Submission No 47

INQUIRY INTO DRUG AND ALCOHOL TREATMENT

Organisation: Fresh Start Recovery Programme

Date received: 1/04/2013

Submission to Inquiry - Drug and alcohol treatment

Dear Sirs,

I am here as the founder and medical director of Fresh Start Recovery Programme (www.freshstart.org.au) a not for profit supported by the West Australian Government for 15 years in a row.

The Fresh Start programme works with the WA government, WA companies and WA Universities as well as Church and Community groups to facilitate the delivery of recovery based pharmacotherapy for those with opiate or polydrug use. The program develops, delivers and validates new treatment methods. While the direct costs of running up to 50 beds, detoxing up to 1000 patients a year and delivering relapse prevention services to 1000 patients per year costs about $6m per year the WA State Government's contribution has risen slowly over 15 years to about half these costs. Fresh Start does not receive any funding from the Federal Government or any State government for the estimated 200-250 patients a year who travel from interstate to be treated in WA.

The remaining $3m is made up from patient fees, donations and support from the company (Go Medical Industries Pty Ltd) and family (O'Neil) that has developed and produced the Naltrexone implants and other pharmacotherapy medications and equipment. The process of developing new forms of pharmacotherapy is expensive with a usual cost for successful new products that reach registration at up to $1.2 billion dollars. The development of the ideal naltrexone systems has been occurring over a 40 year period since Naltrexone was first synthesised in 1963. The work that we carry out in West Australian is for a population of heroin and alcoholic patients that most pharmaceutical companies recognise has low market potential, due to the fact that most of these patients will not be able to pay for the cost of medication or medication development. In this setting, West Australian companies' and Universities have worked together for the good of this patient group and also to facilitate the proper development of medications, as well as protocols that might improve the care of those with alcohol and drug addictions.

The principal institutions involved in this development and validation work are:

Organisation: **Principal contact**.

1. University of Western Australia: **Prof Garry Hulse**
   Psychiatry and Neuroscience. Clinical Research. Prof Garry Jefferies: Clinical hepatology service co-ordination.

2. Curtin University: **Prof Bruce Sunderland**: Formulation Development.

3. Go Medical Industries: **Dr Yandi Lieu** Formulation development, **Mr Chin-Tark Chan**: Naltrexone and Flumazenil production co-ordinator.

4. Edith Cowan University: **Prof Moira Sims**: Addiction specialist, Auditing and review processes.

5. Murdoch University: **Prof Simon Mallet**, Naltrexone production service support.

6. West Australian Chemistry Centre; **Mr Robert Hansen**, naltrexone monitoring and assay development.

7. Next Step and Fresh Start Recovery Programme, Teaching collaboration in training graduates who wish to become addiction specialists the new skills that fellows in addiction medicine need to understand addiction recovery pharmacology.

Currently, Go Medical is in the process of building a new GMP production facility for the manufacture of Naltrexone Implants. GMP facilities were first built in early 2005 eight years ago but unfortunately in 2011 a

fire destroyed this facility resulting in the design and building of new premises. Currently, implants are only able to be produced in temporary facilities for Dr O'Neil's patients being treated at the Fresh Start Recovery Programmes clinic in Perth. As soon as the new facility is finished (expected before December 2013) Go Medical will be able to begin a re-validation and re-licensing process of this new facility to gain GMP status, which should finish by May 2014. As significant improvement in production processes have occurred in the 13 years of naltrexone production and a final pharmacokinetic study will be commenced in June 2014 as well as a challenge study planned in the UK. We are hopeful that registration of the O'Neil Naltrexone Implant should follow shortly after this.

With 13 years clinical experience and studies these are some of the main clinical findings:

1. Prof Hulse demonstrated in 2004 that the therapeutic levels of naltrexone in the blood (above 1ng/ml) were maintained for an average of 280 days post implant. (Hulse *et al*, 2004)

2. The first of 2 RCT's demonstrated that oral naltrexone was superior to implant naltrexone (Hulse *et al*, 2009)

3. The second of 2 RCT's demonstrated that implant naltrexone was superior to routine treatments to take patients off opiates. This work was conducted by the University of Oslo. (Kunoe *et al*, 2009).

4. The review of deaths conducted after 28,000 patient years of service with oral and implant naltrexone conducted in Perth has demonstrated that in the first 4 months post detox, the rate of opiate overdose deaths is 25 times less in the patients with implant naltrexone compared to oral naltrexone, the registered product (Kelty & Hulse, 2012).

These findings are so dramatic and the study so large that the following conclusions have been made by our group.

I. Fresh Start should engage State Governments so that these services are available to high risk groups throughout Australia to reduce the current death rates with the highest risk.

   High risk examples:

   Post Jail
   People with a known history of opiate use who are leaving jail have a risk of death of up to 100 times their peer group (from opiate overdose death). It is a failure of duty of care, to be aware that a naltrexone implant inserted prior to their release would eliminate the risk of opiate overdose death and still make the patient no offer of treatment to stop this risk before being released form incarceration. Methadone does not offer the same protection form overdose deaths, and may increase the risk of the person prolonging their legal and illegal opiate use. (Kimber *et* al, 2010; demonstrated that the average number of years injecting was 5 if not placed on methadone and 20 if placed on methadone).

   Post pregnancy Infant deaths.
   One of the NSW health department policies that deserver's review is pregnancy management with opiates.

   Dr Lucy Burns (Burns, 2010), noted 24.3 infant deaths per 1000 live births among NSW patients exposed to methadone in pregnancy in the years 1995-2002. This rate of deaths in these children was noted to be at least 6 times the rate of controls she selected. For those who are not using methadone in the community the rate of 0.8 infant deaths per 1000 patients would be considered the normal rate. This strongly suggests that the babies of NSW mothers who have been exposed to methadone in pregnancy are being managed in a less than ideal way.

   This is a serious issue as the babies and in NSW cases the mothers are usually being offered no

choice. The current literature suggests that the fact that methadone is so slowly removed from the infant that it suppresses respiratory drive of the infant between 6 and 12 weeks particularly when the baby is sleeping. There is no respirator drive suppression in the infant with naltrexone and no growth retardation and so services or studies in these areas deserve government support. All of the available data suggests these deaths of infants to be preventable.

II. Fresh Start as a service and WA as a State have provided naltrexone to any citizen, including pregnant patients, wanting to come off opiates since 1997. The WA Liberal and Labour Governments have together supported the decision to pay for oral naltrexone for any patient wishing to come off opiates since 1999.

Both governments have also subsidised the Fresh Start Recovery Programme as long as the service has no cost barriers that would stop West Australian citizens who are seeking support coming off opiates. (We receive no subsidy for Eastern States patients from WA, Eastern States or Federal Governments). The WA government subsidies have been made at a rate of $6100 per patient detoxing.

This WA government support for medication support for addicts contrasts to NSW. In NSW the incidence of methadone is more than 2 times the rate per head of population that WA has. In NSW opioid addicted patients are only offered pharmacotherapy to stay on opiates while in WA they are offered medication which assists them off of opioids as well as pharmacotherapy to maintain their opioid dependence. (In WA more than 8000 have presented for naltrexone).

This difference in government policy may relate to less than half the rate per head of population being held on methadone in WA as patients in WA are facilitated out of addiction.

In Edinburgh Jo Kimber (BMJ 2010) demonstrated that the average length of injecting opiates was 5 years in heroin addicts not given methadone while the average length of injecting opiates was 20 years if placed on a methadone program.

Conclusion

If placed on a naltrexone implant all patients stop injecting opiates and from our experience we estimate that 50% achieve a long term (greater than 5 year) recovery from one treatment alone.
With a service available that provides repeat implants as required the majority of patients (greater than 85%) of patients make a sustained recovery with just 3 years of implant services.

We are recommending that:

1. The NSW government immediately set up a fund to monitor the outcomes of the patients travelling to Perth for treatment.

2. Set up a system to fund the Perth treatment of high risk patients who are at increased risk of death if untreated, who seek to come off opiates until a satisfactory service is established in NSW.

3. That the NSW government will accept that those patients who seek pharmacotherapy support to come off opioids will be treated as well as those who seek to stay on opioids.

In the NSW setting patients seeking pharmacotherapy to come off opioids have been disadvantaged compared to WA patients. We will work with the NSW government to continue to share our service with NSW patients but we are asking for appropriate financial support in treating these patients. We need support with patients currently demanding access to this government service, research and follow up of these patients and funds to minimise the potential delays between now and registration.

Thank you for examining these notes and asking questions relating to these statements.

Reference List

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