Health Sciences Speaker Series

What Do Investors Need to Know About Your Dealings with the FDA? Practice Pointers for Health Sciences Companies

Aline Fairweather
Scott Jones
Sharon Klein
Pamela Palmer

Pepper Hamilton LLP
Attorneys at Law

August 1, 2017

We Will Start at 12PM PT/ 3 PM ET

Currently There is No Sound - All Lines Muted

Pepper Hamilton LLP
Attorneys at Law

Capabilities

Best Lawyers

More than 65 lawyers listed, including 4 as **Lawyer of the Year**

75+

lawyers highly rated by **Super Lawyers** and **Rising Stars**

SERVICES

BUSINESS
GOVERNMENT REGULATION
HEALTH SCIENCES
INTELLECTUAL PROPERTY
INTERNATIONAL
LITIGATION

INDUSTRIES

CONSTRUCTION
ENERGY
FINANCIAL
FOOD, ALCOHOL AND BEVERAGE
HEALTH SCIENCES
HIGHER EDUCATION
INVESTMENT FUNDS
LIFE SCIENCES
MEDIA, COMMUNICATIONS AND ENTERTAINMENT
NONPROFIT ORGANIZATIONS AND FOUNDATIONS
PHARMACEUTICAL AND MEDICAL DEVICE
RETAIL
TECHNOLOGY
TRANSPORTATION

Pepper Hamilton LLP
Attorneys at Law

Global Reach

INTERNATIONAL NETWORK

Pepper Hamilton is the exclusive member firm in Pennsylvania for **Lex Mundi** — the world's leading network of independent law firms with in-depth experience in 100+ countries worldwide.

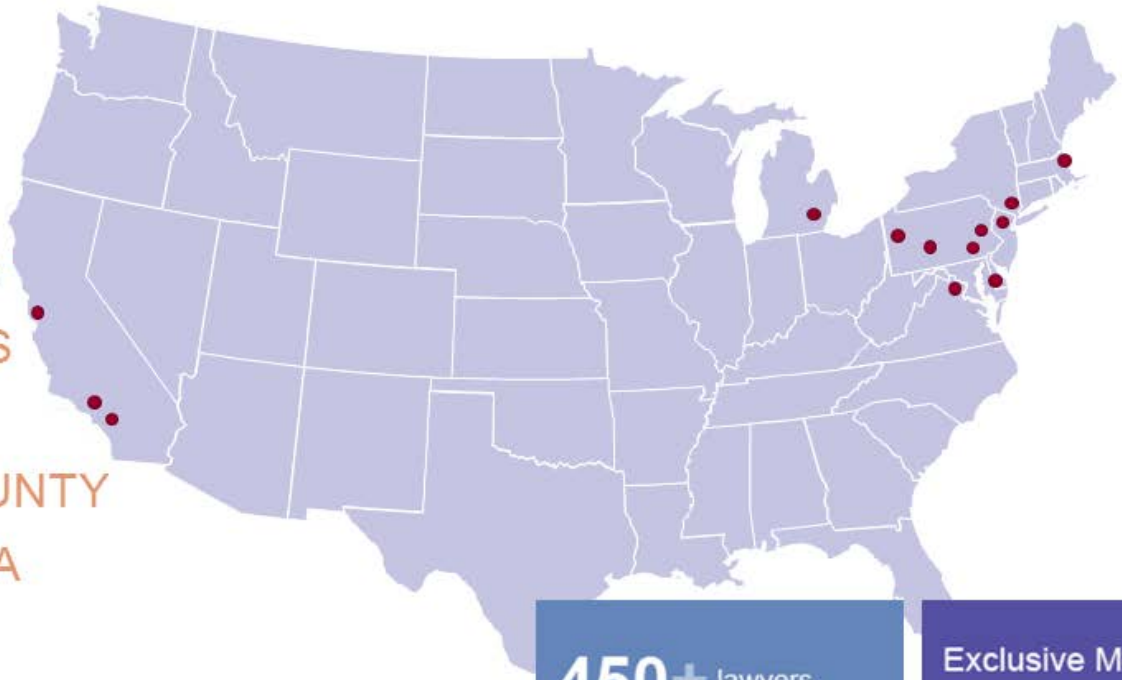
Through the Lex Mundi global network, we can provide our clients with preferred access to more than 21,000 lawyers around the world — all from a single point of contact.

Individually, each Lex Mundi member firm is a leader in its local market. Collectively, Lex Mundi firms provide global legal resources with unmatched depth and breadth. Working with other Lex Mundi firms, we are able to seamlessly handle our clients' most challenging cross-border transactions and disputes.

Pepper Hamilton LLP
Attorneys at Law

Locations

BERWYN
BOSTON
DETROIT
HARRISBURG
LOS ANGELES
NEW YORK
ORANGE COUNTY
PHILADELPHIA
PITTSBURGH
PRINCETON
SILICON VALLEY
WASHINGTON
WILMINGTON



450+ lawyers

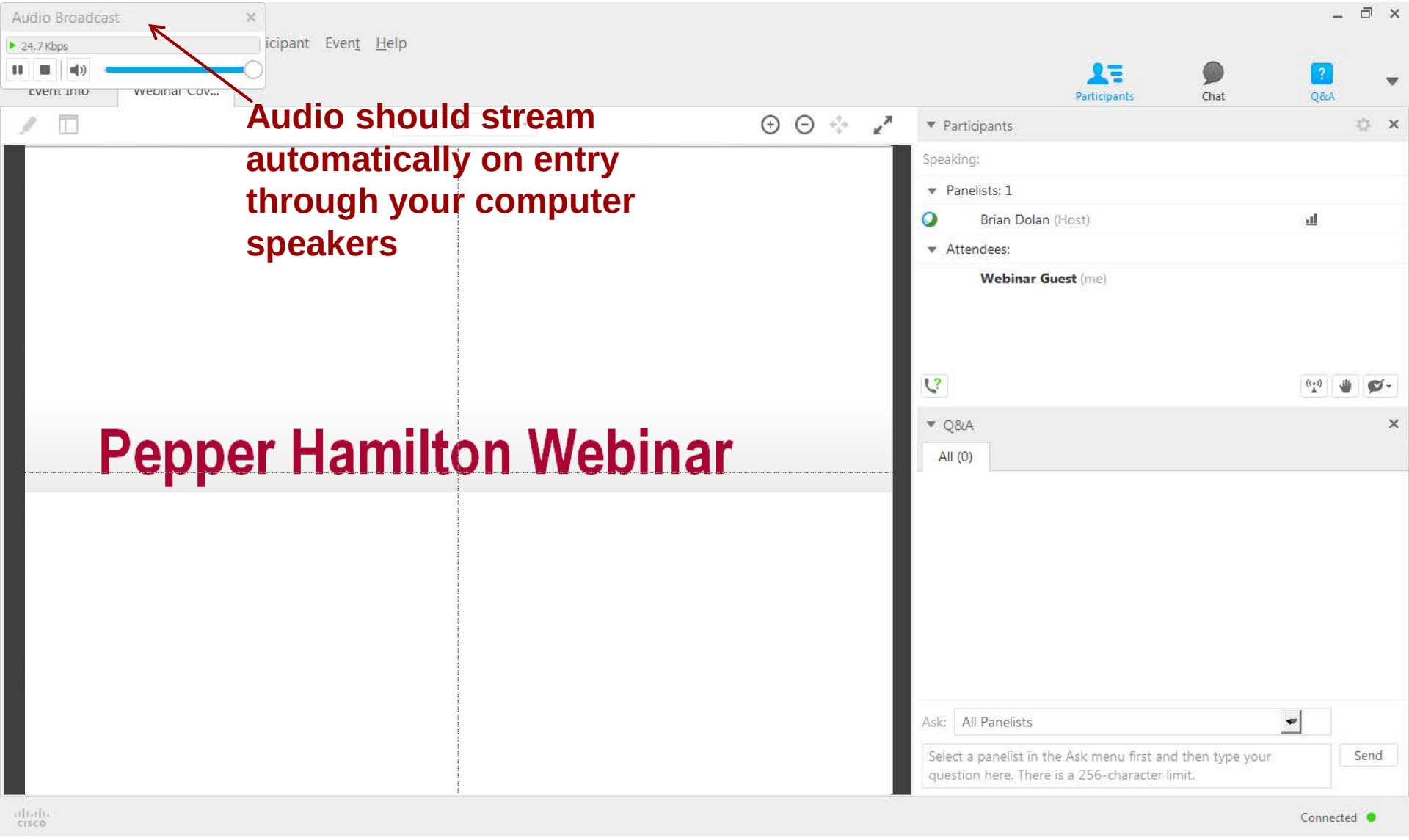
13 offices in U.S.

125+ years of serving clients

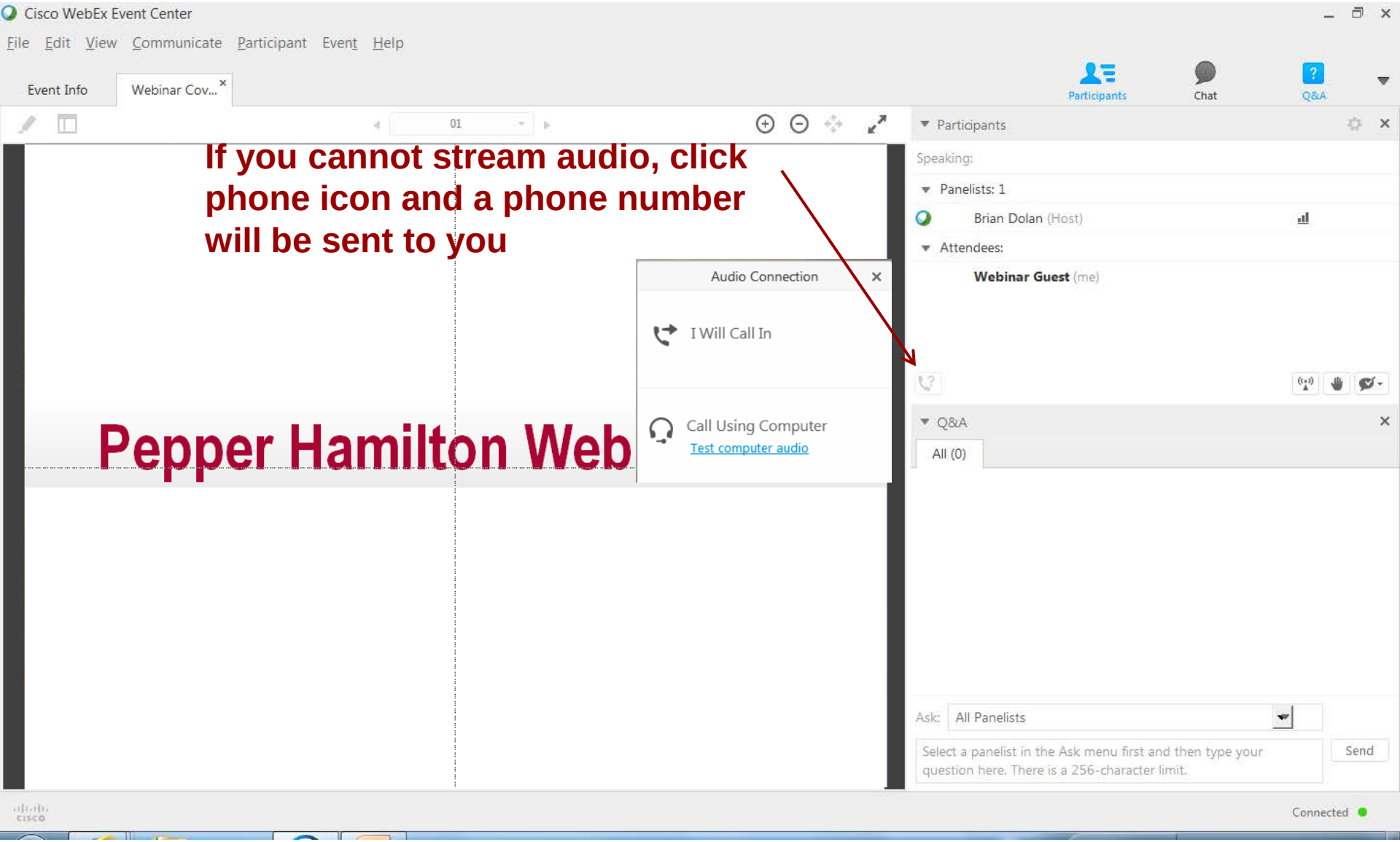
Exclusive Member
Lex Mundi
Firm for Pennsylvania

Pepper Hamilton LLP
Attorneys at Law

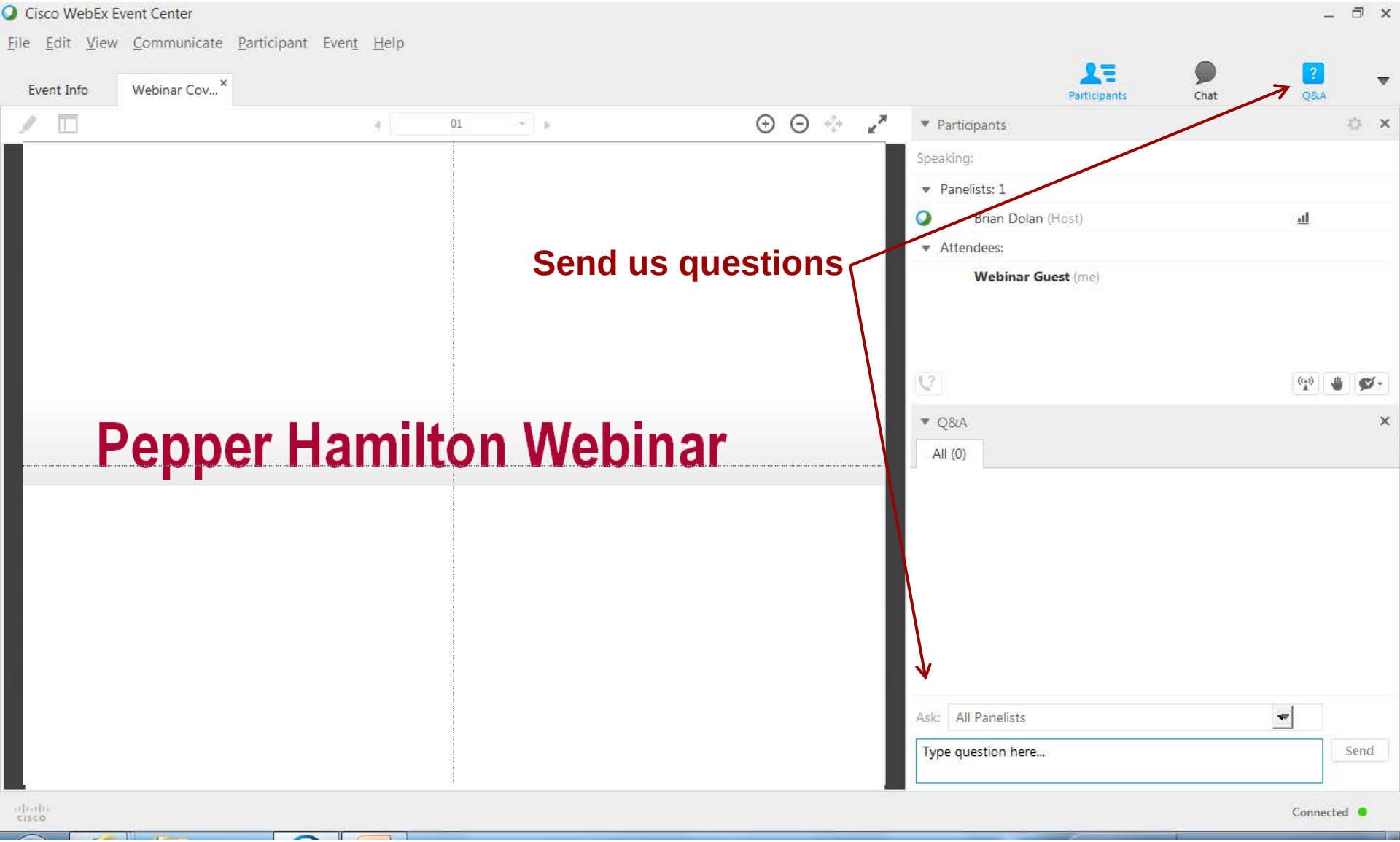
Audio


Audio Broadcast
24.7 Kbps
Participant Event Help
Participants
Chat
Q&A
Audio should stream automatically on entry through your computer speakers
Pepper Hamilton Webinar
Participants
Speaking:
Panelists: 1
Brian Dolan (Host)
Attendees:
Webinar Guest (me)
Q&A
All (0)
Ask: All Panelists
Select a panelist in the Ask menu first and then type your question here. There is a 256-character limit.
Send
Connected

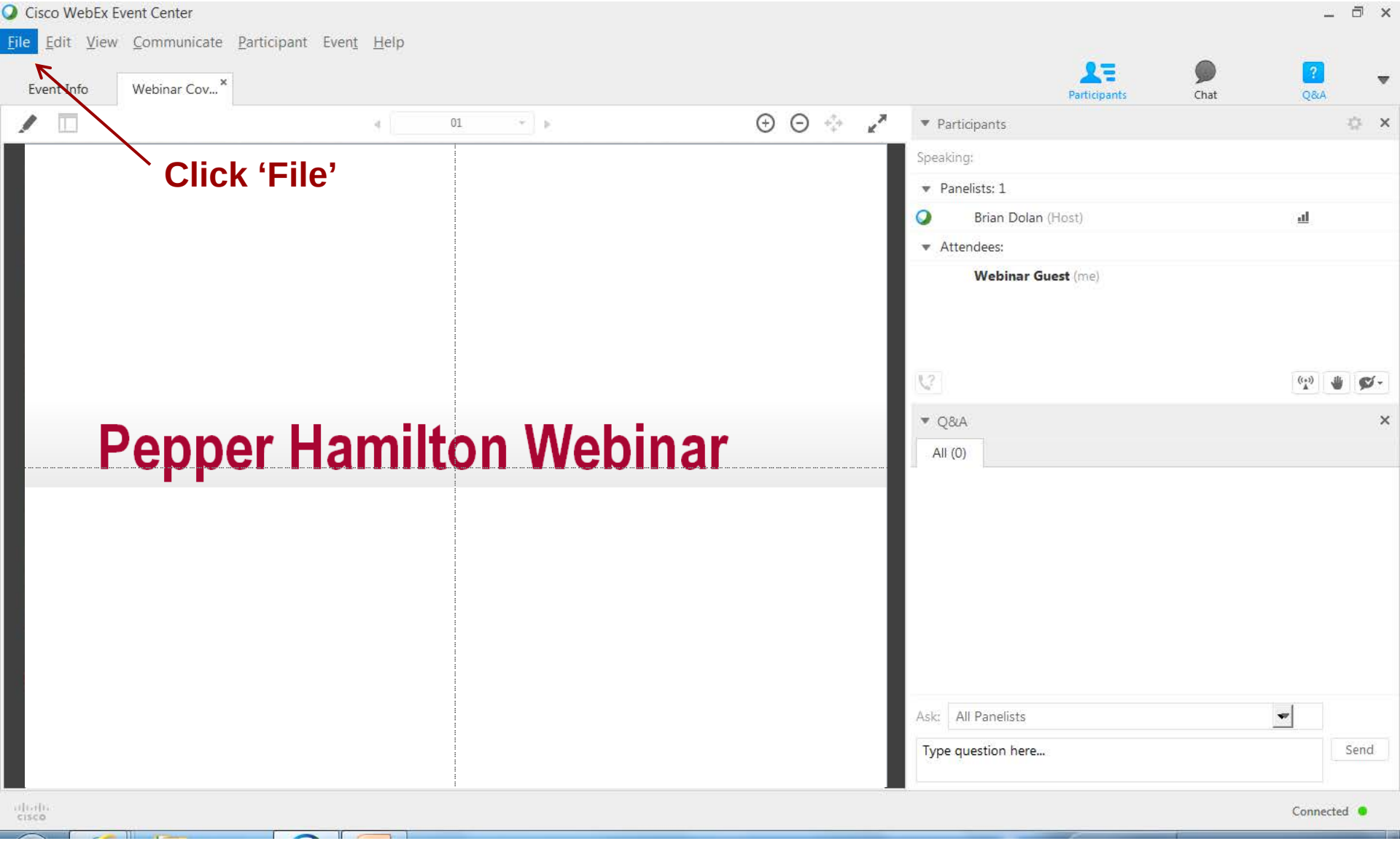
Audio


Cisco WebEx Event Center
File Edit View Communicate Participant Event Help
Event Info
Webinar Cov...
Participants
Chat
Q&A
If you cannot stream audio, click phone icon and a phone number will be sent to you
Audio Connection
I Will Call In
Call Using Computer
Test computer audio
Pepper Hamilton Web
Participants
Speaking:
Panelists: 1
Brian Dolan (Host)
Attendees:
Webinar Guest (me)
Q&A
All (0)
Ask: All Panelists
Select a panelist in the Ask menu first and then type your question here. There is a 256-character limit.
Send
Connected

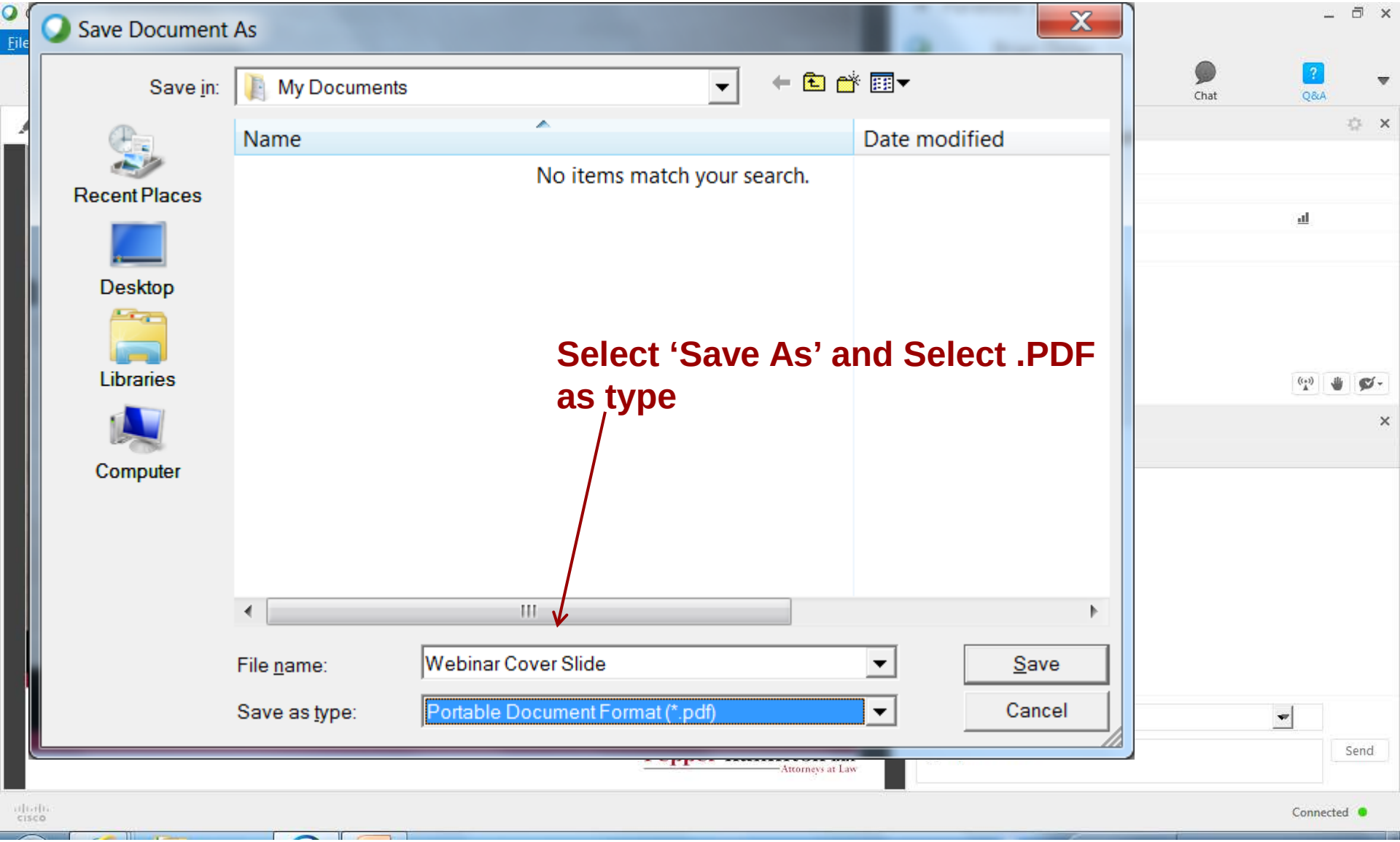
Q&A


Cisco WebEx Event Center
File Edit View Communicate Participant Event Help
Event Info
Webinar Cov...
Participants
Chat
Q&A
Send us questions
Pepper Hamilton Webinar
Participants
Speaking:
Panelists: 1
Brian Dolan (Host)
Attendees:
Webinar Guest (me)
Q&A
All (0)
Ask: All Panelists
Type question here...
Send
Connected

Download PPT Slides



Download PPT Slides



CLE credit available in CA

Contact Brian Dolan at dolanb@pepperlaw.com for CLE form

Pepper Hamilton LLP
Attorneys at Law

Aline Fairweather

Partner, Health Sciences

215.981.4807

fairweathera@pepperlaw.com

- Defends and counsels pharmaceutical, medical device and life sciences companies, with a particular focus on complex scientific issues and FDA regulation.
- Counsels FDA-regulated companies on regulatory compliance and litigation risk in matters involving clinical trials, regulatory enforcement, labeling, advertising and promotion and responses to agency inquiries. Advises life sciences clients on regulatory issues in connection with commercial transactions, including counseling on corporate investor materials, securities filings, press releases and other corporate communications.
- Represents pharmaceutical and medical device manufacturers in multidistrict litigation and state coordinated proceedings, and in actions brought by state attorneys general and governmental and private insurers.

Pepper Hamilton LLP
Attorneys at Law

Scott R. Jones

Partner, Health Sciences
215.981.4562
jonessr@pepperlaw.com

- Concentrates his practice in merger and acquisition transactions, venture capital financing and private equity transactions, and SEC matters.
- Experience in the acquisition and disposition of public and private companies as well as public and private offerings of equity and debt securities.
- Also counsels senior management and boards of directors of companies on governance, disclosure and transactional matters.

Pepper Hamilton LLP
Attorneys at Law

Sharon R. Klein

Partner, Health Sciences
949.567.3906
kleins@pepperlaw.com

- Handles matters relating to information technology data rights and telemedicine as well as a variety of corporate and intellectual property matters, in particular, helping technology and outsourcing clients grow and succeed
- Advises life sciences businesses on planning, drafting and implementing privacy, security and data protection policies and “best practices,” compliance with applicable laws, regulations and rules, and crisis management and litigation strategies for non-compliance.

Pepper Hamilton LLP
Attorneys at Law

Pamela S. Palmer

Partner, Commercial Litigation Practice Group

213.928.9814

palmerp@pepperlaw.com

- Handles complex business litigation and internal investigations focusing on shareholder claims, securities and disclosure, class actions, derivative suits, mergers, consumer and competition claims.
- Represents companies, officers, directors and professional service providers in fiduciary duty, business judgment and professional liability cases, SEC and other regulatory enforcement matters.
- Advises clients on corporate governance, disclosure, indemnification and insurance.

Pepper Hamilton LLP
Attorneys at Law

Agenda

- Why good disclosure matters
  - Investors
  - The SEC and the FDA
- What to disclose
- Whether to disclose
- When to disclose
- Securities fraud class actions
- Shareholder derivative suits
- SEC enforcement actions
- Disclosure practice pointers

Why Good Disclosure Matters

- Uptick in securities class action filings
  - Between January 1 and August 1, **twenty four** life sciences companies were sued for alleged securities fraud after announcing disappointing clinical trial or FDA regulatory events
  - The pace of such securities fraud actions filed in 2017 against life sciences companies is outstripping the pace in 2016

Why Good Disclosure Matters

- FDA and SEC inter-agency cooperation
  - Procedure for FDA employees to refer suspected misstatements to SEC Division of Enforcement
  - FDA contacts
  - Training of FDA and SEC staff
  - Electronic communication between agencies
  - Sharing of non-public records/information

Why Good Disclosure Matters

- March 2015 – Director of SEC's Division of Enforcement speaks on disclosure of dealings with the FDA
  - "Accuracy of reporting in your dealings with the FDA is critical to getting investors the information they need. FDA dealings and approvals are the lifeblood of your business and so are important to investment decisions. . . . So much turns on those interactions and not being straight with investors will have significant consequences."

What You Need to Disclose

- *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 44 (2011)
  - Section 10(b) of the Securities Exchange Act of 1934 and SEC Rule 10b-5 "***do not create an affirmative duty*** to disclose any and all material information."
  - Rather, disclosure is required "only when necessary 'to make . . . statements made, in the light of the circumstances under which they were made, not misleading.'"

- *Omnicare Inc. v. Laborers District Council Constr. Ind. Pension Fund*, 135 S.Ct. 1318, 1329 (2015)
  - When are opinions misleading? When the company fails to state facts ***"necessary to make its opinion not misleading***," such as lack of basis for the opinion, or knowledge of contrary facts.

What You Need to Disclose

- Materiality
  - To prevail on a Section 10(b) claim, a plaintiff must show that the defendant made a statement that was "***misleading*** as to a ***material*** fact." *Basic v. Levinson*, 485 U.S. 224, 238 (1988).
  - This materiality requirement is satisfied when there is "a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." *Id*. at 231-232.
  - Note: Materiality is not negated by the absence of statistical significance, nor does "the total mix standard" "mean that pharmaceutical manufacturers must disclose all reports of adverse events." *Matrixx*, 563 U.S. at 44.

Whether to Disclose

- Educate company employees
  - Confidentiality policy
  - Insider trading policy
  - Disclosure obligations
- Foster communications with employees
- Form and properly maintain a disclosure committee

Whether to Disclose

- Properly assess materiality in light of the company's development pipeline
  - Companies generally have a lot of non-public information, but not all of it is material
  - Generally, only information that a reasonable investor would take into consideration in determining whether or not to transact in the company's stock (whether buying or selling) is material
  - A good rule of thumb is that if you think your company's stock will move if the information is disclosed, it is likely material

Whether to Disclose

- Where other business partners are involved, make sure they are on the same page with disclosures around the shared collaboration, information and projects
- Keep emotions in check and consider information objectively
  - Fear of market reaction should not prevent the disclosure of bad news
  - Excitement over good news should not cause the company to disclose unripe information

When to Disclose

- Be patient and make sure information is ripe before disclosing
- Consider consulting with the FDA to ensure disclosure is consistent with the agency's position before making a disclosure
- Be mindful of your calendar
  - Investor presentations
  - Development timeline
- Disclosure may be required where a company filing is due, the information relates to a Form 8-K trigger, Regulation FD is tripped or the company is about to enter into an offering

When Shareholders Sue

- When a life sciences company faces higher risk of being sued for alleged securities fraud
  - The company announces, or investors otherwise learn about, a disappointing clinical trial or FDA event – especially during the development of the company's flagship product candidate
  - where the company's stock price drops significantly (>10-15%) immediately following the disappointing news

2017 Securities Fraud Class Actions

- Allege materially misleading statements or omissions
- Typical allegations
  - Misled investors about status of clinical trials
  - Misled investors about FDA's view of product
  - Overstated approval prospects
  - Understated or failed to update product timelines
  - Overstated commercial viability

2017 Securities Fraud Class Actions

Alleged Misrepresentations

Public Statement	Why Allegedly Misleading
Clinical Trials	
• Positive clinical trial data for approval	• FDA asks for more data; false interim analysis
• Phase II data bodes Phase III success	• Phase III trial fails to reach primary endpoint
• Clinical trial designed to support approval	• Design change could not support approval
• Per IDMC Phase III trial is continued	• Per IDMC Phase III is later discontinued
Labeling	
• Potential label claim	• FDA does not approve label claim
Safety	
• Favorable safety profile	• Significant adverse events/clinical holds
Commercialization Timeline	
• Anticipated timeline for launch	• FDA asks for more manufacturing information
Regulatory Action	
• Anticipated FDA submission	• Foreign regulatory investigation
• Anticipated acceptance of NDA filing	• FDA issues Refusal to File letter

Private Securities Class Action

- Filed against company and senior officers who allegedly made materially misleading statements or omissions
- Section 10(b) – Must allege that defendants acted with "scienter" (intent to defraud) in connection with the purchase or sale of a security
- Section 11 – Strict liability for companies for misleading statements or omissions in a registration statement
- Plaintiffs must overcome procedural protections against "abusive" securities class actions enacted in the Private Securities Litigation Reform Act
  - including pleading fraudulent intent with factual particularity
  - satisfying lead plaintiff-lead counsel competition
  - discovery stay pending motion to dismiss

Parallel Shareholder Derivative Litigation

- Filed derivatively “on behalf of” the company against its officers and directors
- Asserts claim that officers and directors breached fiduciary duties owed to the company by …
  - committing securities fraud alleged in the securities class action
  - violating other laws or regulations
  - breach of loyalty or conscious disregard of fiduciary duties
- Often repeats verbatim allegations in securities class action
- Can only be pursued by stockholders after satisfying the “demand requirement”

SEC Enforcement Actions

- What types of disclosures and omissions are attracting the SEC's attention
  - status of company's FDA application(s)
  - status of clinical trials
  - adverse FDA decisions
  - ability to comply with FDA regulations
  - communications with foreign regulatory authorities

SEC Enforcement Actions

- If the SEC initiates an enforcement investigation/proceeding
  - Expect both the company and individual officers and directors to be targeted
- Settlement with the SEC (or loss of an action) can mean
  - Millions of dollars in civil money penalties
  - Disgorgement of allegedly illegal gains
  - Executives being barred from serving in senior positions at public companies
  - Revocation of securities registration

Disclosure Practice Pointers

- Have a complete understanding of the facts
- Talk with regulatory agencies
- Be complete and truthful
- Don’t misstate or omit material facts
- Balance the good and the bad
- Don’t presume FDA approval
- Don’t promote unapproved products

Disclosure Practice Pointers

- Don’t overreach or over-promise
  - No over-optimistic timelines
  - No unsubstantiated comparative claims
  - Don’t overstate potential market size
- Mitigate bad news with care
  - Accurate explanations of agency actions
  - Real company plans, with associated risks

Disclosure Practice Pointers

- Consider supplementing/correcting prior disclosures
- Risk factors and forward looking statement disclaimers
  - Don’t cut and paste forward looking statements
  - Risk factors should be detailed and tailored
  - Risk factors should be assessed and revised on a regular basis
- Keep all public materials consistent and updated
  - Investor communications
  - Company website

Questions & Answers

For more information, visit

www.pepperlaw.com

Pepper Hamilton LLP
Attorneys at Law