

New Frontiers in Safety Surveillance

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Harvard Medical School

Chief Innovation Officer
Boston Children's Hospital

@johnbrownstein



Digital Phenotype



Digital Phenotype



IG-CaramelBomBBB @caramelbombbb

I need my Ambien back:(I can't sleep to save my life!

9 months ago Reply Retweet Favorite

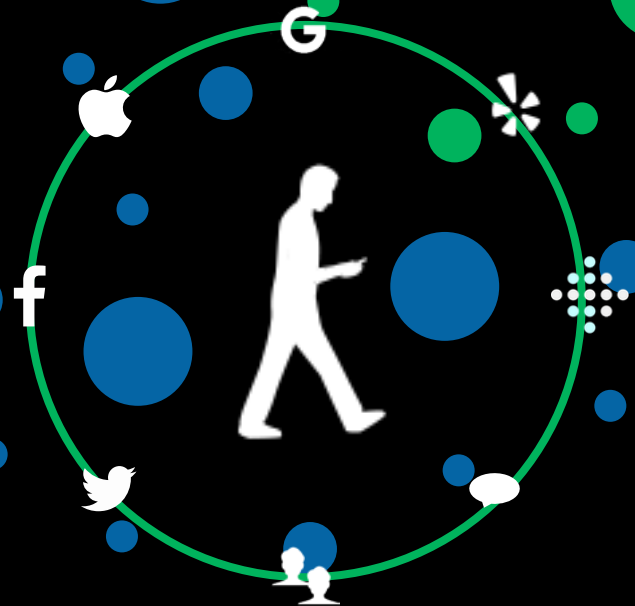


Mac @rbhaze_

Grandma gave me some Percocet for my pain. She came clutch

10 months ago Reply Retweet Favorite

Drug diversion & abuse





Digital disease detection picks up early signals

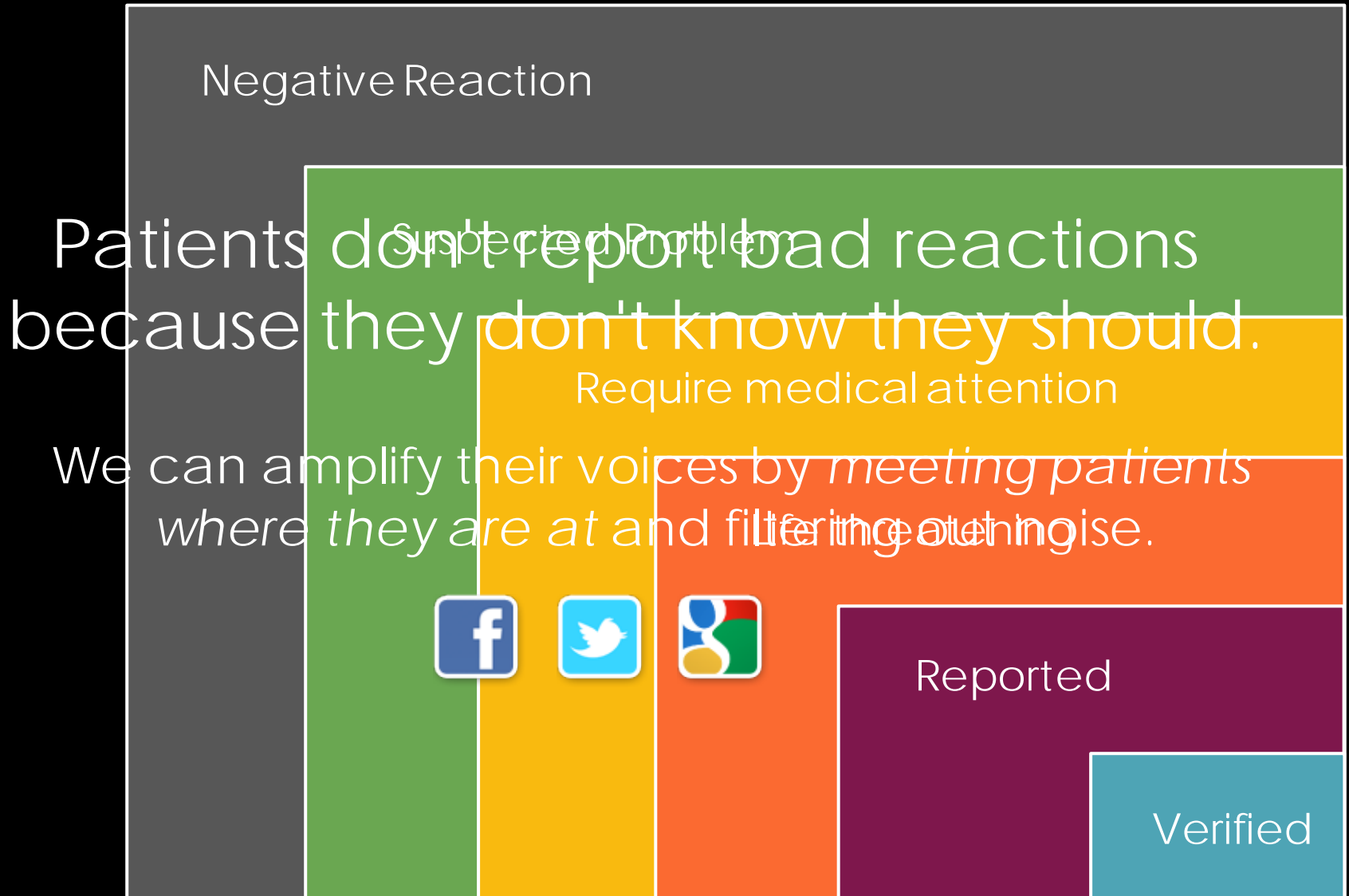
Traditional public health monitoring





Distribution of Disease

Medicine Use



Vernacular-to-Regulatory Translation

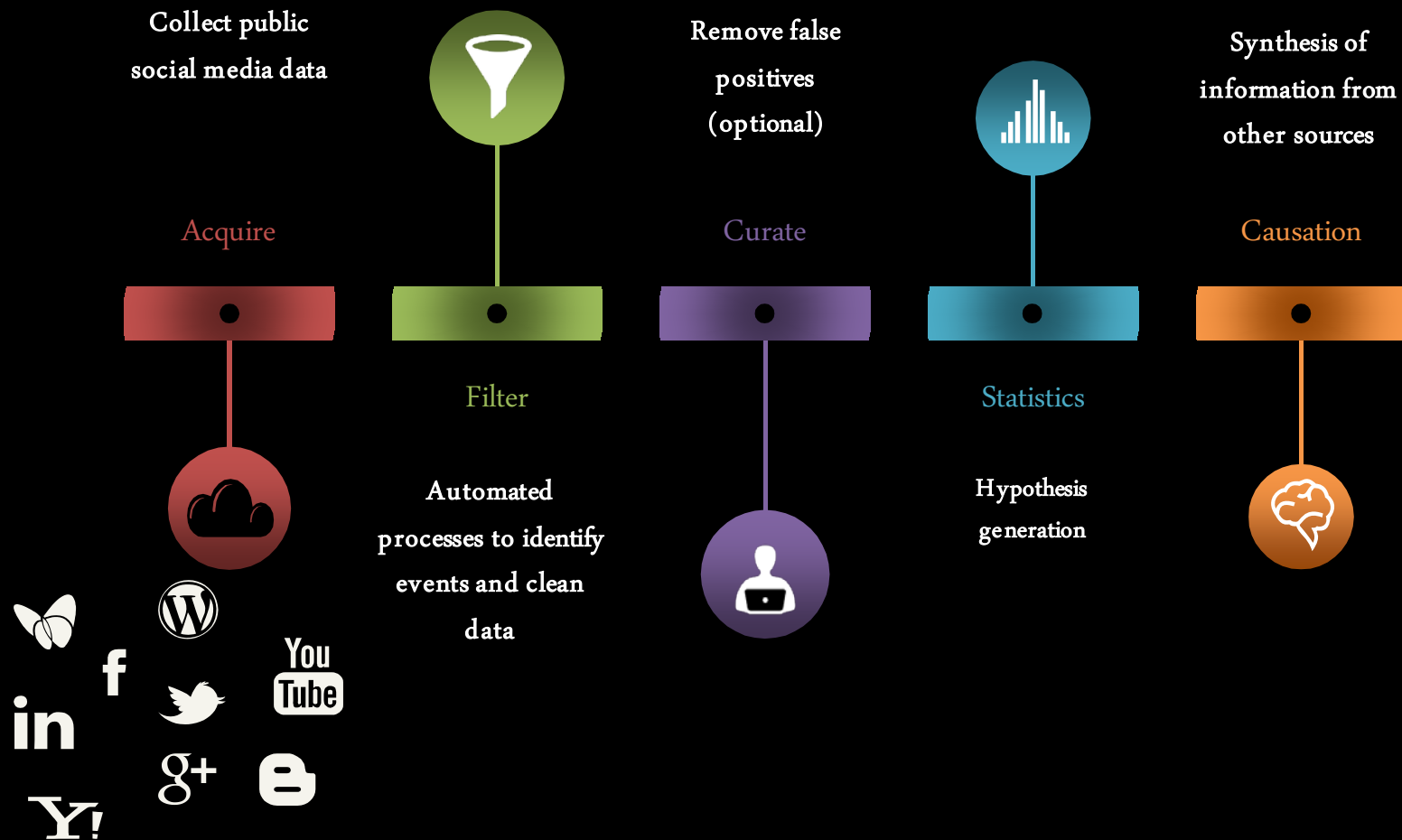






FDA-sponsored social media monitoring platform

Data Flow for MedWatcher Social



visual snow dont want to eat cross vision lost my appetite
apetite surpressed googley eyed no appetitey doublevision
blind appetite is nonexistent blurry vision miss feeling hung
anorexic double vision #notevenhungry blindness cant eat
ouldn't see making me eat like a mouse vision change blurry
st appetite lost their eyesight didn't get hungry seeing doub
can't eat killed my apetite googly eyed lost teh appetite
lost apetite crosseyed killed my appetite seeing weird cou
cross eyed seeing weird colour stomach small changes in vis
lack of apetite never want to eat seeing weird color never h

Typos

visual snow dont want to eat cross vision lost my appetite
apetite surpressed googley eyed no appetitey doublevision
blind appetite is nonexistent blurry vision miss feeling hung
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can't eat killed my apetite googly eyed lost teh appetite
lost apetite crosseyed killed my appetite seeing weird cou
cross eyed seeing weird colour stomach small changes in vis
lack of apetite never want to eat seeing weird color never h

Visual impairment

MedDRA 10047571

Visual impairment

SNOMED 397540003

Decreased appetite

MedDRA 10061428

Loss of appetite

SNOMED 79890006

PROS

CONS

PROS

CONS



Mar 23

Xanax and **Hydrocodone** is like having a **blackout** without the drinking and the hangover

Expand

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15

12

0

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37

15

2

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1

1

44

55

4

5

0

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4

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113

1

6

0

0



██████████ ██████████ Mar 23

Xanax and **Hydrocodone** is like having a **blackout** without the drinking and the hangover

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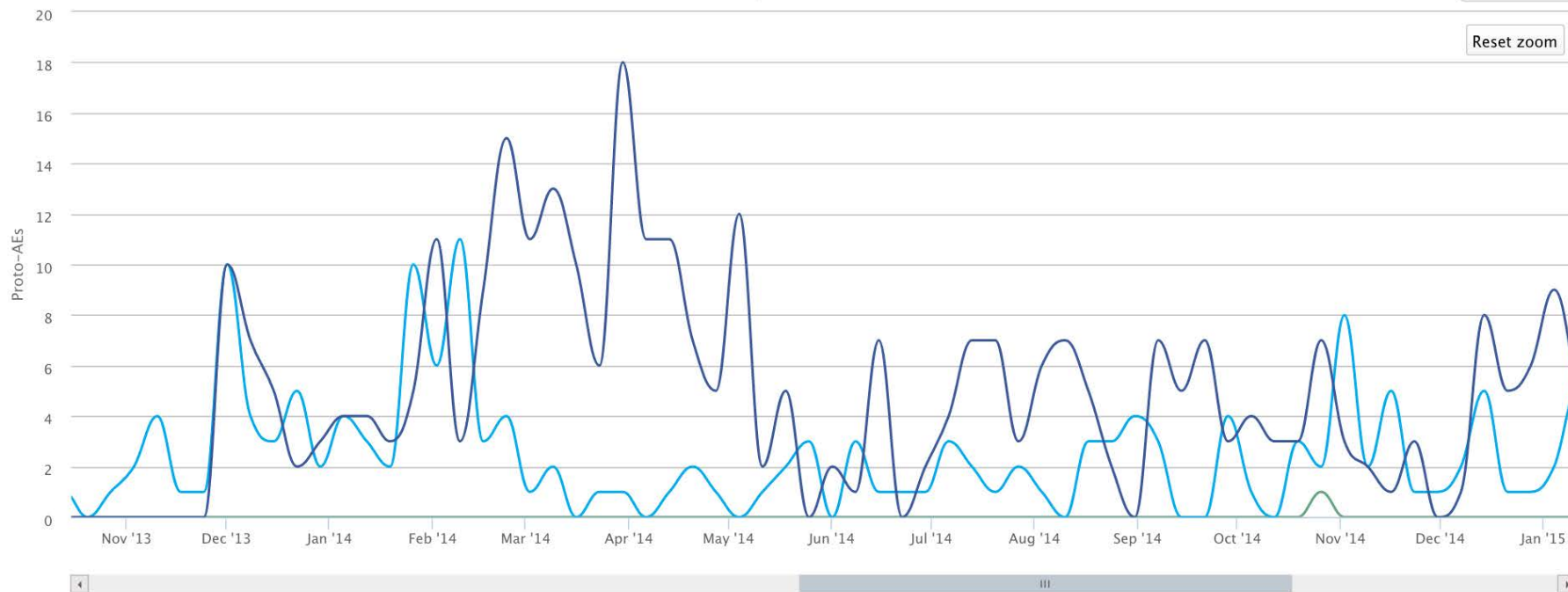
John ▾

Proto-AEs

per week

Facebook
Twitter
Forums

Reset zoom



Twitter ⓘ
266 Proto-AEs
5918 Mentions

Facebook ⓘ
375 Proto-AEs
7747 Mentions

Forums ⓘ
1 Proto-AEs
3 Mentions

642 Proto-AEs, 13668 Mentions found ([View attrition](#))

— since Jan 1 2012

59,429,028 total posts in DB
Latest post on Sep 14, 2015 @ 03:13pm

[View System Stats](#)

System Performance

57M



Posts mentioning
medical products

380k



Manually classified to
identify AEs

68%



Precision
-
Positive predictive
value

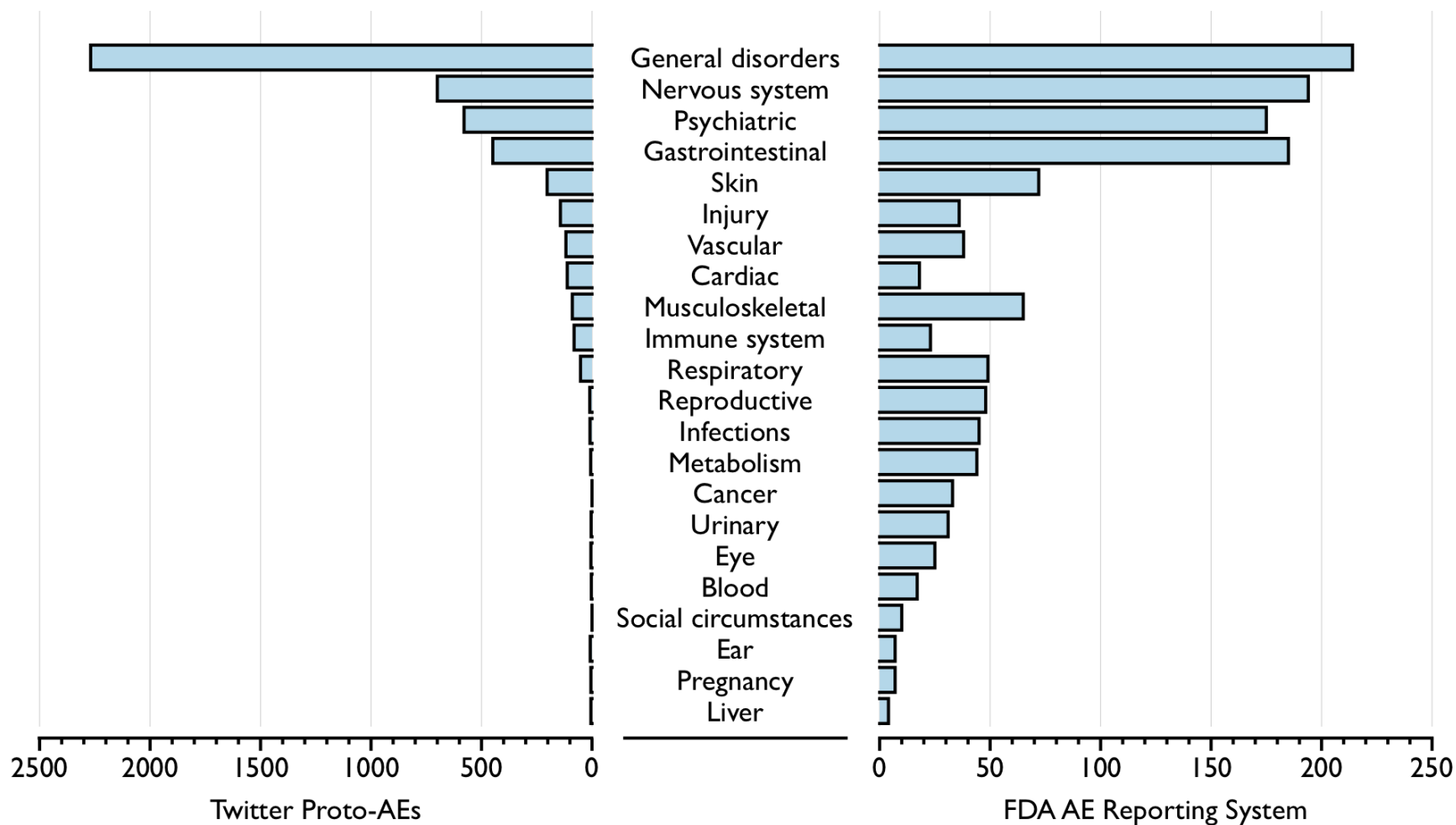
88%



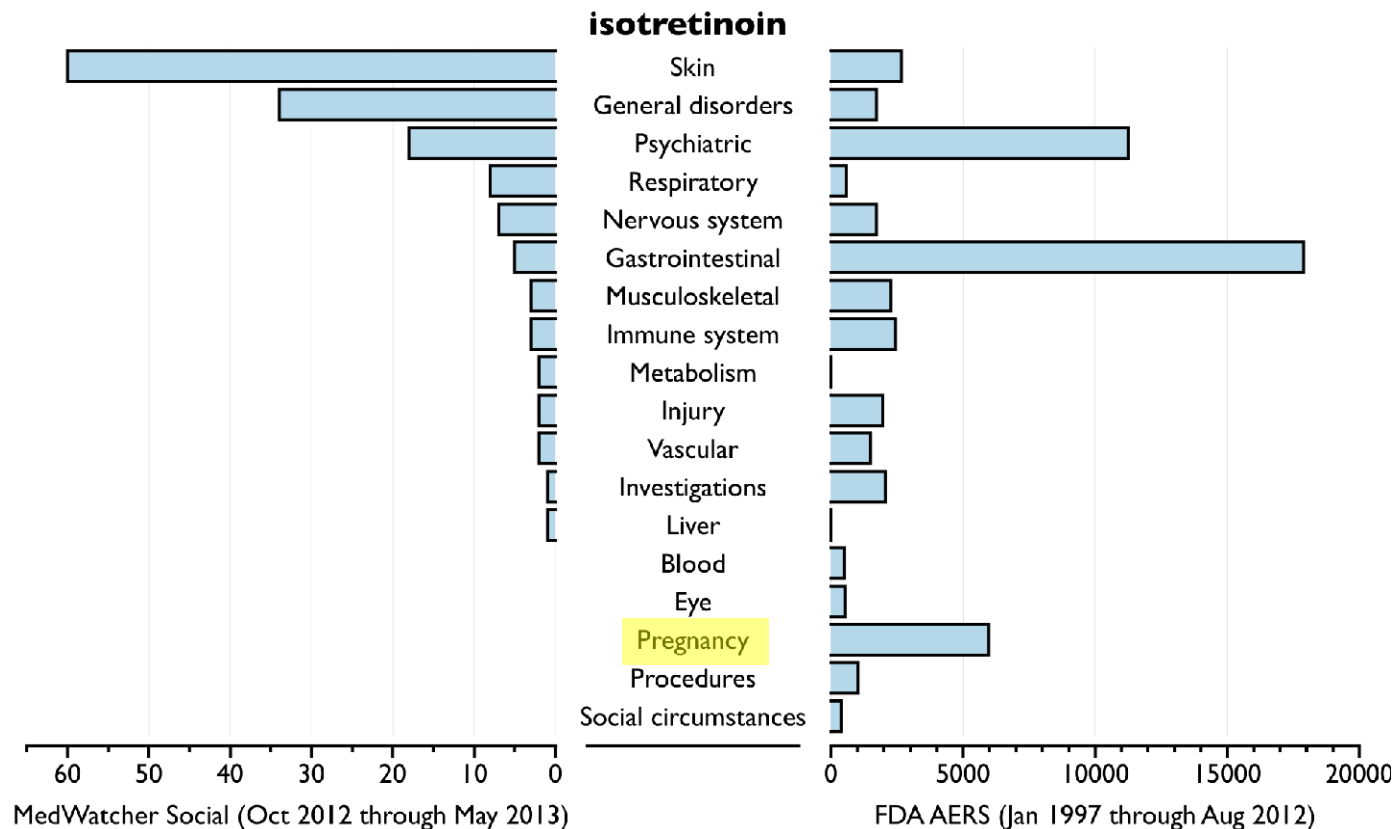
Recall
-
Sensitivity

Overall Association

All Medical Products



Isotretinoin (Accutane) for Acne



- Accutane + tanning isn't a good combination. My lips are SO chapped. #accutaneprobz
- this hair loss is seriously scaring me im going to stop accutane right now bye
- My liver is keeping me up again. :(I'm probably going to be babying it for the rest of my life after accutane gave me hepatitis. No fun.
- having to put vaseline on your eyelids because they are so dry and hurt so bad <<<< #accutane #accutaneprobz

KNOWN FREQUENCY ADVERSE EVENTS

Medicine Guide

Preferred terms appearing in social media and not appearing



10

VERY COMMON
decreased blood sugar levels, diarrhoea, nausea

100

COMMON
bronchitis, constipation, abdominal distension, faster heart rate, feeling dizzy, flatulence, gastritis, gastro-oesophageal reflux, headaches, indigestion, inflammation of nose/throat, injection site problems, loss of appetite, antibodies to Victoza, skin rash, stomach pain, tiredness, toothache, vomiting

1k

UNCOMMON
dehydration, malaise, itching, kidney problems, urticaria

10k

RARE / VERY RARE
anaphylaxis, angioedema, GI problems, pancreatitis, hypersensitivity

SOURCE

emc+ Medicine Guide, Jan 16, 2015, Datapharm
medicines.org.uk

Original Research Article

Digital Drug Safety Surveillance: Monitoring Pharmaceutical Products in Twitter

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- (2) Children's Hospital Informatics Program, Boston Children's Hospital, Boston, USA
- (3) Department of Pediatrics, Harvard Medical School, Boston, USA
- (4) Center for Biomedical Informatics, Harvard Medical School, Boston, USA
- (5) Epidemico, Inc., Boston, USA
- (6) Georgetown University Medical Center, Washington, DC, USA
- (7) US Food and Drug Administration (FDA), Silver Spring, USA
- (8) University of North Carolina at Chapel Hill, Chapel Hill, 27599, USA
- (9) 266 Newbury Street, 2nd Floor, Boston, MA 02116, USA



@user I just restarted taking victoza which made me so sick to my stomach till my body got used to it.

Twitter, May 3, 2014

Aside from the nausea (worse today) and occasional bouts of hypoglycemia (better today), four days on Victoza and down 5.3 lbs! Amazing!

Facebook, December 9, 2014



IN THEIR OWN WORDS

Typical Proto-AEs & Patient Benefits

//

Anyone else having issues with **plugger jamming** on their **flex pen** of victoza? The only difference I see is the new needles . I had to stick myself 4 times today to get almost a full dose. Frustration. Doesn't seem related to where I am into pen, first dose, midway , last. **Third pen this has happened on in a row**

Facebook, December 9, 2014

//

IN THEIR OWN WORDS

Product Quality Issues



I have 2 boxes of victoza insulin pens if interested inbox for more information

Facebook, February 3, 2015

Please, if anybody is on Victoza for diabetes or insulin resistance < i ordered too much stock and it is non returnable being a fridge item > please pop in at [redacted] pharmacywill organise a good price to compensate for my blunder.



Facebook, February 27, 2015

IN THEIR OWN WORDS

Diversion & Re-Sale



Just bought 4 Victoza pens
from my pharmacy (CVS).
\$800 out of pocket. Uggg. :(

Facebook, February 6, 2015



IN THEIR OWN WORDS

Product Pricing

//

Had my first injection of Victoza. So if it doesn't kill me from one of side effects my sugar should stabilize. One side effect is puzzling. "For type 2 Diabetics only. Not intended for type 1 diabetics". I'm the poster child for type 1 Diabetics.

Facebook, February 6, 2015

//

IN THEIR OWN WORDS

Off-label
Use

Engaging users directly



Dragonnnncaaaaaaaat~
@drgncat

[Follow](#)

Also my kidneys have been swollen ever since I've been on Viibryd.. but its also been super hot out..

[Reply](#) [Retweet](#) [Favorite](#) [More](#)

4:37 PM - 24 Jun 13



MedWatcher @med_watcher

14 Aug

@drgncat -- noticed you're having an issue with Viibryd. @med_watcher invites you to notify the @US_FDA: tinyurl.com/ldclek3

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MEDWATCHER

Make drugs, devices + vaccines safer

Track and report side effects of drugs, vaccines and medical devices.

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epidemico



Boston Children's Hospital



Back Product Info

* Product
Continuous Ventilator



Include a Photo

Medical Countermeasure



What other medications or medical products were you using at the time of this side effect?

Antibiotics, via iv line.

Why were you using this device?

Pt suffering from severe pneumonia.

Continue



News



Watch List



Search



Report



Settings

Product Info Event Info

* Date of Event
May 27, 2014

* What happened?

Please describe your experience in as much detail as you can, including any other ongoing illness, allergies, relevant birth defect or other medical conditions. Provide any available lab data.

Oxygen pressure sensor was alarming, but oxygen pressure was within normal range.

Check all outcomes that you attribute to this event.



Non-serious



Other serious



Hospitalization



Disability/permanent damage



Birth defect



Life-threatening



Death



News



Watch List



Search



Report



Settings



Instagram

4.27 @checkit0utgirl

my mom got some OxyContin pills. ya boy boutta be faded

Noemi ❤️ @noemi_boo18

@ChinooChino lol they use to be morphine and now she sells vicorine something like that

Mac @rbhaze__

Grandma gave me some Percocet for my pain. She came clutch

MJ Caan @mjcaan

Oh yeah. You stole all that morphine for nothing. #Helix



crackphotoz Look what I get!!!!!! At least one good thing came out of this!!!! Oh daym! Like I'm going to get so much bank selling this shit! **#oxycodone #money #bank #godblesslamar** 12h



crackphotoz

Raydem Johnsten

[T | M | L] 12h

X-Pro II



❤️ 9 💬 0

#money, #oxycodone, #bank, #godblesslamar,



Instagram



pharmacypimpin

pharmacypimpin

[T | M | L] 7d

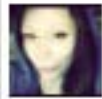
Normal



❤️ 19 💬 1

🔑 #benzo, #norcos, #actavis, #hitech, #percocet, #oxycontin, #hydrocodone, #oxycodone, #xanax, #hydromorphone, #promethazine, #morphinesulfate, #blues, #valium, #opana, #oc80, #morphine, #dilaudid, #fentanyl, #oc, #vcut, #m30, #oxymorphone, #methadone, #a215, #k9, #mbox, #opiates, #op,

♥️ @3hunv, @dem6n6l6gy187, @808_mafia, @idontknowhattodowithmyhands,



pandauhh
Ynattirb Radec

[T | M | L] 1w
X-Pro II



❤️ 12 💬 0

🔖 #benzo, #goodshit, #shittinonem,
#hydrocodone, #pharmacy, #pills, #1mg, #10,
#hydros, #eat, #xanax, #opiate, #allsmiles,
#footballs, #yum, #xan, #silly,

♥️ @goaskkatttt, @ninny3g, @tinsley402,
@yoshelove,

+

-

See what others paid

e.g. dilaudid california

Search

\$

Did you get a good deal?

Submissions are anonymous

* Name of drug

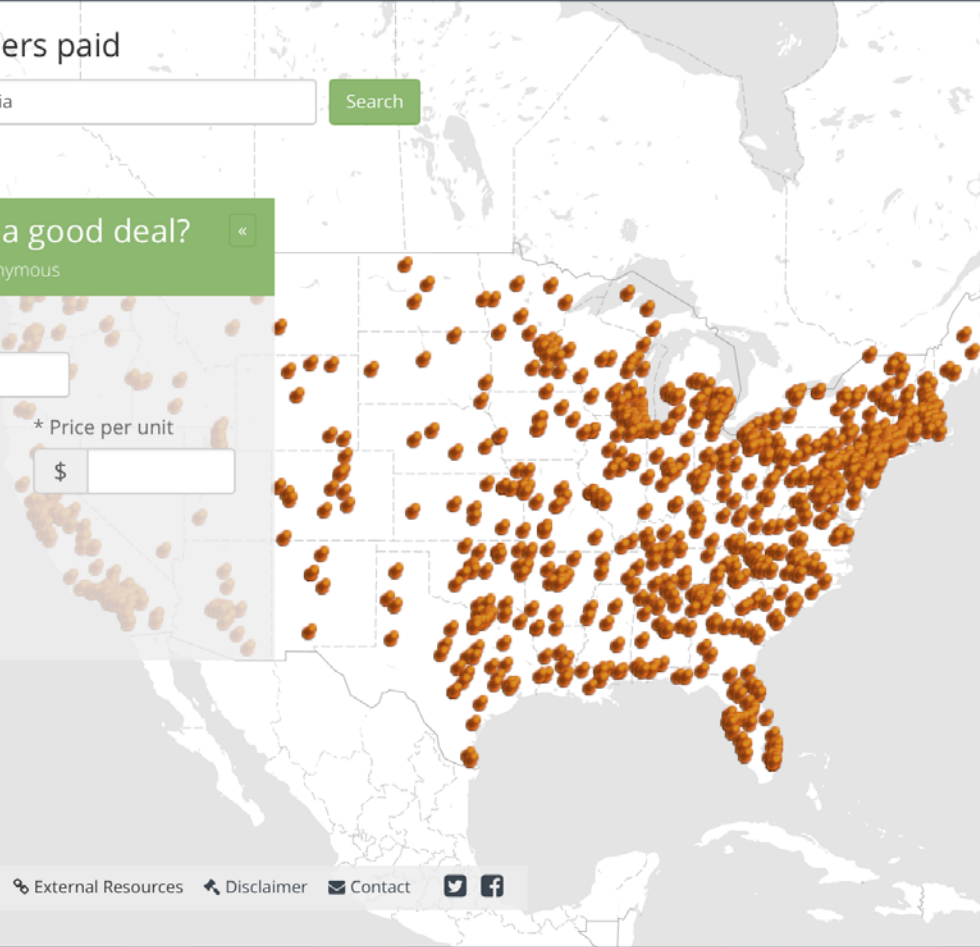
* Formulation

* Price per unit

\$

Please choose a drug to see formulation options

Continue



\$15 Mar 4 2015	Xanax, 2mg pill Texas	Rate: \$ \$ \$ \$ \$
\$1 Mar 4 2015	hydrocodone (generic Vicodin), 5mg pill Illinois	Rate: \$ \$ \$ \$ \$
\$25 Mar 4 2015	Dilaudid, 4mg pill Georgia	Rate: \$ \$ \$ \$ \$
\$10 Mar 4 2015	OxyContin (new OP, hard to crush), 40mg pill Albuquerque, New Mexico	Rate: \$ \$ \$ \$ \$
\$4 Mar 4 2015	Adderall, 10mg pill Erie, Pennsylvania	Rate: \$ \$ \$ \$ \$
\$5 Mar 4 2015	Vyvanse, 40mg pill Russellville, Arkansas	Rate: \$ \$ \$ \$ \$
\$3 Mar 4 2015	Klonopin, 1mg pill St Louis, Missouri	Rate: \$ \$ \$ \$ \$
\$8 Mar 4 2015	Adderall XR, 20mg pill Philadelphia, Pennsylvania	Rate: \$ \$ \$ \$ \$
\$10 Mar 4 2015	Adderall, 30mg pill Houston, Texas	Reasonable \$ \$ \$ \$ \$
\$4 Mar 4	Percocet, 10/650mg pill Swainsboro, Georgia	Rate: \$ \$ \$ \$ \$

See what others paid

New Orleans, Louisiana

Search



2015		
\$8 Feb 26 2015	Adderall XR, 30mg pill	Rate: \$ \$ \$ \$ \$
\$20 Feb 25 2015	morphine, 60mg pill	Cheap \$ \$ \$ \$ \$
\$5 Feb 21 2015	Xanax, 0.5mg pill	Rate: \$ \$ \$ \$ \$
\$8 Feb 11 2015	Adderall, 30mg pill	Reasonable \$ \$ \$ \$ \$
\$5 Feb 9 2015	Vyvanse, 30mg pill	Reasonable \$ \$ \$ \$ \$

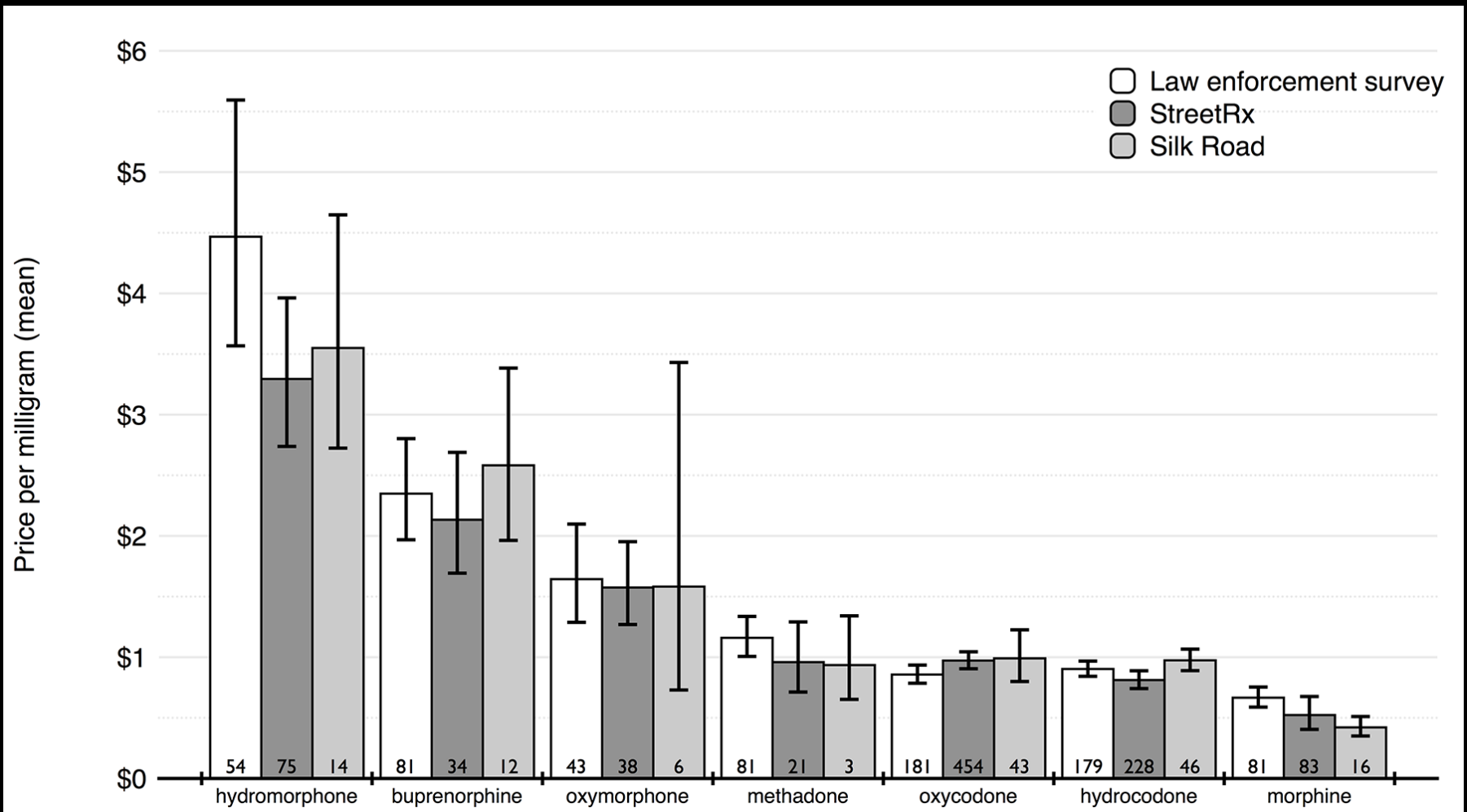
Prices for Any — New Orleans

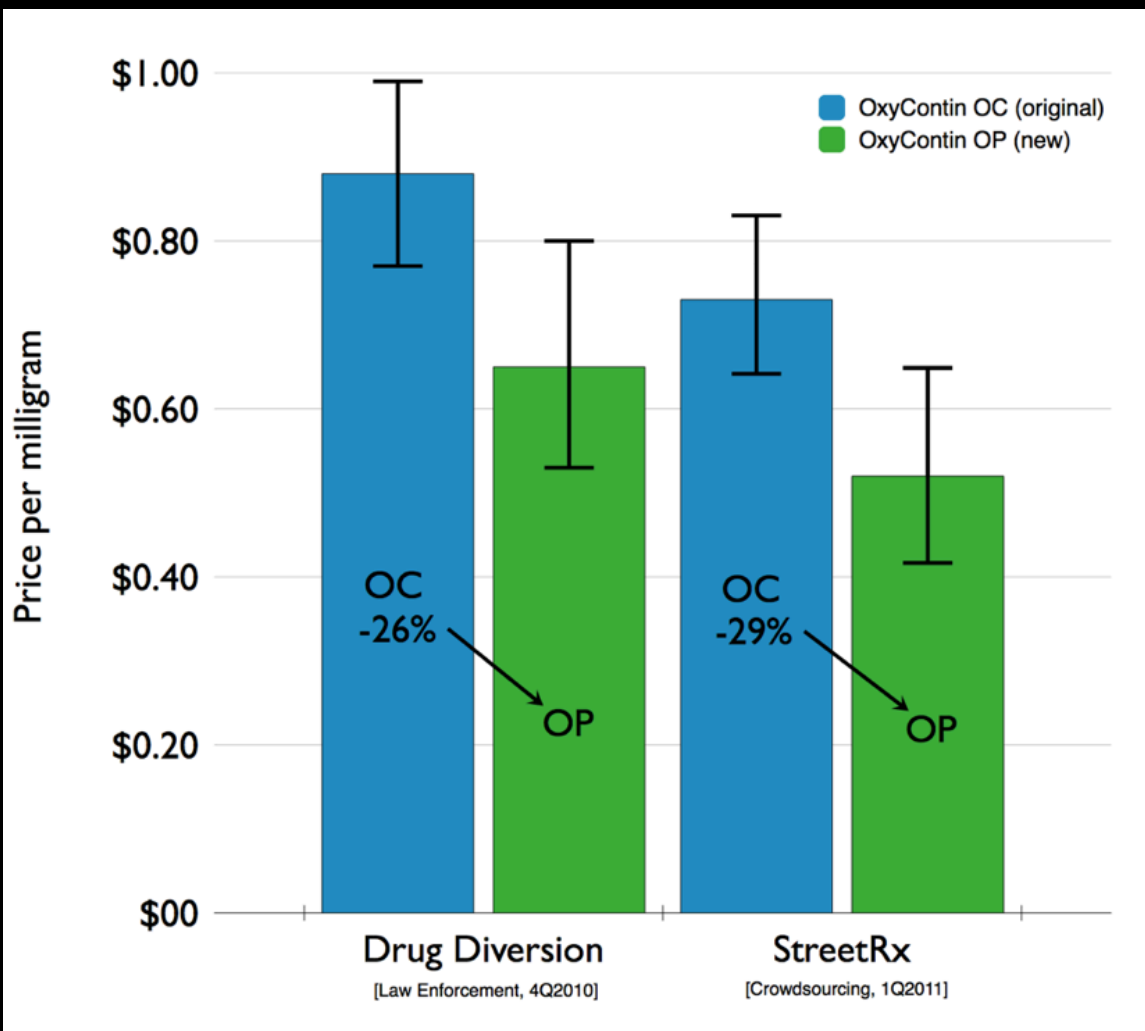
☐ Include products with the same active ingredient

\$0.53 Mar 3 2015	Fioricet (WITHOUT codeine), pill Louisiana	Rate: \$ \$ \$ \$ \$
\$20 Mar 3 2015	Norco hydrocodone, 7.5/325mg pill Louisiana	Overpriced \$ \$ \$ \$ \$
\$10 Mar 3 2015	Adderall, 30mg pill Laurel, Mississippi	Not Bad \$ \$ \$ \$ \$
\$10 Mar 2 2015	Norco hydrocodone, 10/325mg pill Baton Rouge, Louisiana	Overpriced \$ \$ \$ \$ \$
\$2 Mar 1 2015	Apo-Oxycodone CR (imprinted APO OCD), 80mg pill Baton Rouge, Louisiana	Overpriced \$ \$ \$ \$ \$
\$5 Feb 28 2015	Adderall XR, 30mg pill Covington, Louisiana	Cheap \$ \$ \$ \$ \$
\$3 Feb 28 2015	clonazepam, 1mg pill Houma, Louisiana	Rate: \$ \$ \$ \$ \$
\$10 Feb 28 2015	Xanax, 2mg pill Louisiana	Overpriced \$ \$ \$ \$ \$
\$10 Feb 28 2015	methadone, 10mg pill Baton Rouge, Louisiana	Overpriced \$ \$ \$ \$ \$

Drug	Crowdsourced Data from StreetRx		Predicted Relative Potency	Clinical Equianalgesic Potency ^b
	n	Mean, US\$ (95% CI)	(95% CI) ^a	Milligrams
Hydromorphone	75	3.29 (2.74-3.96)	6.3 (5.8-6.8)	4
Oxymorphone	38	1.57 (1.27-1.95)	3.0 (2.9-3.2)	3
Methadone	21	0.96 (0.71-1.29)	1.8 (1.8-1.9)	1.5
Oxycodone	454	0.97 (0.90-1.04)	1.9 (1.5-2.2)	2
Hydrocodone	228	0.81 (0.74-0.89)	1.5 (1.3-1.8)	1
Morphine	83	0.52 (0.40-0.68)	1.0	1
Tramadol	21	0.05 (0.03-0.07)	0.1 (0.07-0.13)	0.3

Cross-Validation of Black Market Prices





Multiple strikes with a hammer deforms but does not crush reformulated tablets into powder



agorahooawayfoe.onion/cat/zCdhkeCh2D

Wallet 0.00000000 BTC
0 NEW MESSAGES
LOG
































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(10+)

Other (100+)

Services (400+)

	Name	Price		Vendor
	80MG OXY AGORA OXY DEAL 1 PERSON PER WEEK This is only available to one person a week. 80mg oxycontin sells around \$120 all day. This deal gives you 10x 80mg oxycontin for only \$750 including shipping. after you the same person has ...	2.40874559 BTC	 From:  Australia	 Cocaine_Oxy_Vape_Australia  5.00/5, 25~40 deals
	OXYCODONE 30mg \$35 each!! X 30 PILLS (MFG by Xanodyne 54 199 IMPRINTS RARE!) OXYCODONE 30mg QUANTITY: 30 PILLS PRICE: \$35 MFG: Xanodyne Pharmaceuticals, Inc. AR 199 IMPRINT (THESE ARE THE OLD ONES FROM A WHILE BACK, NOT SURE HOW WE CAME UP ON THESE BUT ARE STRAIGHT FROM S ...	3.91699092 BTC	 From:  USA	 ladyskywalker  4.93/5, 300~500 deals
	15mg RoxycodoneOxycodone IR Full escrow on all my opiate products. I have Green A214/Peach 113 Roxycodone/Oxycodone 15mg IR pharmaceutical grade pills. This listing is for 1 Green A214/Peach 113 Roxycodone/Oxycodone 15mg IR ...	0.05558643 BTC	 From:  USA	 opiateconnect  4.92/5, 200~300 deals
	OxyContin 10mg / 10 Tabs These are Oxycontin 10mg Instant Release pills. They are the "old formula" and can be smoked, snorted, I-Ved or popped. There is a thin white coat that can be washed off so it can be crushed. Thi ...	0.37057624 BTC	 From:  Germany	 zunidog  4.80/5, 200~300 deals
	1 HYDROCODONE 5mg PILL ONLY \$4.99 *****SALE PRICE***** PRICE***** This listing is for 1 5mg Hydrocodone pill. This is a white oblong pill with red dots and imprint of V3 ...	0.01849175 BTC	 From:  USA  To: usa	 lifecare  4.82/5, 100~150 deals
	20mg Oxycodone x 50 Oxycodone 20mg 50 pills Oval white pills, OXY on one side, and 20 on the other side (It is not my picture, i just borrowed it. But the pills looks like these in the picture, but mine are oval) Oxycodone 30mg • non-FE listing	3.33518621 BTC	 From:  Canada  To: Worldwide	 blow  4.83/5, 150~200 deals

OTHER SOCIAL MEDIA EFFORTS AT FDA

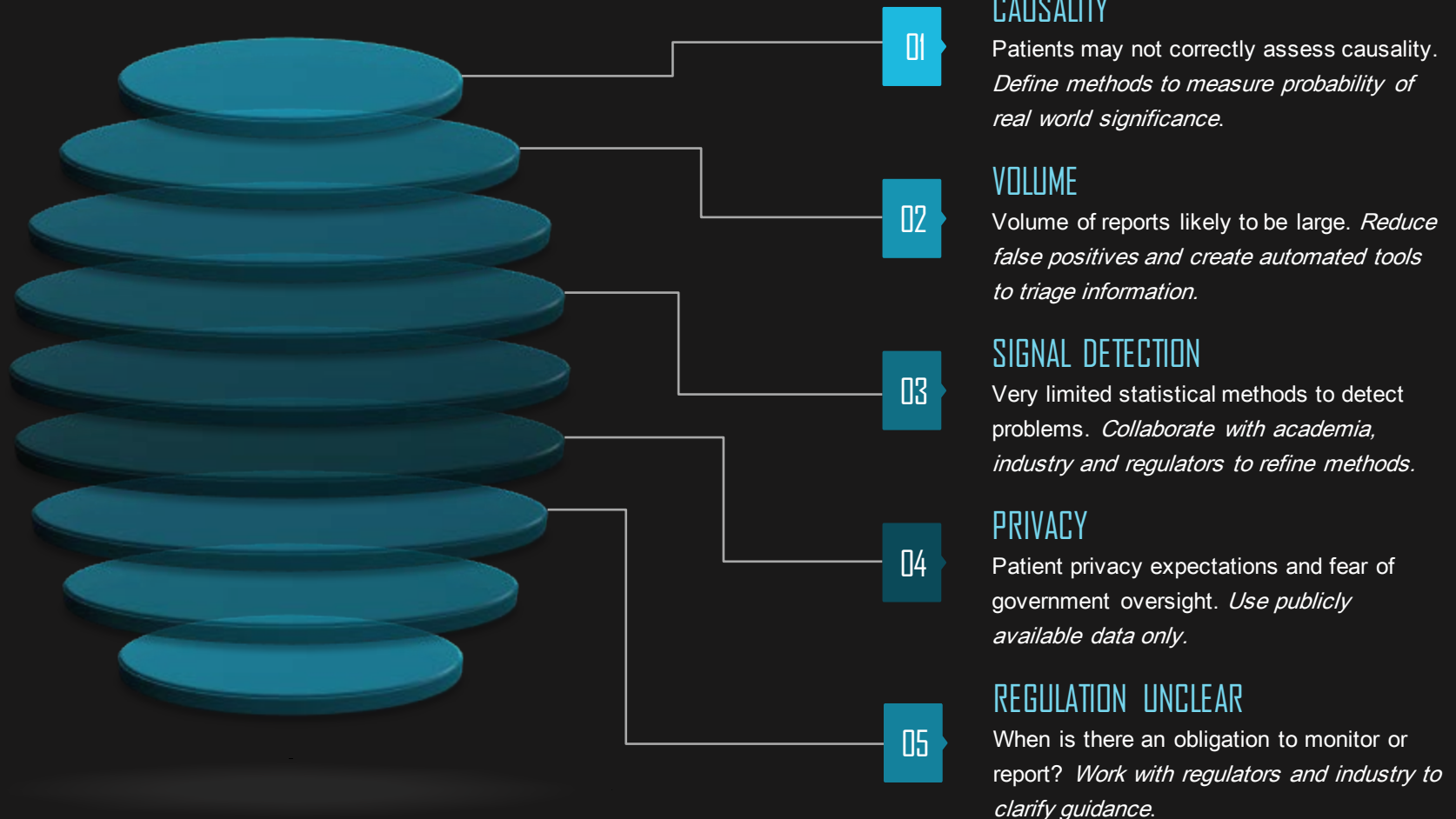
Tobacco products

- FDA Center for Tobacco Products
- Monitoring existing and emerging tobacco products
- Use, outcomes, perceptions, attitudes

Supply chain monitoring

- FDA Office of International Programs
- Monitoring China-to-US supply chain vulnerabilities
- Food, drug, and ingredients

LIMITATIONS OF SOCIAL MEDIA



Questions?

John_brownstein@harvard.edu

 [@johnbrownstein](https://twitter.com/johnbrownstein)