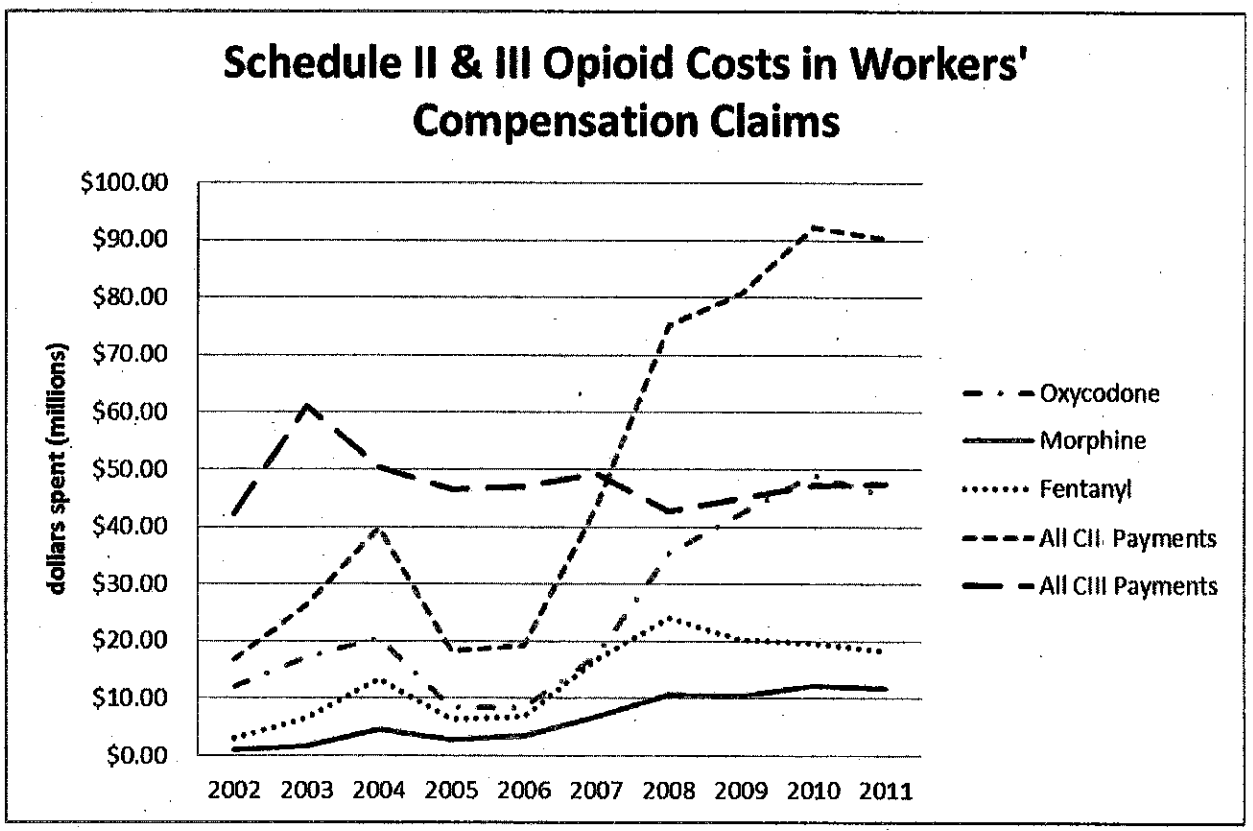
Background Paper for
Joint Hearing of the Senate Labor and Industrial Relations and Assembly Insurance Committees
March 20, 2013

A series of studies conducted by the California Workers' Compensation Institute (CWCI) have highlighted a seemingly inexplicable rise in opioid prescriptions by physicians in the workers' compensation system. Among the most troubling trends identified in these studies is the widespread use of potent Schedule II narcotics in patients with low back pain (without spinal cord involvement). As detailed below, Vicodin (brand name for hydrocodone) is a Schedule III narcotic. Schedule II narcotics are the strongest painkillers that can be legally prescribed. A 2011 CWCI study found that nearly one-half of all Schedule II opioid prescriptions were written for such injuries.

CWCI provided the data illustrated in the chart below. The chart shows dramatic shifts in the cost of Schedule II drug costs over time while the costs for Schedule III drugs has been relatively stable after a brief spike in costs in 2003. For example the cost for fentanyl increased nearly 8 fold between 2002 and 2008 and the cost for morphine has increased more than 10 fold in the same period.



Some of the more commonly prescribed narcotics include oral forms of fentanyl that are approved by the Food and Drug Administration (FDA) only for the treatment of breakthrough pain in cancer patients already taking opioids on a continuous basis. Fentanyl is the most potent opioid in the CWCI study and is considered to be 75 to 100 times more potent than oral morphine. CWCI found the following patterns in prescribing fentanyl in non-surgical back patients:

- 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.

The FDA has released a number of public health advisories regarding the dangers attached to the use of fentanyl including the following admonition regarding oral fentanyl: "...should not be used to treat any type of short-term pain including headaches or migraines, post-operative pain, or pain due to injury." A 2007 safety warning issued by the FDA states:

> "The fentanyl skin patch contains the opioid fentanyl, a potent narcotic. The skin patch was approved by FDA in 1990 for use in patients with persistent, moderate-to-severe pain who have become opioid tolerant – meaning that they have been using another strong opioid narcotic pain medicine around-the-clock, and have been using the medicine regularly for a week or longer. ***The skin patch is most commonly prescribed for patients with cancer.***"(emphasis added)

In that same advisory, the FDA's director of the Division of Anesthesia, Analgesia and Rheumatology Products stated, "While these products fill an important need, improper use and misuse can be life-threatening. Therefore, it is crucial that doctors prescribe these products appropriately and that patients use them correctly."

CWCI studies also report significant growth in the prescribing of all Schedule II opioids in the workers' compensation system. In 2002, prescriptions for Schedule II opioids were 1.1% of all prescriptions in the system. That percentage peaked at 6.7% in the first half of 2011. Schedule III opioid prescribing rates have experienced little variation in the same 10 year period.

Growth in Schedule II prescribing is not limited to the workers' compensation system. The Los Angeles Times (Times) recently reported that the use of prescription painkillers quadrupled between 1999 and 2010. That growth in prescriptions has been accompanied by an equally dramatic increase in the abuse of prescription drugs. Beginning in 2007 the number of emergency room visits involving prescription drugs outnumbered those involving illicit drugs. The Centers for Disease Control estimates 15,500 deaths resulted from prescription painkiller overdoses in 2009. CDC estimates that for every death, there are 130 individuals who are abusing or are dependent on prescription painkillers. The Times' series has drawn considerable attention among policymakers in Sacramento and Senator DeSaulnier has introduced Senate Bill 809 to provide funding for improved monitoring of controlled substance use and require prescribers to check a statewide controlled substance monitoring database (CURES).

Background

Controlled Substances

There is a subset of dangerous drugs (any drug requiring a doctor's prescription) known as "controlled substances." Controlled substances include drugs that have been determined by the DEA to have the "potential for abuse" and are subject to much more vigorous regulation than other prescription drugs. A controlled substance is placed into one of five categories (known as Schedules) based on an assessment of the risk associated with the drug as follows:

Schedule I -- The drug has: 1) high potential for abuse, 2) has no currently accepted medical use, and 3) no accepted standards for safe use. Examples include: hallucinogens (LSD, Peyote, hallucinogenic mushrooms), and heroin.

Schedule II -- The drug has: 1) high potential for abuse, 2) a currently accepted medical use, and 3) may lead to severe psychological or physical dependence. Examples include: stimulants (Ritalin, Adderall, and other amphetamines) and pain killers (such as Oxycontin, morphine, Percodan, fentanyl, Demerol).

Schedule III -- The drug has: 1) less potential for abuse than the drugs in schedules I and II, 2) has an accepted medical use, 3) abuse of the drug may lead to moderate or low physical dependence or high psychological dependence. Examples include: pain killers (Vicodin, Ketamine, and Codeine) and anabolic steroids.

Schedule IV -- The drug has: 1) a low potential for abuse relative to the drugs in schedule III, 2) an accepted medical use, 3) abuse of the drug may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III. Examples include: pain killers (such as Tylenol 4, Soma, Darvon), anti-anxiety drugs (such as Xanax and Valium), and sedatives (such as Ambien and Lunesta).

Schedule V -- The drug has: 1) a low potential for abuse relative to the drugs or other substances in schedule IV, 2) an accepted medical use, 3) abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV. Examples include cough syrup with codeine.

Controlled Substance Utilization Review and Evaluation System (CURES)

CURES is a database operated by the Department of Justice that requires pharmacies to submit information regarding ***controlled substance*** prescriptions dispensed by that pharmacy. CURES allows licensed healthcare prescribers eligible to prescribe controlled substances, pharmacists authorized to dispense controlled substances, law enforcement, and regulatory boards access to a patient's controlled substance prescription history.

Opioids

Opioids are derived from the opium poppy (or synthetic versions of it) and used for pain relief. Examples include hydrocodone (Vicodin), oxycodone (OxyContin, Percocet), fentanyl (Duragesic, Fentora), methadone, and codeine.

The Joint hearing of the Assembly Insurance and Senate Labor and Industrial Relations Committee is intended to begin a discussion of ways to address, in the workers' compensation system, a problem that has near universal acknowledgement among interested parties.