A close-up, low-angle photograph of a hand moving a white chess piece on a checkered board. The lighting is dramatic, with strong highlights and deep shadows, creating a sense of focus and strategy. The background is dark and out of focus.

***PsychRights Medicaid Fraud Initiative
Against Psychiatric Drugging of
Children & Youth***

NARPA Annual Rights Conference

September 4, 2014, SeaTac DoubleTree

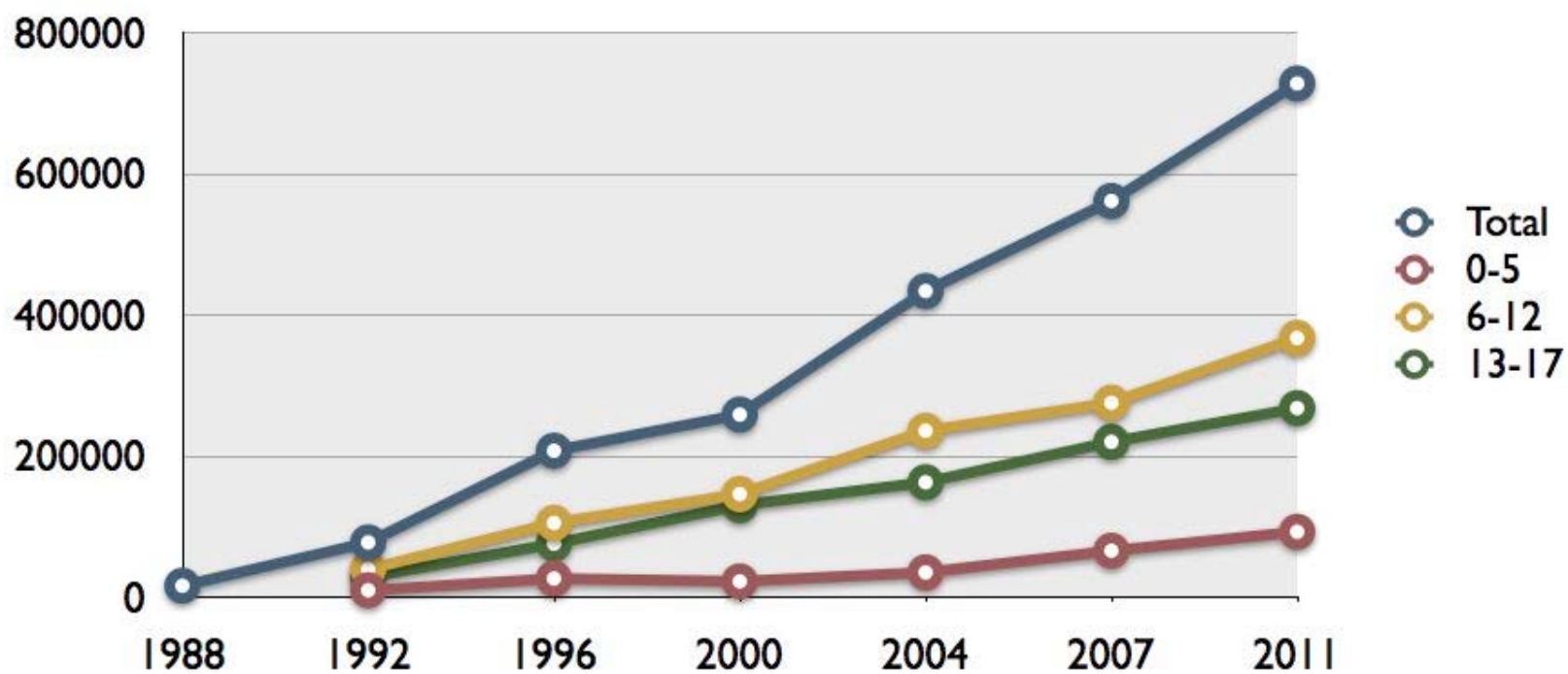
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Law Project for Psychiatric Rights (PsychRights®)

- Public Interest Law Firm
- Mission: Mount Strategic Litigation Campaign Against Forced Psychiatric Drugging and Electroshock.
- Drugging of Children & Youth a Priority
- I Am on Hiatus



Children on SSI Disability Due to Mental Illness in the Prozac Era



Prior to 1992, the government's SSI reports did not break down recipients into subgroups by age. Source: Social Security Administration reports, 1988-2007.

Medicaid Off-Label Outpatient Drug Coverage Limited to Uses “Supported” by Drug References Known as Compendia

- Medicaid reimbursement prohibited for outpatient drug prescriptions except for “medically accepted indications,” which means indications approved by the Food and Drug Administration (FDA) or supported in at least one of the following compendia:
 - American Hospital Formulary Service Drug Information,
 - United States Pharmacopeia-Drug Information (or its successor publications), or
 - DRUGDEX Information System.



DRUGDEX® Consults

RECOMMENDATION, EVIDENCE AND EFFICACY RATINGS

RESPONSE

The Thomson Efficacy, Strength of Evidence and Strength of Recommendation definitions are outlined below:

Table 1. Strength Of Recommendation		
Class I	Recommended	The given test or treatment has been proven to be useful, and should be performed or administered.
Class IIa	Recommended, In Most Cases	The given test, or treatment is generally considered to be useful, and is indicated in most cases.
Class IIb	Recommended, In Some Cases	The given test, or treatment may be useful, and is indicated in some, but not most, cases.
Class III	Not Recommended	The given test, or treatment is not useful, and should be avoided.
Class Indeterminant	Evidence Inconclusive	

Medically Accepted Indications for Pediatric Use of Certain Psychotropic Medications

by The Law Project for Psychiatric Rights (PsychRights)


Drug	Indication (diagnosis)	FDA Approval	DRUGDEX Support for Off-Label Use	DRUGDEX Recommendation Level
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Key:

White Background: Medically Accepted Indication
Orange Background: Pediatric Indication cited, but not supported by DRUGDEX
Red Background: No Pediatric FDA Approval or DRUGDEX citation

<u>Abilify</u> (Aripiprazole) - Antipsychotic				
	Autistic disorder-Psychomotor agitation	Yes (6-17)		
	Bipolar I Disorder - Adjunctive therapy with lithium or valproate for Acute Manic or Mixed Episodes	Yes (for 10 yrs old and up)		
	Bipolar I Disorder, monotherapy, Manic or Mixed Episodes	Yes (for 10-17 years old re acute therapy)		
	Schizophrenia	Yes (for 13-17 years old)		
<u>Adderall</u> (amphetamine/dextroamphetamine) - Central Nervous System Agent; CNS Stimulant				
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 3 years old and up re: [immediate-release] and 6 years old and up re: [extended-release] drug)		
	Narcolepsy	Yes (for 6 years old and up (immediate release only))		
<u>Ambien</u> (zolpidem) - nonbarbiturate Hypnotic				
	Insomnia, Short-term treatment	No		Class III
<u>Anafranil</u> (clomipramine) - Antidepressant; Antidepressant, Tricyclic; Central Nervous System Agent				
	Obsessive-Compulsive Disorder	Yes (for 10 years and up)		
	Depression	No		Class IIb

Examples of Drugs With No Pediatric Medically Accepted Indications as of May of 2010 (*per se* False Claim)

- 
- Symbyax
(Zyprexa &
Prozac together)
 - Cymbalta
 - Geodon
 - Paxil
 - Invega
 - Trazadone
 - Saphris

False Claims Act

(31 U.S.C §3729, et seq.)

- Civil War Era Statute to Address Rampant Fraud Against Government
- Amended in 1986, 2009 and 2010
- Allows citizens to bring suit on behalf of the government and share in recovery if any.
- Called “Relators” (for the King)



Penalties

- \$5,500 to \$11,000 per false claim, plus treble damages.
 - Each offending prescription a false claim

31 USC §3729(a)

Liability

- It is a False Claim to:
 - (A) knowingly present, or cause to be presented, a false or fraudulent claim for payment or approval
 - (B) knowingly make, use, or cause to be made or used, a false record or statement material to a false or fraudulent claim

(to the Federal Government)

31 USC §3729(a)(1)



Knowingly Defined As:

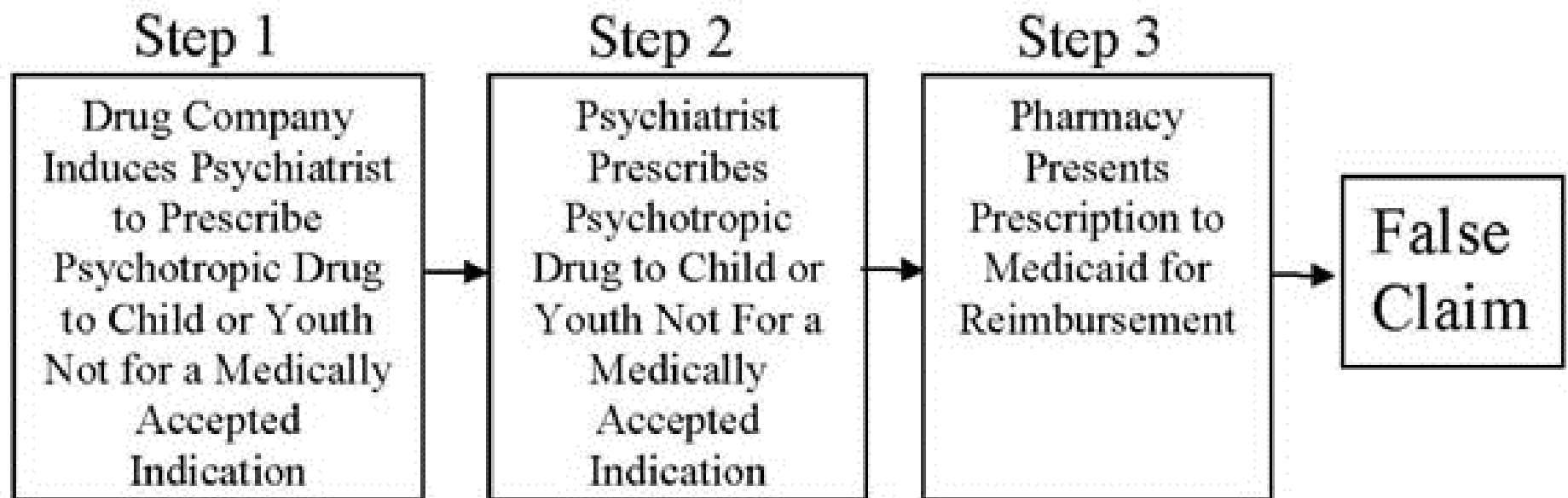
- (i) Actual knowledge;
- (ii) Deliberate ignorance of the truth or falsity; or
- (iii) Reckless disregard of the truth or falsity

No proof of intent to defraud required

31 USC §3729(b)(1)(a)



Fraudulent Scheme



Pfizer/Geodon Settlement

- Multiple Drugs/Relators
- \$2.3 Billion in Criminal Fine and *Qui Tam* Recovery
- \$1.3 Billion Criminal Fine & Forfeiture
- US and States split \$1 Billion civil recovery
- *Qui Tam Relators* split \$102 million
- Promotion of Geodon for use in children for non-medically accepted indications.



Zyprexa Settlement

- \$1.4 Billion Combined *Qui Tam* & Criminal Penalties
- \$800 million *Qui Tam* Recovery
- *Qui Tam* Relators split \$79 million
- According to NY Times, the release of the Zyprexa Papers caused investigation to “gain momentum”



These \$Billion Settlements Against Drug Manufacturers Not Stopping Massive, Inappropriate Psychiatric Drugging of Children & Youth

- Cost of doing business.
- Have established practice by psychiatrists and other prescribers
- The Government is continuing to pay the false claims



Other Liable Parties

- Prescribers:
 - Cause the Medicaid claims to be submitted
 - 7th Cir. Held if Dr. Knows patient is on Medicaid, “knowingly” causes claim unless comes forward with contrary evidence
 - Should know the prescriptions are not for medically accepted indications
- Employers liable for same reason
- Pharmacies:
 - Make the false claims
 - Know or should know not for medically accepted conditions



Other Pediatric non-Medically Accepted Indications (*per se* Medicaid Fraud)

- Virtually All Polypharmacy?
- Otherwise, have to check specific diagnosis with Drugdex (as a practical matter)
 - Medically Accepted Indications Chart
 - Neuroleptics for Oppositional Defiant Disorder diagnosis
 - Seroquel for sleep



Filed Under Seal (in Secret)

- Complaint filed under seal for 60 days to allow Government time to investigate and decide whether to intervene and take over case.
- Seal can be extended for “good cause.”
- Average is 13 months.
- Zyprexa: 5 years; Geodon 4 years

31 USC §3730(b)



Relator Recovery

- If Government intervenes and takes over case, Relator receives 15% to 25%.
- If Government doesn't intervene, Relator receives 25% to 30%.

31 USC §3730(d)



Prosecution of Case

- If government intervenes and takes over case, *Relator* can still participate unless found to interfere with or unduly delay the Government's prosecution of the case, or repetitious, irrelevant, or harassing
- If government does not intervene, *Relator* gets to proceed.
- Government can settle or dismiss, but subject to court supervision with *Relator* input.

31 USC §3730(c)

Pre-2010 Public Disclosure Bar

- “No court shall have jurisdiction over an action under this section **based upon** the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information. ”

31 USC §3730(e)(4)(A)



2010 Public Disclosure Bar

(4)(A) The court shall dismiss an action or claim under this section, **unless opposed by the Government**, if **substantially the same allegations or transactions** as alleged in the action or claim were publicly disclosed--

- (i) in a **Federal** criminal, civil, or administrative hearing in which the Government or its agent **is a party**;
- (ii) in a congressional, Government Accountability Office, or other **Federal** report, hearing, audit, or investigation; or
- (iii) from the news media,

unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

31 USC §3730(e)(4)(A)

Original Source

“original source” means an individual who either (i) prior to a public disclosure under subsection (e)(4)(a), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section.

31 USC §3730(e)(4)(B)
Current (2010) Version



First to File Rule

- “In no event may a person bring an action . . . which is based upon allegations or transactions which are the subject of a civil suit or an administrative civil money penalty proceeding in which the Government is already a party.”

31 USC §3730(e)(3)

Questions (to be litigated)

- What does “support” in a compendia mean?
 - Drugdex Codes
 - Can a positive report of “3 mentally deficient children & adolescents” receiving Depakote generating a IIb rating constitute “support?”
 - Is almost all polypharmacy a violation?
- Can Prescribers, Employers & Pharmacies be charged with knowledge?
 - *Heckler* (Supreme Ct) held charged with knowledge of program requirements
 - 7th Cir.



Miscellaneous

- Particularity – Civil Rule 9(b)
- Attorney required.
- Six Year Statute of Limitations



Model Complaint

- Drafted for former foster youth, but anyone with non-public information (i.e., specific prescriptions) can bring.
 - Used in *ex rel. Watson v. King-Vassel*



A Tale of Two Cases

PsychRights v. Matsutani (9th Cir.)

- 30+ Defendants
- Ignored Susan Stefan's Excellent Advice Not to Name So many
- 9th Circuit in non-precedential Disposition: The government knows all about the fraud and doesn't care so why should we? (Public Disclosure Bar)

Watson v. King-Vassel 7th Cir

- Psychiatrists Cause False Claims When Prescribing Off-Label to Medicaid Patient not supported by Any Compendia
- Won in trial court on Public Disclosure Bar Issue Lost in 9th Circuit -- *Baltazar* (7th Cir.)
- On Remand, trial court threatened *relator* into folding

Matsutani (9th Cir)

Relators' suit is "based upon" . . . prior public disclosure." "[T]he evidence and information in the possession of the United States at the time the False Claims Act suit was brought was sufficient to enable it adequately to investigate the case and to make a decision whether to prosecute." The Medicaid records relators obtained from their Alaskan FOIA requests already were required by statute to be supplied to the federal government. . . . [U]nlike in *ex rel. Baltazar* relators here haven't provided "vital facts that were not in the public domain."



***Matsutani* (Continued)**

“Relators’ suit concerns ongoing conduct, not specific and discrete time periods The public disclosure bar thus applies here to all claims at issue, including those made after the relevant disclosures.”



Matsutani (Continued)

“This disposition is not appropriate for publication and is not precedent except as provided by 9th Cir. R. 36-3.”

9th Cir. R. 36-3(a):

(a) Not Precedent. Unpublished dispositions and orders of this Court are not precedent, except when relevant under the doctrine of law of the case or rules of claim preclusion or issue preclusion.



Ex rel. Watson **(7th Cir.)**

“Under the applicable interlocking provisions of the False Claims Act and laws governing Medicaid, the federal government generally will not pay for medications prescribed for purposes not approved by the FDA or “supported” by any of several pharmaceutical reference books (called “compendia”).”



Ex rel. Watson **(Continued)**

“Because there were no indications that were supported for certain drugs for *any* patient of N.B.’s age, Watson argues, the prescriptions to N.B. must not have been for a medically accepted indication. This analysis, says Watson, would not require the assistance of an expert. We agree.”



Ex rel. Watson **(Continued)**

“A reasonable jury could plausibly interpret the evidence Watson assembled to show that King-Vassel recklessly disregarded the fact that N.B. received Medicaid assistance, and that claims for payment for his prescriptions would be submitted to Medicaid.”



Ex rel. Watson **(Continued)**

“[A]bsent some affirmative evidence that King-Vassel’s prescriptions did not cause a claim to be filed, Watson should have been able to rely on traditional, time-tested notions of causation . . . we do not think a jury needs expert testimony to understand that writing a prescription to a person insured by Medicaid will likely cause a claim to be filed with Medicaid.”



7th Circuit

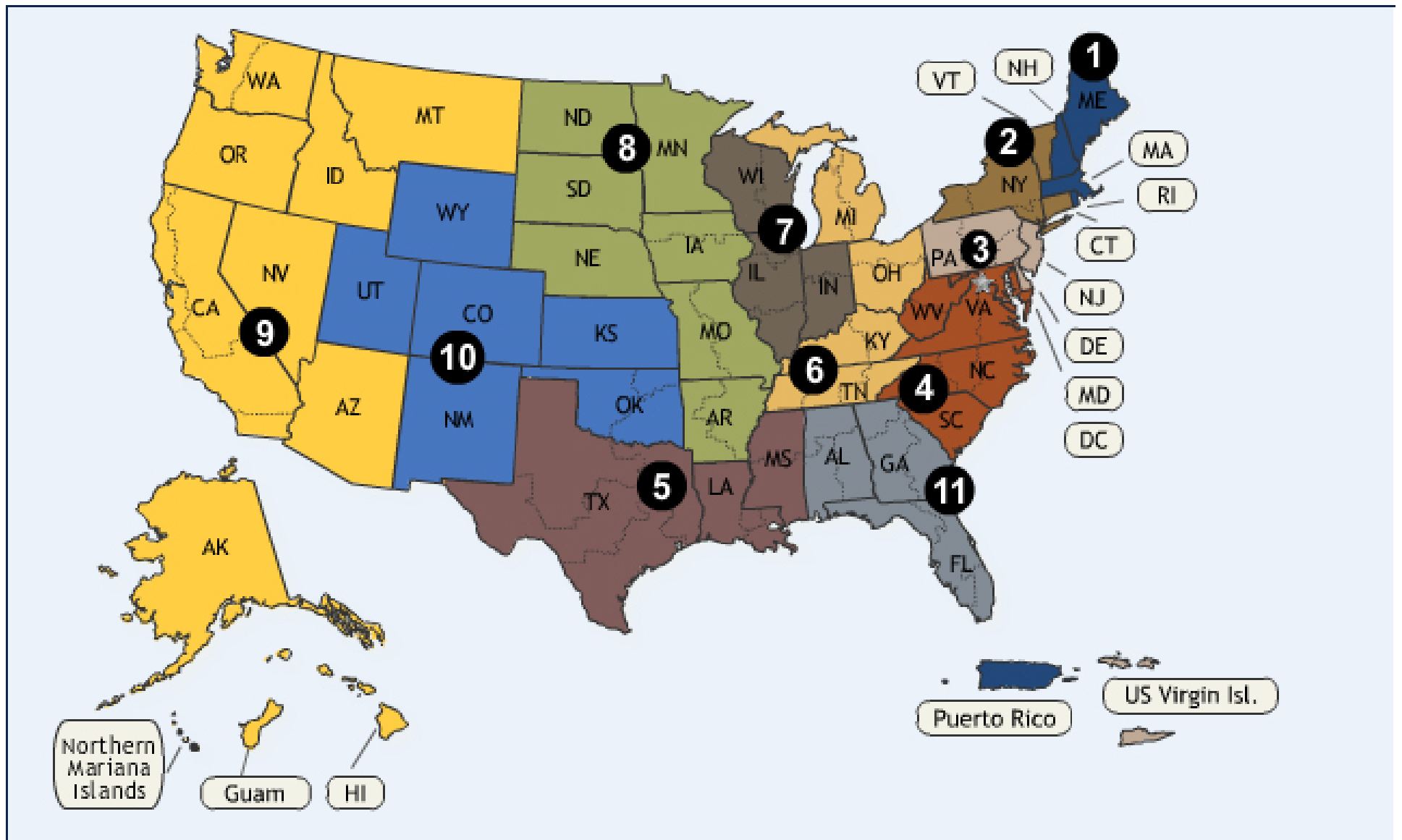
- Perpetrator and False Claim(s) Must be Publicly Disclosed to Trigger Public Disclosure Bar. *ex rel. Baltazar*, 635 F.3d 866 (2011)(2011)
- Off-Label prescription for a use not “supported” by compendia presented to Medicaid is a False Claim. *ex rel. Watson* (2013)
- Prescriber Causes False Claim by Writing Such Prescription. *Id.*
- Absent Evidence to Contrary Prescriber charged with “knowingly” causing claim within meaning of False Claims Act if Knows Medicaid Patient. *Id.*



Let's Do Some Cases!!!

- Our Children's Lives Depend On It.
- Could Raise substantial funding for alternatives and legal representation
 - Big Pharmacy Hard, but could be Serious Money





Carpe Diem

