KING & SPALDING

Litigation Affecting Regulatory & Quality Professionals

February 28, 2018

PRESENTED BY:

Executive Director, Senior Counsel - Litigation & Commercial Eye Care, Allergan
Donald P. Bunnin, Esq.

Associate General Counsel and Chief Compliance Officer, ABIOMED, Inc.
Sean C. Flynn, Esq.

Partner, King & Spalding LLP
Jeffrey S. Bucholtz, Esq.

Partner, King & Spalding LLP
John C. Richter, Esq.

Relevant Cases

United States v. Caronia (2d Cir. 2012, criminal prosecution)

- Holding: prosecution for misbranding based on truthful/non-misleading promotion alone violated the 1st Amendment
- Legacy: 2d Cir. becomes testing ground for 1st Amendment challenges to restrictions on off-label promotion

Amarin v. FDA (S.D.N.Y.) (dec. action/PI decision 2015, settled 2016)

- Legacy: amplified holding in *Caronia*, clarified *Caronia* not a one-off

Pacira v. FDA (S.D.N.Y.) (dec. action, settled in 2015)

- Legacy: built on *Caronia/Amarin* momentum by challenging what constitutes on-label v. off-label and winning

United States v. Vascular Solutions, Inc. (W.D. Tex. 2016)

- Device cleared for laser ablation of varicose veins in lower extremity, with general reference to varicosities but no specific mention of “perforator” veins (which connect superficial and deep veins)
- Device allegedly promoted for treatment of perforator veins, which defendants contended fell within scope of existing clearance’s indications for use and govt. contended was off-label and required supplemental clearance. No evidence or even allegations of patient harm
- Only off-label promotion case against publicly traded company to go to trial
- VSI’s co-founder and CEO, Howard Root, was charged as well
- Govt. charged misdemeanor misbranding and conspiracy to misbrand and felony conspiracy to defraud FDA
- HHS OIG Chief Medical Officer said at a conference that govt. “hand-picked” this case to send message to industry
- Jury returned complete defense verdict on all counts for VSI and Root

United States v. Vascular Solutions, Inc. (W.D. Tex. 2016)

Advances include:

- Jury instructions were explicit that defendants must be acquitted of misbranding if their alleged off-label promotion was truthful and non-misleading
- First time since *Caronia* that First Amendment protection for truthful off-label promotion was recognized outside 2d Cir.
- Govt. sought to avoid First Amendment by alleging false or misleading promotion and conspiracy, but verdict underscores that those allegations are hard to prove
- Testimony and closing argument distinguished sharply between non-binding FDA guidance and informal practice versus actual law, which is much more limited

Legacy: DOJ and FDA are being more cautious about which off-label cases to bring, both as it relates to the truthfulness of the speech at issue and also how clearly off-label it is.

Collegium Untitled Letter

February 9, 2018

The company received an Untitled Letter related to its exhibit booth at the American Society Health-System Pharmacists (ASHP) Summer Meetings & Exhibition 2017.

The letter asserted that the company's exhibit booth makes false or misleading representations because it fails to adequately communicate information about the serious risks associated with Xtampza ER use: namely, due to the use of a side panel displaying warnings in a smaller font and a plain white background and due to the fact that other information about the limitations of the drug's benefits were at the bottom of a panel near the floor and blocked by a table and chair.

The letter states, "The exhibit booth makes false or misleading representations because it fails to adequately communicate information about the serious risks associated with Xtampza ER use. Therefore, the exhibit booth misbrands Xtampza ER within the meaning of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), and makes its distribution violative. 21 U.S.C. 352(a); 321(n); 331(a). *Cf.* 21 CFR 202.1(e)(3)(ii), (e)(5). These violations are particularly concerning given the serious public health impacts of opioid addiction, abuse, and misuse that can lead to overdose and death."

Changes in the New Administration

Scott Gottlieb, the new FDA Commissioner

During his Senate confirmation hearing on April 27, 2017, Gottlieb appeared to support the idea of loosening restrictions on off-label communications. He said he believes “that patients and physicians make the best decisions when they have access to as much truthful, nonmisleading, scientifically based information as possible.”

(Source: https://www.bna.com/offlabel-drug-promotion-b73014450900/)

Jan. 2018 – FDA again delayed the “intended use” final rule issued in the final days of the Obama Administration while promising further rulemaking

The Sessions Memorandum

November 16, 2017

Attorney General Sessions, recognizing "the fundamental requirement that agencies regulate only within the authority delegated to them by Congress," issued a memorandum significantly restricting the Department of Justice's use of its own guidance documents:

"Agencies may use guidance and similar documents to educate regulated parties through plain-language restatements of existing legal requirements or provide non-binding advice on technical issues through examples or practices to guide the application or interpretation of statutes and regulations. But guidance may not be used as a substitute for rulemaking and may not be used to impose new requirements on entities outside the Executive Branch. Nor should guidance create binding standards by which the Department will determine compliance with existing regulatory or statutory requirements."

"Guidance documents should not be used for the purpose of coercing persons or entities outside the federal government into taking any action or refraining from taking any action beyond what is required by the terms of the applicable statute or regulation. . . . To the extent guidance documents set out voluntary standards (e.g., recommended practices), they should clearly state that compliance with those standards is voluntary and that noncompliance will not, in itself, result in any enforcement action."

The Brand Memorandum

January 25, 2018

Associate Attorney General Rachel Brand issued a memorandum significantly restricting DOJ's use of executive agency guidance documents in affirmative civil enforcement actions. The Brand Memo

- Reinforces the long-standing principle that guidance documents are just that—recommendations for regulated industries—and not law;
- Emphasizes that guidance may not create new legal obligations beyond the scope of existing statutes and regulations;
- Prohibits DOJ litigators from "effectively convert[ing] agency guidance into binding rules" by using noncompliance with guidance to establish violations of law.

"Department litigators may not use noncompliance with guidance documents as a basis for proving violations of applicable law in ACE [affirmative civil enforcement] cases . . . agency guidance documents cannot create any additional legal obligations."

The Impact of the Brand Memorandum

- The Brand Memo signals a welcome return to first principles regarding following the law when engaged in law enforcement.
- But the Brand Memo has important limits:
    - it doesn't bind HHS-OIG or anyone else outside of DOJ.
    - it applies by its terms only to civil enforcement actions. The rule-of-law and fair-notice principles animating the memo should apply (even more so) in criminal cases.
    - the line between using guidance documents for permissible purposes and effectively converting guidance into binding rules will not always be clear or easy to enforce
- The Memo provides new bases for advocacy, as the government has often sought to frame theories of liability around non-binding guidance documents. Not only will companies be able to point to the Brand Memo to dissuade line attorneys from pursuing theories of liability not clearly within statutory or regulatory text, but they will also have new avenues of appealing to Main Justice when line decisions appear to conflict with this new Department policy.
- The Memo does not limit companies' use of guidance for *defensive* purposes.

Q&A

- What are the issues that your clients are asking about the most these days?
- What are areas where more and/or clearer FDA guidance would be helpful?
- What are the areas of greatest disagreement with DOJ's, FDA's, or OIG's approach?