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STATEMENT OF

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BEFORE THE

CONTROLLED SUBSTANCE STANDARDS COMMITTEE
FLORIDA BOARD OF PHARMACY
FLORIDA DEPARTMENT OF HEALTH

**FOR A PUBLIC MEETING CONCERNING ISSUES WITH PATIENTS FILLING
PRESCRIPTIONS FOR CONTROLLED SUBSTANCES**

PRESENTED ON
AUGUST 10, 2015

DOUBLETREE HILTON
DEERFIELD BEACH, FLORIDA

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**STATEMENT OF DIVERSION PROGRAM MANAGER SUSAN C. LANGSTON
MIAMI FIELD DIVISION, DRUG ENFORCEMENT ADMINISTRATION
BEFORE THE CONTROLLED SUBSTANCE STANDARDS COMMITTEE
FLORIDA BOARD OF PHARMACY
AUGUST 10, 2015**

Committee Chairman Meshad, Committee Chairwoman Weizer, Members of the Committee, and Members of the Public:

Good Afternoon. My name is Susan Langston. I am the Diversion Program Manager for the Drug Enforcement Administration (DEA), Miami Field Division. I am in charge of all regulatory matters relating to doctors, pharmacies, drug distributors, and all other individuals and companies registered with the DEA in Florida to handle controlled substances under federal law.

I am joined today by Jeffrey Walsh, Assistant Special Agent in Charge of the DEA's Orlando District Office. We are both honored to appear before you today to discuss the very important topic of patient access to controlled substances.

I would like to start by recognizing the patients and family members here today who are needlessly suffering and see no relief in sight. Your voices have been heard by the DEA loud and clear. We have listened to your tragic stories and we truly empathize with you all.

I hope that today I will be able to inform everyone here of the DEA's roles and responsibilities and clarify any misinformation or misunderstandings. We are here today in good faith and with the best of intentions and our goal is to do our part to make sure all legitimate pain patients receive whatever medications they need to live happy, healthy, and productive lives.

Prescription drug abuse has been a devastating public health crisis in the United States for many years. As you all know, Florida has long been known as the pill mill capital of the world. At one time, 11 Floridians a day were dying of prescription drug overdoses. This is still an epidemic that has caused incredible harm to those suffering from the disease of addiction, as well as their families and entire communities throughout Florida.

The mission of the DEA's Office of Diversion Control is to protect the public, which includes legitimate pain patients, by preventing, detecting, and investigating the diversion of pharmaceutical controlled substances from legitimate channels while ensuring an adequate and uninterrupted supply of pharmaceutical controlled substances are available to meet medical needs. We take this mission very seriously with regard to both preventing drug abuse and diversion and ensuring medications are available to those who desperately need them.

2010 to 2011 was the peak of Florida's pharmaceutical drug abuse epidemic. Drug abusers from all over Florida, as well as the entire country, often traveled hundreds or even thousands of miles to visit Florida's notorious rogue pain clinics that had absolutely nothing to do with providing medical care. At that time, most of the narcotic pain pills prescribed by those pill mill physicians

were dispensed directly from the pain clinics and the involvement of a separate retail pharmacy was not necessary.

In 2011, the State of Florida adopted legislation known as the Anti-Pill Mill Bill that restricted doctors from selling actual pills from these pain clinics. This new law shifted the dispensing of most narcotic pain killers to actual pharmacies. This shift heightened pharmacists' responsibilities and they were suddenly faced with circumstances many never had dealt with before. Most pharmacists transitioned just fine, but some pharmacists failed and became caught up in the pill mill world. The DEA had to take action to address the problem.

The DEA's Miami Field Division increased inspections at pharmacies as part of our efforts to tackle the pill mill problem and to combat pharmaceutical drug abuse and diversion. Unfortunately, there are still unscrupulous doctors and pharmacists in Florida. However, what we have discovered through our inspections is that most pharmacists are kind, caring, well-trained, and highly competent. They have good professional relationships with their patients and are a vital part of a patient's health care team. Our inspections also revealed some very disturbing things at some pharmacies such as: local law enforcement reports of drug dealing in parking lots, a victim of an intravenous drug overdose in a pharmacy bathroom, drug seekers lined up at pharmacies to get their prescriptions filled, and volume-based bonuses and pressure from pharmacy owners and pharmacy staff that caused many pharmacists to go against their professional oaths to do no harm.

Although we have increased pharmacy inspections during the past few years, less than one percent of the pharmacies in Florida have been formally sanctioned by the DEA. Please allow me to give you some statistics. There are 69,492 retail pharmacies in the United States registered with the DEA to dispense controlled substances. 4,902 of those retail pharmacies are located in Florida. Our largest chain pharmacies in Florida are Walgreens with 859 locations and CVS with 744 locations. Out of almost 5,000 retail pharmacies in Florida, the DEA has initiated formal proceedings to revoke the DEA Registrations of 23 pharmacies since 2011. We are waiting on administrative hearings and/or final decisions in ten of those cases. Only three pharmacies in Florida have had their DEA Registrations formally revoked since 2011.

I assure you that the pharmacies the DEA's Miami Field Division have taken action against for ignoring red flags of abuse and diversion were undoubtedly contributing, on a major scale, to the abuse and diversion of controlled substances. These were not situations where a few questionable prescriptions fell through the cracks or a pharmacist was having a bad day. These cases involved unquestionable patterns of behavior that had to be stopped for the health and safety of the public.

The DEA Miami Field Division's pharmacy inspection process is designed to make sure pharmacies are in compliance with federal record keeping, security and other requirements. During these inspections we inform pharmacists of current trends to be on the lookout for and we ask for their assistance in both preventing diversion and making sure people with legitimate medical conditions receive the medications they need.

Under federal law, a pharmacist has a responsibility to fill only prescriptions issued for a legitimate medical purpose and in the usual course of professional practice. This corresponding responsibility regulation is designed to help prevent the diversion of controlled substances through drug-seeking behavior. Drug-seeking behavior is one of two things: A person trying to obtain controlled substances not for a legitimate medical purpose and for the sole reason of feeding a drug addiction or a person trying to obtain controlled substances to divert into the illegal market.

If a pharmacist discovers a red flag that a prescription may indicate suspicious or drug-seeking behavior, then the pharmacist must exercise caution and resolve the red flag prior to filling the prescription. A red flag of diversion (or a red flag of anything) is merely a circumstance that something could be out of the ordinary or suspicious. It is a general attention marker. If a pharmacist encounters a red flag, then asking a question of the patient, calling the doctor's office, combined with using common sense, will often offer a reasonable explanation to clear that red flag.

We recognize that the vast majority of controlled substance prescriptions are written by highly trained and ethical medical professionals who are treating legitimate medical conditions. We also recognize that the vast majority of controlled substance prescriptions written by doctors are for legitimate medical purposes and are issued in the usual course of professional practice. A great deal of the time a red flag at a pharmacy can easily be explained and once it is resolved, there should be no problem filling that prescription.

Although we ask pharmacists to be on the look-out for suspicious activities that may indicate drug abuse and diversion, we are not asking pharmacists to be medical doctors. We are not asking pharmacists to review medical records, MRI reports, x-rays or to diagnose patients. We simply want pharmacists to be aware that there is an epidemic of pharmaceutical drug abuse in this country and to use their education, experience, professional judgment, ethics, and common sense to not knowingly participate in this national health crisis.

I heard the deeply troubling story of Aiden Lopez, a four year old cancer survivor who was recently diagnosed with stage-three kidney cancer. Poor Aiden has gone through more pain in his four years of life than many of us will ever have to endure. He had surgery recently and was prescribed medication for his pain. Incredibly, however, three pharmacies refused to fill his prescription. How can that possibly happen? What were the red flags of drug abuse and diversion with Aiden that three pharmacists could not resolve? What drug seeking behavior could this four year old child possibly exhibit to make any reasonable pharmacist using common sense question the validity of his medical condition?

I am also troubled when I hear stories of patients who have been going to the same pharmacy for years and, all of a sudden, that pharmacy elects to stop filling their controlled substances prescriptions. Legitimate patients should not have to travel or do the "pharmacy crawl" to acquire their medications.

The DEA inspections at pharmacies and our actions against pharmacies that fill prescriptions with obvious, highly suspicious, blatant, and undeniable red flags of abuse and diversion and

drug-seeking behavior should never, in any way, cause any person who needs medication legitimately to go without. The staff of the DEA's Miami Field Division is horrified to hear the heart breaking stories of cancer patients, hospice patients, surgery patients and legitimate pain patients being forced to endure needless suffering. Many of us at the DEA have also had family members and friends who have been turned away at pharmacies for no apparent reason whatsoever. This has to stop and it has to stop now.

Unfortunately, the DEA cannot force a pharmacist to fill a prescription, but what I can do is pledge our sincere commitment to this Committee, the medical and pharmacy communities, and most of all to the public, and ensure you all that the last thing we want to do is interfere with valid medical treatment. I want to make myself perfectly clear when I say that pharmacists do not need to fear the DEA when they use their professional judgment, experience, education, training and common sense to fill legitimate prescriptions.

The DEA works with pharmacists and we are out in the field visiting pharmacies on a regular basis. We are accessible and we try to answer questions, but the DEA does not give out a check list or tell a pharmacist his or her job is black and white – because it is not. Each patient should be treated on an individual basis. Each patient has a different diagnosis and needs that should be addressed by the pharmacist. The DEA expects that trained pharmacists are able to demonstrate they are filling opioids for a legitimate medical purpose. They can accomplish this by getting to know their customers so that they can make an informed decision. Pharmacists are the last gatekeepers before controlled substances are released to the public. The DEA and the public at large depend on pharmacists to make the final assessment whether a prescription appears to be legitimate or not.

I would also like to clarify a misunderstanding with the terms “Quotas” and “Thresholds.” The DEA does not impose a quota on the amount of controlled substances a wholesale distributor can sell to a pharmacy. Likewise, the DEA does not issue any sort of threshold in this way either. The DEA does not impose a quota or a threshold on the number of prescriptions a pharmacy can fill or the amount of drugs a pharmacy can dispense.

Since the early 1970s, DEA regulations have required non-practitioners such as wholesale distributors to design and operate a system to disclose suspicious orders of controlled substances. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. In 2011, the DEA released a document called “Know your customer.” This document contains suggested questions distributors should ask customers prior to shipping controlled substances. Short of providing arbitrary thresholds to distributors, the DEA cannot provide more specific suspicious orders guidance, as the variables that indicate an order may be suspicious are very fact intensive and differ from distributor to distributor, and from customer to customer. I would like to emphasize that the DEA has no authority to control otherwise legitimate business decisions of DEA registrants. As a result, the DEA cannot direct how distributors conduct their business, including the amount of controlled substances lawfully distributed or dispensed to customers such as pharmacies. The DEA has repeatedly and emphatically informed distributors that arbitrary thresholds are inappropriate, negatively impact legitimate patients and are an inadequate substitute for fulfilling their obligations under federal law.

In closing, I would like to thank everyone for attending this meeting. It is very important that the DEA works with pharmacies, doctors, wholesale distributors, and others to prevent diversion and to ensure legitimate patients are able to obtain medications. I guarantee you have the DEA Miami Field Division's unwavering commitment on both of those fronts.

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