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Personal submission

Dear Ann,

Re: National Pharmaceutical Drug Misuse Strategy

Thankyou for the opportunity to provide a personal submission

I acknowledge that it is a difficult task to devise reasonable public policy in this area. In this submission I outline some of my concerns about what could eventuate in the governments' response to a National Pharmaceutical Drug Misuse Strategy.

My particular concerns centre on the rights accorded to people suffering from chronic pain, especially their rights to treatment. My perspective is that of physician treating patients in outer and inner city areas and as a consultant physician assisting general practitioners, specialists and health services in regional rural NSW – for patients attending public clinics and a clinic for the homeless.

It is too easy to think that stronger legislation and law enforcement will fix the problem. On the contrary the problem is likely to worsen if this should happen. The issue has to be understood in the context of the changing epidemiology of chronic pain which, for many reasons, is increasing in prevalence; secondly that these problems are associated with profound co-morbidities in mental and physical health (prevalence also increasing, again for many reasons); thirdly that current systems of health care neglect/avoid these complexities and, finally; that primary health care doctors, nurses and others feel disempowered by the complexities of the problems and the legislation which controls access to pain medicines.

About two years ago I took up these issues with the NSW Department of Health, in particular, the way the provisions of the NSW Poisons and Therapeutic Substances Act were being administered and, indeed, the Act itself. (See attachment) Although I have not looked into this, I suspect that legislation and procedures in other states have similar problems.

My concerns in taking this matter up were about the rights of patients with complex disorders associated with pain and the dilemmas created for front-line practitioners in the current arrangements in the administration of the Poisons Act in NSW.

- **The Act:** in the long-term this needs review. As noted in the attached paper it does not specify the objectives for controlling access to medications for pain. It should more closely align with legislation in the alcohol and drug and mental health areas.
- **Policy directions:** the policies governing the role of Pharmaceutical Services Branch should be more closely aligned with responsibilities of the Department of Health for mental health, alcohol and other drugs and suicide risk.
- **Administrative issues:** the processes for authorisation of the prescription of opiates (and other substances) should be decentralised to a regional (Area Health Service) level. At a central level the role should be monitoring, policy development, research and investigation. Greater use should be made of modern information technology.
- **Medical committee:** the role of the medical committee in its current configuration should be regarded more as a technical advisory committee. It should be replaced by processes more akin to the role of the Mental Health Tribunal or similar bodies; that may be more readily organised at a local level.
- **Rights and ethical issues:** the rights of patients and the ethical issues faced by practitioners should be elevated in the decision-making process and the proper concerns of front-line practitioners acknowledged and acted upon.
- **Education and support:** the Department of Health should put more effort into engagement with and support of front-line practitioners. There needs to be recognition that health services are not a 'flat playing field'. Access to support services are not available in certain health service areas and the populations differ in the level of social disadvantage and their ability to access specialised services such as pain and addiction services, let alone primary health care.

Opioids in pain management: dependence and addiction

In clinical practice and legislation it is important to separate two different but confused problems, namely dependence and addiction (dependence in this context is tolerance to a drug and withdrawal symptoms on cessation). These issues are confused in the NSW legislation and widely confused in the public mind as well as among health service providers.

Dependence occurs with all substances that affect neurotransmitters whether they are dopamine agonists, anti-cholinergics, GABA blockers and the like. It occurs in the treatment of Parkinson's disease, movement disorders and dystonias and a range of other conditions including psychiatric disorders. Some call this biological dependence. Thus dependence on a drug is not confined to the opioids or the 'psycho-active' substances.

Addiction, on the other hand, is a problem of a 'reward system' which has gone "haywire". These people need addiction programmes.

The likelihood that a chronic pain patient will become 'addicted' to opioids is estimated to be quite high in some epidemiological studies and others put it at about 5+%. The differences are probably due the populations being sampled. In my clinical experience the risk of addiction is low in the treatment of pain with opioid analgesics. When addiction occurs in pain management, it must be dealt with, but it is essential that addiction should not be the main preoccupation when treating people who are experiencing unremitting pain.

Just as important, is that people in addiction treatment programmes should not be denied proper investigation and management of chronic pain, as chronic pain is common in this group. The rates of chronic pain in methadone maintained patients are of the order of 50%,

excluding episodes of acute pain. Indeed patients are not infrequently admitted to a methadone programme to treat their chronic pain. Amongst disadvantaged population groups, alcohol and cannabis are commonly used to blot out continuing pain or at least to make it bearable and this can also lead on to unsanctioned use of opioids.

The general clinical experience (practice-based evidence) is that opiates can help with chronic pain but they will never be the panacea for an essentially intractable problem. In my experience, if a drug is not helping in chronic pain, especially an opioid, the patient is the first to say they want to stop the medication. There is, I am afraid, a pervasive myth that people use these drugs because they like them; most people don't.

Front-line doctors, nurses and others are expected to help patients with chronic pain and this will continue into the future as a matter of necessity, especially as there are so few specialist options for treatment; pain clinics are simply unavailable for the majority of people and are unlikely ever to be the answer.

The problem of getting access to treatment for pain is a global issue. There is an international initiative for the *UN Commission on Human Rights* to recognise the treatment of pain as a human right, and the *International Narcotics Control Board* said, in March 2011, that 80% of the world's people have insufficient access to pain relief and are suffering unnecessarily because of it.

Diversions of pharmaceutical opioids

The other issue is diversion. (See [attachment](#))

The problem of diversion lies in the domain of social welfare and cultural/social factors related to community wellbeing. It is not a medical or health care problem *per se*. Why is there an increased demand for mind-altering substances? It is the paradox of western countries that increasing wealth and consumer goods are associated with increasing prevalence rates of anxiety, insecurity and depression; the US being the worst in this respect and Australia not far behind. Chronic pain is also increasing but different factors are responsible for this.

Prescribing doctors can't do much about this situation, but there is inadequate access to pain treatment and addiction management programmes especially for those living in socially disadvantaged and rural areas.

The point I wish to emphasise, is that in dealing with diversion we must not expect health care professionals to become police officers or undercover agents. If controls/regulations are to be used this should be the responsibility of an agency(s) external to the doctor-nurse-psychologist-patient relationship.

In my opinion, we in Australia should be cautious about looking to the US for solutions. The US approach to drugs and drug treatment is markedly different from Australia's and for a large proportion of the US population access to treatment is limited or non-existent.

The issues covered above are dealt with in more detail in the [attachment](#).

I wish you and your colleagues well in undertaking this reference.

With best wishes.

Attachment

Commentary: Poisons and Therapeutic Substances Act and the Pharmaceutical Services Branch

The problem of chronic pain

Chronic pain due to non-malignant disease is ubiquitous and has a high prevalence rate as shown by studies in Australia and overseas. The UK Chief Medical Officer Sir Liam Donaldson recently made statements about this problem and the need for more pain services.¹

Chronic pain can be of great severity to the point where people wish to end their lives and at the extreme end contemplate and/or seek euthanasia. Chronic pain due to malignancy is treated more compassionately and effectively. There are better services available for patients with cancer pain, namely, palliative care.

The Medical Journal of Australia published a paper on the extent and cost of chronic back pain in May 2009 which argued that back pain should be one of the national health priorities.² There have been studies from the RNSH Pain Research Unit on the costs and prevalence of chronic pain and other studies. For example, an Australian study in 2002 reported that up to 20 per cent of the population suffer from chronic pain which is strongly associated with social disadvantage.³

Up until fairly recently most medical thinking about chronic pain has focused on end organ damage and its treatment. But recent research and conceptualisation focuses on two competing paradigms (there are others). One is that the problem is locally generated and due to structural abnormalities and/or changes in peripheral nervous system's sensitivity to both non-noxious and noxious stimuli. The other approach is that there are problems in the centrally organised neurobiological processes primarily located in the thalamus, the limbic system and somatosensory cortical areas. It is at this level that the dysphoric states such as anxiety and depression are so closely linked with the experience of pain.

The management of chronic pain requires more thoughtful and different relationships with the patient experiencing pain than is commonly available. Pain like mental disturbances and other subjective experiences such as anxiety and sense perceptions are not measurable or observable in a physical objective manner.

¹ Thousands 'left in pain' due to shortage of specialist clinics, Gaby Hinsliff, Political Editor, The Observer, Saturday 14th March 2009

² Briggs A and Buchbinder R. Back pain: A National Health Priority Area in Australia? Medical Journal of Australia 2009;190 (9), 499-502.

³ Blyth FM, March LM, Brnabic AJ M, Jorm LR, Williamson M, Cousins MJ. Chronic pain in Australia: a prevalence study *Pain* 2001; 89: 127-134.

The treatment of chronic pain is poor and the patients who suffer from pain are often marginalised in the same way as people with mental illness, but because they often require opiates, they are further marginalised and discriminated in the same way as people who suffer from addictions.

While there are debates about the links between the pharmacological/physiological dependence on a narcotic for the relief of chronic pain and that of addictive behaviour, and the degree to which they overlap, there is a difference between the ongoing need for relief of chronic pain and biological dependence on a drug, and the reward seeking behaviour of addiction. The estimates of the prevalence of addictive behaviour in persons receiving opioids for chronic pain are generally low - of the order of less than 5 per cent.⁴

Unfortunately this is not commonly appreciated and this lack of appreciation leads to the marginalisation of people with chronic pain and public policies which act against their interests.

General practitioners are the main resource

General practitioners are the largest group of health service providers treating and supporting people with chronic pain problems. Specialist pain clinics are few and far between and very difficult to access especially for those who depend on the public health system, namely, the poor and those who cannot afford private health insurance. Waiting lists in the public system pain clinics can be many months indeed years.

Furthermore, medical services generally, and pain clinics and addiction services in particular, are poorly funded and grossly deficient in outer urban areas and rural areas. Pain clinics, drug and alcohol clinics, and services for co-existing mental health and substance use disorders, are not a priority in the public health care system.

It is widely acknowledged that primary health care - general practice - is overburdened with clinical demands. Complex patients with multiple needs are extremely difficult to manage in these environments.

General practitioners, in my experience, are inadequately supported in managing patients with multiple needs especially by the medical system itself. In the case of patients with the problems of persisting pain, mental illness and substance abuse problems the support is extremely poor.

It would not be surprising therefore, that in dealing with the legislation and the regulations in New South Wales (and in other states) involved in seeking approval to prescribe opioid analgesics, that front-line doctors are reluctant to get involved and find the experience frustrating and disempowering.

The Poisons and Therapeutic Substances Act needs review

The Poisons and Therapeutic Substances Act was drafted a long time ago to control poisons. Included amongst the poisons are substances which are legitimate and effective

⁴ Fishbain DA, Cole B, Lewis J, Rosomoff HL and Rosomoff RS. What Percentage of Chronic Non-malignant Pain Patients Exposed to Chronic Opioid Analgesic Therapy Develop Abuse/Addiction and/or Aberrant Drug-Related Behaviours? A Structured Evidence-based Review, Pain Medicine, 2008; 9(4) 444-459.

agents for medical treatment. The opiates are a group of medications which effectively relieve pain and at one level can be life-saving and at another improve the quality of life of those with persistent pain and lessen their disablement.

The legislation which seeks to control the use of these and other substances does not in anyway describe the intended benefits of so doing nor the conditions under which these agents are beneficial and the reason for their therapeutic use.

Neither does the legislation speak to safety, health needs and outcomes or to the aspects of the use of opiates which are acceptable and appropriate; nor whether certain uses are regarded as more problematic than others.

The legislation refers to a "medical committee" which is small in size and has no parameters for its constitution or function. As presently constituted it appears to act as a decision-making body. Given the lines of authority in the Department of Health and the role of a Minister it may be more appropriate to describe this committee is a *technical advisory committee*.

Discussion below will refer to the appropriateness of the Medical Committee as a quasi decision-making body.

Communication from the PSB to practitioners

I have read many letters sent from the PSB to general practitioners and to me. They carry implied threats of sanctions if the practitioner does not or is unable to meet the requirements set out in the letters. There is a tone and presumption that the front-line doctor has not had regard to the issues and problems in prescribing opioid analgesics for patients.

In my experience this is an area in which medical practitioners are very careful and give much thought, and attempt to get advice, in managing patients with persisting pain. This level of medical care requires more than the evidence base (which is extremely limited and narrow in focus) but it does require judgement, tacit knowledge, dealing with ambiguity and the evolving narratives of the patient's experience.

The nature of the communications, in my opinion, reinforce the alienation of doctors from the bureaucratic processes with the perception that their professional skills are not respected or, indeed, trusted.

Commissioner Peter Garling's report into Acute Care Services highlighted the wider alienation and disenfranchisement of professionals in the public hospital system because of a breakdown in the respect for professional skills and commitment.⁵

Clinicians within the public health system

There are special issues for clinicians working in the public health system who are managing complex patients with pain and related problems.

Generally these clinicians work alongside peers in units which work collectively to deal with a range of defined problems such as chronic pain. With the problem of chronic pain the clinicians are responding to, or attempting to manage, problems/predicaments which are

⁵ Commissioner Peter Garling, Report of the Special Commission of Inquiry into Acute Care Services in NSW Public Hospitals, November, 2008.

already well established. In these circumstances it is the unit as a whole which should have the relationship with the body(s) authorising the use of particular medications as in the use of opioid analgesics for pain and methadone and buprenorphine for addiction.

The highest load of problematic patients occurs in services which are underfunded (compared with prestigious units and hospitals) and in an environment in which there are few parallel services and support staff. This is the case in the South West of Sydney and in the Shoalhaven where I work. I am sure this is the case in other outer urban and rural areas in NSW. The patients referred to these units are poor and very rarely can access private specialists; in particular - pain clinics, psychiatrists and private addiction units/specialists. Never-the-less these poorly funded units are often the last port of call for difficult clinical problems.

I believe that the PSB, as part of the Department of Health, has a special responsibility to engage with and support the clinicians working in these difficult circumstances; after all do they not share common interests and goals for patient care and public health?

Medical committee, micromanagement and the rights of patients (and clinicians)

The Medical Committee as presently constituted operates as a clinical decision committee.

Its decisions are based on inadequate information. It reviews applications made on a prescribed form. I believe that most doctors accompany the form with a letter of explanation about the case. The form is one page and does not allow for relevant information about the patient's problems, needs, progress and functional capacity to be included. Its language is outdated.

Patients with chronic pain share the characteristics of other patients with subjective health problems and disturbed behaviours. At the point of authorising the prescription of an opioid analgesic the principal issue of concern is addiction. Addiction is formally classified as a mental health condition.

In the assessment of mental illness under the Mental Health Act the rights of patients are protected by legislation – reviews of decisions, consent to treatment, presence of advocates, hearing of evidence from the person and others, judicial review and reviews by an independent tribunal.

In Social Security there is provision for appeals against decisions and presentation of evidence from other sources. The forms used are structured to provide the relevant information for administrative assessments to be made.

In the criminal justice system and the courts, judicial and Parole Board decision processes allow representation of the individual and for a range of evidence to be presented. More to the point, there are strong appeal processes.

The above measures are to protect the autonomy and rights of the individual.

No such right or processes of appeal exist in the procedures authorising a doctor to prescribe an opioid analgesic to a patient in just as difficult and as contested circumstances.

In my view the processes should allow at least for medical officers and relevant others to present the case for prescribing opioid analgesics for particular patients if they believe it is in

the interests of the patient to do so. Further, and more properly, the patient themselves should be able to do this. Decisions would then be on a sounder basis and the PSB and Medical Committee would not be involved in micromanaging cases for which they have little direct clinical responsibility or knowledge.

Inconsistent expectations

Doctors seeking approval to prescribe on behalf of their patients have no guidance apart from the brief form referred to above and occasional publications of evidence-based guidelines. The requirements of the PSB for input from doctors is unclear and in my knowledge often inconsistent.

Further the administrative responses are out of phase with the imperatives and timeliness of clinical decision-making. In other words doctors have to guess when approval may be provided and act hoping their actions will be approved and at other times knowing their actions may not be formally approved.

The least that should happen would be for the PSB and the Medical Committee to define the parameters to be met for prescriptions to be authorised.

Recommendation: The PSB and the Medical Committee in consultation with front-line clinicians, especially general practitioners, design a template for doctors requesting an authority to prescribe an opioid analgesic. In addition to the ‘physical pain and medical aspects’ this should include information about mental status, suicide risk and the capacity or otherwise for alternate approaches in that particular medical/social setting.

Competing clinical problems and ethical dilemmas

Commonly those affected by chronic pain have multiple needs. The physical illness and disablement is of its own sufficient to demand a broader clinical assessment and evaluation than is allowed by the current paper-based approach.

The special concern I have is in the ethics of managing people with co-existing mental health problems and in managing suicide risk in the processes currently in place.

Overlap with mental illness is the “norm” in these patients – most are depressed and almost all have considered ending their lives. I have had to deal with patients frequently who have outlined their plans for suicide. It is not enough in these circumstances to say that the patient needs psychiatric treatment. What they need is effective management of pain. Thus, on a number of occasions, I have felt that the restrictions on prescribing have contributed to the risk of suicide - placing the front-line clinician in an invidious position.

Chronic pain is a potent factor in suicide and it is a principal reason for requesting euthanasia.

Recommendation: The PSB re-examine its policies and practices in relation to government policy and professional practice for co-existing mental health and substance use problems and in assessing and managing suicide risk. The management of this programme should be more closely aligned with mental health and alcohol and drug problems.

Decentralisation – a plan for assessments, approval and follow-up

Those in the best position to make decisions about the management of patients are those who know the local services - their range and capacity. Assessments and decision-making made at a local level would be more collaborative and relevant to the local scene and are more likely to be accepted and supported by clinicians. The decisions would be based on knowledge, respect and trust.

A possible arrangement could be for a senior/respected clinician say Director of D&A, Director of Pain Medicine, or Director of Psychiatry, or experienced General Practitioner to chair an advisory group involving relevant regional specialists and general practice representatives, a legal person and an independent respected community member and/or patient advocate.

In such an arrangement the PSB, centrally, would be involved in monitoring and overseeing and in organising investigations of problematic patterns of prescribing. There would also be the possibility for the PSB officers to undertake epidemiologic studies relevant to the problems of pain, the patterns of opiate use and to investigate issues of diversion.

Such an arrangement would enhance administrative efficiency and I believe improve effectiveness. In my opinion such collaborative and educative approaches would do more to lessen the trafficking of opioids and other substances than increasing emphasis on controls and sanctions.