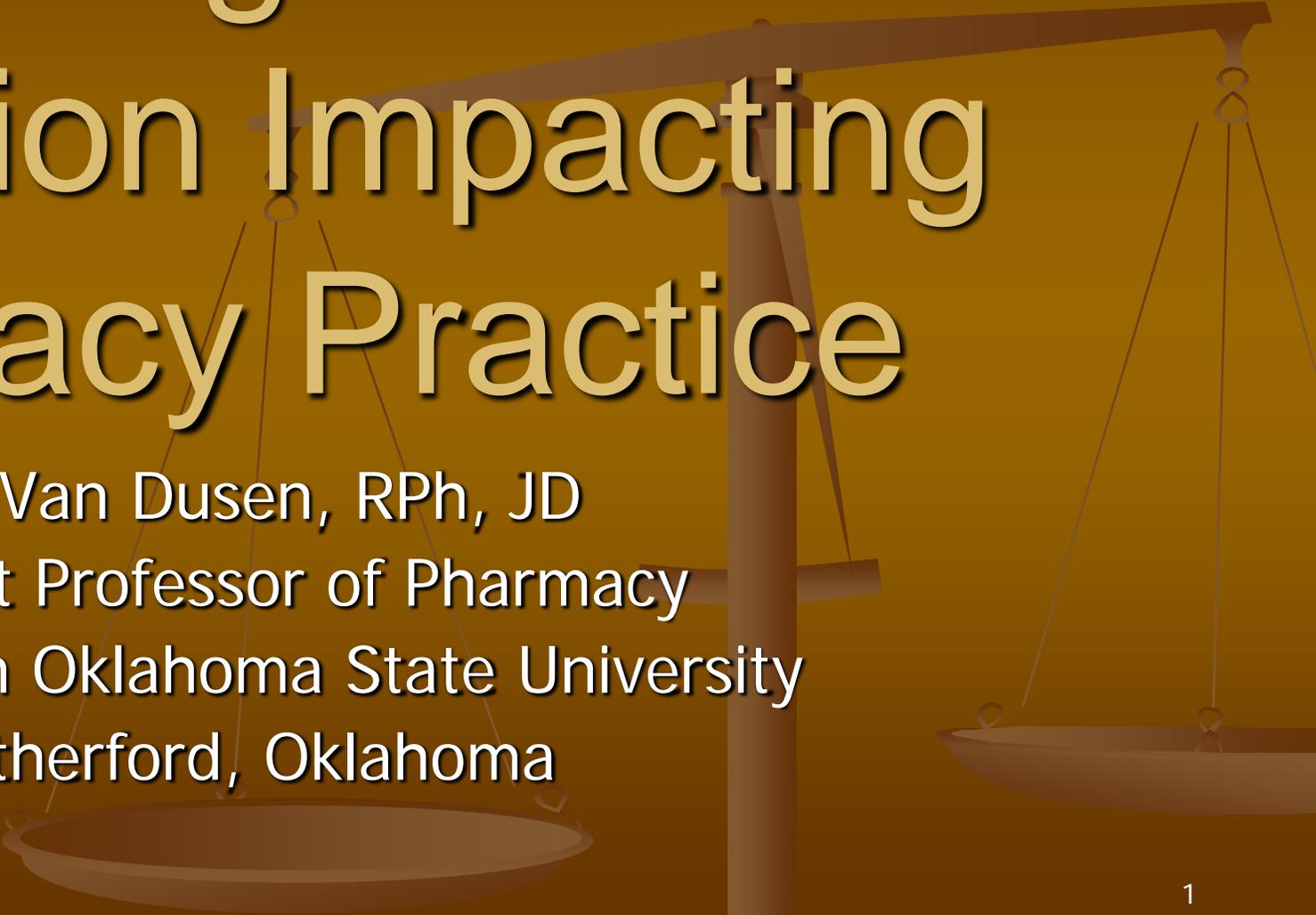
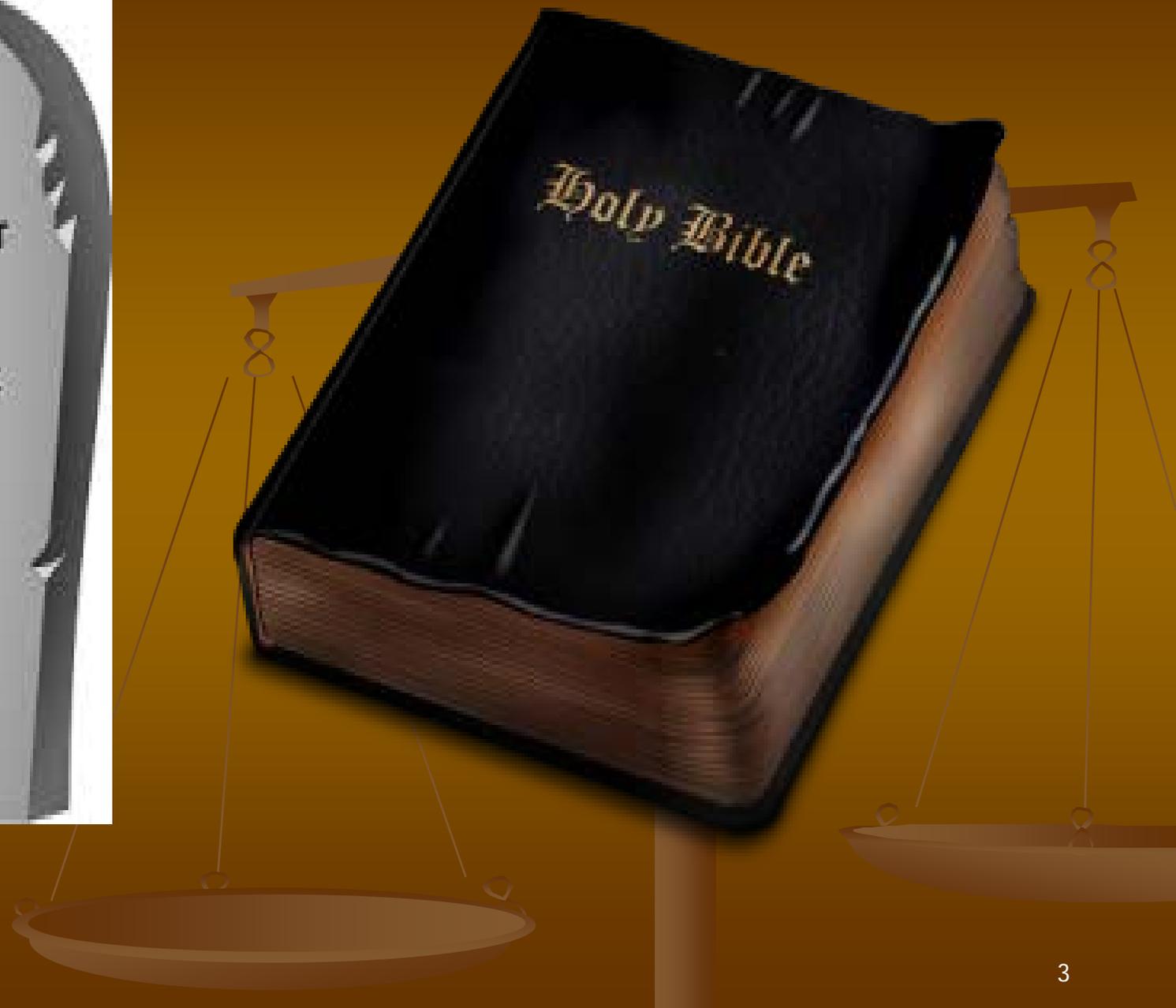


Recent Litigation and Legislation Impacting Pharmacy Practice



Virgil Van Dusen, RPh, JD
Bernhardt Professor of Pharmacy
Southwestern Oklahoma State University
Weatherford, Oklahoma



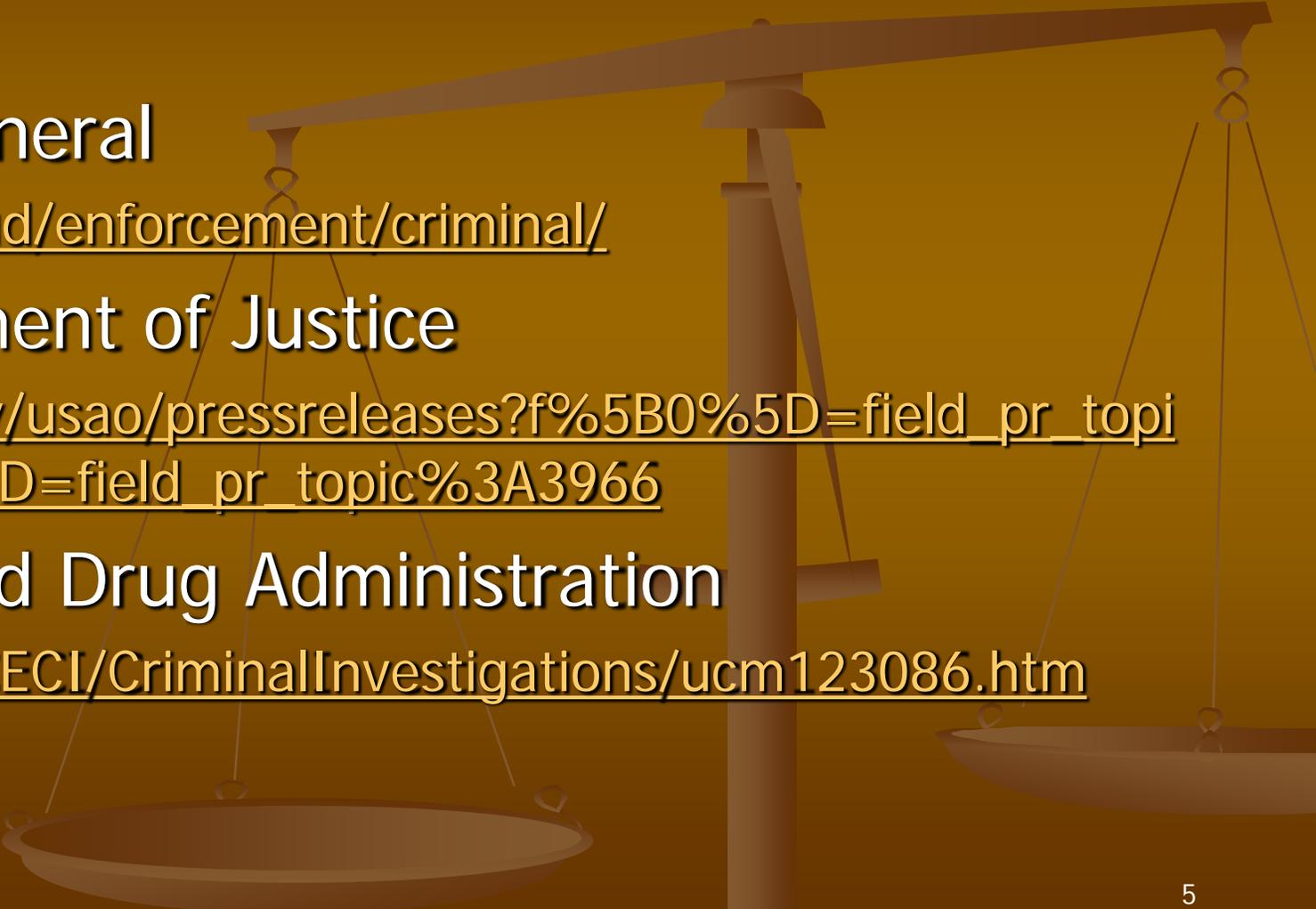


3 Primary Areas of Litigation

- 1) Criminal
- 2) Civil
- 3) Administrative



Civil and Criminal Enforcement Records



- Office of Inspector General

- <https://oig.hhs.gov/fraud/enforcement/criminal/>

- United States Department of Justice

- https://www.justice.gov/usao/pressreleases?f%5B0%5D=field_pr_topic%3A34671&f%5B1%5D=field_pr_topic%3A3966

- United States Food and Drug Administration

- <https://www.fda.gov/ICECI/CriminalInvestigations/ucm123086.htm>



■ Opioid-Related Litigation

Two Pharmacists Convicted of Pill Mill Participation

- A husband/wife team in Atlanta were convicted of dispensing CDSs for a "pill mill" pain clinic.
- They were convicted of drug trafficking, illegally dispensing, and money laundering.
- Many of their patients traveled from counties throughout Georgia and other states to receive drugs such as Oxy, Hydrocodone, Xanax and Soma.
- In one year they purchase eleven times more Oxy than the average pharmacy in Georgia.
- They generated more than \$5 million from unlawful prescriptions.

Two Pharmacists Convicted of Pill Mill Participation

- They purchase luxury vehicles money for U.S. based Nigerian purchasers who then deposited money into the pharmacist's accounts that we located in Nigeria.
- The two were sentenced to 19 & 20 years respectively.
- Each were ordered to pay \$2.5 million in restitution.
- This case was prosecuted by the U.S. Attorney's office of the Northern District of Georgia.
- <https://www.justice.gov/usao-ndga/pr/two-pharmacists-convicted-illegally-dispensing-patients-pill-mill>
- <https://www.justice.gov/usao-ndga/pr/two-doctors-and-clinic-owners-sentenced-operating-pill-mills-metro-atlanta>
- <https://www.justice.gov/usao-ndga/pr/two-pharmacists-sentenced-19-and-20-years-prison-and-ordered-pay-5-million-restitution>
- Reported October 27, 2017

Dispensing a CDS Without a Prescription

- A Santa Fe pharmacist allowed another person to order testosterone using his DEA registration number.
- He was charged with dispensing without a prescription, possession with intent to distribute and conspiracy.
- He plead guilty, his license was suspended by the NM Board of Pharmacy and he sold his pharmacy.
- This case was prosecuted by the U.S. Attorney's office of N.M.
 - <https://www.justice.gov/usao-nm/pr/former-santa-fe-pharmacist-pleads-guilty-and-sentenced-conviction-misdemeanor-charge>
 - Reported 12/13/2016
 - See: https://www.dea.gov/pr/multimedia-library/publications/drug_of_abuse.pdf

Pharmacy Guilty of Tampering with Narcotics

- Pharmacist Thomas Kellermann, 65, plead guilty of tampering with hydromorphone and morphine vials.
- He would return to the pharmacy after hours and on weekends, would withdraw drugs from the vials, and then inject saline into the vials, gluing the plastic caps back on the vials and placing them back into stock.
- He was to be sentenced on May 9, 2018
- Federal Anti-Tampering Act: <https://www.fda.gov/downloads/ICECI/Inspections/IOM/UCM127494.pdf>
- <https://www.justice.gov/usao-nh/pr/former-new-hampshire-pharmacist-pleads-guilty-tampering-narcotics-bedford-pharmacy>
- Reported January 11, 2018

Compounding Pharmacy Dopes Horses

- Kohll's Pharmacy in Omaha, NE, was found guilty of conspiracy and introduction of adulterated and misbranded drugs into interstate commerce.
- Demorphin (frog juice) was given to horses to mask pain and act as a stimulant.
- This case was prosecuted by the U.S. Attorney's office of the Western District of Louisiana.
- <https://www.fda.gov/ICECI/CriminalInvestigations/ucm585924.htm>
- http://www.omaha.com/money/kohll-s-pharmacy-is-sentenced-in-conspiracy-to-boost-racehorses/article_587fe29a-7cad-58ae-af4a-00c51e53ae40.html
- Reported November 7, 2017

Walgreens

To Pay \$80 Million for Oxycodone Violations

- 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.
- The investigation also uncovered hundreds of examples of inaccurate or incomplete recordkeeping for controlled substances at Walgreens stores located throughout Colorado.

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>

CVS

- Pays \$77.6 Million To Settle with DEA in Meth Case

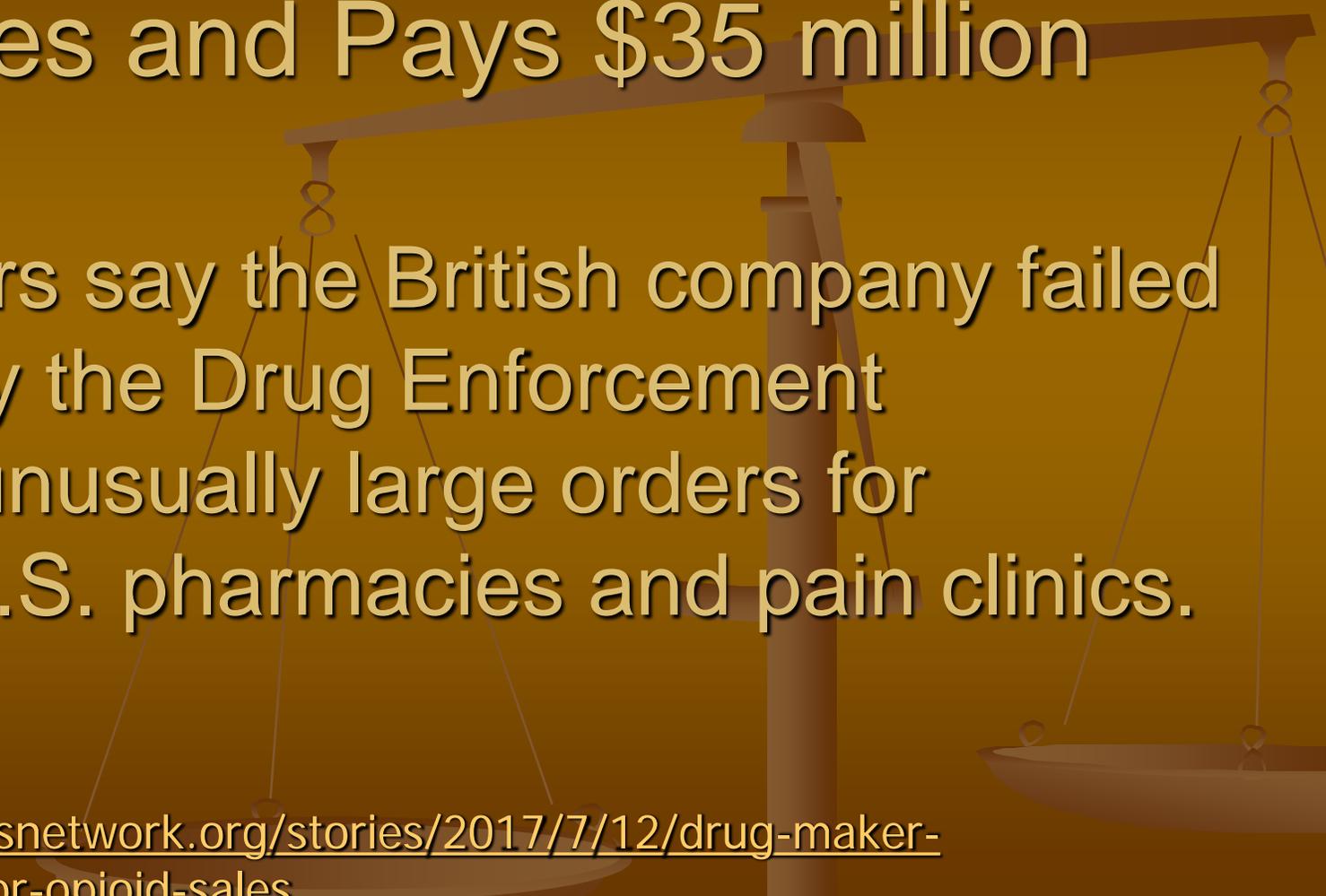
- CVS failed to comply with laws limiting sales of pseudoephedrine which led directly to an increase in methamphetamine production throughout the state.

- <https://www.dailynews.com/2010/10/14/cvs-hit-with-record-77-million-fine-for-not-regulating-meth-ingredient/>

CVS

- Pays \$11 Million to Settle Drug Records Case
- CVS maintained invalid "dummy" DEA registration numbers or numbers other than the valid DEA registration number of the prescribing practitioner on dispensing records, which were at times provided to state prescription drug monitoring programs.

- http://www.justice.gov/usao/okw/news/2013/2013_04_03.html



- Drug Manufacturer Fails to Report Suspicious Sales and Pays \$35 million fine

Federal prosecutors say the British company failed to detect and notify the Drug Enforcement Administration of unusually large orders for oxycodone from U.S. pharmacies and pain clinics.

- <https://www.painnewsnetwork.org/stories/2017/7/12/drug-maker-pays-35-million-fine-for-opioid-sales>

Cardinal Health

■ Pays \$34 Million To Settle Pain Killer Case

- Cardinal failed to report to DEA suspicious orders of hydrocodone that it distributed to pharmacies that filled illegitimate prescriptions originating from rogue Internet pharmacy Web sites.

- https://www.justice.gov/archive/usao/co/news/2008/October08/10_2_08.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>

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>

UPS Pays \$40 Million because of Illicit Drug Deliveries

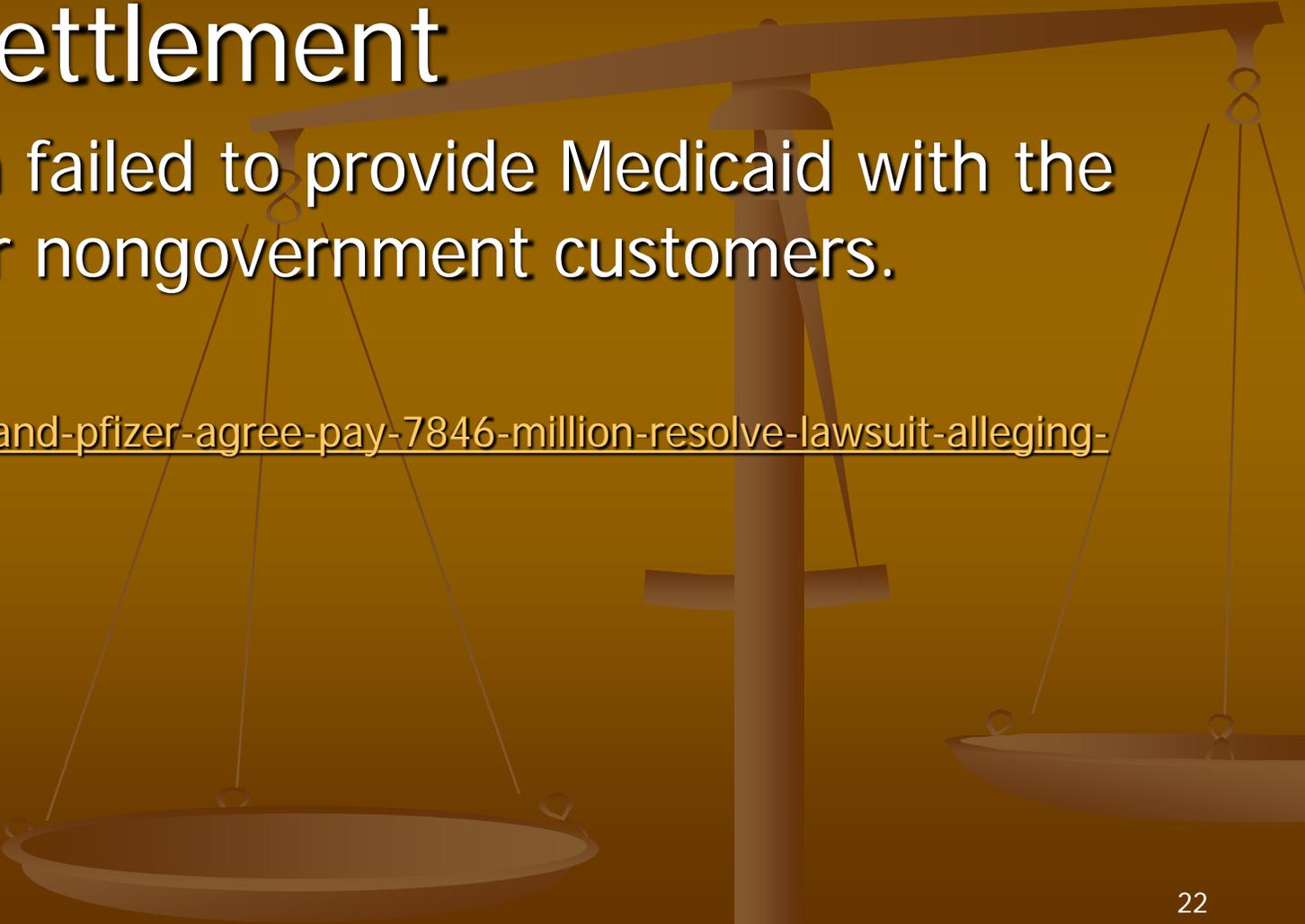
A federal criminal probe connected to deliveries it made for illicit online pharmacies.

- <https://www.cbsnews.com/news/ups-to-pay-40-million-to-end-federal-investigation-into-illicit-drug-deliveries/>



■ Pharmacy Fraud-Related Cases

Fraud



- **\$784,000,000 Settlement**
- Case: Pfizer and Wyeth 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>

\$100 Million Fraud by Florida Pharmacist

- This was a massive compounding fraud case.
- It affected insurance companies, Medicare and TRICARE.
- Fraudulent claims were for pain and scar creams.
- Real estate, cars and boats were forfeited.
- 8 guilty and waiting sentencing.
- This case was prosecuted by U.S. Attorney's office of the Middle District of Florida.
- <https://www.justice.gov/opa/pr/owner-florida-pharmacy-pleads-guilty-100-million-compounding-pharmacy-fraud-scheme-real>
- Reported November 6, 2017

Pharmacy Employee Charged in Conspiracy

- A non-pharmacist employee was charged in falsely billing public and private insurance providers \$1.5 million for medications that were never dispensed.
- FedEx records were allegedly forged to indicate the medications were shipped to recipients to make it appear that the medications were shipped to patients.
- The case is being prosecuted by the U.S. Attorney's office in the District of New Jersey.
- <https://www.justice.gov/usao-nj/pr/pharmacy-employee-charged-15-million-health-care-fraud-conspiracy>
- Reported January 24, 2018
- The charge and allegations in the complaint are merely accusations, and the defendant is considered innocent until proven guilty.

Kmart Settles for Overbilling

- Kmart agreed to pay \$32.3 million for overbilling Medicare, Medicaid and TRICARE on generic drugs they had received at discounted prices.
- They offered discounted drugs to cash-paying customers but did not offer the same discount to the government.
- The whistleblower, a pharmacist, will receive \$9.3 million.
- This case was prosecuted by the U.S. attorney for the Southern District of Illinois.

- <https://www.justice.gov/opa/pr/kmart-corporation-pay-us-323-million-resolve-false-claims-act-allegations-overbilling-federal>
- Reported December 22, 2017

N.C. Pharmacist Goes to Prison

- The pharmacist billed Medicare/Medicaid for Ketoprofen extended release capsules that he did not use in creating a compounded pain-relief cream.
- He lost his license and paid \$2 million back.
- He got a year in federal prison. He was 35 years old.
- This case was prosecuted by the U.S. Attorney's office in the Eastern District of North Carolina
- <https://www.justice.gov/usao-ednc/pr/north-carolina-pharmacist-sentenced-prison-medicare-and-medicaid-fraud>
- Reported October 11, 2017

Pharmacy Uses Unused Medications

- MedFast Pharmacy picked up unused medications from residents of nursing homes where they were repackaged.
- As a result different lot numbers and expiration dates were commingled in stock bottles and, as a result, ended up being misbranded.
- Medicare/Medicaid not reimbursed for unused drugs and billed for misbranded drugs.
- Prosecuted by U.S. Attorney's office in Western District of Pennsylvania.
- Pharmacist received probation and 150 hours community service.
- <https://www.justice.gov/usao-wdpa/pr/medfast-pharmacist-sentenced-probation-community-service-fraud-scheme>
- Reported October 17, 2017

Pharmacy Settles Fraudulent Claims to Medicare

- Glades Drug agreed to pay \$300,000 to settle claims that it violated the False Claims Act by not requiring copayments from Medicare or TRICARE beneficiaries.
- A whistleblower, who was a technician, initiated this suit.
- This *qui tam* would result in a fee being to the whistleblower.
- This case was prosecuted by the U.S. Attorney's office of the South District of Florida.

- <https://www.justice.gov/usao-sdfl/pr/glades-drugs-agrees-pay-united-states-300000-settle-allegations-fraudulent-claims>
- Reported December 18, 2017

■ Miscellaneous Pharmacy Litigation



Litigation Regarding PBMs

- Klein, et.al. v. Prime Therapeutics, Express Scripts, and CVS Health (Case No. 0:17-cv-01884(D.MN. 2017))
 - Class action against three major PBMS on behalf of Epipen purchasers with ERISA health plans for contributing to Epipen price inflation through rebates and breaching their fiduciary duty to plan members.
- Boss v. CVS Health Corp. (Case No. 2:17-cv-01823(D.N.J. 2017))
 - Class action against leading US drug makers and PMBs—including CVS, Express Scripts and OptumRx—alleging collusion to fix prices for insulin, leading to skyrocketing costs and windfall profits for companies.

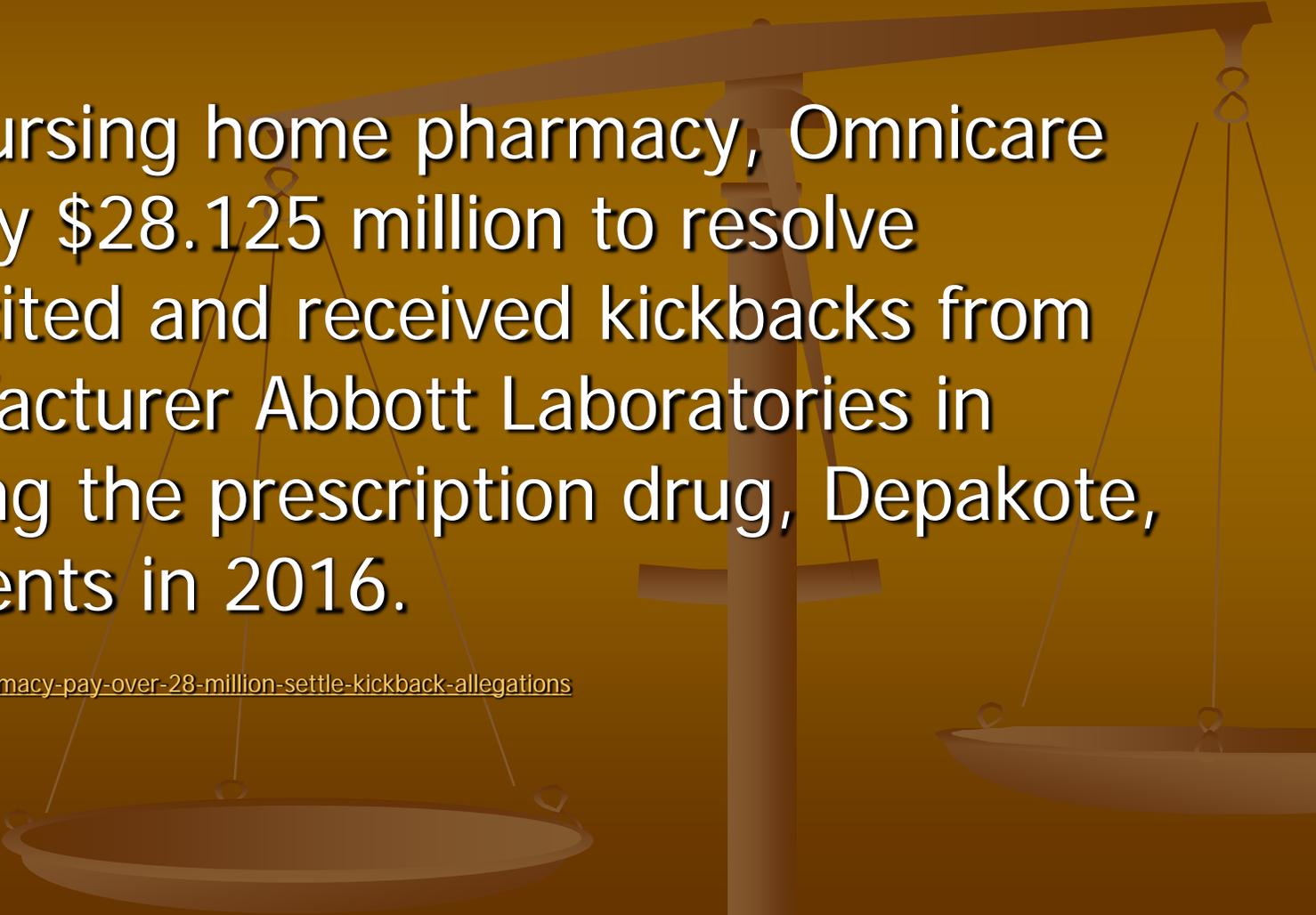
Hospitals to Sue CMS over 340B Drug Cuts

- Beginning January 1, 2018 CMS will only pay for drugs acquired through the 340B program at the average sales price (ASP) minus 22.5%, which is different from the ASP plus 6% that it previously paid.
- CMS believes that hospitals will still not be underpaid for the cost of the acquisition of such drugs.
- A Federal judge has blocked the suit which now allows CMS to move forward with reduction in payments.

<http://www.modernhealthcare.com/article/20171101/NEWS/171109982>

- <https://www.washingtonexaminer.com/hospitals-should-accept-the-cuts-to-340b-drug-payments/article/2646628>
- <https://revcycleintelligence.com/news/judge-denies-hospital-org-attempt-to-block-340b-drug-payment-cut>

Kickbacks by Omnicare



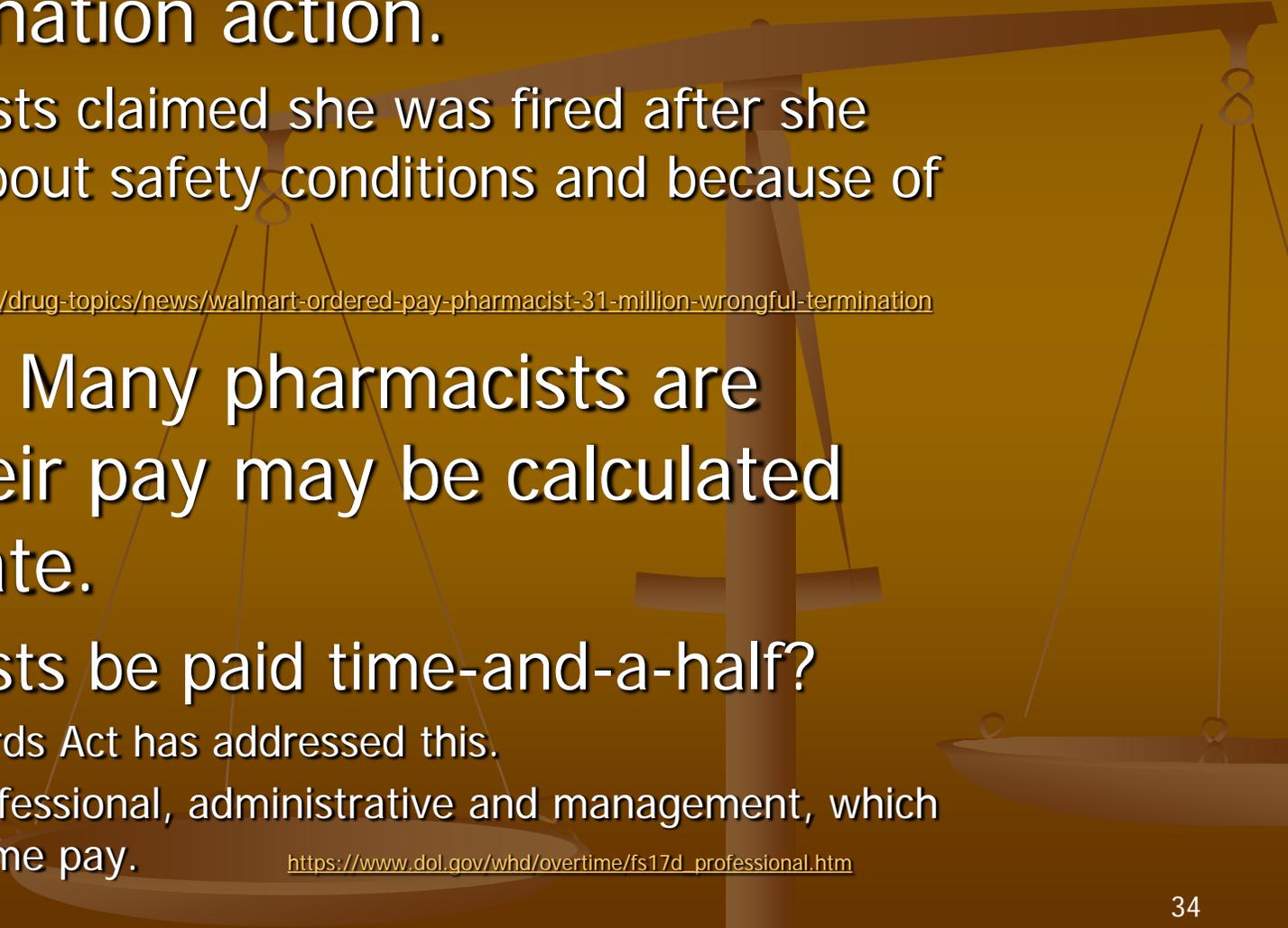
- The nation's largest nursing home pharmacy, Omnicare Inc., has agreed to pay \$28.125 million to resolve allegations that it solicited and received kickbacks from pharmaceutical manufacturer Abbott Laboratories in exchange for promoting the prescription drug, Depakote, for nursing home patients in 2016.

- <https://www.justice.gov/opa/pr/nation-s-largest-nursing-home-pharmacy-pay-over-28-million-settle-kickback-allegations>

Florida Pharmacy Involved in Kickback

- Pharmacist Larry Howard was convicted of conspiracy to pay kickbacks and or receiving kickbacks.
- He paid an individual to refer patients to a doctor selected by Howard who then prescribed pain or scar cream. The creams could cost up to \$17,000/bottle.
- In an 8 month time frame TRICARE paid \$4.3 million because of illegal kickbacks.
- <https://www.justice.gov/opa/pr/pharmacy-owner-medical-doctor-and-patient-recruiter-convicted-43-million-pain-and-scar-cream>
- Reported January 12, 2018

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

Antitrust Concerns

- Rite Aid initially planned to sell 865 stores to Fred's
 - Walgreens was going to buy 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.
 - Now the plan is for Walgreens to only buy a portion of the Rite Aid stores.

■ <https://www.aol.com/article/finance/2016/12/20/rite-aid-to-sell-865-stores-to-freds/21631995/>

■ <https://www.usatoday.com/story/money/2018/01/04/walgreens-rite-aid/1003860001/>

Walgreens Sued for Generic Overcharges

- The lawsuit accuses Walgreens of operating an undisclosed dual pricing scheme in which people who pay for generic drugs in cash are charged a lower price than the price reported to health insurers, Medicare, and Medicaid.
- A federal judge March 9, 2018, allowed the insured customers to move forward with claims of fraud and violations of more than a dozen states' consumer protection laws.
- *Dorothy Forth, et al. v. Walgreen Co., et al.*, Case No. 1:17-cv-02246, in the U.S. District Court for the Northern District of Illinois, Eastern Division. 2017
- <https://www.upi.com/CVS-Walgreens-sued-for-overcharging-pharmacy-customers/3071502380238/>
- <https://bnanews.bna.com/employee-benefits/walgreens-forced-to-defend-generic-drug-pricing-challenge>

Recent Legislative and Regulatory Changes



DEA Changes Registration Renewal Process

- The DEA will no longer send its second renewal notification by mail. Instead, an electronic reminder to renew will be sent to the email address associated with the DEA registration.
- If a renewal application is submitted in a timely manner prior to expiration, the registrant may continue operations, authorized by the registration, beyond the expiration date until final action is taken on the application.
- DEA allows the reinstatement of an expired registration for one calendar month after the expiration date. If the registration is not renewed within that calendar month, an application for a new DEA registration will be required.
- See: www.deadiversion.usdoj.gov/drugreg/index.html

FDA Issues Final Rule Amending List of Drug Products That May Not Be Compounded

- While the Federal Food, Drug, and Cosmetic Act (FD&C Act) that allow the marketing of unapproved compounded drugs. Drug products on the list may not be compounded because the drug products have been withdrawn or removed from the market for safety or effectiveness reasons.
- Some of the drugs (24 categories) include: *Oral Chloramphenicol, Adenosine Phosphate, Propoxyphene.*
 - See: <https://www.gpo.gov/fdsys/pkg/FR-2016-10-07/pdf/2016-24333.pdf>
 - See: <https://www.fda.gov/Drugs/DrugSafety/ucm524320.htm>

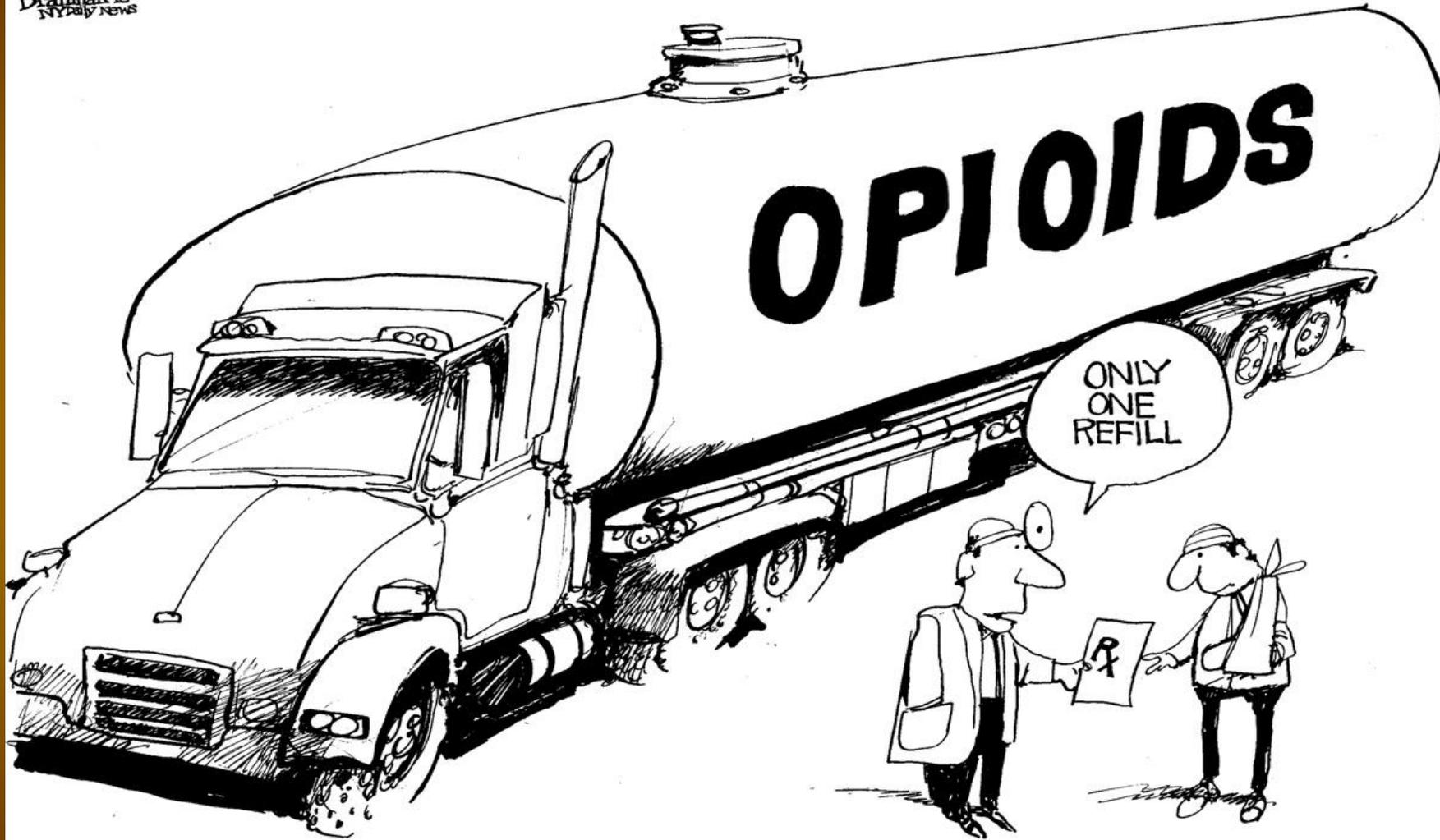
Transferring of Unfilled Electronic CDS Rxs

- On July 7, 2017, DEA addressed concerns about confusion over whether a pharmacy can forward unfilled electronic prescriptions for controlled substances (EPCS) to another pharmacy.³⁸ DEA clarified that a DEA-registered pharmacy may forward an unfilled original EPCS to another DEA-registered pharmacy, including prescriptions for Schedule II controlled substances.
- See: <http://www.ncbop.org/PDF/LMillerDEAGuidanceTransferofOnFileCSPrescriptions.pdf>

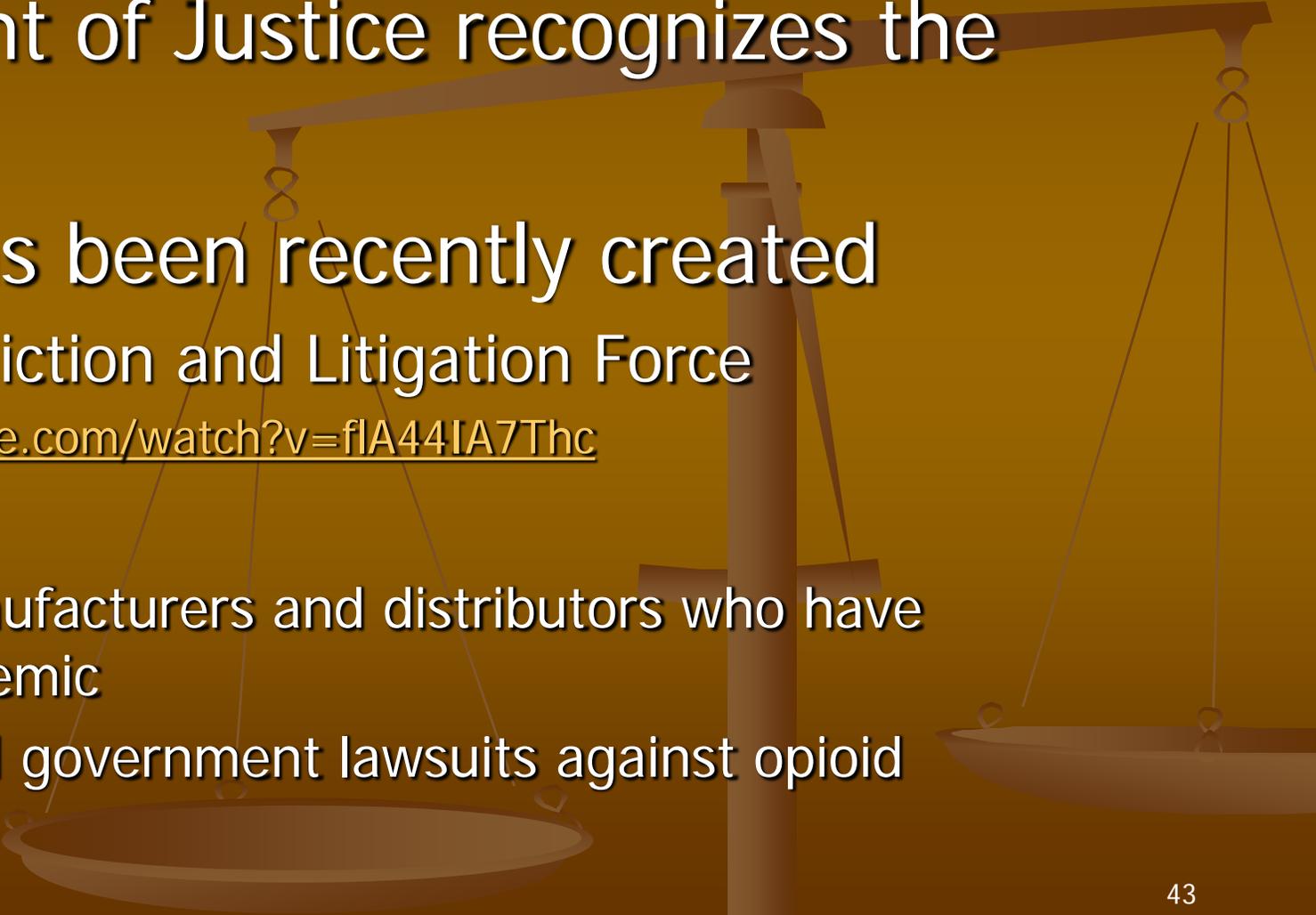
The Opioid Crisis



Branhall '16
NY Daily News



Opioid Litigation

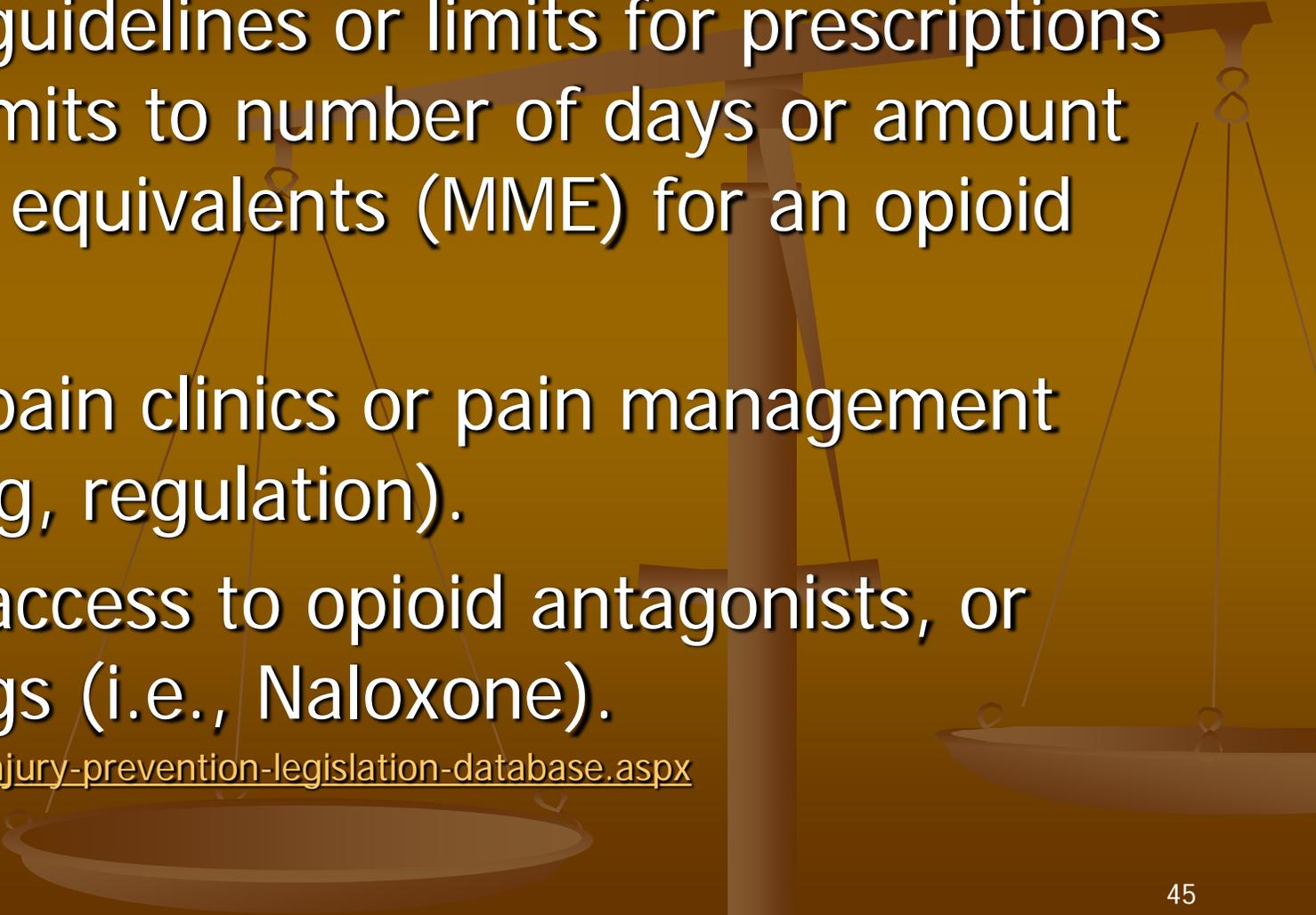


- The U.S. Department of Justice recognizes the problem.
- A new task force has been recently created
 - The Prescription Interdiction and Litigation Force
 - <https://www.youtube.com/watch?v=flA44IA7Thc>
 - Purpose:
 - Targeting of opioid manufacturers and distributors who have contributed to this epidemic
 - To assist state and local government lawsuits against opioid manufacturers

States, Counties, Cities Filing Opioid Lawsuits

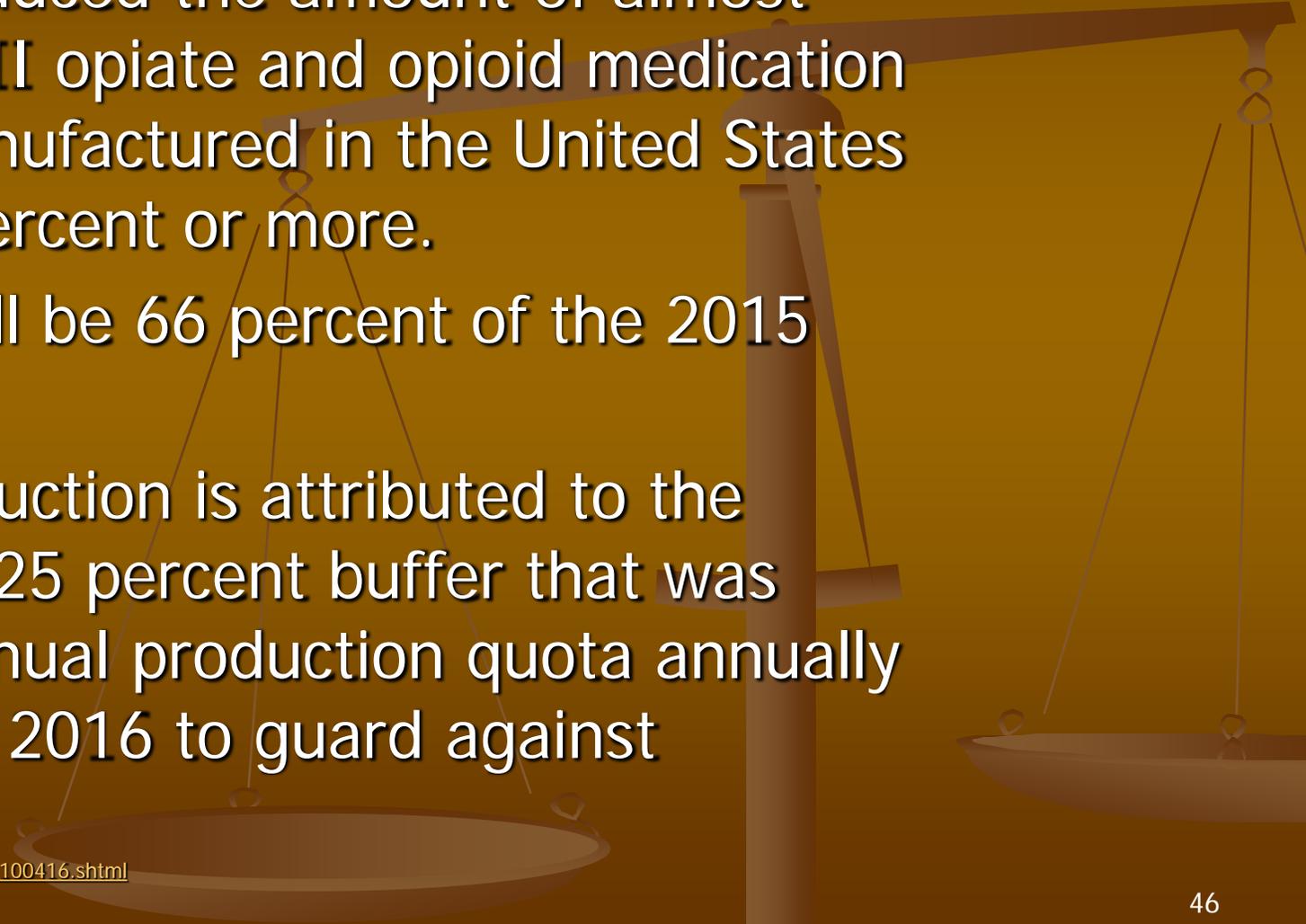
- Michigan cities, counties file lawsuit against 21 drug companies, distributors and pharmacies accusing them of helping fuel the national opioid epidemic.
 - <http://www.foxnews.com/health/2017/12/20/michigan-cities-counties-opioid-lawsuit-targets-drug-companies-pharmacies.html>
- Cherokee Nation Files Action against pharmacies, wholesalers
 - <https://www.npr.org/sections/codeswitch/2017/04/25/485887058/cherokee-nation-sues-wal-mart-cvs-walgreens-over-tribal-opioid-crisis>
- Ohio, New Mexico File Actions against manufacturers
 - <http://abc6onyourside.com/news/local/ohio-attorney-general-files-lawsuit-against-5-drug-makers-over-opioid-addiction-epidemic>
 - <http://www.jurist.org/paperchase/2017/09/new-mexico-files-lawsuit-against-big-pharma-companies.php>

Opioid Abuse Prevention Legislation in 2017



- Legislation related to guidelines or limits for prescriptions of opioids, including limits to number of days or amount of morphine milligram equivalents (MME) for an opioid prescription.
- Legislation related to pain clinics or pain management facilities (e.g., licensing, regulation).
- Legislation related to access to opioid antagonists, or overdose reversal drugs (i.e., Naloxone).
- See: <http://www.ncsl.org/research/health/injury-prevention-legislation-database.aspx>

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>

DEA mandates reduction in opioid manufacturing for 2018

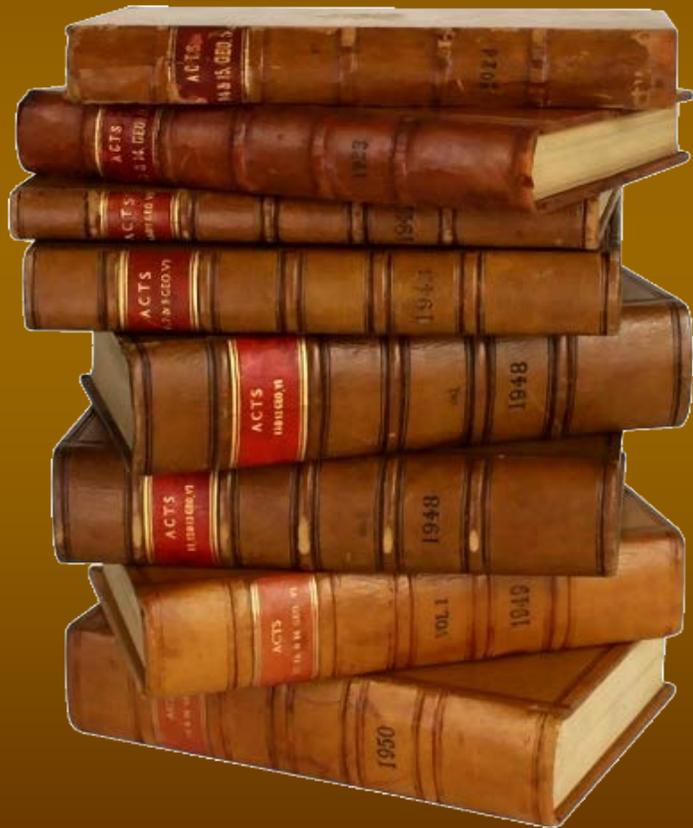
- DEA's finalized annual aggregate production quotas (APQs) for 2018 mandate a 20% reduction in the amount of opiate and opioid medication—including oxycodone, hydrocodone, oxymorphone, hydromorphone, morphine, codeine, meperidine, and fentanyl—that may be manufactured in 2018.
- Quotas are aimed at preventing a diversion while simultaneously satisfying annual needs.
 - See: <http://www.pharmacist.com/article/dea-mandates-reduction-opioid-manufacturing-2018>
 - See: <https://www.dea.gov/divisions/hq/2017/hq080417.shtml>
 - See 2017 info: <https://www.dea.gov/divisions/hq/2016/hq100416.shtml>
 - See history of CII quotas: https://www.deadiversion.usdoj.gov/quotas/quota_history.pdf

Comprehensive Addiction and Recovery Act of 2016

- The Act amended the Controlled Substances Act (CSA) to expand the categories of practitioners (nurse practitioner or physician assistant) who may, under certain conditions on a temporary basis, dispense a narcotic drug in Schedule III, IV, or V for the purpose of maintenance treatment or detoxification treatment.
- DHHS, by regulation, increased to 275 the maximum number of patients that a practitioner may treat for opioid use disorder without being separately registered under the CSA for that purpose.

Our Pharmacy Life is Complicated by Law

Laws are Complex



Grace is Not!





This is your chance to ask a lawyer a question without getting charged!