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

Alex Swedlow, MHSA
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., Gardner, L. Analysis of Medical and Indemnity Benefit Payments, Medical Treatment and Pharmaceutical Cost Trends in the California Workers' Compensation System. CWCI, June 2012.

2 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

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

4 Neuhauser, F., Swedlow, A.,Wynn, B. Impact of Physician-Dispensing of Repackaged Drugs on California Workers' Compensation, Employers Cost, and Workers' Access to Quality Care. Commission on Health and Safety and Workers' 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 Workers' Compensation System. California 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: California Workers' 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:

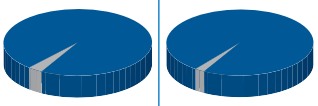
- compound drug prescriptions as a percentage of all workers' compensation prescriptions;
- compound drug payments as a percentage of all workers' compensation pharmaceutical payments;
- average number of ingredients per compound drug;
- average amount paid per compound drug prescription;
- average amount 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

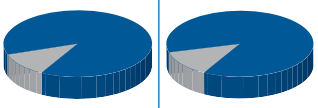
Prescription Type	Pre-AB 378 (Jan - Jun 2011)	Post-AB 378 (Jan - Jun 2012)	% Change (Pre:Post AB 378)
			
Non-Compound	96.9%	98.0%	1.1%
Compound	3.1%	2.0%	-35.4%

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%**

About the Authors

Alex Swedlow, MHSA, is Executive Vice President of Research for the California Workers' Compensation Institute.

Eileen Auen, MBA, is Chairman and CEO of PMSI, Inc.,

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About CWCI

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