



California Workers' Compensation Institute
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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 study⁵ 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 grouper⁷ 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

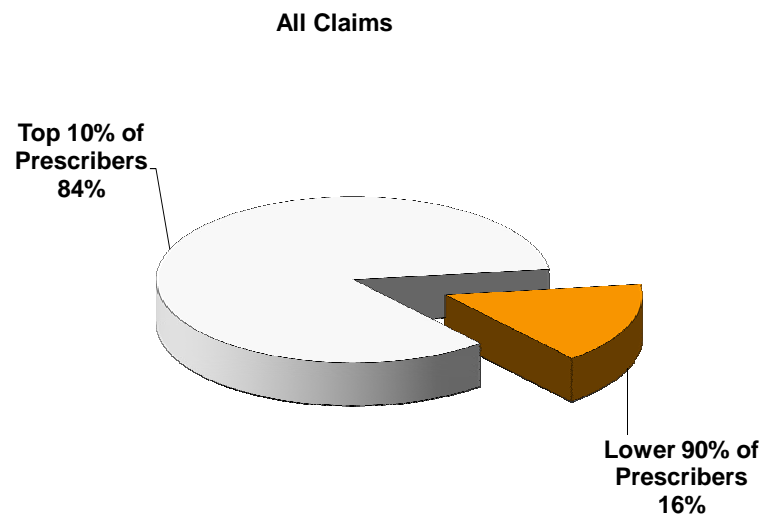


Chart 1 shows that the 917 physicians who comprised top 10 percent of Schedule II opioid prescribers in the study sample accounted for 84 percent of the fentanyl prescriptions in the sample (39,912 prescriptions, or an average of 53.5 prescriptions per physician). In contrast, the remaining 8,257 physicians 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).



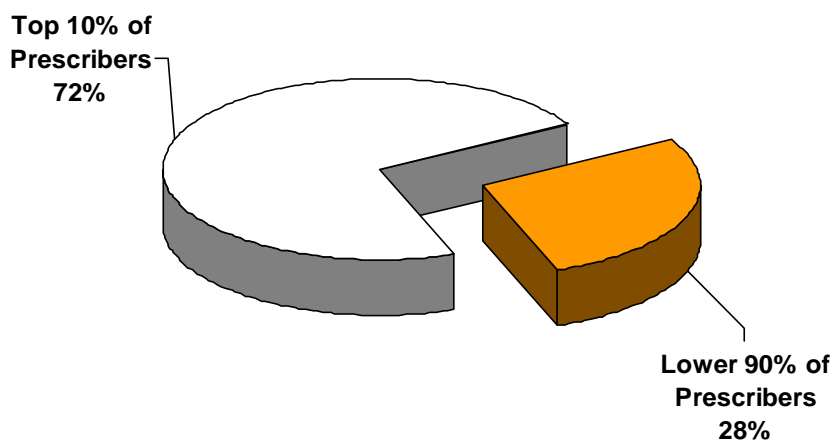
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Fentanyl Prescribed by High- vs. Low-Volume Schedule II Opioid Prescribers -- Non-Surgical Medical Back Claims

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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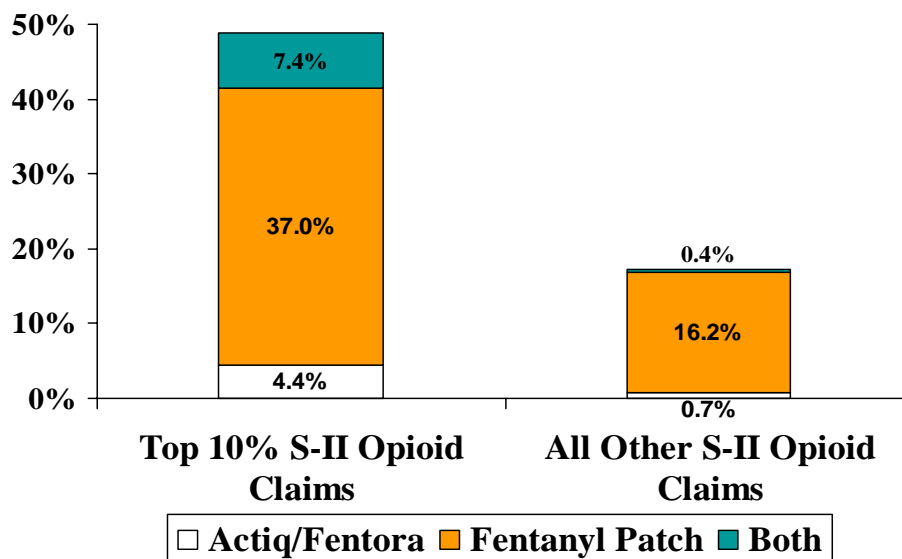
Types of Fentanyl Prescribed to Injured Workers

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



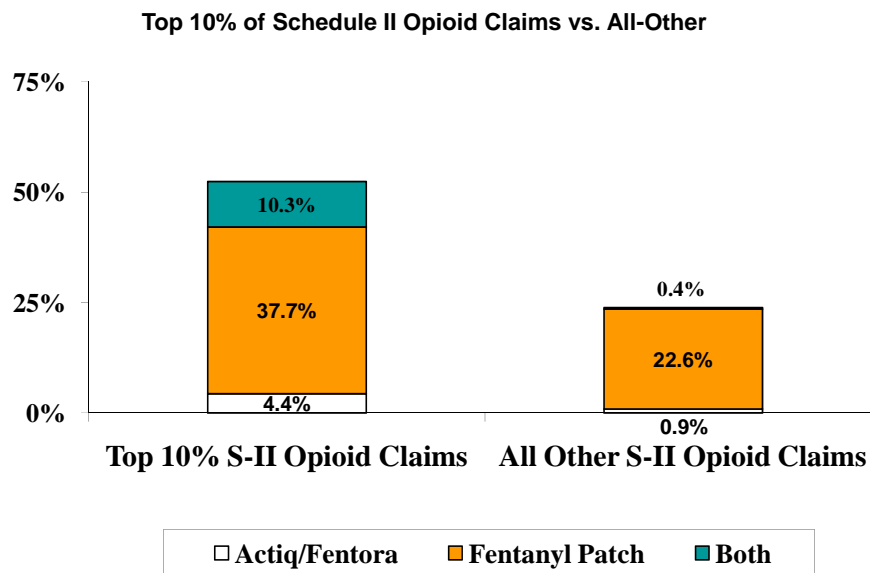
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percent (2,462 claims) involved fentanyl patches, 0.7 percent (106 claims) had an Actiq or Fentora prescription, and 0.4 percent (61 claims) had both types of fentanyl prescriptions, for an aggregate total of 17.3 percent (or more than 1 out of 6) 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-Surgical Medical Back Injury
-- % of Claims Involving Actiq/Fentora, Fentanyl Patch or Both



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.