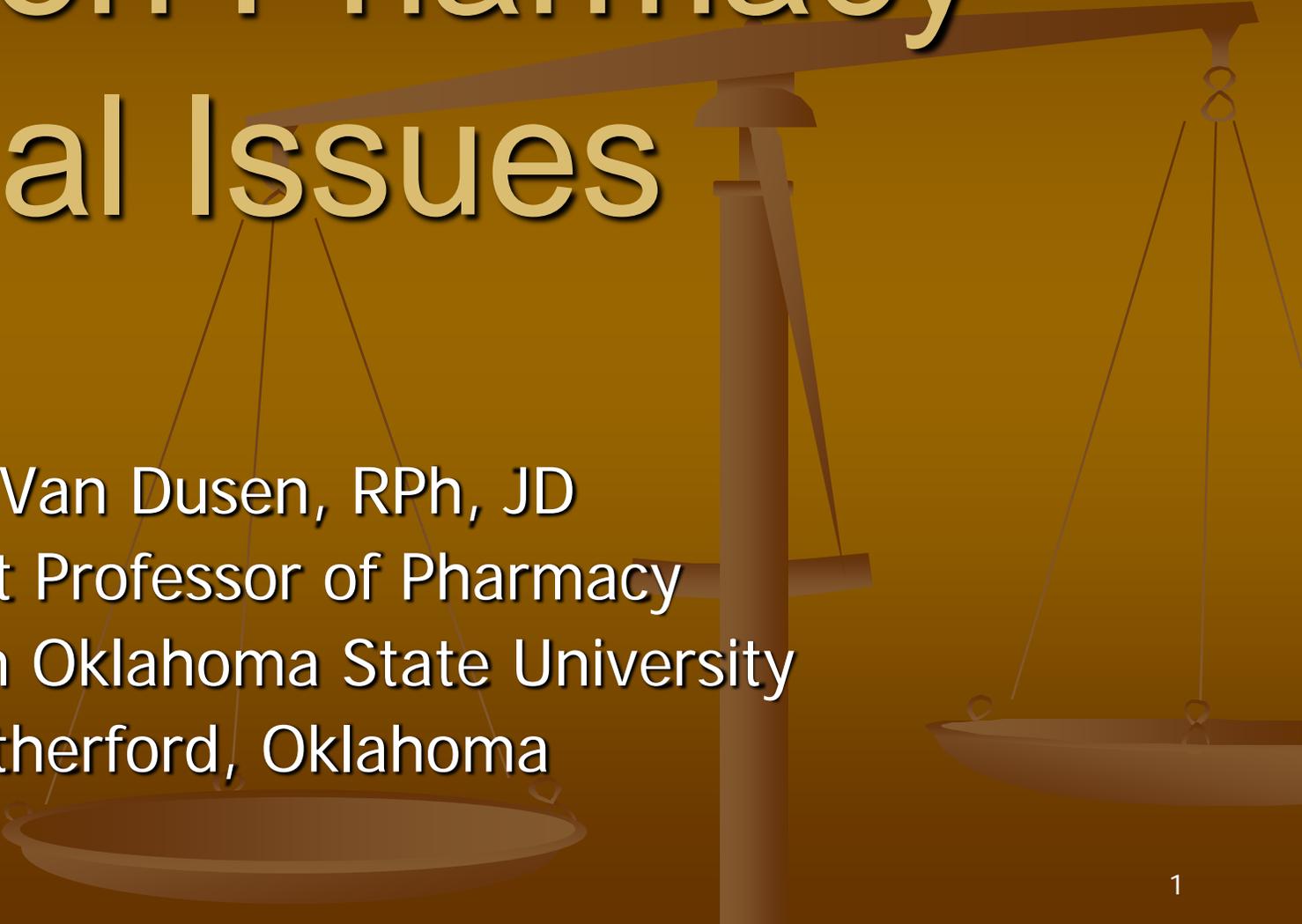
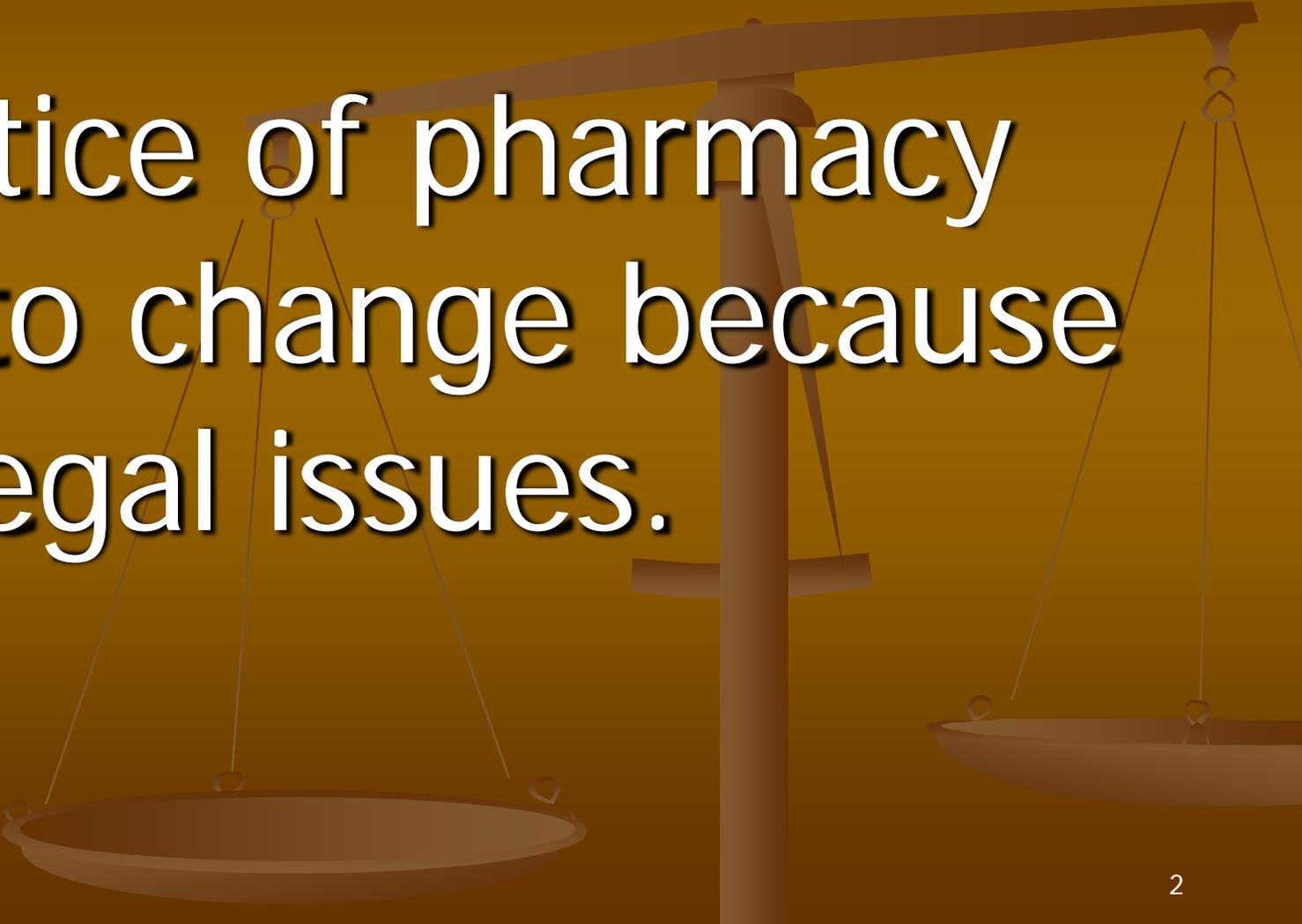


Update on Pharmacy Legal Issues



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- 
- The practice of pharmacy continues to change because of legal issues.

Anyone connected to the world of pharmacy is affected by legal issues:

- Manufacturers
- Wholesalers
- Governmental Entities
- Chains
- Pharmacy owners
- Hospitals
- Delivery entities



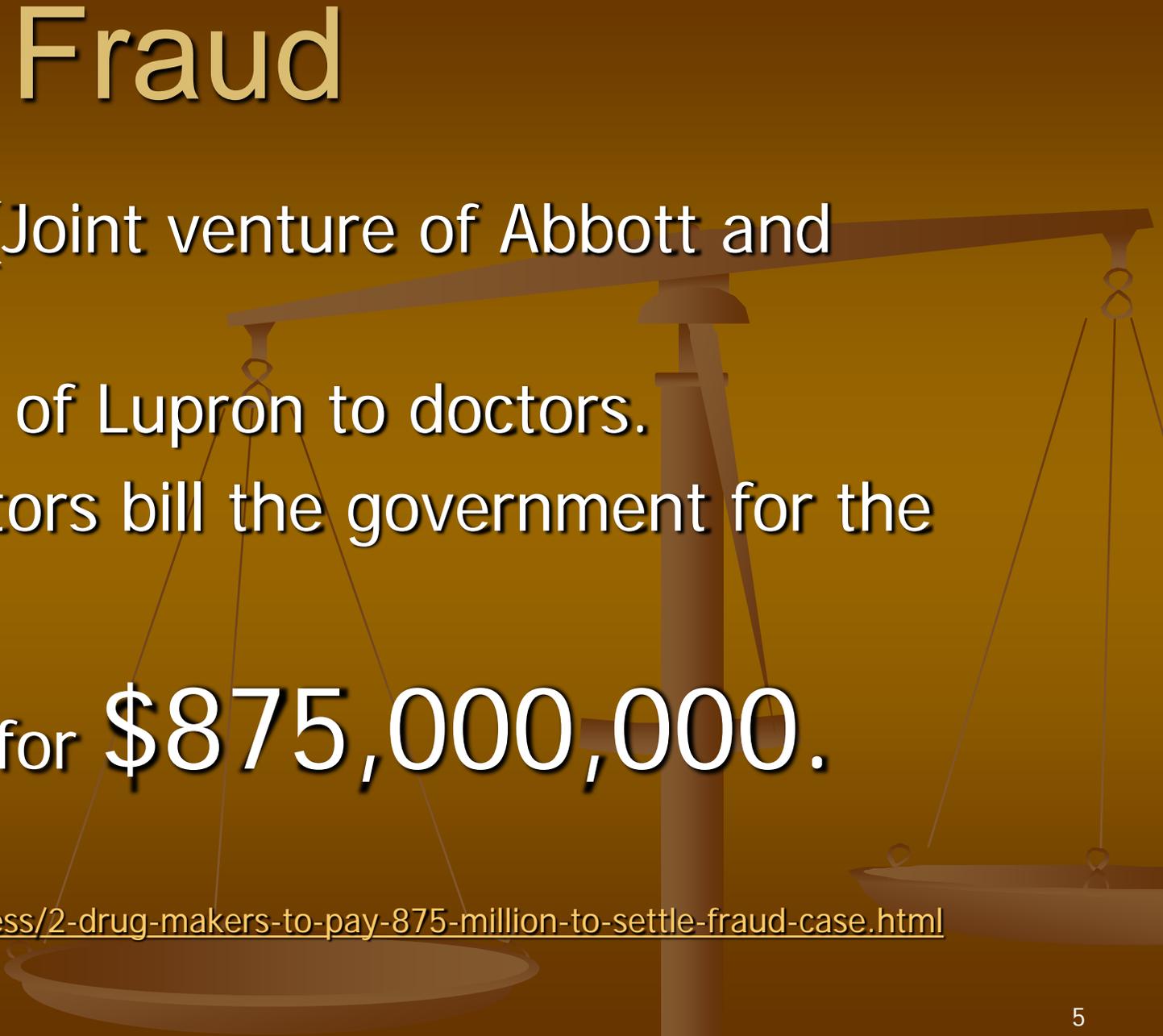
■ **Pharmacists**

Fraud



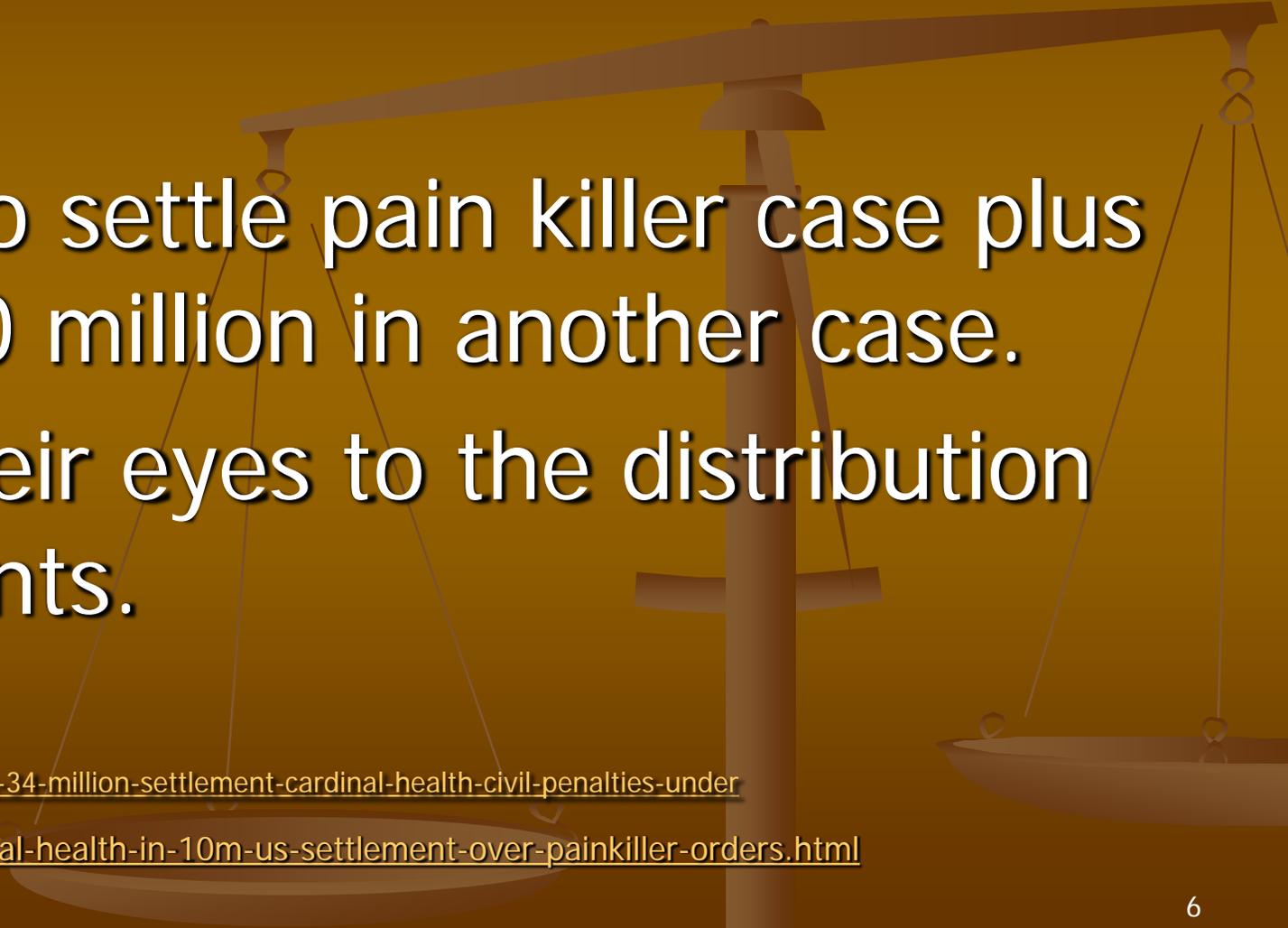
- \$784,000,000 Settlement
- Case: Pfizer failed to provide Medicaid with the same discounts as other nongovernment customers.
- Date: February, 2016
 - <https://www.justice.gov/opa/pr/wyeth-and-pfizer-agree-pay-7846-million-resolve-lawsuit-alleging-wyeth-underpaid-drug-rebates>

Fraud



- TAP Pharmaceuticals (Joint venture of Abbott and Takeda)
- Provided free samples of Lupron to doctors.
- They then helped doctors bill the government for the products.
- They agreed to settle for **\$875,000,000.**
- <http://www.nytimes.com/2001/10/04/business/2-drug-makers-to-pay-875-million-to-settle-fraud-case.html>

Cardinal Health



- Pays \$34 million to settle pain killer case plus and additional \$10 million in another case.
- Cardinal closed their eyes to the distribution of CDS to registrants.

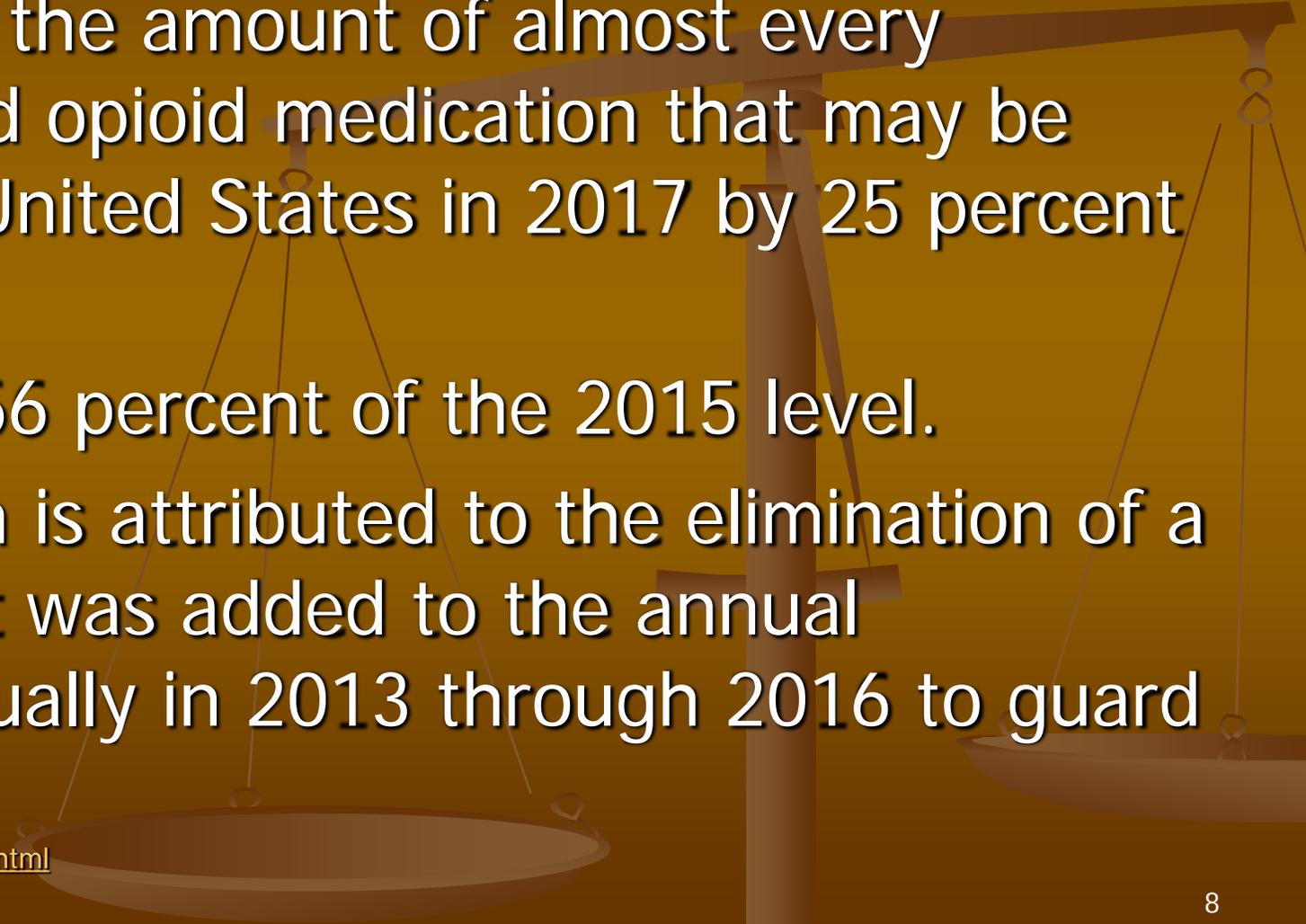
■ <https://www.justice.gov/usao-mdfl/pr/united-states-reaches-34-million-settlement-cardinal-health-civil-penalties-under>

■ <http://www.foxnews.com/health/2016/12/23/cardinal-health-in-10m-us-settlement-over-painkiller-orders.html>

Wholesaler Limits on CDS Purchases

- Cardinal wholesale facility in Florida suspended by DEA in 2012.
 - <https://www.dea.gov/divisions/mia/2012/mia020612p.html>
- Cardinal Health in the past cut off more than 300 pharmacies from purchasing CDSs.
 - <https://www.practicalpainmanagement.com/treatments/pharmacological/next-barriers-care-your-local-pharmacy>
- Pharmacies have sought relief in court to obtain CDS from wholesalers who cut them off.
 - <http://www.pharmacytimes.com/publications/issue/2013/september2013/pharmacy-law-lawsuit-to-resume-pharmacy-access-to-controlled-substances>

Opioid Production Cut



- The DEA has reduced the amount of almost every Schedule II opiate and opioid medication that may be manufactured in the United States in 2017 by 25 percent or more.
- Hydrocodone will be 66 percent of the 2015 level.
- Much of this reduction is attributed to the elimination of a 25 percent buffer that was added to the annual production quota annually in 2013 through 2016 to guard against shortages.

■ <https://www.dea.gov/divisions/hq/2016/hq100416.shtml>

Disposing of CDSs

- CDS drug take-back programs have been operating for years with many operated by state agencies.
- The DEA also now offers an option.
- Pharmacies, once their registration is modified, may become authorized collectors.
- Retail sites, hospitals and long-term care facilities may operate receptacles.
- Walgreens was one of the first to roll out "kiosks."

■ <https://www.dea.gov/divisions/hq/2014/hq090814.shtml>

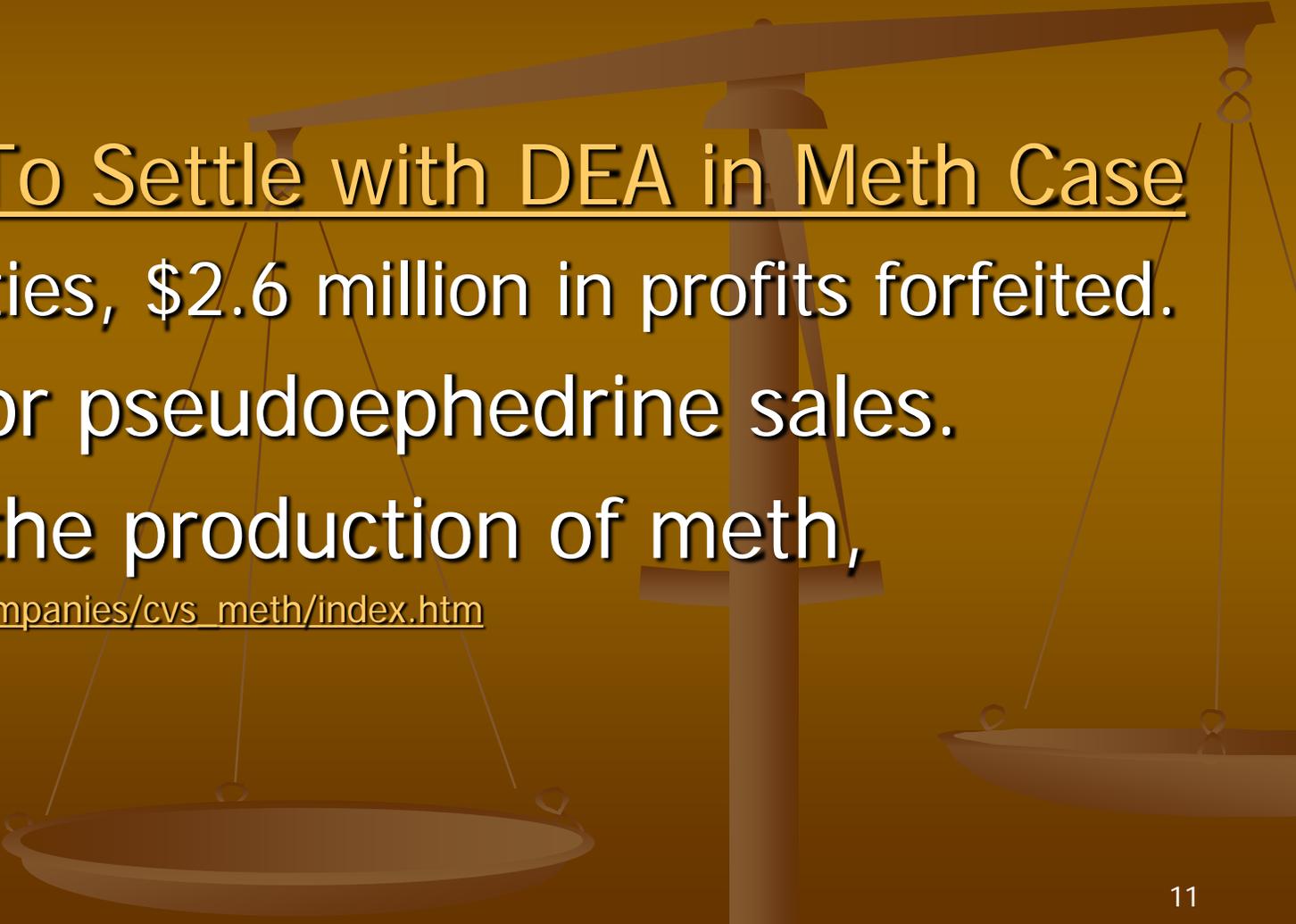
■ https://www.deadiversion.usdoj.gov/drug_disposal/index.html

■ <http://www.foxnews.com/health/2016/02/10/walgreens-to-roll-out-kiosks-that-dispense-drug-antidote-without-prescription.html>

Walgreens

- Paid \$80 Million for wrongfully distributing Oxycodone.
- The investigation uncovered instances of Walgreens stores filling fraudulent prescriptions; filling prescriptions written by a physician with an expired DEA registration; filling prescriptions lacking an address and/or DEA registration number, in violation of DEA regulations; and dispensing controlled substances to customers without a prescription. (Over 1600 violations!)
- <https://www.justice.gov/usao-co/pr/colorado-us-attorneys-office-participated-settlement-where-walgreens-agrees-pay-record-80>

CVS



- Pays \$77.6 Million To Settle with DEA in Meth Case
 - \$75 million in penalties, \$2.6 million in profits forfeited.
- CVS failed to monitor pseudoephedrine sales.
- Knowingly allowed the production of meth,
 - http://money.cnn.com/2010/10/14/news/companies/cvs_meth/index.htm

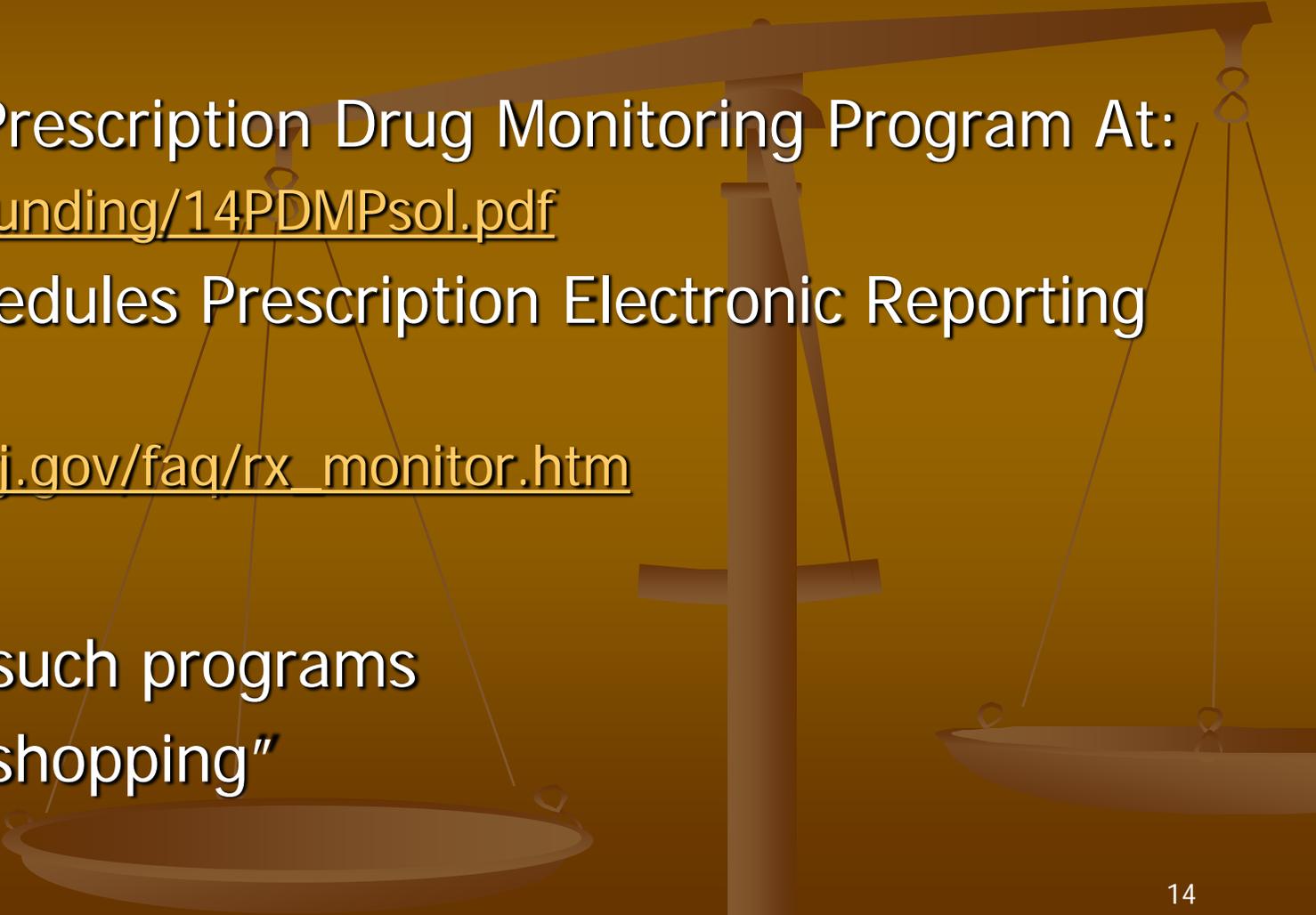
CVS

- **CVS paid a \$22M penalty for unlawful prescription drug distribution in Sanford, FL in 2015.**
- U.S. Drug Enforcement Administration investigation that found employees at two pharmacies in Sanford distributed controlled substances without legitimate prescriptions.
- This activity by CVS employees was associated with a “pill mill.”
- <http://www.orlandosentinel.com/news/breaking-news/os-cvs-health-fine-pill-mill-dea-20150513-story.html>

DEA Inspections

- As part of the yearly plan, DEA offices throughout the nation are beginning to make inspections of pharmacies a part of their routine.
- In the past, visits by the DEA were part of an organized investigation.

Prescription Monitoring Programs



■ Federal legislation

- 2002: Harold Rogers Prescription Drug Monitoring Program At:
 - <https://www.bja.gov/Funding/14PDMPsol.pdf>
- 2005: National All Schedules Prescription Electronic Reporting Act
 - www.deadiversion.usdoj.gov/faq/rx_monitor.htm

■ State legislation

- Almost all states have such programs
- Helps prevent "doctor shopping"

Prescription Monitoring Program Fraud

- CVS Pays \$11 Million to Settle Drug Records Case
- Creating, entering and maintaining invalid "dummy" DEA registration numbers or numbers other than the valid DEA registration number of the prescribing practitioner on dispensing records
- http://www.justice.gov/usao/okw/news/2013/2013_04_03.html

Herbal Claims Questioned by FDA

- Herbal supplements are notorious for making exaggerated claims.
- For example: Cili Minerals claims their product PoLith are intended to treat: autism, bipolar disorder, brain injury, epilepsy, hepatitis, liver cirrhosis, Parkinson's disease, stroke.
- FDA sends warning letter.
- <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm446541.htm>
- <http://onlinelibrary.wiley.com/doi/10.1111/fct.12148/full>

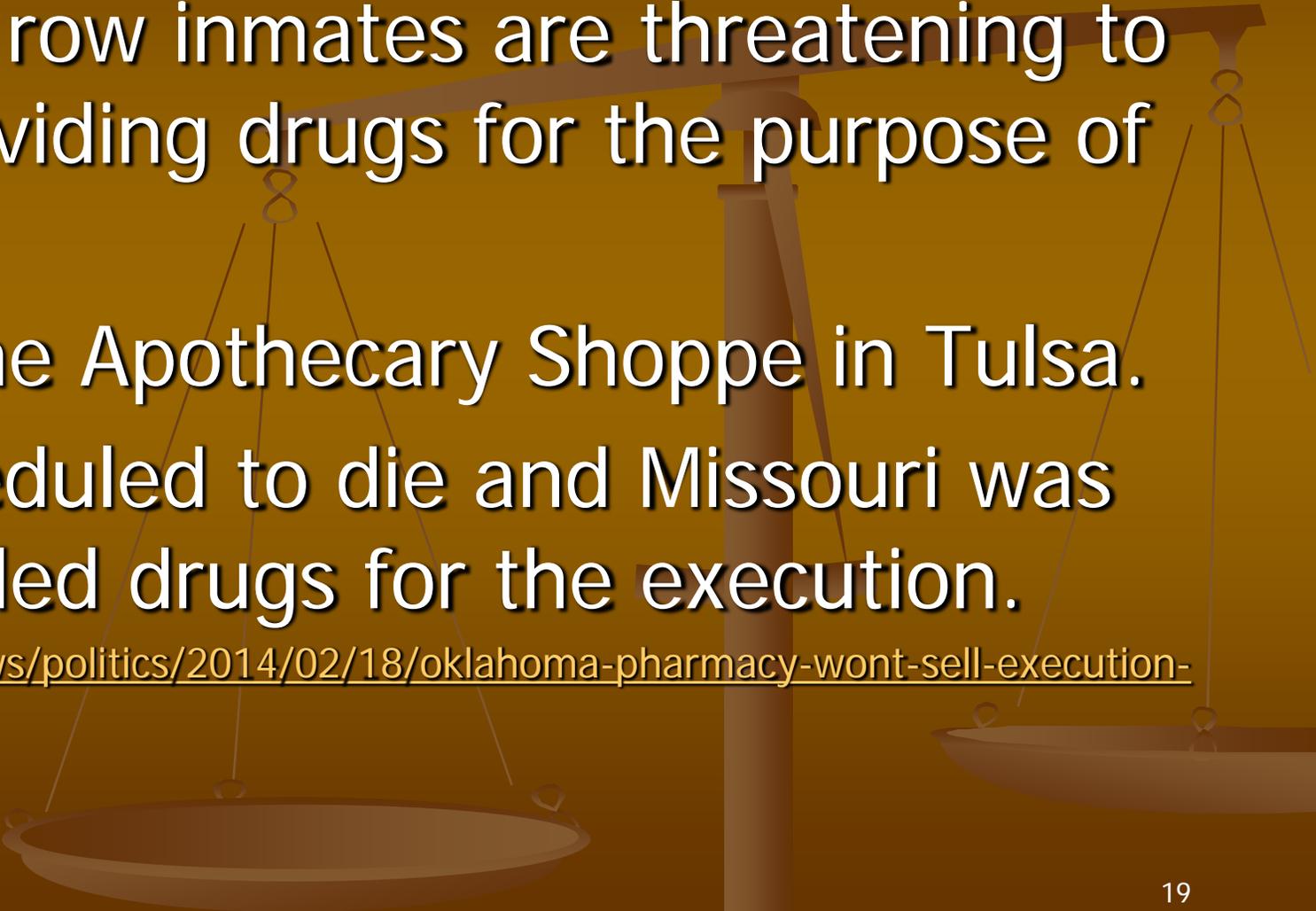
Herbal Mislabeling by Chain Pharmacies

- New York Attorney General investigating herbal misbranding.
- Bottles of Echinacea and other products contained no active ingredient.
- DNA testing on hundreds of bottles of store-branded herbal supplements found that 4 out of 5 contained none of the herbs listed on the label.
- Major store chains involved includes GNC, Target, Walmart and Walgreens

OTC Claims Questioned by FDA

- Walgreens' claims regarding Wal-Born was fictitious.
- Walgreen Company agreed to give almost \$6 million in 2010 to settle FTC charges in the Walgreens Wal-Born settlement lawsuit.
- FTC charged that Walgreens misleadingly publicized that its Wal-Born supplement line could successfully fight germs, prevent colds, and increase the immune system.
- <https://www.ftc.gov/sites/default/files/documents/cases/2010/03/100323walgreensstip.pdf>

Drugs Used for Executions

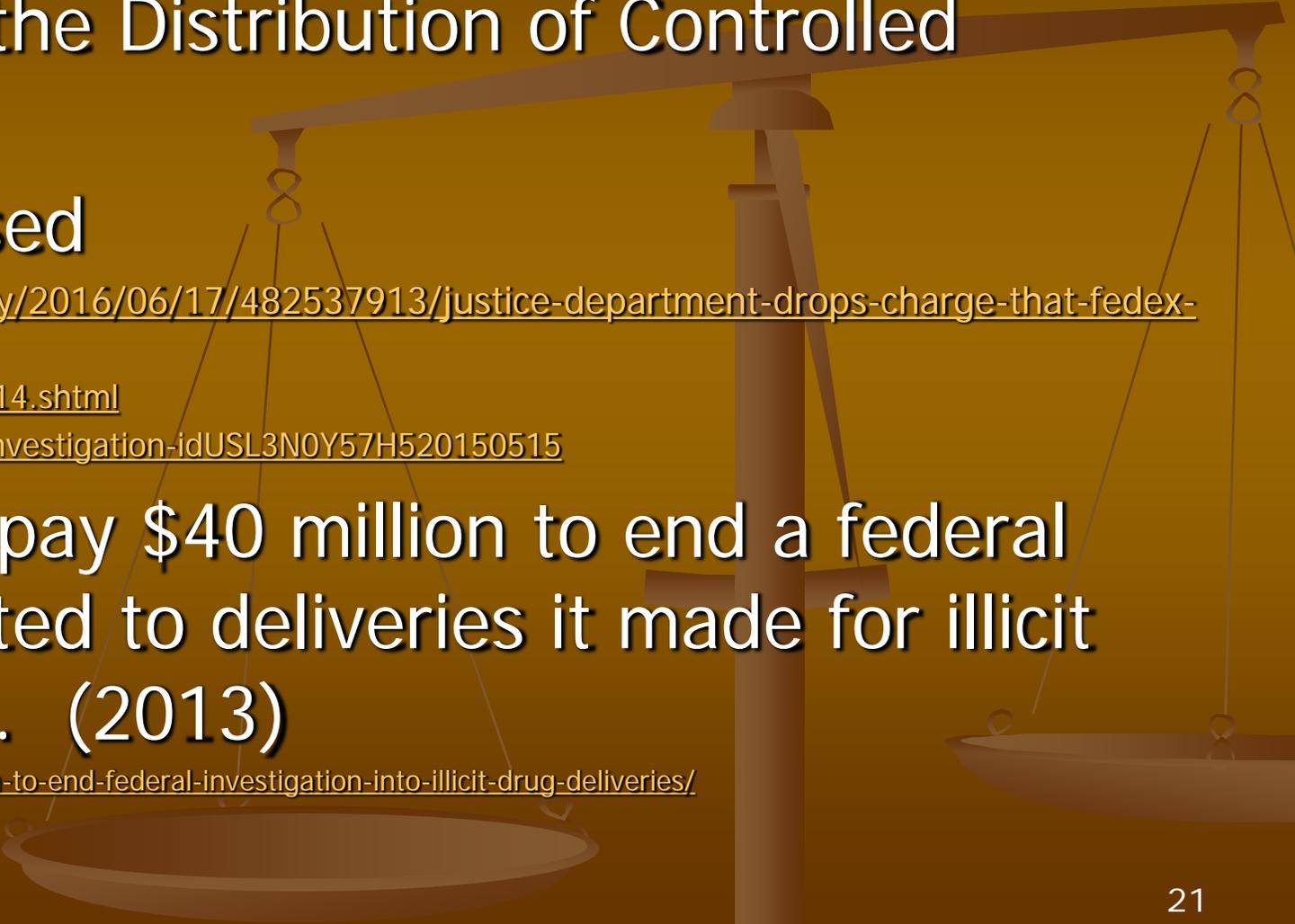


- Attorneys for death row inmates are threatening to sue pharmacies providing drugs for the purpose of execution.
- This happened to the Apothecary Shoppe in Tulsa.
- An inmate was scheduled to die and Missouri was looking for the needed drugs for the execution.
- <http://www.news-leader.com/story/news/politics/2014/02/18/oklahoma-pharmacy-wont-sell-execution-drug-to-missouri/5571897/>

Oklahoma Case No. 1295

- Pharmacist billed Medicaid for prescriptions not delivered.
 - Oklahoma Case No. 1295
- Amount billed was over \$350,000.
- His license was revoked in 2015.
 - <https://nabp.pharmacy/wp-content/uploads/2016/06/OK012015.pdf>
 - <http://www.cnbc.com/id/100000091>
 - <https://www.justice.gov/usao-mdpa/pr/old-forge-pharmacist-sentenced-15-months-imprisonment-health-care-fraud-case>
 - <http://drugtopics.modernmedicine.com/drug-topics/news/pharmacy-owner-pay-feds-425-million-fine>

FedEx/UPS



- Indicted in its Role in the Distribution of Controlled Substances
- Case has been dismissed
 - <http://www.npr.org/sections/thetwo-way/2016/06/17/482537913/justice-department-drops-charge-that-fedex-shipped-for-illegal-pharmacies>
 - <http://www.dea.gov/divisions/sf/2014/sf071814.shtml>
 - <http://www.reuters.com/article/fedex-drugs-investigation-idUSL3N0Y57H520150515>
- Yet UPS (UPS) had to pay \$40 million to end a federal criminal probe connected to deliveries it made for illicit online pharmacy sales. (2013)
 - <http://www.cbsnews.com/news/ups-to-pay-40-million-to-end-federal-investigation-into-illicit-drug-deliveries/>

Google

- Seriously, who could in good faith sue those nice folks at



- In 2011, Google agreed to pay \$500 million to settle allegations by the Justice Department that it profited from ads for illegal online pharmacies.
- Ads also encouraged prescription purchases from Canada.
- <https://www.justice.gov/opa/pr/google-forfeits-500-million-generated-online-ads-prescription-drug-sales-canadian-online>

Personal Importation of Drugs

- U.S v. Rx Depot 290 F.Supp. 2d 1238 (N.D. Okla. 2003)
- The United States brought this civil enforcement action to prevent and deter the illegal importation of prescription drugs from Canada.
- Government also went after the profits.
 - <http://law.justia.com/cases/federal/district-courts/FSupp2/290/1238/2326289/>
 - <https://www.justice.gov/osg/brief/rx-depot-inc-v-united-states-opposition>
 - <http://drugtopics.modernmedicine.com/drug-topics/content/court-shuts-down-rx-depot-storefronts>

Personal Importation of Drugs

- What can be imported?
- FDA personnel are not to examine personal baggage. This responsibility rests with the CBP. It is expected that a CBP officer will notify their local FDA district office when he or she has detected a shipment of an FDA-regulated article intended for commercial distribution, or an article that FDA has specifically requested be detained, or an FDA regulated article that appears to represent a health fraud or an unknown risk to health.
 - <https://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm179266.htm>

New England Compounding Center

- In 2012 NECC recalled more than 2,000 products after distributing 17,000 vials of methylprednisolone for injection contaminated with fungi to 23 states that resulted in over 60 deaths.
 - NECC filed for bankruptcy.
- Twelve other individuals, all associated with NECC, including six other pharmacists, the director of operations, the national sales director, an unlicensed pharmacy technician, two of NECC's owners, and one other individual were charged with additional crimes including racketeering, mail fraud, conspiracy, contempt, structuring, and violations of the Food, Drug and Cosmetic Act.
- Two Pharmacists Charged with 25 Murders in 7 States
 - 12 Others Charged with Multiple Criminal Acts

New England Compounding Center Outcome

- Barry J. Cadden, the former co-owner and head pharmacist at a Framingham company that shipped tainted drugs across the country, causing more than 60 deaths and hundreds of illnesses, was convicted of fraud and racketeering, though a federal jury refused to brand him a murderer.

- <https://www.bostonglobe.com/metro/2017/03/22/jury-reaches-verdict-new-england-compounding-center-trial/AMxQoZBV3E1hGMf1q7gSbP/story.html>

Drug Quality and Security Act of 2013

- This Act really has a focus on outsourcers!
 - If compounders register with the FDA as outsourcing facilities, hospitals and other health care providers can provide their patients with drugs that were compounded by these outsourcing facilities that are subject to CGMP requirements and federal oversight.
- How do you know if someone is a licensed outsourcer?
 - <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm378645.htm>
- Drugs produced by compounders that are not registered as outsourcing facilities must meet certain conditions of section 503A to qualify for the exemptions specified in that section.
 - <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm>

Biosimilars and the Purple Book

- Biosimilars are a type of biological product that is licensed (approved) by the FDA because they are highly similar to an already FDA-approved biological product.
 - Albumin, certain vaccines, globulins, etc.
 - <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm241719.htm>
- The “Purple Book” lists biological products, including any biosimilar and interchangeable biological products, licensed by the FDA.
 - <https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/therapeuticbiologicapplications/biosimilars/ucm411418.htm>

Internet/Social Media/Mobile Medical Apps

- How information regarding drugs and devices may be presented is regulated.
 - <https://www.fda.gov/downloads/drugs/guidances/ucm401087.pdf>
- There is a requirement for correcting misinformation about prescription drugs and medical devices.
 - <https://www.fda.gov/downloads/drugs/guidances/ucm401079.pdf>
- Some mobile apps may be deemed medical devices and, as a result, are regulated.
 - <https://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf>

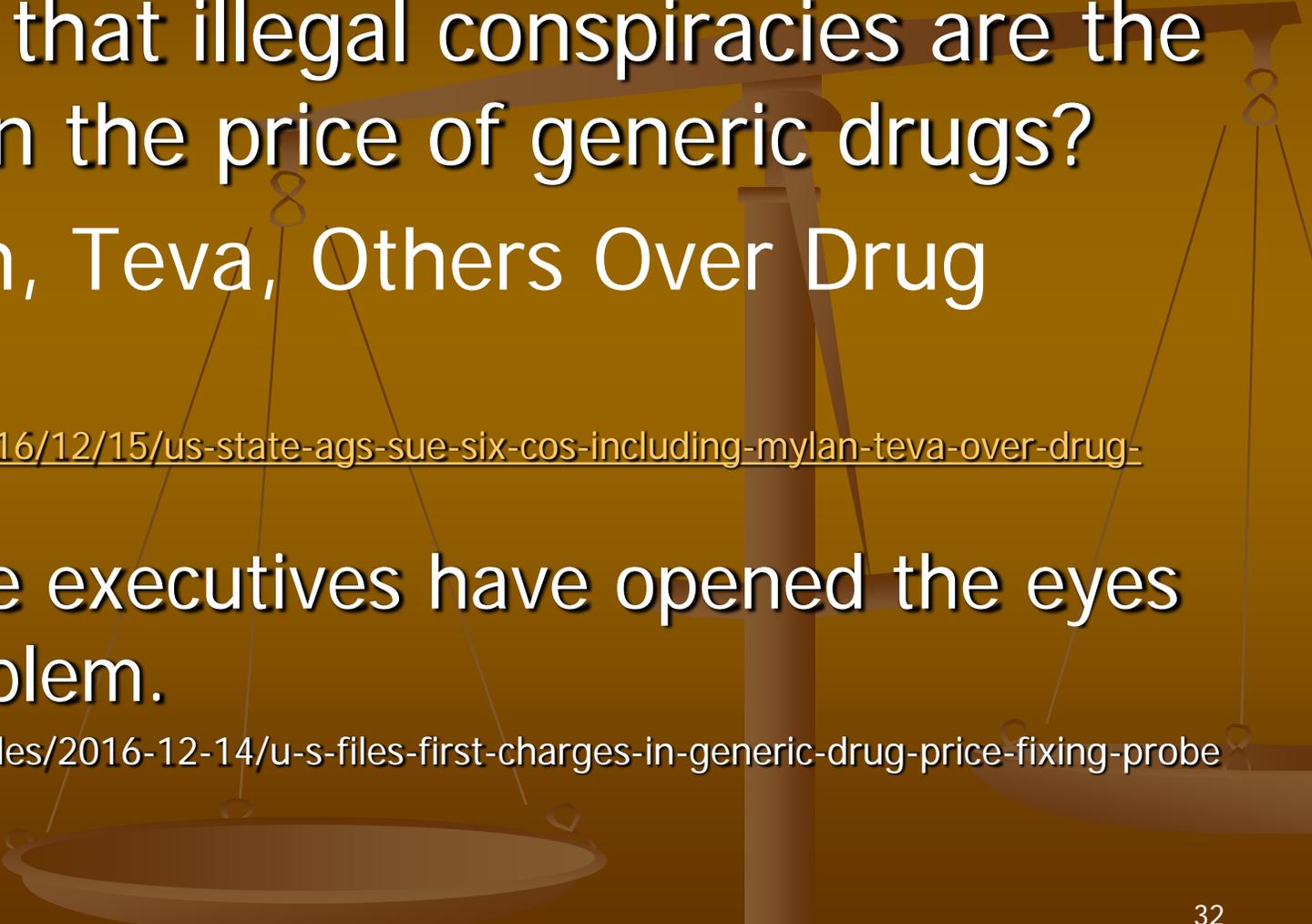
Unused Prescription Drugs

- The general rule is that, once dispensed, a prescription drug cannot be returned to the pharmacy to be dispensed again.
- A Louisiana pharmacy owner pled guilty in 2014 to charges she bribed nursing home workers to return unused drugs, then repackaged and resold them as new in what amounted to a \$2.2 million Medicare windfall scheme.
- <https://www.justice.gov/opa/pr/owner-baton-rouge-pharmacy-pleads-guilty-directing-22-million-health-care-fraud-scheme>

Stormans v. Weisman

- This was case involving Washington state rules that force pharmacy owners and pharmacists to sell morning-after and week-after abortion pills contrary to their religious beliefs instead of allowing them to refer customers to nearby pharmacies.
- The 9th Circuit ruled in favor of the State of Washington.
- **The U.S. Supreme Court refused to hear the appeal yet Justice Samuel Alito, joined by Chief Justice John Roberts and Justice Clarence Thomas, dissented from the denial and would have agreed to hear the case.** https://www.supremecourt.gov/opinions/15pdf/15-862_2c8f.pdf
 - <https://www.adflegal.org/detailspages/press-release-details/us-supreme-court-allows-extreme-washington-state-pharmacy-policy-to-stand>

Drug Pricing Litigation

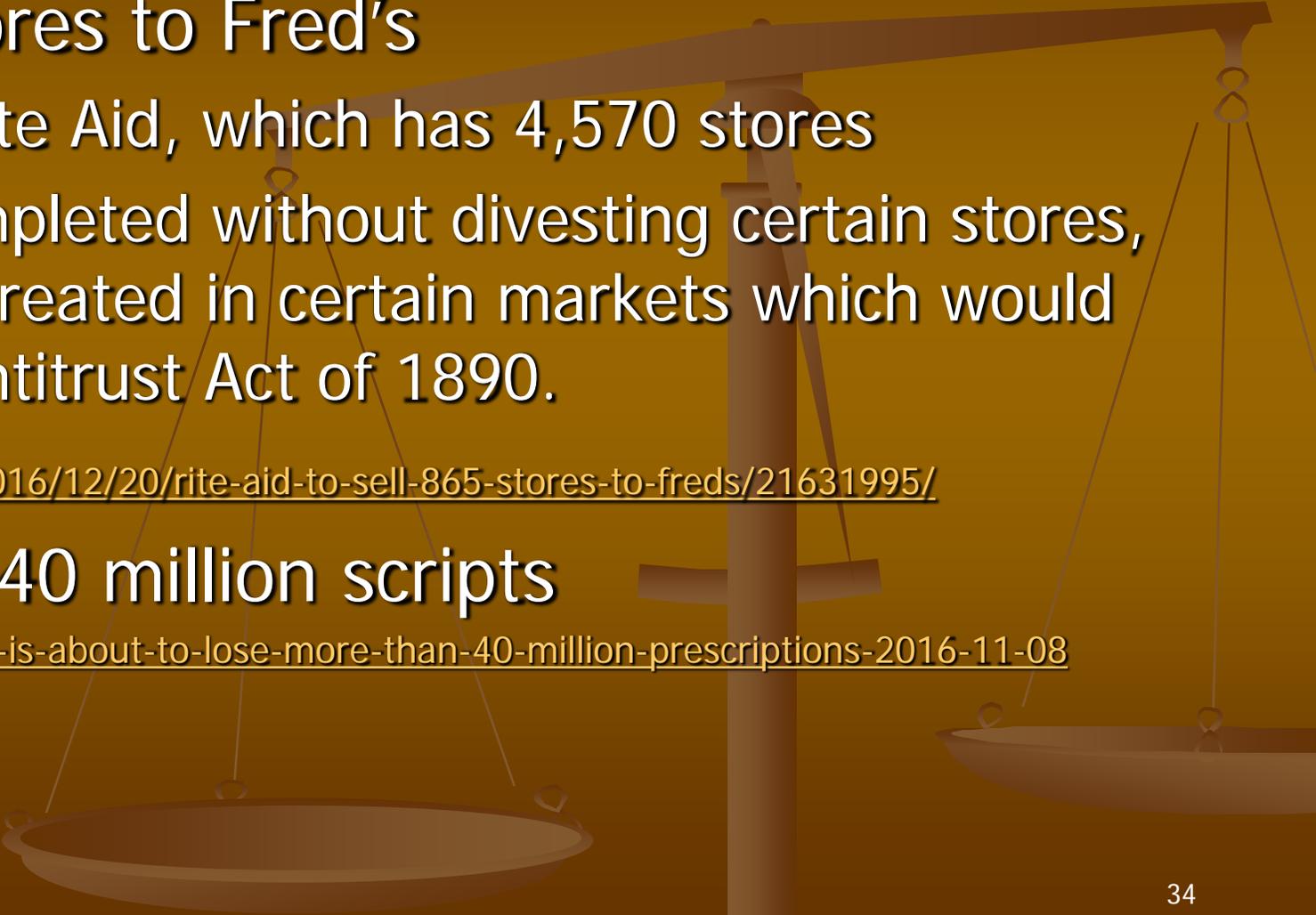


- Could it be possible that illegal conspiracies are the cause of increases in the price of generic drugs?
- 20 States Sue Mylan, Teva, Others Over Drug Pricing.
 - <http://www.foxbusiness.com/politics/2016/12/15/us-state-ags-sue-six-cos-including-mylan-teva-over-drug-pricing.html>
- Guilty pleas from some executives have opened the eyes of the feds to this problem.
 - <https://www.bloomberg.com/news/articles/2016-12-14/u-s-files-first-charges-in-generic-drug-price-fixing-probe>

HIPAA

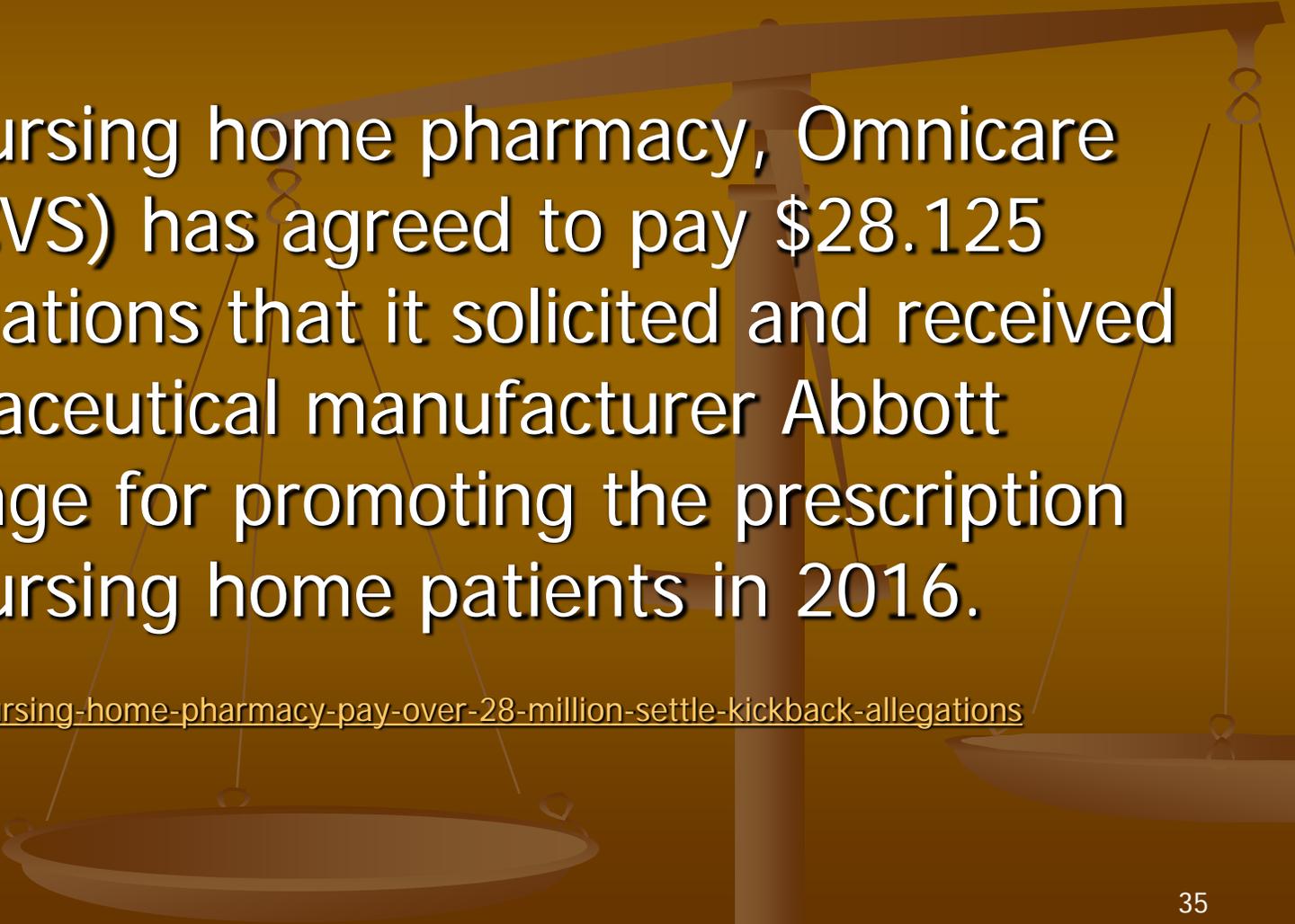
- CVS, with over 6,300 stores agreed to pay \$2.25 million for violations of throwing away PHI in dumpsters.
 - <https://www.ftc.gov/news-events/press-releases/2009/02/cvs-caremark-settles-ftc-chargesfailed-protect-medical-financial>
- Walgreens paid \$1.44 million because a pharmacist disclosed PHI and it was alleged Walgreens was negligent in training the pharmacist.
 - <http://www.beckershospitalreview.com/legal-regulatory-issues/walgreens-pays-1-44m-for-alleged-hipaa-violation.html>
- Two NYC hospitals fined \$4.8 million for data breach which allowed 6,800 patients' PHI to be disclosed.

Antitrust Concerns



- Rite Aid to sell 865 stores to Fred's
 - Walgreens is buying Rite Aid, which has 4,570 stores
 - Should the sale be completed without divesting certain stores, monopolies would be created in certain markets which would violate the Sherman Antitrust Act of 1890.
 - <https://www.aol.com/article/finance/2016/12/20/rite-aid-to-sell-865-stores-to-freds/21631995/>
- CVS losing more than 40 million scripts
 - <http://www.marketwatch.com/story/cvs-is-about-to-lose-more-than-40-million-prescriptions-2016-11-08>

Kickbacks



- The nation's largest nursing home pharmacy, Omnicare Inc., (and owned by CVS) has agreed to pay \$28.125 million to resolve allegations that it solicited and received kickbacks from pharmaceutical manufacturer Abbott Laboratories in exchange for promoting the prescription drug, Depakote, for nursing home patients in 2016.
- <https://www.justice.gov/opa/pr/nation-s-largest-nursing-home-pharmacy-pay-over-28-million-settle-kickback-allegations>

HIPAA AND OCR

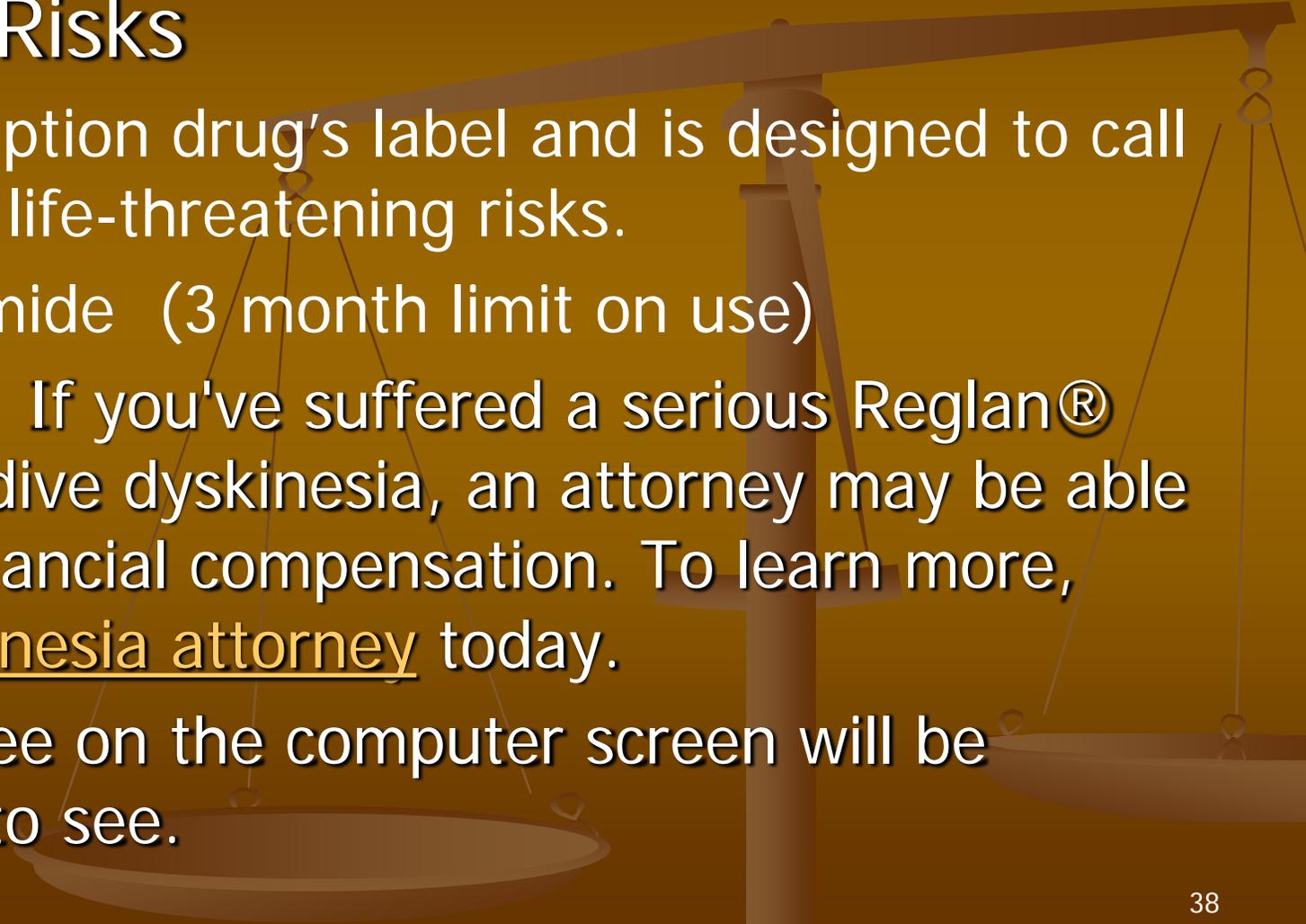
- OCR enforces penalties associated with violations of HIPAA.
- Penalties may be assessed for the following:
 - Failure to give timely breach notification.
 - Failure to have a business associate agreement.
 - Failure to adequately manage security risks.
 - Failure to have a secure disposal of paper PHI.
 - <https://www.hhs.gov/hipaa/newsroom/index.html>

Employment Law

- Walmart to pay pharmacist \$31 million for wrongful termination action.
 - The pharmacist claimed she was fired after she complained about safety conditions and because of her gender.
 - <http://drugtopics.modernmedicine.com/drug-topics/news/walmart-ordered-pay-pharmacist-31-million-wrongful-termination>
- Overtime pay: Many pharmacists are salaried but their pay may be calculated on an hourly rate.
- Should pharmacists be paid time-and-a-half?
 - The Fair Labor Standards Act has addressed this.
 - We are considered professional, administrative and management, which is exempt from overtime pay.

https://www.dol.gov/whd/overtime/fs17d_professional.htm

Malpractice



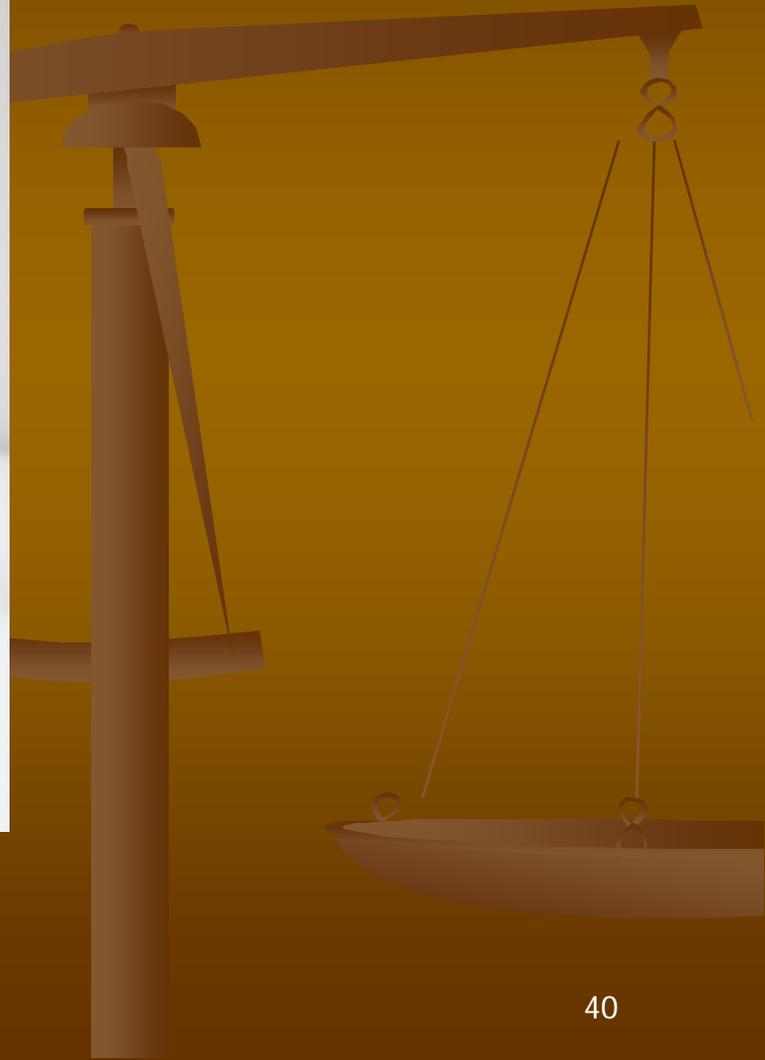
■ Black Box Warning Risks

- It appears on a prescription drug's label and is designed to call attention to serious or life-threatening risks.
- Example: Metoclopramide (3 month limit on use)
- Found on TD website: If you've suffered a serious Reglan® side effect such as tardive dyskinesia, an attorney may be able to help you recover financial compensation. To learn more, [contact a tardive dyskinesia attorney](#) today.
- Warnings you would see on the computer screen will be generated to the jury to see.

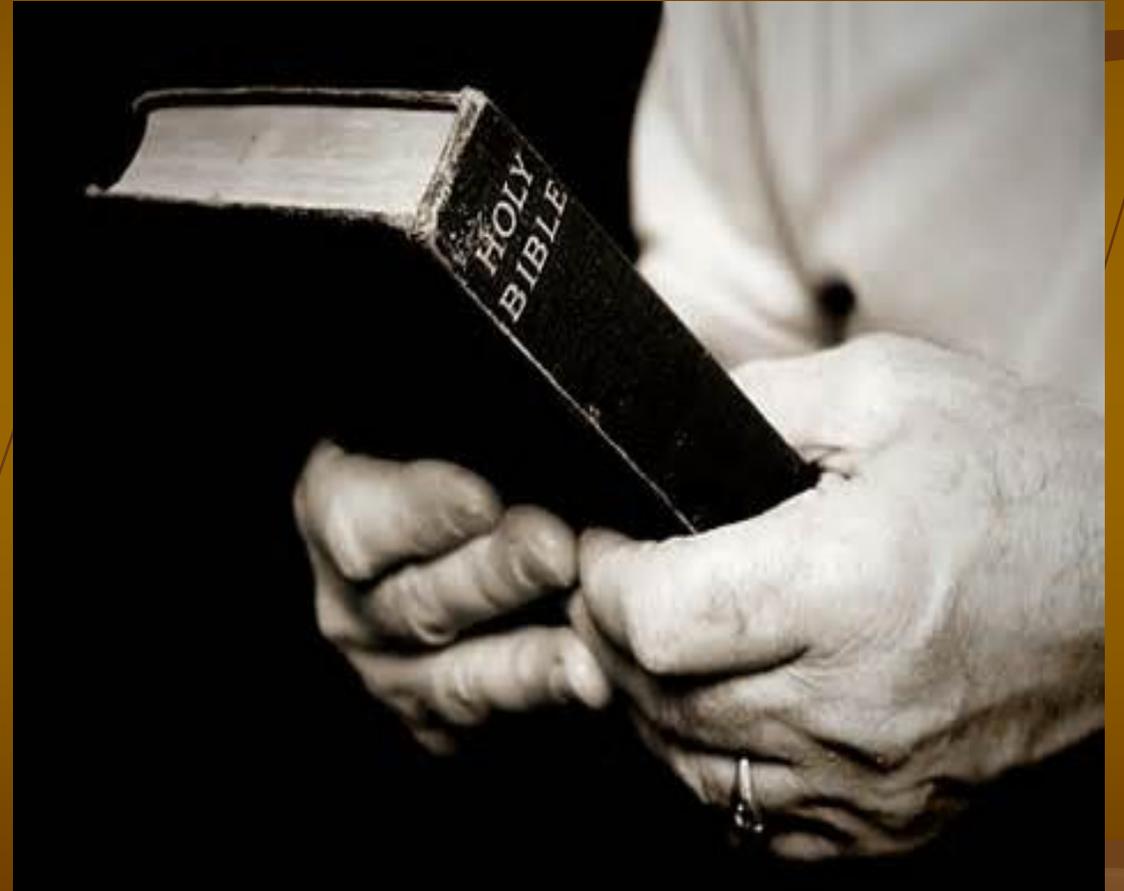
Chains Question Doctor's Prescriptions

- NJ sanctions 31 doctors in just the last year for overprescribed painkillers and other narcotics.
 - <http://www.foxnews.com/us/2017/03/09/opioid-rx-abuse-probe-sees-record-31-doctors-hit-with-sanctions-in-new-jersey.html>
- CVS cuts off doctors who prescribe too many narcs.
 - <http://www.nbcnews.com/health/cvs-cuts-docs-who-prescribe-too-many-narcotics-6C10975693>
- Dallas physician has file an action against multiple pharmacies for interfering with his ability to practice (tortious interference with contractual relationship) by refusing to fill CDS scripts for his patients and for conspiracy with intent to harm. Suing for more than \$1 million.
(DC-17-04655 (Filed April 20, 2017))

The Law Can Make Life Complex



Some Things Don't Change



The Future

- The law has been and always will be a part of our life in pharmacy practice.
- The law can be burdensome.
- But as Christians we live with a new command—love.
 - Love your God.
 - Love your neighbor.

