PAIN MANAGEMENT, OPIOID PRESCRIBING AND DISPENSING, AND RISK MITIGATION

ATTORNEY-CLIENT PRIVILEGED / CONFIDENTIAL / WORK PRODUCT

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BY THE NUMBERS

Annual

$55 billion in healthcare and social costs

$20 billion in emergency and inpatient care.

Per Day

650,000+ opioid prescriptions

3,900 initiate nonmedical use of Rx Opioids

580 initiate heroin use

78 die in opioid-related overdose (more than car crashes)

Stats:

US Consumes 90% of world's opiates

1/3 of all opioid prescriptions are being abused (castlight health)

CHALLENGES

Who Should Treat Pain

Primary Care?	Orthopedists?	Pain Management?	Chiropractors?	Anesthesiologists?
Physiatrists?	Neurologists?	Physical Therapists	Nurses?	PAs?

What is Pain?

pān/

Noun

1.physical suffering or discomfort caused by illness or injury.

"she's **in** great **pain**"

“TREATING” PATIENTS

Don’t Treat?

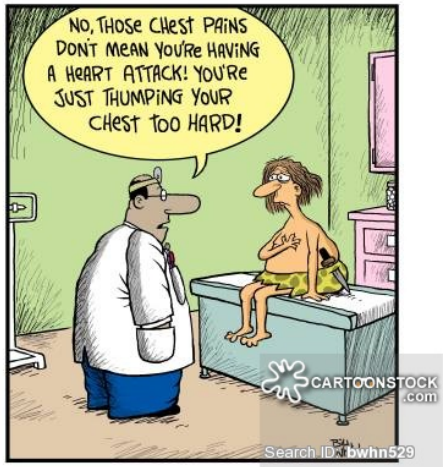
“Withholding Treatment”

- Pain and Suffering (1991: $15mm; 2001: $1.5 mm) “Compassion in Dying”
- Terminating Patient vs. “Patient Abandonment”

  Can you “terminate?” (ACOs, CINs, Etc.)
- Patient Satisfaction
- Social Media

SHARED-SAVINGS OPPORTUNITIES

*$20 billion annually in Opiate emergency department and inpatient care



THE GOVERNMENT

Focusing on poor record-keeping/ documentation

- Patient Contracts (Agreement to see one physician for pain, drug-testing)

Government Sending Fake Patients to Practices (Security Risk Analysis)

- "Fake" Patient brought an x-ray of a dog, still received opiates
- Negative Urine

31 Doctors Sanctioned in NJ for over-prescribing in 2016.

Take Steps to Avoid Scrutiny and Protect Your Practice

CDC GUIDELINES ON PAIN MANAGEMENT

Determining when to initiate or continue opioids for chronic pain

- Selection of non-pharmacologic therapy, non-opioid pharmacologic therapy, opioid therapy
- Establishment of treatment goals
- Discussion of risks and benefits of therapy with patients

Opioid selection, dosage, duration, follow-up and discontinuation

- Selection of immediate-release or extended-release and long-acting opioids
- Dosage considerations
- Duration of treatment
- Considerations for follow-up and discontinuation of opioid therapy

Assessing risk and addressing harms of opioid use

- Evaluation of risk factors for opioid-related harms and ways to mitigate/reduce patient risk
- Review of prescription drug monitoring program (PDMP) data
- Use of urine drug testing
- Considerations for co-prescribing benzodiazepines
- Arrangement of treatment for opioid use disorder

NEW JERSEY OVERDOSE PREVENTION ACT

On May 2, 2013, Governor Christie signed into law the "Overdose Prevention Act“

The Overdose Prevention Act specifically provides that when a person, in good faith, seeks medical assistance for a person believed to be experiencing a drug overdose, whether the person is seeking assistance for him/herself or for another, the person calling for help and the person experiencing the overdose shall not be arrested, charged, prosecuted, or convicted for certain specified criminal offenses. The specified crimes and offenses are as follows:

1. obtaining, possessing, using, being under the influence, or failing to make lawful disposition of any controlled dangerous substance or analog in violation of subsection a., b., or c. of N.J.S.A. 2C:35-10;
2. inhaling the fumes or possessing a toxic chemical in violation of subsection b. of N.J.S.A. 2C:35-10.4;
3. using, obtaining, attempting to obtain, or possessing any prescription legend drug or stramonium preparation in violation of subsection b., d., ore. ofN.J.S.A. 2C:35-l 0.5;
4. acquiring or obtaining a controlled dangerous substance or analog by fraud in violation ofN.J.S.A. 2C:35-13;
5. unlawfully possessing a controlled dangerous substance that was lawfully prescribed or dispensed in violation ofN.J.S.A. 2C:35-24; and
6. using or possessing with intent to use drug paraphernalia in violation of N.J.S.A. 2C:36-2, or having under control or possessing a hypodermic syringe or other instrument for using a controlled dangerous substance or analog in violation of subsection a. of N.J.S.A. 2C:36-6.

NEW JERSEY OPIOID OVERDOSE PREVENTION 2017

A practitioner shall not issue an initial prescription for an opioid drug which is a prescription drug in a quantity exceeding a five-day supply for treatment of acute pain.

A health care professional authorized to issue prescriptions shall, prior to issuing a prescription for an opioid drug which is a Schedule II controlled dangerous substance, discuss with a patient who is under 18 years of age and is an emancipated minor, or with the patient's parent or guardian if the patient is under 18 years of age and is not an emancipated minor, the risks of developing a physical or psychological dependence on the controlled dangerous substance or prescription opioid drug and, if the prescriber deems it appropriate, such alternative treatments as may be available.

NALOXONE

"...Naloxone is an inexpensive and easily administered antidote to an opioid overdose. Encouraging the wider prescription and distribution of naloxone or similarly acting drugs to those at risk for an opioid overdose, or to members of their families or peers, would reduce the number of opioid overdose deaths and be in the best interests of the citizens of this State [New Jersey]..."

N.J. Stat. Ann. § 24:6J-2

Any prescriber or other health care practitioner who prescribes or dispenses an opioid antidote in good faith, and in accordance with the provisions of this subsection, shall not, as a result of the practitioner's acts or omissions, be subject to any criminal or civil liability, or any professional disciplinary action under Title 45 of the Revised Statutes for prescribing or dispensing an opioid antidote in accordance with P.L.2013, c. 46 (C.24:6J-1 et seq.).

N.J. Stat. Ann. § 24:6J-4

PHYSICIAN PRESCRIBING OF NALOXONE

A prescriber or other health care practitioner who prescribes or dispenses an opioid antidote in accordance with subsection a. of section 4 of P.L.2013, c. 46 (C.24:6J-4), shall ensure that overdose prevention information is provided to the antidote recipient. The requisite overdose prevention information shall include, but is not limited to: information on opioid overdose prevention and recognition; instructions on how to perform rescue breathing and resuscitation; information on opioid antidote dosage and instructions on opioid antidote administration; information describing the importance of calling 911 emergency telephone service for assistance with an opioid overdose; and instructions for appropriate care of an overdose victim after administration of the opioid antidote.

N.J. Stat. Ann. § 24:6J-5

NALOXONE STANDING ORDERS

A non-patient specific prescription—or standing order—is a signed and dated document issued by a prescriber to direct the dispensing of a prescribed drug to an individual not specifically identified at the time of its issuance.

The following elements should be included: (i) indication that the naloxone was dispensed pursuant to a non-patient specific prescription; (ii) the name of the prescriber; (iii) the opioid antagonist being prescribed, including the route of administration and dosing; (iv) the date of the dispensing or furnishing; and (v) identification of the group of trained overdose responders who may have access to the naloxone under the prescription, where applicable.

TIRF-REMS

Risk Evaluation and Mitigation Strategy (REMS) Access Program

Because of the risk for misuse, abuse, addiction, and overdose, Transmucosal Immediate Release Fentanyl (TIRF) is available only through a restricted program required by the Food and Drug Administration, called a Risk Evaluation and Mitigation Strategy (REMS). Under the Transmucosal Immediate Release Fentanyl (TIRF) REMS Access program, outpatients, healthcare professionals who prescribe to outpatients, pharmacies, and distributors must enroll in the program.

TIRF is indicated for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.

Patients considered opioid tolerant are those who are taking for one week or longer, around-the-clock medicine consisting of at least 60 mg of oral morphine per day, at least 25 mcg of transdermal fentanyl per hour, at least 30 mg of oral oxycodone per day, at least 8 mg of oral hydromorphone per day, or at least 25 mg oral oxymorphone per day, or at least 60mg oral hydrocodone per day, or an equianalgesic dose of another opioid daily for a week or longer. Patients must remain on around-the-clock opioids when taking TIRF.

TIRF-REMS – GOVERNMENT INVESTIGATIONS

Seeking Victims in the Subsys Medication Case

The FBI is seeking victims who may have been prescribed the fentanyl-based pain medication Subsys, a powerful narcotic intended to treat cancer patients suffering intense episodes of breakthrough pain, between March 2012 and December 2016.

On December 8, 2016, several pharmaceutical executives and managers formerly employed by Insys Therapeutics, Inc., were arrested on charges that they led a nationwide conspiracy to bribe medical practitioners in various states, many of whom operated pain clinics, to get them to prescribe Subsys. In exchange for bribes and kickbacks, the practitioners wrote large numbers of prescriptions for their patients, most of whom were not diagnosed with cancer.

The indictment also alleges that the now former corporate executives charged in the case conspired to mislead and defraud health insurance providers who were reluctant to approve payment for the drug when it was prescribed for non-cancer patients. To achieve this goal, it is alleged that the defendants set up a "reimbursement unit" which was dedicated to obtaining prior authorization directly from insurers and pharmacy benefit managers.

TIRF-REMS – GOVERNMENT INVESTIGATIONS

CONSUMER ALERT

Attorney General and Division of Consumer Affairs Warn the Public About the Dangers in Using the Highly Potent Fentanyl Spray “Subsys” Outside Its Approved Use to Treat Cancer Pain

New Jersey Board of Medical Examiners Permanently Revokes License of Middlesex Doctor for Indiscriminately Prescribing “Subsys,” A Highly-Restricted Spray Form of Painkiller Fentanyl to His Patients

New Jersey Board of Medical Examiners Temporarily Suspends License of Camden County Doctor Amid Allegations She Indiscriminately Prescribed Painkiller "Subsys," to Patients, Including One That Died

NEGLIGENCE

If 1/3 of all opioid prescriptions are being abused, are 1/3 of opioid prescriptions negligent?

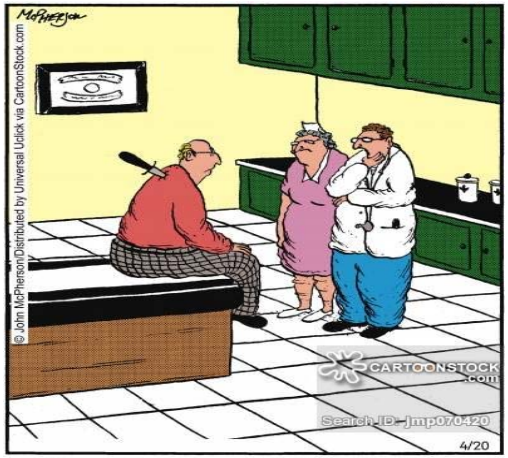
Breach of Duty?

Causation: Did negligent prescribing lead to addiction?

Damages……

Lost Income Cost of Treatment Pain and Suffering

Sympathetic Jurors: “You made me an addict”



"You say it's a sharp, stabbing pain. Hmmmm ... sharp ... stabbing pain."

OTHER CHARGES

Drug-Induced Death/ Money Laundering:

March 2, 2017 A New Jersey family doctor has been indicted for illegally selling high-dose prescriptions of the painkiller oxycodone to known drug addicts and dealers, among other patients, one of whom fatally overdosed, state Attorney General Christopher S. Porrino said Thursday.

Strict liability for drug-induced death for allegedly prescribing the oxycodone that killed a 26-year-old man in Clifton.

The charges Kang faces are strict liability for first degree drug-induced death, first-degree money laundering, second degree conspiracy, second-degree unlawful distribution of oxycodone, third-degree unlawful distribution of oxycodone within 1,000 feet of a school, third-degree filing of a fraudulent state tax return, and third-degree failure to pay state income tax, Porrino said.

During a May 12 raid of the doctor's office, authorities found incomplete patient records that in most cases contained no plan of care for patients and no medical justification for prescribing them narcotics, along with "gross deviations" from medical standards, according to Porrino.

Murder:

Dr. Hsiu-Ying "Lisa" Tseng, who prosecutors say is the first doctor convicted of murder in the United States for recklessly prescribing drugs to patients, was accused of ignoring "red flags" about her prescribing habits, including the overdose of a patient in her clinic and nine phone calls in less than three years from authorities informing her that patients had died with drugs in their system.

Prescribing without "Good-Faith" Exams (Worthless Service?) -

Note: Intentional/ Criminal Acts are Typically Not Covered by Professional Liability Insurance

(Med Mal Requires Patient Care)

COMPREHENSIVE COMPLIANCE PLANNING

1. Implementation of written policies, procedures and standards of conduct;
2. Designation of a member to serve as compliance officer;
3. Effective training and education;
4. Enforcement of standards through disciplinary guidelines;
5. Internal monitoring and auditing; and
6. Prompt response to detected offenses and development of corrective action.

COMPREHENSIVE COMPLIANCE PLANNING

Ensure that alternative, non-opioid therapies, have been attempted and optimized prior to initiating any opioid therapy for chronic pain management and/or pain therapy.

Prescribers shall be made aware if the Practice's home state maintains a state prescription drug monitoring program (PDMP) or similar registry to gather information regarding the misuse of opioids.

PDMP sites or similar federal and state registries shall be queried prior to prescribing any opioid treatment plan in an attempt to identify patients that may have prescriptions from other providers that would preclude any further prescribing of opiates.

Prescribers shall set realistic goals for pain and function and discuss the risks and benefits of the opioid therapy with the patient. Prescribers shall obtain a written consent from the patient acknowledging that the patient was properly advised of the risks and benefits of the proposed therapy and requiring patient to comply with certain responsibilities and obligations

COMPREHENSIVE COMPLIANCE PLANNING

Prescribers shall conduct thorough examinations, run applicable labs, and conduct a urine drug screen prior to initiating any opioid therapy.

Prescribers shall assess baseline pain and function utilizing the PEG scale.

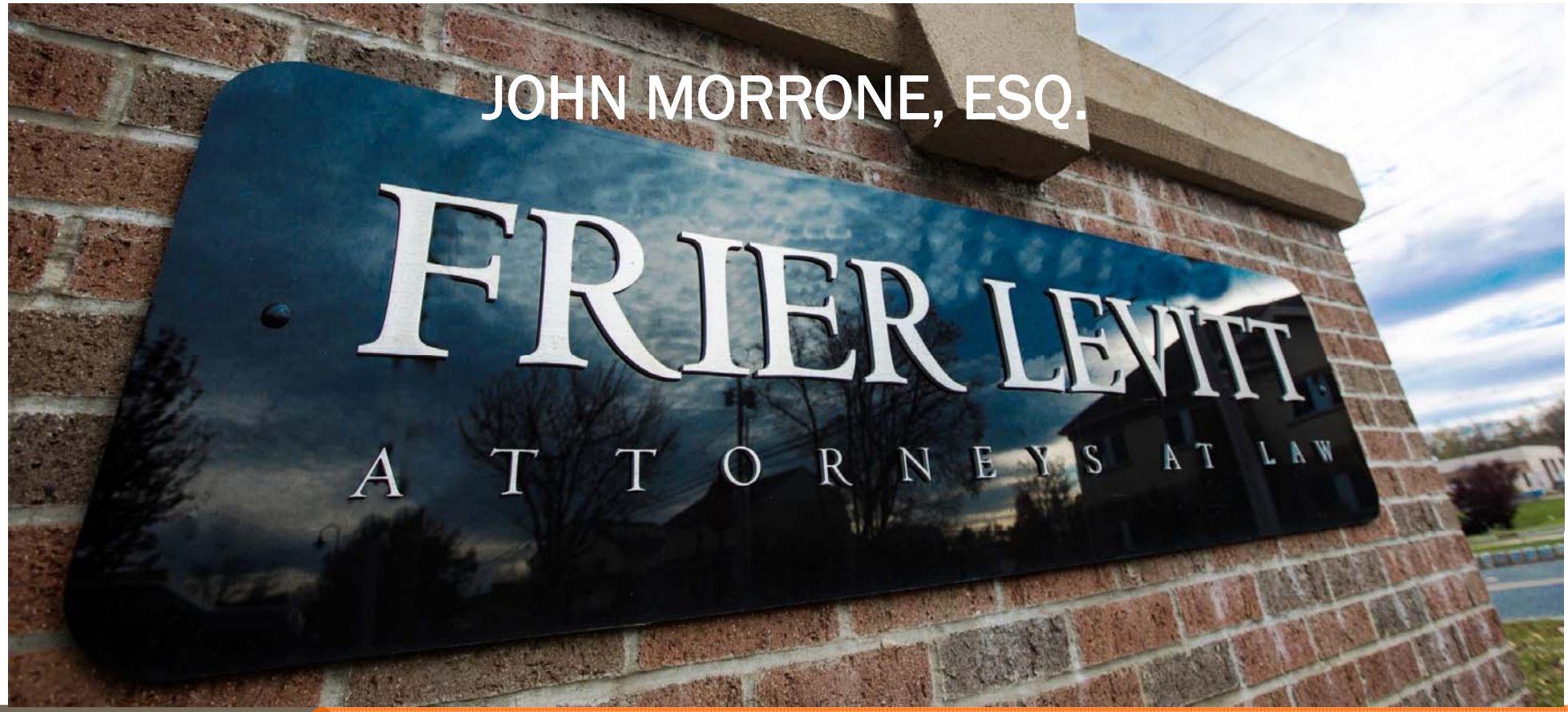
Prescribers shall be required to schedule an initial reassessment within 1-4 weeks of the initiation of the opioid therapy.

Prescribers shall endeavor to, first, prescribe short-acting opioids using lowest dosage on product labeling.

If renewing prescriptions without a patient visit, Prescribers shall confirm that a return visit is scheduled at least 3 months from the last visit.

When a patient arrives for a follow up visit, Prescribers shall confirm clinically meaningful improvements in pain and function without significant risks or harm prior to continuing the use of any opioids.

Prescribers shall endeavor to minimize the time period for which opioid therapy is utilized, minimizing or weaning from the use of such opioids at a clinically accepted rate and as deemed reasonable for a particular patient.



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