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Sent: Wednesday, August 18, 2010 11:56 AM
To: Terri Nataline
Cc: Andrea Licari; Theresa Cassidy
Subject: Kadian Q2 NAVIPPRO Report
Attachments: Actavis Q2 2010 Report_FINAL 8.18.2010.pdf

Hi Terri

Attached please find the Q2 2010 KADIAN NAVIPPRO report. We would be happy to set up a call with you to discuss the findings or answer any of your questions. Once again, thank you for your understanding regarding the delay of submission. The Annual Safety Report will be sent on Monday 8/23.

Best,
Janine





August 18, 2010

**National Addictions Vigilance Intervention and
Prevention Program (NAVIPPRO™)**
Drug Abuse Surveillance Report 2010: Volume 2

Analysis of Data for KADIAN®: Q2 2010 (4/1/2010 – 6/30/2010)

PREPARED FOR:

Actavis by Inflexxion, Inc.

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I. EXECUTIVE SUMMARY

Data Collection Period: 4/1/2010 – 6/30/2010

INTRODUCTION:

The National Addictions Vigilance Intervention and Prevention Program (NAVIPPRO™) is a program that monitors prescription drug abuse in the United States. NAVIPPRO™ surveillance allows for in-depth analysis of abuse of prescription analgesics, including analysis of product-specific rates of abuse, locations of abuse including potential hot spot areas, changes in abuse rates over time, and demographic analysis of populations of prescription drug abusers. NAVIPPRO™ surveillance also incorporates multiple data sources so that clients may have a comprehensive and scientifically valid assessment of their products abuse potential among various at-risk or sentinel populations. This surveillance includes analyses from Inflexxion's proprietary data sources; ASI-MV® Connect, CHAT™, and Web Informed Services (WIS™): Internet Monitoring and Surveys on Prescription Drug Misuse, as well as analyses from other available data sources (e.g., FDA-AERS and Dawn *Live!*).

This surveillance report provides an analysis of data from the NAVIPPRO™ system for KADIAN® compared to six other prescription opioid products during the current reporting quarter (April 1, 2010 through June 30, 2010). KADIAN® is a modified-release morphine sulfate pain reliever intended for patients with moderate to severe chronic pain and is a powerful Schedule II controlled substance. Due to the potential risks of misuse, abuse, overdose, and addiction associated with morphine-based analgesic products, post marketing surveillance is an essential component of a comprehensive risk management strategy for this medication.

ASI-MV® CONNECT:

The ASI-MV® Connect system gathers data on patients entering substance abuse treatment from a network of public and private treatment centers throughout the United States. These patient data are aggregated and used to monitor prescription drug abuse among this sentinel or at-risk population. The ASI-MV® Connect assesses abuse of specific products, so it is possible to compare a single product or compound against other similar products/compounds, as well as to find geographic areas of high and low prescription drug abuse.

- To date, the ASI-MV® Connect network contains data from 585 substance abuse treatment centers located in 38 states. These sites have contributed data from over 173,000 adult patient assessments. During the current reporting quarter (Q2 2010), there were 353 treatment facilities located in 33 states that contributed data to the ASI-MV® Connect network and a total of 16,571 patient assessments.
- During the second quarter of 2010 (Q2 2010), the rate of past 30 day abuse for any prescription opioid product among the ASI-MV® Connect treatment center population was 16.1 cases per 100 ASI-MV® Connect assessments. The states with the highest observed prescription opioid abuse rates were West Virginia (63.0 cases per 100 assessments), Nevada (60.0 cases per 100 assessments), and Kentucky (57.9 cases per 100 assessments). Rates of prescription opioid abuse reported from treatment centers within the ASI-MV® Connect network were also relatively higher in the states of Tennessee (38.5 cases per 100 assessments), Massachusetts (33.3 cases per 100 assessments), Missouri (33.0 cases per 100 assessments), and South Carolina (28.2 cases per 100 assessments). However, reported rates of prescription opioid abuse in the states of Kentucky, Nevada, and Massachusetts should be interpreted with

caution, as these rates are based on a low number of overall assessments submitted from treatment centers in each of these states during the reporting period (n<25).

- Review of prescription opioid abuse rates for KADIAN[®] and the six comparator products evaluated in this report during Q2 2010 indicated that the highest abuse rates were for OxyContin[®] (4.68 cases per 100 assessments) and Vicodin[®] brand and generic products (3.75 cases per 100 assessments), followed MS Contin[®] brand and generics (0.87 cases per 100 assessments), Opana[®] ER (0.47 cases per 100 assessments), KADIAN[®] (0.21 cases per 100 assessments), Duragesic[®] (0.18 cases per 100 assessments), and AVINZA[®] (0.07 cases per 100 assessments). Thus, among the morphine products monitored in this report, the rate of abuse reported for KADIAN[®] was lower than the rate reported for MS Contin[®] brand and generic products but higher than the rate of abuse reported for AVINZA[®].
- When considering the medical availability of a particular opioid product based on the number of prescriptions written, a different pattern of abuse was observed for KADIAN[®] and the six comparator products reviewed. Based on prescription volume, the highest reported rates of past 30 day abuse during Q2 2010 were for OxyContin[®] (60.95 cases per 100,000 prescriptions written), Duragesic[®] (57.72 cases per 100,000 prescriptions written), and Opana[®] ER (51.17 cases per 100,000 prescriptions written). The next highest rate of abuse was reported for KADIAN[®] (33.10 cases per 100,000 prescriptions written), followed by MS Contin[®] brand and generic products (16.44 cases per 100,000 prescriptions written), AVINZA[®] (0.74 cases per 100,000 prescriptions written), and then Vicodin[®] brand and generic products (2.49 cases per 100,000 prescriptions written). Thus, KADIAN[®] had the highest rate of abuse of the morphine products monitored in this report (KADIAN[®], MS Contin[®] brand and generics, and AVINZA[®]) when considering the number of prescriptions written for these drugs.
- During the second quarter of 2010, KADIAN[®] abuse was reported by 34 patients entering substance abuse treatment within the ASI-MV[®] Connect system. These cases were reported in ten states: Michigan (n=11), Missouri (n=8), Tennessee (n=6), Maryland (n=2), West Virginia (n=2), California (n=1), Kentucky (n=1), New Mexico (n=1), North Carolina (n=1), Oklahoma (n=1). The highest rates of KADIAN[®] abuse during the current reporting quarter were reported from the Appalachian states of Kentucky (5.3 cases per 100 assessments) and Tennessee (1.9 cases per 100 assessments) as well as the bordering state of Missouri (1.2 cases per 100 assessments). However, the reported rate of KADIAN[®] abuse in Kentucky should be interpreted with caution as it was based on a low number of overall assessments submitted from one substance abuse treatment center within the ASI-MV[®] Connect network in the state (n<20).
- Analysis of monthly abuse rates over the 12-month period July 2009 through June 2010 showed that rates of KADIAN[®] abuse remained below one case per 100 patient assessments, and did not exceed established control limits of three standard deviations above or below the baseline rate of KADIAN[®] abuse during this time (i.e., 12-month mean abuse rate for the drug). Monthly rates of KADIAN[®] abuse generally fluctuated near the mean rate of KADIAN[®] abuse over the 12-month period of July 2009 through June 2010, and were below the mean rate of abuse throughout the current reporting quarter (Q2 2010).

CHAT[™]

CHAT[™] (Comprehensive Health Assessment for Teens) is a web-enabled behavioral health assessment tool for adolescents (targeted at patients aged 18 years and younger) entering treatment for drug or alcohol abuse. Launched in June 2009, CHAT[™] gathers data from adolescents in a network of participating substance abuse treatment settings throughout the United States. These data are aggregated and used to monitor substance abuse patterns within a sentinel population of adolescent

prescription drug abusers. Information is collected at the product-specific level, allowing for the comparison of abuse among similar products.

- Since the launch of the CHAT™ program in June 2009 through the current reporting quarter ending on June 30, 2010, the CHAT™ network includes 697 adolescent patient assessments contributed from 62 substance abuse treatment sites, located in 17 states throughout the United States. During Q2 2010, the CHAT™ network collected data from 33 substance abuse treatment centers in 10 states that contributed 143 adolescent patient assessments.
- During Q2 2010, 7 cases (4.9%) of prescription opioid abuse were reported among adolescent patients from treatment centers in 4 of the 10 states contributing data to the CHAT™ network during the period. These states included: Michigan (n=3), New York (n=2), Hawaii (n=1), and New Jersey (n=1).
- There were no cases (n=0) of past 30 day KADIAN® abuse reported during Q2 2010 by adolescent patients entering substance abuse treatment within the CHAT™ system. Likewise, there were also no cases (n=0) of past 30 day abuse of Duragesic® or AVINZA® reported via the CHAT™ network. During Q2 2010, three individuals (n=3) reported past 30 day abuse of OxyContin®, three individuals (n=3) reported past 30 day abuse of Vicodin® brand and generic products, one individual reported past 30 day abuse of Opana® ER, and one individual reported past 30 day abuse of MS Contin® brand and generic products via CHAT™ assessments.

WIS™: INTERNET MONITORING

WIS™ Internet monitoring systematically collects and stores information from eight Internet-based discussion forms focused on recreational drug abuse. These monitored websites constitute a consistent, stable, sentinel population of recreational drug abusers that can be defined by their drug abuse activities/characteristics and analyzed over time to detect emerging trends and potential risks associated with the use and abuse of specific opioid products. These data are analyzed quantitatively and qualitatively for the purpose of characterizing both the amount and types of discussion occurring with respect to specific products within these communities.

- During the second quarter of 2010, 61 posts related to KADIAN® were identified in the WIS™ Internet monitoring archive. These posts were contained within 48 distinct threads and were written by 50 unique authors.
- Within the WIS™ Internet monitoring archive during Q2 2010, the level of discussion pertaining to KADIAN® continued to increase from the level of discussion observed during the previous three quarters (Q3 2009 through Q1 2010) and was statistically significantly greater than the level of discussion observed in Q3 2009. Furthermore, the level of discussion pertaining to KADIAN® remained statistically significantly lower than the three prescription opioid comparator products: OxyContin®, Vicodin®, and MS Contin®.
- In contrast to what was observed during previous quarters, however, the largest proportion of KADIAN®-related posts during Q2 2010 did not discuss KADIAN® in a general context, but rather discussed routes of administration associated with the use of KADIAN® (52.5%). Within the posts that discussed routes of administration, injection was discussed most frequently (87.5%), followed by snorting (15.6%), rectal administration (6.3%) and parachuting (6.3%). In addition to the increase in KADIAN®-related discussion associated with routes of administration, increases in the level of conversation regarding extraction techniques and negative consequences were also observed during Q2 2010 over levels observed in previous quarters. Furthermore, while an increase in the level of topic specific discussion (i.e., discussion about routes of administration, extraction techniques, etc.) was observed during the

current quarter, no new routes of administrations or extraction techniques relating to the abuse and misuse of KADIAN[®] were identified.

OTHER DATA:

- Data for Q2 2010 from Dawn *Live!* were unavailable at the time of this report. In January 2010, SAMSHA suspended all access to data from the Dawn *Live!* system. Therefore, monitoring of drug-related emergency department visits for KADIAN[®] was not possible for the current quarter. SAMSHA posted on their Dawn *Live!* website that the inability to access these data is temporary. However, as of the date of this quarterly report, data from Dawn *Live!* were still unavailable. Data previously requested directly from SAMSHA through email correspondence was met with the reply that "The Office of Applied Studies (OAS) is experiencing significant personnel and resource constraints, making it impossible for us to continue to respond to external requests to the same extent that we were able to do in the past. I regret that we cannot currently provide you with analyses that you request. I will keep your request in mind both as we develop new procedures and, as time and resources permit, will try to provide you with a more complete response."
- Review of data from FDA-AERS available through Q4 2009 and released during the current reporting quarter (Q2 2010) indicated that there were two KADIAN[®]-suspected adverse event cases. One of the four cases had an outcome listed as 'other', one adverse event case required an initial or prolonged hospitalization, and the remaining two adverse event cases required an initial or prolonged hospitalization and ultimately resulted in death. Examination of PRR/EBGM values available through Q4 2009 and released during Q2 2010 indicated that the highest values for the category of overdoses were reported for OxyContin[®], followed by KADIAN[®], Avinza[®], Opana[®] ER, MS Contin[®], Vicodin[®], and then Duragesic[®]. With respect to the drug abuse categories (drug and chemical abuse, drug abuser), the highest PRR/EBGM values were again reported for OxyContin[®], followed by Opana[®] ER, KADIAN[®], Vicodin[®], MS Contin[®], Duagesic[®], and then Avinza[®]. Thus, for each of the adverse event categories examined in this report (overdoses, drug and chemical abuse, drug abuser), of the monitored morphine products, KADIAN[®] had the highest reported PRR/EBGM values available through Q4 2009.
- During the second quarter of 2010, a total of 52 news media articles pertaining to prescription opioids in general were identified. The majority of these articles (98.1%) discussed the misuse/abuse of prescription opioid medications, and approximately 27% of articles included discussion of pain management through the use of these types of drugs. There were no general news media articles (n=0) identified which specifically mentioned KADIAN[®], and only one article which mentioned morphine.
- A total of 102 articles involving prescription opioids and legislative/law enforcement activity were identified during the second quarter of 2010. Nearly 55% of articles involved arrests for unlawful possession or distribution of prescription opioid products, and 52% involved legislation related to these types of medications. During Q2 2010, there were six articles (n=6) identified which mentioned morphine, and one article (n=1) which mentioned KADIAN[®]. The one article pertaining to KADIAN[®] discussed a pharmacy robbery in Philadelphia, Pennsylvania wherein several prescription opioid products, including KADIAN[®], were stolen by a man named Roy Allen Bowman.
- During the current reporting quarter (Q2 2010), there were no DEA media releases pertaining to KADIAN[®], morphine, or prescription opioids in general.
- A total of 68 academic research articles were identified during the current reporting quarter which pertained to any prescription opioid medication. Of these 68 articles, six articles pertained to morphine. There were no academic research articles identified during Q2 2010

which pertained specifically to KADIAN®. In June 2010, an academic article written by members of Inflexxion staff entitled 'Geographic information systems and pharmacoepidemiology: using spatial cluster detection to monitor local patterns of prescription opioid abuse,' was published in the journal *Pharmacoepidemiology and Drug Safety*. This article discussed the generation of geographic risk maps using substance abuse treatment center data in New Mexico to identify clusters of drug-specific prescription opioid abuse.

II. WHAT IS NAVIPPRO™?

NAVIPPRO™ (National Addictions Vigilance Intervention and Prevention Program) is a national program that includes surveillance and prevention and intervention education programs for substance abuse. The surveillance component of NAVIPPRO™ examines multiple data sources for indicators of prescription drug abuse. The system is designed to allow pharmaceutical companies, public health agencies, and risk management professionals access to timely and product-specific information about the abuse of a particular product compared to other prescription products. NAVIPPRO™ incorporates both quantitative and qualitative data to provide comprehensive surveillance of abuse of prescription medications. Incorporating multiple data sources ensures that all channels that may present information regarding prescription drug abuse are proactively monitored. The various data sources are intended to complement each other, since an indication of a rise in abuse of a particular product found in one data source may then be examined and evaluated via other sources. Continuous examination of these independent and complementary streams of information permits timely monitoring of trends in drug abuse at a product-specific level.

COMPONENTS OF NAVIPPRO™ SURVEILLANCE:

A. PROPRIETARY DATA SOURCES

- ASI-MV® Connect: proprietary surveillance of adult patients entering substance abuse treatment
- CHAT™: proprietary surveillance of adolescent patients entering substance abuse treatment
- Web Informed Services (WIS™): monitoring of proprietary data source of Internet discussions

B. OTHER DATA SOURCES

- Dawn *Live!*: SAMHSA's emergency room drug-related visits data
- FDA-AERS: FDA's Adverse Event Reporting System
- DEA Articles
- Media Monitoring
- Academic Research Articles

III. NAVIPPRO™ DRUG ABUSE SURVEILLANCE DATA

3.1. INTRODUCTION

The following report provides an analysis of abuse and misuse of KADIAN® during the second quarter of 2010 (April 1, 2010 through June 30, 2010). KADIAN® is a modified-release morphine sulfate pain reliever intended for patients with moderate to severe chronic pain in need of continuous 24-hour therapy over an extended period of time. The morphine contained in KADIAN® is a powerful opioid and a Schedule II controlled substance. Due to the potential risks of misuse, abuse, overdose, and addiction associated with morphine-based analgesic products, post marketing surveillance is an essential component of a comprehensive risk management strategy for this medication. The following report presents information from several data streams from the NAVIPPRO™ system which were reviewed in order to provide an analysis of observations and patterns of KADIAN® abuse in relation to six other prescription opioid products over the current reporting quarter among sentinel or at-risk populations. The report includes analysis of patient data from adult and adolescent substance abuse treatment centers (ASI-MV® Connect and CHAT™, respectively), analysis of Internet discussion by a sentinel population of prescription opioid abusers participating on Internet drug forums (WIS™: Internet Monitoring), Dawn *Live!*, FDA-AERS, DEA media publications, media monitoring, and academic research articles.

3.2. ASI-MV® CONNECT

3.2.1. BACKGROUND

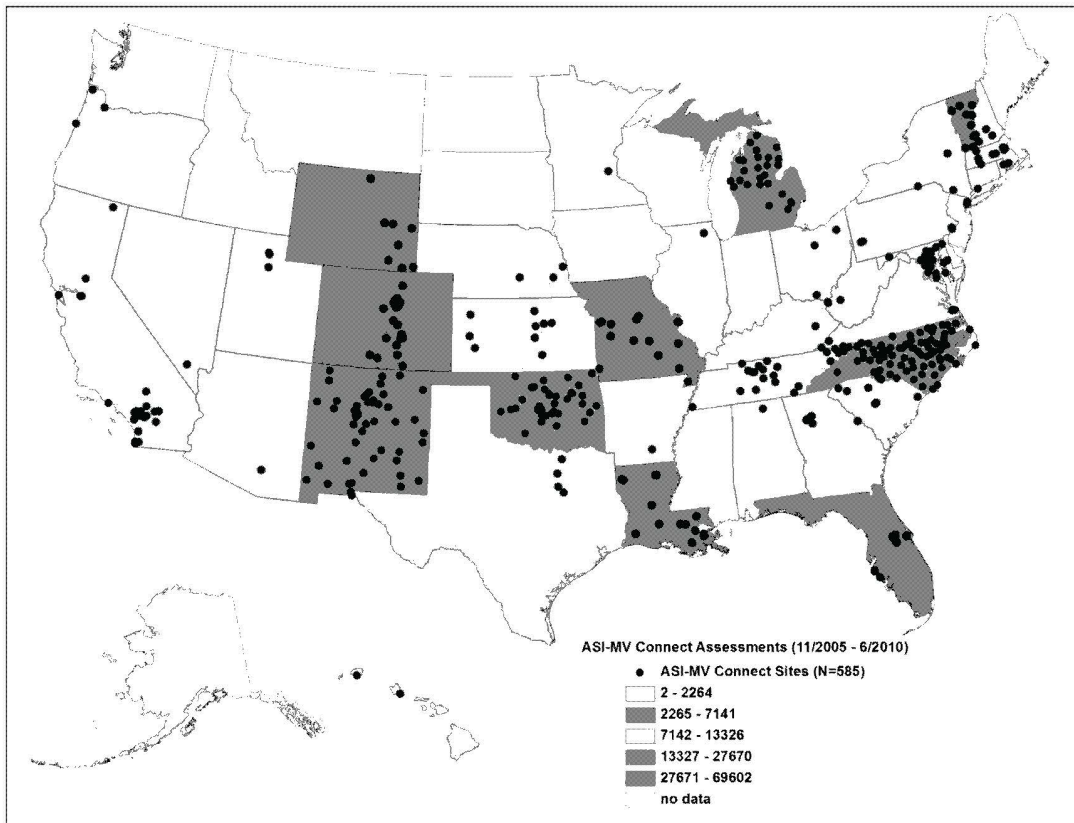
The Addiction Severity Index or ASI is a standard tool used in the assessment of substance abuse and related social, health, and economic problems. It is traditionally administered by clinicians in a treatment setting upon intake for substance abuse treatment. The ASI is intended to provide a method of measuring patient problems for treatment purposes, and to ensure that the clinician considers other problems in the patient's life beyond substance abuse (McLellan, 1980).

The ASI-MV® Connect is a computer-administered version of the ASI that has been shown to have good reliability and validity (Butler, 2001). As a self-administered computer-based interview, the ASI-MV® Connect allows for direct entry of self-reported patient information into a computer where the data can be collected and aggregated in real-time for surveillance purposes. The ASI-MV® Connect contains a series of questions about prescription opioid abuse, in addition to the core traditional ASI questions. The ASI-MV® Connect identifies over 50 individual prescription opioid products, not just drug compounds as with most other drug surveillance systems. Information about how each product is abused and how it was obtained is also collected. Sites using ASI-MV® Connect are able to download new modules for drugs as they reach the market, allowing treatment centers, public health agencies, and prescription manufacturers to monitor abuse of drugs at a product-specific level from the time a drug enters the market.

In addition to providing a profile of the characteristics of patients within individual treatment centers, the data are aggregated across all treatment centers and analyzed geographically and temporally for surveillance purposes to monitor abuse of specific compounds or products of interest. These data provide information on the abuse of prescription opioids among a sentinel

population of individuals in treatment for substance abuse. The data allow for a review of abuse trends at a product-specific level on a local scale. The ASI-MV[®] Connect began collecting product specific abuse data for prescription opioids in November 2005. To date, the ASI-MV[®] Connect network has collected data from a total of 585 substance abuse treatment centers located in 38 states (including the District of Columbia), which have contributed over 173,000 adult patient assessments. Figure 1 displays the total ASI-MV[®] Connect sample distribution by state and the location of treatment sites that have contributed data since the network began. In Figure 1, areas illustrated with shades of orange indicate states with larger sample sizes, and areas illustrated with shades of blue indicate states with smaller sample sizes.

Figure 1. Geographic distribution of ASI-MV[®] Connect assessments and treatment centers by state (11/5/2005 – 6/30/2010)



3.2.2. METHODS

Abuse rates for KADIAN[®] and comparator products were examined using temporal and geographic analysis to determine “hot spots” or localized areas of abuse. Also, demographic characteristics such as the gender and age distribution of patients who reported abuse of KADIAN[®] and the six comparator products were reviewed, along with information on the routes of administration reported by these patients and the sources for obtaining KADIAN[®] and the comparator products.

RATES OF PRESCRIPTION OPIOID ABUSE

Rates of abuse were calculated for KADIAN[®] and six comparison products including OxyContin[®], Vicodin[®] (including brand and generic products), Duragesic[®], Opana[®] ER, MS Contin[®] (brand and

generic) and AVINZA[®]. Abuse of a product is captured via self-report during the ASI-MV[®] Connect computer-administered interview. This is defined as having used the product in a way other than prescribed by a doctor at least once during the past 30 days. Respondents are presented with the names of products, as well as pictures of the pills to help distinguish exactly which products s/he has used. For example, patients classified as having abused KADIAN[®] are defined as the number of patients in treatment who report using KADIAN[®] during the past 30 days in a way not prescribed by a doctor.

Three different methods were used to calculate a rate of abuse and are described below. Each method is a different way of conceptualizing the rate and yields a somewhat different result. All three rate calculations are helpful in obtaining a complete picture of the abuse profile for a prescription opioid product. Thus, abuse rates for each drug evaluated in this report are presented using three different denominators including: 1) all ASI-MV[®] Connect assessments during the reporting period, 2) all prescription opioid abusers in the ASI-MV[®] Connect treatment center population during the reporting period, and 3) the number of prescriptions for the specific drug during the reporting period. The first two rate calculations allow an evaluation of the amount of abuse of a given drug among the overall ASI-MV[®] Connect substance abuse treatment center population as well as among patients in the ASI-MV[®] Connect population that report abuse of any prescription opioid. This latter rate provides a sense of the amount of abuse of a particular prescription opioid in relation to other prescription opioids. Calculation of rates per 100,000 prescriptions allows for the evaluation of the level of abuse in relation to the number of available prescriptions for each drug. This third type of rate is intended to provide a measure of the amount of abuse for a particular drug with consideration for the total amount of drug that is potentially abusable (i.e., an estimate of the "at-risk" population) measured as the total number of prescriptions circulating in that time.

When calculating a rate, it is important for the numerator and denominator to correspond with respect to the time period from which the data were drawn. The rates per 100,000 prescriptions were calculated using quarterly prescription volume data (i.e., total number of prescriptions) obtained from a commercial vendor, SDI Health (formerly Verispan, LLC), for the reporting period. These data are derived from the Sub-National Pain Market Prescription Tracking database provided by SDI Health and includes a variety of sources, including pharmacies, payers, and switch houses. Through agreements with a variety of data providers, the SDI Health (data warehouse receives 2 billion prescription claims and 475 million medical claims (both provider and hospital) per year, representing over 150 million unique patients. These prescription data sample nearly 59,000 pharmacies (over 99% of retail stores) in the US and include cash, Medicaid, and third-party transactions. Data are representative of the retail pharmacy universe and do not include other potential channels of distribution, such as long-term care, hospital dispensing, and mail order.

GEOGRAPHIC DISTRIBUTION OF PRESCRIPTION OPIOID ABUSE

ArcGIS was used to map the rates of KADIAN[®] abuse per 100 assessments and KADIAN[®] abuse per 100,000 prescriptions in each state submitting data during the time period examined in this report. The rates of abuse for all prescription opioids per 100 assessments were also mapped at the state level. The value for each state was calculated by aggregating data from all of the treatment centers in each state. When interpreting these data, it is important to note that rates based on small numbers of cases can widely fluctuate and could lead to misleading estimates of abuse. In general, estimates in states that have a low sample size should be interpreted with

extreme caution, as the rate is less precise with lower sample sizes. It should also be noted that the ASI-MV[®] Connect network does not have complete coverage in all participating states. The sites that contributed data are represented by points on the map, so that it is possible to view where in the state the data were collected.

ABUSE RATES OVER TIME

Statistical process control (SPC) methods were used to track the mean or baseline rate of abuse as well as the normal variation in rates of abuse (i.e., rates of abuse will vary from month to month) for each prescription opioid product examined in this report. Trends in the data were examined over a 12-month period including the current reporting period to determine whether the rate of abuse is increasing or decreasing. Additionally, thresholds were set to signal whether an "abnormally high" level of abuse may be occurring. These thresholds are called "control limits," and represent three standard deviations above or below the baseline of the data. Three standard deviations beyond the mean are conventionally used in SPC analysis to determine whether an observation is outside the expected normal variation in the data.

There are two main ways to examine SPC data. First and most intuitive is to calculate the rate of abuse for a given product, month by month, and see whether the rate is increasing or decreasing, and whether any signals can be detected. An alternative way to examine SPC data is to standardize the data. This method can be used to compare the rates of different products to each other. This means that rather than the Y axis representing actual numbers (such as pounds, abuse rates, etc.); the Y axis for standardized data marks the lower control limit, the upper control limit, and the mean for the product (all the means are set at zero, representing zero standard deviations from the mean). In such a situation, the overall rate of abuse is calculated for each product, and then each point on the line represents a measurement of how many standard deviations each measurement falls above or below the mean or overall rate (mean standardized at zero, or zero standard deviations from the mean for that drug). The advantage to this method of analysis is that it allows direct comparisons between products even if their abuse rates are very different. For instance, if the abuse rate of two products were being compared, and one product had an average abuse rate that was low (1 case per hundred assessments), and the other drug had a high abuse rate (30 cases per hundred assessments), by standardizing the data, zero on the Y axis would represent the individual mean for each drug, 1/100 for Drug X and 30/100 for Drug Y. The trend lines of Drugs X and Y are superimposed upon each other, so that it is possible to examine whether Drugs X and Y were increasing or decreasing at a proportionally similar rate, or whether abuse of one of the products is increasing proportionately more than the other.

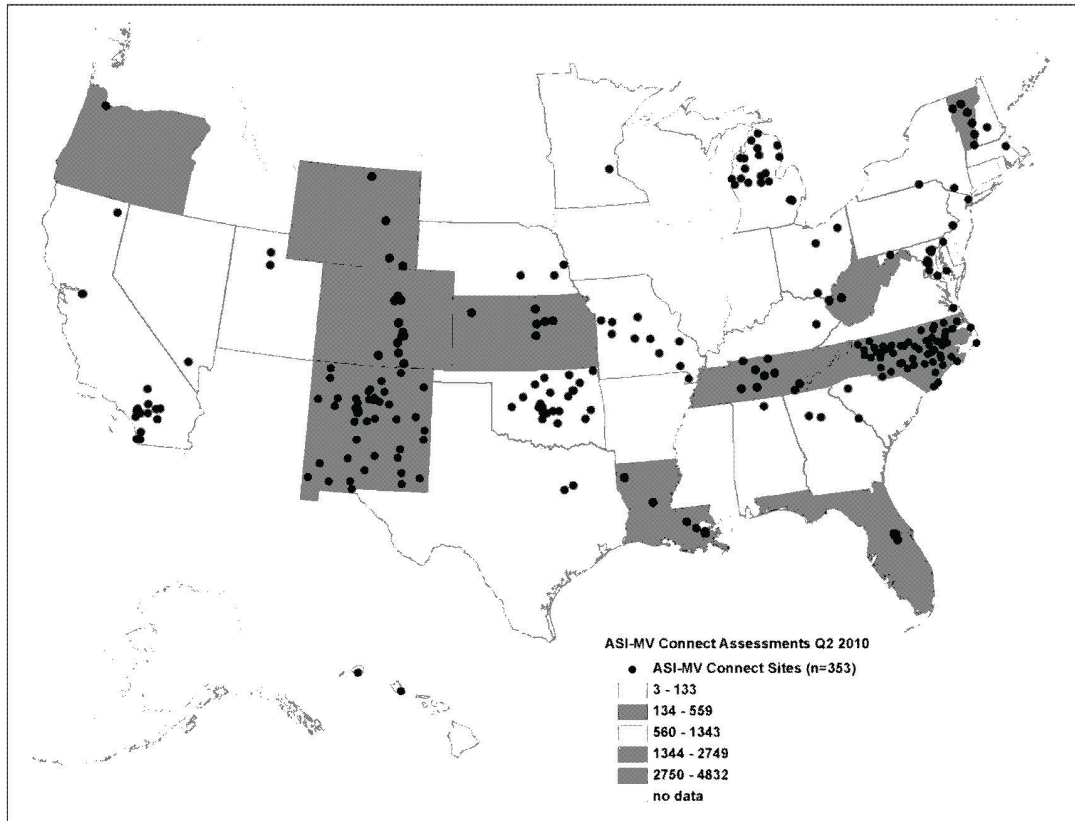
3.2.3. RESULTS

SUMMARY OF PARTICIPANT DATA

During the second quarter of 2010 (April 2010 - June 2010), there were 353 treatment facilities located in 33 states that contributed a total of 16,571 adult patient assessments. Figure 2 displays the distribution of patient assessments by state and the location of treatment sites that contributed data for the reporting period Q2 2010. As shown in Figure 2, the states contributing the most data this quarter were New Mexico (n=4,832), North Carolina (n=2,749), Oklahoma (n=1,343), Michigan (n=1,282), and Maryland (n=1,203). These five states contributed approximately 69% of all ASI-MV[®] Connect assessments completed during Q2 2010. Differences in sample size at the state level are important to consider when interpreting rates of abuse

presented in this report, as calculations for states that contributed larger amounts of data will be more stable than states that contributed smaller amounts of data. In Figure 2, ASI-MV[®] Connect sample sizes are illustrated with shades of orange indicating larger sample sizes and shades of blue indicating smaller sample sizes.

Figure 2. Geographic distribution of ASI-MV[®] Connect assessments and treatment centers by state for 4/1/2010 – 6/30/2010



The demographic frequencies of the ASI-MV[®] Connect patient sample during Q2 2010 indicated that the mean age of patients entering substance abuse treatment was 33.8 years, with an age range of 14-90 years. Approximately 53% of patients entering treatment within the network this quarter were Caucasian and 64.4% were male. Nearly 57% of patients who completed an ASI-MV[®] Connect assessment during the current reporting quarter had never been married, and the greatest percentage of patients (32.5%) reported employment in occupations involving skilled or semi-skilled labor. During the current reporting quarter, over half of the ASI-MV[®] Connect patient population (60.4%) was required to enter treatment by the criminal justice system. Approximately 30% of patients indicated having a chronic medical problem, and nearly 31% of patients reported having a problem with chronic pain. Table 1 displays the demographics characteristics of patients entering treatment within the ASI-MV[®] Connect network during the second quarter of 2010.

Table 1. ASI-MV[®] Connect participant characteristics for Q2 2010 (data collected 4/1/2010 – 6/30/2010)

	Response	Number (N)	Percent (%)
Age	Mean Standard Deviation Range	33.8 11.5 14-90 years	
Gender	Male Female Unknown/No Response	10,670 5,901 0	64.4 35.6 0.0
Race	Caucasian African American American Indian Asian/Pacific Islander/Alaskan Hispanic/Latino Other Race Unknown/No Response	8,808 3,442 863 130 3,328 0 0	53.2 20.8 5.2 <1.0 20.1 0.0 0.0
Marital Status	Married Separated, Divorced, Widowed Never Married No Response	3,225 3,893 9,412 41	19.5 23.5 56.8 <1.0
Employment	Professional Administrative, Clerical, Sales Skilled or Semi-skilled Student Homemaker Other Manual/Unskilled Did not work for pay in last 3 years Disabled No Occupation No Response	1,621 2,310 5,380 874 693 1,612 1,086 992 1,917 85	9.8 13.9 32.5 5.3 4.2 9.7 6.6 6.0 11.6 <1.0
*Criminal justice-required substance abuse treatment	Yes No No Responses	10,006 6,539 26	60.4 39.5 <1.0
Chronic medical problem	Yes No No Response	5,005 11,514 52	30.2 69.5 <1.0
Chronic pain problem	Yes No No Response	5,125 11,420 26	30.9 68.9 <1.0

* The category "Criminal justice-required substance abuse treatment" indicates that admission to substance abuse treatment was required of the respondent as part or in lieu of sentenced jail or prison time.

RATES OF PRESCRIPTION OPIOID ABUSE

In this section, abuse rates and 95% confidence intervals are presented for Q2 2010 for KADIAN[®], and six comparator prescription opioid products: MS Contin[®], AVINZA[®], Duragesic[®], Opana[®] ER, OxyContin[®] and Vicodin[®]. Abuse was measured during the past 30 days only, thus, the abuse rates presented are estimates of recent abuse, not lifetime abuse. Rates presented for

Vicodin[®] and MS Contin[®] include the number of individuals who reported abuse of the brand-name product as well as generic equivalents. The rates of abuse and corresponding 95% confidence intervals for the target and comparator products for Q2 2010 are summarized in Table 2 and illustrated in Figures 3 through 5. Rates by individual treatment facilities are presented in Appendix B.

It should be noted that patients assessed by the ASI-MV[®] Connect report abuse of a particular product by selecting the image of that product. In this way, the ASI-MV[®] Connect collects product-specific data for the purpose of monitoring rates of abuse among a population in substance abuse treatment. Given the similarity in appearance of some brand name products and their generic equivalents, it is possible that individuals who abuse the generic form of a product have selected the image of the brand name product instead. This is likely the case for Vicodin[®] and MS Contin[®], as the ASI-MV[®] Connect does not present separate images for the generic versions of these products. In some cases (e.g., MS Contin[®]), the brand and its generic equivalent are virtually identical in appearance. Therefore, the rates presented in this report for Vicodin[®] and MS Contin[®] products likely reflect reported abuse for a combination of the brand and generic formulations.

Analysis of rates of abuse within the ASI-MV[®] Connect substance abuse treatment center network during the second quarter of 2010 indicated that, of the prescription opioid products monitored in this report, the highest rates of abuse reported were for OxyContin[®] (4.68 cases per 100 assessments) and Vicodin[®] brand and generic products (3.75 cases per 100 assessments). During this period, the next highest rate of abuse was for MS Contin[®] brand and generics (0.87 cases per 100 assessments), followed by Opana[®] ER (0.47 cases per 100 assessments), KADIAN[®] (0.21 cases per 100 assessments), Duragesic[®] (0.18 cases per 100 assessments), and AVINZA[®] (0.07 cases per 100 assessments). Thus, among the morphine products monitored in this report, the rate of abuse reported for KADIAN[®] was lower than the rate reported for MS Contin[®] brand and generic products and higher than the rate reported for AVINZA[®] per 100 ASI-MV[®] Connect assessments.

Within the subset population of individuals in treatment within the ASI-MV[®] Connect network during Q2 2010 who reported past 30 day abuse of any prescription opioid, the highest rates of abuse were again reported for OxyContin[®] (29.07 cases per 100 prescription opioid abusers) and Vicodin[®] brand and generic products (23.29 cases per 100 prescription opioid abusers). The next highest rate of abuse within this population was reported for MS Contin[®] brand and generic products (5.40 cases per 100 prescription opioid abusers), followed by Opana[®] ER (2.93 cases per 100 prescription opioid abusers), KADIAN[®] (1.28 cases per 100 prescription opioid abusers), Duragesic[®] (1.13 cases per 100 prescription opioid abusers), and then AVINZA[®] (0.41 cases per 100 prescription opioid abusers). Again, of the morphine drugs monitored in this report, KADIAN[®] had a higher reported rate of abuse than AVINZA[®] and a lower reported rate of abuse than MS Contin[®] brand and generic products per 100 prescription opioid abusers within the ASI-MV[®] Connect substance abuse treatment center network.

When considering the medical availability of each of the monitored prescription opioid products based on the number of prescriptions written during Q2 2010, the highest rates of abuse were reported for OxyContin[®] (60.95 cases per 100,000 prescriptions written), Duragesic[®] (57.72 cases per 100,000 prescriptions written), and Opana[®] ER (51.17 cases per 100,000 prescriptions written). The next highest rate of abuse was reported for KADIAN[®] (33.10 cases per 100,000 prescriptions written), followed by MS Contin[®] brand and generic products (16.44 cases per

100,000 prescriptions written), AVINZA® (15.18 cases per 100,000 prescriptions written), and then Vicodin® brand and generic products (2.49 cases per 100,000 prescriptions written). Thus, when accounting for the number of prescriptions written during Q2 2010, KADIAN® had the highest rate of abuse of the morphine products monitored in this report (KADIAN®, MS Contin® brand and generics, and AVINZA®).

Table 2. Rates of abuse for KADIAN® and comparator products within the ASI-MV Connect® treatment center population (4/1/2010 – 6/30/2010)

	Total Cases	Cases per 100 ASI-MV® Connect assessments			Cases per 100 prescription opioid abusers assessed			Cases per 100,000 prescriptions		
		Rate	95% CI		Rate	95% CI		Rate	95% CI	
KADIAN®	34	0.21	0.14	0.30	1.28	0.88	1.86	33.10	22.87	48.39
OxyContin®	775	4.68	4.36	5.00	29.07	27.35	30.79	60.95	56.66	65.24
Vicodin® (brand and generics)*	621	3.75	3.46	4.04	23.29	21.69	24.90	2.49	2.29	2.68
Duragesic®	30	0.18	0.12	0.26	1.13	0.76	1.61	57.72	38.96	82.54
Opana® ER	78	0.47	0.37	0.57	2.93	2.29	3.57	51.17	39.82	62.53
MS Contin® (brand and generics)*	144	0.87	0.73	1.01	5.40	4.54	6.26	16.44	13.75	19.12
AVINZA®	11	0.07	0.03	0.12	0.41	0.21	0.74	15.18	7.57	27.17

* Rates presented for Vicodin® and MS Contin® include the number of individuals who reported abuse of the brand name product as well as abuse of their generic equivalents. Given the similarity in appearance of some brand and generic drugs, it is likely some individuals who abuse a generic form of a brand name product may report abuse of that product by selecting the image of the branded product instead.

Figure 3. Rate of abuse of KADIAN® and comparator products per 100 patient assessments within the ASI-MV® Connect treatment center population (4/1/2010 – 6/30/2010)

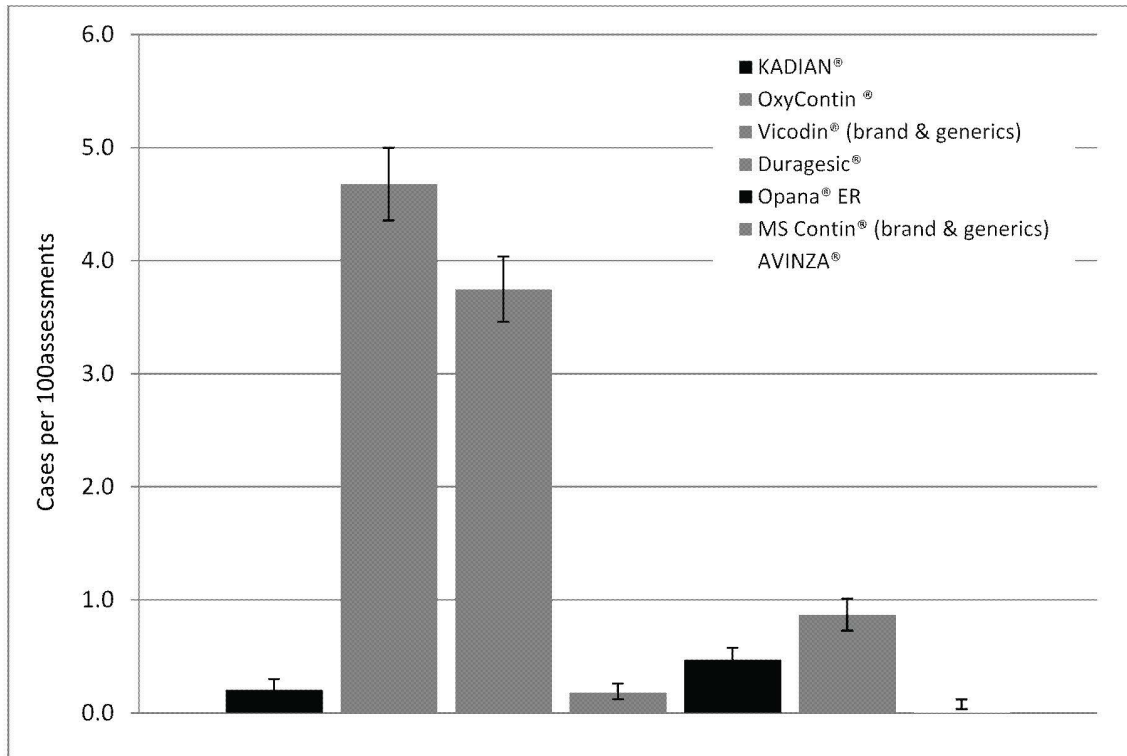


Figure 4. Rate of abuse of KADIAN® and comparator products per 100 prescription opioid abusers within the ASI-MV® Connect treatment center population (4/1/2010 – 6/30/2010)

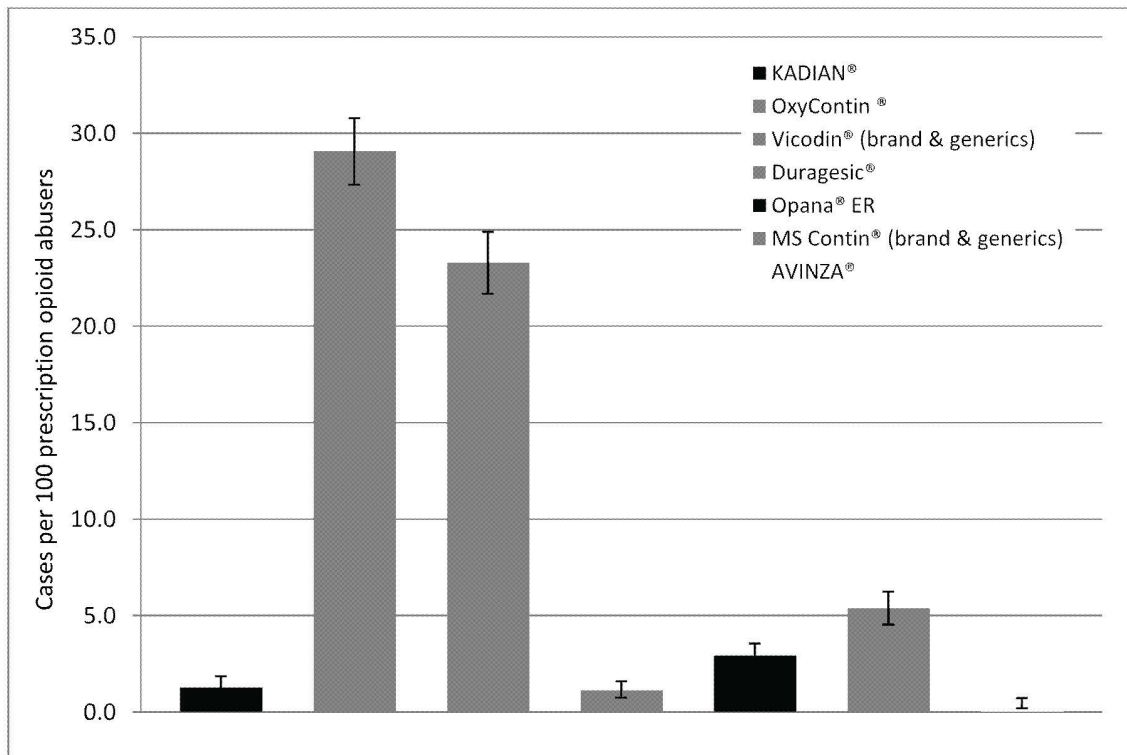
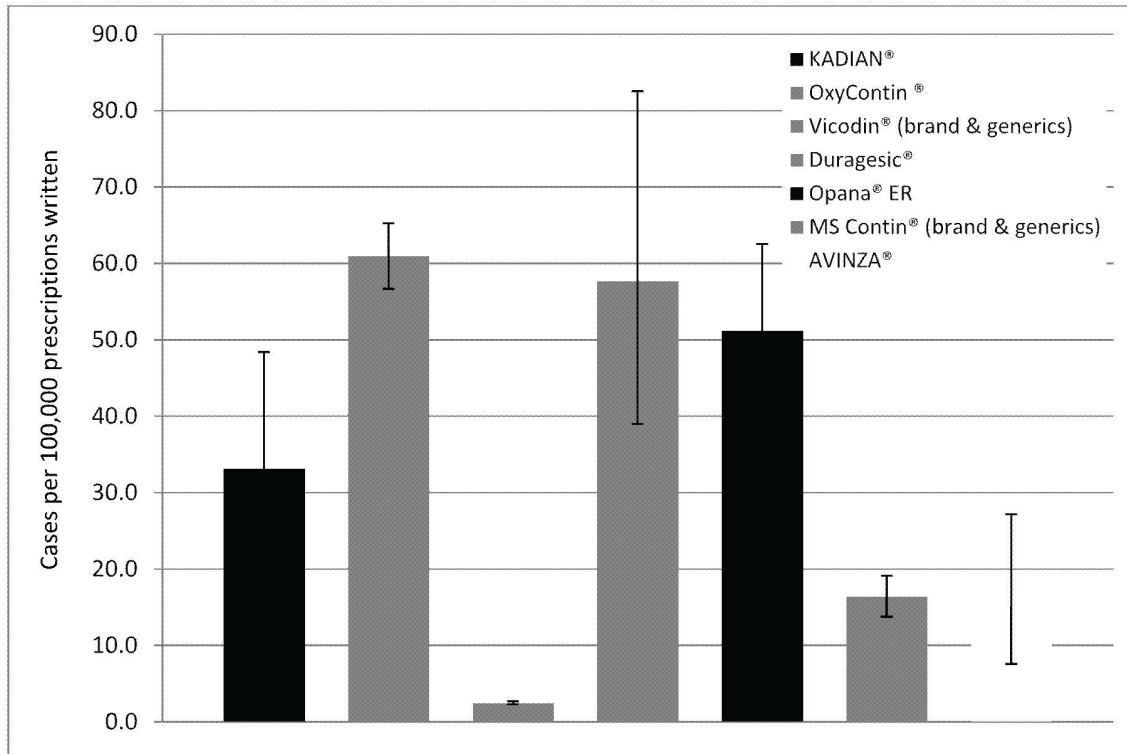


Figure 5. Rate of abuse of KADIAN® and comparator products within the ASI-MV® Connect treatment center population per 100,000 prescriptions written (4/1/2010 – 6/30/2010)



GEOGRAPHIC DISTRIBUTION OF PRESCRIPTION OPIOID ABUSERS

This section examines the geographic distribution of prescription opioid abuse as reported via the ASI-MV® Connect during Q2 2010. Rates of abuse were calculated by state for abuse of any prescription opioid product and for abuse of KADIAN®. In these maps, shades of orange indicate areas where higher rates of prescription opioid abuse were observed and shades of blue represent areas where lower rates of abuse. States that have a low sample size should be interpreted with extreme caution, as the rate is less precise with lower sample sizes. For reference, Appendix B presents the aggregated data from each treatment center contributing data by state for KADIAN® abuse as well as for overall prescription opioid abuse within the ASI-MV® Connect treatment center population for Q2 2010.

Figure 6 illustrates rates of prescription opioid abuse per 100 assessments for any prescription opioid product as a group, as represented by data from ASI-MV® Connect during Q2 2010. Past 30 day abuse of any prescription opioid product was reported by patients entering treatment in 30 of the 33 states that contributed data to the ASI-MV® Connect network during Q2 2010. There were no instances of prescription opioid abuse reported via the ASI-MV® Connect network in the states of Georgia, Minnesota, and New Hampshire. The state reporting the highest rate of prescription opioid abuse during the current reporting quarter was West Virginia with 63.0 cases per 100 ASI-MV® Connect assessments. Rates of prescription opioid abuse were also relatively higher in the states of Nevada (60.0 cases per 100 assessments), Kentucky (57.9 cases per 100 assessments), Tennessee (38.5 cases per 100 assessments), Massachusetts (33.3 cases per 100 assessments), Missouri (33.0 cases per 100 assessments), and South Carolina (28.2 cases per 100 assessments). It is important to note, however, that the reported rates of prescription opioid abuse in Kentucky, Nevada, and Massachusetts should be interpreted with extreme caution, as

these rates are based on a low number of overall assessments submitted from each of these states during the reporting period (n<25).

Figure 6. Rate of abuse of all prescription opioid products per 100 patient assessments within the ASI-MV[®] Connect treatment center population (4/1/2010 – 6/30/2010)

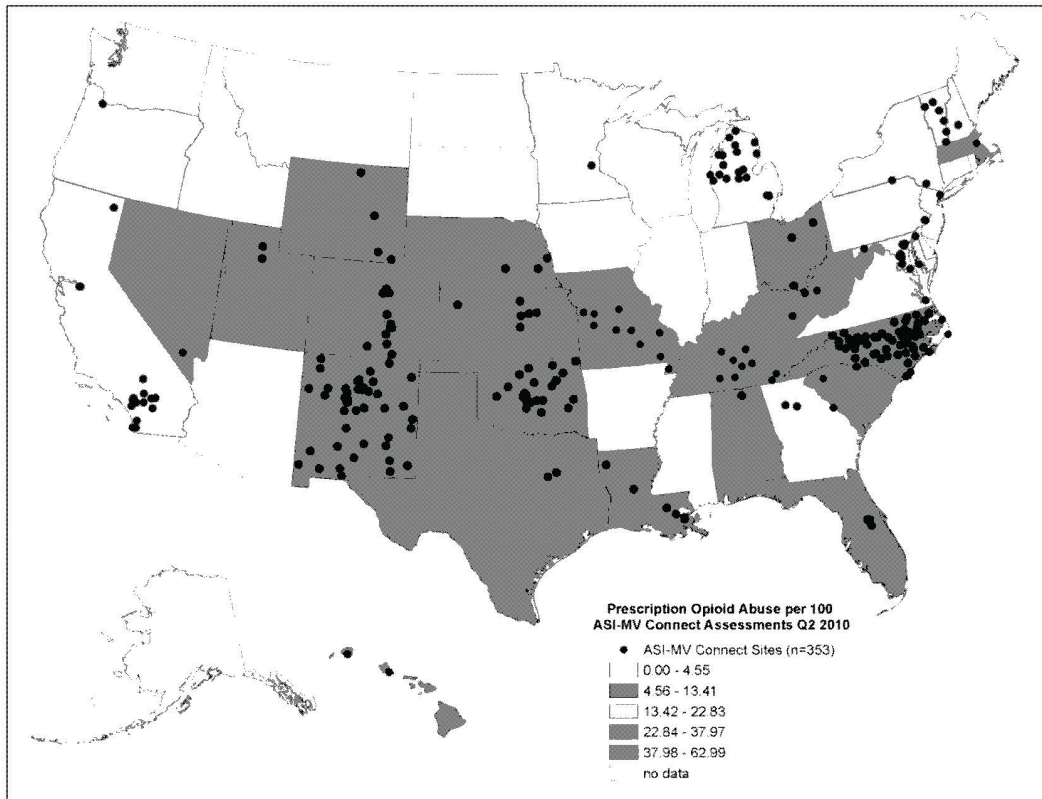
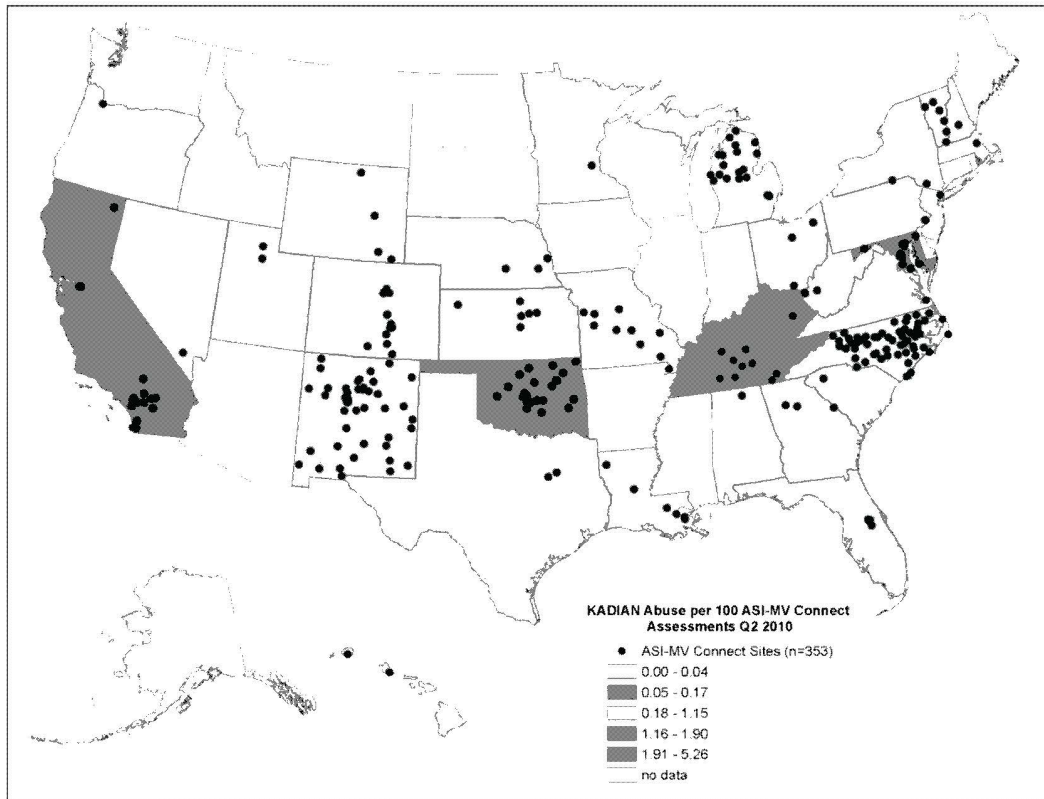


Figure 7 presents rates of KADIAN[®] abuse among the ASI-MV[®] Connect population as number of cases per 100 ASI-MV[®] Connect assessments for each state. In Figure 8, the rate of KADIAN[®] abuse is calculated differently; the map in this figure presents the number of patients in a state who reported past 30 day abuse of KADIAN[®] during Q2 2010 divided by the total number of KADIAN[®] prescriptions written in that state during the reporting period. In these maps, shades of orange indicate higher rates of prescription opioid abuse and shades of blue indicate lower rates. Again, rates in states that have a low sample size should be interpreted with caution, as the rate is less precise with smaller sample sizes. The sites that contributed data are represented by points on the map, so that it is possible to view where in the state the data were collected.

During Q2 2010, there were a total of 34 cases of KADIAN[®] abuse reported through the ASI-MV[®] Connect network of adult substance abuse treatment centers. These cases were reported in 10 states: Michigan (n=11), Missouri (n=8), Tennessee (n=6), Maryland (n=2), West Virginia (n=2), California (n=1), Kentucky (n=1), New Mexico (n=1), North Carolina (n=1), and Oklahoma (n=1). The highest rates of KADIAN[®] abuse during the current reporting quarter were reported from the Appalachian states of Kentucky (5.3 cases per 100 assessments) and Tennessee (1.9 cases per 100 assessments) as well as the bordering state of Missouri (1.2 cases per 100 assessments). However, the rate of KADIAN[®] abuse reported in the state of Kentucky

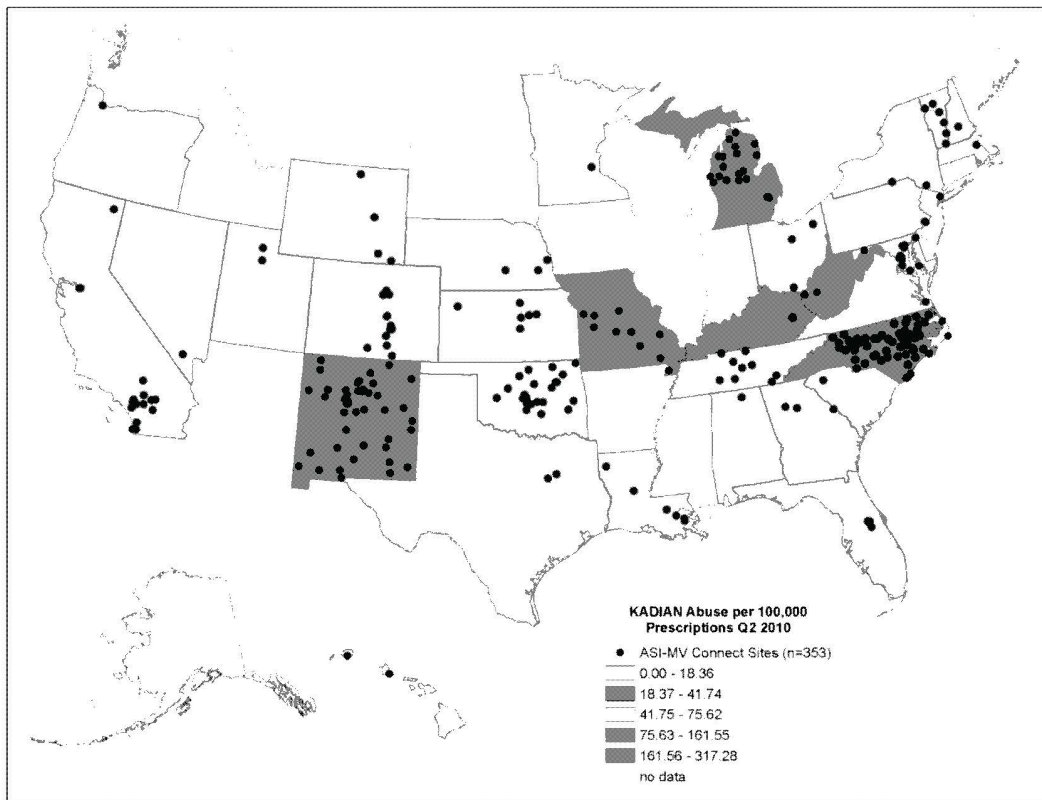
should be interpreted with caution, as it is based on a small number of overall assessments submitted from the state during Q2 2010 (n<20).

Figure 7. Rate of abuse of KADIAN® per 100 patient assessments within the ASI-MV® Connect treatment center population (4/1/2010 – 6/30/2010)



When accounting for the number of prescriptions written for KADIAN® in each state during Q2 2010 (Figure 8), the highest rates of KADIAN® abuse were observed in Michigan (317.3 cases per 100,000 prescriptions written), New Mexico (311.5 cases per 100,000 prescriptions written), Missouri (263.2 cases per 100,000 prescriptions written), and West Virginia (161.6 cases per 100,000 prescriptions written). Other states with relatively higher reported rates of KADIAN® abuse compared to other states that contributed data to the ASI-MV® Connect network during the current reporting quarter included Tennessee (75.6 cases per 100,000 prescriptions written) and Maryland (73.8 cases per 100,000 prescriptions written).

Figure 8. Rate of abuse of KADIAN[®] within the ASI-MV Connect[®] treatment center population per 100,000 prescriptions written (4/1/2010 – 6/30/2010)



ABUSE RATES OVER TIME

This section examines the fluctuation of abuse rates over time for KADIAN[®], AVINZA[®], MS Contin[®] (brand and generics), OxyContin[®], Vicodin[®] (brand and generics), Duragesic[®], and Opana[®] ER, using statistical process control (SPC) methods. It is important to not only assess how much a particular product might be abused, but also to monitor whether the rate of abuse increases or decreases over time. This is particularly important in surveillance activities where frequent monitoring of a phenomenon adds the capability to detect a potential signal of increasing abuse so that appropriate actions can be taken. One aspect to note about using SPC for signal detection is that it views the baseline rate of abuse as normal and not of concern; only significant increases in the baseline rate of abuse are of concern. This may seem counterintuitive, since at the beginning of a study there may be some areas with higher rates of abuse and others with lower rates of abuse. Data in previous sections are useful for examining rates of abuse by geography. However, the purpose of analyses in this section is to examine whether there are significant increases or decreases in the existing baseline rate of abuse of a product over time, regardless of whether the baseline rate is considered to be acceptable or not.

Figure 9 presents the unstandardized rate of KADIAN[®] abuse from July 2009 through June 2010, (i.e., the 12-month period corresponding with the current reporting quarter). As shown in Figure 9, the rate of KADIAN[®] abuse remained below one case per 100 patient assessments over the entire 12-month period. Monthly rates of KADIAN[®] abuse were highest during January 2010 and lowest during July 2009.

Figure 9. Rate of abuse of KADIAN[®] per 100 patient assessments within the ASI-MV[®] Connect treatment center population (7/1/2009 – 6/30/2010)

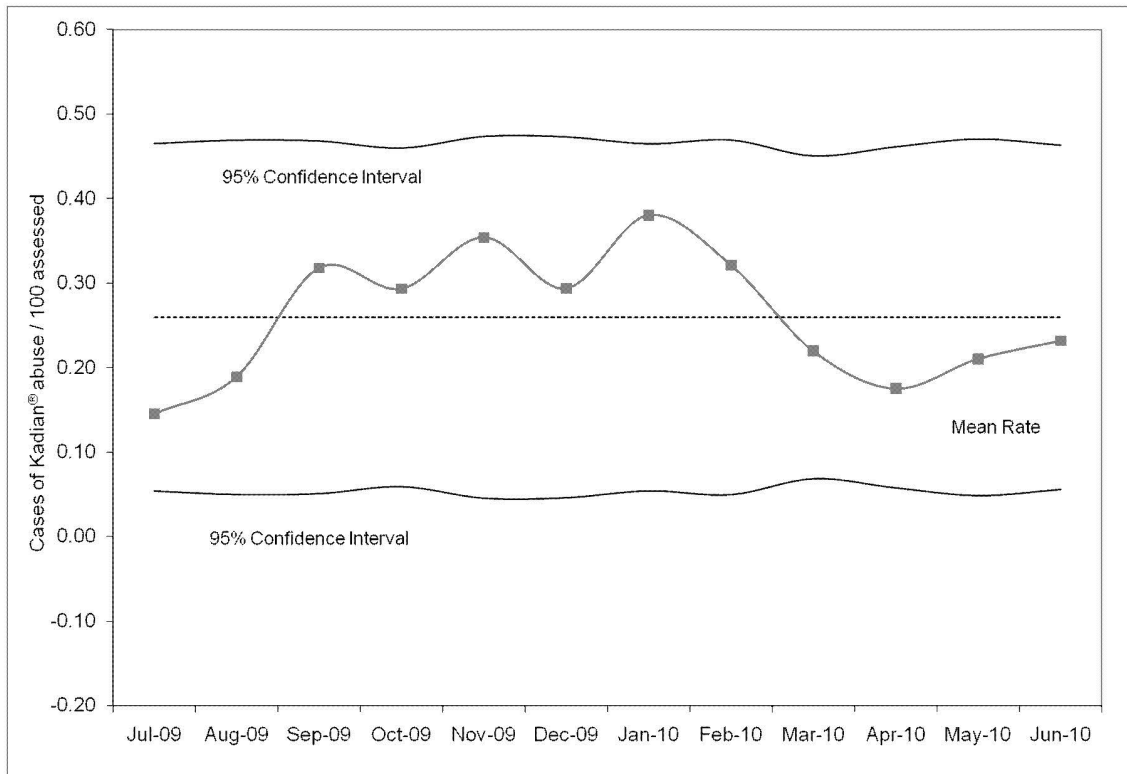


Figure 10 shows the standardized rate of abuse for KADIAN[®] over the 12-month period (July 2009 through June 2010). During the 12-month period reviewed, monthly rates of KADIAN[®] abuse remained within established control limits of three standard deviations above or below the mean rate. While rates of KADIAN[®] abuse fluctuated near the baseline throughout the 12-month period, rates of KADIAN[®] abuse were above the mean from September 2009 through February 2010 and below the mean during July and August 2009 and April 2010 through June 2010.

Figure 10. Standardized rate of abuse of KADIAN[®] per 100 patients assessments within the ASI-MV[®] Connect treatment center population (7/1/2009 – 6/30/2010)

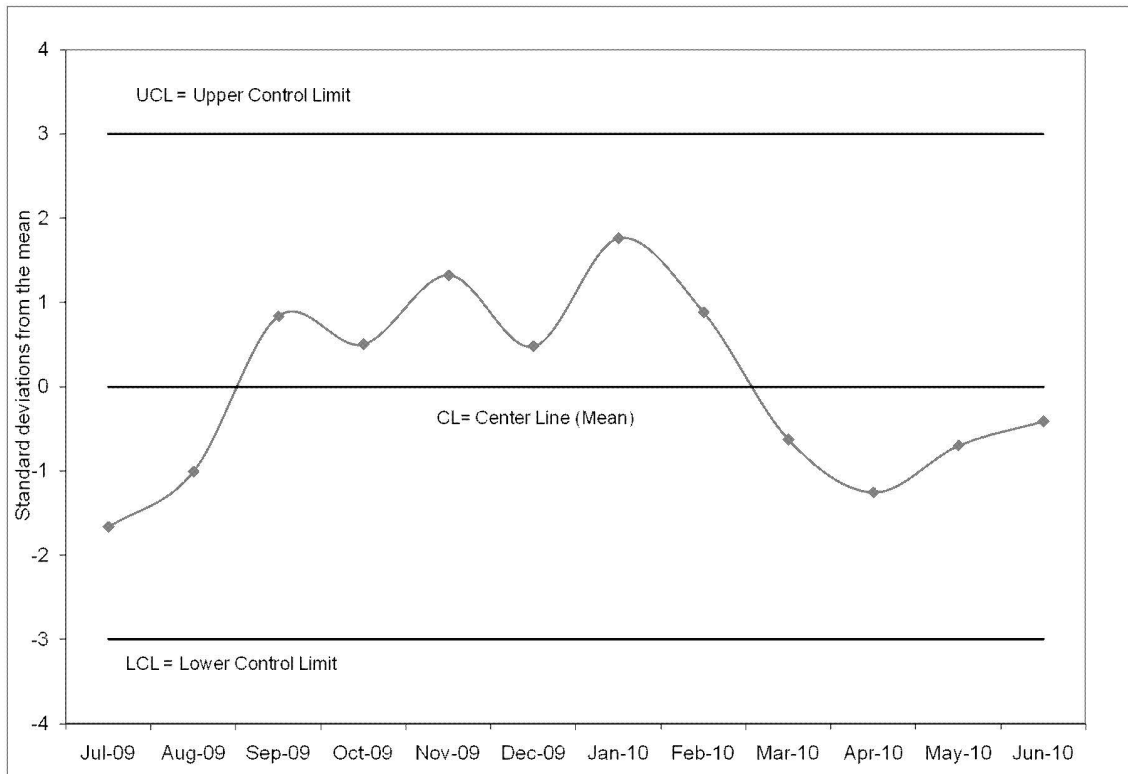


Figure 11 and 12 show standardized abuse rates over time for KADIAN[®] as well as all prescription opioid products as a group and comparator drugs. Rates were calculated as the number of cases of reported abuse per 100 patient assessments within the ASI-MV[®] Connect treatment center population. During the 12-month period, the rate of abuse for all prescription opioid products as a group dropped below the lower control limit in July 2009. The rate of abuse for all prescription opioid products remained within the established control limits of three standard deviations above or below the mean for the remainder of the 12-month period; the rate of abuse was below the baseline from August 2009 through October 2009 and in February 2010. Conversely, the rate of abuse for any prescription opioid as a group was above the baseline during November 2009 through January 2010 and March 2010 through June 2010.

With respect to the morphine products monitored for this report, rates of abuse for KADIAN[®], AVINZA[®] and MS Contin[®] brand and generic products remained within established control limits of three standard deviations above or below the mean, with the exception of MS Contin[®] brand and generic products in July 2009 and April 2010 (below and above the control limit, respectively). With respect to KADIAN[®], monthly rates of abuse fluctuated near the mean throughout the 12-month period, and were lowest during July 2009 and greatest during January 2010.

Figure 11. Standardized rate of abuse of any prescription opioid product and extended-release morphine products within the ASI-MV[®] Connect treatment center population (7/1/2009 – 6/30/2010)

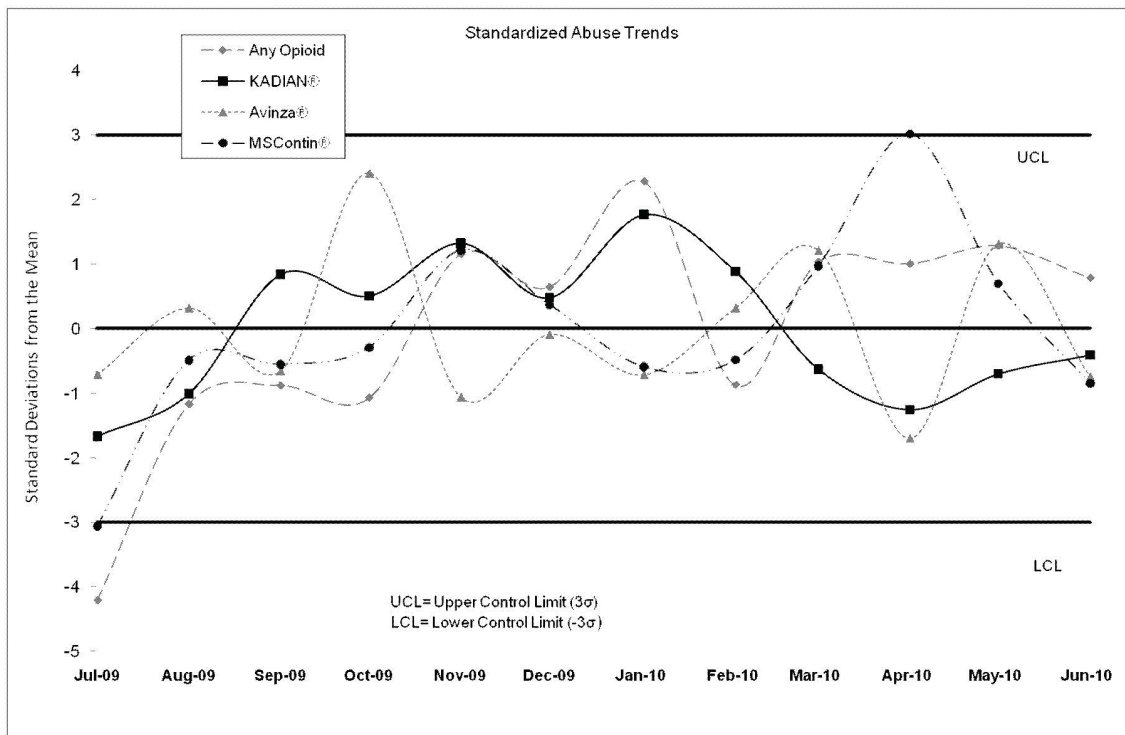
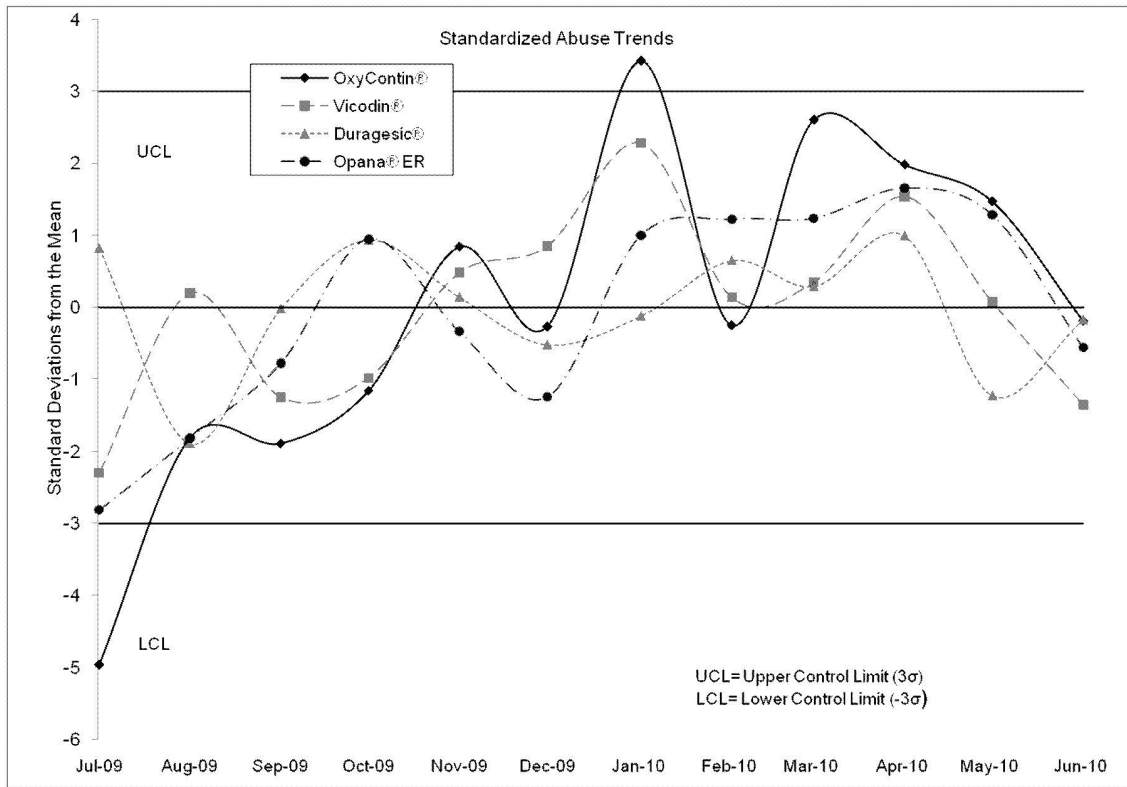


Figure 12 displays the abuse rates over time for OxyContin[®], Vicodin[®], Duragesic[®], and Opana[®] ER during the 12-month reporting window of July 2009 through June 2010. Over the course of the 12-month reporting window, rates of abuse for Vicodin[®], Duragesic[®], and Opana[®] ER remained within established control limits of three standard deviations above or below the mean. Monthly rates of abuse for OxyContin[®], however, fluctuated by month and were lower than the established lower control limit during July 2009 and above the upper control limit during January 2010. During the current reporting quarter (Q2 2010), monthly rates of abuse for OxyContin[®], Vicodin[®], Duragesic[®], and Opana[®] ER were above the mean rate of abuse at the beginning of the quarter (i.e., April 2010) and below the mean rate of abuse at the end of the quarter (i.e., June 2010).

Figure 12. Standardized rates of abuse of comparator products within the ASI-MV[®] Connect treatment center population (7/1/2009 – 6/30/2010)

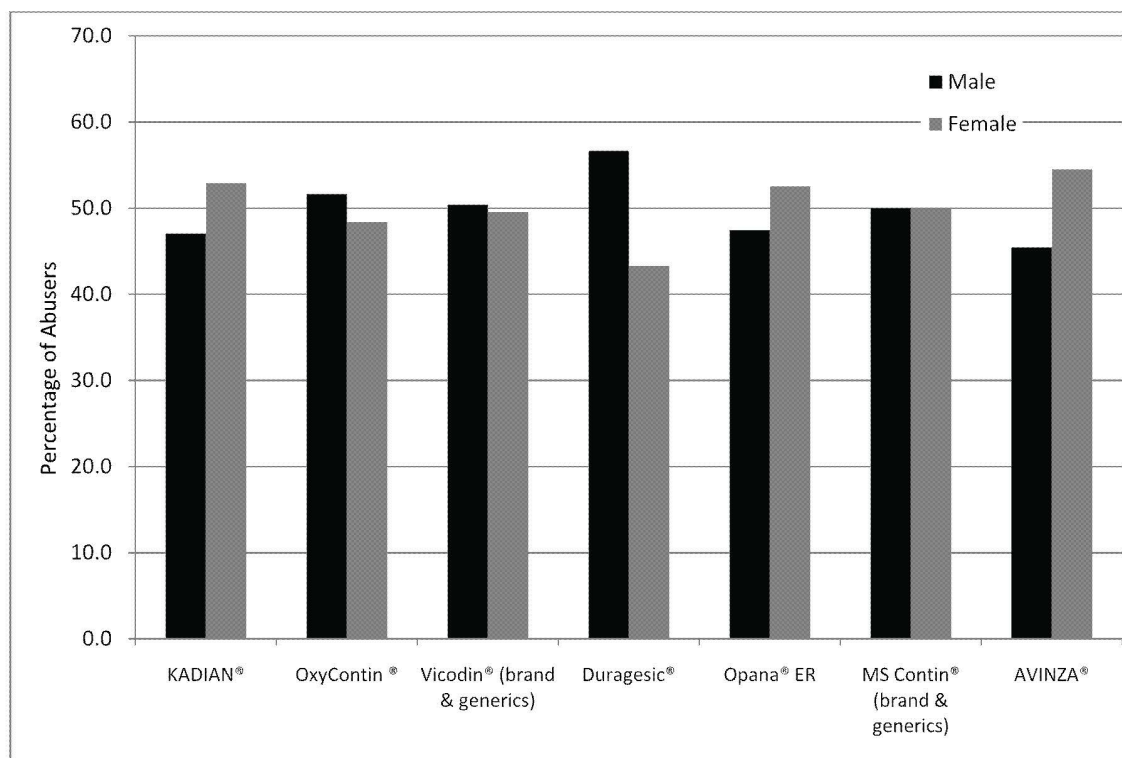


DEMOGRAPHIC ANALYSIS OF PRESCRIPTION OPIOID ABUSERS

This section presents the demographic characteristics of the individuals who reported abuse of the following prescription opioid products: KADIAN[®], MS Contin[®] and generic equivalents, AVINZA[®], Duragesic[®], Opana[®] ER, OxyContin[®], and Vicodin[®] and generic equivalents. Review of this data permits examination of whether there are certain demographic groups abusing one opioid product more than others. Knowledge of the demographics of the abusers may help in crafting targeted interventions. Demographic factors analyzed include: the gender and age distribution of patients who reported abuse of the prescription opioid products evaluated in this report, as well as the reported routes of administration, and sources for KADIAN[®] and the six comparator products.

Figure 13 illustrates the proportion of males and females in the ASI-MV[®] Connect treatment center population who reported abuse of the products monitored in this report during Q2 2010. With respect to the morphine products monitored in this report, past 30 day abuse of KADIAN[®] was reported by a greater percentage of females (52.9%) than males (47.1%). Similarly, more females than males reported abuse of AVINZA[®] within the past 30 days (54.5% females and 45.5% males), while an equal proportion of males and females reported past 30 days abuse of MS Contin[®] brand and generic products. Of the non-morphine based prescription opioid products monitored in this report, more males than females indicated past 30 days abuse of Duragesic[®] (56.7% males and 43.3% females), OxyContin[®] (51.6% males and 48.4% females), and Vicodin[®] brand and generic products (50.4% males and 49.6% females). Conversely, a greater percentage of females than males reported past 30 days abuse of Opana[®] ER during Q2 2010 (52.6% females and 47.4% males).

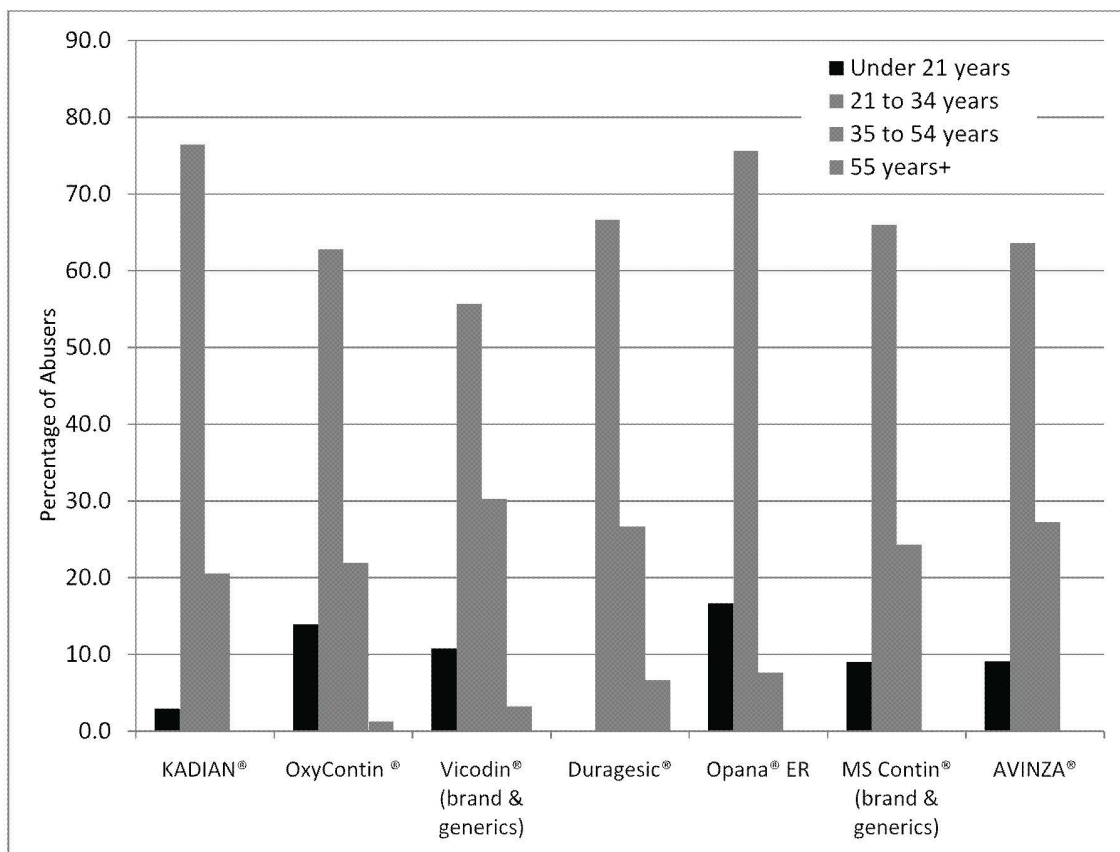
Figure 13. Gender frequency of patients within the ASI-MV Connect treatment center population who reported abuse of KADIAN® and comparator products during (4/1/2010 – 6/30/2010)



	KADIAN®		OxyContin®		Vicodin® (brand and generics)		Duragesic®		Opana® ER		MS Contin® (brand and generics)		AVINZA®	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Male	16	47.1	400	51.6	313	50.4	17	56.7	37	47.4	72	50.0	5	45.5
Female	18	52.9	375	48.4	308	49.6	13	43.3	41	52.6	72	50.0	6	54.5

Figure 14 illustrates the age range of the individuals within the ASI-MV® Connect population who reported abuse of the seven prescription opioids monitored in this report during Q2 2010. For each of the prescription opioid products monitored in this report, the greatest proportion of those who indicated past 30 day abuse were between the ages of 21 to 34 years (55.7%-76.5%). Very few individuals aged 55 years or older reported abuse of any of the prescription opioid products (0.0%-6.7%). With respect KADIAN®, 76.5% of those who reported past 30 day abuse of the drug were between the ages of 21 to 34 years, while 20.6% were between the ages of 35 to 54 years, and 2.9% were under the age of 21 years. There were no individuals (n=0) aged 55 years or older who indicated past 30 days abuse of KADIAN® during Q2 2010. A similar age distribution was observed with respect to those who reported past 30 days abuse of the other morphine products monitored in this report (i.e., AVINZA® and MS Contin® brand and generics).

Figure 14. Age distribution of patients within the ASI-MV[®] Connect treatment center population who reported abuse of KADIAN[®] and comparator products (4/1/2010 – 6/30/2010)



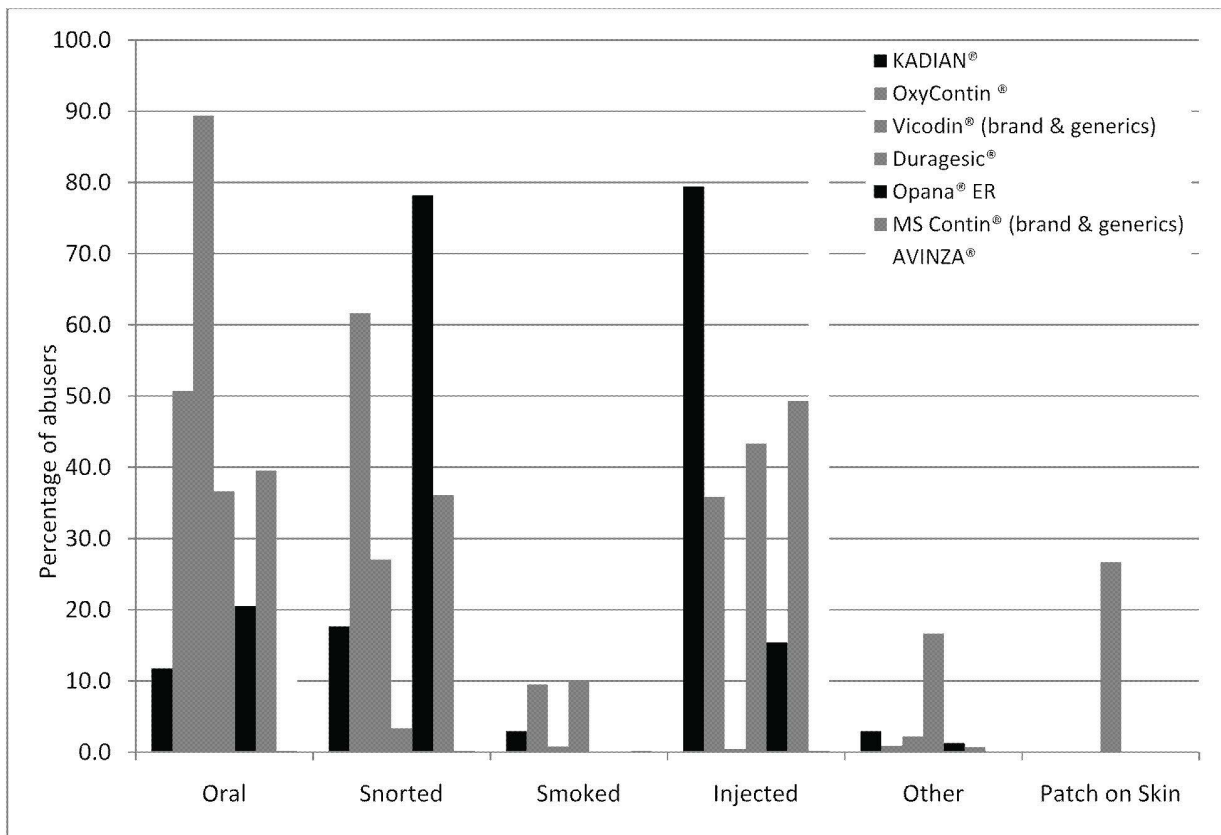
	KADIAN [®]		OxyContin [®]		Vicodin [®] (brand and generics)		Duragesic [®]		Opana [®] ER		MS Contin [®] (brand and generics)		AVINZA [®]	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Under 21	1	2.9	108	13.9	67	10.8	0	0.0	13	16.7	13	9.0	1	9.1
21-34	26	76.5	487	62.8	346	55.7	20	66.7	59	75.6	95	66.0	7	63.6
35-54	7	20.6	170	21.9	188	30.3	8	26.7	6	7.7	35	24.3	3	27.3
55+	0	0.0	10	1.3	20	30.3	2	6.7	0	0.0	0	0.0	0	0.0

Figure 15 illustrates the routes of administration reported within the ASI-MV[®] Connect patient population during Q2 2010 for individuals who indicated abuse of any of the seven prescription opioid products monitored in this report. Injection was the route of administration reported most frequently among the morphine-based products monitored in this report (79.4% for KADIAN[®], 81.8% for AVINZA[®], 49.3% for MS Contin[®]). The second most frequently reported route of administration for KADIAN[®] was snorting (17.6%), followed by oral ingestion (11.8%), smoking (2.9%), and 'other' routes of administration (2.9%). For AVINZA[®] and MS Contin[®] brand and generic products, oral ingestion was the route of administration reported with the second greatest frequency, followed by snorting. Smoking was reported by 9.1% of those who indicated past 30 days abuse of AVINZA[®]. Less than one percent (0.7%) of individuals who indicated past

30 days abuse of MS Contin® brand and generic products reported utilizing 'other' routes of administration.

Of the non-morphine based prescription opioid products monitored in this report, in general, oral ingestion and snorting were the routes of administration reported most frequently by those indicating past 30 days abuse of these drugs. However, injection was the route of administration reported most frequently by those who indicated abuse of Duragesic® (43.3%), followed by oral ingestion (36.7%), patch on skin (26.7%), 'other' routes of administration (16.7%), smoking (10.0%), and then snorting (3.3%). Injection was also reported by 35.9% of those who reported past 30 day abuse of OxyContin®, 15.4% of those who indicated past 30 day Opana® ER abuse, and less than one percent (0.5%) of those who reported past 30 day Vicodin® brand and generic abuse. A large proportion of individuals also reported snorting OxyContin® (50.7%), snorting Opana® ER (78.2%), and orally administering Vicodin® brand and generic products (89.4%).

Figure 15. Distribution of routes of administration reported by patients within the ASI-MV® Connect treatment center population who reported abuse of KADIAN® and comparator products (4/1/2010 – 6/30/2010)

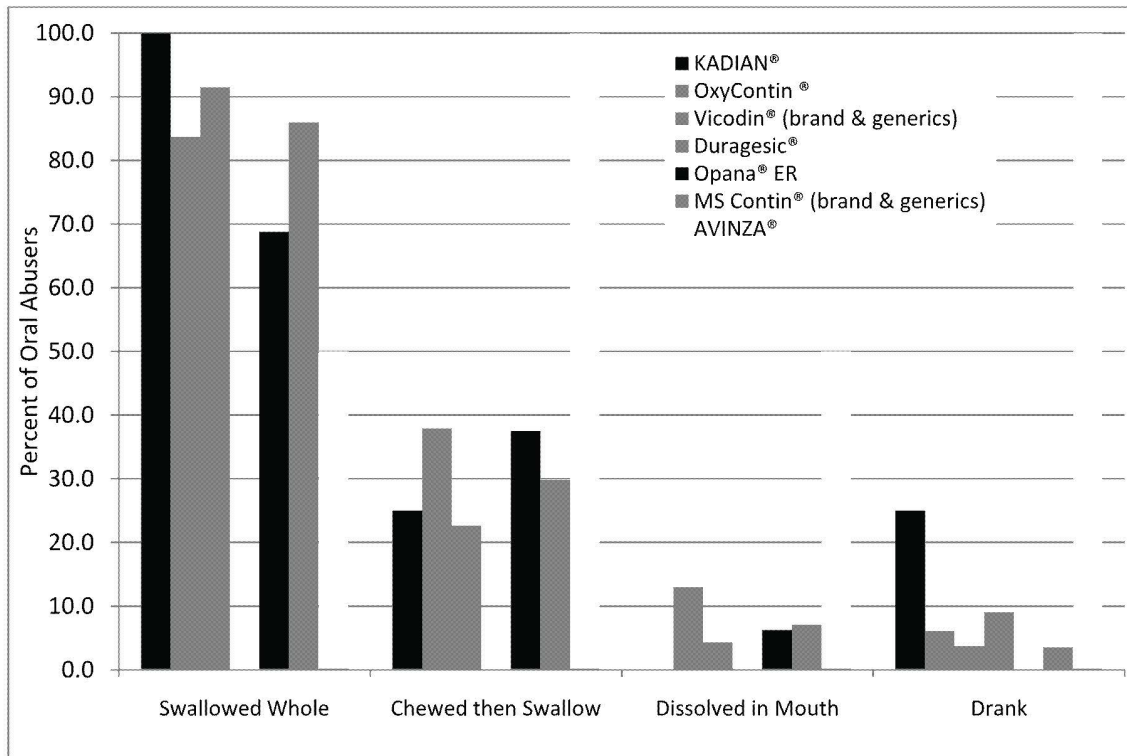


*Routes of administration in the above graph are not mutually exclusive and do not sum to 100%

Figure 16 illustrates the specific oral routes of administration reported by adults within the ASI-MV® Connect patient population who indicated past 30 day abuse KADIAN® and comparator products via oral ingestion during Q2 2010. With the exception of those who abused Duragesic® in the past 30 days, the oral routes of administration indicated most frequently were swallowing whole (50.0%-100.0%), and chewing and then swallowing (22.7%-100.0%). Those who reported past 30 day abuse of KADIAN® via an oral route of administration swallowed the drug whole (100.0%), chewed and then swallowed the drug (25.0%), and drank the drug after dissolving it in liquid (25.0%). All of the individuals who indicated past 30 day abuse of AVINZA® via an oral

route of administration reported drinking the drug after dissolving it in a liquid. With respect to Duragesic®, 81.8% of those who reported oral abuse of drug sucked on the patch, 72.7% chewed on the patch, and 9.1% drank the contents of the patch after dissolving it in liquid.

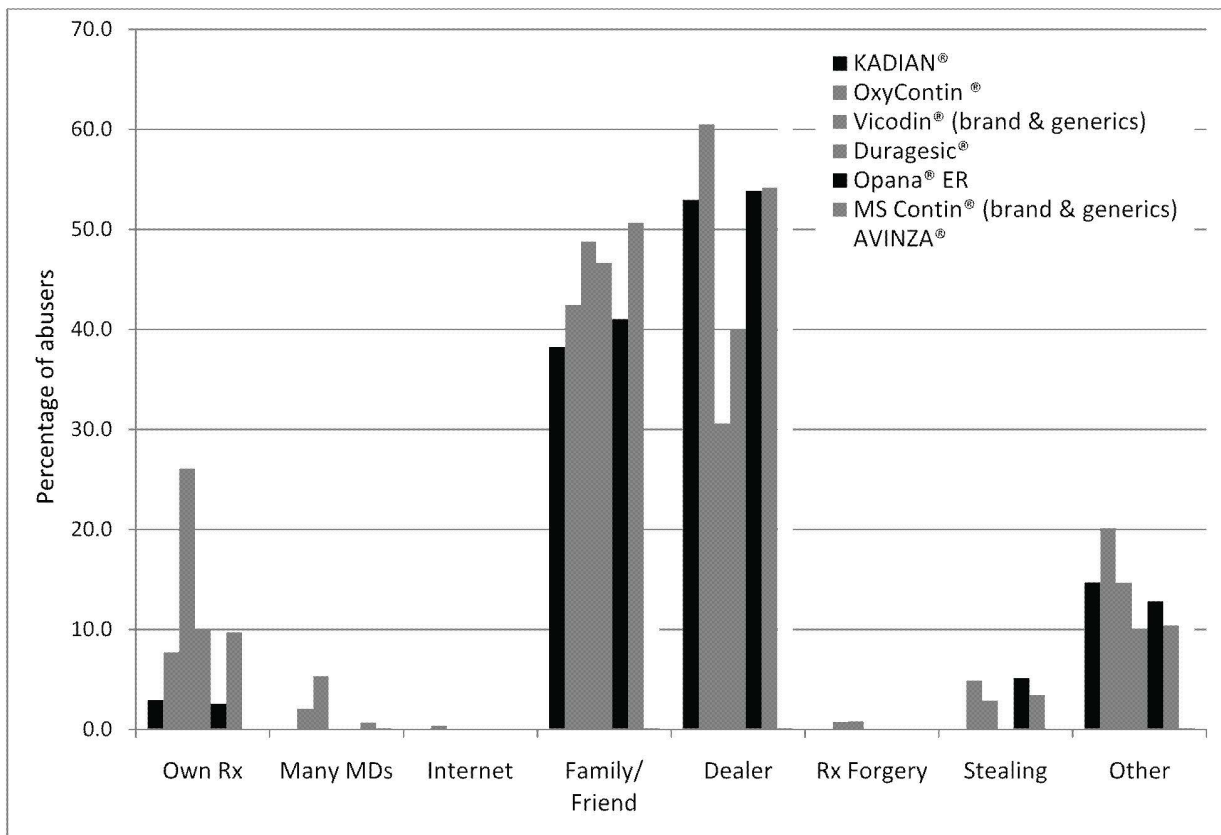
Figure 16. Distribution of oral routes of administration reported by patients within the ASI-MV Connect treatment center population who reported abuse of KADIAN® and comparator products (4/1/2010 – 6/30/2010)



*Routes of administration in the above graph are not mutually exclusive and do not sum to 100%

Figure 17 illustrates the sources of procurement reported by those who indicated past 30 day abuse of KADIAN® and the six comparator products within the ASI-MV® Connect patient population during Q2 2010. Obtaining the product from a dealer (30.6%-63.6%) or from a friend/family member (18.2%-50.7%) was mentioned with the greatest frequency of individuals who indicated past 30 day abuse of KADIAN® and the comparator products. With respect to KADIAN®, after obtaining the drug from a dealer or a friend/family member, 14.7% of individuals reported obtaining the product from 'other' sources, and 2.9% from one's own prescription. Approximately 26% of those who reported past 30 day abuse of Vicodin® brand and generic equivalents reported obtaining the drug from one's own prescription. 'Other' sources of procurement were reported by between ten and twenty percent of those indicating abuse of the monitored prescription opioid products.

Figure 17. Distribution of sources of procurement reported by patients within the ASI-MV Connect treatment center population who reported abuse of KADIAN® and comparator products (4/1/2010 – 6/30/2010)



*Categories for sources of procurement in the above graph are not mutually exclusive and do not sum to 100%

3.3. CHAT™

3.3.1. BACKGROUND

The CHAT™ (Comprehensive Health Assessment for Teens) is a behavioral health assessment tool for adolescents (targeted at aged 18 years and younger) entering treatment for drug or alcohol abuse. The CHAT™ is a proprietary data source of the National Addictions Vigilance Intervention and Prevention Program (NAVIPPRO™) and is intended to monitor substance abuse patterns within a sentinel population of adolescents entering treatment for substance abuse within a network of participating centers and other facilities such as alternative schools and mental health programs throughout the United States. Similar to the ASI-MV® Connect, data from the CHAT™ sites are aggregated and used to monitor substance abuse patterns within a sentinel population of adolescent entering treatment for substance abuse. Information from the CHAT™ is collected at a product-specific level, including data on routes of administration and source of the drug, allowing for the comparison of abuse among similar products. The CHAT™ was developed with support from the National Institutes of Health, National Institute on Drug Abuse and has demonstrated validity and reliability as an assessment tool for adolescents in the treatment setting (Lord, et al. 2009). The assessment also contains audio and video for those with low literacy.

Data collection and surveillance using the CHAT™ began in June 2009 from a limited number of participating adolescent treatment centers. Treatment sites that serve the adolescent population are recruited to the CHAT™ network on an ongoing basis. Since June 2009, the CHAT™ system has been continually growing in the number of participating treatment sites as well as its geographic coverage.

3.3.2. METHODS

Data from the CHAT™ are collected via a self-administered, computer-based interview, which asks questions related to adolescent experiences in five different domain areas including, self and personality factors, family and peer relations, physical and emotional health, psychological issues, and drug use experiences. The questions included in the CHAT™ assessment are tailored specifically towards the adolescent population. Questions on substance abuse include photos of specific prescription medications for identification of brand and generic stimulants and opioid products as well as street names for the drugs of interest. The CHAT™ collects data at a product-specific level, including route of administration and source of procurement. Information collected is geographically specific at the patient home 3-digit ZIP code level.

Abuse of a product is captured via self report during the CHAT™ computer-administered interview, and is defined as having used the product in a way other than prescribed by a doctor at least once during the past 30 days. Respondents are presented with the names of products, as well as pictures of the products to help distinguish exactly which products patients have used. For example, patients who admit to having used any oxymorphone products during the past 30 days in a way not prescribed by a doctor are classified as having abused oxymorphone.

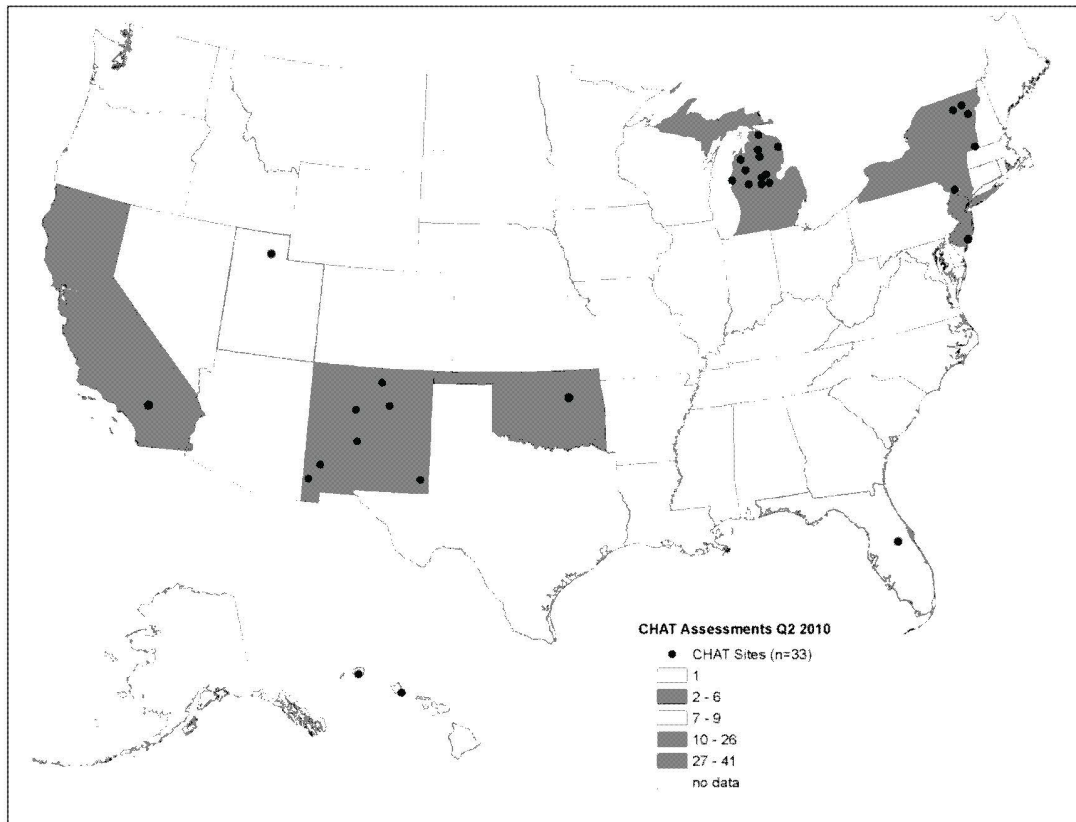
The data collected from the CHAT™ can be analyzed in a number of different ways in order to best characterize the level of abuse of a particular prescription medication compared to similar drugs within the same class. Rates of abuse are calculated within the total CHAT™ population (i.e., the total number of abuse cases per CHAT™ assessments), the subset population of individuals who reported past 30 days abuse of any prescription medication (i.e., the total number of abuse cases per 100 prescription or opioid abusers), and is also calculated based on the medical availability of a particular drug (i.e., the total number of abuse cases per 100,000 prescriptions written). Data collection through CHAT™ began in June 2009 and therefore the system currently contains a small number of total adolescent assessments. Although the sample size is insufficient to conduct meaningful statistical analysis at this time, the data are presented and summarized descriptively for purposes of this report.

3.3.3. RESULTS

SUMMARY OF PARTICIPANT DATA

During the second quarter of 2010, the CHAT™ network collected data from 33 treatment centers in 10 states that contributed 143 adolescent patient assessments. The states contributing the most data within the CHAT™ population were Michigan (n=41) and Vermont (n=34). Collectively, these two states contributed approximately 52% of all adolescent patients assessments submitted to the CHAT™ network during the current reporting quarter. Figure 18 displays the distribution of assessments by state, and the location of treatment sites that contributed data for the reporting period April 1, 2010 through June 30, 2010. In Figure 18, states with shades of orange indicate larger CHAT™ sample sizes, and states in shades of blue indicate smaller sample sizes.

Figure 18. Geographic distribution of CHAT™ assessments and treatment centers by state (4/1/2010 – 6/30/2010)



Demographic characteristics of the CHAT™ adolescent treatment center population during Q2 2010 are presented in Tables 4 and 5. The majority of patients entering treatment who completed the CHAT™ assessments during the Q2 2010 reporting period were between the ages of 15 and 18 years (79.0%), Caucasian (73.4%), and lived with one or both biological or adoptive parents (82.5%). Approximately 64% of patients entering treatment within the CHAT™ network were male. Just over 88% of patients were enrolled in a school program, and nearly 20% of patients had been in a controlled environment within the past 30 days. Approximately 25% of the CHAT™ patient population reported that they were currently taking prescribed medication for an emotional, behavioral, or learning problem. Similarly, nearly 25% of patients reported a current physical problem or illness during the current reporting quarter. Nearly 18% of patients also reported a current pain problem.

Table 3. CHAT™ participant characteristics (4/1/2010 – 6/30/2010)

	Response	Number (N)	Percent (%)
Age	Age Distribution	0	0.0
	10 – 14 years	26	18.2
	15 – 18 years	113	79.0
	Over 18 years	4	2.8
	Mean	15.8	
	Standard Deviation	1.4	
	Range	12-20 years	
Gender	Male	91	63.6
	Female	52	36.4
	Unknown/No Response	0	0.0
Race	Caucasian	105	73.4
	African American	7	4.9
	American Indian	8	5.6
	Asian/Pacific Islander/Alaskan	2	1.4
	Hispanic/Latino	11	7.7
	Middle Eastern	0	0.0
	Other	10	7.0
	Unknown/No Response	0	0.0
Current Living Situation	One or Both Biological or Adoptive Parents	118	82.5
	Other Relatives	5	3.5
	Legal Guardian	7	4.9
	Friends	1	<1.0
	Partner or Spouse	3	2.1
	Foster Family	5	3.5
	Alone	0	0.0
	Other	4	2.8
	Unknown/No Response	0	0.0
Currently Enrolled in School	Yes	126	88.1
	No	17	11.9
School Program	Public school	83	58.0
	Private school	6	4.2
	GED program	5	3.5
	Alternative school or program	19	13.3
	Home school	5	3.5
	Technical, trade/beauty, vocational school	2	1.4
	Treatment or detention center school	0	0.0
	College	4	2.8
	Other	2	1.4
	Unknown/No Response	0	0.0
	Not Asked/Not Enrolled in School	17	11.9

Table 4. CHAT™ participant characteristics (4/1/2010 – 6/30/2010)

	Response	Number (N)	Percent (%)
Past 30 days in a controlled environment (jail, substance abuse treatment, etc.)	Yes	28	19.6
	No	115	80.4
	Unknown/No Response	0	0.0
Currently taking medication for emotional, behavioral, or learning problems.	Yes	35	24.5
	No	107	74.8
	Unknown/No Response	1	<1.0
Current physical problems or illnesses	Yes	35	24.5
	No	108	75.5
	Unknown/No Response	0	0.0
Current pain problem	Yes	25	17.5
	No	118	82.5
	Unknown/No Response	0	0.0

ADOLESCENT ABUSE OF PRESCRIPTION OPIOID PRODUCTS

During the current reporting quarter (April 1, 2010 through June 30, 2010), past 30 day abuse of any prescription opioid was reported by 7 adolescent patients (4.9%) at substance abuse treatment centers. Among these patients, there were no instances (n=0) of past 30 day abuse of KADIAN®, Duragesic®, or AVINZA®. During Q2 2010, three individuals (n=3) reported past 30 day abuse of OxyContin®, three individuals (n=3) reported past 30 day abuse of Vicodin® brand and generic products, one individual reported past 30 day abuse of Opana® ER, and one individual reported past 30 day abuse of MS Contin® brand and generic products.

GEOGRAPHIC DISTRIBUTION OF ADOLESCENT PRESCRIPTION OPIOID ABUSERS

This section examines the geographic distribution of any prescription opioid abuse as reported by a CHAT™ assessment during the current reporting period. During Q2 2010, past 30 day abuse of any prescription opioid was reported by 7 adolescent patients at substance abuse treatment centers located in four states: Michigan (n=3), New York (n=2), Hawaii (n=1), and New Jersey (n=1). There were no reports (n=0) of past 30 day abuse of KADIAN® in the ten states participating in the CHAT™ adolescent treatment center network during the period.

Table 5. Geographic distribution of all prescription opioid abusers by state within the CHAT™ treatment center population (4/1/2010 – 6/30/2010)

State	Number of Sites	Total Assessments	Number of Prescription Opioid Abusers	Prescription Opioid Abuse Per 100 Assessments	Number of KADIAN® Abusers
CA	1	6	0	0.0	0
FL	1	1	0	0.0	0
HI	2	9	1	11.1	0
MI	14	41	3	7.3	0
NJ	1	4	1	25.0	0
NM	7	18	0	0.0	0
NY	1	26	2	7.7	0
OK	1	3	0	0.0	0
UT	1	1	0	0.0	0
VT	4	34	0	0.0	0
TOTAL	33	143	7	4.9	0

DEMOGRAPHIC ANALYSIS OF ADOLESCENT PRESCRIPTION OPIOID ABUSERS

This section examines the demographic factors related to the abuse of selected prescription opioid products in the 30 days prior to treatment in the CHAT™ network of adolescent substance abuse treatment centers. Two of the three individuals who reported past 30 day abuse of OxyContin® were male, and one individual was female. With respect to Vicodin® brand and generic products, one patient was male and the other two individuals were female. During the current reporting quarter, the one individual who indicated past 30 day abuse of Opana® ER was male and the one individual who reported past 30 days abuse of MS Contin® brand and generic products was female. Table 6 summarizes the gender distribution of adolescents who reported past 30 day abuse of the prescription opioid products monitored in this report.

Table 6. Gender frequency of patients within the CHAT™ treatment center population who reported abuse of KADIAN® and comparator products (4/1/2010 – 6/30/2010)

	KADIAN®		OxyContin®		Vicodin® (brand and generics)		Duragesic®		Opana® ER		MS Contin® (brand and generics)		AVINZA®	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Male	N/A	--	2	66.7	1	33.3	N/A	--	1	100.0	0	0.0	N/A	--
Female	N/A	--	1	33.3	2	66.7	N/A	--	0	0.0	1	100.0	N/A	--

Table 7 displays the age distribution of adolescent patients who reported past 30 day abuse of selected prescription opioid products during Q2 2010. One of the three individuals who indicated past 30 day abuse of Vicodin® brand and generic products was between the ages of 10 to 14

years, and the remaining two individuals were between the ages of 15 to 18 years. With respect to those who reported past 30 day abuse of OxyContin® (n=3), Opana® ER (n=1), and MS Contin® brand and generics (n=1), each of these individuals was between the ages of 15 to 18 years.

Table 7. Age distribution of patients within the CHAT™ treatment center population who reported abuse of KADIAN® and comparator products (4/1/2010 – 6/30/2010)

	KADIAN®		OxyContin®		Vicodin® (brand and generics)		Duragesic®		Opana® ER		MS Contin® (brand and generics)		AVINZA®	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Under 10 years	N/A	--	0	0.0	0	0.0	N/A	--	0	0.0	0	0.0	N/A	--
10-14 years	N/A	--	0	0.0	1	33.3	N/A	--	0	0.0	0	0.0	N/A	--
15-18 years	N/A	--	3	100.0	2	66.7	N/A	--	1	100.0	1	100.0	N/A	--
Over 18 years	N/A	--	0	0.0	0	0.0	N/A	--	0	0	0	0	N/A	--

Table 8 presents the routes of administration utilized by adolescent patients who indicated past 30 day abuse of selected prescription opioid products during the period of Q2 2010. Oral ingestion and snorting were the only routes of administration reported by those who had abused any of the products monitored in this report. All three of the individuals who indicated abuse of OxyContin® orally ingested the drug, and two of these individuals also reported snorting the drug. Similarly, all three individuals who indicated past 30 day abuse of Vicodin® brand and generic products orally ingested the drug, and one individual also reported snorting the drug. Opana® ER was snorted by the one adolescent patient reporting abuse during Q2 2010, and the one adolescent patient who indicated past 30 day abuse of MS Contin® brand and generics indicated snorting the drug and also taking it orally. Of those adolescent patients who reported oral administration of the prescriptions opioid products monitored in this report, the majority reported swallowing the drug whole. One individual who reported oral administration of OxyContin® during the current reporting quarter also indicated chewing and then swallowing the drug.

Table 8. Distribution of routes of administration reported by patients within the CHAT™ treatment center population who reported abuse of KADIAN® and comparator products (4/1/2010 – 6/30/2010)

	KADIAN®		OxyContin®		Vicodin® (brand and generics)		Duragesic®		Opana® ER		MS Contin® (brand and generics)		AVINZA®	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Oral	N/A	--	3	100.0	3	100.0	N/A	--	0	0.0	1	100.0	N/A	--
Snort	N/A	--	2	66.7	1	33.3	N/A	--	1	100.0	1	100.0	N/A	--
Smoke	N/A	--	0	0.0	1	33.3	N/A	--	0	0.0	0	0.0	N/A	--
Inject	N/A	--	0	0.0	0	0.0	N/A	--	0	0.0	0	0.0	N/A	--
Other Route	N/A	--	0	0.0	0	0.0	N/A	--	0	0.0	0	0.0	N/A	--

* Categories for routes of administration in the above table are not mutually exclusive and do not sum to 100%.

Table 9 presents the sources of procurement utilized by adolescent patients who reported abuse of the prescription opioid products monitored in this report during Q2 2010. A dealer and a family member/friend were the sources of procurement reported most frequently by adolescent patients. One of the three individuals who indicated abuse of OxyContin® also reported obtaining the drug from an 'other' source, and one of the three individuals who indicated past 30 day abuse of Vicodin® brand and generic products also reported stealing the drug.

Table 9. Distribution of sources of procurement reported by patients within the CHAT™ treatment center population who reported abuse of KADIAN® and comparator products (4/1/2010 – 6/30/2010)

	KADIAN®		OxyContin®		Vicodin® (brand and generics)		Duragesic®		Opana® ER		MS Contin® (brand and generics)		AVINZA®	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Own Prescription	N/A	--	0	0.0	0	0.0	N/A	--	0	0.0	0	0.0	N/A	--
Multiple Doctors	N/A	--	0	0.0	0	0.0	N/A	--	0	0.0	0	0.0	N/A	--
Internet	N/A	--	0	0.0	0	0.0	N/A	--	0	0.0	0	0.0	N/A	--
Family or Friend	N/A	--	3	100.0	1	33.3	N/A	--	0	0.0	1	100.0	N/A	--
Dealer	N/A	--	2	66.7	2	66.7	N/A	--	1	100.0	1	100.0	N/A	--
Prescription Forgery	N/A	--	0	0.0	0	0.0	N/A	--	0	0.0	0	0.0	N/A	--
Stealing	N/A	--	0	0.0	1	33.3	N/A	--	0	0.0	0	0.0	N/A	--
Other	N/A	--	1	33.3	0	0.0	N/A	--	0	0.0	0	0.0	N/A	--

* Categories for sources of procurement in the above table are not mutually exclusive and do not sum to 100%.

3.4. WEB INFORMED SERVICES (WIS™): INTERNET MONITORING

3.4.1. BACKGROUND

Internet monitoring is currently considered a critical component of any comprehensive pharmaceutical surveillance program. Mounteney and Leirvåg (2004) assert that the Internet is routinely considered a "leading edge" or "sensitive" data source that comprises an important element of any "early warning" system for drug use, as well as for infectious diseases (Eysenbach, 2003). Increasingly, individuals with common interests seek one another out online in order to share information, or "chat," via chat rooms, bulletin boards, and online communities (Zinkhan, et al., 2003). Access to websites is easy, requires little commitment on the part of users, and sites can be fairly reliable and convenient sources of information. The Internet is fast, easy, inexpensive, and its structure is decentralized, international, anonymous, unsupervised, and unregulated (Tsftati & Weimann, 2002). Therefore, wide varieties of individuals are able to both access and post information regarding the use and abuse of pharmaceuticals online.

The goal of this type of surveillance is to detect emerging trends and potential risks in Internet chatter concerning specific products, not to estimate prevalence or incidence of on-going substance abuse of a particular pharmaceutical product. Internet monitoring of drug abuse forums is an essential tool to keep in touch with a diverse population of drug-abusing individuals. Given the influential nature of the Internet, this type of surveillance may also serve as a strong predictor of national prescription drug abuse trends.

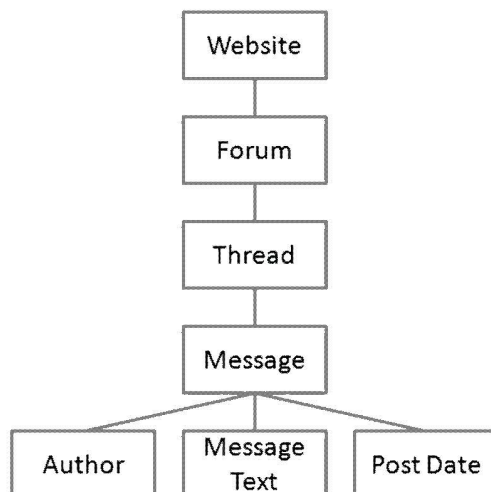
This section of the report presents a quantitative and qualitative analysis of current and past Internet discussion regarding Opana and three comparator drugs: OxyContin®, Vicodin®, and Duragesic®. Data were collected for this report using Inflexxion's web-grabber technology, and were subsequently stored for further analysis in the Web Informed Services (WIS™) Internet monitoring archive (a proprietary database of Internet discussion on drug-related message forums).

3.4.2. METHODS

POST COLLECTION

Inflexxion utilizes a systematic web-grabber technology to monitor targeted drug-related message boards on the Internet. The web-grabber enables Inflexxion to collect posts daily and to capture the verbatim body of the text, time of post, message board where the post was found, screen name of the poster, and the title of the thread from which the post was drawn. The general hierarchy found on Internet message boards is presented in Figure 19. Posts are stored in Inflexxion's Web Informed Services (WIS™) Internet monitoring archive (a Microsoft® SQL server™ database), and are assigned a unique identifier. Similarly, each new author and each new thread are assigned a unique identifier, making it possible to query counts of posts, threads, and unique authors within the archive. This archive is a proprietary data source of Inflexxion and represents a unique resource, as message board moderators routinely delete old posts without a clear schedule or rationale. Therefore, unless an archive such as the WIS™ database actively captures these posts, they are likely to be lost to research. A previous study conducted by Inflexxion found that the posts on these message boards discuss numerous drug as well as non-drug topics, such as movies, relationship issues, politics, etc. (Butler et al., 2007). Thus, the existence of the WIS™ archive also allows future examination of topics related to drug use/abuse that are not currently being considered.

Figure 19. Internet monitoring message board hierarchy



MONITORED WEBSITES

Currently, Inflexxion monitors and stores the content of drug-related message boards on eight websites that were selected for inclusion in the WIS™ Internet monitoring archive. These monitored websites constitute a consistent, stable population of recreational drug abusers and their online communications, providing Inflexxion with access to an established cohort of individuals that can be defined by their drug abuse activities and characteristics. Monitored websites were selected for inclusion based upon a set of pre-defined criteria specifying that each website must: (a) include a message board component, (b) be unedited, (c) promote free discussion of psychoactive drug use, (d) be open to the public, (e) be privately funded (e.g., private donations), (f) be maintained/moderated by volunteers, and (g) be an English language site. The WIS™ Internet monitoring archive does not include content from chat sites, weblogs, any form of email communication (i.e., "spam"), or any information regarding prescription opioid availability via online pharmacies.

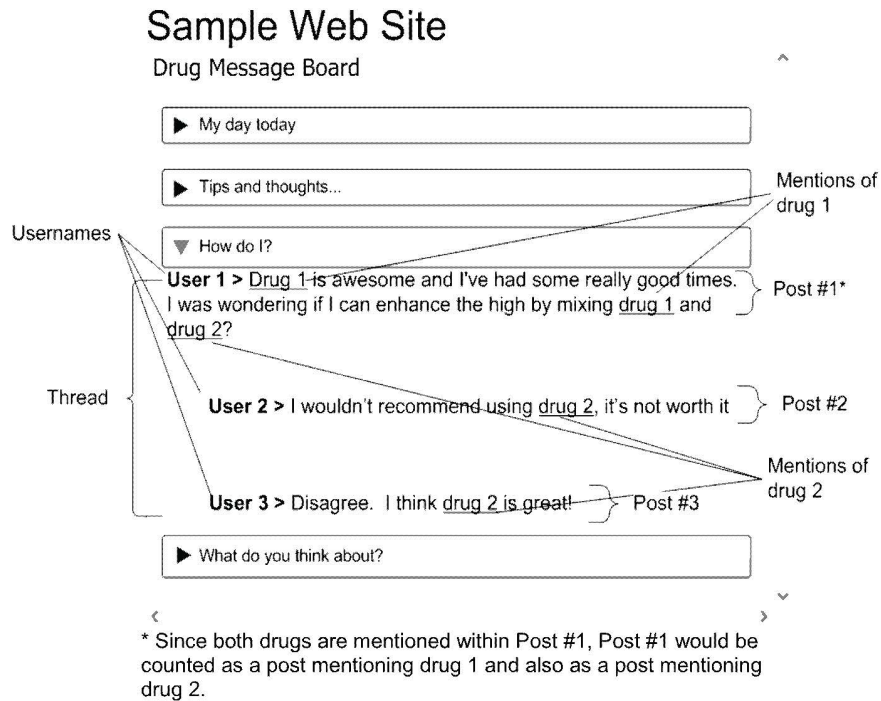
MESSAGE BOARD TERMINOLOGY

There are four terms that are relevant to Internet discussions (Figure 20):

- **Mention:** Any instance that a word (such as the name of a drug or its synonym) appears.
- **Post:** A single message entered by one user. A single post (message) may contain one or more specific mentions of a drug or none at all.
- **Unique Author:** A unique author is defined as a unique username posting during a particular timeframe on a website. Some unique authors post only once, some many times (e.g., someone with a unique username posting once during March 2009 would be counted as a single unique author, and someone posting 15 times during the same period would also be counted as a single unique author).
- **Thread:** A collection of posts, much like a conversation or discussion, on the same subject and displayed in chronological order. A thread generally begins with a specific message or question and includes all subsequent responses to that message. Within a thread, any given post may mention one (or more) of the target drugs, may make several mentions of any single target drug, or may contain no mentions of a particular target drug. In fact, the majority of posts within a given thread address drugs other than the target drugs (illegal

or pharmaceutical), or may deal with virtually any other topic (e.g., political discussions, movies, relationship issues, etc.).

Figure 20. Visual representation of relationship between mention, post, and thread on a sample message board



WIS™ SAMPLING

Depending on the research question, SQL queries are designed to identify posts during a given time period that match search-string criteria for a target drug(s). Search-string queries search the body of each post in the WIS™ Internet monitoring archive and contain correct spellings of the target drug(s) as well as common misspellings, slang, and/or wildcard characters in order to identify as many relevant posts as possible from the archive. As monitoring continues and new trends emerge, search strings are modified to include new terminology and/or eliminate keywords that falsely identify posts as being related to the target drug(s). Using these queries, it is possible to obtain counts of posts, threads, and unique authors discussing the target drug(s) or to pull the post information for review and categorization.

In 2010, Inflexxion updated the search string queries for KADIAN® as well as the three comparator products: OxyContin®, MS Contin® and Vicodin®. These changes focused on adding new slang terminology (i.e., new words and misspellings) to the search string queries associated with each of the products of interest. The new updated queries are therefore more inclusive and provide a more accurate representation of the level of discussion associated with KADIAN® and the three comparator products. It should also be noted that post, thread and author counts calculated and presented for previous quarters in 2009 (i.e., Q3 – Q4 2009) were recalculated for this report using the new search string queries so that direct comparisons across quarters within this report is possible. Comparing post, thread and author counts from this report to previous reports, however, is not possible as the numbers provided in previous reports were calculated using the older search string queries.

QUANTITATIVE ANALYSIS

A quantitative analysis was conducted on the WIS™ Internet monitoring archive to examine the characteristics of discussion occurring on monitored Internet websites for KADIAN® and three comparator drugs (i.e. OxyContin®, MS Contin® and Vicodin®). Results are presented by quarter for the 12-month time period (July 2009 – June 2010) corresponding with the current reporting quarter (April – June 2010). For context, counts of the total number of posts, threads, and unique authors by quarter for the one-year time period and by the target drugs are presented. Additionally, because these analyses were conducted for overall post, unique author, and thread counts, and did not involve review of the content of posts, it is possible that these counts include false positive results. In this analysis, a false positive would be mistakenly identifying a post as pertaining to a target drug, while a false negative would be failing to identify a post as pertaining to a target drug. Because the data were aggregated, it is not possible to quantify the false-positive or negative rate observed in these results.

In order to estimate the level of Internet discussion related to KADIAN® and the three comparator drugs (OxyContin®, MS Contin® and Vicodin®), counts of posts, threads, and authors identified in the WIS™ Internet monitoring archive were calculated by quarter for the 12-month time period (July 2009 – June 2010) corresponding with the current reporting quarter (April – June 2010). Proportions (P) were calculated as the proportion of product-specific posts, threads, and authors per 100 posts, threads, and authors within the WIS™ Internet monitoring archive for a given time period. Confidence intervals for each proportion were calculated at the 95% confidence level and when necessary (i.e., sample size <50), were calculated using a Poisson distribution.

QUALITATIVE TOPIC ANALYSIS

A qualitative topic analysis was performed on the total sample of KADIAN®-related posts written during the reporting period to highlight the level of discussion pertaining to different topics. Posts were reviewed and target-drug content was classified as pertaining to four topics areas: routes of administration, extraction techniques, procurement, and negative consequences associated with use of KADIAN®. When a post's content did not apply to one of the four topic categories previously mentioned, posts were classified into a general categories and identified as: abuse-related, not abuse-related, and quote¹. Due to the unstructured nature of message board content, many posts pertain to more than one topic area (e.g., posts that discuss extraction techniques also often mention an intended route of administration). As such, posts were assigned to each applicable category; thus the categories are not mutually exclusive.

Similar to the quantitative analysis, counts of the five topic categories (i.e., routes of administration, extraction techniques, procurement, negative consequences, and general) were calculated for the current reporting quarter and by quarter for the 12-month period corresponding with the current reporting quarter. Proportions (P) were calculated as the proportion of topic category counts per 100 KADIAN®-related posts for a given time period. Confidence intervals for each proportion were calculated at the 95% confidence level, and when necessary (i.e., sample size <50), using a Poisson distribution.

¹ One function of many Internet message boards is the ability to "quote" another post. By doing this, the individual writing a new post can reference what another user has said. The general (quote) category was created in order to capture posts that mention a target drug only in a quotation. When the author of the new post does not reference the target drug in the original content of the post, and only by quoting another, the general (quote) category was used for classification.

SELECTION OF INTERESTING POSTS

A selection of interesting posts from the sample of KADIAN[®]-related posts is presented to provide examples of the variety of discussions that took place on message boards during the current reporting period. Posts of interest were identified by the reviewer during the qualitative topic analysis and were chosen to highlight potential new information regarding KADIAN[®] (e.g., new route of administration, extraction technique, or recipe), or examples of general KADIAN[®] related discussion among users. While posts presented in this section of the report were de-identified (i.e., identifying information such as username was removed), no other content was altered.

3.4.3. RESULTS

QUANTITATIVE ANALYSIS OF WIS[™] INTERNET MONITORING DATA

During the past 12 months (July 2009 through June 2010), over 1.36 million posts were cataloged in the WIS[™] Internet monitoring archive. Of the over 1.36 million posts collected, more than 300,000 were written during the current reporting quarter, April 1, 2010 through June 30, 2010. Overall, during the current quarter, the total number of posts written on the eight monitored websites decreased from the levels observed in the previous quarter (Q1 2010). While the overall level of conversation decreased, the total number of distinct threads (i.e., conversations) and unique authors remained consistent suggesting that that even though discussion levels were lower over the past quarter the population of individuals participating in these online communities has remained stable. Table 10 presents the current WIS[™] Internet monitoring archive characteristics by quarter over the last 12 months.

While the aggregate counts presented in Table 10 represent the number of posts, threads, and authors in the entire WIS[™] Internet monitoring archive, the aggregate counts presented in Table 11 present the number of posts, threads, and authors which discussed KADIAN[®] and the three comparator drugs, OxyContin[®], MS Contin[®], and Vicodin[®] during the current quarter. Of the over 300,000 posts written during the current quarter, 61 posts discussed KADIAN[®], 2,495 referred to OxyContin[®], 528 mentioned MS Contin[®] and 788 discussed Vicodin[®]. These data indicate that KADIAN[®] continues to be discussed in a smaller number of posts than all three of the comparator products: OxyContin[®], MS Contin[®] and Vicodin[®].

Table 10. Aggregate counts of posts, threads, and authors within the WIS[™] Internet Monitoring Archive (7/1/2009 - 6/30/2010)

Reporting Quarters	Posts	Threads	Authors
Q3 2009	313,833	20,293	11,376
Q4 2009	362,993	21,440	12,268
Q1 2010	361,452	21,603	13,023
Q2 2010	317,458	21,468	13,004
Total	1,365,387	73,902*	31,277*

*Due to the characteristics of threads and authors (i.e., a thread may be active across quarters and an author may post in more than one quarter) the total number of distinct threads and unique authors during the 12-month period will not equal the sum of the quarterly counts. See section 3.4.2. regarding message board terminology.

Table 11. Aggregate counts of posts, threads, and authors mentioning KADIAN[®] and comparator products within the WIS[™] Internet Monitoring Archive (4/1/2010 – 6/30/2010)

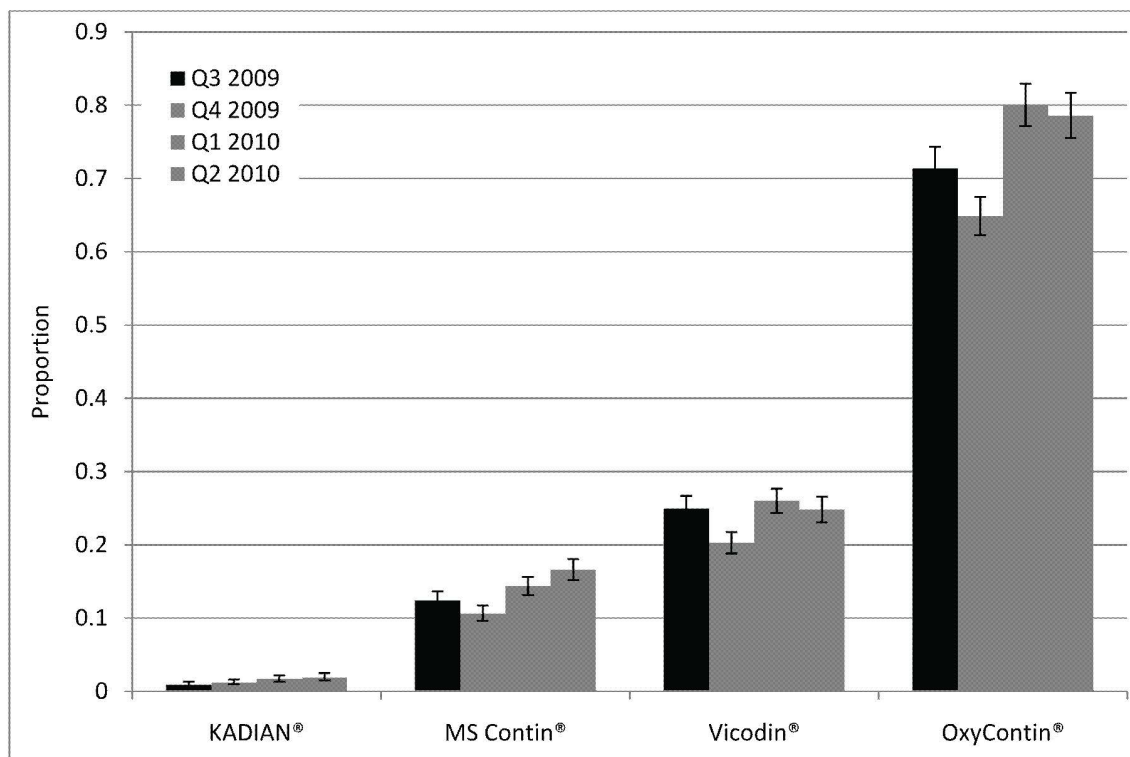
	Posts	Threads	Authors
KADIAN[®]	61	48	50
OxyContin[®]	2,495	1,238	1,325
MS Contin[®]	528	356	397
Vicodin[®]	788	515	560

During Q2 2010, the proportion of posts in which KADIAN[®] was discussed continued to increase from the level of discussion observed in Q3 2009. Furthermore, the level of conversation associated with KADIAN[®] during the current quarter was statistically significantly greater than the level of discussion observed in Q3 2009 (i.e., the beginning of the 12-month period associated with the current quarter). While discussion of MS Contin[®] also increased during the current quarter, the proportion of conversation pertaining to OxyContin[®] and Vicodin[®] decreased, albeit not statistically significantly. Comparatively, however, discussion regarding KADIAN[®] remained low in relation to the three comparator products: MS Contin[®], Vicodin[®] and OxyContin[®].

With respect to the proportion of threads (i.e., distinct conversations) and unique authors discussing KADIAN[®] during the current quarter, the proportion of threads in which KADIAN[®] was mentioned increased similarly to posts while the proportion of unique authors discussing KADIAN[®] decreased. The proportion of threads and authors pertaining to OxyContin[®], however, both decreased statistically significantly in comparison to Q1 2010, but remained consistent with the proportion of threads and authors discussing OxyContin[®] during the second half of 2009 (i.e., Q3 and Q4 2009). The proportion of threads and authors discussing Vicodin[®] and MS Contin[®] in Q2 2010 remained consistent with Q1 2010 as no statistically significant differences were observed.

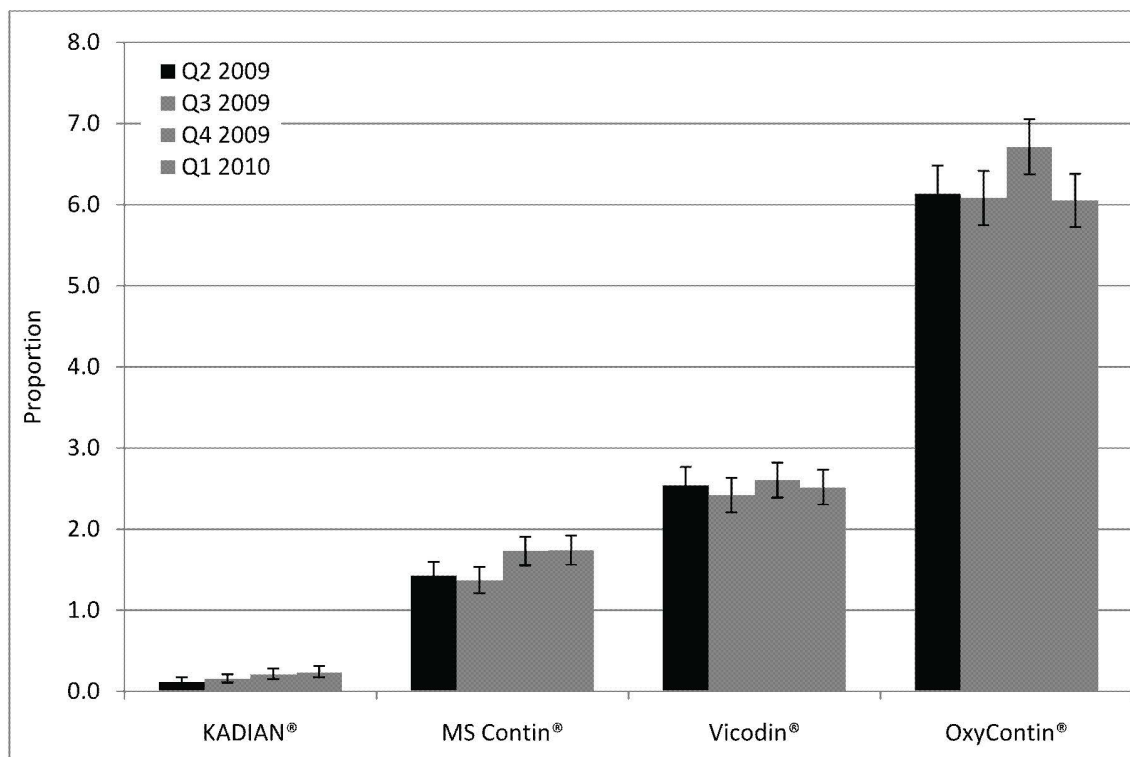
Figures 21 – 23 illustrate the proportion of KADIAN[®]-related posts, threads, and authors by quarter for the 12-month reporting period (July 2009 – June 2010).

Figure 21. Proportion (P) of posts (per 100) mentioning KADIAN® and the comparator products by quarter (7/1/2009 – 6/30/2010)



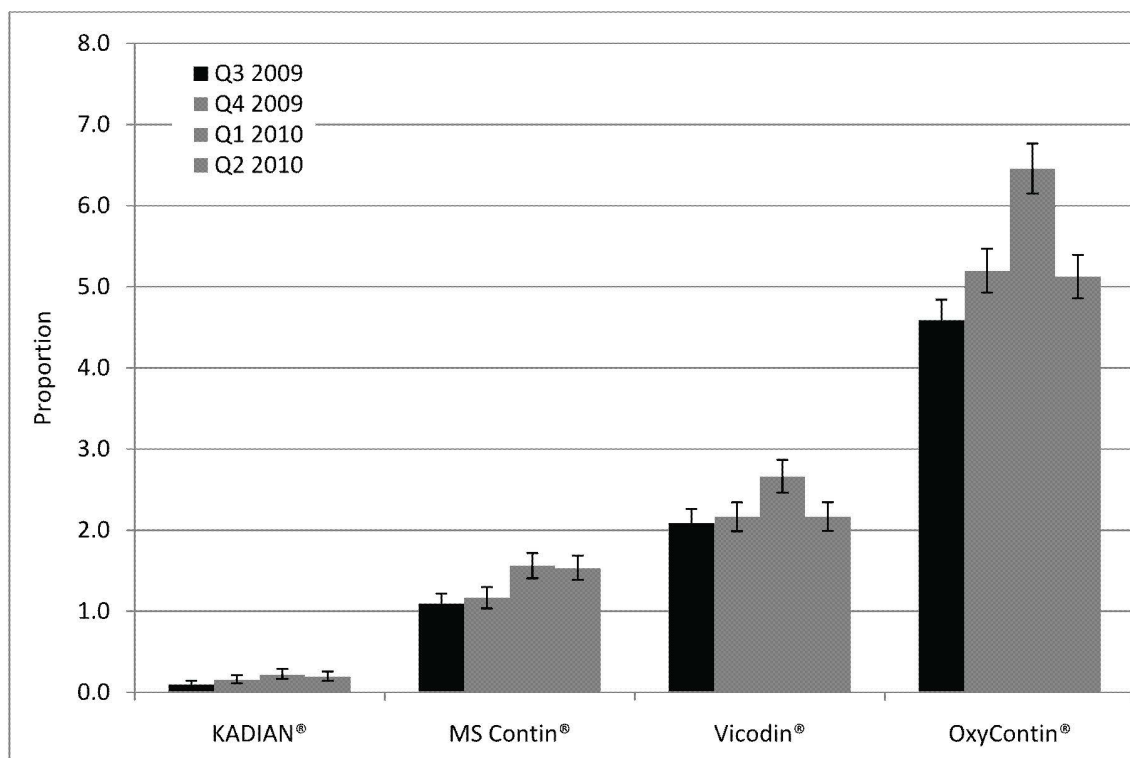
	Q3 2009			Q4 2009			Q1 2010			Q2 2010		
	P	95% CI		P	95% CI		P	95% CI		P	95% CI	
KADIAN®	0.009	0.006	0.013	0.012	0.010	0.016	0.017	0.013	0.022	0.019	0.015	0.025
OxyContin®	0.12	0.11	0.14	0.11	0.10	0.12	0.14	0.13	0.16	0.17	0.15	0.18
MS Contin®	0.25	0.23	0.27	0.20	0.19	0.22	0.26	0.24	0.28	0.25	0.23	0.27
Vicodin®	0.71	0.68	0.74	0.65	0.62	0.67	0.80	0.77	0.83	0.79	0.76	0.82

Figure 22. Proportion (P) of threads (per 100) mentioning KADIAN® and the comparator products by quarter (7/1/2009 – 6/30/2010)



	Q3 2009			Q4 2009			Q1 2010			Q2 2010		
	P	95% CI		P	95% CI		P	95% CI		P	95% CI	
KADIAN®	0.11	0.07	0.16	0.16	0.11	0.21	0.21	0.15	0.28	0.23	0.17	0.31
OxyContin®	1.43	1.25	1.60	1.37	1.21	1.53	1.73	1.55	1.91	1.74	1.56	1.92
MS Contin®	2.54	2.31	2.77	2.42	2.20	2.63	2.60	2.39	2.82	2.52	2.30	2.73
Vicodin®	6.13	5.79	6.48	6.08	5.75	6.42	6.71	6.37	7.05	6.05	5.72	6.38

Figure 23. Proportion (P) of authors (per 100) mentioning KADIAN® and the comparator products by quarter (7/1/2009 – 6/30/2010)



	Q3 2009			Q4 2009			Q1 2010			Q2 2010		
	P	95% CI		P	95% CI		P	95% CI		P	95% CI	
KADIAN®	0.10	0.06	0.14	0.16	0.11	0.21	0.22	0.17	0.29	0.19	0.14	0.26
OxyContin®	1.09	0.97	1.22	1.17	1.03	1.30	1.56	1.41	1.72	1.54	1.39	1.69
MS Contin®	2.09	1.92	2.26	2.16	1.99	2.34	2.66	2.46	2.87	2.17	1.99	2.34
Vicodin®	4.59	4.33	4.84	5.20	4.93	5.47	6.46	6.15	6.76	5.12	4.86	5.39

QUALITATIVE TOPIC ANALYSIS OF KADIAN® SAMPLE

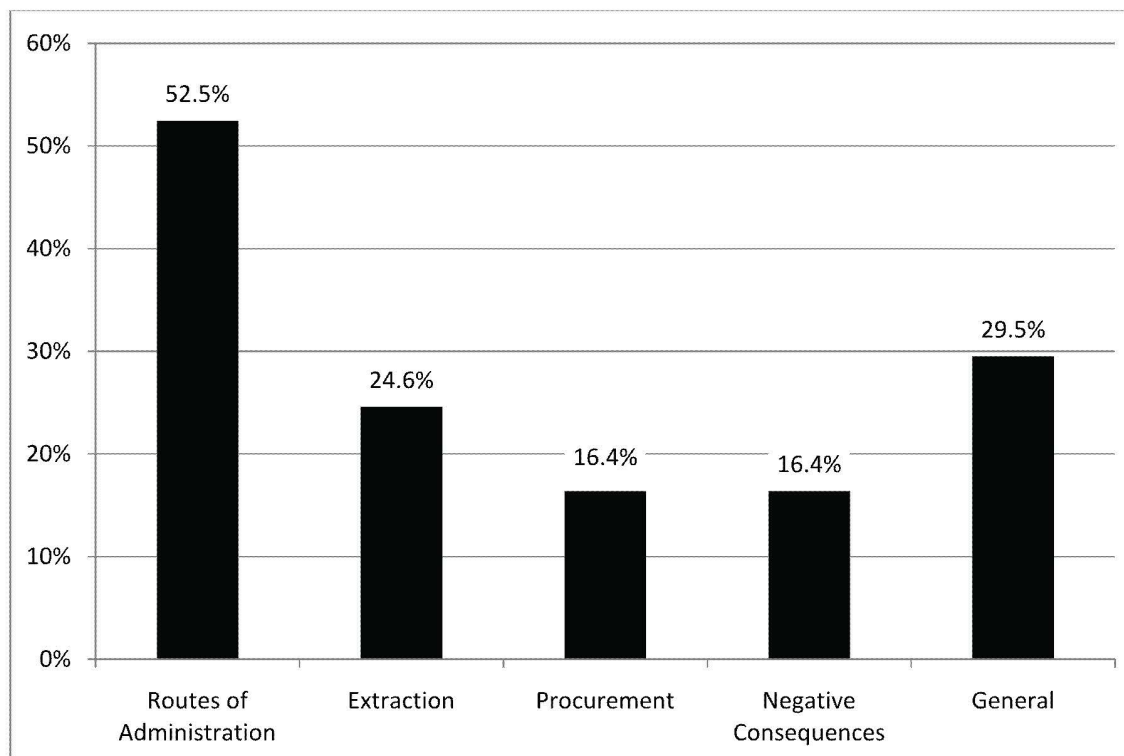
In an effort to characterize the nature of KADIAN®-related discussion occurring on the monitored websites, the total sample of posts pertaining to KADIAN® between April 1, 2010 and June 30, 2010 were reviewed. Each post was coded according to five topic categories: routes of administration, extraction techniques, procurement, negative consequences and general discussion. Figure 24 presents the proportion of the five topic categories for the current quarter and Figure 25 by quarter for the corresponding 12-month period (July 2009 – June 2010). Due to the unstructured nature of message board content, it should be noted that topic categories are not mutually exclusive, and therefore several categories may be assigned to a single post.

During the current quarter, the greatest proportion of KADIAN®-related posts written discussed routes of administration (52.2%) and of these posts injection was discussed with the greatest frequency (87.5% of all route of administration-related posts). KADIAN® was discussed in a

general context (i.e., the content of the discussion was unspecified and did not pertain to any of the other topics categories) with the next greatest frequency (29.5%), followed by discussion of extraction techniques (24.6%). Sources of procurement and negative consequences associated with the abuse of KADIAN[®] were also discussed during the current quarter albeit at a lower frequency than that of the other three categories (16.4% each).

A detailed description of each topic category is presented below.

Figure 24. Proportion of topic categories for KADIAN[®]-related posts (4/1/2010 – 6/30/2010)



Routes of Administration (n=32): 52.5% of the KADIAN[®] posts written during Q2 2010 were categorized as relating to routes of administration. The route mentioned in the greatest proportion of administration-related posts was injection (n=28, 87.5%), followed equally by oral administration and snorting (n=5, 15.6% each), and rectal administration (n=2, 6.3%). Of the posts that discussed injection, the majority mentioned intravenous injection (n=21, 65.6%), while the remaining seven (21.9%) did not specify the type of injection discussed. With respect to oral ingestion, two (6.3%) authors reported parachuting the product while swallowing the product whole and drinking it in a solution was mentioned once respectively (3.1%). One author also mentioned taking KADIAN[®] orally but did not specify a particular oral route. No mentions of smoking, sublingual administration or chewing the product were identified during the current quarter.

Extraction (n=15): Extraction techniques were discussed in 24.6% of all KADIAN[®] posts written during Q2 2010 and all 15 posts referenced physical techniques for removing the morphine from the KADIAN[®] capsule. Of the 15 extraction related posts, the majority (n=10, 66.7%) discussed multi-step physical procedures such as crushing, dissolving, and filtering KADIAN[®]. The remaining 5 posts (33.3%) mentioned one-step physical techniques such as crushing the beads within the KADIAN[®] capsule before administration.

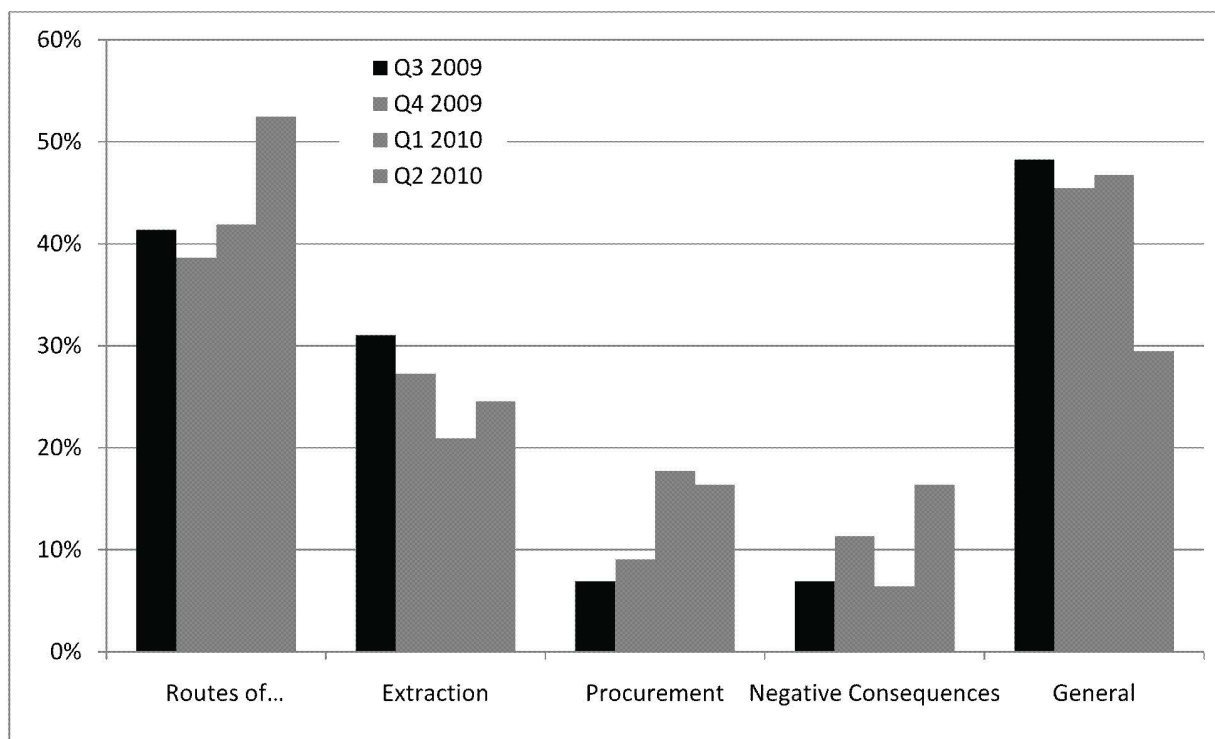
Procurement (n=10): 16.4% of the KADIAN[®]-related posts written during the current reporting quarter discussed sources of procurement of the drug. Of these posts, the largest proportion of authors mentioned obtaining KADIAN[®] from their own prescription (n=6, 60.0%) followed by procuring the product from a dealer (n=3, 30.0%). One author who mentioned obtaining KADIAN[®] did not specify the source of procurement (n=1, 10.0%).

Negative Consequences (n=10): During Q2 2010, 16.4% of the KADIAN[®]-related posts written discussed negative consequences associated with the abuse of the drug, the largest proportion of which referenced minor physical afflictions such as a headache or nausea (n=4, 40.0%). Three authors during the current quarter mentioned withdrawals (30.0%), two referenced addiction (20.0%) and one mentioned overdose (10.0%). No reports of legal issues or drug testing were identified.

General discussion (n=18): 18 of the KADIAN[®] posts written during Q2 2010 were categorized as being general in nature as these posts did not discuss topics related to any of the other specified categories (e.g., I like KADIAN[®]!). Of these posts, the majority (n=9, 50.0%) discussed KADIAN[®] in an abuse-related context. Five (27.8%) of the remaining posts were not abuse-related and discussed KADIAN[®] within the context of legitimate use for pain management and only four posts mentioned KADIAN[®] within the context of a quote from a previous post (22.2%)

During the current quarter, the proportion of KADIAN[®]-related posts that discussed KADIAN[®] in a general context decreased in comparison to the level of general-related conversation observed in the previous three quarters (Q3 2009 – Q1 2010). Coinciding with this decrease, an increase in the proportion of posts discussing routes of administration and negative consequences was also observed. Furthermore, discussion of both routes of administration and negative consequences during the current quarter reached the highest levels observed during the 12 month period corresponding with Q2 2010. While slight fluctuations in the level of discussion pertaining to sources of procurement and negative consequences were also observed during Q2 2010, in general, the proportion of discussion pertaining to these two topics remained consistent with the levels observed in Q1 2010.

Figure 25. Proportion of topic categories for KADIAN[®]-related posts by quarter (7/1/2009 – 6/30/2010)



	Q3 2009			Q4 2009			Q1 2010			Q2 2010		
	P	95% CI		P	95% CI		P	95% CI		P	95% CI	
Routes of Administration	0.41	0.21	0.72	0.39	0.23	0.62	0.42	0.27	0.62	0.52	0.36	0.74
Extraction	0.31	0.14	0.59	0.27	0.14	0.48	0.21	0.11	0.36	0.25	0.14	0.41
Procurement	0.07	0.01	0.25	0.09	0.02	0.23	0.18	0.09	0.32	0.16	0.08	0.30
Negative Consequences	0.07	0.01	0.25	0.11	0.04	0.26	0.06	0.02	0.26	0.16	0.08	0.30
General	0.48	0.26	0.81	0.45	0.03	0.07	0.47	0.31	0.67	0.30	0.17	0.47

SELECTION OF INTERESTING KADIAN[®] POSTS

Between April 1, 2010 and June 30, 2010 a total of 300 KADIAN[®]-related posts were randomly selected and reviewed for the current report. The following section presents 10 of these posts, all of which were selected in order to highlight the nature of KADIAN[®]-related discussion that was observed over the current reporting period. The posts are reproduced here exactly as they appear on each forum, excluding identifying information (i.e., username). Thus, all spelling, grammatical, and punctuation errors are from the original source and have not been altered.

During the current quarter, many authors discussed routes of administration and associated extraction techniques. Among these conversations, methods for preparing KADIAN[®] for intravenous injection were discussed most frequently. While the details of each extraction technique varied by author, in general, most authors discussed crushing the beads within the

KADIAN® capsule, and dissolving the powder into a liquid, filtering and then intravenously injecting the solution. For example, one author stated: "my procedure was to grind up the balls into powder in a mortar and pestle, like i was going to parachute it. then i put in some water, agitated without heat, filtered through cotton, and slammed it." A similar procedure was also described by another author who instead of injecting the solution, rectally administered it: "SWIM just crushed an 80mg Kadian in a pill crusher, mixed with warm water and shot it in his a**." In addition to injection, other routes of administration were also discussed during the current quarter. For example one author stated that they preferred to parachute KADIAN® "i used to parachute kadian all the time. IMO this is the best way" while another mentioned snorting the product: "Then kadian started going up the nose."

Negative consequences associated with the abuse of KADIAN® were also frequently discussed during the second quarter of 2010. Several authors referenced experiencing a histamine reaction after injecting KADIAN® and a few authors discussed issues associated improper injection (i.e., missing ones vein). For example, one author who reported looking "red and flushed for half an hour" after they injected KADIAN® indicated that they "really have to try antihistamines" and then asked "How come I don't get itchy at all if you eat them?" Another author, who also injected KADIAN®, relayed the following experience: "i shot up something like 15 kadian 80's over the course of six days. same procedure as outlined above, used alcohol swabbing, etc. i missed a shot and got a terrifying lump."

Post 1 It's common enough among people who shoot pills to get abscesses. Especially if you don't use a micron filter. A good friend of mine got a nasty abcess from shooting kadians (morphine pills) that had to be treated with anti-biotics and had to be drained as well. I was damn lucky i never got anything worse then cotton fever when i was IVing. I used to shoot dillys and various morphine pills mainly kadians and esslons but on 2 occasions i was dumb enough to shoot mscontins. Those fucking pills are just plain nasty and your looking at a amputation if you inject them for very long. The various morphine pills on the market are murder for your veins and i just used a cotton as a filter and often it was not clear to say the least . Even after missing a shot in my hand (that fucking burned) i never got a abcess. So i count myself as one lucky bastard in that regard. I knew the risks full well will i was doing it but it mattered little to me at the time. I still remember the second thoughts id always get after seing that dirty sludge left over in the cooker after doing up a morphine shot. I always hesitated abit but once the reality of junk sickness hit me it didnt matter.

Post 2 I have the same problem and it sucks because I can get Kadians cheap. But the pins and needles on my scalp/feet/arms/ legs just sucks with anything over about 60mgs for me. And then I look red and flushed for half an hour. But then the nod gets good. I really have to try antihistamines, but I've been trying to cut back on IV. How come I don't get itchy at all if you eat them? And I eat up to 300mgs at a time w/ no itchiness. Also, Stones fucking rock, GnR rocked back in the day, and the Beatles are lame.

Post 3 It's my #1 pick only because it's around and cheap. Where I live (Bay Area) pills are just too damn expensive and the good shit is super rare (dillies, morph ir, etc). Although I got hooked up last week with 100mg kadian's for \$2 each never seen them before and the dude who I got them from obviously did not know the true price of these things.

Trust me I would love to stop shooting this dirty ass tar, plus the quality has gone completely downhill and basically not worth it. However since i am addicted I keep buying the crap anyways.

Post 4 SWIM just crushed an 80mg Kadian in a pill crusher, mixed with warm water and shot it in his ass. SWIM's face is numb. SWIM has no opiate tolerance whatsoever and this dose was extremely enjoyable.

Post 5 Yeah so it was a Kadian 60mg. I poured the white beads into a coffee mug and used the back of a knife to crush them up into a fine powder. Then I poured it into a bowl and took out as many of the shell pieces as I could with tweezers. I filtered the entire thing three times through a q-tip cotton and was left with about 50cc of a milky white solution. Banged the whole thing and I got a short rush and am barely feeling anything. Oh well. Thanks for your help. If I had done half I'd have been really disappointed, more so than I am now. I've done morphine once in the past orally and felt nothing, guess I'll just stick with what I know gets me high, although the offer of any opiate is way too hard to turn down, heh.

Post 6 i just got done (a bit less than a week ago) with an iv kadian (morphine sulfate xr with the little balls) binge. my procedure was to grind up the balls into powder in a mortar and pestle, like i was going to parachute it. then i put in some water, agitated without heat, filtered through cotton, and slammed it. obviously this is unsafe as HELL, and i really regret doing it. please don't shoot these. just parachute the powder, like everyone said. if you're absolutely determined, get a fucking micron filter. please. i missed a shot, got a lump that terrified the shit out of me, and is only now going down. i could have fucked myself up permanently. it's just not worth it. the morphine rush is incredibly itchy (not sure if this is entirely due to histamine release or also impure solution made from pill) but it is quite pleasurable. nowhere close to heroin though.

Post 7 just a bit of a counterpoint... i shot up something like 15 kadian 80's over the course of six days. same procedure as outlined above, used alcohol swabbing, etc. i missed a shot and got a terrifying lump. missing shots with pills is MUCH more likely to fuck you up real bad. OTOH, i used to parachute kadian all the time. IMO this is the best way. the high is actually better - an IV morphine rush off kadians is an itchy thing, not as good as heroin - and orally it'll last much longer. do yourself a favor and parachute.

Post 8 Weed and ritalin(i thought it was the shit) at first when I was 15. Started smoking weed regularly, then used E for the first time shortly after. I was amazed by the high of ecstasy and the bond I felt it gave me and my mates. I still believe this helped us have the friendship we all have today. Unfortunately we're irresponsible and started using opiates the next year. At first just perc's, tabs, or the occasional OCs down the hatch. Then kadian started going up the nose. Then more OCs, methadone(oral of course) now another yr later my friend has a full out morphine IV addiction and i'm slowly losing him. I miss the E days

Post 9 The Avanzia's **[Username removed]** is talking about are called Kadian here, if I'm thinking I know what he;s talking about. They come in a capsule filled with tiny beads.

The beads are harder than shit to crush all the way and you really don't want that plasticity coating in you. I don't snort, though, so I don't trip on those little plasticky coatings

Post 10 I have been reading ur posting about how to inject kadian 100mg.and how u take one pill and try to make 4,3 or 2 hits out of it.swims believes in doing it all at once.to get the full affect.i have been on the for many years.and swims no alot of ways to do it to get a good hit.# 1 take the 100mg capules and put it in a pill crusher and crush to a fine power.it won't all be fine but thats alright.#2-take the power out of the crusher and put it in a spoon.#3 get a one cc needle.and put 1.4 units in the spoon.so almost 1 and a half needles full of water.in spoon.if not it will be hard to draw up.cause it will be to thick.#4 mix it together real good just use the end of the needle and mix it real good.#5 do not cook what so ever.if u do it will turn to jell.and it is basicly fucked if u cook it.so don't what so ever that is really important.#6 get a filter by cutting the filter off a smoke or a tube.#7cut filter in half and place in the spoon.allow the liquid to soak up in the filter.#8.then take the needle and draw the liquid up.it will be cloudy.but thats what its suppose to look like . then u know what to do next.and enjoy.you can repeat the same steps over and over until there is no more drug left.as long as its cloudy it still has the drug in it.when it starts to get clear then u know its no good no more.U can probley get 4-5 washes out of a 100mg capules.and believe me it is worth it.need to know more about it ask. what ever u need to know don't want to see anyone hurt them selfs if its not done right.

IV. OTHER DATA

4.1. DAWN LIVE!

The Drug Abuse Warning Network (*Dawn Live!*) is a program administered by SAMHSA (Substance Abuse and Mental Health Services Administration). The purpose of *Dawn Live!* is to collect information regarding drug-related visits to emergency departments (EDs) nationwide in order to survey trends over time in drug use, misuse, abuse, and consequences. This section presents data on ED visits involving morphine compounds and KADIAN[®] from the *Dawn Live!* database. Although *Dawn Live!* is a real-time database, the level of completeness in reporting from participating hospitals and EDs is variable. Further, the data are not available at any specific geographic or site level. Records of ED visits that involve a drug are classified by *Dawn Live!* data abstractors into one of several different case types. For surveillance of KADIAN[®], *Dawn Live!* researchers suggest exploring non-medical use as a relevant outcome, which encompasses the case types of overmedication, malicious poisoning, and "other" (toxicity, withdrawal, illicit use).

In January 2010, access to *DAWN Live!* was suspended by SAMHSA, preventing the retrieval and analysis of the *Dawn Live!* data associated with the current reporting period. Data for the current reporting quarter was requested directly from SAMHSA, and below is the response communicated via email from Al Woodward, PhD, MBA and Acting *Dawn Live!* Team Leader:

"The Office of Applied Studies (OAS) is experiencing significant personnel and resource constraints, making it impossible for us to continue to respond to external requests to the same extent that we were able to do in the past. I regret that we cannot currently provide you with analyses that you request. I will keep your request in mind both as we develop new procedures and, as time and resources permit, will try to provide you with a more complete response."

4.2. FDA-AERS

The FDA describes its adverse event database as follows: "The Adverse Event Reporting System (AERS) is a computerized information database designed to support the FDA's post-marketing safety surveillance program for all approved drug and therapeutic biologic products. The ultimate goal of AERS is to improve the public health by providing the best available tools for storing and analyzing safety reports. The FDA receives adverse drug reaction reports from manufacturers as required by regulation. Health care professionals and consumers send reports voluntarily through the MedWatch program." Inflexxion subscribes to the QScan service, a software program created by DrugLogic, which allows for analysis of FDA-AERS data.

The FDA-AERS system utilizes a classification method called a MedDRA number for coding the adverse event outcomes. MedDRA, the Medical Dictionary for Regulatory Activities, is a medically valid terminology utilized within the regulatory environment, and developed by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). It is owned by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA).

4.2.1. ADVERSE EVENT CASE REPORTS

METHODS

Using FDA-AERS data obtained via the QScan service, cases were searched from all relevant reports in which KADIAN[®] was suspected as a cause of the adverse event. This analysis encompasses the most recent data available from FDA-AERS: cases reported through December 31, 2009. Due to the FDA's approximately two-quarter lag between closing the data set and releasing data to the public, these reports are the most timely adverse event data available in AERS. The data included are: 1) case reports since the FDA approval of KADIAN[®] where KADIAN[®] was suspected as a cause of the adverse event and 2) the proportional reporting rates (PRR) of KADIAN[®] and comparator drugs. Note the FDA-AERS data may contain reports from multiple sources on the same patient (i.e., same event for a patient reported by hospital, by a clinical research organization, by a drug manufacturer, by the National Institutes of Health, etc.). Results presented below include *all* cases reported during the relevant report period, including possible duplicate cases from within this period as well as from earlier time periods.

Proportional reporting rates (PRR) are presented as the second set of results from the FDA-AERS data and are described in an article by Evans, Waller, and Davis. The PRR calculates the proportion of reactions for a drug where the comparator is all other drugs in the database. This statistic is similar to that of relative risks in epidemiology. PRRs are used in pharmacovigilance to detect possible signals. In addition, the empirical Bayes geometric mean (EBGM) is used in this analysis. The algorithm that calculates EBGM addresses both statistical variability due to small sample size and multiple comparisons by using a technique called "Bayesian shrinkage." This statistical technique results in a single relative reporting ratio, similar to the PRR, but adjusted for factors described above.

RESULTS

As illustrated in Table 12, there were 4 KADIAN[®]-suspected adverse events reported in the most recent available data FDA-AERS data (i.e., data was available through the fourth quarter of 2009). One of the four cases had an outcome listed as 'other', one adverse event case required an initial or prolonged hospitalization, and the remaining two adverse event cases required an initial or prolonged hospitalization and ultimately resulted in death.

Table 12. KADIAN® suspected adverse event cases as reported in FDA-AERS (data available through the fourth quarter of 2009 - 12/31/2009)

Case ID	Sex	Manufacturer Control Code	FDA Report Receipt Date	Age	Drugs	Reactions	Outcomes
6419395	F	1000007480	10/13/2009	75	LEXAPRO KADIAN LISINAPRIL	fatigue suicidal ideation	OTHER
6523859	F	JP-JNJFOC-20091100009	12/31/2009	55	DUROTEP DUROTEP OPSO MORPHINE HYDROCHLORIDE MORPHINE HYDROCHLORIDE MORPHINE HYDROCHLORIDE MOBIC MORPHINE HYDROCHLORIDE DUROTEP LAC B KADIAN MAG-LAX MORPHINE HYDROCHLORIDE MORPHINE HYDROCHLORIDE TRYPTRANOL OPSO	somnolence rectal cancer dyskinesia	HOSPITALIZATION - INITIAL OR PROLONGED DEATH
6523859	F	JP-JNJFOC-20091100009	12/31/2009	55	MOBIC LAC B MAG-LAX MORPHINE HYDROCHLORIDE MORPHINE HYDROCHLORIDE DUROTEP DUROTEP DUROTEP KADIAN OPSO OPSO MORPHINE HYDROCHLORIDE MORPHINE HYDROCHLORIDE MORPHINE HYDROCHLORIDE MORPHINE HYDROCHLORIDE TRYPTRANOL	dyskinesia rectal cancer somnolence	HOSPITALIZATION - INITIAL OR PROLONGED DEATH
6522619	M	KADN20090131	12/24/2009	27	KADIAN OXYCODONE HYDROCHLORIDE ULTRAM DULOXETINE HYDROCHLORIDE MUSCLE RELAXANTS ANTICONVULSANT PHENCYCLIDINE HYDROCHLORIDE PHENCYCLIDINE HYDROCHLORIDE	blood chloride increased blood creatine phosphokinase increased body temperature increased convulsion drug abuse drug screen positive electrocardiogram qt prolonged electrocardiogram st segment abnormal hypertension hypotension lung consolidation multiple drug overdose intentional mydriasis nystagmus sinus tachycardia somnolence suicide attempt tremor unresponsive to stimuli	HOSPITALIZATION - INITIAL OR PROLONGED LIFE-THREATENING

* A listing of -1 within the age category indicates missing data.

4.2.2. PROPORTIONAL REPORTING RATIOS

METHODS

Proportional reporting rates (PRR) were used in the analysis of FDA-AERS data and are described in an article by Evans, Waller, and Davis. The PRR calculates the proportion of reactions for a drug where the comparator is all other drugs in the database. This statistic is similar to that of relative risks in epidemiology. PRRs are used in pharmacovigilance to detect possible signals. In addition, the empirical Bayes geometric mean (EBGM) is used in this analysis. The algorithm that calculates EBGM addresses both statistical variability due to small sample size and multiple comparisons by using a technique called 'Bayesian shrinkage.' This statistical technique results in a single relative reporting ratio, similar to the PRR, but adjusted for factors described above. PRRs and EBGMs were calculated for KADIAN[®], as well as OxyContin[®], Vicodin[®], Duragesic[®], AVINZA[®], Opana[®] ER, and MS Contin[®].

The PRRs and EBGMs for KADIAN[®] are compared to those of OxyContin[®], Vicodin[®], and Duragesic[®], AVINZA[®], Opana[®] ER, and MS Contin[®]. The date ranges used to calculate the PRR and EBGM are different for each product; the start date for each analysis is the date for which the product was approved by the FDA. Therefore, the time frame for OxyContin[®] begins on December 13, 1995; for Vicodin[®] on January 8, 1983; for Duragesic[®] on August 8, 1990; and for Opana[®] ER on June 22, 2006. The time frames for analysis for KADIAN[®], Avinza[®], and MS Contin[®] were July 4, 1996, March 21, 2002, and May 30, 1987, respectively. The relevant adverse event types considered in this analysis include overdose (MedDRA number 12.5.5, which includes intentional, accidental, and poly drug overdoses), drug and chemical abuse (MedDRA number 24.7.4), and drug abuser (MedDRA 24.7.4.1). These MedDRA adverse event codes are based on MedDRA version 13.0.

RESULTS

PRRs and EBGMs are presented in Table 13 for KADIAN[®] and comparator drugs. These data help to determine whether a particular prescription opioid has a markedly higher proportion of abuse-related adverse events in comparison to other similar or target comparison products. Because of the small number of reported adverse events involving KADIAN[®], the EBGM is likely a more reliable statistic with which comparisons across the products can be made. While the ratios for the categories presented in Table 13 are high in a number of instances, this is expected as it is known that prescription opioids compared with other drugs are misused and abused. Therefore, the appropriate comparison should be whether a particular prescription opioid has a markedly higher proportion of abuse-related adverse events relative to other similar opioid products.

Examination of PRR/EBGM values available through Q4 2009 and released during Q2 2010 indicate that the highest values for the category of overdoses were reported for OxyContin[®], followed by KADIAN[®], Avinza[®], Opana[®] ER, MS Contin[®], Vicodin[®], and then Duragesic[®]. With respect to the drug abuse categories (drug and chemical abuse, and drug abuser), the highest PRR/EBGM values were again reported for OxyContin[®], and followed by Opana[®] ER, KADIAN[®], Vicodin[®], MS Contin[®], Duagesic[®], and then Avinza[®]. Thus, for each of the adverse event categories examined in this report (overdoses, drug and chemical abuse, drug abuser), of the monitored morphine products, KADIAN[®] had the highest reported PRR/EBGM values available through Q4 2009.

Table 13. Proportional Reporting Ratios (PRRs) and Empirical Bayes Geometric Mean (EBGM) for KADIAN[®] suspected adverse event cases and comparator drugs

Product	Statistic	Adverse Events		
		Overdoses 12.5.5	Drug and Chemical Abuse 24.7.4.	Drug Abuser 24.7.4.1
KADIAN [®]	PRR	10.69	31.31	31.45
	EBGM	8.40	17.34	17.98
AVINZA [®]	PRR	9.26	9.34	9.39
	EBGM	6.80	1.78	1.58
MS Contin [®]	PRR	7.13	16.56	16.64
	EBGM	6.10	10.46	10.63
Opana [®] ER	PRR	8.61	36.42	36.60
	EBGM	6.14	9.41	10.50
OxyContin [®]	PRR	12.11	106.35	107.14
	EBGM	11.03	67.49	67.83
Vicodin [®]	PRR	5.51	18.62	18.71
	EBGM	4.76	12.85	13.02
Duragesic [®]	PRR	2.27	11.38	11.44
	EBGM	2.07	9.22	9.27

4.3. DRUG ENFORCEMENT AGENCY (DEA)

Information from the DEA regarding prescription opioids is monitored from several sources and is listed below. These sources include:

- DEA Microgram Bulletin: a monthly publication highlighting new techniques in forensic analysis and techniques used by traffickers of illicit substances.
- DEA Prescription Medicines News Releases website: a website that disseminates information regarding prescription drug seizures and prosecutions.

- DEA Office of Diversion Control website: a website that contains information regarding the diversion of precursor chemicals for pharmaceuticals and changes to the Controlled Substances Act scheduling status of those substances.
- Dateline DEA: a biweekly newsletter monitored for any information pertaining to the drug of interest or prescription opioid abuse.

FINDINGS

There were no DEA publications identified which pertained specifically to KADAIN[®], morphine, or prescription opioid medications during Q2 2010.

4.3. MEDIA MONITORING

4.3.1. NEWS REPORTS

METHODS

Searches were conducted using RSS feeds from Google News™ to monitor news articles pertaining to KADIAN[®], morphine, and prescription opioids in general. The searches focused on news articles pertaining to prescription opioid abuse trends, addiction, overdose, and other related topics. Results were reviewed for content and a list of relevant article references was compiled. See Appendix D for the list of references pertaining to prescription opioids in general and search strings used as inclusion criteria.

RESULTS

During the second quarter of 2010, there were no general news media articles (n=0) identified which specifically mentioned KADIAN[®], and only one article which mentioned morphine. The one article pertaining to morphine ('Formulation Opioids to Deter Abuse Remains a Challenge,' Monthly Prescribing Reference, 5/8/2010) mentioned the opioid compound briefly among several other opioid compounds in a discussion of the development of abuse deterrent opioid formulations.

A total of 52 news media articles pertaining to prescription opioids in general were identified during the second quarter of 2010 (Table 14). The majority of these articles (98.1%) discussed the misuse/abuse of prescription opioid medications, and 26.9% of articles included discussion of pain management through the use of these types of drugs. During Q2 2010, overdose related to prescription opioid drugs was discussed in 57.1% of articles. Twenty-five percent of articles involving prescription opioid medications discussed the misuse/abuse of these drugs in the adolescent/teen population. Addiction of prescription opioid medications was mentioned in 19.2% of articles, prevention of misuse, abuse (98.1%) and/or addiction was mentioned in 23.1% of articles, and treatment for prescription opioid addiction was mentioned in 7.7% of articles identified during the current reporting quarter.

Table 14. News report topics during Q2 2010 (4/1/2010 – 6/30/2010)

	April 2010 (n=14 articles)		May 2010 (n=12 articles)		June 2010 (n=26 articles)		Total Q2 2010 (n=52 articles)	
	N	%	N	%	N	%	N	%
Addiction	2	14.3	5	41.7	3	11.5	10	19.2
Adolescent/Teen	4	28.6	3	25.0	6	23.1	13	25.0
Misuse/Abuse	14	100.0	11	91.7	26	100.0	51	98.1
Overdose	8	57.1	4	33.3	18	69.2	30	57.1
Pain Management	3	21.4	2	16.7	9	34.6	14	26.9
Prescription Monitoring	0	0.0	0	0.0	0	0.0	0	0.0
Prevention	2	14.3	5	41.7	5	19.2	12	23.1
Treatment	1	7.1	3	25.0	0	0.0	4	7.7

* Categories are not mutually exclusive and therefore percentage values will not amount to 100%.

ARTICLES PERTAINING TO KADIAN®

No articles identified during Q2 2010.

ARTICLES PERTAINING TO MORPHINE

May 2010

1. 'Formulation Opioids to Deter Abuse Remains a Challenge,' Monthly Prescribing Reference, 5/8/2010
 - Web Address: <http://www.empr.com/formulating-opioids-to-deter-abuse-remains-a-challenge/article/169777/>
 - Drugs: hydrocodone, oxycodone, morphine, fentanyl, methadone, hydromorphone, general opioid
 - Subjects: Misuse/Abuse, Prevention, Pain Management

4.3.2. LEGISLATIVE ACTIVITY & LAW ENFORCEMENT NEWS

METHODS

Searches were conducted using RSS feeds from Google News™ to monitor articles about law enforcement events involving KADIAN®, morphine, and prescription opioids in general. The searches focused on news articles pertaining to legislative activity involving drug abuse, controlled substances, prescribing practices, and other related topics. Results were reviewed for content, and a list of relevant article references was compiled. See Appendix C for the list of references pertaining to prescription opioids in general, and search strings used as inclusion criteria.

RESULTS

During the second quarter of 2010, one article (n=1) was identified which involved KADIAN® and legislative activity/law enforcement. This article ('Roy Allen Bowman, of Philadelphia Charged in Pharmacy Burglary,' 7th Space Interactive, 5/2/2010) discussed a pharmacy robbery in Philadelphia, Pennsylvania wherein several prescription opioid products, including KADIAN®, were stolen by a man named Roy Allen Bowman. There were six articles identified during the current reporting quarter which mentioned morphine along with legislative/law enforcement activity.

A total of 102 articles involving prescription opioids and legislative/law enforcement activity were identified during the current reporting quarter (Table 15). Nearly 55% of articles involved arrests for unlawful possession or distribution of prescription opioid products, and 52% involved legislation related to these types of medications. Prescription forgery/fraud was discussed in approximately 36% of articles pertaining to prescription opioid products and legislative/law enforcement activity during the current reporting quarter, and pharmacy robberies were discussed in nearly 25% of the articles identified. Articles pertaining to arrests, lawsuits, or the loss of a medical license for a medical professional comprised nearly 24% of articles, and less than ten percent of articles (8.9%) discussed robberies not involving a pharmacy.

Table 15. Legislative and law enforcement news reports during Q2 2010 (4/1/2010 – 6/30/2010)

	April 2010 (n=40 articles)		May 2010 (n=17 articles)		June 2010 (n=45 articles)		Total Q2 2010 (n=102 articles)	
	N	%	N	%	N	%	N	%
Arrests	19	47.5	9	52.9	28	62.2	56	54.9
Legislation	19	47.5	12	70.6	22	48.9	53	52.0
Medical Professional	9	22.5	5	29.4	10	22.2	24	23.5
Pharmacy Robbery	6	15.0	1	5.9	4	8.9	11	24.4
Prescription Forgery/Fraud	10	25.0	1	5.9	5	11.1	16	35.6
Robbery-Other	2	5.0	1	5.9	1	2.2	4	8.9

ARTICLES PERTAINING TO KADIAN®

May 2010

1. 'Roy Allen Bowman, of Philadelphia Charged in Pharmacy Burglary,' 7th Space Interactive, 5/2/2010
 - Web Address:
http://7thspace.com/headlines/343249/roy_allen_bowmanof_philadelphia_charged_in_pharmacy_burglary.html
 - Drugs: KADIAN®, oxycodone, OxyContin®, hydromorphone, oxymorphone, Methadone, Nucynta®, Opana®, Percocet®, Percodan®, morphine
 - Subjects: Arrests, Pharmacy Robbery

ARTICLES PERTAINING TO MORPHINE

April 2010

1. Bolton MM, 'Dedham man charged in alleged prescription drug scam,' The Boston Globe, 4/16/2010
 - Web Address:
http://www.boston.com/yourtown/news/dedham/2010/04/dedham_man_facing_federal_pris.html
 - Drugs: oxycodone, OxyContin[®], Percocet[®], morphine
 - Subjects: Arrests, Legislation, Medical Professional, Robbery Other
2. Doyle J, 'Drugmaker's quick slide from the top,' St Louis Dispatch, 4/4/2010
 - Web Address:
<http://www.stltoday.com/stltoday/business/stories.nsf/0/B0C2F13DDBB4B69B862576FA00160CBB?OpenDocument>
 - Drugs: morphine
 - Subjects: Legislation
3. Pizzi D.M., 'FDA: Morphine Approval Will Resolve Drug Shortage,' Pain Medicine News, 4/15/2010
 - Web Address:
http://www.painmedicineneeds.com/index.asp?section_id=375&show=dept&issue_id=621&article_id=14956
 - Drugs: morphine
 - Subjects: Legislation

May 2010

1. Kertscher T, 'Pill-pushing physicians,' Milwaukee Wisconsin Journal Sentinel, 5/23/2010
 - Web Address: <http://www.jsonline.com/watchdog/watchdogreports/94680554.html>
 - Drugs: general opioid, OxyContin[®], oxycodone, morphine, methadone
 - Subjects: Arrests, Legislation, Medical Professional
2. 'Roy Allen Bowman, of Philadelphia Charged in Pharmacy Burglary,' 7th Space Interactive, 5/2/2010
 - Web Address:
http://7thspace.com/headlines/343249/roy_allen_bowmanof_philadelphia_charged_in_pharmacy_burglary.html
 - Drugs: KADIAN[®], oxycodone, OxyContin[®], hydromorphone, oxymorphone, Methadone, Nucynta, Opana[®], Percocet[®], Percodan[®], morphine
 - Subjects: Arrests, Pharmacy Robbery

June 2010

1. 'Modesto Police Make Massive Prescription Drug Bust,' CBS Channel 13 News, 6/23/2010

- Web Address: <http://cbs13.com/local/elderly.pill.pusher.2.1768411.html>
- Drugs: OxyContin®, Vicodin®, morphine, methadone
- Subjects: Arrests

4.4. ACADEMIC RESEARCH

4.4.1. RESEARCH ARTICLES PUBLISHED IN Q2 2010

METHODS

Automated PubMed searches were run weekly, covering over 5,000 medical journals and 5 million articles published since 1950. Results were screened for their relevance to prescription drug abuse and/or a specific compound (i.e., all articles mentioning a compound of interest, regardless of content, as well as articles not mentioning the compound but pertaining to the subject of prescription opioid abuse). Review of the table of contents of selected academic journals was also conducted. Search results were reviewed and a list of references was compiled for the reporting period.

RESULTS

During the second quarter of 2010, there were no academic research articles identified which pertained specifically to KADIAN®. There were, however, six academic research articles identified which pertained to morphine. Of these six articles, topics ranged from a study comparing two morphine formulations for the treatment of cancer pain (Ridgway, et al., 'Clinical Efficacy and Safety of Once-Daily Dosing of a Novel, Prolonged-Release Oral Morphine Tablet Compared With Twice-Daily Dosing of a Standard Controlled-Release Morphine Tablet in Patients With Cancer Pain: A Randomized, Double-Blind, Exploratory Crossover Study') to the conversion from morphine to methadone for the treatment of pain (Pollock et al., 'Morphine to Methadone Conversion: An Interpretation of Published Data'). A total of 68 academic articles were identified during the current reporting quarter which pertained to any prescription opioid medication. Of these 68 articles, approximately 68% involved discussion of the misuse/abuse of prescription opioids, and nearly 59% discussed the use of these types of medications for the treatment of chronic pain. During the current reporting quarter, several articles (n=14, 20.6%) pertained to the treatment of prescription opioid addiction, discussing the use of methadone, buprenorphine, and naltrexone implants as well as case management and other topics associated with addiction treatment. Other article topics this quarter included discussion fentanyl buccal formulations for the treatment of breakthrough pain, factors associated with prescription opioid overdoses, and the balance between adequate pain treatment and the prevention of prescription opioid abuse.

In June 2010, an academic article written by members of the Inflexxion staff was published in the journal *Pharmacoepidemiology and Drug Safety*. This article, entitled 'Geographic information systems and pharmacoepidemiology: using spatial cluster detection to monitor local patterns of prescription opioid abuse,' discussed the generation of geographic risk maps using substance abuse treatment center data in New Mexico to identify clusters of drug-specific prescription opioid abuse. The abstract for this academic article is included below:

Brownstein, J.S., Green, T.C., Cassidy, T.A., Butler, S.F. (2010). Geographic information systems and pharmacoepidemiology: using spatial cluster detection to monitor local

patterns of prescription opioid abuse. *Pharmacoepidemiology and Drug Safety*, 19(6), 627-637.

Abstract: PURPOSE: Understanding the spatial distribution of opioid abuse at the local level may facilitate public health interventions. METHODS: Using patient-level data from addiction treatment facilities in New Mexico from ASI-MV[®] Connect, we applied geographic information system (GIS) in combination with a spatial scan statistic to generate risk maps of prescription opioid abuse and identify clusters of product- and compound-specific abuse. Prescribed opioid volume data was used to determine whether identified clusters are beyond geographic differences in availability. RESULTS: Data on 24 452 patients residing in New Mexico were collected. Among those patients, 1779 (7.3%) reported abusing any prescription opioid (past 30 days). According to opioid type, 979 patients (4.0%) reported abuse of any hydrocodone, 1007 (4.1%) for any oxycodone, 108 (0.4%) for morphine, 507 (2.1%) for Vicodin or generic equivalent, 390 (1.6%) for OxyContin, and 63 (0.2%) for MS Contin or generic equivalent. Highest rates of abuse were found in the area surrounding Albuquerque with 8.6 patients indicating abuse per 100 interviewed patients. We found clustering of abuse around Albuquerque ($P = 0.001$; Relative Risk = 1.35, and a radius of 146 km). At the compound level, we found that drug availability was partly responsible for clustering of prescription opioid abuse. After accounting for drug availability, we identified a second foci of Vicodin abuse in the southern rural portion of the state near Las Cruces, NM and El Paso, Texas and bordering Mexico (RR = 2.1; $P = 0.001$). CONCLUSIONS: A better understanding of local risk distribution may have implications for response strategies to future introductions of prescription opioids

ARTICLES PERTAINING TO KADIAN[®]

There were no articles pertaining to KADIAN[®] identified during Q2 2010.

ARTICLES PERTAINING TO MORPHINE

April 2010

1. Brownstein, J.S., Green, T.C., Cassidy, T.A., Butler, S.F. (2010). Geographic information systems and pharmacoepidemiology: using spatial cluster detection to monitor local patterns of prescription opioid abuse. *Pharmacoepidemiology and Drug Safety*, 19(6), 627-637.
2. Ridgway, D., Sopata, M., Burneckis, A., Jespersen, L., Andersen, C. (2010). Clinical Efficacy and Safety of Once-Daily Dosing of a Novel, Prolonged-Release Oral Morphine Tablet Compared With Twice-Daily Dosing of a Standard Controlled-Release Morphine Tablet in Patients With Cancer Pain: A Randomized, Double-Blind, Exploratory Crossover Study. *Journal of Pain and Symptom Management*, 39(4), 712-720.

June 2010

1. Leppert W. (2010). Dihydrocodeine as an Opioid Analgesic for the Treatment of Moderate to Severe Chronic Pain. *Current Drug Metabolism*. Advance online publication.
2. Mintzer, M.Z., Lanier, R.K., Lofwall, M.R., Bigelow, G.E., Strain, E.C. (2010). Effects of repeated tramadol and morphine administration on psychomotor and cognitive performance in opioid-dependent volunteers. *Drug and Alcohol Dependence*. Advance online publication.

3. Pollock, A.B., Tegeler, M.L., Morgan, V., Baumrucker, S.J. (2010). Morphine to Methadone Conversion: An Interpretation of Published Data. *The American Journal of Hospice and Palliative Care*. Advance online publication.
4. Yang, Q., Xie, D.R., Jiang, Z.M., Ma, W., Zhang, Y.D., Bi, Z.F., Chen, D.L. (2010). Efficacy and adverse effects of transdermal fentanyl and sustained-release oral morphine in treating moderate-severe cancer pain in Chinese population: a systematic review and meta-analysis. *Journal of Clinical and Experimental Cancer Research*, 29(1), 67.

ARTICLES PERTAINING TO PRESCRIPTION OPIOIDS IN GENERAL

April 2010

1. Chapman, C.R., Lipschitz, D.L., Angst, M.S., Chou, R., Denisco, R.C., Donaldson, G.W., Fine, P.G., et al. (2010). Opioid Pharmacotherapy for Chronic Non-cancer Pain in the United States: A Research Guideline for Developing an Evidence-Base. *The Journal of Pain*. Advance online publication.
2. Comer, S.D., Sullivan, M.A., Vosburg, S.K., Manubay, J., Amass, L., Cooper, Z.D., Saccone, P., Kleber, H.D. (2010). Abuse liability of intravenous buprenorphine/naloxone and buprenorphine alone in buprenorphine-maintained intravenous heroin abusers. *Addiction*, 105(4), 709-718.
3. Crofford, L.J. (2010). Adverse effects of chronic opioid therapy for chronic musculoskeletal pain. *Nature Reviews Rheumatology*, 6(4), 191-197.
4. Derry, S., Moore, R.A., McQuay, H.J. (2010). Single dose oral codeine, as a single agent, for acute postoperative pain in adults. *Cochrane Database of Systematic Reviews*, 4(CD008099).
5. Fentanyl buccal soluble film (Onsolis) for breakthrough cancer pain. (2010). *The Medical Letter on Drugs and Therapeutics*, 52(1336), 30-31.
6. Fitzgibbon, D.R., Rathmell, J.P., Michna, E., Stephens, L.S., Posner, K.L., Domino, K.B. (2010). Malpractice claims associated with medication management for chronic pain. *Anesthesiology*, 112(4), 948-956.
7. Jamison, R.N., Clark, J.D. (2010). Opioid medication management: clinician beware! *Anesthesiology*, 112(4), 777-778.
8. Kreek, M.J., Borg, L., Ducat, E., Ray, B. (2010). Pharmacotherapy in the treatment of addiction: methadone. *Journal of Addictive Diseases*, 29(2), 200-216.
9. Lussier, D., Richarz, U., Finco, G. (2010). Use of hydromorphone, with particular reference to the OROS formulation, in the elderly. *Drugs and Aging*, 27(4), 327-335.
10. Meade, C.S., Weiss, R.D., Fitzmaurice, G.M., et al. (2010). HIV Risk Behavior in Treatment-Seeking Opioid-Dependent Youth: Results From a NIDA Clinical Trials Network Multisite Study. *Journal of Acquired Immune Deficiency Syndromes*. Advance online publication.
11. Minett, W.J., Moore, T.L., Juhascik, M.P., Nields, H.M., Hull, M.J. (2010). Concentrations of Opiates and Psychotropic Agents in Polydrug Overdoses: A Surprising Correlation Between Morphine and Antidepressants. *Journal of Forensic Sciences*. Advance online publication.

12. Moller, M., Karaskov, T., Koren, G. (2010). Opioid Detection in Maternal and Neonatal Hair and Meconium: Characterization of an At-Risk Population and Implications to Fetal Toxicology. *Therapeutic Drug Monitoring*. Advance online publication.
13. Pelissier-Alicot, A.L., Sastre, C., Baillif-Couniou, V., et al. (2010). Buprenorphine-related deaths: unusual forensic situations. *International Journal of Legal Medicine*. Advance online publication.
14. Pergolizzi, J., Pappagallo, M., Stauffer, J., et al. (2010). The Role of Urine Drug Testing for Patients on Opioid Therapy. *Pain Practice*. Advance online publication.
15. Ridgway, D., Sopata, M., Burneckis, A., Jespersen, L., Andersen, C. (2010). Clinical Efficacy and Safety of Once-Daily Dosing of a Novel, Prolonged-Release Oral Morphine Tablet Compared With Twice-Daily Dosing of a Standard Controlled-Release Morphine Tablet in Patients With Cancer Pain: A Randomized, Double-Blind, Exploratory Crossover Study. *Journal of Pain and Symptom Management*, 39(4), 712-720.
16. Shaheen, P.E., LeGrand, S.B. Walsh, D., et al. (2010). Errors in Opioid Prescribing: A Prospective Survey in Cancer Pain. *Journal of Pain and Symptom Management*, 39(4), 702-711.
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4.4.2. CONFERENCES

The following section presents a list of conferences related to pain management, prescription opioid abuse, risk management, and other pertinent topics. The conferences are organized chronologically.

September 2010

1. American Medical Association PAINWeek® 2010

Dates: 9/8/2010 to 9/11/2010

Location: Las Vegas, Nevada

2. American Academy of Pain Management

Dates: 9/21/2010 to 9/24/2010

Location: Las Vegas, Nevada

November 2010

1. National Association of Drug Diversion Investigators 21st Annual Conference

Dates: 11/16/2010 to 11/19/2010

Location: Indianapolis, Indiana

May 2011

1. American Pain Society (APS) Conference

Dates: 5/19/2011 to 5/21/2011

Location: Austin, Texas

June 2011

1. College on Problems of Drug Dependence (CPDD) Conference

Dates: 6/18/2011 to 6/23/2011

Location: Hollywood, Florida

2. Drug Information Association (DIA) Conference

Dates: 6/19/2011 to 6/23/2011

Location: Chicago, Illinois

VI. DISCUSSION

During the second quarter of 2010, there were 2,666 cases of prescription opioid abuse reported within the ASI-MV[®] Connect network. Of these reports, 34 individuals reported abusing KADIAN[®] within the 30 days prior to entering substance abuse treatment. These 34 individuals completed assessments from treatment centers located in the following ten states: Michigan (n=11), Missouri (n=8), Tennessee (n=6), Maryland (n=2), West Virginia (n=2), California (n=1), Kentucky (n=1), New Mexico (n=1), North Carolina (n=1), and Oklahoma (n=1). The highest rates of KADIAN[®] abuse during the current reporting quarter were reported from the Appalachian states of Kentucky (5.3 cases per 100 assessments) and Tennessee (1.9 cases per 100 assessments) as well as the bordering state of Missouri (1.2 cases per 100 assessments). These states also had relatively higher rates of prescription opioid abuse in general (57.9 cases, 38.5 cases, and 33.0 cases per 100 assessments for Kentucky, Tennessee, and Missouri, respectively).

In relation to the comparator products, the rate of KADIAN[®] abuse per 100 ASI-MV[®] Connect assessments (0.21 cases per 100 assessments) was lower than the rate of abuse for OxyContin[®], Vicodin[®] brand and generic products, MS Contin[®] brand and generic products, and Opana[®] ER; and higher than the rate of abuse of Duragesic[®] and AVINZA[®]. A similar pattern was also observed with respect to the rates of abuse per 100 prescription opioid abusers assessed. When considering for medical availability, however, the rate of KADIAN[®] abuse (per 100,000 prescriptions written) was greater than that of the other two morphine sulfate comparator products reviewed for this report (AVINZA[®], MS Contin[®] brand and generics). Furthermore, throughout the 12-month period corresponding with the current reporting quarter (July 2009 – June 2010), the monthly rate of KADIAN[®] abuse remained within established control limits and was less than one case per assessments.

Seven instances of prescription opioid abuse were reported within the CHAT[™] adolescent treatment center population during the current reporting quarter. Of these seven cases, three individuals reported past 30 day abuse of OxyContin[®], three individuals reported past 30 day abuse of Vicodin[®] brand and generic products, one individual reported past 30 day abuse of Opana[®] ER, and one individual reported past 30 day abuse of MS Contin[®] brand and generic products. There were no instances of past 30 day abuse of KADIAN[®], Duragesic[®], or AVINZA[®] reported during Q2 2010.

There were 61 KADIAN[®]-related posts written by 50 unique authors and contained within 48 distinct threads identified within the WIS[™] Internet monitoring archive during Q2 2010. During the current quarter, the level of discussion pertaining to KADIAN[®] continued to increase from the level of discussion observed during the previous three quarters (Q3 2009 through Q1 2010) and was statistically significantly greater than the level of discussion observed in Q3 2009. However, the level of discussion pertaining to KADIAN[®] remained statistically significantly lower than the three prescription opioid comparator products: OxyContin[®], Vicodin[®], and MS Contin[®]. The proportion of KADIAN[®]-related posts written during Q2 2010 that discussed KADIAN[®] in a general context decreased from levels observed during the previous three quarters (Q3 2009 – Q1 2010), coinciding with increases in the proportion of posts discussing routes of administration and negative consequences. The greatest proportion of KADIAN[®]-related posts written during Q2 2010 discussed routes of administration (52.2%) and of these posts injection was discussed with the greatest frequency (87.5% of all route of administration-related posts). KADIAN[®] was discussed in a general context with the next greatest frequency (29.5%), followed by discussion of extraction techniques

(24.6%), sources of procurement (16.4%), and negative consequences associated with the abuse of KADIAN[®] (16.4%).

There were no KADIAN[®]-related DEA media publications, general news media articles, or academic research articles published during Q2 2010 (n=0), and only one news article pertaining to KADIAN[®] and legislative activity/law enforcement (n=1) identified during the period. Thus, in general, media discussion of KADIAN[®] was limited during Q2 2010. Examination of the most recent available data from the FDA-AERS dataset through Q4 2009 indicated that there were two KADIAN[®]-suspected adverse event cases, one of which had an outcome listed as 'other' and the second of which had an outcome of hospitalization and death. PRR/EBGM values for KADIAN[®] revealed that, of the morphine products monitored, KADIAN[®] had the highest reported PRR/EBGM values available through Q4 2009.

Findings from the current NAVIPPRO[™] surveillance report suggest that, in comparison to other prescription opioid products reviewed, the level of KADIAN[®] abuse during Q2 2010 remained consistent with previous quarters; within the ASI-MV[®] Connect population the rate of KADIAN[®] abuse (per 100 assessments) was lower than OxyContin[®], Vicodin[®] brand and generic products, MS Contin[®] brand and generic products, and Opana[®] ER, and greater than Duragesic[®] and AVINZA[®]; there were no instances of KADIAN[®] abuse reported within the CHAT[™] network; and with respect to the WIS[™] Internet monitoring archive, KADIAN[®] was discussed less frequently than OxyContin[®], MS Contin[®] and Vicodin[®]. While the pattern of KADIAN[®] abuse observed within the ASI-MV[®] Connect population during Q2 2010 remained consistent in relation to the comparator products, the level of KADIAN[®] abuse reported was lower than the rate of abuse observed in the previous quarter. Likewise, the level of discussion within the WIS[™] Internet monitoring archive pertaining to routes of administration associated with KADIAN[®] increased during Q2 2010.

VII. REFERENCES

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APPENDIX A: GLOSSARY OF TERMS

Abuse: Defined as using a pharmaceutical product in a way not prescribed by a physician. In the ASI-MV® assessment, abuse is assessed by asking whether the patient has ever used a particular drug/product, and if the patient answers yes, asking, “On how many of these days did you use {drug name} in a way not prescribed by your doctor?” Any answer other than zero indicates abuse during the past 30 days.

Abuse rates: Ways of measuring the prevalence of abuse. There are many ways to describe prevalence of prescription opioid abuse, but three calculations used in this report are defined below. To be clear, the first two measures are proportions, where the numerator is a subset of the denominator and the value can range from 0 to 100%. The third measure represents a rate, which can range from 0 to infinity. Here, the numerator is a count of the number of people reporting abuse of a specific drug in the past 30 days over the one year reporting period, but the denominator is the total number of prescriptions written per one-year of unit time, or the total potentially-abusable (i.e., “at-risk”) prescriptions circulating in one year’s time. These values represent true rates and will be reported per unit time; they are not proportions. For ease of reading, however, this report will use the term “rate” to indicate any of the calculations defined below.

$$\begin{aligned}
 \text{Cases per 100 assessments} &= \frac{\text{Number of people who report using the drug non-medically in the past 30 days}}{\text{Total number of assessments}} *100 \\
 \text{Cases per 100 opioid abusers assessed} &= \frac{\text{Number of people who report using the drug non-medically in the past 30 days}}{\text{Number of people who report using any opioid non-medically in the past 30 days}} *100 \\
 \text{Cases per 100,000 Rx} &= \frac{\text{Number of people who report using the drug non-medically in the past 30 days}}{\text{Total number of prescriptions written for the drug}} *100,000
 \end{aligned}$$

ArcGIS: Software used for creating maps of data. This software is used to map ASI-MV® Connect surveillance data.

ASI-MV®: Abbreviation of Addiction Severity Index – Multimedia Version. A self-administered computer-based assessment given to patients entering addiction treatment, which provides an assessment of severity of employment, medical, legal, drug and alcohol use, psychiatric, and family/social problems.

Client: A person who takes the ASI-MV® Connect, often a patient who is entering substance abuse treatment; other sites also administer the ASI-MV® Connect, including DWI programs and state assistance offices/welfare programs.

Confidence interval (CI): If independent samples are taken repeatedly from the same population, and a mean is calculated for each sample, the confidence interval is a range within which 95% of the sample means would fall. In this way we can specify the degree of certainty that the true population mean is within the confidence interval. The width of the confidence interval reflects how well the estimate or the obtained mean is of the true mean. A very wide interval indicates that more data should be collected before definitive statements can be made.

Control limits: A term used in statistical process control analyses, indicating the “normal variance” of the data. The upper control limit is traditionally set at three standard deviations above the mean (+3SD), and the lower control limit is three standard deviations below the mean (-3SD). Observations that fall outside of the established control limits indicate a statistically abnormal measurement, which might indicate that the phenomenon being measured has changed from its historically normal limits.

Diversion: Any action which removes medication from the legal to illegal channels.

Drug Enforcement Agency (DEA): Federal agency charged with enforcing the controlled substances laws and regulations of the United States. The DEA brings to the United States criminal and civil justice system those organizations and principal members of organizations involved in the growing, manufacture, or distribution of controlled substances appearing in or destined for illicit traffic in the United States. It also recommends and supports non-enforcement programs aimed at reducing the availability of illicit controlled substances on the domestic and international markets. Data from the DEA used in this report include published special reports and news bulletins.

Empirical Bayes Geometric Mean (EBGM): This is a measurement that calculates the proportion of adverse events for a given product, compared to other selected products. It is a variation on proportional reporting rate (PRR) that addresses both statistical variability due to small sample size and multiple comparisons, by using a technique called “Bayesian shrinkage.”

Food and Drug Administration Adverse Event Reporting System (FDA-AERS): FDA-AERS is a database that provides comprehensive data on reports of adverse events associated with physician visits. This database allows for comparison of proportional reporting rates and empirical Bayes geometric means of adverse events among drugs.

Mean: The average, calculated as the sum of measurements, divided by the total number of measurements.

Medical Dictionary for Regulatory Activities (MedDRA): MedDRA is a medically-valid terminology utilized within the regulatory environment, developed by the International Conference on Harmonisation (ICH). The FDA-AERS system utilizes this terminology to code and report adverse event outcomes reported to them. The MedDRA terminology is owned by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA).

Misused drug: Defined as taking a prescription not as prescribed, but without the intention of achieving mood-altering effects; for example, mistakenly taking two pills instead of one. This term is used to differentiate user intent as either unintentional (misused) or intentional (abused).

Prescription opioid abuser: Any patient who uses prescription opioids for mood-altering effects. Abuse is defined by the ASI-MV® assessment as anyone who admits using a prescription opioid product in a way not prescribed by a physician.

Proportional Reporting Rate (PRR): The PRR is a statistical approach that can be used to determine whether the proportion of specified reactions for drugs of interest exceed what might be expected as a result of chance and possible background noise due to variable reporting (Evans, et al. 2001). The PRR calculates the proportion of reactions for a drug where the comparator is all other drugs in the database. This statistic is similar to that of a relative risk in epidemiology. PRRs are used in pharmacovigilance to detect possible signals of spontaneous adverse events.

Rx: Abbreviation for “prescription.”

Site or treatment site: A discrete address at which the ASI-MV® Connect is administered, such as a drug treatment center, DWI center, probation office, etc.

Standard deviation (SD): A measure of variability in a sample of data. Standard deviation is calculated as the square root of the variance.

Statistical Process Control (SPC): A statistical methodology that was originally developed to monitor ongoing quality in manufacturing, by taking measurements of products, and watching for products manufactured outside of acceptable limits. More recently, these statistical methods have been applied to any situation in which continuous monitoring of data is necessary. SPC analyzes the average variability of a phenomenon, and calculates whether future observations are within or outside of normal limits.

APPENDIX B: RATES OF ABUSE BY STATE AND TREATMENT FACILITY WITHIN THE ASI-MV[®] CONNECT TREATMENT CENTER POPULATION

State	Site ID Number	Site Zip Code	Total Assessments	Prescription Opioid Abusers Assessed	KADIAN [®] Abusers Assessed	Prescription Opioid Abuse / 100 Assessments	KADIAN [®] Abuse / 100 Assessments	KADIAN [®] Abuse / 100,000 Prescriptions
AL	Whole State	N/A	82	11	0	13.4	0.0	0.0
	1	35802	82	11	0	13.4	0.0	0.0
CA	Whole State	N/A	707	145	1	20.5	0.1	5.7
	1	92103	22	4	0	18.2	0.0	0.0
	3	95204	53	19	0	35.8	0.0	0.0
	4	95205	22	9	0	40.9	0.0	0.0
	5	92311	56	10	0	17.9	0.0	0.0
	7	92314	33	4	0	12.1	0.0	0.0
	10	92504	79	7	0	8.9	0.0	0.0
	12	92220	41	4	0	9.8	0.0	0.0
	13	92501	86	31	0	36.0	0.0	0.0
	16	92506	16	2	0	12.5	0.0	0.0
	17	92252	12	2	0	16.7	0.0	0.0
	18	92252	40	10	1	25.0	2.5	5.7
	19	92284	17	2	0	11.8	0.0	0.0
	20	92025	111	18	0	16.2	0.0	0.0
	21	92501	24	5	0	20.8	0.0	0.0
	22	96101	1	0	0	0.0	0.0	0.0
	25	92571	52	5	0	9.6	0.0	0.0
	26	92506	8	1	0	12.5	0.0	0.0
	27	92210	30	10	0	33.3	0.0	0.0
	28	91941	3	1	0	33.3	0.0	0.0
	29	92531	1	1	0	100.0	0.0	0.0
CO	Whole State	N/A	559	68	0	12.2	0.0	0.0
	2	80905	52	6	0	11.5	0.0	0.0

State	Site ID Number	Site Zip Code	Total Assessments	Prescription Opioid Abusers Assessed	KADIAN® Abusers Assessed	Prescription Opioid Abuse / 100 Assessments	KADIAN® Abuse / 100 Assessments	KADIAN® Abuse / 100,000 Prescriptions
	3	81001	95	24	0	25.3	0.0	0.0
	6	80214	54	1	0	1.9	0.0	0.0
	7	80233	29	2	0	6.9	0.0	0.0
	8	80202	67	4	0	6.0	0.0	0.0
	9	80011	33	4	0	12.1	0.0	0.0
	10	81008	2	1	0	50.0	0.0	0.0
	11	81008	84	14	0	16.7	0.0	0.0
	12	81004	10	1	0	10.0	0.0	0.0
	13	81082	11	1	0	9.1	0.0	0.0
	14	81101	19	3	0	15.8	0.0	0.0
	17	81008	31	1	0	3.2	0.0	0.0
	19	81089	6	0	0	0.0	0.0	0.0
	20	80903	16	1	0	6.3	0.0	0.0
	23	80226	6	0	0	0.0	0.0	0.0
	24	81003	44	5	0	11.4	0.0	0.0
DC	Whole State	N/A	133	3	0	2.3	0.0	0.0
	1	20018	53	0	0	0.0	0.0	0.0
	3	20020	25	0	0	0.0	0.0	0.0
	4	20001	55	3	0	5.5	0.0	0.0
FL	Whole State	N/A	194	13	0	6.7	0.0	0.0
	5	34744	134	7	0	5.2	0.0	0.0
	11	32805	15	2	0	13.3	0.0	0.0
	14	32808	30	0	0	0.0	0.0	0.0
	17	32805	8	1	0	12.5	0.0	0.0
	18	32803	7	3	0	42.9	0.0	0.0
GA	Whole State	N/A	18	0	0	0.0	0.0	0.0
	1	30052	5	0	0	0.0	0.0	0.0
	5	30909	1	0	0	0.0	0.0	0.0
	7	30090	12	0	0	0.0	0.0	0.0

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HI	Whole State	N/A	38	5	0	13.2	0.0	0.0
	1	96813	27	3	0	11.1	0.0	0.0
	2	96741	11	2	0	18.2	0.0	0.0
KS	Whole State	N/A	289	23	0	8.0	0.0	0.0
	2	67401	128	11	0	8.6	0.0	0.0
	3	67410	17	1	0	5.9	0.0	0.0
	4	66441	39	1	0	2.6	0.0	0.0
	5	67460	43	1	0	2.3	0.0	0.0
	6	66901	56	9	0	16.1	0.0	0.0
	7	67701	6	0	0	0.0	0.0	0.0
KY	Whole State	N/A	19	11	1	57.9	5.3	39.6
	1	41339	19	11	1	57.9	5.3	39.6
LA	Whole State	N/A	360	40	0	11.1	0.0	0.0
	3	71360	62	1	0	1.6	0.0	0.0
	5	70112	154	7	0	4.5	0.0	0.0
	6	70068	72	15	0	20.8	0.0	0.0
	8	70058	21	0	0	0.0	0.0	0.0
	9	70726	43	15	0	34.9	0.0	0.0
	11	71112	8	2	0	25.0	0.0	0.0
MA	Whole State	N/A	21	7	0	33.3	0.0	0.0
	12	02127	11	3	0	27.3	0.0	0.0
	13	02127	9	3	0	33.3	0.0	0.0
	15	02127	1	1	0	100.0	0.0	0.0
MD	Whole State	N/A	1203	244	2	20.3	0.2	73.8
	4	21230	75	12	0	16.0	0.0	0.0
	5	21613	109	12	0	11.0	0.0	0.0
	9	21214	88	9	0	10.2	0.0	0.0

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	16	21921	138	30	0	21.7	0.0	0.0
	18	21215	411	111	0	27.0	0.0	0.0
	21	20746	88	6	0	6.8	0.0	0.0
	22	20695	48	7	0	14.6	0.0	0.0
	23	20785	25	2	0	8.0	0.0	0.0
	25	21501	66	15	0	22.7	0.0	0.0
	27	21501	48	13	1	27.1	2.1	36.9
	28	21502	42	13	0	31.0	0.0	0.0
	29	20740	23	1	0	4.3	0.0	0.0
	33	20650	9	3	0	33.3	0.0	0.0
	34	21502	33	10	1	30.3	3.0	36.9
MI	Whole State	N/A	1282	285	11	22.2	0.9	317.3
	1	49721	38	8	0	21.1	0.0	0.0
	2	49735	63	8	0	12.7	0.0	0.0
	5	48624	35	10	0	28.6	0.0	0.0
	6	48640	48	15	0	31.3	0.0	0.0
	7	48858	59	26	1	44.1	1.7	28.8
	8	48858	31	5	0	16.1	0.0	0.0
	11	49420	11	1	0	9.1	0.0	0.0
	12	49431	23	6	0	26.1	0.0	0.0
	13	49307	2	0	0	0.0	0.0	0.0
	15	49707	63	8	0	12.7	0.0	0.0
	16	49601	89	8	0	9.0	0.0	0.0
	17	49721	23	3	0	13.0	0.0	0.0
	18	49686	130	8	1	6.2	0.8	28.8
	19	49738	32	9	0	28.1	0.0	0.0
	20	49721	26	3	0	11.5	0.0	0.0
	21	49770	37	8	0	21.6	0.0	0.0
	22	49770	48	25	1	52.1	2.1	28.8
	23	49684	70	23	2	32.9	2.9	57.7
	24	49707	56	20	1	35.7	1.8	28.8

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	25	48617	44	6	0	13.6	0.0	0.0
	27	49304	10	3	0	30.0	0.0	0.0
	28	48750	30	6	1	20.0	3.3	28.8
	31	48340	71	5	0	7.0	0.0	0.0
	32	48640	24	9	0	37.5	0.0	0.0
	33	49686	46	11	0	23.9	0.0	0.0
	34	49684	55	26	4	47.3	7.3	115.4
	36	48342	53	10	0	18.9	0.0	0.0
	37	49307	34	6	0	17.6	0.0	0.0
	38	48640	5	1	0	20.0	0.0	0.0
	41	48858	10	5	0	50.0	0.0	0.0
	42	48329	16	3	0	18.8	0.0	0.0
MN	Whole State	N/A	9	0	0	0.0	0.0	0.0
	1	55454	9	0	0	0.0	0.0	0.0
MO	Whole State	N/A	694	229	8	33.0	1.2	263.2
	3	63857	3	0	0	0.0	0.0	0.0
	4	64735	152	52	0	34.2	0.0	0.0
	5	64093	91	25	1	27.5	1.1	32.9
	6	65560	107	52	2	48.6	1.9	65.8
	9	65560	24	7	1	29.2	4.2	32.9
	11	63901	59	26	3	44.1	5.1	98.7
	12	65052	62	24	0	38.7	0.0	0.0
	13	65203	11	2	0	18.2	0.0	0.0
	14	63640	66	28	1	42.4	1.5	32.9
	15	64086	75	9	0	12.0	0.0	0.0
	16	65401	44	4	0	9.1	0.0	0.0
NC	Whole State	N/A	2749	300	1	10.9	0.04	41.7
	1	27534	5	2	0	40.0	0.0	0.0
	3	27959	58	15	0	25.9	0.0	0.0

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	4	28560	116	21	0	18.1	0.0	0.0
	8	28349	19	2	0	10.5	0.0	0.0
	9	28585	5	0	0	0.0	0.0	0.0
	10	28501	76	7	0	9.2	0.0	0.0
	11	27845	9	0	0	0.0	0.0	0.0
	12	27839	32	2	0	6.3	0.0	0.0
	13	27530	118	11	0	9.3	0.0	0.0
	14	28540	75	7	0	9.3	0.0	0.0
	15	27889	39	5	0	12.8	0.0	0.0
	16	28328	37	4	0	10.8	0.0	0.0
	17	28112	2	0	0	0.0	0.0	0.0
	18	28425	28	3	0	10.7	0.0	0.0
	19	28557	55	7	0	12.7	0.0	0.0
	20	27892	43	2	0	4.7	0.0	0.0
	21	27856	62	6	0	9.7	0.0	0.0
	22	27886	36	3	0	8.3	0.0	0.0
	23	28580	18	3	0	16.7	0.0	0.0
	24	28302	291	28	0	9.6	0.0	0.0
	26	27701	83	7	0	8.4	0.0	0.0
	27	28412	279	29	0	10.4	0.0	0.0
	28	27701	84	9	0	10.7	0.0	0.0
	30	28422	44	7	0	15.9	0.0	0.0
	31	27601	192	14	0	7.3	0.0	0.0
	32	27983	24	0	0	0.0	0.0	0.0
	33	27909	31	6	0	19.4	0.0	0.0
	34	27375	19	5	0	26.3	0.0	0.0
	36	27516	42	2	0	4.8	0.0	0.0
	37	27295	6	3	0	50.0	0.0	0.0
	38	28025	28	8	0	28.6	0.0	0.0
	39	27101	214	23	1	10.7	0.5	41.7
	40	27834	123	12	0	9.8	0.0	0.0
	41	27954	35	6	0	17.1	0.0	0.0

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	42	27401	83	3	0	3.6	0.0	0.0
	43	28144	25	5	0	20.0	0.0	0.0
	44	27546	21	1	0	4.8	0.0	0.0
	45	27589	2	1	0	50.0	0.0	0.0
	46	27253	20	4	0	20.0	0.0	0.0
	48	28697	32	8	0	25.0	0.0	0.0
	49	27055	4	0	0	0.0	0.0	0.0
	50	27932	10	1	0	10.0	0.0	0.0
	51	27262	60	5	0	8.3	0.0	0.0
	52	28677	10	0	0	0.0	0.0	0.0
	55	27017	1	0	0	0.0	0.0	0.0
	57	27858	1	0	0	0.0	0.0	0.0
	58	28327	12	0	0	0.0	0.0	0.0
	61	28376	14	2	0	14.3	0.0	0.0
	62	28170	21	0	0	0.0	0.0	0.0
	63	27801	16	3	0	18.8	0.0	0.0
	64	27986	20	0	0	0.0	0.0	0.0
	70	28640	7	0	0	0.0	0.0	0.0
	71	27028	1	0	0	0.0	0.0	0.0
	72	27893	32	4	0	12.5	0.0	0.0
	74	28677	4	1	0	25.0	0.0	0.0
	76	28681	5	0	0	0.0	0.0	0.0
	81	27203	18	3	0	16.7	0.0	0.0
	84	27520	2	0	0	0.0	0.0	0.0
NE	Whole State	N/A	84	6	0	7.1	0.0	0.0
	1	68803	60	5	0	8.3	0.0	0.0
	2	68510	9	0	0	0.0	0.0	0.0
	3	68144	15	1	0	6.7	0.0	0.0
NH	Whole State	N/A	3	0	0	0.0	0.0	0.0
	2	03303	3	0	0	0.0	0.0	0.0

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NM	Whole State	N/A	4832	629	1	13.0	0.02	311.5
	1	87507	27	3	0	11.1	0.0	0.0
	2	87102	14	3	0	21.4	0.0	0.0
	4	87401	49	2	0	4.1	0.0	0.0
	5	87571	95	15	0	15.8	0.0	0.0
	7	87024	11	0	0	0.0	0.0	0.0
	8	87113	54	5	0	9.3	0.0	0.0
	9	87505	1	0	0	0.0	0.0	0.0
	10	88004	160	15	0	9.4	0.0	0.0
	11	87801	34	3	0	8.8	0.0	0.0
	12	88101	203	21	0	10.3	0.0	0.0
	13	87110	440	115	0	26.1	0.0	0.0
	14	88240	54	12	0	22.2	0.0	0.0
	16	87106	374	68	0	18.2	0.0	0.0
	17	88130	38	1	0	2.6	0.0	0.0
	18	88401	54	12	0	22.2	0.0	0.0
	19	87501	86	15	0	17.4	0.0	0.0
	20	88310	219	25	0	11.4	0.0	0.0
	22	87901	14	1	0	7.1	0.0	0.0
	23	87301	50	2	0	4.0	0.0	0.0
	24	87102	21	2	0	9.5	0.0	0.0
	25	87301	4	0	0	0.0	0.0	0.0
	26	87004	105	4	0	3.8	0.0	0.0
	28	87305	20	0	0	0.0	0.0	0.0
	29	88202	85	11	1	12.9	1.2	311.5
	31	87701	1	0	0	0.0	0.0	0.0
	32	88435	23	4	0	17.4	0.0	0.0
	33	87108	59	4	0	6.8	0.0	0.0
	34	87504	181	16	0	8.8	0.0	0.0
	36	87505	23	6	0	26.1	0.0	0.0
	37	87031	9	0	0	0.0	0.0	0.0

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	39	87552	1	0	0	0.0	0.0	0.0
	40	88220	68	7	0	10.3	0.0	0.0
	41	87102	90	13	0	14.4	0.0	0.0
	43	87031	57	7	0	12.3	0.0	0.0
	44	88061	73	9	0	12.3	0.0	0.0
	45	88030	33	7	0	21.2	0.0	0.0
	48	88061	53	5	0	9.4	0.0	0.0
	49	88220	24	3	0	12.5	0.0	0.0
	51	87124	64	10	0	15.6	0.0	0.0
	52	88001	261	27	0	10.3	0.0	0.0
	55	87732	4	0	0	0.0	0.0	0.0
	58	87571	22	2	0	9.1	0.0	0.0
	61	87571	69	10	0	14.5	0.0	0.0
	62	88345	49	6	0	12.2	0.0	0.0
	63	87016	10	0	0	0.0	0.0	0.0
	64	87031	76	8	0	10.5	0.0	0.0
	66	87108	66	5	0	7.6	0.0	0.0
	70	87532	31	7	0	22.6	0.0	0.0
	72	87701	55	7	0	12.7	0.0	0.0
	73	87020	44	4	0	9.1	0.0	0.0
	74	87107	73	0	0	0.0	0.0	0.0
	78	88415	6	0	0	0.0	0.0	0.0
	79	87740	28	3	0	10.7	0.0	0.0
	80	88220	18	2	0	11.1	0.0	0.0
	81	87533	1	0	0	0.0	0.0	0.0
	82	87323	1	0	0	0.0	0.0	0.0
	83	87701	62	6	0	9.7	0.0	0.0
	84	87701	1	0	0	0.0	0.0	0.0
	85	87566	19	2	0	10.5	0.0	0.0
	88	74145	94	16	0	17.0	0.0	0.0
	89	88220	162	16	0	9.9	0.0	0.0
	90	87401	36	2	0	5.6	0.0	0.0

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	92	87401	15	3	0	20.0	0.0	0.0
	93	87402	168	19	0	11.3	0.0	0.0
	94	88210	11	1	0	9.1	0.0	0.0
	96	88310	133	17	0	12.8	0.0	0.0
	97	87532	16	4	0	25.0	0.0	0.0
	98	87016	1	0	0	0.0	0.0	0.0
	101	88021	47	4	0	8.5	0.0	0.0
	102	88030	39	2	0	5.1	0.0	0.0
	104	87110	28	0	0	0.0	0.0	0.0
	106	87401	33	4	0	12.1	0.0	0.0
	108	87701	5	0	0	0.0	0.0	0.0
	110	87401	12	1	0	8.3	0.0	0.0
	112	87124	2	0	0	0.0	0.0	0.0
	113	88300	24	3	0	12.5	0.0	0.0
	115	87301	1	0	0	0.0	0.0	0.0
	118	88220	6	0	0	0.0	0.0	0.0
	119	88240	10	2	0	20.0	0.0	0.0
	122	87401	13	1	0	7.7	0.0	0.0
	123	87031	66	10	0	15.2	0.0	0.0
	124	87031	38	7	0	18.4	0.0	0.0
	125	88203	2	1	0	50.0	0.0	0.0
	126	88045	1	0	0	0.0	0.0	0.0
	127	87102	1	1	0	100.0	0.0	0.0
	128	87035	1	0	0	0.0	0.0	0.0
NV	Whole State	N/A	15	9	0	60.0	0.0	0.0
	1	89129	15	9	0	60.0	0.0	0.0
NY	Whole State	N/A	78	17	0	21.8	0.0	0.0
	3	10032	34	7	0	20.6	0.0	0.0
	6	13827	3	0	0	0.0	0.0	0.0
	7	10940	41	10	0	24.4	0.0	0.0

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OH	Whole State	N/A	41	3	0	7.3	0.0	0.0
	1	44902	19	1	0	5.3	0.0	0.0
	2	44266	21	2	0	9.5	0.0	0.0
	4	45662	1	0	0	0.0	0.0	0.0
OK	Whole State	N/A	1343	91	1	6.8	0.07	18.4
	6	73069	288	28	1	9.7	0.3	18.4
	10	74135	6	0	0	0.0	0.0	0.0
	11	74820	57	2	0	3.5	0.0	0.0
	15	73134	4	0	0	0.0	0.0	0.0
	16	73069	10	0	0	0.0	0.0	0.0
	17	73116	13	0	0	0.0	0.0	0.0
	18	74354	74	2	0	2.7	0.0	0.0
	19	74868	3	0	0	0.0	0.0	0.0
	20	73601	7	0	0	0.0	0.0	0.0
	24	74017	21	2	0	9.5	0.0	0.0
	25	74066	60	5	0	8.3	0.0	0.0
	26	74105	328	16	0	4.9	0.0	0.0
	29	73772	1	0	0	0.0	0.0	0.0
	31	73129	2	0	0	0.0	0.0	0.0
	32	73105	1	0	0	0.0	0.0	0.0
	34	74003	18	0	0	0.0	0.0	0.0
	36	73105	30	1	0	3.3	0.0	0.0
	37	74074	22	4	0	18.2	0.0	0.0
	38	74074	143	2	0	1.4	0.0	0.0
	41	74653	19	0	0	0.0	0.0	0.0
	42	74653	58	10	0	17.2	0.0	0.0
	43	74801	3	0	0	0.0	0.0	0.0
	44	73109	3	0	0	0.0	0.0	0.0
	45	74801	10	1	0	10.0	0.0	0.0
	46	73019	11	0	0	0.0	0.0	0.0

State	Site ID Number	Site Zip Code	Total Assessments	Prescription Opioid Abusers Assessed	KADIAN® Abusers Assessed	Prescription Opioid Abuse / 100 Assessments	KADIAN® Abuse / 100 Assessments	KADIAN® Abuse / 100,000 Prescriptions
	47	74820	21	7	0	33.3	0.0	0.0
	48	73080	9	2	0	22.2	0.0	0.0
	49	73127	30	0	0	0.0	0.0	0.0
	50	74578	8	1	0	12.5	0.0	0.0
	51	73118	23	2	0	8.7	0.0	0.0
	52	74462	10	2	0	20.0	0.0	0.0
	53	74074	42	1	0	2.4	0.0	0.0
	54	73701	7	3	0	42.9	0.0	0.0
	55	74105	1	0	0	0.0	0.0	0.0
OR	Whole State	N/A	217	38	0	17.5	0.0	0.0
	3	97208	217	38	0	17.5	0.0	0.0
PA	Whole State	N/A	22	1	0	4.5	0.0	0.0
	2	19141	6	0	0	0.0	0.0	0.0
	5	19124	16	1	0	6.3	0.0	0.0
SC	Whole State	N/A	39	11	0	28.2	0.0	0.0
	2	29607	39	11	0	28.2	0.0	0.0
TN	Whole State	N/A	316	120	6	38.0	1.9	75.6
	12	37083	2	0	0	0.0	0.0	0.0
	16	37206	3	2	0	66.7	0.0	0.0
	17	38462	73	39	1	53.4	1.4	12.6
	19	37206	3	0	0	0.0	0.0	0.0
	21	37091	76	47	3	61.8	3.9	37.8
	22	37083	19	5	0	26.3	0.0	0.0
	24	37166	14	4	0	28.6	0.0	0.0
	25	37040	22	5	1	22.7	4.5	12.6
	26	37130	102	18	1	17.6	1.0	12.6
	28	37311	1	0	0	0.0	0.0	0.0
	29	37303	1	0	0	0.0	0.0	0.0

State	Site ID Number	Site Zip Code	Total Assessments	Prescription Opioid Abusers Assessed	KADIAN® Abusers Assessed	Prescription Opioid Abuse / 100 Assessments	KADIAN® Abuse / 100 Assessments	KADIAN® Abuse / 100,000 Prescriptions	
TX	Whole State	N/A	94	6	0	6.4	0.0	0.0	
	1	75156	92	6	0	6.5	0.0	0.0	
	2	75110	2	0	0	0.0	0.0	0.0	
UT	Whole State	N/A	20	2	0	10.0	0.0	0.0	
	1	84405	19	2	0	10.5	0.0	0.0	
	3	84107	1	0	0	0.0	0.0	0.0	
VA	Whole State	N/A	4	0	0	0.0	0.0	0.0	
	3	23504	4	0	0	0.0	0.0	0.0	
VT	Whole State	N/A	460	105	0	22.8	0.0	0.0	
	2	05661	34	8	0	23.5	0.0	0.0	
	3	05401	108	12	0	11.1	0.0	0.0	
	5	05401	78	27	0	34.6	0.0	0.0	
	7	05401	10	8	0	80.0	0.0	0.0	
	8	05641	102	26	0	25.5	0.0	0.0	
	9	05156	3	0	0	0.0	0.0	0.0	
	10	05302	65	19	0	29.2	0.0	0.0	
	11	05401	57	3	0	5.3	0.0	0.0	
	13	05088	3	2	0	66.7	0.0	0.0	
	WV	Whole State	N/A	335	211	2	63.0	0.6	161.6
		1	25703	153	97	1	63.4	0.7	80.8
		2	25064	166	101	1	60.8	0.6	80.8
3		25701	16	13	0	81.3	0.0	0.0	
WY	Whole State	N/A	311	33	0	10.6	0.0	0.0	
	4	82001	19	0	0	0.0	0.0	0.0	
	5	82001	26	5	0	19.2	0.0	0.0	
	6	82072	48	2	0	4.2	0.0	0.0	
	8	82003	114	15	0	13.2	0.0	0.0	

State	Site ID Number	Site Zip Code	Total Assessments	Prescription Opioid Abusers Assessed	KADIAN® Abusers Assessed	Prescription Opioid Abuse / 100 Assessments	KADIAN® Abuse / 100 Assessments	KADIAN® Abuse / 100,000 Prescriptions
	10	82801	33	2	0	6.1	0.0	0.0
	11	82801	43	8	0	18.6	0.0	0.0
	12	82637	24	0	0	0.0	0.0	0.0
	13	82001	3	0	0	0.0	0.0	0.0
	14	82801	1	1	0	100.0	0.0	0.0

APPENDIX C: RATES OF ABUSE BY STATE AND TREATMENT FACILITY WITHIN THE CHAT™
TREATMENT CENTER POPULATION

State	Site ID Number	Site Zip Code	Total Assessments	Prescription Opioid Abusers Assessed	KADIAN® Abusers Assessed	Prescription Opioid Abuse / 100 Assessments	KADIAN® Abuse / 100 Assessments	KADIAN® Abuse / 100,000 Prescriptions
CA	Whole State	N/A	6	0	0	0.0	0.0	0.0
	2	92315	6	0	0	0.0	0.0	0.0
FL	Whole State	N/A	1	0	0	0.0	0.0	0.0
	3	34744	1	0	0	0.0	0.0	0.0
HI	Whole State	N/A	9	1	0	11.1	0.0	0.0
	1	96813	7	0	0	0.0	0.0	0.0
	2	96741	2	1	0	50.0	0.0	0.0
MI	Whole State	N/A	41	3	0	7.3	0.0	0.0
	3	49684	3	0	0	0.0	0.0	0.0
	4	49721	1	0	0	0.0	0.0	0.0
	5	49721	10	0	0	0.0	0.0	0.0
	7	49735	5	0	0	0.0	0.0	0.0
	8	49307	2	1	0	50.0	0.0	0.0
	9	48640	1	0	0	0.0	0.0	0.0
	10	48858	1	0	0	0.0	0.0	0.0
	11	48624	4	1	0	25.0	0.0	0.0
	12	49707	4	0	0	0.0	0.0	0.0
	14	49601	5	0	0	0.0	0.0	0.0
	16	48617	2	0	0	0.0	0.0	0.0
	17	48858	1	1	0	100.0	0.0	0.0
NJ	18	49738	1	0	0	0.0	0.0	0.0
	19	49431	1	0	0	0.0	0.0	0.0
NJ	Whole State	N/A	4	1	0	25.0	0.00	0.0

State	Site ID Number	Site Zip Code	Total Assessments	Prescription Opioid Abusers Assessed	KADIAN® Abusers Assessed	Prescription Opioid Abuse / 100 Assessments	KADIAN® Abuse / 100 Assessments	KADIAN® Abuse / 100,000 Prescriptions
	1	08225	4	1	0	25.0	0.0	0.0
NM	Whole State	N/A	18	0	0	0.0	0.00	0.0
	4	87801	3	0	0	0.0	0.0	0.0
	7	88240	9	0	0	0.0	0.0	0.0
	11	88045	1	0	0	0.0	0.0	0.0
	14	88061	2	0	0	0.0	0.0	0.0
	16	87701	1	0	0	0.0	0.0	0.0
	18	87124	1	0	0	0.0	0.0	0.0
	21	87571	1	0	0	0.0	0.0	0.0
NY	Whole State	N/A	26	2	0	7.7	0.0	0.0
	1	10940	26	2	0	7.7	0.0	0.0
OK	Whole State	N/A	3	0	0	0.0	0.00	0.0
	2	74066	3	0	0	0.0	0.0	0.0
UT	Whole State	N/A	1	0	0	0.0	0.0	0.0
	1	84405	1	0	0	0.0	0.0	0.0
VT	Whole State		34	0	0	0.0	0.0	0.0
	1	05661	2	0	0	0.0	0.0	0.0
	2	05641	11	0	0	0.0	0.0	0.0
	3	05401	19	0	0	0.0	0.0	0.0
	4	05302	2	0	0	0.0	0.0	0.0

APPENDIX D: MEDIA MONITORING ARTICLES

General Media News

April 2010

1. Allen W, 'Prescription Drug Abuse Declared Public Health Emergency In Scioto County,' The Community Common, 4/4/2010
 - Web Address: http://communitycommon.com/view/full_story/6914252/article-Prescription-Drug-Abuse-Declared-Public-Health-Emergency-In-Scioto-County?instance=home_news_lead
 - Drugs: general opioid
 - Subjects: Misuse/Abuse, Overdose
2. Bevins E & McIntosh J, 'Task force to give painkillers more attention,' Parkersburg News and Sentinel, 4/5/2010
 - Web Address: <http://www.newsandsentinel.com/page/content.detail/id/528425.html?nav=5061>
 - Drugs: general
 - Subjects: Misuse/Abuse, Overdose, Adolescent/Teen
3. 'Brown Details Corey Haim's "Doctus Pills and Efforts to Crack Down on Prescription Drug Abuse,' Imperial Valley Weekly, 4/6/2010
 - Web Address: <http://tribwekchron.com/2010/04/brown-details-corey-haims-doctus-pills-and-efforts-to-crack-down-on-prescription-drug-abuse/>
 - Drugs: Vicodin
 - Subjects: Misuse/Abuse, Overdose
4. Elliott B, 'Worst drug pusher might be our medicine cabinets,' Marin Independent Journal, 4/4/2010
 - Web Address: http://www.marinij.com/lifestyles/ci_14819866
 - Drugs: Vicodin, OxyContin, general opioid
 - Subjects: Misuse/Abuse, Overdose, Adolescent/Teen
5. Feals J, 'Risky behavior: Bullying, Rx abuse,' Seacoastonline.com, 4/4/2010
 - Web Address: <http://www.seacoastonline.com/articles/20100404-NEWS-4040329>
 - Drugs: OxyContin, Percocet, Vicodin,
 - Subjects: Misuse/Abuse, Adolescent/Teen
6. Hendricks B, 'Gender Gap in Prescription Pain Drug Abuse: Study Shows Men and Women Have Different Risk Factors for Abuse of Prescription Painkillers,' 4/29/2010
 - Web Address: <http://www.webmd.com/mental-health/news/20100429/gender-gap-in-risk-of-rx-pain-drug-abuse>
 - Drugs: general opioid
 - Subjects: Misuse/Abuse
7. Levi I, 'Chronic Pain Meds: Creating New Addicts Every Day in NJ,' LocalTalkNews.com, 4/17/2010
 - Web Address: <http://localtalknews.com/opinion/letters/278-sunrise-detox-stirling-painkillers-drug-abuse-addiction-detox>
 - Drugs: general opioid
 - Subjects: Misuse/Abuse, Addiction, Treatment
8. Maugh II TH, 'Mortimer Sackler dies at 93; arts patron was co-owner of Purdue Pharma,' Chicago Tribune, 4/19/2010
 - Web Address: <http://www.chicagotribune.com/news/nationworld/la-me-mortimer-sackler19-2010apr19,0,3052794.story>
 - Drugs: OxyContin
 - Subjects: Pain Management, Misuse/Abuse, Addiction

9. 'Mother describes losing child to prescription drug abuse,' The Mercury, 4/16/2010
 - Web Address: <http://www.pottstownmercury.com/articles/2010/04/16/news/doc4bc87346734de603530865.txt>
 - Drugs: Vicodin, OxyContin, general opioid
 - Subjects: Misuse/Abuse, Overdose
10. Mozes A, 'Prescription Drug Abuse Sending More to Hospitals,' US News and World Report, 4/6/2010
 - Web Address: <http://www.usnews.com/health/family-health/pain/articles/2010/04/06/prescription-drug-abuse-sending-more-to-hospitals.html>
 - Drugs: Vicodin, Percocet, general opioid
 - Subjects: Pain Management, Misuse/Abuse, Overdose
11. Rolland M, 'Oklahoma looks for answers on teen painkiller abuse,' NewsOK.com, 4/15/2010
 - Web Address: http://www.newsok.com/oklahoma-looks-for-answers-on-teen-painkiller-abuse/article/3454016?custom_click=pod_headline_politics
 - Drugs: hydrocodone, oxycodone, Lortab, Percocet, general opioid
 - Subjects: Misuse/Abuse, Adolescent/Teen, Prevention, Pain Management
12. Rutledge M, 'Prescription drug deaths on the rise,' Cincinnati.com, 4/19/2010
 - Web Address: <http://news.cincinnati.com/article/20100419/NEWS0103/4180394/Drug+deaths+on+the+rise>
 - Drugs: general opioid
 - Subjects: Misuse/Abuse, Overdose
13. Silva C, 'State expecting record number of drug deaths,' The Oklahoma Daily, 4/15/2010
 - Web Address: <http://www.oudaily.com/news/2010/apr/15/state-expecting-record-number-drug-deaths/>
 - Drugs: hydrocodone, oxycodone, general opioid
 - Subjects: Misuse/Abuse, Overdose
14. 'Strickland: State to fight prescription drug abuse,' Lancaster Eagle Gazette, 4/2/2010
 - Web Address: <http://www.lancastereaglegazette.com/article/20100402/NEWS01/4020302>
 - Drugs: general opioid
 - Subjects: Misuse/Abuse, Prevention

May 2010

1. 'Autopsy confirms overdose in Huneycutt case,' BlueRidgeNow.com, 5/18/2010
 - Web Address: <http://www.blueridgenow.com/article/20100519/ARTICLES/5191012/1042>
 - Drugs: oxymorphone
 - Subjects: Misuse/Abuse, Addiction, Overdose
2. Brogadir J, 'Prescription drugs and teenagers: Stories of relapse, and recovery,' NECN, 5/18/2010
 - Web Address: <http://www.necn.com/05/18/10/Prescription-drugs-and-teenagers-Stories/landing.html?blockID=237289&feedID=4215>
 - Drugs: OxyContin, Vicodin, Percocet, general opioid
 - Subjects: Misuse/Abuse, Addiction, Treatment
3. Burgin S, 'WLKY Investigates: Methadone Use In Louisville,' WLKY.com, 5/20/2010
 - Web Address: <http://www.wlky.com/news/23623350/detail.html>
 - Drugs: methadone, general opioid
 - Subjects: Misuse/Abuse, Addiction, Treatment, Overdose
4. 'EXALGO™ Provides 24-Hour Management of Moderate-to-Severe Chronic Pain,' Monthly Prescribing Reference, 5/7/2010

- Web Address: <http://www.empr.com/exalgo-provides-24-hour-management-of-moderate-to-severe-chronic-pain/article/169709/>
 - Drugs: Exalgo
 - Subjects: Pain Management
5. 'Formulating Opioids to Deter Abuse Remains a Challenge,' Monthly Prescribing Reference, 5/8/2010
- Web Address: <http://www.empr.com/formulating-opioids-to-deter-abuse-remains-a-challenge/article/169777/>
 - Drugs: hydrocodone, oxycodone, morphine, fentanyl, methadone, hydromorphone, general opioid
 - Subjects: Misuse/Abuse, Prevention, Pain Management
6. Foster J, 'Officials: Local teens' misuse of medications near crisis,' The Herald, 5/21/2010
- Web Address: <http://www.heraldonline.com/2010/05/21/2185309/officials-local-teens-misuse-of.html>
 - Drugs: general opioid
 - Subjects: Misuse/Abuse, Overdose, Prevention, Adolescent/Teen
7. Helwick C, 'For Prescription Opioid Dependence, Relapses Associated With Shorter Treatment Course,' MedScape Medical News, 5/24/2010
- Web Address: <http://www.medscape.com/viewarticle/722342>
 - Drugs: general opioid
 - Subjects: Misuse/Abuse, Addiction, Treatment
8. Katski G, 'Painkiller abuse becoming a problem,' Washington Daily News, 5/25/2010
- Web Address: <http://www.wdnweb.com/articles/2010/05/25/news/doc4bfb0bbba8ef1735535852.txt>
 - Drugs: general opioid
 - Subjects: Misuse/Abuse, Prevention
9. Keating S, 'Oxycontin Epidemic Plagues North County Youth,' San Diego Entertainer Magazine, 5/20/2010
- Web Address: <http://www.sdentertainer.com/news/oxycontin-epidemic-plagues-north-county-youth/>
 - Drugs: OxyContin
 - Subjects: Misuse/Abuse, Overdose, Adolescent/Teen
10. Superville DR, 'Risky prescription drugs are easy for kids to obtain,' NorthJersey.com, 5/21/2010
- Web Address: http://www.northjersey.com/news/health/medication/94561484_Prescription_drug__abuse_ca_n__ruin_lives_.html
 - Drugs: Vicodin, general opioid
 - Subjects: Misuse/Abuse, Addiction, Adolescent/Teen, Prevention
11. 'Veteran NFL player says league's substance abuse policy leaves door wide open for street drugs,' 5/15/2010
- Web Address: http://www.nydailynews.com/sports/football/2010/05/15/2010-05-15_former_player_says_nfl_is_league_of_junkies.html
 - Drugs: Percocet, Vicodin, Toradol, general opioid
 - Subjects: Misuse/Abuse
12. Zimmer R, 'State drug task force adopts recommendations,' MarionStar.com, 5/14/2010
- Web Address: <http://www.marionstar.com/article/20100514/NEWS01/5140306>
 - Drugs: general opioid
 - Subjects: Misuse/Abuse, Prevention

June 2010

1. Beaty J, 'Pill Party: Abuse of prescription meds spikes,' McAlester News, 6/20/2010
 - Web Address: <http://mcalesternews.com/local/x1703932158/Pill-Party-Abuse-of-prescription-meds-spikes>
 - Drugs: general opioid
 - Subjects: Misuse/Abuse, Adolescent Teen, Overdose
2. Borigini M, 'Opioid Contracting in Chronic Pain: Broken Before the Parties Sign,' Psychology Today, 6/28/2010
 - Web Address: <http://www.psychologytoday.com/blog/overcoming-pain/201006/opioid-contracting-in-chronic-pain-broken-the-parties-sign>
 - Drugs: general opioid
 - Subjects: Misuse/Abuse, Addiction, Overdose Prevention, Pain Management
3. Brown JM, 'Abuse Of Prescription Drug Blamed In Southport Overdose Case,' WMBB Channel 13 News, 6/25/2010
 - Web Address: http://www.panhandleparade.com/index.php/mbb/article/abuse_of_prescription_drug_blamed_in_southport_od_case/mbb7724288/
 - Drugs: tramadol
 - Subjects: Misuse/Abuse, Overdose
4. Canfield J, 'NH facing two big drug problem problems,' Cabinet.com, 6/2/2010
 - Web Address: <http://www.cabinet.com/cabinet/cabinetletters/756403-308/nh-facing-two-big-drug-problem-problems.html>
 - Drugs: Oxycontin, methadone, Vicodin, Percocet, Demerol , fentanyl, general opioid
 - Subjects: Misuse/Abuse, Overdose, Pain Management
5. 'CDC issues statement and recommendations regarding prescription drug misuse,' Monthly Prescribing Reference, 6/4/2010
 - Web Address: <http://www.empr.com/cdc-issues-statement-and-recommendations-regarding-prescription-drug-misuse/article/171717/>
 - Drugs: OxyContin, Percocet, Vicodin, general opioid
 - Subjects: Misuse/Abuse, Pain Management, Overdose, Prevention
6. 'CDC: One in Five Teens Has Abused Prescription Meds: Report Offers Docs Recommendations to Help Curb Misuse of Opioids,' AAFP News Now, 6/16/2010
 - Web Address: <http://www.aafp.org/online/en/home/publications/news/news-now/health-of-the-public/20100616cdcdrugreports.html>
 - Drugs: general opioid
 - Subjects: Misuse/Abuse, Overdose, Adolescent/Teen, Prevention, Pain Management
7. Cecala P, 'Springville has an illegal drug problem but help is here for the duration,' 6/2/2010
 - Web Address: http://www.metrowny.com/cj_story.php?time_hash=0f33b6bfce07653170e3cb0b55bf6def
 - Drugs: general opioid
 - Subjects: Misuse/Abuse
8. 'Charges May be Filed in Marshfield Teen's Overdose Death,' KSPR Channel 33 ABC News, 6/22/2010
 - Web Address: <http://www.kspr.com/news/local/96943964.html>
 - Drugs: oxymorphone
 - Subjects: Misuse/Abuse, Overdose, Adolescent/Teen
9. 'Coroner: Overdose killed Avenged Sevenfold drummer,' Soundspike.com, 6/17/2010
 - Web Address: http://www.soundspike.com/news/article/139-coroner__overdose_killed_avenged_sevenfold_drummer.html
 - Drugs: oxycodone, oxymorphone

- Subjects: Misuse/Abuse, Overdose
10. 'Diversion of Prescription Drugs A Growing Concern,' North Country Gazette, 6/30/2010
 - Web Address: http://www.northcountrygazette.org/2010/06/30/growing_concern/
 - Drugs: general opioid
 - Subjects: Misuse/Abuse, Overdose
 11. Hamaker P, 'Birmingham emergency rooms overcome with nonmedical use of prescription drugs,' Examiner.com, 6/22/2010
 - Web Address: <http://www.examiner.com/x-6180-Birmingham-Science-News-Examiner~y2010m6d22-Birmingham-emergency-rooms-overcome-with-nonmedical-use-of-prescription-drugs>
 - Drugs: oxycodone, hydrocodone, methadone, general opioid
 - Subjects: Misuse/Abuse, Overdose, Prevention
 12. Hunt J, 'Misuse of drug leading to deaths,' Charleston Daily Mail, 6/21/2010
 - Web Address: <http://www.dailymail.com/News/201006200404>
 - Drugs: fentanyl
 - Subjects: Misuse/Abuse, Overdose
 13. Jones T, 'Local group fights prescription pill abuse,' The Berkshire Eagle, 6/13/2010
 - Web Address: http://www.berkshireeagle.com/ci_15286012?source=most_viewed
 - Drugs: general opioid
 - Subjects: Misuse/Abuse, Prevention
 14. Laino C, 'Drug Tests Not Immune from False Positives,' CBSNews.com, 6/1/2010
 - Web Address: <http://www.cbsnews.com/stories/2010/06/01/health/webmd/main6537635.shtml>
 - Drugs: general opioid
 - Subjects: Misuse/Abuse, Drug Testing
 15. Landau E, 'CDC: 1 in 5 high schoolers abuse legal drugs,' CNN, 6/3/2010
 - Web Address: <http://pagingdrgupta.blogs.cnn.com/2010/06/03/cdc-1-in-5-high-schoolers-abuse-legal-drugs/>
 - Drugs: general opioid, OxyContin, Percocet, Vicodin
 - Subjects: Misuse/Abuse, Adolescent/Teen
 16. McCollum D, 'East Texas ERs find Rx drugs as big of problem as illegal drugs,' KTRE News Channel 9, 6/25/2010
 - Web Address: <http://www.ktre.com/Global/story.asp?S=12709466>
 - Drugs: general opioid, Vicodin
 - Subjects: Misuse/Abuse
 17. 'Our view on drug addiction: Doctors abet growing abuse of pain medication,' USA Today, 6/20/2010
 - Web Address: http://www.usatoday.com/news/opinion/editorials/2010-06-21-editoril21_ST_N.htm
 - Drugs: general opioid
 - Subjects: Misuse/Abuse, Pain Management, Addiction
 18. 'Prescription drug abuse common and deadly,' WMBFNews.com, 6/1/2010
 - Web Address: <http://www.wmbfnews.com/Global/story.asp?S=12572589>
 - Drugs: general opioid
 - Subjects: Misuse/Abuse, Addiction, Adolescent/Teen, Overdose
 19. 'Prescription Pain Abusers Flood ERs,' NewsMaxHealth, 6/18/2010
 - Web Address: http://www.newsmaxhealth.com/health_stories/prescription_pain_abusers/2010/06/18/323292.html
 - Drugs: general opioid, oxycodone

- Subjects: Misuse/Abuse, Overdose
20. Rabin RC, 'Hazards: Emergencies Over Legal Drugs Increase,' The New York Times, 6/21/2010
- Web Address: <http://www.nytimes.com/2010/06/22/health/research/22haza.html>
 - Drugs: oxycodone, hydrocodone, methadone, general opioid
 - Subjects: Misuse/Abuse, Pain Management, Overdose
21. Santana S, 'Oxycodone, Xanax deaths increase dramatically in Broward, report shows,' South Florida Sun Sentinel, 6/30/2010
- Web Address: <http://www.sun-sentinel.com/health/fl-florida-drug-report-20100630,0,4441582.story>
 - Drugs: oxycodone
 - Subjects: Misuse/Abuse, Overdose
22. Saunders M, 'Teen's death shows need for vigilance with medicine,' SouthWestIowa News, 6/4/2010
- Web Address: http://www.southwestiowanews.com/articles/2010/06/04/around_the_region/doc4c08ff02cba3b780663195.txt
 - Drugs: general opioid
 - Subjects: Misuse/Abuse, Overdose, Adolescent/Teen
23. Stockton R, 'Opioid Abuse Skyrockets,' Foodconsumer.org, 6/18/2010
- Web Address: http://www.foodconsumer.org/newsite/Politics/32/opioid_abuse_skyrockets_061820100141.html
 - Drugs: hydrocodone, oxycodone, methadone, general opioid
 - Subjects: Misuse/Abuse, Overdose
24. Szalavitz M, 'Difficulties in Determining a Drug Overdose Death,' TIME, 6/16/2010
- Web Address: <http://www.time.com/time/health/article/0,8599,1996831,00.html?xid=rss-topstories>
 - Drugs: fentanyl, hydrocodone, oxycodone
 - Subjects: Misuse/Abuse, Pain Management, Overdose
25. Willis E, 'Family practice drops patient for drug abuse,' Battle Creek Enquirer, 6/1/2010
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