



DEA Update  
Market Leadership Meeting

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PLAINTIFFS TRIAL  
EXHIBIT  
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## The New HOT Topic



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The new hot topic in the news is the epidemic America has: Prescription Pain Drug Abuse



## Florida Pill Mill Busts

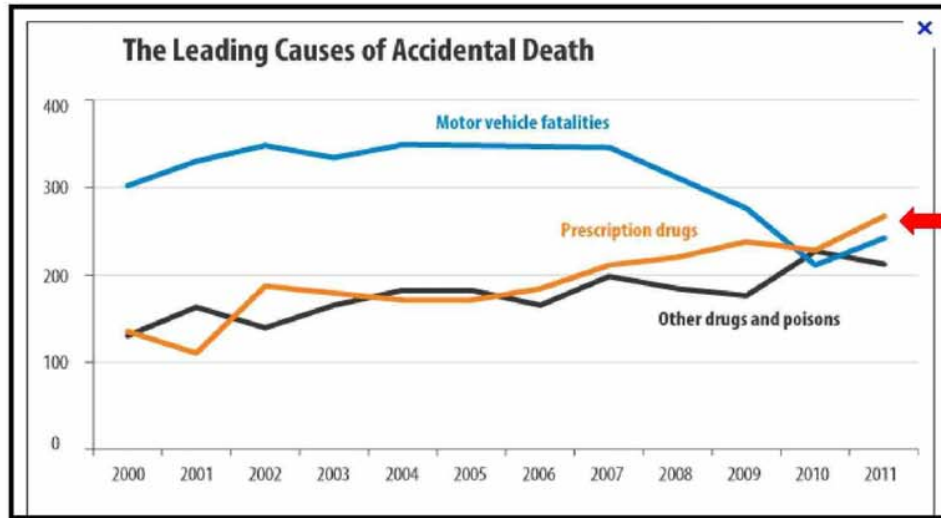


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## Leading Cause of Death - Prescription Drugs



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This particular stat came out of California, but there were multiple examples across the country where the leading cause of accidental death is prescription pain medications (opioid use). This national problem has brought increased scrutiny to physicians, pharmacists and drugs wholesalers from regulators, policy makers and law enforcement.



## Title 21 Code of Federal Regulations

### ***Section 1306.04 Purpose of issue of prescription.***

*(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, **but a corresponding responsibility rests with the pharmacist who fills the prescription.** An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act ([21 U.S.C. 829](#)) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.*

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Pharmacists are required by DEA regulations to ensure that prescriptions for controlled substances are dispensed for a legitimate medical purpose. This legal responsibility is pursuant to Title 21 code of Federal regulations. The important point of this regulation is "the corresponding responsibility rests with the pharmacist who fills the prescription"



## Timeline of Events

Pre-August  
2010

- Steady increase in FL pill mills
- Prescribers dispensing medications

October  
2010

- Change in Florida legislation restricts prescriber dispensing to only 72 hour supply of pain medications

October 10-  
March 11

- Dramatic increase in the number of opioid pain medications prescriptions seen at retail stores

July 2011

- Florida law amended to prohibit practitioners from dispensing C2-3, except in very limited instances

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## Timeline 2012

April 2012

- Administrative Inspection Warrants were served on 6 stores and the Jupiter DC

May – June 2012

- 8 stores voluntarily removed all C-II products, Xanax and Soma
- Re-launch of Good Faith Dispensing Policy

September 2012

- ISO was issued for the Jupiter DC

November 2012

- Order to Show Cause issued to 3 of the original Florida pharmacies

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Early this year the DEA took action against Walgreens. In April DEA Agents executed inspection warrants on 6 Walgreens pharmacies. An administrative subpoena was simultaneously served on the Jupiter, Florida Distribution Center. In addition the DEA requested data from two more stores and the mail facility in Orlando. These warrants and subpoena requested production of certain records of controlled substance prescriptions, transaction data, including form of payment, and other prescription information.

In response, we voluntarily and proactively removed all CII, xanax and soma from the 8 stores

In September when the Immediate Suspension Order was issued to Jupiter, all C3-5 had already been shifted to other DCs. All C2 product we had at Jupiter was locked up by the DEA

In November, DEA issued an Order to Show Cause to 3 of the 6 pharmacies that were initially visited in April. Hearings will also be scheduled in these matters

**Redacted - Attorney Client Privileged and Attorney Work Product**

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## Timeline

December  
2012

- Target Drug GFD pilot begins in FL and Vegas

January  
2013

- Sanction prescriber pilot begins NJ and PA

February  
2013

- DEA administrative hearing begins

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In December we started a pilot in FL and Vegas where we have the pharmacies complete a checklist for each rx filled for a Target Drug (oxy, hydromorphone, methadone) and call the prescriber for quantities over 120 (>60 for cash rx's) at least once every 90 days

This month we sent sanction letters to 8 prescribers in NJ and PA to let them know we will no longer accept controlled substance prescriptions written by them in our pharmacies.

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## Operational Steps Taken

- In June, we re-launched our Good Faith Dispensing Policy across the Chain
- Pilots
  - Target Drug Good Faith Dispensing in FL and NV
  - Prescriber Sanctioning in NJ and PA – 8 prescribers total
- Invalid Prescriber DEA removal from IC+

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While our first responsibility is to help patients secure the medications they need, we also understand our role in helping reduce the inappropriate use of controlled substances in the communities we serve. As part of our ongoing commitment, we have taken action to focus our field and store leadership on good faith dispensing.

In June we re-launched our Good Faith Dispensing policy. However, we have learned more about DEA's expectations around GFD and we felt the steps we were taking with GFD did not go far enough. The game has changed; we can no longer rely on the "I spoke to the prescriber and he said it was okay." This is especially true when the prescriber may be assisting the patient to inappropriately use controlled substances. We are going down a different path now and we have to make sure that we are prepared.

So, we are piloting the TD GFD in a FL and NV. This consists of a checklist to be used every fill and a required phone call to the prescriber at least once every 90 days.

Another pilot is the prescriber sanctioning where we identified high prescribing physicians over select controlled substances as compared to their peers. In some cases, opioid pain medications are all some of these physicians prescribe. This type of prescribing pattern can put us at risk if we do not ensure the prescriptions were issued for a legitimate medical purpose. In certain cases, the risk to continue dispensing these medications is too great and Walgreens will no longer fill controlled substances issued by these prescribers.

We had a COMPASS Communication last week announcing that we are removing Invalid DEAs

What is it?

A new IC+ enhancement is being released this week that will flag and remove Invalid DEA #'s

How will I know the DEA number was removed because it was invalid?

When the prescriber's DEA # is removed, a message will be put in the comment field of the Prescriber Inquiry window that says:

WARNING INVALID DEA #. DO NOT ADD DEA #. DO NOT FILL C2-5 RxS FOR THIS PRESCRIBER.

What do I need to know?

Pharmacy staff must look in the prescriber inquiry window for the message above before adding a DEA #.

If the message above is in the profile, do not register the prescriber again and do not add the DEA # back into IC+.

Pharmacy staff must verify that the prescriber's DEA number is valid from the DEA website before registering any prescriber.  
SNet -> RxOps-> Filling Prescriptions -> Good Faith Dispensing -> DEA Diversion Website -> Registration Validation or click link below  
(<https://www.deadiversion.usdoj.gov/webforms/validateLogin.jsp>)

What do I do if this is a refill?

Speak with the patient to ask if they have a new prescriber they would like you to contact for a new prescription. If they do not have a new prescriber, they need to contact their existing prescriber for next steps, as Walgreens cannot fill this prescription under the current prescriber.

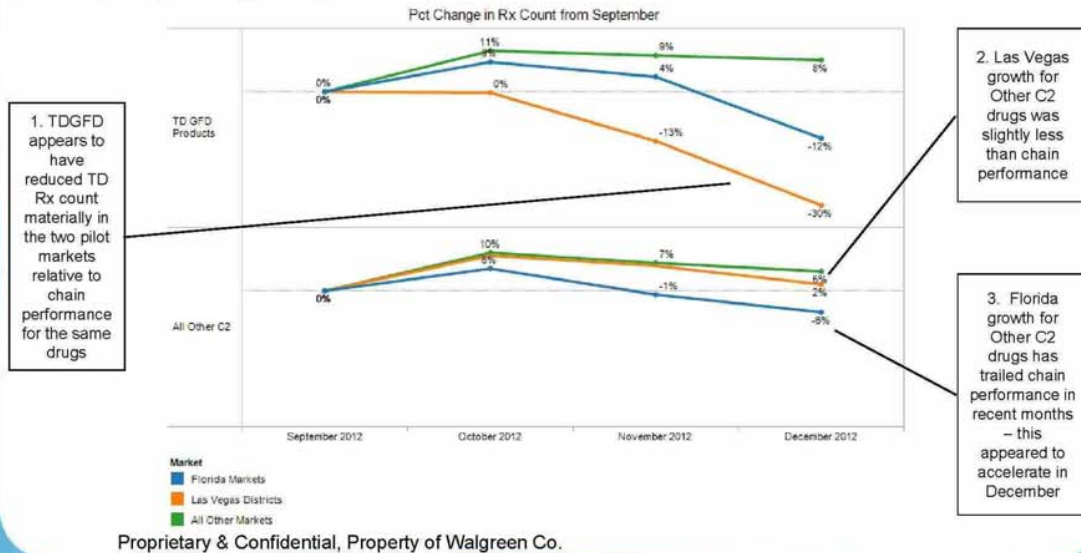
What if this is a new prescription?

Return the prescription to the patient and let them know they need to contact the prescriber for next steps.



## C2 Dispensing Patterns in Pilot Areas

Dispensing data by selected markets for the 4 months ending December 2012 suggest that TDGFD is impacting the Target Drugs as anticipated.



So, what is the impact of GFD? I cannot stress enough that we cannot approach this as "impacting volume". Our objective is a safe and regulated environment to keep our stores/pharmacists from scrutiny from these agencies.

Realistically, bottom line, yes sales are going to be impacted. However, some would say that we shouldn't even be filling some of these prescriptions.

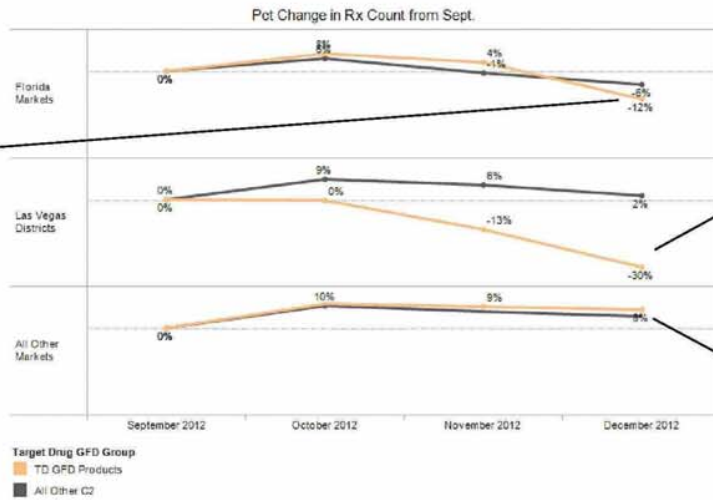
How is this going to impact my sales, what is it going to do to my "good customers" numbers show that we can address the issue without significantly impacting our other business.



## C2 Dispensing Patterns in Pilot Areas

Dispensing data by selected markets for the 4 months ending December 2012 suggest that TDGFD is impacting the Target Drugs as anticipated.

1. TDGFD appears to have reduced TD Rx beyond the observed decrease in Other C2



2 Las Vegas growth in TD has been trailing its growth in Other C2 since October – gap widened in December with TDGFD pilot

3. Remainder of chain has seen growth in TD slightly exceed growth for Other C2

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# Reporting Tools

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## Expired DEA CAP Override

Rx #	Store	Sold Date	Campaign ID	DEA #	Prescriber First Name	Prescriber Last Name	Drug	RPH	Consult Completed Date	Comments	Sold?
1491441	Xxxx	12/28/2012	Doctor Suspension	AP6572716	NATE	PETTINGER	OXYCODONE 30MG IMMEDIATE REL TABS	EXW	12/28/12 7:20 PM	Consultation Completed:	YES
1900255	Xxxx	12/26/2012	Doctor Suspension	BP4716594	JAMES	POGUE	CONTOUR TEST STRIPS 100'S	NAH	12/26/12 1:33 PM	Consultation Completed:	YES
3002349	Xxxx	12/26/2012	Doctor Suspension	BP4716594	JAMES	POGUE	VIT D 50,000 IU D2 (ERGO) CAPS (RX)	ERL	12/26/12 12:01 PM	Consultation Completed:	YES
3017623	xxxx	12/26/2012	Doctor Suspension	BP4716594	JAMES	POGUE	OMEPRAZOLE 20MG CAPSULES	ERL	12/26/12 12:01 PM	Consultation Completed:	YES

- Each week RxIntegrity gets a report showing CAP overrides
- We need documentation back from the RXS that they discussed with the pharmacist
- We should not be dispensing any controls and for the example of Dr Pogue his medical license was revoked, so non-control rx's are not valid either

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## Top 500 : 100 Store Indexing Report for Oxy

Mkt Name	Dist #	Dist Name	Store #	Store Address	State	Index Trending Since May	3 Mo. Avg Daily Script Ct	In Chain Top 500	In Chain Top 100
Market Name	Xxx	District Name	xxxx	1111 Main St Anywhere	XX	Deterioration 100+ since May	189	x	x
Market Name	Xxx	District Name	xxxx	1111 Main St Anywhere	XX	Deterioration 500+ since May	363	x	x
Market Name	Xxx	District Name	xxxx	1111 Main St Anywhere	XX	Neutral/stable trend	65	x	
Market Name	xxx	District Name	xxxx	1111 Main St Anywhere	XX	Deterioration 400+ since May	176	x	

- Top 500 potential risk stores in the chain for oxycodone
- Ranking is determined by weighted metrics
- Indexing column tells you if the store has improved, deteriorated, stayed the same
- Gives you an indication of where GFD efforts should be focused

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You'll get a spreadsheet provided that shows you the top 500 Potential Risk Stores in the company for Oxycodone. Most recently, the data was for the previous 3 months ending November 2012.

The ranking is determined by weighted metrics:

Overall unit volume

Change in unit volume current 3 months vs prior 3 months

Proportionality to total script business

% Paid by cash (or cash discount card)

note: you may not have any, as this is the top 500 stores only

Index Trending column tells you how the store has improved or deteriorated since May (for the last report generated)

This gives you an indication of where GFD efforts should be focused, particularly if you have a "deterioration of 500+" for a store. This means that 3 months ago, the store was not on the list for Top 500 and now is not only on the list, but in the Top 100.



## Customer Service in Regard to GFD Policy

- Intentionally written with grey areas
- Intended to be used as a guideline
- Does not replace sound professional judgment

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# Suspicious Order Monitoring

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## Suspicious Order Monitoring

How normal and expected transactions are identified:

- Accumulation of Receipts over time period- The system accumulates the amount of each controlled substance over the last six weeks.
- Ceiling Limit- Data mining is done across Walgreens retail pharmacies to determine the maximum amount that a pharmacy should be allowed to receive in a rolling six week time period, based on statistical linear regression. The analysis compares like pharmacies across the country based on script volume and determines by drug what would represent unusual quantities.

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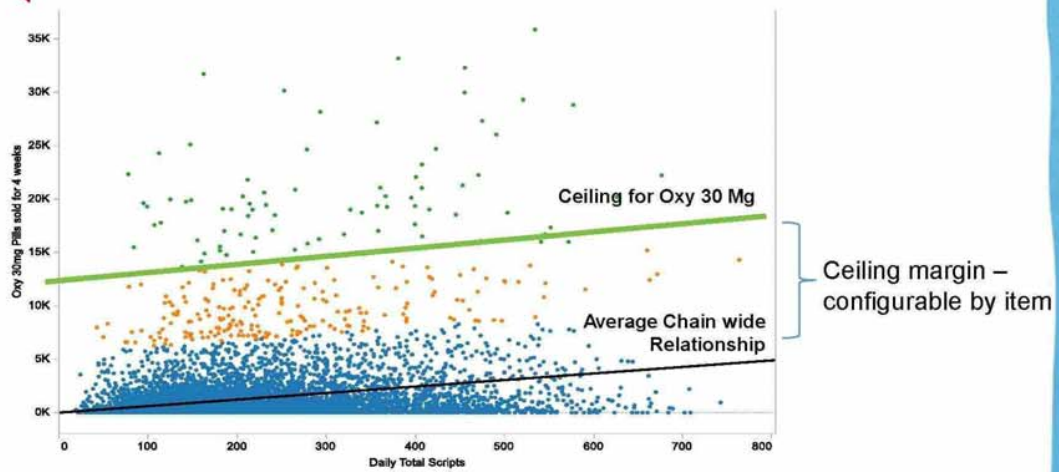
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DEA regulations require that distributors (i.e.; the Walgreen distribution centers) must take reasonable measures to identify its customers, understand the normal and expected transactions conducted by those customers, and identify transactions that are suspicious in nature. Orders must be assessed to ensure that quantities for controlled substances at a specific location are reasonable. In making such assessments, a wholesale distributor may consider the purchasing entity's clinical business needs, location, and population served. In addition, Walgreens must report to the DEA any order that is deemed suspicious.

So the system takes into account normal accumulation for the store over the last 6 weeks and the maximum (a.k.a. ceiling) they should have over a rolling 6 weeks.



# Next Steps Through Inventory Control New Ordering Functionality



Total Scripts Divided by 30 vs. sum of Generic Name Pills. Color shows details about Upper Limit Flag Based on Total Scripts. Details are shown for str\_nbr and str\_nbr (copy). The data is filtered on Date, StoreType (Store List (Store List for Analysts.xlsx)) as an attribute and Composite Rank Top 100 (DEA analysis store Indexing (Store Potential Risk Index 06-04-12 and May - modified for Tableau.xlsx)) as an attribute. The Date filter ranges from 4/1/2012 to 4/1/2012. The StoreType (Store List (Store List for Analysts.xlsx)) as an attribute filter keeps R. The Composite Rank Top 100 (DEA analysis store Indexing (Store Potential Risk Index 06-04-12 and May - modified for Tableau.xlsx)) as an attribute filter excludes Null.

#### Upper Limit Flag Based on Total Scripts

- Below LL
- Store Limit
- Upper Limit

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From an inventory perspective, we are working to ensure stores that are dispensing more controlled substances than the average are brought down closer to the average. These outliers will see a decrease or in some cases, we'll stop shipping certain controlled substances to them until they are brought down to the appropriate levels.



## SOM as it Applies to Cardinal

- Cardinal will limit the entire family of a drug based on monthly purchases
  - example: HC/APAP, Hydromet, Tussionex is all grouped into one
- Orders they flag (ie; your invoice says “Restricted Due to DEA Regulations”) are reported immediately to the DEA
- Cardinal has our sales history by store for the past year, so they can monitor any orders that deviate from the norm
- Anything they deem as suspicious gets cut

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## All Receipts Count Toward Rolling 6-weeks

- Warehouse
- Interstore – should not be doing this
- Vendor

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All receipts count toward the store's rolling six week volume.



## Best Practices For Ordering

- Review all Controlled Substance receipts before posting
  - Adjust the shipped quantity to "0" if you did not receive
  - Post as short when appropriate
  
- On-hands
  - Do not falsely increase/decrease on-hands
  - Do not increase/decrease suggested orders
  - Do not manually inflate your orders

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# Industry Efforts

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## Industry Work

- American Pharmaceutical Association (APhA)
- American Academy of Pain Medicine (AAPM)
- American Medical Association (AMA)
- National Association of Chain Drug Stores (NACDS)
- National Association of Boards of Pharmacy (NABP)

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This is not just a Walgreen issue, this is an industry wide issue. We have been working with or are in conversations with various organizations

Talk to some of the meetings/conversations.....

As we further advance our pharmacy practices to meet these new challenges, we continue to believe that addressing prescription drug abuse will require all parties – including leaders in the community, physicians, pharmacies, distributors and regulators – to play a role in finding practical solutions to combatting abuse while balancing patient access to critical medication

Our goal is to lead the industry to a solution for this problem that affects all areas of healthcare.





## Task Forces and Committee Meetings

- If you or your Supervisors are asked to participate
  - Yes, we need your help!
- Contact us before agreeing to participate
  - Tasha Polster or Al Cater
  - We will ensure that you are fully versed or have additional corporate support
- This team work will ensure we continue to build relationships with state agencies and remain a leader in the industry

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Many state regulators or agencies will ask for your participation in different task forces or committees because of the national presence Walgreens brings. We do need your help, but we also want to make sure that the person participating is fully versed on the national issue and not just seeing it from a district, state, or local level. Contact me or Al Carter and we will ensure that you have what you need from corporate before agreeing to participate.

This is an opportunity to make sure that laws and regulations that are created don't hinder us from continuing in expanding our pharmacy practice to the highest level.

Questions?

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