From: Lisa A Scott
Sent: Tuesday, February 02, 2010 11:47 AM
To: Tom P Napoli
Subject: Presentation
Attachments: FL Presentation 2010.pptx

Tom: See attached.

Scottie

PLAINTIFFS TRIAL EXHIBIT
P-01227_00001

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

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DEA Affairs Organizational Overview

Thomas Napoli, CPP

US Generics

February 2, 2010

Objective

Provide an overview of the DEA Affairs Team

- Who we are
- What we do
- Origins and path forward
- Achievements to date
- Compliance Landscape & Opportunities
- 2010 Goals & Objectives

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Who We Are

An organization that has been reinvented to align itself with the new Watson Culture

- Fulfill our objectives
- Support the sustained growth of the company
- Leverage our operational & regulatory expertise to support the company vision

DEA Affairs Organization: Current State

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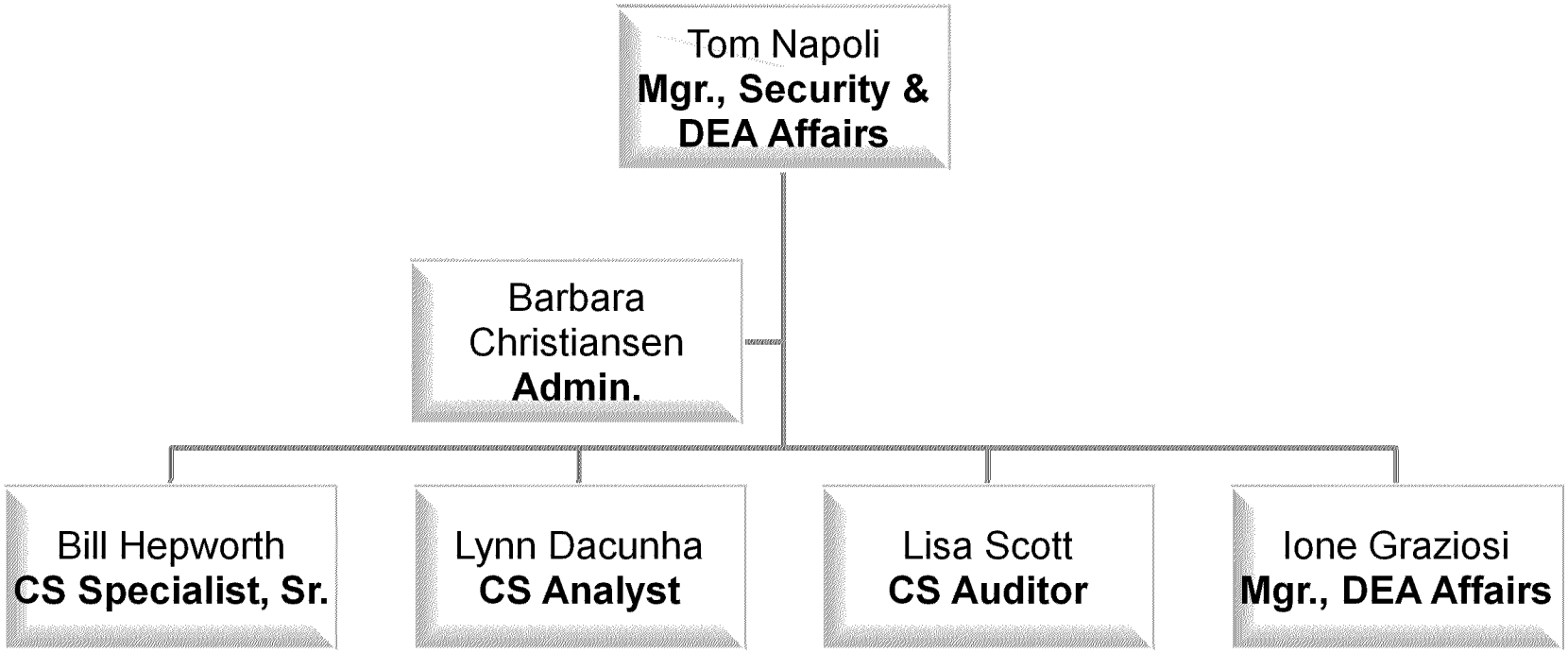

Quota

Site Liaison

Reporting

•Corona

•Carmel

•Florida

R&D/New product Support

Registration & Licensing

Federal & State

Export Control

Audit Program

Investigations

Agency Requests

Policy Development

Inspection support

Quota

Site Liaison

Reporting

•SLC

•Gurnee

Import Control
R&D/New product Support

DEA Affairs Organization: 2010

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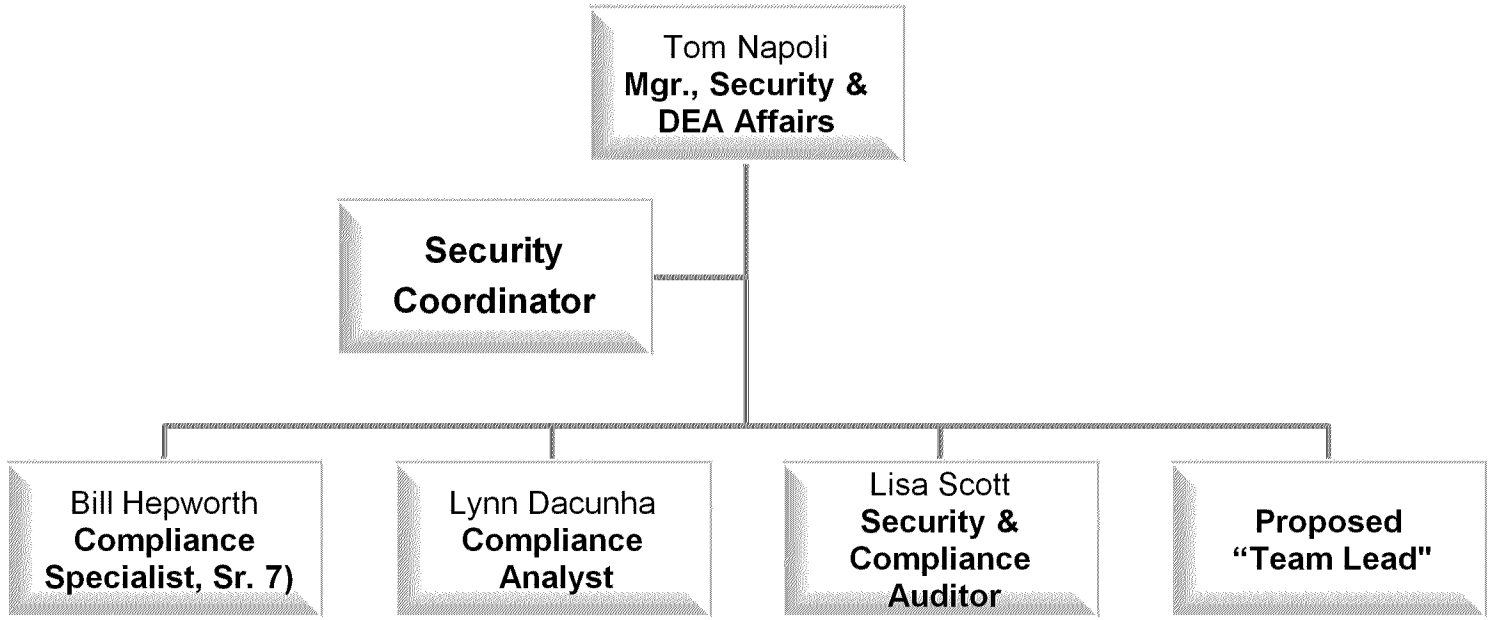

Quota Facilitation
All sites
R&D/New product Support
All sites
Compliance Report Monitoring

Registration & Licensing
Federal & State
Import & Export Control

Audit Program

Investigations

Agency Requests

Inspection preparedness/ support

Placebo program

Theft/Loss reporting

Site SME liaison
All Sites
Training/Awareness
Automated System Oversight

Policy/Procedure Development

Electronic community (portal page) oversight

Coordinate daily activities

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What We Do

Guiding Principles:

• Lead in the development of an overall culture of compliance throughout the controlled substance lifecycle

- Manufacturing
- Procurement
- Distribution
- Product Development

What We Do (continued)

Guiding Principles:

• Ensure that our facilities operate in a manner that guards against theft and diversion of controlled substances by maintaining effective controls and procedures

- Reporting & Recordkeeping
- Operational & Physical Security Controls
- Procedural development

What We Do (Continued)

Guiding Principles:

- Ensure the uninterrupted flow of controlled substance materials to meet the needs of the operation and customers
  - Quota facilitation
  - Import/Export
- Continually monitor the regulatory landscape and proactively anticipate needs
  - Emerging trends
  - Changes in regulatory requirements

Origins

Senior Management Decision was made to integrate the former C/S Compliance Department into the Security Department in April of 2009

- Department renamed Security & DEA Affairs
- Created Synergy where “silos” previously existed

Origins (Continued)

Department focus and management plan was recalibrated to meet the needs of organizational growth

- Previous compliance effort maintained intense ownership of local responsibilities
- No corporate vision or promotion of compliance environment
- Lack of focus on operational environment
- Site relationships with local field offices discouraged

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Path Forward

- Harmonization of Processes
  - Policy and management plan
  - Proliferation of expertise
  - Logical balance of responsibility/accountability
- Risk-based Auditing
  - Audit processes v. completed tasks
  - Integrate auditing & investigation functions
- The "Zero Tolerance" Culture
  - Establish Watson's position on theft/diversion
  - Employee awareness & education
  - Confidential diversion "hotline"

Policy & Plan

Policy to establish authority & expectations

Proprietary compliance manual/handbook

- Comprehensive process & information resource
- Accessible and user-friendly
- Universal best practices “play book”

Proliferation of Expertise

Significantly proliferate expertise to site PPIC teams

- Establish true local ownership (and accountability) of recurring compliance tasks (inventory, ARCOS, etc.)

Business continuity/sustain activities through attrition

- Develop “position above/position below” task fluency for those engaged in DEA compliance activities

Increase DEA Field Office confidence in local abilities

- Establish site representatives as the “go-to” POC for routine compliance matters

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Logical Balance of Responsibility & Accountability

Provide effective centralized leadership

- Program development
- Oversight & maintenance
- Monitor industry landscape

Localize administrative & recurring tasks

- Empowerment & ownership
- Accountability
- Contribution

Automate critical processes

- ARCOS
- Quota
- Suspicious Order Reporting

Audit Processes v. Completed Tasks

Mitigate risk at the source *before* problems materialize

Audit against established *standardized* policy and/or processes v. regulations

- Promote "comprehension" v. "interpretation"
- Close gaps resulting from vague/subjective regulations
- Focus on critical processes that mitigate diversion

Establish continual self-auditing protocols for low-risk recurring administrative tasks

Integrate Audit & Investigations Functions

Establish a cross-functional compliance auditing & diversion investigation entity

- Value-added leveraging of expertise
- Intimate knowledge of processes = unparalleled insight to vulnerabilities

Narrows investigatory gaps by extending Supply Chain Security activities beyond the shipping lanes

Establish Watson's Position on Theft/Diversion

Commit to "Zero Tolerance" policy regarding internal product theft

- Formalize position on filing law enforcement complaints, prosecution of offenders, etc.

Demonstrate our commitment to maintaining a theft-free environment ("walk the walk")

- Ultra-stringent controlled substance accountability processes
- Frequent security inspections at manufacturing plants
- Enhanced physical security measures

Employee Awareness & Education

Visual aid campaign in MFG common areas

- Importance of “talk the talk”
- Daily reminders of lawfulness and compliance

All employees engaged in C/S activities

- External (industry) training for PPIC
- Internal training modules tailored for:
  - Shipping/Receiving
  - Vault & Cage attendants
  - Mfg & Pkg operators
  - Laboratory & QA personnel

Confidential Internal Theft "Hotline"

Compliance/Ethics Hotline

- Manage as a unique, critical issue
- No intermediary review or delayed response
- Historically, employees seek Security when reporting theft

Employee confidence & trust

- Develop reputation as approachable & discreet
- Build confidence in the security "brand"

Visibility of "Hotline" program

- Effective marketing
- Broad exposure

Achievements to Date

Three CSOPs issued

- Two in draft

Subject Matter Expert Program (SME)

- Job Description created/approved
- Position established at Corona site as “pilot”

Transfer of compliance reporting responsibilities to sites

- Inventory/verification
- ARCOS
- YER

Achievements to Date (continued)

Security & Compliance Auditor

- Position created/staffed
- Consolidated C/S audit & investigation function

"Zero Tolerance" Culture

- Developed and delivered theft awareness training to management at all C/S manufacturing sites (400 employees)
- Visual aid campaign promoting:
  - Compliant behaviors
  - Compliance/Ethics hotline "See something/Say something"
- Designated Observer
  - Program initiated at Corona and Florida sites

Achievements to Date (continued)

Automated Compliance Reporting (JDE)

- Quota Summary Report
  - Evaluation in production environment
- ARCOS
  - Data integrity
  - Florida program implemented

Compliance Landscape

In 2008, 6.2 million Americans used prescription-type psychotherapeutic drugs for non-medical purposes in a one month period (2.5% of population)

- More than cocaine, heroin, hallucinogens, and inhalants combined
- Nonmedical use of prescription pain relievers tied with marijuana as having the highest rate of new abusers (2.2 million)

Drugs most frequently implicated in non-medical use (2004 - 2006):

- Benzodiazepines (hydrocodone/alprolozam) - 36 % increase
- Hydrocodone/combinations - 44% increase
- Oxycodone/combinations (primarily Oxycontin) – 56% increase

Compliance Landscape

Presidential mandate to cut drug use – prescription abuse continues to rise

Proliferation of Internet and now pain management centers

- South Florida (just around the corner)
- Los Angeles

Application of traditional principles of enforcement to industry

Challenges

Our products are among the most commonly prescribed for legitimate medical use in the US

- Entered into evidence by Law Enforcement
- Sought after in both legitimate & illicit markets

Corona facility manufactured 5 billion dosage units in 2009, planned increase to 6 billion

- Approximately 80% of production is C/S

Challenges (continued)

Products Include:

Corona

- Hydrocodone
  (Initial quota grant is 25% of aggregate)
- Oxycodone
- Fentanyl
- Methylphenidate
- Diazepam/Lorazepam
- F-line/Butalbital
- Pentazocine

Salt Lake City

- Fentanyl
- Methylphenidate
- Testosterone

Florida

- Hydrocodone
- Amphetamine
- Pseudophedrine (List 1 Chemical)
- Carisoprodol*

Challenges (continued)

Product Development

- Alprazolam
- Armodafinil
- Fentanyl Citrate EQ Oral
- Hydromorphone
- Lisdexamfetamine
- Morphine sulfate
- Oxymorphone
- Zolpidem

Compliance Landscape

Suspicious Order Monitoring (SOM)

- The registrant shall design and operate a system to disclose suspicious orders of controlled substances
  - Unusual size, pattern, frequency
  - Suspicious orders should not be identified on benchmarks/thresholds only
- SOM, as well as "know your customer" efforts, are key to DEA's effort to curb diversion of C/S and listed chemicals
- A number of companies had actions taken against them by DEA for having non-compliant SOM programs
  - Registration suspensions
  - Civil fines

Compliance Landscape (continued)

Distributor Briefing [DEA Regulatory Unit]

- In-depth briefing of registrant's due diligence and regulatory requirements using their own ARCOS data
  - Meeting is one on one
  - Expectations set

Illicit Activities by Employees

- Importance of physical security controls

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2010 Goals & Objectives

SOM

Designated Observer/Physical Controls

SME Program

Site Inspection Preparedness

Quota Project

Placebo Program

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Questions/Comments