finalisation of the review of the Action Plan, a list of recommendations for areas that need to be addressed will be developed and submissions will be sought to undertake this work (Federal Parliament Liaison Group on HIV/AIDS and Related Diseases, 1998:4). This work will be funded by a one-

off supplement of $700,000 which will be made available in 1998-99 (Federal Parliament Liaison Group on HIV/AIDS and Related Diseases, 1998:4).

- **The NHMRC Strategy for the Detection and Management of Hepatitis C in Australia: 1997**

Realising that some significant aspects of Hepatitis C were not dealt with in the National Hepatitis C Action Plan, the NHMRC appointed a Working Party in 1994. Chaired by Professor Reed of the Department of Medicine, University of Western Australia, the Working Party's Terms of Reference were:

1. *To develop clinical protocols for the management of Hepatitis C;*

2. *To develop protocols for the laboratory diagnosis of Hepatitis C, including clinical and public health indications for testing, and the resolution of indeterminate test results;*

3. *To monitor data on treatment for Hepatitis C, including data to be obtained from the database set up as a result of the current NHMRC recommendations for the use of interferon in the management of chronic Hepatitis C;*

4. *To make recommendations on the place of interferon or other treatments in the management of Hepatitis C in children including if appropriate, dose, duration of treatment, and patient monitoring protocols;*

5. *To monitor data on the incidence, prevalence, epidemiology, and natural history of Hepatitis C, and make recommendations as appropriate to control the transmission of the disease, including a review of the surveillance pilot study approved by AHMAC;*

6. *To establish, where appropriate, smaller task groups to undertake specific work and to co-opt special members where necessary; and*

7. *To provide information direct to the AHMAC Education Reference Group, advise the AHMAC Implementation Working Group, and report to the Communicable Diseases Standing Committee of the NHMRC* (NHMRC, 1997:ix).

In dealing with management, the Working Party focused attention on treatment protocols in an endeavour to improve access to treatment, optimise treatment regimes and evaluate data now accumulating as a result of the Section 100 of the *National Health Act, 1953 (Commonwealth)* guidelines (NHMRC, 1997:iv). A cost-effectiveness analysis of interferon usage or care provision was considered outside the Terms of Reference of the Working Party and therefore not included.

The Working Party's final report, *A Strategy for the Detection and Management of Hepatitis C in Australia,* was released in March 1997 and is available on the Internet at http://www.health.gov.au:86/nhmrc/publicat/fullcopy.htm. The Report makes recommendations on:

- laboratory testing;
- treatment protocols and options;
- infrastructure for treatment and management (including expansion of shared-care management);
- funding for trials;
- counselling; and
- access and shared care (NHMRC, 1997:xiii - xiv).

In releasing the final report, the Working Party's Chair commented that the Working Party had:

> *focussed significant attention on treatment protocols in an endeavour to optimise treatment regimes, to improve access to treatment and evaluate data on natural history and response to therapy now accumulating in Australia* (NHMRC-ANCARD, 1997).

ANCARD Chair, Mr Chris Puplick saw the document as a "comprehensive review" of the management of Hepatitis C in Australia which will "act as a blue print for future directions" in dealing with Hepatitis C (NHMRC-ANCARD, 1997).

- **Australian National Council on AIDS and Related Diseases**

In 1996 the Commonwealth government released its third National HIV/AIDS Strategy, 1996-97 to 1998-98. At that time the Strategy was broadened to include blood borne viruses including Hepatitis C. As a result of that decision, the scope of the Australian National Council on AIDS (ANCA) was expanded and the Council became known as the Australian Council on AIDS and Related Diseases (ANCARD). ANCARD is the Commonwealth Government's key advisory body on HIV/AIDS and related communicable diseases that have clear and direct links to HIV/AIDS such as Hepatitis C.

ANCARD has convened a Specialist Sub-Committee on Hepatitis C to advise it on the measures necessary to achieve control of the Hepatitis C infection in Australia. The Committee's Terms of Reference are to advise ANCARD on:

1. the implementation of the National HIV/AIDS Strategy as it relates to Hepatitis C;

2. the evaluation and implementation of the National Hepatitis C Action Plan and the implementation and recommendations of the NHMRC Report: *A Strategy for the Detection and Management of Hepatitis C in Australia* to provide expert advice to ANCARD and all its subcommittees on issues relating to Hepatitis C;

3. activities addressing Hepatitis C being undertaken by Commonwealth, State and Territory Governments and non-government organisations; and

4. how to improve the monitoring of data on the epidemiology, transmission and natural history of Hepatitis C.

The Sub-Committee is made up of experts in a range of fields associated with Hepatitis C including gastroenterology, Hepatitis C viral research, epidemiology and surveillance in addition to the national peak organisation for Hepatitis C and the Australian Intravenous League. ANCARD Chair, Mr Chris Puplick considers the Committee would "play an important role in progressing Australia's response to Hepatitis C" (NHMRC, 1997:2).

ANCARD's 1997-99 Working Plan has been developed around the framework contained in the National HIV/AIDS Strategy. It identifies a number of priority projects specifically targeting Hepatitis C. Examples of Hepatitis C-oriented activities proposed in the Plan include:

- consider establishment and oversee a National Prisons Action Plan to deal with HIV and related diseases especially HCV;

- initiate and oversee development of a strategic plan for HCV transmission prevention;

- consider the recommendations of the review of the National Hepatitis C Action Plan in relation to care and treatment issues and respond in an appropriate manner (ANCARD, undated).

The move to broaden the HIV/AIDS Strategy to include Hepatitis C has not been without criticism or problems. The Hepatitis C Council, for example, has stated that:

> *Our belief is that . . . Hepatitis C policy has been tacked on to the Third HIV Strategy in particular, and HIV funding in general* (Hepatitis C Council supplementary submission).

In evidence before the Committee Dr Nick Crofts commented on a "major problem" with the policy:

> *at the Federal level Hepatitis C is not being accorded a status of its own and the terms of the National Strategy on AIDS and Related Diseases where Hepatitis C is to be addressed where there is significant overlap with issues related to HIV. The practical impact of that is that people are being asked to tackle two diseases of major public health and social significance on the one budget and the one budget being cut back. The social impact of that policy, more than anything else, promotes the sort of divisions that we fortunately have not seen a lot in AIDS, but the divisions between the differing camps, the differing interest groups; Hepatitis C versus HIV; injecting drug users versus the gay community* (Crofts evidence, 28 November 1997).

He elaborated further that:

> *the current policies of not addressing Hepatitis C related issues as specific issues in their own right are promoting that divisiveness, are leading to a lack of emphasis and importance being placed on Hepatitis C related issues* (Crofts evidence, 28 November 1997).

The Executive Officer of the Australian Hepatitis Council, Mr Jack Wallace, has expressed his concern that Hepatitis C is the "poor cousin" in the current AIDS and Related Diseases Strategy (Wallace correspondence, 2 September 1998). He is also concerned that:

> *the linking of Hepatitis C with sexually transmitted infections in national strategies perpetuates the confusion about whether Hepatitis C is sexually transmitted* (Wallace correspondence, 2 September 1998).

To overcome the concerns he has identified, Wallace has proposed the option of redefining ANCARD to the Australian National Council on AIDS and Hepatitis C (Wallace correspondence, 2 September 1998).

The Hepatitis C Council informed the Committee that they are "pleased" that:

> *at the national level, ANCARD under the chairmanship of Mr Chris Puplick, appears to be taking a proactive role in coordinating the national response to Hepatitis C, but there are too many aspects, particularly on the prevention front, where progress is far too slow and in some instances, non-existent* (Hepatitis C Council supplementary submission).

1.2.2 STATE INITIATED TASKFORCES

NSW Health established a Hepatitis C Taskforce in September 1994 to ensure a "consistent, planned approach" to all aspects of Hepatitis C (NSW Health tabled document, 3 October 1997). The Taskforce was made up of clinicians, epidemiologists

and consumer group representatives. Its Terms of Reference were:

- *consideration of the epidemiology of Hepatitis C in NSW;*
- *advice on improvement in surveillance, education and prevention strategies;*
- *consideration of the cost effectiveness of proposed disease control and treatment protocols;*
- *advice on the implementation of the NHMRC Taskforce Report; and*
- *identification of gaps in existing policy and service provision* (NSW Health tabled document, 3 October 1997).

The Taskforce released its report in 1995. It described the known epidemiology of HCV and identified priorities for action in health and other non-health portfolio areas (such as Police, Corrective Services and the Attorney-General) required to address Hepatitis C (NSW Health submission). The Department advised that recommendations are being implemented progressively and they are "working towards full implementation as resources become available" (NSW Health submission). Details of the action being taken on each recommendation were contained in a document NSW Health tabled at its hearing which are reproduced in Appendix Three.

The cost of full implementation of the Taskforce recommendations relating to the Health portfolio has been estimated. NSW Health advised that a comprehensive program of appropriate activities under the health portfolio is estimated to require additional funding of approximately $3,240,000 annually with an additional $1,690,000 in 1998/99 to initiate appropriate actions, making a total of $4,930,000 in 1998/99 (NSW Health submission).

The Hepatitis C Council has described the Taskforce Report as a:

> *strategic document [that] made wide reaching and positive recommendations to address the HCV epidemic in this state. This report, however, has lacked sufficient and committed funding to undertake adequately many of the initiatives proposed* (Hepatitis C Council submission).

1.3 STRUCTURE OF THE REPORT

Chapter Two provides an introductory discussion of the Hepatitis C virus including its aetiology, modes of transmission, natural history, clinical features and genotypes. The discussion also compares and contrasts Hepatitis C with HIV/AIDS. The epidemiology of the Hepatitis C virus is considered, in particular its incidence and prevalence along with projected estimates of the long-term sequelae of the infection. National and state notification rates are also cited.

Chapter Three identifies the primary population groups at risk of contracting the Hepatitis C virus: injecting drug users, inmates in the state's corrections system, people born in certain countries overseas, recipients of infected blood or blood products, health care workers and their patients, people engaging in skin penetration activities (such as acupuncture and tattooing) and transmission from mother to child.

In Chapter Four the Committee examines the social and economic impact Hepatitis C has upon those with the disease. Many of those making submissions to the Committee wrote of the impact the virus has had upon all facets of their lives. The Committee has come to appreciate that HCV radically affects an infected person's personal life, social life, working life and, for many, their financial standing. In addition, many of those with Hepatitis C have experienced discrimination and stigmatisation as a result of a lack of understanding of the disease, and certain stereotypes. In terms of the economic impact of the disease, the chapter looks at two aspects: the impact of the disease upon individuals who are Hepatitis C positive and the broader impact upon the community as a whole.

The Committee was requested to examine current Hepatitis C policies. Chapter Five identifies the policies of NSW Health and reports comments made on the appropriateness of these policies by a range of experts appearing before the Committee. Strategies addressing current inadequacies are identified.

Diagnosing Hepatitis C is examined in Chapter Six. The Chapter looks at the various tests currently used to detect both the antibody and the antigen and the laboratory structure in place to perform these tests. The role of pre- and post-test counselling is discussed and proposals to formalise this process forwarded.

In Chapter Seven the current policies directing the treatment and management of Hepatitis C are identified. The discussion identifies current treatment regimes with particular reference to interferon, the only approved drug therapy. Three relevant medical procedures are also discussed: liver biopsies, liver transplants and treatment of hepatocellular carcinoma.

Chapter Eight builds upon the preceding chapter by identifying issues and concerns raised by witnesses that relate to the way Hepatitis C is currently treated and managed. In particular, the discussion looks at the adequacy of current policies regulating treatment, the adequacy of current treatment regimes and current clinical management practices. The issue of treating and managing prison inmates with Hepatitis C is also considered.

Chapter Nine reviews existing agencies that provide support to those with Hepatitis C. The Hepatitis C Council of New South Wales provides a very broad range of services to meet the needs of those who are Hepatitis C positive and their families. Throughout the report, the Council is referred to as the Hepatitis C Council. Other non-government agencies providing services are also reviewed. Many of these were primarily set up to

provide support to those with HIV/AIDS and have had their scope increased to deal with the Hepatitis C epidemic.

In Chapter Ten a range of preventative strategies to limit the spread of the HCV virus is considered. Given the impact the disease has upon injecting drug users and those in the corrections system, the discussion primarily focuses of the needs of these two population groups. The Chapter also considers the need for a national education campaign to inform the general community on the disease, and minimise discrimination and stigmatisation.

In addition to drawing a number of key conclusions, Chapter Eleven notes that, unlike HIV, the Hepatitis C community is quite disparate and no one group advocates for those with the disease. To overcome this situation the formation of a NSW Parliamentary Liaison Group is proposed to provide a strong advocacy role and influence policy makers at the highest state level.