The Impact of the U.S. Drug Enforcement Agency Schedule Changes for Hydrocodone and Tramadol on California Prescriptions Patterns

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Introduction

The Centers of Disease Control and Prevention (CDC) have declared prescription drug abuse an epidemic, with 14,000 deaths in 2014 involving prescription opioids.\(^{(1)}\) Prescription related mortality is the number one cause of accidental deaths, more than motor vehicle collisions.\(^{(2)}\) In California, over 4,000 people a year die from overdoses of prescription medication.\(^{(3)}\) Opioids are involved in the majority of the accidental overdose deaths, accounting for 61% of these deaths.\(^{(4)}\) There is a direct relationship in the number of prescriptions and number of deaths.\(^{(6)}\)

Hydrocodone containing products (HCP) are the number one prescribed medication in the United States, more than cholesterol and blood pressure medications.\(^{(6)}\) Congress passed the Controlled Substances Act in 1970, and placed hydrocodone in schedule II, and HCP in schedule III.\(^{(8)}\) In 2014, the U.S. Drug Enforcement Administration (DEA) published in the Federal Register the Final Rule, moving HCP from schedule III to the more restrictive schedule II, which was supported by the U.S. Department of Health and Human Services.\(^{(7)}\)

The reasoning given for the schedule change was the high potential for abuse with psychological or physical dependence, as well as the science that adding non-narcotic substances like acetaminophen to hydrocodone does not diminish abuse potential.\(^{(6)}\) The impact of changing HCP to schedule II has several effects for both providers and dispensers: (1) HCP had to be written on hard copy prescription forms, (2) HCP could not be called into the pharmacy and (3) HCP could not be refilled.\(^{(6)}\)

Tramadol is a centrally acting synthetic opioid analgesic first approved in the U.S. in 1995 under the name “Ultram.”\(^{(8)}\) Many providers prescribe tramadol not realizing that the daily dose of tramadol has higher morphine equivalents than hydrocodone. Tramadol comes in a 50 mg tablet, has a morphine milligram equivalent (MME) of 0.1 MME per milligram, and therefore has 5 MME per tablet.\(^{(9)}\) Hydrocodone comes in 5 mg (per tablet) as its lowest dose, containing 1 MME per milligram, and therefore has 5 MME per tablet.\(^{(10)}\) Thus tramadol is equally potent to hydrocodone given the average daily dosing recommendations. Tramadol is advertised as safer than other opioids. However, in addition to the same side effects as other opioids, tramadol can precipitate seizures, especially when combined with alcohol, and when experiencing withdrawal.\(^{(11)}\) Tramadol is addicting and has been implicated in cases of doctor shopping.\(^{(12)}\) Tramadol was rescheduled by the DEA from schedule V to schedule IV, stating an eight-factor analysis concluding that tramadol has a potential for abuse that is lower compared to drugs classified as schedule III and similar to abuse potential of propoxyphene, which is schedule IV.\(^{(8)}\)

Objective

The purpose of this study was to determine the impact of the DEA rescheduling of hydrocodone and tramadol on California prescriptions patterns as documented in the CURES system.
Figure 1. CURES Number Prescriptions
August 2013 - October 2015

Figure 2. CURES Number of Tablets
August 2013 - October 2015
Methods

This is a retrospective descriptive analysis comparing three groups of prescriptions: (1) hydrocodone containing products (HCP), (2) tramadol, and (3) total opioids in the state of California documented through the CURES system for 12 months before and 12 months after the DEA rescheduling of hydrocodone and tramadol. The data were obtained from the California Department of Justice, which manages the CURES system that provided de-identified data of the number of prescriptions and the number of tablets for HCP, tramadol, and total opioids on a monthly basis from August 2013 until August 2015. The number of tablets as well as number of prescriptions were reviewed in order to account for potential changes in length of prescription. Analyses were made for the three groups of medication for 12 months before the schedule change, August 1, 2013, through July 31, 2014, and 12 months after, September 1, 2014, through August 31, 2015. The transition month of August was not included. California data were compared to national IMS data.

Results

The monthly pattern of CURES prescriptions from August 2013 through October 2015 showed a decline in the number of tablets of HCP dispensed, but an increase in the total number of dispensed opioids. Tramadol is shown to enter the database in August 2014, (Figure 1. Number of Prescriptions August 2013 – October 2015 and Figure 2. Number of Tablets August 2013 – October 2015).

For Hydrocodone containing products, the number of prescriptions decreased by 3%, from 15,667,302 to 15,204,104. In evaluating tramadol, the number of prescriptions was available only after the schedule change as 4,151,099 prescriptions. Total opioid prescriptions increased from 23,562,191 to 29,292,835. In order to account for the entry of tramadol into the CURES database, the total opioid measurement, the total opioid data were re-calcualted excluding tramadol. Excluding tramadol, total opioid prescriptions went from 23,562,191 to 25,141,736 reflecting an increase of 6.7%. (Figure 3. Prescriptions before and after DEA Rescheduling).

The number of tablets for HCP increased from 1,079,183,143 to 1,060,648,828, reflecting a decrease of 1.72%. A total of 298,343,473 tramadol tablets were dispensed during this period. Total opioid tablets dispensed went from 1,730,654,629 to 2,119,935,743. Excluding tramadol in order to account for the new data entry, total opioid tablets increased from 1,730,654,629 to 1,821,592,270, reflecting an increase of 5.3%, (Figure 4. Tablets before and after DEA Rescheduling).

Discussion

The DEA reschedule of hydrocodone had the expected effect of reducing the number of prescriptions and tablets by 3% and 1.7% respectively. The decrease represent a decline of over 400,000 prescriptions and 19 million tablets; however, the statistical significance is not determined. The California numbers showed less of an impact compared to the national data of 22% and 16% for prescriptions and tablets. The IMS national study reported that 73.7% of the reduction was attributed to the elimination of automatic refills. It is unclear if California had fewer automatic refills of hydrocodone prior to rescheduling and therefore less of a decline in hydrocodone prescriptions.

The expected effect of the schedule change was to decrease the overall number of prescriptions, especially since hydrocodone is the leading opioid prescription. However, both national and California data showed that total opioid prescriptions and tablets increased despite the DEA rescheduling of HCP. IMS data showed an increase of 4.9% in prescriptions and 1.2% in tablets, while California data showed an increase of 6.7% in prescriptions and 5.3% in tablets. California and IMS data were not identical. The California numbers reflect total opioids excluding tramadol. The IMS data reflect non-hydrocodone products. Despite the difference in data, it appears that Californians have increased use of total opioid prescriptions to a greater degree than the rest of the country after the DEA rescheduling of HCP.

In reviewing the monthly prescription numbers, it is not evident that the data represent a trend rather than continued monthly fluctuations. Future longer-term study of prescription patterns is necessary.

Limitations

This study is limited by the accuracy and completeness of the data provided by CURES and IMS. Ideally, the National Data by IMS Health and the California data presented in this study for hydrocodone prescriptions and tablets should use identical metrics. However, IMS data reviewed non-hydrocodone prescriptions and tablets while this California study reviewed total opioids.
Figure 3. CURES Number Prescriptions before and after DEA rescheduling

Figure 4. Tablets Dispensed before and after DEA Reschedule
Conclusion

The DEA reschedule of hydrocodone containing products in California had the expected effect of reducing the number of prescriptions and tablets by 3% for prescriptions and 1.72% for tablets, but not to the degree reported by national data of 22% and 16%. The total opioid prescriptions across the country increased despite the schedule change. California noted an increase of total opioid excluding tramadol of 6.7% for prescriptions and 5.3% for tablets. IMS National statistics reflected an increase of non-HCP of 22% for prescriptions and 16% for tablets. In reviewing the monthly prescription numbers, it is not evident that the data represents a trend rather than continued monthly fluctuations. Future longer term study of prescription patterns is necessary.

Acknowledgements

Mike Small, Program Manager, Department of Justice, California Prescription Drug Monitoring Program (Controlled Substance Utilization Review and Evaluation System) provided data for the study and has been an advocate for patient safety. For more information on the San Diego Prescription Drug Abuse Medical Task Force and safe prescribing resources, please visit SanDiegoSafePrescribing.org.

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References


