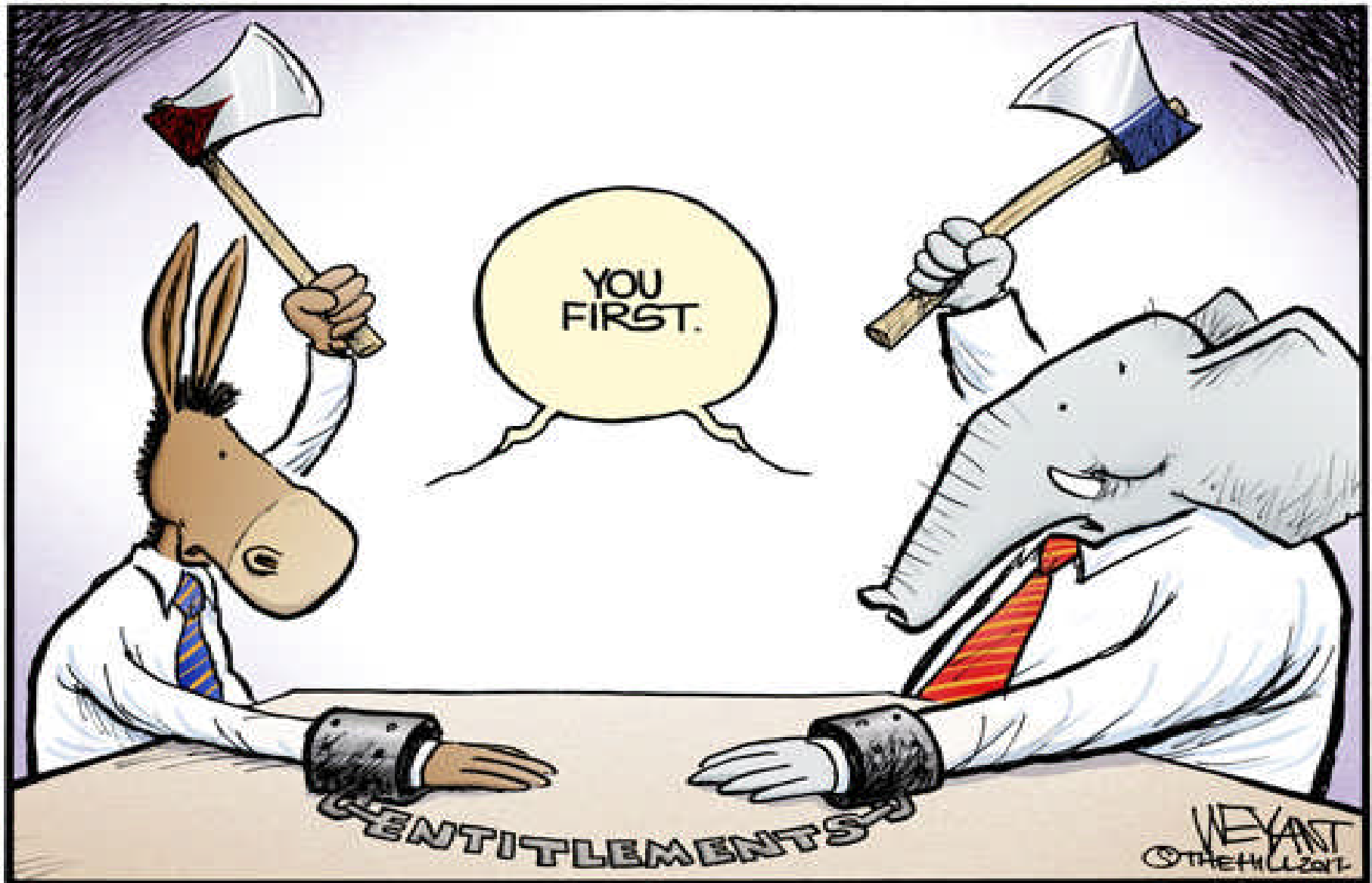


# Gazing into the Crystal Ball: What Will Happen in Washington, DC in 2012

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*Senator Blanche Lincoln*

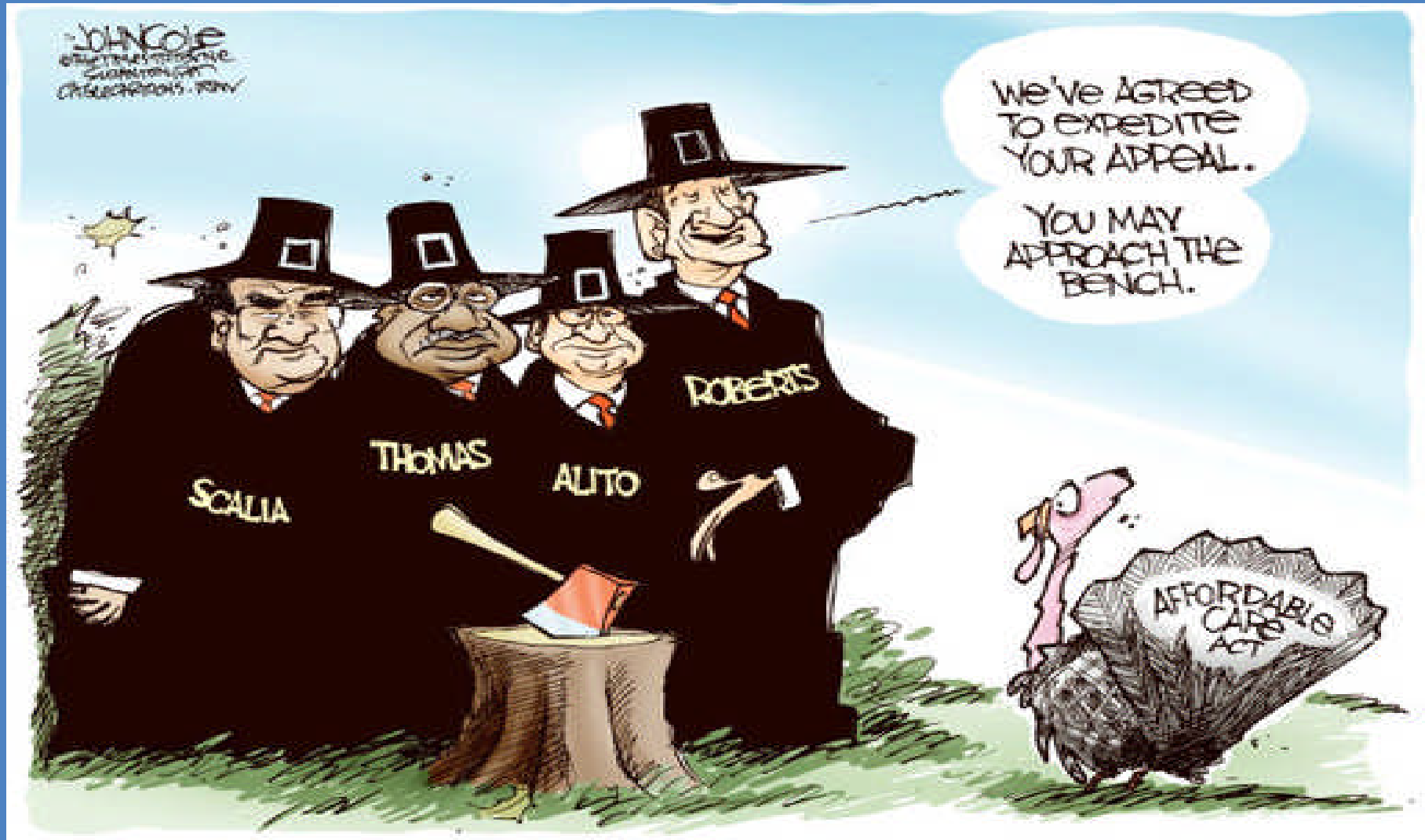
*May 2, 2012*



# Washington: Spring/Summer

- FY 2013 Budget –
  - Deficit Reduction/Reconciliation/Entitlement reform?
  - May, June,...
- Supreme Court decision on ACA
  - Late June/Early July

# Supreme Court: ...Decision June

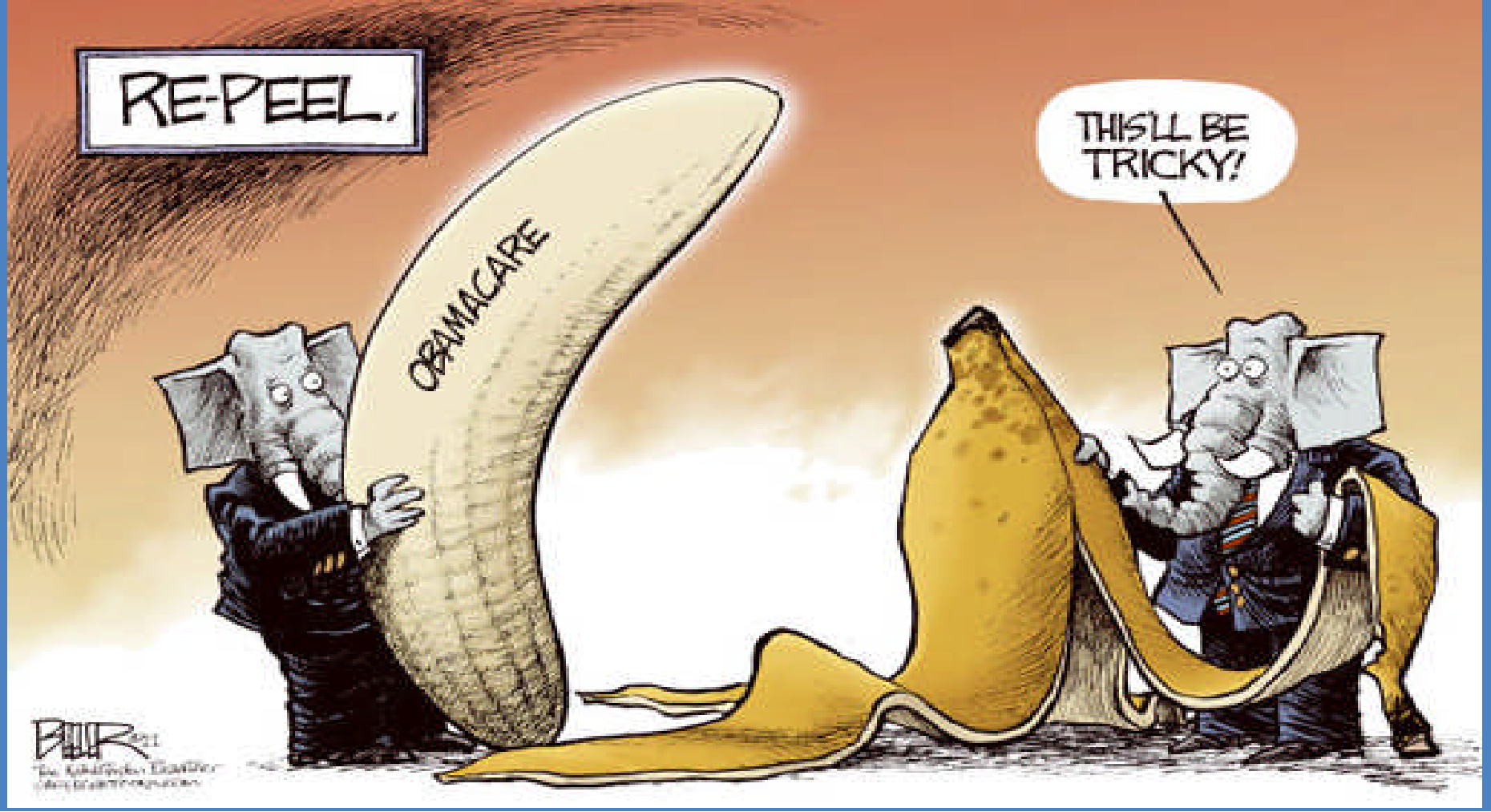


# Supreme Court Decision on ACA

## Four Issues and Possible Action:

- 1. Anti-injunction Act:** This law prevents courts from striking down tax laws until they go into effect; the Court must decide whether this applies and, if it does, then a decision will wait until 2014
  - Expectation: Unlikely
- 2. Individual Mandate:** Requirement that virtually all individuals must have minimum essential coverage; challenged on the basis of Congress' commerce power; striking down the mandate would impact the insurance provisions already in place, but less impact other ACA provisions
  - Expectation: Unclear
- 3. Medicaid Expansion:** Is the Medicaid expansion is an unfunded mandate for the states?
  - Expectation: Unlikely, but significant impact on all Medicaid programs if stricken
- 4. Severability:** If the individual mandate is ruled unconstitutional, whether the rest of the law may stand.
  - Expectation: Unclear, but if found non-severable would strike the entire ACA, with far-reaching impact

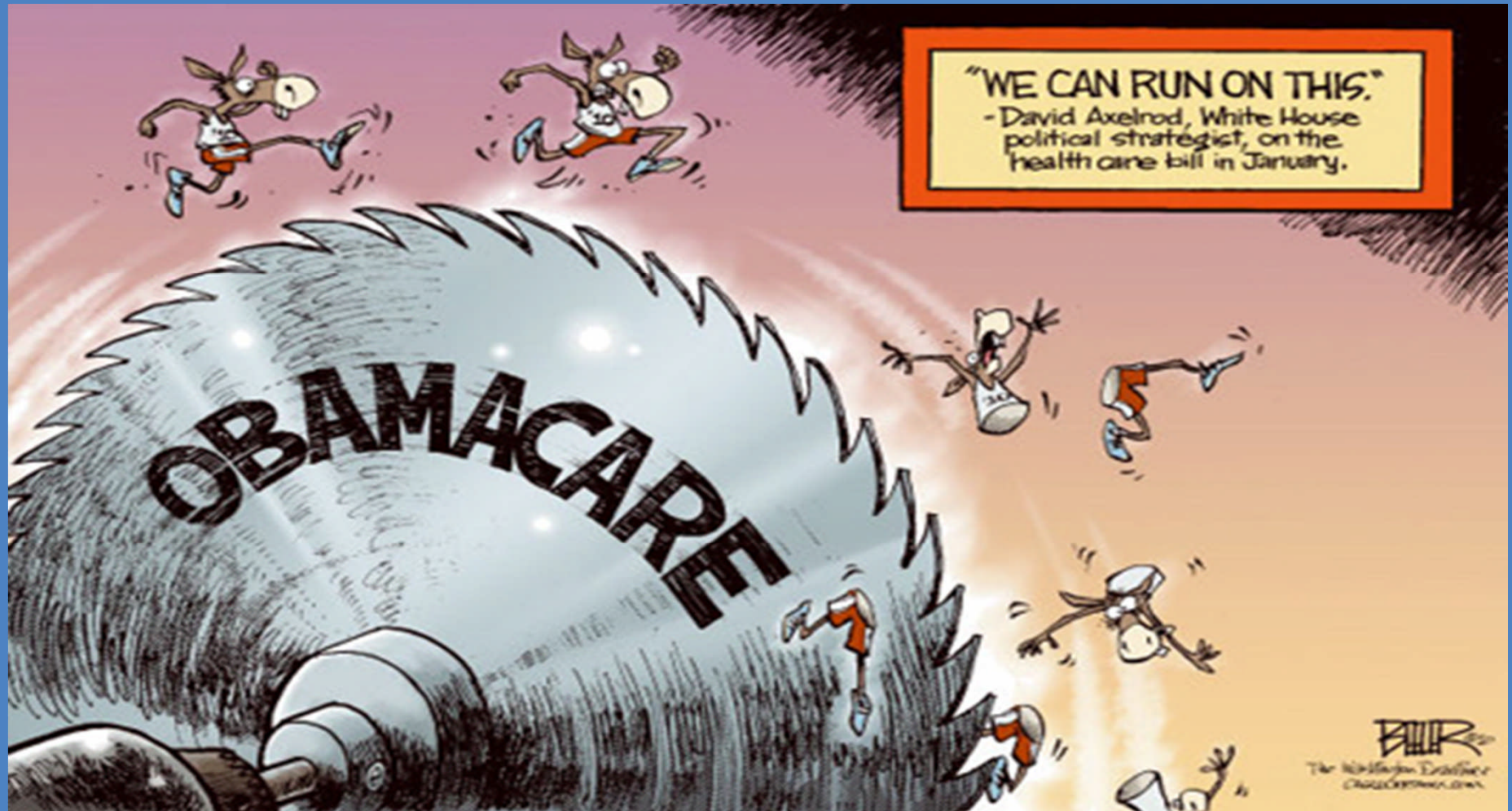
# Supreme Court Decision and/or GOP Election Victory: Repeal becomes more Complicated



# Washington: Fall

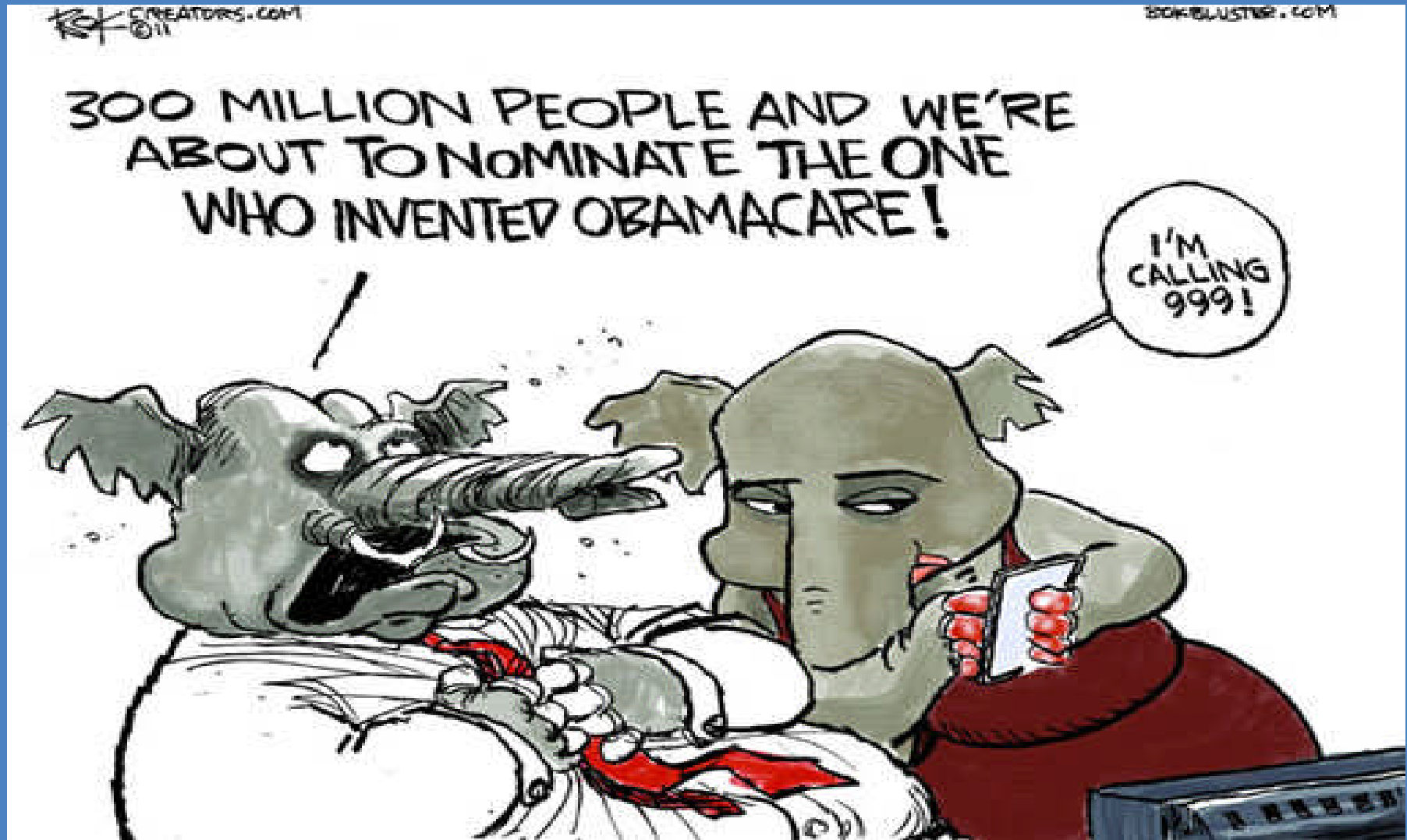
- Debt Limit extension: Effort to tie the extension to additional cuts, including health care? – September
- Election Results: White House, Senate, House –  
November
  - Issues:
    - Economy/Taxes
    - Healthcare/Supreme Court decision
    - Women's issues

# Election 2012: Will Dems Run on or Away from ACA

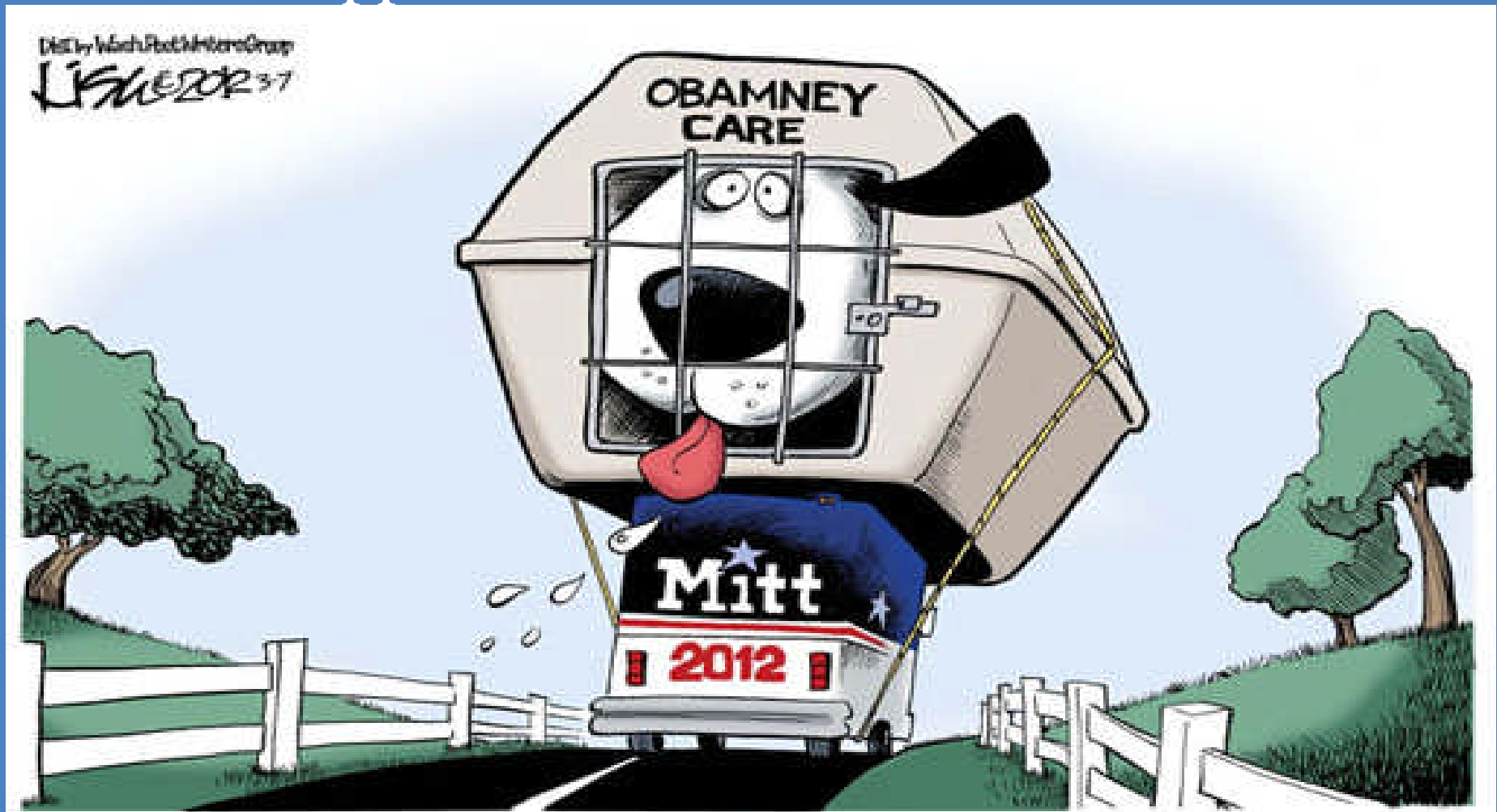




# Election 2012: GOP Ticket



# Election 2012: How will Romney Handle His Support of the Massachusetts Law



# Washington: Winter

- Lame Duck session – November & December
  - Another “doc fix”
  - Expiring tax cuts
  - Possible delay of sequestration and/or new deficit reduction package – November/December
  - Nature and extent of session will depend on results: if GOP gains in House and Senate, look for temporary extensions of major expiring provisions into 2013, not permanent policy changes

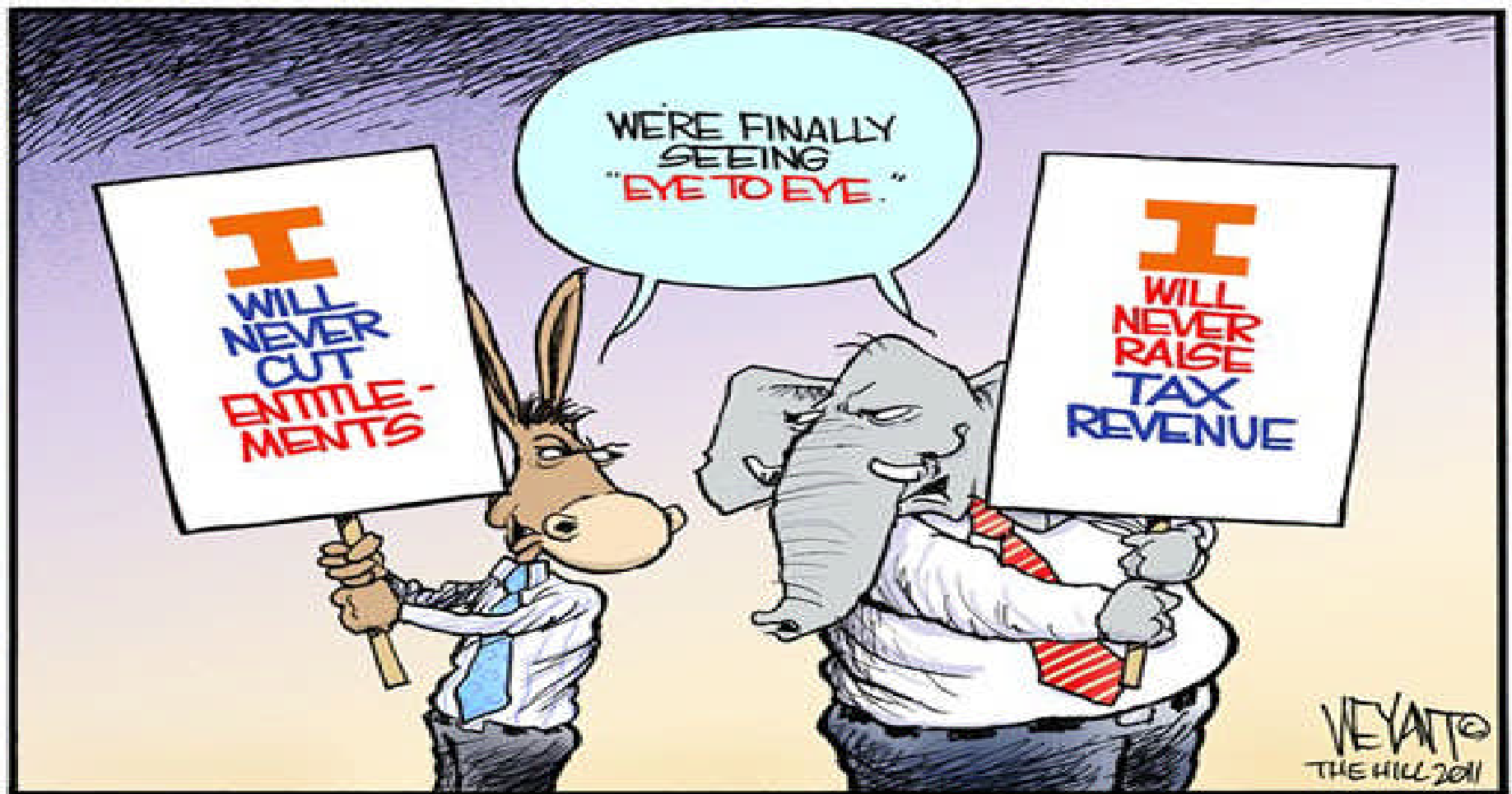
# Lame Duck Session

*\*Note: Lame duck sessions are held after the election (November 6) but before the newly elected officials take office (Jan. 2013)*

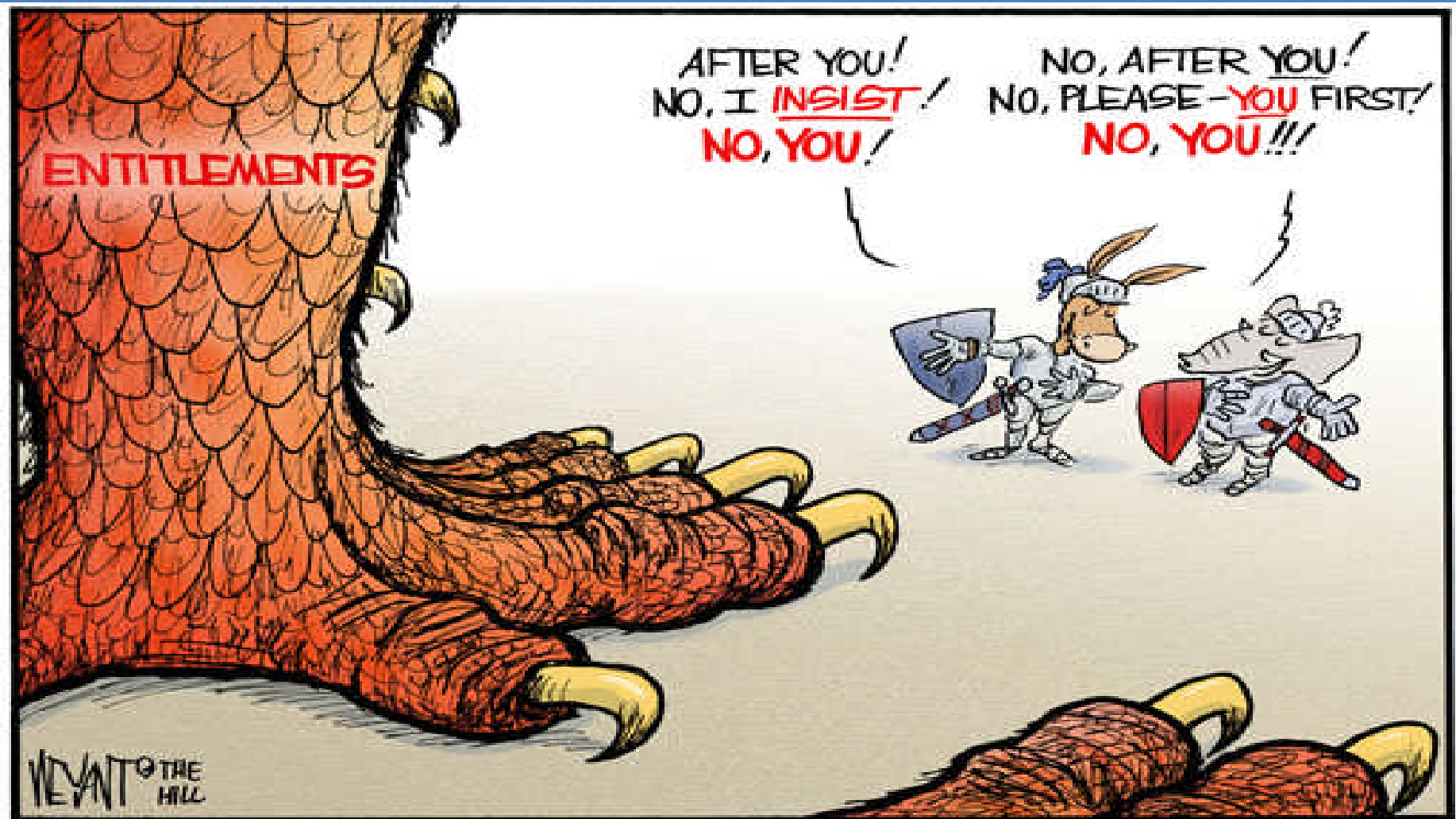
Additional Medicare/Medicaid cuts remain a threat largely for purposes of offsetting other spending priorities (e.g., doc fix) and re-prioritizing of defense and domestic sequester, or to enact additional deficit reduction (e.g. debt limit extension, due September 30)

- The ‘doc fix’ package expires **December 31, 2012**, so a lame duck session will again go through a process of how long to delay the scheduled Medicare physician payment cut, and how to offset the cost of the delay (a 3-month delay costs about \$15 billion)
- **Tax cuts expire December 31<sup>st</sup>**; Congress will consider extending all or a portion of the expiring tax cuts and will also need to decide whether to offset the cost of extension
- **Looming January 1, 2013 effective date for sequester** (across-the-board cuts in all domestic and defense programs, including Medicare provider payments, but excluding Medicaid payments and Medicare beneficiaries):
  - Growing Congressional support for reducing or eliminating the defense portion of the sequester, which could mean increasing cuts to domestic programs and Medicare providers

# Will 2013 Bring a Different Focus? Not Likely



# Will the Next Congress Take on Entitlement Reform?





# **\$4 Billion in Fraud Enforcement and Counting: What is Next for the Health Care Industry?**

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*William R. Mitchelson, Jr.  
T. C. Spencer Pryor*

*May 2, 2012*

# Overview – lay of the land – crystal ball

- It is abundantly clear that the government is focused on health care fraud enforcement and it is becoming increasingly successful in its efforts
- What does this mean for the future? You should expect a continued and likely heightened focus on health care fraud enforcement – this issue is not going away
- The government will likely continue to adapt its enforcement initiatives and its investigative techniques while increasing the resources devoted to health care fraud enforcement





**DEPARTMENT  
of HEALTH  
& HUMAN  
SERVICES**

**Fiscal Year  
2012**

**Office of Inspector General**

*Online Performance Appendix*

## Performance Appendix

Department of Health & Human Services

Office of Inspector General

Measure	FY	Target	Result <sup>2</sup>
1.1.2: ROI resulting from OIG involvement in health care fraud and abuse oversight activities	2012	\$12.3	TBD, October 2012
	2011	\$13.0	TBD, October 2011
	2010	\$15.0	\$16.7 (Target exceeded)
	2009	\$16.8	\$17.6 (Target exceeded)
	2008	\$13.5	\$16.9 (Target exceeded)
	2007	\$11.4	\$16.5 (Target exceeded)

The expected recoveries resulting from OIG investigative and audit oversight of Medicare and Medicaid<sup>3</sup> averaged \$3.8 billion per year for the 3-year period from FY 2008 through FY 2010

**The corresponding ROI for OIG oversight of Medicare and Medicaid for the same 3-year reporting period was \$16.7:\$1.**

the relationship between the annual and 3-year moving averages of OIG expected recoveries from health care activities from FY 2004 through FY 2010 and estimates for FYs 2011 and 2012.

**Performance Measure Tables and Performance Narrative**

**Performance Measure Summary and Reporting for “Expected Recoveries” and ROI**

<b>Measure</b>	<b>FY</b>	<b>Target</b>	<b>Result<sup>1</sup></b>
<b>1.1.1: Expected recoveries resulting from OIG involvement in health care fraud and abuse oversight activities (dollars in millions)</b>	2012	\$3,400	TBD, October 2012
	2011	\$3,300	TBD, October 2011
	2010	\$3,400	\$3,782 (Target exceeded)
	2009	\$3,470	\$3,719 (Target exceeded)
	2008	\$2,623	\$3,268 (Target exceeded)
	2007	\$2,460	\$2,836 (Target exceeded)

<b>Measure</b>	<b>FY</b>	<b>Target</b>	<b>Result<sup>1</sup></b>
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	2007	\$2,460	\$2,836 (Target exceeded)

<sup>1</sup> OIG has updated previously reported expected recoveries and ROI results to fully reflect previously excluded investigative receivables. The revised results are within 1% of previously reported results and do not change OIG's target-achieving status.

## Health Care Fraud Prevention and Enforcement Efforts Result in Record-breaking Recoveries Totaling Nearly \$4.1 Billion

*Largest Sum Ever Recovered in Single Year*

Attorney General Eric Holder and Department of Health and Human Services (HHS) Secretary Kathleen Sebelius today released a new report showing that the government's health care fraud prevention and enforcement efforts recovered nearly \$4.1 billion in taxpayer dollars in Fiscal Year (FY) 2011. This is the highest annual amount ever recovered from individuals and companies who attempted to defraud seniors and taxpayers or who sought payments to which they were not entitled.

Including strike force matters, federal prosecutors filed criminal charges against a total of 1,430 defendants for health care fraud related crimes. This is the highest number of health care fraud defendants charged in a single year in the department's history. Including strike force matters, a total of 743 defendants were convicted for health care fraud-related crimes during the year.

In criminal matters involving the pharmaceutical and device manufacturing industry, the department obtained 21 criminal convictions and \$1.3 billion in criminal fines, forfeitures, restitution and disgorgement under the Food, Drug and Cosmetic Act. These matters included the illegal marketing of medical devices and pharmaceutical products for uses not approved by the Food and Drug Administration (FDA) or the distribution of products that failed to conform to the strength, purity or quality required by the FDA.

The departments also continued their successes in civil health care fraud enforcement during FY 2011. Approximately \$2.4 billion was recovered through civil health care fraud cases brought under the False Claims Act (FCA). These matters included unlawful pricing by pharmaceutical manufacturers, illegal marketing of medical devices and pharmaceutical products for uses not approved by the FDA, Medicare fraud by hospitals and other institutional providers, and violations of laws against self-referrals and kickbacks. This marked the second year in a row that more than \$2 billion has been recovered in FCA health care matters and, since January 2009, the department has used the False Claims Act to recover more than \$6.6 billion in federal health care dollars.

# 2011 FY Health Care Fraud Statistics

- Source: HHS and DOJ Health Care Fraud and Abuse Control Program (HCFAC) Annual Report
  - \$4.1 billion total deposited in Treasury and CMS
    - \$2.4 billion in health care fraud judgments and settlements
    - \$600 million in federal Medicaid money recovered
  - 1,110 new criminal health care fraud investigations opened involving 2,561 potential defendants
  - 1,873 federal health care fraud criminal investigations pending
  - Filed criminal charges in 489 cases involving 1,430 defendants
  - 743 defendants convicted of health care fraud-related crimes

## 2011 FY Health Care Fraud Statistics

- 977 new civil health care fraud investigations opened
- 1,069 pending civil health care fraud matters pending at end of FY 2011
- 2,662 individuals and entities excluded from participation in federal health care programs
  - 1,015 excluded for criminal convictions related to Medicare/Medicaid
  - 233 excluded for criminal convictions related to other programs
  - 206 excluded for patient abuse, 897 for license revocation

## Civil Enforcement and the False Claims Act

- 24 out of the 26 largest relator-initiated recoveries involved health care providers or pharmaceutical companies, according to Taxpayers Against Fraud
- In FY 2011, payments to relators in health care-related FCA cases totaled \$419,484,976
  - CMS Audit disallowances totaled \$74,057,438
  - CMPs totaled \$16,495,458
- Total budget allocation for HCFAC was \$608,065,945
- Total ROI since inception (1997) \$5.1/1; last 3 years \$7.2/1

## National Initiatives in HCFAC

- Health Care Fraud Prevention & Enforcement Action Team (“HEAT”)
- On September 7, 2011, Medicare Strike Force Teams charged 91 individuals in various false billing schemes the government claims resulted in \$295 million in false Medicare billings



# Representative HEAT/Strike Force Cases

- Wheelchairs, wheelchairs, wheelchairs (LA, Houston, Baton Rouge)
  - Kickbacks for patients
- Fictitious Services
  - False/not provided mental health services (Miami)
  - Occupational therapy (Detroit); physical therapy (Detroit)
  - Arthritis kits for dead people (Houston)
  - “Pedicures for profit” billed as “chemical cauterizations” (Brooklyn)
- Distribution and false claims for controlled substances, e.g. Oxycodone, Morphine (Tampa)

## For The Larger Recoveries

- Pharmaceutical Companies
- Hospital-Based Providers
- DME Suppliers
- Physician Billing
- Pharmacy Billing
- Violation of Physician Self-Referral Law and AKS

## Pharmaceutical Recoveries

- GlaxoSmithKline: \$600 million for allegations related to Kytril (nausea and vomiting in cancer patients). Allegations that this and other drugs manufactured in Puerto Rico facility were adulterated. Subsidiary entered criminal felony plea and paid a criminal fine of \$150 million
- Abbott Labs, B. Braun Medical, Roxane Labs, Dey, Inc.: \$701 million settlement in *qui tam* action alleging false reporting/inflating of AWP and “marketing the spread” between reimbursement and alleged “true price” of drugs

## Pharmaceutical Cases

- Off-Label Promotion
- Elan Corporation: \$60 million related to Zonegran (approved for partial seizures related to epilepsy allegedly marketed for psych disorders, weight loss)
- Allergan Inc.: \$600 million related to Botox Therapeutic (approved for strabismus and blepharospasm allegedly promoted for headache, pain and juvenile cerebral palsy). \$375 million in criminal fines and forfeiture, \$225 million in civil settlements

## Off-Label Cases

- Kos Pharmaceuticals: \$41 million to resolve civil and criminal liability relating to Advicor and Niaspan. Allegations included payments to doctors for off-label use and promotions, free trips for physicians. (Drug approved for high cholesterol, off-label use for mixed dyslipidemias)
- UCB, Inc.: \$34.4 million for criminal and civil FCA liability re Keppra (approved for seizures, alleged off-label promotion for headache, migraine, bipolar disorder)

## Off-Label Cases

- Novo Nordisk: \$25 million for NovoSeven-related off-label promotion allegations (approved for hemophilia, alleged off-label for trauma-related hemorrhage)
- *United States ex rel. Colquitt v. Abbott Labs et al.*: *Qui Tam* action filed in Northern District of Texas (Dallas) alleging use of biliary stents in treatment of peripheral vascular disease. Allegations state FDA concluded that biliary stents are not safe and effective for vascular use

# Hospital Cases

- One-Day Stays/Medical Necessity
  - Santa Clara Valley Hospital: \$4.3 million for one-day stays that should have been outpatients with observation services. Used OIG Self-Disclosure Protocol
  - *Tenet v. Community Health System*: Securities Law complaint filed during takeover battle alleging improper admissions of patients and corresponding misleading financial statements. Dismissed for lack of standing on March 21 after takeover bid dropped
  - Denver Health Medical Center: \$6.3 million paid to resolve *qui tam* related to allegations of short hospital stays lacking medical necessity

## Hospital Cases

- Christus Health: Paid \$1 million for allegedly submitting unallowable costs in cost report while maintaining separate cost report without improper cost, on advice of consultant
- Kyphoplasty cases
- St. John's Health System: \$318 million for billing group counseling meetings as group medical psychotherapy claims and misbilling lower-level practitioners without appropriate modifiers



## Other Significant Cases

- Guidant LLC: \$9.3 million for failure to grant warranty credits and rebates for pacemakers and defibrillators that were explanted under warranty causing “inflated costs”
- BlueCrossBlueShield of Illinois: \$25 million for alleged scheme to terminate coverage for “medically fragile, technologically dependent children” in order to shift costs to Medicaid program. Allegation that BCBSIL adopted internal guidelines more restrictive than policy coverage provisions

## Other Significant Cases

- CVS Pharmacy (1) approximately \$1 million for drugs dispensed by excluded pharmacist; (2) \$17.5 million to US and 10 states for bills to Medicaid when patients covered by 3<sup>rd</sup>-party insurance
- Renal Care Group/Fresenius Medical Care Holdings: \$82.6 million for dialysis supplies billed by subsidiary supply company that was not independent of patients' dialysis facilities
- APS Healthcare: \$13 million to resolve FCA liability regarding Georgia Medicaid managed care for failure to provide case and disease management

## Kickbacks and Self-Referrals

- Medline, Inc.: \$85 million for allegations that kickbacks were paid to health care providers in violation of the AKS and FCA to induce purchase, lease or order of medical supplies or DME
- Serono Labs: \$44.3 million for allegedly paying health care providers to induce promotion of Rebif, an MS drug
- Detroit Medical Center: \$30 million relating to allegations of Stark and AKS violations for below FMV office space and undocumented lease arrangements with referring physicians

## Kickbacks and Self-Referrals

- St. Jude Medical: \$16 million for allegations of physician kickbacks to induce use of company's pacemakers and defibrillators through use of post-market studies

## Other Fraud and Abuse Provisions

- FCA “claims” now apply to any payments made through insurance “exchanges” at the state level if federal funds are involved.
- 60-day rule: The Fraud Enforcement and Recovery Act of May 2009 expanded the definition of a “reverse false claim” to include the knowing retention of overpayments.
- ACA requires overpaid funds to be reported and returned within 60 days of “identification” or when corresponding cost report is due.

## Increase In Prosecutions/Exclusions

- FDA states it intends to increase Criminal Division prosecutions of responsible corporate officers and “corporate counsel”
  - *“FDA Criminal Division to Increase Prosecutions,”* The Wall Street Journal (March 4, 2010)
- *US v. Lauren Stevens*
  - Corporate counsel indicted for “Obstruction of Proceeding” and False Statements to FDA for response to FDA information request

## OIG Issues New Guidance On Exclusions

- In October of 2010, OIG issued new guidance on use of exclusion powers, indicating its willingness to use them more frequently
- Individuals with a direct or indirect ownership or control interest in a sanctioned entity and who know or should know of the conduct may be excluded along with any officer or managing employee of a sanctioned entity

## OIG Exclusion

- Factors OIG will consider in deciding whether to exclude individual
  - Circumstances of the misconduct and seriousness of the offense
  - The individual's role within the sanctioned entity
  - The individual's actions in response to the misconduct
  - Information about the entity



Questions?



# Challenging the Government's New Theories of Liability

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*William H. Jordan*  
*Alston & Bird*

*Tim Renjilian*  
*FTI Consulting*

# Brave New World of Compliance Programs

- Every health care company will have a compliance program, but changes needed to many programs as a result of FERA, ACA, and enforcement trends
  - Sentencing Guidelines: Require periodic assessment of compliance program to ensure that it adequately addresses risk areas
- New Risk Areas for health care companies
  - Dodd-Frank – it's not just for financial companies
  - “Reverse” False Claims and 60-Day Overpayment Provision
  - Adequate Measures to ensure that new reporting requirements/certifications under ACA are accurate and truthful
  - Responsible Corporate Office Doctrine

# Dodd-Frank Whistleblower Provisions

- SEC adopts final whistleblower program rule on May 25, 2011
  - Whistleblowers entitled to between 10-30 percent of total sanctions in excess of \$1MM
    - Size of award depends on significance of information provided by whistleblower, law enforcement interest, degree of assistance, and whether whistleblower participated in internal compliance procedures before contacting SEC.
      - NO REQUIREMENT that whistleblower actually did notify compliance department or others inside company in first instance
    - Award may be decreased based on whistleblower's culpability, unreasonable delay, or interference with internal compliance procedures.
      - Note that award is not eliminated, but merely decreased

# Dodd-Frank Whistleblower Provisions Cont'd

- Some employees or information excluded from eligibility:
  - Those with “pre-existing legal or contractual duty” to report violations
  - Information based on a communication subject to attorney-client privilege or gained as a result of legal representation
  - Officers, directors, trustees, or partners to extent information obtained in connection with company’s addressing potential non-compliance, but does not exclude officers who become aware of other members of senior management that are engaging in securities violations
  - Compliance Officers or others in internal audit
  - Independent accountants
  - Information gained in violation of federal or state criminal law as determined by a court
- Except that individuals are eligible if:
  - Reasonable basis to believe that reporting is necessary to prevent substantial harm or that entity is engaging in bad faith conduct that will impede an investigation
  - 120 days have elapsed since whistleblower reported internally
    - Note that this puts a de facto 120-day clock on many investigations
- Important consideration for internal reporting –
  - Whistleblower who reports internally before or at the same time he or she reports to the SEC will receive full credit for information that the company reports to the SEC as if the whistleblower had done so

# What Rules Mean for Health Care Companies

- SEC has shown increased willingness to investigate health care companies in areas traditionally part of DOJ or HHS-OIG enforcement
  - **July 2010:** SEC launches investigation of home health companies amid allegations in Wall St. Journal of manipulation of therapy thresholds
  - **May 2011:** CVS Caremark discloses subpoena by SEC regarding its PBM and MAPD businesses
- FCA settlements/congressional investigations as basis for SEC review of disclosures/revenue recognition
- Whistleblowers have incentive to file qui tam with DOJ and state AGs and report to SEC before or, at least, at the same time as internal reporting
- 120-day clock for internal investigations and self-reporting determinations

# Reverse False Claims and the 60-day clock

- Reverse FCA attaches to:
  - “Any person who ... knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government...”
    - Obligation: “an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor/licensee relationship, from a fee-based or similar relationship, or from the retention of any overpayment....”
  - FCA also applies to a “contractor, grantee, or other recipient, if the money or property is to be spent or used on the government’s behalf or to advance a government program or interest.”
  - PPACA establishes 60-day clock for return of “identified” overpayment (or date of corresponding cost report)
    - Health care companies should consider how this requirement relates to quality audits, compliance reviews, and regular bill audit processes

# Examples of overpayment identification issues

- “Identification” – does this mean the “fact” of the overpayment or the “amount” of the overpayment?
  - Feb. 2012 rules state that it is when the overpayment is known or should be known
  - Ports FCA-like rules into overpayment identification
- WellCare Health Plans: \$137.5MM to settle allegations that it avoided repayment of overpayments, inflated reinsurance payments, disenrolled Medicaid beneficiaries that company considered unprofitable
  - Criminal case against former CEO, GC, CFO, and other executives.



## Increased Use of Responsible Corporate Officer Doctrine

- Decades-old strict liability theory that has obtained new life given HHS-OIG permissive exclusions rules
  - OIG focus on holding owners, officers, and managing employees personally accountable for corporate wrongdoing
  - OIG authority to exclude owner of sanctioned entity if he or she knew or should have known of the conduct constituting the basis of the sanction – “OIG will operate with a presumption in favor of exclusion, [which] may be overcome when OIG finds that significant factors weigh against exclusion.”
    - Circumstances of the conduct and seriousness of the offense
    - Individual’s role in the misconduct
    - Information about the entity and its history of misconduct
- K-V Pharma: OIG coupled non-exclusion of K-V Pharma with exclusion of former board chairman and major shareholder

# Increasing Accountability and Individual Liability

- Government increasingly refusing to provide releases for current and former officers and directors
- Creates issues related to indemnification obligations of companies
  - If company settles, it does not want to pay again if former officer or director also settles and then seeks indemnification
- Potentially creates conflicts between interests of executives and interests of shareholders

# Trends in Theories of Liability

- Retention of overpayments
- Quality of Care/Medical Necessity
  - One day stays
  - Failure to have sufficient documentation to justify admission
    - Government examines internal audits
- Upcoding or Improper coding
  - E&M coding
- Off-label promotion
- Clinical trial billing

# Trends in Theories of Liability

- Kickbacks and Discounts
  - “Naked” v. “Hidden” discounts
  - Swapping allegations of Part A v. Part B
- Foreign Corrupt Practices Act
  - Particularly in areas of pharma, device, electronic records
- Claims against managed care plans
  - Risk Adjustment Data Validation audits (RADV)
  - Part D billing issues

# Challenging the Government's Theories

- Examine standard used for measuring “true” claim
  - Objective or subject to interpretation?
  - Requires physician/professional judgment?
  - Review medical literature, training materials
- Examine the government's/relator's math
  - Often seek to extrapolate from very limited sample size
  - Will calculate single damages inappropriately
- Demonstrate that compliance program worked effectively
  - Corrective action implemented; employee discipline; etc.
- Criticize novel theories, but recognize that the FCA is the primary vehicle to demonstrate savings in federal programs

# Issues Affecting Ability to Resolve Cases

- Parallel investigations / state AG involvement
- Individual exposure
- Whistleblower issues
  - Declined cases routinely go forward
  - Retaliation claims
  - Limitations on public statements
- Securities disclosures
- Potential for exclusion of individual or company



# Best Practices for Compliance Programs in the Age of Program Integrity Contractors

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*Donna P. Bergeson*

*Alston + Bird Health Care Forum*

*May 2, 2012*

“It is dangerous to be right, when the  
government is wrong.”

---

*Francois-Marie Arouet de Voltaire*  
*1694-1778*



# The Legal Environment

- Health care is one of the most highly regulated industries
- Compliance guidance has been issued by the OIG for many healthcare suppliers and providers (1998-2005)
- OIG guidance is not the law, but it is the interpretation of the agency that investigates alleged violations of the law
- Providers continue to experience enforcement actions
- Qui Tam (whistle blower) actions are profitable to disgruntled employees and to the government

## Recent Developments

- Health Care Reform Act mandates HHS begin requiring certain “core elements” in compliance plans as a CoP
- HHS has not yet issued a final rule on this mandate
- HHS has stated its expectation that the “core elements” will look like the 7 elements the OIG has recommended for effective compliance programs
- 2-2-11 Federal Register: “we intend to do further rulemaking on compliance plan requirements and will advance specific proposals at some point in the future.”

# OIG Guidance:

## 7 Elements of an Effective Compliance Program

- Written policies and procedures with Standards of Conduct
- Designation of a compliance officer
- Effective training
- Internal auditing and monitoring
- Developing open lines of communication
- Enforcing standards through well-publicized disciplinary guidelines
- Responding to detected offenses and developing corrective action initiatives

# Special Attention on Nursing Facilities

- Nursing facilities have an independent requirement in PPACA to establish a compliance program.
- Under PPACA, nursing facilities must have a compliance program in operation by March 23, 2013.

# Most recent Development

- In 2012, OIG rolled out a new website called Compliance 101  
<http://www.oig.hhs.gov/compliance/101/index.asp>
  - Links to previously provided industry-specific program guidance
  - Training videos and presentations
  - Educational materials for Boards of Directors
  - Educational materials for physicians

## Best Practices Beyond the 7 Elements

- Compliance officer is a direct report to the CEO and Board (does not report to GC or CFO)
- Compliance dept. has its own budget (“important efforts get budgeted”)
- Board meetings include a standing report from the compliance officer
- Compliance education is provided to the Board “regularly”
- Meetings occur between the CO and CEO
- Disciplinary actions for compliance violations are publicized (de-identified)
- Regular self-assessment of compliance program occurs
- Periodic external assessments are made of the effectiveness of the Compliance Program

# Governing Board Leadership / Liability

- US Sentencing Commission recommended greater responsibility be placed on boards for oversight and management of Compliance Programs; Congress adopted effective November 1, 2005
- OIG has emphasized Board responsibility with written educational materials, video training segments, and frequent presentations in the lecture circuit from 2004 to the present
- External compliance program reviews demonstrate satisfaction of the Board's oversight responsibilities and can protect your Board members against allegations that they have breached their duties when compliance concerns inevitably arise

# Ineffective Compliance Programs & The False Claims Act

- The government contends that an ineffective compliance program is enough to subject a provider to FCA penalties
  - Penalties can include significant financial penalties (triple damages plus \$5,500 - \$11,000 per claim) and administrative penalties (CIA, CCA or exclusion from federal programs)
  - *A BRIGHT SPOT: US ex rel. Bunk v. Birkard Globistics*, ED Virginia, Feb 14, 2012: determined that the \$5500 minimum penalty was “unconstitutionally excessive” under the facts of that case pursuant to the excessive fines clause of the 8<sup>th</sup> Amendment. [*Happy Valentines Day; don't count on getting similar love!*]





“It is dangerous to be right, when the  
government is wrong.”

---

*Effective compliance programs will likely result in the  
discovery of mistakes by your organization. Rob is now  
going to discuss how to lessen the danger when you report  
those mistakes.*



# Trends & Issues in Health Care Self-Disclosures

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*Rob Stone*

*Alston & Bird, LLP*

*Health Care Forum*

*May 2, 2012*

# The Flip Side of an Effective Compliance Program

- Effective Compliance Programs identify problems – that's part of what they're supposed to do!
- How to respond to issues identified through compliance program mechanisms (other than conduct a thorough investigation)?
- Requires input of entire compliance/business/legal team
- Wide range of potential responses – vary depending on facts
  - Nothing
  - Internal corrective actions (training, employment action, restrictions, medical staff/professional board referral)
  - Submit a routine refund
  - Self-Disclose

# Risks & Benefits of Self-Disclosure

- Risks are fairly obvious
  - Government spotlight on your organization
  - Cannot predict amount of settlement or other potential consequences (e.g., CIA)
  - Lengthy process
  - Cannot “un-ring the bell”
- Potential benefits
  - Cuts off potential *qui tam* actions & running of the “60 day clock” for FCA liability
  - Government policy is to take into consideration the fact that a provider self-disclosed
  - 2008 change in policy related to waiver of ACP
  - Allows you to control the narrative (or at least the first version of it)

# Relationship Between FCA Revisions & Rise in Self Disclosures

- The utilization of various self-disclosure mechanisms has been increasing due, in part, to recent statutory changes to the False Claims Act
- Fraud Enforcement Act of 2009 (FERA)
  - Expanded FCA liability for retention of overpayments by a person who knowingly and improperly avoids or decreases an obligation to pay to the government
- Affordable Care Act (2010)
  - Providers must, within 60 days after the date on which an overpayment has been “identified” (or the date any corresponding cost report is due), report and return the overpayment and notify the recipient of the reason for the overpayment
- After the 60 day window closes *the overpayment converts to a False Claim*

## Where to Disclose

- DHHS OIG– disclosure must include AKS or FCA issue – no “pure” Stark violations
- CMS– Self Referral Disclosure Protocol (only potential or actual Stark violations)
- DOJ (Note recent Bristol Settlement)
- Simple refund to MAC or other claims processor (generally limited to simple or negligent billing errors)
- If under a CIA – follow those reporting mechanisms
- If currently engaged with investigators – likely report to those investigators

# The OIG Route

- OIG Self Disclosure Protocol has been around since 1998
- It is a known factor
- Many settlements have been reached through this process
- Can address AKS or False Claim violations (among other issues)
- In March 2009, OIG issued open letter stating they would no longer be accepting disclosures through the SDP that did not include “colorable” AKS violation. Leaving providers no where to go to address technical Stark law violations
- ACA also changed the law to state explicitly that claims submitted pursuant to kickbacks are, *per se*, false claims
- ACA required the Secretary of HHS to create a self-disclosure protocol for actual or potential violations of the Stark Law

# CMS Report to Congress on the Self-Referral Disclosure Protocol

- PPACA Required CMS to submit a Report to Congress on the progress of the SRDP
- As of March 9, 2012, 150 total disclosures submitted
  - 125 hospitals
  - 2 community mental health centers
  - 11 clinical labs
  - 2 DME
  - 1 Ambulance
  - 8 Group Practices
  - 1 other



# CMS Report on Self-Referral Disclosure Protocol

- 8 have been settled (2 after the Report was released)
- 61 Awaiting Requested Information
- 51 Under CMS Review
- 20 Administrative hold
- 3 Referred to law enforcement
- 9 Withdrawn by disclosing entity
- Settlements have ranged from \$60.00 to \$579,000
- Of the 8 settled, 5 have been for under \$22,000

# Recent Proposed Rule Related to Retention of Overpayments

- Applicable look period
  - 4 years – current re-opening period for CMS
  - 6 years – statute of limitations for false claims
  - 10 years – recently PROPOSED re-opening period by CMS
- But see – FAQ released by CMS in the last week
  - “A disclosing party will satisfy [the requirements of the SRDP] by submitting a financial analysis setting forth the total amount actually or potentially due and owing for claims improperly submitted and paid within the time frame established for reopening determinations...”

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# Recent Proposed Rule Related to Retention of Overpayments

- Definition of “Identified”
  - First moment it is alleged (even if not confirmed)?
  - When the fact is confirmed, but amount unknown?
  - When the amount has been determined?
  - Proposed Rule: When “the person has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the overpayment”
    - Cannot take a “head in the sand” approach and stop doing self-audits or compliance checks
  - If facts warrant it, the Preamble allows time for a “reasonable inquiry” made with “all deliberate speed” before the 60 day clock starts

## Trends in Self-Disclosures

- Potential buyer diligence – Pre-closing Activity
- New owner diligence – Post-closing Activity
- Clear violation comes to light
- Pure Stark law issues identified through routine compliance efforts
  - Much trickier than they used to be
  - Note – often an argument exists that arrangement appearing to be a Stark violation is actually in compliance. Requires careful review of facts and analysis of Stark guidance

## A+B Recent Examples

- Hospital employed physician receiving % of certain hospital ancillary revenues
- Payments by hospital-based physician as part of an exclusive agreement
- Various undocumented (or under-documented) physician arrangements (EKG reads, medical directorships, medical staff leadership stipends, MOB lease)
- Incorrect identification of provider services
- Other Physician/Hospital System utilization issues



# Trends & Issues in Health Care Self-Disclosures

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*Rob Stone*

*Alston & Bird, LLP*

*Health Care Forum*

*May 2, 2012*

# Hot Topics in Civil Healthcare Litigation, Privacy, and Antitrust

Brian R. Stimson  
Wade Miller  
Adam Biegel



# Non-Participating Provider Litigation

## Health Net and United Class Action Settlements

- *Wachtel v. Health Net, Inc.*, 2:01-cv-04183 (D.N.J. Aug. 31, 2001)
  - Subscribers in *Wachtel*, *McCoy*, and *Scharfman* alleged underpayment of non-par benefits due to database flaws and use of outdated data, as well as concealment of database flaws and lack of candor in responding to questions regarding UCR
  - Pled ERISA claims for benefits due, § 502(a)(1)(B), breaches of fiduciary duties, § 502(a)(3), failure to supply information on request, § 104(b)(4), and a deficient SPD, § 102, as well as RICO claims
  - D.N.J. rejected exhaustion defense to non-statutory ERISA claims on grounds of futility and deemed exhaustion
  - Certified classes for litigation, finding that common course of conduct in interpreting contracts and failing to disclose non-par methodology predominated; approved \$215 million settlement in August 2008
  - As part of settlement, Health Net agreed to stop using Ingenix

## Health Net and United Class Action Settlements

- *The Am. Med. Ass'n, et al. v. United Healthcare Corp.*, No. 1:00-cv-02899 (S.D.N.Y. filed April 12, 2000)
  - Subscribers, providers, and medical associations sued United, its affiliates, and Ingenix under ERISA, RICO, and the Sherman Act
    - ERISA and RICO claims similar to those in *Wachtel*
    - United and Ingenix allegedly violated the Sherman Act by using Ingenix databases to reduce UCR determinations, which induced other payers to use the databases, which restrained “price” competition among both payers and providers, and inflated subscribers’ out-of-pocket costs
  - S.D.N.Y. found that plaintiffs stated RICO and Sherman Act claims
  - After “Stage One” discovery regarding proper parties, S.D.N.Y. granted SJ on associations’ claims and certain ERISA claims
  - United settled investigation by NY AG and also reached class-wide settlement for \$350 million in January 2009, which the S.D.N.Y. approved in October 2010

## New York Attorney General Settlements

- NY AG began investigating Ingenix in February 2008, focusing on alleged conflicts of interest arising from its use by payers
- Settled with United in January 2009, and then settled with 11 more payers, including WellPoint, CIGNA, and Aetna
- Settlements required payers to stop using Ingenix and fund “Fair Health,” a non-profit database of non-par payment information
- Some payers reserved the right to use alternative non-par methodologies (e.g., multiple of Medicare)
- No judicial finding of systemic problem with Ingenix databases, yet class action litigation continued

## Pending Non-Par Litigation

- Multi-district and related actions against major payers under ERISA, RICO, the Sherman Act, and state law:
  - *In re WellPoint, Inc. Out-of-Network “UCR” Rates Litig.*, MDL 09-2074 (C.D. Cal. filed Aug. 20, 2009)
  - *Franco v. Connecticut Gen. Life Ins. Co.*, No. 07-cv-6039 (D.N.J. filed Dec. 20, 2007)
  - *In re Aetna, Inc. Out-of-Network “UCR” Rates Litig.*, MDL-2020 (D.N.J. filed July 30, 2007)
- Additional actions against smaller or different kinds of payers
- Still no adjudication of alleged systemic problems with Ingenix databases (but moving in that direction)
- Pending actions have produced conflicting legal opinions and may continue for years

***In re WellPoint*, 2011 WL 3555610  
(C.D. Cal. Aug. 11, 2011)**

- Providers have standing by assignment
- Ass'n plaintiffs have individual and representative standing
- "Per se" claim for price-fixing survives (for now) because alleged conspiracy is horizontal, via Ingenix
- Claim under rule of reason survives, as data market and market for non-par services are allegedly linked
- RICO conspiracy claim survives; other RICO claims dismissed w/o prejudice
- ERISA claims are proper even though WellPoint is not plan or administrator
- Exhaustion of non-statutory ERISA claims unnecessary due to futility
- ERISA fiduciary claims survive

***Franco v. CIGNA*, 2011 WL 4448908  
(D.N.J. Sept. 23, 2011)**

- Providers have no standing because failed to plead proper assignments
- Ass'n plaintiffs have no individual standing under Sherman Act or RICO, or representative standing
- No "per se" claim – at best, agreement to cap reimbursement, which does not affect prices or premiums
- No claim under rule of reason, as encouraging participation in network does not does not exclude providers or restrain them from competing; use of flawed data is not anticompetitive
- RICO claims of some plaintiffs survive based on alleged mail/wire fraud
- ERISA claims survive, except fiduciary claims based on alleged nondisclosure

## Non-Par Litigation Going Forward

- Significant antitrust implications for data sharing
- The Courts will encounter merits issues during class certification phase, when considering expert testimony regarding downward skewing (or lack thereof)
- As one payer has argued:
  - “[M]ore than 80 percent of [the payer’s] claims paid using an Ingenix database as a reference tool are allowed at full billed charges. [The plaintiffs’ expert] has admitted that this is what you would ‘expect to see’ if the Ingenix database was ‘really truly representative.’”
- Plaintiffs must show that alleged database flaws exist and predominate over individualized issues of assignment, balance billing, and exhaustion

## Non-Par Litigation Going Forward

- While class actions continue, payers are:
  - Moving to Medicare-based payment methodology
  - Suing to stop “outrageous” charges, *see, e.g., Aetna Health, Inc. v. Nejad*, No. CAM-L-4958-10 (N.J.Super. Ct. filed Sept. 30, 2010) (action for insurance and common law fraud, negligent misrepresentation, violations of medical board examiner regulations, and tortious interference)
- PPACA Emergency Services Provision
  - Requires payment of the higher of (1) the median in-network rate, (2) the UCR, or (3) the Medicare rate, 45 C.F.R. § 147.138(b)(3)
  - Effective on January 1, 2011 for non-grandfathered plans
  - Presents issues regarding how to properly calculate median in-network rate and the UCR



***Civil Actions for  
Data Privacy Breaches***

## Civil Actions for Data Privacy Breaches

### STATE LAW CLAIMS

- Some courts have dismissed common law and statutory claims for lack of injury and insufficient pleading. *Resnick v. AvMed, Inc.*, No. 1:10-cv-24513-JLK, 2011 WL 1303217 (S.D. Fla. Apr. 5, 2011).
- HIPAA and other federal laws may also preempt state law claims for wrongful disclosure. See, e.g., *Fisher v. Yale Univ.*, No. X10NNHCV044003207S, 2006 WL 1075035 (Super. Ct. Conn. Apr. 3, 2006); *Darcangelo v. Verizon Commc'n, Inc.*, 292 F.3d 181 (4th Cir. 2002).
- But other courts have allowed state law claims under state malpractice laws. See, e.g., *M.O. v. IMA, Inc.*, No. 53C01-0604-PL-00723 (Cir. Ct. Ind. 2010)..
- Several class action suits have recently been filed in California under the Calif. Medical Information Act. See, e.g., *Pardieck v. Sutter Health*, No. 34-2011-00114396 (Sacramento Super. Ct. Cal.); *Debaeke v. St. Joseph Health System, et al.*, No. 2012-251417 (Sonoma Super. Ct. Cal.)

## Civil Actions for Data Privacy Breaches

### ***FEDERAL LAW CLAIMS***

- There is no federal claim because there is no private right of action under HIPAA. *See, e.g., Sneed v. Pan Am. Hosp.*, 370 F. App'x 47, (11th Cir. 2010).
- Courts have rejected several recent efforts to convert HIPAA violations into civil RICO claims. *See, e.g., Wheeler v. Hilo Med. Ctr.*, No. 09-00533 JMSKSC, 2010 WL 1711993 (D. Haw. Apr. 27, 2010); *Vavro . Albers*, No. 2:05CV321, 2006 WL 2547350 (W.D. Pa. Aug. 31, 2006); *Dickerson v. TLC Lasik Ctrs.*, C.A. No. 6:10-cv-00685-JMC, 2011 WL 382443 (D.S.C. Feb. 3, 2011).

## Civil Actions for Data Privacy Breaches

### *THE LATEST RICO THEORY: IDENTITY THEFT*

- In *Muecke Co., Inc. v. CVS Caremark Corp.*, No. 6:10-cv-00078, EC N. 1, at ¶¶ 95-122 (S.D. Tex. Sept. 30, 2010), several independent pharmacies filed a putative RICO class action against CVS Caremark based on the use of the plaintiffs' customer data.
- The pharmacies allege violations of the federal Identity Theft Act, which is a RICO predicate act. 18 U.S.C. § 1961(1).
- The Identity Theft Act criminalizes the use of “a means of identification of another person” in violation of federal law. 18 U.S.C. § 1028(a)(7).
  - The Act defines “a means of identification of another person” to include common identifiers such as patient name, SSN, and DOB, as well as “unique biometric data.” 18 U.S.C. § 1028(d)(7)(A).
  - This broad language could reach health care claims data.

## Civil Actions for Data Privacy Breaches

### ***THE LATEST RICO THEORY: IDENTITY THEFT***

- The pharmacies allege that CVS Caremark violated the Act (and RICO) by receiving their customer data and using the information in connection with HIPAA violations. Complaint at ¶ ¶ 109-116.
- The pharmacies' primary obstacle: RICO is not a vehicle for pursuing violations of statutes which are enforced through an administrative process. *McCulloch v. PNC Bank Inc.*, 298 F.3d 1217 (11th Cir. 2002).
- *Muecke Co.* presents a closer call than the previous RICO/HIPAA cases because Identity Theft Act violations are RICO predicate acts, and HIPAA's complaint procedure is relatively weak.
- The Court recently granted a motion to compel arbitration

## Civil Actions for Data Privacy Breaches

- Takeaways
  - Ensure you have a HIPAA Compliance plan in place
  - Be aware of state law requirements
  - In the event of a potential data breach, promptly conduct a risk assessment
  - Provide notice to patients promptly when required

# Hot Topics – Antitrust

## Health Care Forum 2012

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## Antitrust in Post-ACA World

- Support for antitrust principles and policy
- Their application (in public & private litigation)
  - Mergers
  - Contractual relations
    - MFNs and other exclusionary conduct
    - Pharmaceutical settlements
  - Partnerships
    - Joint activities
- Compliance/risk assessments



## Antitrust Principles and Policy

- Objective: competition to promote quality, choice and cost reduction
  - Relevant to all aspects of business planning/operations
    - Unilateral, bilateral and multi-lateral conduct
    - Per se illegal or “facts and circumstances”
- Track record of application to health care
  - Statements of Enforcement Policy (1996)
  - Health care hearings and report (2004)
  - Flow of enforcement actions and private litigation

## Antitrust Principles and Policy

- Handing a megaphone to enforcers



- “[L]ike many reforms driven by the power of competition to create consumer welfare, the success of these legislative and regulatory efforts will depend as much upon healthy competitive markets free from undue concentration and anticompetitive behavior as it will upon regulatory change. In short, enactment of the Affordable Care Act makes effective antitrust policy more important than ever.”

-- Asst. Atty. Gen. Varney, May 24, 2010



- “The FTC has played, and will continue to play, an important role in protecting and promoting competition to lower costs and improve quality, and believes that continued effective antitrust enforcement is a necessary component of any plan to improve health care.”

-- FTC Bureau of Competition Director Feinstein, December 10, 2010

## Mergers

- What we've seen
  - New guidelines, broader remedies
  - Never quite “under the radar”
  - Health care reform an impetus, not a defense
- Examples
  - Challenges to hospital, payor and other mergers
  - Agency defeats and “no actions”
- What to expect: aggressive reviews (in all areas – sometimes by states) so be prepared

## Contractual Relations

- What we've seen
  - MFNs
    - Plain vanilla often non-controversial
    - Added risk factors of market share, differential requirement
    - BCBS/MI test case – higher prices and barrier to entry?
  - Exclusionary conduct
    - United Regional, West Penn
- What to expect: courts and agencies policing the boundaries

## Contractual Relations

- What we've seen
  - Pharmaceutical settlements
    - Continued effort by FTC to suppress
    - Eleventh Circuit rejection and Third Circuit hope
- What to expect: teeing up a “game-changer”

## Partnerships

- What we've seen
  - Joint activities – contracting
    - Usual drum-beat of settlements
    - GAO report on adequacy of advice
    - Criticism of state “bubbles”
  - The new vehicle – ACOs (public and private)
    - Policy statement (draft and final) but new?
  - Continued interest in GPOs, information exchange, *Noerr* activities and McCarran
- What to expect – looking for models of good/bad

## Compliance/Risk Assessment

- Antitrust policies/training
  - To set internal alert system – offensively and defensively
- Antitrust analysis
  - Development of procompetitive evidence and themes – where does it fall?

# RESPONDING TO THE CRISIS

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## SECURITIES DISCLOSURES, THE MEDIA, AND INTERNAL COMMUNICATIONS

*May 2, 2012*

*John Jordak*

*Mark Ray*

*Tod Sawicki*



# THE “CRISIS”

- What are we talking about?
  - Subpoena from a governmental agency
    - SEC
    - OIG
    - DOJ
    - State regulator
  - Securities litigation if stock price drops
- Must consider disclosure issues and how the media may play a role
- Is it really a “crisis”?
  - Lots of moving pieces, but not a crisis if a plan is in place.

# WHAT TO DO WHEN YOUR COMPANY RECEIVES A SUBPOENA

- Don't panic
- Decide who will coordinate the response internally
  - CLO
  - Compliance
  - CFO
  - Other
- Call counsel
  - Resist the temptation to go it alone. Lots of traps along the way.

# WHAT TO DO WHEN YOUR COMPANY RECEIVES A SUBPOENA (CONT.)

- Assess the agency that issued the subpoena
  - What is its jurisdiction – civil? criminal?
  - Past history dealing with its requests, etc.
- Focus on the precise requests
  - Documents?
  - Testimony?
  - Both?
  - Possibility of narrowing through negotiations?

# WHAT TO DO WHEN YOUR COMPANY RECEIVES A SUBPOENA (CONT.)

- What areas of your company are implicated
  - Will affect the response team
  - May affect timing of response
  
- Document retention
  - Issue document hold immediately
  - Over inclusive
  - Hard copy vs. e-document issues
  - Emails
  - Laptops
  - Departing employees
  - Confidentiality
  - International operations

# WHAT TO DO WHEN YOUR COMPANY RECEIVES A SUBPOENA (CONT.)

- Production issues
  - Rolling vs. dump
  - Privilege preservation
  - Follow-up from the requesting agency
  - Keep track of what you produce
  - Consider leverage points with the government
  
- Testimony
  - Interview relevant employees to learn the story
  - Prepare witnesses
  - Sworn testimony vs. informal meeting
  - Stick with the story

# WHAT TO DO WHEN YOUR COMPANY RECEIVES A SUBPOENA (CONT.)

- What is the government after?
  - Relationship with government official running the investigation
  - Third-party requests?
    - Talk with third-party counsel
  - Individual investigation or industry-wide review
  - Whistleblower
  - Competitor complaint
  - Billing irregularities
  
- Carrier Issues
  - Give notice early and often
  - Coverage analysis
  - Role of the broker

# SECURITIES LITIGATION

- Typically prompted by a drop in share price
  - At least 15% drop in a single day
  - No subsequent rebound in price
- Who is suing?
  - Disappointed investors
  - Private Securities Litigation Reform Act favors party with largest financial stake as lead plaintiff
  - Institutional investors, particularly pension funds, often emerge as lead plaintiffs
  - Increased competition at lead plaintiff stage between plaintiff's firms
  - Should be driven by shareholder, but in reality driven by a cadre of plaintiff's lawyers

## SECURITIES LITIGATION (CONT.)

- Types of cases
  - Shareholder class action
    - Typical claims in securities class actions
      - Securities Act of 1933
        - Section 11- Liability for material misstatements or omissions in a Registration Statement
        - Section 12 – Liability for material misstatements or omissions in a Prospectus
        - Section 15 – “Control” person liability



## SECURITIES LITIGATION (CONT.)

- Securities Exchange Act of 1934
  - Section 10(b) and SEC Rule 10b-5 – Liability for material misstatements or omissions in connection with the purchase or sale of a security if made with scienter. Statute under which “fraud on the market” claims are brought.
  - Section 20 – “Control” person liability
- Venue
- Class period

## SECURITIES LITIGATION (CONT.)

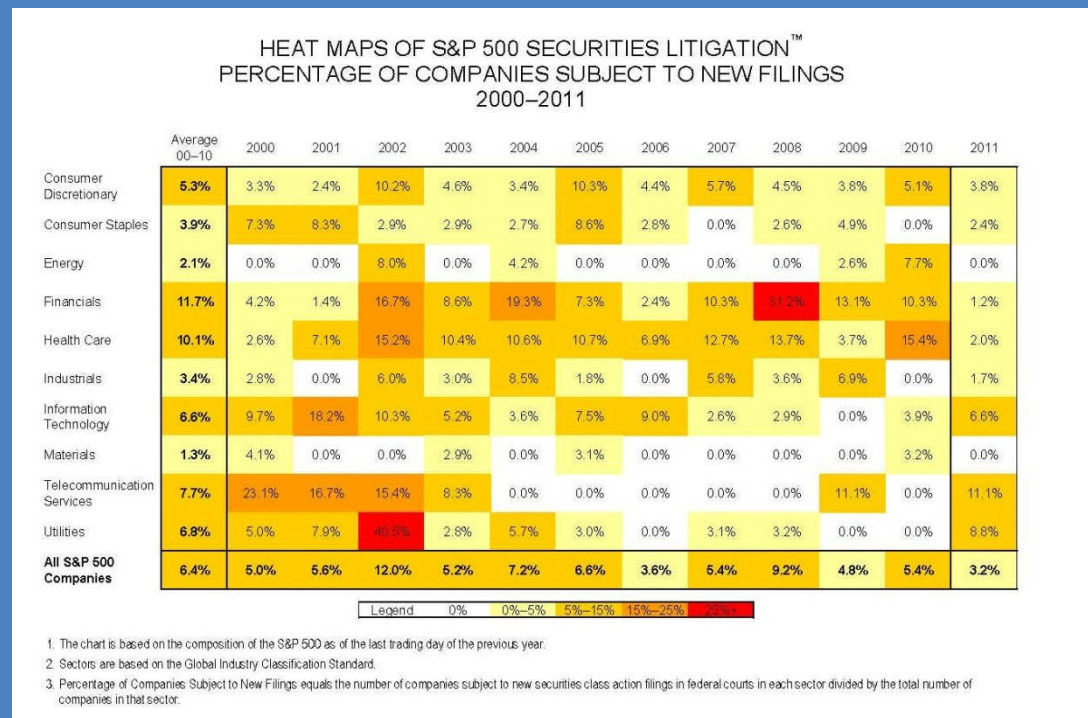
- Derivative action
  - Allegations – breach of fiduciary duty under state law
  - Demand made or excused
  - Venue – state of incorporation and/or principal place of business

# SECURITIES LITIGATION (CONT.)

- Statute of Limitations
  - 1933 Act claims
    - Sections 11 and 12(a)(2): 1 year after discovery of violation made or should have been made, but not later than 3 years after offering/sale
    - Section 12(a)(1): 1 year after the actual violation, but no later than 3 years after the offering
  - 1934 Act claims
    - Earlier of 2 years after discovery of violation or 5 years after actual violation
  - Breach of fiduciary duty – varies by state

# SECURITIES LITIGATION (CONT.)

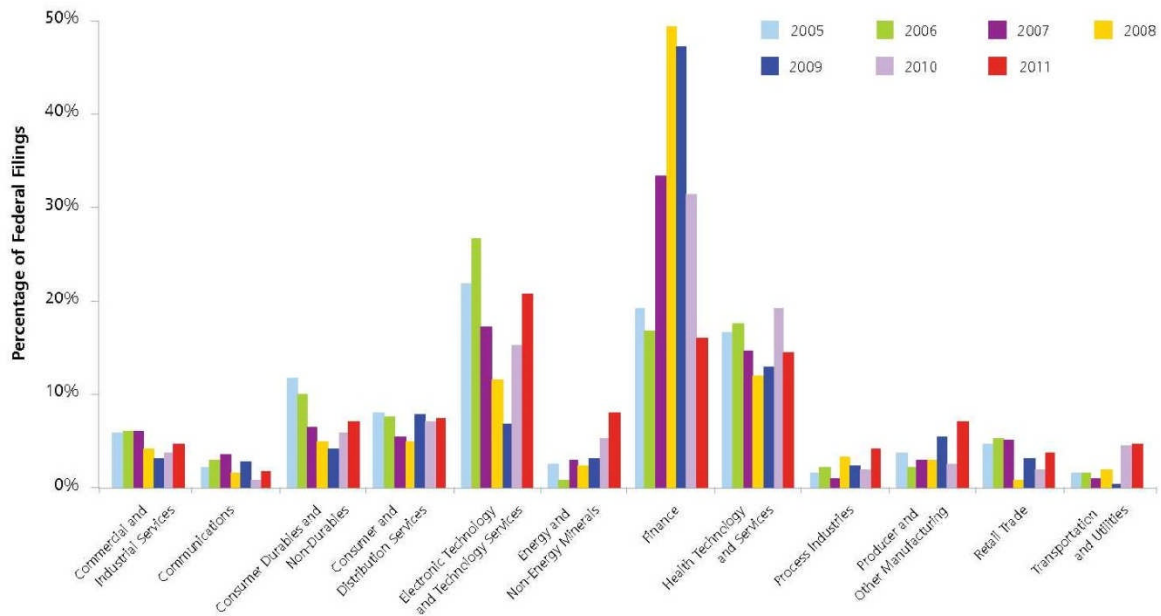
- Who is getting sued?



Source: Cornerstone Research

# SECURITIES LITIGATION (CONT.)

Percentage of Filings by Sector and Year  
January 2005 – November 2011



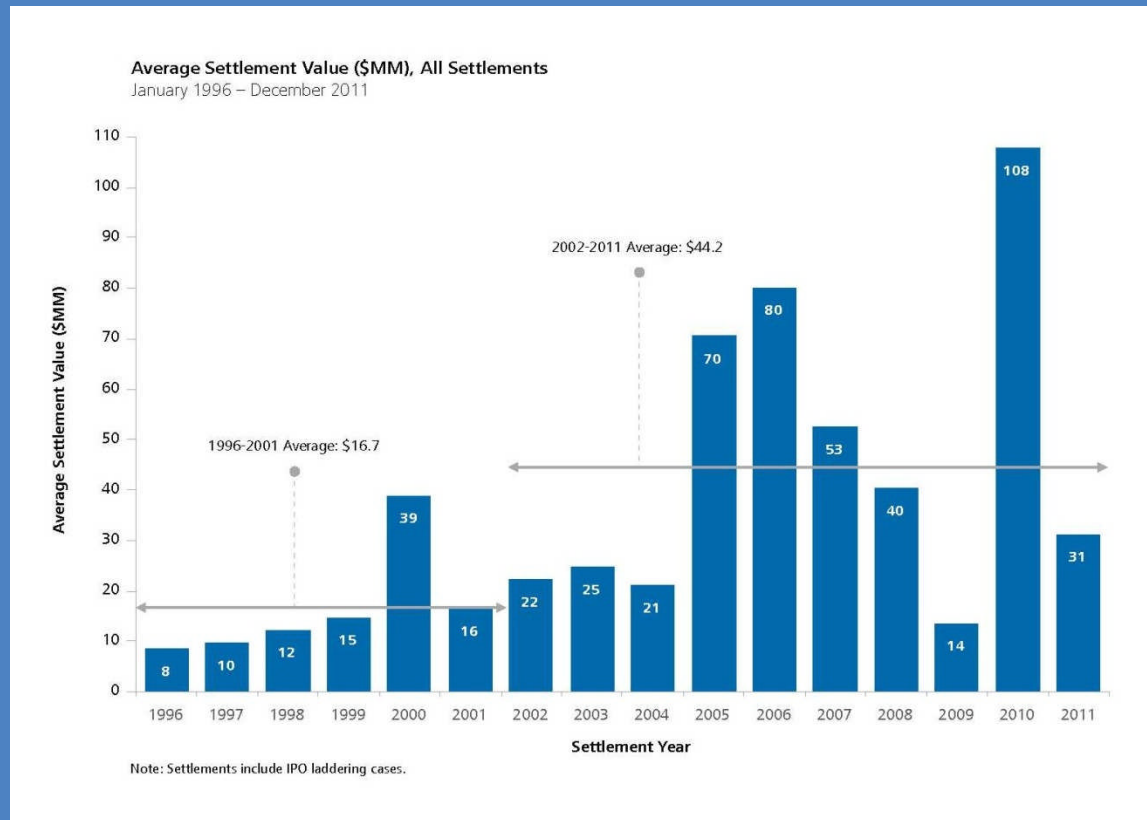
Note: This analysis is based on the FactSet Research Systems, Inc. economic sector classification. Some of the FactSet economic sectors are combined for presentation.

Source: NERA

## SECURITIES LITIGATION (CONT.)

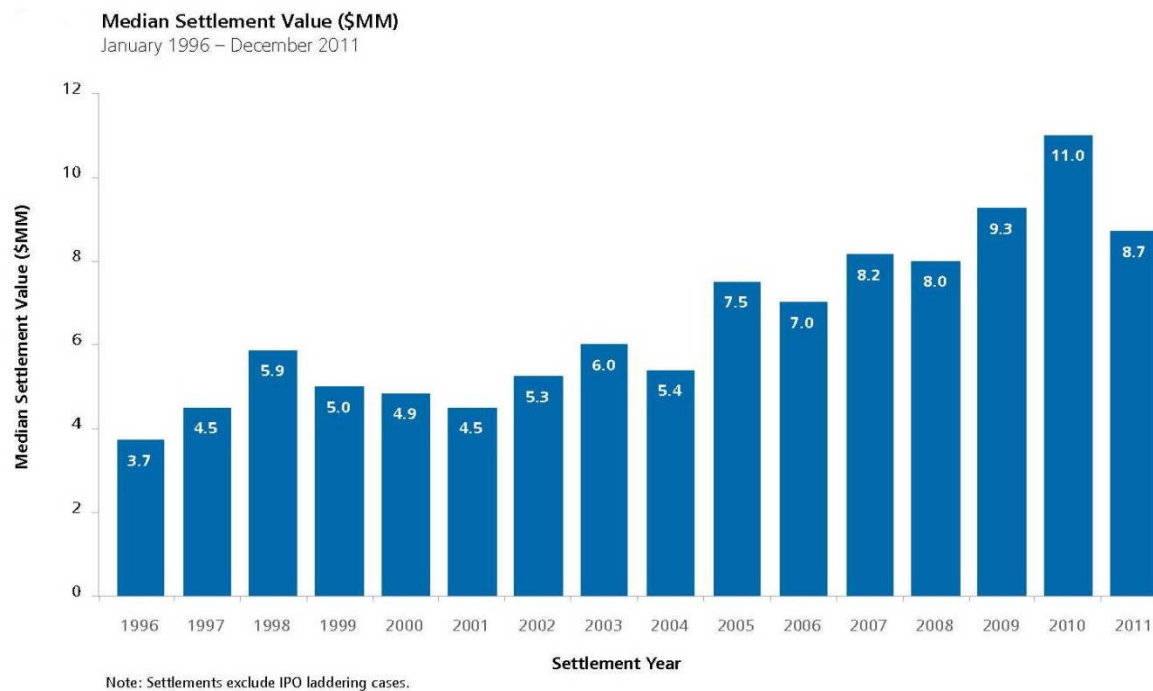
- How do these cases get resolved
  - Dismissed on motion practice
  - Tried
  - Settled

# SECURITIES LITIGATION (CONT.)



Source: NERA

# SECURITIES LITIGATION (CONT.)



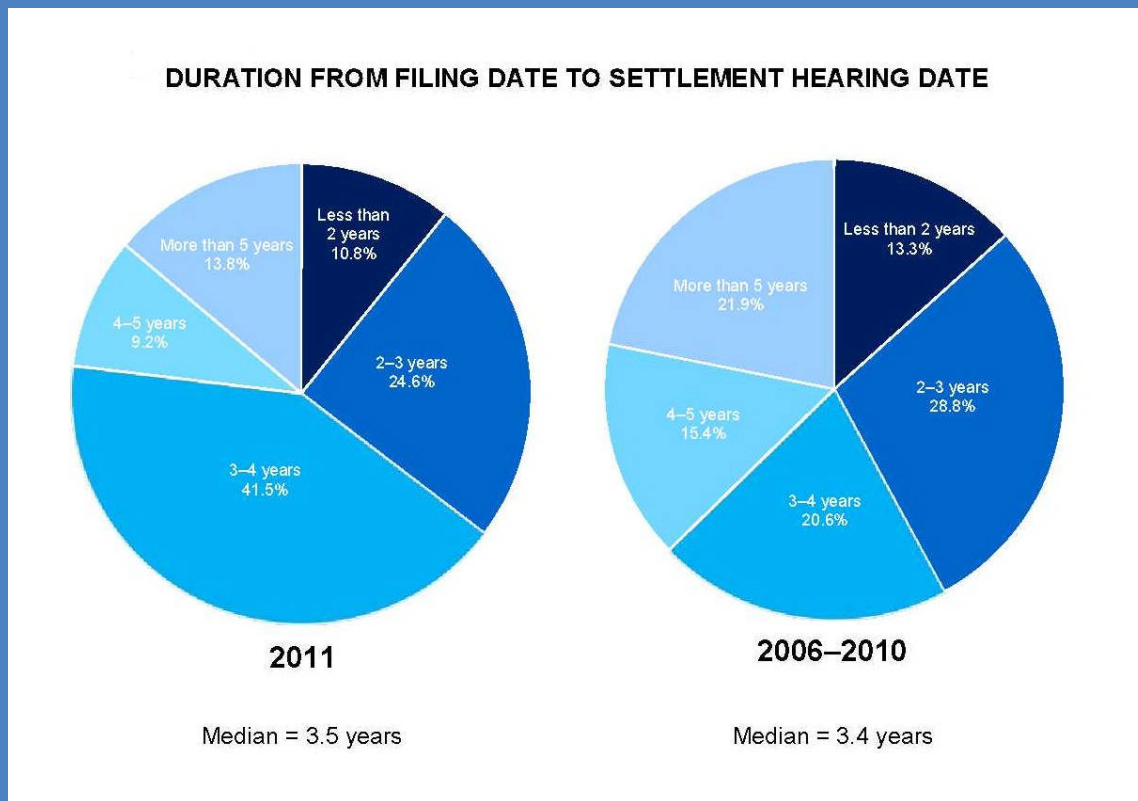
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## SECURITIES LITIGATION (CONT.)

- How do these cases get resolved
  - Dismissed on motion practice
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  - Settled
  - Duration

# SECURITIES LITIGATION (CONT.)



Source: NERA

## SECURITIES LITIGATION (CONT.)

- How do these cases get resolved
  - Dismissed on motion practice
  - Tried
  - Settled
  - Duration
- Who Pays?

## SECURITIES LITIGATION (CONT.)

- How to avoid or minimize liability
  - Adequate risk factors and forward-looking statement language to take advantage of the Reform Act's Safe Harbor – meaningful cautionary language
  - Tie any disappointing news to the risk factors
  - Crisis management plan – in writing; plan for the worst right now
  - Document retention programs
  - D&O insurance
    - Highly negotiated
    - Work closely with broker and counsel to understand what company needs
  - Beware of insider trading and tipping
  - Set up trading windows – generally shortly after results are announced for a set number of days
  - 10b5-1 trading plans – automatic execution of trades at set times
  - Comply with Regulation FD

# WHAT TO DISCLOSE AND WHEN

- What will the SEC disclose?
  - The SEC generally does not disclose the existence of an investigation and, if asked, will refuse to confirm or deny that it is investigating a particular target. If the investigation results in an enforcement action, that action will become public in the form of a public release.
  
- What should the company disclose?
  - No specific requirement to disclose the existence of an SEC investigation. If the company chooses to make a public disclosure, the CLO should coordinate with the response team to ensure that the message is consistent and honest. The CLO also needs to be mindful of Regulation FD obligations
  - Typically wait until a Wells Notice is issued

## WHAT TO DISCLOSE AND WHEN (CONT.)

- Should the company ever deny an ongoing investigation?
  - Denying the existence of an investigation can have serious consequences. Among other things, it in and of itself can give rise to a claim of misleading public disclosure and has the strong potential to be interpreted by the SEC as an “uncooperative” move.
- Cardinal Rule: If the company chooses to speak, it must do so fully and honestly

# WHAT TO DISCLOSE AND WHEN (CONT.)

- Consider materiality
  - Materiality of the investigation (e.g., where the company or a whistleblower reported the matter to the SEC in the first place and the underlying facts known to the company suggest that the scope of the fraud is material) and the likelihood of a restatement or enforcement action. A company should also consider, from the standpoint of materiality, the scope of its insurance coverage and whether it would be exposed to significant unreimbursable defense costs.
- Consider timing of disclosure
  - 10-K filing on the horizon
  - Impending offering
  - Internal control disclosures
- Leaks
  - Industry review
  - Reg FD
  - Be ready to address leak quickly

## DEALING WITH THE MEDIA

- Best approach: don't play out an investigation with the media
- Beware of ethical rules
- Speaking “off the record”
- Consider using a PR firm
  - Protect the attorney-client privilege
- Reg FD issues
- Control the flow of information
- Coordinated approach





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---

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  - Individual investigation or industry-wide review
  - Whistleblower
  - Competitor complaint
  - Billing irregularities
  
- Carrier Issues
  - Give notice early and often
  - Coverage analysis
  - Role of the broker

# SECURITIES LITIGATION

- Typically prompted by a drop in share price
  - At least 15% drop in a single day
  - No subsequent rebound in price
- Who is suing?
  - Disappointed investors
  - Private Securities Litigation Reform Act favors party with largest financial stake as lead plaintiff
  - Institutional investors, particularly pension funds, often emerge as lead plaintiffs
  - Increased competition at lead plaintiff stage between plaintiff's firms
  - Should be driven by shareholder, but in reality driven by a cadre of plaintiff's lawyers



## SECURITIES LITIGATION (CONT.)

- Types of cases
  - Shareholder class action
    - Typical claims in securities class actions
      - Securities Act of 1933
        - Section 11- Liability for material misstatements or omissions in a Registration Statement
        - Section 12 – Liability for material misstatements or omissions in a Prospectus
        - Section 15 – “Control” person liability

## SECURITIES LITIGATION (CONT.)

- Securities Exchange Act of 1934
  - Section 10(b) and SEC Rule 10b-5 – Liability for material misstatements or omissions in connection with the purchase or sale of a security if made with scienter. Statute under which “fraud on the market” claims are brought.
  - Section 20 – “Control” person liability
- Venue
- Class period

## SECURITIES LITIGATION (CONT.)

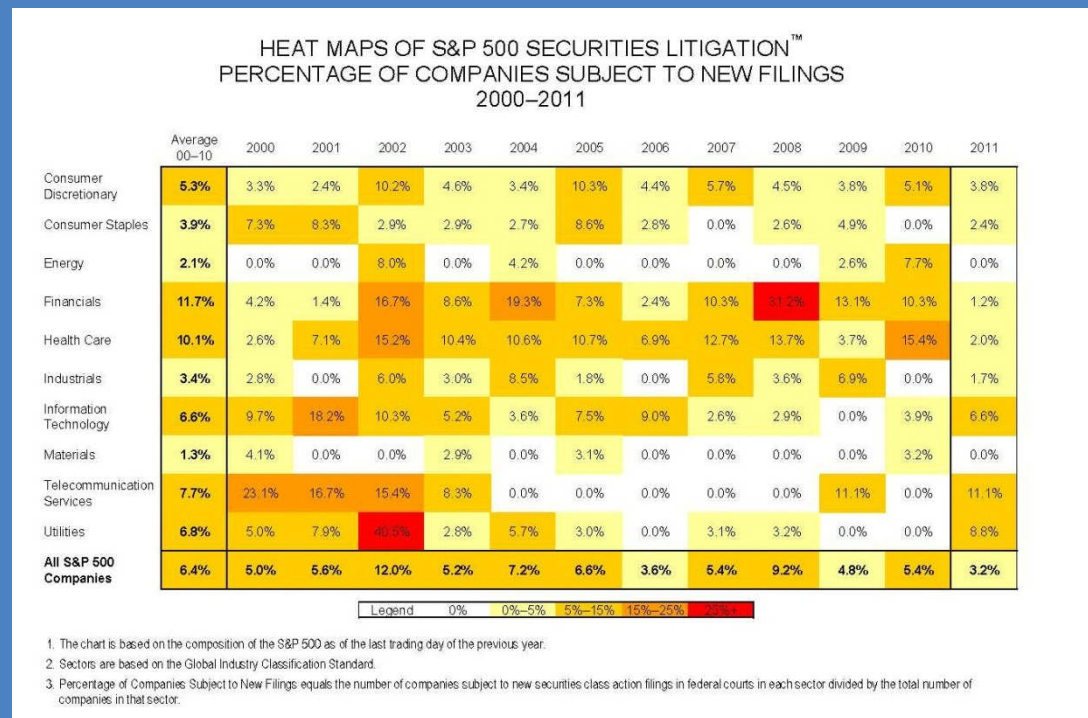
- Derivative action
  - Allegations – breach of fiduciary duty under state law
  - Demand made or excused
  - Venue – state of incorporation and/or principal place of business

# SECURITIES LITIGATION (CONT.)

- Statute of Limitations
  - 1933 Act claims
    - Sections 11 and 12(a)(2): 1 year after discovery of violation made or should have been made, but not later than 3 years after offering/sale
    - Section 12(a)(1): 1 year after the actual violation, but no later than 3 years after the offering
  - 1934 Act claims
    - Earlier of 2 years after discovery of violation or 5 years after actual violation
  - Breach of fiduciary duty – varies by state

# SECURITIES LITIGATION (CONT.)

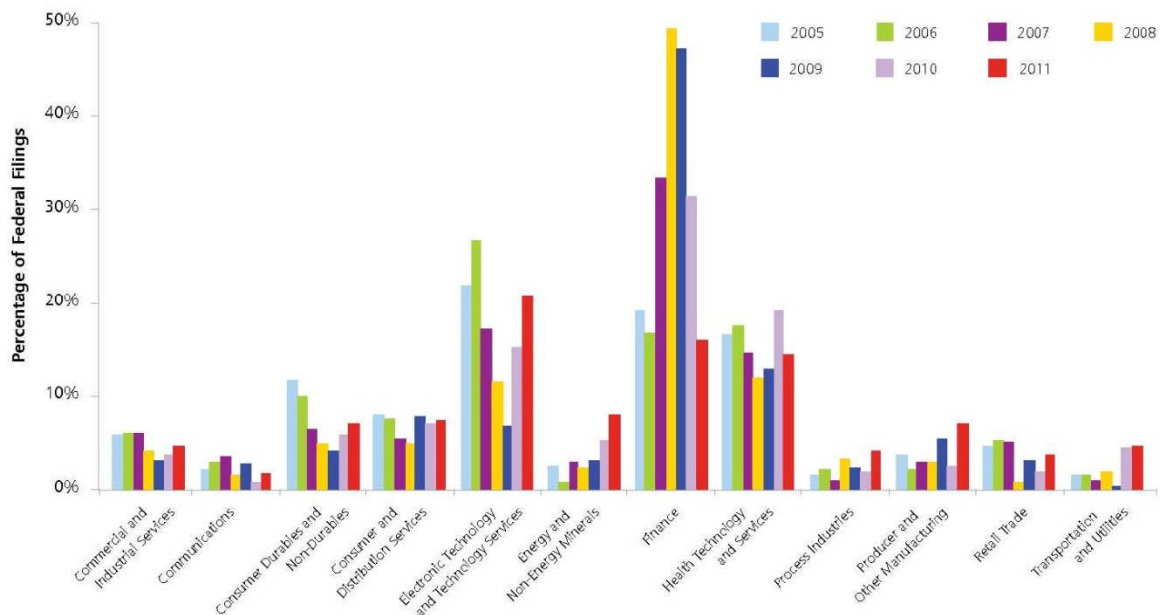
- Who is getting sued?



Source: Cornerstone Research

# SECURITIES LITIGATION (CONT.)

Percentage of Filings by Sector and Year  
January 2005 – November 2011



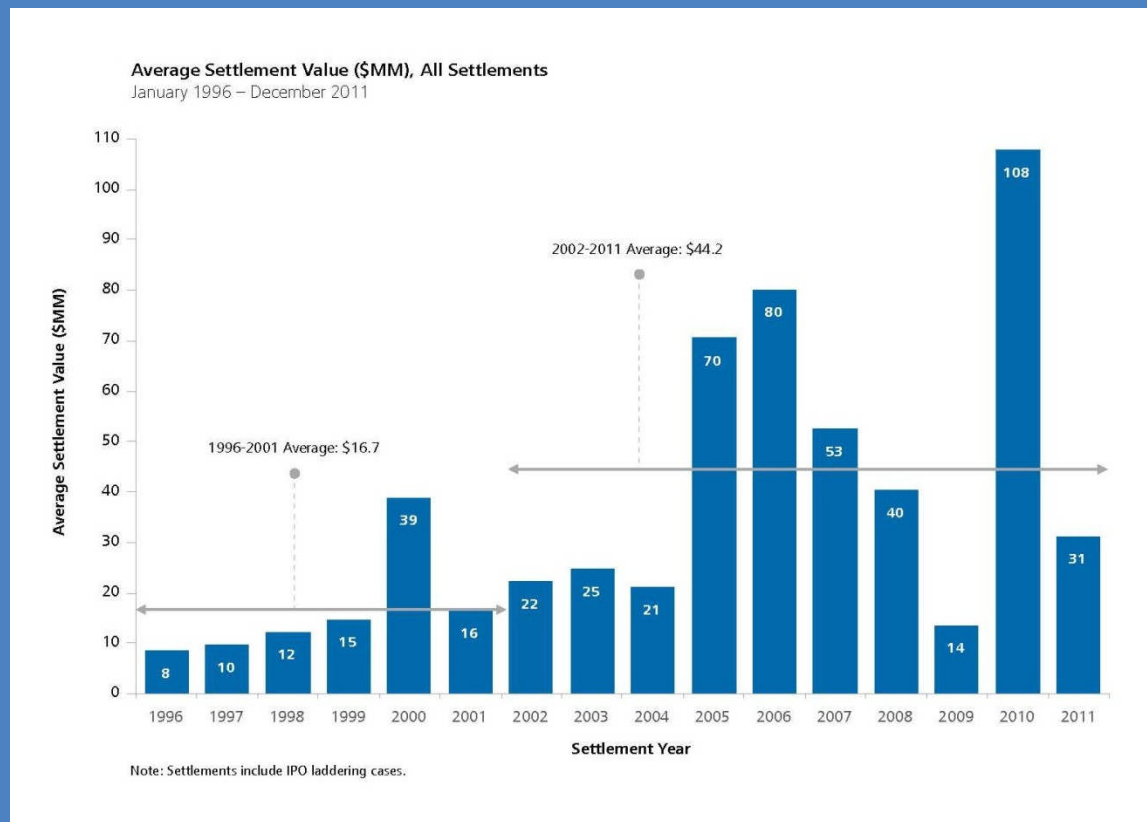
Note: This analysis is based on the FactSet Research Systems, Inc. economic sector classification. Some of the FactSet economic sectors are combined for presentation.

Source: NERA

## SECURITIES LITIGATION (CONT.)

- How do these cases get resolved
  - Dismissed on motion practice
  - Tried
  - Settled

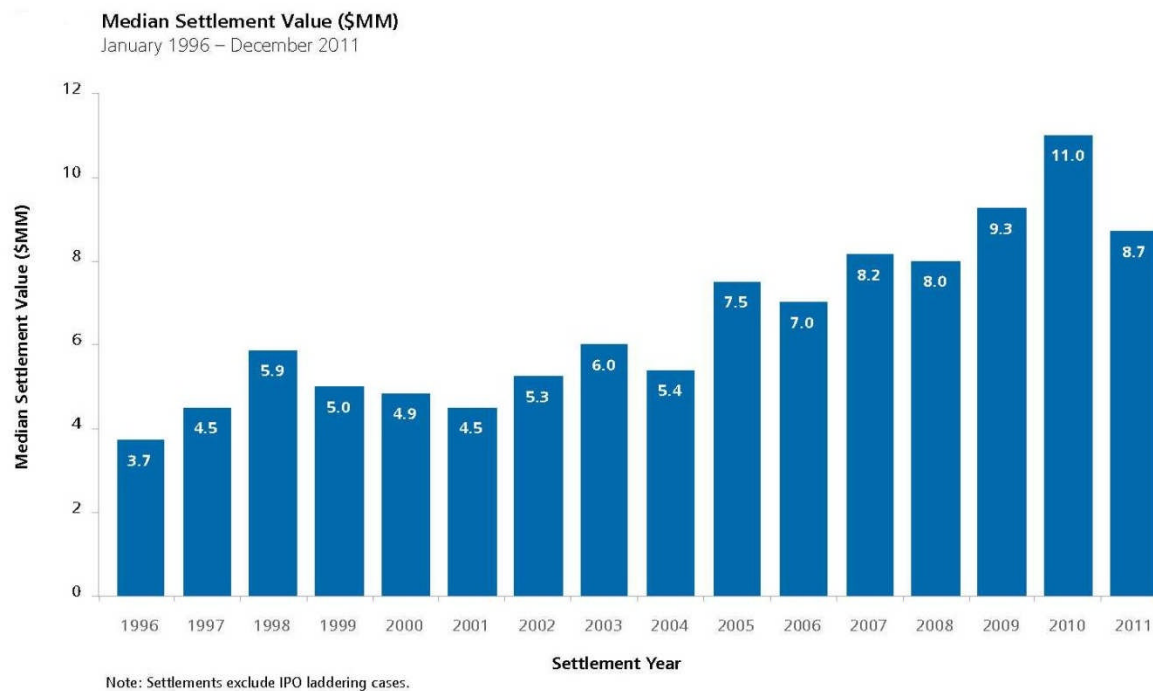
# SECURITIES LITIGATION (CONT.)



Source: NERA



# SECURITIES LITIGATION (CONT.)

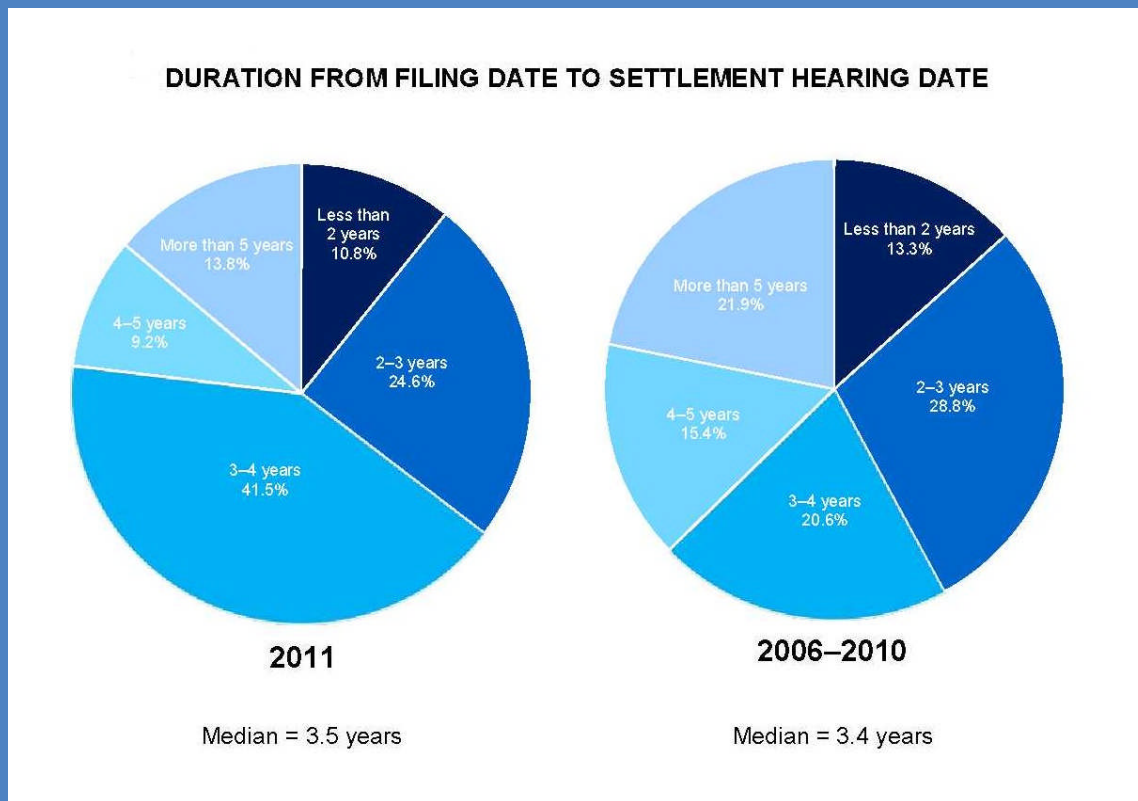


Source: NERA

## SECURITIES LITIGATION (CONT.)

- How do these cases get resolved
  - Dismissed on motion practice
  - Tried
  - Settled
  - Duration

# SECURITIES LITIGATION (CONT.)



Source: NERA

## SECURITIES LITIGATION (CONT.)

- How do these cases get resolved
  - Dismissed on motion practice
  - Tried
  - Settled
  - Duration
- Who Pays?

## SECURITIES LITIGATION (CONT.)

- How to avoid or minimize liability
  - Adequate risk factors and forward-looking statement language to take advantage of the Reform Act's Safe Harbor – meaningful cautionary language
  - Tie any disappointing news to the risk factors
  - Crisis management plan – in writing; plan for the worst right now
  - Document retention programs
  - D&O insurance
    - Highly negotiated
    - Work closely with broker and counsel to understand what company needs
  - Beware of insider trading and tipping
  - Set up trading windows – generally shortly after results are announced for a set number of days
  - 10b5-1 trading plans – automatic execution of trades at set times
  - Comply with Regulation FD

# WHAT TO DISCLOSE AND WHEN

- What will the SEC disclose?
  - The SEC generally does not disclose the existence of an investigation and, if asked, will refuse to confirm or deny that it is investigating a particular target. If the investigation results in an enforcement action, that action will become public in the form of a public release.
  
- What should the company disclose?
  - No specific requirement to disclose the existence of an SEC investigation. If the company chooses to make a public disclosure, the CLO should coordinate with the response team to ensure that the message is consistent and honest. The CLO also needs to be mindful of Regulation FD obligations
  - Typically wait until a Wells Notice is issued

## WHAT TO DISCLOSE AND WHEN (CONT.)

- Should the company ever deny an ongoing investigation?
  - Denying the existence of an investigation can have serious consequences. Among other things, it in and of itself can give rise to a claim of misleading public disclosure and has the strong potential to be interpreted by the SEC as an “uncooperative” move.
- Cardinal Rule: If the company chooses to speak, it must do so fully and honestly

# WHAT TO DISCLOSE AND WHEN (CONT.)

- Consider materiality
  - Materiality of the investigation (e.g., where the company or a whistleblower reported the matter to the SEC in the first place and the underlying facts known to the company suggest that the scope of the fraud is material) and the likelihood of a restatement or enforcement action. A company should also consider, from the standpoint of materiality, the scope of its insurance coverage and whether it would be exposed to significant unreimbursable defense costs.
- Consider timing of disclosure
  - 10-K filing on the horizon
  - Impending offering
  - Internal control disclosures
- Leaks
  - Industry review
  - Reg FD
  - Be ready to address leak quickly



## DEALING WITH THE MEDIA

- Best approach: don't play out an investigation with the media
- Beware of ethical rules
- Speaking “off the record”
- Consider using a PR firm
  - Protect the attorney-client privilege
- Reg FD issues
- Control the flow of information
- Coordinated approach

# Health Care Forum 2012: Compliance, Investigations and Litigation after Health Care Reform

*Compliance and Quality Under ACA*

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*Dawnmarie Matlock and Michael Park*  
*Alston & Bird LLP*

*May 2, 2012*

# Overview

- Quality Reporting
- ACA Payment Policies Related to Quality of Care
- Delivery System Reforms

# Quality Reporting Overview

- Who Is (Will Be) Required to Report Quality Measures
- Public Reporting of Quality Data
- Value-based Purchasing

# Providers Required to Report Quality Data

- Medicare “Pay-for-Reporting”
  - Hospital inpatient (Inpatient Quality Reporting (IQR) Program)
  - Hospital outpatient (Outpatient Quality Reporting (OQR) Program)
  - Ambulatory Surgical Centers (ASCs)
  - Home Health
  - Physicians (Physician Quality Reporting System (PQRS))
  - Long term acute care hospitals (LTACHs) (2014)
  - Inpatient rehabilitation facilities (IRFs) (2014)
  - Hospices (2014)
  - Psychiatric hospitals (2014)

# Providers Required to Report Quality Data

- Other Medicare Provider Quality Reporting
  - Skilled nursing facilities (SNFs)
  - Dialysis Facilities
  - Prospective Payment System (PPS)-exempt Cancer Hospitals
- Medicaid
- Children's Health Insurance Program (CHIP)

# Public Reporting of Quality Data

- “Quality of Care Finders” on Medicare.gov:
  - Hospital Compare
  - Nursing Home Compare
  - Home Health Compare
  - Dialysis Compare
  - Physician Compare
- Provides information on:
  - Provider contact information
  - Comparison of services provided and quality of care

# Public Reporting of Quality Data

- Future Public Reporting
  - IRFs
  - LTACHs
  - Hospices
  - Psychiatric Hospitals



# Value-based Purchasing (VBP)

- Current VBP programs
  - Hospital Value-Based Purchasing (VBP) Program
  - Dialysis Facility End Stage Renal Disease (ESRD) Quality Incentive Program (QIP)
- Testing VBP
  - Home Health Pay-for-Performance Demonstration
  - Nursing Home Value-based Purchasing Demonstration
- HHS Implementation plans for VBP programs
  - ASCs (submitted April 2011)
  - SNFs (due October 2011)
  - Home Health (due October 2011)

# VBP

- Future VBP programs
  - Physician value-based payment modifier (2015)
  - Psychiatric hospitals (pilot by 2016)
  - LTACHs (pilot by 2016)
  - IRFs (pilot by 2016)
  - Hospices (pilot by 2016)
  - Cancer hospitals (pilot by 2016)

# Hospital VBP

- Likely to serve as template for future VBP programs
- VBP incentive payments must be made to a hospital in fiscal years in which the hospital meets established performance standards
- Secretary to begin making value-based incentive payments to hospitals for discharges occurring on or after October 1, 2012
- Payments to be funded for FY 2013 through one percent reduction to FY 2013 base operating DRG payments for each discharge and reductions to be phased up to two percent in FY 2017 and subsequent years

# Hospital VBP

- Measure categories currently included in VBP:
  - AMI, HF, PN, surgical care, HAIs and HCAHPs
- Performance standards
  - CMS establishing performance standards for each measure designed to challenge hospitals to continually improve or maintain high levels of performance
  - Performance standards include levels for achievement and improvement
  - Hospitals must exceed Achievement Performance Standard (achievement threshold) to receive points for achievement or Improvement Performance Standard (the improvement threshold) for each proposed measure that reflects each specific hospital's performance on the measure during the baseline period
  - Benchmarks also established for purposes of performance measurement

# Hospital VBP

## ■ Scoring

- Achievement score - Hospital earns 0-10 points for achievement based on where performance for measure falls relative to the achievement threshold and the benchmark
- Improvement score - Hospital earns 0-9 points based on how much performance on measure during the performance period improves from performance during the baseline period
- Higher of achievement score or improvement score is used
- Measure scores then rolled up to score for domain
- Domain scores combined to calculate total performance score

# Hospital VBP

- Domain weighting for total performance score
  - FY 2013 – Process of care (70%) and HCAHPS (30%)
  - FY 2014 –Process of care (45%), HCAHPS (30%) and Outcomes (25%)
- Calculation of value-based incentive payment
  - Hospital's total performance score converted into value-based incentive payment
  - Hospital can earn more than it pays in
- Hospital performance to be publically reported on Hospital Compare

# ESRD QIP

- Dialysis facilities required to meet or exceed quality performance standards in order to receive full Medicare payment
- Payments to be reduced by up to 2 percent for failure to meet performance standards
- Payment adjustments based on performance two years earlier so payment adjustments in 2014 based on performance in 2012
- Measures for 2014 payments include three clinical measures and three reported measures
- Dialysis facilities required to post in prominent location CMS certificate that displays total performance score and individual score on each quality measure

# Physician Value-based Payment Modifier

- First Stage: Physician feedback
  - Physician Quality and Resource Use Reports (QRURs) to be shared confidentially with individual physicians and group practices
  - QRURs to provide comparison of physician performance (resource use and quality of care) with peers
- Second Stage: Value-based payment modifier
  - Physician Fee Schedule payments to be adjusted based on physician performance in resource use and quality
  - Starts with limited group of physicians in 2015 and applied to all physicians in 2017



# ACA Payment Policies Related to Quality of Care Overview

- Hospital Readmissions Reduction Program
- Preventable Conditions

# Hospital Readmissions Reduction Program

- Applicable hospitals with excess readmissions for applicable conditions will have base operating MS-DRG payments reduced by adjustment factor
- Maximum reductions to increase from 1 percent in 2013 to 3 percent in 2015 and beyond
- Starting in 2013 with 3 conditions (AMI, HF and PN) and expanding to 7 conditions in FY 2015
- Implementation
  - Readmissions Reduction Program effective for discharges on or after October 1, 2012 (FY 2013)
  - FY 2012 Inpatient Prospective Payment System (IPPS) Final Rule addressed performance measurement aspects
  - FY 2013 IPPS to address issues related to the adjustment factor

# Preventable Conditions

- Current Medicare payment policy:
  - HACs
    - Hospitals required to report primary and secondary diagnoses present on admission when submitting claims on or after October 1, 2007
    - Since 2008, hospitals do not receive additional Medicare payments for complications acquired during inpatient stay for certain hospital acquired conditions (HACs)
    - Currently 10 HACs (e.g., falls, pressure ulcers, air embolism)
  - 2009 NCDs (wrong site, wrong procedure, wrong patient)
- ACA Section 3008
  - Starting in 2015, Medicare required to reduce payments by 1 percent for hospitals in top quartile of national, risk-adjusted HAC rates
  - Confidential reports on HAC to be shared with individual hospitals starting in 2015
  - Hospital-specific information on HACs to be publically reported on Hospital Compare
  - Secretary to study and issue report by January 2012 on expansion of ACA policy to other settings

# Preventable Conditions

- Medicaid
  - State Medicaid plans prohibited from making payments for “provider preventable conditions” (PPCs)
  - Two categories of PPCs:
    - Healthcare –acquired conditions apply to inpatient hospital setting and overlap with Medicare HAC conditions
    - Other provider preventable conditions (OPPSs) are additional conditions and apply to inpatient and outpatient settings beyond hospitals
  - Effective July 1, 2011, but states can implement by July 1, 2012

# Delivery Systems Reform Overview

- Bundling
- Accountable Care Organizations

# Bundling

- Combining payment for physician, hospital and other provider services into a single bundled payment for services provided to patient during episode of care
- ACA-related bundling initiatives
  - CMMI Bundled Payments for Care Improvement Initiative
  - National Pilot Program on Payment Bundling (ACA Section 3023)

# CMMI Bundled Payments for Care Improvement Initiative

- Two bundling approaches to be tested
  - Retrospective – Usual FFS payments made and then reconciliation of total payment for episode with predetermined target price
  - Prospective – Negotiated single lump sum payment made instead of FFS payments
- Proposals requested for four models
  - Model 1 – Acute care hospital stay only (Retrospective)
  - Model 2 – Acute care hospital stay plus PAC (Retrospective)
  - Model 3 – PAC only (Retrospective)
  - Model 4 - Acute care hospital stay only (Prospective)

# CMMI Bundled Payments for Care Improvement Initiative

## ■ Quality Requirements

- Awardees required to comply with CMS requests for monitoring and evaluation:
  - Providing data
  - Allowing access for site visits
  - Participating in surveys and interviews

## ● Quality Measure Reporting

- Model 1 awardees must report all Hospital IQR measures and must propose additional quality measures
- Model 2-4 awardees must propose quality measures



# CMMI Bundled Payments for Care Improvement Initiative

- Types of Quality Measures to Be Reported
  - Quality and efficiency measures (e.g., functional status improvement, complications, mortality and readmission rates)
  - Patient experience of care
- Participation in other Medicare quality reporting initiatives
  - Awardees required to receive full payment updates in the past for reporting IQR and OQR quality measures
  - Not only will continued participation be required, but maintaining or improving performance on IQR, OQR and PQRS measures expected
- Applications for Model 2-4 due April 30, 2012 (must have submitted letter of intent)

# National Pilot Program on Payment Bundling

- Who can participate
  - Entity comprised of providers and suppliers including: hospital, physician group, SNF and HHA
  - Secretary must develop participation requirements to ensure applicable beneficiaries have adequate choice of providers and suppliers under the pilot
- What is an episode of care
  - Period of time that includes three days prior to admission to hospital for applicable condition through 30 days post discharge
  - Secretary has authority to define period of time differently
- Quality reporting requirements
  - Entity required to report quality measures (process, outcome and structure) related to care provided during episode determined by Secretary
- To be implemented by January 1, 2013

# Accountable Care Organizations

- Accountable Care Organization (ACO) is organization of health care providers that agrees to be accountable for the quality, cost, and overall care of Medicare beneficiaries who are who are assigned to it.
- Goals:
  - Promote accountability for a fee-for-service patient population
  - Coordinate items and services under Medicare Parts A and B
  - Encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery

# Medicare Shared Savings Program

- ACA Sec. 3022 requires Secretary to establish the Medicare Shared Savings Program by Jan. 1, 2012
- Participating ACOs that meet quality performance standards and savings requirements are eligible to share savings
- Quality Measures
  - Before an ACO can share in savings, it must demonstrate meeting quality performance standards
  - ACOs must report 33 quality measures in 4 key domains to serve as the basis for assessing, benchmarking, and rewarding ACO quality performance: (1) Patient/Caregiver Experience; (2) Care Coordination/Patient Safety; (3) Preventive Health; and (4) At-Risk Population

# Medicare Shared Savings Program

- Quality Performance Standards
  - In Year 1, ACO will be considered to meet the ACO Quality Performance Standard if it has reported on all applicable quality measures
  - In Year 2, ACO will have to report on 8 quality measures and achieve performance at a minimum attainment level for 25 measures
  - In Year 3, ACO will have to report on 1 quality measure and achieve performance at a minimum attainment level for 32 measures
- CMS will monitor and assess ACO performance using a range of methods such as analysis of financial and quality data and beneficiary or provider complaints and audits. Monitoring will include:
  - Compliance with quality performance standards: if minimum attainment levels are not met for one or more domains, CMS to warn the ACO and may subject it to a corrective action plan and to re-evaluate the following year
  - Continued underperformance will result in termination.

# Questions?

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# Practical Steps to Prepare for the Supreme Court's Decision: What if the ACA Disappears?

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*ALSTON + BIRD LLP*  
*Health Care Forum 2012*  
*May 2, 2012*  
*Paula M. Stannard*

# Overview

- The Issues Before the Supreme Court
- The Potential Outcomes
- The Implications of These Outcomes
- Practical Steps to Prepare for the Supreme Court's Decision



# The Issues before the Supreme Court

- Anti-Injunction Act
- Individual Mandate
- Severability
- Medicaid Expansion

# The Issues before the Supreme Court

- Anti-Injunction Act
  - Does the Supreme Court have the authority, given the Anti-Injunction Act (AIA), to consider the constitutionality of the “individual mandate,” given that penalties for non-compliance do not take effect and would not be paid until 2015?
  - The AIA, enacted in 1868, provides that “no suit for the purpose of restraining the assessment or collection of any tax shall be maintained in any court by any person.”
  - A taxpayer generally must pay a tax before being able to challenge it.
  - If applicable, AIA may prohibit the Court from ruling on the constitutionality of the individual mandate until 2015 or later.
  - The Court could, as it has in “extraordinary cases” in the past, recognize the government’s waiver of the AIA’s application, or hold that an exception applies, and proceed.
  - Unlikely that the Court will hold that AIA bars it from deciding case now.

# The Issues before the Supreme Court

- The Individual Mandate
  - Does Congress have the authority under the Commerce Clause and the Necessary and Proper Clause to require virtually all individuals to have minimum essential coverage – to purchase health insurance with the essential health benefits package?
  - There is a presumption that the statutes Congress passes are constitutional.
    - This presumption can be overcome. The more novel the exercise of Congressional authority, the less likely it is that courts will give much weight to the presumption. The lack of federal statutes imposing a similar obligation may suggest an assumed Congressional lack of power.
  - Commerce Clause power encompasses, among other things, the power to regulate activities having a substantial relation to interstate commerce (i.e., those activities that substantially affect interstate commerce).
  - Factors:
    - Whether the activity being regulated is economic in nature.
    - Whether the statute contained jurisdictionally limiting language (to ensure a connection between that which is regulated and interstate commerce).
    - Whether Congress made formal findings on the effect of the activity on interstate commerce.
    - Whether the connection between the activity and its effect on interstate commerce was close or attenuated.

# The Issues before the Supreme Court

- The Individual Mandate
  - Additional Considerations:
    - Whether “activity” is required under the Commerce Clause.
    - If so, whether the failure to purchase health insurance (or the decision not to purchase health insurance) is “activity” and whether such activity is “economic.”
    - Whether there is a limiting principle with respect to the exercise of Congress’s Commerce Clause power, that would permit Congress to exercise power under the Commerce Clause in this case, but that would not make the Commerce Clause power unlimited.
  - Congress’s actions must accommodate the Constitution’s federalist structure and preserve a distinction between what is national and what is local.
  - Commerce Clause cannot be interpreted in a way that would grant Congress a general police power.

# The Issues before the Supreme Court

- The Individual Mandate:
  - Necessary and Proper Clause:
    - Not an independent source of federal power, but a provision that empowers Congress to exercise a means which may not be within its enumerated powers to accomplish a purpose (end) within its enumerated powers.
    - These means must be appropriate, plainly adapted, and not prohibited or inconsistent with the letter and spirit of the Constitution.
  - Factors:
    - The breadth of the Necessary and Proper Clause.
    - Whether there is a history of federal involvement in the particular area and whether the legislation is a modest addition to that area.
    - Whether there are sound reasons for the legislation in light of the government's interest.
    - Whether the legislation accommodates state interests.
    - Whether the legislation is narrow in scope.
  - The standard of review, under the Commerce Clause and the Necessary and Proper Clause, appears to be an “exacting” rational basis test.

# The Issues before the Supreme Court

- Severability
  - If the Supreme Court finds the individual mandate unconstitutional, can the rest of the ACA remain, or are some (or all) of its other provisions so entwined with the individual mandate that they cannot be severed and the entire ACA must fall?
  - There is a presumption in favor of severability.
  - Focus of the analysis seems to be on Congressional intent. Tests:
    - *Functional Independence*. Can the other provisions function independently of the unconstitutional provision? Or are some or all of the other provisions so intertwined with the unconstitutional provision that they cannot function as intended by Congress without the unconstitutional provision?
    - *Structure and Purpose*. Would Congress have passed some or all of the remaining provisions had it known that the provision was unconstitutional?
    - *Legislative Bargain*. Would Congress have enacted the statute (or parts of it) in the absence of the unconstitutional provision, or is the unconstitutional provision the heart of the legislation and the statute would not have been adopted in its absence?
    - *Statutory Goal*. Can Congressional intent be fulfilled in large measure without the unconstitutional provision?

# The Issues before the Supreme Court

## ■ Medicaid Expansion

- Are the conditions placed upon the States' receipt of Medicaid dollars to cover more Americans unconstitutionally coercive? Or do the States have a choice?
- Constitutional principles:
  - Congress cannot commandeer States' legislative processes. The federal government cannot compel States to implement federal regulatory programs by legislative or executive action.
  - Congress cannot use the Spending Power to coerce States to do the same.
- The ACA expands Medicaid eligibility to residents earning up to 133% of the FPL.
- If the Court finds the strings attached to Medicaid expansion to be unconstitutional, it would have to determine whether the expansion provision is severable from the remainder of the law.
- If the Court finds that the Medicaid expansion is constitutional, Medicaid expansion would proceed unless the Court strikes down the individual mandate and finds that the mandate is not severable from the remainder of the law (or at least not severable from the Medicaid expansion).

# Potential Outcomes

- The Anti-Injunction Act applies.
- The Supreme Court upholds the ACA in its entirety.
- The Supreme Court finds the Individual Mandate unconstitutional and
  - Strikes the ACA in its entirety.
  - Strikes only the Individual Mandate.
  - Strikes the Individual Mandate and the insurance reforms explicitly associated with the Individual Mandate in the ACA.
  - Strikes the Individual Mandate, the insurance market reforms, and other provisions related to the individual mandate, the tax credits, and funding for it . . . .
  - Strikes the Individual Mandate, stays implementation of the ACA, and remands for hearing on severability (or appoints a Special Master to report to the Court on severability).
- The Supreme Court could stay its ruling for a period of time.



## Implications: The ACA is upheld.

- Still “law of the land.”
- Implementation continues.
- Some States will move forward.
- Efforts to repeal and replace – and the 2012 Elections.
- Some increased stability for stakeholders implementing aspects of the law. For example:
  - Delivery system reforms.
  - ACOs.
- Not an end to litigation over ACA provisions. For example:
  - Independent Payment Advisory Board.
  - Physician-owned Hospitals.
  - Contraceptive Mandate on Health Plans, Health Insurers, and TPAs.
  - Health Insurance Market Regulations.

# Implications: The ACA is struck in its entirety.

- Two years after passage. Millions of dollars spent. Creation of CMS Center for Medicare & Medicaid Innovation and Federal Coordinated Health Care Office. Grants and contracts issued. Medicare and Medicaid reimbursement rates adjusted. Health insurance policies changed. What happens?
- Prospectively:
  - Government can no longer take action on the basis of ACA provisions.
  - Considerations:
    - Does HHS have independent legal authority – apart from the ACA – to undertake the actions authorized by the ACA?
    - If so, does HHS have appropriated funds to continue implementation of the program or activity?
- Completed Activities:
  - What does an inseverability decision mean?
  - Would repayment of monies paid out be required? Would CMS be required to reimburse reduced payments?

# Implications: The ACA is struck in its entirety.

- Creation of CMS Centers and Offices
  - Administrative authority to create new offices and centers and reorganize existing offices and centers.
- New Programs
  - Medicare and Medicaid Programs
    - Can the program be authorized using CMS's demonstration authority or its waiver authority?
    - Examples:
      - ACOs.
      - Duals demonstrations.
      - State family planning services.
      - Money follows the person rebalancing.
      - PACE
      - Removal of barriers to home and community based services.
  - Public Health/Public Health Grant Programs
    - Community-based collaborative care grants.
    - Healthy aging, living well grant program.
    - School-based health care centers.

# Implications: The ACA is struck in its entirety.

## ■ Completed Activities:

- Can the situation be analogized to actions taken under a subsequently repealed statute?
- Was there valid statutory authority for the action when it was undertaken?
- Is it a contract or can it be analogized to a contract?
  - The government can be held to the benefit of bargains struck with private entities.
- Would the Supreme Court take a view similar to that announced in *Chicot County Drainage District v. Baxter State Bank*, 308 U.S. 371 (1940):

The courts below have proceeded on the theory that the Act of Congress, having been found to be unconstitutional, was not a law; that it was inoperative, conferring no rights and imposing no duties, and hence affording no basis for the challenged decree. . . . It is quite clear, however, that such broad statements as to the effect of a determination of unconstitutionality must be taken with qualifications. The actual existence of a statute, prior to such a determination, is an operative fact and may have consequences which cannot justly be ignored. The past cannot always be erased by a new judicial declaration. The effect of the subsequent ruling as to invalidity may have to be considered in various aspects, . . . . Questions of rights claimed to have become vested, of status, of prior determinations deemed to have finality and acted upon accordingly, of public policy in the light of the nature both of the statute and of its previous application, demand examination. . . . [I]t is manifest from numerous decisions that an all-inclusive statement of a principle of absolute retroactive invalidity cannot be justified.

# Implications: The ACA is struck in its entirety.

- Health Insurance Market Reforms:
  - Provisions already effective – and current health insurance policies and group health plan documents.
  - State Health Insurance Laws
    - What requirements do they impose?
    - Would any new provisions be affected by striking the ACA?
      - State requirements in place prior to the ACA.
      - State requirements adopted after the ACA, but not tied to the ACA.
      - State requirements adopted after the ACA and expressly tied to the ACA.
- ACA High Risk Pools
- Unrelated Statutes in the ACA
  - Indian Health Care Improvement Act Reauthorization
  - Biosimilars Approval Pathway
  - Elder Justice
  - Student Loan Program Takeover

# Implications: Only the Individual Mandate falls.

- Health Insurers
  - Individual mandate designed to prevent adverse selection from community rating, bar on pre-existing condition exclusions, guaranteed issuance, etc.
  - Experience of the States.
  - Potential claim that health insurance market regulations violate the Takings Clause by precluding health insurers from obtaining a reasonable rate of return.
- Hospitals
  - Reductions in Medicare and Medicaid Disproportionate Share Hospital (DSH) payments.
  - Reductions in market basket updates.

# Implications: Only the Individual Mandate falls.

- Taxes and Fees
  - Cadillac Health Plans
  - Health Insurance Tax
  - PhRMA Fees
  - Medical Device Fees
- Medicare Advantage Cuts

# Implications: The Individual Mandate falls with. . .

- “Related provisions” (guaranteed issuance, community rating)
  - Are the other ACA insurance market reforms sustainable without the Individual Mandate?
  - Can the Exchanges work?
- Title I (Insurance Provisions, Exchanges, Employer Mandate, etc.)
  - Can the Medicaid expansion provisions work without the Title I?
  - Tax and Fee provisions remain.
  - The “Other” MLR Provisions.



# Practical Steps to Prepare for the Supreme Court's Decision

- Consider the nature of your rights or obligations under the ACA
  - Is there other law – federal or state – that could provide independent authority?
  - Do you have a legal interest from a contract, grant, or other binding document?
  - Is there a contract, a grant, or other document associated with your interest that might address your rights or obligations – or provide termination provisions?
  - Are you subject to fees or taxes under the ACA?
- Are there programs that you would like to see continued (or conversely that you would like to see ended)?
  - Is there other authority under which such program could proceed?
  - Are there appropriated monies to carry out the program?

# Practical Steps to Prepare for the Supreme Court's Decision

- Consider if there is a need to educate Executive Agencies on
  - Continuing authority for favored programs.
  - How appropriated monies can be used for such programs.
  - Why continuing authority should not be exercised with respect to other programs.
- Consider if there is a need to educate Congress on
  - Need to act to remedy problems or inconsistencies that may be created by the ruling.
  - Need to appropriate monies to replace monies appropriated under ACA.
- Consider if there may be litigation options
  - Challenges to implementation of the ACA (if upheld), both statutory and constitutional.
  - Challenges to remaining ACA provisions.
  - Challenges to government attempts to withdraw vested contracts or grants.
  - Suits seeking reimbursement of payment reductions.

# Questions?

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