Message

From: LOWRY Leslie [Leslie.Lowry@cegedim.com]
Sent: 10/12/2012 10:41:57 AM
To: LOWRY Leslie [Leslie.Lowry@cegedim.com]
CC: BUZZEO Ronald [Ron.Buzzeo@cegedim.com]
Subject: BuzzeoPDMA SOM Seminar - Electronic Presentations
Attachments: 1 - Opening R Buzzeo P Hamby.pdf; 2 - Basics of SOM R Buzzeo.pdf; 3 - Legal Considerations for SOM L Barber.pdf; 4 - Systems Considerations P Hamby.pdf; 5 - SOM Investigative Programs Caverly Williamson.pdf; 6 - Legal Case Studies J Gilbert.pdf

Thank you for attending the BuzzeoPDMA SOM seminar. We hope that you found the meeting to be informative and helpful. As promised, I have attached electronic copies of the presentations from the seminar. If you need any assistance please feel free to contact me and I can put in touch with one of our business development associates or consultants.

Thank you-

Leslie Lowry | Compliance Projects Coordinator
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Phone: 804-230-5007 | Fax: 804-267-1746 | email: leslie.lowry@cegedim.com
Office Hours - 8:30 AM - 2:30 PM EST - Monday - Friday
BuzzeoPDMA SOM and Controlled Substance Seminar - October 11, 2012 - Hyatt Regency Chicago O'Hare
Click Here to Register - SOM and CS Seminar

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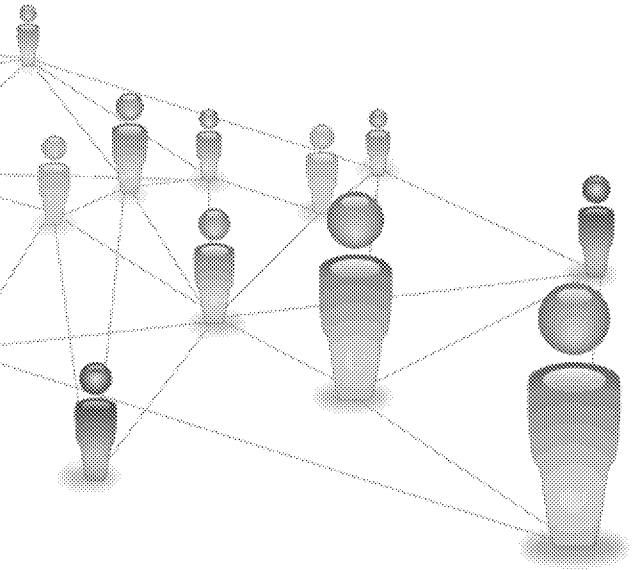
PLAINTIFFS TRIAL EXHIBIT
P-19682_00001

Welcome

Suspicious Order Monitoring Seminar
Regulatory Issues and Handling Increased Enforcement



Hyatt Regency O'Hare
October 11, 2012

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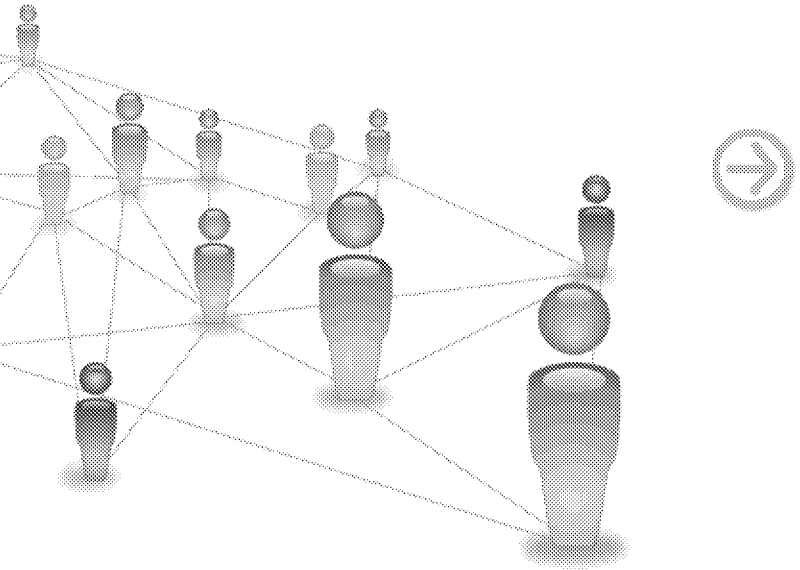
WELCOME



Ronald W. Buzzeo, RPh – Chief Compliance Officer

Paul Hamby – Senior Director, Regulatory Consulting Services

October 11, 2012

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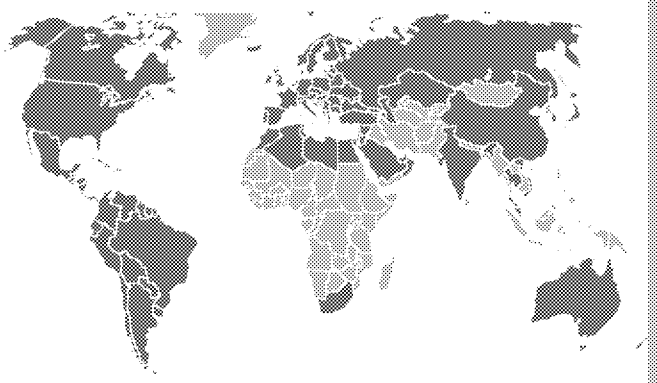
Group Overview

42+ years
experience improving sales and marketing

8,200
employees worldwide

M€ 911
revenue in 2011 ($1.1M). Listed on NYSE Euronext Paris



86
countries supporting customers

Global Solutions for Healthcare and Life Sciences

CRM & Data
for Life Sciences and Biotechs

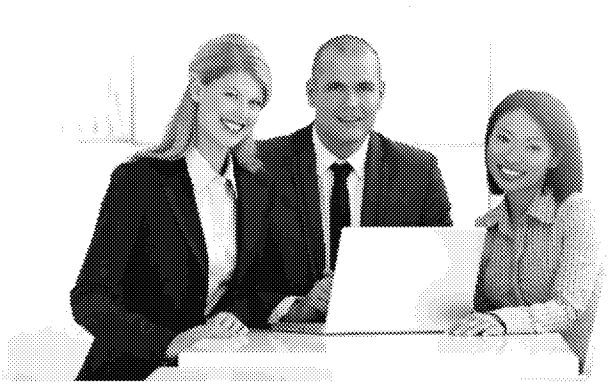
Software & Services
for Healthcare Professionals

Solutions & Services
for Healthcare Insurers

Solutions & Services

COMPLY Regulatory Environment

Compliance Solutions



Aggregate Spend & Transparency

Federal / State Consulting & Solutions

Sample Management

Computer Systems Validation

Field Inventory & Audit Services

Compliance Solutions

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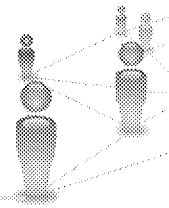
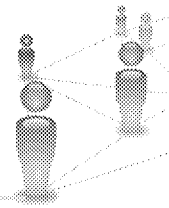


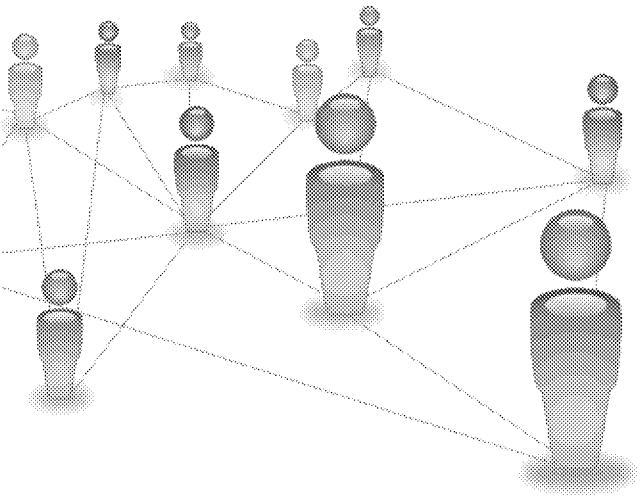
- **Founded in 1991 (formerly BuzzeoPDMA, Inc.)**
- **Acquired by Dendrite in 2005; Cegedim acquired Dendrite in 2007**
- **Areas of Focus**
  - **Controlled Substances Act and DEA Policy**
  - **Prescription Drug Marketing Act and FDA Policy**
  - **Computer System Validation – Part 11 Requirements**
  - **State Specific Regulatory Requirements**
  - **Operational Support via Outsourcing**
  - **Compliance Document & Process Management powered by Qumas**
- **300+ Clients - Pharmaceutical and Life Science Companies, Drug Distributors and Pharmacy Retailers.**
- **Regulatory and Operational Experience-based**
- **Professional Working Relationships with DEA, FDA, State Agencies, and Regulatory Law Firms**

Agenda



- The Basics: SOM Regulatory and Policy Requirements
- Legal Implications and Considerations for SOM
- System Considerations – Computer Models, Algorithms, Statistics and More
- Building an Effective Investigative Program
- Lessons from Case Studies: “Real World” SOM Challenges
- Compliance Panel

THE BASICS: SOM REGULATORY AND POLICY REQUIREMENTS



Ronald W. Buzzeo, R.Ph.
Chief Compliance Officer

October 11, 2012

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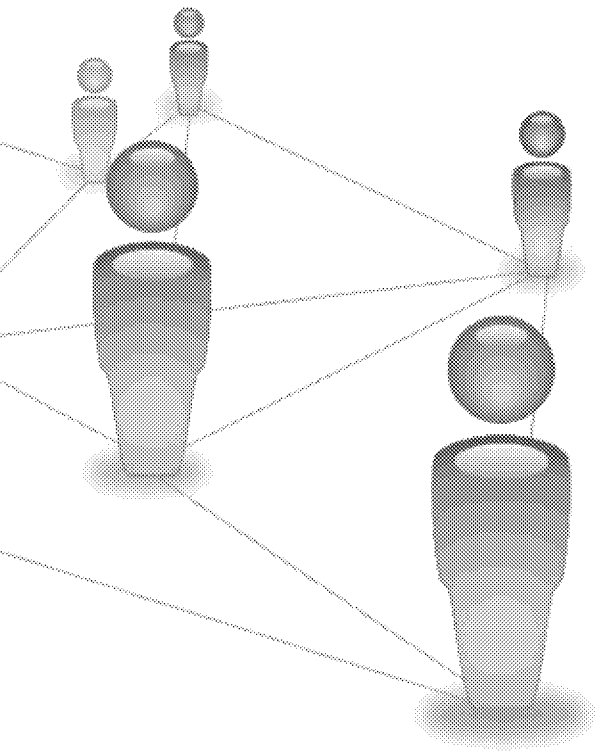
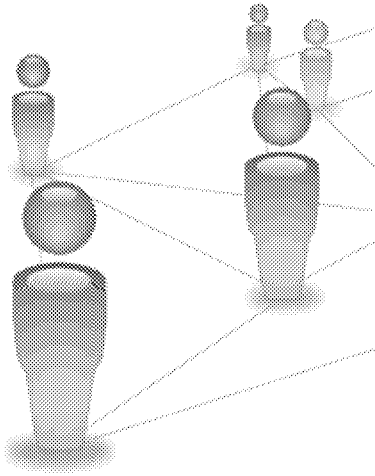
Agenda



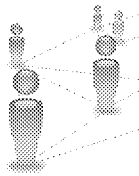
- Compliance Trends
  - Changing Landscape
  - Congressional Testimony
  - DEA Actions
- Pharmaceutical Drugs of Abuse
- Previous Reporting Requirements
- Regulatory Requirements / DEA's Policy Letters
- Red Flags
- Five Steps to a SOM Program

Controlled substance abuse is a major public health and law enforcement problem domestically. The federal agency charged with regulating these drugs is the Drug Enforcement Administration (DEA). Understanding DEA's requirements and enforcement efforts are important to preventing regulatory violations.



Compliance Trends
The Changing Landscape
Congressional Testimony
DEA Actions

Compliance Trends



DEA, US Attorney and State scrutiny is growing in all areas, particularly in Manufacturing, Distribution, R & D, and Pharmacy

- Companies not meeting regulatory requirements for controlled substances, prescription drugs and List I chemicals
- Inconsistent implementation of regulatory (DEA, PDMA and State) requirements
- Lack of understanding of regulatory requirements
- Increased inspections by DEA, States and FDA
- State oversight in licensing, pedigree, gift reporting, counterfeit, outdates and damaged

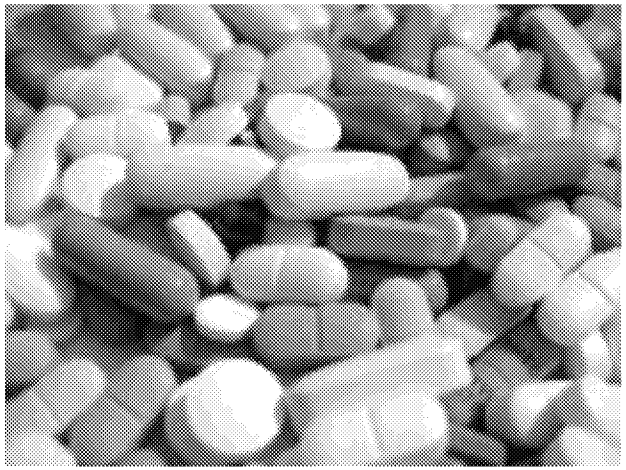
- Multi-Million dollar fines and penalties being levied
  - 2008 – 2012: $185,000,000 in fines and numerous registration actions
  - Several large pending cases
  - Pharmacy
  - Manufacturer
  - Distributor

Lack of sufficient SOM / "know your customer" initiatives is a particular DEA hot issue

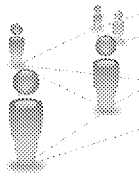
The Changing Landscape

Drug Enforcement Administration

- **Developments in regulatory controls**
  - Diversion and abuse of US manufactured Controlled Substances
    - Internet Pharmacy
    - Pain Clinics
    - Prescriptions
  - Record keeping, prescription and reporting violations
  - List I Chemicals
  - Controlled Substances
    - Suspicious Order Monitoring (SOM)
      - Sept / 06 Letter
      - Feb / 07 Letter
      - Dec / 07 Letter
  - Suspension and/or civil fines



DEA Congressional Testimony



- **Discussion of closed system of distribution and regulatory controls**
- **Two-pronged Reorganization/Restructuring in 2008**
  - Expansion of Tactical Diversion Squads
    - As of 6/1/2012 there were 48 operational TDS units
    - 286 Authorized task force officer positions
  - Enhanced Regulatory Oversight
    - Distributor, manufacturer and health care community initiatives
      - Warning signs
- **Increase in frequency of scheduled inspections**
  - **Additional dedicated Diversion Investigators.**
    - FY 2011 budget requested 60 investigator positions
    - FY 2012 budget requested 50 DI positions
  - All Diversion Investigators have completed training

Recent DEA Actions

- **$50 Million**
  - Dispensing CS without a prescription signed by a practitioner
  - Dispensing CS without an oral prescription called in by practitioner
  - Prescriptions missing essential elements
  - Not properly documenting partially filled prescriptions

- **$2.75 Million**
  - Internal thefts
  - Failure to report mail delivery losses
  - Inventory discrepancies
  - Fictitious DEA registration numbers

DEA Actions

Recent DEA Actions (Continued)

- Immediate suspension of two Florida Distribution Center's registration
- Revocation of a Florida DC registration for 2 years
- Revocation of the registrations of 2 chain pharmacies in Florida

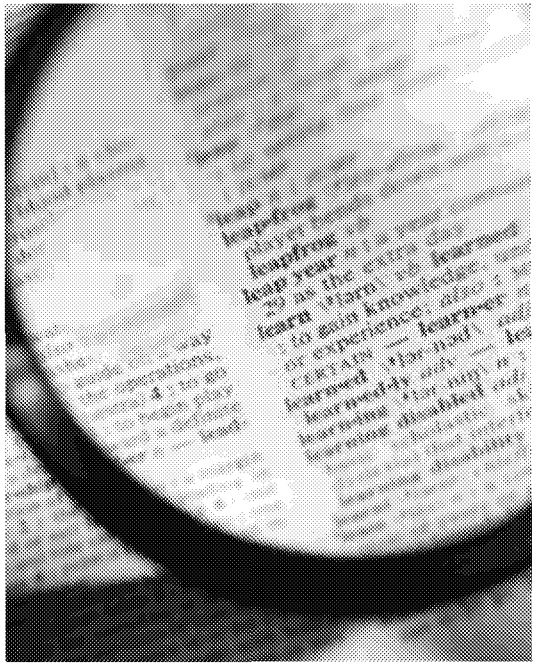
DEA Actions

Recent DEA Actions (Continued)

- **A growing number of companies have had actions taken against them by DEA for having non-complaint SOM programs and inadequate "know your customer" approaches.**

- **DEA Actions related to SOM / "Know your customer" since 2007:**
  - Immediate Suspension of DEA Registrations
  - Show Cause actions to deny the DEA Registration
  - Loss of DEA Registration
  - Large Civil Fines
  - Subpoenas / Criminal prosecution

REGULATORY ACTIONS

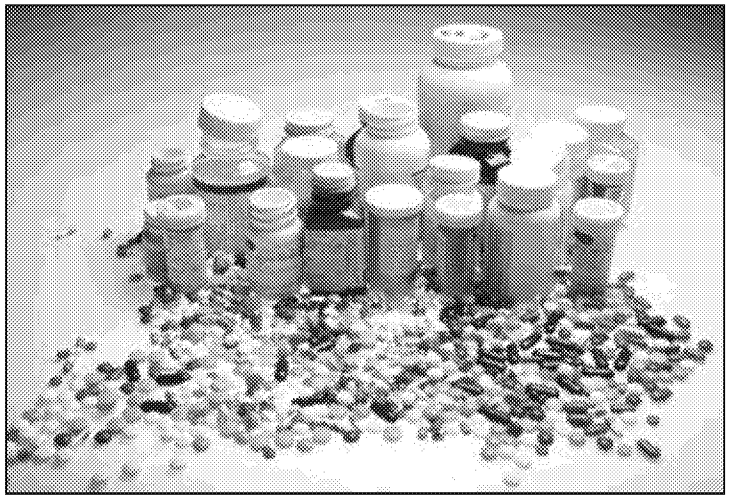


Controlled Substances Actions

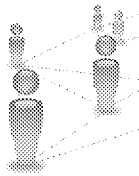
Penalties and Fines

- Administrative sanctions;
  - Letter of Admonition
  - Administrative Hearing
  - Immediate Suspension/Loss of Registration
- DOJ Civil Prosecution. Consent Decree. Fines
- DOJ Criminal Prosecution. Fine. Jail. Forfeiture
- Board of Pharmacy Action. Licensure.

PHARMACEUTICAL DRUG ABUSE IN THE UNITED STATES



Drug Abuse Environment

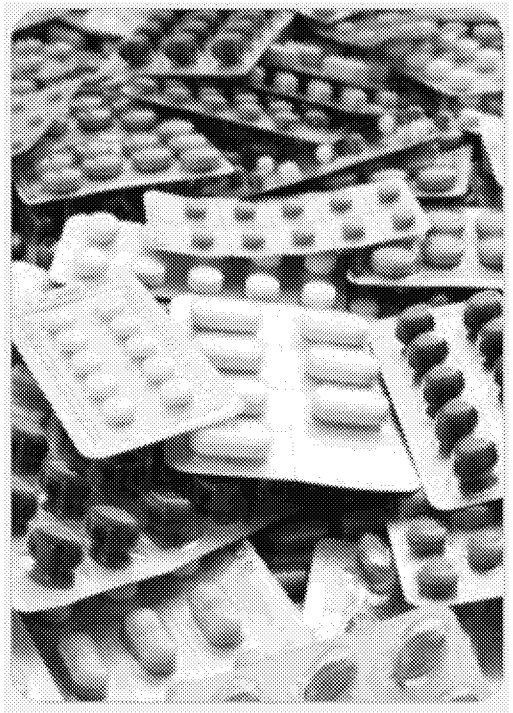


- **Annual 2010 National Survey on Drug Use and Health**
  - Hydrocodone is most frequently abused by high school seniors
  - 7 million individuals reported non-medical use of prescription drugs during the past year
  - 3.2% of 12 to 17 year olds reported non-medical use of pain relievers
- **Annual 2011 National Survey on Drug Use and Health**
  - Hydrocodone is most frequently abused by high school seniors
  - 6.1 million individuals reported non-medical use of prescription drugs during the past year
  - 2.3% of 12 to 17 year olds reported non-medical use of pain relievers

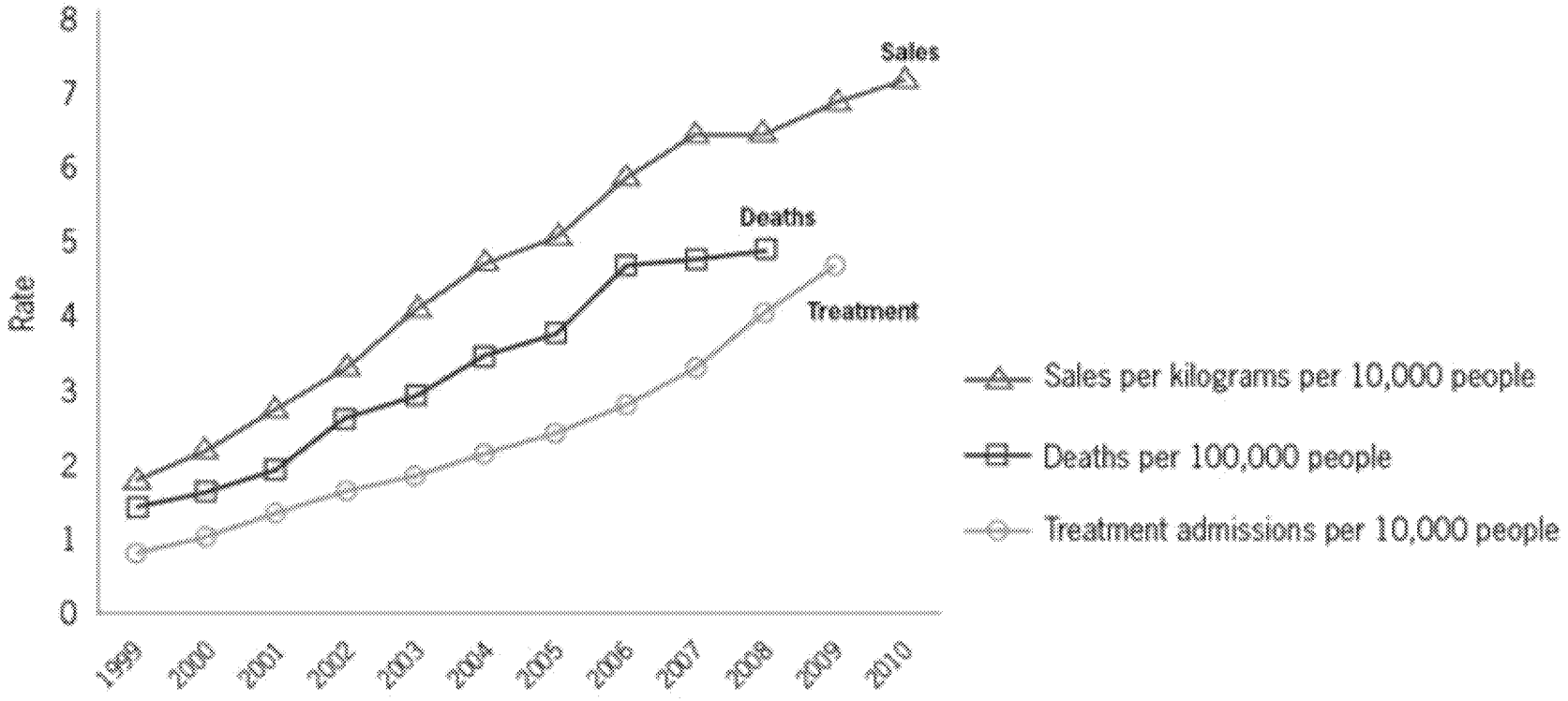
Attributed to increased law enforcement and education

Drug Abuse Environment

- **Prescription Drug Abuse – A major healthcare concern**
  - Report – November 2011 – Center for Disease Control and Prevention
    - More people die from prescription drug abuse from heroin abuse
    - Fourfold increase in drug overdose deaths from prescription drug abuse in the last decade

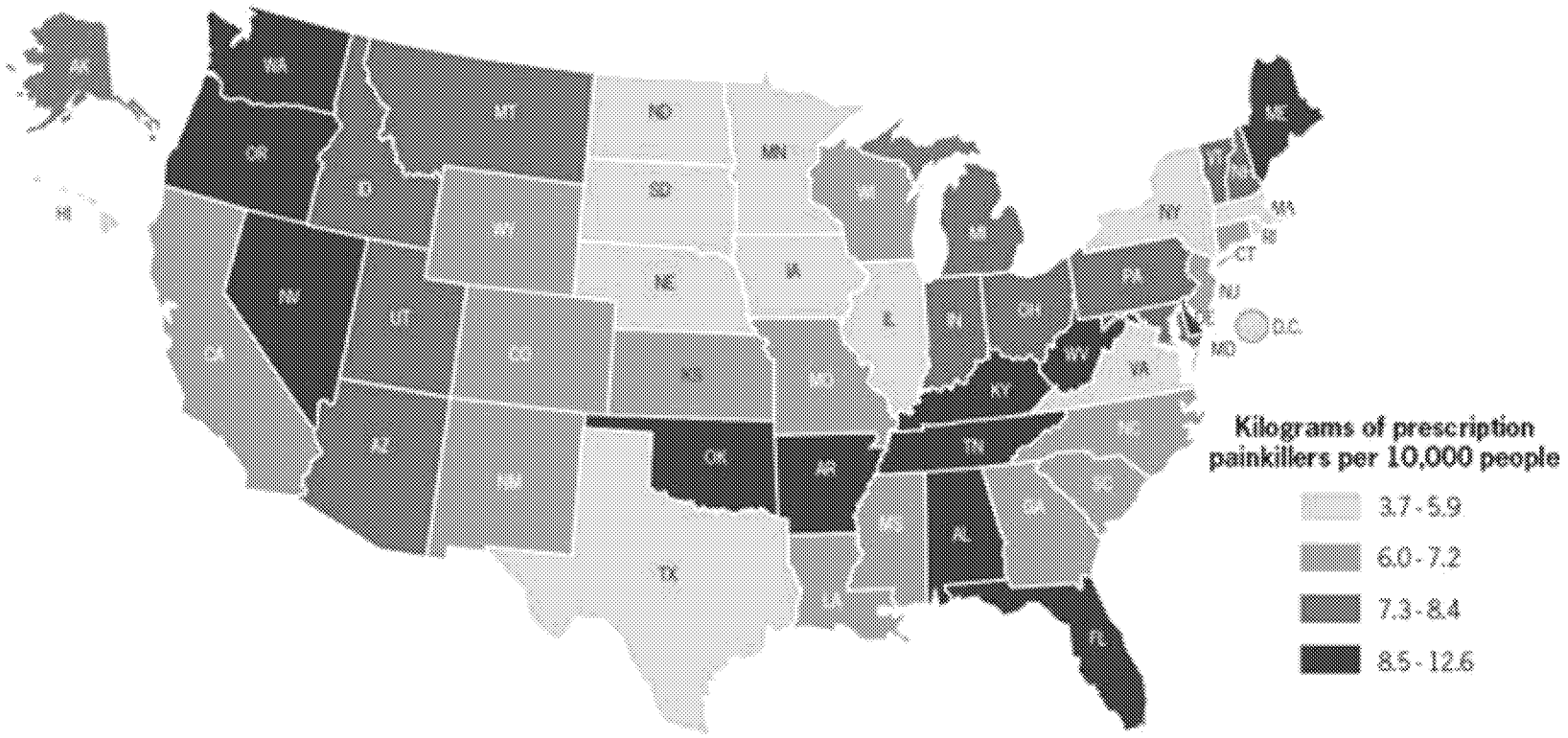


Rates of Painkiller Sales, Deaths, and Treatment Admissions



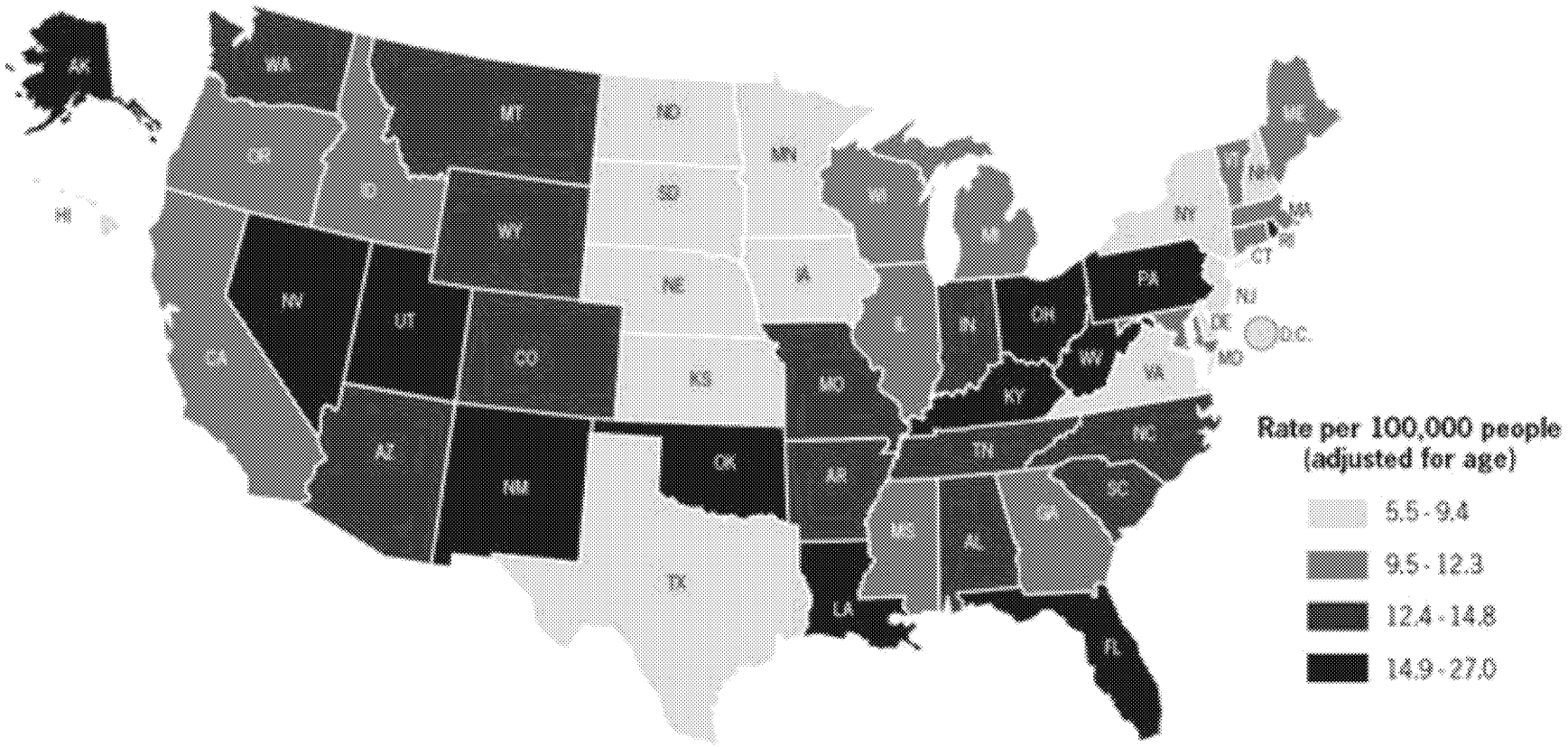
SOURCES: National Vital Statistics System, 1999-2008; Automation of Reports and Consolidated Orders System (ARCOS) of the Drug Enforcement Administration (DEA), 1999-2010; Treatment Episode Data Set, 1999-2009

ARCOS Per Capita Distribution

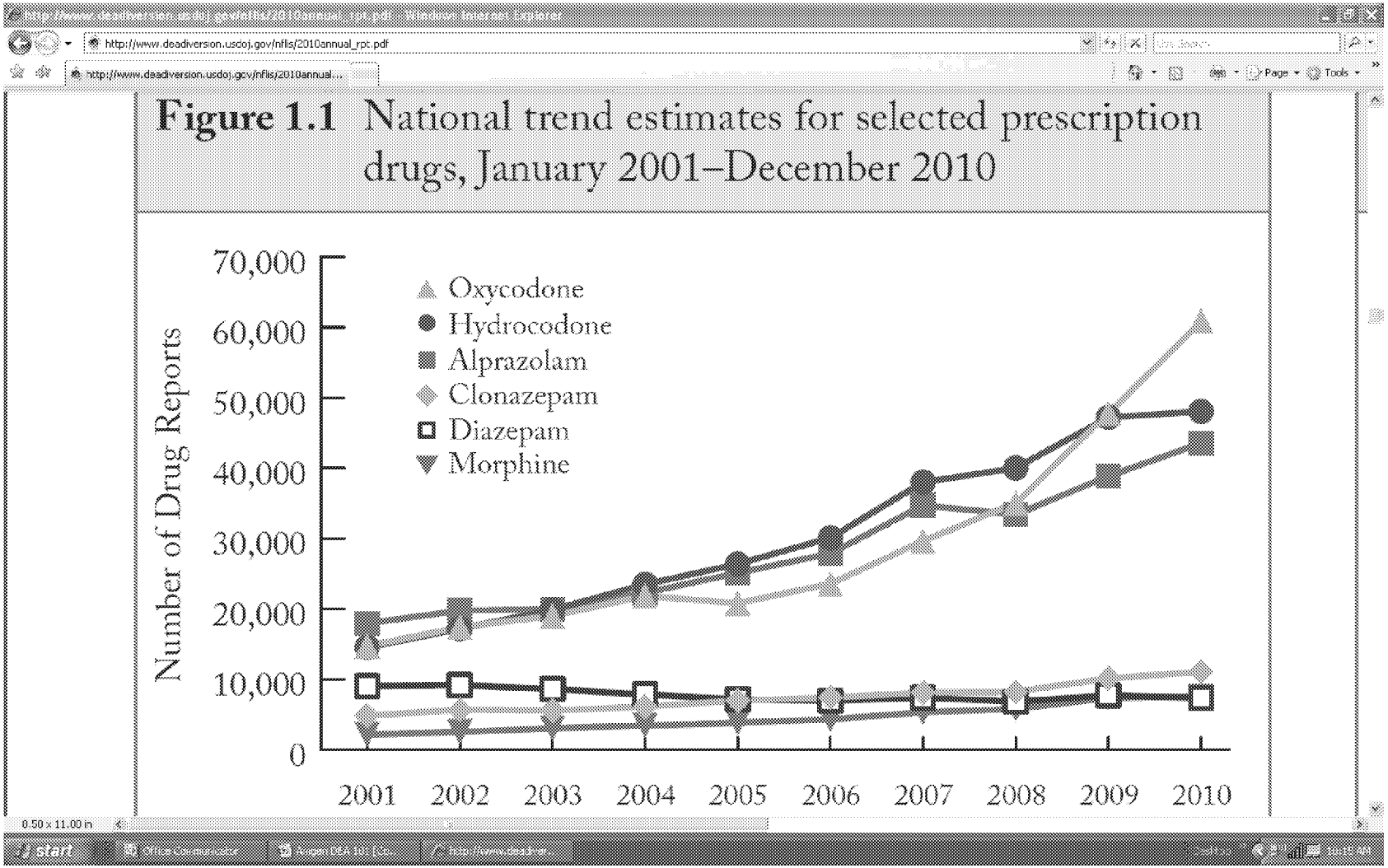


SOURCE: Automation of Reports and Consolidated Orders System (ARCOS) of the Drug Enforcement Administration (DEA), 2010

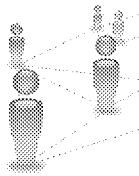
Drug Overdose Death Rates by State



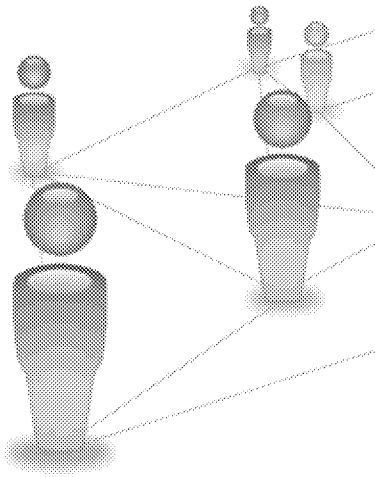
National Forensic Laboratories System



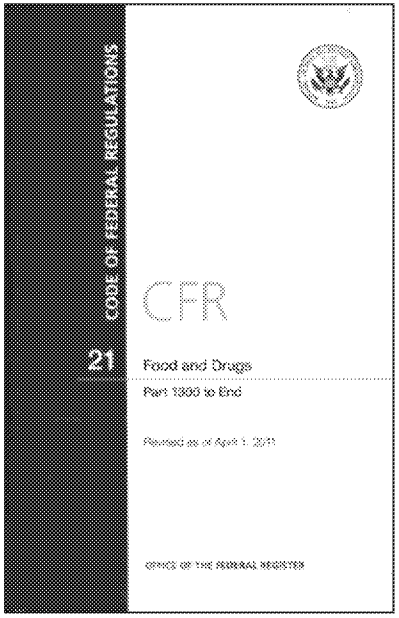
What does the future likely hold?



- Expect continued pressure from DEA on distributors, manufacturers and the health care community
- Expect diversion trends to continue to change
- Expect volume to continue as one of the primary factor that DEA considers when taking action against a distributor
- Expect DEA to obtain your SOPs, due diligence files, emails about compliance, internal memorandum, etc
- Expect some of your customers to be engaged, either wittingly or unwittingly, in diversion
- DEA reviewing entire distribution chain and health care community



PREVIOUS REPORTING REQUIREMENTS



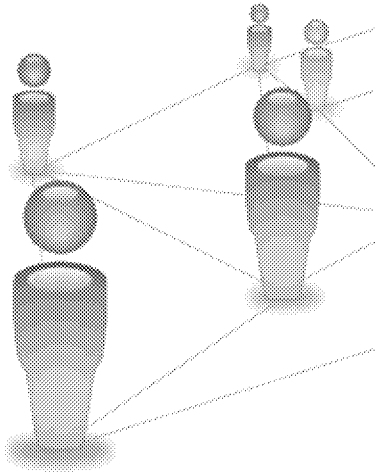
Code of Federal Regulations SOM Requirements

Controlled Substances – 21 CFR 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.

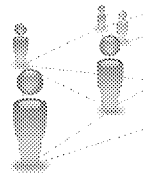
Previous Reporting Requirements

- **30 Day Reports**
  - After sale/distribution reports
    - Suspicious orders
    - Excessive orders
- **Internet Pharmacies**
- **DEA Identified Source of Drugs**



REGULATORY REQUIREMENTS
DEA's POLICY LETTERS

Code of Federal Regulations SOM Requirements



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- Further iterated in September 06, February 07, and December 2007 DEA memoranda
- December 2007 memorandum: "This letter is being sent to every entity in the United States registered with the DEA to manufacture or distribute controlled substances."

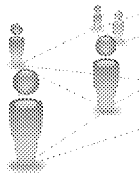
Code of Federal Regulations SOM Requirements

Listed Chemicals – 21 CFR 1309.71

(b) In evaluating the effectiveness of security controls and procedures, the Administrator shall consider the following factors:
… (8) The adequacy of the registrant's or applicant's systems for monitoring the receipt, distribution, and disposition of List 1 chemicals in its operations.

(a) All applicants and registrants must provide effective controls and procedures to guard against theft and diversion of List 1 chemicals…

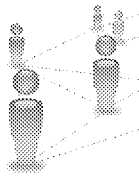
Common SOM Pitfalls



System Challenges and Responses

- **"Threshold" based systems are not sufficient**
  - Threshold-based approaches only identify large orders as compared to a "reasonable" value or historic mean
  - Threshold based approaches do not review all orders
  - Do not meet the regulations.
    - "… a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient."
    - **December 27, 2007, DEA memorandum**

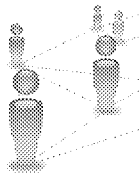
Common SOM Pitfalls



Investigative Challenges and Responses

- **Potentially suspicious orders must be reviewed before completing sale and shipping**
  - "Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels."
  - **December 27, 2007, DEA memorandum**

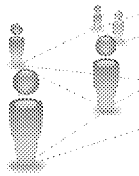
Common SOM Pitfalls



Investigative Challenges and Responses (continued)

- **Well-defined and sufficient "due diligence" efforts should be in place and followed.**
  - Confirm the legitimacy of new (and existing) customers.
  - Balance: Motivation to quickly clear legitimate orders vs. regulatory need to hold / cancel / report on orders that are truly "suspicious."
  - "Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted."
  - **December 27, 2007, DEA memorandum**

Common SOM Pitfalls



Investigative Challenges and Responses (continued)

"Cutting" orders to a volume that puts the order under a threshold is not acceptable

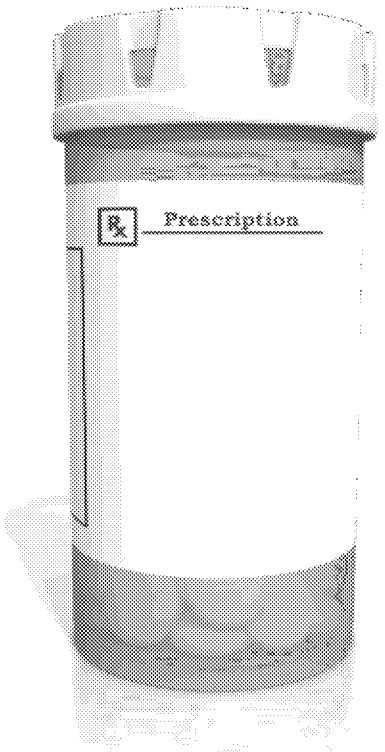
- Thresholds are not acceptable.
- DEA has previously stated on this topic, "that's like saying a little bit of diversion is okay."

RED FLAGS

Red Flags

Questionable Activities (not all inclusive)

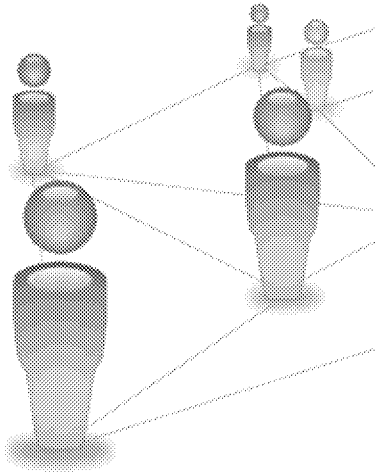
- Extended use of combination Schedule III pain medication, other Schedule III and IV and the highly abused Schedule II street drugs. Lack of contract between patient and physician
- Detail responsibility of each in treatment
  - Lack of treatment plan
- Lack of alternative treatments



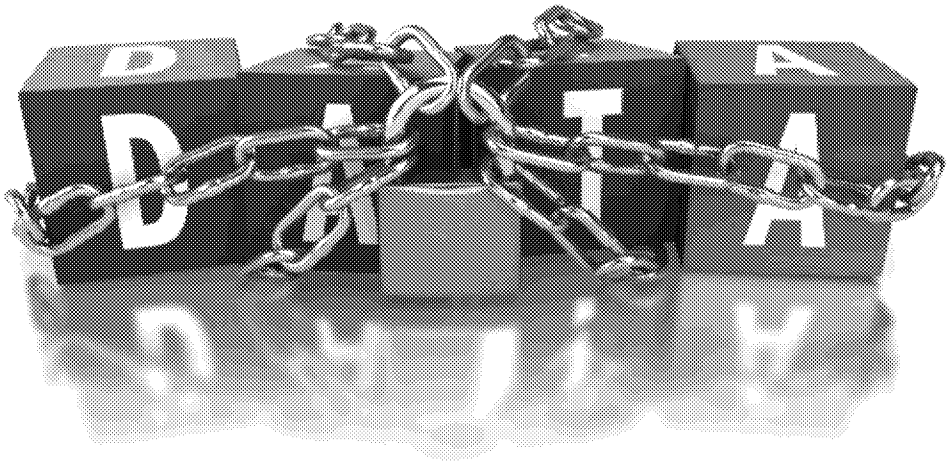
Red Flags

Red Flags (not all inclusive)

- Cash
- Out-of-state patients
- Large % of CS vs NCS
- Lack of patient contracts
- Lack of alternative treatments
- DEA Compliance Issues
- Lines of patients
- Suspicious activities
- Guards
- Pay cash prior to entering office



SOM PROGRAM



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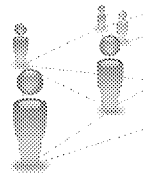
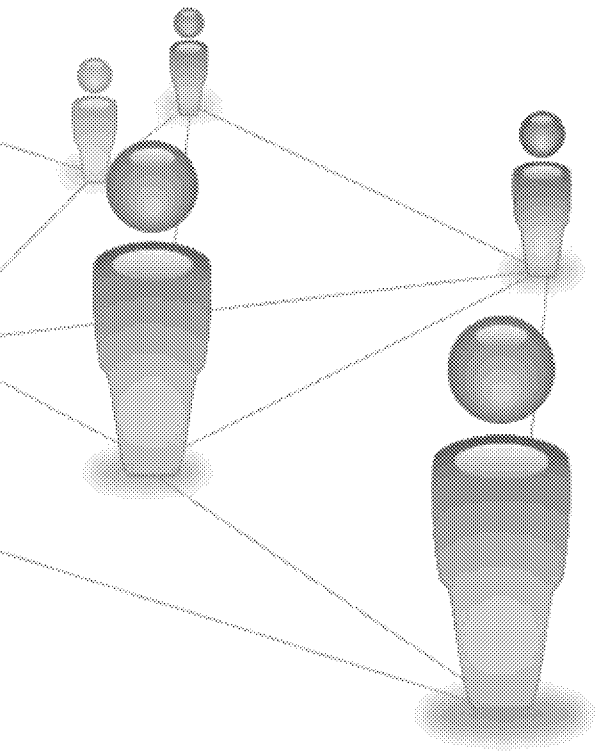
SOM Program - 5 Key Program Elements



- **Appropriate due diligence and "know your customer" activities**
  - Determine legitimacy of existing and potential new customers and customer's customers
- **SOM Model**
  - SOM System based only on order size thresholds are insufficient
  - Identifies orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency
  - Statistically based model – highly recommended
- **Appropriate review and/or investigations of pended orders**
- **SOM SOPs**
  - Procedures to identify investigative process, process to clear orders, DEA reporting, closing accounts, etc.
- **Training**
  - Development of a culture of compliance with the regulatory requirements and respect for the danger of controlled substance abuse

Thank You for Your Attention



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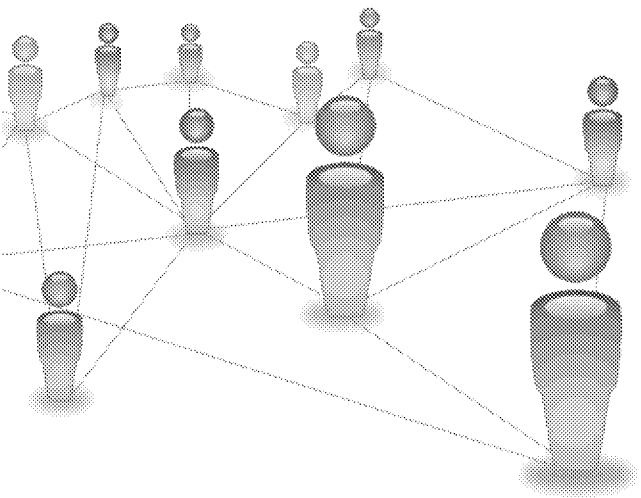
Through the Looking Glass: Legal Considerations for Your SOM Program



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October 11, 2012

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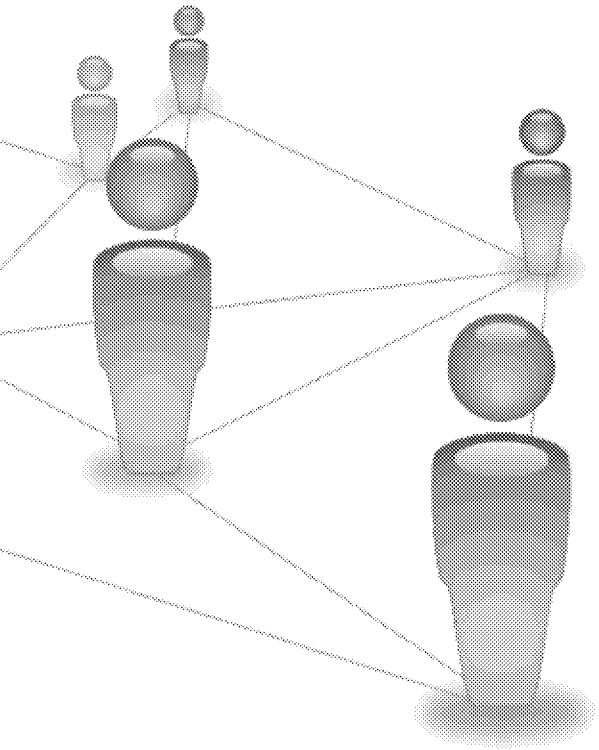
Agenda



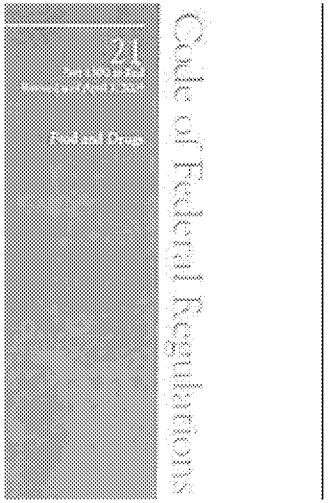
- Legal Requirements
- Enforcement Ramifications
- Practical Tips from a Former DEA Insider

Legal Requirements

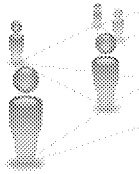
Legal Requirements

21 CFR 1301.74(b)

- Registrant to design and operate system
- System must disclose to registrant suspicious orders
- Registrant must report suspicious orders to DEA upon discovery
- Suspicious orders are orders
  - of unusual size
  - that deviate substantially from the normal ordering pattern
  - of unusual frequency



Legal Requirements



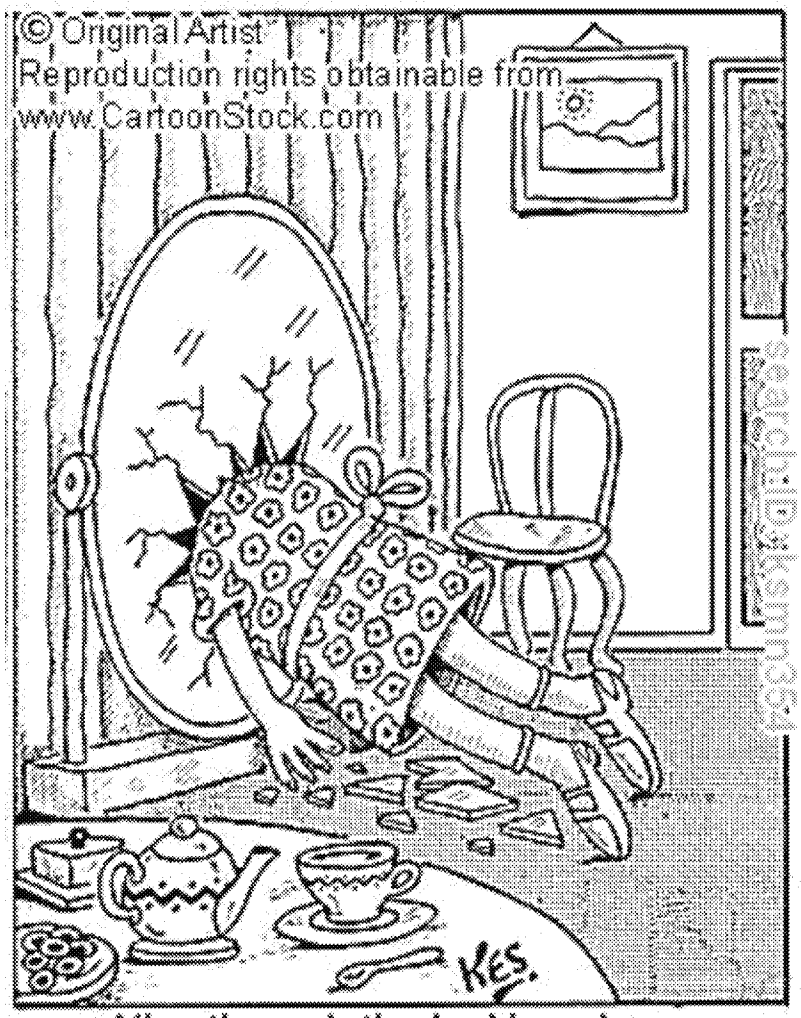
- Design
- Operate
- Detect
- Report

But what is unusual?

Legal Requirements

- **What is unusual**
  - Size Alone – Volume of specific controlled substances ordered is disproportionate to orders for other drugs
  - Pattern Alone – Normal volume of limited controlled substances, but little or no other drugs
  - Frequency Alone – ??
- **DEA Guidance**
  - "DEA does not approve or otherwise endorse any specific system for reporting suspicious orders"

Enforcement Ramifications



Alice through the looking glass.

Enforcement Ramifications

Administrative Actions

- Detecting and reporting suspicious orders is part of maintaining "effective controls against diversion"
  - 21 C.F.R. 1301.71 – DEA must consider SOM program in determining if registrant maintains effective controls against diversion
  - 21 USC 823-824 – Maintaining effective controls against diversion is a factor in DEA's decisions denying or revoking a registration
- Filling suspicious orders ***may*** be failing to maintain effective controls against diversion (DEA letter to registrants)
- Southwood - 72 Fed. Reg. 36487 (2007)

Southwood Decision

"Accordingly, I further conclude that Respondent repeatedly violated federal regulations by failing to report suspicious orders. 21 CFR 1301.74(b). …[T]he record also clearly establishes that Respondent's experience in distributing controlled substances is characterized by ***recurring distributions of extraordinary quantities*** of controlled substances to entities which then ***likely diverted*** the drugs by filling prescriptions which were unlawful. Moreover, Respondent's ***due diligence*** measures were wholly inadequate to protect against the diversion of the drug" (emphasis added).

Southwood Decision

"Respondent commenced supplying the pharmacies ***showing little interest in determining whether they were engaged in lawful activity***. Moreover, Respondent ***continued to supply the pharmacies*** even after being advised by this Agency of the likely illegality of their activities. Finally, while Respondent eventually undertook some inquiries, it then frequently ***ignored*** the information it obtained from the pharmacies themselves, which indicated that they were ***likely filling unlawful prescriptions***, and continued to supply most of them" (emphasis added).

Enforcement Ramifications

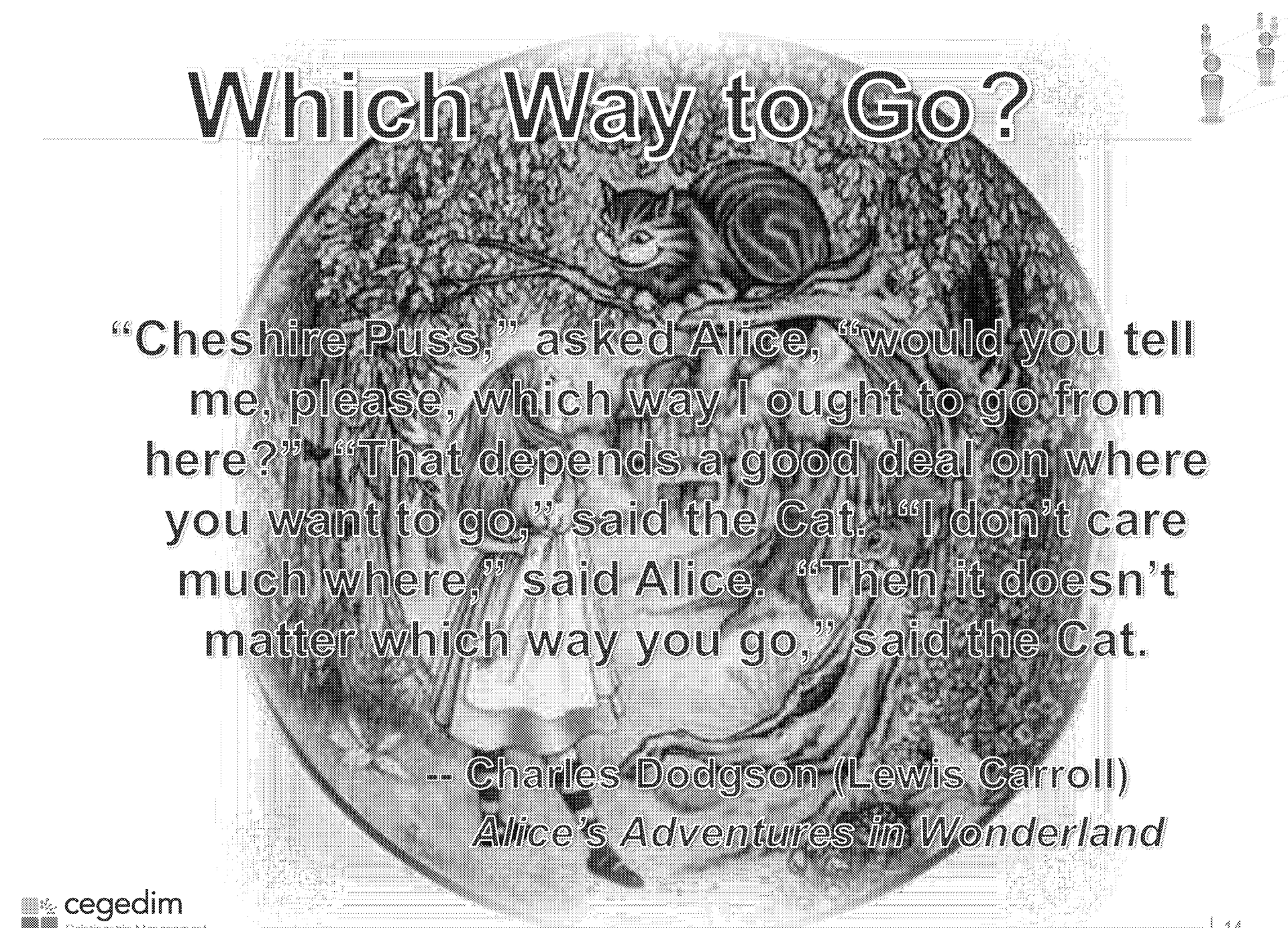
- **Civil Penalties**
  - 21 USC 842 provides for civil penalties for failing to make a report "required by this subchapter or subchapter II…"
  - No reported cases on civil penalties for failing to report suspicious orders of controlled substances under 21 CFR 1301.74(b)
- **Criminal Penalties**
  - If 21 USC 842 applies to failures to report suspicious orders, the criminal provisions of that section also apply to failures to report suspicious orders
  - Criminal penalties require that the violation be committed "knowingly"

Practical Tips

Practical Tips

- Suspicious Orders or Suspicious Customers or both?
- Underreporting and Over reporting
- Timing of Reports
- Use of Formulas
- Filling Orders Reported as Suspicious
- Documentation

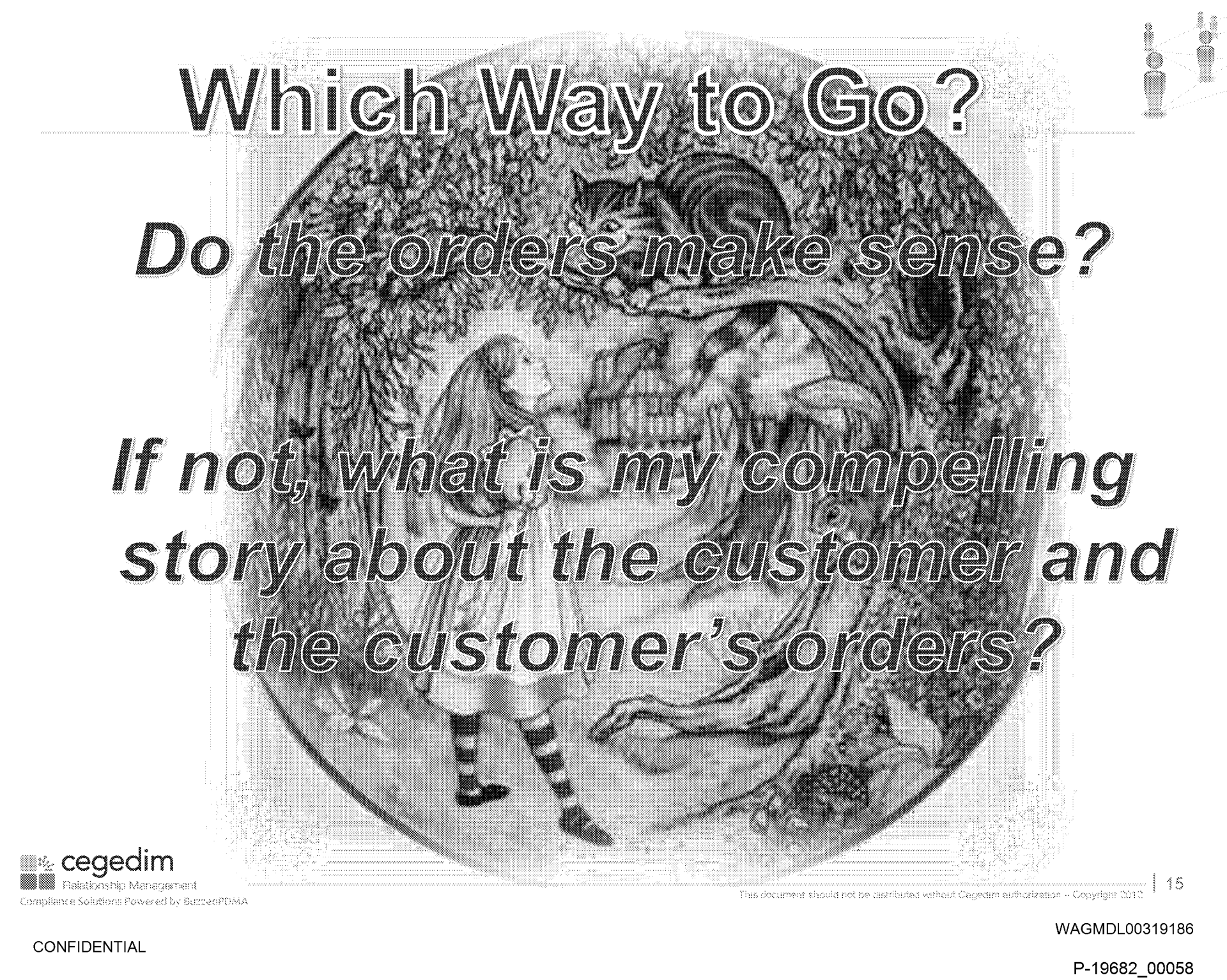
Which Way to Go?



"Cheshire Puss," asked Alice, "would you tell me, please, which way I ought to go from here?" "That depends a good deal on where you want to go," said the Cat. "I don't care much where," said Alice. "Then it doesn't matter which way you go," said the Cat.

-- Charles Dodgson (Lewis Carroll)
Alice's Adventures in Wonderland

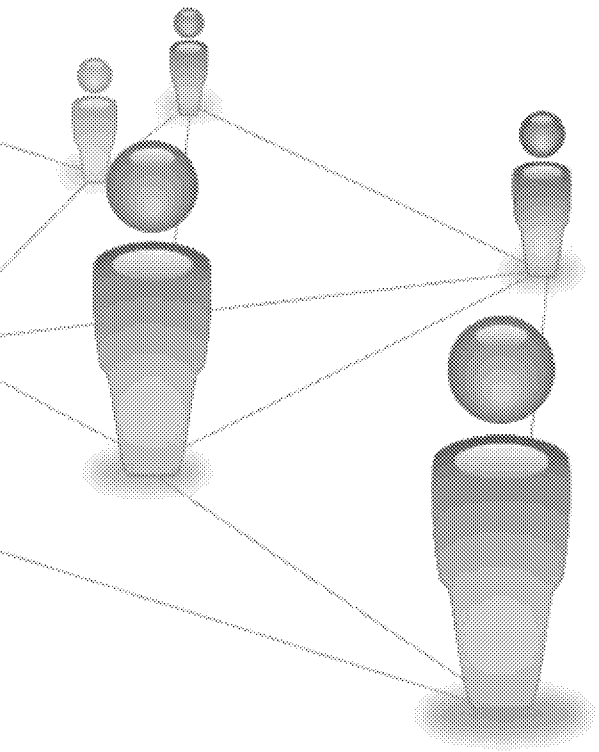
Which Way to Go?



Do the orders make sense?

If not, what is my compelling story about the customer and the customer's orders?

Thank You for Your Attention



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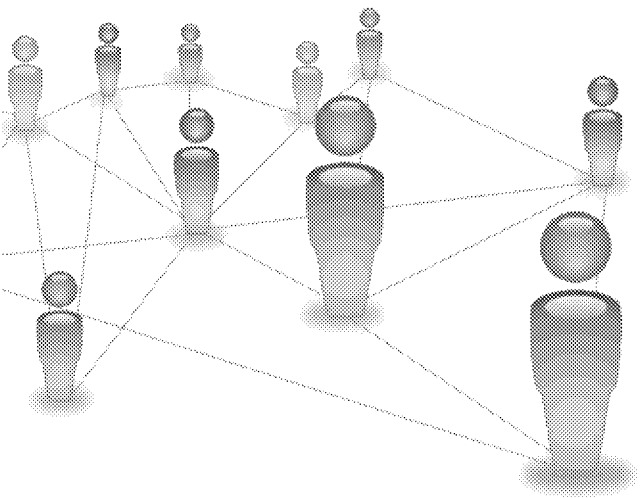
SYSTEM CONSIDERATIONS – COMPUTER MODELS, ALGORITHMS, STATISTICS AND MORE



Paul Hamby, Senior Director, Regulatory Consulting Services

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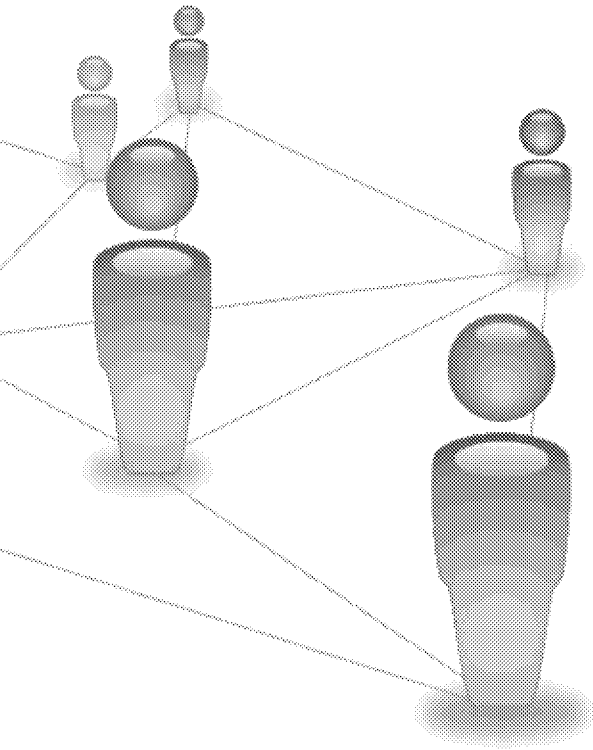
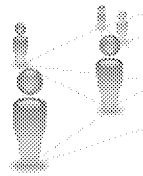


- DEA Requirements
- Best and Worst System Practices
- Statistical Systems for SOM
- IT Considerations and Implications
- Conclusions

SOM Program - 5 Key Program Elements



- **Appropriate due diligence and "know your customer" activities**
  - Determine legitimacy of existing and potential new customers and customer's customers
- **SOM Model**
  - SOM System based only on order size thresholds are insufficient
  - Identifies orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency
  - Statistically based model – highly recommended
- **Appropriate review and/or investigations of pended orders**
- **SOM SOPs**
  - Procedures to identify investigative process, process to clear orders, DEA reporting, closing accounts, etc.
- **Training**
  - Development of a culture of compliance with the regulatory requirements and respect for the danger of controlled substance abuse

Code of Federal Regulations SOM Requirements

Controlled Substances – 21 CFR 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.***

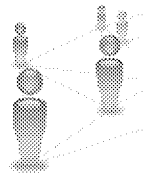
- Further iterated in September 06, February 07, and December 2007 DEA memoranda
- December 2007 memorandum: "This letter is being sent to every entity in the United States registered with the DEA to **manufacture** or **distribute** controlled substances."

Listed Chemicals – 21 CFR 1309.71

(a) All applicants and registrants must provide **effective controls** and **procedures** to guard against theft and diversion of List 1 chemicals…

(b) In evaluating the effectiveness of security controls and procedures, the Administrator shall consider the following factors:
… (8) The **adequacy of the registrant's or applicant's systems for monitoring the receipt, distribution, and disposition of List 1 chemicals** in its operations.

SOM System ~~Best~~ Worst Practices



- **Not using the order management system to assist with automated order review and evaluation**
- **System uses only size-based "threshold" criteria to evaluate orders**
  - Frequently relies only on arbitrarily "best guesses" of reasonable values at which to "pend" or hold orders
  - Does not (and can not) anticipate the multiple dynamics associated with evaluating order pattern, frequency, size of orders, size and categories of accounts, etc.
  - Not statistically supportable so less defensible
- **System allows for "cutting" orders to a "more acceptable" order size**
  - Was the original volume requested suspicious?
  - Are you foregoing your responsibility under the regs to review, investigate, and potential report?

SOM System Best Practices

- **Ensure the system evaluates EACH of your customer's orders – product by product – comparing the latest order with HISTORICAL ORDERING PATTERNS for that customer and product.**

- **Review and confirm the legitimacy of EVERY order BEFORE IT IS SHIPPED.**
  - Should have system mechanism to "pend" or hold orders that are not in line with previous ordering size, frequency, or pattern / history.

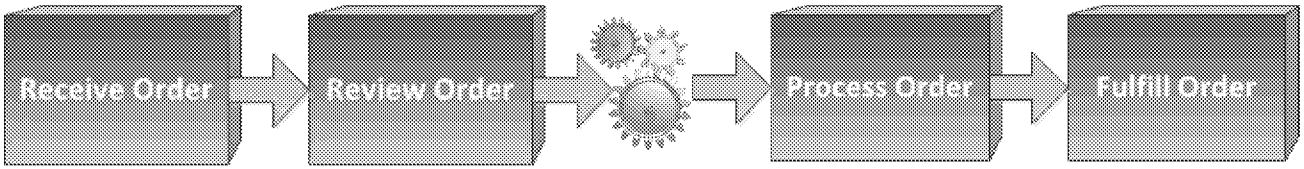
- **Include all controlled substances (Schedule II, III, IV, and V) and listed chemicals.**

- **If necessary, update order management system to include a STATISICALLY BASED approach to identify "orders of interest."**
  - Statistically viable system is more justifiable and defensible.
  - An opinion: About the only way to effectively look for the "*deviating substantially from a normal pattern*" requirement.

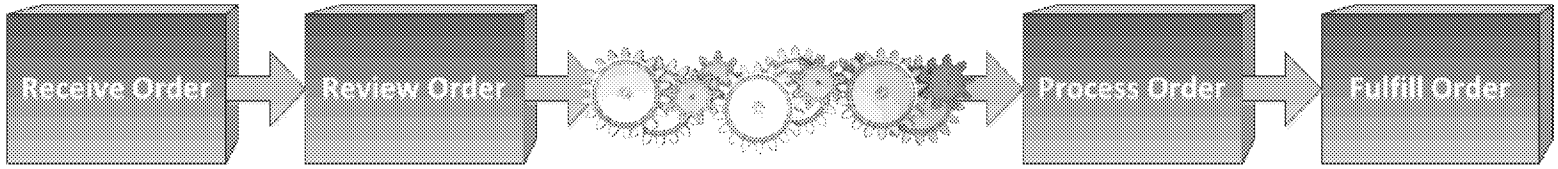
Statistically Defensible Order Pending System

- **Based on and grounded in statistics, not "best guesses"**
  - Statistical model: a formula that is derived using probabilistic arguments and is used to describe or simplify a complex reality.
- **Best (only?) way to evaluate DEA's "normal pattern" requirement**
- **More sophisticated (i.e., defensible) order evaluation**

WITHOUT Statistical Evaluation = LESS sophisticated / LESS Defensible



WITH Statistical Evaluation = MORE sophisticated / MORE Defensible

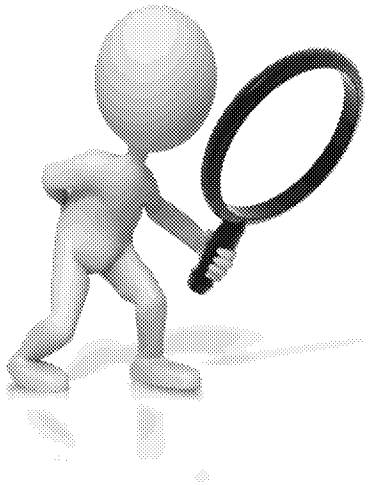


Statistically Defensible Order Pending System

More sophisticated way to look at orders

- Compare *current order* of a drug with the *historical ordering pattern* of that drug by that customer
  - Gauges statistical "likelihood" that the product order is fraudulent/erroneous
- Examine multiple order characteristics (or attributes), all in parallel (such as order size, history, trends, frequency, etc.)
- Allows "weighing" of various attributes in the overall calculations
  - Giving greater significance to certain key order attributes

Statistically Defensible Order Pending System



An over simplified example

Statistically you determine:

- Size of order should be worth 53.8% of the evaluation,
- Frequency should be worth 21.6%,
- Degree that the ordering size is changing over time (increasing) should be worth 8.4%,
- Etc.

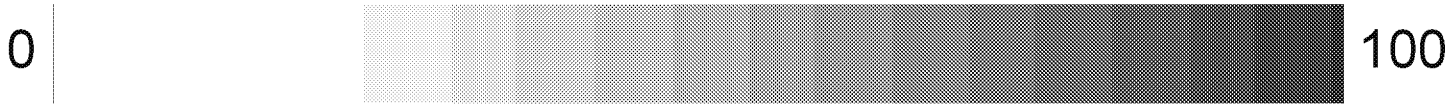
"Suspicion" Score = .538 x (*Size Eval Algorithm*) + .216 x (*Freq Eval Algorithm*) + …

Note: Determining proper "weighing" and each individual "Eval Algorithm" is the hard part – requires *significant* statistical analysis of historical ordering pattern of YOUR products by YOUR customers

Statistically Defensible Order Pending System

Other Benefits of the Power of Statistics

- Can introduce concepts such as level of order "suspiciousness"
  - *Could* be used as a tool to deploy different investigative responses



  - For example, score of:
    - 0 - 25: Deemed not suspicious
    - 26 - 50: Deemed moderately suspicious
      - *Triggers: phone follow up, requires customer to supply reason in writing*
    - 51 - 75: Deemed highly suspicious
      - *Triggers: on site review / visit*
    - 76+: Deemed severely suspicious
      - *Triggers: immediate reporting to DEA*
- Can better account for "unusual" events – seasonal drug products, sales promotions, etc.
- **Biggest benefit -> *Significantly* more defensible**
  - Helps make better, more defensible decisions

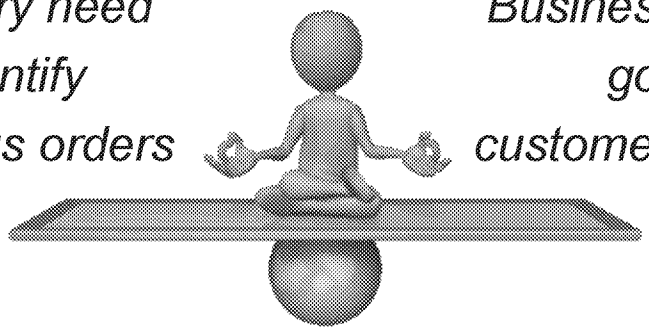
Best Practices for Implementing a Statistical System

- **Use the "right" resources and tools** *(probably most important)*
  - Need Life Sciences knowledgeable, DEA regulatory knowledgeable statisticians (or a Trusted Vendor)
  - If not using a vendor, likely requires investment in a statistical analysis tool
- **Use the "right" data for the development of the model**
  - Should be developed using **your** company's specific data
    - Provides a "custom fit" for your company's customer and product base, order history, and business model
- **Use the "right" order attributes (characteristics) in the evaluation**
  - Attributes ***must*** be chosen and focused on satisfying DEA regulations
    - Should support identification of potentially suspicious behavior which can manifest itself in many different ways (multiple "techniques" / "creative" diverters)
  - Include "enough" attributes to sufficiently compare current order vs. historical levels
    - *As an example, Cegedim deploys cloud based and non-cloud based SOM statistical algorithms. We typically compare and review at least 8 – 12 ordering characteristics in parallel in real time.*

Best Practices for Implementing a Statistical System

- **Run it at the "right" time**
  - Should run on your existing order management system for real-time identification of "orders of interest"
- **Strike the "right" balance:**
  - Should be optimized to balance:

Regulatory need to identify suspicious orders



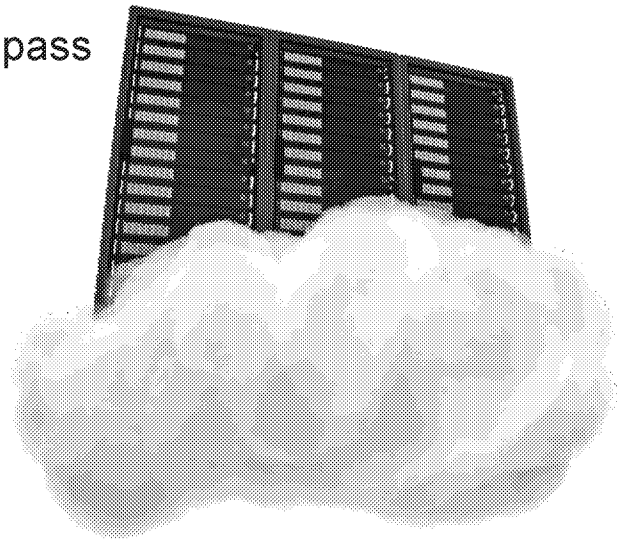
Business needs, goals, customer satisfaction

- **Maintain the system the "right" way**
  - Should be setup so that the system "auto adjusts" itself over time
  - When tuning is necessary, should support modification in a straight forward way
    - Adjust sensitivity, false positive/negative rates, "excessive" pends, etc.–when necessary
    - Fully confirm and/or "rebalance" the statistical values and assumptions periodically (recommended ~ at least once yearly)

IT Considerations and Implications

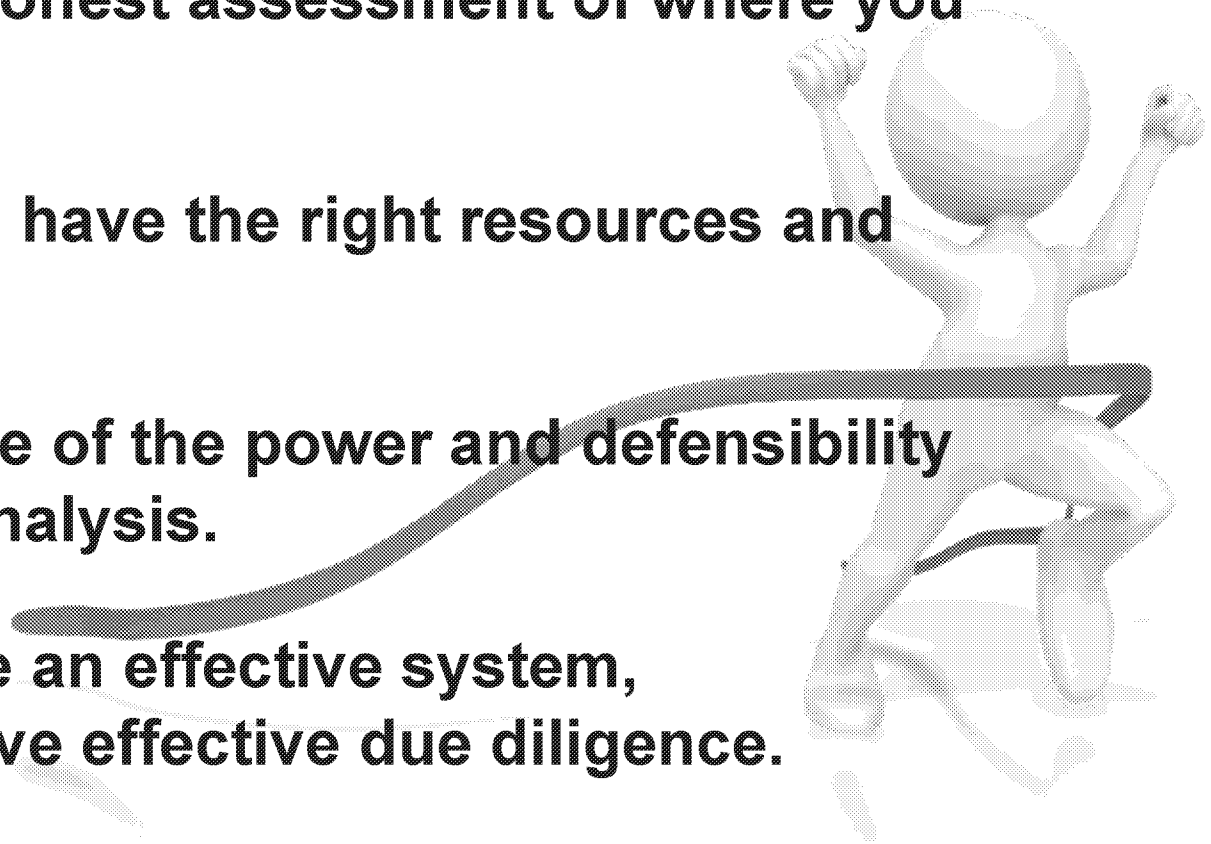
Typically models are deployed in one of three ways:

- **Integrated directly into an existing order management system**
  - Most significant IT integration
    - Can be significant cost and time investment
    - All data continues to only reside in your order management system
- **Utilize an external "bolt on" type application**
  - Less IT integration
    - Create interfaces to the "bolt on" application to pass order information back and forth
- **Utilize a "cloud based" platform**
  - Least IT integration
    - Support web based "call outs" with order information to cloud based system
    - Indication of suitability of the order is returned from the cloud

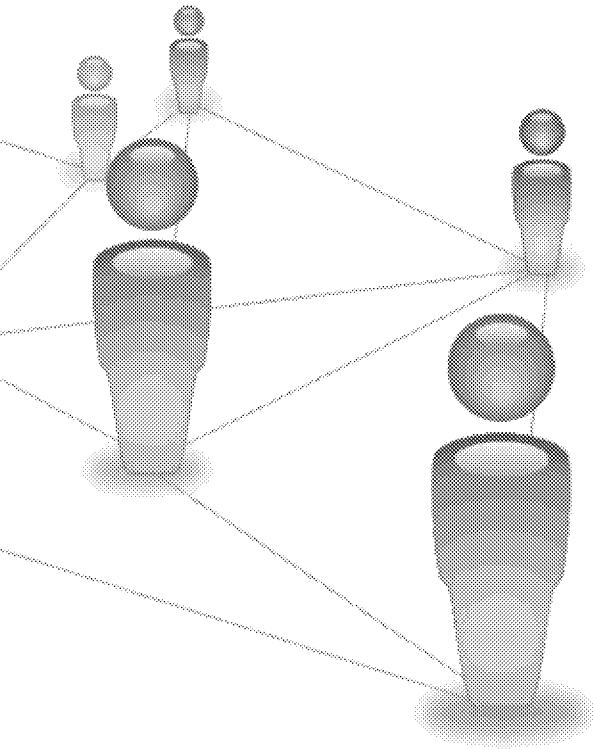


Conclusions

- **It can be done!** ***(And it must be done…)***
- **Start with an honest assessment of where you are today.**
- **Make sure you have the right resources and tools.**
- **Take advantage of the power and defensibility of statistical analysis.**
- **Once you have an effective system, ensure you have effective due diligence.**



Thank You for Your Attention



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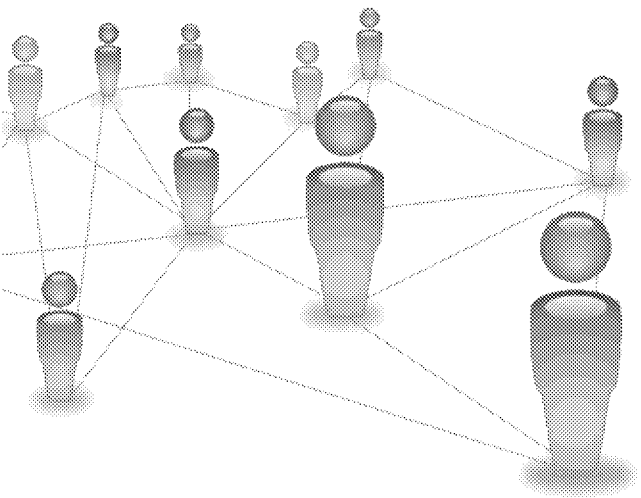
Building an Effective Investigation Program



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Mark Caverly, Senior Regulatory Consultant

October 11, 2012

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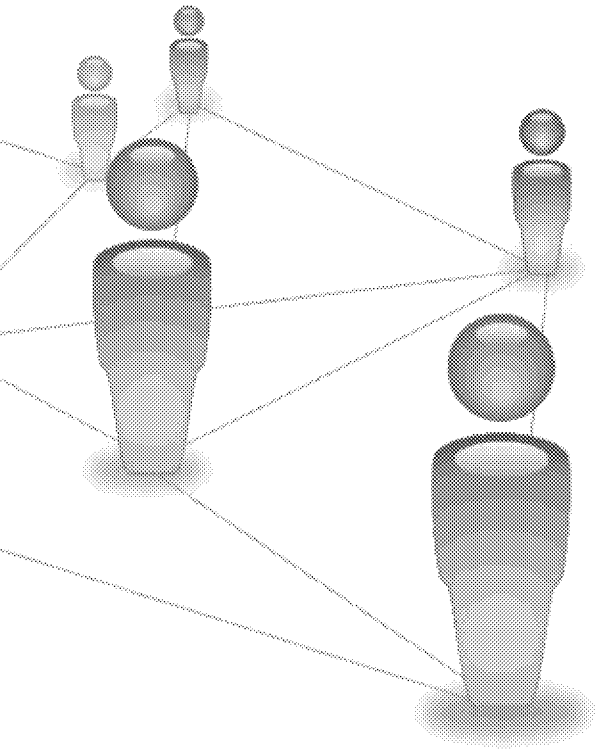
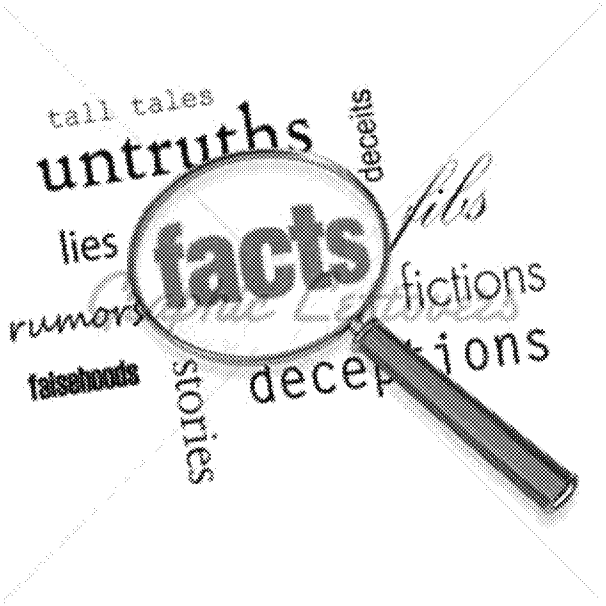
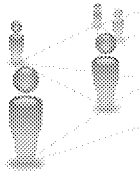


- Know Your Customer
- Tracking Distributions
- Clearing Orders
- DEA Reporting
- Corporate Values

Know Your Customer

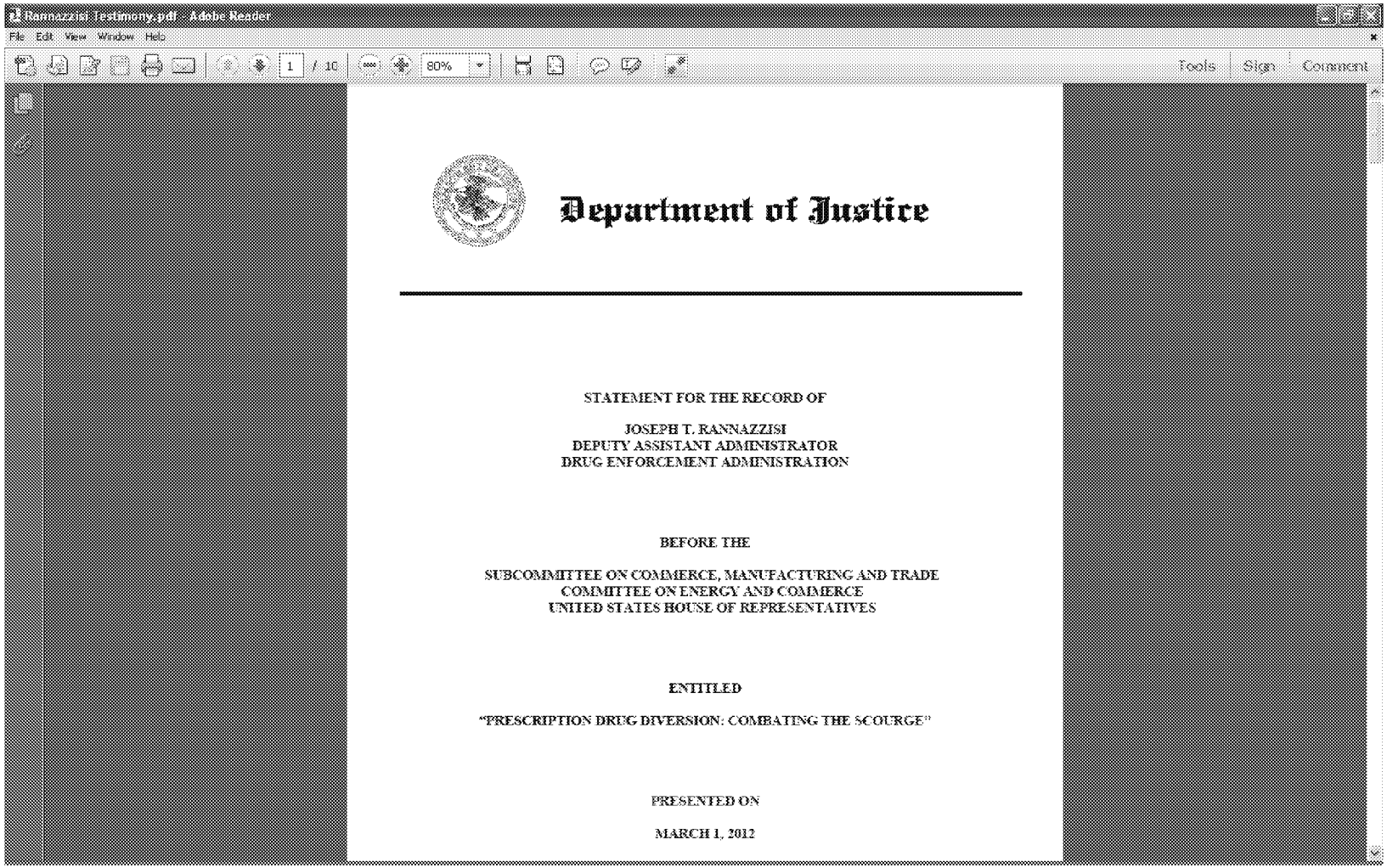


First Know Yourself

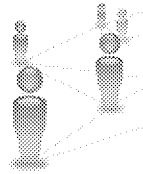


- What drugs do we handle?
- Are they among the most abused?
- Are controlled substances a significant part of our business success?
- Where are our customers located?
- What kind of customers are they?
- What does our corporate culture say about preventing the abuse of our controlled substances?

Second Know about the DEA and Drug Abuse

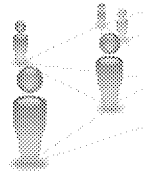


Pertinent DEA and Drug Abuse Information



- **The DEA**
  - DEA.gov
  - deadiversion@usdoj.gov
- **National Association of Drug Diversion Investigators**
  - Naddi.org
- **National Institute on Drug Abuse**
  - Drugabuse.gov
- **The Federal Register**
  - Federalregister.gov
- **OMB Regulation Tracking**
  - www.reginfo

Additional information sources



- Local Boards of Pharmacy
- DEA Meetings and Training Events
- Outside training events
- Google “alerts”

New Customers – Common Scenarios

➢ Questionnaires

- Licenses/registrations
- Ownership
- Types of Drugs Desired/Current Suppliers
- Business type
  - Pharmacy
  - Compounding Pharmacy
  - Wholesale Distribution
- Estimated Needs
  - Prescription Usage Reports
- Red Flags
  - Cash vs. Insurance
  - Controlled vs. Non-controlled
  - Out of state customers

New Customers - Continued

- **On Site Due Diligence Visits**
  - Photos
  - Site orientation (hospital setting, strip shopping mall/out of state plates).
  - Limited prescription/record review
  - Customer Compliance Agreement Forms
- **On Site Surveillance Reviews**
  - Observations of customer activity
- **Follow up Internet Investigations**
  - Business information
  - License information
  - Other

Tracking Distributions

Ground Zero

- "Title 21 CFR 1301.74(b), specifically requires that a registrant design and operate a system to disclose to the registrant suspicious orders of controlled substances."

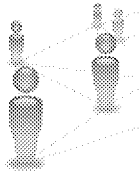
- "… DEA does not approve or otherwise endorse any specific system for reporting suspicious orders."

  - Correspondence to Registrants
    - 12.27.2007

Suspicious Order Defined at 21 CFR 1301.74(b)

- **"Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."**

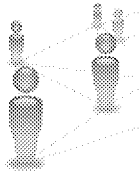
SOM Key Questions provided by DEA



- **During 14th Pharmaceutical Industry Conference**
  - October 2009

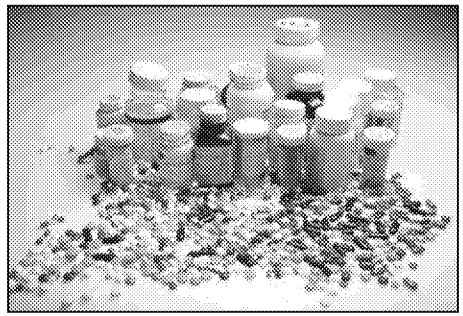
- **Questions:**
  - What is my customer's practice area?
  - How does this customer's order compare with similar customers?
  - How does this customer's recent orders compare with the customer's historical orders?
  - Can the customer explain peculiarities or anomalies in its orders?
  - Are there readily observable warning signs about certain localities?

Distributor Initiative "Warning Signs"



- Type of drug(s) ordered
- Orders of unusual size – Volume, volume, volume
- Orders that deviate from a normal pattern
- Frequency of orders
- Breadth and type of products ordered
- Location of the customer
- Percent of controlled versus non-controlled substances ordered

SOM Computer Modeling Recommendations

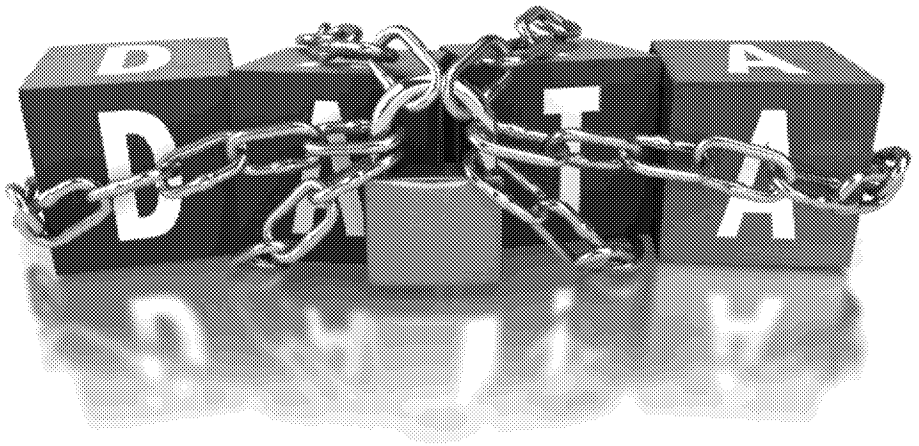


- **Measure for size, pattern and frequency – *at a minimum***
- **Normalize/reduce to active ingredient in each order**
- **Analyze each order using real time data (dynamic v. static)**
- **Analyze each order independently**
  - Avoid thresholds/quotas/allotments
- **Use statistical modeling techniques**

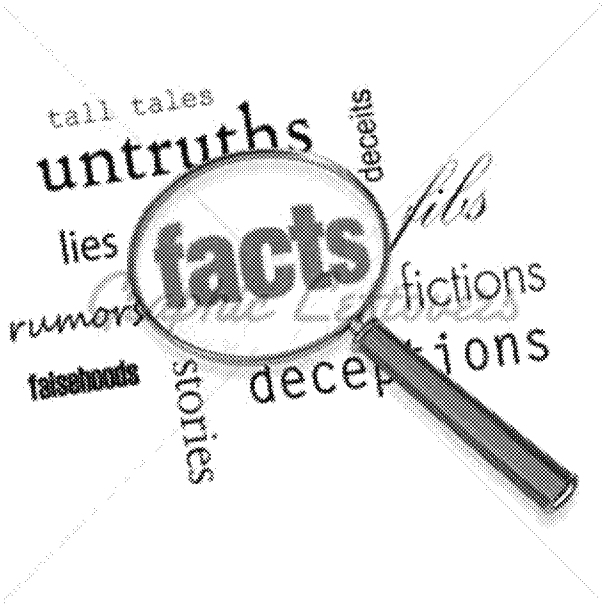
SOM Computer Modeling Recommendations

Use all of your tools

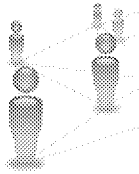
- **Compare purchases with others in the same class of trade**
- **Use statistical calculations**
  - Standard deviation
  - Mean/Mode
  - Moving averages
- **Use proprietary data**
  - Marketing data
  - Population data
  - Charge back data
  - Other



Clearing Orders



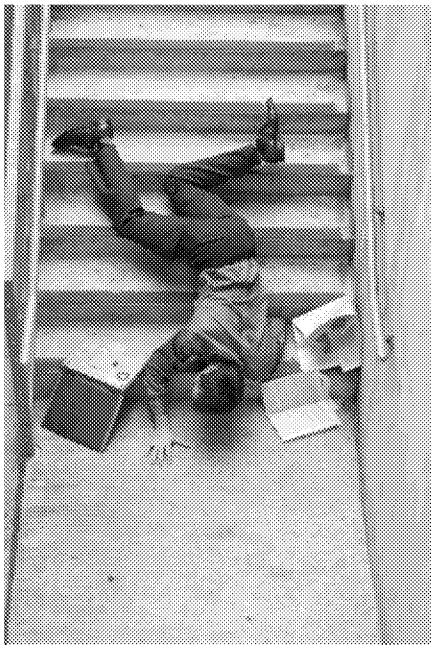
Common Order Investigation Scenarios



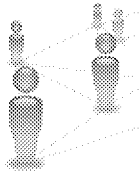
- **Customer telephone calls**
  - Purchasing affected by registrant incentives
  - Purchasing affected by drug shortages
  - Other suppliers are out of business
- **Requests for information**
  - Drug usage reports
  - Drug purchase reports (from other suppliers)
- **On site visits**
  - In person interviews
  - Review records and/or other documents
  - Corroborate information

Pitfalls

- **Relying on drug usage reports**
  - Having prescriptions on file may not be enough
- **Relying too heavily on customer service staff**
  - It is their job to keep customers happy
- **Losing site of the forest for the trees**
  - We get lots of pended orders in every Monday/NBD
- **Providing customers with TMI**
  - It's due to your order frequency



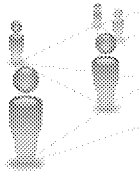
Clearing Orders



- **Investigative activity should be documented**
  - Frequently documented in the computer record
  - On site reviews will contain printed materials
- **The entire investigative history should be available to review**
  - Frequently "pended" and approved accounts raise suspicion
- **Management should approve/clear pended orders**
  - Staff may organize background information
- **Procedures should be in place**

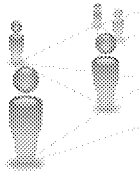
DEA Reporting

Reporting Suspicious Orders



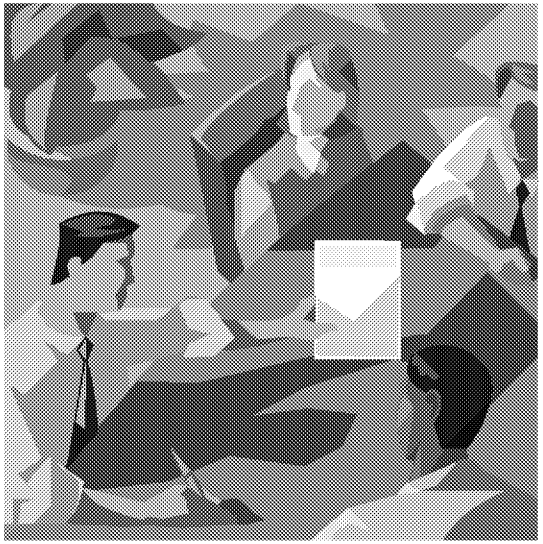
- **Reporting suspicious orders is a legal requirement**
- **Decisions may have to be made without all the facts, information and/or data that would be relevant**
- **There are no legal presumptions**
  - Accounts are not "innocent until proven guilty"
  - There is no burden to prove "beyond a reasonable doubt"
- **It's business – not personal**

Reporting Suspicious Orders

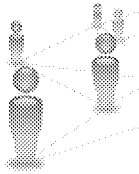


- **Procedures should be in place**
  - Should be reported by a management official
  - Orders should be reported to the local office of the DEA (unless instructed otherwise)
  - Reports should be verbal and in writing
- **Questions regarding the account will need to be answered**
  - Is the order being reported an anomaly
  - Should all the accounts orders be cancelled
  - Is the account problematic

Corporate Values

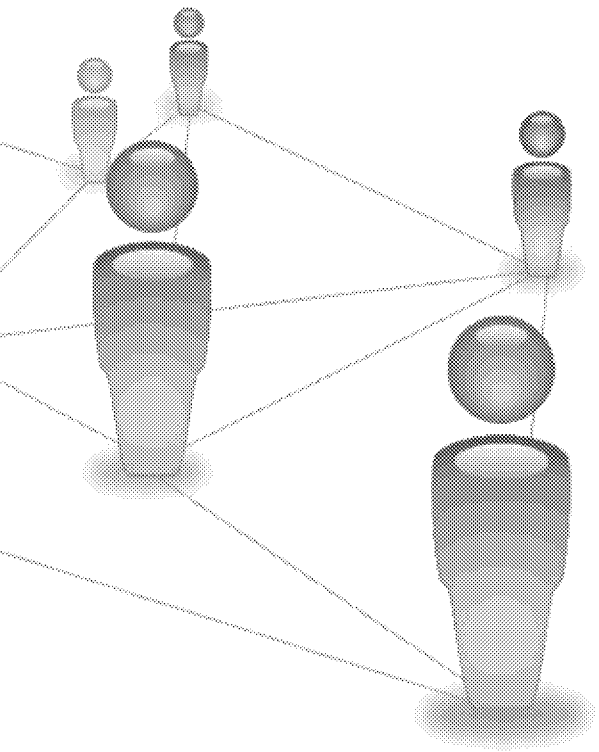


Some rhetorical questions



- What role does DEA compliance have in the firm?
- What role does sales have in the firm?
- Is the topic of "drug abuse" limited to employee drug abuse or does it include abuse of products handled by the firm?
- Is it all the DEA's problem?
- What kind of message comes from the leadership?
- Is there SOM training?
- Is it limited to DEA Compliance or provided to employees on the line?

Thank You for Your Attention



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Case Study: Real World "SOM" Challenges

BuzzeoPDMA SOM Seminar
Hyatt Regency O'Hare
October 11, 2012

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DEA Guidance

- Reporting a suspicious order does not relieve the distributor of the responsibility to maintain effective controls against diversion
- Registrant cannot rely on customer's DEA registration and state licensure
- Deviation from normal pattern is not determined by order size
- Suspicious nature of an order depends not on a pattern of ordering by customer but on patterns of registrant's customer's base and patterns "throughout . . . the regulated industry."

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DEA Guidance

- Rigid formulas may be insufficient
- Registrants must conduct an independent analysis of suspicious orders prior to completing a sale
- Reporting an order as suspicious will not absolve the registrant responsibility if registrant knew, or should have known, that the controlled substances were being diverted."

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Caught in the Cross-Hairs
Getting on Law Enforcement's Radar

- High Volumes
  - ARCOS data
- Customer Investigations
- Geographic Area
- Significant patterns of thefts/losses
- Routine Inspection

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Caught in the Cross-Hairs
Getting on Law Enforcement's Radar

- Reports and Reporting Errors
- Leads from other Investigators
- Disgruntled employees
- Government initiatives
- Prescription Drug Monitoring Program Data

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Who are the Gatekeepers?

- Manufacturers
- Distributors
- Pharmacies
- Prescribers

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Manufacturer SOM Case Study

- Sales of Drug Increase by Geographic Area
- Review of Charge Back Data - evaluating customer's customer
- Entry into New Geographic Markets
- Changes in Customer Demands
- Quotas

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Distributor SOM Case Study

- Increase in orders from geographic areas coinciding with changes in law or licensing
- Due Diligence Files – trap for the unwary
- Site Visits - double edged sword
- Geographic trends
- Changes in Market Demand
- Customers - wholesale vs retail
- Statistical Analysis

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Pharmacy SOM Case Study

- Changes in State Laws and Regulations
- Evaluating Patients, Prescribers or both?
- Corresponding Responsibility
- Geographic
- Drug Combinations
- Cash versus insurance patients
- Awareness of Drug Tends

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Prescriber SOM Case Study

- Increase in pain patients
- Age, geographic area
- Education Training
- ??????

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Questions?
Thank you!

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