
From: Joseph Tomkiewicz
To: Sarah Everingham
Sent: 3/2/2018 2:55:35 PM
Subject: PowerPoint
Attachments: 2017 Joe Tomkiewicz PDMA Conference - v2.pptx

Best regards,



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PLAINTIFFS TRIAL
EXHIBIT

P-03660_00001



The 27th annual

Sharing Conference

COMPLIANCE • TRANSPARENCY • PDMA • OIG

October 22 – 24, 2017 • Baltimore Marriott Waterfront

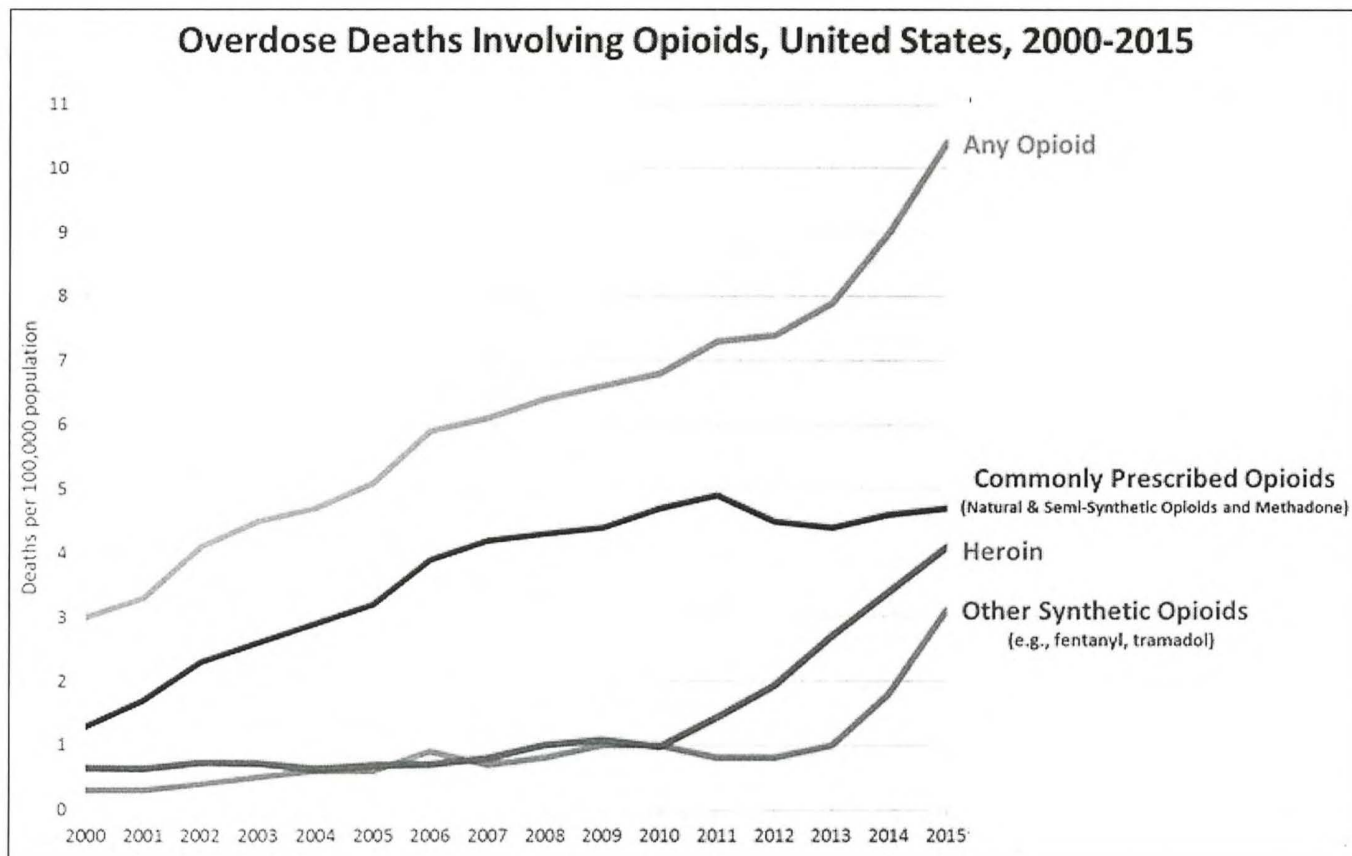
Clearing a Path to Compliance

DEA: Selling and Promoting High Risk Drugs

Joe Tomkiewicz
Teva Pharmaceuticals



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21 C.F.R. § 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.”



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“Know Your Customer” Policy

“It is fundamental for sound operations that handlers take reasonable measures to identify their customers, understand the normal and expected transactions typically conducted by those customers, and, consequently, identify those transactions conducted by their customers that are suspicious in nature.”

http://www.dea diversion.usdoj.gov/chem_prog/susp.htm



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Red Flags



79188

Federal Register / Vol. 81, No. 218 / Thursday, November 10, 2016 / Notices

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 15–2]

Jones Total Health Care Pharmacy, L.L.C., and SND Health Care, L.L.C.; Decision and Order

On April 29, 2015, Administrative Law Judge Gail A. Randall (hereinafter, ALJ) issued the attached Recommended Decision.¹ Therein, the ALJ found that “Respondents violated recordkeeping requirements by failing to record whether Jones Pharmacy’s biennial inventory was taken at the opening or close of business, and by failing to indicate the number of tablets per opened commercial container, the number of tablets shipped in each commercial container, and the number of commercial containers that [were] on hand.” R.D. at 59 (citing 21 CFR

many of the prescriptions could not be resolved by the pharmacists. *Id.* at 64.

The ALJ specifically rejected Respondent’s contention that its owner (Ms. Chereese Jones) was simply naïve or unaware of various indicia (otherwise known as red flags) that the prescriptions her pharmacy filled lacked a legitimate medical purpose as well as its contention that during the relevant time period, Florida pharmacists were generally “unaware of the . . . concept of ‘red flags.’ ” R.D. at 66–69. The ALJ was unpersuaded by the testimony of Respondent’s Expert that pharmacists were generally unaware of the concept of red flags during the relevant time period, noting that while Respondent’s Expert claimed to have based her opinion on a review of the Agency’s administrative decisions, those decisions contradicted her testimony. *Id.* at 68–69.

Finding that the Government met its burden of proof, the ALJ then addressed

Having considered the record in its entirety including Respondent’s Exceptions, I find that while several of its contentions with respect to the ALJ’s factual findings are not without merit, I adopt the ALJ’s credibility findings and conclude that most of the ALJ’s factual findings are supported by a preponderance of the evidence. I further conclude that the ALJ’s factual findings support her legal conclusions that: (1) Respondent’s pharmacists dispensed numerous controlled substance prescriptions in violation of the Agency’s corresponding responsibility rule, *see* 21 CFR 1306.04(a); (2) Respondent has not accepted responsibility for its misconduct; and (3) that there is sufficient overlap in the ownership and control of Jones Pharmacy and SND Healthcare such that Jones’ misconduct supports the denial of SND’s application.²

Accordingly, I adopt the ALJ’s legal conclusions, as well as her implicit



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Suspicious Orders

United States Court of Appeals
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued January 12, 2017

Decided June 30, 2017

No. 15-1335

MASTERS PHARMACEUTICAL, INC.,
PETITIONER

v.

DRUG ENFORCEMENT ADMINISTRATION,
RESPONDENT

On Petition for Review of a Final Order
of the Drug Enforcement Administration



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Monitoring Your Customer's Customers

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Tuesday, July 11, 2017

Mallinckrodt Agrees to Pay Record \$35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations

Mallinckrodt LLC, a pharmaceutical manufacturer and one of the largest manufacturers of generic oxycodone, agreed to pay \$35 million to settle allegations that it violated certain provisions of the Controlled Substances Act (CSA) that are subject to civil penalties, Attorney General Jeff Sessions of the Justice Department and Acting Administrator Chuck Rosenberg of the Drug Enforcement Administration (DEA) announced today.

This is the first settlement of its magnitude with a manufacturer of pharmaceuticals resolving nationwide claims that the company did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. These suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone in Florida and elsewhere. The settlement also addressed violations in the company's manufacturing batch records at its plant in Hobart, New York. Both sets of alleged violations impact accountability for controlled substances, and the compliance terms going forward are designed to help protect against diversion of these substances at critical links in the controlled substance supply chain.

"In the midst of one of the worst drug abuse crises in American history, the Department of Justice has the responsibility to



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Flagging An Order

- Manual Review vs. Computer Review
- Algorithm
- Pitfalls



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Investigating An Order

- Size, Pattern, Frequency
- Red Flags
- Clearing Red Flags



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Investigating An Order

- Consistency With Customer's Previous Orders
- Patterns
- Market Conditions
- Remaining Red Flags



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Customer Investigation

- Ongoing Due Diligence
- End Customer Inquiry
- Prescriber Inquiry



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Ongoing Due Diligence - Customer Investigation

- Recent Increase in Frequency of Controlled Substance Orders
- Small Privately Owned Distributor
- LTC Pharmacy License at Same Address
- Ten Felony Counts of Mail Fraud and Money Laundering



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End Customer Inquiry - Pharmacy Investigation

- Staff Pharmacist's License on Probation
- Disciplined for Dispensing Controlled Substances Without Valid Prescriptions
- Barred from Owning a Pharmacy or Working as PIC
- Pharmacy Owned by LLC
- LLC "Controlled" by Spouse
- Top Dispenser of Controlled Substances



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End Customer Inquiry

- Campus Location
- Specialty Pharmacy
- Medication Protocols



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Prescriber Inquiry - Physician A

- Fined and License Placed on Probation
- Injected “Extra” Controlled Substance During Surgery and Overdosed
- Moved to Another State, Opened an Urgent Care Center
- Listed as a Top Oxycodone Prescriber
- 75 Miles from Pharmacy



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Prescriber Inquiry - Physician B

- Fined and License Placed on Probation
- Overprescribing Controlled Substances
- Malpractice Resulting in a Patient's Death Due to Overdose
- Listed as a Top Buprenorphine Prescriber
- 40 Miles from Pharmacy



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Prescriber Inquiry - Physician C

- License Suspended and Placed on Probation
- Sexually Harassing Staff
- Trading Controlled Substances for Sex with Underage Patients
- Listed as a Top Buprenorphine and Opioid Prescriber



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Prescriber Inquiry

- Geographic Location
- Board Certification
- Practice Specialty
- Treatment/Medication Protocols



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Forgotten Avenues of Diversion

- Physician Samples
- Exports
- Contract Manufacturing



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Managing Conflicts

- Customers
- Customer Service
- Sales

Thank You!

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the Sharing Conference to view
the workshop presentations.**

