

**From:** Nancy Baran  
**To:** Michael Perfetto; Michael Clarke; John Duff; John LaRocca  
**Sent:** 10/19/2012 7:10:38 PM  
**Subject:** ABC Meeting Presentation  
**Attachments:** Partnership Mtg ABC Oct 22 FINALNB.pptx

Attached is a copy of the ABC presentation for Monday. I apologize for not sending it over sooner. This week has been filled with all kinds of "opportunities." There are no other words to describe it...

I recognize that I am not leaving you with much time to absorb this, but rest assured I feel very well prepared to present this material in the most collaborative way. While our goal is to ensure ongoing compliance, my priority is first and foremost maintaining positive customer relationships.

I welcome your comments, questions or concerns. The last 4 pages of this presentation call are the meat of what is being presented. If you read nothing else, please read over the last page. There is one paragraph that may read a little too strong.

Thanks in advance.

Michael and John – I will see you on Monday at 10:30 in Chesterbrook. My cell is 908-425-1380.

Have a nice weekend.

Nancy

**Nancy Baran**

*Director, Customer Service*

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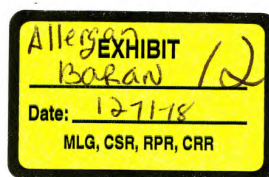
Actavis

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*Suspicious Order **Monitoring***

*Partnership Meeting  
AmerisourceBergen*

*Chesterbrook, PA*

*October 22, 2012*



# Agenda

- **Brief overview of SOM Initiative - Actavis**
- **Review of ARCOS data specific to Oxy 15mg and Oxy 30mg**
- **High level presentation of SOM Process - Amerisource**
- **General discussion around opportunities for collaboration**



# Meeting Participants

## AmerisourceBergen

- Ed Hazewski - Director, Corporate Security and Regulatory Affairs
- Steve Mays - Senior Director, Regulatory Affairs
- Elizabeth Campbell - Senior Counsel
- Chris Caselenuovo - Counsel
- Rita Knepley - Counsel

## Actavis Inc.

- Nancy Baran - Director, Customer Service/Controlled Substance Compliance
- Michael Clarke - Ethics & Compliance Officer
- John Duff - Sr. Director Legal



# Suspicious Order Monitoring Requirement

## Controlled Substances - Requirement 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
- Orders of unusual frequency

## System Challenges & Responses

- “Threshold” based systems are not sufficient
- “Cutting” orders to a volume that puts the order under a threshold is not acceptable.
- DEA has stated on this topic, “That is like saying a little bit of diversion is okay.”

## Investigative Challenges & Responses

- Potentially suspicious orders must be reviewed before shipment occurs. Investigation must be fully documented.
- Well defined and sufficient “due diligence”
  - 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 on orders as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.



# ACTAVIS - Total SOM Solution

## 1. Enhanced SOM systems & processes (Direct Sales)

- Engaged Cegedim Compliance Solutions - 2011 (former DEA consulting team and Ph.D. statisticians)
- Implemented an enhanced statistical model into existing order management system
- Model developed based on an extensive review/analysis of historical data
- Model is fully retuned yearly based on a more current sample of data

## 2. Know your customer- due diligence

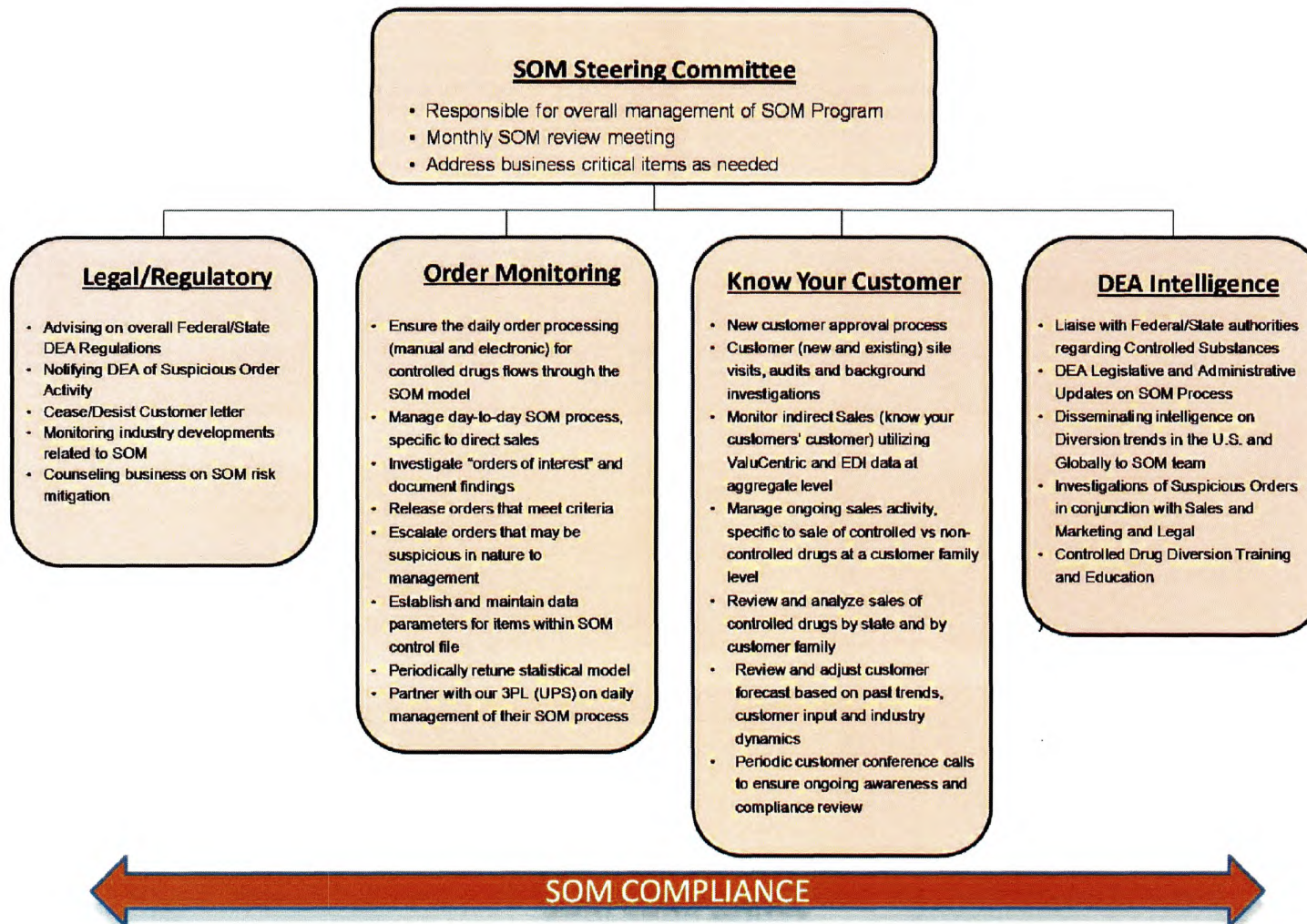
- New Account Review Process
- SOM process review with existing customers
- Compliance Acknowledgment Form
- Site Visits during 2012 - more in-depth review of SOM Process

## 3. Know your customer's customer (Indirect Sales)

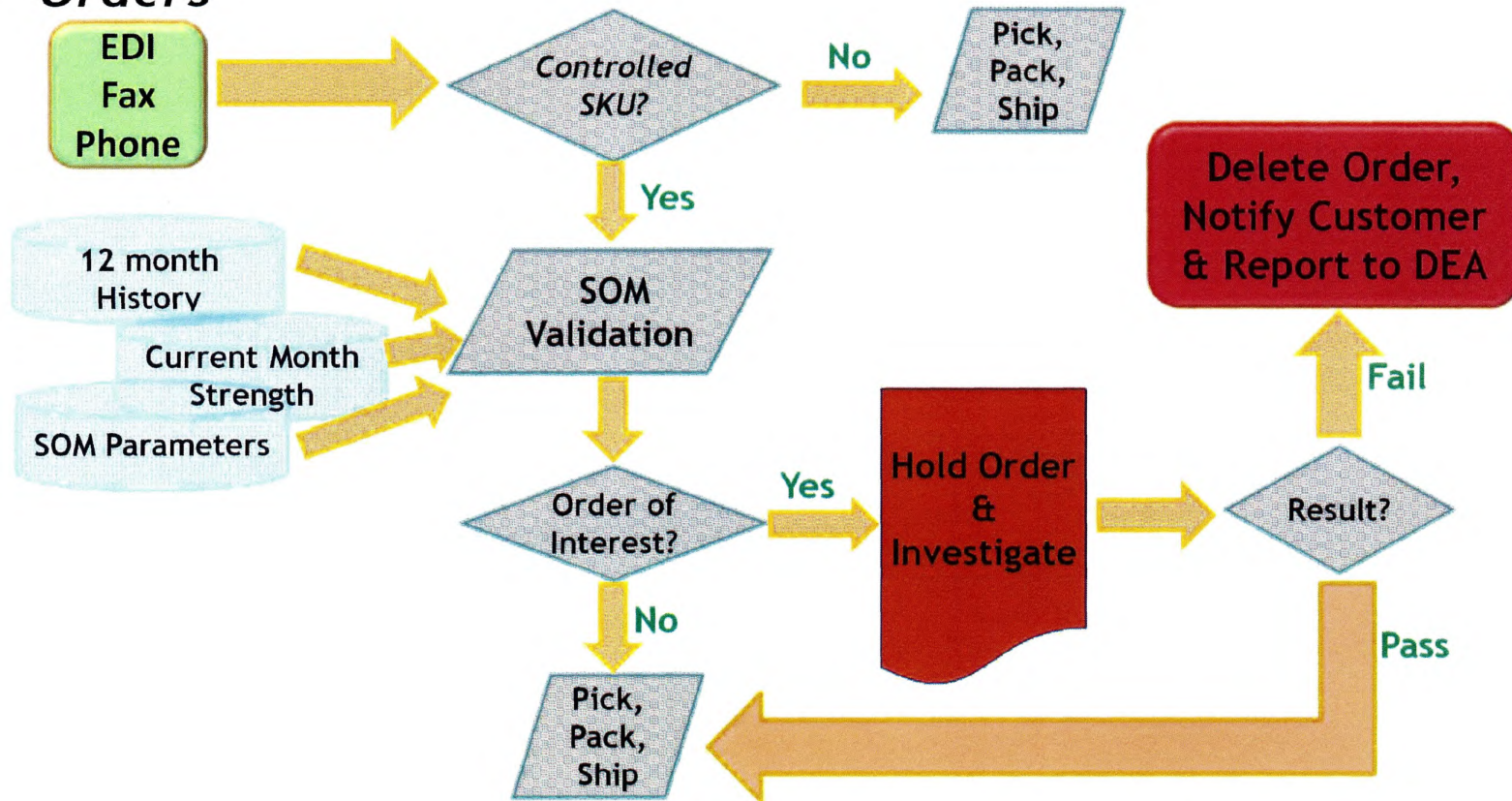
## 4. Develop SOP's, Processes, Best Practices



# SOM - Overall Process



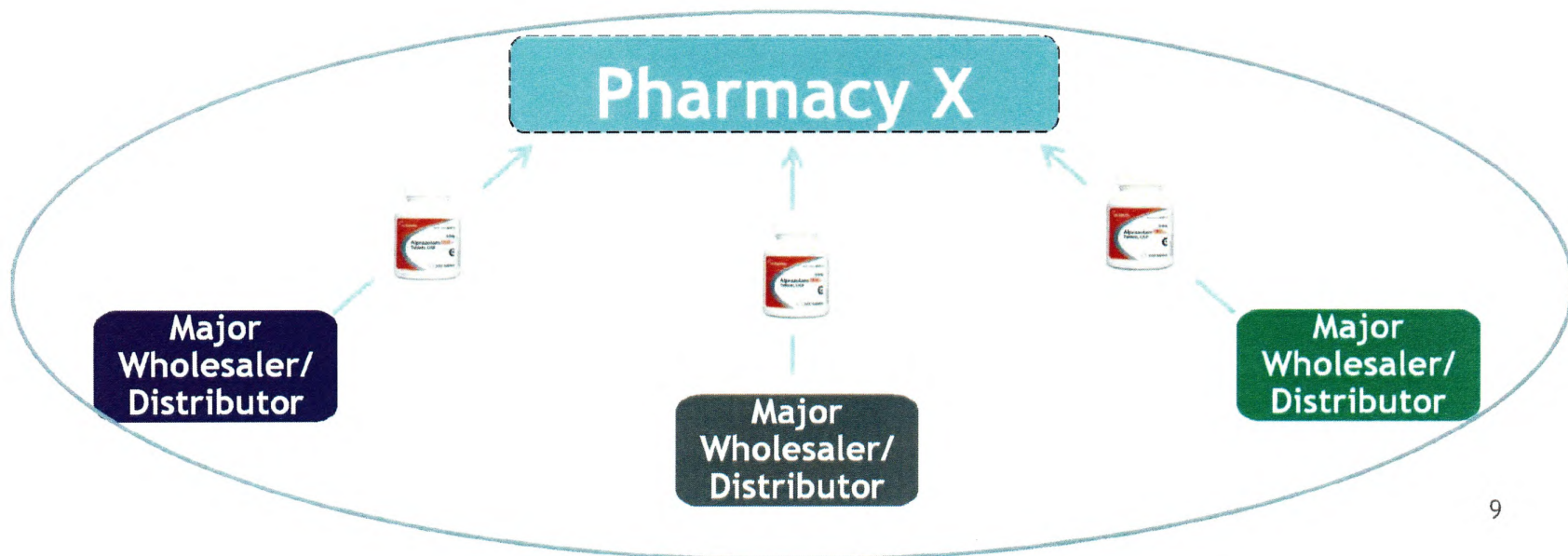
## Orders



# Monitoring Indirect Sales

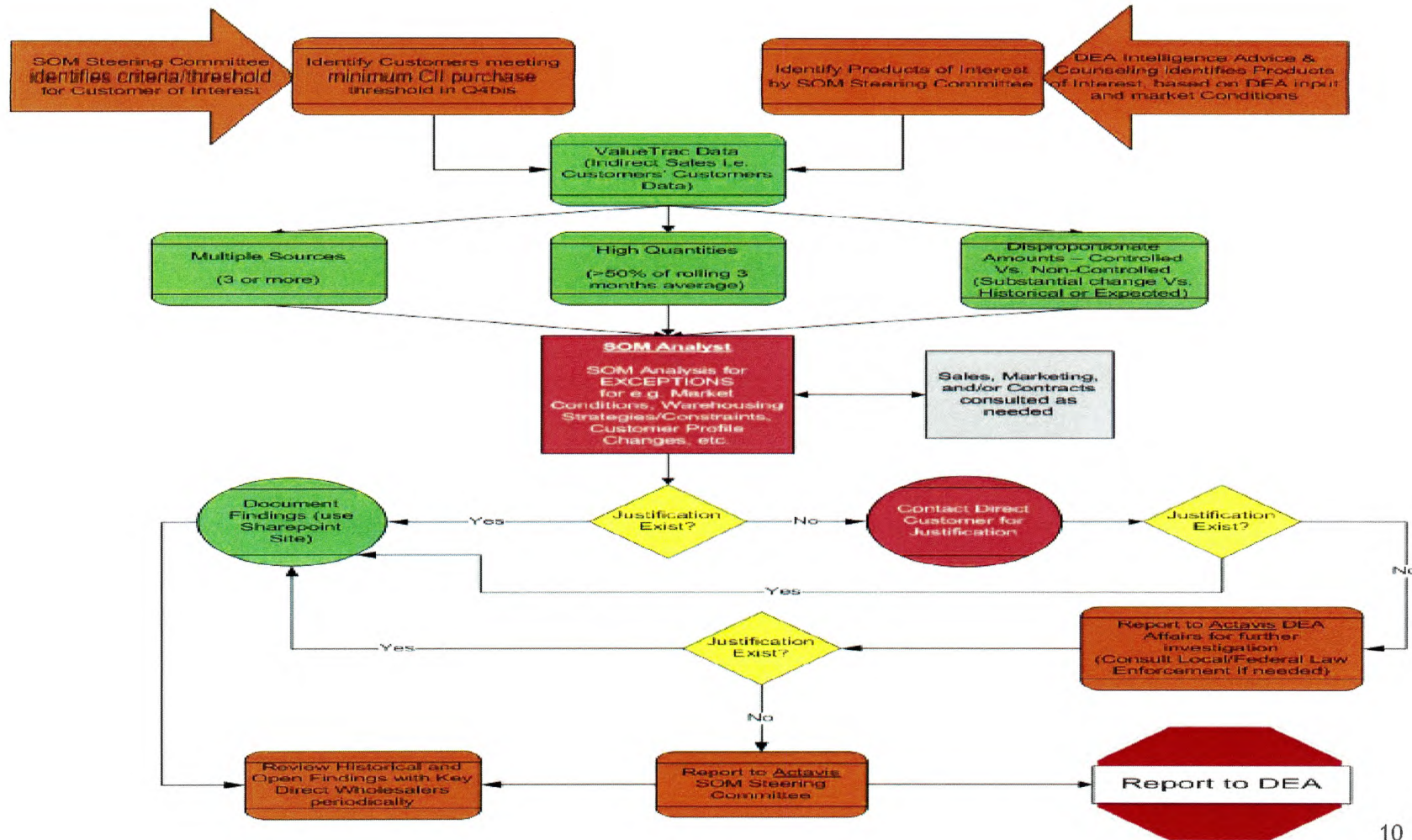
## Actavis

- pharmacies that receive a specific product from multiple wholesalers.
- above average sales of a specific product at the pharmacy level.
- pharmacies that order ONLY a high-risk product.



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# Suspicious Order Monitoring Indirect Sales Process Flow





## TOP 50 PHARMACIES Sales of Oxycodone 30mg

January 1, 2012 - June 2012

(not all of June being reported at the time these statistics were reported)

### NDC 287911

Rank	Buyer's DEA Number	Buyer's Name	Buyer's City	State	Zip	Total Pills	Total Bottles (DEA ARCOS)	Wholesaler (s)	Actavis CB Jan 1 - June 30 2012	Quantity of Oxy 30mg 100ct - 867 data	Disproportionate Oxy Activity	Comments
1	BF7000526	FOOD CITY PHARMACY #674	KNOXVILLE	TN	37919	628,100	6,281	ABC - BIRMINGHAM	6905	5177	89%	2010: ranked #1 Oxy 15mg and Oxy 30mg, 2011: #1 for 30mg and #29 for 15mg
3	FF1280089	FOOD CITY PHARMACY # 616	KNOXVILLE	TN	37932	279,200	2,792	ABC - BIRMINGHAM	2912	2446	98%	2011: ranked #36 for Oxy 15mg, # 9 for 30mg
5	BF9649508	FOOD CITY PHARMACY #694	KNOXVILLE	TN	37919	227,400	2,274	ABC - BIRMINGHAM	2548	1940	87%	2011: ranked # 17 for Oxy 30mg.
6	AW9808568	WINDSOR PHARMACY	EAST BRUNSWICK	NJ	08816	193,800	1,938	ABC - BETHLEHEM and Wholesaler #2	1905	1548	77%	dual sourcing - 2010: ranked #13 for Oxy 30mg, 2011: ranked # 39 for Oxy 30mg,
11	FR1435355	ROCKY'S MED SHOPPE, LLC	BOGALUSA	LA	70427	151,600	1,516	ABC - HOUSTON	160	140	100%	unable to reconcile DEA units with sales data. Uncertain where customer is getting their supply.
12	AK3221140	KEANSBURG DRUGS	KEANSBURG	NJ	07734	149,100	1,491	ABC - BETHLEHEM	1608	1286	89%	
15	BB6383169	BELEW DRUG	KNOXVILLE	TN	37917	138,700	1,387	ABC - BIRMINGHAM	1502	1157	85%	
17	FH1306984	HOPKINS PHARMACY	PHILADELPHIA	PA	19128	136,800	1,368	ABC - THOROFARE and Wholesaler # 4	1441	1357	94%	dual sourcing
20	FH0825313	HUMANA PHARMACY INC DBA RIGHTSOURCE	WEST CHESTER	OH	45069	132,900	1,329	ABC - THOROFARE and Wholesaler # 4	1537	918	10%	dual sourcing
21	BH4285309	HEALTHWISE PHARMACY	TAMPA	FL	33614	132,900	1,329	ABC - ORLANDO	1365	936	94%	
26	BS7719795	SHAYONA PHARMACY	PERTH AMBOY	NJ	08861	128,600	1,286	ABC - BETHLEHEM	1401	1126	95%	
28	BD1649978	DISNEY PHARMACY SERVICES	POWELL	TN	37849	119,700	1,197	ABC - BIRMINGHAM	1649	1023	93%	
37	BE9503687	E. HARTMAN LLC DBA DEAL DRUGS	NASHVILLE	TN	37211	110,600	1,106	ABC - PADUACHI and Wholesaler #5	1240	378	87%	dual sourcing
41	FB2049446	BYPASS PHARMACY, INC	BECKLEY	WV	25801	107,500	1,075	ABC - RICHMOND	1171	861	92%	
49	AH2731025	HOLLYWOOD DISCOUNT PHARMACY	HOLLYWOOD	FL	33021	101,800	1,018	ABC - ORLANDO	1208	926	91%	



**TOP 50 PHARMACIES**  
**Sales of Oxycodone 15mg**  
 January 1, 2012 - June 2012  
 (not all of June being reported at the time these statistics were reported)  
**NDC 287811**

Rank	Buyer's DEA Number	Buyer's Name	Buyer's City	State	Zip	Total Pills	Total Bottles (DEA ARCOS)	Wholesaler (s)	Actavis CB Jan 1 - June 30 2012	Quantity of Oxy 30mg 100ct - 867 data	Quantity of Oxy 15mg YTD 867 data	Disproportionate Oxy Activity
2	AB9244497	BERNIE'S PHARMACY	ANCHORAGE	AK	99508	127,600	1,276	ABC - Seattle	1355	1639	1835	92%
3	FB2049446	BYPASS PHARMACY, INC	BECKLEY	WV	25801	105,800	1,058	ABC - Richmond	985	1430	1422	92%
5	BF7000526	FOOD CITY PHARMACY #674	KNOXVILLE	TN	37919	88,000	880	ABC - Birmingham	920	5177	528	89%
17	FU1700512	UPSTATE PHARMACY CROSS CREEK	GREENVILLE	SC	29605	72,800	728	ABC - Morrisville	850	296	630	93%
21	FF1280089	FOOD CITY PHARMACY # 616	KNOXLEY	TN	37932	69,600	696	ABC - Birmingham	348	2446	24	98%
28	FJ1305689	JK SERVICES OF SARASOTA LLC	BRADENTON	FL	34202	63,000	630	ABC - Orlando	351	378	189	96%
42	BM8708692	MEDICAP PHARMACY	NEW BERN	NC	28560	53,600	536	ABC - Morrisville	343	275	223	84%



**Pharmacies Purchasing from Multiple Wholesalers**  
 Sales of Oxycodone 15mg and 30mg (NDC 00228-2878-11, 00228-2879-11)  
 January 1, 2012 to October 15, 2012

SAMPLE

Buyer's DEA Number	Buyer's Name	Buyer's City	State	Zip	Wholesaler (s)	Quantity of Oxy 30mg 100ct - 867 data	Quantity of Oxy 15mg YTD 867 data	Disproportionate Oxy Activity
FM1807289	Okie's Pharmacy	Maynardville	TN	37807	ABC - Birmingham and one other wholesaler (1)	1477 bottles/147,700 dosage units	479	85%
BR9523172	Dao Pharm	Morton	PA	19070	ABC - Thorofare and 2 other wholesalers (3) (2)	1712 bottles/171,200 dosage units	923	96%
BA0775912	Apple Discount Drugs	Clinton	TN	37716	ABC - Birmingham and one other wholesaler (1)	1113 bottles/111,300 dosage units	420	80%
AK3221140	Keansburg Drugs	Keansburg	NJ	07734	ABC - Bethlehem and 2 other wholesalers (2) and (3)	1958 bottles/195,800 dosage units	394	89%
AW9808568	Windsor Pharmacy	East Brunswick	NJ	08816	ABC - Bethlehem and 1 other wholesaler (2)	2388 bottles/238,800 dosage units	668	82%



The previous charts were compiled from ARCOS reports submitted to the DEA . The data was reviewed and purchases of a few customers were addressed during our discussion.

The mentioning of specific customers is NOT to be implied that the sale of controlled substances to these customers is illicit or that they may be involved in illicit activities.

It also should NOT be inferred that based upon the documentation provided to you that your company should terminate or restrict business with any customer discussed for the purposes of this presentation.

It is incumbent upon you to know your customers, fully review all orders for controlled substances and to exercise due diligence procedures prior to deciding whether or not to terminate or restrict sales to any customer.

As a manufacturer, Actavis takes significant measures to ensure the integrity of the product supply-chain, especially where controlled substances are involved. One of our primary goals is to minimize any potential for diversion of such products. We are confident that you, as an important participant in the controlled substance supply chain, share this objective.

Thank you for the opportunity for meeting with us today. As a key customer, we appreciate the continued partnership and collaboration and look forward to ensuring our mutual ongoing compliance as it relates to Suspicious Order Monitoring activities. We have had similar meetings with other customers and plan to expand this program as part of an ongoing series of due diligence activities.





Partnership Meeting  
AmerisourceBergen  
*Chesterbrook, PA*

