Red Flags for Potential Substance Abuse and/or Diversion

- Filling prescriptions for controlled substances but drug testing negative for those same controlled substances
- Testing positive for illegal substances or controlled substances not prescribed
- Concurrent use of alcohol and illicit drugs (identified in records or through drug testing)
- Missing medical or treatment appointments repeatedly/failure to follow through with treatment other than obtaining controlled substances
- Changing treating doctors at critical junctures in the claim e.g. doctor questioning nature and extent of claimed injury; planning to discharge; planning to P&S; provider refusing to prescribe controlled substances or expressing concerns regarding use of controlled substances
- Emergency Department visits to obtain medications
- Need to see M.D. prior to scheduled appointment due to distress over pain
- Any medical provider expressing concerns regarding abuse or diversion
- Any information claimant is selling drugs, forging prescriptions, stealing drugs
- Trying to obtain controlled substances before the renewal date e.g. ran out of meds early due to pain; lost meds; meds were stolen; need early refill due to vacation; family member or friend took them
- Failing to disclose a past history of substance abuse or addiction
- Lying about a history of substance abuse, addiction, or treatment
- Any medical records indicating prescribing of Suboxone or Subutex or any medications associated with opioid withdrawal or detox
- Financial problems/needing money e.g. check was lost, calling to see when money will come, demanding payment or reimbursement for benefits to which claimant is not entitled, etc.
- Criminal history of arrest and/or conviction for alcohol or drug related charges
- Excessive absenteeism- leaves of absences, calling in sick frequently
- Family problems/stress at home due to personal behaviors
- Worsening pain/no relief from pain medications
- Subjective complaints of pain with no objective medical evidence to explain stated levels of pain
- **CURES report**-
    - obtaining & filling prescriptions from multiple providers for the same controlled substance
    - filling controlled substances at different pharmacies
    - filling prescriptions for other controlled substances, especially opioids, and not disclosing to treating doctor

- **obtaining** prescriptions, but **not filling** prescriptions (selling prescriptions?)
- dispensing physician or dispensing pharmacy not reporting filled prescriptions to PDMP/CURES

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Estimated Savings from Enhanced Opioid Management Controls through 3rd Party Payer Access to the Controlled Substance Utilization Review and Evaluation System (CURES)

Alex Swedlow
John Ireland

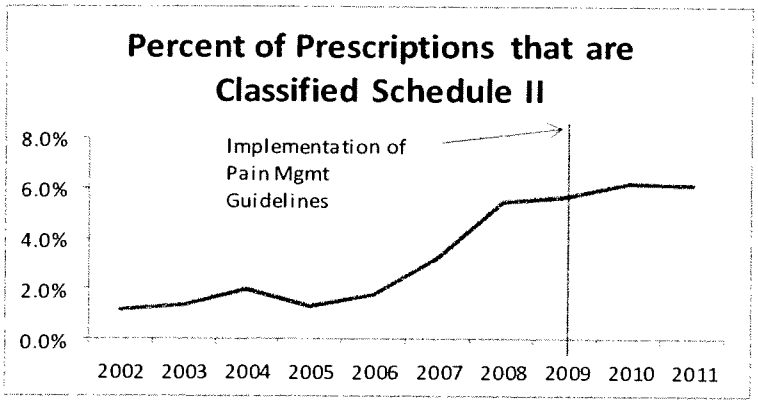
January 2013

Background

Excessive opioid utilization has become a national public health issue as well as a known cost driver in the California Workers' Compensation System. Studies have documented the increase in opioid prescriptions and the association of graduated opioid use and adverse outcomes, including delayed recovery for injured workers, added claims costs, and high rates of litigation.[1]

In 2009, in an effort to establish controls on opioid utilization, the Division of Workers' Compensation implemented a chronic pain management guideline within the Medical Treatment Utilization Schedule. However, recent research that measured the use of Schedule II opioids in California workers' compensation through June of 2011 found that utilization of these narcotic painkillers continued to increase following the implementation of the pain management guideline.[2] Though the study also included preliminary data from the 3rd and 4th quarters of 2011 that indicated a recent reduction in the use of Schedule II opioids, utilization still remained significantly higher than evidence-based guideline recommendations (Exhibit 1).

Exhibit 1. Percent of Prescriptions that are Classified Schedule II



In contrast, the Texas Department of Insurance, Division of Workers' Compensation recently adopted a closed formulary pharmacy rules in an attempt to better control pharmaceutical utilization and their associated cost. In a preliminary report on the impact of the closed formulary that was effective on claims

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after August, 2011, Texas reported not only a marked decrease in the use of brand drugs but also a nine percent drop in the use of opioids and a 57 percent reduction in opioids requiring preauthorization.[3]

Among the factors contributing to the rapid escalation in the use of Schedule II opioids in the California workers' compensation system are the structural limitations of the medical cost controls. Unlike federal programs and most group health plans, the California workers' compensation system has fewer supply-and-demand-side controls to manage the utilization and cost of pharmaceuticals. The lack of such control mechanisms as co-payments, deductibles, closed formularies and limited generic substitution restrict third-party payers' ability to adequately manage pharmaceutical costs. In addition, because workers' compensation accounts for less than 5% of the total California healthcare economy, monitoring potential abuses by patients and physicians across other payment systems is limited.

Some California workers' compensation stakeholders have suggested that enabling third-party payer access to the Controlled Substance Utilization Review and Evaluation System (CURES) would improve quality of care, utilization and cost controls and assist employer and payer efforts to more effectively address prescription drug fraud and abuse. The CURES system currently lacks an operational budget and seeks funding before July 2013, when the system will be taken off-line. In an effort to provide an analysis on the value of appropriate funding of CURES as a viable tool for controlling the utilization and cost of opioids, the authors have compiled data and constructed a model to estimate the:

- current volume of California workers' compensation claims in which opioids are prescribed;
- level of opioid use for claims with prescriptions opioids; and
- estimated savings that could be generated by integrating 3rd party payer access to the CURES database with other medical cost containment strategies.

Estimating Claims with Opioid Utilization

Exhibit 2 shows the estimated number of California work injury claims from accident year 2011 in which opioids were prescribed and the distribution of claims based on the number of Schedule II and Schedule III opioid prescriptions filled within the first 24 months of injury.

Exhibit 2. Estimated Number of AY 2011 California WC Claims with Opioid Prescriptions and Distribution by Number of Opioid Prescriptions Dispensed at 24 Months Post-Injury

Total Claim Count (AY 2011)	500,000	
Percentage of Claims with Opioids	23.1%	
Total Opioid Claims	115,447	
# of Opioid Prescriptions @ 24 Months	**% of Claims**	**Estimated Number of AY 2011 Claims w/ Opioids**
1 prescription	41.1%	47,434
2-3 prescriptions	24.7%	28,508
4-7 prescriptions	13.6%	15,745
>7 prescriptions	20.6%	23,760
Total Opioid Claims	100.0%	115,447

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There were approximately 500,000 California workers' compensation claims in accident year 2011.[4] To estimate the proportion of those claims that involved opioid prescriptions, the authors analyzed a sample of 417,508 claims with 2007-2009 dates of injury from the California Workers' Compensation Institute (CWCI) Industry Claims Information System[5] (ICIS) database and identified 23.1 percent (96,400 claims) that included a payment record for at least one opioid prescription in the first 24 months following the date of injury. The authors then applied that percentage to the estimated 500,000 claims from AY 2011 to derive an estimated population of 115,447 claims from AY 2011 that involved opioid prescriptions.

The authors also categorized the opioid claims from the ICIS sample into four groupings based on the number of prescriptions that had been dispensed in the first two years. The resulting distribution showed that 41.1 percent of the claims involved a single opioid prescription; 24.7 percent had 2 to 3 prescriptions; 13.6% had 4 to 7 prescriptions; and 20.6 percent had more than 7 opioid prescriptions. Those percentages were then applied to the 115,447 opioid claims estimated for AY 2011 to produce the distribution shown in Exhibit 2.

Estimating System-wide Savings through 3rd Party Payer Access to CURES

Prior studies have documented the high proportion of California workers' compensation claims with opioid use that is not supported by the evidence-based medical literature and the workers' compensation medical treatment utilization schedule (MTUS). CWCI has estimated that almost half of all claims with Schedule II opioids fall outside the pain management medication recommendations included in the evidence-based medical literature.[6] Many workers' compensation payers, as well as other stakeholders, believe that access to the CURES system, coupled with enhanced medical cost containment strategies including medical provider networks (MPN) monitoring and utilization review (UR) – could significantly reduce the average number of prescriptions and the average dose levels of workers' compensation claims that utilize opioids.

In Exhibit 3, the authors' produced a conservative estimate of the potential savings available through access to CURES data. The model used the estimated number of opioid claims within each of the four opioid utilization categories (noted in Exhibit 2) and applied a cost-reduction savings factor against the average medical and indemnity benefit payments per claim.[7]

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Exhibit 3. Potential Workers' Compensation Savings from Enhanced Opioid Management Controls Via CURES

		Average Paid Benefits from 2008 Study		Estimated Total Benefits Paid on 2011 Claims			Potential Savings		
Claims by Opioid Scripts	Claim Count	Med Ben	Indem Ben	Medical Benefits	Indemnity Benefits	Est. % Savings	Medical Benefits	Indemnity Benefits	Tot Benefits
1	47,434	$3,909	$4,351	$185,398,901	$206,391,638	-	-	-	-
2-3	28,508	5,321	5,781	$151,700,753	$164,807,267	3.0%	$4,551,023	$4,944,218	*$9,495,241*
4-7	15,745	7,640	8,709	$120,292,830	$137,119,795	5.0%	$6,014,641	$6,855,990	$12,870,631
>7	23,760	9,132	11,813	$ 216,976,537	$280,677,161	7.0%	$15,188,358	$19,647,401	$34,835,759
Total	115,447	$5,820	$6,777	$674,369,021	$788,995,861		$25,754,022	$31,447,609	$57,201,631
								Est. CURES Operating Budget:	$3,700,000
								Workers' Comp Return-on-Investment	$15.5 : $1

The authors estimate that the enhanced opioid management controls offered by 3rd party payer access to CURES data would produce no cost savings for claims with only one opioid prescription, but estimate a 3 percent reduction in total benefits paid on claims with 2 to 3 opioid prescriptions; a 5 percent reduction in payments on claims with 4 to 7 opioid prescriptions; and a 7 percent reduction in payments on claims with more than 7 opioid prescriptions. Under this scenario, the total estimated cost savings on AY 2011 claims is $57.2 million.

Return-on-Investment

The operating budget for the CURES system is estimated at $3.7 million[8]. Should the California workers' compensation system cover the cost of the entire CURES system operating budget, the return-on-investment is estimated at $15.5:$1.

Actual savings and ROI will depend upon several factors, including access to CURES system data; medical and pharmaceutical cost trends; injury mix; medical cost containment/utilization review intervention; and applicable workers' compensation statutes, rules and regulations.

About CWCI

The California Workers' Compensation Institute, incorporated in 1964, is a private, non-profit organization of insurers and self-insured employers conducting and communicating research and analyses to improve the California workers' compensation system.

[8] CURES 2.0: An Integrated Approach to Preventing Prescription Drug Abuse and Diversion. California Department of Justice. December 2012

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CWCI

California Workers' Compensation Institute

BULLETIN

1111 Broadway, Suite 2350, Oakland, CA 94607 (510) 251-9470 www.cwci.org

January 15, 2013

No. 13-02

As state policymakers consider options for continued funding of California's $3.7 million a year Controlled Substance Utilization Review and Evaluation System (CURES), the state's prescription drug monitoring program, a new CWCI analysis suggests that allowing third party payer access to CURES data would improve quality of care and strengthen utilization and cost control over opioid prescriptions dispensed to injured workers, which for accident year 2011 claims alone could save an estimated $57.2 million.

Excessive use of prescription painkillers has become a nationwide public health problem, and a huge cost driver in California workers' compensation, where highly addictive "Schedule II" narcotics such as oxycontin, morphine and fentanyl have been widely used, even for relatively minor sprain and strain injuries. In 2011, the Division of Workers' Compensation adopted chronic pain management guidelines to help control the use of these drugs to treat injured workers, but they have continued to account for a large proportion of workers' compensation prescriptions. An Institute report published last August included initial data from the second half of 2011 that indicated the first downturn in the use of these drugs in several years, but that same research showed that Schedule II narcotics accounted for a record 6.7 percent of all California workers' compensation prescriptions dispensed in the second quarter of 2011 - six times the proportion noted in 2002 -- and 20.8 percent of the prescription payments - nearly five times the percentage recorded in 2002.

One tool California does have to combat prescription drug abuse is CURES, its 3-year old electronic prescription monitoring program run by the Department of Justice. The program allows doctors, pharmacists and law enforcement agencies to track the prescription history of patients receiving opioids to identify fraud and abuse patterns. Many workers' compensation stakeholders assert that access to CURES data, coupled with enhanced medical cost containment strategies involving pharmacy benefit managers, medical provider network monitoring and utilization review, could significantly reduce the volume of inappropriate opioid prescriptions dispensed to injured workers. However, since a $70 million cut in the Department of Justice budget was announced in late 2011, the state has struggled to come up with the $3.7 million a year needed to finance CURES, so the program could be in jeopardy if a new source of funding isn't found before the new fiscal year begins in July.

To assess the potential savings that could be generated if CURES data were available to workers' compensation payers, study authors Alex Swedlow and John Ireland applied workers' compensation pharmacy data from prior studies and CWCI's Industry Claims Information System database to estimate that 23 percent (or 115,447) of the 500,000 California job injury claims in accident year 2011 involved opioid prescriptions.

As noted in the table below, the Institute researchers projected that access to CURES would generate no savings on the 41 percent of workers' compensation opioid claims that involve a single prescription within the first two years of injury, but the potential savings from reduced medical and indemnity payments on the 59 percent of the opioid claims that involve multiple prescriptions would range between 3 to 7 percent, depending on the volume of opioid prescriptions dispensed – which translates to a total of $57.2 million on AY 2011 claims.

Potential Workers' Compensation Savings from Enhanced Opioid Management Controls Via CURES

		Average Paid Benefits from 2008 Study		Estimated Total Benefits Paid on 2011 Claims			Potential Savings		
Claim Category by # of Opioid Scripts	Claim Count	Med Ben	Indem Ben	Medical Benefits	Indemnity Benefits	Est. % Savings	Medical Benefits	Indemnity Benefits	Total Benefits
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								Est. CURES Operating Budget:	$3,700,000
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Debate over the funding of CURES continues, as Attorney General Kamala Harris last week urged Governor Brown to restore funding for the program in light of the state's improving budget picture. In addition, following a Los Angeles Times report on prescription drug deaths and an editorial urging lawmakers to fund the CURES program, Senators Darrell Steinberg and Curren Price announced they will back legislation to increase California Medical Board oversight of physicians dispensing narcotics, while both Senator Mark DeSaulnier and Assemblyman Bob Blumenfield said they plan to introduce bills to improve the CURES database, and to require that authorities use it to identify inappropriate prescribing and dispensing.

In the meantime, the Institute has distributed its analysis "Estimated Savings from Enhanced Opioid Management Controls Through Third Party Payer Access to CURES" to the California Department of Justice, the California Department of Insurance, the White House Office of National Drug Control Policy, and the Brandeis Prescription Drug Monitoring Program Center of Excellence. The analysis is also posted in the Research section of the Institute's website, www.cwci.org.

BY/

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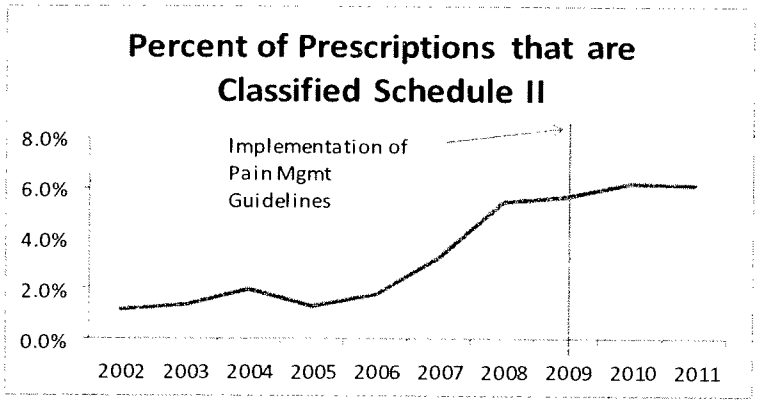

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Return-on-Investment

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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).

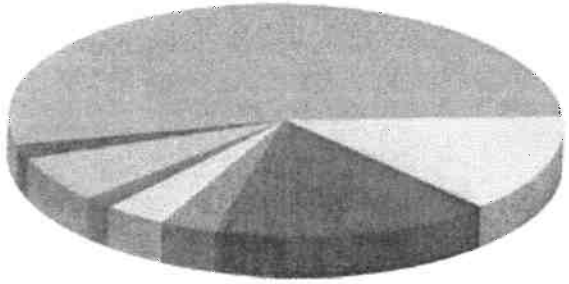
In contrast to the 10-year trend in Schedule II opioid use, Schedule III opioids (primarily various forms of hydrocodone with acetaminophen) have accounted for a much more consistent share of workers' compensation prescriptions and prescription payments. Other than the post-reform years of 2005 and 2006, 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

Prescriptions



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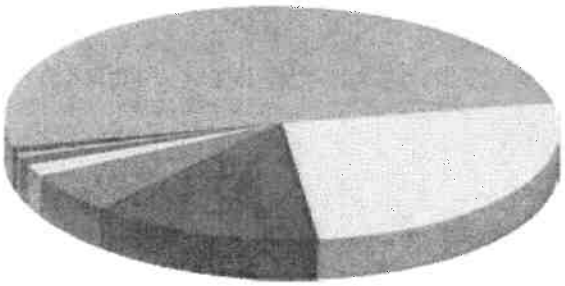

Schedule II Opioids	# of Prescriptions in Sample	% of Prescriptions	Total $ Paid in Sample	% of Total Paid
Oxycodone	175,985	53.0%	$49,978,919	50.7%
Fentanyl	45,434	13.7%	$26,136,655	26.5%
Morphine	54,458	16.4%	$12,982,949	13.2%
Oxymorphone	11,255	3.4%	$5,439,477	5.5%
Hydromorphone	12,271	3.7%	$1,534,618	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

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The only other Schedule III drug category that accounted for

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The average amount paid for these prescriptions was relatively

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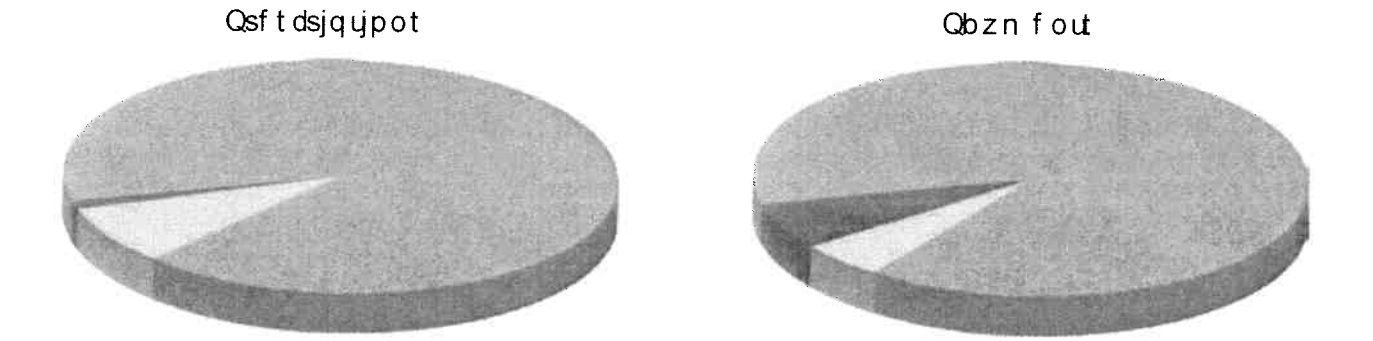

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CWCI RESEARCH SPOTLIGHT REPORT... ***Prescribing Patterns of Schedule II Opioids Part 2: Fentanyl Prescriptions in California Workers' Compensation. April 27, 2011***

Background: CWCI's March 2011 publication examined prescribing patterns for Schedule II opioids in the California workers' compensation system.[1] The study found that a relatively small percentage of medical providers prescribe the majority of these powerful, highly addictive narcotics. In addition, nearly half of the Schedule II opioid prescriptions in the study were for minor back injuries – typical sprains and strains – even though such use is not supported by the medical literature and the American College of Occupational and Environmental Medicine says they are "typically not useful in the sub-acute and chronic phases."

Of the Schedule II opioids included in the Institute's study, the most potent is fentanyl, which is 75 to 100 times more powerful than oral morphine. Although fentanyl can be administered intravenously, all of the fentanyl prescriptions in the Institute study sample were either administered via a skin patch (transdermal) or as a lozenge or effervescent tablet (transmucosal). Due to increases in dosing errors and abuse of fentanyl drug products, the FDA has issued several warnings regarding the drug. For example, in July 2005, the FDA issued a health advisory regarding the safe use of fentanyl skin patches in response to reported fatalities among patients using the narcotic,[2] and in December 2007, the FDA issued another safety warning in response to continued reports of life-threatening side effects.[3] The FDA also has issued several recall notices of fentanyl patches for reasons of accelerated drug release or leaking gel – both conditions potentially leading to adverse reactions. In addition, in September 2007, the FDA issued a more specific warning regarding Buccal Fentanyl (Fentora and Actiq),[4] stating "Buccal Fentanyl should be used only to treat breakthrough cancer pain (sudden episodes of pain that occur despite round-the-clock treatment with pain medication) in cancer patients who are taking regularly scheduled doses of another narcotic (opioid) pain medication and who are tolerant (used to the effects of the medication) to narcotic pain medications. This medication should not be used to treat pain other than chronic cancer pain." Despite these admonitions, use of fentanyl in workers' compensation systems continues to

[1] California Workers' Compensation Institute, Prescribing Patterns of Schedule II Opioids in California Workers' Compensation. Research Update. CWCI March 2011
[2] U.S. Food and Drug Administration, U.S. Department of Health and Human Services, FDA Issues Public Health Advisory on the Fentanyl Patch, News Release, July 15, 2007
[3] U.S. Food and Drug Administration, U.S. Department of Health and Human Services, FDA Issues Second Warning on Fentanyl Skin Patch, *Deaths and serious injuries from improper use*, News Release, Dec. 21, 2007
[4] U.S. Food and Drug Administration, U.S. Department of Health and Human Services, FDA Warns of Potential Serious Side Effects with Breakthrough Cancer Pain Drug, News Release, Sept. 26, 2007

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increase, as evidenced by CWCI's March 2011 study, as well as a 2010 NCCI study[5] and a recent federal court suit by the US Postal Service against Cephalon, the manufacturer of fentanyl lozenges and effervescent tablets.[6]

Data: The Institute's March 2011 study used a special administrative data sample obtained from workers' compensation pharmacy bills contributed by pharmacy benefit management organizations (PBMs). The data included the prescribing physician's name and Drug Enforcement Administration (DEA) number, the prescribed medication, the billed and paid amount per prescription, and the National Drug Code (NDC) and other descriptive details about the drugs. Additional drug classification data included the drug therapy class, drug group class, drug source and DEA classification. The detailed information on each prescription included the quantity and dosage of each prescription. The Institute's Industry Claims Information System (ICIS) database yielded additional data, including the diagnosis classifications for the workers' compensation claims in which these drugs were prescribed. Because some of the claims involved multiple diagnoses, a clinical grouper[7] was used to identify the primary diagnosis code and diagnostic category for each claim.

The study included data on a total of 233,276 Schedule II opioid prescriptions, identified from 16,890 California workers' compensation claims with dates of injury between January 1993 and December 2009, each of which had a payment record for at least one Schedule II opioid prescription. There were 9,174 prescribing physicians associated with the 16,890 claims, and 42 percent of the claims in the sample had more than one prescribing physician. Although injured workers sometimes do not fill every prescription that is written for them, the PBM data used in the Institute study included the fill date on which the Schedule II drugs were dispensed to the injured workers, and all 233,276 of the prescriptions in the study sample were filled between January 2005 and December 2009, resulting in $86 million in workers' compensation pharmacy payments.

[5] National Council on Compensation Insurance, 2010 NCCI Prescription Drug Research Brief, January 2011.
[6] BIO SmartBrief "USPS Subpoenas Cephalon Regarding Cancer-Pain Drug Fentora." February 14, 2011
[7] Dyani Diagnosis Grouper was provided by Axiomedics Research Inc.

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Results: For this analysis, the authors refined the claim sample from the earlier study to examine those claims that had at least one prescription for fentanyl in any form, including Actiq, Fentora, any other form of generic oral transmucosal fentanyl citrate, Duragesic, or any other generic form of fentanyl transdermal system. The results, noted in Table 1, reveal that:

- More than 1 out of 5 (20.5 percent) of the Schedule II opioid claims in the study sample had at least one prescription for fentanyl;
- Fentanyl prescriptions represented more than 1 out of 5 (20.3 percent) of the Schedule II opioid prescriptions in the sample; and
- More than 1 out of 4 (25.8 percent) of the physicians who wrote Schedule II opioids prescriptions for injured workers prescribed fentanyl.

Table 1: Fentanyl Claims, Prescriptions & Prescribers: Schedule II Opioid Claims, All Injuries

	Schedule II Opioids	Fentanyl	Fentanyl as % of Schedule IIs
Number of Claims	16,890	3,460	20.5%
Number of Prescriptions	233,276	47,450	20.3%
Number of Prescribing Physicians	9,174	2,364	25.8%

Further segmenting the sample to include only those claims with a primary diagnosis of "Medical Back Problems without Spinal Cord Involvement" produced a sample of 5,253 claims, of which 1,404 (27 percent) had at least one fentanyl prescription (Table 2). The data from these 5,253 claims reveal that:

- More than 1 out of 4 (27 percent) of the non-surgical medical back claims treated with Schedule II opioids had at least one prescription for fentanyl;
- Fentanyl prescriptions accounted for more than 1 out of every 5 (21.8 percent) of the Schedule II prescriptions in the non-surgical medical back cases; and
- Three out of 10 doctors who wrote Schedule II prescriptions for non-surgical medical back patients prescribed fentanyl.

Table 2: Fentanyl Claims, Prescriptions and Prescribers
Schedule II Opioid Claims -- Medical Back Problems w/o Spinal Cord Involvement

	Schedule II Opioids	Fentanyl	Fentanyl as % of Schedule IIs
Number of Claims	5,253	1,404	26.7%
Number of Prescriptions	93,394	20,407	21.8%
Number of Prescribing Physicians	4,126	1,240	30.0%

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Fentanyl Prescribed by High- v. Low-Volume Schedule II Opioid Prescribers

CWCI's March 2011 analysis found that of the 9,174 Schedule II opioid prescribers in its study sample, the top 10 percent (based on volume of prescriptions) accounted for 79 percent of the Schedule II opioid prescriptions, 87 percent of the morphine equivalents, and their prescriptions accounted for 88 percent of all workers' compensation pharmacy dollars paid for these drugs.

For this analysis, the authors determined the total volume of fentanyl prescriptions written by the top 10 percent of the Schedule II opioid prescribers in the study sample (917 physicians) and compared that figure to the total for the other 90 percent of the medical providers (8,257 physicians) who prescribed these drugs.

Chart 1 - Percentage of Fentanyl Prescriptions in any Form (transdermal or transmucosal) Written by the Top 10% and Bottom 90% of Schedule II Opioid Prescribing Physicians

All Claims

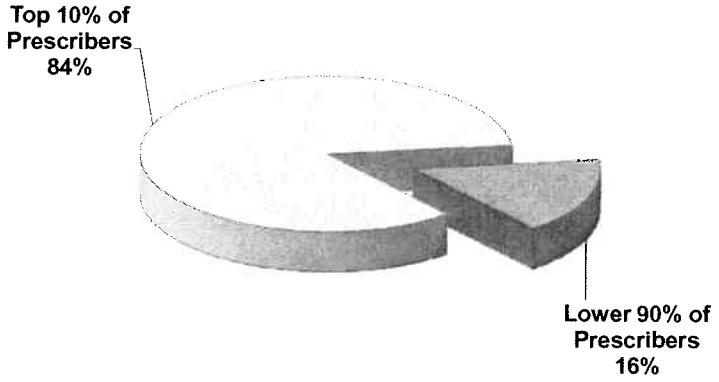

Chart 1 shows that the 917 physicians who comprised top 10 percent of Schedule II opioid prescribers in the study sample accounted for 84 percent of the fentanyl prescriptions in the sample (39,912 prescriptions, or an average of 53.5 prescriptions per physician). In contrast, the remaining 8,257 physicians who prescribed Schedule II opioids to injured workers accounted for just 16 percent of the fentanyl prescriptions (7,538 prescriptions, or less than 1 prescription per physician).

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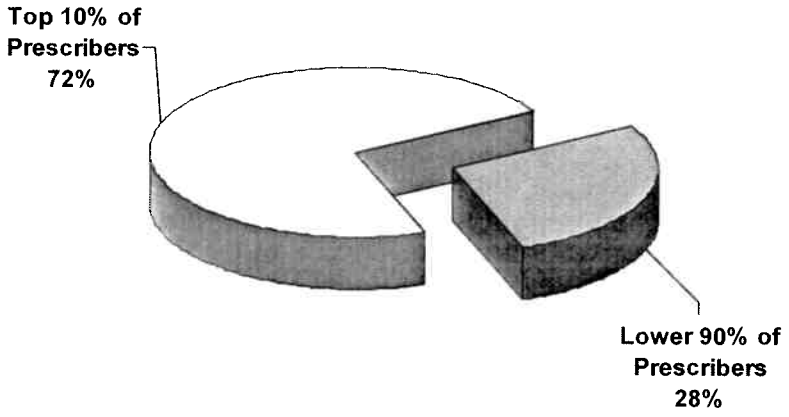
Fentanyl Prescribed by High- vs. Low-Volume Schedule II Opioid Prescribers -- Non-Surgical Medical Back Claims

The authors next determined the distribution of fentanyl prescriptions among high-volume Schedule II opioid prescribers for non-surgical medical back claims. The results, shown in Chart 2, indicate that the use of fentanyl in non-surgical medical back cases is still highly concentrated among a relatively small number of physicians, though slightly more widespread than for all claims in which opioids are used.

Chart 2 -- Percentage of Fentanyl Prescriptions in any Form (transdermal or transmucosal) for the Top 10% and Bottom 90% of Schedule II Opioid Prescribing Physicians

Non-Surgical Medical Back Claims



Among the 4,126 Schedule II opioid prescribers in the subsample of 5,253 non-surgical medical back claims, the top 10 percent (413 physicians) accounted for 72 percent of the fentanyl prescriptions in the sample (14,723 prescriptions or 35.6 prescriptions per physician). Conversely, the remaining 3,713 physicians accounted for the other 28 percent of the fentanyl prescriptions written for non-surgical medical back claimants (5,684 prescriptions or 1.5 prescriptions per physician).

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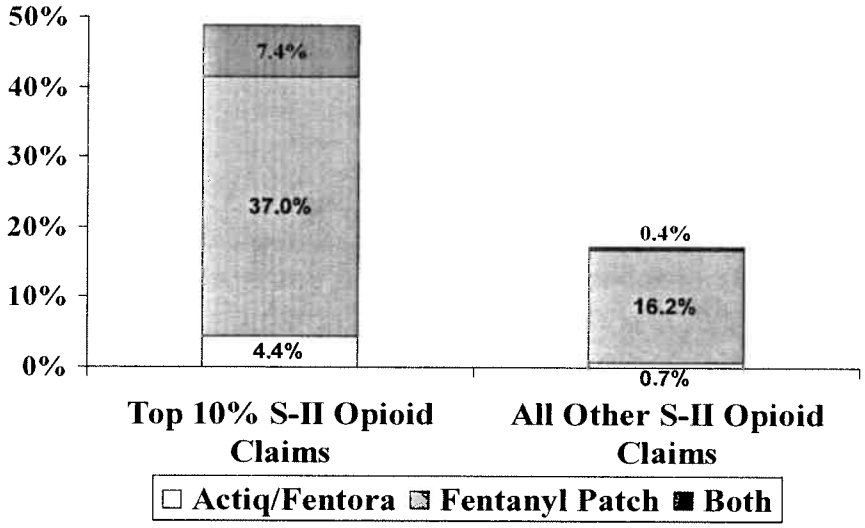
Types of Fentanyl Prescribed to Injured Workers

To gain a better understanding of the types of fentanyl prescribed to injured workers, the authors reviewed the 16,890 Schedule II opioid claims in the sample and, using the National Drug Code detail from the prescription data, categorized the claims into three groups:

1) those that had fentanyl patches as the only type of fentanyl prescription on the claim;
2) those that had fentanyl lozenges (Actiq) or effervescent tablets (Fentora) as the only type of fentanyl prescription, and
3) those that had both types of fentanyl.

Chart 3 shows the distribution of the various forms of fentanyl in the top 10 percent of the Schedule II opioid claims (1,690 claims) and in the other 90 percent of Schedule II opioid claims (15,200 claims).

Chart 3 - Percent of Schedule II Opioid Claims With Prescriptions for Actiq/Fentora, Fentanyl Patch or Both -- Top 10% of Schedule II Opioid Claims vs. All Other



Among the 10 percent of the claims in the study sample with the most Schedule II opioid prescriptions, 37.0 percent (625 claims) had at least one fentanyl patch prescription, 4.4 percent (74 claims) had an Actiq or Fentora prescription, and 7.4 percent (125 claims) had both types of fentanyl prescriptions. Thus, all together, almost half (48.8 percent) of these high-volume Schedule II opioid claims had at least one fentanyl prescription. In contrast, among the 15,200 claims that comprised the other 90 percent of the Schedule II opioid claims, 16.2

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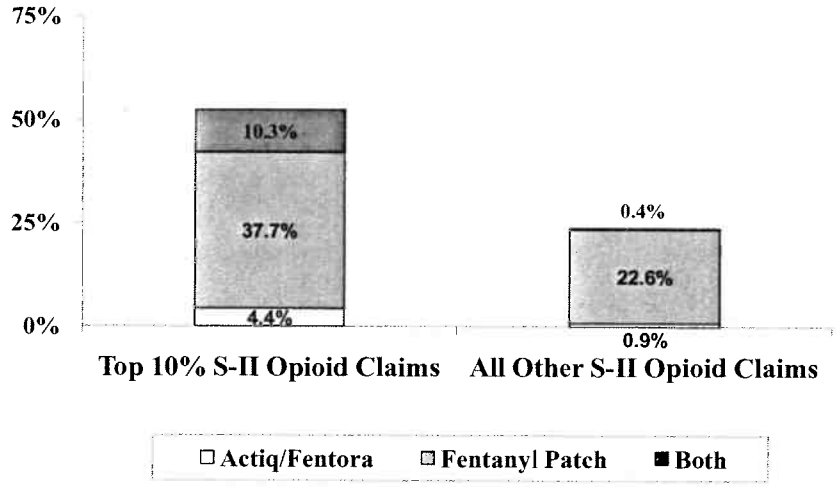
percent (2,462 claims) involved fentanyl patches, 0.7 percent (106 claims) had an Actiq or Fentora prescription, and 0.4 percent (61 claims) had both types of fentanyl prescriptions, for an aggregate total of 17.3 percent (or more than 1 out of 6) of these lower volume Schedule II opioid claims that involved some form of fentanyl. In both the high-volume and the lower-volume Schedule II opioid claim samples, the transdermal patch was by far the leading form of fentanyl prescribed to injured workers.

Types of Fentanyl Prescribed in Non-Surgical Medical Back Claims

Because injury types vary among the sample of claims, the analysts again looked at the types of Fentanyl that were prescribed for the subset of claims with a primary diagnosis of minor back injury not involving the spine and not needing surgical intervention. Once again, for comparative purposes, the results were broken out separately for the 10 percent of the non-surgical medical back claims with the greatest number of Schedule II opioid prescriptions (525 claims) and for the balance of the non-surgical medical back cases (4,728 claims) that involved Schedule II opioids.

Chart 4 -- Schedule II Opioid Claims for Non-SurgicalMedical Back Injury -- % of Claims Involving Actiq/Fentora, Fentanyl Patch or Both

Top 10% of Schedule II Opioid Claims vs. All-Other



Among the 525 cases that comprised the 10 percent of the minor back injury claims with the most Schedule II opioid prescriptions, 37.7 percent (198 claims) had at least one fentanyl patch prescription, 4.4 percent (23 claims) had an Actiq or Fentora prescription and 10.3 percent (54 claims) had both types of fentanyl prescriptions. Among the subsample of non-surgical back cases with the highest volume of Schedule II opioid

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prescriptions, more than half (52.4 percent) had some form of fentanyl prescribed, so the rate of fentanyl use on these minor back claims was even higher than the 48.8 percent rate noted for all high-volume Schedule II opioid claims. In contrast, among the other 4,728 minor back injury claims that had one or more Schedule II opioid prescriptions, 22.6 percent (1,069 claims) involved fentanyl patches, 0.9 percent (43 claims) involved Actiq or Fentora, and 0.4 percent (19 claims) had both the patches and Actiq or Fentora. All together, some form of fentanyl was used in nearly one quarter (23.9 percent) of the lower volume Schedule II opioid claims for minor back problems, compared to 17.3 percent of the lower volume Schedule II opioid claims involving all injury types. Thus, the minor back cases showed a heavier reliance on fentanyl, particularly among the relatively low opioid usage claims.

Summary: Parts 1 and 2 of the CWCI Schedule II Opioid Prescribing Patterns research series have shown that the 10 percent of physicians who write the most Schedule II opioid prescriptions for injured workers in California are associated with 79 percent of all workers' compensation prescriptions for these types of narcotics, and for 84 percent of the fentanyl prescriptions. Most of the fentanyl prescriptions were transdermal patches, which have limited FDA approved uses and have been the subject of multiple FDA warnings. California workers' compensation pain management guidelines also say the patches should only be used for chronic pain patients requiring round-the-clock therapy, who have developed a tolerance for other opioids, and whose pain cannot be managed by other therapy. Furthermore, there was no evidence of cancer-related illness or injury among any of the injured workers in the study sample, indicating that off-label use of fentanyl lozenges or tablets, which are only FDA approved for breakthrough, chronic cancer pain, has become an issue in the California system. The study found that off-label use of fentanyl was concentrated in the 10 percent of the claims (1,690 cases) with the highest volume of Schedule II opioid prescriptions, where nearly 12 percent (199 cases) had prescriptions for lozenges or tablets. The rate of off-label use was even higher for the top 10 percent of medical back cases with the most Schedule II opioid prescriptions – where 77 of the 525 patients, or nearly 15 percent, were prescribed fentanyl lozenges or tablets.

Later this year, CWCI will release Part 3 of its Schedule II Opioid Prescribing Patterns research analyzing differences in dosage patterns between high- and low-frequency prescribers over the course of an injury.

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ABOUT CWCI

The California Workers' Compensation Institute, incorporated in 1964, is a private, non-profit organization of insurers and self-insured employers conducting and communicating research and analyses to improve the California workers' compensation system. Institute members include insurers that collectively write about 80 percent of California workers' compensation direct written premium, as well as many of the largest public and private self-insured employers in the state.

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CWCI
Research Notes

February 2013

Current Trends in Compound Drug Utilization and Cost in the California Workers' Compensation System

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Eileen Auen, MBA

Summary

Recent public health concerns and legislative actions have raised the profile of compound drug utilization in the California workers' compensation system. In 2011, California lawmakers enacted Assembly Bill 378, which took effect January 1, 2012. The legislative intent of this statute was to control the increase in prescriptions for and the costs associated with compounded pharmaceutical products in the California workers' compensation system through the implementation of unit price controls. This study examines changes in compound drug utilization and payments before and after the implementation of AB 378 by measuring the volume of compound drugs prescribed to California injured workers and the amounts reimbursed for those drugs in the first half of 2011 to the comparable data from the first half of 2012. Among the key findings:

- **Declining Share of Workers' Compensation Prescriptions, But Increasing Share of the Prescription Dollars:** Compound drugs fell from 3.1 percent of California workers' compensation prescriptions in the first half of 2011 to 2.0 percent of the prescriptions dispensed to injured workers in the first six months of 2012, a relative decline of 35 percent; yet at the same time, compound drug reimbursements increased from 11.6 percent to 12.6 percent of California workers' compensation prescription payments, a relative increase of 9 percent.
- **Higher Average Payments:** Over the same period, the average amount paid per compound drug prescription increased 68.2 percent from $460.42 to $774.21, while the average paid for a non-compound drug prescription decreased 4.6 percent from $112.78 to $107.61.
- **More NDC Ingredients and Increased Payments Per Ingredient Yet No Change in Days' Supply:** The average number of NDC ingredients used within compounded drugs dispensed to California injured workers increased from 3.4 in the first half of 2011 to 3.8 in the first half of 2012, a 13.1 percent increase; while the average paid per NDC ingredient increased 48.7 percent from $135.63 to $201.67. In addition, there was a 25.5 percent increase in the quantity per NDC ingredient but virtually no change in the average days' supply per compound drug prescription, suggesting that more potent compound drugs are being dispensed.
- **Quality of Care and Cost Concerns:** There is little evidence from clinical trials to support the use of many of the compound drugs dispensed to injured workers. Ingredients such as Dextromethorephan are reimbursed at significantly higher levels than alternative therapeutic equivalents without adequate cost/benefit evaluation. The lack of rigorous independent evaluation and the lack of federal and state oversight limit the California workers' compensation payers' ability to control compound drug utilization and cost.

Background

Pharmaceutical utilization and cost has been a fluid and controversial issue for over a decade in the California workers' compensation system. In recent years, as concerns have grown about the quality and the escalating cost of care given to injured workers, state legislators and regulators have made several attempts to curb the growth in pharmaceutical prescription pricing and packaging. In 2002, California lawmakers passed Assembly Bill 749, the first of several workers' compensation reforms that included provisions to modify the delivery of pharmacy benefits and contain the rapidly escalating cost of prescription drugs used to treat injured workers. In January 2004, the California Division of Workers' Compensation adopted a pharmacy fee schedule that capped maximum reimbursements for pharmacy services and drugs at 100 percent of Medi-Cal rates, which at the time, were at least 10 percent below the average wholesale price (AWP) for prescription drugs, plus a dispensing fee. However, these legislative and regulatory adjustments, which focused on unit price controls, were only partially successful in containing the growth in workers' compensation prescription drug costs. Following the full implementation of the 2002-2004 reforms, the average amount paid for pharmaceuticals on a California workers' compensation indemnity claim within the first two years of injury more than doubled from $599 to $1,234 between accident years 2005 and 2009.[1]

Several factors contributed to the rapid increase in workers' compensation pharmaceutical costs, including the changing mix of drugs used to treat injured workers, most alarmingly, the well-documented increase in the use of Schedule-II opioid painkillers, even in the treatment of relatively minor injuries.[2,3] In addition, prior to 2007, medications not covered by Medi-Cal – such as repackaged drugs dispensed from a physician's office – were often paid according to the 2003 Official Medical Fee Schedule. That schedule set maximum fees at 140 percent of the AWP for generic drugs, and 110 percent of the AWP for brand drugs, plus a dispensing fee, resulting in reimbursements well beyond levels established in 2004. This differential pricing paid physicians who dispensed repackaged drugs directly from their offices significantly more than pharmacies for the same medications. Neuhauser (2006) found that workers' compensation reimbursements for repackaged drugs often exceeded the amounts paid for equivalent pharmacy-based prescriptions by 500 percent or more. As a result, by 2006, repackaged drugs dispensed by doctors accounted for more than half of all workers' compensation prescriptions dispensed in California, and nearly 60 percent of all workers' compensation prescription dollars. In April 2007, the Division of Workers' Compensation responded by revising the pharmacy fee schedule which, as of March of that year, largely eliminated the differential pricing. The effect was immediate, as both the volume of repackaged drugs and the amounts paid for these medications plummeted, declining more than 90 percent by 2011.[5]

After the repackaged drug regulations took effect, some manufacturers began promoting compound drugs, medical foods and convenience packs (or "co-packs") that included prescription medications and "medical foods" to California workers' compensation medical providers. Ireland (2010) found that between the first quarter of 2006 and the first quarter of 2009, total payments for these products increased from 2.3 percent to 12.0 percent of all pharmaceuticals in the California workers' compensation system.[6]

Controversies with Compound Drugs

Compounding pharmacies provide drugs to patients who may experience challenges obtaining specific prescription medications that are not available through conventional means. Such challenges include special formulation requirements to improve tolerance or products that lack a critical mass of potential patients to make their manufacturing economically viable. Although many compound drugs outside of workers' compensation are related to hormone replacement, dermatology, children's formulations for those who can't swallow pills and anti-cancer treatment, most of the compounded drugs in the California workers' compensation system are pain management medications delivered through topical creams.

1 Ireland, J., Swedlow, A., Gardnet, L. Analysis of Medical and Indemnity Benefit Payments, Medical Treatment and Phatmaceutical Cost Trends in the California Workets' Compensation System. CWCI, June 2012.

2 Swedlow, A., Gatdnet, L., Ireland, J., Genovese, E. Pain Management and the Use of Opioids in the Treatment of Back Conditions in the Califotnia Workets' Compensation System. Reportt to the Industry. CWCI. June 2008

3 Swedlow, A., Ireland, J., Johnson, G. Ptescribing Patterns of Schedule II Opioids in California Wotkets' Compensation. Research Update, CWCI. March 2011

4 Neuhauset, F., Swedlow, A.,Wynn, B. Impact of Physician-Dispensing of Repackaged Drugs on Califotnia Workers' Compensation, Employets Cost, and Workers' Access to Quality Care. Commission on Health and Safety and Workets' Compensation. July 2006

5 Ireland, J., Swedlow, A., Gardner, L. Analysis of Medical and Indemnity Benefit Payments, Medical Treatment and Pharmaceutical Cost Trends in the California Wotkets' Compensation System. Califotnia Workers' Compensation Institute. June 2012.

6 Ireland, J., & Swedlow, A.. The Cost and Utilization of Compound Drugs, Convenience Packs, and Medical Foods in California Workers' Compensation CWCI Research Notes: Califotnia Wotkers' Compensation Institute. (August 2010)

Multiple reports have documented the differences between drug compounding and conventional drug manufacturing. Compound drugs do not fall under FDA jurisdiction, and therefore they are not subject to the same standards and protocols as traditional pharmaceuticals. Instead, the responsibility to regulate compound drugs rests with Boards of Pharmacy on a state-by-state basis. In California, the production, distribution and pricing of compound drugs are all regulated by the state Code of Regulations.[7]

There have been several recent events that have called into question the safety and efficacy of drug compounding. In 2006, the U.S. Food and Drug Administration (FDA) published a review of surveys conducted on compounding pharmacies.[8] The survey found that 33 percent of compounded finished product samples did not conform to product labeling standards in terms of potency and/or content uniformity, and that such discrepancies can lead to medication errors and health risks for patients who rely on compounded drugs. The report concluded that "Poor quality compounded drugs are a serious public health concern, as improperly compounded products have been linked to grave adverse events, including deaths."

In 2010, the controversy over quality control for compound drugs crossed over into veterinary medicine when a veterinary compounding pharmacy in Florida was challenged by the FDA for its manufacture and distribution of a vitamin supplement which proved fatal to 21 championship polo ponies during the U.S. Open Polo Championships in April 2009.[9]

More recently, a multi-state investigation by the Centers for Disease Control and Prevention (CDC) was initiated following a 2012 outbreak of fungal meningitis and other infections associated with compound drugs and medical products from the New England Compounding Center (NECC) in Framingham, Massachusetts. Laboratory tests conducted by the CDC and FDA found bacterial and/or fungal contamination in unopened vials of betamethasone, cardioplegia, and triamcinolone solutions distributed and recalled from NECC. According to the CDC, as of January 2013, 678 people in 19 states who had been exposed to preservative-free methylprednisolone acetate (MPA) injections linked to one of three lots produced by the NECC had contracted meningitis, and 44 had died.[10]

Assembly Bill 378

Assembly Bill 378, signed into law in 2011 and implemented on January 1, 2012, was designed to curb the increased use of and the rapidly growing costs associated with compounded pharmaceutical products in the California workers' compensation system. The measure sought to reduce the amounts paid for compounded drugs used to treat injured workers through the adoption of additional unit price controls and billing conventions. AB 378 strengthened the pharmacy fee schedule by requiring that any compounded drug used to treat an injured worker must be billed at the ingredient level by the compounding pharmacy or dispensing physician, with each ingredient identified using the applicable National Drug Code (NDC) of the ingredient and the corresponding quantity. The bill also prohibited separate reimbursement for ingredients with no NDC. Workers' compensation reimbursements for compounded medications were set at the rates allowed by Medi-Cal for each ingredient, plus a dispensing fee equal to that allowed by Medi-Cal. The maximum reimbursement for a compound drug dispensed by a physician was set at 300 percent of the physician office's Documented Paid Cost, but in no case could that amount exceed $20 above the Documented Paid Cost.[11] AB 378 also added compound drugs and other "pharmacy goods" to the list of medical products and services that workers' compensation physicians are prohibited from self-referring. Self-referral has been associated with higher utilization and cost when compared to similar services procured from non-self-referring physicians.[12, 13]

Due to the recent passage and implementation of AB 378, and the increased awareness and concern about the quality of compound drug manufacturing, there is a high degree of interest in evaluating preliminary outcomes associated with the bill's legislative intent. The following study was commissioned to measure changes in the utilization and reimbursement of compound drugs in California workers' compensation since the implementation of AB 378.

7 Title 8, Cal. Code of Regs. §9789.40

8 U.S. Food and Drug Administration, 2006 Limited FDA Survey of Compounded Drug Products (http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm204237.htm)

9 Milenkovich, N., FDA Argues Legal Definition of Compounding After Deaths of 21 Polo Ponies. Drug Topics, Dec 15, 2010, Volume 154, Issue 12

10 Centers for Disease Control and Prevention. Update on Multistate Outbreak of Fungal Meningitis. (http://www.cdc.gov/hai/outbreaks/meningitis.html)

11 In addition to the billing provisions of AB 378, the state adopted regulatory changes in April 2011 that affected workers' compensation medical billing -- including bills for compound drugs. These regulations set new medical billing standards for paper bills submitted on and after October 15, 2011, and included standardized billing forms, required fields and code sets, required supporting documentation, and transmission standards.

12 Mitchel, J. Urologists' Self-Referral For Pathology Of Biopsy Specimens Linked To Increased Use And Lower Prostate Cancer Detection. Health Affairs April 2012 vol. 31 no. 4 741-749

13 Swedlow, A., Johnson, G., Smithline, N., Milstein, A. Increased Costs and Rates of Use In The California Workers' Compensation System As A Result Of Self-Referral By Physicians. The New England Journal of Medicine. Vol. 327, No. 2: 1502-1506 November 1992.

Data & Methods

For this study, the authors compiled a special data set of conventional non-compound and compound drugs. The data set was unique in that it contained detailed information linking all NDC components or National Drug Code (NDC) ingredients within each compound prescription. The data was divided into two time periods:

- **Pre-AB 378:** prescriptions filled between January 1 through June 30, 2011; and
- **Post-AB 378:** prescriptions filled between January 1 through June 30, 2012.

The time frames were designed to limit a potential bias in the seasonality of injuries and associated pharmaceutical regimens. The final dataset contained 586,575 compound and non-compound prescriptions that were dispensed to injured workers across the two time periods, resulting in a total of $71,457,069 in workers' compensation payments.

In order to measure the preliminary outcomes of utilization and reimbursement before and after the implementation of AB 378, the authors explored several key dimensions of utilization and cost, including changes in:

- compound drug prescriptions as a percentage of all workers' compensation prescriptions;
- compound drug payments as a percentage of all workers' compensation pharmaceutical payments;
- average number of ingredients per compound drug;
- average amount paid per compound drug prescription;
- average amount paid per ingredient within compound drugs;
- average quantity per ingredient per compound; and
- average days' supply per compounded presecription.

Results

Exhibit A displays the breakdowns of compound versus non-compound drugs among California workers' compensation prescriptions from the pre- and post-AB 378 study samples.

Exhibit A. Distribution of California Workers' Compensation Prescriptions

Compound Vs. Non-Compound Drugs
Pre- and Post AB 378 Study Samples

Prescription Type	Pre-AB 378 (Jan - Jun 2011)	Post-AB 378 (Jan - Jun 2012)	% Change (Pre:Post AB 378)
Non-Compound	96.9%	98.0%	1.1%
Compound	3.1%	2.0%	-35.4%

The prescription drug distribution from the pre-AB 378 sample shows compound drugs comprised 3.1 percent of all California workers' compensation prescriptions prior to the implementation of the statute, while the breakdown for the post-AB 378 sample shows that in the first six months after the law took effect, compound medications accounted for only 2.0 percent of the prescriptions dispensed to injured workers – a relative decline of 35.4- percent from the year-earlier figure.

Exhibit B shows the distribution of California workers' compensation prescription payments between compound and non-compound drugs for the pre- and post-AB 378 samples.

Exhibit B. Distribution of California Workers' Compensation Prescription Payments

Compound Vs. Non-Compound Drugs
Pre- and Post AB 378 Study Samples

Prescription Type	Pre-AB 378 (Jan - Jun 2011)	Post-AB 378 (Jan - Jun 2012)	% Change (Pre:Post AB 378)
Non-Compound	88.4%	87.4%	-1.1%
Compound	11.6%	12.6%	9.0%

Even though compound drugs accounted for a much smaller share of California workers' compensation prescriptions after AB 378 became law, the percentage of workers' compensation prescription dollars used to pay for these drugs continued to grow, climbing from 11.6 percent of all prescription payments prior to the reform to 12.6 percent after AB 378 took effect -- a relative increase of 9 percent.

Exhibit C. shows the average amounts paid for compound and non-compound prescriptions from the pre- and post-AB 378 samples.

Exhibit C. Average California Workers' Compensation Prescription Payments

Compound Vs. Non-Compound Drugs
Pre- and Post-AB 378 Study Samples

Prescription Type	Pre-AB 378 (Jan - Jun 2011)	Post-AB 378 (Jan - Jun 2012)	% Change (Pre:Post AB 378)
Non-Compound	$112.78	$107.61	-4.6%
Compound	$460.42	$774.21	68.2%
All (Non-Compound + Compound)	$123.56	$120.68	-2.3%

As noted above, the average amount paid for all California workers' compensation prescription drugs in the sample decreased 2.3 percent, from an average of $123.56 for the pre-AB 378 prescriptions to an average of $120.68 in the post-AB 378 sample. Despite this overall decline, however, the average amount paid per compound drug increased 68.2 percent from $460 to $774 per prescription, which stands in sharp contrast to the 4.6 percent decline in the average payment per non-compound drug prescription over the same period.

Compound drugs are formulated from multiple ingredients, which under AB 378, must be billed at the ingredient level using the applicable NDC. Exhibit D displays the average number of ingredients in compound drugs used in California workers' compensation before and after AB 378 took effect, as well as the average amounts paid per ingredient, the average quantity of each ingredient, and the average days' supply per compounded prescription.

Exhibit D. Average Number of Ingredients, Payment per Ingredient, Quantity per Ingredient & Days' Supply per Compound

California Workers' Compensation Compound Drugs
Pre- and Post-AB 378 Study Samples

	Pre-AB 378 (Jan - Jun 2011)	Post-AB 378 (Jan - Jun 2012)	% Change (Pre:Post AB 378)
Avg NDCs per Compound	3.4	3.8	13.1%
Avg Paid per NDC	$135.63	$201.67	48.7%
Avg Quantity per NDC	31.5	39.5	25.5%
Avg Days' Supply per Compound	30.0	28.9	-3.5%

The results show that after the unit price controls of AB 378 were put in place, both the volume of ingredients used in the workers' compensation compound drugs, and the average amount paid per ingredient increased. The average number of NDC ingredients per compound prescription rose from an average of 3.4 in the first half of 2011 to an average of 3.8 in the first half of 2012 – a 13.1 percent increase; while the average amount paid per ingredient increased 48.7 percent, from $135.63 to $201.67. The data also show a 25.5 percent increase in the quantity per NDC in the first half of 2012. In addition, there was an immaterial change (-3.5 percent) in the average days' supply per compound drug prescription. Increases in quantity per NDC with no change in days' supply is indicative of higher compound potency.

There are eight therapeutic classes of ingredients found in the compound drug study sample. Pharmaceutical adjuvants such as Pencream and Ultraderm, which are essentially inactive ingredients that are combined with active ingredients to facilitate delivery to the body, are the most prevalent class. On the other hand, the anti-inflammatories (i.e. Fluribiprofen and Ketoprofen Powders) account for the highest percentage of payments. Exhibit E shows the incidence and payment distributions for the top 8 compound drug ingredient categories within the pre- and post-AB 378 study samples.

As noted in Exhibit E, the NDC category with the highest rate of growth in both incidence and price was the cough and cold category, specifically the ingredient Dextromethorephan Powder, a synthetic morphine derivative typically used as a cough suppressant. This ingredient, which is also sometimes used for neuropathic pain management, has recently been linked to recreational drug use. Within the study sample, this ingredient was found to be exclusively combined with anti-depressants.

Exhibit E. California Workers' Compensation Prescriptions – Top 8 Compound Drug Ingredients and Distribution of Payments

Pre- and Post-AB 378 Study Samples

	Percent of Compound Ingredients (NDCs)			Percent of Total Paid		
NDC Category	**Pre-AB 378** (Jan - Jun 2011)	**Post-AB 378** (Jan - Jun 2012)	**% Change*** (Pre:Post AB 378)	**Pre-AB 378** (Jan - Jun 2011)	**Post-AB 378** (Jan - Jun 2012)	**% Change*** (Pre:Post AB 378)
Anti-Inflammatories	9.6%	15.1%	56.8%	24.2%	48.8%	102.0%
Bulk Drugs and Chemicals	33.2%	23.3%	-30.0%	62.7%	36.1%	-42.5%
Dermatological	22.4%	17.0%	-24.3%	1.8%	0.9%	-52.5%
Pharmaceutical Adjuvants	23.6%	24.5%	3.6%	4.2%	4.3%	2.6%
Skeletal Muscle Relaxants	4.0%	5.0%	20.7%	5.0%	4.1%	-18.1%
Cough/Cold	0.4%	6.4%	1,386.0%	0.2%	3.4%	2,141.5%
Anti-Depressants	4.3%	6.8%	59.2%	1.7%	2.4%	46.2%
Anti-Convulsants	< .01%	< .01%	31.3%	< .01%	< .01%	28.8%
Total**	97.6%	98.1%	0.5%	99.7%	100.0%	0.3%

* The percentages shown for the ingredient and payment distributions are rounded to the nearest 0.1%, but to be precise in measuring the growth rates for each NDC category, the relative changes (% Change, Pre:Post AB 378) were calculated using actual, unrounded percentages.

** Totals do not include vitamins, unclassified drugs, hypnotics, ulcer drugs, diuretics, or antiseptics.

The leading NDC components within each of the top 8 compound pharmaceutical categories used in California workers' compensation are included in Appendix A.

Discussion

The changes in the utilization and cost of compound drugs associated with the implementation of AB 378 point to a mixed bag of statutory and administrative successes and remaining challenges. The successes are found in the legislative intent to curb compound drug utilization, as the data show that compound drugs fell from 3.1 percent of California workers' compensation prescriptions prior to AB 378 to 2 percent of the prescriptions after the law took effect. Among the factors likely to have contributed to this decrease is the widespread publicity surrounding the recent fatalities linked to compound drugs, as well as the growing concerns about sub-standard quality controls associated with drug compounding. Many payors report that the utilization review systems within their pharmacy benefit management programs have become increasingly vigilant in regard to compound drug requests, with stricter enforcement available from adherence to guidelines supported by the California Workers' Compensation Medical Treatment Utilization Schedule.[14] It is also reasonable to associate the decrease in compound prescriptions to the self-referral prohibitions of AB 378, which removed a layer of economic conflict of interest that had become a diagnostic and ancillary service cost driver in the California workers' compensation system.

The remaining challenges are found in the unintended consequences associated with the reform: the growing percentage of prescription dollars used to pay for compound drugs; the higher average payments per compound prescription; and the increased number and the higher quantities of ingredients per compound with little change in the average days' supply. The increase in the number and quantity of ingredients with the same days' supply typically implies a more potent dosage, which would be consistent if patients were experiencing more severe pain or physicians/pharmacies were trying to substantiate the increase in ingredients and cost. Regardless, the provider and compounding pharmacy community would have to make a strong argument that their patient profile has shifted to significantly sicker patients requiring higher dosages, or that new evidence for each drug shows that higher dosages are required to receive the same responses -- a difficult argument to substantiate given the paucity of clinical trials.

Calculating total healthcare costs follows a simple formula:

Unit Price x Number of Units = Total Cost

Over the years, federal, group, and workers' compensation medical management strategies have experimented with emphasizing combinations of unit price controls through fee schedules and/or controls on the number of units through medical treatment guidelines or other strict administrative

14 Title 8, Cal. Code of Regs., §9792.20-9792.26.

limits. California workers' compensation medical reforms enacted in 2003 and 2004 implemented several combinations of unit price and utilization control in an attempt to reduce the overall cost of care. The results were mixed, as increases in fees for evaluation and management services and medical legal reports were not associated with changes in utilization, whereas "strict" 24-visit caps on physical medicine and chiropractic care continue to yield significant reductions in both utilization and cost from pre-reform levels.[15] Health services research has long suggested that emphasis on one strategy, such as fee schedules, can create economic incentives to increase utilization. It is arguable that the results of this study suggest that the potential savings intended by AB 378's unit price controls on compounded drugs were quickly offset through adjustments in the count and volume of compound drug ingredients, as well as the use of higher priced components.

The study also showed new trends in ingredient selection. For example, between the first half of 2011 and the first half of 2012, Dextromethorephan, a cold and cough medication increased from 0.4 to 6.4 percent of all compound ingredients. Dextromethorephan use in compounds is considered controversial to some in that it has recently been associated with recreational drug use, and while some clinicians cite evidence of its efficacy for the treatment of neuropathic pain and improving tolerance to opioids, the lack of conclusive support is justification for caution. In addition, there is little, if any, evidence from clinical trials to show that when compounded with topical creams, many of the cough/cold, antidepressant and muscle relaxant ingredients listed in Appendix A can be adequately absorbed through the skin without compromise. Lacking adequate studies and extensive testing of these compounds by vehicle, pH, or dosage ranges, there are few objective means to verify the clinical benefit of many of the compound products containing these ingredients.

The lack of rigorous independent evaluation and inadequate federal and state oversight of drug compounding limit the California workers' compensation system from optimal pharmaceutical management of compound pharmaceuticals. The history of healthcare public policy shows that effective medical management balances fair market pricing with scientifically-based, efficacious treatment standards. If legislators and regulators remain convinced that compound drug use requires additional controls, they will need to reinforce compound drug unit price controls with stricter utilization controls. The California workers' compensation system may consider the lessons from other healthcare delivery systems. Wynn noted that Medicare has strict prohibitions against the use of non-FDA approved medications[16] and Sellars provides additional justification for such a prohibition: " A primary tenet of traditional compounding is that an FDA-approved product should be used wherever possible to meet a patient's individual medical needs, because, despite best compounding practices extemporaneous formulations generally lack studies to document stability, bioavailability, pharmacokinetics, pharmacodynamics, efficacy and safety. This tenet restricts the use of compounded drugs to where they are medically necessary and protects the public from intentional circumvention of the FDA approval and regulatory process that consumers rely on for safe and effective therapies"[17] In terms of the use of compound medications in California workers' compensation, prohibitions similar to those imposed by Medicare could be accomplished through additional legislation or modifications to the existing medical treatment utilization schedule, or through the adoption of a pharmaceutical formulary.

The data used in the analysis contained some limitations. The analysis only considered ingredient cost and did not include dispensing fees or other administrative costs. Dispensing fees are generally higher for compounds and were increased when the California workers' compensation system fee schedule was set at 100 percent of Medi-Cal's fee schedule, so future studies should attempt to measure changes in dispensing fees. In addition, AB 378 required medical billing changes, including more detailed itemization of NDCs associated with compounds. Whether or not these new coding standards contributed to the observed cost differences in a material way is unknown, and is an area to consider in future research. Finally, AB 378 was implemented in January 2012, so there has been limited time for system-wide reaction and adjustment. However, California's history with pharmaceutical reform shows how swiftly utilization trends can change (the most notable example being the 90 percent drop in the utilization and cost of repackaged drugs within 12 months of the elimination of differential pricing), so the authors will continue to monitor compound drug utilization, formulation and reimbursement trends.

15 Ireland, J., Swedlow, A., Gardner, L. Analysis of Medical and Indemnity Benefit Payments, Medical Treatment and Pharmaceutical Cost Trends in the California Workers' Compensation System. California Workers' Compensation Institute. June 2012.

16 Wynn, B. Use of Compound Drugs, Medical Foods, and Co-Packs in California Workers' Compensation Program –Working Paper. Prepared for the Commission on Health, Safety and Workers' Compensation. January 2011

17 Sellers, S., Utian, W. "Pharmacy Compounding Primer for Physicians: Prescriber Beware," Medscape, Dec. 12, 2012.

Appendix A. Distribution of California Workers' Compensation Compound Drug Ingredients and Payments Top 8 Ingredient Categories (Jan-Jun 2011 vs. Jan-Jun 2012)

Anti-Inflammatories	2011 NDC	2012 NDC	% Change	2011 Payments	2012 Payments	% Change
Flurbiprofen Powder	5.2%	9.1%	74.5%	14.9%	34.7%	133.2%
Ketoprofen Powder	4.3%	6.0%	39.2%	9.3%	14.1%	52.4%
Piroxicam Powder	0.1%	< .05%	-84.5%	< .05%	< .05%	
Nabumetone Tablet 750MG	< .05%	N/A		< .05%	N/A	
Percent of Total NDC's for Period	9.6%	15.1%	56.8%	24.2%	48.8%	102.0%
Bulk Drugs and Chemicals	**2011 NDC**	**2012 NDC**	**% Change**	**2011 Payments**	**2012 Payments**	**% Change**
Tramadol HCL Powder	11.1%	8.3%	-25.2%	37.4%	28.8%	-23.1%
Menthol Crystals	9.5%	6.3%	-33.7%	0.4%	0.2%	-64.7%
Diclofenac Powder Sodium	8.3%	3.7%	-55.2%	20.9%	3.6%	-82.8%
Gabapentin Powder	1.6%	2.0%	21.8%	3.0%	2.7%	-10.4%
Lidocaine Powder	0.8%	0.9%	18.4%	0.1%	< .05%	-41.8%
L-Menthol Crystals	0.4%	0.6%	60.0%	0.4%	< .05%	-90.3%
Dextrometh Powder	0.2%	0.4%	105.1%	0.5%	0.7%	30.2%
Ketamine Hydrochloride Powder	0.1%	0.1%		< .05%	0.1%	
Ethoxy Ethanol Liquid Reagent	0.1%	0.1%	12.5%	< .05%	< .05%	
Hyaluronic Powder Sodium	0.1%	< .05%	-64.2%	0.3%	0.1%	-72.7%
Isopropyl Liquid Palmitate	0.1%	< .05%	-89.6%	< .05%	< .05%	
Glycerin Liquid	0.7%	< .05%	-95.8%	< .05%	< .05%	
Ethoxy Liquid Diglycol	0.1%	< .05%	-57.8%	< .05%	< .05%	
Hydroxyethyl Cellulose Powder	< .05%	< .05%		< .05%	0.1%	
Ranitidine Hydrochloride Powder	< .05%	< .05%		< .05%	< .05%	
Cellulose Powder NF	< .05%	< .05%		< .05%	< .05%	
Lecithin Soy Granules	< .05%	0.5%		< .05%	< .05%	
Olive Oil	< .05%	N/A		< .05%	N/A	
Ethoxy Liquid Diglycol	< .05%	N/A		< .05%	N/A	
Lecithin Granules	< .05%	N/A		< .05%	N/A	
Acetamin Powder USP/NF	< .05%	< .05%		< .05%	< .05%	
Fluorescein Powder Sodium	< .05%	N/A		< .05%	N/A	
Polysorbate Solution 20	< .05%	N/A		< .05%	N/A	
Mercaptopurine Powder	< .05%	N/A		< .05%	N/A	
Carbomer Powder 934P	< .05%	N/A		< .05%	N/A	
Ammonium Powder Bicarbonate	< .05%	N/A		< .05%	N/A	
Glucosamine Powder	N/A	0.1%		N/A	< .05%	
Ketoconazole Powder	< .05%	N/A		< .05%	N/A	
Lansoprazole Powder	N/A	< .05%		N/A	< .05%	
Corn Starch Powder	N/A	< .05%		N/A	< .05%	
Percent of Total NDC's for Period	33.2%	23.3%	-30.0%	62.7%	36.1%	-42.5%

Appendix A. Distribution of California Workers' Compensation Compound Drug Ingredients and Payments Top 8 Ingredient Categories (Jan-Jun 2011 vs. Jan-Jun 2012) – continued

Dermatologicals	2011 NDC	2012 NDC	% Change	2011 Payments	2012 Payments	% Change
Capsaicin Powder	10.7%	7.2%	-33.0%	1.60%	0.60%	-62.8%
Camphor Granules	7.2%	3.4%	-53.2%	< .05%	< .05%	
Camphor Crystal Synthetic	1.8%	3.3%	77.8%	< .05%	< .05%	
Lidocaine Hydrochloride Powder	2.6%	3.2%	21.7%	0.20%	0.20%	26.0%
Percent of Total NDC's for Period	22.4%	17.0%	-24.3%	1.8%	0.9%	-52.5%
Pharmaceutical Adjuvants	**2011 NDC**	**2012 NDC**	**% Change**	**2011 Payments**	**2012 Payments**	**% Change**
Pencream Cream	15.5%	8.9%	-42.4%	1.4%	0.7%	-50.8%
PCCA Lipoderm Cream Base	5.3%	5.5%	4.2%	1.1%	0.8%	-31.5%
Ultraderm Cream	1.6%	4.6%	192.6%	1.6%	2.0%	27.0%
Penderm Cream	0.4%	4.1%	854.9%	0.1%	0.9%	714.8%
Poloxamer Powder 407	0.1%	0.5%	350.9%	< .05%	< .05%	
Pluronic Gel F127 20%	0.1%	0.3%	140.3%	< .05%	< .05%	
Lecithin Gel	0.1%	0.2%	392.4%	< .05%	< .05%	
Camphor Gum Gum Blocks	0.2%	0.1%	-35.5%	< .05%	< .05%	
Versabase Cream	0.10%	< .05%	-85.90%	< .05%	< .05%	
Sorbic Acid Powder	< .05%	< .05%		< .05%	< .05%	
PLO Transdermal Cream	< .05%	< .05%		< .05%	< .05%	
Ethyl Alcohol Solution 100%	< .05%	< .05%		< .05%	< .05%	
Lactose Powder Monohydrate	< .05%	< .05%		< .05%	< .05%	
Lipmax Solution	< .05%	N/A		< .05%	N/A	
Potassium Sorbate Crystal	< .05%	N/A		< .05%	N/A	
Potassium Powder Sorbate	< .05%	N/A		< .05%	N/A	
PCCA-Plus Oral Suspension Vehicle	< .05%	N/A		< .05%	N/A	
Plo Gel Mediflo Pre-Mixed	< .05%	N/A		< .05%	N/A	
Alba-Derm Cream	< .05%	N/A		< .05%	N/A	
Mediderm Cream Base	< .05%	N/A		< .05%	N/A	
Sweet-Sugar Free Syrup	< .05%	N/A		< .05%	N/A	
Versapro Cream Base	< .05%	< .05%		< .05%	< .05%	
Percent of Total NDC's for Period	23.6%	24.5%	3.6%	4.2%	4.3%	2.6%
Skeletal Muscle Relaxants	**2011 NDC**	**2012 NDC**	**% Change**	**2011 Payments**	**2012 Payments**	**% Change**
Cyclobenzaprine Hydrochloride Powder	3.8%	5.0%	31.4%	4.7%	4.1%	-13.9%
Baclofen Powder	0.2%	0.1%	-63.7%	0.2%	< .05%	-96.0%
Tizanidine Tablet 4MG	< .05%	N/A		< .05%	N/A	
Percent of Total NDC's for Period	4.0%	5.0%	20.7%	5.0%	4.1%	-18.1%

Appendix A. Distribution of California Workers' Compensation Compound Drug Ingredients and Payments Top 8 Ingredient Categories (Jan-Jun 2011 vs. Jan-Jun 2012) – continued

Cough/Cold	2011 NDC	2012 NDC	% Change	2011 Payments	2012 Payments	% Change
Dextromethorphan Hydrobromide Monohydrate Powder	0.3%	6.4%	2100.5%	< .05%	3.4%	9304.5%
Dextromethorpahn Hydrobromide Powder	0.1%	N/A		0.1%	N/A	
Percent of Total NDC's for Period	0.4%	6.4%	1386.0%	0.2%	3.4%	2141.5%
Anti-Depressants	**2011 NDC**	**2012 NDC**	**% Change**	**2011 Payments**	**2012 Payments**	**% Change**
Amitriptylin Hydrochloride Powder	4.2%	6.8%	62.0%	1.6%	2.4%	47.4%
Trazodone Powder	0.1%	< .05%	65.2%	< .05%	< .05%	
Percent of Total NDC's for Period	4.3%	6.8%	59.2%	1.7%	2.4%	46.2%
Anti-Convulsants	**2011 NDC**	**2012 NDC**	**% Change**	**2011 Payments**	**2012 Payments**	**% Change**
Carbamazepin Powder	< .05%	< .05%	31.3%	< .05%	< .05%	28.8%
Percent of Total NDC's for Period	0.03%	0.04%	31.3%	< .05%	< .05%	28.8%
Sub-Total	**97.6%**	**98.1%**	**0.5%**	**99.7%**	**100.0%**	**0.3%**

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About CWCI

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