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PHARMA COMPLIANCE CONGRESS

Preparing to Be Acquired and Pre-Deal Due Diligence

October 2015

U.S. v. Fabian & Facteau

- Two executives of a medical device company, Acclarent, were indicted on April 8, 2015 – President/CEO and the VP of Sales.
- 18-count indictment alleging conspiracy, securities fraud, wire fraud, distribution of an adulterated device, and misbranding.
- Approved Indication: FDA approved the device to "mechanically maintain an opening to the sinus for 14 days" after surgery and to be used only with saline.
- Sale: In 2010, Acclarent was purchased by Ethicon, Inc., a subsidiary of Johnson & Johnson ("J&J")

The Charges

- Securities Fraud (15 U.S.C. 78j(b) & 78ff(a),17 C.F.R. 240.10b-5) (Counts 2-4)
  - The Indictment charges that Defendants "concealed" from J&J and Ethicon "Acclarent's illegal conduct in promoting and distributing Stratus as a steroid delivery device."
  - Allegedly, during negotiations for the sale, Defendants made "fraudulent statements and material omissions" about Stratus's design and intended use, as well as promotion of the device, in order to make Acclarent a "more desirable target" and "increase payments received from Ethicon."
  - The Indictment cites Defendants' representations on compliance and regulatory matters made in the 2010 merger agreement. Each count of securities fraud is associated with a separate pay-out of Acclarent Stock and Options under the agreement.

The Charges

- Wire Fraud (18 U.S.C. 1343, 1349, and 2) (Counts 5-8)
  - Four counts assert a theory of fraud on the FDA by devising a scheme to sell Stratus fraudulently for an intended use not approved by the FDA (as a steroid delivery device) and by hiding that conduct from FDA.
  - Each count is associated with a separate email from the defendants or a company sales rep allegedly promoting off-label use by stating that the device "allows for direct bathing with a solution for the infected sinuses [and] . . . for patient not to have to take oral steroids." In Count 7, the Indictment cites an email from the VP of sales, referencing a sales training program for promotion of the Stratus device.

The Charges: Title 21

- Distribution of Adulterated Substances (21 U.S.C. 331(a), 333(a)(1)-(2), 351(f)(1)(B) (Counts. 9-19).
  - The Indictment asserts 5 counts of sale of an adulterated substance, defined as a "Class III device that lacked an FDA-approved pre-market approval"
  - Acclarent allegedly sought FDA clearance by representing that Stratus was comparable to medical devices already on the market for mechanically maintaining an opening to the sinus following surgery and moistening the sinus with saline, when Acclarent actually designed and intended to promote use of the Stratus device to deliver a thicker steroid substance rather than saline.

The Charges: Title 21

- Misbranding/Lack of Adequate Directions for Use (21 U.S.C. 331(a), 333(a)(1)-(), 352(a), 352(f), 352(o) (Counts. 14-18)
  - The indictment also cites 5 counts of misbranding, alleging that sales of Stratus involved false and misleading labeling and inadequate directions for use.
  - The indictment cites to promotional materials prepared in advance of the stratus launch where the device is pictured with a milky substance rather than clear saline. The promotional materials cited in the Indictment explain that the use of other than saline in the stratus devise is an off-label use (being explored in further clinical trials) and that the device was only cleared for use with saline.

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- Alleged Off-Label Promotion:
  - The April 8, 2015 indictment alleges that Acclarent marketed Stratus as a steroid delivery device instead of saline. Allegedly the device was designed specifically to elute a thicker substance and that saline would run right out after injection.
  - In April, 2007, Acclarent pursued a broader clearance for the device, that it might be indicated “for use to irrigate the sinus space for diagnostic and therapeutic procedures.”
  - In December, 2007, FDA determined that use of the Stratus devised as a delivery system for a steroid raised “significant risks” and ordered Acclarent to halt additional clinical studies on this use.

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- The Company was sold
- The purchaser discovered these activities and directed Acclarent to stop all promotion and notify the FDA. Acclarent did notify the FDA, but allegedly continued promoting Stratus after this.

Government Theory: Off Label Promotion

The Food, Drug, Cosmetic Act ("FDCA"), prohibits the misbranding of drugs. 21 U.S.C. 331(a).

- Drugs are misbranded where their labeling does not contain "adequate directions for use," which are limited to a drug's "intended use." 21 U.S.C. 352(f); 21 C.F.R. 201.5.
- When a company promotes a product beyond its approved indication or in a manner not "consistent with" the approved prescribing information, it creates a new "intended use" and is therefore misbranded.

Elements of a Misdemeanor FDCA Offense:

- To distribute, or cause the distribution of, a drug in connection with interstate commerce as outlined in the statute, *and*;
- The drug was adulterated or misbranded.
- No element of knowledge or intent

Elements of a Felony FDCA Offense:

- Above acts, with "intent to defraud or mislead

Defenses to Misbranding

- Truthful, non-misleading statements about an approved drug are not actionable as either a misdemeanor or felony under the FDCA's criminal provisions-- even if they are not expressly stated in the product's PI
  - The PI is only "a summary" of the information supporting approval. 21 CFR 201.56(a)(1).
- Statements about a product that are truthful and non-misleading are protected commercial speech under the First Amendment and cannot be criminally prosecuted. U.S. v. Caronia (2d Cir. 2012)

Government Theory: Securities Fraud

- Section 11 of the Securities Act grants investors a private right of action for material misstatements or omissions in registration statements.
  - No scienter required
    - The investor does not need to prove that the defendant acted with any intent to deceive or defraud.
    - *See Omnicare, Inc. v. Laborers Dist. Council Const. Indus.*, 135 S.Ct. 1318 (Mar. 24, 2015)

- Section 10b of the Exchange Act grants investors a private right of action for material misstatements or omissions made any forum (e.g. press releases).
  - Scienter is required

Wire/Securities Fraud – As Applied to Opinions

- Misstatement Liability -- statement of opinion does not constitute an untrue statement of fact simply because the opinion ultimately proves incorrect. So long as:
  - Speaker believes (i.e. sincerely holds) his opinion; and
  - Any stated underlying facts contained in the opinion are true.

- Omission Liability – liability can exist if:
  - Registration statement omits material facts about the company's inquiry into, or knowledge about, a statement of opinion, AND
  - Those omitted facts conflict with what a reasonable investor would take from the statement.
    - This is an objective inquiry.
    - Specificity of opinion matters.

Securities Fraud – As Applied to Opinions

- What if speaker did not believe his opinion but opinion turned out to be true?

- The Supreme Court, in recent *dicta*, stated that Section 11 would not impose liability.
  - "[S]uch an inadvertently correct assessment is unlikely to cause anyone harm."

Securities Fraud – Recent D. Mass. Decisions

- "Bespeaks Caution" Doctrine can protect statements in press releases.
  - "when statements of soft information such as forecasts, estimates, opinions or projections are accompanied by cautionary disclosures that adequately warn of the possibility that actual results or events may turn out differently, the soft statements may not be materially misleading under the securities laws."

Battle Construction Co., Inc. v. InVivo Therapeutics Holdings Corp., 2015 WL 1523481 (D. Mass. April 3, 2015)

Securities Fraud – Recent D. Mass. Decisions

- Interpretations of data constitute "non-actionable expressions of opinion" unless:
  - The company's opinions were both objectively and subjectively false; or
  - Self-embedded facts within the opinion are not true; or
  - Material facts about the opinion holder's inquiry into or knowledge concerning a statement of opinion were omitted.
- "It is not illegal … to paint a positive or optimistic picture when disclosing information to investors as long as such a picture is not misleading."

  Corban v. Sarepta Therapeutics, Inc., 2015 WL 1505693 (D. Mass. Mar. 31, 2015)
  - Case involved statements and omissions about a company's drug candidate for the treatment of a rare disease

Government Theory: Exclusion From All Federal Health Care Programs

- Significant collateral consequences exist for conviction of fraud.
- The Social Security Act requires mandatory exclusion of an entity and/or individual from participating in all federal health care programs if convicted of certain felonies, including fraud.
  - *See* 42 U.S.C. 1320a-7(a)(1)-(4).
- OIG "shall exclude … [a]ny individual or entity that has been convicted for an offense … in connection with the delivery of a health care item or service … consisting of a felony related to fraud …."
  - *Harkonen v. Sebelius*, 2013 WL 5734918, *2 (N.D. Cal. 2013)

“In connection with the delivery of a health care item or service”

- “In connection with the delivery of a health care item or service” requires:
  - Common sense connection or nexus between:
    - the underlying facts and circumstances of the offense, and
    - the delivery of health care items or services to individuals for their health care needs.
- Statements made in press release (which served as the basis for felony wire fraud conviction) have been found to constitute “delivery of a health care item or service.”

Hypo

Facts

- SaveAlot Pharma, Inc., based in San Fran
- Publicly traded company
- Aggressive Acquirer
- Growth by acquisition, no R&D (only marketed products)
- Revenue roughly $10B/year

Compliance

- You are an N of 5 in Compliance
- Mostly focused on US but have existing EU operations/sales
- Focus is on Latin America, MEA

Potential Deal #1

- Latin America Pharma
- Sales in all LA countries
- Boots on the ground
- Full acquisition

Deal #1 Questions

- Pre-Close
  - What are must-reviews if at all?
  - How much pre-close diligence do you obtain?
  - What is your focus during the pre-close?
    - Does it matter if you are N of 1 or 5 or 10?
- Post-Close
  - Where do you start?
  - What is your focus now?
  - The dye has been cast but so what…

Deal #1: Switch Chairs

- As Entity being acquired, what are your risks?
  - What disclose
  - From which sources in company
  - How does message look from ten steps away
  - Your business risks?
  - Your compliance/enforcement risks?

Potential Deal #2

- Asset purchase from Global Pharma
- MEA is the possible license (scope)
- No boots on the ground and theory is Named Patient/Distributors

Deal #2

- Pre-Close
  - Is your focus/must-haves any different?
  - Because this is an asset purchase is it different?
  - To the extent different, what is your focus?
  - Is there anything geographically different?
- Post-Close
  - Again, any differences from Deal #1?
  - What is your focus now?

Deal #2: Switch Chairs

- Does your preparation change?
- Do your disclosures change?
- Your business risks?
- Your compliance/enforcement risks?

Other Takeaways – Planning

Plan Before and For the Deal

- Plan Before there is a deal
  - Sensitize BD and executive team to importance of compliance before an acquisition is in the pipeline
  - Identify key resources if the regular M&A counsel or advisors don't have the capability to assist
  - Create an expectation that external resources will be in the deal budget; make it part of the compliance culture
  - Develop a diligence list that can be included as part of the standard diligence request list submitted by the BD team

Other Takeaways – Planning cont'd

- Plan for the Deal
  - Understand the deal structure and objectives
  - Align with the business team on strategic rationale
  - Consider the target's profile and indicators of risk
  - Take into account key variables and common challenges
  - Set expectations and have your plan as part of the overall deal timeline

Other Takeaways – Select Key Variables

- Deal structure: company acquisition, carveout, product acquisition, etc.
- Target: public or private?
- Geography
  - The FCPA, UK Bribery Act and more
- Available resources, both internal and external
  - How many on internal team? How many of them are in the tent?
  - Does the deal counsel have the necessary experience?
- Stage of product development
- Nature of target's business and use of third parties
  - Manufacturing, promotion, distribution, etc.
  - Third parties can impact risk profile
- Prior/ongoing compliance matters (CIAs, investigations, etc.)

Other Takeaways – Select Challenges

- The expectations of others
  - Compliance not often considered a significant risk
  - Rarely viewed as having the ability to scuttle a deal
- Speed at which the transaction is moving
- Potential limitations on availability of information
  - Deal speed
  - Small group of people in the tent on the target side, or on your side
  - External advisors (yours and theirs) filter the wrong information
  - Potential antitrust concerns
- The importance of finding “synergies”
  - Not every deal should have synergies on the compliance side

Other Takeaways – High-level Observations

- Diligence can be more than just having discussions to understand what the target is doing
- Discussions about what the target is doing help to form an assessment of a compliance culture, which speaks to risk and potential for increased future costs
- Consider the broader context
  - Do promotional materials match up to public statements (i.e., SEC filings, earnings materials, etc.)?
  - Are there any employee related trends, litigation or claims?
  - Can you spot check ("audit") certain items? Match actual payments with payment limits under policies.

Other Takeaways – High-level cont'd

- Be careful of how your team writes about potential issues that are identified
  - Avoid conclusory statements
  - Consider privilege
- "Guess what, we're violating the law!"
  - Targets don't tell you that
  - Unlikely to find problems that people are trying to hide
  - Hard to identify fraud and major instances of non-compliance

Other Takeaways –Target Considerations

- Acquisition can bring compliance issues to the surface
  - Can crater a deal
  - Acquirer may (will likely?) report issues when they are discovered post deal
    - Can lead to personal liability
    - In smaller companies, this can be used to help “scare” people straight in general operations
- Consider using your own advisors to do “sell-side” diligence prior to providing information
- Consider a diligence exercise in the absence of a deal

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