From: mrmapes@gmail.com on behalf of Mike Mapes <mmapes@cs-cg.com>
Sent: Thursday, May 26, 2011 7:04 PM
To: Grail, Efrem M.; DiBello, Michael; Han, Marjorie (Legal)
Subject: DRAFT letter re: SOM and Resume
Attachments: Schein.Letter.doc; Resume.MRM3.pdf

Suspicious Order Monitoring

Efrem,

I have attached a draft of the letter concerning the SOm program at Henry Schein, Inc. I have some background in the letter about the DEA requirements, as I believe that I am a unique position to talk about those requirements.

Please review and then we can discuss.

After we discuss this, I will complete the report to Henry Schein, Inc. concerning the observations from the SOM review.

Thanks,

Mike Mapes

719-650-0294

CS Consulting Group
2595 Dallas Parkway
Suite 206
Frisco, TX 75034

CONFIDENTIAL - WORK -PRODUCT PRIVILEGE

Efrem. M. Grail
Reed Smith LLP
Reed Smith Centre
225 Fifth Avenue
Pittsburgh, PA 15222-2716

May 23, 2011

Re: Henry Schein, Inc.

Dear Mr. Grail,

The purpose of this letter is to advise you of the results of my review of the controlled substance Suspicious Order Monitoring program (SOM) used by the Henry Schein, Inc., 135 Duryea Road,. Melville, New York 11747. The SOM program is used to monitor the orders for controlled substances at each of the distribution centers operated by Henry Schein, Inc.

On April 28, 2011 and April 29, 2011 Michael Schneidereit and I performed an on-site review of the SOM program at Henry Schein, Inc. The review included meetings with relevant employees of Henry Schein, Inc., review of documents, and following specific transactions from the establishment of an account to the review of orders placed by the customer for controlled substances. Additionally, Henry Schein, Inc. provided several documents after the visit for our review.

The Henry Schein, Inc. SOM program was designed to meet the requirements of reporting suspicious orders to the Drug Enforcement Administration (DEA) as found in Title 21, Code of Federal Regulations, Section 1301.74(b).

In 2005 as part of the effort by DEA to deal with illegal sales by Internet pharmacies, DEA began changing their interpretation of 21 CFR § 1301.74(b). Prior to this time all registrants were, with DEA approval, reporting suspicious sales at the end of each month to DEA. The reports contained sales that had been made that exceeded limits set by the company. Starting in October of 2005, DEA met with individual companies to advise them that DEA now expected the companies to report suspicious orders when discovered, rather than reporting suspicious sales after the fact as had been the industry standard in the past. DEA started the meeting with the companies that handled the largest quantities of controlled substances and the companies that were suspected of selling controlled substances to pharmacies who sold the drugs illegally using the

Internet, then DEA scheduled meetings with other companies. DEA held a meeting with Henry Schein, Inc. to explain the new interpretation of 21 CFR § 1301.74(b) in October of 2009.

In 2007, DEA initiated efforts to inform the pharmaceutical industry of the change of interpretation of 21 CFR §1301.74(b). This was accomplished by discussion of the new standards at the DEA Pharmaceutical Industry Meeting, held in Houston, Texas on September 11 - 13, 2007.

In 2007, Henry Schein, Inc. started the lengthy process of implementing a new SOM program. This process included changing policies and procedures for new customer set up, new policies for when to complete site visits of customers, integration of new SOM software, and new policies of the actions to take when an order is identified by the new SOM program as suspicious. The process also included providing training to all Henry Schein, Inc. employees who are involved in the process at any level. In addition to the training provided, Henry Schein, Inc. currently holds monthly meeting of the regulatory and business people involved in the SOM process.

In April of 2009, the New SOM software was placed into production at Henry Schein, Inc. At the same time, the new policies and procedures were implemented. As with any software, the new system needed to run in an operational mode for some time and be adjusted to meet all of the goals of the SOM program at Henry Schein, Inc.

The older system was based on the number of bottles of specific drugs sold to specific customers. The new, more complex program, includes setting thresholds based on sales history for specific customer types and specific drug ingredients. This allows Henry Schein, Inc. to put all of a specific drug sold to a customer together to see how much of a specific active ingredient the customer is purchasing, regardless of the manufacturer, strength, or package size. The current customers of Henry Schein, Inc. are divided into market segments and practice types. The controlled substances distributed are divided into approximately thirty groups. In addition the the group thresholds, the SOM system creates limits for specific customers, based on past history of the customer. All of the thresholds are subject to constant review and adjustment.

As the new system provided information concerning specific customers that were above the thresholds that were set, Henry Schein, Inc. was investigating each instance to see if the order was excessive or if there were issues with the system or thresholds. Based on this information, Henry Schein, Inc. stopped shipping to some customers and worked to fine tune and focus each of the thresholds that had been set. The process of fine tuning the thresholds continues today, and will continue as long as the system is in use.

Henry Schein, Inc. has provided a listing of each of the thresholds that have been set for each customer type and each drug ingredient. A review of the thresholds shows that the current thresholds are appropriate for the customer base to which Henry Schein, Inc. supplies controlled substances.

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The process for orders at Henry Schein, Inc. includes a check of the business background of the company, a check of the DEA registration and the appropriate state license of the company, a check of the Internet concerning the company and it's principals.

Based on the information obtained, Henry Schein, Inc. may perform an on-site review of the company before selling controlled substances to the company. henry Schein, Inc. has developed several checklists that are used to document visits to current and potential controlled substance customers. The checklists are specific for wholesalers, solo physicians, pharmacies, and dispensing physician clinics.

An order that is deemed as suspicious by Henry Schein, Inc. now cannot be shipped until the order is released by three levels of corporate management.

Currently every time a new customer makes their first order for controlled substances, the SOM system stops that order and sends for review.

Based on the review of the entire SOM system of Henry Schein, Inc., my experience with DEA, and review of other SOM systems, it is my opinion that the older monthly suspicious sales report that was used by Henry Schein, Inc. met the requirements for reporting suspicious orders to DEA at that time. Further, it is my opinion that the current system that reports suspicious orders for controlled substances after extensive due diligence, reviews of thresholds, and continual monitoring meets the current suspicious order monitoring requirements in 21 CFR 1301.74(b).

Michael R. Mapes
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PROFESSIONAL EXPERIENCE

March 2009 to Present
Chief Compliance Officer
Assured Pharmacy, Inc.

Responsible for planning, developing and implementing a comprehensive compliance program for the pain management pharmacies operated by Assured Pharmacies, Inc. This position requires working with all levels of management to develop policies and procedures that insure compliance with the various state and federal regulations related to the practice of pharmacy. Develop and implement policies to insure that the pharmacy employees follow industry best practices. Developed and implemented a company wide pre-employment and employee drug testing program. Review the operations of the pharmacies through daily on line inspection of all prescriptions dispensed looking for anomalies in the data that suggest dispensing of drugs for other than legitimate medical purposes. Perform complete on-site reviews of the operations of each pharmacy at least three times annually.

October 2007 to Present
Pharmaceutical Regulatory Consultant
CS Consulting Group

Both as an independent consultant and working with CS Consulting Group, performed consulting with controlled substance importers, manufacturers, distributors, researchers, mail service pharmacies, and retail pharmacies to assure that they are in compliance with all federal and state regulations and laws related to the handling of controlled substances. The clients range from single independent pharmacies, to chain pharmacies with hundreds of stores, to large mail service pharmacies, to Fortune 50 pharmaceutical companies. I work with all levels of management to develop and implement policies and procedures that enhance the compliance posture of the companies. I frequently perform reviews of specific aspects of a company business to provide guidance on compliance improvement. I have worked with several companies to review and improve the controlled substance suspicious order monitoring programs.

August 1999 to October 2007
Drug Enforcement Administration
Office of Diversion Control
Washington, DC 20537

Managed the Planning and Resources Section, which was responsible for personnel issues, financial management, and contract management for the DEA Office of Diversion Control. Was responsible to provide updates to the DEA Deputy Assistant Administrator on the status of personnel, financial, and contract issues. The entire program was funded through the registration fees paid by the pharmaceutical community.

Managed the e-Commerce Section, which was responsible for development and implementation of the Controlled Substances Ordering System, which is a Public Key Infrastructure program to allow electronic ordering of controlled substances. This program was designed to move from a paper-based system to order schedule II controlled substances to a electronic system that electronically and securely allows DEA registrant to order schedule II controlled substances. When fully implemented this program is expected to save the pharmaceutical community $75 - $85 million annually in costs associated with paper processing.

Planned, developed, and implemented a program for all controlled substance distributors in the United States that required the companies to complete significant due diligence on prospective and current customers to reduce the illicit use of pharmaceutical controlled substances. This initiative resulted in multi-million dollar fines against several large pharmaceutical companies and a significant reduction in the diversion of controlled substances from legitimate channels to the illicit market. This program completely revamped the requirements for the companies to report suspicious orders for controlled substances to DEA.

Managed the Regulatory Section, which was created to coordinate civil and administrative regulatory actions against registered drug and chemical manufacturers, importers, exporters, distributors, doctors, and pharmacies. This section dealt with confidential investigations of all aspects of the pharmaceutical, medical, and pharmacy communities. The Regulatory Section worked with field investigators in 70+ offices to coordinate information that could impact multiple investigations.

February 1998 to July 1999
United Nations
International Narcotics Control Board
Vienna, Austria

Was the DEA Liaison to the United Nations, International Narcotics Control Board (INCB). Worked with the United Nations to monitor compliance by member countries with international treaties related to narcotics, psychotropic substances, and precursor chemicals. Coordinated the exchange of investigative information between countries involved in investigations of international trafficking of pharmaceutical drugs or precursor chemicals. As the DEA Liaison, I was responsible to provide information to DEA and other agencies such as the ONDCP, and the State Department to assure that United States policies were in conformity with all international drug control treaties.

March 1990 to January 1998
Group Supervisor/ Diversion Program Manager
Drug Enforcement Administration
Denver, Colorado

As the Group Supervisor, I supervised investigations of applicants seeking to obtain a DEA registration to handle controlled substances. This involved a review of the background of the applicant and any employees, the physical security of the facility, the record keeping systems of the applicant, and the past experience of the applicant in handling of controlled substances. Supervised periodic investigations of those authorized to handle controlled substances to review their compliance with laws and regulations. Registrants who were not in compliance were subject to administrative, civil, or criminal sanctions.

Supervised criminal investigations related to the diversion of pharmaceutical controlled substances and precursor chemicals in the states of Colorado and Wyoming. Additionally, I conducted training and liaison activities with law enforcement and regulatory agencies.

Promoted to regional manager for Colorado, Utah, New Mexico and Wyoming. As regional manager set the priorities for investigations, worked with regional management and DEA headquarters to obtain additional resources, performed evaluations of the training needs of regional employees, and completed annual performance evaluations of regional personnel.

February 1986 to March 1990
Instructor
DEA Office of Training
FBI Academy
Quantico, Virginia

Developed, implemented, and presented training programs to DEA, FBI, and state and local law enforcement officers related to drug investigations. My primary areas of expertise were pharmacology and drug identification, evidence handling, and the investigation of diversion of controlled substance by health professionals.

June 1985 to February of 1986
Staff Coordinator, DEA HQ
Washington, DC

Worked as a staff coordinator in the Office of Diversion Control. Primary function was to coordinate actions against DEA registrants as a result of field investigations with other elements within DEA HQ.

April 1977 to June 1985
Investigator
Drug Enforcement Administration
Detroit, Michigan and Cleveland, Ohio

Conducted investigations of applicants seeking to obtain a DEA registration to handle controlled substances. This involved a review of the background of the applicant and any employees, the physical security of the facility, the record keeping systems of the applicant, and the past experience of the applicant in handling of controlled substances. Conducted periodic investigations of those authorized to handle controlled substances to review their compliance with laws and regulations. Those registrants who were not in compliance were subject to administrative, civil, or criminal sanctions.

Conducted criminal investigations of violations of the federal Controlled Substances Act by pharmacists, doctors, and others who were illegally selling pharmaceutical controlled substances for other than a legitimate medical purpose. Investigations resulted in numerous arrests, prosecutions, and convictions in federal and state courts for illegal sale, conspiracy, and operating a continuing criminal enterprise.

June 1974 to October 1976
Deputy Sheriff
Muskegon County Sheriff's Department
Muskegon, Michigan

Worked as a Deputy Sheriff starting in the Marine Patrol Unit patrolling Lake Michigan and inland lakes for boater safety and investigation of boating accidents. Worked as a Deputy Sheriff in the Fruitport Township detachment as a road patrol Deputy Sheriff. Performed traditional police functions of patrol, accident investigation, investigation of criminal activity, and answering calls for police service.

EDUCATION

Ferris State University
Big Rapids, Michigan
B.S. Degree in Criminal Justice

Muskegon Community College
Muskegon, Michigan
A.A. Degree in Police Science