



**Naltrexone Implants –
*a drug user perspective***

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OVERVIEW



- Naltrexone Implants – for or against?

- Key Concerns:
 - Safety
 - Efficacy
 - Informed Consent
 - Cost to consumer

- Does anyone really care?



*Is AIVL “Against”
Naltrexone Implants?*

NALTRXONE IMPLANTS FOR OR AGAINST?



-
- *Being ‘accused’ of being anti-naltrexone*
 - *AIVL can afford to be ‘anti’ anything purely for ideological reasons*
 - *We represent drug users – if we are concerned about the health, safety or human rights of drug users we will say so*
 - *Equally – we support anything that is about **GENUINELY** expanding access to treatment but it must be safe, efficacious, monitored, affordable and based on informed consent*

NALTRXONE IMPLANTS FOR OR AGAINST?



-
- *If these criteria are met – it is about individual choice – not up to us to tell people what treatment is best for them*
 - *BUT...*
 - *If it doesn't meet the above criteria – we will say so to anyone who will listen*
 - *It is just getting someone to listen...*

KEY CONCERNS



Safety:

- Continuing safety questions
- No TGA approval in Australia
- Only GMP licensing for *“the manufacture of naltrexone implants for clinical trial use only”* or for individuals patients *“under direct care”* via GMP exemption
- Is supplying naltrexone implants under Cat A SAS exemption for *“unregistered devices where the patient is suffering from a life-threatening condition and where there is a lack of alternative treatments”*

KEY CONCERNS



Safety:

- But the NHMRC clinical trial ended some time ago – many 1000s manufactured for use outside of clinical trial environment
- So then GMP exemption BUT...
- This requires patient to be “under direct care”
- But what does this mean?
- Consumers have contacted AIVL with concerns and complications they put down to lack of follow-up

KEY CONCERNS



Safety:

- What about the many people who live outside of Perth and WA and even outside of Australia - NZ?
- How are they under direct care?
- Is it only when the device is being implanted?
- What's more, who is monitoring the appropriate level of direct care is occurring?

KEY CONCERNS



Safety:

- Cat A SAS exemption for *“unregistered devices where the patient is suffering from a life-threatening condition and where there is a lack of alternative treatments”*
- But can we really say that people stabilised on methadone or bupe are suffering a life-threatening condition?
- Can we really say there is a “lack of alternative treatments” for opioid dependency?
- How can the TGA answer “yes” to these questions when they are the body that has rigorously evaluated and monitored approvals for methadone and bupe?

KEY CONCERNS



Safety: Biggest Concerns...

- The number of naltrexone implant related deaths and adverse events both during naltrexone treatment and following naltrexone cessation.
- Case analysis from NCIS and hospital audits have investigated deaths and severe adverse events – severe opiate withdrawal, dehydration, infection at implant site requiring surgery and psychiatric disorders.
- Concluded: there is a need to “*challenge the notion that naltrexone implants are a safe procedure*” – careful case selection and closer monitoring to protect vulnerable and marginalised population.

KEY CONCERNS



Safety: Biggest Concerns...

- Reports of refusal to remove unwanted implants either due to severe pain, complications or just changing their mind/not suitable.
- AIVL has heard accounts of people removing their own implants after being refused removal of the devices.
- Clients showing up at NSP with bloodied implant in hand seeking assistance after desperate self-removal.

KEY CONCERNS



Efficacy:

- Evidence of effectiveness?
- Claims of 100% effectiveness – but where is the data and what is “effective” who defines “efficacy” and “success”?
- Must be defined over time based on individual treatment goals and often involves many treatment episodes.
- Is follow-up data recorded on every person with an active implant? Unlikely – near impossible.
- Cannot measure those who dropped out, cannot be contacted, those who return to active drug use after implant expires and non-opioid based drug use.

KEY CONCERNS



Informed Consent:

- Under Cat A SAS doctors are required to “inform their patients that they are using an unregistered product”.
- Serious questions about whether every patient, every parent really does understand that naltrexone implants are not registered for the treatment of opioid dependence in Australia.
- Highly marginalised and vulnerable group – what real ‘choice’ do we have even if we do understand?
- We rely on the TGA to protect us against the use of medical devices that have not been through the usual rigorous standards of approval and monitoring.

KEY CONCERNS



Cost to Consumer:

- Unclear about the cost of naltrexone implant treatment
- Some report paying \$5000 per implant with 2 and 3 implants resulting in \$10,000, \$15,000 treatment bills
- Patients have written to AIVL about the pressure of having automatic deductions from their benefits for long period to pay for treatment
- Fund raising in metropolitan news papers
- Suggests to community that consumers do not pay for treatment

Fresh Start Recovery Programme
Helping Families with Addictions

Support our Christmas Fundraising Appeal
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Help us reach our target

\$1 million needed to support 200 patient treatments (1000 addicts treated each year)

Cost of treating one heroin addict \$5,000

Cost of *not* treating one heroin addict \$1 million + needless suffering + life destroyed

Fresh Start achieves results without substituting one addictive substance for another

6000 addicts already treated

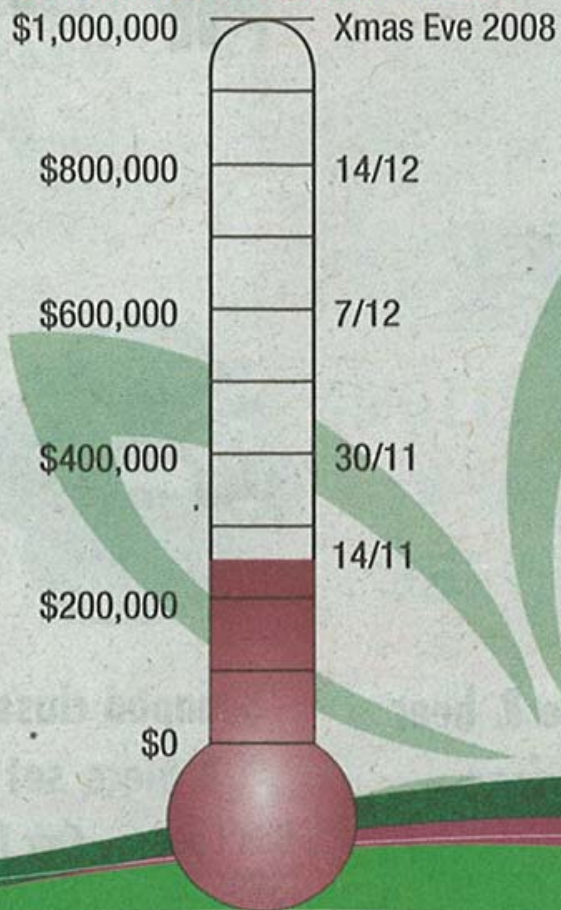


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KEY CONCERNS



Cost to Consumer:

- But very unclear about who qualifies for free or low cost treatment and who does not. How is this decided?
- Also puts enormous pressure on consumers not to “fail” treatment
- Particularly if family has paid for thousands for treatment
- Research shows that most people need multiple treatment episodes
- Anecdotal evidence suggests many people return to using following implant expiration.
- Suggests to people that they have ‘failed’ the treatment with 100% success rate – what does that mean for them?



Does Anyone Really Care?



Thank You