Antitrust Law Issues for Health Care Providers

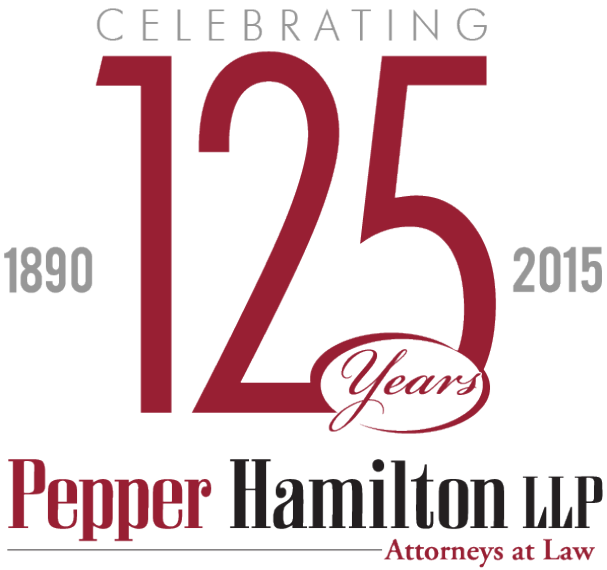
Presenters

Jan P. Levine

Robin P. Sumner

Moderator

Mark A. Kadzielski



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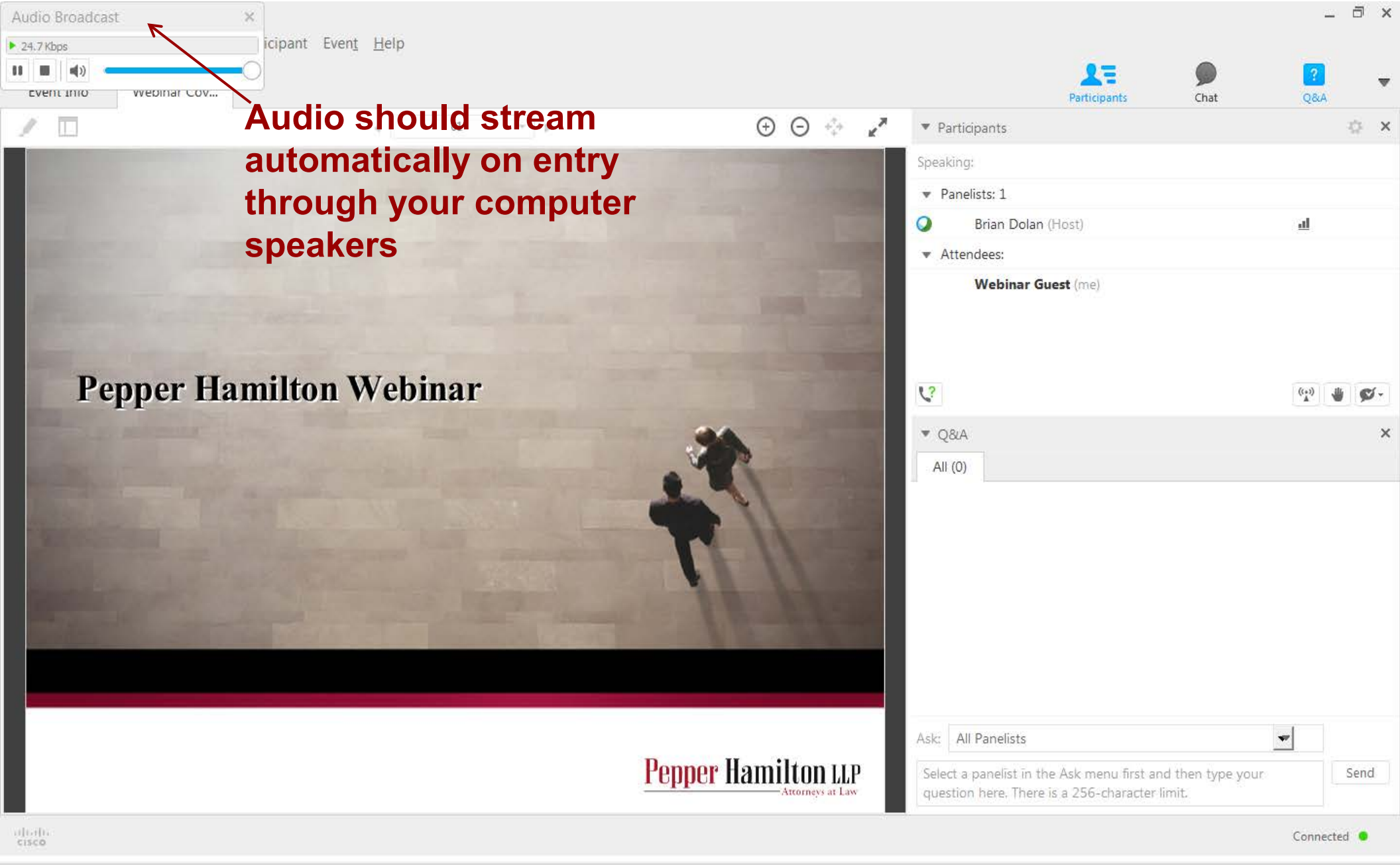
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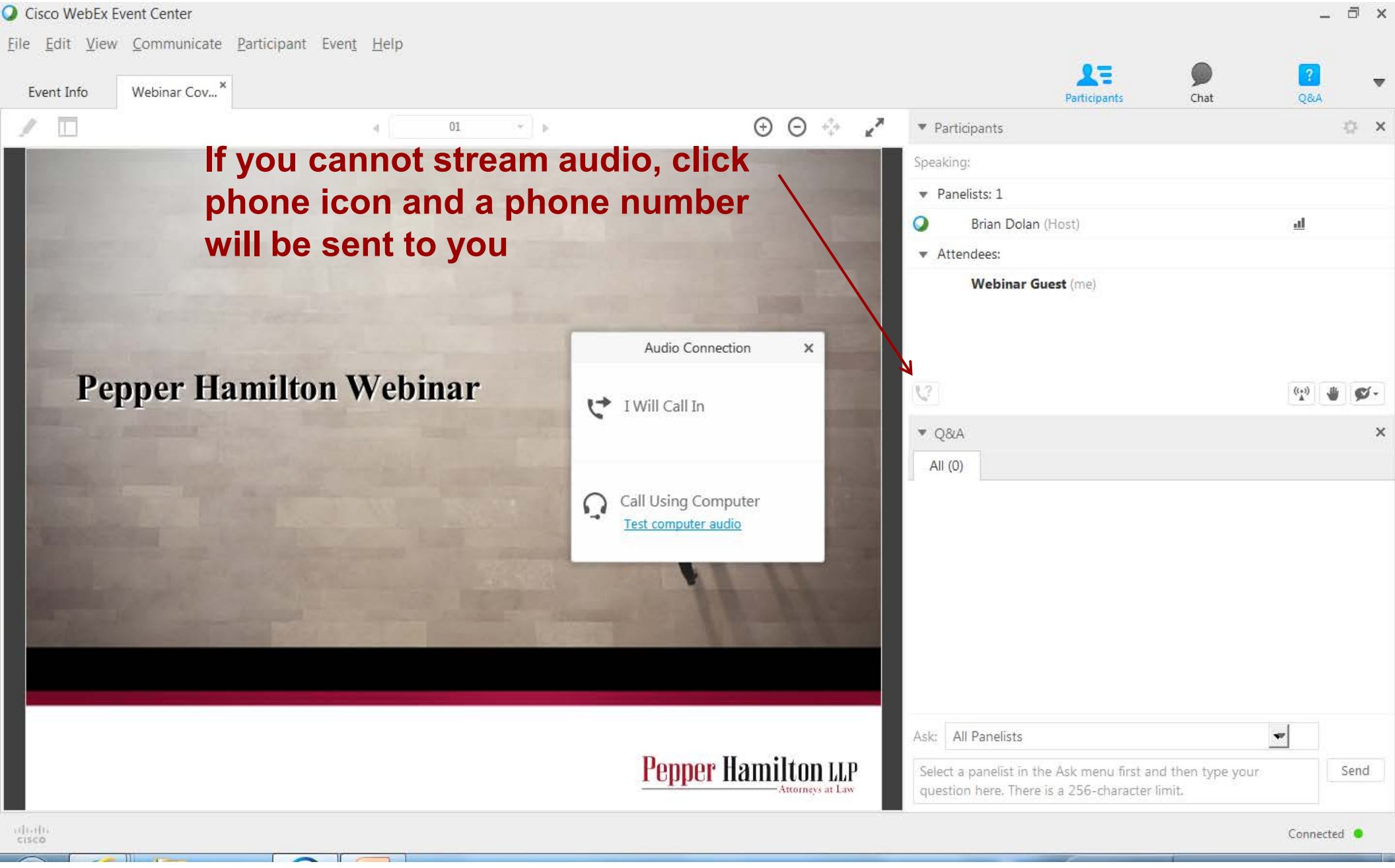
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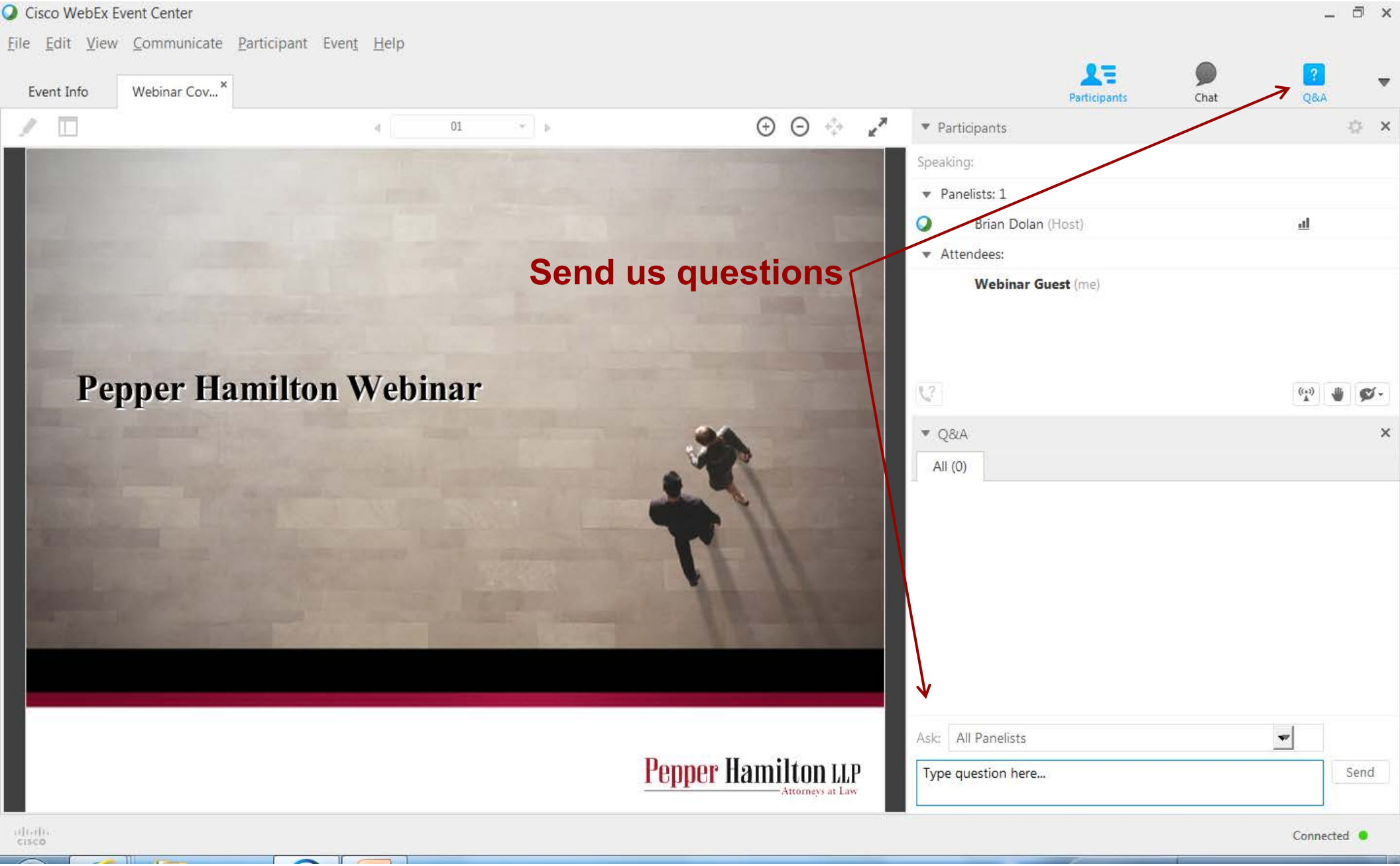
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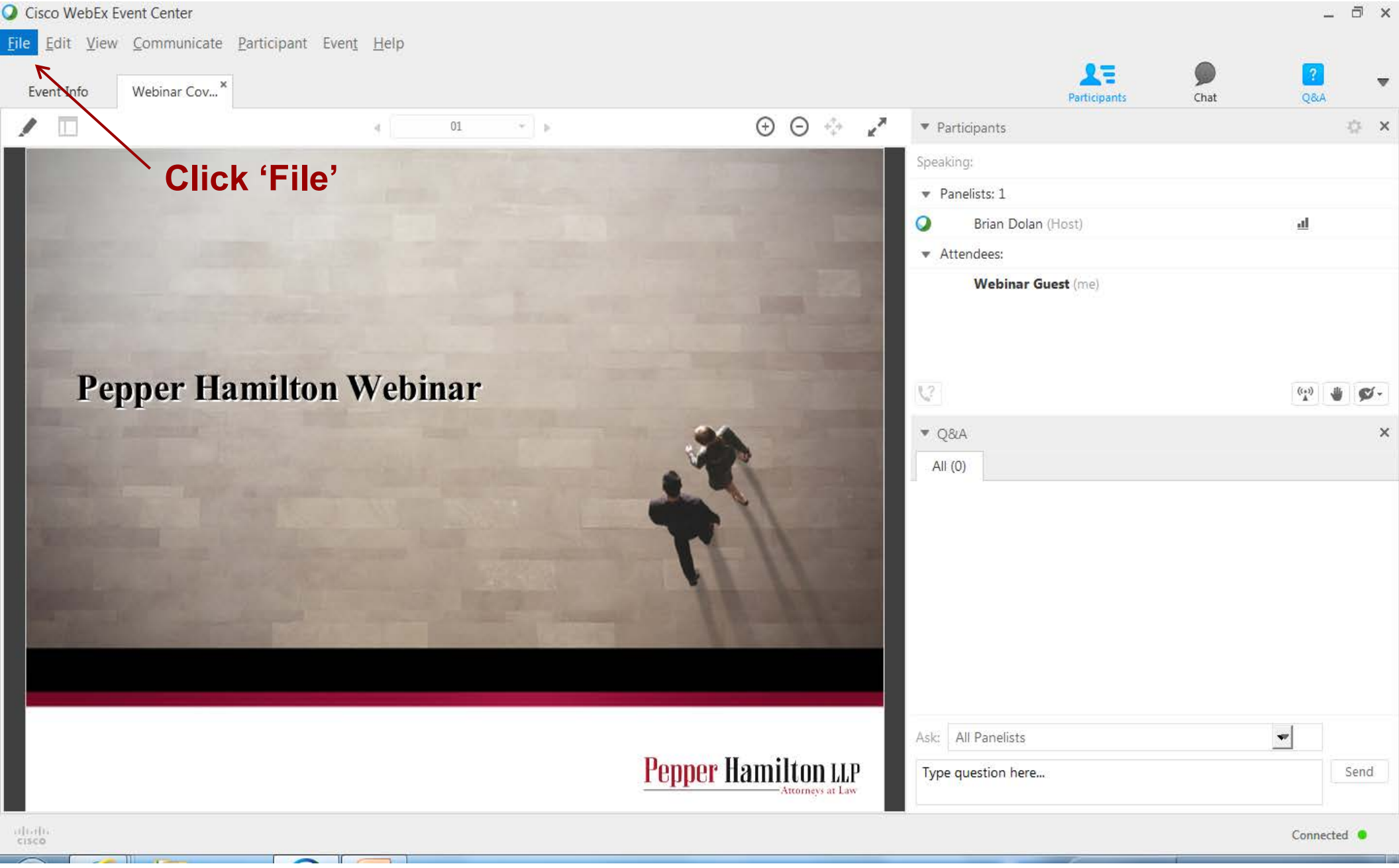

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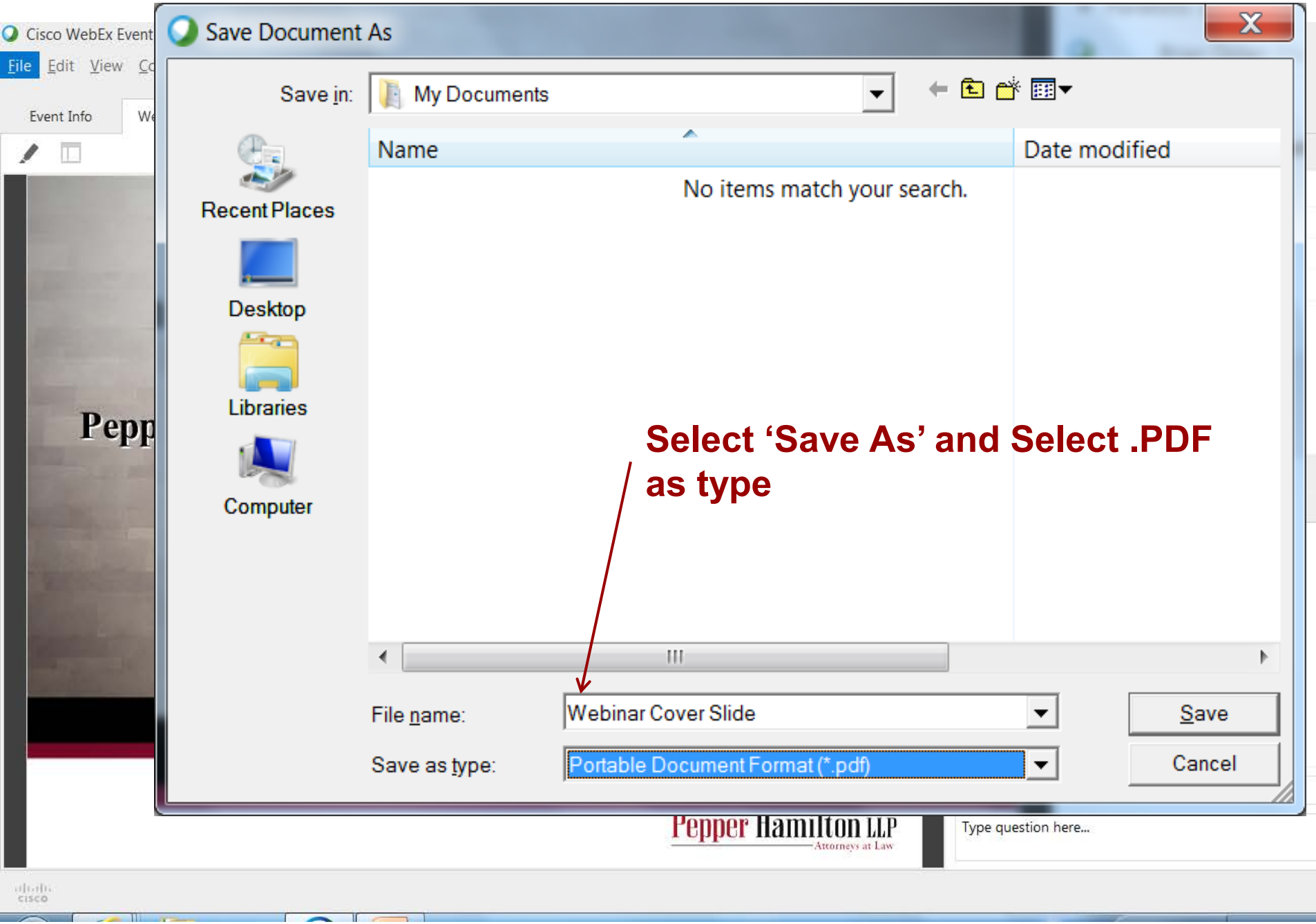

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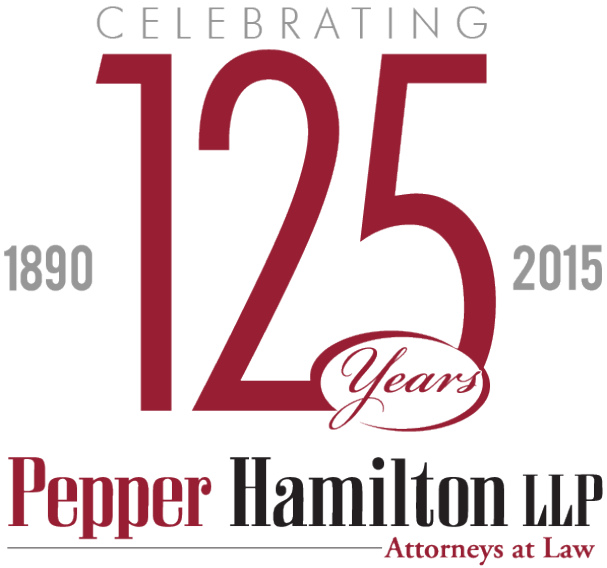

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Mark A. Kadzielski

Partner and National Chair of Health Care Services Practice

- Represents hospitals, medical staffs, managed care enterprises, and institutional and individual health care providers throughout the United States.
- Work includes government regulatory investigations, contracting issues, credentialing, peer review, licensing, medical staff bylaws, joint commission accreditation and Medicare certification.
- Has prepared more than 200 sets of medical staff bylaws and has handled numerous peer review hearings and appeals, including litigation in many courts.

Jan P. Levine

Partner and Co-Chair of Commercial Litigation Practice Group

- Practice focuses on health care litigation, data breach, antitrust/unfair trade practices, and directors' and officers' liability.
- Completed the American Health Lawyers Association's arbitration and advanced mediation training and the International Institute for Conflict Prevention & Resolution's mediation training, and is a graduate from Temple University's Academy of Advocacy.

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Pepper Hamilton LLP
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Robin P. Sumner

Partner, Commercial Litigation Practice Group

- Practice focuses on antitrust/competition law, securities law and complex civil litigation, including class actions and multi-district litigation.
- Significant experience litigating a variety of cases in the health care industry, including cases alleging violations of antitrust laws and the False Claims Act.

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Pepper Hamilton LLP
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Jan P. Levine

FTC's State Action Crusade
A Broader Perspective on Phoebe and North Carolina Dental

Overview of the State Action Doctrine

- The State Action Doctrine balances federal and state interests
  - Provides antitrust immunity to the federal antitrust laws for actions by "the state" and for those that act pursuant to state authority ("nonsovereign actors")
  - The antitrust immunity extends to nonsovereign actors, only if:
    - The state **"clearly articulated and affirmatively expressed" a "state policy to displace competition"**
      - In other words, the state must specifically mandate that it intends to displace the antitrust laws
    - The **state actively supervises** the conduct

FTC Victories

- FTC has won two recent victories that narrow the parameter of the State Action Doctrine.
- Both cases arise in the health care context.
  - Prong 1 - "Clearly Articulated" standard: *FTC v. Phoebe Putney Health Sys*., 133 S. Ct. 1003 (2013) (hospital merger case)
  - Prong 2 – "Active Supervision" standard: *N.C. State Bd. of Dental Exam'rs v. FTC*, 135 S. Ct. 1101 (2015) (dental licensing board case)

The State Action Task Force

- In 2001, FTC Chairman Tim Muris convened the State Action Task force. Its initial head was Ted Cruz, then-Director of the Office of Policy Planning.
- The task force was concerned that lax application of the two prongs of the state action test endangered national competition goals.
- The Report recommended:

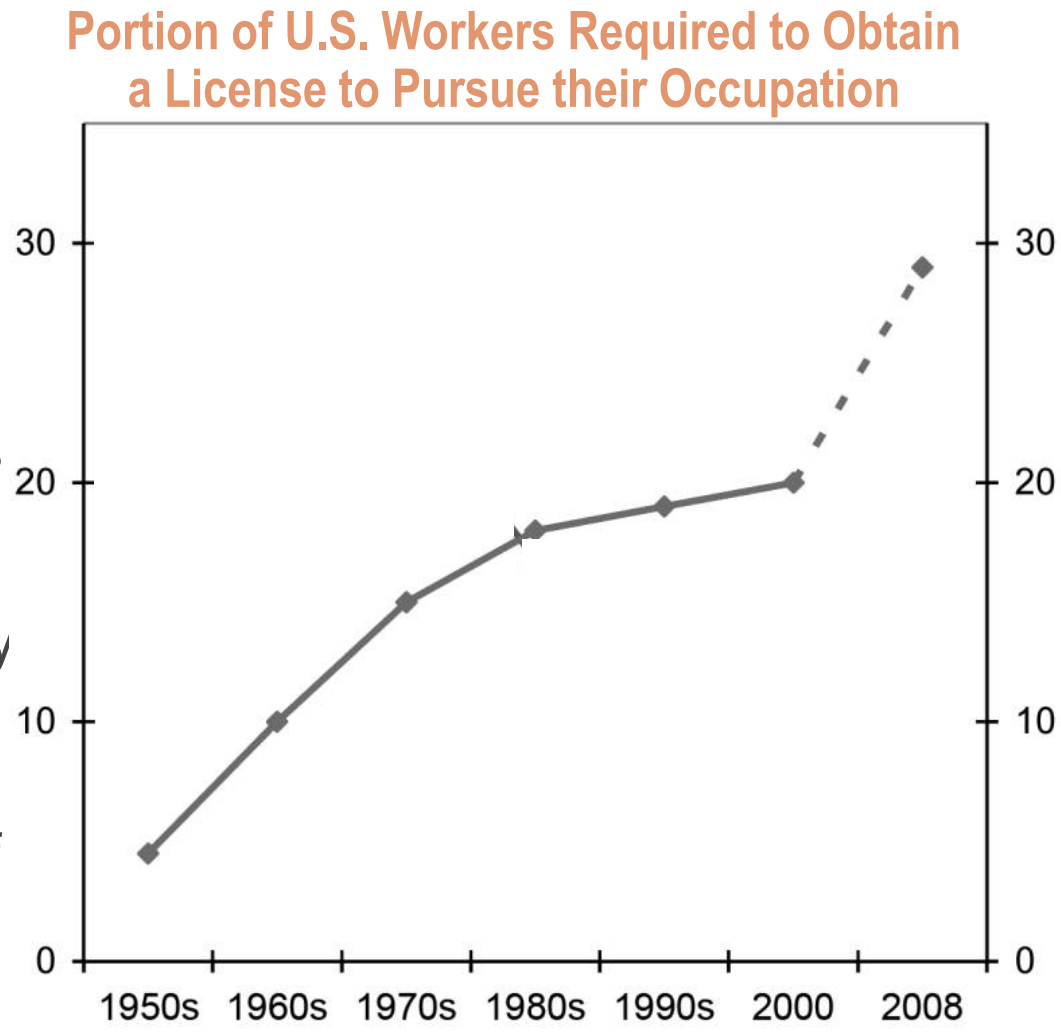
  "[R]e-affirm[ing] a clear articulation standard tailored to its original purposes and goals;"

  "[C]larify[ing] and strengthen[ing] the standards for active supervision;"

  "[C]larify[ing] and rationaliz[ing] the criteria for identifying government entities that should be subject to active supervision."

FTC Advocates that States Reign in Licensing

- FTC has called for "re-evaluation of the excessive state licensing regimes that have developed over the years."
- Studies have found that prices increase by as much as 33% as a result of occupational licensing, and improved quality and safety is often not the result.
- "[T]he drag on the economy of excessive occupational licensing is counted in the hundreds of billions of dollars annually."

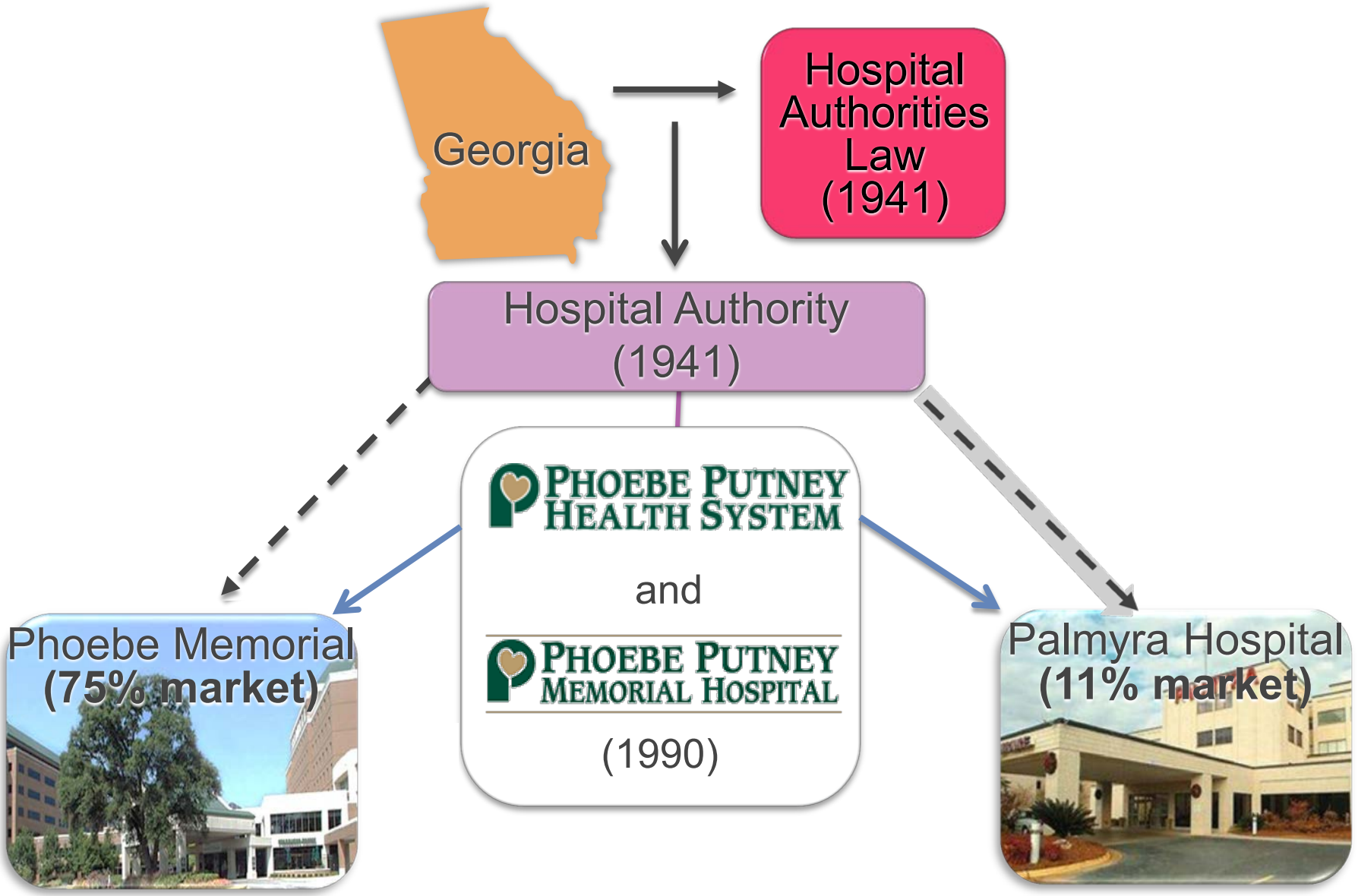


Source: Morris M. Kleiner & Alan B. Kruger, *Analyzing the Extent and Influence of Occupational Licensing on the Labor Market*, 31 J. Lab. Econ. 173 (2013)

FTC Campaign Against Certificate of Need ("CON") Laws

- FTC has encouraged the repeal or narrowing of CON laws, which require that health care services providers seek approval from a state entity to enter the market.
  - It argues that by "creat[ing] barriers to entry and expansion," CON laws lead to higher prices and expenditures in health care markets.
  - FTC believes that CON laws – like occupational licensing – are an example of the "Brother, May I" problem (*i.e.,* competition is impeded when a "competitor" is required to seek permission from an "incumbent competitor" to enter a market.)

The Phoebe Merger Refresher



FTC Challenge

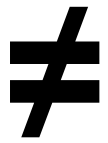
- FTC sought to block the merger
  - Relevant geographic market: Albany, GA area
  - Relevant product market: hospital services
  - Parties shares 86% - a virtual monopoly – not contested
- Hospital Authority and hospitals argued the state action doctrine immunized their conduct.
- District Court granted the motion to dismiss and the 11th Circuit affirmed on state action grounds.

Question Presented (Prong 1)

- Did the wording of the statute "**clearly articulate**" Georgia's intent to displace federal antitrust laws in regard to acquisitions by the Hospital Authorities?
  - The Hospital Authorities Law allowed each city and county in Georgia to operate its own hospital authority. Hospital authorities were granted powers including "**to acquire by purchase, lease, or otherwise and to operate projects**."

Phoebe Putney: Supreme Court Finds No State Action Immunity (2013)

- Unanimous decision from Justice Sotomayor
  - "'simple permission to play in a market'"



    "'foreseeably entail[ing] permission to roughhouse in that market'"
  - A policy to displace competition must be "**clearly articulated and affirmatively expressed**"
  - Holding: "Georgia has not clearly articulated and affirmatively expressed a policy to allow hospital authorities to make acquisitions that substantially lessen competition"

Phoebe Putney Postscript: FTC Wins the Battle but Loses the War

- In the end, FTC was unable to achieve divestiture.
- The state regulatory scheme of requiring a certificate of need (CON) meant that no other hospital could acquire the divested Palmyra hospital.

FTC Fights On

- FTC's disappointment refueled its efforts to convince states that CON laws should be repealed or narrowed.
- FTC also has encouraged states *post-Phoebe* to forego enacting legislation that "clearly articulates" displacing competition in health care markets, arguing that such legislation impedes rather than fosters lower costs and higher quality health care.
  - *See* Letter from FTC to Sen. Shields re Request for Comment on Oregon Senate Bill 231A (May 18, 2015); Letter from FTC to Sen. Ranzenhofer and Rep. Abinanti re New York Senate Bill 2647 and New York Assembly Bill 2888 (June 5, 2015).

Meanwhile in North Carolina, Prong 2 is the Focus

Teeth whitening businesses were opening around the state, including in malls, offering a lower priced alternative to whitening services than was provided by dentists

Dental Regulation in North Carolina

- NC regulates dentistry
  - Characterized as a state agency
  - 8 member Board
    - 6 **active** dentists (market participants) elected by other licensed dentists
    - 1 dental hygienist elected by other licensed dental hygienists
    - 1 consumer member appointed by the Governor

North Carolina State Board of Dental Examiners ("Board")

The NC Dental Board Takes a Stand

- The Board received complaints from dentists about the pricing and quality of mall kiosk whitening services.
- The Board determined that "teeth whitening" fell under the "Practice of Dentistry," and, therefore, the teeth whitening kiosks were engaged in the "unauthorized practice of medicine."
- North Carolina's Dental Practice Act states that a person "shall be deemed to be practicing dentistry" if that person, *inter alia*, "[r]emoves stains, accretions or deposits from the human teeth," but is silent as to whether teeth whitening constitutes the practice of dentistry.
  - The Board is authorized to promulgate rules and regulations governing the practice of dentistry, provided that they are not inconsistent with the Act and are reviewed by the North Carolina Rules Review Commission.
  - The Act provides that if the Board suspects an individual of engaging in the unlicensed practice of dentistry, it may bring an action in state court or refer the matter to the District Attorney.

The NC Dental Board Acts

- Instead of bringing an action in court or promulgating a rule, the Board began a cease and desist letter campaign aimed at providers and mall operators.
- The letters alleged that the teeth whitening in kiosks was the "**unauthorized practice of dentistry**"
  - At least 47 "letters" sent to approximately 29 non-dentist providers
  - Included threats of potential criminal consequences
  - NC did not have a role in reviewing the cease and desist letters

The FTC's Challenge

- The FTC found these Board actions to be anti-competitive and argued that, because the Board's actions constituted private party (nonsovereign) conduct, **Prong 2** "active supervision" needed to be met:
  - Without active supervision, it is not clear that the practitioners of the Board were acting pursuant to state policy or self-interest
  - The FTC characterized the oversight here as generic and "does not substitute for the required review and approval of the 'particular anticompetitive acts'"

The Board's Justification

- The Board argued that **Prong 1** "clear articulation" was met, and the analysis should stop there.
  - Before the Supreme Court, the Board conceded that it was not actively supervised and argued that it did not need to be.
  - Rather, it argued that oversight was sufficient because state delegations to agencies have safeguards:
    - Board members took an oath to the state
    - The Board was subject to "traditional" public entity duties: compliance with State ethics rules, open meetings rules, public records laws, Administrative Procedures Act

Kennedy Opinion (Joined by Roberts, Ginsburg, Sotomayor, & Kagan)

- The Court held that the Board was not immune from the antitrust laws because its actions were not "actively supervised" by the state.
  - State agencies are not necessarily sovereign actors.
  - Because of the potential for dual allegiances, "market participants cannot be allowed to regulate their own markets free from antitrust accountability."
  - "A state board on which a controlling number of decision makers are active market participants in the occupation the board regulates must satisfy [the] active supervision requirement…"

Kennedy Opinion (Joined by Roberts, Ginsburg, Sotomayor, & Kagan)

- The Court left open the possibility that agency officials may be protected from damages and reminded that states can indemnify agency members.
- Active supervision:
  - Need not entail day-to-day involvement in an agency's operations
  - Need "realistic assurance" that a nonsovereign's actions are pursuant to state policy
  - Supervisors must review the substance of the anticompetitive decisions, not merely the procedures used to produce it
  - State supervisor may not be an active market participant

North Carolina Dental Postscript: FTC Advice to States re Licensing Boards

- Limiting anticompetitive activity by boards will avoid the state action issue entirely – re-evaluate "excessive state licensing regimes."
- "[S]tate boards need not be controlled by active market participants. These individuals could comprise less than a majority – or . . . abstain . . . ."
- States may choose to actively supervise via a variety of methods.
- Boards can immunize their conduct by seeking injunctions from the courts (thus obtaining *Noerr-Pennington* immunity) or by promulgating rules reviewed by the state.

Alito Dissent (Joined by Scalia & Thomas)

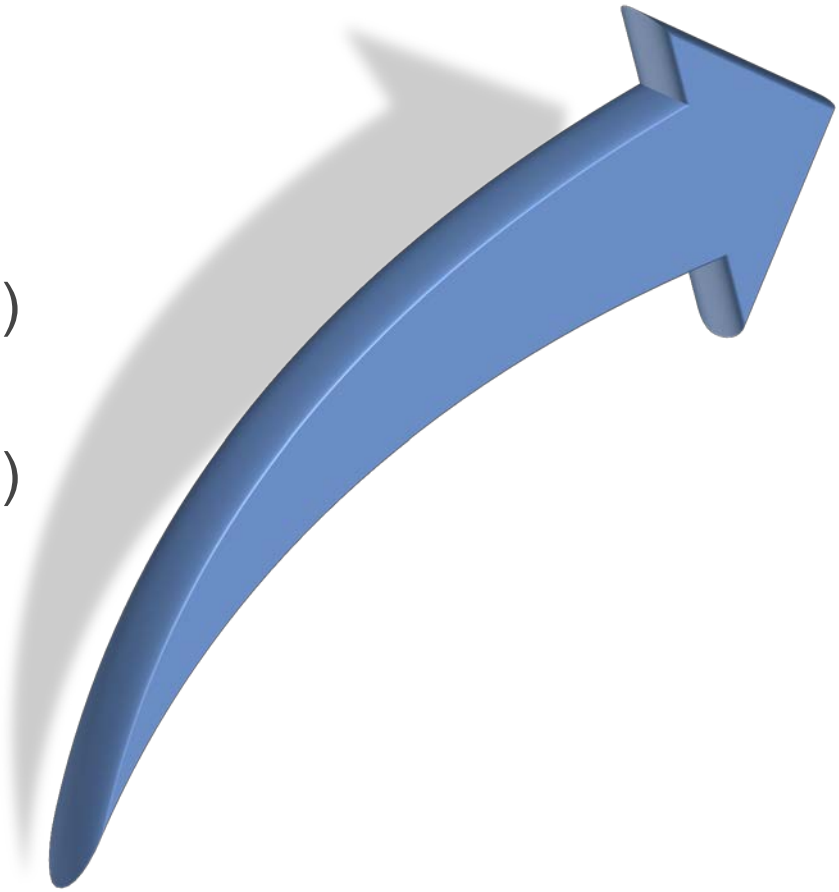
- The antitrust laws "do not apply to state agencies; the [Board] is a state agency; and that is the end of the matter."
- There is nothing new about medical and dental boards, nor the suspicion that they are pursuing their own self-interests.
- The Court's decision is likely to undermine states' choices to entrust regulation to those with expertise, and leaves open several questions:
  - What is a "controlling number"?
  - What is an "active market participant"?
  - What is the scope of the market in which a member may not participate while on the board?
- Also, the Court's opinion suggests that other types of regulatory capture might strip immunity.

Robin P. Sumner

Hot Topics in Health Care Competition
Will the Government Pursue Cross-Market Consolidations?

The Government Winning Streak in Health Care Consolidation

- The last time the government lost a hospital or physician merger case was when the it lost 6 in a row in the 1990s.
- Since then, the government has won its last 8 challenges.
  - *FTC v. Evanston* (2008)
  - *FTC v. Inova* (2008)
  - *FTC v. OSF Rockford* (2012)
  - *FTC v. Renown Health* (2012)
  - *FTC v. Reading* (2012)
  - *FTC v. Phoebe Putney* (2013)
  - *FTC v. Promedica* (2014)
  - *FTC v. St. Luke's* (2014)



A New Wrinkle: Cross-Market Mergers

- Consolidation in non-overlapping geographic markets
- Consolidation in non-overlapping product markets
- Consolidation of providers and insurers

Government Concern about Cross-Market Consolidation

April 2012 Statement after Closing Highmark/West Penn Investigation

"Vertical agreements, such as the affiliation agreement, can reduce competition by limiting entry or expansion by third parties."

Deborah L. Feinstein June 2014 Statement

"A vertical provider transaction could raise concerns, e.g., if a hospital acquired so many physicians in a particular specialty that a competing hospital would be unable to provide that service because it lacks access to the needed physicians."

Edith Ramirez Remarks at 2015 Examining Health Care Competition Workshop

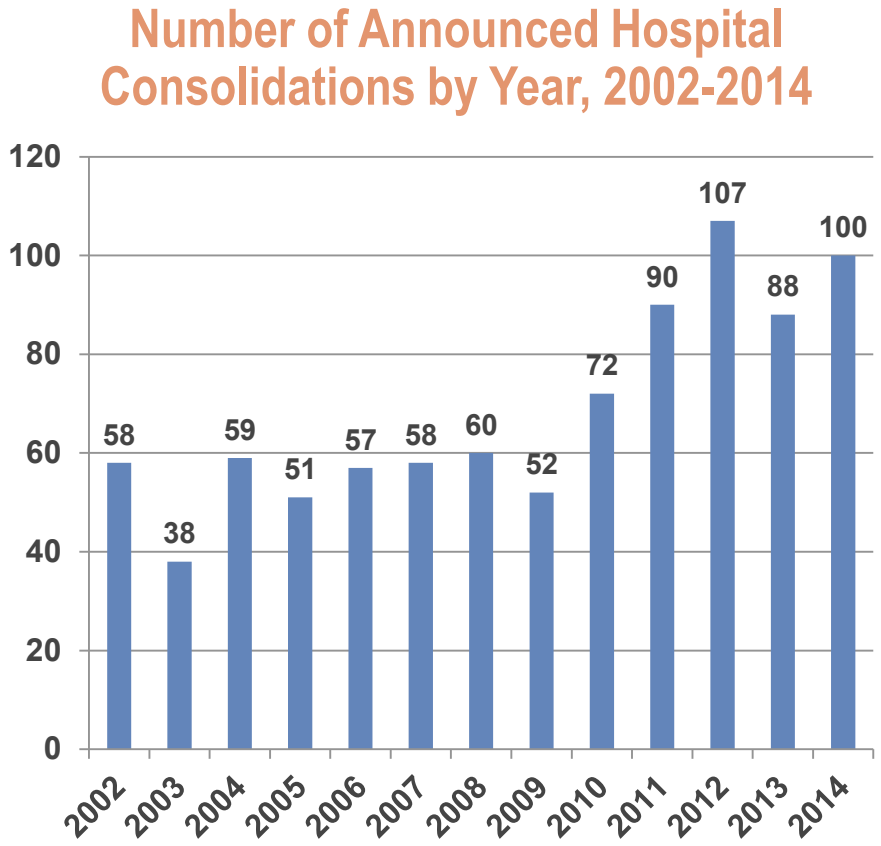
"[W]e now here growing concern that provider consolidation in non-overlapping product or geographic markets may also lead to higher prices."

William J. Baer Remarks at 2015 Examining Health Care Competition Workshop

Vertical "transactions [may] create conglomerates with the market power and bargaining leverage to adversely affect competition."

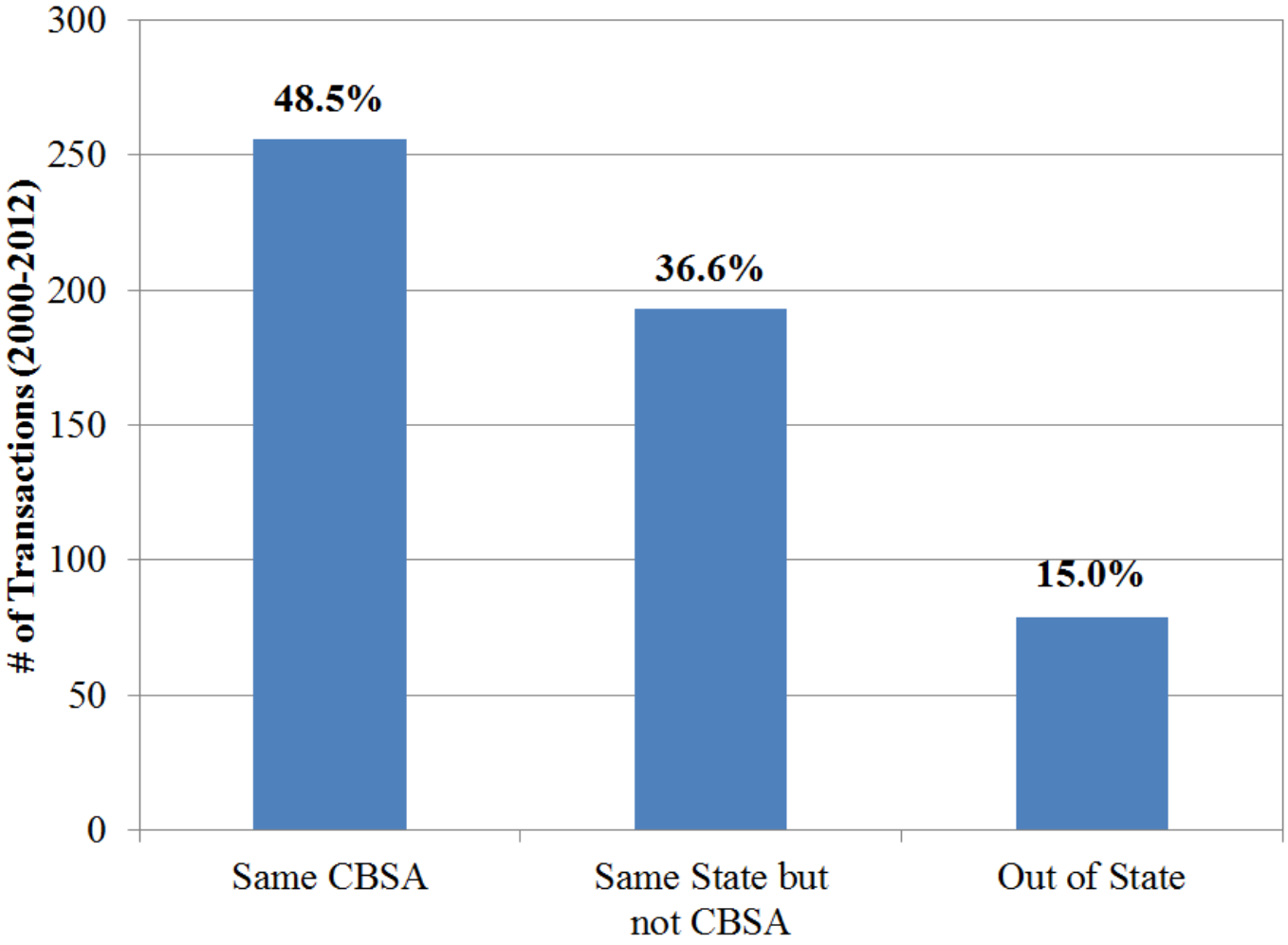
Post-ACA Pick-up in Hospital Mergers

- Perception that hospital systems need scale to transition from a traditional fee-for-service model to a value-based payment model
- Do hospital systems need to consolidate to integrate successfully?



Source: Irving Levin Associates, Inc.

Many Hospitals that Merge Do Not Have Any Traditional Horizontal Overlap



Source: Leemore Dafney, Slides from FTC/DOJ Examining Health Care Competition Workshop

Notes: Counties outside a CBSA are treated as their own CBSA in the above. Dafny, Ho, Lee (2015)

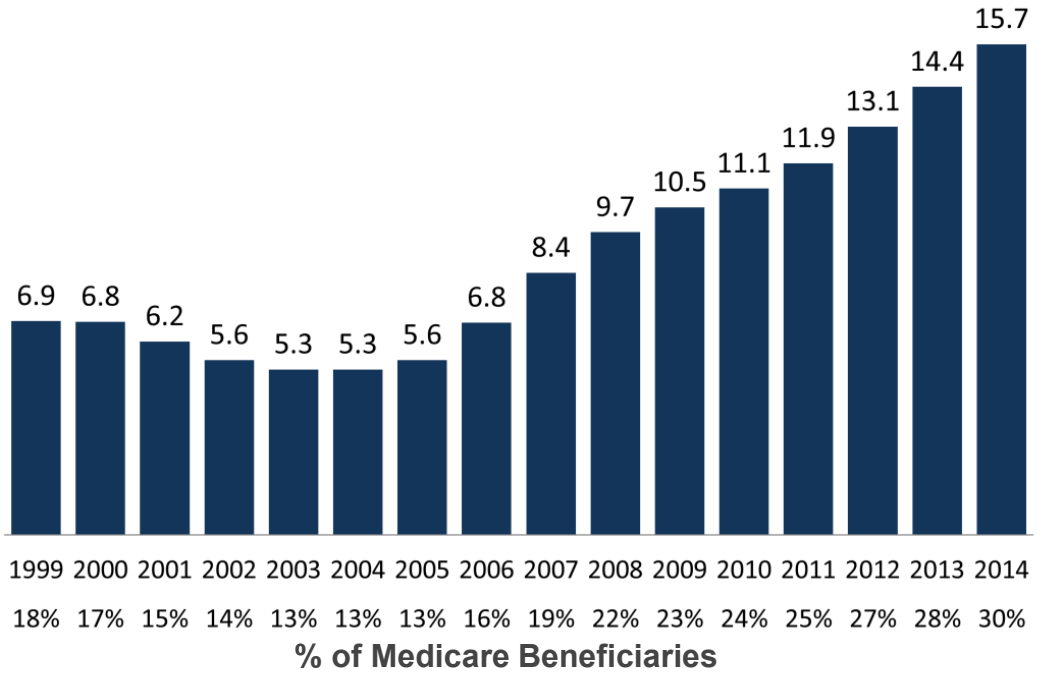
Increased Physician Employment by Hospitals

- Drivers of Physician/Hospital Consolidation
  - Clinical integration
  - Medicare payment
  - Access to investment capital
- More physicians are employed by hospitals than in the past, but the total number is probably not above 25 percent of all physicians.

Insurer/Provider Consolidation: The "Kaiser-ification" of American Health Care

- About 14% of US hospitals have an HMO and 14% have a PPO
- Drivers of Insurer/Provider Consolidation
  - Position for Medicare Advantage and Medicaid enrollment
  - Manage risk
  - Increase leverage
  - Avoid lock-out

Total Medicare Private Health Plan Enrollment, 1999-2014 (in millions)



Note: Includes MSAs, cost plans, demonstration plans, and Special Needs Plans as well as other Medicare Advantage plans.

Source: The Henry J. Kaiser Family Foundation

Potential Competitive Harms of Cross-Geographic Consolidation

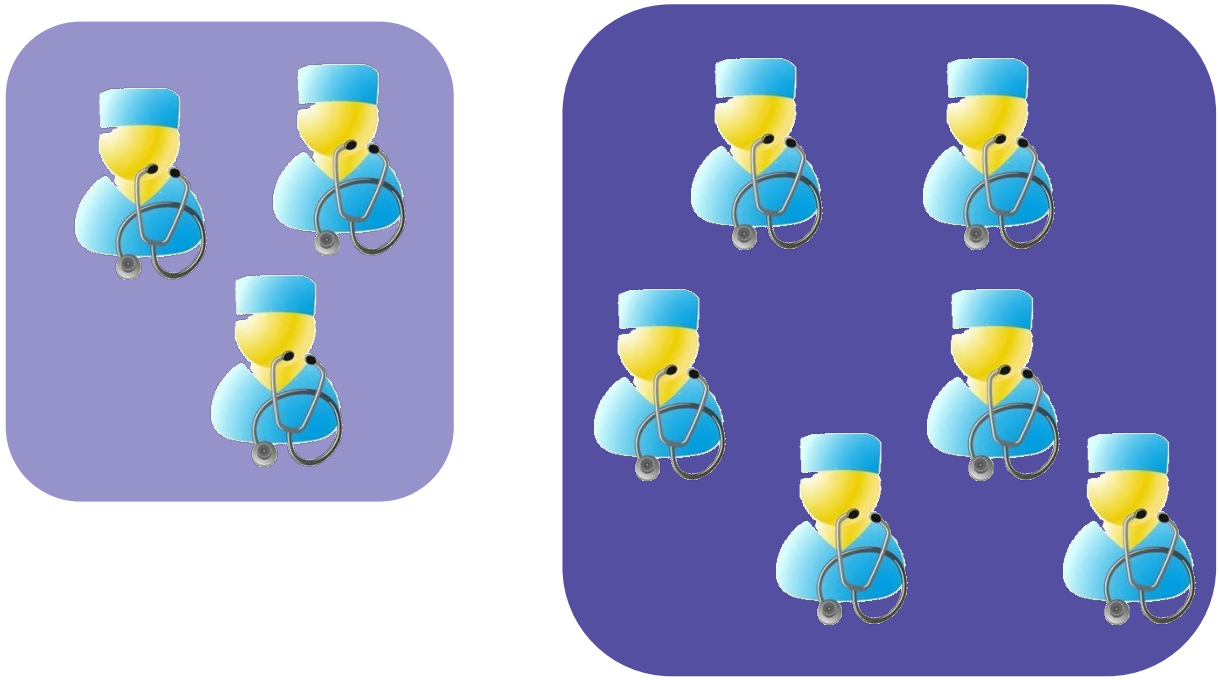
- Growing evidence that cross-geographic hospital mergers increase provider leverage and result in higher hospital prices, e.g.:
  - Participants in one study noted that provider leverage depends on how big the hospital system is and how much of an insurer's patient volume it generates.[1]
  - Another study found that hospitals increased net reimbursement rates by 14 to 18 percent after joining an out-of-market hospital system. [2]

[1] Berenson et al., *The Growing Power of Some Providers to Win Steep Payment Increases from Insurers Suggests Policy Remedies May be Needed*, Health Affairs 2012.

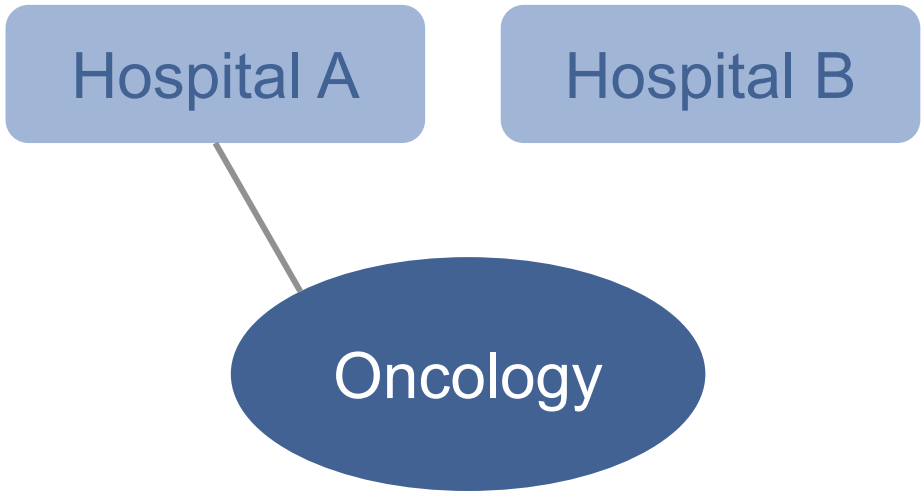
[2] Lewis & Pflum, *Hospital Systems and Bargaining Power: Evidence from Out of Market Acquisitions*, 2014.

Potential Competitive Harms of Hospital/Physician Integration

Leverage



Foreclosure



Efficiencies of Hospital/Physician Consolidation May Not Be Realized

- Most integration is focused on financial, not clinical factors.
- Evidence of efficiencies of hospital-physician integration is underwhelming.[1]
  - Recent studies suggest that costs rise when hospitals own physician groups.
  - Studies show mixed results re effect on quality.
  - Recent studies show that prices rise when hospitals acquire physicians.

[1] *See, e.g.*, J. Michael McWilliams, et al., *Delivery System Integration and Health Care Spending and Quality for Medicare Beneficiaries*, 173(15) J. AMA. Internal Medicine 1447 (Jun. 17, 2013); John Kralewski, et al., *Do Integrated Health Care Systems Provide Lower-Cost, Higher-Quality Care?,* 40:2 J. of the Acad. of Physician Execs. 14 (March/April 2014); Laurence C. Baker, et al., *Vertical Integration: Hospital Ownership of Physician Practices Is Associated with Higher Prices and Spending*, 33:7 Health Affairs 756 (May 2014).

Potential Competitive Harms of Provider/Insurer Consolidation

- Provider/Insurer consolidation presents similar risks of anticompetitive harms as hospital/physician integration.
  - **Leverage**
    If many health systems in a market are all acquired by only a couple insurers, competition will decrease.
  - **Foreclosure**
    If one insurer acquires a provider with high patient demand, other insurers may be locked out.

Jan P. Levine

Privacy as a Possible Emerging Antitrust Issue and Uses of HIPAA in Privacy Litigation

Privacy as a Potential Antitrust Concern

- The FTC has started to consider the possible effect of privacy issues on economic efficiencies and competition. Although FTC Commissioner Maureen Ohlhausen warns that consumer privacy protection is best accomplished through consumer protection laws rather than through antitrust scrutiny. (i.e., HIPAA, HITECH and consumer protection laws limit the use and dissemination of health information)
- In recent addresses, however, both Ms. Ohlhausen and FTC Director Deborah Feinstein (Bureau of Competition) have noted that privacy could be viewed as a form of non-price competition.
  - Issues:
    (1) big data as an asset or commercial good
    (2) a merger's effect on competition in terms of privacy policies and technology
- In addition, Sen. Al Franken (Minn) – a member of both the Privacy, Technology and the Law and Antitrust, Competition Policy, and Consumer Rights Committees – has expressed concern over "dominant market" players having "less incentives" to give consumers meaningful choices in terms of privacy.

Privacy as an Issue in Merger Review

- While hospital mergers bring efficiencies and lower costs to hospital administration, they may also bring with them a number of antitrust/privacy considerations:
  - Valuing privacy technology and protections related to patient health and personal information as an asset
  - Evaluating whether choice of post-merger technology increases or decreases privacy protection afforded to consumers of healthcare services
  - Developing an integration strategy to maintain high standards for protection of patient information post-merger

HIPAA and Privacy Litigation

- HIPAA applies to:
  - **Protected Health Information ("PHI")**: Data that identifies a specific person and describes his/her demographics, medical status/history, and payment for care.
    - ePHI: PHI maintained or transmitted in electronic form
  - "**Covered Entities**"
    - Health care providers who conduct electronic transactions
    - Health plans
    - Health care clearinghouses
  - "**Business Associates**"
    - Creates, receives, maintains or transmits PHI on behalf of a Covered Entity
    - Provides certain services (identified in the Rule) involving PHI, to or for, a Covered Entity (eg., consulting, management, administrative, financial)

Enforcement

- HIPAA does not create a private cause of action
- The HHS Office for Civil Rights ("OCR")
  - Investigates complaints
  - Conducts compliance reviews
  - Performs education and outreach
  - Imposes civil monetary penalties
- Department of Justice ("DOJ")
  - Imposes criminal penalties
- State Attorney General
  - May bring civil actions on behalf of state residents for HIPAA violations

Regulatory Enforcement

- Parkview Health System (6/23/14)
  - 71 banker's boxes of patient files left in physician's driveway
  - $800,000 civil penalty
- New York Presbyterian and Columbia University (5/7/14)
  - Disclosed ePHI of 6,800 to internet search engines
  - $4.8 million civil penalty
- Concentra Health Services (4/21/14)
  - Unencrypted laptop stolen from physical therapy center
  - $1.725 million civil penalty
- QCA Health Plan, Inc. (4/14/14)
  - Unencrypted laptop stolen from employee's car (148 records)
  - $250,000 civil penalty
- Affinity Health Plan, Inc. (8/7/13)
  - Failure to erase data contained on photocopier hard drive
  - Contained ePHI for 344,579 individuals
  - $1,215,780 civil penalty

Regulatory Enforcement

- Wellpoint, Inc. (7/7/13)
  - Security weaknesses in on-line application database exposed pHI for 612,000 individuals
  - $1.7 million civil penalty
  - $100,000 fine (State of Indiana)
  - $50,000 reimbursement to customers
- University of California at LA Health System (7/6/11)
  - Unauthorized employees repeatedly looked at ePHI of numerous patients
  - $865,500
- Cignet (2/4/11)
  - Failure to provide 41 patients with copies of their records
  - Failure to respond to OCR investigation
  - Failure to respond to OCR subpoena
  - $4.3 million civil penalty

HIPAA and Private Causes of Action

- Even though there is no statutory "private cause of action," HIPAA standards are plead within other causes of action in both cyber breach class actions and individual privacy cases:
  - negligence per se
  - breach of implied contract
  - invasion of privacy
  - intentional infliction of emotional distress
  - wrongful disclosure of medical information
- State common claims may not be precluded or "pre-empted" by HIPAA and HIPAA can provide for the standard of care
- *Byrne v. Avery Center* – Connecticut Supreme Court (Nov. 2014)
- *R.K. v. St. Mary's Med. Ctr., Inc.* – Supreme Court of Appeals West Virginia (Nov. 2012)

Questions & Answers