COMPLIANCE SOLUTIONS POWERED BY BUZZEO PDMA

Via Email: Tom.Napoli@Watson.com

September 21, 2011

Thomas Napoli, Manager,
Security and DEA Affairs
Watson Pharmaceuticals
Morris Corporate Center III
Parsippany, New Jersey 07054

Dear Tom:

Please find enclosed a report with our recommendations regarding Watson's Suspicious Order Monitoring (SOM) system. As we discussed during our on site visit, Watson's current approach is based upon thresholds which are somewhat arbitrary and not in conformance to the specific requirements of the regulations. We also noted that there are requirements for reporting suspicious orders of List I chemicals and that Watson does not have any system in place to address this regulatory requirement.

We enjoyed meeting with you and your staff and were appreciative of their time and efforts to provide a meaningful briefing on Watson's SOM approach. Please let me know if you have any questions regarding the report or other SOM issues. As you requested, we will send Watson a proposal for further SOM support assistance and I hope to work with you more in the near future on a new and improved system.

Sincerely,

Bob

Robert C. Williamson
Manager, DEA Consulting

cc: Scott K. Soltis, CPP, Executive Director, Global Security and DEA Affairs
Scott.Soltis@Watson.com

PLAINTIFFS TRIAL EXHIBIT
P-27804_00001

SUSPICIOUS ORDER MONITORING (SOM) ASSESSMENT

Watson Pharmaceuticals
Morris Corporate Center III
400 Interpace Parkway
Parsippany, NJ 07054

BACKGROUND:

On September 8, 2011, Robert C. Williamson, Manager, Cegedim Compliance Solutions Powered by BuzzeoPDMA (CCS), and Jonathan Kuhn, Statistical Consultant, Richmond Data Analytics, visited Watson Pharmaceuticals' (Watson) corporate headquarters at the address noted above.

The purpose of the visit was to provide an "onsite review and assessment" of Watson's current Suspicious Order Monitoring (SOM) system in light of Drug Enforcement Administration (DEA) regulations and guidance documents. Watson is a manufacturer of branded and generic pharmaceuticals, including approximately 35 controlled substances and 10 in development. Drugs are manufactured in California, Utah and Florida and then distributed to customers from the firm's distribution center in Gurnee, Illinois. Watson services around 200 active customer accounts, which include McKesson and Amerisource; national pharmacy chains, such as Walgreens and CVS; and numerous smaller niche wholesalers. Watson ships to 1000 to 1500 individual distribution centers. Controlled substance sales were described as profitable and important to Watson's ongoing business success. List I chemicals (PSE) are also sold by the firm; however, no efforts have been developed to integrate orders for List I chemicals into the firm's SOM system.

Thomas Napoli, Manager, Security and DEA Affairs, hosted the meeting and coordinated presentations from Watson staff. Watson's approach to SOM implementation involves the coordination of sales/marketing, customer service and security/regulatory components within the Watson organizational umbrella. (DEA security and regulatory components merged in 2010.) Accounts are established through the firm's sales force and are managed by customer service. Customer service employees appear to take the lead in setting up new accounts, although there appears to be a high level of coordination with sales in these initial endeavors. Once the customer account is established and approved, it was indicated that all controlled substance orders are evaluated by Watson's current SOM system. It was indicated that the current SOM system "pends" approximately 40 orders per day. Customer service employees utilize multiple internal tools to initially evaluate the order. If the pended order cannot be cleared of suspicion, it is forwarded to security/regulatory for further investigation. Reportedly, Watson does not reduce pended orders to satisfy their internal thresholds. It was indicated that all "pended" orders are investigated and cleared as received or cancelled and reported to the DEA. According to staff, approximately 10 percent of the pended orders are forwarded to security/regulatory

for further investigation. (These are now classified as "orders of interest.") It was indicated that one order has been reported to the DEA.

Approximately 15 Watson employees participated and/or presented at the meeting. Scott K. Soltis, CPP, Executive Director, Global Security and DEA Affairs, opened the meeting and participated in all the sessions. Napoleon Clark, Executive Director, Marketing, attended the early session. Mary Woods, Executive Director, Customer Service, attended remotely from California and was an active participant and presenter. Justin Park, Business System Analyst III, was also in attendance and provided system logic and rules. Watson staff was uniformly attentive and helpful for all the presentations.

The report contains Regulatory Findings and Discussion Items. Citations are provided where appropriate. Recommendations are provided throughout.

FINDINGS

1. Finding:

Watson's current SOM system is inconsistent with the specific requirements noted in the regulations and with written guidance provided by the DEA to all registrants.

Watson's SOM system is based upon a customer grouping referred to as a "class of trade" and a "multiplier." Each customer is assigned to a "class of trade," which consists of similar sized customers. Average purchases of individual NDC's are calculated for the customers in the "class of trade." A multiplier is then used to determine what might possibly be suspicious based upon the average order for the members in the class of trade. Any order an individual makes that is in excess of the multiplier established for the class of trade would be "pended" for investigation by Watson staff.

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, and orders of unusual frequency."

DEA Correspondence of 12.27.2007

"Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount exceeds the amount ordered the previous month by a certain percentage or more is insufficient."

Recommendation:

Watson should re-visit their entire approach to SOM to fully address the specific regulatory requirements and other guidance documents provided by the DEA, to include evaluating all orders on the basis of size, frequency, and order pattern deviation.

2. Finding:

Watson does not have a suspicious order monitoring system for List I chemicals.

Requirement:

21CFR 1310.05 (a) (1)

"Each regulated person shall report to the Special Agent in Charge of the DEA Divisional Office for the area in which the regulated person making the report is located, as follows:

(1) Any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of this part."

Recommendation:

Watson must address the List I chemical sales in addition to controlled substances in order to be compliant with the DEA's regulations. Watson should add evaluation of List I chemical sales to an appropriate and robust SOM process.

DISCUSSION ITEMS

1. **Milligram Strength**

   Watson's system evaluates each item ordered and does not "normalize" for different milligram strengths

   The current system looks only at NDC level history. Since an NDC specifies package size and strength, this leaves the possibility for distributing orders over several package sizes and strengths. Doing so would significantly increase the amount of narcotics which would be ordered without identification. This amounts to a significant reduction in sensitivity under Watson's current approach.

   A further complication of tracking exclusively at the NDC level is a high volume of unnecessary reviews. New packaging and/or strengths of existing active ingredients do not have sufficient history and cannot be evaluated on the basis of

previous purchases. This results in redundant reviews of orders. Account orders are being reviewed only because a different package was ordered.

Recommendations:

- An effective approach to SOM tracks and trends order volume in milligrams at the active ingredient level. This type of system is less susceptible to potentially illicit activity that could be caused by intentional distribution of orders across strengths and packages. Furthermore this change will reduce unnecessary reviews for changes in products.

- History should be tracked at the active ingredient level so that new products with existing active ingredients can utilize the system immediately. This will largely eliminate "break-in" periods for customers who have a history of ordering a particular active ingredient, but begin ordering a new package or strength.

2. Inventory Management Adjustments

During discussions with staff it was learned that some accounts, such as McKesson and Amerisource Bergen, have "managed inventories." This is a system that allows Watson to independently make shipments to these customers in order to maintain pre-set inventory levels.

Orders for these accounts can be (and are) frequently approved by staff simply because the inventory is low. If the account suddenly begins to move more of a controlled substance per month, even if it is for unknown and potentially unacceptable reasons, the low inventory will trigger increased order sizes. Those orders will be approved because inventory is low. In this sense the system is "self gaming."

Recommendations:

- The system should identify orders based on unexplained changes in ordering behavior. Reduced inventory is an *indicator* of increased product movement. It is not a justification for increased order size.

- The purpose of considering inventory levels when reviewing identified orders is to make sure the account is not increasing their inventory size without justification.

- If the account has for some reason ordered less than is typical and is ordering more to catch up, then inventory level can be part of the decision to clear an order. But first Watson should establish what is typical ordering behavior and verify that they have recently ordered at less than typical volume.

3. New Account Set Up

Mary Woods described the new account set up procedures. According to Ms. Woods, around ten new accounts are established each year. An account set up form is used to open the account. A review of the items contained on the form disclosed a long list of specific details which are used by Watson to determine whether or not to open the new account.

During the account due diligence process, it was indicated that Watson will secure a copy of federal and state licenses for prospective new customers. Additional information pertaining to the customer's proposed need for controlled substances will be solicited. Independent forecasting information will be compared to what the customer states their anticipated need will be and evaluated for consistency. Financial information will be solicited from independent sources.

Reportedly, on site visits are conducted by sales representatives (DNA's) at the customer's corporate level; however, actual warehouse visits are not conducted and photographs are not taken.

Recommendations:

- New account set up procedures should be expanded to include List I chemicals. Such procedures would by necessity include an amended customer due diligence form.
    - Identifying information pertaining to the principals should be included on the new account form, including questions related to whether they have been personally employed by or operated a business which has been the subject of previous federal or state controlled substance investigations or actions.
- On site customer visits should be conducted at individual warehouse locations which will be receiving controlled substances. Interior and exterior photographs should be included in the new account documentation file. Prospective customers may not allow internal photographs of security and/or other proprietary items; however, the exterior of the warehouse and the business setting should be included in the new account documentation.
- Watson should develop a "Compliance Agreement" document which serves to advise the prospective account of the legal requirements for handling controlled substances and Watson's expectations for customers that receive controlled substances from Watson. This form should be signed by a responsible individual at the firm and included in the account set up documentation.

4. Other Recommendations

- It was noted during discussions that there may be instances where staff will determine that a pended order is not suspicious and clear the order for shipment. It is recommended that management officials clear all pended orders of suspicion. The process should also be included in an SOP if not currently the case.

- According to Watson staff, the report identified as EDI 867 shows to whom their customers are selling. It is recommended that this report and other independent information be developed and incorporated into Watson's SOM system to assure that the firm is not unwittingly contributing to drug abuse in a locality or through a method of sales and distribution that would not normally surface through individual customer sales analysis.

- An integral part of a suspicious order monitoring system is a sophisticated set of historical markers. Markers should be designed in such a way as to facilitate statistical identification. Properly designed and configured, they form the foundation of a non-threshold based adaptive system. Some general examples of markers are:

    - Linear prediction of monthly active ingredient order volume
    - Statistical scoring of active ingredient order volume vs. history
    - Statistical scoring of active ingredient order volume vs. short term trend
    - Statistical scoring of active ingredient order volume vs. long term trend
    - Identification of hi/low frequency ordering behavior

- An identification model should be *trained* to identify suspicious orders by utilizing markers like those described above. Training involves collecting a set of orders which display both typical appropriate ordering behavior as well as orders which display patterns typical of unacceptable selling and/or distribution practices. In order to achieve an appropriate level of sensitivity and reduce the false positive rate as much as possible, unacceptable ordering patterns should be built upon typical ordering behaviors. Watson should avoid creating "bad orders" from scratch results as this could result in models with very high false positive identification rates.

QUALIFICATIONS:

1. The foregoing analysis reflects our observations and recommendations based on information and individuals made available to us by the company during the one day high level overview. An in-depth review of additional records and interviews with additional representatives would likely result in additional issues and recommendations.

2. The foregoing recommendations represent our best professional judgment based on our knowledge of the Controlled Substances Act (CSA), the implementing regulations and our experience with them. Many of the requirements of the CSA and regulations there under are subject to interpretation and are subjective. Implementation of these recommendations does not guarantee that the Drug Enforcement Administration (DEA) would not find any violations; the recommendations must be considered with this mind.

3. No analysis has been provided as to the consequences of current or prior violations of the CSA and the implementing regulations, if any, which may be noted in this report.