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Hepatitis B.

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HEPATITIS B

**REPORT OF THE STANDING COMMITTEE ON HEALTH AND WELFARE,
SOCIAL AFFAIRS, SENIORS AND THE STATUS OF WOMEN**

**BARBARA GREENE, M.P.
CHAIR**

**STANLEY WILBEE, M.P.
CHAIR
SUB-COMMITTEE ON HEALTH ISSUES**

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HOUSE OF COMMONS

CHAMBRE DES COMMUNES

Issue No. 6

Reçu n° 6

Wednesday, February 12, 1992

Le mercredi 12 février 1992

Chair: Barbara Greene

Barbara Greene

HEPATITIS B

Minutes of Proceedings and Evidence of the Standing Committee

Procès-verbaux et témoignages de Comité permanent de la

Health and Welfare,
Social Affairs,
Seniors and the Status
of Women

Santé et du bien-être
social, des affaires
sociales, du troisième
âge et de la condition
féminine

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CONCERNANT

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Troisième rapport à la Chambre: Hépatite B

**BARBARA GREENE, M.P.
CHAIR**

**STANLEY WILBEE, M.P.
CHAIR**

SUB-COMMITTEE ON HEALTH ISSUES

FEBRUARY 1992

HOUSE OF COMMONS

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Wednesday, February 12, 1992

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Le mercredi 12 février 1992

Présidence: Barbara Greene

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Procès-verbaux et témoignages du Comité permanent de la

Health and Welfare, Social Affairs, Seniors and the Status of Women

Santé et du bien-être social, des affaires sociales, du troisième âge et de la condition féminine

RESPECTING:

Consideration of the First Report of the Sub-Committee on Health Issues

Future Business

INCLUDING:

Third report to the House: Hepatitis B

CONCERNANT:

Étude du premier rapport du Sous-comité sur les questions de santé

Travaux futurs

Y COMPRIS:

Troisième rapport à la Chambre : Hépatite B

Third Session of the Thirty-fourth Parliament,
1992

Troisième session de la trente-quatrième législature,
1992

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The Standing Committee on Health and Welfare, Social Affairs, Seniors and the Status of Women has the honour to present its

THIRD REPORT

In accordance with its mandate under Standing Order 108(1), your Committee established a Sub-Committee and assigned it the responsibility of examining the subject of Hepatitis B.

INTRODUCTION

The Sub-Committee submitted its First Report to the Committee.

HEPATITIS B

Your Committee adopted the following Report which reads as follows :

THE RISKS OF HEPATITIS B INFECTION

HEPATITIS B IN CANADA

VACCINATION AGAINST HEPATITIS B

COST OF HEPATITIS B VACCINE

INFORMATION AND EDUCATION

IMMIGRATION AND HEPATITIS B

INCIDENCE AND REPORTING OF HEPATITIS B IN CANADA

HEPATITIS B AND HEALTH-CARE WORKERS

HEPATITIS B AND ABORIGINAL POPULATIONS

CHRONIC FANGUIC SYNDROME

APPENDIX A – THE NEW ZEALAND PROGRAM

APPENDIX B – LIST OF WITNESSES

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LIST OF RECOMMENDATIONS

RECOMMENDATION NO. 1

The Sub-Committee recommends that the Federal Government, in cooperation with the provinces and territories, develop and implement a universal immunization program for neonates against hepatitis B. The Sub-Committee further recommends that the Federal Government fund at least 50% of the costs of this immunization program and that appropriate cost-sharing agreements be made with the provinces and territories.

RECOMMENDATION NO. 2

The Committee recommends that the Federal Government, in cooperation with the provinces and territories, develop a "catch-up" program to immunize children at 10 years of age, the purpose being to effect immunization prior to the children's reaching high school age. The Sub-Committee further recommends that the Federal Government fund at least 50% of the costs of this catch-up immunization program and that appropriate cost-sharing agreements be made with the provinces and territories.

RECOMMENDATION NO. 3

The Sub-Committee recommends that the Federal Government develop a program, in cooperation with the provinces and the territories, to routinely test pregnant women for hepatitis B infection. Where the test is positive, the baby should receive hepatitis B immune globulin and hepatitis B vaccine in accordance with the recommendations of the Canadian Immunization Guide.

RECOMMENDATION NO. 4

The Committee recommends that the Federal Government, through the Departments of Health and Welfare and Supply and Services, conduct a study on the pricing of hepatitis B vaccine: first, to determine why the prices of identical vaccines vary significantly between different countries; second, to ensure that the negotiations on price with vaccine manufacturer(s) are conducted with full knowledge of prices paid in other jurisdictions; and, third, to ensure that those vaccines of acceptable quality that are supplied to Canada will be available at the lowest possible price on the world market.

RECOMMENDATION NO. 5

The Sub-Committee recommends that Health and Welfare Canada, in cooperation with provincial and territorial health departments, develop and implement information and education programs to combat hepatitis B, to prevent the spread of this disease in Canada. Such programs should be directed to the Canadian public generally, and to identified high-risk groups and communities.

RECOMMENDATION NO. 6

The Sub-Committee recommends that the Federal Government develop a program to deal with the possibility that hepatitis B might be spread within Canada by immigrants from regions of the world where the disease is endemic and occurs at intermediate or high incidence among the population. Such a program could include universal immunization of all immigrants to Canada, prior to their entry into this country, or a selective immunization program to apply only to immigrants from regions of intermediate and high endemicity.

RECOMMENDATION NO. 7

As an alternative to Recommendation No. 6, the Sub-Committee recommends that the Federal Government study and evaluate the need for, and potential effectiveness of, a program for the screening of immigrants to Canada for hepatitis B infection. The Sub-Committee further recommends that, where an immigrant to Canada tests positive for hepatitis B infection, immunization of all uninfected and susceptible family members against hepatitis B shall be mandatory, prior to their entry into this country.

RECOMMENDATION NO. 8

The Sub-Committee recommends that Health and Welfare Canada review the effectiveness of the program requiring that all cases of hepatitis B diagnosed in Canada be reported to the Laboratory Centre for Disease Control, to ensure that reporting of this disease will be as complete as possible.

RECOMMENDATION NO. 9

The Sub-Committee recommends that Health and Welfare Canada review the need for a comprehensive epidemiological study of hepatitis B in Canada and, if appropriate, design and implement, in cooperation with the provinces and territories, an epidemiological study to determine the incidence of hepatitis B in this country.

RECOMMENDATION NO. 10

The Sub-Committee recommends that the Federal Government, through Health and Welfare Canada, take the lead in initiating discussions with provincial and territorial governments, and with associations of health-care professionals, toward the development and implementation of a national policy on the mandatory testing and immunization of health-care professionals for hepatitis B.

HEPATITIS B IN CANADA

INTRODUCTION

The struggle against infectious disease is an integral part of human civilization. Enormous strides have been made against disease in the twentieth century, especially through the development of vaccines and antibiotics. The immunization of populations, or particular target groups, has brought many once-devastating diseases under control. Some diseases, notably smallpox, have been all but eradicated through the use of vaccines.

Prevention of disease is the first line of defense in health care. In a world made continually smaller by modern transportation technologies, geographic boundaries have become almost meaningless as barriers to infectious disease. Many Canadians travel extensively throughout the world, on business, for government, and for recreation. Also, Canada is a destination of choice for immigrants from many countries. One consequence of a shrinking and crowded world is the spread of infectious diseases which normally would be largely confined to their regions of origin. One such disease is hepatitis B.

Hepatitis B is a devastating disease in many parts of the world. The incidence of hepatitis B is increasing in Canada and the disease has the potential to become a major problem in this country. In this report, we discuss the various aspects of hepatitis B, and we propose a number of recommendations to reduce the spread of this disease in Canada. Appropriately, our approach to this disease is objective and, in some cases, rather technical. It is important, however, to bear in mind the enormous cost exacted by hepatitis B in terms of human suffering and personal tragedies.

The first witness the Sub-Committee heard on this issue was Mrs. Bobbi Bower, a private citizen from British Columbia. Mrs. Bower presented eloquent and moving testimony to the Sub-Committee about the death of her 16-year old daughter, who was a promising young model, from hepatitis B in December 1989. Mrs. Bower's daughter left home in the autumn of 1989 and spent five weeks associating with street people. During this period, she contracted hepatitis B. Unfortunately, she developed the very rare fulminant type of hepatitis that leads to rapid destruction of the liver and is often fatal. Mrs. Bower's daughter died six days after her hepatitis B was diagnosed.¹

Although this very tragic case is not typical of the usual course of hepatitis B infection, the Sub-Committee believes that hepatitis B presents a serious potential threat to Canadian society. It also presents a major challenge to governments in terms of policy development in the health-care field. The threat of hepatitis B to health-care workers, and their patients, has recently been dramatized in the case of a surgeon in Nova Scotia who was infected by a patient and who subsequently may have infected two other patients while performing surgery.²

¹ *Minutes of Proceedings and Evidence of the Sub-Committee on Health Issues of the House of Commons Standing Committee on Health and Welfare, Seniors and the Status of Women (hereafter, Proceedings), Issue 1, 3 October 1991, p. 14.*

² Deborah Jones, "Hepatitis leaves Halifax surgeon an operating room outcast", *Canadian Medical Association Journal*, 15 November 1991, p. 1345-1348.

There is no cure for hepatitis B, but we have the technology to prevent the spread of this disease in Canada through the use of a safe and very effective vaccine. There will be significant costs involved in a coordinated program of disease prevention, but the failure to institute such a program will also have very high costs. This report discusses the issues associated with hepatitis B. The testimony is to be found in Issue Nos. 1-5 of the Sub-Committee on Health Issues of the Third Session of the Thirty-Fourth Parliament.

HEPATITIS B

Hepatitis is a term for a number of serious liver diseases: the word itself is derived from the Greek and means "inflammation of the liver". Hepatitis may be caused by a number of agents, including alcohol, drugs, or environmental chemicals, but is most often caused by one of a number of hepatitis viruses. The hepatitis B virus (HBV) is associated with a wide spectrum of liver disease, including acute hepatitis, chronic hepatitis, cirrhosis of the liver, and hepatocellular carcinoma or liver cancer.

The incubation period for hepatitis B is about 6 to 25 weeks. Some stages of the disease may be only mildly symptomatic, or there may even be no symptoms, and many people are in this latter category. More serious symptoms include loss of appetite, tiredness, and general feelings of weakness, symptoms similar to those caused by influenza. Jaundice, a yellowing of the skin, may occur, and a fever may also be present.

In very rare cases, fulminant hepatitis, the most serious acute form of the disease, may develop. This rapidly progressive form of the disease often results in death as massive sections of the liver are destroyed. Death occurs as a consequence of liver failure.

In most cases of hepatitis B, the disease runs its course in four to eight weeks, except in the elderly and in cases contracted through blood transfusion. In these cases, death rates may reach 10 to 15%. Chronic hepatitis may occur in 5 to 10% of HBV infections. Full-blown chronic active hepatitis may occur and eventually lead to cirrhosis. A subclinical chronic carrier state may develop in some patients, and this state reportedly is the one most likely to lead to liver cancer. Thus, it is important to realize that even mild symptoms of hepatitis can lead to serious complications in the affected person.

The likelihood of becoming a carrier of the virus varies inversely with the age at which infection occurs. For infants infected at birth by a carrier mother, the rate of carriage can be up to 90%. For children infected before five years of age, the probability of becoming a carrier is between 25% and 50%. In comparison, acutely infected adults have only a 5% to 10% probability of becoming carriers. The difference appears to be that the immune systems of the very young are less successful at eliminating the virus, after the disease has run its course, than are adult immune systems.

THE RISKS OF HEPATITIS B INFECTION

Persons infected with HBV carry the virus in all body fluids, including blood, semen, vaginal secretions, saliva, sweat, urine, and even tears. The disease is usually spread through exposure to the body fluids from infected individuals. Thus, health-care professionals, including dental professionals, are often at risk, particularly in surgery, or in emergency and rescue situations where bleeding is common. For the same reasons, police and firefighters and emergency/rescue personnel can be at higher risk. Students training for these professions are also at risk.

Hepatitis B is a sexually transmitted disease (STD): the virus can be transmitted by sexual contact with an infected person. Homosexually active males, promiscuous heterosexuals, and prostitutes are at increased risk. The sharing of needles to inject illicit drugs is another highrisk activity. Other highrisk groups include correctional officers and prisoners in institutions, embalmers and funeral directors, and staff and residents of institutions for the mentally handicapped.

One group at considerable risk of contracting hepatitis B are the many young people who leave home each year to become, for varying periods of time, "street people". Variously referred to as "runaways" or "curb-kicker kids", these young people experiment with sex and drugs, usually in ignorance of the high risks of contracting the infectious diseases that are associated with such behaviour.

With a disease such as hepatitis B, the chain of risk can reach back into the original community when the runaway comes back home. Mrs. Bower's daughter, for example, returned home and re-established a former relationship. Her partner became infected by the hepatitis B virus. Later, when he became involved in a new relationship, he passed the virus on to his new partner.³

HEPATITIS B IN CANADA

Worldwide, hepatitis B affects some 50 million people annually and is reported to cause more than two million deaths each year. An estimated one billion persons are infected by the virus and some 300 million persons are believed to be chronic carriers of the virus. Regions of the world are classified as being of high endemicity, where the carrier rate is 7-20%; of intermediate endemicity, with a carrier rate of 2-7%; and of low endemicity, with a carrier rate of 2% or less. Hepatitis B is present at a very high rate in tropical Africa, in East and Southeast Asia, and in parts of South America.

Canada is a country with a low endemicity of hepatitis B. The virus is present at a low incidence in the general population. Dr. Laurence Blendis, representing the Canadian Liver Foundation, testified that the prevalence of the virus in Canada, as determined through testing of blood some ten years ago by the Canadian Red Cross, was about 0.2-0.3% in most provinces, and about 0.5% in Quebec.⁴ The rates are much higher in some subpopulations in Canada, however, and these include some aboriginal groups living in northern parts of Canada, and in Canadian residents who have emigrated to Canada from areas of the world where hepatitis B is present at high levels of endemicity.

Hepatitis B has been a notifiable disease in Canada since 1969. Physicians are required to report diagnosed cases to local health agencies who then forward the information to provincial or territorial health ministries. The data are combined into specific age and sex groupings and ultimately forwarded to the Laboratory Centre for Disease Control (LCDC) at Health and Welfare Canada. Difficulties associated with the correct diagnosis of the disease have impacts on the treatment and spread of hepatitis B and also on the accuracy of data on trends in disease occurrence and numbers of persons in Canada who may be carriers of the disease.

The available information indicates that hepatitis B is increasing in Canada. The Canada Diseases Weekly Report, a publication of Health and Welfare Canada, states in the 3 August 1991 issue that: "The reported incidence of hepatitis B in Canada has increased by a factor of 2.5 during

³ *Proceedings*, Issue 1, p. 20.

⁴ *Proceedings*, Issue 2, p. 7.

the period 1980 to 1989.”⁵ There are two reasons for this reported increase. One is that the disease actually is increasing in frequency in this country; the second reason is that diagnostic procedures have improved over the decade and physicians are more likely to identify and report actual cases. However, between 50% and 90% of cases of hepatitis B are subclinical and never come to the attention of medical practitioners.

The Sub-Committee received disturbing testimony that hepatitis B may be seriously under-reported in Canada, the foregoing statements notwithstanding. Dr. Blendis made the following statements:

“Everybody knows that the incidence rates (of hepatitis B) are hugely under-reported ... every time a laboratory ... makes a diagnosis of hepatitis .. they have to report it to the public health authorities. When the public health authorities receive the report, they send me a form to fill out about the details of the case. I estimate that I get only one form in ten of the patients who are diagnosed, and it may be even less.”⁶

Dr. J.Z. Losos, Director General of Health and Welfare Canada’s Laboratory Centre for Disease Control, agreed with the suggestion that hepatitis B is under-reported in Canada and stated that “under-reporting in any disease is a commonplace problem with public health”.⁷ Dr. Losos did not agree that there were ten times as many carriers of HBV as the incidence statistics show, but he did not offer an alternate figure.

VACCINATION AGAINST HEPATITIS B

Currently, there is no effective treatment for hepatitis B, except to treat the symptoms of the disease. As noted above, most patients recover from the infection after a period, and most adult patients eliminate the virus from their systems. Anti-viral drugs are not effective against hepatitis B. The principal weapon against this disease is vaccination to prevent the infection in the first place.

A vaccine against hepatitis B became available in 1982. This vaccine was derived from the blood plasma of humans infected by the virus. In 1987, new vaccines became available which were produced by yeast strains genetically modified to synthesize the viral surface antigen, designated as “HBsAg”. Thus, these recombinant DNA (rDNA) vaccines do not contain any virus particles. Instead, they consist of a highly purified protein antigen. The vaccines, two of which are available in Canada, are known to be effective in conferring immunity in up to 95% of those persons who are vaccinated.⁸

An important issue to be considered in developing an immunization program for any disease is that of the costs and benefits of such a program. A basic objective is to identify and quantify the benefits to be obtained from an immunization program. Such benefits are both direct and indirect and may include a real decrease in disease incidence as more and more people are made immune to the infectious agent, and the possibility that the disease might be eradicated from the population, or nearly so. This could lead to significant reductions in present and future health-care expenses, and lower economic impacts of the disease in terms of employee absenteeism and premature deaths of affected persons, including wage-earners. The reduction in human suffering from the disease obviously is a major consideration although the dollar value cannot be calculated.

⁵ Health and Welfare Canada, “National Advisory Committee (NACI) Statement on Universal Immunization Against Hepatitis B”, *Canada Diseases Weekly Report*, 3 August 1991, p. 170.

⁶ *Proceedings*, Issue 2, p. 8.

⁷ *Proceedings*, Issue 1, p. 37.

⁸ *Proceedings*, Issue 2, p. 15.

Immunization programs are expensive, however, both in terms of the cost of the vaccines and the technical and administrative costs associated with their delivery. The possible dollar costs of a universal neonate immunization program for hepatitis B can be crudely estimated simply by multiplying the current cost of vaccine by the number of neonates born in Canada each year.

In 1989, there were 392,505 live births in Canada. At present, the cost of hepatitis B vaccine is about \$70 for a course of three doses. The annual cost to immunize all neonates would thus be about \$27.5 million, for vaccine alone. If a catchup program involving 10-year olds were instituted at the same time, the vaccine costs would double to about \$55 million for each year that the dual program was in effect. It is essential to note, however, that high quality hepatitis B vaccine is being sold in some countries, notably New Zealand, at prices much lower than the current price in Canada. The Sub-Committee firmly believes that the vaccine can be acquired at much lower prices than we are currently experiencing.

Since the first introduction of the vaccine in 1982, immunization has been restricted to designated high-risk groups. The effectiveness of this strategy has been questioned by several witnesses before the Sub-Committee. Even among the most astute and concerned high-risk group, the health-care professionals, immunization programs reportedly have achieved only a 50-70% success rate. Part of the difficulty is that immunization requires a course of three injections (four, in some exceptional cases) over a period of six months, and the full course of doses is necessary to ensure that immunity is achieved.

In August 1991, the National Advisory Committee on Immunization (NACI) issued a statement on a program of universal immunization against hepatitis B. The NACI noted that, in spite of the targeted immunization program, the incidence of the disease has continued to increase. With the possible exception of health-care professionals, high-risk groups, including those that account for the majority of cases of hepatitis B, have been difficult to reach and bring into the immunization program.

The NACI statement notes that there is "an emerging consensus among experts in the field that universal immunization during childhood is the key to the control of hepatitis B virus infection in North America". The NACI has recommended, following a review of the evidence, that "to achieve significant control of hepatitis B in Canada, universal immunization should be implemented. This is in addition to the present high-risk group strategy."⁹

Several witnesses testified to the Sub-Committee on the desirability of a universal immunization program for hepatitis B. Although the Sub-Committee does not believe that hepatitis B is a major health problem in Canada generally at the present time, except in certain groups and communities, we are persuaded that the potential exists for this disease to become a major problem in the future. We agree with the NACI recommendation that a universal immunization program against hepatitis B is desirable.

We also believe that, to make the program effectively universal, the federal government should take the lead, not only in policy development, but in providing funding to the provinces and territories. In the case of the ten provinces and the Northwest Territories, that funding should cover at least 50% of the program's costs. In the case of the Yukon, the federal government should fund 100% of the costs of the hepatitis B immunization program, in accordance with current funding arrangements with the Yukon for other immunization programs. We make the following recommendation.

⁹ Canada Diseases Weekly Report, 3 August 1991, p. 165.

RECOMMENDATION NO. 1

The Sub-Committee recommends that the Federal Government, in cooperation with the provinces and territories, develop and implement a universal immunization program for neonates against hepatitis B. The Sub-Committee further recommends that the Federal Government fund at least 50% of the costs of this immunization program and that appropriate cost-sharing agreements be made with the provinces and territories.

A universal immunization program for neonates will protect the new generation of Canadians against hepatitis B, but there is a generation of children that will not benefit from this program. Testimony presented to the Sub-Committee noted that when children reach adolescence, they are at a higher risk of contracting sexually transmitted diseases (STDs) if and when they become sexually active. It is important, therefore, to extend the hepatitis B immunization program to these children prior to their entering high school.

The Sub-Committee believes, based partly on the New Zealand experience (see Appendix A), that a "catch-up" program is necessary to protect this group of children. We feel that, concurrent with a universal program to immunize neonates, a catch-up program should be adopted to immunize 10-year olds. The program could run for ten years, at the end of which period the neonate program will have reached that age group. Funding for this immunization program should be the same as that described above for the neonate program.

RECOMMENDATION NO. 2

The Committee recommends that the Federal Government, in cooperation with the provinces and territories, develop a "catch-up" program to immunize children at 10 years of age, the purpose being to effect immunization prior to the children's reaching high school age. The Sub-Committee further recommends that the Federal Government fund at least 50% of the costs of this catch-up immunization program and that appropriate cost-sharing agreements be made with the provinces and territories.

In cases where a child is born to an infected mother, it is necessary to immunize the child immediately and also administer hepatitis B immune globulin which contains a high antibody titer against HBV. The Sub-Committee received testimony that some jurisdictions in Canada routinely test pregnant women for hepatitis B in order that their babies can be vaccinated at birth.

Murray Krahn and Allan S. Detsky, in a study of the cost-effectiveness of hepatitis B vaccination, state that an estimated 70% of Canadian women are screened at present (1989) and that Alberta screens all prenatal patients through the blood-banking system.¹⁰ Elsewhere in Canada, the screening is dependent upon the initiative of the individual physician. Dr. Noni MacDonald, subsequent to her appearance before the Sub-Committee on behalf of the Canadian Paediatric Society, suggested that the 70% estimate is much too high.

The Sub-Committee believes that screening of pregnant women for hepatitis B should be a standard procedure across Canada. The basis of our concern is that if a child is infected at birth, he/she has about a 90% chance of becoming a chronic carrier. The problem here is twofold: the chronic carrier may pass the virus on to other people, and will be at increased risk of liver damage in later life, including an increased risk of liver cancer.

¹⁰ Murray Krahn and Allan S. Detsky, *Universal Vaccination Against Hepatitis B in Canada: A Cost-Effectiveness Analysis*, (Unpublished), 3 October 1990, p. 15.

The Canadian Immunization Guide, Third Edition (1989) recommends that a baby born to an infected mother should immediately receive an injection of hepatitis B immune globulin, and a course of three infant doses of hepatitis B vaccine, the initial dose being given within seven days of birth, and the other two doses at one month and six months after the first.¹¹

RECOMMENDATION NO. 3

The Sub-Committee recommends that the Federal Government develop a program, in cooperation with the provinces and the territories, to routinely test pregnant women for hepatitis B infection. Where the test is positive, the baby should receive hepatitis B immune globulin and hepatitis B vaccine in accordance with the recommendations of the Canadian Immunization Guide.

COST OF HEPATITIS B VACCINE

The cost of hepatitis B vaccine is an important issue in the consideration of any immunization program that might be adopted in Canada. At present, only certain high-risk groups are targeted for immunization but, even in that relatively restricted use, vaccine cost is an issue and may, indeed, be a deterrent to immunization in some cases. There are a number of aspects to the vaccine-cost issue and these are discussed below.

Mr. Frank Evans, a consultant to several pharmaceutical companies, testified that effective vaccines against HBV first came on the market in 1982.¹² The vaccine originally introduced was derived from human blood plasma containing viral surface antigen (HbsAg) collected from persons who were carriers of the virus. Although those vaccines proved to be entirely safe in practice, when the AIDS virus was identified in 1985 there was some public concern because the same populations with hepatitis B infections, and from whom the plasma was collected, also had a relatively high incidence of infection by human immunodeficiency virus (HIV), the virus believed to cause AIDS.

In 1987, commercial supplies of a new hepatitis B vaccine became available, and these were produced using recombinant DNA technology. Genetically modified strains of yeast were used to produce the HBV surface antigen (HbsAg) which was then highly purified and incorporated into a vaccine. With this methodology, there is no possibility of any viral contamination. These vaccines have proven to be completely safe and highly effective against the hepatitis B virus. The plasma-derived vaccines are no longer available in Canada.

According to the testimony of Mr. Evans, the price of the vaccine was \$155 per dose in 1987 and this dropped to \$90 when the new recombinant vaccine was introduced.¹³ The lowest current price in Canada for the vaccine is about \$23.89 per dose. An immunization course typically consists of three doses of vaccine, given at intervals. Thus, hepatitis B immunization currently costs about \$72, in situations where the vaccine is purchased in bulk and the lowest current price applies.

¹¹ Health and Welfare Canada, *Canadian Immunization Guide*, Third Edition — 1989, Minister of Supply and Services Canada, Cat. No. H49-8/1989E, p. 54.

¹² *Proceedings*, Issue 3, p. 7.

¹³ *Proceedings*, Issue 3, p. 11.

For some high-risk groups, depending on relevant provincial programs, immunization can be obtained at a public health clinic at no charge. However, for many, perhaps most, Canadians the price will be substantially higher than the lowest current price of bulk-purchased vaccine. For example, in British Columbia, an individual can purchase the vaccine through a pharmacy and have the inoculations done by his/her family physician without charge under the provincial health-care plan. An informal survey of prices at Vancouver pharmacies indicated a price range for three doses of vaccine between \$102.49 and \$132.

The Sub-Committee has evidence indicating that the cost of hepatitis B vaccine is significantly lower in some other countries than it is in Canada. In New Zealand, for example, which has a universal immunization program against hepatitis B, information from the Department of Health in Wellington states that cost per course of three doses of recombinant vaccine purchased in bulk by the department is less than \$10 NZ. (At current exchange rates this would be less than \$7 Canadian.) This 10-fold price differential is very difficult to understand. Testimony from Mr. Evans states that the price of the vaccine is "volume-sensitive"; that is, the larger the volume purchased, the lower the price per unit.¹⁴

An important factor in the price of the vaccine is the fact that the patent for the viral genetic sequence used to produce the vaccine in yeast is held by a single company, Biogen Inc. of Cambridge, Massachusetts.¹⁵ There is no "generic" brand of hepatitis B vaccine and, given the fact that the production technology is extremely advanced, there may never be. Also, vaccine quality control apparently is a high-cost component of the production process, and this will probably not decrease significantly in the future.

There are two multinational pharmaceutical companies that have received a notice of compliance (that is, government approval) for the hepatitis B vaccine in Canada; SmithKline Beecham Biologicals and Merck, Sharp and Dohme. Neither company produces the vaccine in Canada. Dr. A.J. Liston, Assistant Deputy Minister of Health and Welfare Canada's Health Protection Branch, stated that the two companies market their vaccine on a world-wide basis.¹⁶ This fact makes the large price differential between Canada and New Zealand very difficult to comprehend.

Mr. Evans, and several other witnesses, testified that the price of vaccine is a function both of the volume purchased and of negotiations between the manufacturer and the purchaser.¹⁷ In Canada, the provincial governments must make the decision about specific immunization programs within their jurisdictions although the federal government may offer advice as well as data on which to base decisions.

In their study of hepatitis B immunization programs, Krahn and Detsky also state that vaccine price is a function of volume purchased:

The prospects of progressive reduction of price .. are good. As with many pharmaceutical products, the ratio of development costs to marginal production costs of Hepatitis B vaccine is high. Pricing policies, therefore, are at least partially determined by volume of usage. Negotiations between policymakers in Canada and pharmaceutical manufacturers have revolved around this issue:

¹⁴ *Proceedings*, Issue 3, p. 12.

¹⁵ *Proceedings*, Issue 3, p. 10.

¹⁶ *Proceedings*, Issue 1, p. 29.

¹⁷ *Proceedings*, Issue 3, p. 17.

policymakers have asked for reduced vaccine prices without assurances of policies ensuring wide usage. Manufacturers have continued to insist that lower prices are contingent on increased volume of sales.¹⁸

The federal government can, and does, become involved in bulk purchasing of vaccines in order to obtain the lowest possible price for the participating provinces. Dr. Losos commented on this point, with specific reference to the hepatitis B vaccine:

The department (of Health and Welfare) does assist the provinces in bringing together the purchasing agents for the provinces, and under the quarterbacking of the Department of Supply and Services they negotiate with the companies the best deal possible, as far as cost of vaccines is concerned.

The cost of these vaccines, the hepatitis B vaccines, has been very high right from the beginning and it is part of the complicating factor in their wide-scale application. But the department does, in fact, negotiate bulk-purchasing agreements with companies. The provinces then buy however much they feel they need and want and which vaccine they need.¹⁹

The Sub-Committee's concern in this area is two-fold. First, for a universal immunization program against hepatitis B to be effective, it is necessary for all provinces and the two territories to participate. For this to happen, the vaccine must be available at an acceptable price. Second, we are concerned that the negotiations over vaccine price should be carried out with clear reference to the prices being paid for vaccines of acceptable quality and purity in countries such as New Zealand.

While we accept that companies should receive a fair return for a high-quality product, we want to ensure that Canadians do not have to pay an excessive price for this vaccine because of deficiencies in the price-negotiating process. The experience of the New Zealand authorities in negotiating a low price for the vaccine is very encouraging for the development and implementation of a universal immunization program in Canada.

RECOMMENDATION NO. 4

The Committee recommends that the Federal Government, through the Departments of Health and Welfare and Supply and Services, conduct a study on the pricing of hepatitis B vaccine: first, to determine why the prices of identical vaccines vary significantly between different countries; second, to ensure that the negotiations on price with vaccine manufacturer(s) are conducted with full knowledge of prices paid in other jurisdictions; and, third, to ensure that those vaccines of acceptable quality that are supplied to Canada will be available at the lowest possible price on the world market.

INFORMATION AND EDUCATION

Effective information and education programs are essential in the fight against any disease. The hepatitis B virus is a robust and highly infectious pathogen but it is essentially confined to bodily fluids and it is not spread through the air in the manner of colds and influenza. With adequate

¹⁸ Krahn and Detsky (1990), p. 7.

¹⁹ *Proceedings*, Issue 1, p. 29.

information, therefore, the spread of hepatitis B can be reduced by the adoption of sensible precautions. The various high-risk groups and activities were noted above. If precautions are taken in high-risk occupations, in sexual activities, and even in drug use (e.g., not sharing needles and syringes), the transmission of HBV can be mitigated and even eliminated.

A universal neonatal and "catch-up" immunization program will effectively break the chain of disease transmission, but those individuals and groups not included in this program still will need to exercise appropriate caution in their activities, whether occupational or social. The wide availability of information on hepatitis B and its modes of transmission will assist in reducing its spread in Canada.

RECOMMENDATION NO. 5

The Sub-Committee recommends that Health and Welfare Canada, in cooperation with provincial and territorial health departments, develop and implement information and education programs to combat hepatitis B, to prevent the spread of this disease in Canada. Such programs should be directed to the Canadian public generally, and to identified high-risk groups and communities.

IMMIGRATION AND HEPATITIS B

The fact that hepatitis B is much more prevalent in other regions of the world than it is in Canada is an issue that must concern health policy makers in this country. Canada is a country-of-choice for many persons, particularly from developing countries, who are seeking opportunities for a better life for themselves and their families.

Dr. Laurence Blendis, in his testimony, identified immigration from regions of high endemicity of HBV as an important means by which hepatitis B could be spread in Canada:

We are looking at a tremendous increase in the incidence (of hepatitis B in Canada) The question is, why is this happening? ... the world is becoming a village and we (in Canada) are not in an isolated setting. We are getting new citizens from all over the world all the time, and those citizens are coming from the areas of high prevalence of hepatitis B ... One reason I predict our numbers (of hepatitis B cases) will continue to rise sharply is because of our immigration pattern.²⁰

In 1989, Canada received 190,342 immigrants. Of this total, the breakdown by continent of Last Permanent Residence is as follows: Asia, 48.3%; Europe 27.2%; North and Central America, 6.7%; Africa, 6.4%; Caribbean, 5.7%; and South America, 4.6%. Of the almost 92,000 immigrants from Asia, some 45.5% came from Hong Kong, the Philippines, Vietnam and Kampuchea, all areas of high endemicity of hepatitis B. Sub-Saharan Africa is rated as a region of high endemicity and North Africa as intermediate endemicity. Guyana, the principal country of origin of immigrants from South America in 1989, also has a high endemicity of hepatitis B.²¹

The federal government has the sole jurisdiction for the processing and approval of visitors and immigrants to this country. There are two federal acts which deal with immigration and disease: the Quarantine Act and the Immigration Act. The Quarantine Act was created to address diseases that could be dealt with by the quarantine of an individual until he was free of the disease. This is not

²⁰ *Proceedings*, Issue 2, p. 9.

²¹ Employment and Immigration Canada, *Annual Report 1989-1990*, p. 45-47.

really applicable to hepatitis B because of the significant percentage of persons, particularly children, who go on to become chronic carriers of the virus. The act itself is regarded as rather obsolete in the modern era of transcontinental air travel.

The Immigration Act gives the federal government the power to govern the entry into Canada of both immigrants and visitors. There is authority in the act, under Section 19(1)(a) to refuse admission to a person who is suffering from a disease (or other form of health impairment) if that person is "likely to be a danger to public health or public safety" or who might reasonably "cause excessive demands on health or social services".

While the existence of a disease is relatively easy to prove or disprove, questions of public health and safety, and the assessment of demands on health or social services, are matters of informed opinion required to be rendered by at least two medical officers. Thus, there is a judgement component.

Section 11 of the act requires that every would-be immigrant (and visitors of a prescribed class) shall undergo a medical examination. These examinations, for practical reasons, are almost always conducted in the country of origin of the immigrant. In theory, at least, persons with contagious diseases are denied admission to Canada. Such diseases include active tuberculosis, syphilis, some cases of active leprosy, and active typhoid carriers. However, for disease conditions that are treatable, exclusion need not be permanent: once the disease has been successfully treated the individual could be reconsidered for admission into Canada.

For hepatitis B, persons who do not display symptoms of acute hepatitis B are not generally screened out for immigration because routine testing for the disease, or the presence of the virus, is not carried out. If the person were from a country of high endemicity of HBV, liver function tests might be required, and a person with a damaged liver might be screened out on the basis of concern about possible costs of future medical care.

There is apparently much less concern about the HBV carrier status of a prospective immigrant. HBV carriers who do not have demonstrable liver damage or other symptoms of the disease are not considered to be a problem in terms of the probable future cost to Canadian health services. There appears not to be significant concern, on the part of immigration authorities, that an HBV carrier could spread the disease after arrival in Canada.

There is also no requirement that immigrants to Canada be immunized against any infectious disease. Once in Canada, however, provincial authorities may advise that children who attend school should be vaccinated against certain diseases. However, vaccination is not mandatory.

The Sub-Committee has concerns about these aspects of immigration, specifically as they relate to hepatitis B. While we do not wish to see prospective immigrants refused entry to Canada on the basis of their having hepatitis B, or because they have had the disease, we believe that positive actions should be taken by the federal government to minimize the health risks to the families of such persons and to the Canadian community at large.

RECOMMENDATION NO. 6

The Sub-Committee recommends that the Federal Government develop a program to deal with the possibility that hepatitis B might be spread within Canada by immigrants from regions of the world where the disease is endemic and occurs at intermediate or high incidence among the population. Such a program could

include universal immunization of all immigrants to Canada, prior to their entry into this country, or a selective immunization program to apply only to immigrants from regions of intermediate and high endemicity.

RECOMMENDATION NO. 7

As an alternative to Recommendation No. 6, the Sub-Committee recommends that the Federal Government study and evaluate the need for, and potential effectiveness of, a program for the screening of immigrants to Canada for hepatitis B infection. The Sub-Committee further recommends that, where an immigrant to Canada tests positive for hepatitis B infection, immunization of all uninfected and susceptible family members against hepatitis B shall be mandatory, prior to their entry into this country.

INCIDENCE AND REPORTING OF HEPATITIS B IN CANADA

We have noted above that there is concern about the effectiveness and the completeness of the reporting of hepatitis B in Canada, and also about the actual incidence of hepatitis B in Canada. The testimony and evidence we have seen suggests that the reporting of the disease is not complete although hepatitis B has been a notifiable disease in Canada since 1969.

The evidence also strongly suggests that the incidence of hepatitis B in this country may be at least an order of magnitude greater than the published statistics indicate. While we accept the testimony of Dr. Losos that all diseases are commonly underreported, we believe that more accurate reporting is desirable and better knowledge about disease incidence would be useful.

RECOMMENDATION NO. 8

The Sub-Committee recommends that Health and Welfare Canada review the effectiveness of the program requiring that all cases of hepatitis B diagnosed in Canada be reported to the Laboratory Centre for Disease Control, to ensure that reporting of this disease will be as complete as possible.

RECOMMENDATION NO. 9

The Sub-Committee recommends that Health and Welfare Canada review the need for a comprehensive epidemiological study of hepatitis B in Canada and, if appropriate, design and implement, in cooperation with the provinces and territories, an epidemiological study to determine the incidence of hepatitis B in this country.

HEPATITIS B AND HEALTH-CARE WORKERS

The question of hepatitis B and health-care workers has been brought into sharp focus in recent months because of the situation at the Halifax Victoria General Hospital involving Dr. Reginald Yabsley, the hospital's head of orthopaedic surgery. Dr. Yabsley learned in the fall of 1986 that he had been infected with the hepatitis B virus, probably by a patient. The infection was detected as a result of blood-screening by the Canadian Red Cross after Dr. Yabsley made a blood donation.

In addition to contracting hepatitis B, Dr. Yabsley became a carrier of the virus, meaning that he would be continually infective, probably for his lifetime. He continued to perform operations while taking precautions to prevent transmission of the virus to his patients. Nonetheless, two patients did contract hepatitis B, possibly from Dr. Yabsley. The doctor performed his last surgery on July 31, 1991, and then voluntarily gave up his surgical privileges at the hospital.²²

The Yabsley case raises important questions for Canada's health-care system. The health status of health-care professionals is an important issue, particularly where an infectious disease is involved. The Sub-Committee recognizes two important questions in this context. Both questions relate to the issue of hepatitis B which is the subject of this report, but they clearly apply to other serious infectious diseases.

First, should health-care professionals, particularly surgeons, dentists and dental surgeons, be required to undergo mandatory testing for serious infectious diseases, including hepatitis B, other forms of infectious hepatitis, and the human immunodeficiency virus (HIV)?

The second question is: where an effective vaccine is available, as is the case with hepatitis B, should all health-care professionals be required, by law, to be vaccinated?

Each of these matters falls under provincial jurisdiction, as does the delivery of health services generally. The Sub-Committee believes that the federal government can play a role in both issues, however. Although health matters fall under provincial authority, we believe that exacting national standards for health care comprise a worthy concept, and should be an achievable goal in Canada. The federal government could provide leadership in this area, and assist the provinces to develop and implement common policies on both issues.

In the matter of mandatory testing of health-care workers for certain infectious diseases, such as hepatitis B, the Sub-Committee believes that such testing should be carried out whenever there is a demonstrable threat to patient well-being. We recognize that, in cases such as Dr. Yabsley's, a positive test can result in career termination. Where this happens, the matter of compensation for the affected person may legitimately be raised, and should be fairly dealt with. Our overriding concern, however, is for the well-being of the patient.

In the matter of mandatory immunization of health-care workers against hepatitis B, the Sub-Committee believes that this should be implemented for the general public good. When the first vaccines for hepatitis B became available, health-care workers were identified as a target group because of the obvious health risks that they encounter in their work. To date, immunization has been offered to health-care professionals on a voluntary basis. This program has not been successful in stemming the spread of hepatitis B in Canada, nor have health-care workers universally accepted immunization.

In Dr. Yabsley's case, failure to immunize against the virus has resulted in the premature termination of his career, and the loss of a highly skilled surgeon to Canada's health-care system. The Sub-Committee believes that immunization against hepatitis B should be considered a requirement for employment in the health-care field in much the same way that prescribed educational and training credits also are requirements. Adoption of this policy will protect patients and the health-care workers themselves.

²² Deborah Jones (1991), p. 1346.

RECOMMENDATION NO. 10

The Sub-Committee recommends that the Federal Government, through Health and Welfare Canada, take the lead in initiating discussions with provincial and territorial governments, and with associations of health-care professionals, toward the development and implementation of a national policy on the mandatory testing and immunization of health-care professionals for hepatitis B.

HEPATITIS B AND ABORIGINAL POPULATIONS

Several witnesses referred to the fact that some aboriginal populations in Northern Canada have a much higher level of endemicity of hepatitis B than the Canadian average. Evidence was provided by Health and Welfare Canada, principally from studies of population groups in the Northwest Territories and in Northern Labrador. The studies involved the prevalence of HBV serologic markers within the populations, that is, the presence in blood samples of hepatitis B surface antigen (HbsAg) or the antibody to the surface antigen (anti-HBs). A positive test for the surface antigen indicates that the person is infected with the virus and is a carrier; the presence of the antibody (anti-HBs) indicates that the person has had hepatitis B but is no longer infected.

The Inuit and Dene populations tested had significantly higher prevalence of both serologic markers than did non-natives (predominantly Caucasians). In the Northwest Territories study, the Caucasian population had a seroprevalence rate of 0.3% for HbsAg and 8.5% for anti-HBs. For the Inuit population studied, the rate for HbsAg was 3.9% and for anti-HBs, 24.5%. Comparable, but not identical, results were obtained in the study in Northern Labrador.

These seroprevalence rates among the aboriginal populations in the study indicate that hepatitis B virus is probably endemic in these groups. The Sub-Committee did not receive evidence on the epidemiology of hepatitis B in such populations. However, the seroprevalence rates are somewhat similar to those observed in some regions of Asia which have an intermediate or high endemicity of HBV. A suggestion was made to the Sub-Committee by Dr. Laurence Blendis, representing the Canadian Liver Foundation, that the hepatitis B virus became established among aboriginal groups in these communities "thousands of years ago with the immigration (over the North Polar regions) of peoples from Southeast Asia".²³

Whatever the source of the high incidence of serological markers among these specific groups, or other groups of aboriginal peoples, it is clear that this is an area of significant concern. The Sub-Committee does not make any recommendations specific to aboriginal communities. All of the recommendations in this report, including those for a universal neonate and "catch-up" immunization program, the screening of pregnant women for hepatitis B, and information and education programs, are meant to apply equally to all Canadians, wherever they live and whatever their racial or ethnic origins.

CHRONIC FATIGUE SYNDROME

The question of the possible relationship between Chronic Fatigue Syndrome (CFS) and hepatitis B vaccine was raised during the Sub-Committee's hearings because of the publication of a number of newspaper stories suggesting that immunization of individuals with hepatitis B vaccine

²³ *Proceedings*, Issue 2, p. 14.

had led, in a number of cases, to development of CFS. The source of these claims is the Nightingale Research Foundation of Ottawa, a registered charitable organization that concerns itself with this disease.

Chronic Fatigue Syndrome, or CFS, is a complicated and serious disease, the causes of which are not known with precision. Although the disease has been dubbed the "malaise of the 1980s", and is also, rather derisively, known as "Yuppie flu", the condition has been recognized for a very long time under a variety of names. Some of these names are: postviral fatigue syndrome, postinfectious neurasthenia, myalgic encephalomyelitis, Icelandic Disease, and Royal Free Disease.

Testimony on CFS was received from Dr. Irving Salit of the University of Toronto and the Toronto Hospital, and from a number of other medical witnesses. (Although invited by the Sub-Committee, the Chairman of the Nightingale Research Foundation, Dr. Byron Hyde, was unable to appear as a witness.) Dr. Salit's clinical research is based on experience with more than 600 patients.²⁴

Chronic Fatigue Syndrome often starts as an influenza-like illness, with typical symptoms of sore throat, fatigue, and swollen lymph glands. Where CFS differs from influenza is that the symptoms do not go away. The principal symptom is an incapacitating fatigue that renders many patients unable to work and, in very serious cases, unable even to get out of bed to perform the basic routines of life.

In general, CFS is a disease of adults, most commonly occurring between the ages of 20 and 40 years, with an average age in the early 30s. Dr. Salit has found that two-thirds of his patients are single, two-thirds are female, many are of higher socio-economic status, and about 20% are in the health profession.

Patients afflicted by CFS have many symptoms in addition to debilitating fatigue, including mild fever, swollen lymph glands, muscle weakness, muscle aching (myalgia), headaches, pains in the joints (arthralgia), sleep disturbance, and neuropsychologic complaints. Depression is also a common symptom associated with CFS.

The causes of CFS are, as suggested above, speculative. The etiology appears to include a "triggering event", some precursor factor that initiates the development of CFS. Infection by the Epstein-Barr Virus (EBV) occurs in about half the cases. Many other viral infections are also associated with the disease, as are a number of bacterial infections. Some patients who have had allergic reactions to various agents, motor vehicle accidents, or other stressful events, have gone on to develop CFS.

The disease can typically continue for a period of about two years. During this time, the patient usually improves slowly and, although recovery may not be complete after two years, the patient is generally very much better. The illness does not appear to shorten a person's lifespan, and does not appear to damage any major organs. There is some suggestion that the condition may recur in some patients.

Several important points were made in connection with this issue during our hearings. The first is that the hepatitis B vaccine currently in use is a highly purified protein produced through recombinant DNA technology. The vaccine is regarded as completely safe by officials at Health and Welfare Canada, and by all of the medical witnesses who appeared before the Sub-Committee.

²⁴ *Proceedings*, Issue 4, p. 12.

A second point is that currently available information suggests that CFS may be associated with an immune system that is somewhat abnormal, in Dr. Salit's words an immune system that is "sort of turned on a little bit".²⁵ The suggestion was made that this could happen when the immune system was challenged by one of a number of infectious agents, or agents with antigenic properties. It might also happen in a major stress situation, as in a motor vehicle accident or a marriage breakup.

The Sub-Committee has not received, or been referred to, any evidence showing a cause-effect relationship between CFS and hepatitis B immunization. The observation that some 20% of CFS patients may work in the health-care field, together with the fact that about 50% of such persons may have been immunized against hepatitis B, suggests an association between the disease and the vaccine that, on the available evidence, is entirely circumstantial.

No cause-effect relationship having been demonstrated between the hepatitis B vaccine and CFS, the Sub-Committee believes that suggestions of such a relationship are irresponsible and potentially very damaging to medical efforts to control the spread of hepatitis B in this country through immunization programs.

Dr. J.Z. Losos, Director General of Health and Welfare Canada's Laboratory Centre for Disease Control (LCDC) informed the Sub-Committee that studies and surveillance programs have been set up between the LCDC and its collaborators to determine if there is any association between the hepatitis B vaccine and CFS.²⁶ The Sub-Committee agrees with, and commends, this initiative. Because the question has been raised and has received enough publicity to raise public concern, this matter must be dealt with on the basis of evidence rather than speculation.

²⁵ *Proceedings*, Issue 4, p. 9.

²⁶ *Proceedings*, Issue 1, p. 28.

APPENDIX A

THE NEW ZEALAND PROGRAM

Several witnesses cited the hepatitis B vaccination program in New Zealand as an example that Canada might emulate to combat the threatened spread of hepatitis B infection in this country.

The principal focus of the immunization program in New Zealand has been the protection of children against infection because of their relatively high risk of becoming lifetime carriers of the hepatitis B virus. Such carriers are the major source of infection for others and they are also at some risk of developing chronic liver disease later in life.

Epidemiological studies of hepatitis B in New Zealand were carried out in the 1980s. Among the findings were the following: carrier rates amongst New Zealanders of European origin were less than 1% and the lifetime risk of infection in this group was less than 10%. Among Pacific Islanders and Maoris, however, the carrier rates were between 5% and 10% and the lifetime risk of infection could exceed 50%. New Zealand falls into the category of "intermediate endemicity" according to the World Health Organization (WHO) classification.

Canada somewhat resembles New Zealand in having a general population of largely European extraction with low endemicity of hepatitis B, and certain communities – e.g., aboriginal peoples and immigrants from Asia and Equatorial Africa – with high endemicity. Australia and the United States display comparable endemicity patterns in their populations.

In New Zealand, the transmission of virus from mother to child during birth is thought to contribute about 20-30% of the carrier pool (vertical transmission) for hepatitis B virus. The remainder results predominantly from the spread of virus between young children in the school environment (horizontal transmission). This latter mode of transmission is common in the North Island of New Zealand. There, the climate is warmer than the South Island, and the children wear lighter clothing. They are thus more subject to cuts and scrapes during play, and the possibility of transmission through blood is increased.

New Zealand's immunization program for hepatitis B was based on recommendations made by the Communicable Disease Control Advisory Committee, a body roughly equivalent to Canada's National Advisory Committee on Immunization (NACI). In 1985, the New Zealand Department of Health set as its initial target the highest risk group, namely the infants of highly infectious carrier mothers, a group of about 300 infants per year.

In 1986, additional funding was allocated to extend the program to include neonates of all carrier mothers, about 1500 infants per year. In 1987, the program was further extended to include all neonates in seven out of 18 health districts in the country. These seven districts were rated as "high risk" for early-childhood infection. This phase of the program marked the first time that an attempt was made to bring horizontal, as well as vertical, transmission of the virus under control.

In February of 1988, the New Zealand Cabinet, acting on recommendations from the Department of Health, approved extension of the immunization program to all neonates. Free immunization was also made available to close contacts of women identified as carriers from tests

carried out during pregnancy. A pre-school "catch-up" program for all children under five years of age on 29 February 1988 was instituted at the same time. This age group was chosen because of the higher risk of infection resulting in chronic carriage of the virus. The extension of the program to all neonates and infants followed the availability of data showing that the vaccine was effective at a low dose, thus reducing vaccine costs.

In December 1989, the original plasma-derived vaccine had been replaced by the new yeast-derived vaccine, produced through recombinant DNA technology, and the cost of vaccine had decreased considerably. The government was able to consider a further extension of the program, including, for the first time, school-aged children.

The New Zealand immunization program was reviewed in February 1990. The current program now consists of the following elements. Free immunization against hepatitis B is available to all children under the age of 16 years, from general practitioners. Free immunization is available to all susceptible household/family contacts and sexual partners of persons identified as carrying the virus. There is also a prenatal screening program, and immunoglobulin plus vaccine is available to infants of carrier mothers.

The New Zealand Department of Health's approach to occupational groups is that the responsibility for safety and protection of employees in the workplace rests with employers. Other groups at risk from hepatitis B, including intellectually handicapped children, intravenous drug users, homosexually active men, hemophiliacs and prisoners, have been the responsibility of medical practitioners. In some cases, programs have been developed for them, usually by the organization that is responsible for their care. The Department acknowledges that it is likely that most of these groups will be underserved, for a variety of reasons.

The Government of New Zealand has had to address a number of sensitive issues associated with hepatitis B. These included specific targeting of Maori and Pacific Island groups who had a high endemicity of the virus, and debating the need for pre-vaccination testing of groups and individuals. Canada may have to face similar sensitive issues given the high endemicity in certain aboriginal populations and the fact that many immigrants to Canada come from regions of high disease incidence.

List of Witnesses

Your Committee requests that the Government table a comprehensive response to this report.

A copy of the relevant Minutes of Proceedings and Evidence No. 6 will be made available upon request.

	ISSUE No.	DATE
Bower, Bobbi	1	October 3, 1991
Canadian Liver Foundation: Ralph Davis, President	1	October 3, 1991
Canadian Liver Foundation: Dr. Laurence Blendis, Member	2	October 10, 1991
Health Protection Branch: Dr. A. J. Liston, Assistant Deputy Minister, Health Protection Branch; Dr. J.Z. Losos, Director General, Laboratory Centre for Disease Control.	1	October 3, 1991
Pediatric Society of Canada: Dr. Noni MacDonald; Dr. Victor Marchessault.	2	October 10, 1991
Pharmaceutical Industry Mr. Frank E. Evans, Consultant	3	October 24, 1991
The Toronto Hospital: Dr. Irving Salit, Head, Division of Infectious Diseases; Director HIV Clinic	4	November 7, 1991
University of Manitoba Mr. Allen Ronald, Professor of Internal Medicine and Microbiology.	3	October 24, 1991

Microbiology

of Internal Medicine and

Mr. Allen Hornell, Professor

University of Manitoba

October 24, 1961

The Clinic

of Infectious Diseases, Director

Dr. David Staff, Head, Division

The Toronto Hospital

November 7, 1961

Mr. Frank E. Evans, Consultant
Pharmaceutical Industry

October 24, 1961

When I received your letter regarding the proposed meeting of the Canadian Society for the Study of Infectious Diseases, I was pleased to hear that you had organized such a meeting. I am sure that the meeting will be a most successful one and that it will be a most valuable contribution to the study of infectious diseases in Canada. I am sure that the meeting will be a most valuable contribution to the study of infectious diseases in Canada. I am sure that the meeting will be a most valuable contribution to the study of infectious diseases in Canada.

The Government of Canada has been most helpful in providing the necessary facilities for the meeting. I am sure that the meeting will be a most successful one and that it will be a most valuable contribution to the study of infectious diseases in Canada. I am sure that the meeting will be a most valuable contribution to the study of infectious diseases in Canada. I am sure that the meeting will be a most valuable contribution to the study of infectious diseases in Canada.

Dr. Lawrence Blumberg, Member
Canadian Liver Foundation
1000 University Avenue, Toronto, Ontario M5G 1S5
October 9, 1961

Dear Dr. Blumberg,
I am pleased to hear that you are interested in the Canadian Liver Foundation. I am sure that the meeting will be a most successful one and that it will be a most valuable contribution to the study of infectious diseases in Canada. I am sure that the meeting will be a most valuable contribution to the study of infectious diseases in Canada. I am sure that the meeting will be a most valuable contribution to the study of infectious diseases in Canada.

List of Witnesses

The following witnesses were called to give evidence at the trial of the accused on the charges of conspiracy to defraud. The witnesses were called to give evidence at the trial of the accused on the charges of conspiracy to defraud. The witnesses were called to give evidence at the trial of the accused on the charges of conspiracy to defraud.

REQUEST FOR GOVERNMENT RESPONSE

WEDNESDAY, FEBRUARY 12, 1992

(9)

Your Committee requests that the Government table a comprehensive response to this report.

A copy of the relevant Minutes of Proceedings and Evidence (*Issue No. 6 which includes this report*) is tabled.

Respectfully submitted,

BARBARA GREENE,
Chair

REQUEST FOR GOVERNMENT RESPONSE

Your Committee requests that the Government table a comprehensive response to this report. A copy of the relevant Minutes of Proceedings and Evidence (Issue No. B which includes this report) is tabled.

Respectfully submitted,

BARBARA GREENE,
Chair

MINUTES OF PROCEEDINGS

WEDNESDAY, FEBRUARY 12, 1992

(9)

[Text]

The Standing Committee on Health and Welfare, Social Affairs, Seniors and the Status of Women met **IN CAMERA** at 3:42 o'clock p.m. this day, in Room 306, West Block, the Chair, Barbara Greene, presiding.

Members of the Committee present: Edna Anderson, Barbara Greene, Jean-Luc Joncas, Jim Karpoff, Rey Pagtakhan, Barbara Sparrow, Stan Wilbee.

In attendance: From the Research Branch of the Library of Parliament: Tom Curren and Odette Madore, Research Officers.

The Committee proceeded to the consideration of future business.

It was moved, —That the Standing Committee on Health and Welfare, Social Affairs, Seniors and Status of Women authorize the transfer of \$10,059.90 from within its approved budget for travel to Washington, D.C. of its Sub-Committee on the Status of Women, from March 9 to March 11, 1992, and that the Member for Saint-Hubert and the necessary staff accompany the Sub-Committee.

After debate, it was moved, —That the motion be amended by changing the total amount from 10,059.90 to \$11,859.90 and by adding immediately after "Saint-Hubert" the following: "the Member for Calgary-South-West, a Committee Member from the Official Opposition".

After debate, the amendment was agreed to.

And the question being put on the main motion, as amended, it was agreed to.

The Chair presented the First Report of the Sub-Committee on Health Issues.

It was agreed, —That the Committee ask the Chair to present the First Report of the Sub-Committee on Health Issues as the Third Report of the Standing Committee to the House of Commons.

It was agreed, —That, pursuant to Standing Order 109, the Committee request that the Government table a comprehensive response to this Report.

It was agreed, —That, the Committee print 3,000 copies of this Report, in tumble bilingual format, with a distinctive cover page.

It was moved, —That the Committee invite the Minister to appear immediately.

After debate, it was moved, —That the motion be amended by adding the words "after the tabling of the Budget".

After debate, the question being put on the amendment, it was agreed to by a show of hands:
Y:3 — N:2.

After debate, the question being put on the main motion, as amended, it was agreed to by a show of hands: Y:4—N:0.

It was agreed, —That the Committee decide to hear further testimony on the Poverty Report once the Minister has tabled his response to the Report.

It was moved, —That the Committee commence a study of reproductive technology.

After debate, the question being put on the motion, the result of the show of hands was announced: Y:3—N:3.

Whereupon the Chair voted in the affirmative.

It was moved, —That the Committee endorse the funding by the Federal Government for the Planned Parenthood Federation of Canada.

After debate, the question being put on the motion, it was defeated on a show of hands: Y:2—N:4.

It was agreed, —That the Planned Parenthood Federation of Canada be invited to appear before the Committee.

It was moved, —That the Committee hold emergency hearings into all aspects of licensing and approval of implant techniques.

After debate it was moved, —That the motion be tabled until a later date.

After debate, the amendment was negated.

And the question being put on the main motion, it was negated.

It was agreed, —That all further meetings of the Committee shall be public unless the Clerk is otherwise authorized by the Committee.

At 4:58 o'clock p.m., the Committee adjourned to the call of the Chair.

Eugene Morawski
Clerk of the Committee

