File Provided Natively

PLAINTIFFS TRIAL
EXHIBIT

P-03732_00001

EXHIBIT

PENGAD 800-631-6989

McGinn-13

12/14/18 mR
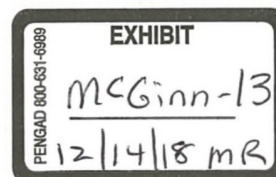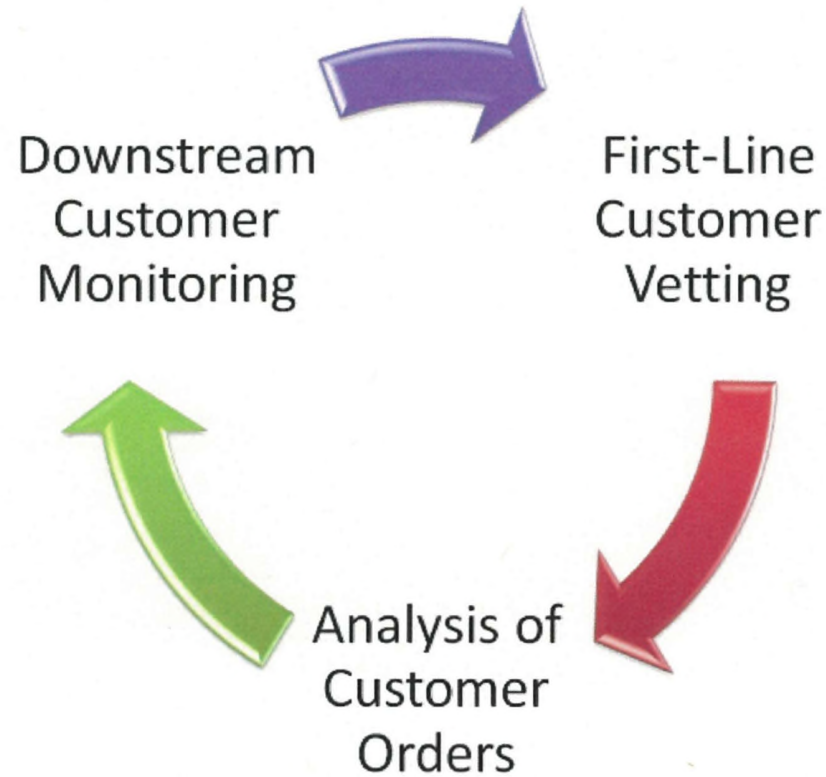
TEVA_MDL_A_02336504

P-03732 _ 00001

Suspicious Order Monitoring (SOM)

Colleen McGinn

001

Complete SOM Solution

First-Line Customer Vetting → Analysis of Customer Orders → Downstream Customer Monitoring → (cycle)

Model Program
First Line Customer Vetting

- Customer Responsibility Agreement
- Self-Assessment Questionnaire
- Site Visit
  - Photos, compliance review, dispensing records
- D&B Check
- Copies of Licenses and Registrations

- Corporate Structure and identity of employees
- Customer base
- Customer's SOM procedure
- New Customer Approval
  - Scoring system
- Initial purchase parameters
- Close monitoring of purchases for 6 mos. – 1 yr.
- Assign risk score

003

Model Program
Analysis of Customer Orders

- SORDS
  - Compare by:
    - Order history for 24 months (rolling)
    - Frequency of orders
    - Type of registrant
    - Customer location
    - % controlled vs. non-controlled products ordered
    - States without active Prescription Monitoring Programs (PMPs)
    - RADARS Data
    - Risk Map/REMS data

- "Orders of Interest"
  - Create SOP for handling orders outside of normal parameters
  - Document review
  - Create Oversight Committee
    - Review history of all "Orders of Interest" quarterly

- Suspicious Orders
  - Create SOP for identification and reporting of Suspicious Orders to DEA
  - Review by Oversight Committee
  - Notification to customer

004

Model Program
Downstream Customer Monitoring

- ValueCentric Data
  - First-time purchases
  - Above average sales
  - Multiple wholesaler activity
  - Disproportionate sales
- Chargeback Data
  - Reimbursed difference between the Wholesalers Actual Cost (WAC) and the contracted price paid by the indirect customer purchased from a wholesaler.
  - May also include: negative charge backs for product returns, administrative and service fees, and chargeback adjustments.
  - Data can be used to follow product through supply chain
- NOT AVAILABLE FOR ALL PRODUCTS
  - Actiq, Fentora (Checking with Chris Heckler)

005

Gap Assessment

Activity	Current SOM Program	Model SOM Program

First-Line Customer Vetting	• Bank References
	• Dunn and Bradstreet Report
		Current measures PLUS:
		• On-site customer visit for:
		    • Level of DEA Compliance
		    • Thorough understanding of customer's operation
		    • Pictures, if permitted
		• Customer Responsibility Agreement
		• Customer Self-Assessment Questionnaire
		• Risk Score Assignment
		• Create method for reporting unusual transactions

	Frequency: Once	Frequency: Initial Setup Risk Based

Gap Assessment

Activity	Current SOM Program	Model SOM Program

SORDS	• Validation of customer's DEA registration
	• Verify normal ordering pattern based on historical data (24 mos.) by product class
		• Orders of unusual size, frequency or deviating from normal pattern
		• Comparison of order with registrants of same type
		• Customer location
		• Risk Map/REMS data
		• Breadth and type of products ordered.
		• Orders of Interest Investigations
		    • Proceduralize process
		    • Review by Oversight Committee

	Frequency: With every CS order Review of upper control limits every 6 mos.	Frequency: With every order Review of upper control limits every 6 mos. Oversight review every quarter

007

Gap Assessment

Activity	Current SOM Program	Model SOM Program
Know Your Customer's Customer	N/A	• Use Value Centric and chargeback data to evaluate risk.
	Frequency: N/A	Frequency: Quarterly

Project Setup Costs

Contracted Costs		In-House Costs	
One Time Setup:	$ 5,000	Program Setup by Consultant:	
Site Visits:		One Time Charge	$ 5,000
(222 sites x $3795/ea.)	$ 842,490	40 Site Visits ($3795/ea)	$ 151,800
Travel:		Hire 2 FTEs	$ 150,000 (?)
(222 sites x $1,000/ea.)	$ 222,000	Travel:	
	$ 1,069,490	(222 sites x $1,000/ea.)	$ 222,000
			$ 528,800

Contracted Costs $1,069,490
In-House Costs $ 528,800
Potential Savings $ 540,690 (?)

Next Steps

1. Develop SOM Implementation Task Force

   - Include representatives from:

     - Diversion Operations

     - Legal

     - Commercial Sales

     - IT

     - Customer Service

   - Goal: To identify key contacts for timely implementation of the program

Next Steps

2. Program Launch by 3rd Party

- Mobilize SOM Task Force and 3rd Party to develop program architecture

- Create SOPs for customer approval, risk assessment, handling "Orders of Interest" and Suspicious Orders

- Conduct 40 customer visits accompanied by Diversion Operations

  – Goal: To develop robust SOM program.

011

Next Steps

3. Hire 2 Diversion Investigators
   - Analyze customer order data
   - Review "Orders of Interest"
   - Conduct customer site visits
   - Review SORDS upper control limits

   - Goal: To maintain a robust, in-house SOM program.

Next Steps

4. Conduct Periodic audits of SOM system

    – Internal audit of suspicious orders, compliance procedures and results

    – Reviews/Revision of SOPs and employee training

    – Review of SORDS design and thresholds

    – Goal: To adapt the SOM process with changing needs.

SOM Development Process

Develop Architecture → Create SOM Task Force → Develop SOPs → Build Customer Self-Assessment Questionnaires

Customer Site Visits → Conduct Risk Assessment → Perform On-site Visits with 3rd Party → Hire 2 Diversion Investigators → Start In-House Audit Program

Order Review → Conduct Risk Assessment → Conduct "Orders of Interest" Investigations → Monitor for Suspicious Orders

SOM Program Audit → Review Process → Make changes as necessary