

New report shows growing off-label narcotic use in California

Buccal Fentanyl is not approved by the U.S. Food and Drug Administration for musculoskeletal injuries. Yet, a new study shows it's being prescribed for dozens of injured workers with minor back pain in California.

Part 2 of the California Workers' Compensation Institute's study on Prescribing Patterns of Schedule II Opioids focuses on the use of fentanyl in the California workers' comp system. The data sample was obtained from pharmacy bills contributed by pharmacy benefit management organizations with injury dates between January 1993 and December 2009.

Fentanyl can be administered intravenously as a skin patch or as a lozenge or effervescent tablet. The prescriptions in the study included those prescribed as a skin patch or orally.

While the FDA has issued various warnings about the drug over the past years, there was a particular warning in 2007 about Buccal Fentanyl, also called Actiq lozenges or Fentora effervescent tablets.

"Buccal Fentanyl should be used only to treat breakthrough cancer pain . . . 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," the FDA said. "This medication should not be used to treat pain other than chronic cancer pain."

Despite that warning, CWCI reports more than 14 percent of claims with minor back injury had at least one prescription for Actiq or Fentora. "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 report states.

The use of off-label narcotics is not restricted to California. Nor is it a small problem in the workers' comp system.

"I'd argue from a medical management standpoint it's the most significant problem we have," said Joe Paduda, principal of Health Strategy Associates and author of the blog, Managed Care Matters. "It's not just that they cost a lot of money -- they do; but there's ample evidence to suggest the use of narcotic opioids for an extended period of time to treat musculoskeletal injuries is contraindicated."

In addition to the cost -- about \$3,000 to \$4,000 a month -- Paduda says the off-label use of these drugs to treat minor injuries creates a plethora of other problems. "There are side effects, such as sexual dysfunction, constipation, and

sleeplessness," he said. "So people need other medications to deal with the side effects."

Additionally, there are risks of addiction as well as abuse or diversion of the drugs. Finally, there's the risk of death.

"Opioids slow down the respiration rate," Paduda explained. "You build up a tolerance for a certain dose, but your body doesn't build up the pulmonary tolerance. People go to sleep and die."

The question of how to address the growing issue of narcotics -- especially off-label use -- in the workers' comp system is starting to be addressed by several states. Washington, for example, has established policies and practice guidelines for physicians who prescribe Schedule II narcotics.

"I think there's a growing recognition on the part of state regulators and legislators that they've got to solve this problem," Paduda said.