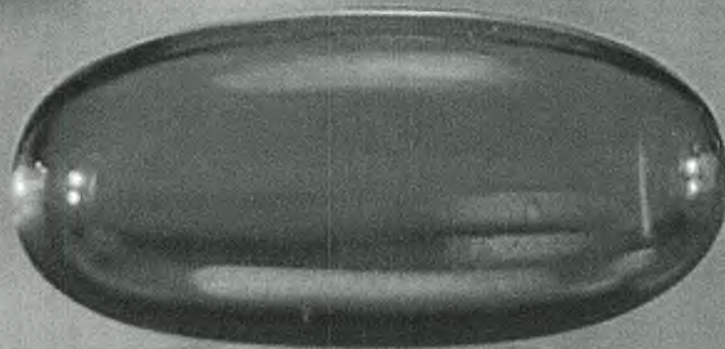


Suspicious Order Monitoring

Joseph Tomkiewicz, Diversion Operations Manager

2014



PLAINTIFFS TRIAL
EXHIBIT
P-03722_00001



So, What Are We Talking About

History

How Cases Are Being Prosecuted

Customer Due Diligence

Monitoring for Suspicious Orders

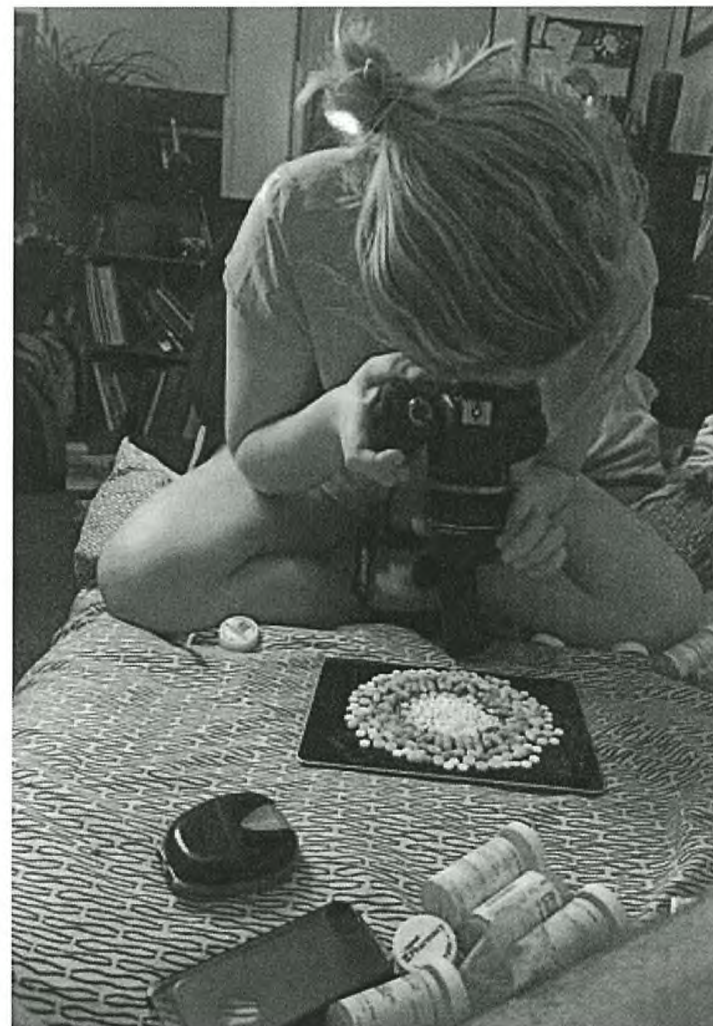
Monitoring Our Customers

Monitoring Our Customers' Customers

Feel Free to Interrupt Me And Ask Questions



A quick note about these photos...





McKESSON

Empowering Healthcare



CardinalHealth

Essential to care™

CVS/pharmacy®
Expect something *extra™*

Walgreens
AT THE CORNER OF **HAPPY & HEALTHY™**



AmerisourceBergen®



CVS/pharmacy[®]
Expect something *extra*.[™]

Two Retail Stores in Florida

3 million tablets of oxycodone



CardinalHealth

Essential to care™

Four Retail Stores in Florida

Increased Thresholds Without Adequate Justification

Lakeland, FL Distribution Center



Walgreens
AT THE CORNER OF HAPPY & HEALTHY™

6 Stores in Florida

Jupiter, FL Distribution Center

"PAY FOR PLAY" and "CANDY DR"



Walgreens
AT THE CORNER OF HAPPY & HEALTHY™

41 Prescribers Noted

2 Were Ophthalmologists

Only 7 DEA Registrations were Surrendered

Only 10 State Licenses Suspended

2 State Licenses Expired

29 Prescribers Still Active, 24 Without Any Discipline



One Small Retail Pharmacy Customer in New Jersey in 2010

Six Prescriptions

1/14/2010 - Three prescriptions totaling 540 tablets of oxycodone

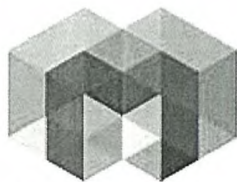
1/21/2010 - One prescription for 120 tablets of oxycodone

1/28/2010 - Two prescriptions totaling of 360 tablets of oxycodone

Operation Oxymoron

Criminal Investigation into ABC

http://www.deadiversion.usdoj.gov/fed_regs/actions/2010/fr1026_10.htm



Mallinckrodt

August 23, 2011 DEA Meeting

September 16, 2011 Letter to 43 Distributors

16 DEA Agents for 6 Weeks

Due Diligence Program



“Know Your Customer” Policy

“It is fundamental for sound operations that handlers take reasonable measures to identify their customers, understand the normal and expected transactions typically conducted by those customers, and, consequently, identify those transactions conducted by their customers that are suspicious in nature.”

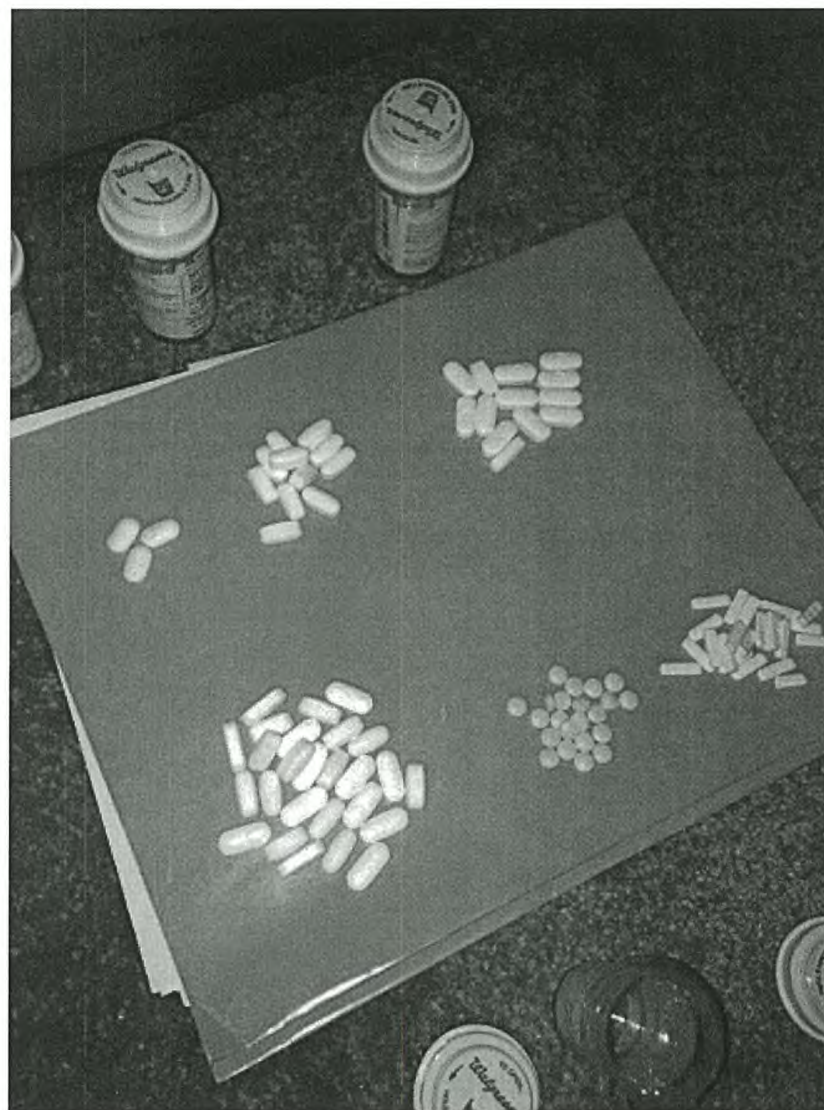
http://www.deadiversion.usdoj.gov/chem_prog/susp.htm



How Well Do We Know Our Customers?



Walgreens
AT THE CORNER OF HAPPY & HEALTHY™





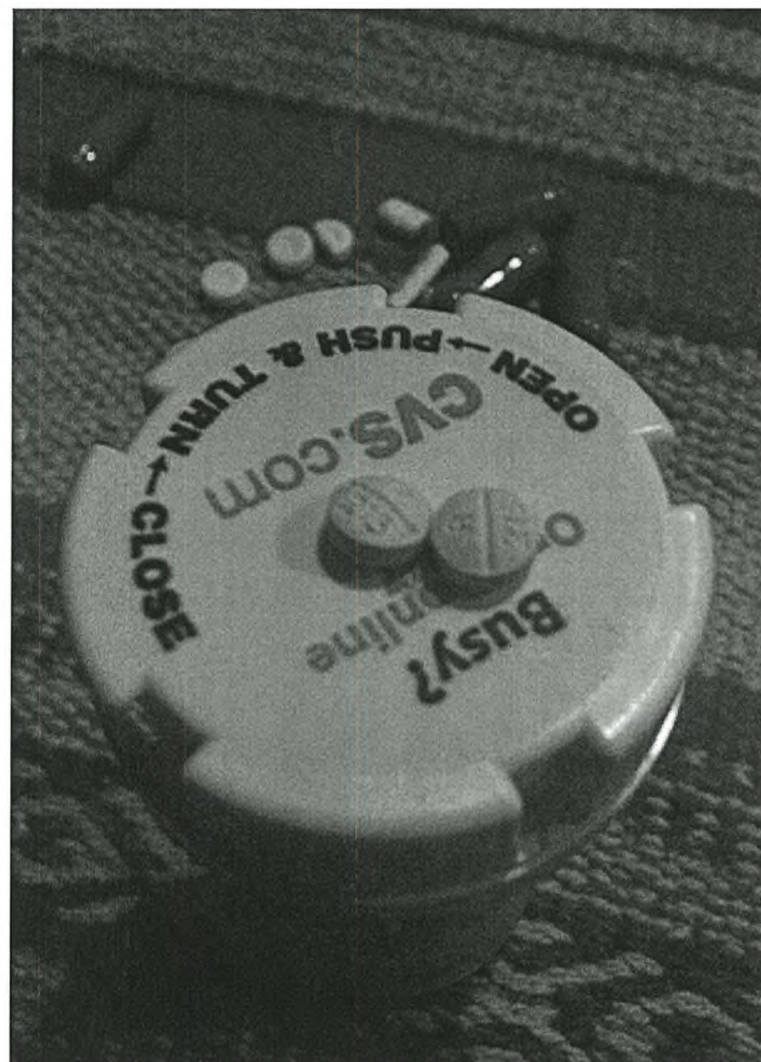
PHARMACY

With us, it's personal.



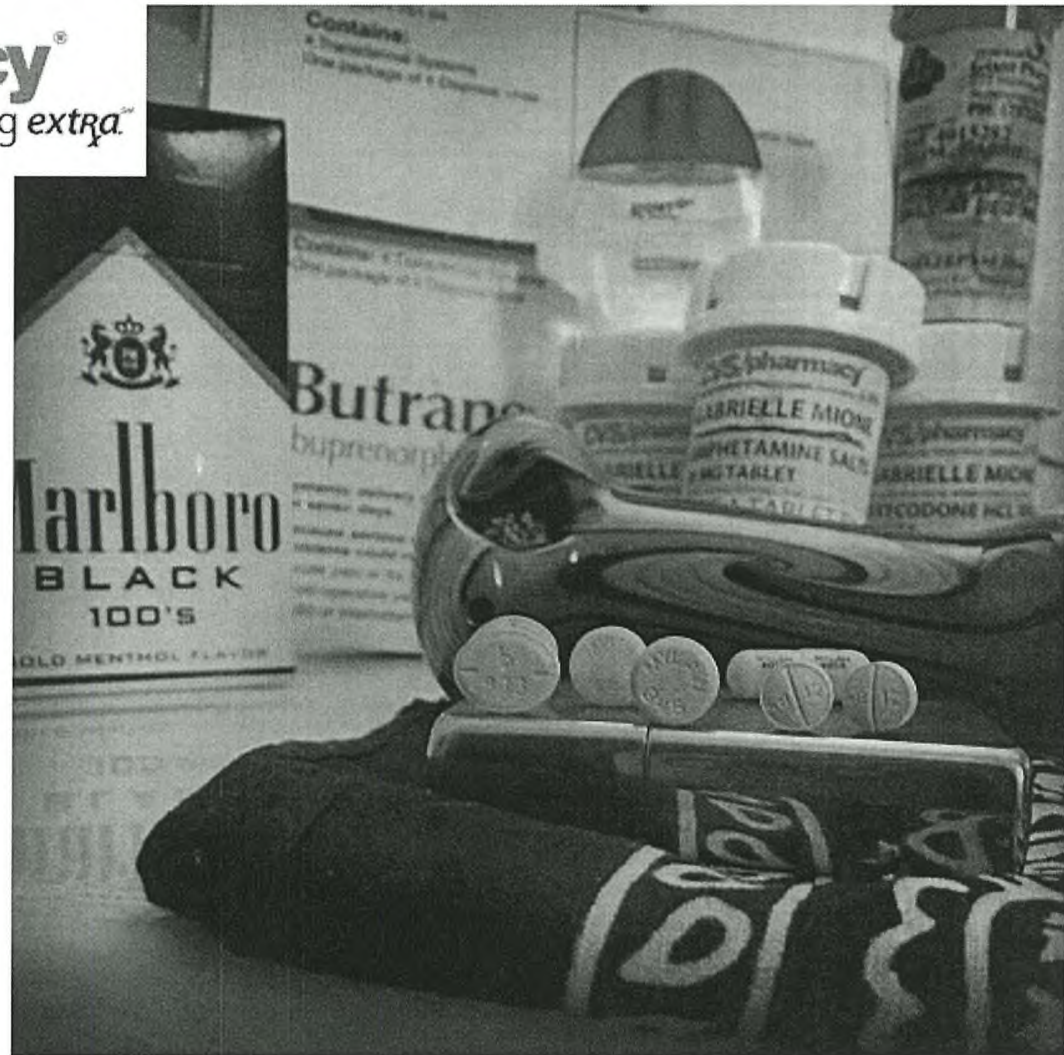


CVS/pharmacy[®]
Expect something *extra*.[™]



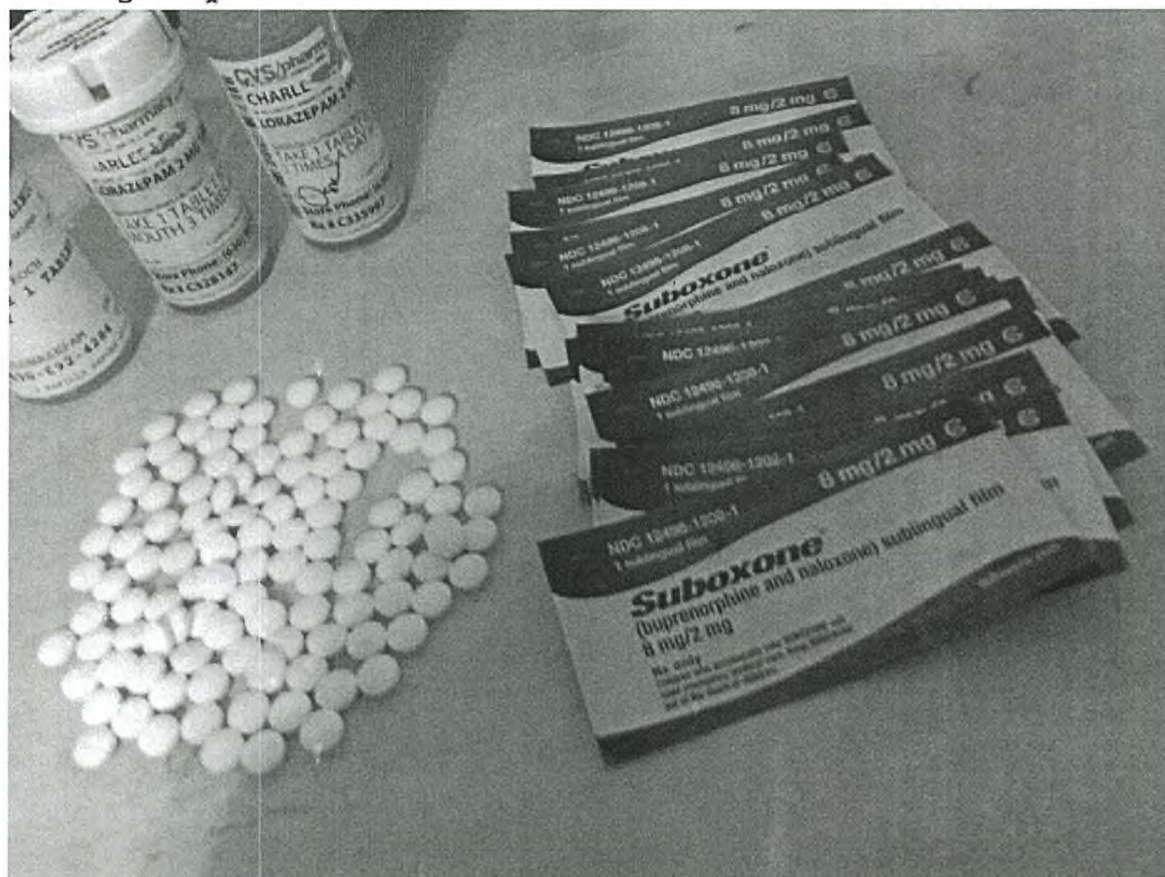


CVS/pharmacy[®]
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CVS/pharmacy®
Expect something *extra™*



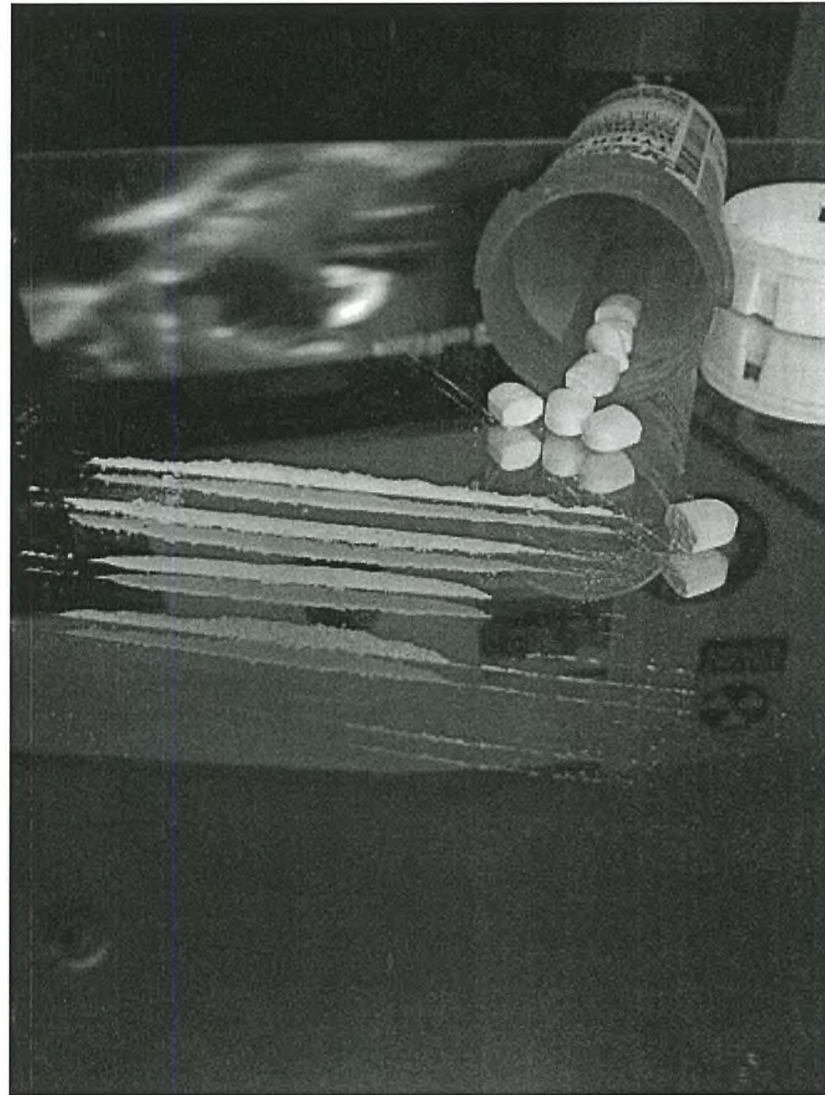


CVS/pharmacy[®]
Expect something *extra*.™





CVS/pharmacy[®]
Expect something *extra*[™]





If they're getting prescriptions, why is that a problem for the pharmacy, the wholesaler, or the manufacturer?



21 C.F.R. § 1306.04 (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.”

(emphasis added)



“If you’re waiting to die, you should die in comfort and dignity. It’s very different than if you’re attempting to have a functional life, because these drugs are relatively incompatible with having a functional life.” —Dr. Lewis S. Nelson, Medical Toxicologist, New York University School of Medicine

Thomas, Katie. "Doubts Raised About Off-Label Use of Subsys, a Strong Painkiller." *New York Times*, May 13, 2014. <http://www.nytimes.com/2014/05/14/business/doubts-raised-about-off-label-use-of-subsys-a-strong-painkiller.html> (accessed May 15, 2014).



“I want to drag a CEO out of his office in handcuffs.”



Prosecution Strategy

“How much diversion is ok?”

The Appearance of ‘Turning a Blind Eye’

The Sales Department

Very Aggressive Prosecution

Very Wide Subpoenas

Personal Intimidation of Employees and Their Families



Subpoenas and Discovery

Reports

Spreadsheets

Presentations

Emails

Context is Everything

:)



Where Has The Focus Been?

Street Drugs

Hydrocodone

Oxycodone

Buprenorphine

Hydromorphone

Oxymorphone

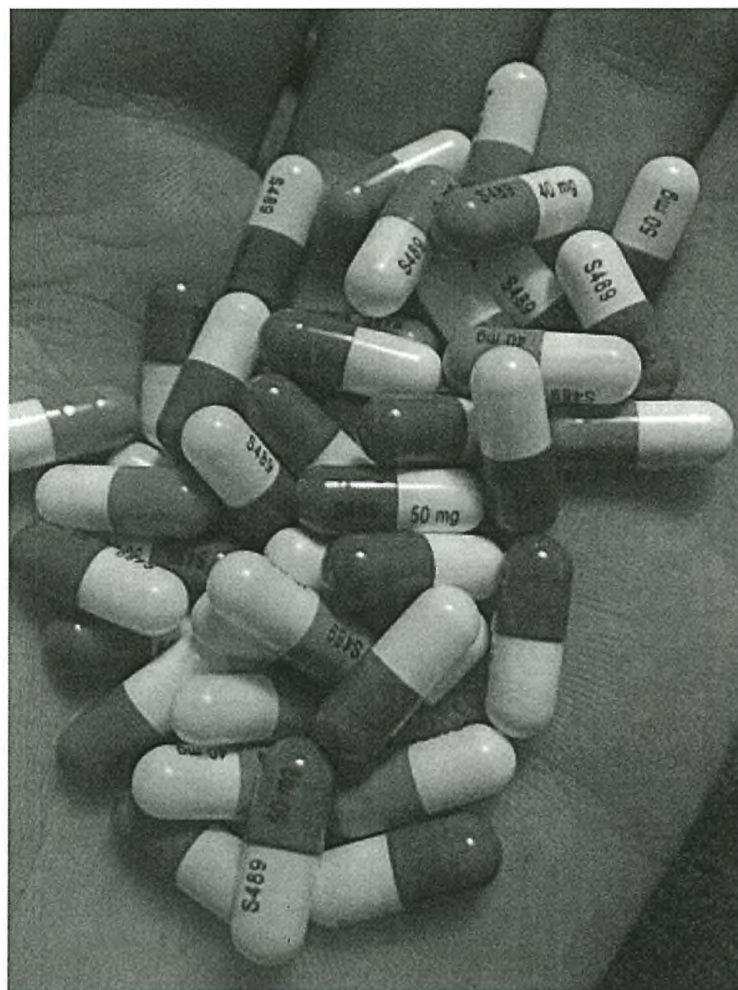
Methadone

Alprazolam





Amphetamines Are Coming...



**21 C.F.R. § 1301.74 (b)**

“The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”



What Does That Mean?

Size, Pattern and Frequency

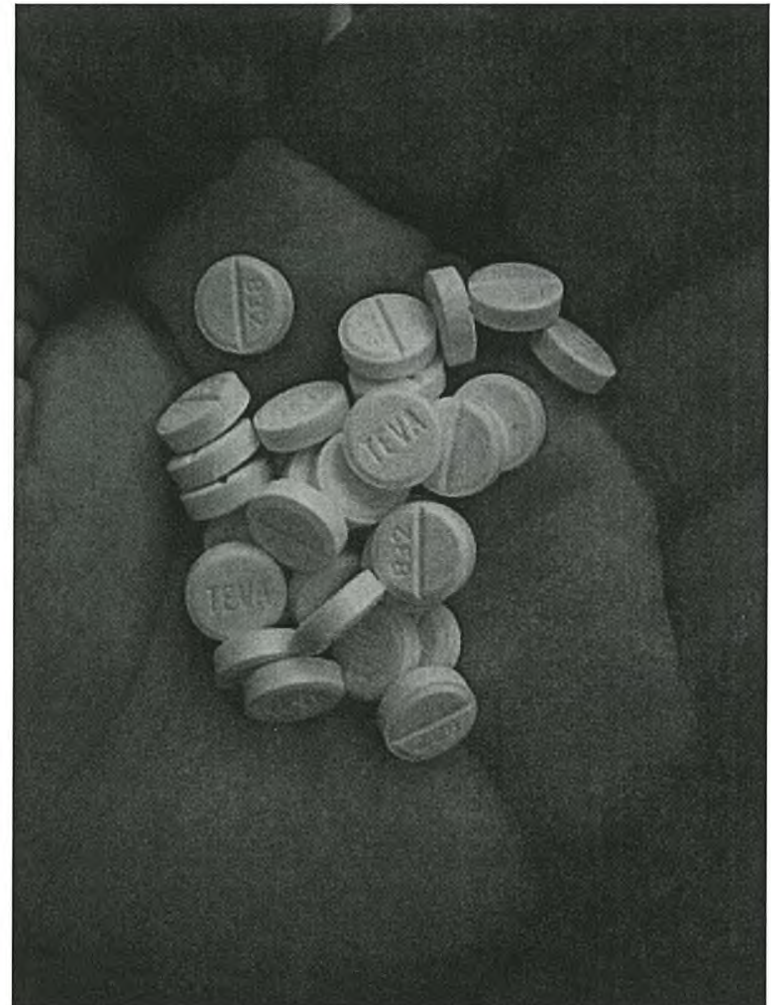
Identify Before It Would Have Shipped

No Guidance From The DEA

No Endorsement From The DEA

But They'll Let You Know

If You Screwed Up







Customer Due Diligence

Maintain Current Demographic
Information

Know Our Customers' Business Models

What Data Do We Have Available

What About Questionnaires?



Suspicious Order Monitoring

Computer Algorithm

Manual Investigation

Red Flags

If All Red Flags Cannot Be Cleared, It Is A
Suspicious Order

User Requirement Document Has Been
Given to IT



Monitoring Our Customers

Analysis of Purchases

Statistical Outliers

On-Site Investigations

Due Diligence?

Any Investigations?

Their Suspicious Order Monitoring
Program



Monitoring Our Customers' Customers

"Knew or should have known"

Incentivizing Abuse

Contract Pricing

Off-Label Prescriptions



21 C.F.R. § 1306.04 (c)

“A prescription may not be issued for "detoxification treatment" or "maintenance treatment," unless the prescription is for a Schedule III, IV, or V narcotic drug approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment and the practitioner is in compliance with requirements in §1301.28 of this chapter.”



What Does The Future Hold?



Bristol-Myers Squibb
Together we can prevail.®

Lilly

Johnson & Johnson



GlaxoSmithKline



What Does The Future Hold?

SOPs

Customer Due Diligence

Update SORDS

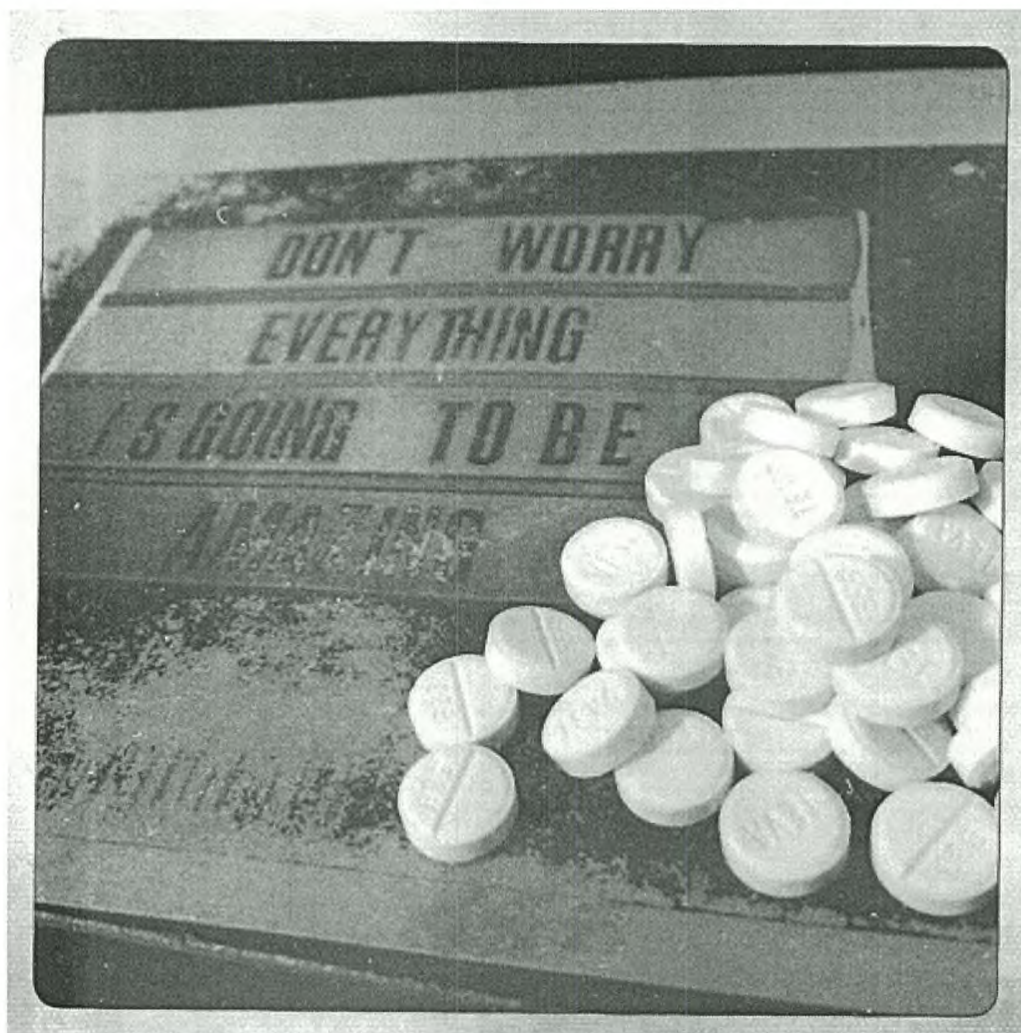
Customer Risk Evaluation

Training

Customer Road Show

Chargeback Data







Suspicious Order Monitoring

2014



TEVA

live
your
life



File Provided Natively