# Inquiry into the Adequacy and Appropriateness of Prevention and Treatment Services for Alcohol and Illicit Drug Problems in Western Australia

## Education and Health Committee

## Legislative Assembly, Parliament of Western Australia

## Terms of Reference:

(1) *To inquire into the adequacy and appropriateness of prevention and treatment services for alcohol and illicit drug problems in Western Australia, with particular reference to:*

*(a) the evidence base, content, implementation and resourcing (including teacher training) for health education and other interventions on alcohol and illicit drugs for school-aged students;*

*(b) the evidence base, adequacy, accessibility and appropriateness of the broad range of services for treatment and support of people with alcohol and drug problems and their families, and the most appropriate ways to ensure integrated care; and*

*(c) the adequacy of the current education and training of medical and allied health professionals in the alcohol and drug field.*

This submission is a response to the following Term of Reference:

*(b) the evidence base, adequacy, accessibility and appropriateness of the broad range of services for treatment and support of people with alcohol and drug problems and their families, and the most appropriate ways to ensure integrated care*

I cannot comment specifically on the adequacy or otherwise of services for people with alcohol and drug problems in Western Australia as I have never worked in that state. However, I believe that such services in most parts of the world fall well short of the quantity and quality of services provided for all other health conditions. I assume that this is also the case in Western Australia. This submission is therefore primarily concerned with the evidence base and appropriateness of naltrexone services (especially naltrexone implants) in Western Australia as this is an area I have followed very closely for several years and that has considerable bearing on the situation in Western Australia.

Naltrexone blocks the action of heroin (and all other opiates). Naltrexone implants, an experimental treatment for heroin dependence, have been used in Australia for about the last 8 years. The implant formulation is intended to provide low and steady naltrexone blood levels to be maintained without requiring (often unreliable) patients to take the drug orally and very reliably on a daily basis. As yet, naltrexone implants have not been approved by the regulatory body of any country for the management of heroin dependence. The reason that naltrexone implants have not been approved by the regulatory body of any country for the management of heroin dependence is that the current evidence for the effectiveness and safety of naltrexone implants is minimal. In these circumstances, where a drug (or device) is of unknown effectiveness and safety, the drug (or device) is not allowed for use in routine clinical practice but the drug (or device) can be used in research which is carried out under the supervision of a human research and ethics committee (which conforms with the requirements stipulated by the NHMRC). Naltrexone implants have been manufactured in Australia by Go Medical, a company in Perth, since the early part of this decade.

I am concerned that:

(1) Patients receiving naltrexone implants manufactured by Go Medical appear to be developing complications at a concerning rate;

(2) Although initially an excessive rate of complications was only suggested by clinical anecdotes, a recent publication documented a series of 12 cases of which eight appeared to be particularly convincing regarding the development of complications following insertion of naltrexone implants (Nicholas Lintzeris, Soung Lee, Lucinda Scopelliti, James Mabbutt and Paul S Haber. Unplanned admissions to two Sydney public hospitals after naltrexone implants**.** Medical Journal of Australia. 2008; 188 (8): 441-444);

(3) The complications of naltrexone implants include infections, pain and suffering, and excessive hospital admissions;

(4) I was invited to write an editorial to accompany the above paper (Alex D Wodak, Robert Ali, David Henry and Lloyd Sansom Ensuring the safety of new medications and devices: are naltrexone implants safe? Medical Journal of Australia 2008; 188 (8): 438-439**).** My co-authors included a very experienced clinician and influential government advisor on alcohol and drugs **(**Professor Robert Ali), a former Chair of

the Economics Sub-Committee of the Pharmaceutical Benefits Advisory Committee (Professor David Henry), and the current Chair of the Pharmaceutical Benefits Advisory Committee (Professor Lloyd Sansom);

(5) Naltrexone implants manufactured by Go Medical in Perth have failed to meet required Good Manufacturing Practice (GMP) standards. These are not just minor technical breaches of unnecessary red tape. Despite these breaches, the relevant regulatory body (the Therapeutic Goods Administration) has inexplicably failed to stop further manufacture of naltrexone implants. The regulation of pharmaceutical agents (and devices) helps to protect patients and is an important part of the public health care system;

(6) GMP standards include meeting the fastidious levels of sterility required for any device (such as a hip prosthesis or cardiac pacemaker) which is permanently surgically implanted in the human body. According to public statements made by clinicians who support naltrexone implants, several thousand naltrexone implants have been inserted in Western Australia and other states. Yet as Go Medical has failed to achieve GMP, it has only been permitted under a TGA licence to produce supplies in limited numbers sufficient for use in clinical trials. At most only a few hundred naltrexone implants have been used in clinical trials in Australia. Contrary to the requirements of the TGA licence, naltrexone implants have been exported to other states of Australia and to other countries. The Special Access Scheme (Category A), specifically intended only for patients with a terminal illness and very limited life expectancy, has been used inappropriately to enable naltrexone implants to be inserted clinically on virtually a routine basis;

(7) On 22 October 2008, Ms Jane Halton, Secretary of the Department of Health and Ageing, gave evidence to the Senate Committee on Community Affairs and said:

> *'I can tell you that there has been a very long conversation with Dr O'Neil about the need to ensure that, if he is manufacturing, he meets good manufacturing practice. That has not happened, and the TGA is basically discharging its regulatory responsibilities in its dialogue with Dr O'Neil'.*
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> *'As has been pointed out to Dr O'Neil I do not know how many times, he can ensure that his manufacturing practice meets the standard that is required of every other manufacturer in this country. I do not think that is unreasonable'.*

(8) On 25 February 2009, Dr Rohan Hammett, National Manager of the TGA, said:

> *My understanding is that that is correct—that they have been exporting the product previously. It has been emphasised to them that, under the conditions of their licence as a clinical trials manufacturer, they are not eligible to do that.*

(9) It is hard to understand why no action was taken by the TGA or Department of Health and Ageing (DoHA) before the comments made by the Secretary on 22 October 2008 and the comments made by the National Manager of the TGA on 25 February 2009. I find it even harder to understand why no action has been taken by the TGA or DoHA after the comments made by the Secretary of the Department of Health and Ageing on 22 October 2008 and the comments made by the National Manager of the TGA on 25 February 2009;

(10) It is on the public record that Go Medical has also been manufacturing naltrexone implants at Curtin University. The legal status of manufacture of naltrexone implants at Curtin University warrants review;

(11) The WA government estimated on 9 January 2009 that it had provided at least $8 million to Go Medical over 8 years to assist the naltrexone implants programme
http://www.mediastatements.wa.gov.au/Pages/WACabinetMinistersSearch.aspx?ItemId=131147&minister=Jacobs&admin=Barnett
On 19 March 2009, the WA government announced that it had provided an additional $1 million to Go Medical
http://www.news.com.au/perthnow/story/0,21598,25211471-2761,00.html
The total financial support provided by the Commonwealth government is also believed to be substantial but the amount of financial support has not been announced. The substantial sums provided to a commercial organisation by the WA and Commonwealth governments have been made available notwithstanding multiple and long standing breaches of the Therapeutic Goods Act, and despite documented cases of serious complications published in a respected, peer reviewed medical journal which have also been observed by many other clinicians. This is a matter of some concern as the pharmaceutical regulatory system is being undermined if an exception is made for one product to not have to follow the rules;

(12) It is even more perplexing that no action has been taken despite the forthright public comments made by the Secretary of the Department of Health and Ageing, the National Manager of the TGA and considerable coverage of these matters in the media;

(13) It is hard to believe that this situation, that is, the surgical permanent implantation of devices over many years which fail to meet required standards into thousands of patients would be tolerated in any other patient group. This seems to be tolerated in this population because they are 'only injecting drug users';

(14) Since the thalidomide catastrophe in the 1960s, all new medications (and devices) are considered ineffective and unsafe until evidence emerges to demonstrate effectiveness and safety. We still do not have good evidence of the effectiveness and safety of naltrexone implants as a treatment for heroin dependence. Therefore, naltrexone implants should not be available for routine purposes. I support the rigorous evaluation of naltrexone implants to assess their efficacy, safety and cost-effectiveness provided that these studies at least meet the scientific and ethical standards required for medical research in Australia.

(15) I would be very happy to be questioned by the committee regarding this evidence if the committee chose to do that. This could be by teleconference, videoconference or a face to face meeting if the committee visited Sydney.

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