Consultation: Prescription strong (Schedule 8) opioid use and misuse in Australia – options for a regulatory response

Thank you for the opportunity to contribute to this examination of prescription opioid use and misuse in Australia and potential options for a regulatory response to the issues identified.

In 2014 our twenty five year old son died suddenly and unexpectedly from an overdose which involved the opioid fentanyl.

We found out from the coroner's investigation into our son's death that the long list of drugs prescribed to him by his GP was inappropriate and often contradictory. This clearly demonstrates that we have the investigative, analytical and regulatory system the wrong way round. We need to prevent these tragedies from occurring and in the process achieve better health outcomes and stop the country sliding into the level of attrition experienced by America.

Things cannot continue the way they are. Urgent measures must be taken to prevent further deaths from schedule 8 opioids. I have more than thirty years working in public health including working with General Practitioners, Preventive and Community Health and Health Policy. Please take serious note of our recommendations which are informed by personal experience and a professional view.

1. Limit the prescription of schedule 8 drugs to specialists with the appropriate knowledge and expertise to prevent or minimise risks associated with tolerance, addiction, concurrent use with other drugs, self medication and misuse.
2. Ensure the provision of 24 hour evidence based advice and mandated education to specialist prescribers.
3. Implement a nationwide specialist schedule 8 opioid service with the remit and authority to implement urgent, comprehensive and long term measures to stop the increase in harms and deaths associated with opioid drugs.
   This should include gathering data, monitoring emerging trends, providing 24 hour advice to specialist providers, research and evidence about efficacy, alternative treatments and issues surrounding concurrent use with other prescribed drugs - including benzodiazepines and pathways to and from other drugs including illicit drugs.

Our son suffered back pain and his GP had trialled a number of other pain medications before prescribing fentanyl to him eight days before his death. We still struggle to understand why he had been prescribed this schedule 8 drug for a condition that we as parents, did not consider to be 'chronic'. When we later spoke to our son's GP he appeared surprised at our concern that he had prescribed this serious medication. He indicated that it was widely used and had little regard for our concerns about its appropriacy or safety.

Our son also had a history of anxiety and depression. Over time he had been prescribed a number of medications including benzodiazepines, also noted as present in the toxicology report. As parents we had become very concerned about our son's increasing reliance on stronger and more addictive medications and lack of alternatives offered by his treating GP and psychiatrist.

From the outset, our son researched other ways to help or heal himself. He continued his efforts to study, developed his own physical activity and nutrition regimes, learned to play the guitar, and explored paid and unpaid work opportunities. Over time, his research included understanding the side effects and tolerance levels of his prescribed medications. Latterly, we discovered his research had extended to illicit drugs – in particular where there have been studies of their application to treat anxiety, or reduce the limiting effects of this condition.

The coroner found that our son was struggling to deal with a combination of physical pain and severe anxiety. She noted both fentanyl and benzodiazepines as medications that should be closely monitored by the prescribing doctor. She went on to question the GP's decision to prescribe dual benzodiazepine therapy with fentanyl to a patient who was at risk of substance abuse. The coroner also noted that the prescription of multiple drugs that had the potential for addiction should have been an alert to GP to

closely monitor drug use and compliance. This clearly did not occur. Inadequate history and note taking by the GP were also noted, suggesting that inadequate levels of care had been provided.

We have become increasingly alarmed with the growing trends towards the use, dependence on and role of prescribed schedule 8 opioids in the record levels of tragic overdose and untimely deaths besetting Australia - particularly in light of the lack of evidence for their efficacy or safety in treating chronic or non-cancer pain. Also of concern is the less publicised US trend towards concurrent benzodiazepine/ opioid use. Nearly 30% of fatal "opioid" overdoses also involved benzodiazepines. According to the British Medical Journal[1] the incidence of concurrent benzodiazepines/opioids use increased by roughly 80% from 2001 to 2013, which significantly contributed to the overall population risk of opioid overdose.

Any regulatory action taken towards addressing opioid use and misuse in Australia must be part of a broader strategy that has a public health and not a criminal justice perspective. This should incorporate mandatory education for prescribing practitioners in order to minimise inappropriate or unsafe prescribing practices; alternative options and treatment for patients who have become dependent; and *non-stigmatising* awareness campaigns for the broader community. Awareness raising should include the appropriacy and efficacy of opioids; the warning signs of addiction and the role of and access to Naloxone in reversing opioid overdose. Care should be taken to ensure that any response is monitored carefully for unintended consequences, for example with regards to access to or uptake of other licit or illicit drugs.

Learnings from the United States must be critically monitored and utilised if Australia is to avoid further devastating effects of this public health tragedy.

We are happy for the committee to receive this privileged information but request that it is maintained and used with anonymity for personal and family reasons.

We support the following potential options outlined in the consultation paper:

Option 2: Consider a review of the indications for strong (S8) opioids.

- We support a review of the current indications for strong opioid products and their alignment to clinical guidelines for the appropriate use of these products. This must include;
    - A review of PBS advice on opioids to accommodate evidence that now clearly indicates that opioids are not working in patients who experience chronic and severe musculoskeletal pain;
    - A requirement for better diagnosis or evidence prior to the prescription of opioids to eliminate inappropriate diagnosis where misuse may be the patient goal; and
    - The consideration of other medications that have been prescribed to avoid the very real risks associated with concurrent benzodiazepine/opioid use.

Option 3: Consider whether the highest dose products should remain on the market, or be restricted to specialist/ authority prescribing.

- We support specialist only / authority prescribing to minimise harm from escalating dosage and dependence and to ensure greater consideration of other treatment options for pain whilst minimising use for non chronic pain where there is limited evidence for efficacy.
- We support a reflection of the US Centre for Disease Control and Prevention 2016 guidelines on opioid prescribing – with an emphasis on the need to carefully justify why the medication and dose is needed – in order to ensure prescribing practice that considers the higher risks of addiction or overdose from these products.
- We agree wholeheartedly that fentanyl is an issue of concern owing to its strength and heightened risks related to its shorter time to overdose. We strongly urge that its continued use outside of cancer related pain relief be seriously considered. The PBS and TGA guidelines relating to this drug should be changed to reflect current lack of evidence for its efficacy in treating chronic non-cancer pain.

[1] http://www.bmj.com/content/356/bmj.j760

- Our son's GP indicated that fentanyl was commonly used - as if this was a valid reason to prescribe it. He appeared to have no awareness of current evidence about its limited efficacy for chronic pain. We maintain that GPs are time poor and *generalists* by profession. Prescription of drugs such as this should be by specialists with the appropriate knowledge, experience and access to specialist advice.

Option 4: Strengthening of Risk Management Plans for opioid products

- We support a mandated Risk Evaluation and Mitigation Strategy for opioids similar to that used in the US with a focus on health care professional education and training. This should include mandatory and regular Continuing Medical Education for those who prescribe opioids in order to ensure awareness of current and emerging evidence, trends and risks including:
  - Greater emphasis on the risks of tolerance, potential for addiction, dependence, escalation of dosage, self medication, misuse and related psychosocial factors;
  - Risks of concurrent benzodiazepines/opioids use;
  - Trends in overdose and death related to opioids ;
  - Evidence of associated harms that would indicate need for a different approach in intervention;
  - Pathways to and from illicit drugs;
  - Risk management and the use of and access to naloxone similar to the approach by Health Canada which allows naloxone to be provided proactively to those who might experience or witness an opioid overdose;
  - Alternative pain management/treatments; and
  - Importance and examples of exit strategies for opioid use (and other schedule 8 drugs).
- Prescribing practitioners must have a *current* understanding of the evidence for efficacy, risks and mitigation strategies for schedule 8 opioids for their patients – including with regards to concurrent use with other medications, and issues surrounding tolerance, and the potential for addiction or escalation to or relationship with illicit drugs.
- The internet provides ready access to advice about how to convince your GP that you need prescribed pain medications such as opioids – practitioners should be aware of this.
- Prescription of schedule 8 opioids must be carefully considered and justified by appropriate examinations, full patient history and consideration of interaction with all other drugs used by the patient and complete record taking of decisions.

Option 5: Review of label warnings and revision to Consumer Medicines Information

- We support the placement of warnings on the packaging of opioid products that identify the risk of dependence and overdose and their lack of efficacy in the long term treatment of chronic non-cancer pain. Additional warnings should also form part of the manufacturers' packaging.
- This would help to reduce inappropriate prescribing and reinforce messages about the serious risks of these medications both for the patient and for the person prescribing and the pharmacist supplying them.
- Carers and family members may also be alerted to the risks with the opportunity for increased awareness and observation of potential signs of addiction and / or overdose.

Option 6: Consider incentives for expedited TGA review of improved products for pain relief and opioid antidotes

- We support the TGA implementation of measures that relate to the approved circumstances in which the medicine can be prescribed, the pack sizes available, and ensuring comprehensive information in the Product Information and Consumer Medicines Information regarding the risk of dependence, addiction and the potential for misuse or abuse.
- We also support the expedited formulation of new antidotes that allow carers to administer them more simply.
- This should be supported by a considered approach to awareness and education strategies to ensure maximum reach and uptake by people who may be in a situation to intervene in an opioid overdose.

Option 7: Potential changes to use of appendices in the Poisons Standard to provide additional regulatory controls for strong S8 opioids

- We support limiting prescribing of S8 opioids to certain medical practitioners (such as palliative care physicians for high-dose opioids in patients with cancer pain and specialist pain medicine physicians for high-dose opioids in patients with chronic non-cancer pain), allowing access for ongoing prescribing for GPs in remote areas – with additional education and awareness re risks etc as above.
- This should be supported by mandatory education for health professionals reflecting the approach taken by the US FDA and ensuring greater medical practitioner awareness of current best practice in prescribing of opioids.
- Consideration should be made to reflecting this in an annex to the Poisons Standard in Australia.
- ➢ Opioid medications are products with serious risks attached to their use. This should be reflected in product regulation rather than clinical practice.

Option 8: Increase health professional awareness of alternatives to opioids (both S4 and S8 opioids) in the management of chronic pain

- We support mandatory prescriber education for all health practitioners who are able to prescribe controlled substances
- We support the option to extend health professional awareness of and access to existing clinical guidelines for the management of acute and chronic pain and advice on the use of non-pharmacological and alternate pharmacological therapies for the management of pain.
- We support a review of Tramadol as a schedule 8 drug. This should be accompanied by careful monitoring of current trends with regards to its role in overdose, tolerance and / or escalation to schedule 8 drugs with regards to the potential for a shift towards Tramadol if opioids become less accessible.
- We agree that PBS restrictions can cause a prescribing physician to critically reflect on choice of medicine and support options to better manage opioid prescribing through the PBS. The requirement for a specialist review prior to prescription, narrowing the group of approved prescribers and requiring a telephone authority is critical
- ➢ The establishment of a nationwide specialist schedule 8 opioid service with the remit and authority to implement comprehensive measures to prevent harms associated with opioid medications would provide national consistency to an evidence based approach. This would reduce the costs of ambulance services, intensive care and coroner's reports that are associated with the tragic consequences of overdose and deaths by prescription opioids.
- ➢ We support a collaborative approach - however the bias and clear conflict of interest of the pharmaceutical industry should be avoided. The approach taken to this industry should reflect the learnings from tobacco control and the proven misrepresentation provided by the tobacco industry.

Other identified issues

Any steps taken towards real-time prescription monitoring should;

- be refocused towards helping doctors and pharmacists identify patients who are at risk of harm due to dependency and less on doctor shopping and diversion of medicines;
- include monitoring of multiple prescriptions and other drugs including benzodiazepines that are commonly associated with deaths, overdose, dependence, increased tolerance and/or self-medication.

Kind regards

[redacted]