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Life sciences securities litigation and enforcement issues

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Life sciences companies in the crosshairs

- More than 32 percent of all securities class actions are against life sciences companies; number has risen three straight years
- Often triggered by adverse FDA decisions or communications, clinical holds, bad trial results, adverse event reports and safety problems
- Life sciences companies also facing scrutiny from plaintiff lawyers and SEC over financial reporting and internal controls
- Other risks: whistleblowers, FCPA and TCPA

Focus on efficacy, safety, FDA approval status and accounting issues

- 56% of 2014 claims alleged misrepresentations or omissions re: product efficacy or prospects/timing of FDA approval
- 44% of 2014 claims alleged financial reporting/accounting

Allegations in 2014 Securities Fraud Lawsuits Against Life Sciences Companies	Number of Lawsuits
Alleged misrepresentations and/or non disclosures regarding product efficacy	5
Alleged misrepresentations and/or non disclosures regarding financial reports/accounting improprieties	8
Alleged misrepresentations and/or non disclosures regarding product safety	8
Alleged misrepresentations and/or non disclosures regarding marketing practices	4
Alleged misrepresentations and/or non disclosures regarding prospects/timing of FDA approval	5
Alleged misrepresentations and/or non disclosures regarding insider trading	3
Other alleged misrepresentations and/or non disclosures, including misrepresentations regarding CMO's continued employment with company and timing of completion of clinical trial	7
Alleged misrepresentations and/or non disclosures regarding manufacturing process	3

Duty of disclosure is paramount

- Common template for securities class action:
  - An unfavorable event (e.g., FDA nonapproval or negative study outcome) causes a sudden drop in stock price
  - Plaintiffs file suit and attack the company's disclosures in the months or years preceding the stock drop
  - Plaintiffs argue that the disclosures were overly optimistic and did not adequately warn about skeptical interim comments from the FDA or problems with the study
  - Company's ability to win MTD turns on gap between what its executives allegedly knew at the time of the disclosures and what they told the market
- Core issue: Materiality
  - SCOTUS: A company does not have an affirmative duty to disclose all material information that an investor might want, but it can be liable for not disclosing material facts that are necessary to prevent its affirmative disclosures from being misleading

Matrixx Initiatives and omissions liability

- *Matrixx Initiatives, Inc. v. Siracusano* (2011)
  - Pharmaceutical company stated that it "believes statements alleging that intranasal Zicam caused anosmia (loss of smell) are completely unfounded and misleading"
  - Clinical trials had shown no statistically significant rise in adverse events for Zicam versus placebo
  - Company learned of ten patients who allegedly lost sense of smell, followed by nine product liability lawsuits
  - Court: While there is no freestanding duty to disclose all bad facts, companies must disclose material facts if omitting would render affirmative statement misleading

Matrixx Initiatives (cont'd)

- *Matrixx Initiatives, Inc. v. Siracusano* (2011)
  - Even though adverse event reports did not show statistically significant correlation with loss of smell, failure to disclose adverse events arguably rendered company's denials misleading
  - Adverse event reports not automatically immaterial merely because they are statistically insignificant
  - Materiality judged from standpoint of reasonable investor, not management
  - Company also implied it had conducted studies on anosmia when in fact no study specifically targeted loss of smell
  - Company took other internal actions (*e.g.*, convening panel to examine issue, pressuring scientist not to use company's name) creating inference that nondisclosure was motivated by fear of stock price drop rather than belief information was immaterial

Omnicare: Omissions still problematic

- *Omnicare Inc. v. Laborers District Council* (2015)
  - No liability for "pure" opinions that are "sincerely held" by speaker **But…**
  - Embedded facts in statements of opinion can be actionable if untrue
  - Opinions can trigger *Matrixx*-style liability if company omits contrary facts that would render opinion misleading
  - The statement at issue in *Matrixx* used the word "believes" and arguably was an opinion
  - If opinion conveys impression that it was based on reasonable inquiry, speaker can be liable if it did not perform such inquiry
  - Mere fact that speaker knew of facts "cutting the other way" will not create liability unless facts are severe enough that they would render opinion misleading to reasonable investor

Sanofi decision

- *Tongue v. Sanofi*, No. 15-588, 2016 WL 851797 (2d Cir. Mar. 4, 2016)
  - No duty to disclose interim FDA communications as long as their public disclosures are sufficiently qualified and would not be materially misleading to reasonable investor without disclosure of the omitted facts
    - Liability for opinions can rest on either of two grounds:
      - (1) The opinion is *both* objectively false and disbelieved by the defendant at the time it was expressed
      - (2) The opinion is sincerely held and otherwise true as a matter of fact but the speaker omits information whose omission makes the statement misleading to a reasonable investor
    - Even if a company is aware of significant information that undercuts its expressed opinion or projection, liability will not lie where the plaintiffs are sophisticated investors and the omitted information amounts to a fact that merely "cut[s] the other way"

Application to life sciences companies

- Courts are generally reluctant to impose liability for not disclosing interim hiccups during FDA approval process
  - *Vallabhaneni v. Endocyte, Inc.*, No. 1:14-cv-01048-TWP-MJD, 2016 WL 51260, at *12 (S.D. Ind. Jan. 4, 2016) ("***[E]ven assuming the FDA's interim criticism of the Phase 2 study design was as severe as the Plaintiff suggests, numerous courts have concluded that a defendant pharmaceutical company does not have a duty to reveal interim FDA criticism regarding study design or methodology***";
- Dismissals have been granted in cases where the FDA: (i) expressed concerns about ongoing clinical studies; (ii) criticized the design of an ongoing study; (iii) expressed safety concerns; (iv) expressed concerns about the company's analysis of study results; (v) had requested additional studies; and (vi) had expressed reservations about a drug's efficacy

Companies must watch affirmative statements

- Dismissal denied where company disclosed a seemingly favorable 7 percent mortality rate for drug group arm without disclosing that patients in control group had zero deaths. *Delcath Systems Inc. Secs. Litig.*, 36 F. Supp. 3d 320, 332 (S.D.N.Y. 2014). 36 F. Supp. 3d 320, 332 (S.D.N.Y. 2014)
- Dismissal denied where company underplayed concerns about drug stability, submitted three months of stability data when FDA had asked for six months, and implied the submission was in "response" to FDA's request when it did not comply with FDA's request for six months of data. *KB Partners I LP v. Pain Therapeutics Inc.*, 11-CA-1034-SS, (W.D. Tex. Dec. 1, 2015)

Lessons

- Selective disclosures and “cherry-picking” favorable information pose significant risks
- Companies must assess how bad news fits into context of prior disclosures to determine if duty to disclose exists
- Opinions should be clearly identified and appropriately qualified; avoid words like “completely unfounded”
- Executives must carefully game-plan Q&A portions of earnings calls to avoid misleading statements
- Companies should have disclosures reviewed by counsel who understands securities litigation impact
- Companies should establish a disclosure review committee to make decisions on public disclosures
- Suits often target investor presentations and press releases where controls are less robust than 10-Ks

SEC enforcement trends

- Accounting-related enforcement actions up 46%
- Probing companies for non-GAAP financials, MD&A, risk/trends disclosures and impairments
- Strong emphasis on companies that do not timely report material weaknesses in internal controls
- Increasingly willing to bring non-fraud-based claims
- Has obtained big penalties without proving fraud
  - $80 million against Monsanto (Feb. 2016)
  - $46.9 million against Life Partners (Jan. 2015)
- SEC Chief Accountant: Life sciences companies must watch internal controls and revenue recognition

Emphasis on “non-fraud” violations and individual liability

- Section 13(a) of Exchange Act prohibits companies from filing false or untimely Form 10-Ks/10-Qs
- Section 13(b)(2)(A) requires companies to keep books, records, and accounts which in reasonable detail accurately and fairly reflect the company’s transactions and dispositions of assets
- Section 13(b)(2)(B) requires companies to devise system of internal controls with reasonable assurance
- Rule 13a-14 requires accurate SOX certifications
- Sections 17(a)(2) and 17(a)(3) of Securities Act prohibits raising money by misstatements/omissions
- SEC pursuing CEOs, CFOs, CAOs, audit chairs, internal audit managers and others who “cause” violations

Emphasis on non-periodic disclosures

- While SEC internal controls rules target 10-K and 10-Q disclosures, SEC has warned companies to maintain sufficient controls over press releases and presentations
- Many suits against life sciences companies arise from non-periodic disclosures where controls may be less robust – *e.g.*, updates on clinical trials and NDA status
- Life sciences companies should ensure all disclosures are thoroughly vetted by disclosure counsel and that an appropriate internal review process exists

Enforcement snapshot: AVEO Pharmaceuticals (March 2016)

- FDA recommended to AVEO before IPO that AVEO conduct an additional clinical trial for kidney cancer drug
- AVEO did not disclose FDA recommendation
- AVEO issued press releases suggesting that FDA only asked for explanation of results from first trial rather than whole new clinical trial
- AVEO CMO stated he could not “speculate” on what FDA “might be thinking” or “might want [AVEO] to do”
- AVEO paid $4 million penalty; claims against former CEO, CFO and CMO ongoing

SEC scrutinizing SOX certifications

- CEOs and CFOs must certify internal controls were designed and that they personally evaluated effectiveness of ICFR
- A material weakness only requires a “reasonable possibility” that a material misstatement will not be detected
- SEC pursuing companies and individuals for:
  - Not timely disclosing material weaknesses
  - Not personally evaluating effectiveness of ICFR
  - Not maintaining documentation to support evaluation
  - Using incorrect standard for evaluating deficiencies
  - Relying excessively on outside consultants
  - Inadequate disclosure controls over investor presentations and other less formal communications

Recent internal controls enforcement actions

- **QGSI:** Penalty and D&O bar where executive unfamiliar with Treadway Commission standards and concealed inventory control deficiencies from auditors
- **Saba Software:** $2.5 million clawback against CEO where deficient controls did not detect time-entry scheme
- **JDA Software**: $750,000 penalty for nonfraudulent control deficiencies in not establishing VSOE
- **PolyCom:** $750,000 penalty for control deficiencies leading to $200,000 in fudged expenses going undetected

Recent enforcement actions (cont'd)

- **Stein Mart:** $800,000 penalty for allowing marketing department to make accounting decisions about markdowns
- **MuscleFarm:** $700,000 penalty against company, $150,000 against CEO and $30,000 against CFO and audit chair for not reporting $500,000 in executive perks
- **Trinity Capital:** Fraud case against bank for manipulating loan loss disclosures, with non-fraud internal control charges against former VP of internal audit
- **Magnum Hunter:** $250,000 penalty after disclosing 14 MWs and terminating auditor; SEC alleged that MWs improperly classified as significant deficiencies and should have been disclosed earlier

Internal controls takeaways

- Certifying officers must adequately explain how they evaluated controls and must know the standards
- Companies should maintain contemporaneous documentation of internal control judgments
- For every deficiency, management and audit committees must ask whether it is a MW and be able to explain and document why it does not
- Accounting departments must be adequately staffed, with sufficient training and lines of responsibility
- Disclosure controls should cover press releases and investor presentations as well as 10-Ks/10-Qs

SOX certifications as basis for civil liability

- Accounting restatements and internal control deficiencies are traditionally insufficient to support Rule 10b-5 liability
- But arguments about false SOX and auditor certifications may be gaining traction
  - *In re OSG Securities* (S.D.N.Y.): Inaccurate auditor "opinion" on tax liability held to be actionable misstatement under Section 11
  - *In re Symbol Technologies* (E.D.N.Y.): Restated SOX certifications found to support 10b-5 fraud claim

FCPA scrutiny of life sciences companies

- Drugs and medical devices are frequently purchased by foreign governments, leading to bribe/kickback opportunities
- Clinical trials may be conducted at government facilities or with government employees, which can also create FCPA risk
- Life sciences companies must scrutinize overseas contracts and business practices to ensure compliance with FCPA and foreign anti-corruption laws

FCPA overview

- Enacted in 1977 to combat bribery of foreign officials by U.S. companies
- Contains two primary provisions (1) anti-bribery provision and (2) accounting and internal control provisions
- DOJ and SEC are agencies responsible for FCPA enforcement
- FCPA liability is concern for publicly-traded and private companies
- FCPA liability is concern for individual corporate actors working for a private company that conducts business outside the US

What is prohibited?

- Anti-bribery provisions prohibit
  - *"corruptly"* paying or offering to pay
  - *"anything of value"*
  - to *"foreign official"*
  - directly or indirectly
  - to secure *"improper advantage"*; influence foreign official in order to "obtain or retain business"
- Criminal liability attaches for *"willful"* violation
- Compliance difficult because "foreign officials" may have dual roles or be hard to identify

Increased focus on individuals

- On September 9, 2015, DOJ issued a memorandum entitled "Individual Accountability for Corporate Wrongdoing" (the "Yates Memorandum") outlining six steps that prosecutors should take in all future investigations

1. To qualify for any cooperation credit, corporations must provide the DOJ **all relevant facts relating to the individuals** responsible for the misconduct
2. Both criminal and civil corporate investigations should **focus on individuals from the outset** of the investigation
3. The criminal and civil attorneys handling a corporate investigation should routinely be in communication with each other
4. **Absent *"extraordinary circumstances"*** or approved departmental policy, **individuals will receive no release from civil or criminal liability** as part of the DOJ's resolution of investigations involving corporate wrongdoing
5. DOJ attorneys are admonished not to resolve corporate matters without a plan to resolve related individual matters and to memorialize any declinations as to individuals in such cases
6. The Department's civil enforcement attorneys are directed to focus consistently on individuals in addition to the company and to evaluate whether to bring suit against an individual based on factors other than the individual's ability to pay

Pointers for avoiding liability

- Conduct due diligence on contracting parties, particularly when venturing into new or high-risk foreign markets
- Conduct a background check on all parties involved
  - agents, consultants, distributors, licensees, representatives
  - search Office of Foreign Asset Control (OFAC) sanctions list
- Understand role of all parties and agents
  - why are they involved?
  - what do they actually do?
  - what is relationship with government agencies and officials?
- Include provision in contract requiring compliance with FCPA and allowing termination if any anti-corruption law is violated
- Also consider limiting duration of contract in unfamiliar high-risk jurisdictions so that ties can be severed easily if corruption issues arise

Rise of the whistleblower

- Dodd-Frank whistleblower bounty program has contributed to heightened SEC enforcement risk
- Many life sciences companies have significant turnover and can face whistleblower complaints from disgruntled employees
- SEC now receives 4,000 tips per year
- Bounties paid to foreign workers, officers and even compliance personnel
- Specialized plaintiff firms have encouraged whistleblowers to come forward

Individuals can be liable for retaliation

- Federal court holds that individual directors of life sciences company could be liable for terminating whistleblower
  - *Wadler v. Bio-Rad Labs.*, 2015 WL 6438670 (N.D. Cal. Oct. 23, 2015)
- Sarbanes-Oxley provides that an *"officer, employee, contractor, subcontractor, or agent"* can violate the Act
  - Court concluded that although statutory language ambiguous, director may be held individually liable as an *"agent"* given broad purpose of Sarbanes-Oxley
- Dodd-Frank permits whistleblowers to sue an *"employer"* for retaliation but does not define *"employer"*
  - Court concluded that Congress intended that Dodd-Frank provide for individual liability at least as extensive as Sarbanes-Oxley

Difficult situations

- What if your trusted advisor blows the whistle (HR employee or in-house legal counsel)?
- What if whistleblower is a compliance officer whose job is to investigate misconduct?
- What if your whistleblowing employee won't cooperate during the investigation?
- What if you need to fire your whistleblower?
  - When?
  - Balance of Documentation
  - Limited Release

Encourage whistleblowers to report internally

- Take complaints seriously and treat whistleblowers with respect; many whistleblowers go to SEC after reporting internally and being spurned
- Make sure employees know and trust the person to whom internal complaints should be directed
- Provide written company policies to employees
- Effective internal monitoring and auditing essential
- Ask employees to identify all potential complaints during exit interviews and sign appropriate releases

Confidentiality agreements: SEC Rule 21F-17(a)

- *"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 . . . with respect to such communications"*
- SEC pursuing companies that do not include carve-out language protecting whistleblowers
- Big issue for life sciences companies due to importance of confidentiality agreements
- Individuals, including lawyers, can be liable

TCPA “junk fax” class actions

- Many pharma companies still send faxes to pharmacies
- Telephone Consumer Protection Act imposes $500 penalty per “unsolicited” fax containing “advertising” materials
- Strict liability; class certification creates strong settlement pressure
  - *E.g.*, recent $15 PharMerica settlement in Nov. 2015
- Any encouragement to recommend drug or touting of drug benefits can be construed as advertising
- Companies liable for faxes sent by marketing department or outside vendors
- Companies must also include opt-out language, although that alone will not excuse liability
- Make sure legal department or outside counsel oversees and vets any fax communications


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