The *Harkonen* Conviction and the Scientific Exchange Doctrine

Pharma Congress: State and Federal Enforcement of Off-Label Promotion

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Facts Regarding of Actimmune

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- Dr. W. Scott Harkonen was the CEO of InterMune from 1998 to 2003 and a member of the Board of Directors
- Actimmune has two narrow orphan indications:
  - for reducing the frequency and severity of serious infections associated with Chronic Granulomatous Disease and
  - for delaying time to disease progression in patients with severe, malignant osteopetrosis
- DOJ alleged that InterMune falsely marketed Actimmune (interferon gamma-1b) to treat idiopathic pulmonary fibrosis (IPF)
- Company settled civil and criminal claims for $36M in 2007
  - $6.2M to the States
  - Deferred Prosecution Agreement
  - Corporate Integrity Agreement

Harkonen's Conduct

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- InterMune issued a press release announcing the results of a clinical trial of Actimmune for treatment of IPF on August 28, 2002
- "InterMune Announces Phase III Data Demonstrating Survival Benefit of Actimmune in IPF: Reduces Mortality by 70% in Patients with Mild to Moderate Disease"
  - The study had failed to achieve its primary endpoint, and these conclusions were based on post-hoc subset analyses
  - InterMune presented these data to FDA which found them insufficient to support an indication without further testing
- Government alleged that Harkonen:
  - Drafted the press release's title and controlled its contents
  - Hired a marketing firm to evaluate the release's effect on pulmonologists' willingness to prescribe
  - Sent release to all sales reps
  - Faxed to more than 2000 pulmonologists
  - Included the press release along with drug shipments by specialty pharmacies

The Indictment and the Motion to Dismiss

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- Harkonen was indicted in March 2008
- Charged with two counts related to the press release:
  - wire fraud, 18 USC 1343
  - FDCA causing the misbranding of a new drug and disseminating the press release with "intent to defraud or mislead." 21 USC 331(k), 333(a)(2) and 352(a)
- Harkonen filed a motion to dismiss the indictment which included two arguments

  1) The press release did not constitute labeling for Actimmune
     - Rather, it fell within a safe harbor for scientific exchange

  2) The press release was protected by the First Amendment as pure scientific speech or commercial speech intertwined with scientific speech

The District Court Rejected Both Arguments

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1) The press release is labeling under the *Kordel* doctrine

- "… labeling under the FDCA is construed expansively, such that it may encompass nearly every form of promotional activity, including package inserts, pamphlets, mailing pieces, fax bulletins, reprints of press releases, and all other literature that supplements, explains, or is otherwise textually related to the product."

2) The press release is not protected speech under the First Amendment

- "That the speech is a press release and not a peer-reviewed publication, that it refers to a specific commercial product on the Market (Actimmune), and that it was unquestionably disseminated for commercial benefit…are allegations that take the speech at issue outside the realm of pure speech and move it towards the realm of commercial speech."
- "Government has right to regulate false and misleading statements made to doctors and patients about drug products…."

The Trial

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- Jury trial in Northern District of California lasted three weeks
- Harkonen put on witnesses who alleged that others in the company were responsible for the press release
- Found guilty of wire fraud on September 29, 2009
  - Acquitted of misbranding charge
- Sentencing has not yet occurred:
  - Maximum penalty under 18 USC 1343 is 20 years in prison, $250K fine and 3 years of supervised release

DDMAC on News Material

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- Tom Abrams, answering questions at a FDLI conference in September, stated that press releases describing a specific product should be submitted to FDA/DDMAC under Form 2253
- October 8, 2009: FDA issued a Warning Letter to King Pharmaceuticals for video news releases regarding Embeda (morphine sulfate and naltrexone HCl) Extended Release Capsules
  - Omitting and/or minimizing the risk information
  - Failing to present the limitations of Embeda's approved indication, and
  - Presenting misleading claims

Difficult Balance with Scientific Exchange Doctrine

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- Section 312.7 recognizes that companies have a need to announce data, particularly to investors
- Now must carefully assess risks
  - Especially with respect to new data about approved products
- FDA/SEC MOU may take on new meaning
  - When is the announcement made? How is it presented?
- Submit on Form 2253 if the press release will be used in the field
  - Harkonen's use of the release beyond notifying investors through the media was a critical factor in influencing whether it was "scientific exchange"

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