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Avoiding Legal Conflict with the DEA

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This monograph provides an overview of the federal Drug Enforcement Administration's regulatory role, including the fundamental goal of reducing, if not eliminating, the diversion of controlled substances from medical use to non-medical use. A review of recent court cases places agency goals, and conflicts with health professionals, into a contemporary context. Basic DEA regulations are discussed.

Learning Objectives

Pharmacist

1. List the major responsibilities of the Drug Enforcement Administration.
2. Describe the rules established by the DEA to prevent drug diversion.
3. Discuss legal cases interpreting the responsibilities of pharmacists to comply with DEA requirements.

Pharmacy Technician

1. Discuss the role of the DEA as a regulatory agency.
2. List rules established by the DEA for handling of medications at a pharmacy.
3. Describe techniques that can be used to comply with DEA rules.

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DEA Rules In Perspective

The Drug Enforcement Administration (DEA) is not a health care agency. It is a law enforcement agency that is tasked with the responsibility of preventing (an impossibility) or reducing (more realistic) the abuse of chemical substances. A significant challenge for the DEA is that the crime it seeks to prevent is not just a crime, it is an illness. Yet the DEA does not see drug abuse in terms of illness. The result is that people who are depressed or lonely or are frustrated, become criminals through the poor choices they make to abuse chemical substances, some of which are used as medications.

Viewed from a health care perspective, part of the solution to the problem of substance abuse lies in the treatment of underlying illnesses that lead to poor choices through which people self-medicate. Social solutions to the problem of substance abuse can be found in relieving loneliness and frustration that many people who abuse chemicals experience.

None of these solutions are within the realm of the DEA. Instead, the DEA focuses primarily on the supply side for solutions, based on the idea that if people lack access to chemicals that are subject to abuse, then they will not be able to abuse them, and the problem of substance abuse will end.

Pharmacists find themselves entangled with the DEA because pharmacists are a source of supply for chemicals that can be abused. The DEA has developed rules that apply to people who handle “controlled substances” which is their term for chemicals that are subject to abuse. These rules must be followed by pharmacists to assure that rule violations do not lead to leaks from the distribution system (known as diversion to the DEA), else pharmacists will be viewed by DEA as contributors to the illicit supply of abused chemicals.

Following the DEA rules need not present a conflict with responsibilities to patients. Pharmacists can meet the needs of patients while practicing within the legal framework established by the DEA.

While DEA rules may seem unnecessary and counterproductive at times, they are genuinely intended to protect the public. The rules must be learned, and systems must be developed to assure that the rules are followed by pharmacy personnel with no exceptions.

DEA Structure & Function

The DEA is led by an Administrator who is appointed by the President, with the advice and consent of the Senate. The Administrator is responsible to the Attorney General of the United States; thus the DEA is within the US Department of Justice.

Most of the personnel and other resources at the DEA are focused on the seizure of illicit drugs and the prosecution of illicit drug dealers. This is the realm of DEA Special Agents.

For those in the health care fields, the most important office within the DEA is the Office of Diversion Control. This group is dedicated to preventing the non-medical use of pharmaceutical products. Most of the activities of this group are undertaken by Diversion Investigators (DIs). When a pharmaceutical product is used for its euphoric effect, rather than its therapeutic effect, it has been diverted.

DIs are aware of the need to treat pharmaceutical manufacturers, physicians, and pharmacists, differently from the criminal street dealers brought to justice by Special Agents.

Exemplary Case: Gonzales v. Oregon

"Can the federal government tell state licensed health professionals how to practice their professions?"

The background of this case is complex yet interesting. In 1997, Senator John Ashcroft of Missouri was one of several United States Senators to request that US Attorney General Janet Reno adopt the position that the State of Oregon's "Death With Dignity" law violated the federal Controlled Substances Act. This state act authorized physicians to issue prescriptions for controlled substances to be used by terminally ill patients to choose when and how they would die, and it authorized pharmacists to honor those prescriptions.

The position of Senator Ashcroft was that this use of controlled substances was not for a "legitimate medical purpose," and therefore was a violation of federal law.

Attorney General Reno disagreed, and she refused to enforce the CSA against Oregon physicians and pharmacists.

In 2001, Ashcroft was appointed US Attorney General. One of this first actions was to declare the Oregon law to be a violation of federal law. The State of Oregon sued Ashcroft and won. Ashcroft appealed. Subsequently, Attorney General Ashcroft resigned from office and was replaced by Alberto Gonzales. The case as it was presented to the US Supreme Court was captioned as Gonzales v. Oregon.

The implications were huge. Can the federal government tell state licensed health professionals how to practice their professions?

All language in italics below is quoted directly from the legal opinion of the United States Supreme Court.

Factual Background by the Court

The question before us is whether the Controlled Substances Act allows the United States Attorney General to prohibit doctors from prescribing drugs for use in physician-assisted suicide, notwithstanding a state law permitting the procedure. The dispute before us is in part a product of political and moral debate, but its resolution requires an inquiry familiar to the courts: interpreting a federal statute to determine whether executive action is authorized by, or otherwise consistent with, the enactment.

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The present dispute involves controlled substances listed in Schedule II, substances generally available only pursuant to a written, nonrefillable prescription by physician. A 1971 regulation promulgated by the Attorney General requires that every prescription for a controlled substance "be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice."

To prevent the diversion of controlled substances with medical uses, the CSA regulates the activity of physicians.

The State of Oregon enacted the Oregon Death With Dignity Act (ODWDA) in 1994. For Oregon residents to request a prescription under ODWDA, they must receive a diagnosis from their attending physician that they have an incurable and irreversible disease that, within reasonable medical judgment, will cause death within six months.

The Interpretive Rule

On November 9, 2001, without consulting Oregon or apparently anyone outside his Department, the Attorney General issued an Interpretive Rule announcing his intent to restrict the use of controlled substances for physician-assisted suicide. The Attorney General Ruled: Assisting suicide is not a "legitimate medical purpose" and prescribing, dispensing, or administering federally controlled substances to assist suicide violates the CSA.

In response, the State of Oregon, joined by a physician, a pharmacist, and some terminally ill patients, all from Oregon, challenged the Interpretive Rule in federal court.

The United States District Court entered a permanent injunction against the Interpretive Rule's enforcement. The Court of Appeals held the Interpretive Rule invalid, ruling that the Interpretive Rule altered the "usual constitutional balance between the States and the Federal Government.."

The Scope of Federal Authority

The structure of the CSA conveys unwillingness to cede medical judgments to an executive official who lacks medical expertise. The government contends the Attorney General's decision here is a legal, not a medical, one. This generality, however, does not suffice. The Attorney General's Interpretive Rule places extensive reliance on medical judgments and the views of the medical community. This confirms that the authority claimed by the Attorney General is both beyond his expertise and incongruous with the statutory purposes and design.

Under the government's theory, moreover, the medical judgments the Attorney General could make are not limited to physician-assisted suicide. Were this argument accepted, he could decide whether any particular drug may be used for any particular purpose, or indeed whether a physician who administers any controversial treatment could be deregistered.

The statute and our case law amply support the conclusion that Congress regulates medical practice only insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood. Beyond this, however, the statute manifests no intent to regulate the practice of medicine generally. The silence is understandable given the structure and limitations of federalism, which allows the States great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort and quiet of all persons.

"The statute manifests no intent to regulate the practice of medicine generally."

The Court's Conclusion

In the face of the CSA's silence on the practice of medicine generally and its recognition of state regulation of the medical profession it is difficult to defend the Attorney General's declaration that the statute impliedly criminalizes physician-assisted suicide.

"To read prescriptions for assisted suicide as constituting "drug abuse" under the CSA is discordant with the phrase's consistent use throughout the statute, not to mention its ordinary meaning."

The Interpretive Rule rests on a reading of the prescription requirement that is persuasive only to the extent one scrutinizes the provision without the illumination of the rest of the statute. Viewed in its context, the prescription requirement is better understood as a provision that ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, the provision also bars doctors from peddling to patients who crave the drugs for those prohibited uses. To read prescriptions for assisted suicide as constituting "drug abuse" under the CSA is discordant with the phrase's consistent use throughout the statute, not to mention its ordinary meaning.

For all these reasons, we conclude the CSA's prescription requirement does not authorize the Attorney General to bar dispensing controlled substances for assisted suicide in the face of a state medical regime permitting such conduct.

The Take-Home Message

"DEA has authority over drug diversion, abuse, and addiction. Their rules cannot establish medical practice standards."

Health professionals and their patients dodged a huge bullet when this case was decided by the Supreme Court of the United States. As the court said, had the federal government won the case, then federal law enforcement agencies with no expertise in health care could have established medical standards to which state licensed health professionals would have had to adhere. They could have limited patients to two dosage units daily of any controlled substance. They could have established a ceiling dose for opioids of 20 mg oral morphine equivalent daily. They could have forbidden off-label use of controlled substances.

Fortunately, the court recognized that these consequences were possible and that they would be undesirable. State authority to establish and oversee health care standards was upheld in this case. The DEA has authority over drug diversion, abuse, and addiction. Their rules cannot establish medical practice standards.

The Closed System of Distribution

The CSA is supposed to create a closed system of distribution for controlled substances.

The system classifies controlled substances into schedules, depending on their potential for abuse. The system permits only certain registered individuals or business to allow access to scheduled drugs. Cradle-to-grave recordkeeping is required for scheduled drugs. Lastly, the system imposes strict requirements for security and distribution.

"In a black market, standard law enforcement is not available to resolve disputes."

The purpose of the closed system is to allow access to controlled substances by those who need them for legitimate medical purposes, but deny access for those who use them recreationally for their euphoric effect.

The goal of the DEA, with regard to pharmaceutical controlled substances, is to prevent diversion to non-medical use. Any pharmaceutical controlled substance that is used non-medically has escaped the closed system and is considered to have been diverted.

Diversion from a system that has many leaks leads to a black market in diverted pharmaceuticals. In a black market, standard law enforcement is not available to resolve disputes. The absence of law & order creates a demand for organized crime to assist in the resolution of disputes, and bring order out of chaos, through the establishment of alternate distribution systems.

Defining Addiction and Abuse

The Federation of State Medical Boards (FSMB) has adopted a policy defining terms that are sometimes subject to differing interpretations.

"Addiction" is defined as "a primary, chronic, neurobiological disease, whose development and manifestations are influenced by genetic, psychosocial, and environmental factors." Addiction is often said to be characterized by "behaviors that include impaired control over drug use, craving, compulsive use, and continued used despite harm."

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"Dependence" is "a state of biologic adaptation evidenced by a withdrawal syndrome when the drug is abruptly discontinued," and it "is neither necessary nor sufficient to diagnose addiction."

"Tolerance" is common in opioid treatment. It is a "state of physiologic adaptation in which exposure to a drug induces changes that result in diminution of one or more of the drug's effects over time." It is "not the same as addiction."

"Abuse" is maladaptive drug use that results in harm or places the user at risk of harm. It involves use in a manner that "deviates from approved medical, legal, and social standards, generally to achieve a euphoric effect."

The Crisis of Prescription Drug Abuse

Data on prescription drug abuse vary depending on the source of the data and the methods of data collection. Regardless of the data, there is little disagreement that a crisis exists. Even one unintended death warrants taking extra efforts to avoid contributing to diversion, abuse, and addiction.

All diverted prescription drugs were at one time contained within the closed system. How do they get out of the closed system?

Many controlled substances are diverted at the patient level; stolen from patients, given by patients to others, or sold by patients.

Controlled substances may also be dispensed to non-patients who dupe health care professionals into providing access with no medical need.

Lastly, there are professional criminals who treat controlled substances merely as a commodity to be bought and sold.

The War on Drugs

Richard Nixon was the first president to declare war on drugs. Every president since has made the same declaration. "War" has also been declared on poverty, disease, and other social problems. What this usually signifies is a commitment by government to confront a problem with the same spirit and resources that accompany a wartime commitment to national defense.

Potential negative consequences of declaring war on drugs include factors like confusion caused by the "fog of war," harm from "friendly fire," and the inevitability of "collateral damage."

The notion of a war on drugs misses the point that the problem really isn't the drugs themselves, it is illegal use of the drugs. Demonizing drugs with a negative slogan can lead patients to think that drugs are bad, and that even medical use of drugs should be avoided.

The war on drugs is controversial due to its cost and its relatively poor return on investment. The positive outcomes claimed by drug warriors are their numbers of arrests and convictions, and the seizure of contraband with a high street value. But the problem of drug abuse has not been solved through warfare.

Some critics of the war on drugs have suggested that the metaphor of war focuses too many resources on law enforcement and incarceration, taking resources away from education and treatment.

OxyContin

"As a result of the Oxycontin crisis of the early 2000s, lessons have been learned and the chance of a repeat crisis with another product is low."

OxyContin was approved in 1996. Most people agree that when used as instructed in the product labeling, by well-trained health professionals, and by patients who follow directions and observe cautions, OxyContin is a safe and effective opioid analgesic.

Unfortunately, this safe and effective product was used unsafely and ineffectively by people who, either intentionally or unintentionally, did not protect themselves from harm.

The media contributed to the problem by teaching the public which product to abuse and how to abuse it.

As a result of the OxyContin crisis of the early 2000s, lessons have been learned and the chance of a repeat crisis with another product is low.

Among other lessons, regulatory compliance specialists are determined now to closely monitor data showing patterns of opioid use and react quickly to signals that indicate abuse.

Education of health care professionals has been expanded.

The language in the labeling of opioids has been strengthened.

Specific, exacting, regulatory compliance systems for opioids are now a high priority.

Abuse-Deterrent Options

"ADO technology cannot solve the problem of prescription drug abuse."

Some drug abusers alter the dosage form of opioid products to provide a quicker and more intense feeling of euphoria. By crushing or dissolving a tablet of an opioid product, it becomes possible to inject or sniff the drug.

An ADO may work by adding an opioid antagonist, using an osmotic core that prevents immediately drug release, creating a gummy matrix when the tablet is crushed, or adding a low dose aversive drug like niacin that is unpleasant, but not harmful, when inappropriately large doses of a product are ingested.

Many drug abusers swallow prescription drugs whole, and some ADO technologies will have no effect. But ADOs are one tool to reduce the risk of diversion and abuse.

ADO technology cannot solve the problem of prescription drug abuse. A new molecule that is not abused will provide a better solution than a safer dosage form of existing drugs.

The Decade of Pain Control

"The unbalanced emphasis on access to pain treatment in 2000 led to relaxed attitudes toward diversion."

In 1999, the Veterans Health Administration launched a "Pain as the 5th Vital Sign" initiative, requiring a pain intensity score at all clinical encounters.

In 2000, the Joint Commission on Accreditation of Healthcare Organizations (now known as the Joint Commission) established expansive accreditation standards for the assessment and treatment of pain.

Just a few months later, Congress passed a law that declared the ten years beginning January 1, 2001 as the Decade of Pain Control and Research.

It didn't work. In 2013, the Federation of State Medical Boards cited a significant body of evidence suggesting that many Americans still suffer from chronic pain and much of that pain is inadequately or ineffectively treated.

What went wrong?

The unbalanced emphasis on access to pain treatment in 2000 led to relaxed attitudes toward diversion. The Decade of Pain Control unwittingly created a monster. The predictable unbalanced law enforcement reaction to widespread availability of opioids still limits access for chronic pain patients.

It's all about finding balance.

Pain Clinics

Pain medicine is a medical specialty, and many highly skilled and ethical physicians practice in what are known as "pain clinics."

Unfortunately for the legitimate specialists, the phrase "pain clinic" was hijacked for several years by unscrupulous business people who would hire a clueless physician to legitimize the clinic, and then use the clinic to divert opioid analgesics to drug dealers and abusers.

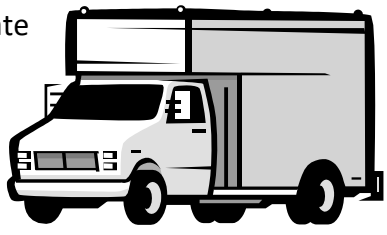
"The unbalanced emphasis on access to pain treatment in 2000 led to relaxed attitudes toward diversion."

The bogus pain clinics were often hard to distinguish from legitimate pain practices. They maintained extensive medical records, they required imaging to confirm pathology, and they insisted that their "patients" return frequently for follow-up. It was all a ruse, and it was eventually exposed. New rules for pain clinics in Florida and in other states now impose requirements that make it unlikely (but not impossible) for criminals to divert opioids through pain clinics.

Better laws and enhanced enforcement activities have helped, but they are not foolproof. Specialists in pharmacy regulatory compliance now accept responsibility for preparing criteria that distinguish between legitimate pain practices and bogus pain clinics.

Suspicious Orders

DEA regulations require that a registrant "design and operate a system to disclose to the registrant suspicious orders of controlled substances." "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." Suspicious orders must be reported to the DEA.



"Suspicious orders must be reported to the DEA."

This rule requires that wholesalers monitor pharmacy orders for controlled substances and determine when the orders are unusual or are substantial deviations from normal. The

result is that some pharmacies do not consistently receive the supply of product they feel they need, leading to denial of necessary medication for patients.

Compliance with this requirement compels collaboration between wholesalers and their pharmacy customers.

Pharmacies can develop strategies for prescription screening that use the available supply of opioids and assure that no suspicious orders are submitted. They can help wholesalers comply with DEA requirements.

Theft or Loss of Controlled Substances

A pharmacy must notify in writing the local DEA Diversion Field Office within one day of discovery of a theft or significant loss of a controlled substance. The pharmacy must also complete DEA Form 106. If, after initial notification to the DEA, further investigation determines that no theft or loss actually occurred, DEA Form 106 need not be submitted, but DEA must be notified of this fact to explain the absence of Form 106.

The CSA does not define a "significant" loss. This determination is left to the judgment of the registrant. The DEA advises that repeated small losses, and losses that lack a rational explanation, should be considered significant.

DEA also advises that considerations in determining whether a loss is significant include:

The quantity lost.

The specific controlled substance.

A pattern of losses.

Local trends.

When all or part of an in-transit shipment of controlled substances fails to reach its intended destination, the supplier is responsible for reporting to the DEA.

Breakage and spillage of controlled substances is not considered a "loss" of controlled substances.

Central Fill Pharmacy

Central fill pharmacies are permitted to prepare both initial and refill prescriptions, subject to all state and federal regulations.

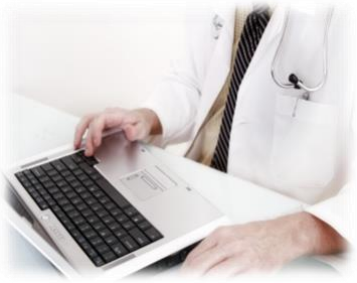
"Central fill pharmacies are permitted to prepare both initial and refill prescriptions."

Prescription information must be provided to an authorized central fill pharmacy by a community pharmacy. Prescriptions for controlled substances in Schedules II, III, IV, and V may be transmitted electronically from a community pharmacy to a central fill pharmacy.

The transmitting community pharmacy must:

- Write CENTRAL FILL on the Rx, with name, address, DEA number of central fill pharmacy, name of transmitting pharmacist and date.
- Include all Rx information.
- Maintain Rxs for 2 years.
- Record details of receipt from a central fill pharmacy.
- Indicate the number of refills remaining.
- Central fill pharmacies must:
- Retain a copy of the Rx.
- Record the date of receipt of an Rx, name of dispensing pharmacist & dispensing date.
- Record the date & method of delivery.

Internet Pharmacy



Under federal law it is illegal to deliver, distribute, or dispense a controlled substance by means of the Internet unless an online pharmacy holds a modification of its DEA registration authorizing it to operate as an online pharmacy.

An online pharmacy includes:

- Any website that sells or offers to sell controlled substances.
- Any person who operates such a website.
- Any person who pays a practitioner to issue prescription to customers of such a website.
- Any pharmacy that knowingly or intentionally fills prescription from such a website.
- Any person who sends an email soliciting business for such a website.
- The law exempts from this definition those pharmacies engaged in legitimate telepharmacy and telehealth.

Court Case: United States v. Joseph

This case reviews the criminal convictions of three defendants; a physician (Green), a physician assistant (Mack), and a pharmacist (Joseph). What is important about this case is how the government related the violation of a basic controlled substance prescription signature rule to the more esoteric violation of the legitimate medical purpose rule.

When the government can show that seemingly sloppy health professionals can't even follow the basic rules of procedure in health care practice, it makes it easier for the government to infer that these same practitioners were not using good faith in determining whether their patients qualified to receive controlled substances. Good or bad faith is hard to determine. A pre-signed signature on a prescription speaks for itself.

The foundational contention in this case is that all three defendants provided controlled substance medications to people who did not have a legitimate medical need, and that the defendants were acting outside the usual course of professional practice. The far less important issue of pre-signed prescriptions takes center stage in proving the lack of good faith on the part of the defendants.

The Court's Opinion

Experts for both the prosecution and defense stated that doctors are not permitted to pre-sign prescriptions. The relevant federal regulation provides that "all prescriptions for controlled substances shall be dated as of, and signed on, the day when issued." These regulations are designed to ensure that the doctor examines the patient before delivering the prescription and to ensure that there is a legitimate medical reason for delivering the prescription. An expert in pain management and internal medicine who testified on behalf of the defendants, testified that there are "no exceptions" to the rule that doctors "cannot pre-sign Schedule II prescriptions." But he testified that, in some circumstances, it might be acceptable "from a clinical point of view" for a physician assistant to give a patient a new prescription for a drug that a medical doctor has already prescribed for that patient in the past.

"When the government can show that seemingly sloppy health professionals can't even follow the basic rules of procedure in health practice, it makes it easier for the government to infer that these same practitioners were not using good faith in determining whether their patients qualified to receive controlled substances."

The record establishes that Green and Mack delivered Schedule II prescriptions to patients who were never examined by a physician. Based on Green's pre-signing and pre-dating of the prescriptions, and Mack's delivery of those prescriptions to Green's patients, they violated the Act.

Mack delivered the prescriptions based on her judgment that the patients had a legitimate medical need for the Schedule II substances, but she lacked authority to make that medical conclusion. And a physician's delivery of a prescription without conducting any physical examination of the patient provides strong evidence to support a conviction under the Act.

What This Case Teaches

The rules matter. Sometimes pharmacists are tempted to bend the rules ever so slightly as an accommodation to patients and to prescribers. This is a temptation that must be resisted with controlled substances, regardless of the circumstances. The DEA can use evidence of rule violations to create an atmosphere of distrust when the conduct of a pharmacist is being evaluated. If a pharmacist can't even be trusted to follow some simple rules for prescription format, how can we expect the pharmacist to exercise good professional judgment in the screening of prescriptions?

"If a pharmacist can't even be trusted to follow some simple rules for prescription format, how can we expect the pharmacist to exercise good judgment in the screening of prescriptions?"

The rules are sometimes counterintuitive. What difference does it make whether the prescriber actually signed the prescription on the day it was issued, as long as we know that the prescriber intended for the patient to receive the medication? In regulatory compliance, it makes a big difference. Signing a prescription on the day it is issued is mandatory.

Court Case: Nguyen v. United States

Florida physician Dr. Andrew Nguyen was arrested for allegedly prescribing controlled substances without conducting a physical examination of patients. In fact, Dr. Nguyen had conducted physical exams of all patients for whom he prescribed controlled substances.

"There are some circumstances under which the United States allows itself to be sued under a 'discretionary function' exception within the FTCA."

The charges against Dr. Nguyen were dropped. Dr. Nguyen then sued the United States under the Federal Tort Claims Act (FTCA). While the Unites States is generally protected from liability by sovereign immunity, there are some circumstances under which the United States allows itself to be sued under a "discretionary function" exception within the FTCA. In the court opinion excerpted below, Dr. Nguyen is appealing from dismissal of his lawsuit by the District Court. The ruling of the lower court is reversed.

The Court's Opinion

"All of the evidence that law enforcement officers had then, as well as now, showed that he was guilty of no crime. They arrested him anyway."

This appeal brings us the question of whether the waiver of sovereign immunity in the Federal Tort Claims Act extends to claims of false arrest, false imprisonment, and malicious prosecution arising from the acts or omissions of federal investigative or law enforcement officers. The facts of this case shows why Congress has chosen to waive sovereign immunity of the United States in some circumstances, and the plaintiff's story illustrates the value of living in a country where a citizen may pursue claims against the government in those circumstances.

What happened to Dr. Nguyen's practice is what happens to the established professional practices of many doctors who are caught committing crimes involving controlled substances. The record as it now exists indicates that Dr. Nguyen's arrest was not based on any evidence of wrongdoing at all. All of the evidence that law enforcement officers had then, as well as now, showed that he was guilty of no crime. They arrested him anyway.

Dr. Nguyen's arrest grew out of a three month investigation led by DEA Agent Robert Yakubec. Deputy Carlisle of the Gilchrist County Sheriff's Office was the arresting officer. Deputy Carlisle did not receive any evidence from the investigation until after Dr. Nguyen had been arrested. When asked why a physician or pharmacist was not consulted before he signed the arrest affidavit, Deputy Carlisle responded that the "DEA, Mr. Bob and them was running the show and they were doing it the way they seen fit." He testified that if he had known that a physical examination had been conducted, he never would have included a statement to the contrary in the arrest affidavit.

There had been a physical examination each time before medication was prescribed. The affidavit and arrest warrant were based on a false statement.

What This Case Teaches

The biblical statement that "the truth will set you free" is often used in academia to support the idea that liberty is based on knowledge. Some pharmacists and other health professionals have taken this statement to heart. When faced with accusations of wrongdoing, they have assumed that if they clearly explain everything they have done, then the truth will show they have done nothing wrong. Unfortunately, DEA investigations are not always about the truth, as the case above shows. The agency goal may be to obtain a conviction rather than to achieve justice.

"Inviting the DEA in to a practice site for a 'tell all' clarification meeting is a huge mistake."

This being the case, pharmacists and other health professionals are well advised to seek legal counsel at the first suggestion that the DEA is conducting an investigation. Inviting the DEA in to a practice site for a "tell all" clarification meeting is a huge mistake. It is unlikely to clarify ambiguities that may have led to an inaccurate understanding of the truth.

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NAME _____

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☐ PHARMACIST ☐ PHARMACY TECHNICIAN

CPE Monitor ePID _____ BIRTHDATE (MM/DD) _____

IF LICENSED IN FLORIDA, FL LICENSE # _____

EMAIL ADDRESS _____

LESSON EVALUATION

Please fill out this section as a means of evaluating this lesson. The information will aid us in improving future efforts. Either circle the appropriate evaluation answer, or rate the item from 1 to 7 (1 is the lowest rating; 7 is the highest).

1a. PHARMACISTS ONLY: Does this lesson meet the learning objectives? (Circle choice).

List the major responsibilities of the Drug Enforcement Administration.	YES	NO
Describe the rules established by the DEA to prevent drug diversion.	YES	NO
Discuss legal cases interpreting the responsibilities of pharmacists to comply with DEA requirements.	YES	NO

1b. TECHNICIANS ONLY: Does this lesson meet the learning objectives? (Circle choice).

Discuss the role of the DEA as a regulatory agency.	YES	NO
List rules established by the DEA for handling of medications at a pharmacy.	YES	NO
Describe techniques that can be used to comply with DEA rules.	YES	NO

2. Was the program independent & non-commercial? YES NO

	Low Relevance					Very Relevant
3. Relevance of topic	1	2	3	4	5	6	7

4. What did you like MOST about this lesson? _____

_____

5. What did you like LEAST about this lesson? _____

_____

6. How would you improve this lesson? _____

_____

PLEASE MARK THE CORRECT ANSWER(S)

1. Under which of the following circumstances is it generally considered appropriate for a pharmacy to ignore DEA regulations?
   a. A patient desperately needs a medication.
   b. A patient is a good friend of the pharmacist manager.
   c. The prescribing physician has authorized a violation of DEA regulations.
   d. None of the above.

2. Within which department of the United States Government is the DEA located?
   a. Food and Drug Administration.
   b. National Institutes of Health.
   c. Department of Justice.
   d. Health and Human Services.

3. What state's "Death with Dignity Act" was challenged in the Gonzales case?
   a. Washington.
   b. Oregon.
   c. California.
   d. Alaska.

4. What was the name of the United States Attorney General who initially issued an Interpretive Rule regarding illegality of physician-assisted Suicide?
   a. Ashcroft.
   b. Reno.
   c. Holder.
   d. Gonzales.

5. What term is used to describe a controlled substance that has escaped the closed system of distribution and is used non-medically?
   a. Diverted.
   b. Adulterated.
   c. Misbranded.
   d. Unapproved.

6. According to the Federation of State Medical Boards (FSMB) there is a specific term used with reference to "a state of biologic adaptation evidenced by a withdrawal syndrome when the drug is abruptly discontinued." What is the specific term that is defined by this language?
   a. Addiction.
   b. Dependence.
   c. Tolerance.
   d. Abuse.

7. Who was the first United States President to declare war on drugs?
   a. Johnson.
   b. Nixon.
   c. Kennedy.
   d. Clinton.

8. In what year did the Joint Commission on Accreditation of Healthcare Organizations (now the Joint Commission) establish expansive standards for the assessment and treatment of pain?
   a. 2000.
   b. 2005.
   c. 2010.
   d. 2015.

9. What DEA controlled substance prescription rule was of concern in the case of United States v. Joseph?
   a. Pre-signed prescriptions.
   b. Undated prescriptions.
   c. Omitted strength in prescriptions.
   d. Missed drug-drug interactions.

10. Under what circumstances is it advisable for a pharmacist, without legal representation, to invite the DEA into a practice site for a "tell all" clarification when it is known that the DEA is conducting an investigation?
    a. The facts clearly establish that no rules have been violated.
    b. The rule violations are of a trivial nature.
    c. Personnel who committed violations have been terminated from employment.
    d. None of the above.