The Pricing and Distribution of Repackaged Drugs: Cost Effects to the California Workers' Compensation System, Payers and Providers

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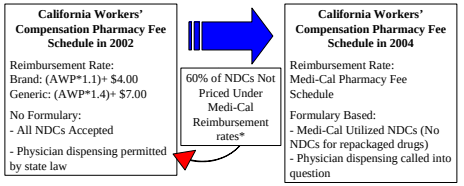
BACKGROUND



- Non-equivalency due to repackaged dispensed drugs
- For 2 years, legislation and regulation reforms have been proposed to resolve the inconsistency between Medi-Cal and Workers' Compensation Reimbursement
- Currently, no legislation has been passed to the resolve pricing of repackaged drugs
  - SB 292 attempted to reprice repackaged drugs based on underlying manufacturer NDCs (legislation not passed)

WHAT IS A REPACKAGED DRUG?

- A pharmaceutical product that is removed from the original manufacturer container with an original NDC and put into a new container with new quantities, therefore requiring a new NDC, with a new repackaging company label and price for the medication
- It is of interest to determine who dispenses repackaged drugs to determine the value provided

- Repackaged pharmaceuticals are provided through a company that may be referred to as a repackager, distributor (wholesaler), manufacturer, or retailer (pharmacy) making it difficult to define or identify repackaging companies
- To repackage a pharmaceutical, a company at a minimum must be licensed as a manufacturer

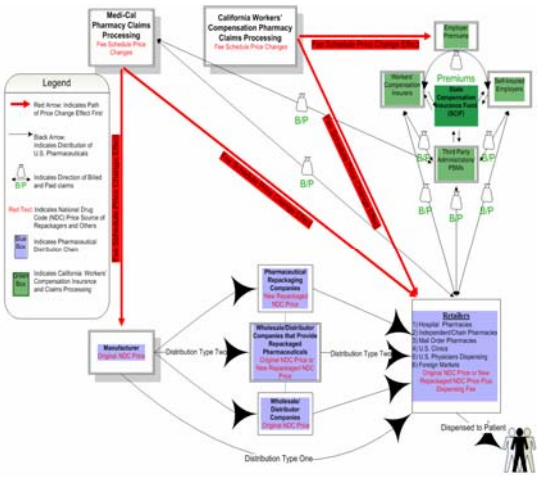
OBJECTIVE

- The purpose of this paper is to assess costs, potential savings with alternative pricing systems, and model predictors of repackaged pain and pain-related pharmaceutical costs
- In addition, we describe the distribution of repackaged pharmaceuticals through the U.S. drug distribution system

METHODS

- Data Source and Sample
  - Non-profit research organization data from 2002 representing ~13% of all California WC pharmacy claims
  - Pain and pain-related pharmaceutical claims of Insured employers
- Utilization and Cost Analysis (SAS Version 8.02)
  - Mean costs, utilization, and characteristics
  - Cost savings with alternative reimbursement rates: t-tests
  - Cost per analysis of manufacturer vs. repackaged drug costs with alternative reimbursement rates
- Log Ordinary Linear Regression (OLS) and Generalized Linear Model (Proc GenMod in SAS)
  - Model to explain cost per pill of repackaged drugs

PRICE & DISTRIBUTION MODEL

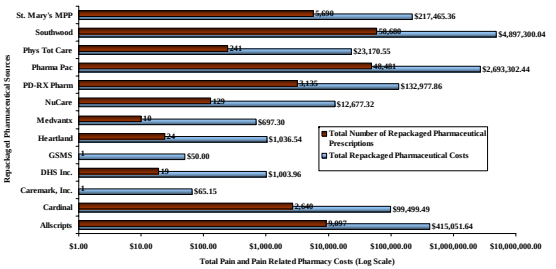


RESULTS

Repackaged Pharmaceutical Characteristics

	Total Pain and Pain Related Pharmacy Costs ($)	Pain and Pain Related Manufacturer Packaged Pharmaceutical Costs ($)	Pain and Pain Related Repackaged Pharmaceutical Costs ($)	Percentage of Total Pain and Pain Related Pharmacy Costs that are Repackaged	Number of Pain and Pain Related Repackaged Pharmaceutical NDCs	Percentage of Total Pain and Pain Related NDC's that are Repackaged	Number of Pain and Pain Related Repackaged Pharmaceutical Prescriptions	Percentage of Total Pain and Pain Related Prescriptions that are Repackaged
Grand Total	$38,968,233	$30,473,933	$8,494,298	21.80%	22	55.29%	126,148	27.27%
Total Brand/Generic*	$8,714,223	$8,638,047	$76,180	0.87%	124	43.96%	1,501	3.46%
Alprazolam	$44,425	$44,425	$0	0.00%	0	0.00%	0	0.00%
Carisoprodol	$403,111	$402,981	$234	0.06%	4	40.00%	6	0.26%
Fentanyl	$1,529,384	$1,529,384	$0	0.00%	0	0.00%	0	0.00%
Cyclobenzaprine	$27,086	$22,895	$4,192	15.47%	12	85.71%	142	16.22%
Diazepine	$540,749	$537,659	$3,699	0.68%	10	50.00%	22	1.30%
Hydrocodone	$821,488	$798,447	$23,041	2.80%	34	48.57%	490	3.39%
Morphine	$414,052	$414,052	$0	0.00%	0	0.00%	0	0.00%
Naproxen	$18,355	$14,307	$4,047	22.05%	18	69.23%	80	31.01%
Oxycodone	$4,400,160	$4,398,101	$2,059	0.05%	4	8.33%	14	0.12%
Propoxyphene	$80,557	$73,108	$7,458	9.26%	7	41.18%	243	11.67%
Relafen	$434,854	$403,400	$31,452	7.23%	31	91.18%	484	9.42%
Total Brand Only	$16,728,703	$15,778,707	$950,001	5.68%	102	69.71%	11,225	8.07%
Celecoxib	$4,870,023	$4,387,545	$482,478	9.91%	26	82.35%	6,013	13.73%
Gabapentin	$23,414	$0	$23,414	100.00%	21	100.00%	263	100.00%
Lansoprazole	$398,309	$398,268	$40	0.01%	1	14.29%	1	0.02%
Metaxalone	$401,712	$375,208	$26,505	6.60%	10	90.48%	704	10.12%
Omeprazole	$664,266	$662,468	$1,858	0.28%	2	35.71%	13	0.43%
Ranitidine	$678,698	$670,208	$8,492	1.25%	7	50.00%	82	1.46%
Ziprasidone	$4,586,712	$4,318,037	$268,674	5.86%	33	67.31%	3,283	7.39%
Sertaline	$607,856	$607,856	$0	0.00%	0	0.00%	0	0.00%
Tizanidine	$724,219	$724,219	$0	0.00%	0	0.00%	0	0.00%
Tramadol	$1,902,544	$1,779,670	$123,475	6.49%	29	90.32%	2,699	10.40%
Venlafaxine	$696,863	$693,507	$3,356	0.48%	7	35.00%	38	0.80%
Zolpidem	$1,174,089	$1,162,378	$11,710	1.00%	17	80.95%	152	1.07%
Total Generic**	$13,525,302	$6,057,185	$7,468,117	55.22%	434	54.81%	113,407	44.72%
Alprazolam	$300,045	$288,268	$11,777	3.93%	13	26.62%	238	4.23%
Carisoprodol	$3,867,160	$1,129,298	$2,677,870	70.34%	52	58.59%	20,234	43.64%
Cyclobenzaprine	$784,490	$258,399	$526,091	67.06%	52	75.00%	11,799	61.07%
Fentanyl	$33,328	$32,998	$330	0.99%	2	14.29%	3	0.92%
Diazepine	$80,278	$70,774	$9,505	11.84%	4	18.18%	68	11.67%
Hydrocodone	$3,983,641	$2,984,561	$999,080	25.08%	142	54.46%	28,715	23.96%
Morphine	$477,920	$477,920	$0	0.00%	0	0.00%	0	0.00%
Naproxen	$3,413,781	$766,744	$2,646,957	77.54%	108	54.01%	36,856	72.45%
Oxycodone	$36,383	$36,383	$0	0.00%	0	0.00%	0	0.00%
Propoxyphene	$667,119	$11,567	$595,552	98.09%	40	90.91%	15,488	98.00%
Relafen	$1,287	$332	$955	74.22%	7	77.78%	14	77.78%

Repackaged Pharmaceutical Sources



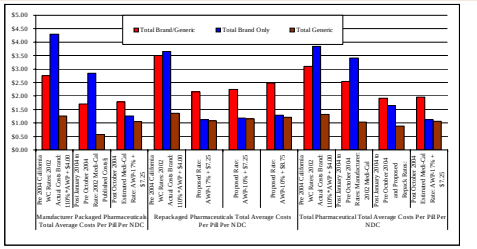
RESULTS

Potential Costs Savings with Alternative Reimbursement Rates

	Pre 2004 California Workers' Compensation Rates: 2002 Actual Costs Brand: 110%*AWP + $4.00 Generic:140%*AWP + $7.00 (Total Pharmacy Costs = $38,968,233)		Post January 2004 to Pre October 2004 and Proposed Repackaged Drug Rates: Manufacturer Packaged: 2002 Medi-Cal Published Costs§ Repackaged: AWP-17% + $7.25 (Total Pharmacy Costs = $24,599,497)		Percent Change and Significance for Repackaged Pharmaceuticals Between Pre 2004 and Proposed Fee Schedule Costs
	Manufacturer Packaged	Repackaged *** (Percentage of Total Pharmacy Costs)	Manufacturer Packaged	Repackaged *** (Percentage of Total Pharmacy Costs)	(t-test and p-value)***
Grand Total	$30,473,935	$8,494,298 (21.8%)	$19,164,376	$5,435,121 (22.15%)	36.01% (t =4.87; p<0.0001)
Anti-Anxiety/Sleep Aids	$1,495,071	$22,555 (1.49%)	$780,269	$11,800 (1.49%)	47.68% (t=3.08; p=0.004)
Antidepressants	$2,579,394	$25,050 (0.96%)	$1,587,539	$17,269 (1.08%)	31.06% (t=2.62; p=0.01)
Anti-Ulcer Agents	$1,060,677	$2,831 (0.27%)	$693,860	$1,356 (0.05%)	52.08% (t=1.91; p=0.1)
Schedule II narcotics	$6,888,048	$2,389 (0.03%)	$4,775,828	$1,584 (0.03%)	33.7% (t =1.77; p=0.14)
Schedule III or greater narcotics	$5,646,744	$1,748,605 (23.64%)	$3,404,154	$1,485,946 (31.13%)	15.02% (t=6.40; p<0.0001)
NSAIDS	$9,890,367	$3,434,563 (25.78%)	$6,297,786	$1,327,551(17.02%)	61.35% (t=3.68; p=0.0003)
Skeletal Muscle Relaxant/Anticonvulsants	$2,912,834	$3,258,385 (52.8%)	$1,624,941	$2,589,614 (61.44%)	20.52% (t=3.29; p=0.001)

*Pre 2004 Pharmacy fee Schedule: Generic drugs: (AWP x 1.4) + $7.50 dispensing fee, Brand name drugs: (AWP x 1.1) + $4.00 dispensing fee
**Medi-Cal Estimated Acquisition Cost (EAC): (0.83 * AWP) + $7.25 dispensing fee
***Selected cost reductions which are statistically significant between pre and post 2004 fee schedules for repackaged pharmaceuticals= p<0.05

Mean Cost Per Pill Using Alternative Reimbursement Rates:



§ 2002 Medi-Cal published rates obtained from Medi-Cal drug utilization files
* Only cost/pill of oral capsules and tablets of the selected pain and pain related medications (1,210 of 1,315 total NDCs)

- The majority, but not all NDCs that did not have a Medi-Cal equivalent cost are repackaged pharmaceuticals (55.3%)
- Generic medications accounted for the majority of repackaged costs (88%)
- Companies most commonly associated with repackaged pharmaceutical costs were Southwood Pharmaceuticals (33.1%) and Pharma Pac (31.7%)
- Total repackaged pharmaceutical costs could be reduced by 36% ($3,059,177) using an alternative formula based on Medi-Cal formulae (AWP-17% + $7.25)
- On a per prescription basis, repackaging costs an additional $20 when compared to a Medi-Cal pharmacy dispensed medications
- Alternative rates: reductions on a cost per pill basis vary between 36%-40%
  - AWP-10%+ $7.25 (5.5% greater than the EAC) and
  - AWP-10% + $8.75 (13.4% greater than the EAC)
- Regression Analysis: Variables that were significantly predictive of increasing total average repackaged costs per NDC included:
  - Generic medications (p=0.005) and time on market < 7yrs (p=0.006)

CONCLUSIONS

- If the workers' compensation legislation reimbursement rate is set too low
  - This could lead to patient access problems affecting overall patient care
  - Varying the dispensing fee may allow the dispenser such as a physician to keep more of the payment than if the AWP alone is changed; depending on negotiations made with pharmaceutical repackagers and insurers, mitigating potential access limitations
- To avoid access problems, step-wise reductions in reimbursement rates are appropriate
- Future studies should examine if the added price is worth the increased access that repackaged pharmaceuticals afford and what cost and value are acceptable for pricing repackaged drugs