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# Whistleblower Law and the Health Care Industry

October 23, 2014

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# Agenda

1. The Latest Developments In False Claims Act Case Law
2. Application Of Sarbanes-Oxley Whistleblower Provisions To Non-profit Health Care Organizations
3. Developing An Effective Whistleblower Policy
4. Can Or Should Arbitration Be Used?
5. The Do's and Don'ts of Conducting Whistleblower Investigations

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# The False Claims Act: Its Past, Recent and Future History

The False Claims Act, 31 U.S.C. § 3729, authorizes the United States, or "relators" acting on behalf of the United States to recover monetary damages from parties who submit, or cause others to submit, fraudulent claims for payment by the federal government.

Since 1986, a majority of FCA cases have been brought by *qui tam* relators, and a large majority of the settlements and judgments obtained have come from health care providers.

# The FCA Prohibits a Range of Activities

- Knowing presentation of a false or fraudulent claim to the federal government (31 U.S.C. § 3729(a)(1))
- Knowing use or creation of a false record or statement to get such a claim paid by the government ((a)(2))
- Conspiring to defraud the federal government to get a false or fraudulent claim paid ((a)(3))
- Intentional failure to return all federal government money or property ((a)(4)
- Intentional making and issuance of a receipt for more than what the federal government actually received ((a)(5));
- Knowing purchase or receipt of property from an unauthorized federal official ((a)(6)
- Knowing creation or use of a false record or statement to decrease a monetary obligation to the government ((a)(7)).

# The Consequences of Losing an FCA Case Are Great

- Treble damages assessed on a per claim basis
- Civil penalties of up to $11,000 per claim.
- Program suspension, debarment and exclusion for entities, officers, directors and employees and related parties.

# Recent False Claims Act Amendments

The FCA was amended in 2009 by The Fraud Enforcement and Recovery Act of 2009 ("FERA") and in 2010 by the Patient Protection and Affordable Care Act ("ACA").

These are the most significant amendments to the FCA since the *qui tam* amendments of 1986, and were intended to reverse certain adverse court precedents, give the government greater power and increase *qui tam* relator resistance to dismissal.

# Elimination of Presentment Requirement

FERA expanded FCA liability by eliminating the "presentment" requirement, overruling the Supreme Court's decision in *Allison Engine Co. v. United States ex rel. Sanders*, 128 S. Ct. 2123 (2008)).

# Expansion of “Claim”

FERA expanded the term “claim” under the FCA to include “money or property spent or used on the Government’s behalf or to advance a government program or interest” and where the government provides or reimburses for the claim.

# Public Disclosure and Original Source Bars Substantially Lowered

The ACA modified the FCA to allow the federal government to have the final word on whether a court may dismiss a case based on a public disclosure. 31 U.S.C. § 3730(e)(4)(A). A relator still may overcome the public disclosure bar if an "original source," and the definitional stricture has been eased. 31 U.S.C. § 3730(e)(4)(B).

# Health Care Overpayments to be Remitted in 60 Days

The ACA provides that Medicare and Medicaid overpayments must be reported and returned within 60 days of discovery or the date a corresponding cost report is due lest FCA liability ensue.

# Reverse False Claims Expanded

FERA extended liability to "knowingly and improperly avoid[ing] or decreas[ing] an obligation to pay or transmit money or property to the Government."

# Anti-Kickback Liability = FCA Liability  Criminal = Civil

The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) bans payment of anything of value improper in exchange for referring patients to receive certain services that are paid for by the government. Courts had been divided on whether kickbacks were violations of the FCA. The ACA removed all doubt by providing that claims submitted in violation of the Anti-Kickback law automatically constitute false claims for purposes of the FCA, and that "a person need not have actual knowledge … or specific intent to commit a violation" of the Anti-Kickback Statute.

# Fed. R. Civ. P. 9(b) – The Focal Point of a Split

Rule 9(b) provides that *"[i]n alleging fraud," a "party must state with particularity the circumstances constituting fraud."*

# 3rd Circuit Backs Lighter FCA Standard

- *Foglia v. Renal Ventures Management LLC,* No. 12-4050, 2014 U.S. App. LEXIS 10549 (3rd Cir. June 6, 2013):
- In June 2014, the Third Circuit revived a False Claims Act suit determining that whistleblowers don't have to provide specific examples of false claims to prevail over an early motion to dismiss their case.
- "While that conclusion does not itself commit us to the more nuanced standards favored by the First, Fifth and Ninth circuits, it is hard to reconcile the text of the FCA, which does not require that the exact content of the false claims in question be shown, with the 'representative samples' standard favored by the Fourth, Sixth, Eighth and Eleventh circuits," the decision said.

# 8th Cir. Also Takes Lenient View of Rule 9(b)

- In *United States ex rel. Thayer v. Planned Parenthood*, 765 F.3d 914 (8th Cir. 2014), the Eighth Circuit, departing from earlier precedent, held that an FCA whistleblower with first-hand knowledge of a company's billing or claims process need not provide specific examples of alleged fraudulent claims in order to survive the requirement that a fraud claim be pleaded with particularity.

# *Takeda* was *the* Case – or so we Thought

- *United States ex rel. Nathan v. Takeda Pharm. Co*., 707 F.3d 451 (4th Cir. 2013), cert. denied, 81 U.S.L.W. 3650 (U.S. Mar. 31, 2014):
  - involved the Fourth Circuit's application of a stringent 9(b) pleading standard that led to the dismissal of the case.
  - Many thought that the initial cert. denied was just a tentative ruling that the case was premature for Supreme Court resolution.
  - However, on October 6, 2014, SCOTUS again denied cert. in the First Circuit's version of the dispute. *United States ex rel. Ge v. Takeda Pharm. Co*., U.S., No. 13-1236, cert. denied 10/6/14 ).

# The Abiding Split in the Circuits

- While all circuits require facial fidelity to the 9(b) standard in FCA claims, the specific application has resulted in a circuit split.
  - The Fourth, Sixth, and Eleventh Circuits follow a stricter application of the standard, requiring not only the general details of the alleged fraud but also representative examples of the alleged fraudulent claims.
  - The First, Third, Fifth, and Ninth, and now the Eighth, Circuits allow a relaxed application of Rule 9(b), requiring only "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.

# Whistleblowers Almost Always Protected in the Supreme Court

- On March 4, 2014, in a 6-3 decision, the Supreme Court held in Lawson v. FMR, LLC that Section 806 of the Sarbanes-Oxley Act (SOX) protects employees of a public company's private contractors and subcontractors.
  - The Court determined that, to thwart another Enron-like debacle, outside professionals, even if not employees of the public company, should be protected by §806 because they have a responsibility to report fraud without fear of retaliation. The Court's statutory interpretation of §806 aligns with the current Department of Labor's (DOL) view that §806 also protects employees of many private companies.
  - The anti-retaliation provision of the FCA – the so called "(h)" claims –would receive similar treatment.

# Enforcement and Litigation Trends

- More criminal cases, especially against individuals, including assertion of Responsible Corporate Officer Doctrine.
- Easier and more-frequent exclusion of executives under relaxed OIG regulation
- More cases brought on quality of care and worthless services claims
- Retentions of overpayments are sitting ducks
- Privilege withering in advice of counsel cases and challenged in *Upjohn* type cases
- Counter to lowering standing, intent and claims by amendments are those courts strictly enforcing Rule 9.
- 8th Amendment challenges to limit the government to actual loss as base.
- Cases based on HIPAA and other cybersecurity – implied certification.
- ICD-10 will be the basis for FCA Upcoding Cases based on CPT and HCPCS code sets.

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# The Sarbanes-Oxley Act of 2002

- The Sarbanes-Oxley Act of 2002 (SOX) was enacted July 30, 2002 in response to Enron bankruptcy (among others)
  - Section 806 is the whistleblower protection provision, prohibiting adverse employment actions against whistleblowers (18 U.S.C. §1514A)
  - Unlike certain other whistleblower laws – including the False Claims Act – SOX does ***not*** include a monetary incentive to reward whistleblowers

# The Sarbanes-Oxley Act of 2002

- Section 806 applies to public companies:

  - No company with a class of securities registered under section 12 of the Securities Exchange Act of 1934 (15 U.S.C. 78l), or that is required to file reports under section 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78o(d)), or any officer, employee, contractor, subcontractor, or agent of such company, may discharge, demote, suspend, threaten, harass, or in any other manner discriminate against an employee in the terms and conditions of employment because of any lawful act done by the employee--

# The Sarbanes-Oxley Act of 2002

- Section 806 Protects external or internal report or complaint by employee that the employer has violated or is violating
  - "[S]ection 1341 [frauds and swindles],
  - 1343 [fraud by wire],
  - 1344 [bank fraud], or
  - 1348 [securities and commodities fraud],
  - any rule or regulation of the Securities and Exchange Commission,
  - or any provision of Federal law relating to fraud against shareholders."

# Dodd-Frank Act amended SOX

- With the passage of Dodd-Frank, SOX Is More Protective of Whistleblowers Than Ever:
  - No pre-dispute arbitration of whistleblower retaliation claims
  - SOX rights and remedies cannot be waived by agreement with employees
  - Statute of limitations increased from 90 to 180 days
  - Definition of “publicly traded company” covered by SOX is greatly expanded

# *Lawson v. FMR LLC* (134 S. Ct. 1158 March 4, 2014)

- First Supreme Court decision interpreting Section 806 of SOX
- Held that the SOX whistleblower protection provisions protect the employees of *private* companies that contract with public companies that are directly covered by the Act
- Opened up an enormous pool of potential whistleblower claimants
- Thus, Section 806 would apply to a non-profit if the non-profit is a contractor of a publicly-traded company

# How SOX Applies Directly to Non-Profits

- There are two aspects of SOX that are **directly** applicable to non-profits:
  - Retention of documents related to lawsuits
  - Strengthened whistleblower protection via *federal criminal statute*

# Falsifying Records is a Crime

- Section 802 of SOX makes it a crime to knowingly alter, destroy, mutilate, conceal, cover up, falsify or make a false entry in any record, document, or tangible object with the intent to impede, obstruct, or influence the investigation or proper administration of any matter within the jurisdiction of any federal department or agency or any case filed under the federal bankruptcy code.
  - Violators may be fined and/or imprisoned for up to 20 years

# Falsifying Records / Official Proceedings

- Section 1102 of SOX makes it a crime to "corruptly" alter, destroy, mutilate, or conceal a record, document or other object, or attempt to do so, with the intent to impair the object's integrity or availability for use in an "official proceeding."
  - "Corruptly" is not defined
  - Violators may be fined and/or imprisoned for up to 20 years
- Section 1102 of the Act also makes it a crime to otherwise obstruct, influence or impede "any official proceeding" or attempt to do so.
  - Violators may be fined and/or imprisoned for up to 20 years.
- Investigations by either the Internal Revenue Service or the Equal Opportunity Employment Commission, among others, would constitute "official proceedings"

# Whistleblower Protection

- Section 1107 (“Retaliation against informants”):
  - ***“Whoever knowingly, with the intent to retaliate, takes any action harmful to any person, including interference with the lawful employment or livelihood of any person, for providing to a law enforcement officer any truthful information relating to the commission or possible commission of any Federal offense, shall be fined under this title or imprisoned not more than 10 years, or both.’’***

# SOX Takeaways for Non-Profits

- Certain criminal provisions of SOX apply to non-profits
- The civil whistleblower protections do not apply directly to non-profits, but do apply to contractors of publicly-traded companies
- SOX does *not* mandate that non-profits implement a whistleblower policy and procedure
- Most commentators recommend that non-profits establish procedures in any event
  - Encourages individuals in the organization to come forward with a problem at an early stage
  - May minimize risk of liability under the criminal provisions
  - Promotes open communication for the benefit of the organization

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# SOX—UNQUESTIONED KEY GOAL
## Prevent Fraud, Fiscal and/or Other Serious Impropriety

- Result—corporations made compliance programs more robust
- SOX required internal reporting channels to facilitate employees blowing the whistle on corporate misconduct to their supervisors, 15 USC 578 j – 1 (m)(4)
- Companies established/expanded multi-channel internal reporting mechanisms, including, e.g.:
  - Hotlines
  - Board audit committee complaint procedures
  - Normal supervisory channels
  - Office of the General Counsel

# Purposes of Robust Internal Compliance Programs

- Stop fraud and fiscal or other impropriety as quickly as possible
- To be able swiftly to remediate any inappropriate activities and limit any damage to the company and shareholders
- To deter fraud and fiscal or other impropriety
- To protect staff, shareholders, customers
- To meet regulatory expectations and requirements
- Part of commitment to principles of good governance
- Factor under sentencing guidelines

# To Be or Not to Be Mandatory

- SOX caused reexamination of the question of whether to make internal reporting mandatory
- Many companies in health care believed mandatory reporting was necessary
  - To secure consistent and prompt reporting
  - To minimize harms through prompt action against fraud or fiscal or other impropriety or other wrongdoing
  - To provide maximum protections to customers, clients and shareholders
  - To be consistent with the SOX requirement that senior management sign and affirm the accuracy of the financials
    - Gave some greater level of confidence
- Number of companies began to require annual certifications by employees that they were not aware of or had reported any fraud, fiscal, or other consequential impropriety of which they were aware

# Protection of Whistleblowers from Retaliation as Key Component of Mandatory Reporting

- Recognition that employees will not use internal reporting if fear of retaliation
- SOX provided whistleblower protections in certain situations
- Health Care organizations generally assure non-retaliation for good faith whistleblowers
- Discipline of individuals who retaliate is essential

# Dodd-Frank and the Undermining of Corporate Compliance Programs

- The Whistleblower Bounty Program
- Whistleblowers who provide the SEC or CFTC with information that is:
  1. Original,
  2. Specific,
  3. Credible,
  4. Timely, and
  5. Leads to successful SEC enforcement action where SEC obtains $1 million or more in sanctions, can get:
     - Bounty of 10-30 percent of the amount collected by the government
- Bounty award of at least 10 percent is mandatory for whistleblowers meeting the statutory and regulatory requirements

# Mandatory Internal Reporting Rejected

- SEC claims mandatory internal reporting could discourage at least some potential whistleblowers
  - There are significant numbers of whistleblowers who would respond to the financial incentive offered by the whistleblower program by reporting **only** to the Commission, but who would not come forward **either** to the Commission or to the entity if the financial incentive were coupled with a mandatory internal reporting requirement. 17 C.F.R. pts. 240 and 249, Implementation of the Whistleblower Provisions of Section 21F of the Securities and Exchange Act of 1934 at 103 (emphasis in the original).
- Consistent with that position, SEC Whistleblower Rule 21F–17 provides:

  No person may take any action to impede an individual from communicating directly with the Commission staff about a possible securities law violation, including enforcing, or threatening to enforce, a confidentiality agreement (other than agreements dealing with information covered by [certain sections of the rules]) with respect to such communications.

17 C.F.R. § 240.21F-17(a).

# Mandatory Internal Reporting Rejected (cont'd)

- Taken together with the Bounty Program—affirmative incentive for whistleblower to bypass internal corporate compliance program
  - Only SEC/CFTC response is that initial internal reporting is one of many factors that can positively influence the amount of a bounty award

# Mandatory Internal Reporting Rejected (cont'd)

- Similarly, the CFTC final whistleblower rules rejected mandatory initial internal reporting
  - The Commission declines to mandate that whistleblowers report potential violations internally either before or concurrent to reporting to the Commission. The Commission believes that to require internal reporting could raise the risk of retaliation, and have a chilling effect on whistleblowers who are inclined to come forward and bring information to the attention of the Commission. For these same reasons, the Commission has decided not to deem lack of cooperation with an internal investigation a basis to render a person ineligible for an award (footnote omitted) (emphasis added).

  76 Fed. Reg. at 53194 (Aug. 25, 2011).

- Similarly, in the background and summary of the Whistleblower Rules, the CFTC stated:

  > Upon consideration of the comments, the Commission has determined that it is inappropriate to require whistleblowers to report violations internally to be eligible for an award.

  Id. at 53173.

# What's a Health Care Organization to Do? (cont'd)

- Communicate with the complainant about the process and the results as much as possible under the particular circumstances
- Have an annual execution of the Code of Conduct or Code of Ethics and an explicit affirmation (if true) by every employee that they are not aware of any fraud or fiscal or other impropriety and they are aware of the company's internal reporting systems

# What's a Health Care Organization to Do?

- Make corporate compliance an unquestioned part of the basic fiber of the organization and inculcate the ethical dimension in all aspects of the organization's activities
- Show the commitment to corporate compliance of the entire C-suite
- Provide incentives for employees to report internally
- Assure non-retaliation protection is well known and stringently enforced
- Assure complaints/disclosures made are promptly investigated and appropriate actions are taken

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# Mandatory Arbitration of Employee Claims

- Many employers have mandatory arbitration to resolve all employee claims, including whistleblower retaliation claims
- Why?
  - Generally less costly than court litigation
  - Generally faster
  - Less public
  - To limit damages and avoid runaway juries
  - Consistent with the internal handling of matters

# The Compounded Evil—The Banning of Mandatory Pre-Dispute Arbitration Clauses for Dodd-Frank Whistleblower Claims

- Section 748 of Dodd-Frank and Section 23 of CEA authorized Whistleblower Rules of the SEC and CFTC
- They have chosen to bar mandatory arbitration even as the Supreme Court continues to endorse arbitration for resolutions of employment and other disputes
  - CFTC regs provide, 17 C.F.R. § 165.19:

    > The rights and remedies provided for in this Part 165 of the Commission's regulations may not be waived by an agreement, policy, form, or condition of employment, including by a pre-dispute arbitration agreement. No pre-dispute arbitration agreement shall be valid or enforceable if the agreement requires arbitration of a dispute arising under this Part (emphasis added).
- SEC is to the same effect

# Carving Out Whistleblower Claims From Arbitration

- Thus, for covered employers, consider modifying any mandatory arbitration programs to exclude whistleblower claims that may fall under the SEC Whistleblower Regulations

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# Understanding Context: Profile of a Whistleblower

- Not your average complainant
  - Invoked corporate or external code
  - Has internal, non-public information
  - Has access to controls and processes
  - Participates in investigation or proceeding
  - Me issues v. Us issues

- Tension between theory and reality
  - The altruistic whistleblower
  - The whistleblower with an agenda
    - Endangered employee
    - *Qui tam* opportunist

# Understanding Context: Profile of a Whistleblower Complaint

- Likely to receive high-level attention
- Likely to receive public attention
- Likely to receive media attention
- Likely to prompt employee, client/customer and vendor inquiries
- Likely to require immediate attention, irrespective of remedial procedure invoked
- Good defense may be secondary in significance and immediacy to reaction from board, investors, business community, media, and public

# What Makes Whistleblowing Investigations Unique

- Two distinct considerations:
  - A report of a compliance breach
  - The claimed retaliation against a whistleblower

# Context of the Investigation

- Context supplies reasons that investigation should not be formulaic:
  - Identity of complainant
  - Source of complaint
  - Individuals and entities identified or implicated in complaint
  - Subject matter of complaint

# Objective of Investigation

- Factual record
- Investigative report addressing particular inquiry or legal considerations
- Basis for decision making
- Defense in anticipated proceeding

# Selection of Investigator

- Relationship to complainant
- Relationship to persons named by complainant
- Relationship to decision makers
- Ability to assert privilege against disclosure
- Prospect of becoming a witness:
  - Investigative notes
    - Attorney impressions
    - Impressions of others
  - Notes of witness interviews
    - Attorney impressions
    - Impressions of others
  - Investigative reports

# Selection of Decision Maker

- Independence – status relative to:
  - Distance from complainant
  - Distance from substance of complaint
  - Distance from investigation
- Role as potential witness

# Litigation Considerations

- Affirmative use of investigative report and contents
- Waiver of privilege
- Plaintiff's discovery
- Summary judgment—uncontested material facts
- Creation of witnesses who are not investigators or decision-makers
  - Downstream information management
  - Upstream information management

# Wrapping It Up

- Control assignment of roles
  - Avoid self-selection
  - Avoid default
  - Avoid unintended consequences
- Control communications
  - Recipients
  - Timing

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**OIG Warns Pharmaceutical Manufacturers of Improper Part D Beneficiary Coupon Use**

by Constance Wilkinson, Alan Arville, and Benjamin Zegarelli

October 2014

On September 19, 2014, Inspector General ("OIG") safeguards to prevent M coupons may not be comp 30 pharmaceutical compa and the pharmacy claims study found that these s written disclaimers and w pharmacy, and (2) while manufacturers use inaccu

Simultaneously with the is stating that manufacture programs do not induce f drugs over generics.[2] The identified deficiencies in

**Whistleblowers Rewarded Again by SEC and the Judiciary**

September 10, 2014

By Stuart M. Gerson; Frank C. Morris, Jr.; and Meghan F. Chapman*

On August 29, 2014, two whistleblower developments of particular interest to health care and life science entities emerged from the Securities and Exchange Commission respectively. The SEC, through its 0 to a compliance professional who that led to an enforcement action ts the first time that the agency has a compliance professional.

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**Massachusetts Now Requires Employers to Provide Domestic Violence Leave**

September 18, 2014

By Barry A. Guryan and Kate B. Rhodes

Massachusetts has enacted a law requiring employers with 50 or more employees to grant employees "domestic violence leave." The law, entitled "An Act [R]elative to [D]omestic [V]iolence," was approved by Governor Deval Patrick on August 8, 2014, and took effect immediately.

Under this new law, employers with 50 or more employees must provide employees with up to 15 days of paid or unpaid leave in any 12-month period if:

- the employee, or a family member of the employee, is a victim of "abusive behavior";
- the employee is not the perpetrator of the abusive behavior against the employee's abused family member; and
- the employee is using the leave from work to do any of the following:
  - seek or obtain medical attention, counseling, victim services, or legal assistance;

e July 2014 issue of *Take 5*, "Five Labor and Employment Issues Faced by Health re Employers," was written by **Michael F. McGahan,** a Member of the Firm, and sociates **D. Martin Stanberry** and **Daniel J. Green.**

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CLIENT ALERT

**September 2014 Immigration Alert**

Sixth Circuit Expands the Liability of Health Care Employers for Sponsorship Costs

USCIS Expands H-1B Eligibility for Nurses

Obama Administration Warns ACA Sign-Ups to Provide Proof of Legal Status

California Supreme Court Expands Rights of Immigrants Working in that State

OSC Issues Technical Assistance Regarding Employer's Receipt of Excess Documentation During the Form I-9 Process

OSC Settles Immigration-Related Discrimination Claims Against Staffing Agency

Colorado Employers Must Use New Affirmation Form Starting October 1, 2014

Silicon Valley Man Receives 10-Month Sentence for H-1B Fraud

DOS Issues October 2014 Visa Bulletin

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**I. Sixth Circuit Expands the Liability of Health Care Employers for Sponsorship Costs**

On August 20, 2014, the U.S. Court of Appeals for the Sixth Circuit issued its decision in *Kutty v. U.S. Department of Labor*, No. 11-6120 (6th Cir. 2014) ("*Kutty*"). In *Kutty*, several foreign physicians sued the

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# Q&A

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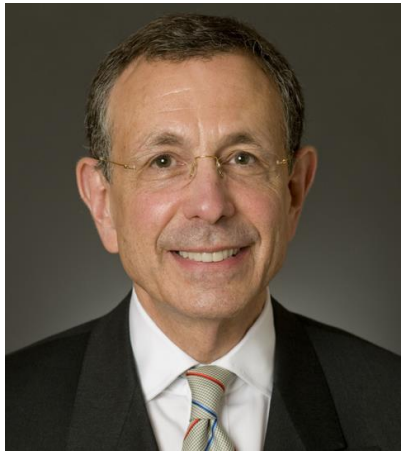

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