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(Roughly) Twelve Months in Health Care Law A Roller Coaster Journey

First Monday in October 2013 (10/7/13)
Elizabeth Carder-Thompson
Washington, D.C.

Portions of this presentation appeared in the Year in Review 2013 Keynote at the American Health Lawyers Association Annual Meeting (ECarder-Thompson and JSchroder).

*With thanks to many fine contributors of interesting cases and technical assistance:
Nancy Bonifant, Meghan Gyory, Scot Hasselman, Debra McCurdy*

Fasten Your Seatbelts

- Health Care Reform
- Fraud and Abuse
- Health Info and HIPAA
- Medicare and Medicaid
- Pharma and Device
- Research



Health Care Reform



What's happened since the Supreme Court upheld the Affordable Care Act?

House GOP Votes to Repeal Obamacare for 40th Time

Huffington Post 8/2/13

- See Rep. Tom Price (R-Ga) “Keep the IRS Off Your Health Care Act of 2013”
- New York Times calculated that, as of May, these efforts had accounted for 15% of time on House floor *NYTimes 5/14/13*

As Government Shuts Down, Obamacare Moves Forward

Washington Post 9/30/13

Throughout, agencies have continued to implement health reform regulations under the ACA

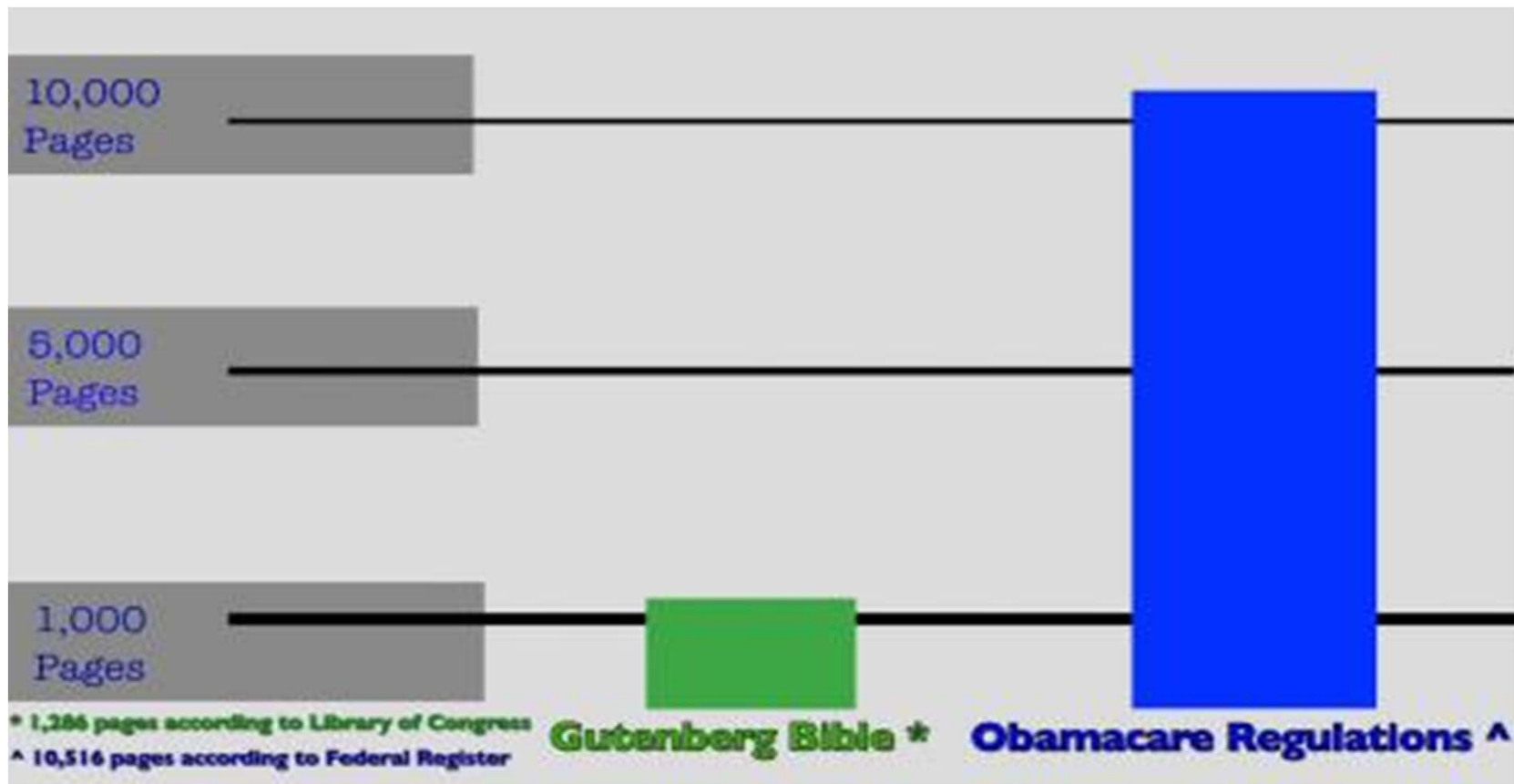
True to Predictions...Avalanche of Post-Election Rules:

- Final rule on essential health benefits, calculating actuarial value, accreditation standards. *78 Fed Reg 12833 (Feb. 25, 2013)*
- Final ACA health insurance market reform rules (fair health insurance premiums, guaranteed insurance availability and renewability, statewide insurance risk pools, enrollment in catastrophic plans, and insurance rate reviews). *78 Fed. Reg. 13405 (Feb. 27, 2013)*
- Final rule on employment-based wellness programs. *78 Fed. Reg. 33157 (June 3, 2013)*
- Final rule on Medicaid and CHIP eligibility & enrollment *78 Fed. Reg. 42159, July 15, 2013)*
- ACA benefit, payment parameter rules for 2014 *78 Fed. Reg. 15409 (March 11, 2013)*
- Final rule on federal funding for Medicaid expansion. *78 Fed. Reg. 19917 (April 2, 2013)*
- Final rule on health insurance exchange “navigators.” *78 Fed. Reg. 42823 (July 17, 2013)*
- Final rule on ACA Medical Loss Ratio for MA/Part D. *78 Fed. Reg. 31283 (May 23, 2013)*
- Final ACA Exchange/Qualified Health Plan financial integrity and oversight standards. *78 Fed. Reg. 54069 (Aug. 30, 2013).*
- Final ACA Medicaid DSH funding reduction rule. *(Sept. 18)*

And those were just the final HHS/CMS regs: more in the avalanche

- OSHA interim final rule to protect employees against retaliation by an employer for reporting alleged violations of various insurance provisions *78 Fed. Reg. 13222 (Feb. 27, 2013)*
- OPM final rule re multistate insurance plans that will be offered on state health insurance exchanges beginning in January 2014. *78 Fed. Reg. 15559 (March 11, 2013)*
- IRS proposed rule re ACA's annual fee on covered entities engaged in the business of providing health insurance. *78 Fed. Reg. 14034 (March 4, 2013)*
- IRS final rule on 2.3% medical device excise tax, and proposed rule on employer "shared responsibility" requirements for employee health coverage *77 Fed. Reg. 72924 (Dec. 7, 2012); 78 Fed. Reg. 218 (Jan. 2, 2013)*
- IRS final rule on individual "shared responsibility" payments – but employer mandate delayed one year *78 Fed. Reg. (Aug. 30)*
- IRS proposed rule on employer insurance reporting requirements. *78 Fed. Reg. 54986 (Sept. 9.)*
- IRS proposed rule on ACA insurance premium tax credit. *78 Fed. Reg. 25909 (May 3, 2013)*
- IRS proposed rule on Medical Loss Ratio. *78 Fed. Reg. 27873 (May 13, 2013)*
- IRS/ERISA/CMS Proposed Insurance Waiting Period Rule. *78 Fed. Reg. 17313 (March 21, 2013)*

Obamacare Regulations Are Eight Times as Long as Bible



The Affordable Care Act Three Years Later

Kaiser Family Foundation Publication #8429 (March 2013)



1) Private Insurance and Exchanges:

- Young adults on parents' policies to age 26
- 17 states and DC are establishing exchanges
- No coverage exclusions for children with pre-existing conditions
- Medical loss ratio and rate review in place/premiums lower
- Health plans must provide Summary of Benefits and Coverage

The Affordable Care Act Three Years Later (contd)

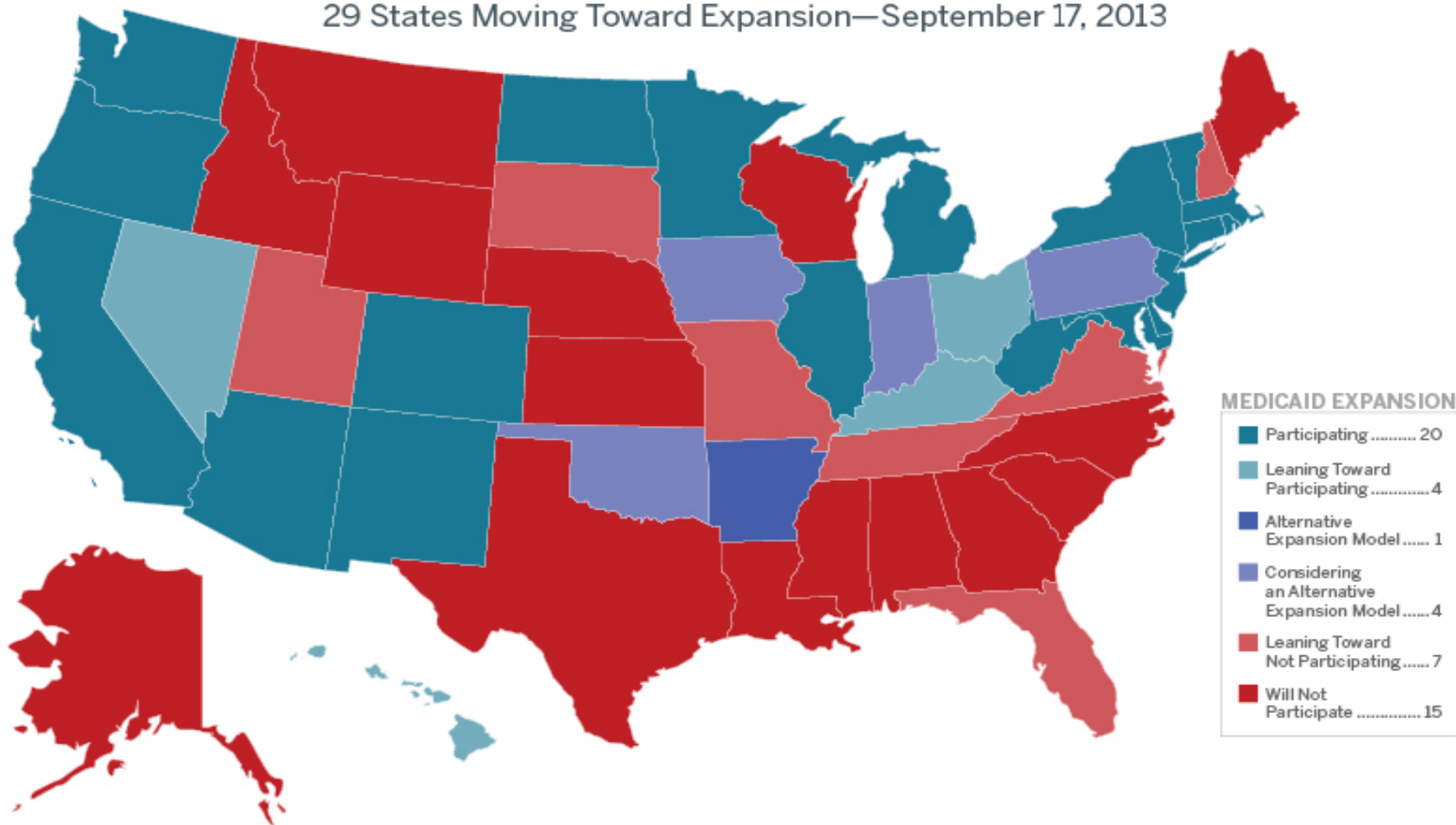
2) Medicaid

- Medicaid expansion supported in 27 states
- Medicaid expanded to adults in 7 states
- Low-income children/pregnant women still primarily covered by Medicaid and CHIP
- Most states have modernized/streamlined Medicaid enrollment
- Health home option adopted by 10 states
- Many states have expanded home/community-based long-term services



Beyond the Pledges: Where the States Stand on Medicaid

29 States Moving Toward Expansion—September 17, 2013



Notes: Based on literature review as of 9/17/13. All policies subject to change without notice.
HHS has announced that states can obtain a waiver to use federal funds to shift Medicaid-eligible residents into private health plans.
The District of Columbia plans to participate in Medicaid expansion and will operate its own exchange.

Source: American Health Line, <http://ahlalerts.com/2012/07/03/medicaid-where-each-state-stands-on-the-medicaid-expansion/>, accessed 9/17/13.

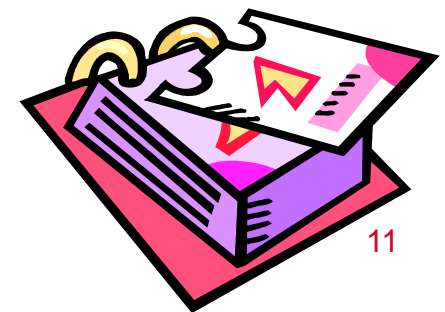
The Affordable Care Act Three Years Later (cont'd)

3) Access to Primary Care

- Increased M/M payments to primary care providers
- Increased state health center patient capacity
- National Health Service Corps ranks have tripled since 2008, in medically underserved communities
- Expansion efforts underway for primary care workforce

4) Access to Preventive Care

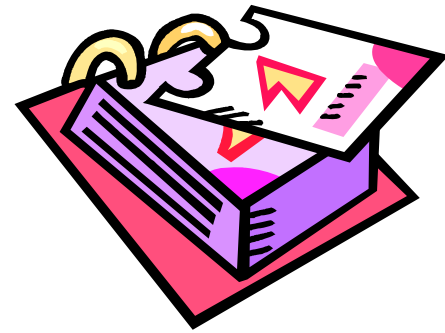
- Medicare and most private insurance now provide preventive benefits with no cost-sharing
- New Prevention and Public Health Fund



The Affordable Care Act Three Years Later (cont'd)

5) Medicare

- 52.5% discount on brand name Part D drugs in doughnut hole
- New delivery system/payment initiatives, including ACOs and bundled payments
- Miscellaneous savings measure



6) Dual Eligibles

- Some states developing/testing models that align Medicare/Medicaid financing

Sounds good, but...

Health Care Reform Survey Shows Public Divided And Unaware About Key Benefits

Posted: 03/20/2013 1:01 pm EDT | Updated: 03/21/2013 10:44 am EDT



Setting the Stage for the Supreme Court

Under ACA, health plans must cover women’s “preventive care” services, including all contraceptive methods; exception for religious employers

- Suits allege violations of Religious Freedom Restoration Act, rights to free speech, exercise, and establishment clause rights under 1st Amendment - 60 suits unfolding nationally
- Most decisions thus far found substantial likelihood of success at motion stage – others held that for-profit entities cannot assert religious rights, or corporate form is impediment to asserting *owners’* rights.

- *BNA Health Law Reporter* 5/9/13, 10/2/13; *Law 360* 10/4/13; see, e.g, *Korte v. HHS* (Docket No. 1203841) 7th Cir.; *Newland v. Sebelius*, No. 12-1380 (10th Cir. Oct. 3, 2013); *Hobby Lobby Inc. v. Sebelius* 2012 WL 6930302 10th Cir. oral arguments pending; *Conestoga Wood Specialties v. Sebelius*, case no. 13-1144 (3d Cir. 7/26/13). See also *SCOTUSBlog* 6/27/13



ACA Employer Mandate: Courts Defend but Administration Delays

White House Delays Employer Mandate Requirement Until 2015

Washington Post 7/2/13

Treasury Dept. Blog Post, “Continuing to Implement the ACA in a Careful, Thoughtful Manner” 7/2/2013

In the meantime....

Fourth Circuit Refuses to Strike ACA Employer Mandate

Unanimous panel rejected challenge to employer mandate, which “is simply another example of Congress’s longstanding authority to regulate employee compensation offered and paid for by employers in interstate commerce.” *Liberty University v. Lew*, No. 10-2347 (4th Cir. 7/11/13)

See also [*Sissel v. HHS*](#), D.D.C., No. 1:10-cv-1263, 6/28/13 (upholding employer mandate; Senate did not violate Origination Clause when it used “gut-and-amend” procedure to strip language out of bill that originated in House and insert language of ACA)

Ongoing ACA-Related Fraud and Abuse Activity

Current activities by fraudsters: blast emails, calls, faxes, home visits, invoking the ACA as a pretext for seeking Medicare numbers, bank identifiers from consumers.

New OIG Alert: <https://oig.hhs.gov/fraud/consumer-alerts/alerts/marketplace.asp>; new HHS/FTC interagency initiative announced 9/18/13 re consumer fraud, privacy violations

Concerns:

- Fraudulent exchange navigators
- Bogus exchange websites
- Selling exchanges to *Medicare* beneficiaries
- Consumer income eligibility fraud
- Cybercrime
- Agent/broker fraud

Expect more FCA enforcement

“The ACA oxygenates the federal whistleblower law ...[to] thwart...fraud that could chew at the underpinnings of the monumental reform effort.” **Dennis Jay, Executive Director, Coalition Against Insurance Fraud BNA 8/21/13**

In some less anticipated developments:

Ways and Means issues subpoena for
Obamacare P.R. documents *Politico 11/14/12*

HHS [Secretary] asking firms for money
for Obamacare. *Washington Post 5/11/13*



And at the state level.....

South Carolina Lawmakers Propose 5-Year Jail Sentence for 'Obamacare' Implementation

Federal officials could face fines and jail terms under proposed legislation



US News 12/17/12



Fraud and Abuse



Fraud & Abuse Roadmap

- Numbers + Initiatives
- OIG and CMS Developments
- Criminal False Claims
- False Claims/Qui Tam
- Kickbacks
- Stark
- Exclusions
- FCPA
- Insider Trading
- Pharma/Device Developments
- Going after Individuals
- F&A Miscellany



Fraud and Abuse: Numbers + Initiatives

DOJ, HHS Announce Record-Breaking Fraud Recoveries in FY 2012 *DOJ Press Release 2/11/13*

- Health care fraud recoveries at \$4.2 B; 826 convictions
- ROI: \$7.90 for every \$1 invested



“Predictive Analytic Technology” Prevented \$115.4M in First Year *CMS Report to Congress 12/21/12*

Fraud and Abuse: Numbers and Initiatives

HEAT: Health Care Fraud Prevention and Enforcement Team – criminal focus

- Joint HHS-DOJ Collaboration – established 5/20/09
- Expanded data sharing, training
- Medicare HEAT Strike Force – began Miami 2007
 - By September 2012: 724 cases charging 1,476 defendants, who had billed Medicare > \$4.6B
- Key areas for prosecution:
 - Mental health
 - Home health
 - DME
 - Physical therapy

Fraud and Abuse: Numbers + Initiatives

Variable Contractor Results

Inaccurate ZPIC Reporting Prevented Effective Oversight, OIG Finds

Medicare RACs “corrected \$939.3M in improper payments” -- but, after “underpayments, appeals, contingency payments, and costs,” recovered \$488.2 M

- **AHA Survey stats:** Q4 2012: 47% increase in medical records requests, 58% increase complex audit denials
- 40% appealed, 70% success rate



OIG Report 4/23/12; CMS Report 2/5/13

Fraud and Abuse: New OIG Guidance

Revised Self-Disclosure Protocol (SDP)

New online submission process (7/8/13)



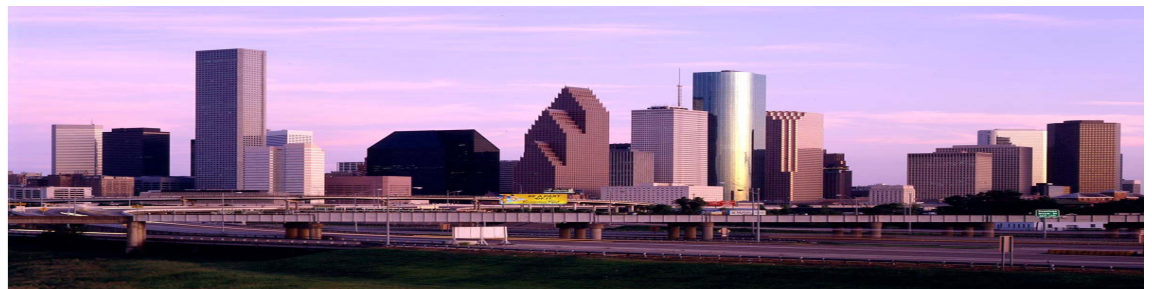
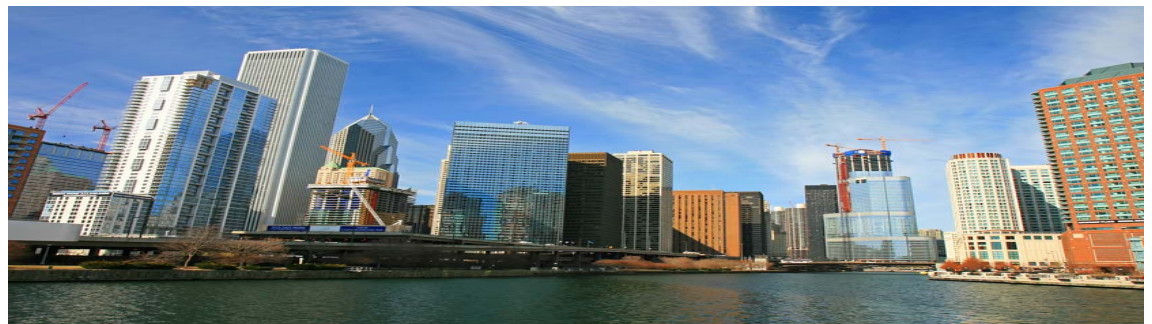
- Recall that 2/12 proposed rule requires provider returns of “overpayments” within 60 days (*but NB this is already a statutory requirement!*)
- Provider’s timely SDP submission would suspend the 60 day limit
- First SDP was in 1998 – 3 open letters since
- Provides guidance on calculating penalties for multiple violations, reporting conduct by excluded individuals, kickbacks

<http://op.bna.com/hl.nsf/r?Open=jswm-96tk9e> 4/17/12

Fraud and Abuse: CMS Initiatives

**CMS Issues First
Temporary
Moratorium on
Provider, Supplier
Enrollment in
Three Areas**

Law360 7/26/13



Criminal False Claims: Portent of the Future?

US v. WakeMed *US v. WakeMed, 2013 WL 595158 (E.D. NC settlement 12/19/12)*

- Raleigh not-for-profit hospital system agreed (after 2 years of negotiations) to deferred prosecution agreement (DPA) and \$8M settlement – had billed cardiac stays as inpatient when should have been outpatient 2003-2010 – criminal plea but civil settlement
- Judge Terrence Boyle initially refused to accept the DPA:

“Why are you coming to court if you tell me you don’t need me – I’m just window dressing in this case?”

“It’s very difficult for society and the court to differentiate between the everyday working Joe or Jane who goes to prison, and the nonprofit corporate giant who doesn’t go to jail, who gets a slap on the hand and doesn’t miss a beat.”

See also **US v. Kuhlman**, in which 11th Circuit insisted GA chiropractor should receive jail time for \$3M insurance fraud scheme. 711 F.3d 1321 (11th Cir. 3/8/13) – petition pending before US Supreme Court

Criminal False Claims/Kickbacks: Sacred Heart Hospital



Two Executives, Five Physicians Charged After Raid of Chicago Hospital

*BNA 4/16/13 US v. Novak, N.D. IL No. 1:13 CR 0312
(4/15/13)*

Alleged kickback conspiracy including
CEO/owner, CFO, physicians

Complaint alleges unnecessary intubations,
tracheostomies, penile implants, controlled
substances prescribing, admissions from ER

\$5M paid to owner's ventures

Criminal Enforcement: cGMPs

Ranbaxy USA Inc.

- Pled guilty to seven felony charges as part of global settlement 5/13/13
- Felony FDCA counts and false statements to FDA
- Will pay \$500M to resolve criminal and FCA liability
 - *Graphic below accompanied a 11/25/04 Rediff interview with CEO re Ranbaxy successes:*



Criminal False Claims – Kazarian Ring

US v. Kazarian *2012 WL 1810214 (SDNY)*

\$100M Medicare fraud billing ring by Mirzoyan-Terdjanian Organization
(Armenian-American organized crime)

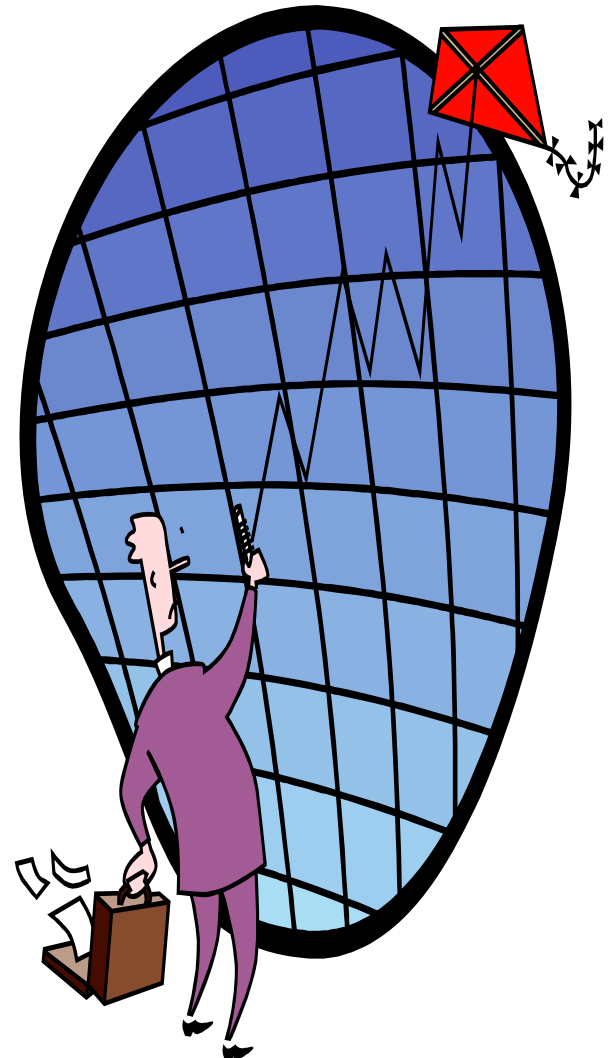
Of 28 defendants charged, 20 have been sentenced

Set up 118 fraudulent providers in 25 states, plus insurance fraud

Ringleader sentenced 8/15/13 to 125 months in prison (upper sentencing limit – double what was urged by defense); involved his father (sentenced + deported) and wife in scheme

Civil False Claims Enforcement FY 2012 – A Deeper Dive into the Numbers

- 647 new qui tam matters filed
- 885 new civil health care fraud investigations opened
- 1,023 matters pending at end of FY 12
- Total FCA recoveries >\$3B
- Total qui tam relators' share: \$284M
- Rate of DOJ intervention: 22%
 - *DOJ Press release 12/4/12*



Fraud and Abuse: False Claims/Qui Tam

Beware the internal audit



US and Wisconsin ex rel. Keltner v. Lakeshore Medical Clinic

2013 WL 1307013 (E.D. WI)

- Former employee of group practice filed qui tam alleging upcoding and more, discovered via internal audit
- Group found errors, made refunds for specific claims from audit, but stopped there
- Claim for reverse false claims survived motion to dismiss

See also US ex rel Myers v. Shands Healthcare et al., Civil Action No. 3:08-cv-441-J-16HTS (M.D. Fla.) (qui tam relator was hospital system's billing consultant, that had responded to RFP to conduct audit).

Fraud and Abuse: False Claims/Qui Tam

U.S. ex rel. Williams v. Renal Care Group Inc., 2012 WL 4748104 (6th Cir. 10/5/12)

Overtaken \$82M FCA judgment against dialysis company

Key reasons defendants were not in “reckless disregard”:

- 1) they sought legal counsel on the issue;
- 2) legal counsel sought clarification on the rules from CMS officials;
- 3) a follow-up letter from counsel referenced a positive conversation with a CMS official & requested confirmation (no answer ever sent)

“Why a business ought to be punished solely for seeking to maximize profits escapes us.”

“[T]hey consistently sought clarification on the issue, followed industry practice in trying to sort through ambiguous regulations, and were forthright with government officials over [their] structure. To deem such behavior ‘reckless disregard’ of controlling statutes and regulations imposes a burden...far higher than what Congress intended...”

Fraud and Abuse: False Claims/Qui Tam

Recent Cases Limiting Application of the FCA:

- FCA complaint accused **Mayo Clinic** of failing to submit required written reports along with bills for lab work
- 8th Circuit: No clear requirement for written report – relators alleged only regulatory noncompliance, not false claims

Ketroser et al. v. Mayo Foundation et al., case number 12-3206 (8th Cir.)

• Relator alleged **Cardinal Health** sold defective devices to the government, violating implied certification of merchantability; 5th Circuit response:

- *“Not every breach of federal contract is an FCA problem.... FCA is not a general enforcement device for federal statutes, regulations, and contracts.”*
- *“[Relator] alleges an implied certification of an implied contract provision that is an implied prerequisite to payment.”*
 - *[Steury v. Cardinal Health, Inc.](#), No 12-20314 (5th Cir. Aug. 20, 2013)*

Fraud and Abuse: False Claims/Qui Tam

Good news or bad news?

U.S. ex rel. Hobbs v. Medquest Associates, *U.S. ex rel. Hobbs v. Medquest Associates*, 711 F.3d 707 (6th Cir. 4/1/13)

Threw out \$11.1M judgment against medical imaging company that submitted >1000 claims using physician supervisors who were not Medicare-approved, billed using another physician's number, and more.

Conditions of **participation** are not conditions of **payment** and thus do not trigger FCA liability

“[We have] little sympathy for MedQuest, which sometimes skirted and appears to have often ignored applicable regulations in the conduct of its centers....At the same time...because [these] regulations are not conditions of payment, they do not mandate the extraordinary remedies of the FCA and are instead addressable by the administrative sanctions available, including suspension and expulsion from the Medicare program.” (emphasis added)

See also US ex rel. Foglia v. Renal Ventures Mgmt 2012 US Dist LEXIS 139160, 2012 WL 4506014 (DNJ 2012) (staffing requirements are conditions of participation not payment)

Fraud and Abuse: False Claims/Qui Tam

Options for Employers?

Company Targeted in FCA Action Fights Back in Counterclaims Against Relators – Survives Motion to Dismiss

- Relators were respiratory therapists working for home health and equipment provider; qui tam alleged breach of VA contracts and thus false claims
- Had signed employment contracts that they would not disclose confidential information or participate in qui tam suits against employer (but would turn over qui tam awards to company nonetheless), would comply with HIPAA, and would notify employer of suspect business
- Employer counterclaimed against relators in M/D action; relators moved to dismiss on public policy grounds; court refused to dismiss – disclosures exceeded scope necessary to pursue qui tam case
- *United States ex rel. Wildhirt v. AARS Forever, Inc.*, 2012 WL 5304092, No. 1:09-cv-1215, (N.D. Ill., Sept. 19, 2013)

Fraud and Abuse: False Claims/Qui Tam

First-to-File Rule

U.S. ex rel. Heineman-Guta v. Guidant Corp. 718 F.3d 28 (1st Cir. 2013)

- An earlier dismissed FCA complaint can still bar later action, under first-to-file rule
- 2009 – Relator’s complaint alleged kickbacks by device company (lavish trips and entertainment to physicians, “speaking honoraria”)
- She didn’t know *another* relator had filed the prior year, with essentially the same facts, and the government had declined to intervene (dismissed/seal lifted 2011)
- Court: Congress did not explicitly incorporate Rule 9(b) particularity requirement into first-to-file bar – first case was still enough to put government on notice of scheme (now split in circuits)

Fraud and Abuse: Moving on to Kickbacks

Many cases are settlements involving drug and device manufacturer remuneration to physicians....

Orthofix Subsidiary to Pay Government \$30M to Settle Illegal Kickback Claims *US ex rel. Hutcheson v. Blackstone Medical, 2010 WL 938361 (D MA 3/12/10); settlement 11/2/12*

\$11.4M Settlement in [Victory Pharma] Kickback Case *Modern Healthcare 12/27/12*

Sanofi-Aventis to Pay \$109M Over Allegations of Free Product Kickbacks to Doctors *AP 12/19/12*

Qui tam cases against pharma companies for Medicare fraud and Medicaid fraud can involve kickbacks, off-label marketing and other improper practices

Phillips & Cohen has been very successful in qui tam cases against pharma companies. We have brought whistleblower cases against pharma companies for off-label marketing, kickback schemes and other Medicare and Medicaid fraud practices. Those whistleblower cases - such as our record-setting cases against GlaxoSmithKline and Pfizer Inc. -- have settled for huge sums and resulted in our clients getting hefty rewards.

Excerpt from website of relator's firm Phillips & Cohen, Washington DC; similar entry covers devices

Fraud and Abuse: Kickbacks

Some directly implicate physicians , labs, hospital officials

Miami Docs Get 10 Years in \$200M Medicare Kickback Scheme *US v. Willner (no. 1:11-cr-20100 SD FL 2012) (indictment 2011 WL 546789)*

Federal Prosecutors Announce Charges in NJ Labs Kickbacks Case
US v. Biodiagnostic Laboratory Services D.N.J. No 13-mj-8106 (4/9/13)

Major NJ Hospital Pays \$12.5M to Resolve Kickback Allegations
www.justice.gov/usao/nj/Press/files/Cooper%20Settlement%20PR.html

Court Sentences New York Hospital Execs to Prison for Role in Kickback Conspiracies *US v. Yaron 2012 WL 2477646 (SD NY 6/28/12)*



Fraud and Abuse: Kickbacks

And some implicate lawyers, too

8 Houston Attorneys Accused of Chiropractor Kickback Scheme Law360 3/25/13; www.khou.com 3/25/13

- Houston personal injury attorneys and one member of TX House of Representatives received arrest warrants on barratry * charges (third degree felony punishable by up to ten years in prison a \$10,000 fine)
- Ringleader Robert Valdez received kickbacks from attorneys to whom he referred accident victims – also sent victims to chiropractic clinics he owned.

* *“Barratry” = “ambulance chasing”*

Fraud and Abuse: Kickbacks

On-call Payments – OIG Advisory Opinion 12-15

- Guarded OK for hospital payments to on-call ER Docs
- Not-for-profit charitable hospital paid per diem to specialist physicians for providing on-call coverage to ER (which had 19% uncompensated care)
- OIG: On-call coverage comp potentially creates “considerable risk”
- **But** this arrangement presented low risk because:
 1. Independent valuation of FMV
 2. Per diem calculated/administered annually
 3. Compensation is for actual services (30-minute availability etc.)
 4. Participation offered equally to all specialists
 5. Hospital absorbs costs and does not pass on to federal programs

Fraud and Abuse: Kickbacks

Physician-Owned Distributors – OIG Special Fraud Alert

PODs are “inherently suspect” under anti-kickback statute

- **Definition:** “any physician-owned entity that derives revenue from selling, or arranging for the sale of, implantable medical devices,” including “physician-owned entities that purport to design or manufacture, typically under contractual arrangements, their own medical devices or instrumentation.”
- **Concerns:** (1) corruption of medical judgment; (2) overutilization; (3) increased costs to federal health care programs and beneficiaries; and (4) unfair competition.

Warning both to physicians and hospitals/ASCs using PODs

OIG Special Fraud Alert March 26, 2013





Moving to Stark (Physician Self-Referral) Issues

First, the headline we've all been waiting for:

flexible mentoring s
spect supportive trust
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communication mo
innovative educ
culture training stable fun
rship inspiration loyalty
ative flexible mentoring
spect supportive trust

BEST PLACES TO WORK™
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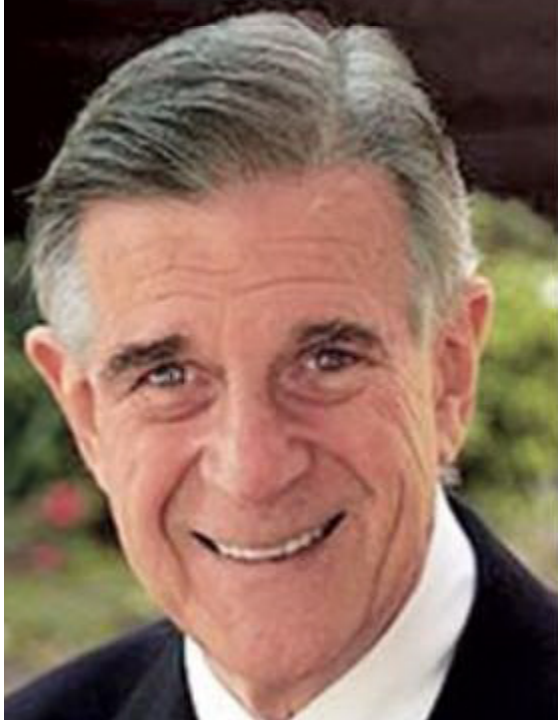
THE HEALTHCARE BUSINESS BLOG
VITAL SIGNS



Pete Stark: Repeal the Stark law

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The healthcare world is populated by scores of legal experts who strive to keep up with the sprawling compendium of statutes, regulations and legal advisories known collectively as the “Stark law.” But the law’s father and namesake, Fortney “Pete” Stark, is not one of them.

Stark, in fact, says he would favor repealing the law as it currently exists and getting back to the law’s initial intent.

The longtime California congressman has kept a low profile since another Democrat narrowly beat him and ousted him from office in 2012 after 40 years in Congress and a long tenure heading a key House healthcare subcommittee. Reached by phone in at his home in Maryland on Thursday, Stark sounded like nothing so much as a Stark law originalist, lamenting the complexity that has been heaped upon the statute since the bill he sponsored was enacted as the Ethics in Patient Referral Act in 1989.

Archives

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70%
 of our hospitals have



44

Fraud and Abuse: Stark Settlements

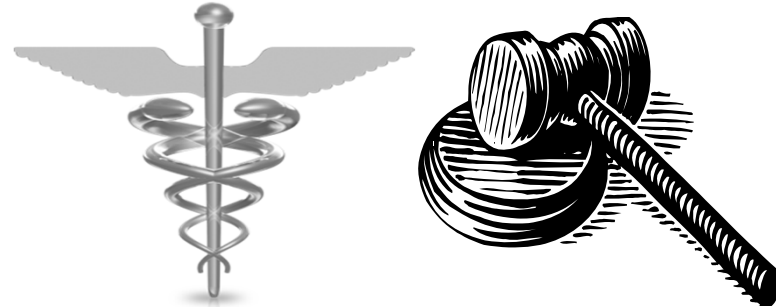
Missouri-Based Health System Agrees to Pay \$9M to Settle FCA, Stark Law Allegations *DOJ Press Release 9/9/12*

Hospital Chain HCA Pays \$16.5M to Settle False Claims Act [and Stark, and Kickback] Allegations Regarding Chattanooga, TN Hospital *DOJ Press Release 9/19/12*

Intermountain Health Care Settles FCA Claims for \$25.5M Following Self-Disclosure of Unlawful Financial Relationships with Physicians *DOJ Press Release 4/3/13*

Adventist Health Pays \$14.1M To Settle False Claims Act [and Stark, and Kickback] Charges *US ex rel. Luque v. Adventist Health, E.D. Cal., No. 2:08-CV-1272, settlement announced 5/13/13*

Fraud and Abuse: Stark Stark Self-Disclosures On CMS Website



- ACA established a self-disclosure protocol that allows providers to disclose voluntarily actual or potential Stark violations with a potential for reduced penalties
 - 37 settlements out of 322 self-disclosures, with collections of \$3.9M; 100 self-disclosures expected in 2013 *BNA 10/2/13*
 - Primarily hospitals
 - <http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self-Referral-Disclosure-Protocol-Settlements.html>

CMS Ban on Per-Click Fees Upheld

CMS appropriately interpreted Stark to restrict per-click leases *Council for Urological Interests v Sebelius 2013 WL 2284885 (DC Cir 5/24/13)*

Fraud and Abuse: Stark

US ex rel Drakeford v. Tuomey

Previous decision: 675 F.3d 394 (4th Cir. 2012)

Vacated \$44M damage award – ordered new jury trial

Procedurally complex, but two Stark law interpretations:

- Physician admission of patient for services to be personally performed = “referral”
- Comp arrangements that take into account *anticipated* referrals implicate the “volume or value” standard

New Decision: Jury found both FCA and Stark violations for 19 part-time physician employment agreements DSC., No. 05-2858, jury verdict 5/8/13

Bonuses were 31% over physician net collections (but note that no evidence of overbilling)

- Jury assessed damages at \$39M – 10/1/13 judgment set total with civil penalties at \$237M for 21,730 improperly submitted claims

Tuomey counsel: Hospitals face “treacherous waters.”



Fraud and Abuse: New OIG Guidance

Special Advisory Bulletin on Effect of Exclusion (5/8/13)

- Updates 1999 guidance
- Exclusion = no payments by federal programs for items and services furnished/directed/prescribed by excluded person, and *providers* face CMPs
- Far reaching examples: excluded individuals cannot prepare surgical trays, dispatch ambulances, direct HR, manage a physician practice, serve as CEO, CFO, GC, provide HIT or strategic planning – unless wholly unrelated to federal programs
- Must screen employees against OIG's LEIE listing



Fraud and Abuse: Insider Trading

Matthew Martoma More or Less Asked Every Doctor that Crossed His Path for Material Non-Public Information

- Alleged scheme: SAC hedge fund manager Matthew Martoma traded on clinical trial information from neurologist/med school professor Sidney Gilman *[since retired]* ... and 20 other physicians *dealbreaker.com 8/23/13*
- Martoma trades netted \$276M for fund – charged with conspiracy and securities fraud *New York Times 12/15/12*
- Hedge Fund Starts to Balk Over Insider Trading Inquiry *NYT 5/18/13*



PHOTO: SPENCER PLATT/GETTY IMAGES

Fraud and Abuse: Insider Trading

SEC subpoenas firm, individuals in a case of leaked information

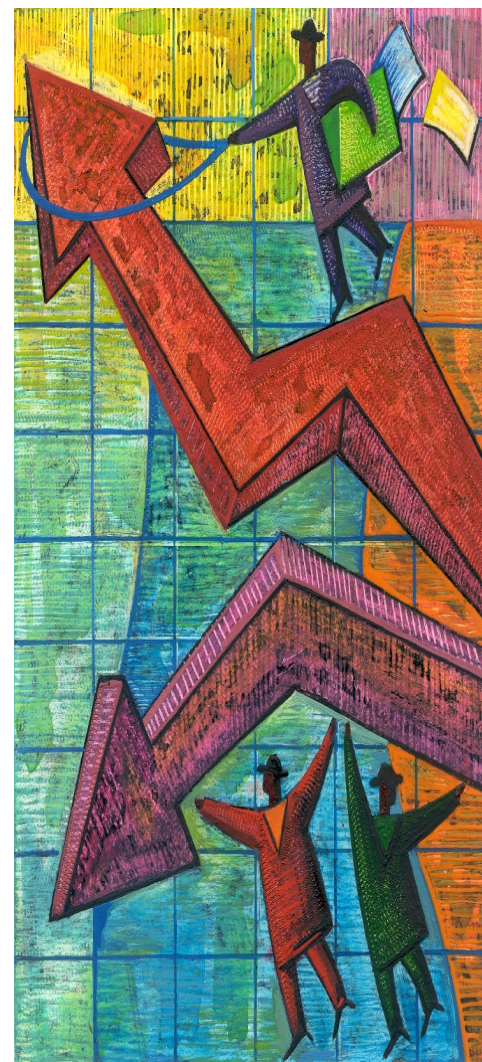
Washington Post 5/1/13

- Height Securities alerted clients of a favorable government decision re Medicare Advantage rates, sparking a surge in trading in Humana, Aetna, others.
- Sen. Grassley launches probe of “political intelligence brokering”

Political intelligence firms set up investor meetings at White House

Washington Post 5/26/13

Tipsy Lawyer Disclosed Secret \$3.6B Pfizer Deal, SEC Says *Law360 9/23/13*



Fraud and Abuse: Foreign Corrupt Practices Act

- Lily to Pay \$29.4M to End SEC Foreign Bribe Case (12/12)
- Teva Announces DOJ Investigating Firm's FCPA Compliance in Latin America (11/12)
- Device Manufacturer Pays \$5M to Settle SEC Suit Over Polish Bribes (4/13)
- SciClone Gets New Subpoena from SEC in FCPA Probe (8/12/13)
- **And Beyond FCPA:**

China to Launch Fresh Pharmaceutical Bribery Probe

Reuters 8/14/13

<http://m.reedsmith.com/chinas-life-sciences-regulatory-crackdown-september-10-update-09-10-2013/>



Trials & Tribulations of Pharma Execs

US v. Harkonen, 2013 WL 782354 (9th Cir 3/4/13), rehearing petition filed 3/29/13

Upheld pharma manufacturer CEO's conviction for wire fraud for "fraudulent" press release regarding clinical drug trials

- Defendant himself was apologetic about release's misleading nature
- He also prevented clinical personnel from viewing release prior to publication
- Stated he would "cut and slice" the data until he got the kind of results he was looking for

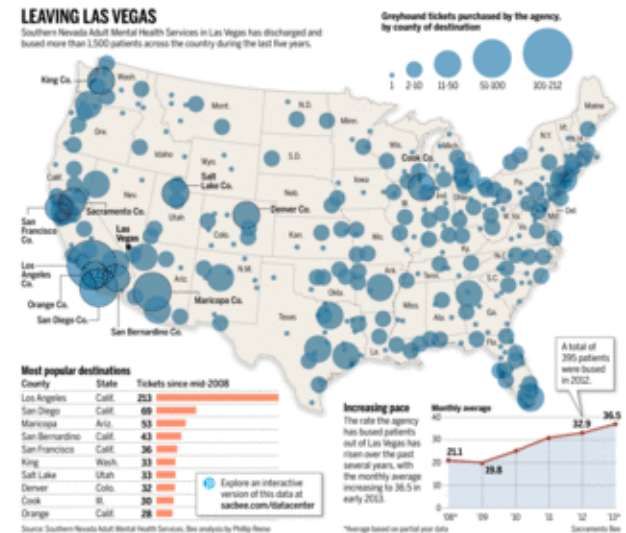
First Amendment does not protect fraudulent speech

Indefatigable defendant filed petition with US Supreme Court 8/5/13; cites scientific study showing promising results in off-label use at issue

Patient Dumping on Steroids

Nevada buses 1,500 mental patients out of state since '08 USA Today (4/26/13)

- One-third of patients wound up in CA
- CMS threatens Medicare termination; L.A. opens criminal probe



US hospitals send hundreds of immigrants back home

Associated Press (4/23/13)

- At least 600 immigrants removed over a five-year period
- Efforts underway to stop this “medical repatriation”

“Hospitals see no real downside to medical repatriation....The victims of this conduct do not speak English, do not think they have any rights, and most are not able to find anyone to advocate for them.” Thomas Duff, plaintiff’s attorney in false imprisonment cases, cited in 22 BNA Health Law Reporter 667 (5/2/13).

Health Info and  HIPAA

Regs, Regs & More Regs

HITECH Final Rule 78 Fed. Reg. 5566 (Jan. 25, 2013)

- Effective 3/26/13, including enforcement provisions; 563 pages of new requirements modifying HIPAA (from 2009 legislation)
- Compliance date 9/23/13 for privacy, breach, security
 - Based on Adheris challenge, HHS released separate (albeit confusing) guidance on “reasonable” financial remuneration re prescription refill reminders
 - No enforcement of these restrictions until 11/7/13
- **Separately, new model notices of privacy practice issued 9/13:**
[http://www.hhs.gov/ocr/privacy/hipaa/modelnotices.html?utm_source=WhatCounts+Publicaster+Edition&utm_medium=email&utm_campaign=HHS+Office+of+Civil+Rights+Releases+Several+Model+Notices+of+Privacy+Practices&utm_content=several+versions+of+a+model+Notice+of+Privacy+Practices+\(NPP\)](http://www.hhs.gov/ocr/privacy/hipaa/modelnotices.html?utm_source=WhatCounts+Publicaster+Edition&utm_medium=email&utm_campaign=HHS+Office+of+Civil+Rights+Releases+Several+Model+Notices+of+Privacy+Practices&utm_content=several+versions+of+a+model+Notice+of+Privacy+Practices+(NPP))

“Most sweeping changes to the HIPAA Privacy and Security Rules since they were first implemented.”

HHS News Release

Major Changes in HITECH Final Rule

- Imposes direct liability on BAs for compliance with privacy & security rules
 - Also expands definition of “BA” to include their subcontractors
- Strengthen limits on use of PHI for marketing and fundraising purposes
- Allows patients to restrict disclosures concerning treatment for which they paid
- Modifications to BA agreements & Notice of Privacy Practices
- Increased and tiered civil money penalty structure
- Replaces breach notification threshold with “more objective” standard
 - Not a “breach” if can demonstrate “low probability PHI has been compromised”

For detailed analysis, see <http://www.reedsmith.com/The-HITECH-Final-Rule--The-New-PrivacySecurity-Rules-of-the-Road-Have-Finally-Arrived-02-19-2013/>

Understatement of The Year

New privacy rule technically tricky

Modern Healthcare Daily Dose (1/21/13)

- Providers must comply with patient request that records of a treatment not be shared with his/her health plan, if patient paid for that treatment out of pocket and in full
- Providers will have to segregate info or redact it prior to disclosure
- No way to notify downstream providers (e.g., pharmacies) who receive electronic orders; likely they will E-bill payor before patients shows up to pay himself
- Suggested solution by HHS: write paper script for self-pay patients

“We agree that it would be unworkable at this point, given the lack of automated technologies to support such a requirement...”

HHS rule commentary

Fallout from Newtown & Aurora

HHS Letter to Providers (1/15/13)

- HIPAA doesn't prevent disclosures to law enforcement, family members or other persons, when patient presents a serious danger to himself or others
 - Includes information from mental health records
 - Already authorized in Privacy Rule at 45 CFR § 164.512(j)

<http://www.hhs.gov/ocr/office/lettertonationhcp.pdf>

HHS Advance Notice of Proposed Rulemaking,

78 Fed. Reg. 23872 (4/23/13)

Proposed rule to allow providers to report to federal database information that would bar a patient from buying a firearm

Numbers.....

Since HITECH breach notification requirements became effective in Sept. 2009:

- There have been 674 breaches involving records of more than 500 patients
 - Only small percentage of these involved hacking
 - Most involved lost or stolen laptops
- Over 22 M individuals' records have been compromised by breaches

<http://www.hhs.gov/ocr/privacy/hipaa/administrative/breachnotificationrule>

Modern Healthcare (12/10/12)

Have You Been “Googled”?

Google to pay \$7M privacy fine

Settlement with AGs in 38 states includes admission,
education.

New York Times (3/13/13)

38 AGs charged Google’s “Street View” cars collected personal data from homes & offices

- While cruising by, cars collected medical & other info from unencrypted wireless networks
- Last summer, Google paid \$22.5M to settle FTC charges it had bypassed privacy settings on Apple’s Safari browser
- Largest civil penalty ever levied by the FTC



Recent Settlement of Note

If Your Old Photocopier Could Talk....



- NY-based Affinity Health Plan discovered its own breach as a result of a report by CBS Evening News
- CBS -- conducting investigation on security risks of digital photocopiers – purchased a used one previously leased by Affinity
- Affinity then self-reported the breach to OCR, paid \$1.2M settlement, entered corrective action plan

<http://www.lifescienceslegalupdate.com/2013/08>

Medicare and Medicaid



In January.....

American Taxpayer Relief Act of 2012 – Fiscal Cliff Averted!

Hospitals Lose – But NASCAR Retains Multi-Million Dollar Tax Break!!



American Taxpayer Relief Act of 2012 Specifics

Temporary fix to physician sustainable growth rate (SGR) – “kicking the can down the road”

Impact was cuts to other providers:

- IPPS payments to hospitals
- DSH payments
- ESRD payments
- Ambulance services for ESRD
- Payments for certain radiology services
- Competitive bidding for diabetic supplies

Extended some Medicare fee-for-service payments

CMS Press Release 1/3/13; AHLA RAP Alert 1/4/13

March Sequester

HHS Officials Begin Implementing Cuts In Federal Health Programs Under Sequester

Per OMB, 5.1 percent spending cut for most HHS programs:

- Federal Hospital Insurance Trust Fund—cut by \$5.7B
- Federal Supplementary Medical Insurance Trust Fund—cut by \$5.3B
- Medicare prescription drug account, federal Supplementary Insurance Trust Fund—cut by \$588M
- Grants to help states establish health insurance exchanges under the Affordable Care Act—cut by \$40M
- Other state grants and demonstrations—cut by \$27M
- Health care fraud and abuse control account—cut by \$57M
- NIH research cut by \$1.5 B; FDA cut by \$209M

Then in April.....

Obama Administration's Proposed FY 2014 Budget Includes \$401B in Health Program Savings

All provider types and drug manufacturers affected

- *Reform physician fee schedule/SGR calculation*
 - *\$740M drug payment cuts (+ rebates)*
 - *\$780M GME cuts*
 - *\$830M post-acute provider cuts*
 - *\$200M cuts to hospital bad debt*
 - *\$190M cut to inpatient rehab hospitals*
 - *\$90M cuts to critical access hospitals*



Today: Many Proposals – Fate TBD

In Shutdown Blame Game, Democrats and Republicans United: It's the Other Side's Fault *Washington Post 10/1/13*

Congressional Wild Cards: government funding, debt ceiling, continuation of sequestration

In addition to spending bills, lawmakers floating plans on

- SGR reform
- Post-acute care
- Medicare cost sharing
- Stark in-office ancillary services



In Other News:

HHS Secretary Sebelius announces Senate confirmation of Marilyn Tavenner (5/15/13)

*Administrator of the Centers for Medicare & Medicaid Services,
U.S. Department of Health and Human Services*



Proposed CMS Rule Boosts Tipster Awards

Proposal would increase to nearly \$10M the potential reward to individuals providing tips that lead to Medicare fund recoveries

(15% of \$66M)

Also would revise enrollment regs

Fed. Reg. 4/24/13



Expansion of Medicare Coverage

Settlement Eases Rules for Some Medicare Patients

New York Times (10/23/12)

- Under class action settlement, CMS will relax rules for skilled nursing, home health & outpatient therapy
 - Former rule required likelihood of medical or functional improvement before Medicare would pay for service
 - Now, only have to show services would “maintain the patient’s current condition or prevent or slow further deterioration,” regardless of whether patient’s condition expected to improve
 - Permits Medicare coverage of many chronic conditions such as Alzheimer’s, MS, spinal cord injuries & stroke
 - Settlement agreement approved by district court in fairness hearing 1/24/13. *Jimmo v. Sebelius* 2011 WL 5104355 (D. VT)

Payment Miscellany for Hospitals

CMS Final Rule: Two Midnights Policy



- Hospital inpatient admissions presumed appropriate for beneficiaries requiring >1 Medicare utilization day (“crossing two midnights”)
- Inadvertent failure to account for admissions by residents
- New FAQs instruct MACs and RACs not to audit against rule through year end – unless hospitals game the system
- <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medical-Review/Downloads/2MidnightInpatientAdmissionGuidanceandPatientStatusReviewsforA-.pdf>.

Final Rule also:

- Increases payments to acute care hospitals
- Makes technical disproportionate share adjustments
- Increases payments for LTCHs

Hospital Readmission Reduction Program

ACA provision to reduce a hospital's base operating DRG payments to account for excess readmissions of:

- acute myocardial infarction,
- heart failure,
- pneumonia
- New Conditions FY15: COPD, hip & knee replacements



Multiple CMS recalculations: 2225 face penalties beginning 10/1 – 18 will lose the maximum 2% reduction per patient for one year; 154 will lose 1%

Kaiser Health 8/2/13

Penalties criticized as unfairly targeting hospitals treating poorest and sickest – also readmission may not be an indicator of quality

“Dead patients can’t be readmitted.” Dr. M. Henderson Cleveland Clinic

Hospital “Value Based Purchasing”

- December 2012: Medicare announced “bonuses and penalties” to 3000 hospitals
- \$1B in payments after 1/1/13 to be tied to quality of care
- Per Kaiser: 1,557 winners / 1,427 losers

<http://www.kaiserhealthnews.org/Stories/2012/December/21/medicare-hospitals-value-based-purchasing.aspx>

Adjustments to measurements made by 8/2/13 Final Rule

Separately:

Medicare Shift Fails to Cut Hospital Infections

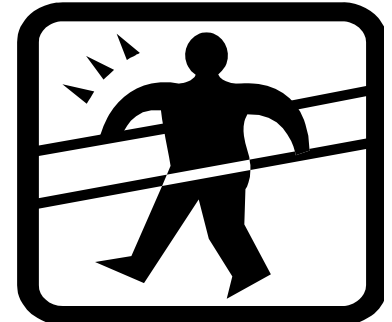
NEJM study found the 2008 payment penalties for hospital-acquired infections had “no impact” on bloodstream and urinary tract infections

Wall Street Journal 10/10/12

Long Term Care Miscellany

OIDG 11/13 Report re 2009 Payments *OEI-02009-00200*

Medicare overpaid nursing providers by \$1.5B;
significant upcoding for therapy services



- *NB: Therapy services = focus of many SNF RAC audits; subject of \$2.7M settlement with nursing home manager*
- *US and TN ex rel. Ottinger v. Grace Healthcare LLC No. 3:10-cv-83 (ED TN 3/8/13)*

4th Circuit Upholds CMS Fine Against NH for Resident's Behavior – "Immediate Jeopardy" *Libertywood Nursing Center*

v. Sebelius, 2013 WL 729786 (4th Cir. 2/28/13)

CMS Announces 1.3% Payment Increase to SNFs for FY 2014 (approx \$470M) *Final Rule 7/31/13*

DMEPOS Miscellany

New “face-to-face encounter” regulations effective 7/1/13 *77 Fed Reg 68891 (Nov. 16, 2012) - but implementation delayed to TBD date (9/13/13)*

Medicare Competitive Bidding Round 2 / National Mail Order Competition : reimbursement to decline average of 45%; for diabetes supplies (mail order and retail) by 72% (1/30/13)

- Oxygen, Oxygen Equip. & Supplies - 41%
- Standard (power & manual) Wheelchairs, Scooters, Accessories - 36%
- Enteral Nutrients, Equip. & Supplies - 41%
- CPAP/RAD & Related Supplies & Accessories - 47%
- Hospital Beds & Accessories - 44%
- Walkers & Accessories - 46%
- Support Surfaces (Group 2 Mattresses & Overlays) - 63%
- NPWT Pumps & Related Supplies & Accessories - 41%

Oct. 2013 – Round 1 recompetete prices cut by average of 37% in 9 CBAs



Hospice Miscellany

1) Hospice Patient Eligibility

The problem of patients living too long....

US ex rel. Singletary v. Harmony Care,

No. 2:10-cv-1404 (DSC) settlement 11/19/12

2) Spending Caps

Full Life Hospice LLC v. Sebelius, 709 F 3d 1012 (10th Cir. 2013) (while other cases have been successful, court finds this challenge untimely)

3) Excessive “continuous home care” (crisis care) claims

- *OIG Report on “Use of General Inpatient Care” OEI-02-10-00490 (May 2013);*
- *OIG also recommended that CMS increase the frequency of hospice recertification surveys (8/29/13)*



More Miscellany: CMS Proposed 2014 OPFS, MPFS Rules Generate Controversy

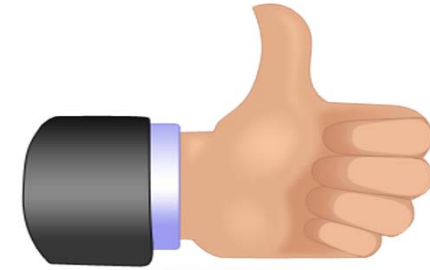
Outpatient Prospective Payment System:

- Expansion of payment bundles (APCs) to spur hospital negotiations with manufacturers, GPO arrangements
 - Package 7 categories of supporting items/services, including certain drugs, certain lab tests, add-on codes, device removals and others.
- Create 29 all-inclusive, “comprehensive APCs” to current device dependent APCs – include diagnostic procedures, lab tests, evaluations, DMEPOS, therapy, and more in single payment

Medicare Physician Fee Schedule:

- Under misvalued code initiative, CMS proposes to reduce physician rates for >200 codes if physician office payment exceeds payment in outpatient hospital department or ASC setting
- Reexamination of settled Clinical Laboratory Fee Schedule payments to determine if technology changes warrant new payment.

Payment Cases of Interest



GME WIN

Teaching hospitals are allowed to correct the number of GME full-time equivalent (FTE) residents beyond the three-year window Medicare regulations allow for review of FTE reimbursement payments

Kaiser Foundation Hospital v. Sebelius, 2013 WL 791272, (DC Cir 3/5/13)

DSH WIN: Struck down Medicare payment calculation rule – Secretary tried to use the complexity of Medicare to hide bad rulemaking.

Allina Health Services v. Sebelius, 2012 WL 5565453 (D DC 11/15/12)

BAD DEBT WIN: Reversed bad debt disallowance – fact that outstanding amounts due hospitals were sent to collection agency does not mean they were “collectible”

District Hospital Partners v. Sebelius, 2013 WL 1209956 (D DC 3/26/13)

Payment Cases: DSH Losses



No equitable tolling of appeals deadline for hospitals

Issue: Could hospitals appeal adverse reimbursement decisions after the deadline expired, if they could show their tardiness was due to government misconduct? CMS argued resulting flood of new appeals could overwhelm the PRRB: “We’ll have chaos, dogs and cats sleeping together....”

Supreme Court: Existing 3-month “good cause” exception is sufficient.

Sebelius v. Auburn Regional Medical Center, *Sebelius v. Auburn Regional Medical Center*, 133 S.Ct. 817 (1/22/13)

Fifth Circuit: Dismissed hospital case seeking DSH payments for low income patients entitled to Part A and Medicaid, but not SSI – Act excludes them. *Memorial Hosp at Gulfport v. Sebelius*, 499 Fed.Appx. 393 (5th Cir 12/6/12)

Sixth Circuit: Two cases

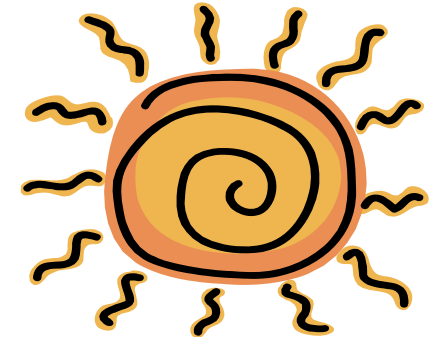
Metropolitan Hospital v. Sebelius, 2013 WL 1705016 (6th Cir 4/22/13) (Medicare-exhausted dual eligible patient days must be included in the Medicare – not Medicaid – fraction of the DSH calculation)

Adventist Health System/Sunbelt v. Sebelius 2013 WL 1705016 (6th Cir. 4/22/13) (no DSH recalculation - denial of \$6 M Medicaid waivers)

Pharma & Device



Pharma & Device Developments



CMS issued “Sunshine Act” final regs

78 Fed Reg. 9458 (Feb. 8, 2013)

- Require drug and device manufacturers to report payments and transfers of value to “covered recipients” – physicians and teaching hospitals – for CMS publication
- Require reporting by distributors taking title
- Require reporting of physician ownership by manufacturers and GPOs (including most PODs)
- Data collection begins 8/13 – last quarter reports due 3/31/14
- CMS developed Sunshine website – first data will be posted 9/14
- CMS introduced mobile apps 7/17/13

ProPublica analyzed data from pharma manufacturer websites 2009-2012:

CA physicians topped the list, receiving payments for research, speaking, consulting, trips and meals of \$242M
LA Times 3/11/13

For detailed analysis see

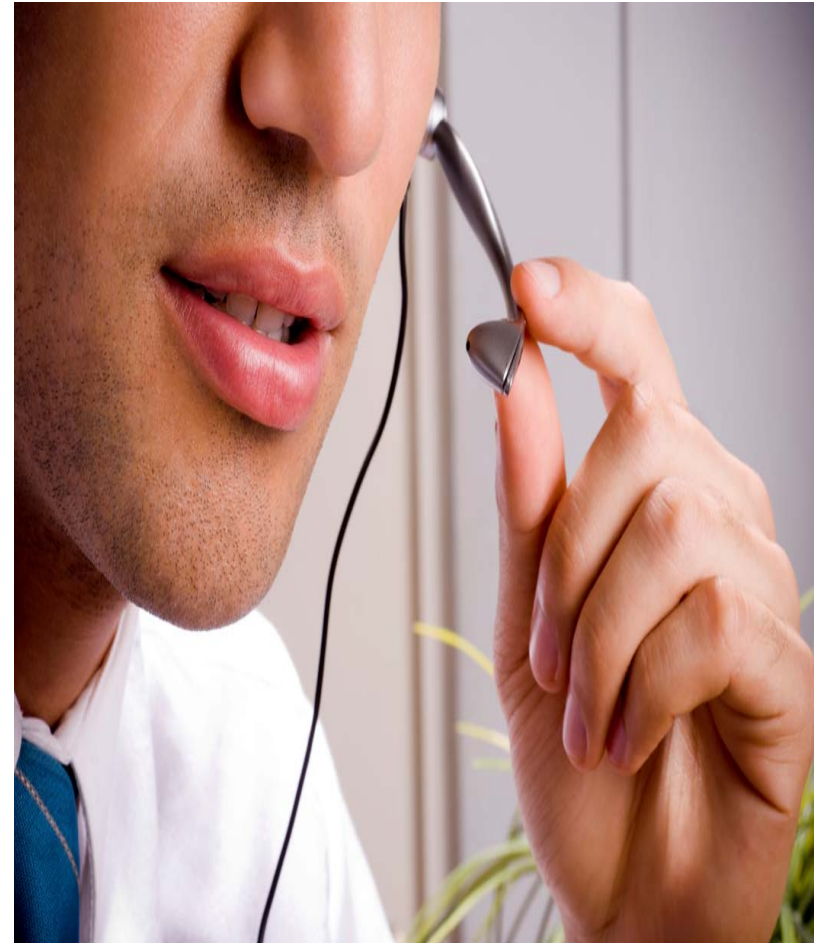
<http://www.reedsmith.com/publications/detail.aspx?publication=11840>

FDA Issues Scam Alert to Consumers 9/25/12

- Callers target those who purchase medications on line
- Identify themselves as FDA agents calling about illegal drug purchases – threaten prosecution unless you pay fine (\$100-\$250K)

FDA's Guidance: *“The call is likely a scam if the so-called agent directs you to send the money by wire transfer to a designated location, usually overseas, or if you are warned not to call an attorney or the police.”*

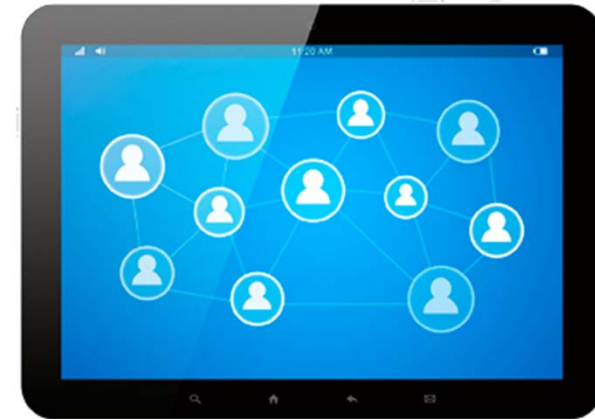
Meanwhile, UPS Agrees to Forfeit \$40M in Payments from Illegal Internet Pharmacies
Nonprosecution Agreement N.D. CA 3/29/13



In Other FDA News

FDA Won't Regulate Smartphones, Tablets as Medical Devices

healthlawyers.org/news 3/22/13



But Wants to Know Why uChek App Doesn't Have PMA Clearance

Life Sciences Law360 523/13

FDA Seeks Tanning Warning – Would Require Cancer Alerts for Tanning Beds, Says People Under 18 Shouldn't Use Them *WSJ 5/7/13*



And Still Other FDA News

FDA Targets 15 Companies Over Bogus Diabetes Treatments *Law 360 7/23/13*

- Warning letters issued to 15 companies
- NHS (below) claimed product “is particularly suited to the prevention and/or treatment of diabetic complications”
- FDA listed multiple reasons: treatments unapproved, undeclared ingredients, and more – seeking to remove from market as unsafe



Pharma & Device Developments

Scant Oversight of Drug Maker in Fatal Meningitis Outbreak

NY Times 10/6/12

- Compounding pharmacies subject to new scrutiny in wake of distribution of contaminated syringes that caused deaths
- Complex regulatory scheme for these entities: FDA and state boards of pharmacy theoretically regulate compounding – but boundaries unclear
- Owners drew \$16M from [NECC] pharmacy tied to deaths *Boston Globe* 1/22/13
- Judge freezes assets of NECC execs *Law360* 1/28/13
 - Lawyer for family of deceased patient:
 - ***“This wasn’t some obscure procedure being done in some obscure hospital. [The family] had sought out a respected neurosurgeon who had been referred by their family doctor, at a respected hospital. How does this happen?”***

Recent Pharma/Device Off-Label Settlements

Company	Anticipated Settlement Amount	Anticipated Settlement Break Down	Issue(s)
Pfizer, Inc./Wyeth Pharmaceuticals, Inc. August 2013	\$490.9 million	<u>Criminal Fine:</u> \$157,580,000 <u>Forfeiture of Assets:</u> \$76,000,000 <u>Civil Settlement:</u> Federal and State Governments \$257,400,000	Wyeth's promotion of Rapamune

Recent Pharma/Device Off-Label Settlements

Company	Settlement Amount	Settlement Break Down	Issue(s)
GlaxoSmithKline July 2013	\$229 million	<u>Civil Settlement</u> KY, LA, MD, MS, NM, SC, WV and UT *These states previously opted out of GSK's settlement in November 2012	Development and marketing of Avandia

Recent Pharma/Device Off-Label Settlements

Company	Settlement Amount	Settlement Break Down	Issue(s)
ISTA Pharmaceuticals Inc. May 2013	\$33.5 million	<u>Criminal Fine:</u> \$18,500,000 <u>Civil Settlement:</u> \$15,000,000	Promotion and sale of Xibrom for unapproved uses <u>15-year exclusion from participating in the federal health care programs</u>

Recent Pharma/Device Off-Label Settlements

Company	Settlement /Sentence	Settlement/Sentence Break Down	Issue(s)
Par Pharmaceuticals March 2013	\$45 million	Criminal Fine: \$18,000,000 Forfeiture of Assets: \$4,500,000 <u>Civil Settlement:</u> Federal and State Governments \$22,500,000	Illegal promotion of prescription drug Megace ES for uses not approved as safe and effective by the FDA

Recent Pharma/Device Off-Label Settlements

Company	Settlement /Sentence	Settlement/Sentence Break Down	Issue(s)
Amgen December 2012	\$762 million	Criminal Fine: \$136,000,000 Forfeiture of Assets: \$14,000,000 <u>Civil Settlement:</u> Federal Government: \$587,200,000 State Governments: \$24,800,000	Illegally introducing a misbranded drug, Aranesp, into interstate commerce

Recent Pharma/Device Off-Label Settlements

Company	Settlement Amount	Settlement Break Down	Issue(s)
GlaxoSmithKline November 2012	\$90 million	<u>Civil Settlement</u> 37 states and DC	Illegal marketing of Avandia and other drugs

Recent Pharma/Device Off-Label Settlements

Company	Settlement Amount	Settlement Break Down	Issue(s)
Boehringer Ingelheim Pharmaceuticals Inc. October 2012	\$95 million	<u>Civil Settlement</u> Federal Government: \$78,455,048 State Governments: \$16,544,952	Off-label promotion allegations concerning four drugs: Aggrenox, Atrovent, Combivent, and Micardis

Recent Pharma/Device Off-Label Settlements

Company	Sentence	Sentence Break Down	Issue(s)
Abbott Laboratories October 2012	\$700.5 million and 5-year term probation	Criminal Fine: \$500,000,000 Forfeiture of Assets: \$198,500,000 Virginia Medicaid: \$1,500,000	Sentenced by U.S. District Court Judge Samuel G. Wilson of the W.D. of Virginia in connection with its guilty plea related to its unlawful promotion of the prescription drug Depakote

Uncertain Future for Off-Label FCA Cases?

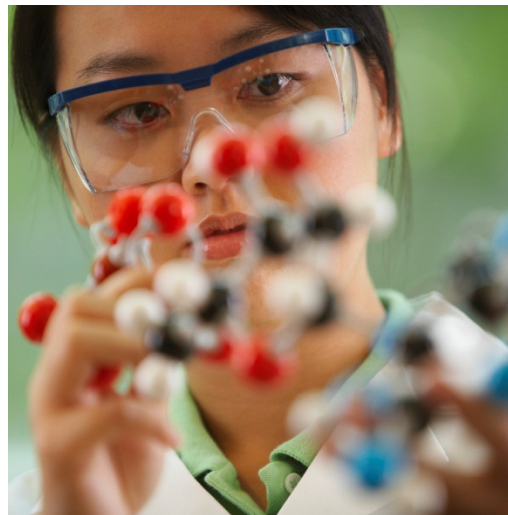
*Pharma/device off-label settlements have continued,
but see....*

US v. Caronia, 2012 WL 5992141 (2d Cir. 12/3/12)

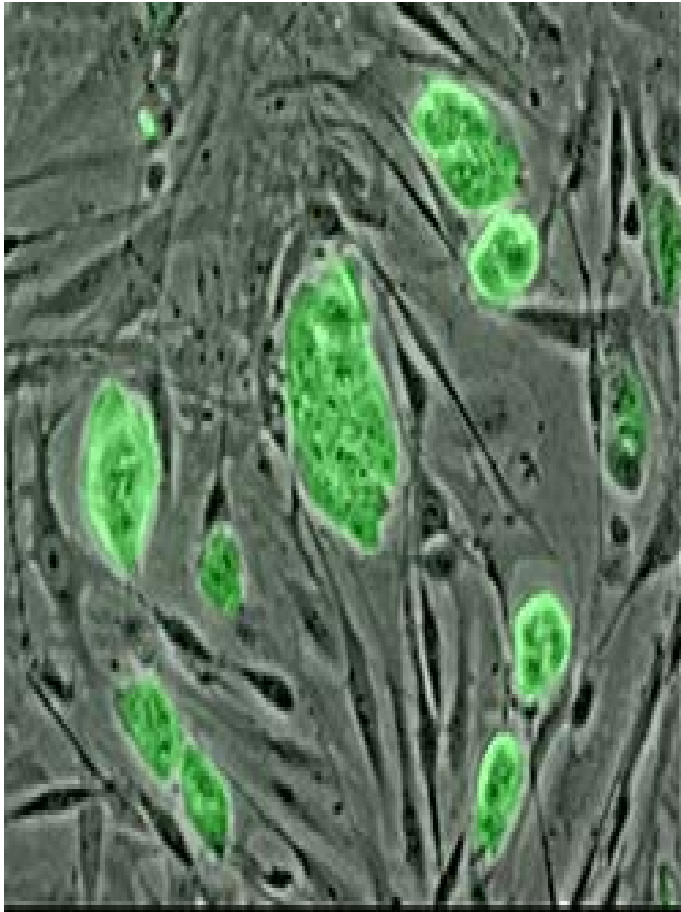


- Reversed the conviction of pharma sales rep Alfred Caronia, accused of conspiring to introduce an “off label,” misbranded drug into commerce
- Second Circuit found “criminalizing the simple promotion of a drug’s off-label use...[raises] First Amendment concerns....” – but limited its finding to FDA-approved drugs for which off-label use is not prohibited....
- Raises significant issues for government in the future: responsible corporate official, causation

Research



Research News



DC Circuit Upholds NIH Stem-Cell Research Funding

- Upheld decision: NIH can fund research involving embryonic stem cells, so long as that research does not involve destruction of a human embryo
- *Sherley v. Sebelius*, 689 F.3d 776 (DC Cir. 8/24/12), cert. denied 1/13 (case number 12-454)

But hard times for research:

FACT SHEET: IMPACT OF SEQUESTRATION ON THE NATIONAL INSTITUTES OF HEALTH (6/3/13
News Release nih.gov)

NIH trials turn away new patients as shutdown obstructs work of scientists, researchers *Washington Post* 10/4/13

Clinical Trial Oversight

FDA to Become Enforcer

- HHS officially delegated to FDA oversight of clinicaltrials.gov compliance 9/12
- FDA to identify failures to submit as well as submission of false/misleading information

<https://www.federalregister.gov/articles/2012/09/26/2012-23598/office-of-the-commissioner-of-food-and-drugs-delegation-of-authority>

FDA Issues Draft Guidance to Institutional Review Boards (IRBs) *77 Fed. Reg. 69631 (Nov. 20, 2012); also 6/14/13*

- Developed guidance with HHS Office for Human Research Protections
- IRBs to review investigator qualifications, ensure adequacy of research sites, assess need to IND/IDE

Research Cases – Grant Fraud

Ex-Penn State Prof. Gets 41 Months for \$3M Grant Fraud

US v. Grimes case no 4:12-cr-00019 (MD PA 11/30/12)

Court Dismisses Claims of [Northwestern Univ.] Double Billing by [Former Employee] Whistleblower, Requires Actual Examples

US ex rel Soulias v. Northwestern Univ., N.D. Ill., No. 1:10-cv-07233, 6/27/13

Whistleblower Kenneth Jones Wins Appeal and Forces Harvard to Trial for Research Fraud

US ex rel Jones v. Brigham and Women's Hospital and Harvard Univ. 678 F.3d 72 (1st Cir 2012)

Full Damages Appropriate in NIH Grant Fraud Case: Dr. Wilfred Gorp and Cornell University

US ex rel Feldman v. Van Gorp and Cornell University 697 F.3d 78 (2d Cir 2012)

Closing thought:





“May you live in interesting times.”

Thank You.

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