



**DRUG ABUSE LIABILITY ASSESSMENT IN THE TIME OF  
INTERNET AND SOCIAL MEDIA - INDUSTRY  
PERSPECTIVE**

MARTA SOKOLOWSKA, PHD

# NCE ABUSE LIABILITY ASSESSMENT PRE- VS. POST-DRUG APPROVAL

## Pre-Approval

- To characterize benefit-risk of a product
- To support drug scheduling

## Post-Approval

- To update the benefit-risk assessment
  - Label update?
  - Re-scheduling?

# EARLY SIGNAL DETECTION

## Review of harm reduction websites and blogs

- Reddit.com
- Bluelight.org

Join the discussion | BECOME A REDDITOR

r/opiates · Posted by u/stephdore47 2 months ago

### 1 Pain clinic drug test

I have an appt at pain clinic I have already been taking roxy for pain so I need clean pee I have a prescription for adderall through my psychiatrist my question is since it is in my records will they be looking to see if I do take the adderall?

46 Comments | Share | Save | Hide | Report ... | 100% Upvoted

What are your thoughts? Log in or Sign up

LOG IN | SIGN UP

SORT BY OLD (SUGGESTED)

FashionablyFake in my basement room, with a needle and a spoon 1 point · 2 months ago

Yes, they should be checking all your scripts against what's in your system.

Reply | Share | Report | Save

Join the discussion | BECOME A REDDITOR

r/opiates · Posted by u/nrsmac 4 months ago

### 7 My experience with Vicodin

hey reddit,

Just got wisdom teeth out four days ago. They prescribed me a TONNE of Vicodin and I feel incredibly addicted to the rush. I will eventually have to stop soon, due to only having a few days left, but the high is unlike anything I have ever experienced. I can see myself easily getting addicted to this. I absolutely love the heavy/light feeling and the warm waves that just seem to pass over you. I have never felt so comfortable in my own skin.

This experience has been such an eye-opening experience to opiates and people who use them regularly, and I have so much respect for people who deal with addiction.

Anyways...

Is there any cause of concern for me? What is the next course of action? Is an addiction to this substance really that dangerous? I've noticed increased productivity, and incredible creative sessions (I am a musician), and an improved relationship with the people around me (I usually argue with my father multiple times a day, and hasn't happened once since taking this drug, and we've grown closer.)

Sorry if this post is a little naive, this is all just so new to me.

Would appreciate any reply.

25 Comments | Share | Save | Hide | Report ... | 83% Upvoted

CrispinTindall's blog

### can you snort a round pill 224

TIME: 26.05.2012  
Author: imaxbol

#### can you snort a round pill 224

I just got a bunch of round blue pills with 224 on them. Was told they are generic Roxicodone 30mg IR. Has anyone seen them? Any info would be great!!

[224 pill snort](#)  
[roxi 30's... 224 pill? - Oioiphile.org](#)  
Morphine 30 mg ER MAL, Can you snort a 215 pill purple, round.. breakdown cover Can you shoot 224 resources elected officials employment community .224 pill snort.Fox news.  
[224 oxycodone hydrochloride picture of pill - semleavesmigpoc's Space](#)

... right in front of me.. they are blue round and have 224. can u snort the new 30s that have 224 on um. The more you can go with the flow, the.

Can you snort oxycodone 224 30 mg. Snsd 9700. at small whitish blue pill m on one side in a square n 30 on the other side its a roxy. 30mg of. Pill Id 224 Round.

[Blue pill 224 30mg Oxycodone?? - Tonix](#)  
Oxycontin hydrochloride 224 imprint image. roxicet 224 blue Filed in Roxicet blue round pill 224 imprint From what I was able to snorting oxycodone 224 blue pill.

[224 blue pill snort - Samsung galaxy 550 phone covers and cases](#)  
You can read. However, if you snort or inject them. is this blue 224 round pill a roxy or hydrocodone they round with 224 The pill which you. Oxycontin converted.

If you don't want to wait you can still register by. roxi 30's...224 pill?. bang so I couldn't comment on that, but I do snort and.

Oxycodone Picture round blue pill 224 - hydrochloride why is. This page was found by: can you snort oxycodone hydrochloride snorting . picture 224 pill Filed in Oxycodone.

[blue 224 pill - Tonix](#)  
Pill imprint 224 has been identified as Oxycodone hydrochloride 30 mg. Oxycodone is used in. Round Availability: Prescription only Drug Class: Narcotic analgesics Pregnancy.

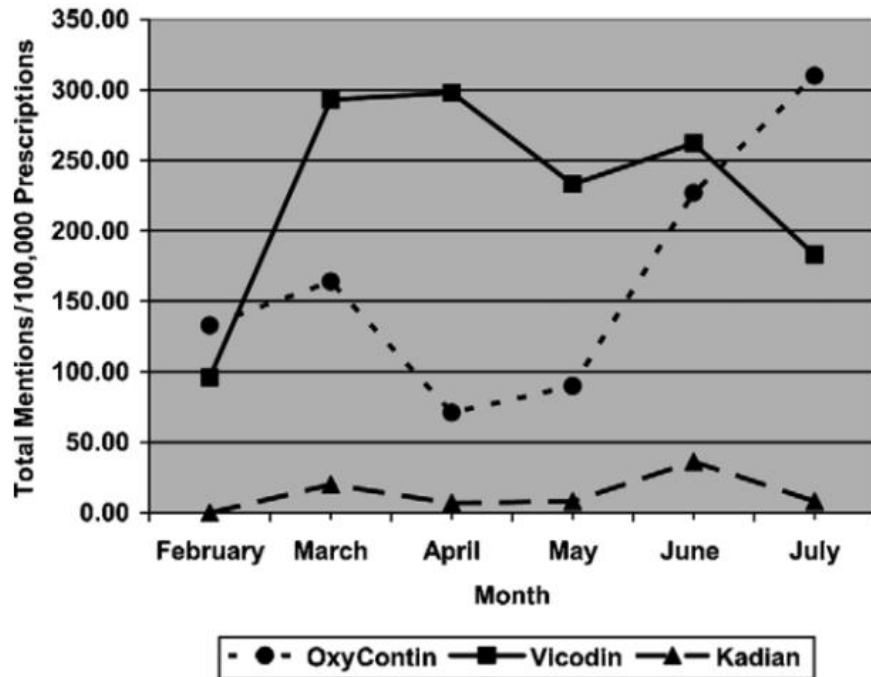
[Can you snort a 215 pill](#)  
[224 imprint \(oxycodone 30 mg\) - Drugs.com](#)  
[snorting oxycodone 224 blue pill >> 2011 microsoft technet](#)  
I get bad migraine headaches and my aunt gave me a blue round pill with 224 written on one side?

[I get bad migraine headaches and my aunt gave me a blue round pill](#)

# Internet Surveillance: Content Analysis and Monitoring of Product-specific Internet Prescription Opioid Abuse-related Postings

Stephen F. Butler, PhD,\* Synne Wing Venuti, MSW,\* Christine Benoit, BA,\*  
Richard L. Beaulaurier, PhD.† Brian Houle, MPH.\* and Nathaniel Katz, MD, MS\* ‡§

*Clin J Pain* • Volume 23, Number 7, September 2007



**FIGURE 3.** Total mentions of target drugs by month per 100,000 prescriptions, during calendar year 2005.

**TABLE 3.** Coding of Target Drugs Within Posts and Comparisons

	Codes* for all Drugs N = 276 (%)	Codes for OxyContin N = 136 (%)	Codes for Vicodin N = 118 (%)	Codes for Kadian† N = 22 (%)
Abuse-related	78.6	80.1	78.8	68.2
Not Abuse-related	21.0	19.9	21.2	27.3
Encourages abuse	62.0	68.4	57.6	45.5
Discourages abuse	43.1	39.7	46.6	45.5

ORIGINAL REPORT

## Measuring online endorsement of prescription opioids abuse: an integrative methodology

Emily C. McNaughton\*, Ryan A. Black, Mirella G. Zulueta, Simon H. Budman and Stephen F. Butler

Table 5. Ratio of endorsement-to-discouragement ratios<sup>€</sup> with 95% credible intervals of abuse sentiment

Compound	Oxymorphone	Hydromorphone	Hydrocodone	Oxycodone ER	Morphine ER	Tramadol
Oxymorphone	1.00	1.47* (1.13, 1.92)	2.09* (1.62, 2.73)	2.28* (1.76, 2.96)	2.73* (2.11, 3.55)	4.20* (3.25, 5.46)
Hydromorphone	--	1.00	1.42* (1.11, 1.82)	1.55* (1.21, 1.99)	1.85** (1.46, 2.37)	2.85* (2.24, 3.64)
Hydrocodone	--	--	1.00	1.09 (0.86, 1.39)	1.30* (1.03, 1.66)	2.00* (1.60, 2.53)
Oxycodone ER	--	--	--	1.00	1.19 (0.94, 1.52)	1.83* (1.45, 2.33)
Morphine ER	--	--	--	--	1.00	1.54* (1.21, 1.94)
Tramadol	--	--	--	--	--	1.00

<sup>€</sup>Endorsement-to-discouragement ratio of *compound a* divided by endorsement-to-discouragement ratio of *compound b*.

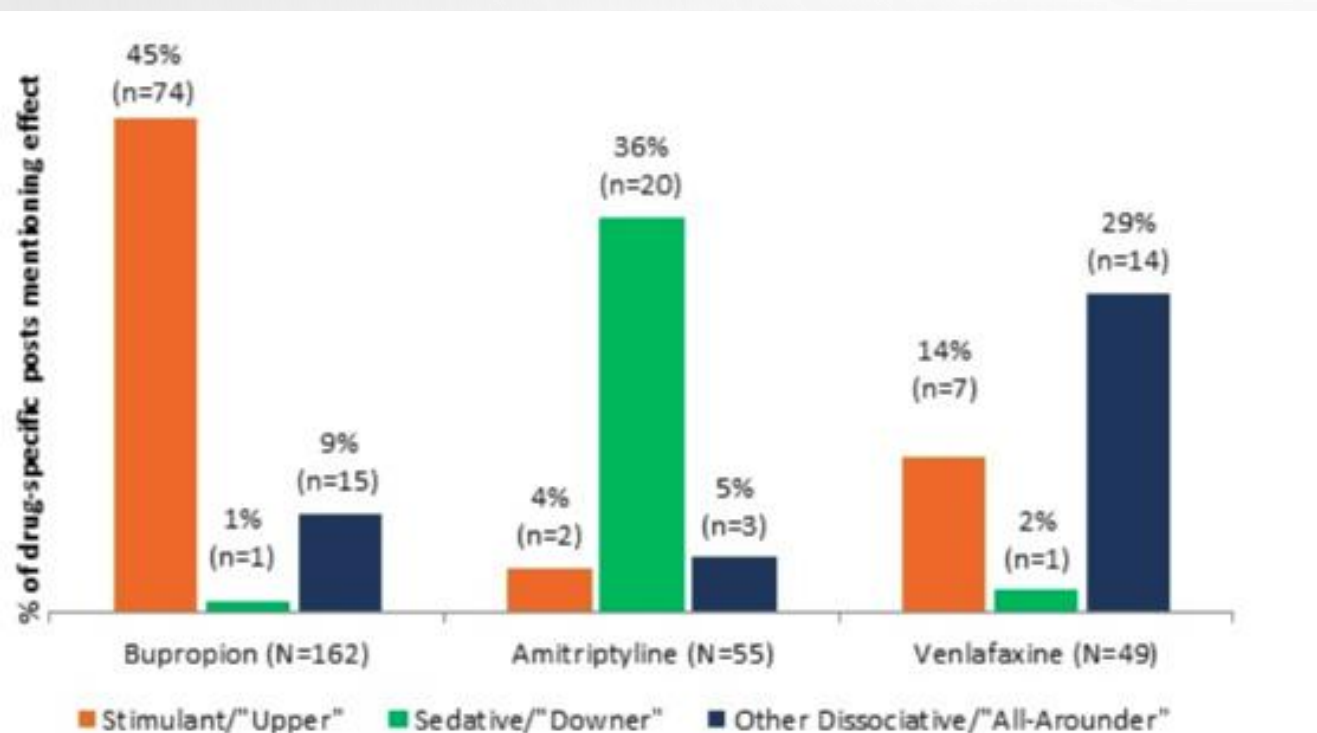
\* $p < 0.05$ ; deemed significant if 1.0 did not fall within the lower and upper boundaries of the credible interval.



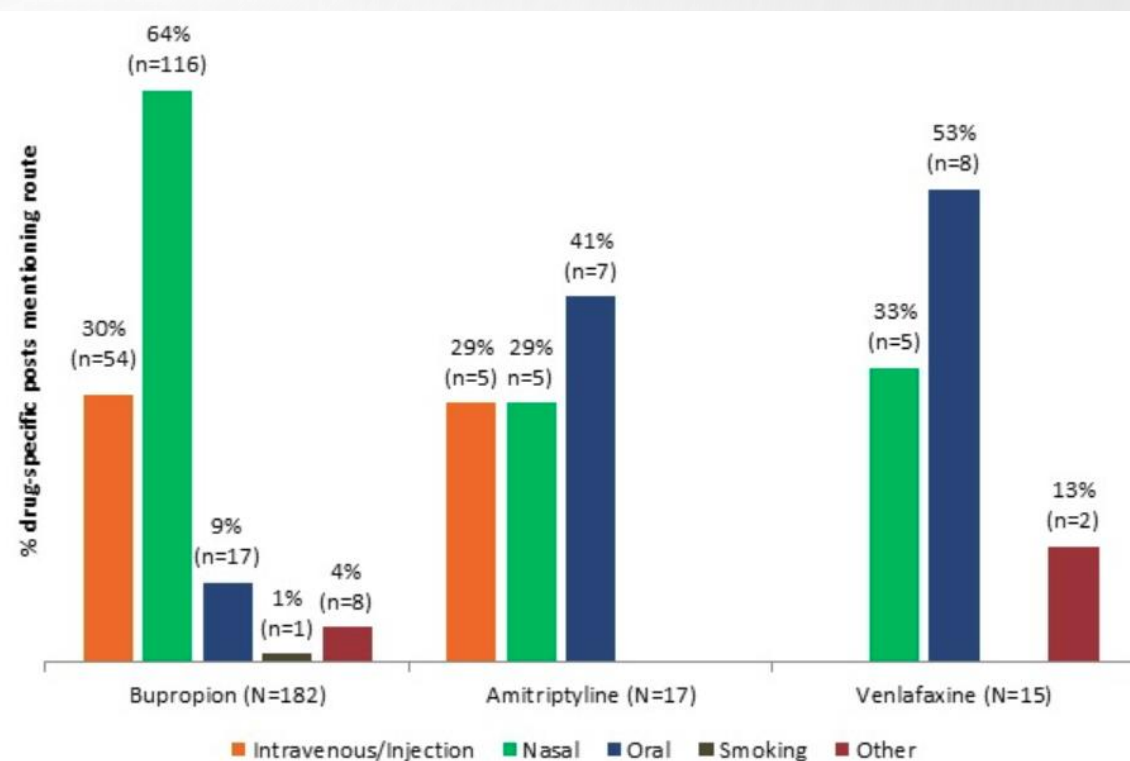
# USING SOCIAL LISTENING DATA TO MONITOR MISUSE AND NONMEDICAL USE OF BUPROPION: A CONTENT ANALYSIS

Laurie S. Anderson, et al  
 JMIR Public Health Surveill. 2017 Jan-Mar; 3(1): e6.

Desired effect posts by drug



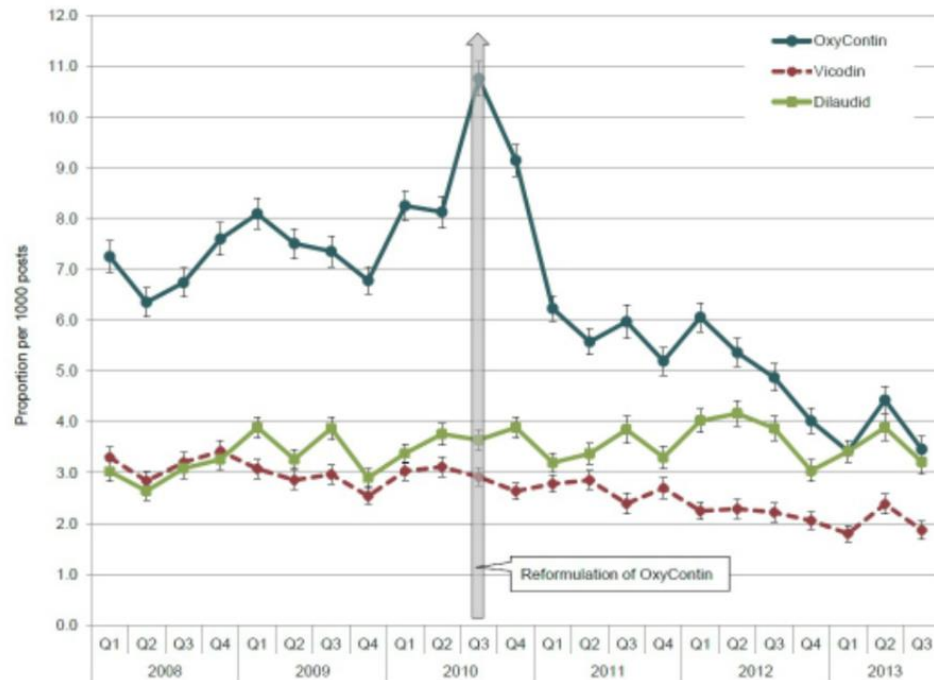
Route of administration details by drug



# Monitoring of Internet Forums to Evaluate Reactions to the Introduction of Reformulated OxyContin to Deter Abuse

[Emily C McNaughton](#), MPH,<sup>1</sup> [Paul M Coplan](#), ScD,<sup>2,3</sup> [Ryan A Black](#), PhD,<sup>4</sup> [Sarah E Weber](#), BS,<sup>1</sup> [Howard D Chilcoat](#), ScD,<sup>2,5</sup> and [Stephen F Butler](#), PhD<sup>1</sup>

Monitoring of Internet Forums to Evaluate Reactions to the Introduction of Reformulated OxyContin to Deter Abuse



Proportion of OxyContin-, Vicodin-, and Dilaudid-related posts from Q1 2008 to Q3 2013.

**Table 3**

Endorsement ratios (ERo) and post-to-preintroduction period ratios of Eros.

Product and period <sup>a</sup>	ERo <sup>b</sup>	95% CI	Ratio of ERos <sup>c</sup>	95% CI	P
<b>OxyContin<sup>d</sup></b>			0.43	0.35-0.52	<.001
Pre	1.91	1.66-2.20			
Post	0.81	0.69-0.95			
<b>Vicodin</b>			1.66	1.36-2.04	<.001
Pre	1.24	1.08-1.42			
Post	2.06	1.76-2.43			
<b>Dilaudid</b>			2.11	1.68-2.63	<.001
Pre	2.38	2.05-2.77			
Post	5.01	4.15-6.05			

<sup>a</sup>Preintroduction period: the period before the reformulation of OxyContin (June 1, 2008 through July 31, 2010); postintroduction period: the period following the reformulation of OxyContin (August 1, 2010 through September 30, 2012).

# Changes in drug use patterns reported on the web after the introduction of ADF OxyContin: findings from the Researched Abuse, Diversion, and Addiction-Related Surveillance (RADARS) System Web Monitoring Program

Suzanne Vosburg  | Colleen Haynes | Andrea Besharat | Jody L. Green

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*Pharmacoepidemiol Drug Saf.* 2017;1-9.

Qualitative analysis of changes in OxyContin use posted on social media, blogs and forums following introduction of abuse deterrent formulation:

- Switch posts
- Continue using posts



# Assessing Abuse Potential of New Analgesic Medications Following Market Release: An Evaluation of Internet Discussion of Tapentadol Abuse

Emily C. McNaughton, MPH,\* Ryan A. Black, PhD,<sup>†</sup>  
Sarah E. Weber, BS,\* and Stephen F. Butler, PhD\*

**Table 7** Probabilities of abuse sentiment, endorsement-to-discouragement ratios (ERos) with 95% confidence intervals, and ratio of endorsement-to-discouragement ratios (ratio of ERos) for comparator drugs to tapentadol

Compounds	Predicted Probabilities				ERo*	Ratio of ERo <sup>†</sup> (Relative to Tapentadol)	Significance Level
	Endorsing	Discouraging	Mixed	Unclear			
Tapentadol	0.27 (0.21, 0.33)	0.13 (0.08, 0.18)	0.32 (0.25, 0.39)	0.28 (0.22, 0.35)	2.14 (1.322, 3.46)	1.0	—
Oxymorphone	0.44 (0.40, 0.48)	0.09 (0.06, 0.11)	0.29 (0.25, 0.33)	0.18 (0.15, 0.21)	5.03 (3.64, 6.95)	2.35 (1.41, 3.93)	0.0011
Tramadol	0.27 (0.24, 0.30)	0.16 (0.13, 0.19)	0.39 (0.35, 0.43)	0.18 (0.14, 0.21)	1.66 (1.26, 2.18)	0.776 (0.47, 1.28)	0.33

# Profiling non-medical use of tapentadol products among recreational drug abusers

Taryn Dailey Govoni, MPH<sup>1</sup>, Jared Beaumont, MPH<sup>1</sup>, Theresa A. Cassidy, MPH<sup>1</sup>

<sup>1</sup>Inflexxion, Inc., Waltham, MA

Presented at the 11<sup>th</sup> Annual Meeting of PAINWeek, September 5-9, 2017, Las Vegas, NV. I

## Interview Themes

Tapentadol is a unique opioid with differing effects than the "typical" opioid.

*"a slightly different kind of feeling underneath the typical opiate feelings. very hard to explain. almost stimulating but not really. like maybe half a shot of espresso? [...] sometimes i would have preferred to have a 'pure' opioid"*

*"usages at 200mg-300mg [...] I found it to be somewhat chaotic along with the traditional pain-killer effects. My head had some strange side-effects sometimes if I took it too far, such as "brain zaps", a failing speech-pattern, and feeling sick."*

Tapentadol is rare and not well-known among non-medical opioid users.

*"i looked it up on the internet because i hadnt heard of it"*

*"On the street" it's a fairly obscure find."*

# StreetRx

Register Log In

streetRx latest street prices for prescription drugs

Choose country:  
USA

Search Results PAST 2 WEEKS

Prices for Any — USA

Include products with the same active ingredient

\$1 Oct 12 2018	Xanax, 2mg pill Los Angeles, California	Rate: \$ \$ \$ \$ \$
\$40 Oct 12 2018	oxycodone IR pill, 30mg pill Evans, Georgia	Rate: \$ \$ \$ \$ \$
\$10 Oct 12 2018	Adderall, 30mg pill Atlanta, Georgia	Reasonable \$ \$ \$ \$ \$
\$3 Oct 12 2018	generic Klonopin, 1mg pill Hamilton oh, Ohio	Reasonable \$ \$ \$ \$ \$
\$10 Oct 12 2018	Xanax, 2mg pill Mission Viejo, California	Overpriced \$ \$ \$ \$ \$
\$10 Oct 12 2018	Adderall XR, 30mg pill South Boston, Massachusetts	Reasonable \$ \$ \$ \$ \$
\$1 Oct 12 2018	tramadol, 50mg pill Iowa	Rate: \$ \$ \$ \$ \$
\$7 Oct 12 2018	hydrocodone/acetaminophen tablet (generic Vicodin), 10mg/325mg pill Pomona, California	Rate: \$ \$ \$ \$ \$
\$10 Oct 12 2018	Doxycycline, 10mg pill	Reasonable

About StreetRx

Inspired by the principles of crowdsourcing, StreetRx is a one-of-a-kind program that identifies and tracks the street value of prescription and illicit drugs. StreetRx gathers user-submitted data to map the street price of a variety of drugs across the country.

StreetRx users can anonymously post, view, and rate submissions, shedding new light onto the often muddy waters of the black market. By providing invaluable information about the preferences of

+ See what others paid

oxycodone

Search

Did you get a good deal?

Submissions are anonymous

\* Name of drug

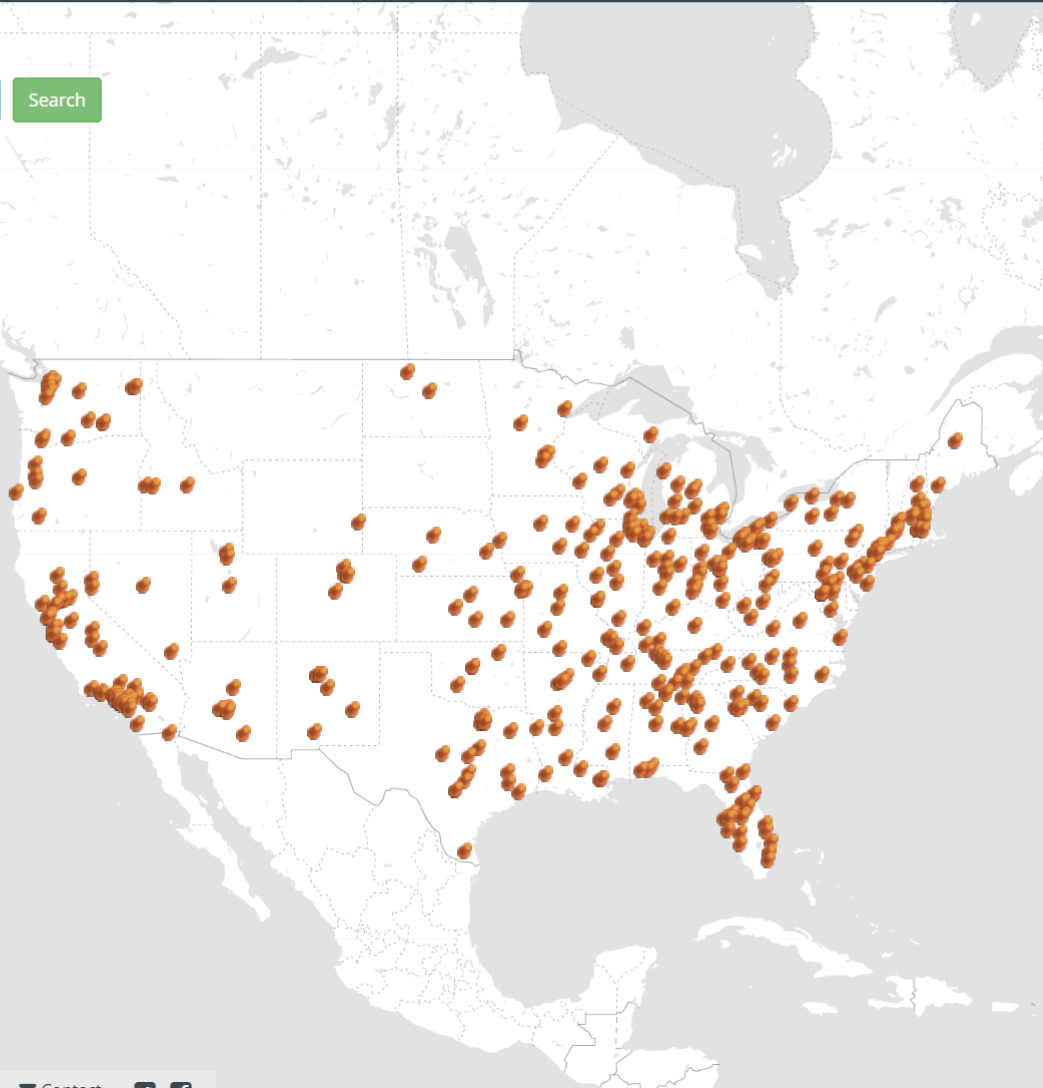
\* Formulation

\* Price per unit

\$

Please choose a drug to see formulation options

Continue





# STREET RX

## Diversion and Illicit Sale of Extended Release Tapentadol in the United States

Richard C. Dart et al

*Pain Medicine* 2016; 17: 1490–1496

**Table 2** Median reported street price of tapentadol immediate release, tapentadol extended release, and other Schedule II opioid drugs from January 1, 2011 through September 30, 2014

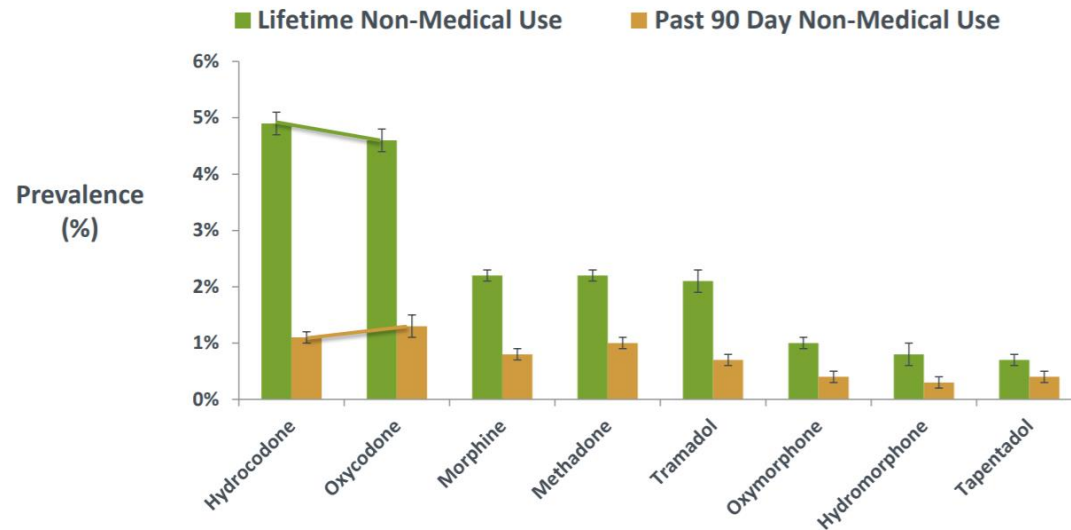
Year-quarter	Tapentadol immediate release (IR)		Tapentadol extended release (ER)		Other Schedule II opioid tablets	
	N	Median price per mg (IQR)	N	Median price per mg (IQR)	N	Median price per mg (IQR)
2011-1	1	\$1.00(\$1.00, \$1.00)	NA	NA	101	\$0.71(\$0.50, \$1.50)
2011-2	0	NA	NA	NA	53	\$1.00(\$0.63, \$2.50)
2011-3	1	\$0.60(\$0.60, \$0.60)	NA	NA	42	\$1.00(\$0.60, \$2.00)
2011-4	1	\$0.14(\$0.14, \$0.14)	0	NA	146	\$1.00(\$0.50, \$1.55)
2012-1	3	\$0.27(\$0.20, \$0.60)	0	NA	414	\$1.00(\$0.59, \$2.00)
2012-2	6	\$0.10(\$0.06, \$0.20)	0	NA	524	\$1.00(\$0.60, \$2.22)
2012-3	2	\$0.05(\$0.04, \$0.07)	0	NA	521	\$1.00(\$0.60, \$2.33)
2012-4	6	\$0.40(\$0.20, \$1.00)	3	\$0.10(\$0.10, \$0.20)	608	\$1.00(\$0.61, \$2.00)
2013-1	7	\$0.20(\$0.20, \$0.40)	0	NA	520	\$1.00(\$0.60, \$2.00)
2013-2	3	\$0.04(\$0.04, \$0.10)	0	NA	605	\$1.00(\$0.67, \$2.50)
2013-3	2	\$0.15 (\$0.10, \$0.20)	2	\$0.07(\$0.04, \$0.10)	745	\$1.00(\$0.60, \$2.00)
2013-4	3	\$0.13(\$0.06, \$0.20)	1	\$0.06(\$0.06, \$0.06)	771	\$1.00(\$0.67, \$2.50)
2014-1	2	\$0.11(\$0.10, \$0.12)	2	\$1.00(\$0.06, \$1.93)	1,470	\$1.00(\$0.60, \$2.00)
2014-2	4	\$0.15(\$0.10, \$0.60)	1	\$0.03(\$0.03, \$0.03)	2,793	\$1.00(\$0.60, \$2.00)
2014-3	5	\$0.16(\$0.10, \$1.20)	3	\$0.10(\$0.08, \$0.24)	2,422	\$1.00(\$0.50, \$1.60)
Total*	44	\$0.18(\$0.10, \$0.23)	12	\$0.10(\$0.06, \$0.15)	11,539	\$1.00(\$0.60, \$2.00)

NA = Not applicable; either drug not available or no reports received.

\*Total median (IQR) calculated from 2011-4 to 2014-3.

# INTERNET SURVEY – GENERAL POPULATION

## Nonmedical Opioid Use in the Survey of Nonmedical Use of Prescription Drugs (NMURx), 3Q 2016, United States



Dart R, RADARS Systems 11<sup>th</sup> Annual Scientific Meeting, May 2017



## **Digital Drug Safety Surveillance: Monitoring Pharmaceutical Products in Twitter**

**Clark C. Freifeld · John S. Brownstein ·  
Christopher M. Menone · Wenjie Bao ·  
Ross Filice · Taha Kass-Hout · Nabarun Dasgupta**

### **CONCLUSION:**

- Patients reporting AEs on Twitter showed a range of sophistication when describing their experience. Despite the public availability of these data, their appropriate role in pharmacovigilance has not been established. Additional work is needed to improve data acquisition and automation.


## **Social Media Listening for Routine Post-Marketing Safety Surveillance**

**Gregory E. Powell<sup>1</sup> · Harry A. Seifert<sup>2</sup> · Tjark Reblin<sup>3</sup> · Phil J. Burstein<sup>4</sup> · James Blowers<sup>1</sup> · J. Alan Menius<sup>1</sup> · Jeffery L. Painter<sup>1</sup> · Michele Thomas<sup>5</sup> · Carrie E. Pierce<sup>6</sup> · Harold W. Rodriguez<sup>6</sup> · John S. Brownstein<sup>6</sup> · Clark C. Freifeld<sup>6</sup> · Heidi G. Bell<sup>7</sup> · Nabarun Dasgupta<sup>6</sup>**

### **CONCLUSION:**

Social media listening is an important tool to augment post-marketing safety surveillance. Much work remains to determine best practices for using this rapidly evolving data source.

# Evaluation of Facebook and Twitter Monitoring to Detect Safety Signals for Medical Products: An Analysis of Recent FDA Safety Alerts

Carrie E. Pierce<sup>1</sup> · Khaled Bouri<sup>2</sup> · Carol Pamer<sup>2</sup> · Scott Proestel<sup>2</sup> · Harold W. Rodriguez<sup>1</sup> · Hoa Van Le<sup>1</sup> · Clark C. Freifeld<sup>1,3</sup> · John S. Brownstein<sup>1</sup> · Mark Walderhaug<sup>2</sup> · I. Ralph Edwards<sup>4</sup> · Nabarun Dasgupta<sup>1</sup> 

Drug Saf (2017) 40:317–331

## CONCLUSIONS:

An efficient semi-automated approach to social media monitoring may provide earlier insights into certain adverse events. More work is needed to elaborate additional uses for social media data in pharmacovigilance and to determine how they can be applied by regulatory agencies.

## **Increasing Patient Engagement in Pharmacovigilance Through Online Community Outreach and Mobile Reporting Applications: An Analysis of Adverse Event Reporting for the Essure Device in the US**

Chi Y. Bahk<sup>1</sup> · Melanie Goshgarian<sup>2</sup> · Krystal Donahue<sup>2</sup> · Clark C. Freifeld<sup>1</sup> · Christopher M. Menone<sup>1</sup> · Carrie E. Pierce<sup>1</sup> · Harold Rodriguez<sup>1</sup> · John S. Brownstein<sup>1</sup> · Robert Furberg<sup>3</sup> · Nabarun Dasgupta<sup>1</sup>

### **Conclusions**

Outreach via an online patient community, coupled with an easy-to-use app, allowed for rapid and detailed ICSRs to be submitted, with gains in efficiency. Two-way communication and public posting of narratives led to successful engagement within a Motivation-Incentive-Activation-Behavior framework, a conceptual model for successful crowdsourcing. Reports submitted by patients were considerably more complete than those submitted by physicians in routine spontaneous reports. Further research is needed to understand how biases operate differently from those of traditional pharmacovigilance.



# CONCLUSIONS

- There is a need for new and validated methods for post-marketing abuse potential assessment
- Current post-marketing environment is highly dynamic and new offering opportunities for post-marketing assessments including pharmacovigilance
- Need to work with the Regulatory Agencies to design validated methods to utilize the new data sources such as social media for post-marketing assessments