

Ohio Pharmacy Litigation Documents – The DEA and the Controlled Substances Act

Summary: The defendant pharmacies in this case are alleged to have violated several sections of the Controlled Substances Act (CSA). The Drug Enforcement Agency (DEA) is tasked with enforcing and implementing the CSA using various administrative procedures and mechanisms, and may prosecute violators. Individuals or entities who order, handle, store, or distribute controlled substances must be registered with the DEA to perform these functions. They are also required to maintain accurate inventories, records, and security of the controlled substances.

Select Documents of Relevance

Document Title: Title 21, Code of Federal Regulations, Part 1301

OIDA ID: <https://idl.ucsf.edu/opioids/docs/#id=gklh0257>

Date: Unknown

Description: The sections of the Controlled Substances Act requiring registrants to have a Suspicious Order Monitoring System (SOM) in place and detailing reporting requirements to the DEA if irregular activity is observed.

Document Title: Prescription Drug Monitoring Program

OIDA ID: <https://idl.ucsf.edu/opioids/docs/#id=rmlh0257>

Date: 2015-07

Description: CVS Pharmacy's corporate policy on pharmacists' use of Prescription Monitoring Programs (PMP) to prevent diversion of controlled substances. All CVS pharmacists are required to register for the PMP in their respective state.

Document Title: Re: pain management doctor

OIDA ID: <https://idl.ucsf.edu/opioids/docs/#id=lnlh0257>

Date: 2014-12

Description: Emails to CVS executive Amy Winchell from pharmacy manager "Deanna" regarding Dr. David Demangone, and the suspicion that his medical office may be running a "pill mill." Pharmacists are encouraged to use "professional judgment" when determining if prescriptions for his patients should be filled.

Document Title: Federal Guidelines for Controlled Substances

OIDA ID: <https://idl.ucsf.edu/opioids/docs/#id=yrlh0257>

Date: 2014-10

Description: CVS pharmacy policy regarding procedures for dispensing controlled substances.

Document Title: DEA and Pharmacy Regulatory Training 211

OIDA ID: <https://idl.ucsf.edu/opioids/docs/#id=qrh0257>

Date: 2012-09

Description: CVS training guide for pharmacists regarding controlled substance prescriptions and guidelines for refusing to fill.

Document Title: Inventory Control – Suspicious Order Policy

OIDA ID: <https://idl.ucsf.edu/opioids/docs/#id=nklh0257>

Date: 2014-08

Description: Giant Eagles company policy and procedures for the identification and reporting requirements of suspicious drug orders.

Document Title: Giant Eagle Drug Control Program

OIDA ID: <https://idl.ucsf.edu/opioids/docs/#id=nklh0257>

Date: 2016-11

Description: Project scope document detailing the criteria for implementing an SOM to come into compliance with the DEA's requirements under the CSA.

Document Title: Settlement Agreement

OIDA ID: <https://idl.ucsf.edu/opioids/docs/#id=sxlh0257>

Date: 2007-02

Description: **Settlement** Agreement between Walmart, the DOJ, and the DEA regarding alleged violations of the CSA, including the filling of unlawful prescriptions.

Document Title: Memorandum of Agreement – Obligations and Expectations

OIDA ID: <https://idl.ucsf.edu/opioids/docs/#id=ljlh0257>

Date: 2011-03

Description: An employee presentation outlining the Memorandum of Agreement between Walmart, the DOJ, and the DEA, detailing remediation measures to be taken by Walmart following allegations of improper dispensing of prescriptions and failures to take action to prevent diversion.

Document Title: In Reference to registration # RH0197170

OIDA ID: <https://idl.ucsf.edu/opioids/docs/#id=zllh0257>

Date: 2006-09

Description: Form letter sent to registrants from the DEA detailing obligations under the Controlled Substances Act (CSA) and potential penalties for violation.

Document Title: Filling C2 – dr. under investigation

OIDA ID: <https://idl.ucsf.edu/opioids/docs/#id=nljh0257>

Date: 2014-12

Description: Emails from Walmart pharmacy manager Donna Hander to executives Debbie Mack and Brad Nelson re: Drs. Howard Diamond and Randall Wade who were later investigated by the DEA. Other pharmacy chains are refusing to fill their patients' prescriptions, and Walmart pharmacists are confused and concerned about what course of action they should take.

Document Title: Pharmacist's Manual: An Informational Outline of the Controlled Substances Act

OIDA ID: <https://idl.ucsf.edu/opioids/docs/#id=zglh0257>

Date: 2006

Description: Manual from the DEA, Office of Diversion Control, detailing the requirements of the Controlled Substances Act for dispensing pharmacists.

OIDA Identification Numbers for Additional Relevant Documents

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| ▪ nr1h0257 | ▪ fmlh0257 | ▪ jglh0257 |
| ▪ pr1h0257 | ▪ gmlh0257 | ▪ rmlh0257 |
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