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The Use of Schedule-II and Schedule-III Opioids in the California Workers' Compensation System

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Background

The conventional therapy for pain can mean prescription of a group of analgesic medications known as opioids. Opioids can be natural, semi-synthetic or wholly synthetic. The naturally occurring opioids are derived from opium. Morphine and codeine are the only two of these naturally occurring opioids that relieve pain. Semi-synthetic opioids include hydromorphone, oxymorphone and oxycodone. Examples of wholly synthetic opioids include levorphanol, fentanyl, methadone, propoxyphene and meperidine.

In many cases opioids are considered controlled substances and are classified by the United States Drug Enforcement Administration either according to their addictive potential or based on historical factors. There are five levels, or schedules, of drugs that have addictive potential. In general, Schedule I is a list of drugs with the most addictive potential, and Schedule V is a list of the least addictive drugs. For example, among opioids, heroin is a Schedule I drug; fentanyl, hydromorphone, pure hydrocodone, pure codeine and morphine are classified as Schedule II drugs; and hydrocodone or codeine compounded with a non-steroidal anti-inflammatory drug such as acetaminophen are classified as Schedule III drugs.

Opioid medications reduce pain by binding to a variety of pain receptors in the central nervous system, including the brain and spinal cord, as well as to receptors in other parts of the body. Different types of opioids bind to different receptors causing various results in addition to the reduction of pain. Common side effects of opioid use include respiratory depression, nausea, constipation, vomiting, itching, euphoria, drug tolerance and addiction. Side effects generally increase with dose. Because responses to opioids can vary from person to person, and because development of tolerance can be addressed by changing the specific type of opioid, it is common for a physician to prescribe more than one analgesic or opioid during a course of treatment for any given individual. The existence of multiple opioid substances, each interacting with more than one receptor, makes opioid prescribing and management a challenge.

The Growing Use of Opioids

Changing attitudes towards pain and pain management have profoundly altered the way opioids are used for its treatment. These changes included difficulties early in the twentieth century convincing patients and physicians that opioids could be used for the treatment of pain without fear of censure; the realization that pain should be treated as a disease; the acceptance that opioids are useful for the treatment of acute and terminal cancer pain; and finally, during the last two decades of the century, the extension of opioid treatment to patients with chronic, nonterminal pain.[1]

This last phase, the use of opioids to treat chronic pain, is the most salient to the recent epidemic of opioid use and abuse. In 1986, Portenoy and Foley published a seminal report estimating addiction risk

[1] Opioids for Chronic Nonterminal Pain, Ballantyre, MD, FRCA, South Med J. 2009; 99(11):1245-1255

during chronic opioid treatment at approximately 5%.[2] This report triggered more widely accepted use of opioids in the treatment of chronic pain. Now, the widespread use of opioids to treat chronic pain is once again being scrutinized. However, it may be, even as Portenoy and Foley pointed out in 1986, that a carefully structured maintenance regimen may be the best course for preventing the emergence of problematic opioid-seeking behaviors. It follows that observed addiction rates are likely to be higher when practice deviates from the careful controlled approach recommended in published guidelines.[3,4,5]

Opioids in the California Workers' Compensation System

The use of opioids in the California worker' compensation system has become commonplace in the treatment of occupational injury. Exhibit 1 shows the growth in the percentage of payments for pharmaceuticals in the California workers' compensation system for Schedule II and III opioids.

Exhibit 1. Estimated Calendar Year Payments for Schedule-II and Schedule-II Pharmaceuticals

	Estimated Total Schedule-II & III Opioid Payments					
Calendar Year	% S-II[6]	% S-III[5]	Total S-II & S-II[5]	Est. Total S-II Paid ($M)	Est. Total S-III Paid ($M)	Est. Total S-II & III Paid ($M)
2002	4.2%	10.6%	14.8%	$16.6	$42.2	$58.8
2003	4.6%	10.5%	15.1%	$26.4	$61.0	$87.4
2004	6.6%	8.4%	15.0%	$39.8	$50.3	$90.1
2005	3.8%	9.6%	13.4%	$18.3	$46.6	$64.9
2006	4.1%	10.0%	14.1%	$19.1	$47.0	$66.1
2007	10.0%	11.3%	21.3%	$43.3	$49.1	$92.4
2008[4]	17.7%	10.0%	27.7%	$75.2	$42.6	$117.8
2009	18.9%	10.5%	29.4%	$80.6	$44.9	$125.5
2010	20.3%	10.4%	30.7%	$92.2	$47.1	$139.3
2011	19.6%	10.3%	29.9%	$90.3	$47.5	$137.8

During calendar year 2002, 14.8 percent of workers' compensation pharmacy payments were for Schedule II (4.2%) and Schedule III opioids (10.6%), more than doubling to 29.9 percent in 2011. Almost all of this increase was associated with Schedule II opioids that grew to 19.6% of all pharmacy dollars, a 369% increase from 2002. It is also worth noting that the spike in Schedule II opioid prescriptions began in 2007, coinciding with the changes to drug repackaging regulations.

[2] Portenoy, RK, Foley, KM, Chronic Use of Opioid Analgesics in Non-Malignant Pain; Report of 38 cases, Pain, 1986 May;25(2);171-86

[3] Ballantyne JC, Mao J. Opioid therapy for chronic pain. N Engl J Med 2003; 349:1943-1953

[4] Goiurlay DL, Heit HA, Almahrezi A. Universal precautions in pain medicine; a rational approach to the treatment of chronic pain. Pain Med 2005;6:107-112

[5] West JE. Aronoff G, Dahl JL, et al. Model guidelines for the use of controlled substances for the treatment of pain. A policy document of the federation of State Medical Boards of the United States Inc [Abstrct]. Euless, Federation of State medical Boards of the United States Inc, 1998.

[6] CWCI 2012

Exhibit 2 takes a more granular look at the specific drugs that accounted for the spike in Schedule II opioid prescriptions shown in Exhibit 1.

Exhibit 2. Estimated Payments for Schedule-II Opioids by Drug Type

	Calendar Year Payments ($M)									
Schedule II Opioids	**2002**	**2003**	**2004**	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**
Oxycodone	$11.9	$17.2	$20.5	$8.4	$8.4	$17.4	$35.2	$42.3	$48.9	$45.4
Morphine	$0.9	$1.7	$4.5	$2.8	$3.4	$6.8	$10.6	$10.5	$12.1	$11.7
Fentanyl	$3.0	$6.5	$13.4	$6.4	$6.7	$16.6	$24.0	$20.3	$19.5	$18.2
Methadone	$0.2	$0.2	$0.3	$0.2	$0.2	$0.3	$0.4	$0.4	$0.4	$0.3
Hydromorphone	$0.3	$0.3	$0.6	$0.2	$0.3	$0.8	$1.1	$1.2	$1.3	$1.9
Oxymorphone	$0.1	$0.1	$0.0	$0.0	$0.0	$1.0	$3.2	$5.0	$7.4	$8.7
Tapentadol								$0.4	$2.1	$3.7
Hydrocodone	$0.1	$0.1	$0.2	$0.1	$0.1	$0.2	$0.2	$0.1	$0.2	$0.1
Codeine	$0.0	$0.0		$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Other	$0.1	$0.2	$0.2	$0.1	$0.1	$0.3	$0.3	$0.4	$0.4	$0.4
Total Payments	$16.6	$26.4	$39.8	$18.3	$19.2	$43.3	$75.2	$80.6	$92.2	$90.3

The most frequently prescribed Schedule II opioid was oxycodone; often referred to by its brand name Oxycontin. In 2002, oxycodone represented almost 72 percent of all payments for Schedule II opioids in the California workers' compensation system. Although this percentage was reduced to 53% by calendar year 2010, the overall annual payments for oxycodone increased 311 percent from $11.9M in 2002 to $48.9M in 2010.

Other Schedule II opioids also took on a larger share of annual pharmaceutical payments during this 10 year period. Fentanyl, an opioid approximately 50 to 100 times as potent as morphine, showed the greatest increase in payments from $3.0M in 2002 to $19.5M in 2010; more than a six fold increase. Morphine (from $0.9 in 2002 to $12.1M in 2010) and Oxymorphone (from $0.1 in 2002 to $7.4M in 2010) also had substantial increases in usage and associated payments.

Exhibit 3 shows the specific drugs that account for the payments of Schedule III opioid prescriptions shown in Exhibit 1.

Exhibit 3. Estimated Payments for Schedule-III Opioids by Drug Type

	Calendar Year Payments ($M)									
Schedule III Opioids	**2002**	**2003**	**2004**	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**
Hydrocodone	$36.8	$54.4	$44.3	$41.4	$42.6	$45.0	$38.0	$39.9	$41.2	$41.2
Codeine	$4.6	$5.1	$4.1	$3.5	$3.1	$1.7	$1.1	$1.1	$1.0	$1.1
Other	$0.7	$1.5	$1.9	$1.7	$1.3	$2.5	$3.5	$3.9	$4.8	$5.2
Total Payments	$42.2	$61.0	$50.3	$46.6	$47.0	$49.1	$42.6	$44.9	$47.1	$47.5

Far and away, the most prolific Schedule III opioid prescribed to California injured workers is Hydrocodone; often referred to by its brand name Vicodin. Hydrocodone accounted for 87% of all Schedule III opioid payments in the California workers' compensation system in calendar year 2002 and still accounted for 87% of the payments in 2010. The dollars spent for Vicodin prescriptions and for Schedule III opioids overall remained consistent, at least relative to the growth in Schedule II opioid payments. Overall, payments for Schedule III opioids grew 11.6 percent from calendar year 2002 through 2010 ($42.2M in 2002 to $47.1M in 2010).

The Use of Schedule-II drugs in the Treatment of Occupational Injuries

Table 4 shows the top 10 injury categories in California workers' compensation for which Schedule II opioids are prescribed, noting the proportion of total Schedule II claims, Schedule II prescriptions, and Schedule II payments that fall into each diagnostic category[7].

Exhibit 4. Distribution of Claims, Schedule II Prescriptions and Schedule II payments by Diagnostic Category

Diagnostic Category	Pcnt of S-II Opioid Claims	Pcnt of S-II Opioid Scrips	Pcnt of S-II Opioid Payments
Medical Back w/o Spinal Cord Invlvmnt	**35.7%**	**47.1%**	**50.2%**
Spine Disorders w/ Spinal Cord or Root Invlvmnt	11.3%	15.1%	16.1%
Cranial & Peripheral Nerve Dis	5.0%	6.8%	6.5%
Degen, Infect & Metabol Joint Dis	9.3%	6.1%	5.4%
Other Injuries, Poisonings & Toxic Effects	**5.5%**	**5.9%**	**6.8%**
Ruptured Tendon, Tendonitis, Myositis & Bursitis	6.0%	3.6%	2.7%
Sprain of Shoulder, Arm, Knee or Lower Leg	**6.8%**	**3.2%**	**2.8%**
Wound, FX of Shoulder, Arm, Knee or Lower Leg	6.3%	2.7%	1.6%
Other Mental Disturb	**1.2%**	**1.7%**	**1.5%**
Other Diagnoses of Musculoskeletal Sys	**1.5%**	**1.4%**	**1.1%**
Percent of Cases Outside Evidence-based Medicine Recommendations	**51%**	**59%**	**62%**

The top 10 diagnostic groups accounted for 88.6 percent of all claims that had at least one Schedule II opioid prescription, 93.6 percent of the opioid prescriptions, and 94.7 percent of the total dollars paid for the opioids. Medical back problems without spinal cord involvement – typically sprains and strains – accounted for 35.7 percent of the work injury claims that involved Schedule II opioids, as well as 47.1 percent of the prescriptions and 50.2 percent of the payments for these medications, making this the number one diagnostic category in California workers' compensation for Schedule II opioids.

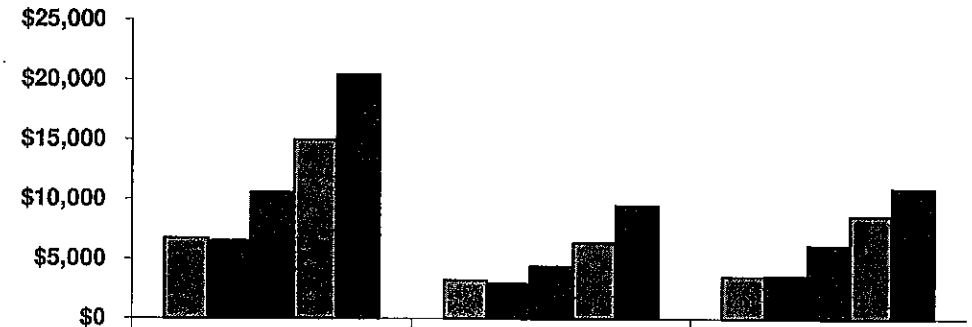
The sample also notes that 59 percent of Schedule II opioid prescriptions are provided to workers suffering injuries which the clinical literature, as well as the opinion of many physicians, are not considered appropriate. The American College of Occupational and Environmental Medicine's Insights

[7] Swedlow A, Ireland J, Johnson G, Prescribing Patterns of Schedule II Opioids in California Workers' Compensation, CWCI, March 2011

refers to the most prominent injury category receiving Schedule II medications, Medical Back Injuries without Spinal Cord Involvement, as "typically not useful in the sub-acute and chronic phases."[8]

Exhibits 5-7 represent the results of a CWCI study of California work injury claims for back conditions with no spinal cord involvement. This study found an association of high levels of opioid use with higher costs and a higher prevalence of other adverse outcomes such as increased likelihood of lost time from work, delayed recovery and more litigation[9]. The study grouped claims into five categories reflective of the amount of accumulated milligrams of "morphine equivalent" ranging from "No MEs" to the highest level of opioid prescription; Level 4. The study shows an association between increasing levels of opioid and higher claim costs, delayed return-to-work, higher likelihoods of lost-time from work and litigation

Exhibit 5. Average Benefit Payments by Morphine Equivalent Level



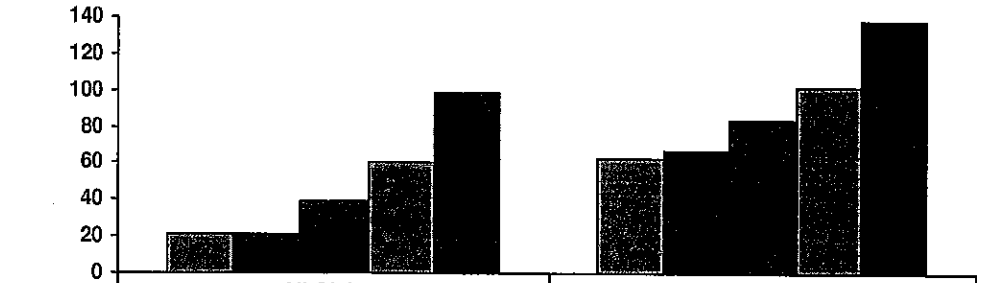
	Total Benefits	Medical	Indemnity
No MEs	$6,733	$3,207	$3,526
Level 1	$6,499	$2,938	$3,561
Level 2	$10,550	$4,411	$6,139
Level 3	$14,950	$6,356	$8,594
Level 4	$20,389	$9,488	$10,901

Among all claims in the sample, the amount of accumulated morphine equivalents (MEs) on a medical back injury without spinal cord involvement during the course of a claim is shown to be strongly associated with increased case-mix-adjusted benefit payments. Claims with no morphine equivalents had an average benefit payment of $6,733 and claims with up to 240 milligrams of morphine equivalent (Level 1) had average paid benefits of $6,499. Case-mix-adjusted total benefit payments increase with each successive increase in the average amount of accumulated morphine equivalents per claim. Average payments increase 62% from $6,499 to $10,550 with the presence of up to 650 milligrams of morphine equivalents (Level 2), increase 130% to $14,350 when up to 2,100 milligrams of morphine equivalents (Level 3) are present and increase 214% to $20,389 with more than 2,100 milligrams of morphine equivalents (Level 4).

[8] Genovese, E., Harris, J., Korevaar, W. Role of Opioids in the Management of Work Injuries – Part I: Focused Literature Review. ACOEM APG Insights, Winter 2007 – Vol. 3/No. 1.

[9] Swedlow A, Gardner L, Ireland J, Genovese E, A Report to the Industry; Pain Management and the Use of Opioids in the treatment of Back Conditions in the California Workers' Compensation System, CWCI, June 2008

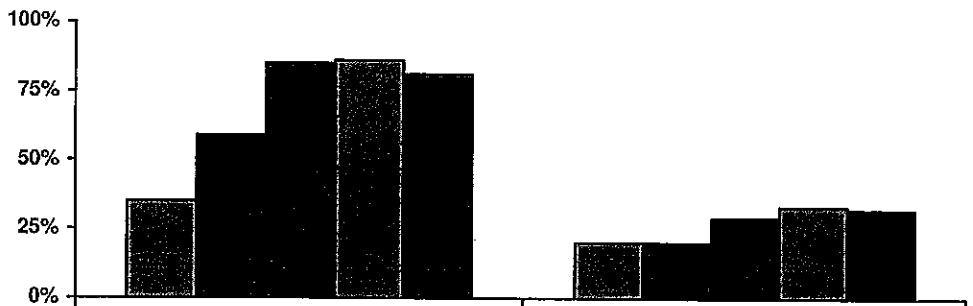
Exhibit 6. TD Days by Morphine Equivalent Level – All Claims versus Indemnity Claims



	All Claims	Indemnity Claims
No MEs	21.3	62.9
Level 1	21.3	66.9
Level 2	38.8	84.2
Level 3	60.6	102.3
Level 4	99	138

The study also examined the degree to which opioid use affected an injured worker's ability to return to work. All claims without morphine equivalents had a case-mix-adjusted average of 21.3 paid lost-time days, while indemnity claims without morphine equivalents had a case-mix adjusted average of 62.9 lost time days. Among all claims, those with Level 4 morphine equivalent usage had a case-mix-adjusted average of 99 lost time fays, or more than 4 times that of all claims with no morphine equivalent usage. Among indemnity claims, those in the Level 4 category of morphine equivalent usage had a case-mix-adjusted average of 138 lost-time days, or about double that of indemnity claims with no morphine equivalent usage.

Exhibit 7. Likelihood Estimate of Lost-time from Work and Attorney Involvement by Morphine Equivalent Category



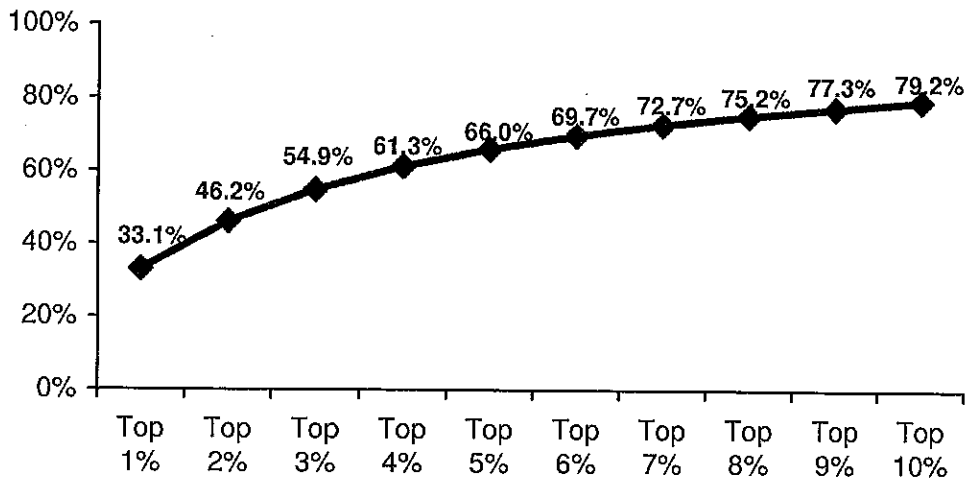
	Presence of Lost Time	Attorney Involvement
No MEs	35%	20%
Level 1	59%	20%
Level 2	85%	29%
Level 3	86%	33%
Level 4	81%	32%

Exhibit 7 shows case-mix-adjusted likelihood estimates for each of the opioid classifications. For example, the likelihood of lost time on a medical back claim with no opiate agonist prescriptions is 35 percent. When Level 1 morphine equivalents were present on a claim, the likelihood of indemnity increased to 59 percent. When Level 2 MEs were present on a claim, the likelihood of indemnity increases to 85 percent. Level 3 claims had an 86 percent likelihood of indemnity and Level 4 claims had a 81percent chance of indemnity. Case-mix adjusted likelihood estimates of litigation range from 20 percent on medical back claims with no opioid prescriptions to a 32 percent likelihood of litigation for Level 4 claims.

Physician Prescribing Patterns

A 2011 CWCI study on prescribing patterns for Schedule II opioids in California's workers' compensation system found that a small percentage of medical providers account for a large majority of these prescriptions[10]. Exhibit 8 shows the cumulative percentage of California workers' compensation Schedule II prescriptions and payments for the top 10 percent of opioid prescribing medical providers.

Exhibit 8. Percent of Schedule II Prescriptions for the Top 10% of Schedule II Prescribing Physicians



The results show that of the 9,174 Schedule II opioid prescribing physicians in the study sample, the top one percent (93 physicians) accounted for nearly one third of the prescriptions; the top three percent (276 physicians) accounted for 54.9 percent of the prescriptions; and the top 10 percent (917 physicians) accounted for 79 percent of the prescriptions.

[10] Swedlow A, Ireland J, Johnson G, Prescribing Patterns of Schedule II Opioids in California Workers' Compensation, CWCI, March 2011