

Controlled Substances

Tough Work, Vital Mission The Facts About DEA



- 1. Regulated by the DEA under the Controlled Substances Act, 21 USC sections 801, et. seq. and 21 C.F.R., sections 1300-1316.
- Regulated by the Attorney General and law enforcement officers under Chapter 893 (part of criminal code) of Florida Statutes.
 - ✓ FL. Statutes 456.44 (prescribing).
- Goal: closed system for making, distributing and dispensing.
- 4. Key source of information=Practitioner's Manual.

http://www.deadiversion.usdoj.gov/pubs/manuals/pract

- 5. Another key source of information is DEA website: www.usdoj.gov/dea
- 6. For a listing of Controlled Substances:

http://www.deadiversion.usdoj.gov/schedules/index.html

Controlled Substances (cont.)

- All states have laws on CS as well (police power) (FS, Chapter 893).
- 8. All states have schedules (FS 893.03).
- 9. CSA justified by Commerce clause (*Lopez*).
- 10. Always follow the stricter law to be safe:
 - Dispensing medical marijuana in CA or CO still violates federal law (although present admin does not enforce (Gonzales v. Raich);
 - b. In case of stricter law on certain amphetamines, e.g., in NJ, state law should be followed (*Lemmon Company*).
 - c. Rohypnol: Schedule IV under CSA; Schedule I in Florida.

Controlled Substances (cont.)

- 11. Morbidity/mortality statistics
 - a. In 2015, the five states with the highest rates of death due to drug overdose were West Virginia (41.5 per 100,000), New Hampshire (34.3 per 100,000), Kentucky (29.9 per 100,000), Ohio (29.9 per 100,000), and Rhode Island (28.2 per 100,000).
 - b. Significant increases in drug overdose death rates from 2014 to 2015 were primarily seen in the Northeast and South Census Regions, including Florida.
 - c. In 2014, there were 19K deaths relating to prescription pain killers.
 - d. Prescription drug abuse = fastest growing drug issue in the U.S.

https://www.deadiversion.usdoj.gov/mtgs/pharm_awareness/conf_2016/march_2016/carter.pdf https://www.cdc.gov/drugoverdose/data/statedeaths.html

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Classification of Controlled Substances

- First—narcotic v. non-narcotic:
 - a. Narcotics are natural or synthetic opioid drugs;
 - b. Derived from the Asian poppy Palaver somniferous;
 - c. E.G., poppy straw or ecgonine; with
 - d. Latin derivation—to sleep.
- 2. The Schedules I-V, descending order of:
 - a. Potential for abuse;
 - b. Accepted medical use; and
 - c. Levels of harm/possibility of dependence.
 - 21 C.F.R. 1308.11-1308.15

CS Classifications (cont.) 3. Schedule I—research only. a. Have high potential for abuse; b. No currently accepted medical use; c. No confirmed safe use; d. Cannot be prescribed or dispensed; e. Many opiates; f. Hallucinogens, e.g. marijuana, LSD, peyote; and g. GHB products not approved by the FDA.

CS Classifications (cont.)

- 4. Schedule II:
 - a. Have a high potential for abuse.
 - b. Have accepted medical uses, albeit w/ severe restrictions.
 - Abuse can lead to severe physical or psychological dependence.
 - d. Narcotics: codeine, morphine, oxycodone, fentanyl or methadone.
 - e. Stimulants: amphetamine, Adderall.
 - f. Depressants: amobarbital, phencyclidine.
 - g. Hydrocodone combination products moved from Schedule III to Schedule II, e.g., Vicodin.

C.S. Classifications (cont.)

- 5. Schedule III:
 - a. Have some potential for abuse, but less than C-I or II.
 - b. Have currently accepted medical uses.
 - c. When abused can lead to moderate –low physical or high psychological dependence.
 - d. May have C-II active ingredients but are compounded or in small enough doses so as not to have a C-II abuse threat.
 - e. Examples of Schedule III narcotics include: products containing not more than 90 milligrams of codeine per dosage unit (Tylenol with Codeine®), and buprenorphine (Suboxone®).
 - f. Examples of Schedule III non-narcotics include: benzphetamine (Didrex®), phendimetrazine, ketamine, and anabolic steroids such as Depo®-Testosterone.

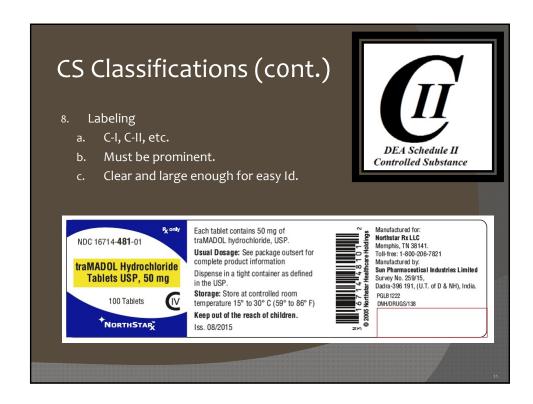
CS Classifications (cont.)

- 6. Schedule IV:
 - a. Have a lower potential for abuse than C-III.
 - b. Have currently accepted medical uses.
 - c. Abuse may lead to limited physical/psychological dependence.
 - d. Examples of Schedule IV substances include: alprazolam (Xanax®), clonazepam (Klonopin®), clorazepate (Tranxene®), diazepam (Valium®), lorazepam (Ativan®), midazolam (Versed®), temazepam (Restoril®), and triazolam (Halcion®).
 - e. Tramadol (Ultram, Ultram ER, Conzip) = recent addition.

CS Classifications (cont.)

- 7. Schedule V:
 - a. Have a low potential for abuse relative to other scheduled drugs.
 - b. Have currently accepted medical uses.
 - c. When abused, may lead to limited physical/psychological abuse.
 - d. Some may not even be Rx.
 - e. Examples of Schedule V substances include: cough preparations containing not more than 200 milligrams of codeine per 100 milliliters or per 100 grams (Robitussin AC®, Phenergan with Codeine®), and ezogabine.

http://www.deadiversion.usdoj.gov/schedules/index.html



CS Registration

- 1. Everyone who handles controlled substances must be registered or exempt from registration.
- 2. Reg. is by category; here="Practitioner".
- 3. Form 224 for a Practitioner; 224a for renewal.
- 4. Can be done on line: www.deadiversion.usdoj.gov; Appendix H of the Manual.
- 5. Certificate of registration is Form 223: must be maintained at the practice location.
- 6. If dispensing is at multiple locations, must have registration for each.
- 7. Need separate registration if distributing to other Practitioners (no more than 5% of dispensed volume).

CS Registration (cont.)

- 8. Can use a health care facility # if only dealing w/ CS w/i the scope of employment of the health care facility.
- Must notify DEA of any change of address and request an amended registration.
- 10. If moving to another state, must secure licensure in new state.
- 11. Must also notify DEA of any practice terminations:
 - ✓ Certificate must be returned and
 - ✓ Any unused 222 forms must be returned.

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CS Registration (cont.)

- 12. Effective January 1, 2017:
 - DEA will only send out one renewal notification letter, by mail, approximately 65 days prior to the expiration date.
 The letter will be sent to the "mail to" address for each DEA registrant.
 - b. Failure to renew prior to the expiration date will result in the original DEA registration not being reinstated.
 - c. DEA's notice also clarifies that, as of January 1, 2017, renewal applicants will need to apply for new DEA registration if attempting to renew after the expiration date or if DEA has not received paper renewal applications by the day of expiration.
 - d. Prescriptions written and dispensed for controlled substances by registrants whose license has expired will be implicated. http://www.pharmacist.com/article/updated-new-dea-registration-requirements january.

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Denial, Suspension or Revocation of CS Registration

- 1. Attorney General can deny a application for registration.
- 2. Must be "in the public interest" (21 USC 823):
 - a. Recommendation of state licensing board;
 - b. Applicant's experience;
 - c. Applicant's conviction record, if any;
 - d. Applicant's record of legal compliance; or
 - e. Any other conduct of applicant relevant to or impacting public health and safety.

Denial, Suspension or Revocation of CS Registration (cont.)

- 3. Automatic DEA knockout factors:
 - a. Falsification of application;
 - b. Felony conviction related to CS;
 - c. Suspension, revocation or denial of a state license;
 - d. Exclusion from Medicare or Medicaid;
 - ✓ Fraud and Abuse issues or
 - e. Commission of acts that would make registration "inconsistent with the public interest."

21 USC 824

CSA Security Requirements

- Applicants and registrants under the CSA must have effective controls and procedures to guard against theft or diversion of any controlled substances which they maintain.
- 2. Required controls depend on type, form and quantity of CS's; location; personnel involved; facility characteristics; and availability of police.
- 3. Highest level for Schedule I.
- 4. Etorphine hydrchloride (M99) (1K + x morphine) & diprenorphine must be kept in a Class V security container (750 pounds/bolted to the floor).
 IN STOCK NOW

CSA Security Requirements (cont.)

- 5. Cannot employ persons whose applications for registration have been denied, revoked or surrendered or who have been convicted of a felony related to CS.
- 6. Must minimize # of script pads and keep them in a safe place.
- 7. Write out the actual amount prescribed so as to prevent alteration.
- 8. Do not use prescription blanks for notes.
- 9. Never sign blanks in advance.
- 10. Have good communication w/ pharmacists.
- 11. Contact DEA regarding suspicious activity.
- 12. Use tamper-resistant prescription pads (required in FL).

CS Record Keeping Rules

- 1. Must keep records of all transactions and do inventories.
- 2. Keep C-I and II records separate; C-III-V can be kept on their own or with other records so long as they are readily retrievable.
- 3. Records must be kept of dispensing.
- 4. Records must be kept of administration if that is a regular part of the practice.
- 5. Records must be kept of detoxification administrations.
- 6. Records must be kept two years.
- 7. Must keep inventory records if one is maintained.

CS Recording Keeping Rules (cont.)

- 8. Must take an inventory every two years:
 - a. When taken (start or end of business day);
 - b. Names of all CS;
 - c. Forms of all CS;
 - d. Number of dosage units of each form;
 - e. Number of commercial containers; and
 - f. Ultimate disposition of all drugs.
- 9. Penalties:
 - a. Registrants held to a "complete and accurate" standard.
 - Negligence in keeping records = finable conduct: 10K per.
 - c. Intentional failure= a crime.
 - d. Defects can create an inference of diversion.

CS Prescriptions

- 1. Two key requirements:
 - ✓ Legitimate medical purpose and
 - ✓ In the usual course of professional practice. Plus:
 - ✓ State requirements for history and physical.
- 2. Can only be issued by those authorized by the state and registered w/ the DEA (or those properly using a health care facility registration).

CS Prescriptions (cont.)

- 3. Special rules on C-II's:
 - a. No refills!
 - b. Scripts generally must be written.
 - c. Writing can be waived in emergencies but may only authorize an amount limited to the time of the emergency; written follow up in 7 days (If not, pharmacist must notify law enforcement).
 - d. May have multiple scripts at the same time for up to a 90 day supply (special medical need and judgment required).
 - e. May be done by fax if original is received prior to dispensing; fax alone only for:
 - i. Direct administration or
 - ii. Residents of LTCFs/hospices.

CS Prescriptions (cont.)

- 4. Schedule III-V:
 - a. Must be by authorized practitioner (check state rules).
 - b. Schedule III and IV may be refilled up to 5 times in 6 months; no limit on C-V refills.
 - May be transmitted to dispenser orally, in writing or by fax.
 - d. May not be outside of US.
- Note: physicians and pharmacists face corresponding liability for CS violations.

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Addiction Treatment Programs

- Must have an opioid treatment facility and must have separate DEA registration (Form 363) if C-II's are involved (methadone/LAAM).
- 2. Also subject to jurisdiction of the Substance Abuse and Mental Health Services Administration (part of HHS).
 - ✓ Maintains listing of approved referral sites
- 3. Can do in office program w/ DEA approval and a separate #, but only w/ a limited C-III formulary (buprenorphine products) and a limited # of patients (DATA).

www.csat.samha.gov

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Addiction Treatment Programs (cont.)

- 4. Pain Treatment distinguished
 - Maintenance and detoxification limited by law to OTPs and DATA treatments.
 - b. May treat pain w/ narcotics indefinitely where pain is intractable and there is no other viable option.
 - c. Gradually withdrawing pain patient from dependence is legitimate.
 - d. Physician can administer three days' dosage to an addict for acute withdrawal symptoms .
 - e. Hospitalized patients may be treated for conditions other than addiction w/ narcotics.
 - f. Florida has specific provisions on pain treatment.

Addiction Treatment Programs (cont.)

- 5. Diagnosing dependence (DSM Criteria):
 - Tolerance the substance has less effect on the patient because their body has developed tolerance. They need more and more of it for satisfaction.
 - b. There are physical/psychological withdrawal symptoms, or the patient takes the substance to avoid experiencing withdrawal, or the patient takes a similar substance to avoid experiencing withdrawal.
 - The patient frequently takes higher-than-intended doses of the substance.
 - d. The patient often tries to quit or cut down.
 - e. More and more time is spent getting hold of the substance, using it, or recovering from its effects.
 - f. The patient's drug use causes him/her to give up social, occupational or recreational activities.
 - g. Even though patients know it causes psychological/physical problems, they continue taking it.

CSA Offenses/Penalties

- 1. Penalties graduated:
 - ✓ Nature of activity;
 - √ What is involved (product/guns/violence);
 - ✓ How much;
 - ✓ Prior record;
 - ✓ Where did the offense occur (Florida add on); and
 - ✓ Death/serious injury to patient or others.
- 2. Section 841 of the CSA:
 - a. Drug trafficking;
 - b. Counterfeiting; or
 - c. Dispensing outside of professional practice prohibited.
 - d. Max penalties: 10 years to life as a guest of the state and 4M in penalties.

CSA Penalties (cont.)

- 3. Section 842:
 - a. Record keeping and procedural violations.
 - b. Minimum violations raised from strict liability to negligence (civil offense).
 - c. Knowing/intentional offenses are criminal.
- 4. Section 843-criminal violation to distribute C-I or II w/o Form 222 knowingly or intentionally (4 yrs./30K).
- 5. Section 844—Intentional or knowing unauthorized possession of CS is criminal; special penalties for cocaine.
- 6. Section 846--Attempts or conspiracies of the above are also illegal.

Other Laws Related to Controlled Substances

- 1. The Controlled Substance Registrant Protection Act of 1984—adds federal investigation, sanction and penalties to those committing crimes against CS registrants (\$500 threshold).
- The Chemical Diversion and Trafficking Act of 1988—places under federal jurisdiction and control 20 chemical and drug making machines (includes ephedrine).
- 3. Anabolic Steroids Act of 2004:
 - a. Criminalizes the distribution or possession of steroids other than for use for the treatment of disease per a prescription.
 - b. Maintains steroids as C-III (note: C-II in NY).
 - c. Expands the list of steroids by more than 100% and includes precursors, salts and esters.

Other Laws Related to Controlled Substances (cont.)

- 4. The Combat Methamphetamine Epidemic Act of 2005:
 - a. Creates category of drugs known as "scheduled listed chemical products".
 - b. Targets substances used to make meth.
 - c. Covers any product containing ephedrine, pseudoephedrine or phenylpropanolamine (PPA).
 - d. Limits sale of the covered products to 3.6 grams per person per day or 9 grams in a month.
 - e. Covered products must be behind the counter or in a locked cabinet.
 - f. Dispensers must record all sales over 60 mg.

Florida CS Rules

- Key law: Florida: Drug Prevention and Control Act, Chapter 893, sections 893.01-893.21 (Schedules at 893.03).
- 2. Selected prescription rules (893.02):
 - a. CS prescription cannot be issued on the same prescription blank with another prescription order for a controlled substance which is named in a different schedule.
 - b. CS prescriptions may not be issued on the same prescription blank as a prescription order for a medicinal drug, as defined in s. 465.003(8), which does not fall within the definition of a controlled substance as defined in this act.
 - c. 893.04—may not dispense more than a thirty day supply of C-III based on an oral prescription in Florida.
 - d. Effective 1/1/17, advanced registered nurse practitioners and physician assistants can prescribe controlled substances but not for more than seven days for C-II generally.

Florida CS Rules (cont.)

- Prescription Drug Monitoring Program (893.055)—gives access to information from dispensers (patient advisory reports") upon request on:
 - a. Prescriber w/ an identifier (DEA/NPI);
 - b. Date and method of payment;
 - c. Patient name, address and DOB;
 - d. CS name, codes, quantity and strength;
 - e. Full ID of pharmacy or other dispenser; and
 - f. "Other appropriate information".

Florida CS Rules (cont.)

- 3. Prescription Drug Monitoring Program (cont.):
 - g. Dispensers are to input the following data:
 - i. Name of prescriber with an identifier, e.g. DEA registration # or CMS NPI #;
 - ii. Date of the prescription;
 - iii. Method of payment;
 - iv. Name, address and DOB of patient;
 - v. Name, code, quantity and strength of the drug;
 - vi. Name, registration # and address of the pharmacy;
 - vii. The name of the persons who actually dispenses the drug; and
 - viii. Other "appropriate" information.

Florida CS Rules (cont.)

- Florida PDMP (cont.):
 - h. Exemptions:
 - i. One time direct administration to a patient;
 - ii. Administration to a patient at a hospital, nursing home, ambulatory surgical center, hospice or ICF for the developmentally disabled;
 - iii. Department of Correction dispensing;
 - iv. ER dispensing;
 - v. HCP dispensing to a child under the age of 16; or
 - vi. Dispensing of a one time 72 hour emergency resupply.

http://www.hidinc.com/flpdmp

Florida CS Rules (cont.)

- 4. 893.065—Counterfeit resistant prescription "blanks":
 - a. Must be used for all C-II-V scripts;
 - b. Distinctive, watermarked paper; with
 - c. Preprinted identifiers of prescriber.
- 5. Health code rule on CS prescriptions (456.44):
 - a. Must take history and do complete PE;
 - b. Must have a written plan that, inter alia, assesses a patient's risk of aberrant drug behavior;
 - c. Must discuss risks/benefits of CS w/ patients;

Florida CS rules (cont.)

- 5. Section 456.44 (cont.)
 - d. Must have written agreement w/ patient as to CS use;
 - e. Must have follow up visits not to exceed three months apart;
 - f. Must refer patients when necessary to achieve treatment goals (e.g., to a board certified pain management physician or an addiction specialist); and
 - g. Must make a complete record of the patient, especially as to pain, e.g.:
 - i. All above elements documented;
 - ii. All test results, including drug tests;
 - iii. All treatments and prescriptions; and
 - iv. A photocopy of a government issued photo id of the patient.

Florida CS Rules (cont.)

- 6. Compassionate Use Statute
 - a. Physicians who have examined and are treating a patient (who is a resident) suffering from cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms may order for the patient's medical use low-THC cannabis to treat such disease, disorder, or condition or to alleviate symptoms of such disease, disorder, or condition, if no other satisfactory alternative treatment options exist.
 - b. Must be a detailed treatment plan, documentation and informed consent
 - c. The term cannabis was amended so that it does not include "low-THC cannabis," as defined in the Compassionate Use law, if manufactured, possessed, sold, purchased, delivered, distributed, or dispensed, in conformance with the law.

FL CS Rules (cont.)

- 7. Emergency Treatment for Suspected Opioid Overdose (FS 381. 887; 2015).
 - An authorized health care practitioner may prescribe and dispense an emergency opioid antagonist (naloxone) to a patient or caregiver.
 - b. A patient or caregiver is authorized to store and possess approved emergency opioid antagonists and, in an emergency situation when a physician is not immediately available, administer the emergency opioid antagonist to a person believed in good faith to be experiencing an opioid overdose, regardless of whether that person has a prescription for an emergency opioid antagonist.
 - Emergency responders are also allowed to possess and administer emergency opioid antagonists as clinically indicated.

FL CS Rules (cont.)

- 7. Emergency Treatment Law (cont.):
 - d. Law contains an immunity provision from civil liability and professional discipline for health care practitioners and does not limit other immunity provisions; e.g., such as that in the 911 Good Samaritan Act.

http://www.drugfreemanatee.org/

FL CS Rules (cont.)

- 8. Amendment 2:
 - a. Allows medical use of marijuana for individuals with debilitating medical conditions as determined by a licensed Florida physician.
 - b. A physician shall not be subject to criminal or civil liability or sanctions under Florida law solely for issuing a physician certification with reasonable care to a person diagnosed with a debilitating medical condition in compliance with this section.
 - c. Debilitating Medical Condition" means cancer, epilepsy, glaucoma, positive status for human immunodeficiency virus (HIV), acquired immune deficiency syndrome (AIDS), post-traumatic stress disorder (PTSD), amyotrophic lateral sclerosis (ALS), Crohn's disease, Parkinson's disease, multiple sclerosis, or other debilitating medical conditions of the same kind or class as or comparable to those enumerated, and for which a physician believes that the medical use of marijuana would likely outweigh the potential health risks for a patient.
 - d. Cannot use in telemedicine.

FL CS Rules (cont.)

- 8. Amendment 2 (cont.):
 - e. "Physician certification" means:
 - A written document signed by a physician, stating that in the physician's professional opinion, the patient suffers from a debilitating medical condition,
 - ii. that the medical use of marijuana would likely outweigh the potential health risks for the patient, and
 - iii. for how long the physician recommends the medical use of marijuana for the patient.
 - iv. A physician certification may only be provided after the physician has conducted a physical examination and a full assessment of the medical history of the patient.
 - v. In order for a physician certification to be issued to a minor, a parent or legal guardian of the minor must consent in writing.

Florida Criminal Drug Offenses 893.13, 893.135

- Improper (unregistered/unlicensed) sale, manufacture, delivery or possession of controlled substances or intent to do
- 2. Unauthorized sale, manufacture, delivery, possession or intent to do any of these:
 - Within 1K feet of a child care facility, park, community center, rec. center or school (between 6 am & midnight);
 - Within 1k feet of a postsecondary educational institution;
 - Within 1k feet of a place of worship;
 - Within 1k feet of a public housing facility; and
 - > Within 1k feet of an assisted living facility.

Florida Criminal Drug Offenses 893.13, 893.135 (cont.)

- 3. Sale or delivery of Schedule I substances in excess of 10 grams.
- 4. Manufacturing methamphetamine or phencyclidine.
- Unauthorized purchasing or intent to purchase controlled substances.
- 6. Unauthorized delivery of CS by an adult to a child.
- 7. Unauthorized importation into the state of CS.
- 8. Trafficking (improper purchase, sale or delivery) in C-Is or C-IIs.
- 9. Violation of 456.44 (6 mo. suspension; 10k fine minimum).
- Additional penalties whenever a violation results in a killing or an natural but not inevitable lethal result; max. penalty = death.
- Homicide occurring in connection w/ CS violation = felony murder.
- 12. Death due to overprescribing = manslaughter.

Selected Florida Criminal Drug Cases vs. Physicians

- DO, of Gulfport, FL, pled guilty in the Circuit Court in Pinellas County, Florida to three counts of Trafficking in Illegal Drugs (Oxycodone) and one count Trafficking in Amphetamine. He was sentenced to 17 years in prison and ordered to pay a fine of \$50,000. DEA registration and DO license revoked.
- 2. Miami, MD pled guilty in federal court to one count of conspiracy to distribute Schedule III and Schedule IV controlled substances, and one count of conspiracy to launder money. He was sentenced to probation for a term of three (3) years with the first six months in home detention and ordered to pay a fine of \$10,000 and a special assessment of \$200.00. He was "retired" from the profession.

Selected Florida Criminal Drug Cases vs. Physicians

- 4. West Palm Beach MD pleaded guilty to two counts of manslaughter and one count of conspiracy to traffic oxycodone after two of his patients died from prescribed medications. He faces up to five years in prison, under the terms of the plea, according to the State Attorney's Office. He also agreed to never practice medicine again.
- 5. Tampa, MD pled guilty in U.S. District Court to one count charging dispensing and distributing controlled substances, namely: Oxycodone, Hydrocodone, and Alprazolam, outside the scope of professional practice. He was found to be prescribing more medication than the patient could safely ingest, by failing to adequately inquire of the patient's medical condition or complaints and by failing to conduct the appropriate physical examination. He got off with probation and fines, but he does have to find a new occupation.

https://www.deadiversion.usdoj.gov/crim_admin_actions/doctors_criminal_cases.pdf

Controlled Substance Cases (cont.)

- 5. State vs. Gonzalez, __ So. 3d __, 38 F.L.W. D1831 (4th DCA 8/28/2013):
 - a. The state may prosecute a doctor who wrote prescriptions in bad faith under sec 893.135, for trafficking in controlled substances, and is not limited to charging crimes under sec 893.13(8), which is limited to prescribing practitioners.
 - b. The plain language of sec 893.135(1) allows charges to be filed without regard for the crimes set out in sec. 893.13.
 - When two statutes govern a person's conduct, the state has the authority to decide whether and how to charge the defendant.

http://floridacriminallawreport.com/tag/crimes-controlled-substances/

