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**From:** Woods, Mary  
**Sent:** Tuesday, October 04, 2011 2:58 PM  
**To:** Boyer, Andrew  
**Cc:** Callahan, Judith  
**Subject:** Investigation Summary - DEA Affairs  
**Attachments:** Investigation Summary Top Rx.docx

Andy,

I need to meet with you, and most likely, Allan and Tony at the same time to discuss the results of the Top RX investigation. We can make some decisions during this call.

All RX orders are currently shipping to TOP RX, but no controls are shipping. I briefly spoke with Tony this AM, and told him I would have the details later today.

I believe you are all together, so if you can let me know when we can work out a meeting time, that would be great. Not sure of you have an opportunity to be in a confidential area, but you will need one for this conversation.

The timing is somewhat critical since Top RX continues to follow up on their control orders. I did reach out to Rita, and Scott last night to let them know we would be trying to complete the review today.

Let me know what may work for you.

Thanks Andy.

Best Regards,

*Mary J. Woods*

Executive Director, Customer Relations  
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**From:** Lisa A Scott  
**Sent:** Tuesday, October 04, 2011 1:43 PM  
**To:** Mary J Woods  
**Cc:** Tom P Napoli  
**Subject:** Investigation Summary

Mary:



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CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

CCSF v Purdue Pharma, et al.  
3:18-CV-7591

**P-31246\_00001**

Admitted: 6/16/2022

ALLERGAN\_MDL\_02187196

P-31246\_00001

Please see attached. Thank you.

**Lisa A. Scott**

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**Overview**

DEA Affairs performed an investigation into a controlled substance "order of interest," in support of the order review process for Watson's suspicious order monitoring program (SOM). As a component of our SOM program, DEA Affairs evaluates orders of controlled substances of unusual size, frequency and pattern from Watson's customers to ensure our product is not destined for illegitimate businesses.

**Executive Summary**

On Friday, August 19, 2011, Customer Relations management notified DEA Affairs that Watson customer TOP RX, Inc. had developed a pattern of canceling controlled substance line items suspended by SAP's suspicious order monitoring system for exceeding the customer's allowable quantity per month or allowable quantity per order. Over a five month time period beginning in March, TOP RX cancelled nine orders when members of Watson's Support Services team requested justifications for the increase in order quantities<sup>i</sup>. On each occasion, a representative from TOP RX cancelled these orders "to ship the rest of the order" or cancelled without providing any explanation; a red flag characteristic of a suspicious order.

On Friday, August 26, Customer Relations and DEA Affairs hosted a Customer Partnership conference call with TOP RX management in an effort to explain Watson's review process for suspended orders, the necessity of providing details when placing orders for increased quantities and to set the expectation for order justifications, in addition to providing TOP RX's management an opportunity to describe their operation, customer vetting process and SOM system.

Communications of note included:

- On three separate occasions during the call, TOP RX stated that they did not sell Hydrocodone to dispensing physicians.
- Customer Relations and DEA Affairs informed TOP RX that their orders would remain on hold until Watson receives sufficient justification.

On Wednesday, September 7, TOP RX forwarded copies of various internal controlled substance procedures and customer questionnaires via e-mail, but did not provide any information supporting order justification. Weekly sales data provided by TOP RX revealed sales of Hydrocodone to numerous dispensing physicians, including shipments to an address other than the one listed on a physician's DEA registration<sup>ii</sup>. Additionally, TOP RX shipped significant quantities of Hydrocodone to an individual pharmacy location in California<sup>iii</sup>.

On Friday, September 9, Customer Relations and DEA Affairs hosted a follow-up Customer Partnership conference call with TOP RX management. DEA Affairs made additional requests for information relative to a justification for the order increases, but no response was provided. When queried re: sales of Hydrocodone to numerous dispensing physicians (despite statements to the contrary during the first partnership call), shipments to an address not reflected on a DEA registration and Hydrocodone sales of significant quantities to an individual pharmacy location, members of TOP RX management were unresponsive and did not provide answers. DEA Affairs requested supporting documentation on three dispensing physicians and the pharmacy location.

On Thursday, September 29, DEA Affairs received a FedEx envelope with three manila folders containing documentation for the three dispensing physicians, but no documentation for the pharmacy location. A number of the documents (questionnaires, etc.) were dated subsequent to the second partnership call held September 9<sup>th</sup>.

To date, TOP RX has not provided any verbal or written justification to explain the increase in their controlled substance order quantities. After reviewing the investigative findings, DEA Affairs has determined TOP RX's orders to be suspicious and in accordance with federal regulation,<sup>iv</sup> must report these suspicious orders to the DEA. As a result, DEA Affairs recommends discontinuing sales of controlled substances to TOP RX.

10/04/2011

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**TOP RX, Inc.**

TOP RX, Inc., a generic pharmaceutical distributor, began operations in 1987. Initially selling short-date and overstocked generics exclusively, TOP RX grew its business to carry a complete line of generic pharmaceuticals, operating from a 23,000 ft<sup>2</sup> warehouse in Bartlett, Tennessee (a suburb of Memphis) and employing more than 100 people. According to a 2009 news article, "TOP RX stands out by being the "primary secondary" supplier on "B" level products or second-tier items which the wholesaler typically sells at increased margins".

**Dr. Christopher J. Fisher, MD**

Dr. Fisher practices critical care surgery and general surgery in Las Vegas, Nevada. Dr. Fisher's DEA registration reflects his office name, Desert Surgical Associates, along with the associated office address and he is affiliated with nearby Sunrise Hospital. An October 2009 questionnaire completed by Dr. Fisher includes the Sunrise Hospital address, although the description of the facility (as requested on the form) is documented as "business complex suite, 3,000 ft<sup>2</sup>, alarm company", a description of his office located at the address on his DEA registration. Sales reports provided by TOP RX reflect shipments against Dr. Fisher's DEA registration number with Sunrise Hospital's ship-to address (Sunrise Hospital and associated DEA registration is not a customer of TOP RX). During a one-on-one phone conversation, a TOP RX representative admitted that shipments were made to the hospital and not to the address on Dr. Fisher's DEA registration. Documents sent via FedEx include a print-out of Dr. Fisher's DEA registrant profile (printed from a national registrant database) with a handwritten note "in system now". However, on a revised questionnaire completed and signed by Dr. Fisher on September 14, 2011, he documented under the comments section, "Meds are delivered to Desert Surgical Associates because that is the registered DEA address of prescriber in compliance with federal and NV state laws." According to a June 1 – August 31, 2011 Dispensary Report generated and submitted by Dr. Fisher, he dispensed 67,550 tablets of Hydrocodone (four strengths/SKUs). The total quantity of Hydrocodone purchased/received during that time period was 83,000 tablets.

**Buena Vista Pharmacy**

Buena Vista Pharmacy is located in Calabasas, California. According to internet websites and a Facebook page, Buena Vista is a mail order pharmacy, described as a "worker's compensation and personal injury lien pharmacy". Buena Vista orders 5 SKUs of Hydrocodone from TOP RX. In a 4 week time period, Buena Vista received a total of 31,500 tablets of these various Hydrocodone strengths, significantly higher than most other pharmacies ordering from TOP RX.

<sup>1</sup> Communication sent to the customer: "In accordance with 21 CFR 1301.74, we are required to conduct an 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."

<sup>2</sup> Dr. Christopher J. Fisher, MD

<sup>3</sup> Buena Vista Pharmacy

<sup>4</sup> 21 CFR 1301.74(b) "The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant."