



OH SNAP

**LECOM 2017 Primary Care
CME Conference at Peek 'n Peak**

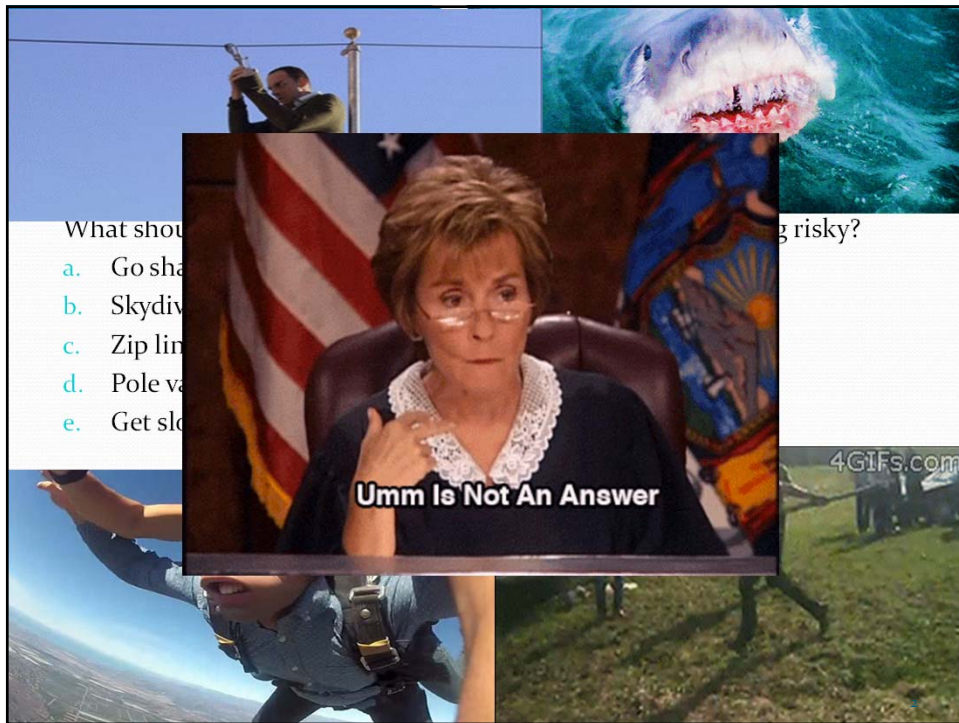
**THE FOUR CAUTIONS OF THE TRIAL
APOCALYPSE**

Richard E. Ferretti, Esq.
Jeffrey E. Myers, Esq.

I AM A DOCTOR NOT A CASE CITATION

imgflip.com

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What should I do?
a. Go shopping
b. Skydiving
c. Zip lining
d. Pole vaulting
e. Get sloped

g risky?

Umm Is Not An Answer

4GIFs.com



Drug Diversion

1. Federal Prohibitions (from the Controlled Substances Act):
 - a. Section 841 (21 USC 841):
 - i. Drug trafficking (commerce outside of the “closed system”); counterfeiting; or dispensing *outside* of professional practice;
 - ii. Max penalties: 10 years to life as a guest of the state and 4M in penalties.
 - b. Section 842: Record keeping and procedural violations:
 - i. Minimum violations changed from strict liability to negligence (civil offense);
 - ii. Knowing/intentional offenses are criminal.
 - c. Section 843—criminal violation to distribute C-I or II w/o Form 222 knowingly or intentionally (4 yrs./30K).
 - d. Section 844—Intentional or knowing unauthorized possession of CS is criminal; special penalties for cocaine.
 - e. Section 846--Attempts and conspiracies of the above are also illegal.

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Drug Diversion (cont.)

2. Typical State law prohibitions:
 - a. Sale or delivery of Schedule I substances outside of legitimate research activities.
 - b. Trafficking: improper purchase, sale, delivery, etc.
 - c. Refusal or failure to make and keep required forms and records.
 - d. Refusal to allow an authorized inspection.
 - e. Failure to use a Form 222 w/ C-I and II's.
 - f. Keep or maintain a building, vehicle, boat or aircraft which is used for improper keeping or selling of controlled substances.
 - g. Reveal or use for personal gain information obtained in enforcement of controlled substance laws.
 - h. Obtain or attempt to obtain controlled substances by fraud, forgery, deception or subterfuge.

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Drug Diversion (cont.)

2. State laws (cont.):
 - i. Affix a false or forged label to a controlled substance container.
 - j. Improperly acquire or store controlled substance precursors.
 - k. Failure to follow state prescription rules, including failure to use counterfeit proof prescription forms.
 - l. Prescribe in such quantities as to harm a patient.
3. Penalties graduated, based upon:
 - a. Nature of activity;
 - b. What is involved (product/guns/violence);
 - c. Quantity involved;
 - d. Harm inflicted; and
 - e. Prior record.

http://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf

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Drug Diversion (cont.)

4. DEA safeguards for Prescribers (Manual, Section III):
 - a. Follow corresponding liability doctrine in the dispensing controlled substances and assist pharmacists in ensuring the validity of all scripts.
 - b. Ensure all security controls for drugs kept at the practice site.
 - c. Keep all prescription blanks in a safe place where they cannot be stolen.
 - d. Minimize the number of prescription pads in use.
 - e. Write out the actual amount prescribed in addition to giving a number to discourage alterations of the prescription order.
 - f. Use prescription blanks only for writing a prescription order/not for notes.
 - g. Never sign prescription blanks in advance.
 - h. Contact the nearest DEA field office to obtain or to furnish information regarding suspicious prescription activities.
 - i. Use tamper-resistant prescription pads.

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Drug Diversion Cases

1. “The modern day case version of 19th century opium dens...” The charges (all 114 of them):
 - a. Issuing prescriptions for controlled substances to patients despite obvious indications that the patients were abusing the medications;
 - b. Falsifying completion of training requirements;
 - c. Signing blank prescriptions and directing and permitting others who were unqualified to fill out the remaining required information, such as name of patient, drug, and dosage;
 - d. Creating a telephonic patient prescription renewal process which allowed persons to obtain controlled substances prescriptions from unlicensed individuals;
 - e. Writing scripts w/o medical review; and
 - f. Prescribing a highly regulated controlled substance (buprenorphine) under the cover of pain management to circumvent federal regulations limiting the number of patients that any given doctor may treat (100 patients).

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Diversion Cases (cont.)

1. The “opium den” (cont.):
 - g. Drugs involved: fentanyl, oxycodone, morphine, and hydrocodone.
 - h. Penalties currently faced:
 - i. 20 years as a guest of the U.S.;
 - ii. 1M fine;
 - iii. State license revocation; and
 - iv. DEA registration cancellation.

<https://www.justice.gov/usao-wdny/pr/local-pain-doctor-named-114-count-indictment-accused-illegally-issuing-hundreds>

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Diversion Cases (cont.)



2. A “Choice” prosecution:
 - a. Choice Medical Services of Rocky Point N.Y. sued civilly in May by the DOJ as part of the government’s Prescription Drug Initiative. In 4 1/2 years the Initiative has led to over 160 prosecutions.
 - b. Among other things, a “sleep specialist” employed by Choice wrote almost 500,000 scripts for 30 mg. oxycodone in one 17 month period.
 - c. The government is seeking:
 - i. An injunction against Choice;
 - ii. Civil money penalties;
 - iii. Forfeiture of bank accounts as well as 13 piece of real estate;
 - iv. Bank accounts worth 400K; and
 - v. A Bentley and other vehicles of the clinic’s owner.

<https://www.justice.gov/usao-edny/pr/united-states-files-civil-complaint-seeking-injunctive-relief-penalties-and-forfeiture>

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Diversion Cases (cont.)

3. Bankrupt in almost every way.
 - a. Philly doc partnered w/ the Pagans Motorcycle Club to recruit fake patients to aid in the illicit distribution of oxycodone (380K pills) and methadone (160K pills).
 - b. Doc netted 2M in cash but as part of the cover-up of his nefarious scheme, he also fraudulently filed for bankruptcy.
 - c. He also used his own children to engage in money laundering.
 - d. Several of the recipients of the doctor’s drugs died from overdoses.
 - e. He was convicted on 123 (acquitted of four) felony counts.
 - f. Some of his confederates testified against him.
 - g. He is looking at 20 years to life; property forfeiture and millions in fines and penalties.

<https://www.justice.gov/usao-edpa/pr/jury-finds-philadelphia-doctor-guilty-running-pill-mill-and-causing-death-through>

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Mens rea

Amount

Fraud and Abuse

1. Mix of criminal, administrative and civil law; enforced at federal and state levels.
2. Key reference sources:
 - a. Federal HHS/Office of Inspector General.
 - b. State Medicaid Fraud Control Units (MFCU's).
3. Health Care Fraud Prevention and Enforcement Action Team (HEAT), created in 2009 to prevent fraud, waste and abuse in the Medicare and Medicaid programs. Recovery Audit Contractors (RACs) handle the civil side.
4. 3.3B recovered in FY 2014; 3.5 B in 2015 (as of 12/14/15). RAC findings: 2.39B in overpayments and 173M in underpayments in FY 2014. Civil penalties are increasing by 96% as of August 29, 2016.
5. 496 criminal prosecutions pending as of May 2016.
<http://www.hhs.gov/news/press/2015pres/03/20150319a.html>; Benesch Health Law.

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Fraud and Abuse (cont.)

6. Fraud: “intentional and knowing deception or misrepresentation with knowledge of possible unauthorized benefit...”
7. Abuse: “practices that are inconsistent with sound fiscal, business or medical practices that result in unnecessary costs or in reimbursement for services that are medically unnecessary or that fail to meet recognized health care standards...”
8. Waste: “negligent or reckless actions that result in unnecessary costs or unnecessary consumption of health care resources...”
9. Current HHS priorities:
 - a. Beneficiary recruitment/unnecessary services.
 - b. Fraudulent Medicare Part D claims.
 - c. Home health care.
 - d. Assisted living facility referrals from hospices.
 - e. Substandard nursing care.

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Fraud and Abuse (cont.)



10. Fifteen federal laws in play:

FCA	PPACA	Stark	Anti-kickback
Exclusion	Wire Fraud	Civil Money Penalties	Criminal Penalties
Anti-Embezz.	False Statements	Obstruction Of Justice	Program Fraud
Rx Marketing	Beneficiary Inducement	MACRA 2015	?

Note: States have laws too. Which applies?

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Fraud and Abuse Cases

1. The latest, greatest “Big Takedown”.
 - a. For the second year in a row, the DOJ and HHS conducted a nation-wide sweep of Medicare “fraudsters” on June 21.
 - b. 301 individuals were arrested in 36 different federal districts and were charged with 900M in fraudulent billing.
 - c. The primary charges:
 - i. Conspiracy to bill for or actually billing for unnecessary services or services never actually provided;
 - ii. Taking or receiving kickbacks;
 - iii. Money laundering;
 - iv. Identity theft;
 - v. Prescription fraud; and
 - vi. Making false statements (max. of ten yrs./fine of 250K).

<https://www.justice.gov/opa/pr/national-health-care-fraud-takedown-results-charges-against-301-individuals-approximately-900>

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Fraud and Abuse Cases (cont.)

2. UPMC, et. al. (July 2016).
 - a. UPMC and two medical groups agreed to pay 2.5M to settle civil False Claims Act violations.
 - b. The matter was initiated by whistleblowers (incentivized under the ACA).
 - c. Key allegations:
 - i. Phantom supervision of surgeries;
 - ii. Exaggeration of surgical procedures; and
 - iii. Billing for surgeries not actually performed.

<https://www.justice.gov/usao-wdpa/pr/false-claims-act-violation-upmc-resolved-25-million>

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Fraud and Abuse Cases (cont.)

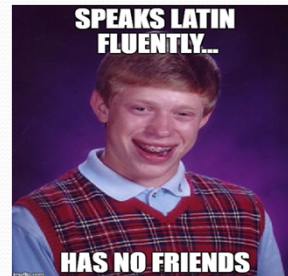
3. Dr. Misdiagnosis.
 - a. Over a four year period, a Florida primary care physician, Dr. Thompson, defrauded Medicare by diagnosing 387 Medicare Advantage beneficiaries with *ankylosing spondylitis*, a rare chronic inflammatory disease of the spine.
 - b. As a result, Medicare paid approximately \$2.1 million in excess capitation fees, approximately 80% of which went to the defendant.
 - c. All or almost all of these ankylosing spondylitis diagnoses were false because in fact, the patients did not have the condition.
 - d. The doctor will be a guest of the state for 46 months and have to pay 2.1M in restitution.

<https://www.justice.gov/usao-sdfl/pr/doctor-who-falsely-diagnosed-hundreds-patients-part-medicare-fraud-scheme-sentenced>

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Harassment

1. More often than not sexual, but now all protected categories are covered (e.g., age, disability national origin, race, religion, etc.).
2. Types of harassment:
 - a. Quid Pro Quo.
 - ✓ What does that mean?
 - b. Hostile Environment.



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Harassment (cont.)

3. Elements of a Quid Pro Quo claim:
 - a. Submission to or participation in unwelcome conduct is made a term or condition of employment; or
 - b. Conditions participation in a program or activity on submission to or participation in unwelcome conduct.
 - c. Harasser must have actual or apparent authority over the victim.
 - d. Material decisions are based on submission to or participation in unwelcome conduct.



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Harassment (cont.)

- 4. Elements of a Hostile Environment claim:
 - a. Conduct because of a protected characteristic;
 - b. That has the purpose or EFFECT of unreasonably interfering with an individual's employment or work performance; or
 - c. Creates an intimidating, hostile or offensive environment.
 - d. Must be severe/pervasive.
 - e. Physically threatening/touching; over the line.
 - f. Intent does not matter!



Harassment (cont.)

- 5. The Reasonable Person Standard.

Subjective vs. Objective:

Was conduct offensive to the particular student?

Would a *reasonable* person find conduct to be offensive?



Sidebar: Examples of Conduct that can Constitute Harassment

Touching	Humiliation/Threats
Advances	Personal space violations
Elevator eyes	Too much "aesthetic appreciation"
Jokes/teasing	Double entendres
Explicit texts/pictures/cartoons	Inappropriate/anonymous emails/texts/chats
Profane language	Certain sexual or racial words
Mocking	Denigrating
Unwanted gifts	Sabotaging
Invasion of privacy	Stalking

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2007 Study of Sex Harassment of Medical Interns and Residents

Type of Conduct	% of Surveyed Residents Experiencing the Conduct
Uninvited sexual advances	22
Overt sexual comments	62
Subtle sexual comments	71
Inappropriate literature in work areas	36
Jokes about women	83

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Harassment Cases

1. Ferguson v. ProMedica Health Systems, Inc.
 - a. A male trauma surgeon is currently suing his former Toledo hospital employer for sexual harassment and retaliation. Why?
 - b. He was subjected to unwanted sexual advances from a female nurse practitioner at work and at a party at his home.
 - c. When he complained, he was allegedly told to “let it blow over” and to “adjust his routine.”
 - d. When he persisted in complaining, his contract was not renewed.
 - e. He is suing for gender discrimination, harassment and retaliation.
 - f. He also added tort claims of “aiding and abetting”, and negligent hiring, retention and supervision. Why?
 - g. What is the source of the greatest exposure for the hospital?

<http://discriminationandsexualharassmentlawyers.com/medical-director-sues-promedica-toledo-hospital-for-sexual-harassment/>

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Harassment Cases (cont.)

2. The kissing (California) doctor case(s).
 - a. A San Diego area physician, described as a “kind, generous and caring physician who has been ambushed by the unfounded complaints of several former female patients” (guess who said that?) has had his license suspended and faces further discipline from the Cal Medical Board.
 - b. He allegedly abused at least five patients via kissing, exposure, inappropriate touching and sexual banter. He attempted to charm patients w/ such alleged lines as “I would love to do your pap smear.”
 - c. In addition to state medical board charges, he also faces civil claims of sexual harassment and battery.
 - d. He could also face liability under a California statute specifically targeting harassment of patients/clients by professionals.

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Harassment Cases (cont.)

3. The Texas two step.
 - a. A jury awarded a total of **499K** to three individuals: an executive assistant who was sexually harassed and two co-workers who were fired when they went to bat for her.
 - b. The chief complaint was that the workplace was dominated by sexually charged, lewd and abusive comments. Some comments were made in the presence of a 15 child on “Bring your Child to Work Day.”
 - c. When the assistant complained, two co-workers supported her and both were fired six week later for alleged but undocumented “performance issues.”
 - d. The case was prosecuted by the EEOC.

EEOC vs. EmCare

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Sidebar: 10 Biggest Legal Mistakes of Physicians on Harassment

1. Not having a written policy.
2. Not documenting complaints.
3. Not posting rules/prohibitions.
4. Not maintaining rules on professionalism.
5. Not documenting discipline.
6. Failing to prevent unprofessional interaction w/ patients.
7. Failing to discourage office romance.
8. Failing to have witnesses of examinations of members of the opposite sex.
9. Not know what insurance will cover.
10. Actually crossing the line.

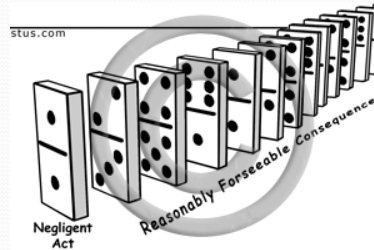
<http://www.seak.com/blog/uncategorized/10-biggest-legal-mistakes-physicians-make-lead-liability-sexual-harassment/>

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Malpractice



1. The *common law* of malpractice or professional negligence is an unintentional tort, for which some level of *fault* must be shown and the following elements proven:
 - a. Duty;
 - b. Breach;
 - c. Damages; and
 - d. Causation:
 - i. Direct; and
 - ii. Proximate.



<https://www.law.cornell.edu/wex/negligence>

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Malpractice (cont.)



2. Also have to watch out for statutes, e.g., Florida Statute: FS, chapter 766.
 - a. ...The alleged actions of the health care provider represented a breach of the **prevailing professional standard of care** for that health care provider. The prevailing professional standard of care... shall be that level of care, skill, and treatment which, in light of all relevant surrounding circumstances, is recognized as acceptable and appropriate by **reasonably prudent similar health care providers**.
 - b. With treatments or procedures, the plaintiff must show that the injury was not within the necessary or reasonably foreseeable results of the surgical, medicinal, or diagnostic procedure:
 - i. *If* there was informed consent; and if
 - ii. The intervention from which the injury is alleged to have resulted was carried out in accordance with the prevailing professional standard of care by a reasonably prudent similar health care provider.

FS, 766.102

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Malpractice (cont.)

2. The Florida Statute (cont.):
 - c. Corporate liability: All health care facilities, including hospitals and ambulatory surgical centers...have a duty to assure comprehensive risk management and the competence of their medical staff and personnel through careful selection and review, and are liable for a failure to exercise due care in fulfilling these duties.
 - d. Ordering, procuring, providing, or administering unnecessary diagnostic tests, which are not reasonably calculated to assist the health care provider in arriving at a diagnosis and treatment of a patient's condition supports a cause of action.
 - e. Comparative negligence is recognized both as to fault **and** apportioning liability among multiple defendants. J & S FS, 766.110-112.

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Malpractice Cases

1. The 12M hernia.
 - a. A 65 year old Connecticut woman suffered massive injuries and was awarded 12M by a jury in Danbury as a result of a routine hernia surgery gone wrong.
 - b. The operation, performed by an experienced surgeon and a resident, seemed to go well but later it was discovered that the patient's colon was punctured. She developed a massive abdominal infection. She then had a heart attack and went into a month long coma.
 - c. Big problem for the defendants: the two docs could not even agree on what happened and ended up blaming each other.
 - d. The surgeon cut his own deal. The verdict was against the hospital.

<http://www.thenationaltriallawyers.org/2014/06/medical-malpractice/>

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Malpractice Cases (cont.)

2. No need for an admission?
 - a. A 26 week pregnant Ohio woman was suffering severe abdominal and head pain.
 - b. She called her OB-GYN practice but her doctor was out of town. The on-call physician told her that she did not need to come in or go to the hospital. He said the cause of the pain was gastric and that it would pass.
 - c. The next day, she suffered a stroke. An expert witness at trial said it was caused by gestational hypertension.
 - d. The baby was later successfully delivered by C-Section, but the mother suffered severe permanent injury.
 - e. The jury returned a verdict against both the practice and the on call doctor.
 - f. The amount: 11M.

<http://www.rossfeller Casey.com/news/jury-awards-11-million-to-pregnant-woman-who-suffered-stroke/>

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Malpractice Cases (cont.)

1. Campbell vs. Temple University Hospital (PA 2011).
 - a. Patient = non-compliant insulin dependent diabetic.
 - b. Over a couple of years, he repeatedly visited the hospital due to his condition.
 - c. On October 13 he presented at the ER with a blood sugar level of 74. He had been there just two days prior with the same condition. He was given glucagon and gluconate. After three hours of treatment his blood sugar level had gone to 118. An hour later he was released.
 - d. 10 hours later he was found non-responsive by his family and he had suffered severe brain damage.
 - e. A jury found him 10% responsible for his injuries.
 - f. For 90% liability, how much did the jury hit the defendants with???

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Malpractice Cases (cont.)

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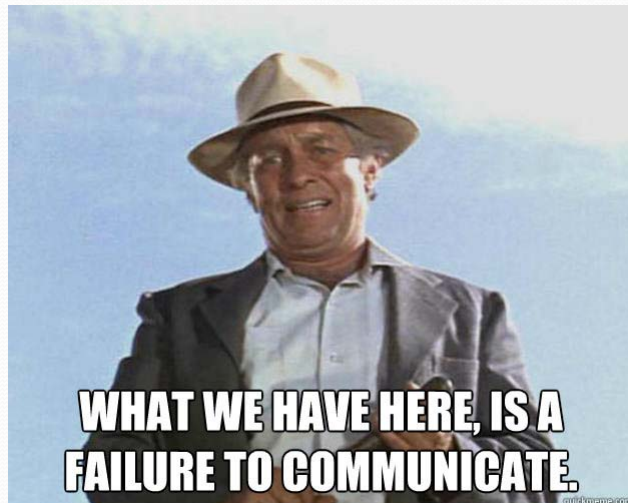
MILLION



Dollars



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