FDLI Advertising and Promotion for Medical Products Conference
October 16-17, 2018

Nontraditional Venues: Are They Promotional?

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AGENDA

- Promotion vs. Non-Promotion
- Is it Promotional?
  - Examples and Discussion
    - Conference Booths
    - Corporate & Investor Communications
    - Co-Promotion / Co-Marketing
    - Medical Affairs Communications
    - Disease Awareness
- Mixing in Social Media
- Liability of Marketing Partners and Third Parties

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PROMOTION VS. NON-PROMOTION

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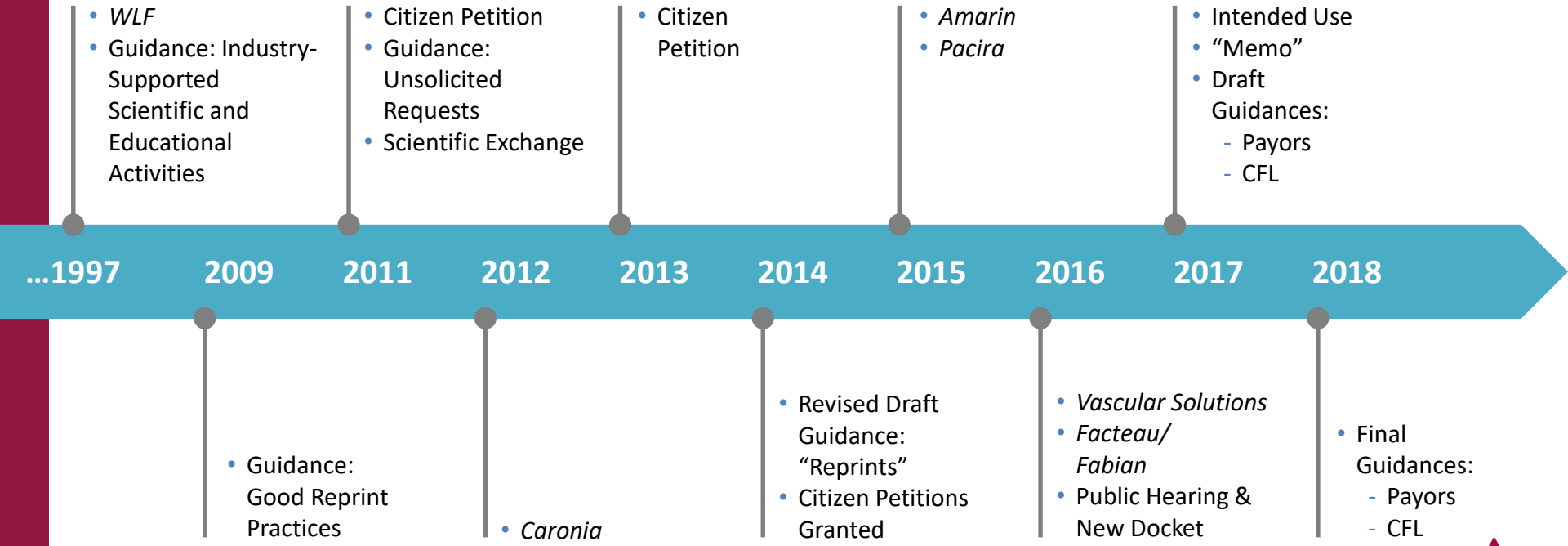
EVOLUTION OF FDA FIRST AMENDMENT POLICY



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WHAT IS NOT (PRODUCT) PROMOTION?

Types of communications, if delivered in a manner consistent with FDA guidance, that are *not* typically considered to be promotional

Scientific Exchange

- Scientific Presentations & Publications
- Independent Scientific & Educational Activities
- Responses to Unsolicited Requests
- Reprints
- ClinicalTrials.gov
- Payor Communications re: Unapproved Drugs & Uses

"Internal" Communications

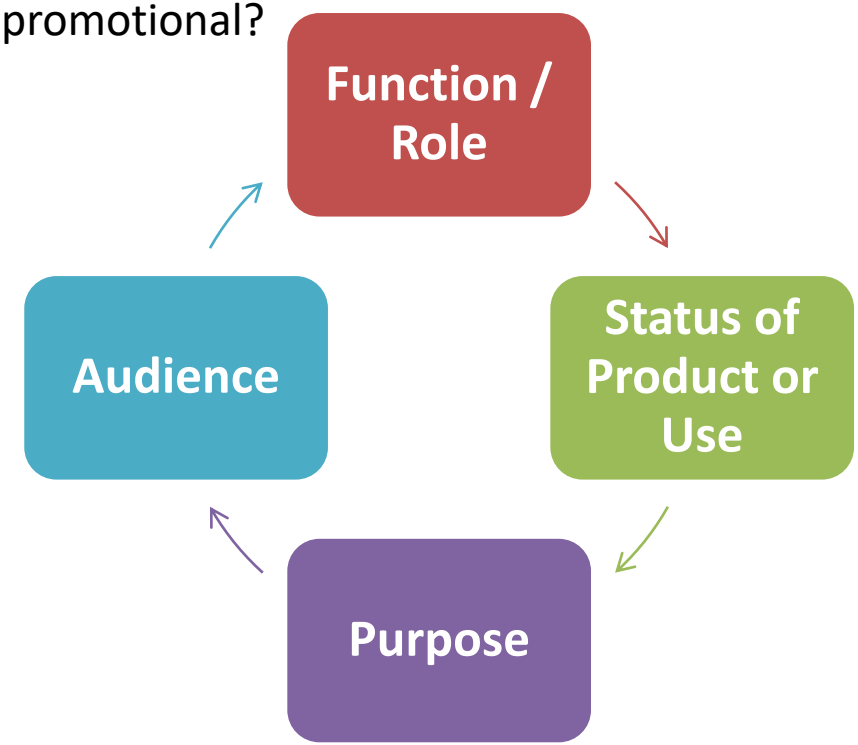
- Consultants
- Clinical Investigators
- Advisory Boards
- Market Research

Other (External) Communications

- Investor Communications
- Corporate Communications
- Disease Awareness / Institutional Advertising
- Clinical Trial Recruiting

SIGNIFICANCE OF ORGANIZATIONAL STRUCTURE AND FUNCTION

What is the role and purpose of your company activities and communications? Promotional or Non-promotional?



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Examples and Discussion

IS IT PROMOTIONAL?

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CONFERENCE BOOTHS

- **Frequency of OPDP Actions Involving Conference Booths**
  - 2015: 23% of Letters
  - 2016: 29% of Letters
  - 2017: 50% of Letters
  - 2018: 50% of Letters

- **Context**: OPDP Letters re advertising on the decline
  - 2010: 52 untitled or warning letters re advertising
  - 2016: 11
  - 2017: 5

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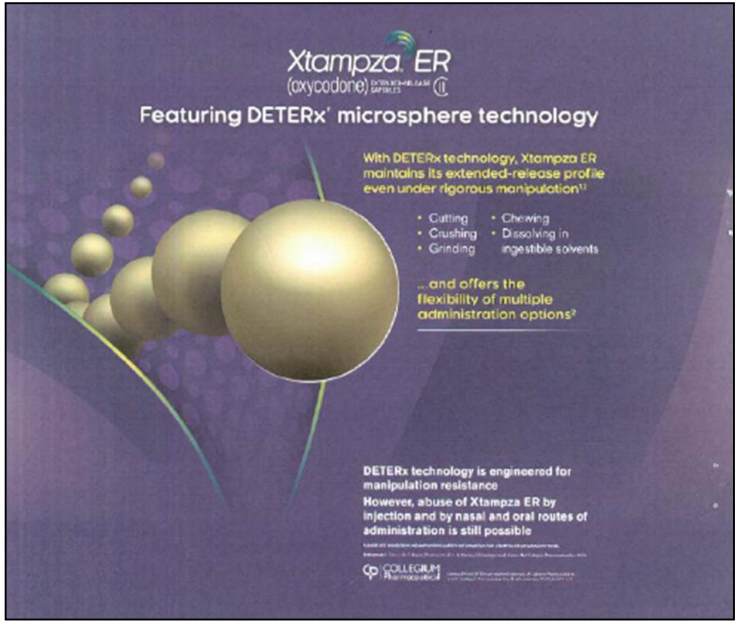
CONFERENCE BOOTHS

- **Untitled Letter to Collegium Pharmaceuticals, Inc.**
  - Date: February 9, 2018
  - Drug: XTAMPA ER – oxycodone extended-release tablets
  - Location: Exhibit Hall at the American Society Health-System Pharmacists (ASHP) Summer Meetings & Exhibit 2017
  - “The current opioid abuse epidemic is a critical public health matter.”



CONFERENCE BOOTHS

Main Display Panel	Side Panel with Risk Information
1) prominently displayed benefit claims;	1) located several feet away from principal display;
2) contained no information regarding limitations of use regarding risks of addiction, abuse, misuse, overdose, and death;	2) was in smaller font size and had plain white background (versus blue for principal);
3) contained no information regarding serious and life-threatening risks in Boxed Warning;	3) not linked visually to principal display panel;
4) presented at eye-level and was easy-to-read (font).	4) presented at bottom of panel near floor and was obscured by a table and chair.

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CONFERENCE BOOTHS

- **Untitled Letter to Celator Pharmaceuticals Inc.**
  - Date: August 25, 2016
  - Drug: CPX-351 (Cytrabine; Daunorubicin) Liposome Injection
  - Location: American Society for Clinical Oncology (ASCO) Annual Meeting

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CORPORATE AND INVESTOR COMMUNICATIONS

- Investor communications can include press releases, investor calls, annual reports and shareholder letters
- Purpose is to provide truthful, non-misleading information, not designed to promote product or influence prescribing patterns
- Publicly traded companies must disclose material developments under SEC; may not make material misrepresentations
- A material misrepresentation is a:
  - False statement of material fact, or
  - Failure to make a statement of fact thereby rendering the statements which were in fact made misleading

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CORPORATE AND INVESTOR COMMUNICATIONS

- **Warning Letter to Aegerion Pharmaceuticals Inc.**
  - Date: November 8, 2013
  - Drug: Juxtapid (lomitapide) capsules
  - Source: CEO broadcast interviews on CNBC's television show, "Fast Money"

Source: CNBC

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EXAMPLE: PRESS RELEASES

- Should describe the exact status of product or new indication if material relates to an investigational new product or use
- Should not contain any statement or suggestion that investigational new drug is safe and effective before FDA approval
- Should not suggest that product or new indication is further along in approval process than it really is
- Use informative, non-promotional language

Untitled Letter Burzynski Institute, 2012

According to OPDP, promoting Antineoplastons as safe and effective for the purposes for which they are under investigation is in violation of 21 C.F.R. § 312.7(a).

The website and press release on the homepage make claims that suggest that the drugs are "well tolerated," "work without causing side effects," and have demonstrated "remarkable" results.

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MEDICAL AFFAIRS ACTIVITIES – MSL ENGAGEMENT

"Scientific Activity" *can mean many things:*

- Unsolicited Requests Relating to Off-Label Uses
- Dissemination of Reprints in Conformance with FDA Guidance
- Funding information presented at bona fide CME Program
- Presenting Research Results at Scientific Conferences
- A company-controlled advisory meeting
- An investigator meeting

- Medical Science Liaisons should be neutral scientific experts on a company's products
- MSLs SHOULD NOT ACT AS A SURROGATE SALES FORCE

Compliance Risks with MSLs

May Be Motivated By:

- Incentive to Sell
- Influence of Sales Division
- Feeling of Lack of Restrictions
- Parity with Physicians
- Access to KOLs

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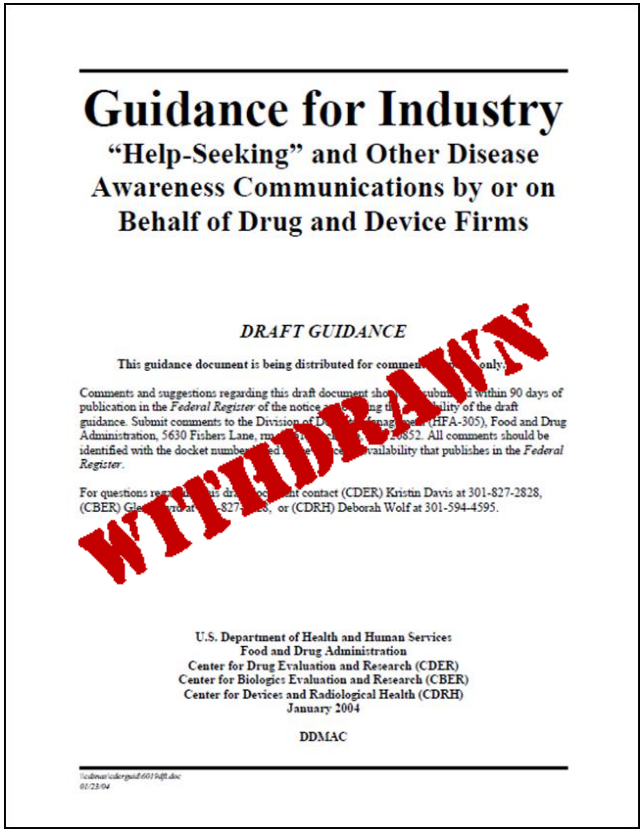
DISEASE AWARENESS



Guidance for Industry

"Help-Seeking" and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms

DRAFT GUIDANCE

This guidance document is being distributed for comment 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 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) Kristin Davis at 301-827-2828, (CBER) Glenn Pinto at 301-827-6210, or (CDRH) Deborah Wolf at 301-594-4595.

WITHDRAWN

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)
January 2004

DDMAC

- Hallmarks of guidance
  - Perceptual similarity
  - Physical proximity

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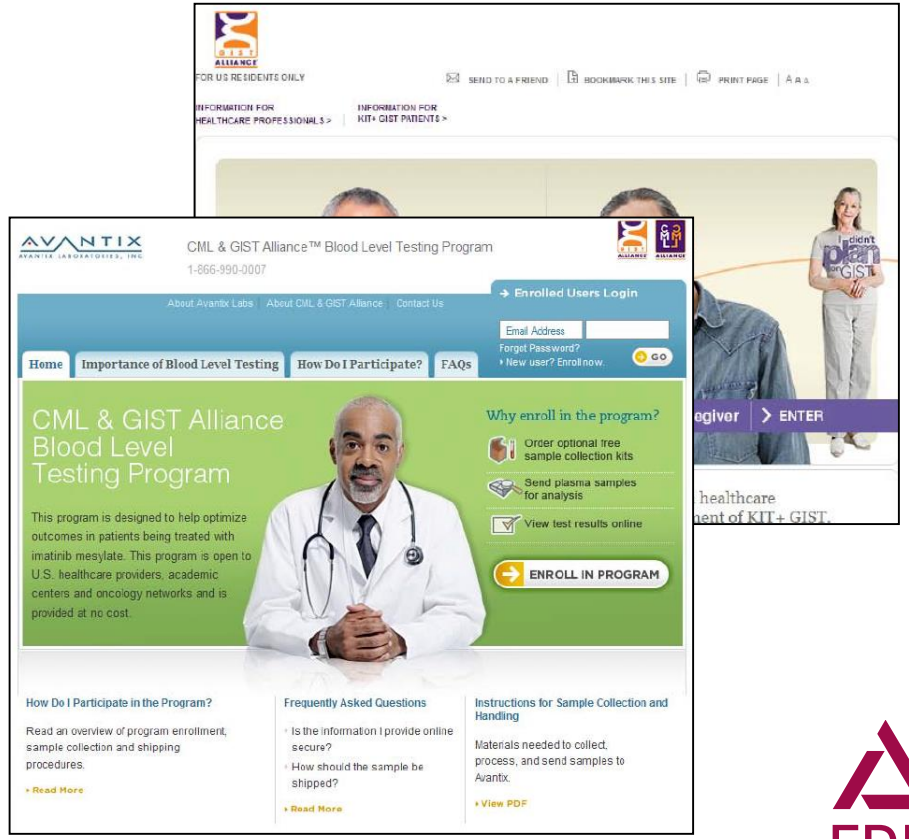
DISEASE AWARENESS

- **Warning Letter to Novartis Pharmaceuticals Corporation**
  - Date: April 21, 2010
  - Drug: Gleevec® (imatinib mesylate)
  - Source: Websites: www.gistalliance.com and www.cmlalliance.com



DISEASE AWARENESS CONSIDERATIONS

Promotional Risks

- Role and purpose of communication
- Timing of communication
- Who will communicate?
- Scope of communication
- Disease awareness “plus”
  - Coming Soon / Reminder
  - Institutional Advertising

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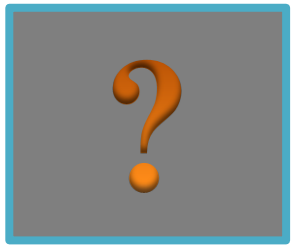
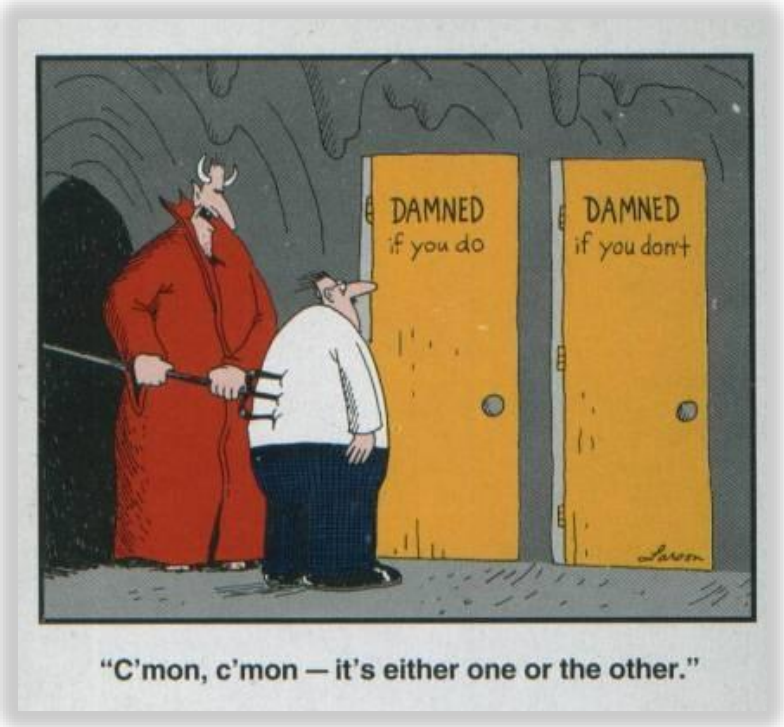
CO-PROMOTION / CO-MARKETING

- Do you – or don't you – coordinate promotion and marketing activities with third parties?
  - How?
- FDA/OPDP "Requests for Information"





Gary Larson, *The Far Side*®

MANUFACTURER LIABILITY FOR THIRD PARTY MARKETING PARTNERS/THIRD PARTIES

- **Examples of third party marketing partners/third parties:**
  - Spokespersons
  - Social media target marketers/vendors
  - Healthcare providers
  - Telemedicine providers
  - Specialty pharmacies
  - Distributors
  - Advocacy groups/patient advocates
  - Third party websites

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MANUFACTURER LIABILITY FOR THIRD PARTY MARKETING PARTNERS/THIRD PARTIES

- **Third Party Website/Spokespersons/Health Care Provider/Patient Advocates**
  - **Untitled Letter to Pfizer Inc.**
  - Date: June 19, 2018
  - Drug: ESTRING – estradiol vaginal ring – indicated for treatment of moderate to severe symptoms of vulvar and vaginal atrophy (VVA) due to menopause
  - Spokespersons: A physician and patient who were paid and trained by Pfizer
  - Promotional Material: Video posted on a website devoted to "Daily Happenings for Michigan Moms and Families;" Pfizer submitted Form FDA 2253
  - Action: During National Women's Health Week, Pfizer created the video by making its paid OBGYN physician and patient available for media interviews, focusing on postmenopausal women's health

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MANUFACTURER LIABILITY FOR THIRD PARTY MARKETING PARTNERS/THIRD PARTIES

- **Third party Website/Spokespersons/Health Care Provider/Patient Advocates**
  - Direct-To-Consumer Advertising
  - False or Misleading with respect to risk
  - Video was "especially concerning from a public health perspective" because it **did not mention boxed warnings** about serious, life-threatening risks (endometrial cancer, breast cancer, dementia, cardiovascular side effects)(Lacked Adequate Directions for Use)
  - Patient spokeswoman declared, "**I do not experience side effects.**" (FDA noted that it misleadingly suggested Estring patients will have similar results without side effects)
  - Video **omitted warnings** about patients who should not use the product
  - Directing viewer's to Estring's website for more information and to speak with own doctors not enough to mitigate risk from the omission of risk information
  - Patient professed "**instant relief**" after starting Estring. FDA noted that it is not aware of data to support claims of instant relief of moderate to severe symptoms of vulvar and vaginal atrophy due to menopause (**Lacked Substantiation**) (Data for approval used endpoints at 12 weeks)

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MANUFACTURER LIABILITY FOR THIRD PARTY MARKETING PARTNERS/THIRD PARTIES

- **Key Points**
  - **Regarding those paid or under control of manufacturer:**
    - **Be aware of exact content**
    - **Balance, Intended Use, Special Patient Populations, Risk Disclosure, Omissions, Boxed Warnings, Unsupported Claims/Substantiation**
    - **Avoid misleading testimonials without risk disclosure**
    - **Do not rely on outside content for explanation**
    - **Manufacturers beware if you have any control or influence over content of third party sites or information disseminated**
    - **Disclose affiliation**

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ADDITIONAL CO-MARKETING CONSIDERATIONS

- **Co-marketing in general is a partnership between two or more entities to jointly market the entities' products and/or services**

- ***Not so simple when the arrangement is between a US life sciences company and an HCP customer / potential customer***

***Examples*:**

- Find-a-Physician Directory
  - Listed on company website
- Shared Promotional Content
  - Provided by a company to a practice or an institution website
- Combined Advertising
  - Designed with HCP and company space in a single ad
- Informational Event
  - Organized to educate patients or referring physicians

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CO-MARKETING (cont'd)

Potential Risk Factors:

- ***Patient safety*** or quality of care issues
- Offering, promising, granting, requesting, accepting kickbacks
- The skewing of clinical decision-making
- Manipulation of the reimbursement system
- Submission of false claims
- Overutilization of medical care paid for by the government
- Promotion of off-label uses

CIA Between the Office Of Inspector General (HHS) and Cardiovascular Systems, Inc., *Released August, 2016*

Requirements for Co-Marketing Activities*

Within 90 days after the Effective Date, CSI shall establish the processes described in this section. CSI shall establish a process to ensure that a **needs assessment** has been completed for any Co-Marketing Activities, prior to engaging in such Co-Marketing Activities. The needs assessment shall identify the business need for performing the Co-Marketing Activities and provide details about the Co-Marketing Activities (i.e., information about the type of Co-Marketing Activities and **the role and contribution of each HCP or HCI involved in the Co-Marketing Activities**). CSI shall establish a process to evaluate the **fair market value** of such Co-Marketing Activities. CSI shall also establish a process ensuring that all arrangements to engage in Co-Marketing Activities are set forth in a **written agreement** that describes **the scope of work to be performed by all parties to the arrangement, the fees to be paid, and any work product that will be produced.**

Emphasis added in red bold font

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MIXING IN SOCIAL MEDIA

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SOCIAL MEDIA

Some Key Questions

- What control/influence do you have over the content?
  - What is your role? What is your responsibility?
- Know your audience: Who are you "talking" to?
- Have you made the right disclosures?
- What type of disclaimers do you need?
- If "comments" are allowed, what will you do with them?

Real World Examples

INFLUENCERS

- Recent FTC Activity
- Perception of Public

PATIENT / CONSUMER "ADVOCATES"

- Limitations Regarding Medical Advice
- Where is this all going?

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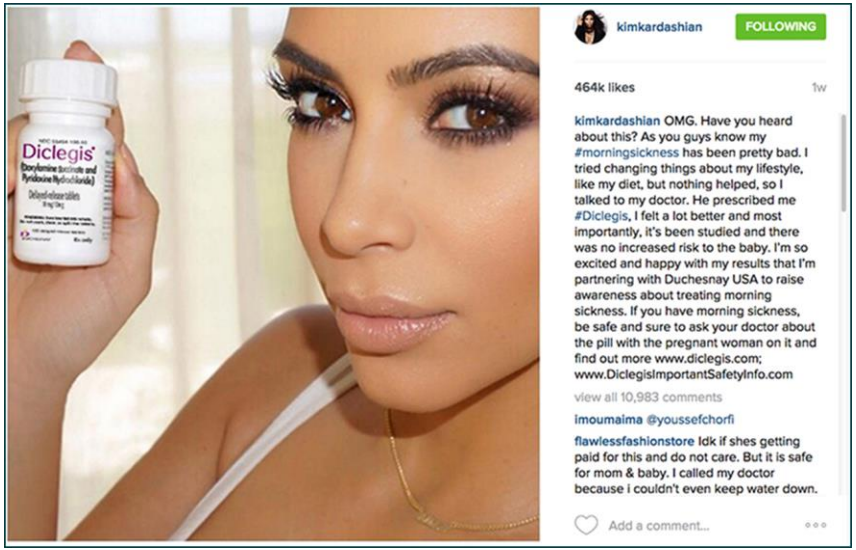
SOCIAL MEDIA & TRANSPARENCY

- **Warning Letter to Duchesnay, Inc.**
  - Date: August 7, 2015
  - Drug: DICLEGIS (doxylamine succinate and pyridoxine hydrochloride) delayed-release tablets
  - Source: Kim Kardashian Social Media Posts



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FTC Staff Reminds Influencers and Brands to Clearly Disclose Relationship

Commission aims to improve disclosures in social media endorsements

FOR RELEASE

April 19, 2017

"After reviewing numerous Instagram posts by celebrities, athletes, and other influencers, Federal Trade Commission staff recently sent out more than 90 letters reminding influencers and marketers that influencers should clearly and conspicuously disclose their relationships to brands when promoting or endorsing products through social media."

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TRANSPARENCY: “When in doubt, disclose”

- FTC requires disclosure of any “material connection” between influencer and sponsoring company
  - Cash, in-kind payment, free product, etc. – if not reasonably expected
  - Ownership interest
  - Family connections
  - Sweepstakes / contest entries?
  - Charitable donations in exchange for review?
- **Use straightforward language**
  - Clear: “Sponsored,” “Paid ad,” or “promotion”
  - Vague: “Thank you,” “Partnered,” “#SP,” “ambassador”
- **Place disclosure where it will be easily seen**

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LIABILITY OF MARKETING PARTNERS AND THIRD PARTIES

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LIABILITY OF MARKETING PARTNERS AND THIRD PARTIES

- **Physician Spokespersons (Key Opinion Leaders)**
  - Context: Physicians paid by manufacturer
    - Sometimes sued with pharmaceutical manufacturers
  - Theory of Liability: Misrepresentation (negligent and intentional), fraud, products liability, RICO, nuisance, negligence, unfair business practices, etc.
  - Motivation: Jurisdiction, Information

- **On-Line Advertising Agencies/Social Media Target Marketers/Patient Advocates**
  - Less likely
  - Must have knowledge of falsity of claims/material misrepresentations
  - Difficult to prove for laypersons hired to market a product
  - Responsibility lies primarily with manufacturer

- **What about FDA and FTC enforcement against marketing partners and third parties?**

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Thank you!

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