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PLAINTIFFS TRIAL EXHIBIT

**P-03740_00001**

**To:**

**From:** I

**Date:** November 13, 2008

**Re:** Controlled Substance Seminar Summary

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During the weeks of May 30th, and June 6th, I had the opportunity to attend the annual Controlled Substance Conference sponsored by Cegedim-Dendrite, as well as a meeting of the NJ Pharmaceutical Industry Group. The conference focused primarily on regulatory and operational issues, DEA enforcement direction and legislative landscape. The conference was facilitated by industry subject matter experts, representing multiple pharma organizations as well as former Drug Enforcement Administration officials. The NJ industry group meeting was facilitated and attended by a cross section of pharma partners engaged in controlled substance activities throughout the northeast region. Topics of discussion included, Quota, organizational changes within DEA, as well as the upcoming Industry Conference. This brief is intended to provide a "snapshot" of current areas of concern and issues in today's regulatory compliance landscape as highlighted by industry professionals. This information is intended for internal management use in an effort to understand and anticipate changes within the regulatory landscape for the development of proactive strategies to enable business operations.

**Areas of Interest/Concern**

**Quota**

Recent activities within the Office of Diversion Control have impacted the Quota process and subsequently lengthened and already intensely bureaucratic process. As the result of an apparent "internal challenge " regarding the delegated authority of quota approval by the of Drug Evaluation Section (headed by Christine Sannerud) , a reorganization was undertaken by Joseph Rannazzisi, Deputy Asst. Administrator, Office of Diversion Control (Mr. Rannazzisi has oversight of the entire diversion control program). The reorganization has resulted in a new unit and approval process that requires Mr. Rannazzisi's ultimate approval and signature on all industry quota grants. The new process has created additional layers, specifically, a vetting review by the Regulatory Section that includes an analysis of ARCOS activity and customer base, as well as a review by Legal prior to approval/signature. The additional layers within the process have lengthened a process that typically cycles within 6-8 weeks to 9-11weeks. Industry peers have confirmed this extended timeline and have received grants that were signed by Mr. Rannazzisi.

A possible root cause of this recent change in the quota process may be found in recent Congressional & Office of National Drug Control Policy (White House) pressure placed on the agency. It has been publicly reported that a component of the ONDCP's action plan is to reduce Rx prescription drug abuse by 15% within five years. Additionally, the recently retired Chief of Policy & Liaison related that Mr. Rannazzisi has been on the "receiving end of some brutal beatings" administered by congress regarding efforts to reduce the prescription drug "epidemic." Of particular note; Representative, Mary Bono Mack (R-CA) has made statements to Mr. Rannazzisi, alluding to the fact that he controls how much product flows into the market. DEA's enforcement direction as well as pressure by ONDCP & Congress to curb the national prescription drug abuse problem has created an environment in which the need for industry to provide for the adequate supply of pain medications for legitimate use has become a low priority.

This reorganization and subsequent process change, will significantly impact the pharma industry and its ability to adequately meet market demand and maintain sufficient inventories. An industry peer from a large manufacturer indicated that cs operations at one of their facilities ceased for two weeks due to a delay in receiving quota grants.

During the Cegedim-Dendrite sponsored CS Conference , representatives from Hyman, Phelps, & McNamara, also echoed industry's frustration with an antiquated "1970's quota process utilized in today's environment."

During the NJ Pharmaceutical Industry Group meeting, a proposal was made to draft a letter from industry to the DEA outlining the current situation and its affect on the industry. This letter would be a documented record of industry's desire for change and efficiency within the current process, to adequately meet market needs. The letter will only be sent upon the affirmation by the represented organization's legal and government affairs functions. In addition to this proposed measure, the group is also seeking to present to DEA at the Industry Conference in September. The presentation would be in a panel format comprised of industry compliance representatives, who will articulate the current situation and propose change.

Former DEA Policy & Liaison Chief, felt that this was an appropriate course, but asserted that the only measures that would be truly effective are legislative. The group was encouraged to engage their respective government affairs and industry groups to actively pursue this issue through elected officials.

From 2007 to the present, DEA has been aggressively evaluating registrant's sales patterns due to continued evidence of diversion, primarily involving narcotics and "internet pharmacies". Numerous registrants were the focus of investigational efforts that resulted in registration revocations and civil prosecutions. In 2006/2007, DEA issued three memorandums reiterating

their position regarding SOM and cautioning industry against the use of systems based on simple mathematical formulas.

It is highly recommended that industry utilize a "total SOM model". This model favors a more statistically based model that dynamically evaluates a variety of order characteristics to determine whether an order should be pended. Characteristics include; order size, ordering frequency, ordering patterns and percentage of CS ordered. This approach is viewed to be more effective and defensible than the traditional approach of just setting a threshold.

The following concepts are to be considered when developing an effective SOM:

- How are new accounts opened? Background check. **"Know your Customers"**
- How are orders evaluated?
- How are orders cleared from suspicion? Appropriate investigative resources/SOP's
- Who reports the suspicious order to DEA? Management oversight.
- Do third party distributors utilize an adequate SOM?

**DEA Shift in Operating Philosophy**
Field offices becoming less "friendly". Shifting from partners to enforcers.

Contributing Factors: "The Perfect Storm"

- Non-medical use of pharmaceutical products now greater than the abuse of cocaine, hallucinogens and inhalants. Among adults 26 or older, 7 million Americans reported non-medical use of prescription medicines in 2006.
- Presidential mandate to cut drug use. Enforcement efforts have been highly successful in areas of illicit drug use – yet one category is rising, prescription medicines. Clandestine Methamphetamine production "shut down in U.S.", mainly in Mexico now.
- Proliferation of internet
- Congressional interest – children dying, tremendous cost to society.
- Dwindling DEA resources

Result:
- Application of traditional principles of enforcement to industry
- Enforcement focus - Co-mingling of enforcement agents and diversion investigators in single enforcement group in all field offices. 400 diversion investigators in the world, more than 1 million registrants. 5,000 special agents, currently hiring.
- All policy decisions made by HQ

**Theft/Loss Focus and Trending**
On Wednesday, October 29, the following DEA (HQ) officials provided a brief update on agency activities as well as facilitated Q & A.:

James Crawford, Special Assistant
Office of Diversion Control

Mark Caverly, Section Chief
Office of Diversion Control

In addition to reiterating the agency's shift to an enforcement posture, the DEA officials spoke about current theft/loss issues (mentioned the Watson shipment theft to audience).

Identified in-transit loss as an area of concern:

- Database creation based on information garnered from 106 reports in an effort to examine trends.
- Stated that industry in general does not do a very good job of reporting theft in a timely manner. Tendency to investigate first, report "three months later".
- Must identify in an SOP the criteria for significant loss and requirement to report.
- Pushing for national industry initiative to have established policies in place for; vetting carriers, security procedures (locks/seals, driver security, tracking, etc.)
- Although pushing for initiatives, agency can not and will not play a role in regulating the transportation industry (no resources and industry is already regulated federally).

**Item of note:** Section Chief, Mark Caverly indicated that the DEA and FDA were engaged in "serious" discussions to re-classify Hydrocodone as a Schedule II controlled substance.

**Miscellaneous:** Discussed VAWD with Buzzeo Compliance Director, Machelle Gray. Felt that the program was a worthwhile endeavor, although progressing slowly. Currently, only 4 states require VAWD certification as condition of distribution (South Carolina, Indiana, Oregon, and Wisconsin coming on line).