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Customer Analysis and SOMS Overview

Import/Export

Will Simmons
Compliance Auditor/Investigator



Customer Analysis & Product Breakdown

- 164 active SKUs
 - 63 Class IV
 - 12 Class III
 - 89 Class II
- 2014: 109 Approved Controlled Substance Customers
- 2015: 103 Approved Controlled Substance Customer
 - 2014: Top 3 = 81%
 - 2014: Top 10 = 93%
 - 2015: Top 3 = 85%
 - 2015: Top 10 = 95%
 - All 2015 are YTD
- 2014: Top 5 = 89%
- 2014: Top 20 = 97%
- 2015: Top 5 = 92%
- 2015: Top 20 = 98%

2014 vs. 2015 (YTD) Family Shipments

Product Family	2015 Shipments YTD (SDU)	2014 Shipments (SDU)
HYDROCODONE/APAP	1,155,204	1,522,346
OXYCODONE/APAP	407,495	555,916
OXYCODONE HCL	308,097	199,648
MIXED AMPHETAMINE ER	103,357	130,397
METHYLPHENIDATE	53,452	78,047
MIXED AMPHETAMINE	39,443	16,248
BUTAL/APAP/CAF	22,175	37,360
FENTANYL PATCH	10,062	12,570
BUTAL/ASA/CAF	8,492	10,816
BUTAL/APAP/CAF/COD	6,930	7,134
NORCO	6,128	11,763
BUTAL/ASA/CAF/COD	5,916	9,027
HYDROCODONE/IBUP	4,262	5,588
MORPHINE SULFATE PAR	3,498	2,637
MORPHINE SUL AVINZA	3,289	4,088
OXYMORPHONE HCL ER	3,256	2,148
DEXTROAMPHETAMINE ER	2,953	898
KADIAN MORPHINE	1,983	1,481
MORPHINE ER (KADIAN)	1,767	738
HYDROMORPHONE ER	1,562	1,485
OXYCODONE/ASPIRIN	1,196	1,751
FIORINAL	431	788
OXYCODONE/IBUPROFEN	105	199

2014 vs. 2015 (YTD) Shipments by Customer

Customer	2015 Shipments YTD (SDU)	2014 Shipments (SDU)	Difference
AMERISOURCEBERGEN CORP	2,826,971,176	3,441,151,990	82%
MCKESSON	731,166,078	831,571,017	88%
WAL-MART STORES	344,080,080	459,959,760	75%
CARDINAL HEALTHCARE INC	253,544,088	395,363,851	64%
ANDA GENERICS INC	58,751,892	80,984,382	73%
THE KROGER COMPANY	39,433,530	48,485,660	81%
MORRIS & DICKSON COMPANY LTD	35,500,940	52,478,840	68%
N C MUTUAL WHOLESALE DRUG	33,455,340	38,817,632	86%
SMITH DRUG COMPANY	27,699,620	36,500,271	76%
EXPRESS SCRIPTS	21,515,870	34,917,250	62%
HD SMITH LLC	16,955,723	28,231,848	60%
MAJOR PHARMACEUTICALS	15,019,800	8,232,000	182%
ROCHESTER DRUG COOPERATIV INC	13,004,460	13,891,726	94%
ALBERTSONS LLC	12,775,720	17,320,080	74%
DROGUERIA BETANCES INC	12,742,420	19,278,340	66%
BELLCO DRUG CORP	10,274,540	16,277,748	63%
GOLDEN STATE MEDICAL SUPPLY INC	9,858,600	6,601,200	149%
OMNICARE DISTRIBUTION CENTER LLC	9,686,160	41,045,880	24%
KAISER PERMANENTE	9,248,960	12,298,320	75%
AMERICAN SALES CO INC	8,256,600	20,231,980	41%

Top Customers

2014 Top Customers

AMERISOURCEBERGEN CORP
MCKESSON
WAL-MART STORES
CARDINAL HEALTHCARE INC
ANDA GENERICS INC
MORRIS & DICKSON COMPANY LTD
THE KROGER COMPANY
SANDOZ INC
OMNICARE DISTRIBUTION CENTER LLC
N C MUTUAL WHOLESALE DRUG

2014 Top Products (FAMILY)

HYDROCODONE/APAP
OXYCODONE/APAP
ALPRAZOLAM
LORAZEPAM
CLONAZEPAM
OXYCODONE HCL
METHYLPHENIDATE AG
DIAZEPAM
CARISOPRODOL
MIXED AMPHETAMINE ER

2015 Top Customers

AMERISOURCEBERGEN CORP
MCKESSON
WAL-MART STORES
CARDINAL HEALTHCARE INC
ANDA GENERICS INC
THE KROGER COMPANY
MORRIS & DICKSON COMPANY LTD
N C MUTUAL WHOLESALE DRUG
SMITH DRUG COMPANY
EXPRESS SCRIPTS

2015 Top Products (FAMILY)

HYDROCODONE/APAP
OXYCODONE/APAP
LORAZEPAM
ALPRAZOLAM
CLONAZEPAM
OXYCODONE HCL
METHYLPHENIDATE AG
DIAZEPAM
MIXED AMPHETAMINE ER
CARISOPRODOL

Vetting Process

Prior to shipping controlled substances to a customer, an extensive vetting process must be completed and approved by DEA Affairs.

- When a customer request to purchase controlled substances, Customer Management provides DEA Affairs the initial customer vetting form to include contact information.

- DEA Affairs will then customize a “Know Your Customer” letter to the potential customer requesting:

- Compliance personnel contact information
- SOMS program and KYC overview including SOPS regarding customer/order vetting
- 6 month customer history for select controlled substances (customer locations and order history)
- Forecast for controlled substance ordering and historical ordering behavior
- Compliance Acknowledgement Form (provided by DEA Affairs)
- Situation depending, a site-visit will also be required

Note: Failure to provide requested information = denial of account. Failure of existing customer to provide information = partnership call and revocation of controlled substance ordering

All information is reviewed by DEA Affairs and maintained in conjunction with SOMS information.

Suspicious Order Monitoring

Regulation: 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.”

“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.

Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders.” *Southwood Pharmaceuticals, Inc.*, 72 FR 36487 (2007)



SOM SYSTEM

SAP System Suspends Orders Based On:

- Class of Trade Avg Qty/Order
- Class of Trade Avg Qty Ordered/Month
- Customer Allowable Qty/Order
- Customer Allowable Qty Ordered/Month

System-Flagged Orders Released Based On:

Customer allowable quantity per month

Current month's order + pending order

IF < allowable quantity per month, release order

IF > allowable quantity per month, contact customer

Order Review and Investigation

Order that exceeds allowable amount:

- Customer is contacted regarding the order utilizing the following verbiage:

“In accordance with 21 CFR 1301.74, we are required to conduct independent analysis of orders prior to completing a sale to determine whether substances are likely to be diverted from legitimate channels. You have been contacted due to the fact that your order placed today has prompted further analysis based on a deviation in one of the following areas; unusual size, frequency, or pattern. In an effort to expedite the investigation process and mitigate any delays or inconvenience, we are requesting supporting information necessary to justify the fulfillment of the order in question.”

Order Review and Investigation

Depending on customer response, Customer Relations will release order or compile information into SOMS Investigation Report and forward to DEA Affairs.

- If released by Customer Relations, a "Release Code" (numeric value) will be assigned to the order.

Common Codes:

01: Customer Contacted and acceptable justification obtained

03: Within Allowable

08: Product Launch

12: Customer Contact Not Required

13: Approved by DEA Affairs

- Once forwarded to DEA Affairs, a more detailed historical examination will be performed as well as additional contact with the customer.

- If orders are approved, DEA Affairs will notify Customer Relations who will release order. Orders not approved are cancelled in entirety, customer blocked, and DEA notified.

Order Review and Investigation



WATSON
Pharma, Inc.

A Subsidiary of Watson Pharmaceuticals, Inc.
311 Bonnie Circle, P O Box 1900, Corona, CA 92878-1900
Tel: 800-272-5525 * Fax: 951-735-2871

SOMS Investigation Form

Sales Order Date	Purchase Order #	Order #
10/23/2014	063107893	764471

Sold To #: 1201047

Ship To #: 1338648

Name
Street
City
State

Amount over allowable

Name
Street
City
State

Item #	Material #	Description	Order Qty	Sales Unit	Description	COT Avg./ord	COT Avg./mth	Cust Allow/ord	Cust Allow/mth	MTD Qty	Pending Qty	Release Qty	Reason Code
30	00228202796	ALPRAZOLAM 0.25MG TAB 1000	228	EA	Suspect (Cus Aw/mth)	82	4,011	287	545	804	0	228	
50	00228202996	ALPRAZOLAM 0.5MG TAB 1000	384	EA	Suspect (Cus Aw/mth)	106	7,776	371	842	1,464	0	384	
60	00228203150	ALPRAZOLAM 1MG TAB 500	800	EA	Suspect (Cus Aw/mth)	154	12,361	500	1,183	2,124	0	600	
70	00228203910	ALPRAZOLAM 2MG TAB 100	1,368	EA	Suspect (Cus Aw/mth)	280	26,062	1,380	3,725	5,394	0	1,368	
100	00228308706	ALPRAZOLAM ER 2MG TAB 60	36	EA	Suspect (Cus Aw/mth)	50	4,111	69	208	192	0	36	12
110	00228308306	ALPRAZOLAM ER 0.5MG TAB 60	60	EA	Suspect (Cus Aw/mth)	45	3,854	94	298	324	0	60	
120	00228308408	ALPRAZOLAM ER 1MG TAB 60	72	EA	Suspect (Cus Aw/mth)	52	5,075	115	344	300	0	72	12
230	00591024005	LORAZEPAM 0.5MG TAB 500	243	EA	Suspect (Cus Aw/mth)	185	16,404	323	676	879	0	243	
260	00228348211	ZOLPIDEM TARTRATE ER 12.5MG TAB 100	204	EA	Suspect (Cus Aw/mth)	118	10,880	254	854	720	0	204	

Items 30, 50, 60, 70, 110, 230, 260 -

Justification provided by customer relations with documentation attached to form.

DEA Contacted / Date / Action

**William
Simmons**

Digitally signed by William Simmons
DN: cn=William Simmons, o=Actavis,
ou=DEA Affairs,
email=wsimmons@actavis.com,
c=US
Date: 2014.10.23 13:23:20 -0400

Signature

Customer Support Representative

Date

Manager Call Center Operations

Date

Location

311 Bonnie Circle, Corona, CA 92880

311 Bonnie Circle, Corona, CA 92880

2014 Historical SOMS

2014

	Jan-14	Feb-14	Mar-14	Apr-14	May-14	Jun-14	Jul-14	Aug-14	Sep-14	Oct-14	Nov-14	Dec-14	2014 Monthly Average
Total Orders Received	1,026	1,012	975	1,069	1,637	1,497	1,697	1,606	1,413	1,897	1,428	1,752	1,417
Total Lines Received	6,958	7,295	7,584	8,491	12,761	11,940	13,553	13,890	13,005	15,111	12,063	13,700	11,363
SOMS Order Pends	619	562	556	483	428	452	383	380	348	626	473	775	507
SOMS Lines P.E.R	1,892	1,637	1,502	1,344	998	1,215	1,039	821	777	1,484	1,657	1,881	1,354

2014 Order Pends: 35% of all orders / 12% of all lines

SOMS Orders requiring DEA Affairs Investigation (July – Dec 2014*)

191 Orders (501 lines)

Average Release Time from DEA Affairs: 26 minutes

Average Release with additional customer contact: 1 hour 46 minutes

2014 values reflect multiple product launches as well as Hydrocodone Rescheduling (October, 2014)

* DEA Affairs Tracking Metrics established July 2014



2015 YTD SOMS

2015

	Jan-15	Feb-15	Mar-15	Apr-15	May-15	Jun-15	Jul-15	Aug-15	Sep-15	Oct-15	YTD Monthly Average
Total Orders Received	1,763	1,569	1,753	1,609	1,581	1,925	1,930	1,894	1,831	1,704	1,756
Total Lines Received	12,576	12,308	14,315	13,506	13,661	15,931	13,155	14,082	14,247	14,142	13,792
SOMS Order Pends	781	504	561	451	450	591	653	486	1,615	485	658
SOMS Lines P.E.R.	1,682	1,012	1,019	709	816	1,102	1,124	800	745	784	979

2015 Order Pends YTD: 37% of all orders / 12% of all lines

SOMS Orders requiring DEA Affairs Investigation (2015 YTD)

304 Orders (797 lines)

Average Release Time from DEA Affairs: 39 minutes

Average Release with additional customer contact: 7 hour 38 minutes

2015 values reflect competitor supply issues, awards and contracts.

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2015 YTD SOMS

YTD 2015 SOMS Volume Metric



	Jan-15	Feb-15	Mar-15	Apr-15	May-15	Jun-15	Jul-15	Aug-15	Sep-15	Oct-15	Nov-15	Dec-15	YTD Monthly Average	2014 Monthly Average
Total Orders Received	1,763	1,569	1,753	1,609	1,581	1,925	1,930	1,894	1,831	1,704			1,756	1,417
Total Lines Received	12,57	12,30	14,31	13,50	13,66	15,93	13,15	14,08	14,24	14,14			13,79	11,36
SOMS Order Pends	781	504	561	451	450	591	653	486	1,615	485			658	507
SOMS Lines P.E.R.	1,682	1,012	1,019	709	816	1,102	1,124	800	745	784			979	1,354

Additional Analysis

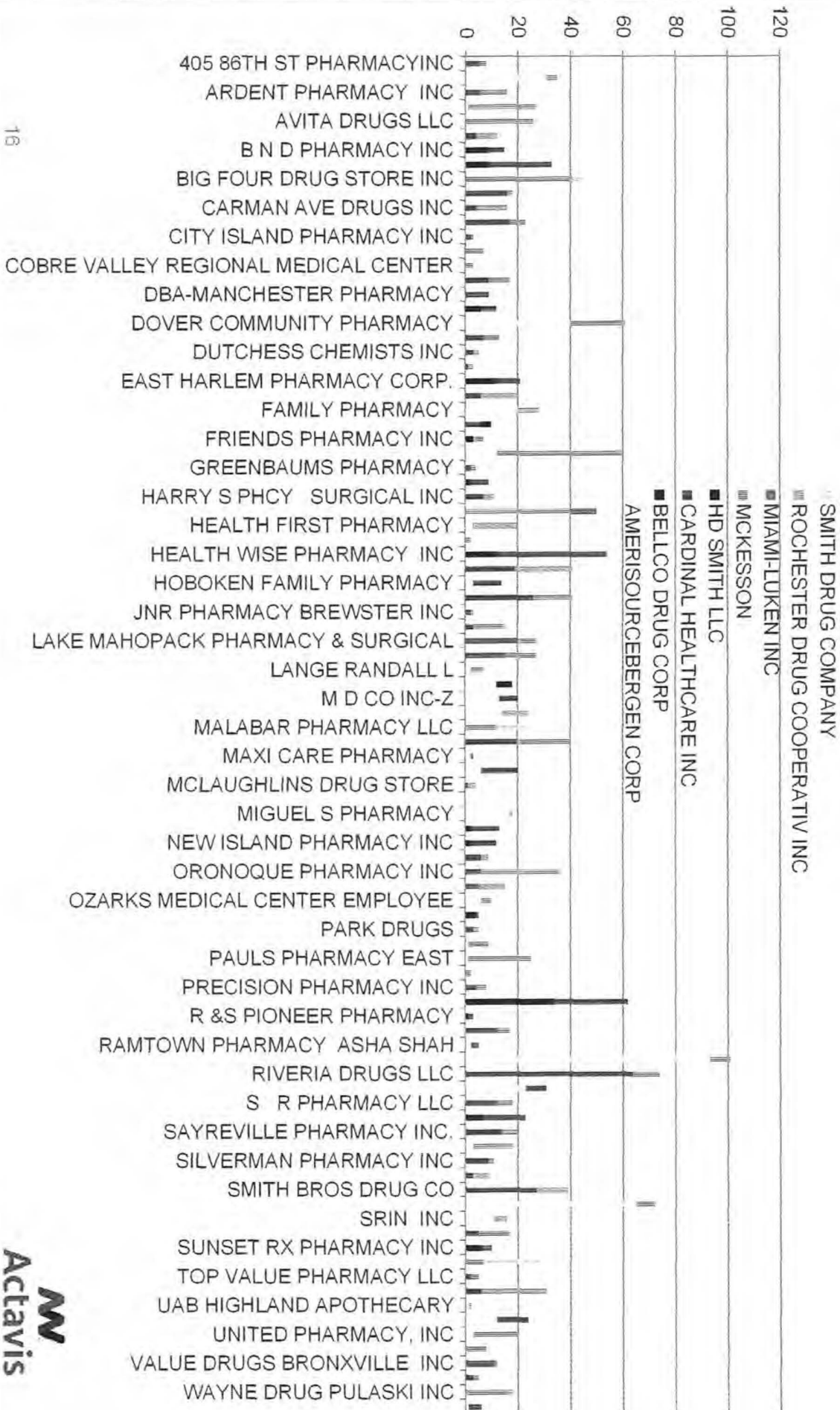
Chargeback

A pharmaceutical chargeback can occur in two similar situations. In the first situation, a wholesaler buys drugs from the pharmaceutical company according to a contract price, and sells them to consumers according to another contract price. When the consumer contract price is lower than the pharmaceutical version, the wholesaler avoids losses by charging the pharmaceutical company for the difference.

Monthly chargeback analysis performed for Oxy and Hydro Products

- Customers purchasing large amounts from multiple distributors
- More than 2 distributors (primary/secondary/tertiary)
- Analyze month over month trends to detect pattern
- Assists in validation of SOMS orders

Additional Analysis



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Import/Export

2014:

135 Total Imports Applied For
125 DEA Form 236
10 DEA Form 357
36 Open at Year End 2014
76 Total completed (2014)

Exports

51 Total Exports Applied For
2 DEA Form 161
49 DEA Form 236
3 Open at Year End
31 Total Completed (2014)

* **Permits**

2015 YTD:

164 Total Imports Applied For
158 DEA Form 236
6 DEA Form 357
100 Closed Out YTD
64 Pending

Exports

62 Total Exports Applied For
46 DEA Form 161
16 DEA Form 236
54 Closed Out YTD
8 Pending*

Questions?