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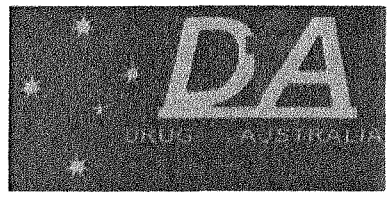


Drug Free Australia

Documentation of Testimony on Australian Drug Policy Experts' Subversion of Illicit Drug Intervention Research Evidence

TO HOUSE OF REPRESENTATIVES STANDING COMMITTEE ON FAMILY AND COMMUNITY SERVICES

Craig Thompson
Jo Baxter
Major General Peter Phillips
Major Brian Watters
Gary Christian

Introduction

In this document Drug Free Australia outlines evidence that various harm minimisation studies and Monographs by some of Australia's leading drug policy researchers, funded by State and Federal Governments, are substantially flawed. Of greatest concern is that these demonstrable errors and irregularities have consistently been in favour of the harm minimisation and/or drug law reform interventions being evaluated and corrections of these errors and irregularities consistently to their detriment.

Drug Free Australia further expresses concern that almost all government-funded Australian 'evidence-based' research in the last 15 years has been adduced to the support of a single ideology, that of harm reduction and its drug normalisation substrates, to the exclusion of research comparing the effectiveness of abstinence-based strategies in relation to these harm reduction/minimisation strategies.

It is the view of Drug Free Australia that various Australian AOD experts may have significantly misled the public and their government sponsors, downplaying the harms and effects of illicit drugs, significantly contributing to the drug epidemic experienced in Australia which has the highest levels of illicit drug use in the developed world and some of the highest drug mortality rates in the developed world. This has led to an incalculable amount of grief and estrangement for families.

Following is a brief critique of five of the most seminal studies supporting harm minimisation or drug law reform initiatives, as examples of Drug Free Australia's contention.

Monograph 52 NEPOD Study – NDARC

NEPOD Study – NDARC and the Oral Naltrexone Fiasco

(Introductory Note: The existence of a significant rate of deaths after oral naltrexone therapy has made this form of treatment very unpopular amongst clinicians in this country. The major naltrexone clinics around the world now uniformly prefer implantable or depot forms of naltrexone which have greatly improved short and medium term success rates, together with unusual safety records associated with the longest acting preparations available such as that available from Go Medical in Perth. Hence the subject of oral naltrexone is no longer a matter of active debate in this country at the present time. What is relevant for our purposes here is the appalling practices which were employed by the addiction establishment in this country to deface and defame the reputation of this treatment).

In 2001 the National Drug and Alcohol Research Centre (NDARC) attached to New South Wales University published the Department of Health and Ageing Monograph No 52 – National Evaluation of Pharmacotherapies for Opioid Dependence (NEPOD).

A Senate Select Committee was advised that the budget was $1.3 million[1] but both the study leader Prof. Richard Mattick, and the senior addictions physician in Australia Dr. Alex Wodak stated several times when the research findings were first presented at the October 2001 APSAD (Australian Professional Society of Alcohol and Drugs) meeting that the budget was $7 million – a discrepancy which would appear to warrant further investigation.

This study was a comparative evaluation of the outcomes of a range of trials of opioid detoxification and maintenance therapies, with 13 studies and 1,500 trial participants, comparing methadone, buprenorphine, LAAM and Naltrexone.

It is of relevance to note that at the time Naltrexone, as a relatively new opiate antagonist pharmacotherapy leading to drug free outcomes, enjoyed a high popular acceptance by the public, as per the results of the 2001 National Household Survey below.

Notwithstanding this popularity in the community, the 5 NEPOD trials assessing naltrexone produced dismal results. Favourable results were only reported for the substitution agonist treatments of methadone, LAAM and buprenorphine.

Measures of Success - Retention Vs. Opiate Free Success

Treatment success can be assessed as either medication compliance (i.e. continuing to take naltrexone, or "retention rates"), or as not taking heroin (i.e. "opiate free success," or "OFS").

[1] http://www.aph.gov.au/senate/committee/clac_ctte/estimates/add_0001/ha_may01.pdf

The exact measure used is important as experience indicates that many patients do not use heroin after they have ceased taking their tablets, and the rates of opiate free success are typically higher than treatment retention.

Retention Rates Extremely Low

The graphs below are taken from pages 26 and 27 of the Monograph show the following retention rates for each treatment, with maintenance therapies averaging retention rates of 44% against Naltrexone averaging just 4%. These results are amongst the lowest ever recorded amongst 57 Medline studies addressing retention rates (see next pages) which averaged 34% retained at the 6 month mark.

Figure 1: Retention of *Heroin Users* in maintenance treatments (methadone, buprenorphine and LAAM)

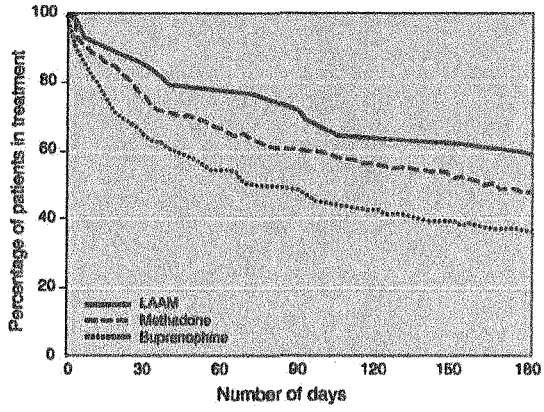
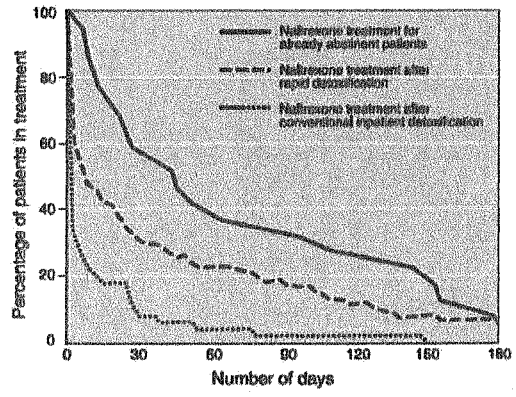


Figure 2: Retention of *Heroin Users* in naltrexone treatments



Opiate-Free Outcomes

With only 8 of 283 Naltrexone trial participants remaining at the 6 month mark, any measure of success regarding drug free outcomes is well below the average 52% drug free outcomes for the 37 Medline articles reporting 6 and 12 month outcomes. A summary table is printed subsequently. While the Cochrane collaboration has criticised many of the Naltrexone studies for not being rigorous enough, the sharp disparities with NEPOD outcomes are remarkable, when judged as both retention rates and opiate free success. Comparisons of retention rates between NEPOD and journal studies are not open to criticism – retention rates are not a complex science.

Invalid Conduct of Naltrexone Trials

The conduct of these Naltrexone trials was so far from satisfactory that it can almost be said that accepted best practice standards were assiduously avoided throughout. For example it is well established in the literature that (1) psycho-social support is mandatory with Naltrexone. This mandatory support was deliberately absent from the NEPOD studies, effectively invalidating the trials. Furthermore it is important that (2) physicians using this treatment have some commitment to it. Such was notably absent from the NEPOD trials with all of the major investigators having publicly expressed disdain for the abstinent or drug free lifestyle. Not that they can be blamed for this – after 20 years of dispensing methadone and seeing largely poor outcomes, it is highly likely that the industry is as addicted to methadone as its patients. Nevertheless the study clearly lacked any kind of in-principal commitment to it which is so vital

to treatment outcomes. Indeed one of the lead investigators, James Bell has recently patented a buprenorphine implant, so actually had a conflict of interest with naltrexone and a significant vested interest in treatment failure. Another very important drawback was (3) the ubiquitous failure to involve carers and responsible adults in the care of the trials' patients. Hence the naltrexone was not given under supervision at any site which has long been identified as an important component of treatment in the literature. These shortcomings are best appreciated by briefly reviewing the individual trials separately.

Specific Comments in Relation to the Naltrexone trials.

1. The largest trial (159 patients) was conducted in Brisbane under the leadership of John Saunders. This trial did not use carers to supervise naltrexone. It also gave oral naltrexone to methadone patients, a practice which has now been discontinued around the country and was associated with an unacceptable rate of brain and kidney damage scored by the triallists as "persisting encephalopathy" and refractory back pain.
2. The second largest trial (150 patients) was conducted in Sydney by Dr John Currie. As an experienced practitioner who had long been involved in the area and was genuinely sympathetic to it he produced very good results with 63% OFS at 6 months. Perhaps unsurprisingly NEPOD was disposed **NOT** to include these results in their overall outcomes, with Currie reporting that disagreement was over his more rigorous 'naltrexone challenge' test, far more effective in testing any self-report of abstinence than the standard NEPOD urine tests. Indeed it is worth presenting a key outcome table from his results in some detail.

Percentages of patients who were non-dependent* on opiates at each follow-up

Type of Patient	Treatment (number of patients)	1 Week	3 Months	6 Months
Heroin Users	Anaesthesia (10)	100%	60%	50%
	Sedation (22)	100%	64%	55%
Methadone Patients	Anaesthesia (32)	100%	66%	62%
	Sedation (43)	98%	69%	71%

Note: * = Patients who dropped out were counted as "dependent" on opioids.

3. Ali in Adelaide[1] conducted a sizeable study with 101 registrants. He used an untried induction procedure in actively opiate abusing patients with no preparatory period of withdrawal. Only 14 of the 48 subjects randomised to rapid detox were even administered any naltrexone at all. Those experiencing any difficulty were simply given methadone. Notwithstanding this obviously novice experience, 8 of these were still taking the tablet at three months, compared to only 1 of those detoxified conventionally through the hospital ward. Such is the learning curve when one tries to re-invent the wheel.
4. Jason White in Canberra studied 17 patients – just enough to begin to learn on.
5. The most awful study of all was performed by James Bell in Sydney. He took 20 patients and gave them oral naltrexone; 20 patients and gave them one **hundredth** of a normal dose, and 20 patients and administered one **thousandth** of a dose. Quite surprisingly the study reported that this approach did not work notwithstanding that 8 of the 20 patients given the 50mg naltrexone dose were abstinent at 6 months (40%; Figure 2)[2]. Furthermore 8 patients transferred voluntarily to the 50mg group. Richard Mattick, present director of NDARC was a co-author of this paper with Bell. As mentioned Bell was also developing a patented buprenorphine implant of his own at the time so he can

hardly be said to be unbiased. Two suicides occurred in this study. Interestingly this work apparently took 3 years to appear in print, an unusually long time, doubtless related to its unsafe design. Given that this unusual trial of highly questionable ethical probity was, as acknowledged in the title of the report a trial of "low dose naltrexone", it was formally erroneous of the NEPOD triallists to include it in a supposed unbiased examination of the efficacy of oral naltrexone therapy as that treatment is commonly understood.

Other inadequacies of the NEPOD naltrexone fiasco were:

1. No carer system used
2. Tablets not administered in crushed up form
3. No antidepressants given
4. Insufficient rehab and social support used
5. Minimal networking with community support agencies to improve social functioning
6. No assistance with housing
7. Re-treatments were not counted towards the success of the program, but rather were counted as failed primary treatments; this is in contrast to the practice in all the serious naltrexone clinics
8. Early referral of patients to alternative treatments when physicians more experienced with naltrexone would likely have found alternative ways to proceed.
9. Follow-up was admittedly incomplete and half hearted (as evidenced in the report). Drug Free Australia's practitioners' experience is that some naltrexone patients are able to quickly return to work. Hence the best way to follow them is with an after hours phone call. Little serious effort was made to follow up results assiduously; no after hours phone calls were made to residences, and social networks were not utilised to track down and follow-up patients; given that this is a highly mobile population simply sending letters to their last known address would hardly appear adequate; This was clearly not done
10. Studies reported dominantly naltrexone retention rather than opiate free success. The former is known to lag significantly behind the latter. One's view of the success of one's work therefore relies heavily on the outcome measure utilised. It is possible to change the results dramatically simply by changing the form of outcome measurement.
11. Systematic biases were in place in favour of methadone. When the results were reported at APSAD and MCDS in 2001 one patient was noted to have died in the methadone group with a brain tumour. This death was excluded from consideration in the published version of their results[3].

In this series, much of the poor results can be directly attributed to failure to adhere to accepted best practice in the field, and the feeling that the NEPOD system was heavily geared against any positive outcome even when they did exist (Bell 50mg and Currie), let alone the obvious misnomer and clear conflict of interest of Bell and Mattick in the low dose trial which was erroneously pooled with the overall results.

Clearly the performance of NEPOD with its 4% success rate including unsafe trials, authors who had major commercial conflicts of interest, and suicides in grossly undertreated patients was well below the mean. They can be shown to have eschewed accepted best practice in every respect, and their reporting gives every indication that this behaviour was both informed and deliberate.

Conclusion

In this context the abysmal performance of oral naltrexone at the hands of these supposed "experts" requires serious explanation, more so when their actions give every indication that there behaviour was deliberate. Drug Free Australia finds the conclusion that the addiction establishment in this country deliberately misled the Australian community - at the cost of $7 million when they only admitted to 1.3 million before a Senate estimates committee - placed lives and brains at risk, and defied accepted best clinical practice when world expert opinion and practice was available in this nation at the time, unavoidable. Clearly this conduct, which, in that it was undertaken by a publicly funded closed consortium of experts, was structurally collusional in nature, is difficult if not impossible to excuse.

Having said that it bears repeating that best clinical practice in this area has now moved on from this debate in that the world's best and longest lasting naltrexone implants are available in Australia from Perth and are being actively sought after by clinicians and researchers alike across the world, the overtly defamatory and unethical behaviour of the Australian addiction industry notwithstanding. They represent so great a quantum leap in both clinical success and patients' safety that this debate can now pass into the archives of history. Of great concern to us however is that the deliberate and publicly funded subterfuge which it crystallised and the attitudes and biases which it exposed remain and continue to inform Governments of individual jurisdictions, the Commonwealth, and the MCDS (Ministerial Council On Drug Strategy) at every level into Australia's future.

Hopefully through efforts such as those of Drug Free Australia today, such trends and entrenched cultures of deception and outright mockery, all in the name of overt drug liberalisation, will begin to be dismantled. We are constrained by our consciences and the wellbeing of our most vulnerable communities to do our very best for our children, our grandchildren and the Australia of tomorrow. The horrendous costs of surrender to the holocaust of drug liberalisation, so recently documented in Switzerland, UK, Netherlands and elsewhere must be resisted if tomorrow's generation is to have the same rights to health, happiness and freedom as we and our parents have enjoyed. The decision and the responsibility ladies and gentlemen, rests with you.

NOTE: This summary of NEPOD irregularities by Dr Stuart Reece, DFA Fellow.

Table 7.: NALTREXONE RETENTION - RAW DATA TABLE FROM 57 STUDIES

SOURCE	AUTHOR	YEAR	NATION	N	*1 MONTH* RETENTION RATE	*N*	*N-TOT*	*3 MONTH*	*N*	*N-TOT*	*6 MONTH*	*N*	*N-TOT*	*12 MONTH*	*N*	*N-TOT*
Y	ANTON	1981	USA	65	60%	39	65	38%	25	65	12%	8	65			
Y	ANTON	1981	USA	25	92%	23	25	60%	15	25	30%	8	25			
Y	AZATIAN	1994		27	1%	1	27									
Y	BELL	1999	AUSTRALIA	30	58%	18	31	20%	6	30						
R ; B	CALLAHAN	1980		167				50%	84	167						
O,Y	CAPONE	1986		50	98%	49	50	60%	30	50	34%	17	50	2%	1	30
O	CIBIN	1989		46							52%	24	46			
O	COCCOLI	1993		342										13%	46	342
Y	CORNISH	1997	USA	34	74%	25	34	62%	21	34	52%	18	34			
O	CURRAN	1976	USA	19							11%	2	19			
Y	CUCCHIA	1998	SWITZERLAND	20	42%	8	20	34%	7	20	20%	4	20			
O,Y	FOY	1998	AUSTRALIA	32	63%	20	32	44%	14	32	34%	11	32	34%	11	32
O,Y	GARCIA-ALONSO	1989	SPAIN	150	72%	108	150	58%	87	150	40%	60	150			
Y	GOLD	1984	USA	15				71%	11	15	73%	11	15			
Y	GOLD	1984	USA	114							61%	70	114			
O	GREENSTEIN	1976	USA	142	41%	41	142							5%	7	142
Y	GREENSTEIN	1984	USA	327							62%	203	327			
Y	GREENSTEIN	1981	USA	242	62%	150	242	23%	56	242	8%	19	242			
Y	GREY	1984	USA	30				15%	5	30						
Y	GREY	1984	USA	30				27%	8	30						
O, R	GUTIERREZ	1995		123	75%	92	123	50%	62	213	30%	37	123	15%	18	123
O	HAAS	1976		32							32%	3	32			
Y	HOLLISTER	1977		73	47%	34	73				14%	10	73			
Y	HOLLISTER	1978		94	60%	56	94	43%	40	94	23%	22	94			
Y	HULSE	1999	AUSTRALIA	100				47%	44	94	31%	29	94			
Y	JUDSON	1984	USA	40										10%	4	40
G	JUDSON	1981	USA	119	44%	52	119	12%	14	119	6%	7	119			
Y	KLEBER	1984		160	80%	128	160	65%	104	160	48%	77	160			
O	LADEWIG	1990		15	93%	14	15									

O	LERNER	1972		15	60%	9	15									
O	LERNER	1972		15										53%	8	15
O	LEWIS	1978	USA	22	27%	6	22									
R ; B	LEWIS	1978		20	50%	10	20									
R ; B, N, O	LING	1984	USA	60				71%	43	60	53%	32	60			
R ; B - Y	NAS	1976	USA	192	48%	92	192	28%	54	192	20%	38	192	12%	23	192
RE	NIDA	1976	USA	883				35%	309	883						
N	NIDA	1976	USA	665	60%	399	665									
O	NOWAK	1993	USA	28							25%	7	28			
R ; B	NRCCCENA	1978	USA	60	60%	36	60	42%	25	60	20%	12	60	8%	5	60
Y	O'BRIEN	1975	USA	54	37%	20	54	15%	8	54	2%	1	54			
O	O'BRIEN	1978	USA	201	40%	80	201									
N	OCHOA	1992	SPAIN	50							52%	26	50			
N	OCHOA	1993	SPAIN	657							60%	394	657			
Y	OSBORN	1986	USA	30				27%	8	30						
Y	PRESTON	1999	USA	58	46%	27	58	26%	15	58						
Y	RABINOWITZ	1997	ISRAEL	83	90%	75	83	56%	46	83	29%	24	83			
O	RAWSON	1979	USA	43										42%	18	43
O	RAWSON	1984A	USA	43												
O	RAWSON	1984B	USA	12	50%	6	12									
O,Y	ROTH	1997	USA	20	100%	20	20	80%	16	20	65%	13	20	20%	4	20
Y	SCHECTER	1975	USA	51	49%	25	51	12%	6	51	2%	1	51			
O,Y	SCHIFANO	1990	ITALY	84							7%	6	84			
Y	SCHUFMAN	1994	ISRAEL	16	75%	12	16	57%	9	16				8%	1	16
O	SIDEROFF	1978		19				47%	9	19	11%	2	19			
O,Y	TENNANT	1984	USA	160	29%	47	160	17%	27	160						
O,Y	WASHTON	1984	USA	15							73%	11	15	73%	11	15
O,Y	WASHTON / GOLD	1984	USA	114							61%	70	114			
					1 MONTH			**3 MONTH**			**6 MONTH**			**12 MONTH**		
	NO. SERIES	55			%	N-EXP	N-TOT	%	N-EXP	N-TOT	%	N-EXP	N-TOT	%	N-EXP	N-TOT
	TOTALS			6333		1723	3031		1207	3256		1276	3321		158	1090
	SIMPLE MEANS				59%			42%			34%			23%		
	CALCULATED MEAN				57%			37%			38%			14%		

TABLE 7.:

OPIATE FREE SUCCESS INDUCED BY NALTREXONE AT SELECTED TIME POINTS – 37 STUDIES

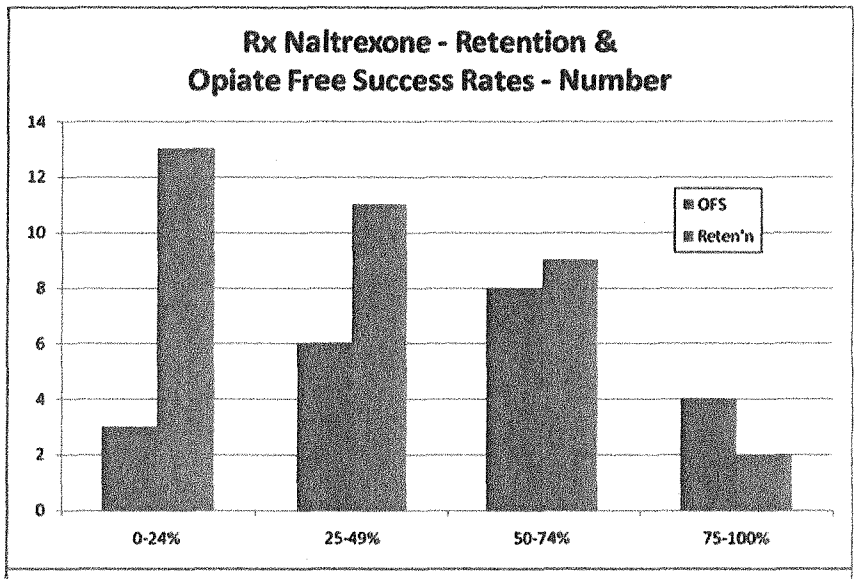
						1 MONTH	*N*	*N-TOT*	*3 MONTH*	*N*	*N-TOT*	*6 MONTH*	*N*	*N-TOT*	*12 MONTH*	*N*	*N-TOT*
SOURCE	AUTHOR	YR	NATION	N	R/S	SUCCESS RATE											
Y	BELL	1999	AUSTRALIA	30	S				37%	11	30						
Y	BREWER	1997	EGYPT	25	S				96%	24	25						
O,Y	CHAN	1996	SINGAPORE	180	S										77%	139	180
Y	CUCCHIA	1998	SWITZERLAND	20	S							40%	8	20			
O,Y	FOY	1998	AUSTRALIA	32	S	53%	17	32	41%	13	32	28%	9	32	31%	10	32
Y	GERRA	1995	ITALY	100	S	97%	97	100	91%	91	100						
Y	GERRA	2000	ITALY	32	S							53%	17	32			
Y	GOLD	1984	USA	15	S							87%	13	15			
Y	GOLD	1984	USA	114	S							82%	93	114	64%	73	114
Y	GREENSTEIN	1984	USA	89	S							32%	28	89			
Y	GREENSTEIN	1984	USA	65	S							32%	21	65			
Y	GREENSTEIN	1984	USA	81	S										33%	27	81
O,Y	GREENSTEIN	1984	USA	300	S	28%	16	58				45%	34	75			
Y	GREENSTEIN	1981	USA	65	S	42%	29	69				32%	21	65			
Y	HULSE	1999	AUSTRALIA	100	S							60%	56	98			
O	JUDSON	1984	USA	117	S										64%	75	117
Y	JUDSON	1984	USA	40	S										35%	14	40
Y	LANDABASO	1998	SPAIN	112	S	89%	100	112	73%	82	112	61%	80	112	42%	47	112
	LERNER	1992	ISRAEL	15	S							71%	11	15	54%	8	15
Y	LERNER	1997	ISRAEL	72	S							61%	44				
	LEWIS	1978	USA	10	S				13%	1	10						
O	LEWIS	1978	USA	22	S										58%	41	22
Y	MAREMMANI	1995	ITALY	25	S	88%	22	25	80%	20	25	68%	17	25			
Y	NETO	1997	PORTUGAL	44	S	98%	43	44	77%	34	44	61%	27	44	57%	25	44
Y	OCHOA	1992	SPAIN	365	S	85%	310	365	75%	274	365	52%	190	365	16%	58	365

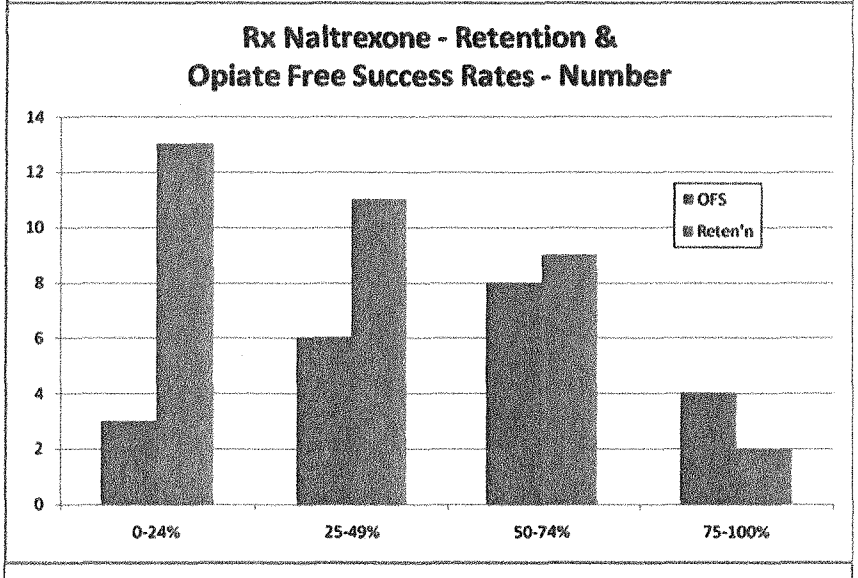
Y	OSBORN	1986	USA	30	S				13%	4	30						
Y	RABINOWITZ	1997	ISRAEL	83	S										57%	47	83
Y	RAWSON	1984	USA	45	S										76%	28	37
Y	RESNICK	1978	USA	265	S							8%	22	265			
O,Y	RESNICK	1978	USA	81	S										33%	27	
O,Y	ROTH	1997	USA	20	S										94%	17	18
Y	SAN	1991	SPAIN	28	S							25%	7	28	14%	4	
O,Y	SCHIFANO	1990	ITALY	84	S							31%	26	84			
Y	SCHUFMAN	1994	ISRAEL	16	S	60%	10	16	37%	6	16						
Y	SEOANE	1997	SPAIN	300	S	93%	279	300									
O,Y	WASHTON / GOLD	1984	USA	114	S							82%	93	114	64%	73	114
O,Y	WASHTON / GOLD	1984	USA	15	S							87%	13	15	73%	11	15
						1 MONTH			3 MONTH			6 MONTH			12 MONTH		
	OPIATE FREE SUCCESS			37		%	N-EXP	N-TOT	%	N-EXP	N-TOT	%	N-EXP	N-TOT	%	N-EXP	N-TOT
	TOTALS						923	1121		560	789		830	1672		724	1389
	MEANS					73%			58%			52%			52%		
	CAL'C MEAN					82%			71%			50%			52%		
	MEDIAN					87%			73%			53%			57%		
	COUNT						10			11			21			18	

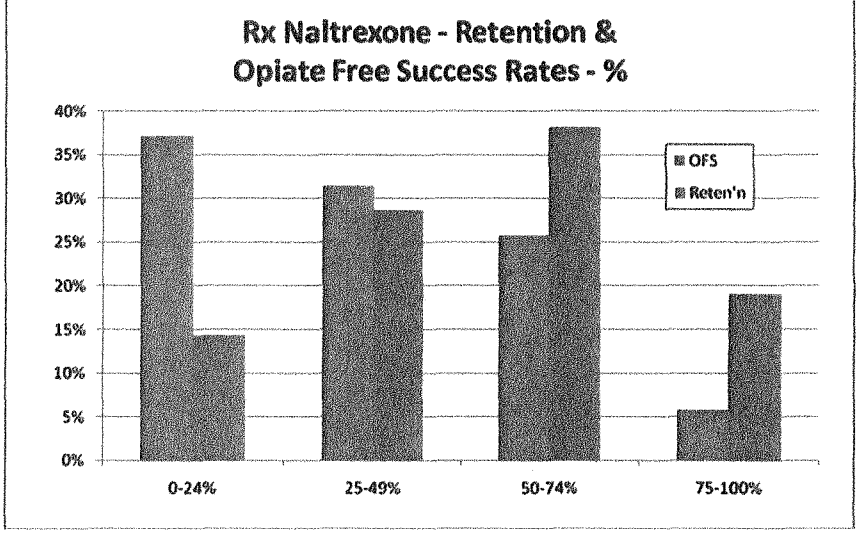
SOURCES:

Y – ORIGINAL PAPER
O – ORPHAN AUSTRALIA, COMPANY DOCUMENTS
N - NETO,
B - BRADFORD,
RA - RABINOWITZ,
G - GINZBURG,
RE - RESNICK 1984

The outcome results of the foregoing tables may be summarised by quartiles as shown.







Monograph 34 – SA Cannabis Decriminalisation

National Drug Strategy Monograph 34, "The social impacts of the cannabis expiation notice scheme in South Australia" gives various misleading and positive readings to negative data on the results of cannabis decriminalisation in South Australia.

Higher Criminal Convictions Glossed

The stated and highly publicised purpose of decriminalisation was to reduce the touted 'harms' to self-esteem and employability that come from a criminal conviction for possession or use of cannabis. Thus decreased criminal convictions would be the clear measure of success for such a legislated change. Despite this Monograph clearly recording that criminal convictions had *actually increased*, with around 2,000 more criminal convictions per year by 1993 than before the decriminalisation measures were introduced in 1987, the import of this most significant failure of drug policy is glossed by the authors as at least leading to lower policing costs surrounding these increased convictions.

Similar Glossing of 'Legal' Perceptions of Cannabis

No comment is drawn from the authors regarding what suggests a major drug policy failure, the fact that 50% of people fined for use or possession of cannabis complained that they thought the substance was now legal. The authors record on page 26 without any evidence of concern about the deterrent failure of cannabis decriminalisation:

> Many of the respondents had erroneous beliefs concerning the law and cannabis. Around one half thought that private use was legal, while one third believed that possession of cannabis (100 grams or less) was also legal.

Because those who have opposed decriminalisation have seen it as a tacit drug legalisation stepping-stone, an independent researcher would surely recommend that more study into the public understanding of decriminalisation needs to be pursued to determine whether this 'legal' perception of cannabis is real, or merely a mitigating excuse to escape penalty.

False Judgment on Rising Cannabis Use

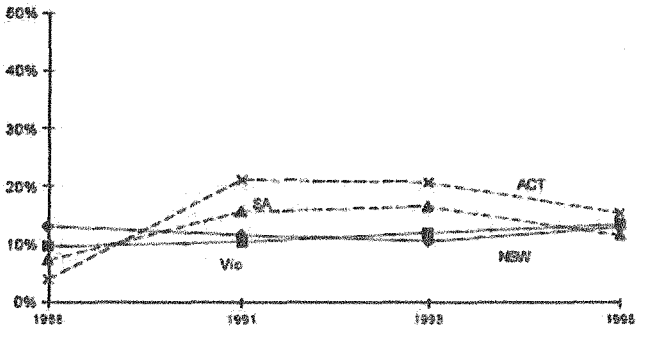
On page viii of the Executive Summary the authors declare that increases in cannabis use for South Australia, as recorded in national population surveys after decriminalisation, are not likely the result of the decriminalisation measures, citing selectively from the data. Graphs from Monograph 31 p 53 (below) reveal substantial rises in Last 12 Month Prevalence as well as Last Month Prevalence in South Australia, which makes their dismissal of this data highly questionable.

The fact that similar rises in the ACT from negligible levels to extremely high levels of cannabis use during the period of ACT's activism and legislative discussions surrounding decriminalisation in that Territory suggests that the rises are the result of decriminalisation. Similar rises in Tasmania do not necessarily negate the thesis, as claimed, that decriminalisation was the most efficient cause for these increases in SA and ACT. Different causes in Tasmania may well have been at play (eg student activism etc etc) which merely need to be sought and identified.

Associated claims in other papers by researchers Christie and Ali[2], that cannabis use did not rise in the United States after decriminalisation, are entirely false. Alaska's legalisation measures led to such high levels of teen cannabis use that they reversed their legislation in 1992. Following decriminalisation in California in 1975 the increase in marijuana use was an enormous 15% for the 18-29 age-group within a 10 month period, a level that if matched by similar rises in tobacco use would horrify the public. Adult use of marijuana rose 7%.[3] In Oregon, after its 1973 decriminalisation of cannabis, use in the 18-29 age group increased by 12% immediately after the change, matched by a rise of 6% in the overall population. In 1974 46% of 18-29 year olds stated that they had ever used drugs while in 1976 it had risen sharply to 62%.[4] These increases are further contrasted with the US National figures from the Household surveys which showed no appreciable increase during the years of these two studies.

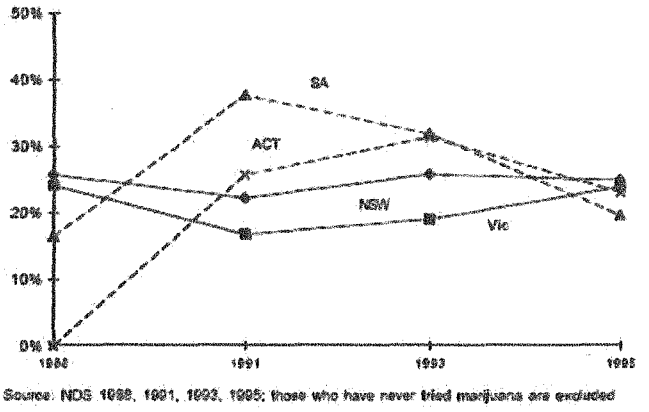
In all, Monograph 34 has the appearance of being an apologetic for drug law reform than being a balanced and dispassionate assessment of the decriminalisation measures.

Figure 4.1: Used in the past 12 months for four jurisdictions



Source: NDS 1988, 1991, 1993, 1995

Figure 4.2: Use marijuana monthly or more often for four jurisdictions, 1988–1996



Source: NDS 1988, 1991, 1993, 1995; those who have never tried marijuana are excluded

[2] Single E, Christie P and Ali R; "The impact of cannabis decriminalisation in Australia and the United States" JPHP 21,2 (2000) pp 157-186

[3] See Cuskey Berger and Richardson (1978) Contemporary Drug Problems 7(4) 491-532

[4] See Cuskey Berger and Richardson (1978) Contemporary Drug Problems 7(4) 491-532 and also Maloff D. (1981) Contemporary Drug Problems 10(3) 307-322

Sydney Injecting Room Evaluation - NDARC

The Kings Cross Medically Supervised Injecting Centre (MSIC) opened on May 6 2001, 6 months after Australia was hit by the heroin drought which continues today. The first 18 months of its operation were evaluated by a team of researchers, mostly drawn from the National Drug and Alcohol Research Centre at New South Wales University. Three of the five evaluators of the injecting room were colleagues in the same NSW University medical faculty as Dr Ingrid Van Beek, Medical Director of the injecting room, making questionable the independence of the evaluation.

The injecting room evaluation gathers excellent data but is characterised by silences, exclusions and failures to conclude from the evidence on those very flashpoints of operational failure which would have led to the closure of the injecting room if properly recorded and reported.

The evident failings of the evaluation were:

1. **Failure to evaluate low utilisation rates by clients**

   The NSW government had been told by injecting room agitators that every injection by a heroin user could be their last, but injecting room clients averaged only 2 – 3 visits per month. This drew no comment or interest from the evaluators. Nor did utilisation rates whereby the injecting room was running at only half its capacity for daily injections after 18 months draw any comment. Any responsible evaluation would question these rates.

2. **Operational considerations and trial design precluded client mortality studies**

   No mortality studies of injecting room clients were pursued to evaluate how many of the injecting room clients had died of heroin overdose since using the injecting room – a highly relevant question. The NEPOD study, run by the same NDARC research centre, studied mortality registers with extreme care, particularly for participants who had been on Naltrexone, but the injecting room argument that asking MSIC registrants to give their name would discourage use of the facility was accepted despite the needs of rigorous evaluation. This lack of mortality data leaves major questions on the effectiveness of this intervention, particularly as no calculation can be done against estimates of lives saved.

3. **Failure by the evaluators to make comparisons re high rates of overdose**

   The evaluation team did indeed note that the overdose rates in the injecting room were high, but failed to compare these rates with other known rates of overdose. This is the most basic of epidemiological comparisons. Drug Free Australia's analysis of the injecting room evaluation nominated four separate comparisons which revealed rates of overdose between 30 and 49 times higher than other estimated rates of overdose.

   If the evaluators had done these necessary comparisons, serious questions would have been raised about the reasons for use of the injecting room. The evaluators themselves supposed that the high overdose rate was due to a more at-risk clientele using the room (which Drug Free Australia has demonstrated not to be true) or alternately because clients were experimenting with higher doses of heroin. The latter explanation implies that the injecting room is aiding the local drug trade, which if announced by the evaluators in the

pages of their evaluation would have certainly led to the closure of the centre. But there was no such comment.

4. **Improper calculations of lives saved**

   The evaluation estimate of 6 lives saved during the 18 month evaluation period was based entirely on the uninterrogated number of heroin overdoses in the room. Using the actual Kings Cross mortality data which was indeed recorded in the MSIC evaluation, the number of lives saved by the injecting room was 0.18 lives in the first 18 months, a figure reinforced by two other methods of calculation.
   a. application of Australian overdose mortality percentages – 0.21 lives saved
   b. adjustment for MSIC high overdose rates – 0.18 lives saved

   The low benefit for high cost ratio thus obtained, if declared, would likely have led to the closure of the facility.

5. **Agnostic honey-pot conclusion contradicting clear evidence**

   The injecting room evaluators returned a finding that there was no evident honey-pot effect of drug dealers being drawn to the doors of the facility despite clear evidence by police which stated that "while other factors, such as police operations, would have contributed to the increase in loitering outside the train station, *there was a notable correlation between the loitering and the MSIC opening times.*"

6. **Failure to compare existing data on decreased public amenity**

   While the MSIC evaluation did indeed report that the heroin drought was responsible for lower numbers of needles being found on the street as well as decreased sightings of public injection, it failed to compare its own published data on the percentage decrease in needle supply in the Kings Cross area in comparison to observed discarded needle and syringe counts in the area. When this comparison is done it is clear that public amenity grew worse, even when the heroin drought is accounted for which is a less comforting scenario than the woolly finding of the evaluation team re public amenity.

7. **Failure to question early injecting room publicity on lives saved**

   Throughout the evaluation period the injecting room and its supporters continued to publicise the fallacy that every overdose intervention in the injecting room equated to a life saved. In fact only 1 in every 25 overdoses is fatal, as is correctly noted by the evaluators, however they failed to criticise those media reports which were influential in increasing public support for the facility.

In summary, the injecting room evaluation failed to calculate important data, or draw valid and required conclusions particularly in those areas where the negative result would have caused such concern for government and the public that closure of the room would have been inevitable.

Return on Investment Report - 2002

In 2002 the Federal Department of Health and Ageing received the report titled "Return on Investment in Needle & Syringe Programs in Australia", which claimed that Australia had saved between $2.4 billion and $7.7 billion via their $122 million investment in needle exchange programs between 1991 and 2000.

Table 2 Net Present Value of Investment in NSPs for HIV and HCV combined.

Discount Rate	Net Present Value, 1991 ($million, Year 2000 Prices)	
	Govt Expenditure	All Expenditure
	Lifetime Costs of Treatment	
5%	$2,402	$2,386
3%	$3,653	$3,637
0%	$7,678	$7,658

The methodologically flawed ecological study compared HIV prevalence in 103 cities with needle exchange against 67 cities without, and HCV prevalence in 60 cities with needle exchange against 40 cities without. Cities with NSP indicated a mean annual decrease in HIV prevalence of 18.6% against an increase of 8.1% for cities without and the differential was used to calculate government savings when applied to Australia. Similar calculations were done on HCV prevalence.

The report makes much of the fact that Australia has less than 2% of its intravenous drug users (IDU) who have contracted HIV. But the thesis is quickly falsified by comparing the prevalence of HCV, which is mostly contracted via shared use of needles by IDU.

Prevalence of HIV in Australian IDU	<2%
Prevalence of HCV in Australian IDU	>70%

The same intervention which has failed to halt Australia's HCV epidemic, with up to 16,000 new cases per year of which 91% are IDU, is credited with the success of halting an HIV epidemic in the very same population of IDU over the very same period. This is logically absurd.

At fault is the ecological study design which assumes a homogeneity of intervention or non-intervention across cities studied, when in fact there is great heterogeneity, with many different confounders not accounted for in such a meta-analytical approach. For instance, the Grim Reaper campaign may have been chiefly responsible for Australia's low rates of HIV, moreso than the needle exchanges which have failed to stop the HCV epidemic.

But ecological studies, too large to assess or calculate the impact of confounders, assume an homogeneity of result across all studies which does not accord with reality. The World Health Organization, in its publication BASIC EPIDEMIOLOGY (1994) stated : "Although easy to conduct and thus attractive, ecological studies are often difficult to interpret since it is seldom possible to examine directly the various potential explanations for findings."

WHO Report - Effectiveness of Needle Programs

In 2004, Australia's Dr Alex Wodak co-produced a paper for the World Health Organisation titled, "Effectiveness of Sterile Needle and Syringe Programming in Reducing HIV/AIDS Among Injecting Drug Users"[5] The claim of the paper was that the effectiveness of needle and syringe programs had been demonstrated in the majority of relevant studies.

In December 2005, Dr Wodak presented the results of this study to the Geneva meeting of the prestigious US Institute of Medicine, only to be followed by Sweden's Dr Kerstin Kall who had studied the same journal studies as those cited by Dr Wodak. Dr Kall demonstrated that Wodak's study was substantially flawed in favour of the success of needle programs, which, when corrected, showed no advantage by these programs at all.

Tables recorded in the Wodak report at pages 35 and 36 indicate 6 studies in favour of the success of needle programs in reducing HIV, with 3 negative and two indeterminate. However Kall corrected Wodak's table of page 35, saying that the Monterosso study was, on its own stated conclusions, indeterminate rather than positive. Further, the inclusion of the study by Heimer et al, also listed as positive, was invalid because it did not measure HIV prevalence among IDUs but only in returned needles, which can not be directly translated into a population. Finally, the study by Ljundberg et al, which Wodak cited as positive, ignores the author's own point that comparisons between Lund (with needle exchange) and Stockholm (where prevalence was 50% amongst IDU between 1983 and 1985 without needle exchange, but with an incidence of just 1% by the time of this study, achieved without needle exchange) mark the study as inconclusive.

Kall's testimony to the US Institute of Medicine led to it changing its stance in its 2006 summary of conclusions on needle programs from one that had previously been positive to one that stated that "Evidence regarding the effect on HIV incidence is limited and inconclusive."[6]

[5] http://www.who.int/hiv/pub/prev_care/en/effectivenesssterileneedle.pdf
[6] http://www.diversityrx.org/ccconf/06/Mitchell.pdf

Conclusion

Drug Free Australia, assisted by Fellows who are academics, epidemiologists, psychologists and medical practitioners, has uncovered major irregularities in some of the most prominent research studies amongst the vast literature on drug policy and illicit drug interventions produced by various of Australia's drug experts, studies almost entirely done with State and Federal government funding.

Of greatest concern are the irregularities which are consistently in favour of the demonstration of harm minimisation or drug law reform 'successes', but when these irregularities are corrected, such successes are anything but evident.

If evidence-based science is being manipulated to support rather more shaky ideological stances in this country, the damage done to individual drug users and their families is perhaps incalculable. The failure of some Australian drug experts to deliver even-handed and unbiased results from their studies may have yielded much death and grief that Australia, as the worst drug abusing country in the developed world with some of the highest drug mortality rates, could have avoided.

[1] McGregor C., Ali R., White J.M., Thomas P., Gowing L. "A comparison of antagonist precipitate withdrawal under anaesthesia to standard inpatient withdrawal as a precursor to maintenance naltrexone treatment in heroin users: outcomes at 6 and 12 months." Drug Alcohol Depend. 2002; 68: 5-14.
[2] Rea F., Bell J.R., Young M.R., Mattick R.P. "A randomised controlled trial of low dose naltrexone for the treatment of opioid dependence." Drug Alcohol Depend. 2004; 75: 79-88.
[3] Digiusto E, Shakeshaft A, Ritter A, O'Brien S, Mattick RP; The NEPOD Research Group "Serious adverse events in the Australian National Evaluation of Pharmacotherapies for Opioid Dependence (NEPOD)." Addiction 2004; 99 (4): 450-460.