

Mallinckrodt Documents – Responding to Illegal Activity

Key finding: Mallinckrodt had processes in place to cooperate with law enforcement in analyzing counterfeit pills, to monitor news and chat sites for unfavorable mentions of their products, and to manage press coverage of illegal use of Mallinckrodt drugs.

Why this is important: Seeing how Mallinckrodt responded to illegal use of its drugs gives insight into its awareness of the opioid epidemic, trends in illicit use, and other issues pertinent to its management of suspicious orders and opioid oversupply.

Evidence

Document Title: Mallinckrodt Oxycodone blog

OIDA ID: <https://idl.ucsf.edu/opioids/docs/#id=xhkf0237>

Date: 2011-11

Description: Compliance Coordinator Eileen Spaulding shared a Google Alerts find with Karen Harper, senior manager for controlled substances compliance, and Richard Nikolaus, security manager, saying, “It’s a blog so it’s pretty much just rambling, but states that the ‘mallies’ are better than others to blow.”

Document Title: RE: CONFIDENTIAL FW: Pharmaceutical Theft AmerisourceBergen

OIDA ID: <https://idl.ucsf.edu/opioids/docs/#id=xtby0245>

Date: 2012-06

Description: The compliance and security team discuss its response to the theft of an AmerisourceBergen shipment that included Mallinckrodt opioid drugs. Spaulding says that “the bottom line is that this cargo theft is the responsibility of AmerisourceBergen,” and the DEA will be working with AmerisourceBergen to investigate, with Mallinckrodt’s support as needed.

Document Title: Police: Drugs Stolen from Covidien

OIDA ID: <https://idl.ucsf.edu/opioids/docs/#id=lkbm0237>

Date: 2013-01

Description: An article in the Oneonta, NY *Daily Star* highlights that powdered oxycodone seized from a local man was traced to the Covidien plant in Hobart and that an employee was suspected of stealing the drug and transferring it to another individual. The drug suspect’s wife is quoted saying that she has heard rumors of internal theft being a problem at the plant. Covidien’s spokesperson, Lynn Phillips, declined to comment on these rumors or the plant’s security, only saying that the company was cooperating with law enforcement.

Document Title: RE: Placebo request - Oxy 30mg - Calhoun/Cleburne County Alabama

OIDA ID: <https://idl.ucsf.edu/opioids/docs/#id=xkxc0237>

Date: 2013-01

Description: Spaulding relays a request for Mallinckrodt Oxycodone 30 mg (M-30s) placebos to John Gillies, then-director of Global Security. "He stated that there has been an explosion in Oxy 30's on their streets and everything has gone from the OC30's to the M30's. They are looking for placebos for reverse buys."

Document Title: [Comparison of the Abuse Potential of Controlled-Release Oxycodone/Acetaminophen Tablets (MNK-795) Versus Immediate-Release Oxycodone/Acetaminophen Tablets in Recreational Users of Prescription Opioids]

OIDA ID: <https://idl.ucsf.edu/opioids/docs/#id=lxnk0236>

Date: 2013-07

Description: This research abstract appears to have been presented at PAINWeek 2013 and represented the work of Mallinckrodt employees, along with Dr. Lynn Webster, who served on the advisory board of Mallinckrodt and several other pharmaceutical companies. The study notes the impact of MNK-795 (Xartemis)'s abuse-deterrent technology (ADT) in lowering abuse-related subjective effects; however, several [complaints](#) against Mallinckrodt argue that the company's emphasis on ADT is not in keeping with CDC guidance.

Document Title: Re: Counterfeit Fentanyl

OIDA ID: <https://idl.ucsf.edu/opioids/docs/#id=qjby0245>

Date: 2016-04

Description: Nancy Stauder, senior director of external communications, raises concerns to John Gillies, vice president for global security, about photos of M30s used in an article about counterfeit drugs containing fentanyl.

Document Title: RE: PLEASE REVIEW ASAP DRAFT RESPONSE - WSJ questions on counterfeit product

OIDA ID: <https://idl.ucsf.edu/opioids/docs/#id=skbh0245>

Date: 2016-10

Description: In this largely redacted email exchange, Mallinckrodt leadership discuss their response to a *Wall Street Journal* reporter's request for information about counterfeit M367s (hydrocodone-acetaminophen) that actually contained fentanyl.

Document Title: [Analysis of Potential Counterfeit Tablets]

OIDA ID: <https://idl.ucsf.edu/opioids/docs/#id=psyk0238>

Date: 2017-02

Description: Mallinckrodt's Center for Analytical Research produced this lab report describing the results of their testing five potentially counterfeit Mallinckrodt Oxycodone HCl-30 mg tablets. The report describes the various tests utilized to examine the tablets in question and compare them with real Mallinckrodt product. The scientists concluded that the suspect tablets were not consistent with Mallinckrodt's and had no Oxycodone HCl.

Document Title: RE: [EXTERNAL] Introductions

OIDA ID: <https://idl.ucsf.edu/opioids/docs/#id=ktgc0237>

Date: 2017-11

Description: Gillies shares with Gustavo Valerio, who worked with counterfeit pharmaceuticals for the Department of Homeland Security, a list of how Mallinckrodt can assist law enforcement and Customs' work, such as their placebo program, laboratory testing, and GPS tracking on prescription bottles.

OIDA Identification Numbers for Additional Relevant Documents

- ythg0237
- yqwx0253
- hyxc0237
- pmgh0245
- jzkc0240
- tqhc0240
- knyd0234
- nnxf0251
- ftkv0251