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WORKERS COMPENSATION & SELF INSURANCE

The Opioid Crisis in America

What Does it Mean for Australia?

By John Walsh

In 1952 the Sackler family bought a small company and transformed it into Purdue Pharma which, over the decades since, became an American pharmaceutical giant largely on the back of one drug, the opioid painkiller Oxycontin.

Fast forward to September 2019 and the company filed for Chapter 11 bankruptcy in an attempt to resolve more than 2,600 federal and state lawsuits initiated by American cities, counties and states that blame Purdue for igniting the US opioids crisis.

New York and other states have asserted that Oxycontin, and opioids developed, distributed and sold by other companies, have caused the deaths of nearly 400,000 people from mid 1990 to date and continues to kill at least 130 people a day from overdoses across America, not to mention the effect of addiction on an indeterminate number of survivors. The suits assert that addiction is responsible for decades of public health crisis and the depletion of governmental resources.

How did it come to this?

Normally when a new drug is introduced into society, it starts with big cities and gradually spreads to the regions. But the opioid epidemic took a different route. The epidemic commenced in isolated "rust belt" counties inhabited by working class families traditionally dependent upon jobs in high risk industries like coal mining, logging and steel milling. Oxycontin was introduced into these regions in the mid-90's and then crept quietly across America from predominantly rural areas to the cities and suburbs over a decade or more.

The epidemic was stealthy and went largely undetected until Princeton researchers in 2015 revealed an analysis that mortality rates among white Americans had quietly risen a half percent annually between 1999 and 2013, while mid-life mortality fell in other affluent countries. The Washington Post, in quoting one of the researchers, reported that:

> *"Half a million people are dead who should not be dead."*

The increase was blamed upon suicides, alcohol-related liver disease and **drug poisonings – predominantly opioids**. At about the same time, a Kaiser Family Foundation poll showed that 56% of Americans knew someone who abused, was addicted to or died from an overdose of opioids.

What is Oxycontin? Oxycontin is an extended-release high-potency preparation of the synthetic opioid, Oxycodone. Oxycodone does not occur naturally but can be synthesised from an inactive compound found in opium poppies.

Oxycodone is an opioid that had been developed by German scientists in the early 1900's. Oxycodone was inexpensive to produce and was already used in other drugs blended with aspirin and similar.

During the 1980s Purdue had great success with an innovative painkiller called MS Contin, a morphine pill with a patented "controlled release" formula. The drug was absorbed slowly from the bowel, entering the bloodstream over several hours.

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MS Contin went on to become the biggest seller in Purdue's history to that time. By the late 80's the patent for MS Contin was about to expire and Purdue executives started looking for a drug to replace it.

Purdue developed a pill of pure oxycodone with a time release formula similar to that of MS Contin and produced it in various doses, including one whose potency far exceeded that of any prescription opioid on the market. One author (Barry Meier) wrote in "*Painkiller"* that "*In terms of narcotic fire power, Oxycontin was a nuclear weapon".*

How Did Oxycontin move into the mainstream? Initially Oxycontin was prescribed in limited circumstances for severe short-term pain associated with surgery or cancer or other end of life ailments. Oxycontin was hailed as a medical breakthrough and thought to be safe because of the patented delayed absorption mechanism which gave long-lasting relief from moderate to severe pain. Purdue, funded research and paid doctors as part of a marketing campaign to change the prescribing habits of doctors generally by making the case that already known opioid addiction concerns were overstated and Oxycontin could safely treat a wide range of illnesses.

In a happy coincidence for Purdue, about the time that the company was developing Oxycontin, some American physicians began to speak out about the problem of untreated chronic pain and the wisdom of using opioids to treat it. Soon Purdue embarked upon a sales campaign targeting physicians who were not pain specialists to prescribe Oxycontin for longer lasting pain caused by arthritis, back pain, sports injuries and fibromyalgia. Over time Purdue paid several thousand clinicians to attend medical conferences and pain management seminars. The company advertised in medical journals, produced promotional videos which included testimonials from pain specialists and sponsored websites about chronic pain.

Within five years of its introduction, Oxycontin is said to have generated a billion dollars a year for Purdue.

Amazingly, the Food & Drug Administration approved Oxycontin in 1995 for use in treating moderate to severe pain and even approved a package insert for Oxycontin which announced that the drug was **safer** than rival painkillers because the delayed-absorption mechanism "*is believed to reduce the abuse liability*". What was not widely known at that time was that the people in rural and regional areas, like Maine and Appalachia, were abusing the drug. People in those areas found out that if you ground the pills up and snorted them, or dissolved them in liquid and injected them, you could override the time-release mechanism and deliver a huge narcotic payload all at once. In fact, even just chewing the tablet in the mouth for a minute before swallowing it allowed very rapid absorption.

As more and more doctors prescribed Oxycontin, more and more people began selling their pills on the black market. The more it was prescribed, the more Oxycontin was abused and wherever the drug spread, addiction followed. Primary and secondary evidence indicated that up to 30% of prescribed opioids were "diverted".

In some cities, crime syndicates set up systems where a driver would collect a "pain patient" from home, drive them to the doctor's appointment, take the patient and script to a pharmacy, collect the script, take the patient back home and pay them cash for the script. The syndicate would also book the next doctor's appointment.

Purdue pinpointed communities where there was a lot of poverty and a lack of education and opportunity. In particular, they were looking at numbers that showed people who had workrelated injuries went to the doctor more often to get treatment for pain. When it first introduced Oxycontin, the company created a program that encouraged doctors to issue coupons for a free initial prescription. Purdue used Information Medical Statistics ("I.M.S") data to target those populations that were susceptible to its product. During the four year life of the program, some 34,000 coupons had been redeemed.

Keith Cicero and Matthew Ellis, who studied opioid abuse at Washington University in St Louis, argued that the epidemic is rooted in two events. The first was the introduction of Oxycontin but the second was a 2001 report on pain treatment from the joint commission accreditation of health care organisations.

As Cicero and Ellis write:

> "*The change in pain treatment ushered in by the joint commission report lead to an increase in the number of opioid prescriptions in the US, and the increase in prescriptions for this particular high dose opioid*

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helped to introduce an unprecedented amount of prescription drugs into the marketplace, generating the whole new population of opioid users".

In recent years it is said that American clinicians have issued about a quarter of a billion opioid prescriptions annually and in 2016 in Ohio, a state particularly hard hit by the epidemic, 2.3 million residents – roughly 1 in 5 people in the state – received a prescription for opioids.

What are the consequences of the opioid epidemic?

The most obvious consequence of the epidemic is that serious opioid overdoses have vastly increased and it is estimated that more American citizens die every week from opioid overdose than are killed in motor vehicle accidents.

The US National Institute on Drug Abuse ("NIDA") have recently published statistics asserting that more than 20% of people who are prescribed opioids for chronic pain will misuse them and a significant proportion eventually go on to use heroin. A little known consequence is that many of those addicted themselves become pushers of illegal drugs to feed their habits.

So what is the relevance of this to Australia?

Gradually the epidemic in America became recognised as a public health crisis and although Purdue responded with slick and deceptive marketing, from about 2002 lawsuits started to emerge from people who had become addicted to Oxycontin after receiving a doctor's prescription. Like tobacco companies, Purdue responded aggressively, but clearly their time has come. Nevertheless, like the tobacco companies, Purdue sought to look abroad for new markets. Purdue moved into Canada and England and in more recent times a related company has moved into Australasia, Latin America and the Middle East with the same previously successful marketing approach.

The opioid epidemic is now also very much occurring in Australia. In September 2019 the Australian Bureau of Statistics noted that:

> *"Opioids accounted for just over 3 deaths per day in 2018. The majority of these opioid-induced fatalities were unintentional overdoses in middle-aged males involved in the use of pharmaceutical opioids, often in the presence of other substances."*

The Bureau went on to note that:

> *"Pharmaceutical opioids are present in over 70% of opioid-induced deaths. The rate of opioid-induced deaths with synthetic opioids present has increased significantly over the last decade."*

It was also noted that "*there were 438 heroin-induced deaths in 2018. This is the highest number of heroin-induced deaths since the year 2000, with the increase being significant over the last five years.*"

The American experience, according to one author (Sam Quinones) in his book "Dreamland: The True Tale of America's Opiate Epidemic", asserts that heroin dealers from Mexico fanned out across the US to supply a burgeoning market of people who had been primed by pill addiction and a team of economists has, after surveying a cohort of people who entered treatment for Oxycontin abuse, found that a third had switched to other drugs, and of those 70% had turned to heroin. It can reasonably be expected that those results are replicated in Australia.

The Bureau of Statistics also point out that:

> *"Pharmaceutical opioids are the most common opioid present in suicidal overdose. Of the 179 opioid-induced suicide deaths, close to 80% had a natural or semi-synthetic opioid present. The natural and semi-synthetic opioids, which include Oxycodone, were the most common prescription opioids present."*

What is my interest?

As a lawyer who practices extensively in the workers compensation jurisdiction, I have noted and particularly since the introduction of the category of "seriously injured worker", introduced by the *Return to Work Act 2014* that secondary impairments resulting from opioid ingestion have emerged and become clear. Those secondary impairments include constipation, gastric reflux, dry mouth and reduced sexual potency, as well as upper and lower digestive disorders and poor dental health because opioids reduce saliva flow. Dental caries may be caused or exacerbated by extended treatment with opioids unless very good dental hygiene practices and regular

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reviews by a dental surgeon are adopted. The cumulative impact of these costs upon compensation authorities must be huge.

US research professor Dr Gary Franklin from the University of Washington tells us that his research has revealed that being prescribed just 7 or more days of an opioid medication within six weeks of sustaining a work injury doubled a worker's chances of being incapacitated a year later.

Becoming dependent on opioid medication clearly posed a significant barrier for recovery, as these workers become "*more and more disabled in the workers comp system*".

Professor Franklin postulates that traditionally workers compensation authorities and insurance companies have not invested in more effective evidence-based treatments such as intensive rehabilitation because it has been cheaper to pay for the pills!

Professor Franklin argues that workers compensation authorities pay for all injured workers treatments and are therefore in a position to require effective pain treatments rather than those that harm workers.

The National Wastewater Drug Monitoring Program has found both Oxycodone and Fentanyl use across SA is on the rise. A separate study of regularly injecting drug users has found Oxycodone is becoming more available on the streets around the nation. University of Adelaide opioid expert Professor Paul Rolan, told *The Advertiser* in November 2018 that opioid-based narcotics provided near instantaneous pain relief, but they cannot solve medical issues in the long term. "*These narcotics are very cheap, they only cost a couple of dollars per pill…meanwhile a physiotherapist appointment or a session with a psychologist can cost hundreds of dollars…it is now a matter of culture change, making it easier for patients to receive wider treatment.*"

In my view, Return to Work SA has both a financial and a moral incentive to take a stand and, in appropriate circumstances, refuse reimbursement for the cost of opioid medication where it is clearly inappropriate or associated with excessive use and which has caused significant harm and impairment.

There is a precedent for such action. Forty years ago, in personal injury litigation, Thermography was a common diagnostic aid. Dr D Thomas was, at the time, an enthusiastic advocate of the process, which he claimed enabled the physician to diagnose certain conditions by measuring the temperature in different parts of the body. Thermography was, however, expensive and its efficacy as a diagnostic tool unproven. Nevertheless, its use became common and widespread in personal injury litigation to diagnose "an injury" in circumstances where accepted conventional diagnostic tools and clinical examination were unable to provide a diagnosis. Quite simply, thermography as a diagnostic tool was open to abuse and, in the late 80's the Supreme Court and the Industrial Court largely put an end to the use of thermography in the compensation setting by making decisions that the expense of thermography was not a "reasonable expense" in accordance with the legislation which existed at the time.

Section 33 of the *Return to Work Act 2014* provides that:

> *"33 – **Medical Expenses***
>
> *(1) Subject to this section, a worker is entitled to be compensated for costs of services described in subsection (2) that are reasonably incurred by the worker in consequence of having suffered a work injury - …*
>
> *(2) (h) medicines and other material purchased on the prescription or recommendation of a health practitioner".*

It has long been recognised that the test to be applied in determining the reasonableness of a worker incurring an expense is that set out in *Metro Meat v Banjanovic*, in particular, it was said by King CJ in that case that:

> *"Generally speaking a worker who acts upon apparently reputable medical advice will be regarded as acting reasonably, even though the advice turns out to be incompetent."*

King CJ went on to qualify the statement above by saying that:

> "*But a worker who obstinately insists on undergoing diagnostics tests or unconventional treatment contrary to advice, or who opts for an unnecessarily expensive method of obtaining diagnosis or treatment, is*

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likely to be judged to have acted unreasonably. Each case must be decided upon its own circumstances and the test is the reasonableness of action of the particular worker in incurring the expense in the circumstances."

It has been said in that context that, differences of medical opinion about the efficacy of a drug are not determinative of the reasonableness of incurring the expense.

In my view it would be entirely reasonable and very appropriate to extend the qualification made by King CJ to treatments (in this case inappropriate long term prescription of opioid medication) which have the potential for deliberate misuse and diversion and actually harm individual workers.

Perhaps it is too much to ask for some creative judicial activism to depart from a long-established authority on the point? However, I believe that at least an attempt should be made which, if unsuccessful, can be used to lobby the government to amend the *Return to Work Act 2014* to provide a mechanism for compensating authorities to restrict inappropriate or excessive opioid prescription as has been championed by Dr Franklin.

There is, for example, very solid evidence that for the commonest of all the work related musculoskeletal conditions, low back pain, opioids are ineffective and are associated with a substantial risk of harm. Use of opioids in such a setting can rightly be determined to be reckless. Can such practice really be viewed as "apparently reputable"?

Section 33 (10) provides a potential mechanism by which Return to Work SA may take some control of the situation because it provides that:

"(10) If a treatment protocol or framework for the provision of services has been published by the Minister under this Section, costs for the provision of those services are only compensable where –

(a) the services are provided in accordance with the protocol or framework; or

(b) the provider of the services establishes, to the corporation's satisfaction, that services outside the terms of the protocol or framework are justified in the circumstances of the particular case."

In 2008 Guidelines were introduced by Drug & Alcohol Services SA and SA Health for South Australian General Practitioners in relation to opioid prescription in chronic pain conditions. We have learned much since 2008 and it should not be too big a task for Return to Work SA to develop a treatment protocol for the provision of opioid medication and to provide a standard to which individuals prescribing such medication and the workers to whom the prescriptions are provided are held to account.

Dr Franklin asserts that no amount of education and awareness programming will change the culture which has developed. In Washington State, the only thing that made a difference was withdrawal of the accreditation of some providers with the workers' comp authority.

Perhaps a treatment protocol and resistance by compensating authorities to payment of costs incurred which do not fit within the treatment protocol will be a step forward in changing the culture.

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