

The Cost and Utilization of Compound Drugs, Convenience Packs and Medical Foods in California Workers' Compensation

by John Ireland, MHSA & Alex Swedlow, MHSA

Executive Summary

In 2002, California lawmakers enacted AB 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 response, state regulators held public hearings and by January 2004 adopted a workers' compensation pharmacy fee schedule. That schedule capped maximum reimbursements for pharmacy services and drugs at 100 percent of the 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, for medications not covered by Medi-Cal – such as repackaged drugs dispensed from a physician's office – maximum reasonable fees were still governed by the Official Medical Fee Schedule that had been in effect in 2003. 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.

This differential pricing system allowed physicians who dispensed repackaged drugs directly from their offices to be paid significantly more than pharmacies for the same medications. A recent Institute study¹ found that in 2006, workers' compensation reimbursements for repackaged drugs often exceeded the amounts paid for equivalent pharmacy-based prescription by 500 percent or more. Given that incentive, some companies began heavily marketing repackaged drug programs to workers' compensation medical providers as a means of enhancing their revenue. 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 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 2008.

After the repackaged drug regulations took effect in March 2007, some companies began promoting compound drugs and convenience packs ("co-packs") comprised of prescription medications and "medical foods" to California workers' compensation medical providers. Even though there are ongoing disputes over whether the use of these substances is appropriate and what the proper reimbursement should be, anecdotal reports from workers' compensation payors suggest their use has increased significantly in recent years. This study examines the issue using prescription data compiled from several regional and national workers' compensation insurance companies to estimate recent changes in the volume and reimbursement of compound drugs, convenience packs and medical foods in California workers' compensation.

Key Findings

- Since California adopted the regulations that addressed the repackaged drug pricing issue in its workers' compensation pharmacy fee schedule, there has been a dramatic shift toward the use of compound drugs, co-packs and medical foods. Between the first quarter of 2006 and the first quarter of 2009, the percentage of National Drug Codes (NDCs) in California workers' compensation associated with compound drugs, co-packs and medical foods has nearly quadrupled from 1.2 percent to 4.7 percent.²
- Over the same three-year span, the total amount charged for these products has grown from 2.2 percent to 11.8 percent of the total dollars billed as "medications" in the California workers' compensation system.
- Similarly, during this same period, the percentage of California workers' compensation medication dollars that paid for compound drugs, medical foods and co-packs increased more than five-fold from 2.3 percent of all drug payments in the first quarter of 2006 to 12.0 percent in the first quarter of 2009.

¹ California Workers' Compensation Institute. Post Reform Outcomes: Changes in Pharmaceutical Utilization and Reimbursement, September 2009.

² For the purposes of this study, "NDC" refers to the codes under which these products were billed.

BACKGROUND

Pharmacy compounding has been described as:

“the combining and altering of ingredients by a pharmacist in response to a licensed practitioner’s prescription, which produces a medication tailored to an individual patient’s special medical needs. In its simplest form, traditional compounding may involve reformulating a drug, for example by removing a dye or preservative in response to a patient’s allergy.”³

In workers’ compensation, compounded drugs are often associated with a means of delivering pain relief through a topical cream. Because of their unique nature, compounded drugs are not FDA-approved for safety and effectiveness.⁴ Instead, responsibility for regulatory oversight has taken place primarily at the state level, and has focused on manufacturing safety issues related to equipment, training, testing, sterile work environment and adulteration.

Co-packs represent a related, but different, type of drug delivery system. Compound drugs and co-packs both include combinations of various substances, at least one of which is a primary acting pharmaceutical drug and others which are often more inert in nature. Compound drugs, however, are medications produced by mixing various component parts, including one or more drugs, while co-packs consist of a drug and a medical food which are manufactured separately, then packaged together and dispensed as a single unit. Medical foods, which are sometimes dispensed separately as well as in co-packs, are defined in the Orphan Drug Act as:

“a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.”⁵

In the California workers’ compensation system, compound drugs, co-packs and medical foods are now broadly dispensed directly from doctors’ offices.

While compound drugs are sometimes billed under the National Drug Code (NDC) of the primary ingredient in the compound, under the California workers’ compensation Official Medical Fee Schedule (OMFS) the proper way to bill and pay them is to use the individual NDCs for each ingredient. Ingredients with no NDC (e.g., distilled water) are not reimbursable under the OMFS. The maximum reasonable fee for a compound drug is the sum of the allowances for each ingredient, plus compounding and dispensing fees as cal-

culated by the price calculator on the Division of Workers’ Compensation (DWC) web site.⁶ In contrast, charges for co-packs submitted on workers’ compensation claims have been billed under a single “NDC,” and claims administrators generally reimburse the prescription drug and the medical food (if medically necessary) separately. According to the FDA, NDC numbers are intended for uniquely identifying drugs and should not be used on the labels of products such as medical foods, which are not drugs. The presence of an NDC number on a product that is not a drug may be a false or misleading representation that misbrands the product under Section 403(a)(1) of the Federal Food, Drug and Cosmetic Act. Nevertheless, some medical foods that have been prescribed for injured workers have been billed under “NDCs” that have been assigned by a labeler.

Due to the paucity of data that clearly identifies compound drugs, medical foods and co-packs, information on the extent to which these substances are being used to treat injured workers -- and the associated costs -- is largely anecdotal. To estimate their prevalence and cost in California workers’ compensation, the authors collected available prescription data from several regional and national workers’ compensation insurance companies.

3 Statement made by Rear Admiral Steven K. Galson, Director for the Center of Drug Evaluation and Research at the Food and Drug Administration before the Senate Special Committee on Aging on April 19, 2007.

4 Kathleen Anderson, Pharm.D, Deputy Director of the Division of New Drugs and Labeling Compliance in FDA’s Center for Drug Evaluation and Research (CDER)

5 Section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3))

6 <http://www.dir.ca.gov/dwc/pharmfeesched/pfs.asp>

DATA

This study examines prescription drugs and other substances ordered by physicians and dispensed to California injured workers from January 2006 through March 2009. The database used in the study includes claim identifiers, national drug codes (NDCs) for the pharmaceuticals included in the study, service dates, and the billed and paid amounts for each NDC. The final database used in the analysis contained 3,352,496 NDCs that generated \$409 million in charges and \$285 million in payments. The Institute grouped the NDCs by the quarter and year of the service into five classifications:

- NDCs for bulk drugs (a primary component of compound drugs)
- NDCs for non-bulk drugs with the same service date as the bulk drugs
- NDCs for medical foods
- NDCs for co-packs, and
- all other NDCs

To identify bulk drugs, the authors used Medicare NDC bulk drug subcategories, which as of December 2008, totaled 2,110 unique NDCs.⁷ To estimate the volume and the billed

and paid amounts for compound drugs, the authors identified all NDCs that included a bulk drug code, then flagged all other pharmaceutical codes that shared the same claim number and service date as additional components of a drug compound. Finally, co-packs and medical foods were identified using the labeler code portion of the “NDC” (the first five digits of the standard NDC composition) used by the primary manufacturer of these substances for California injured workers. The authors found 55 unique NDCs with the labeler code of that company in the study sample: 43 for co-packs and 12 for medical foods. (See Appendix A for a discussion of the limitations of this methodology in measuring various aspects of compound drugs, co-packs and medical foods.)

Table 1 shows the distribution of California workers’ compensation national drug codes and the associated billed and paid amounts for the more than 3.3 million NDCs noted for the entire study period of January 2006 through March 2009, with results broken out across the five NDC classifications. The growth in the use of these products by quarter, as well as the quarterly changes in the billed and paid amounts from 2006 to the first quarter of 2009 are detailed in the following section of this report.

Table 1: Distribution of National Drug Codes, Billed & Paid Amounts by NDC Classification
(Study Sample of California Workers’ Compensation Prescriptions Filled January 2006 – March 2009)

NDC Classification	NDCs		Billed Amount		Paid Amount	
	Count	Percent	Total Billed	Percent	Total Paid	Percent
Bulk Drugs	44,223	1.3%	\$12,243,720	3.0%	\$9,404,960	3.3%
Associated Drugs	30,401	0.9%	\$5,178,628	1.3%	\$3,226,012	1.1%
Co-Packs	36,974	1.1%	\$16,396,762	4.0%	\$12,501,546	4.4%
Medical Foods	21,454	0.6%	\$4,746,696	1.2%	\$3,778,251	1.3%
Subtotal	133,052	3.9%	\$38,565,806	9.5%	\$28,910,769	10.1%
All Other Drugs	3,219,444	96.1%	\$370,463,742	90.5%	\$255,751,767	89.9%
TOTAL	3,352,496	100.0%	\$409,029,548	100.0%	\$284,662,536	100.0%

⁷ http://www.csscooperations.com/new/pdic/combo-hottopic/ndc-redesign-ndc-by-subcat_121008.xls

RESULTS

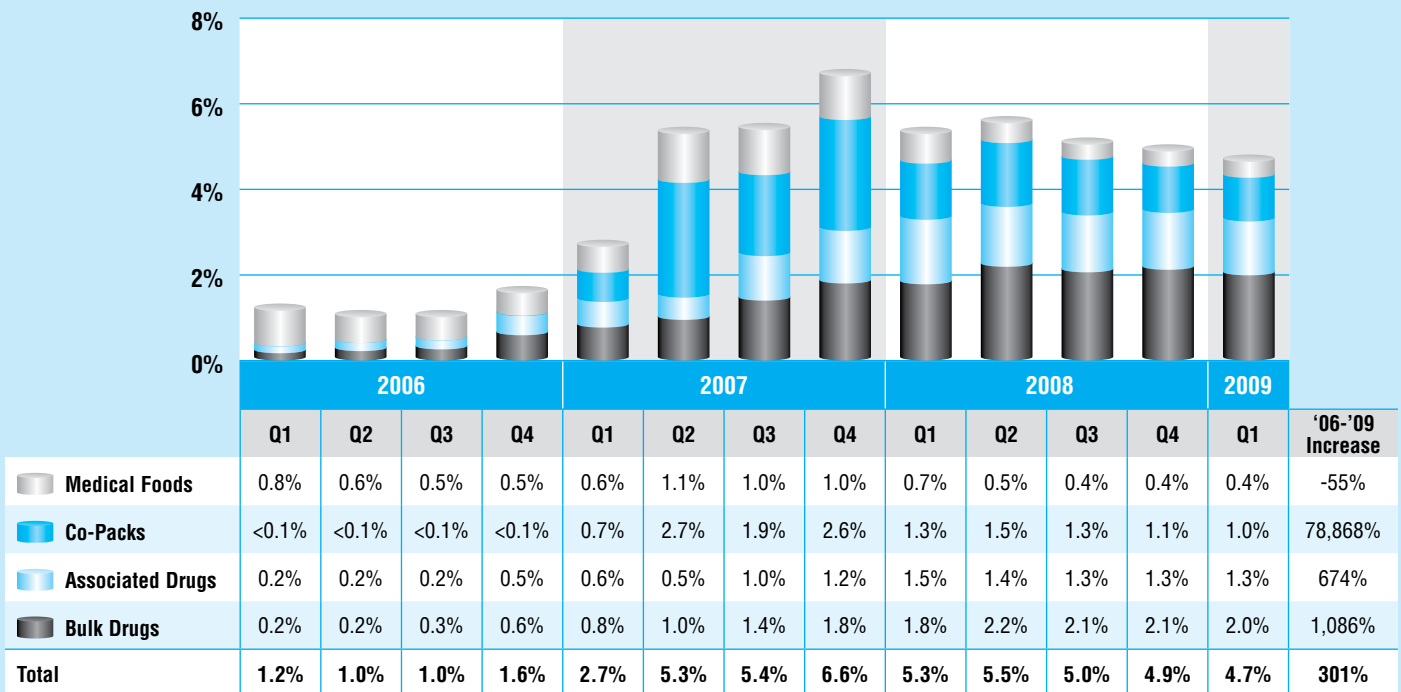
Percentage of California Workers' Compensation Prescriptions

Chart 1 tracks the growth in the percentage of California workers' compensation NDCs associated with compound drugs, co-packs, and medical foods, with quarterly results shown from January 2006 through March 2009. As noted previously, the NDCs that are associated with compound drug prescriptions include those found on the CMS list of bulk drugs and the codes for any drugs with the same fill date as the bulk drugs filled for the same injured worker. This recognizes the customary practice of itemizing each component of a compound drug.

Chart 1 shows that in the third quarter of 2006, compound drugs, co-packs and medical foods together accounted for

only 1.0 percent of NDCs in the California workers' compensation system, but that percentage began to move up in the fourth quarter of 2006 and in the first quarter of 2007, then suddenly doubled in the second quarter of 2007. This surge coincided with the regulatory elimination of differential pricing for repackaged drugs in March 2007 and was initially driven by the increased use of co-packs and medical foods. By the end of 2007, however, the percentage of California workers' compensation NDCs associated with compound drugs also was up sharply, and the combined percentage of codes associated with compound medications, co-packs and medical foods peaked at 6.6 percent of all NDCs – four times the proportion noted a year earlier. Since that peak, the percentage of workers' compensation NDCs associated with these substances has moderated, but has remained well above the levels noted prior to the adoption of the repackaged drug regulations, ranging between 4.7 and 5.5 percent.

Chart 1: Percentage of NDC Codes Associated with Compound Drugs, Co-Packs and Medical Foods



Percentage of Prescription Dollars Billed

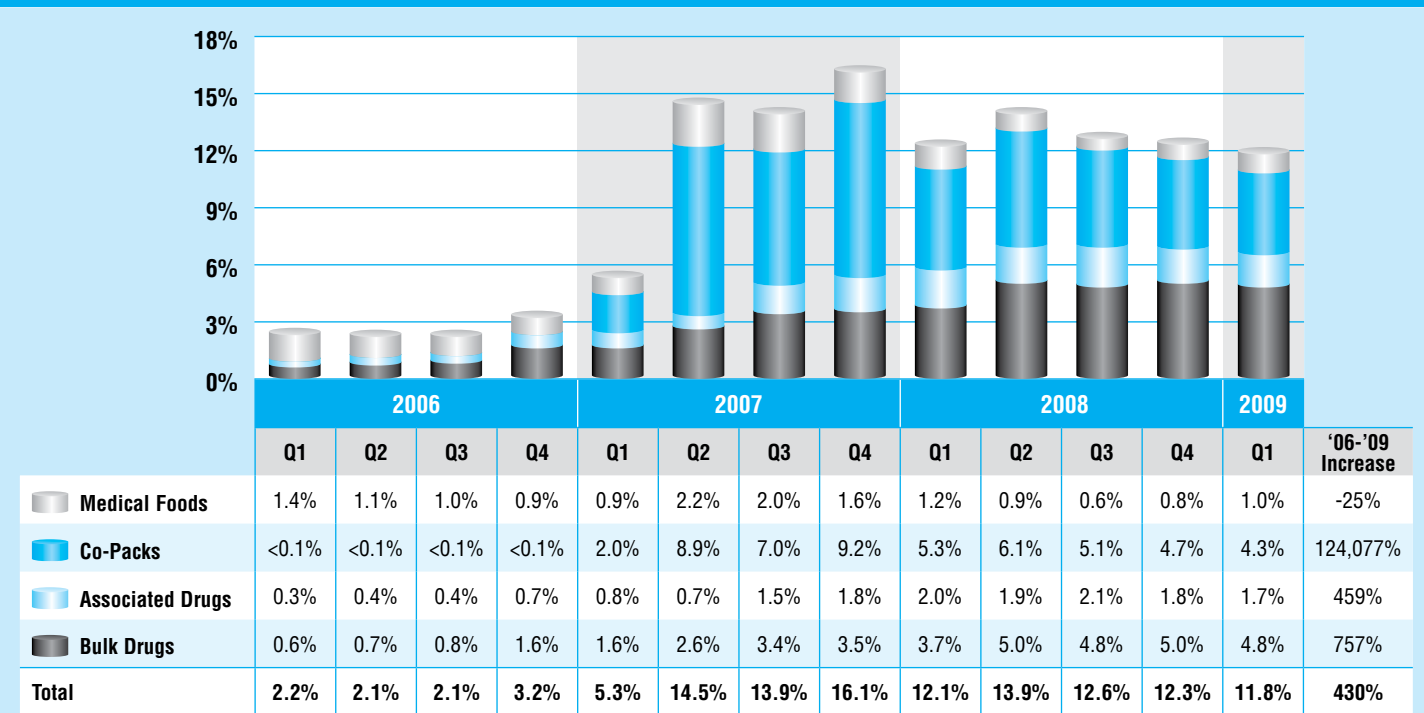
Chart 2 shows the growth in the percentage of prescription dollars billed to California workers' compensation payors for compound drugs, co-packs and medical foods from January 2006 through March 2009.

As the utilization of co-packs surged in early 2007, the percentage of billed dollars for these prescriptions rose sharply, and that percentage remained high through the end of that year before moderating in 2008. Meanwhile, bulk drugs also were becoming more prevalent in workers' compensation, so they too accounted for a growing share of the billed dollars for workers' compensation prescriptions – a trend that began in late 2006 and continued through the second quarter of 2008. Since then, combined bulk drug and associated drug charges

have stabilized at about 7 percent of the total amount billed for injured worker prescription dollars – up from less than 1 percent in the first quarter of 2006.

As with co-packs, medical foods also began to account for a growing share of workers' compensation prescription charges immediately following the implementation of the repackaged drug regulations, more than doubling from 0.9 percent of the prescription charges in the first quarter of 2007 to 2.2 percent in the second quarter of that year. That percentage, however, then dropped steadily over the next year, falling to just 0.6 percent of the prescription charges in the third quarter of 2008, though notably, it has rebounded recently, climbing back to more than 1 percent of the total dollars billed for workers' compensation prescriptions in the first quarter of 2009.

Chart 2: Percentage of California Workers' Compensation Billed Prescription Dollars -- Compound Drugs, Co-Packs and Medical Foods



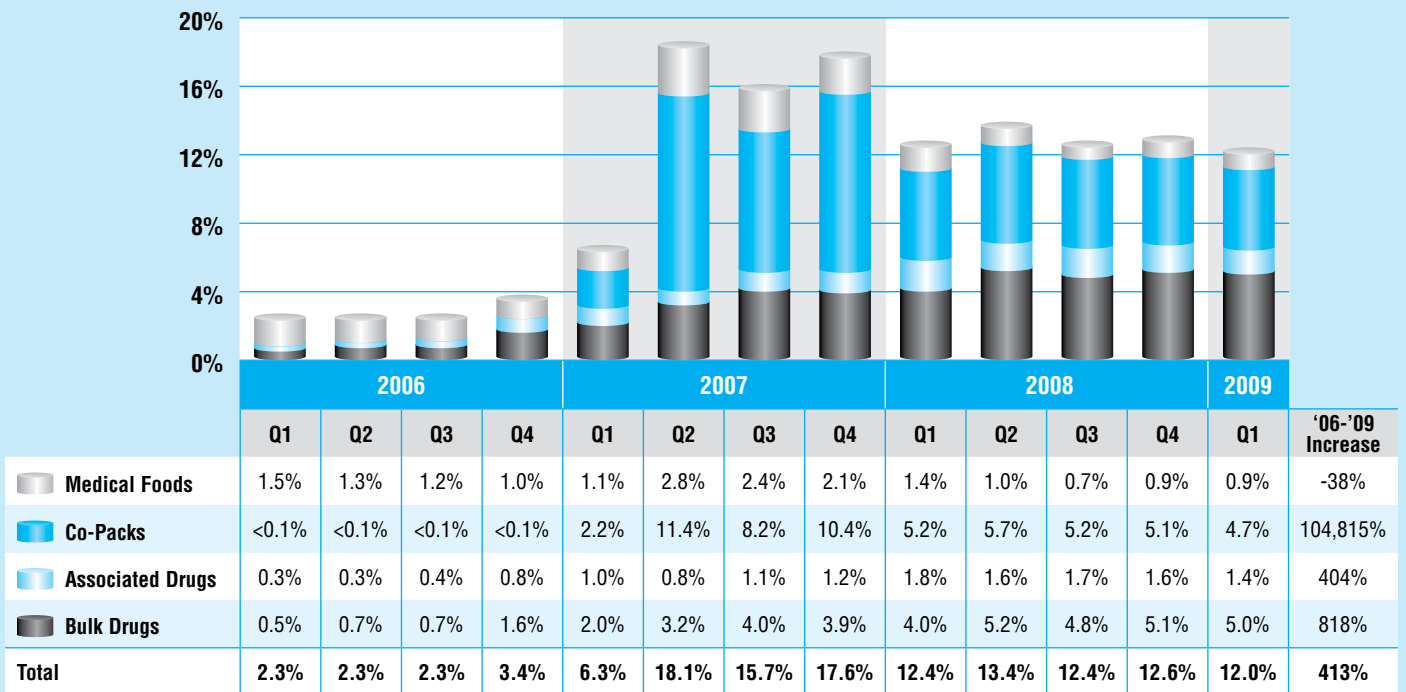
Percentage of Prescription Dollars Paid

The growth trends in the amounts paid for compound drugs, co-packs and medical foods were similar to the trends for billed dollars. Chart 3 shows the changes in the percentage of workers' compensation prescription payments for these products by quarter from January 2006 through March 2009.

As with the billed data, the percentage of California workers' compensation prescription dollars that paid for these products began to increase in late 2006 and early 2007, climbing to 6.3 percent right before the implementation of the repack-

aged drug regulation in March 2007. Immediately after those regulations took effect, the proportion of California workers' compensation prescription dollars that were used to reimburse compound drugs, co-packs and medical foods nearly tripled to more than 18 percent and remained near that record level through 2007. The percentage of prescription dollars paying for these products moderated somewhat in 2008, though the most recent data show that they have continued to consume about 1 out of every 8 dollars paid for injured worker prescriptions in California.

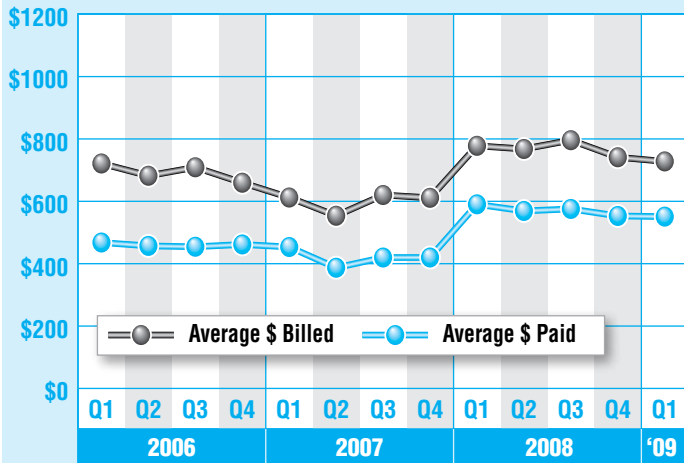
Chart 3: Percentage of California Workers' Compensation Paid Prescription Dollars -- Compound Drugs, Co-Packs and Medical Foods



Average Amounts Billed vs. Paid

Chart 4 plots the quarterly changes in the average amounts billed and paid for compound drug prescriptions (the combination of bulk drug and other same-day NDCs) from 2006 through the first quarter of 2009.

Chart 4: Average Amount Billed and Paid per Compound Drug



The average amount billed for compound drugs in California workers' compensation has fluctuated in recent years, decreasing from \$721 in the first quarter of 2006 to \$554 as the volume of these prescriptions increased in the second quarter of 2007. Average compound drug charges then began to climb, eventually peaking at \$796 in the third quarter of 2008 before retreating to \$728 in the first quarter of 2009. Reflecting a similar pattern, the average amount paid for these compound drug prescriptions fell from \$468 in the first quarter of 2006 to a low of \$387 in the second quarter of 2007, then climbed to a peak of \$590 in early 2008 before edging down slightly to \$551 in the first quarter of 2009.

Chart 5 plots the changes in the average amounts billed and paid for co-packs during the study period. The use of co-packs was negligible prior to 2007 – one reason for the sharp fluctuations in the billed and paid amounts for co-packs prior to 2007. Following the adoption of the repackaged drug regulation in March 2007, however, the use of co-packs soared (with more than 6,200 co-pack NDCs noted in the study sample during the 2nd quarter of 2007), and the amounts billed and paid for co-packs began a steady climb.

Chart 5: Average Amount Billed and Paid Per Co-Pack

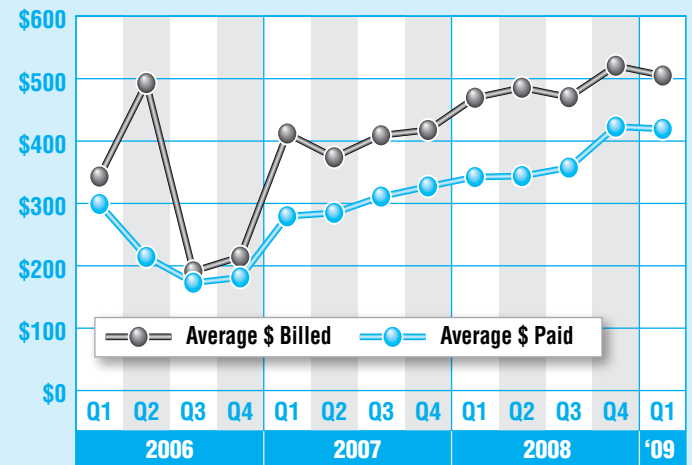
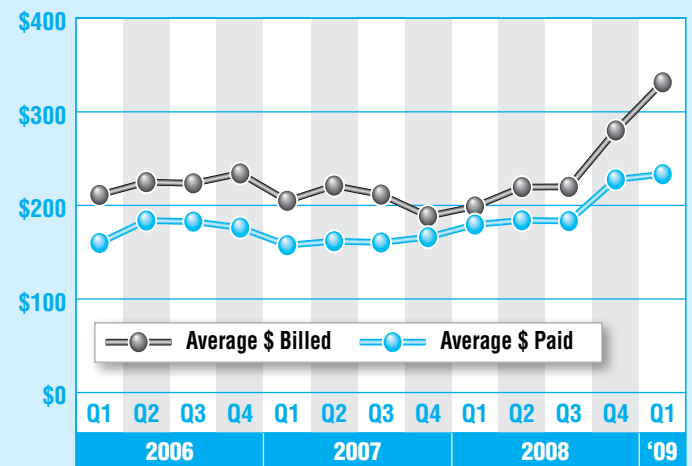


Chart 5 shows the average amount billed for co-packs in California workers' compensation rose from \$374 in the second quarter of 2007 to \$505 in the first quarter of 2009 – a 35 percent increase. Over the same period, the average amount paid for these prescriptions climbed 51 percent from \$279 in the second quarter of 2007 to \$420 in the first quarter of 2009.

The changes in the average amounts billed and paid for medical foods over the three-year span of the study are shown in Chart 6.

Chart 6: Average Amount Billed and Paid Per Medical Food



The average amount billed to workers' compensation payors for medical foods was relatively flat between the first quarter of 2006 and the third quarter of 2008, ranging between \$188 and \$225. The average billed amount for a medical food prescription jumped sharply at the end of 2008, however, climbing to \$280 in the fourth quarter of that year, then continuing up to nearly \$332 per prescription in the first quarter of 2009. This same trend is evident in the paid data, with

average workers' compensation reimbursements for medical food prescriptions showing only minor fluctuations between the first quarter of 2006 and the third quarter of 2008 (ranging between \$160 and \$184), before suddenly increasing to \$228 at the end of 2008 and to \$233 in the first quarter of 2009. A review of the medical food NDCs by quarter reveals that these recent surges in the average billed and paid amounts reflect both a sudden increase in medical food unit prices and a shift toward more expensive medical foods being ordered by physicians to treat injured workers.

Discussion

Compounding drugs is a practice rooted in some of the oldest traditions of medicine, dating back centuries. However, as the practice of medicine became increasingly regulated in the 20th century, and mass production of pharmaceuticals replaced the traditional apothecary, federal oversight of the clinical efficacy and quality of prescription medicines increased and the market for compound drugs was limited to special circumstances in which an individual's needs could not be met by drugs manufactured by standardized means.

In recent years, federal regulators at the Food and Drug Administration (FDA) have become especially concerned about bio-identicals -- drug compounds with the identical pharmacological makeup as manufactured drugs. Prompted by unsubstantiated claims by compounding pharmacies regarding the safety and effectiveness of bio-identical hormone replacement therapy, the FDA became increasingly apprehensive about potential health and safety issues associated with compounded drugs⁸ and ratcheted up its monitoring and enforcement efforts. Evidence of the FDA's growing concern is provided by a December 2006 warning letter that the agency sent to five firms that were in the business of compounding topical anesthetic creams. In that letter, the FDA noted "the serious public health risks" related to these products. (The full text of the letter is in Appendix C of this report.)

The concerns of the federal regulators have been shared by workers' compensation payors who have sensed the growing use of compound drugs, co-packs and medical foods over the last few years, even though the extent to which these substances have been used to treat injured workers was never quantified. To gain a better understanding of how prevalent these medications have become in California workers' compensation and their impact on prescription costs within the system, this study estimated the volume and the amounts billed and paid for compound drugs, co-packs and medical foods, and measured changes in those amounts since 2006.

While the generally accepted rationale for prescribing com-

pound drugs, co-packs and medical foods is to accommodate individuals who, for various reasons, may have difficulty tolerating manufactured medications, there is no evidence to suggest that the need for such products has increased among California injured workers in the past three years. Yet, this study estimates that from 2006 to 2009, the prevalence of billed NDCs associated with compound drugs and co-packs nearly quadrupled from 1.2 percent to 4.7 percent of all NDCs in the workers' compensation system.

There are several theories that may explain this increase. Certainly, some of the increase may reflect successful marketing of the medicinal value of these substances by compounding pharmacies and distributors who assert that pain medication is better tolerated, produces fewer side effects, and is more effective if delivered in a compounded topical cream or gel. Those marketing co-packs and medical foods make similar claims, maintaining that their products address issues of nutritional insufficiency caused by underlying injury or disease processes. A second theory is that the application of more conservative (less invasive) medical treatment for back pain has prompted greater use of pain medications -- including those found in compound drugs and co-packs. A third theory is that some medical providers, manufacturers, labelers, third-party billers and pharmaceutical distributors are using compounded drugs, co-packs and medical foods to circumvent the medical fee schedule by marketing, prescribing, and dispensing these products when less costly, safer and possibly more effective means of delivering needed medication are available.

This third theory is particularly troubling given that the reforms enacted by state policymakers in 2003 and 2004 attempted to address the rising costs and perceived problems with the quality and consistency of medical care in the California workers' compensation system. The intent of those reforms was to establish a more rational pricing system through the adoption of a more comprehensive fee schedule that attempted to set fair-market prices for all aspects of medical care and pharmaceuticals, while setting up a framework for improving the quality of care for injured workers by aligning the standards for "reasonable and necessary care" with the scientific rigors of evidence-based medicine.⁹

As pharmacy costs have escalated over the last five years, there have been numerous debates centering on issues related to prescription drugs in California workers' compensation -- particularly off-label use of various medications, the over-use of Schedule II narcotics, and the appropriateness and necessity of repackaged drugs. More recently, the debate has shifted to compound drugs, co-packs and medical foods. While this study confirms dramatic growth in the use of these products in California workers' compensation since 2006, it has

8 Transcript of FDA Press Conference on FDA Actions on Bio-Identical Hormones, FTS HHS FDA, Moderator: Susan Cruzan, January 9, 2008

9 Harris, JS, Swedlow, A. Evidence-Based Medicine & The California Workers' Compensation System. A Report To The Industry. CWCI. Jan 2004

not gone unnoticed that the largely unregulated and improvisational methods of developing and marketing compound drugs and medical foods has introduced subjective treatment strategies with unknown outcomes for injured workers. The lack of federal oversight and the paucity of evidence-based research on their clinical effectiveness have raised serious questions about their impact on the quality of care. At the same time, there is concern that their growth may be driven by aggressive marketing efforts promoting compound drugs, co-packs and medical foods as a means to generate income for providers who prescribe, manufacture, compound and dispense these products – a concern magnified by this study’s finding that the surge in their use coincided with the adoption of the regulations that eliminated differential pricing for repackaged drugs.

With the meteoric rise in the use of compounds, co-packs and medical foods in the aftermath of the repackaged drug regulations, these products have quickly become a significant pharmaceutical cost driver in the California workers’ compensation system, accounting for nearly 1 out of every 8 dollars paid for injured worker prescriptions. That trend is likely to continue until such time as state policymakers enact statutory controls and increase administrative oversight in order to determine the true efficacy and the appropriate use and reimbursement of these interventions.

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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.

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Appendix A

Data Limitations

The study's ability to measure various aspects of the use of compound drugs and co-packs was limited by the available administrative data. Currently, there are no uniform markers for all components of compound drugs or co-packs available through claims data or medical bill review data. The common practice of billing for each component of a compound drug further complicates the data picture.

In conducting this study, the authors wanted to take a cautious approach in estimating the use of compound drugs, co-packs and medical foods in order to mitigate an over reliance on anecdotes and known data deficiencies. Most of the assumptions used in this study will likely produce conservative estimates of NDCs for compound drugs and co-packs. First, the authors recognize that the Medi-Care listing of bulk compounds and list of labeler codes used in this study are not comprehensive. Second, a compound drug may be prescribed without an associated bulk drug component which, in this analytical framework, would lead to an undercount of compound drugs. Furthermore, anecdotal information suggests that the bulk drug ingredients used in compounded drugs can be billed with non-bulk drug codes, which would lead to further under-identification of compound drugs in this analysis.

While the authors chose to use the list of NDCs associated with bulk drugs as maintained by CMS, two additional sources for this information were considered: one based on a

list of known bulk drug manufacturers; and a second based on a compilation of data using proprietary pharmacy databases. There was significant overlap among these three data sources, but none of the three was comprehensive. The CMS list was chosen because it had the greatest degree of overlap, was the simplest to understand, and was the only list readily available to the public.

On the other hand, other assumptions in this study could have led to some overcounting of these substances. For example, the study assumes that compound drugs use at least one bulk drug component and that these bulk drug components will be itemized on a bill, though the authors recognize that bulk drugs could be used for reasons other than for inclusion in a compound drug, which could lead to a potential over-identification of compound drugs. The authors also attempted to combine NDCs into likely compound drugs, but recognize that there are instances when an injured worker fills multiple prescriptions on the same day, only one of which may be for a compound drug that incorporates a bulk drug component. Finally, there is no stable, comprehensive list of NDCs that reliably identifies co-packs or medical foods. The use of labeler codes to identify these items relies on a list of labelers who supply co-packs and medical foods, and on an assumption that the labelers provide no other pharmaceutical products. This analysis uses the labeler code for the primary supplier of co-packs and medical foods to the workers' compensation industry in California, but others may exist.

Appendix B

NDC Distribution – Bulk Drugs

NDC	NDC Description	NDC Count	% of NDC Count	Cumulative % of NDC Count
51927330100	Gabapentin	5,156	11.7%	11.7%
49452391702	Ketoprofen	3,970	9.0%	20.6%
62991108805	Ketoprofen	3,901	8.8%	29.5%
62991104003	Cyclobenzaprine HCL	2,902	6.6%	36.0%
49452240702	Cyclobenzaprine HCL	2,484	5.6%	41.7%
38779198001	Gabapentin	2,219	5.0%	46.7%
51927180700	Capsaicin	2,117	4.8%	51.5%
51927235200	Ketoprofen	1,419	3.2%	54.7%
49452404002	Lidocaine	1,130	2.6%	57.2%
51927279000	Ketamine HCL	1,013	2.3%	59.5%
63370009925	Gabapentin	981	2.2%	61.7%
51927250100	Cyclobenzaprine HCL	850	1.9%	63.7%
51927270100	Flurbiprofen	772	1.7%	65.4%
49452405001	Lidocaine HCL Monohydrate	679	1.5%	66.9%
51927121300	Lidocaine HCL	674	1.5%	68.5%
63370013025	Ketoprofen	624	1.4%	69.9%
49452324002	Gabapentin	620	1.4%	71.3%
51927200700	Baclofen	572	1.3%	72.6%
51927421300	Gabapentin	541	1.2%	73.8%
49452080702	Baclofen	536	1.2%	75.0%
All Other		11,063	25.0%	100.0%
TOTAL		44,223	100.0%	

NDC Distribution – Associated Drugs

NDC	NDC Description	NDC Count	% of NDC Count	Cumulative % of NDC Count
49452167501	Capsaicin	969	3.2%	3.2%
99999999999	Unknown	602	2.0%	5.2%
38779083703	Capsaicin	593	2.0%	7.1%
60505006501	Omeprazole	528	1.7%	8.9%
49452444001	Menthol	436	1.4%	10.3%
65162062711	Tramadol HCL	417	1.4%	11.7%
77777777777	Unknown	395	1.3%	13.0%
51552054999	Unknown	380	1.2%	14.2%
00143990805	Naproxen	378	1.2%	15.5%
00093521156	Omeprazole	317	1.0%	16.5%
00143117610	Carisoprodol	310	1.0%	17.5%
62175011843	Omeprazole	309	1.0%	18.5%
00591085305	Hydrocodone & Acetaminophen	307	1.0%	19.5%
63874055330	Omeprazole	267	0.9%	20.4%

NDC Distribution – Associated Drugs (Continued)

NDC	NDC Description	NDC Count	% of NDC Count	Cumulative % of NDC Count
53746019405	Naproxen	253	0.8%	21.3%
00603388132	Hydrocodone & Acetaminophen	247	0.8%	22.1%
51552054905	Unknown	241	0.8%	22.9%
49452399901	Unknown	236	0.8%	23.6%
51927309100	Unknown	233	0.8%	24.4%
58016087730	Omeprazole	220	0.7%	25.1%
53746011005	Hydrocodone	207	0.7%	25.8%
51552090299	Gabapentin	194	0.6%	26.4%
63874083490	Hydrocodone & Acetaminophen	183	0.6%	27.0%
00591573101	Baclofen	167	0.5%	27.6%
88888888888	Unknown	166	0.5%	28.1%
00591320201	Hydrocodone & Acetaminophen	164	0.5%	28.7%
00591320301	Hydrocodone & Acetaminophen	163	0.5%	29.2%
60505023004	Nizatidine	146	0.5%	29.7%
58016026130	Carisoprodol	145	0.5%	30.2%
49452496203	Ketoprofen	140	0.5%	30.6%
49452164001	Ketoprofen	139	0.5%	31.1%
00093521001	Omeprazole	138	0.5%	31.5%
63874040190	Etodolac	133	0.4%	32.0%
49452444003	Menthol	128	0.4%	32.4%
00054485321	Ranitidine	123	0.4%	32.8%
00143117601	Carisoprodol	123	0.4%	33.2%
63481068706	Lidoderm Patch	120	0.4%	33.6%
63874033090	Carisoprodol	114	0.4%	34.0%
50111054701	Diclofenac	113	0.4%	34.4%
58016032190	Naproxen	113	0.4%	34.7%
68115091430	Unknown	112	0.4%	35.1%
00406035705	Hydrocodone & Acetaminophen	109	0.4%	35.5%
63874033990	Naproxen	108	0.4%	35.8%
00406036705	Hydrocodone & Acetaminophen	107	0.4%	36.2%
00603546832	Darvocet	105	0.3%	36.5%
63874110309	Gabapentin	102	0.3%	36.8%
27495000602	Dendracin	101	0.3%	37.2%
63874107509	Tizanidine	99	0.3%	37.5%
00185009301	Gabapentin	98	0.3%	37.8%
52959032460	Hydrocodone & Acetaminophen	98	0.3%	38.1%
All Other		18,805	61.9%	100.0%
TOTAL		30,401	100.0%	

Code Distribution – Co-Packs

Code	Description	Code Count	% of Code Count	Cumulative % of Code Count
68405803836	Theratramadol - 90 (Theramine & Tramadol)	6,084	16.5%	16.5%
68405801836	Theraproxen - 90 (Theramine & Naproxen)	6,058	16.4%	32.8%
68405819836	Theracodophen - 650 (Theramine, Hydrocodone & Acetaminophen)	5,992	16.2%	49.0%
68405805836	Therabenzaprine - 90 (Theramine & Cyclobenzaprine)	4,786	12.9%	62.0%
68405800426	Gabtidine (Gabadone & Ranitidine)	4,252	11.5%	73.5%
68405802806	Prazolamine (Theramine & Carisoprodol)	1,717	4.6%	78.1%
68405829836	Theracodophen - Low - 90 (Theramine, Hydrocodone & Acetaminophen)	1,389	3.8%	81.9%
68405801426	Gaboxetine (Gabadone & Fluoxetine)	1,298	3.5%	85.4%
68405809836	Theracodophen - 325 (Theramine, Hydrocodone & Acetaminophen)	1,011	2.7%	88.1%
68405808836	Theraprofen - 90 (Theramine & Ibuprofen)	830	2.2%	90.4%
All Other		3,557	9.6%	100.0%
TOTAL		36,974	100.0%	

Code Distribution – Medical Foods

Code	Description	Code Count	% of Code Count	Cumulative % of Code Count
68405100802	Theramine - 60	5,823	27.1%	27.1%
68405100803	Theramine - 90	4,251	19.8%	47.0%
68405100402	Gabadone - 60	3,567	16.6%	63.6%
68405100302	Sentra PM - 60	3,488	16.3%	79.8%
68405100202	Sentra AM - 60	3,046	14.2%	94.0%
68405100101	Apprim - 120	464	2.2%	96.2%
68405101603	Trepadone - 60	363	1.7%	97.9%
68405100702	Hypertensa - 60	130	0.6%	98.5%
68405100901	Apprim-D - 120	122	0.6%	99.1%
68405100503	Pulmona - 90	108	0.5%	99.6%
68405100602	Virilex - 60	89	0.4%	100.0%
68405100703	Hypertensa - 90	2	0.0%	100.0%
68405181603	Unknown	1	0.0%	100.0%
TOTAL		21,454	100.0%	

Appendix C

FDA NEWS RELEASE

FDA Warns Five Firms To Stop Compounding Topical Anesthetic Creams

FOR IMMEDIATE RELEASE

P06-192

December 5, 2006

Media Inquiries:

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Consumer Inquiries:

888-INFO-FDA

The Food and Drug Administration (FDA) is warning five firms, Triangle Compounding Pharmacy, University Pharmacy, Custom Scripts Pharmacy, Hal's Compounding Pharmacy, and New England Compounding Center, to stop compounding and distributing standardized versions of topical anesthetic creams, which are marketed for general distribution rather than responding to the unique medical needs of individual patients. Firms that do not resolve violations in FDA warning letters risk enforcement such as injunctions against continuing violations and seizure of illegal products.

FDA is concerned about the serious public health risks related to compounded topical anesthetic creams. Exposure to high concentrations of local anesthetics, like those in compounded topical anesthetic creams, can cause grave reactions including seizures and irregular heartbeats. Two deaths have been connected to compounded topical anesthetic creams made by Triangle Compounding Pharmacy and University Pharmacy, two of the five pharmacies receiving warning letters. Similar topical anesthetic creams are compounded by the other firms, and today's action serves as a general warning to firms that produce standardized versions of these creams.

"Compounded topical anesthetic creams, like all compounded drugs, are not reviewed by FDA for safety and effectiveness, and are not FDA-approved. These high-potency drugs may expose patients to unnecessary risk, especially when they are used without proper medical supervision," said Dr. Steven Galson, Director of FDA's Center for Drug Evaluation and Research. FDA is advising consumers who have questions or concerns about compounded topical anesthetic creams to contact their health care providers.

Compounded topical anesthetic creams are often used to lessen pain in procedures such as laser hair removal, tattoos, and skin treatments. They may be dispensed by clinics and spas that provide these procedures, or by pharmacies and doctors' offices.

These creams contain high doses of local anesthetics including lidocaine, tetracaine, benzocaine, and prilocaine. When different anesthetics are combined into one product, each anesthetic's potential for harm is increased. This potential harm may also increase if the product is left on the body for long periods of time or applied to broad areas of the body, particularly if an area is then covered by a bandage, plastic, or other dressing.

The risk of harm is even greater in small children, patients with pre-existing heart disease, and patients with severe liver disease.

FDA-approved topical anesthetic products are commercially available and properly labeled, and are regularly used in health-care settings. However, some pharmacies create their own standardized versions of these products, often including combinations of ingredients and ingredients at higher strengths than found in FDA-approved products, and often lacking appropriate warnings or directions for use.

The five firms warned by FDA have stated that they produce their topical anesthetic creams as part of the practice of pharmacy compounding. Traditional pharmacy compounding typically involves pharmacies preparing drugs that are not commercially available, such as a unique medicine for a patient who is allergic to an ingredient in a FDA-approved drug. This kind of compounding follows a physician's decision that his or her patient has a special medical need that cannot be met by FDA-approved drugs.

FDA normally permits such traditional pharmacy compounding and the agency's action is not targeting this practice. By contrast, FDA is concerned that the five firms receiving warning letters are behaving like drug manufacturers, not traditional compounding pharmacies, because they produce standardized versions of topical anesthetic creams for general distribution.

Consumers and health care professionals should notify FDA of any complaints or problems associated with compounded drugs, including compounded topical anesthetic products. These reports may be made to MedWatch, FDA's voluntary reporting program, by phone at 1-800-FDA-1088, or online at <http://www.fda.gov/medwatch/report.htm>.