NAVIGANT

LIFE SCIENCES

Scientific Exchange: What Every Compliance Officer Should Consider

Saul B. Helman, M.D

October 21, 2015

The Sixteenth Pharmaceutical Compliance Congress and Best Practices Forum

Table of Contents

NAVIGANT
LIFE SCIENCES

What is Scientific Exchange?

NAVIGANT

LIFE SCIENCES

What is Scientific Exchange?

- What is scientific exchange?
  - It is not promotional exchange!

- What does that mean?
  - Promotion = "something (such as advertising) that is done to make people aware of something and increase its sales or popularity"*

*http://www.merriam-webster.com/dictionary/promotion

NAVIGANT
LIFE SCIENCES

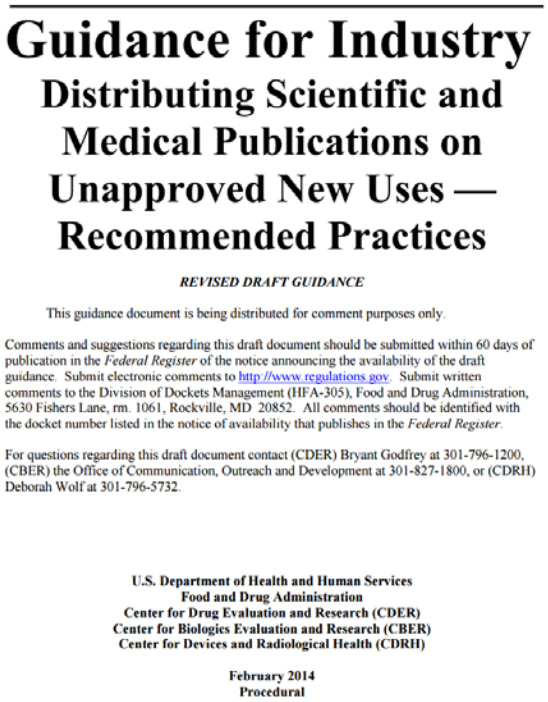
Does the HCP Discern?

- Medical sales representative
- Medical representative
- Pharmaceutical liaison
- Drug representative

NAVIGANT
LIFE SCIENCES

What is Scientific Exchange, Anyway?

- Scientific exchange is
  - clearly non-promotional
  - conducted by scientifically trained professionals
  - held in a forum or context that is conducive and reflective of scientific discussion



Guidance for Industry

Distributing Scientific and Medical Publications on Unapproved New Uses — Recommended Practices

REVISED DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact (CDER) Bryant Godfrey at 301-796-1200, (CBER) the Office of Communication, Outreach and Development at 301-827-1800, or (CDRH) Deborah Wolf at 301-796-5732.

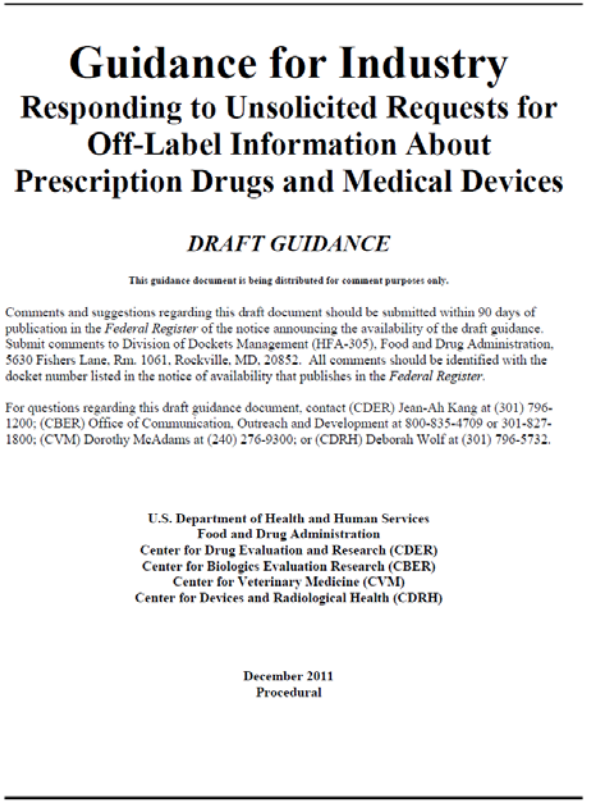
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)

February 2014
Procedural

NAVIGANT
LIFE SCIENCES

What is Scientific Exchange, Anyway?

- It can be proactive or reactive
  - Proactive scientific exchange – publications, compendia, medical education, clinical practice guidelines, company sponsored clinical study discussions, and pre-approval disease state discussions
  - Reactive scientific exchange – responses to an unsolicited inquiry for information, which could include off-label information, and the scientific exchange addresses that inquiry only



Guidance for Industry

Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD, 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft guidance document, contact (CDER) Jean-Ah Kang at (301) 796-1200; (CBER) Office of Communication, Outreach and Development at 800-835-4709 or 301-827-1800; (CVM) Dorothy McAdams at (240) 276-9300; or (CDRH) Deborah Wolf at (301) 796-5732.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation Research (CBER)
Center for Veterinary Medicine (CVM)
Center for Devices and Radiological Health (CDRH)

December 2011
Procedural

NAVIGANT
LIFE SCIENCES

Easy enough! What could possibly go wrong?

- Simply put, if an effective compliance program is not designed, implemented, and operationalized, “scientific exchange” can blur into “off-label promotion,” leading to
  - *Qui tam* actions
  - Federal investigations
  - Investor lawsuits
  - Financial and reputational damage
  - Settlements (141 settlements worth $21B in period 2000-2014)
  - Corporate Integrity Agreements

WHAT’S A COMPLIANCE OFFICER TO DO?!?!?!?!?!?

Better Practices for Separating Scientific Exchange and Promotional Messaging

NAVIGANT

LIFE SCIENCES

Generally speaking…

- Maintain policies and procedures and refresh them regularly in light of evolving government and industry guidance

- Train, audit, and monitor on the separation between scientific exchange and promotional messaging

- Focus on the following seven areas:
  - Promotional Materials
  - Promotional Interactions with HCPs
  - Medical Interactions with HCPs
  - Payer/Formulary Access Interactions
  - Publications
  - Investigator-Initiated Studies
  - Post-market Studies
  - Compendia

NAVIGANT
LIFE SCIENCES

An Evolving Legal Landscape

NAVIGANT

LIFE SCIENCES

U.S. v. Caronia (2012)

- U.S. filed suit against Alfred Caronia, a pharma sales rep, for off-label promotion under Food, Drug, and Cosmetic Act ("FDCA") misbranding provisions

- In U.S District Court, Caronia was convicted of conspiracy to introduce a misbranded drug into interstate commerce

- On appeal to the U.S. Court of Appeals for the Second Circuit, Caronia argued that the "1st Amendment does not permit the government to prohibit and criminalize a pharmaceutical manufacturer's truthful and non-misleading promotion of an FDA approved drug (to physicians) for off-label use, where such use is not itself illegal and others are permitted to engage in such speech."

U.S. v. Caronia cont'd

- The judgment of conviction had to be vacated because the government prosecuted Caronia for mere off-label promotion, and the district court instructed the jury that it could convict on that theory. The government had not established a reasonable fit among its interests in drug safety and public health, the lawfulness of off-label use, and its construction of the FDCA to prohibit off-label promotion.

- Ruling: The court ultimately concluded that the misbranding provisions of the FDCA don't prohibit a pharmaceutical company's truthful off-label promotion

Caronia: Potential Implications

- Creates a level of uncertainty and risk in the industry
  - Should pharma companies begin actively marketing off-label with the jurisdiction of the 2nd Circuit?
  - Risk that reps or other agents will misinterpret the case

- What exactly are “truthful” and “non-misleading?”
  - This was not discussed in much detail in the case because the government never argued, in District Court, that the off-label discussions were false or misleading.
  - Could it be argued that to be “truthful and not-misleading;” it must be included in the label or have substantial evidentiary support?

Amarin Pharma v. U.S. Food and Drug Admin. (2015)

- Case centered around the ability of Amarin Pharma to engage in truthful and non-misleading commercial speech regarding the off-label use of its drug Vascepa
- Court extensively cited U.S. v. Caronia when deciding case
- Nevertheless, the court also acknowledged the risk associated with a lack of controls regarding off-label discussion
- Ruling: Amarin granted preliminary relief to engage in truthful and non-promotional speech regarding off-label use of Vascepa
  - Under Caronia, this speech cannot be the basis of future misbranding prosecution

Amarin: Potential Implications

- Ruling shines light on FDA's stance on proactive promotional activities vs. Scientific Exchange
  - FDA needs to align its promotion policies with 1st Amendment expectations
- Pharma and device companies will use Amarin to bolster defense against off-label allegations
- However, an effective Compliance program is still needed

Thank You!

Saul B. Helman, M.D.
Managing Director & National Practice Lead
Healthcare, Life Sciences, Disputes, Regulatory & Investigations
317.228.8726
saul.helman@navigant.com

NAVIGANT
LIFE SCIENCES


NAVIGANT