RESEARCH UPDATE

Changes in Schedule II & Schedule III Opioid Prescriptions and Payments in California Workers' Compensation

by John Ireland, Bob Young and Alex Swedlow

Revised August 2012[1]

EXECUTIVE SUMMARY

Over the past several years, there has been growing concern about the increased use of opioid painkillers – especially Schedule II drugs such as OxyContin, Fentanyl, Morphine and Methadone – which have become widely used for the treatment of chronic pain in injured workers. This study finds that in the second quarter of 2011, Schedule II medications accounted for 6.7 percent of all California workers' compensation prescriptions and 20.8 percent of the prescription dollars -- nearly five times the levels noted in 2002. However, the most recent California workers' compensation pharmaceutical data, updated through the end of 2011, indicates a possible modification in this trend, with Schedule II drugs declining to 4.9 percent of the workers' compensation prescriptions and 17.7 percent of the prescription payments in the fourth quarter of last year, though the use of Schedule III drugs such as Vicodin has remained relatively stable. As other factors may be influencing the results from the last two quarters of the analysis, the change should be interpreted with caution.

BACKGROUND

In 1970, federal lawmakers enacted the Controlled Substances Act (CSA), which governs the manufacturing, distribution and dispensing of certain powerful and controversial drugs. The Federal Drug Enforcement Administration and the Food and Drug Administration categorized these drugs based on their potential for abuse or addiction. For example:

- Drugs such as morphine and fentanyl, which have a high potential for abuse or addiction, but which also have accepted medical uses, were classified as Schedule II drugs; and
- Drugs such as intermediate-acting barbiturates, anabolic steroids, and hydrocodone/codeine compounded with a non-steroidal anti-inflammatory drug such as acetaminophen, which have less potential for abuse or addiction than Schedule II drugs, and which also have accepted medical purposes, were classified as Schedule III drugs.[2]

1 This publication incorporates material changes to underlying data and results originally reported and published in July 2012

2 As a point for comparison, heroin, which is highly addictive and has no accepted medical use, was classified as a Schedule I drug.

Over the last 5 years, the California Workers' Compensation Institute (CWCI) and other research organizations have conducted studies that have focused on issues surrounding the use of these opioid medications in workers' compensation. CWCI research has documented the rapid growth in the use and cost of Schedule II drugs by injured workers,[3] examined the prescribing patterns of workers' compensation medical providers who write prescriptions for these drugs,[4] and assessed various injured worker outcomes associated with the elevated use of these drugs.[5]

While the Institute research has focused on the experience within the California workers' compensation system, the increased use of Schedule II opioids to treat injured workers is a nationwide issue, as documented in studies by Wang (2011) who found similar utilization patterns in several other state systems, as well as Laws (2012), who found significant variation across various jurisdictions.[6, 7] Recently, CWCI also documented an increasing ancillary cost trend in the growing use and reimbursement of drug tests in the California workers' compensation system, which reached an estimated $100 million in 2011.[8] These studies and others have contributed to a more informed debate about the appropriate use of opioids in the treatment of workplace injuries by identifying the long-term repercussions for injured workers who take them, the need for tighter controls, and the importance of physician education and monitoring programs by payors, pharmacy benefit managers, and utilization review personnel.

In 2009, the State of California initiated a program to electronically track the distribution of Schedule II and III drugs, as well as other controlled substances, when then Attorney General Jerry Brown implemented an internet-based prescription monitoring database as part of the Controlled Substance Utilization Review and Evaluation System (CURES). This tracking system was intended to monitor when these drugs are dispensed, and to provide a tool for doctors and pharmacists to readily obtain a patient's prescription drug history so they could identify and stop prescription drug seekers from doctor shopping and abusing prescription drugs. From the start, however, the CURES program has had its limitations, as it only requires doctors and pharmacies to report that they have dispensed a controlled substance, and does not require them to check with CURES prior to dispensing the drugs. Furthermore, the funding of the CURES program has become problematic due to California's budgetary problems, so alternative sources may be needed if the program is to succeed in the long run.

Other state efforts in regard to the use of Schedule II opioids in workers' compensation have centered on regulatory controls. In 2009, the California Division of Workers' Compensation added chronic pain management guidelines to the workers' compensation Medical Treatment Utilization Schedule (effective July 19, 2009). Initially, there was considerable optimism that these guidelines could help contain the alarming growth of narcotic painkillers for the treatment of chronic pain in workers' compensation – especially for injuries such as sprains and strains where their use is not supported by the medical literature. Following their adoption, however, there was concern that the potential impact of the guidelines had been undermined. Because the final guidelines set a vague definition of chronic pain ("any pain that persists beyond the anticipated time of healing"), lacked explicit recommendations and limits on the use of opioids, and were based on evidence and rating standards that conflicted with – yet superseded – the existing guidelines, many in the workers' compensation community feared that they had lowered the threshold for the use of Schedule II and Schedule III drugs, and that the number of claims in which these medications could be prescribed could increase.

In the nearly three years since the state adopted the workers' compensation chronic pain guidelines and developed the electronic monitoring program within CURES, CWCI and other research organizations have continued to study issues related to the use of opioids in workers' compensation and in other health systems. These studies have spotlighted the costs and the dangers related to the overuse and abuse of these medications, and have garnered the attention of the press and state and federal regulators and legislators. At the same time, claims organizations, self-insured employers, utilization review personnel, pharmacy benefit management companies, and workers' compensation medical providers have implemented programs aimed at assuring that these drugs are only used

3 Swedlow, A., Ireland, J., Gardner, L. Analysis of Medical and Indemnity Benefit Payments, Medical Treatment and Pharmaceutical Cost Trends in the California Workers' Compensation System. CWCI, August 2011

4 Swedlow, A., Ireland, J., Johnson, G. Prescribing Patterns of Schedule II Opioids in California Workers' Compensation. Research Update, CWCI. March 2011

5 Swedlow, A., Gardner, L., Ireland, J., Genovese, E. Pain Management and the Use of Opioids in the Treatment of Back Conditions in the California Workers' Compensation System. Report to the Industry. CWCI. June 2008

6 Wang, D., Mueller, K., Hashimoto D., Chen, J. Interstate Variations in Use of Narcotics. WC-11-01 WCRI, July 2011

7 Laws, C. Narcotics in Workers Compensation. NCCI Research Brief. May 2012

8 Swedlow, A., Young, B. Drug Testing Utilization and Cost Trends in California Workers' Compensation. Research Note, CWCI. May 2012

when appropriate and necessary. While anecdotal reports suggest that these efforts, and the increased awareness of the problems associated with prolonged opioid use, have been helpful, there have been little if any data to confirm any mediation in the increasing trend of opioid use in California workers' compensation.

To gauge the current levels of Schedule II and Schedule III utilization in workers' compensation, and to assess the latest utilization and cost trends for these medications, the authors undertook this study to determine:

1) the percentage of California workers' compensation prescriptions and prescription payments represented by Schedule II and Schedule III opioids;
2) how those percentages have changed across the 10-year period ending in the 4th quarter of 2011; and
3) which types of Schedule II and Schedule III opioids were most heavily prescribed to injured workers in California during that 10-year span.

DATA

For this study, the authors compiled a pharmaceutical data sample drawn from CWCI's Industry Claims Information System[9] database. In total, the sample contained approximately 9.1 million prescriptions that were dispensed to California injured workers between January 2002 and December 2011. Aggregate reimbursements for those prescriptions totaled more than $820 million. Among those 9.1 million prescriptions, the authors identified 331,732 Schedule II prescriptions that were classified as opioid analgesics (3.6 percent of the total), which resulted in nearly $98.6 million in payments (12.0 percent of the prescription dollars paid). In addition, another 1.8 million (19.8 percent) of the prescriptions from the sample were for Schedule III opioid analgesics, for which claims administrators paid $83.7 million (10.2 percent of the prescription reimbursements).

Each prescription contained information on pharmaceutical sources, packaging, formula, class, pricing and other characteristics of the drug sample. The Schedule II and Schedule III opioid analgesic prescriptions from the claim sample were grouped by year (based on the fill date), and classified by active ingredient into major categories (more than 1 percent of the prescriptions). For the Schedule II drugs, there were seven major categories:

- Oxycodone (e.g., OxyContin, Endocet, Percocet)
- Morphine (e.g., Avinza, Morphine Sulfate, Oramorph)
- Fentanyl (e.g. Actiq, Duragesic, Fentora)
- Methadone (e.g. Methadone, Methadose)
- Hydromorphone (e.g. Dilaudid, Hydromorphone)
- Oxymorphone (e.g. Opana)
- Tapentadol (e.g. Nucynta)

Schedule II opioids that did not fall into a major category were put in an "Other" category, though all together, the seven major categories of drugs represented nearly 98 percent of all Schedule II opioid prescriptions filled for California injured workers from 2002 through 2011.

Hydrocodone with acetaminophen, available in various forms (e.g., Vicodin, Lortab, Norco) was the overwhelmingly dominant Schedule III drug category in the study sample, accounting for almost 91 percent of the Schedule III opioid prescriptions dispensed to injured workers during the 10-year study period. The only other Schedule III drug category that accounted for more than 1 percent of the Schedule III opioids in the study sample was codeine, available in various forms (e.g., acetaminophen/codeine, Tylenol with codeine) which accounted for 8 percent of the workers' compensation Schedule III prescriptions.

9 ICIS is a proprietary database maintained by the California Workers' Compensation Institute that contains detailed information, including employer and employee characteristics, medical service information, and benefit and other administrative cost information on more than 4 million workplace injury claims with dates of injury between 1993 and 2011(v13B).

RESULTS

For this analysis, the authors compiled the results by calendar year for 2002 through 2008, then segmented the results by quarter for the final three years of the study (2009 – 2011) to provide a finer view of recent trends.

As noted in the table below, Schedule II opioids increased from 1.1 percent of California workers' compensation prescriptions in 2002 to 2.0 percent of the scripts in 2004, while over the same period, payments for Schedule II opioids grew from 4.2 percent to 6.6 percent of the workers' compensation prescription reimbursements.[10] Immediately following the implementation of the 2002-2004 reforms and the pharmacy fee schedule, the use of Schedule II opioids in California workers' compensation declined briefly, falling to 1.3 percent of all prescriptions and 3.8 percent of the prescription dollars in 2005. That decline, however, was temporary, and by 2006 overall utilization of Schedule II opioids was again trending up.

In 2007, the Division of Workers' Compensation took regulatory action to address the repackaged drug loophole, though even with this revision and the earlier reforms, the utilization and the cost of Schedule II opioids in workers' compensation continued to climb. It was not until the second quarter of 2011 that the use of these medications finally peaked, at which point Schedule II opioids had grown to 6.7 percent of all workers' compensation prescriptions (more than 6 times the 2002 level) and 20.8 percent of the workers' compensation prescription dollars – nearly 5 times the level noted in 2002.

Table 1: Schedule II & III Opioids as a % of Calif WC Prescriptions and Prescription Payments
Calendar Year 2002 – 2011 Fill Dates

Fill Date		Schedule II Opioids		Schedule III Opioids		Schedule II & III Opioids	
		% of Scripts	% of Payments	% of Scripts	% of Payments	% of Scripts	% of Payments
2002		1.1%	4.2%	19.5%	10.6%	20.6%	14.8%
2003		1.3%	4.6%	20.8%	10.5%	22.1%	15.1%
2004		2.0%	6.6%	19.4%	8.4%	21.3%	15.0%
2005		1.3%	3.8%	18.0%	9.6%	19.3%	13.4%
2006		1.7%	4.1%	18.7%	10.0%	20.4%	14.1%
2007		3.3%	10.0%	19.6%	11.3%	22.9%	21.3%
2008		5.5%	17.7%	20.1%	10.0%	25.6%	27.7%
2009	Q1	5.6%	18.0%	19.9%	10.1%	25.5%	28.1%
	Q2	5.5%	18.4%	20.2%	10.5%	25.7%	28.8%
	Q3	5.7%	19.4%	20.1%	10.6%	25.8%	30.0%
	Q4	5.9%	20.0%	20.3%	10.9%	26.2%	30.8%
2010	Q1	5.9%	19.8%	20.0%	10.9%	25.9%	30.7%
	Q2	6.2%	20.5%	19.5%	10.4%	25.7%	30.9%
	Q3	6.2%	20.3%	19.5%	10.1%	25.6%	30.3%
	Q4	6.5%	20.6%	19.5%	10.2%	26.0%	30.8%
2011	Q1	6.7%	20.4%	19.8%	10.2%	26.5%	30.7%
	Q2	6.7%	20.8%	19.9%	10.4%	26.5%	31.2%
	Q3	5.0%	17.1%	19.0%	10.4%	24.0%	27.5%
	Q4	4.9%	17.7%	18.7%	9.7%	23.6%	27.4%

10 Between 2002 and 2004, California adopted reforms that created a pharmacy fee schedule, required injured workers to obtain their medicines and medical supplies from contracted pharmacy networks, required pharmacies to substitute generics for brand drugs unless the physician specified in writing that no substitution should be made, capped maximum reimbursement for pharmacy services and drugs at 100 percent of the Medi-Cal allowance and establish maximum fees for drugs not covered by Medi-Cal at fees that do not exceed the Medi-Cal allowances for comparable drugs. At the same time, additional reforms such as mandatory utilization review, the adoption of the medical treatment utilization schedule, and the introduction of medical provider networks also impacted the delivery of workers' compensation medical benefits, including prescription drugs. After going through the regulatory process, including public hearings, the workers' compensation pharmacy fee schedule took effect January 1, 2004. The new schedule set maximum reasonable allowances for pharmacy services and drugs at the Medi-Cal rates, which in 2004 were at least 10 percent below the Average Wholesale Price (AWP) of the drug. However, for drugs or pharmaceutical services not covered by Medi-Cal (most notably, repackaged drugs dispensed in a physician's office) maximum reasonable fees were still governed by the Official Medical Fee Schedule that was in effect in 2003, which at 140 percent and 110 percent of the AWP for generic and brand name drugs allowed significantly higher fees than the Medi-Cal rates.

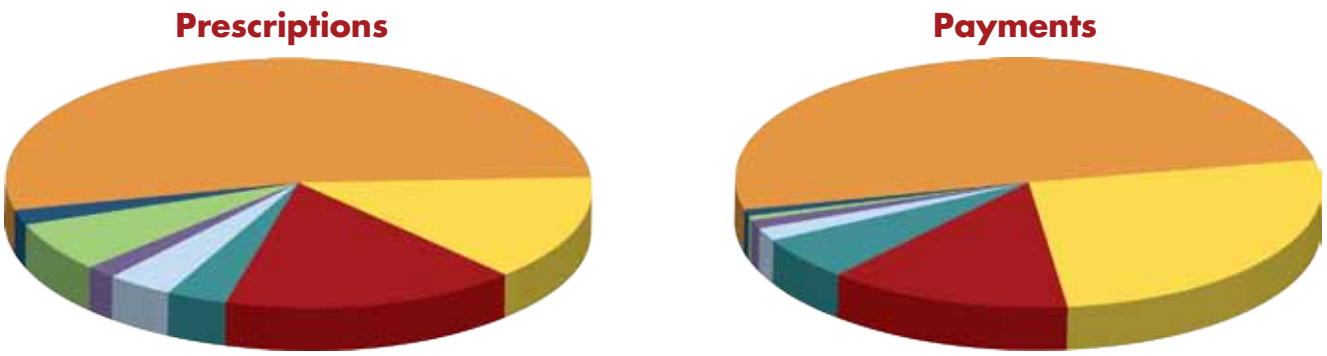
The use of Schedule II opioids began to taper off at the end of 2011, declining to about 5 percent of workers' compensation prescriptions in the 3rd quarter of 2011, while payments for these drugs dropped to about 17 percent of overall workers' compensation prescription expenditures. By the last quarter of 2011, the use of Schedule II opioids stood at 4.9 percent of the scripts and 17.7 percent of the prescription payments. Thus, over the 6-month period ending in December 2011, Schedule II opioids declined from 6.7 percent to 4.9 percent of California workers' compensation prescriptions (a relative decline of 27 percent) and the reimbursements for these drugs declined from 20.8 to 17.7 percent of workers' compensation pharmacy payments (a relative decline of 15 percent).

In contrast to the 10-year trend in Schedule II opioid use, Schedule III opioids (primarily various forms of hydrocodone with acetaminophen) have accounted for a much more consistent share of workers' compensation prescriptions and prescription payments. Other than the post-reform years of 2005 and 2006, when their use dropped slightly, Schedule III opioids have consistently accounted for about one out of five California workers' compensation prescriptions. Similarly, other than the dip in 2004, when the new pharmacy fee schedule first took effect, payments for these drugs ranged between 9.6 and 11.3 percent of the prescription dollars. The latest measurements show a marginal decline in Schedule III opioids, which accounted for 18.7 percent of all prescriptions dispensed to injured workers in the 4th quarter of 2011, with payments for these drugs representing 9.7 percent of workers' compensation drug expenditures in that quarter.

Prescription & Payment Distributions by Drug Type

To see which of the Schedule II and Schedule III opioids are most heavily utilized, and which of these drugs have been the primary cost drivers, the authors prepared distributions showing the breakdowns of Schedule II and Schedule III prescriptions and payments by the specific type of drug. The distributions for Schedule II drugs are shown in Exhibit 2.

Exhibit 2: California Workers' Compensation Schedule II Opioid Prescription & Payment Distributions by Drug Type
CWCI Study Sample: Schedule II Opioid Prescriptions with 2002 – 2011 Fill Dates



Schedule II Opioids	# of Prescriptions in Sample	% of Prescriptions	Total $ Paid in Sample	% of Total Paid
Oxycodone	175,985	53.0%	$49,978,919	50.7%
Fentanyl	45,434	13.7%	$26,136,655	26.5%
Morphine	54,458	16.4%	$12,982,949	13.2%
Oxymorphone	11,255	3.4%	$5,439,477	5.5%
Hydromorphone	12,271	3.7%	$1,534,618	1.6%
Tapentadol	5,514	1.7%	$1,224,551	1.2%
Methadone	20,803	6.3%	$543,605	0.6%
All Other	6,012	1.8%	724,806	0.7%
Total in Study Sample	**331,732**	**100.0%**	**$98,565,580**	**100.0%**

Schedule II opioids that did not fall into one of the seven major categories were placed in an "Other" category, though all together, the seven major categories of drugs represented more than 98 percent of all Schedule II opioid prescriptions filled for California injured workers from 2002 through 2011.

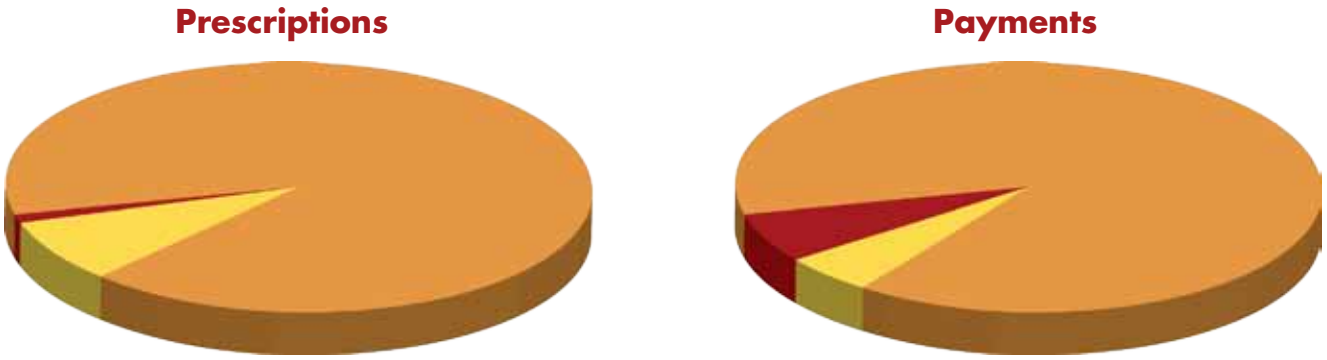
Oxycodone made up more than half the Schedule II opioids dispensed to injured workers in the past 10 years, and accounted for half of all dollars spent for Schedule II opioids in California workers' compensation. Fentanyl ranked second, accounting for 26.5 percent of Schedule II opioid reimbursements, a disproportionate share given that it represents only 13.7 percent of the Schedule II opioid scripts, which reflects the high average cost of these prescriptions. Morphine ranked third in terms of the Schedule II opioid expenditures, accounting for 13.2 percent of the total dollars paid for these drugs, followed by Oxymorphone with 5.5 percent of the total opioid expenditures, also a disproportionate share of the payments due to a relatively high average cost of per prescription.

Exhibit 3 shows the distributions for Schedule III opioids used in California workers' compensation over the past decade.

Hydrocodone with acetaminophen, available in various forms, (e.g., Vicodin, Lortab, Norco) was the overwhelmingly dominant Schedule III drug category in the study sample, accounting for almost 91 percent of the Schedule III opioid prescriptions dispensed to injured workers from 2002 through 2011, and consuming 89 percent of the dollars paid for Schedule III opioids.

The only other Schedule III drug category that accounted for more than 1 percent of the Schedule III opioids in the study sample were the various forms of codeine (e.g., acetaminophen/codeine, Tylenol with codeine) which accounted for 8 percent of the workers' compensation Schedule III opioid prescriptions. The average amount paid for these prescriptions was relatively low, however, so codeine accounted for less than 5 percent of the Schedule III opioid payments over the past decade.

Exhibit 3: California Workers' Compensation Schedule III Opioid Prescription & Payment Distributions by Drug Type
CWCI Study Sample: Schedule III Opioid Prescriptions with 2002 – 2011 Fill Dates



Schedule III Opioids	# of Prescriptions in Sample	% of Prescriptions	Total $ Paid in Sample	% of Total Paid
Hydrocodone	1,622,801	90.9%	$74,333,533	88.8%
Codeine	142,258	8.0%	$4,114,398	4.9%
All Other	20,219	1.1%	$5,227,500	6.3%
Total in Study Sample	**1,785,278**	**100.0%**	**$83,675,431**	**100.0%**

DISCUSSION:

Prior research documented the sharp increases in both the volume and the cost of Schedule II opioids in California workers' compensation, with both utilization and costs trending up rapidly from 2005 through 2008. This study confirms the trends noted in the earlier studies and shows that the use of Schedule II opioids continued at near-record levels well into 2011. The most recent data, however, suggests a possible reduction in the use of Schedule II drugs beginning in the second half of 2011. The study also shows that the use of Schedule III drugs, which can also be addictive, but which have less potential for abuse than Schedule II drugs and are much more widely accepted as a treatment for a broad range of work injuries, has remained fairly steady over the past decade, although signs of a possible slowdown were noted in the last half of 2011.

The decline in Schedule II utilization and cost that began in the second half of 2011 should be interpreted with caution. Other potential factors that can influence the end points of utilization and cost trend lines include billing cycles for year-end services, data submission delay due to processing utilization review decisions and liens. It is also possible that despite the lack of any significant or explicit changes in California workers' compensation legislation or regulations pertaining to opioids, efforts by the payor community (workers' compensation insurers and self-insured employers) to modify medical cost containment oversight and tighten controls over the use of Schedule II painkillers may be having an impact. In addition, the strong spotlight of publicity and the growing awareness of the problems associated with Schedule II medications also may have contributed to a sentinel effect, making doctors, injured workers and payors more cautious in regard to the use of these drugs, and perhaps more willing to seek alternatives for managing pain. Continued monitoring of opioid analgesics in the California workers' compensation system will reveal the actual trend in utilization of these scheduled drugs.

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