AUCKLAND WOMEN'S HEALTH COUNCIL

NEWSLETTER

NOVEMBER 2016

WHAT'S INSIDE:

- **Tarceva – the wonder drug that wasn't**
- **Research participants not covered by ACC**
- **NSU's "consultation" meetings**
- **NZ Bioethics conference "Bioethics and Health Law in the Information Age"**

PO Box 99-614, Newmarket, Auckland. Ph (09) 520-5175
Email: awhc@womenshealthcouncil.org.nz
Website: www.womenshealthcouncil.org.nz

TARCEVA – THE WONDER DRUG THAT WASN'T

Lynda Williams was diagnosed with pancreatic cancer a year ago. She reports on her search for cancer stories written by those diagnosed with pancreatic cancer, and what she found out along the way about the anticancer drug Tarceva:

Recently I bought a book written by Bob Brown, a guy in the US who was diagnosed with Stage 3 pancreatic cancer in March 2008. The title of the book, published in 2011 is "The Ride of my Life: A fight to survive pancreatic cancer." (1) Described on the back cover as "Self-help/ Motivational and Inspirational" it isn't the sort of book I would normally choose to read. It is also loaded to the gunnels with war on cancer imagery, as well as exhortations that you must fight for your life – again, definitely not my cup of tea.

But as books written by patients with pancreatic cancer are almost non-existent, beggars can't be choosers.

The weapons of the war on cancer

Bob fought hard to be provided with all the weapons he wanted – chemotherapy, radiotherapy, and surgery – to wage his war on his particular cancer. He admitted they all come with some collateral damage which after reading his book I feel is a bit of an understatement. However, to give credit where credit is due, he survived for 5 years following his diagnosis and counted himself as one of the few with pancreatic cancer to survive for several years. He also referred to himself as a Whipple surgery survivor.

The final chapter of the book is titled "Lessons from the front line" and features admonitions such as:

"Cancer is ruthless and takes no prisoners. Be ready to do the same."

"The war will be made up of a series of battles, some big, some small. All important;" and

"You'll probably lose some of the battles. Don't lose sight of the war. That's the one you need to win. That's the one you can win."

Three pages of this sort of stuff and I was in danger of losing the will to live!

I then went in search of information about what happened after he published his book. I came across a short talk he gave in November 2012 at a Pancreatic Cancer Awareness Day –

www.youtube.com/watch?v=L0aWhy36ciA

and also an obituary which revealed that Bob died in August 2013. Wanting to know more about what happened to him in 2013 I continued my search but to no avail.

It's hard not to feel cheated when Bob had been so upbeat, telling the rest of us that we must all fight the good fight like he did. I would much prefer that he fessed up when it all started to go downhill and been willing to talk about his final battle. His book ends with his still being a NED (No Evidence of Disease) in 2011 and not taking any chemotherapy drugs. However by the time of his appearance at the Pancreatic Cancer Awareness Day in 2012 he refers to being back on Tarceva (also known by its generic name erlotinib).

After numerous attempts looking for information on what happened to Bob, I gave up and went looking for information about Tarceva instead. I discovered that it is or was used in the treatment of non small cell lung cancer and pancreatic cancer. The list of side effects is predictably daunting, and includes horrible, disfiguring skin rashes and eye irritation along with the usual chemotherapy symptoms such as nausea, vomiting, loss of appetite, serious and ongoing diarrhoea, shortness of breath, cough, blistering or peeling of the skin, etc.

I also came across a couple of stories in the *NZ Herald* about the successful use of this drug, including one written in 2006 about a woman called Anne who "had a Lazarus response" to the drug. (2) The other written in 2010 was about Trudi who was given "at least two years of life that were probably going to be snatched away from her by lung cancer." (3) Both women had lung cancer and both women have since died.

Apparently Tarceva works remarkably well in about 10% of non small cell lung cancer patients. Bill Wilson, a cancer researcher I consulted, says the few individuals who do benefit do so because they have the mutation in the EGFR gene that is known to make tumours sensitive to Tarceva. The mutation is relatively common in non small cell lung cancer but less so in pancreatic cancer, also known as pancreatic ductal adenocarcinoma. Unfortunately the miraculous results in lung cancer patients don't last because the tumours inevitably become resistant.

The use of Tarceva for pancreatic cancer is a different story and can be seen as a chilling case study in the marketing of anticancer drugs when there is no evidence of genuine benefit. The study that resulted in the FDA giving approval to erlotinib was published in the *Journal of Clinical Oncology* in 2007. It revealed that adding erlotinib to gemcitabine (Gemzar) extended survival in pancreatic cancer patients by about a week. Yes, one week! But first you had to get out your cheque book.

Continuing my search for more information I stumbled across a website which revealed that in June 2016 OSI Pharmaceuticals, the manufacturer of erlotinib, along with Roche's Genentech unit had agreed to pay $67 million to settle claims that they misled doctors about the drug's effectiveness in treating lung cancer. This case is significant because it represents the first False Claims Act settlement that turns on cancer-drug survival data. (4)

From the drug's launch in 2004 to 2010 the two companies had overstated the drug's ability to fight lung cancer, while aware that there was very little evidence to support Tarceva in the treatment of the vast majority of lung cancer patients. The data revealed that Tarceva was most effective in non small cell lung cancer patients who had never smoked, or who had the EGFR genetic mutation. The companies' marketing materials and interactions with doctors led them to prescribe Tarceva for newly diagnosed lung cancer patients, even though it was FDA-approved only as a second-line treatment.

OSI was Genentech's marketing partner on Tarceva until 2011 when the Japanese drug manufacturer Astellas bought the company. The

marketing allegations regarding Tarceva range from 2006 to 2011.

Of course, a $67 million fine is peanuts in the world of the pharmaceutical industry. Some drug companies have faced fines of $2 – 3 billion. Genentech was not required to sign a corporate integrity agreement with the US government – in contrast to other deals – and in a statement the Roche unit claimed that its promotions of Tarceva "were and still are entirely proper and in compliance with the law."

As long as these drug companies believe it is "proper" and lawful to overstate the effectiveness of their drugs, they can continue to charge megabucks for them and make billions before the truth gets out, or a more effective drug comes onto the market.

And what about the cancer patients like Trudi who initially had to pay $4,500 a month for Tarceva, the wonder drug that wasn't.

The media hype around the latest wonder drugs isn't helpful either as it targets vulnerable cancer patients desperate for a drug that will work. The media seldom run follow-up stories when it all turns to custard and drug companies are brought before the courts and fined.

It's time to take action against these immoral and manipulative practices. The drug companies are more than happy to use patients to lobby governments for access to their obscenely priced "miracle" drug, regardless of whether it has been proven to be effective long-term or whether it is cost-effective. We patients must not let them use us this way. We must refuse to let them get away with over-stating the effectiveness of their drugs and over charging our health systems which have limited budgets and finite resources.

And we can all help bring this about by signing up to the AllTrials campaign which is an international initiative demanding that the pharma-ceutical industry register all their trials and publicly report all the results.

References

1. Bob Brown. "The Ride of My Life: A Fight to Survive Pancreatic Cancer." Pub. iUniverse Inc. 2011
2. www.nzherald.co.nz/nz/news/article.cfm?c_id=1&objectid=10411576
3. www.nzherald.co.nz/nz/news/article.cfm?c_id=1&objectid=10670744
4. http://www.fiercepharma.com/pharma/genentech-osi-shell-out-67m-to-settle-cancer-drug-marketing-claims-doj
5. www.alltrials.net/

STILL WAITING FOR THE HDC'S CONSULTATION DOCUMENT

The AWHC emailed an Official Information Act request to the Health & Disability Commission at the beginning of October requesting information on when the promised consultation document on enrolling unconscious patients in clinical trials would be released. It was due out in September.

We asked what the consultation process would involve and the expected timeframe. We also asked for information on the appointment of the expert advisory panel, when it was established and who is on it. Maybe this time we will finally get a reply.

RESEARCH PARTICIPANTS IN NZ NOT COVERED BY ACC

The unresolved issue of NZ research participants taking part in clinical trials sponsored by international drug companies but not being entitled to ACC coverage should they be harmed as a result of being in a clinical trial, is described in an essay in a recently published book ”Law, Ethics, and Medicine.” (1) The book was written in honour of Professor Peter Skegg, New Zealand’s founding professor of medical law.

Jo Manning’s essay begins by describing how two people involved in two different commercially-sponsored clinical trials suffered serious harm in 2012. They then spent years fighting for compensation from the drug companies involved. While one finally achieved a financial settlement with the drug company’s insurers the other is still fighting for his compensation.

“The first trial involved a man who suffered injury in a large, Phase III, multi-country, double-blind randomised controlled trial of patients with type-2 diabetes who had never before taken insulin, comparing a new insulin variant medicine with an existing insulin treatment. The aim of the trial was not to treat participants for their condition but to demonstrate that the investigational medicine was not inferior to an existing insulin treatment, and to compare the efficacy and safety of the new drug.”

The second trial involved a man who suffered atrial fibrillation (an irregular and often rapid heart rate) days after taking a new drug for gout. The aim of the study, known as the CRYSTAL study, was to compare the effectiveness and safety of the investigational drug taken in combination with a standard gout medicine alone.

While the Participation Information Sheet (PIS) for those agreeing to take part in commercially-sponsored clinical trials is required to state that if a person suffers harm or an injury as a result of participating in the trial they will not be eligible for cover under the Accident Compensation scheme, few if any participants understand what this really means. This is partly because the PIS usually includes a reference to the sponsor’s obligation to pay compensation, in accordance with the NZ Researched Medicines Industry “*Guidelines on Clinical Trials – Compensation for Injury resulting from Participation in Industry-sponsored Clinical Trials.*” It is not made clear that this is not a legal obligation and they will find themselves having to take on the might of an international drug company and its insurance company’s lawyers.

As Jo Manning’s essay revealed:
“Both companies, at least initially, disputed that the men’s injuries were caused by the investigational drug. It was not until approximately three years later in 2015 that the participant in the CRYSTAL trial finally reached a confidential settlement with the sponsor of his claim for compensation, having suffered significant loss of income in the meantime and after having engaged a high profile lawyer to act for him. A major obstacle to achieving a settlement was that the sponsor’s insurance company took over management to the claim, and it took a strict commercial approach to the claim.” At the date of writing, the second man, despite also getting legal help has still not received any

compensation from the sponsoring company.

Some history

As a result of drastic cuts made to ACC's budget research participants have been excluded from being able to apply for ACC compensation for injuries suffered as a result of participation in commercially-sponsored clinical trials in New Zealand since 1992. In contrast, participants in non-industry trials are covered by ACC.

The Ministry of Health and the Health and Disability Ethics Committees have been aware of the problem for more than a decade. In 2007 the Chairs of the ethics committees called for the repeal of this statutory exclusion. In 2010 the National Ethics Advisory Committee (NEAC) added its voice to the need to review and change this unfair and unethical situation. NEAC repeated its call to repeal the exclusion again in 2014. After learning about the experience of the two men mentioned above, the committee wrote to Peter Dunne, the Associate Minister of Health in November 2014. (2)

In December 2015, NEAC received a response to the advice they had given to Peter Dunne. Both their report to the Minister and his belated response were placed on the NEAC website in April 2016. (2) It is difficult not to see this as a demonstration of their disappointment in his response.

Jo Manning reports that NEAC's suggestion "that some companies conducting clinical trials in New Zealand may be 'failing to comply with NEAC's and Medicines New Zealand's (MNZ) guidance to provide compensation cover for study participants to at least ACC-equivalent standard, and to do so in an expeditious manner.'

Its efforts did not meet with success. Some analysts within the Ministry of Health were concerned about the significant impact on injured individuals from inability to or delay in accessing compensation and agreed that the problem was best addressed by extension of ACC cover to include commercial trials. But officials from ACC and the Ministry of Business, Innovation and Employment briefing Dunne and the Minister for ACC, Hon Nikki Kaye, did not support a law change, and their view prevailed." (1)

This is a very disturbing example of how ensuring that research participants are protected, once the core function of ethics committees, is no longer their main purpose.

Jo Manning's excellent expose of the issues is divided into four parts. Part 1 describes the consensus among commentators that there is a moral obligation to compensate injured research participants. Part 2 outlines the current law and compensation arrangements. Part 3 describes the deficiencies of the MNZ Guidelines, and Part 4 outlines possible responses and alternative options that participants, ethics committees and the Government might adopt to address this most unsatisfactory situation. This essay is a must read.

References

1. "Law, Ethics, and Medicine: Essays in Honour of Peter Skegg." Edited by Mark Henaghan and Jesse Wall. Published by Thomson Reuters NZ Ltd. 2016.
2. http://neac.health.govt.nz/publications-and-resources/advice-minister-health-0/neac-advice-compensation-treatment-injury-0

NSU "CONSULTATION" MEETINGS

The two meetings held by the National Screening Unit (NSU) in mid-October in Christchurch and Auckland were referred to by the NSU as "consultation" meetings. Health authorities, including the Ministry of Health, the NSU and DHBs, have an extraordinary definition of consultation these days. It involves them talking at their audience for several hours and then allowing a very short period of time for people to ask questions. The NSU meetings were no exception.

There were five presentations by Jane O'Hallahan, Karen Canfell from Australia, Marion Savelle, Margaret Sage and Gary Fentiman. It soon became obvious that the main purpose of the meeting was to refute the information about the need for caution before changing the cervical screening test presented at the Cartwright Forum held on 5 August this year. Margaret Sage's presentation was solely focused on refuting what Professor Marshall Austin had said. His presentation is now available on the AWHC website –

http://www.womenshealthcouncil.org.nz/Features/Coming+Events.html

The lack of any real attempt at consultation was most evident in Gary Fentiman's presentation on "Responding to your concerns." He put up a list of public consultation myths, none of which were concerns held by the women's groups who have been involved in promoting cervical screening for over 25 years. They included statements such as cytology is perfect, current screening picks up all the cancers, and current screening is effective for all.

AWHC GENERAL MEETING November 2016

Detailed minutes of this meeting are available on request. Matters discussed included:

- Financial reports
- Grant applications
- Submissions
- Cartwright Forum follow-up actions
- Ethics committee meeting
- AWHC strategic plan

Further information on some of the topics listed above is contained in this issue of the AWHC newsletter.

AWHC NEWSLETTER SUBSCRIPTION

The newsletter of the Auckland Women's Health Council is published monthly.

COST: $30 waged/affiliated group
$20 unwaged/part waged
$45-95 supporting subscription

If you would prefer to have the newsletter emailed to you, email us at awhc@womenshealthcouncil.org.nz

Send your cheque to the Auckland Women's Health Council, PO Box 99-614, Newmarket, Auckland 1149, or contact us to obtain bank account details.

UP AND COMING EVENTS

DISTRICT HEALTH BOARD meetings for November/December 2016:

Waitemata DHB (Website address: www.waitematadhb.govt.nz)
The Waitemata DHB Board meeting opens to the general public at 12.45pm on Wednesday 2 November 2016 and will be followed by the Hospital Advisory Committee meeting which starts at 2pm. Both meetings will be held in the DHB Boardroom, Level 1, 15 Shea Terrace, Takapuna.

The **combined Waitemata DHB and Auckland DHB** Community & Public Health Advisory Committee meeting starts at 2pm on Wednesday 23 November 2016.

Auckland DHB (Website address: www.adhb.govt.nz)
The Auckland DHB Board meeting opens to the general public at 12.45pm on Wednesday 7 December 2016 and will be followed by the Hospital Advisory Committee meeting which starts at 2pm. Both meetings will be held in the A+ Trust Room in the Clinical Education Centre, Level 5, Auckland City Hospital.

Counties Manukau DHB (Website address: www.cmdhb.org.nz)
The Hospital Advisory Committee meeting will be held at 9am on Wednesday 30 November 2016 at Ko Awatea and will be followed by the Board meeting at 1.30pm.

The Community & Public Health Advisory Committee meeting will be held at 1.30pm on 9 November 2016 at 19 Lambie Drive, Manukau.

ETHICS COMMITTEE meetings – dates for the four MOH ethics committees are at:
http://www.ethics.health.govt.nz/about-committees/meeting-dates-venues-minutes

The NZ Bioethics conference on "Bioethics and Health Law in the Information Age" will take place on 27 – 28 January 2017 at the University of Otago, Dunedin.
The conference will feature workshops, general sessions, and presentations focusing on the digitalisation of health in the Information Age. The Information Age refers to the collection and storage of (potential) health-related data and metadata, as well as the technologies that provide the means to manipulate, aggregate, utilise, and disseminate this information. With this shift toward digitalisation comes possibilities for future action. This is an area with which bioethics and law need to keep up

Further information is available at: http://www.otago.ac.nz/bioethicsconference/index.html