CARTWRIGHT ANNIVERSARY SEMINAR

5th August 2008

Presented by Lynda Williams

"GARDASIL – CARTWRIGHT'S DAUGHTER?"

My involvement in the issue of HPV vaccines formally began on 20 February 2006 when a representative from CSL, the manufacturer of Gardasil, came to meet with members of the Auckland Women's Health Council and Women's Health Action. Her visit rang alarm bells.

When drug company reps want to come and visit with women's health groups my alarm bells always start ringing, but this visit was particularly worrying. For a start the young woman couldn't answer many of the questions we had about the research results. She also made claims about there being a reduction in the timeframe between infection with the human papilloma virus (HPV) and the development of cervical cell abnormalities which she said would be substantiated when new research results were published in 2 – 3 months time – this didn't happen. And she was obviously hoping that we would support CSL's endeavours to get the vaccine introduced into the school-based vaccination programme. We made it quite clear that we wouldn't.

We also had major issues around how long the vaccine would last and the need to include males in any anti-HPV vaccination programme. We had other concerns as well and I will come to these later.

But before I say any more about Gardasil, we need to go back and set the scene for why this particular issue is the topic of today's Cartwright lunch time seminar and is one that women's groups are examining through what we refer to as a "Cartwright lens."

Cervical Cancer Inquiry

It is exactly 20 years today since the report of Judge Silvia Cartwright's Inquiry into the treatment of cervical cancer at National Women's Hospital was released. The report marked a watershed in medical history in this country and women's groups have continued to commemorate this special day in various ways every year since 1988. This annual luncheon is one of them.

Judge Cartwright's report recommended sweeping changes in both the practice of medicine and research, as well as various measures for protecting patient rights. The report also recommended the establishment of a national cervical screening programme.

When releasing the report the government of the day promptly made a very public commitment to implementing all of the recommendations in the Cartwright Report. However some of the changes took a lot longer to get off the ground than others. It took six years before the Office of the Health & Disability Commissioner was established with Robyn Stent appointed as the first Commissioner, and two more years before the Code of Consumers' Rights came into effect on 1 July 1996.

The Auckland Women's Health Council and Women's Health Action took a very active role in the two major consultation exercises that took place in 1995 during the development of the Code of Consumers' Rights and produced extensive submissions on the proposed Code.

For me personally, the lynch pins of the Code of Rights have always been

Right 6: the right to be fully informed, and

Right 7: the right to make an informed choice and give informed consent.

The other rights sit around these two essential aspects of the Code.

Cervical Cancer

We now know a lot more about cervical cancer and how and why it develops than we did 20 years ago. We know that the vast majority of cervical cancers occur as a result of the body failing to heal itself from infection by one of dozens of human papillomaviruses (HPV) that women become vulnerable to once they become sexually active.

We know that most HPV infections clear spontaneously – 70% of infected women have got rid of the infection within one year, and 90% have got rid of it within two years.

We know that two types of the virus are responsible for about 70% of cases of cervical cancer – HPV16 and HPV18.

We also know that it takes around 15 years for cervical cancer to develop if the body fails to deal with the infection.

When the National Cervical Screening programme was established in the early 1990s around 90 women died of cervical cancer in New Zealand every year. Over the past 18 years that figure has dropped to 60.

HPV Vaccines
The HPV vaccine is one of the most expensive vaccines ever to come onto the market. It is one of the first vaccines to be designed to prevent a cancer that is caused by a virus – the Hepatitis B vaccine was the first.

In this case both the HPV vaccines now on the market have been shown to be effective against HPV16 and 18 – the two that are responsible for around 70% of all cervical cancers. Until Friday 1 August 2008 I was under the misconception that to be effective the vaccine needed to be given before teenagers become sexually active. On Friday I listened to an interview with Dr Diane Harper, one of the lead researchers on the vaccine who said the vaccine is just as effective when given after a woman has become sexually active, and even if she has already got infected by one of HP viruses.

The difference between the two HPV vaccines is that Gardasil which was developed by CSL and marketed by pharmaceutical company Merck has been shown to be effective against HPV16 and 18 as well as two others, HPV6 and 11 which cause genital warts, while Cervarix which is marketed by another pharmaceutical giant, GSK, is effective against HPV16 and 18 alone.

The New Zealand government has opted to use Gardasil rather than Cervarix.

In the UK the Department of Health recently announced that it had decided to use Cervarix for their HPV vaccination programme which is scheduled to begin in September. It says it will save up to £18.6 million by using Cervarix which is equally effective against HPV16 and 18, but doesn't include the two types that cause around 90% of cases of genital warts.

The Cartwright Issues Surrounding Gardasil
I now propose to examine the introduction of Gardasil into a vaccination programme for young teenage girls from a Cartwright perspective.

- **Informed Consent**

As I have already mentioned I regard informed consent as a key issue:

- in what happened during the "unfortunate experiment" at National Women's Hospital in the 1960s and 1970s,

- in the recommendations contained in the Cartwright Report,

- in the establishment of the Office of the Health & Disability Commissioner,

- in the development and enshrining in legislation of the Code of Consumers' Rights.

And before we go any further I first want to acknowledge that women paid a very high price what we have in place today – the Cartwright Inquiry revealed

that many women died needlessly of cervical cancer, not knowing they had been part of an experiment at NWH.

So how does informed consent work in the current medical and social environment? And how will the need to obtain informed consent be met with respect to this particular vaccination campaign?

Of major concern to me is the Ministry of Health's history when it comes to vaccination campaigns. This is one area where the Ministry has repeatedly abandoned any pretence of adhering to the legal requirement to obtain informed consent. Let me give you a recent example.

The MeNZB vaccination campaign which the Ministry recently announced was now officially over. As a mother of a primary school- aged boy, I got the Ministry's information on meningococcal B and the MeNZB vaccine. Three and a half years ago I attempted to find out as much as I could about this particular vaccine and what the risks of my son catching meningococcal B actually were. I must admit my efforts to obtain the information I needed to make an informed decision were spectacularly unsuccessful. So I made an uninformed decision.

Several weeks ago I stumbled upon some information on the University of Auckland's Immunisation Advisory Centre's website about the MeNZB vaccine that shocked me. The one-page information sheet for health professionals was put on the website two or three months ago.

I learned that only 75% of young children developed a successful immune response after 3 doses of the vaccine; that only 53% of babies who start their 3-dose MeNZB vaccinations at 6 weeks developed the level of immunity needed to protect them from the disease, that the immunity lasted for less than 7 months in young children and only slightly longer than that in older children. In other words all those under 20-year-olds who were vaccinated with the MeNZB vaccine between 2004 and 2007 no longer have any immunity to the disease.

It has been estimated that the hundreds of millions of dollars spent on this vaccine prevented 54 cases of meningococcal B disease and 1.7 deaths.

In consulting with a number of parents who had had their children vaccinated with MeNZB I discovered that all of them believed that their children were protected from getting this disease for decades – if not for life.

My point is this – how long the immunity that a vaccine provides lasts is an important piece of information parents should be told and it should be part of the informed consent process. For MeNZB it could mean the difference between life and death if a parent saw signs of the disease in their child but did not seek medical help soon enough because they believed their child was still protected by the vaccine.

But how long vaccine-induced immunity lasts is not usually part of the information that the Ministry is prepared to divulge. The MeNZB vaccination campaign was more about getting uninformed compliance than obtaining informed consent.

So will it be different with Gardasil? I don't believe so. Dr Diane Harper, the lead researcher I heard interviewed on 1st August, said there is now evidence that the immunity provided by the vaccine has started to wane by 5 years. So this means that boosters will be needed. Who will pay for the 5-yearly or 6 or 7-yearly boosters? And will parents and young women be told they need boosters? With MeNZB, a large proportion of parents of babies did not turn up to the necessary 10-month booster, which meant their babies' immunity disappeared very quickly after the third vaccination. With the Gardasil campaign, it isn't just the vested interests of the Ministry of Health involved, there are also the vested interests of a large pharmaceutical company with a large amount of money at its disposal to promote its product. And as Diane Harper said, the promotion of this particular vaccine is way over the top.

Let's look at some of the advertisements that CSL/Merck have already unleased upon the unsuspecting public.

As with the MeNZB campaign the role of the media is a vital component of the selling of the necessity of getting your 12 – 14 year-old daughter vaccinated with Gardasil. After being subjected to and manipulated by such marketing I would argue that obtaining truly informed consent is less achievable.

The vaccine is already being marketed as "an anti-cancer vaccine." But such a claim is patently false. It will take 20 years before such a claim can be substantiated because it takes around 15 years for cervical cancer to develop, and because we don't know whether other types of HPV will take the place of HPV16 and HPV18.

Another way that informed consent is eroded these days – again by the Ministry of Health – is the targets set by the Ministry for vaccination coverage and the various payments made to health providers for each vaccination given. This was also the case with MeNZB. At a recent vaccination update meeting I attended two months ago, one practice nurse said that she had been given instructions by the GP she worked for that she was to continue "encouraging" parents to have their baby vaccinated with MeNZB because of the payments made to him!

When such forces are at work how likely is it that parents are able to make truly informed decisions about vaccinations like MeNZB and Gardasil?

This issue of obtaining informed consent from young adolescents is also a key component in relation to Gardasil. Given that the government has bought into the drug company propaganda that Gardasil should be given before young teenage girls become sexually active – the target age group is 12 – 14 year olds – how will young adolescents and their parents go about making an informed decision on whether to have the vaccine? Who is making the

decisions about what they need to know – and more importantly what it is "better" that they don't know? How will all the other important messages around this particular vaccine be given – such as the importance to practice safe sex and continue to have regular cervical smears?

I don't see the Ministry of Health paying much attention to these issues, and given the history of threatening those who dare to provide alternative sources of information or who dare refer parents to other sources of information, I don't hold out much hope of a Gardasil vaccination campaign complying with the vision of informed consent contained in the Cartwright Report, or meeting the standards set by the Office of the Health and Disability Commissioner and mandated by the Code of Consumers' Rights.

- **The Doctor - Patient Relationship**

There was a flurry of activity around addressing the balance in the doctor – patient relationship following the release of the Cartwright Report. The paternalistic "doctor knows best" attitude of many doctors was forced to give way to the requirement to engage patients in making informed decisions about their health care by discussing the risks and benefits of any proposed treatment or intervention. It all seemed so much simpler back then – in the immediate post-Cartwright years.

These days the power of the medical establishment is reinforced by the introduction of direct-to-consumer advertising, and the manipulation and financial clout of the pharmaceutical industry. The risks of getting an ailment or falling victim to a disease are routinely expanded and exaggerated by an industry hell-bent on expanding the market for its latest new drug or vaccine and thus increasing their profits. It has become increasingly difficult to find the truth that lies behind the hype surrounding the latest breakthrough, and it often takes several years before the true extent of side effects and the actual benefits of a drug are known. In many highly publicised cases over the past few years drugs have reluctantly been withdrawn once the families of those who have died or the patients who have been harmed start taking out law suits.

In the case of Gardasil, we have already experienced first-hand the efforts of the drug company rep to oversell the risks to women of getting cervical cancer. The drug company rep's argument that the timeframe between being exposed to HPV and the development of cervical cell abnormalities was rapidly reducing has not proved to be true. I have seen no evidence to support her claim that women are succumbing more quickly to cervical cancer.

When a young woman and her mother appear in the doctor's office or sit down to discuss the information provided by the Ministry of Health sent home from school how will they know whether they have been provided with all the facts about Gardasil. Given that such conversations are occurring in an environment already saturated by drug company ads and articles in women's magazines as well as persuasive TV advertising campaigns in which "choice" is framed in terms of making the choice to have the vaccine, the drug or some

other intervention, the dice is heavily loaded against young women and the parents of preteens making an informed decision around Gardasil.

Previous experience with other vaccination campaigns has already shown that parents only get told what the Ministry of Health or the pharmaceutical industry what them to know. Relying on the information given to them by the GP or public health nurse will not enable them to make an informed choice re this vaccine.

- **The Role of Ethic Committees in Protecting Patients**

Ethics committees were totally revamped in the wake of the release of the Cartwright Report. Hospital-based ethics committees were disbanded and replaced with ethics committees that comprised a 50/50 health professional and lay people membership. They were there to protect the health and well-being of both patients and those who were well who were being asked or were volunteering to take part in research trials. Ethics committees were charged with ensuring that researchers followed the guidelines and that participants were able to give true informed consent to taking part in any research trial.

As a member of two of these new ethics committees for almost three years I was at the cutting edge of the changes being introduced, and experienced first-hand the reluctance on the part of some health professionals to accept that lay people had anything to offer, along with the attempts made to prevent ethic committee meetings being held in public. One thing I was totally unaware of 20 years ago was the influence of the pharmaceutical industry in how research trials were conducted. Maybe the researchers had more independence in those days, maybe not.

How long the changes lasted I don't know. What I do know is that the emphasis has undeniably shifted over recent years to a more stream-lined approach that ensures that research applications are dealt with as expeditiously as possible and that few obstacles are put in the way of the research proposal being given the go ahead. Hospital ethics committees have also sprung up again and it is unclear how they operate.

Of course the research trials on Gardasil were all funded by the drug company and the publication of the results of these trials were also controlled by the drug company. When trial results do not meet the drug company's expectations or do not support the claims they have made about their new drug or vaccine, the results often do not see the light of day. Unfavourable results are buried and often not brought to light until after the drug has been unleashed on the general public and serious negative side effects have been reported which the manufacturer cannot ignore or refute.

Research committees post-Cartwright were also charged with overseeing the introduction of new drugs or procedures. This was never a great success as ethics committees always had far too little time for dealing with anything other than the never-ending stream of research proposals that came before them.

The introduction of Gardasil into the vaccination schedule is unlikely to have gone before an ethics committee here in New Zealand, and the reporting of side effects of vaccines has always been a problem area in this country.

- **Political Influences on Health Policy Decisions**

There were undoubtedly vested political interests that influenced the events that followed the publication of the *Metro* article written by Sandra Coney and Phillida Bunkle in June 1987 – the announcement of the government inquiry, how the Inquiry was conducted, the timing of the release of the report, and the decisions made around implementing the recommendations.

Over the past 20 years the political environment surrounding health policy decisions has become more complex – and more obvious. The timing of announcements on women's health policy decisions is based on where we are in our electoral cycle – as opposed to our menstrual cycle.

Both the national cervical screening programme and the breast screening programme were announced and their introduction timetabled just prior to an election. The announcement about the extension of breast screening to women under the age of 50 was also made just prior to an election.

Gardasil is no exception. The present government did a dramatic U-turn on its initial decision to wait another two years before reconsidering the decision to introduce the HPV vaccine into the childhood vaccination schedule, and the implementation of this particular vaccination programme is being carried out in undue haste because we have an election coming up in a few months. Once again we have a health policy decision closely tied to an impending election. And yet again it is a health issue that affects only women. In this particular instance it is the bodies of young women who are being targeted and I would argue experimented upon.

There are still many unresolved issues surrounding the long-term efficacy and the impact of this vaccine. We do not know how long it takes teenagers to clear HPV infections for example, as there are no data on clearance rates among girls. Nor do we know what the actual HPV prevalence rates among youth and young children are.

No girls under the age of 15 years of age were enrolled in the clinical trials of Gardasil, and the youngest of them were followed for only 18 months. Based on the assumption that they will not yet have been exposed to HPV viruses, girls in this age group represent the priority target population for mass vaccination. This is a thin information base on which to construct a policy of mass vaccination for girls between 12 – 19 years.

As I have already mentioned, how long the immunity to HPV16 and HPV18 lasts is also not clear. Dr Diane Harper stated that there is now evidence that five years after being vaccinated women's immunity is showing signs of waning. So it simply does not make sense to vaccinate 12 year olds. Given

that this is one very expensive vaccine, who is going to pay for the 5 yearly booster shots?

- **Women's Health Consumer Groups**

The Cartwright Inquiry occurred as a result of the determined efforts of two women and the organisation they founded 24 years ago – then known as Fertility Action. Fertility Action was a party to the Inquiry and was actively involved in the implementation of all of the recommendations in Judge Cartwright's report. The Auckland Women's Health Council held its first meeting in July 1988, having been set up to represent the views of women in the Auckland region following the establishment of the Auckland Area Health Board. The Cartwright Inquiry and the formation of Area Health Boards throughout the country provided the impetus for the establishment of other regional women's health councils which then led to the formation of the Federation of Women's Health Councils in 1990.

Fertility Action, the various women's health councils, the Federation of Women's Health Councils as well as the increasing number of women's centres all played a significant role in the establishment of the national cervical screening programme, the promotion to women of the cervical screening register, the production of submissions on the Health Commissioner bill, the development of the Code of Consumers' Rights, and various other initiatives that arose out of the Cartwright Inquiry.

However, the health reforms of the early 1990s represented a real set back to the implementation of the recommendations of the Cartwright report. To quote Sandra Coney in "*Unfinished Business: What happened to the Cartwright Report*?"

"The health restructuring created a "window of opportunity enabling the traditional holders of power in the health care area to reassert their interests. Thus they were able to turn the Cartwright recommendations to their own purposes: the maintenance of medical power and self-regulation."

Throughout the bleak period of the 1990s the torch was kept burning by women's health groups which steadfastly refused to give up on the gains that implementing the Cartwright report represented for women's rights in the health care system.

Today there are new and different battles that need to be fought as the power wielded by pharmaceutical giants throughout the world threaten to turn far too many of us into patients and guinea pigs. The introduction of Gardasil can be viewed as another experiment, this time on girls and young women.

It can also be viewed as a significant warning to women that despite the gains we have made, gender still matters. In this instance it is women who are been asked to carry the entire load of reducing the incidence of HPV in New Zealand – and in all those countries who have already introduced Gardasil or Cervarix or are planning to do so. If health authorities in all these countries

were serious about eradicating HPV16 and HPV18 from the population then the vaccination campaign would include the vaccination of boys and young men.

Studies have been done on the Gardasil vaccine in young men, but nothing much came of them – until recently! After all, men don't get cervical cancer, and the fact that they are largely responsible for spreading HPV doesn't count for much in the scheme of things.

But recent research has revealed that HPV16 is also linked to about half of the oral cancers in men, and this has sparked calls for the vaccine to be given to teenage boys. Suggestions have also been made about changing the name of the vaccine if it is going to be given to boys – Mangard was one of them! Merck expects to have more data on the use of the vaccine in teenage boys next year and plans to seek US approval for it's use in young boys. So what does this tell us about how the issue of gender impacts on women in the health care system?

Another issue of concern is that those groups that do not have a high uptake of cervical screening – Maori and Pacific women – also have low rates of participation in childhood vaccination programmes. So why does the Ministry of Health think that Gardasil is going to solve the problem of the comparatively high rates of cervical cancer found in Maori and Pacific populations?

Conclusion
Finally, in conclusion, let me make the following points:

- The only data we have on Gardasil is that provided by the drug companies who undertook and controlled the studies, and also controlled the publication of the results.

- Gardasil is one of the most expensive vaccines to ever come onto the market.

- As some recently published papers have indicated, there are still more questions than answers about Gardasil. This was confirmed in the interview with Gardasil researcher Diane Harper on National Radio's *Nine to Noon* on 1st August.

- The vaccination campaign in this country will no doubt be run like previous Ministry of Health campaigns – parents and young women will be provided with only the information about Gardasil that the pharmaceutical industry and the Ministry of Health want them to have.

- The decision not to include boys and young men in the vaccination programme is indefensible and unethical.

- The reporting of side effects of this vaccine will be tightly controlled and managed by the Ministry and other health agencies.

- If women are given a false sense of security as a result of having been vaccinated with Gardasil, do not understand that the immunity does not last, and that they still need to have regular cervical smears then we could well see an increase in the rate of cervical cancer, rather than a decrease.

For more information and to order a Gardasil Information Pack ($10):

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