Regulation of Biological Product Marketing

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Agenda

- Regulatory Framework
- Fundamental Principles
- Biosimilar Promotion
- Non-Promotional Communications
- Other Relevant Laws and Considerations

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Who's the Boss?

- FDA regulates labeling and advertising of prescription drugs and biologics (FDCA § 502(a), (n))
- CBER-regulated Biologics: Advertising and Promotional Labelling Branch, Office of Compliance and Biologics Quality (OCBQ), CBER
- CDER-Regulated Biologics: Office of Prescription Drug Promotion (OPDP), Office of Medical Policy, CDER

Terminology: Labeling and Advertising

- What is “labeling”?
  - All written, printed, or graphic matter on or accompanying a drug
  - FDA interprets labeling broadly to include nearly all written materials disseminated by the manufacturer (e.g., detail aids, websites, promotional brochures)
- What is “advertising”?
  - Communications that identify and promote a drug in a third-party medium (e.g., printed promotions in newspapers or medical journals, television, and radio broadcasts, or social media posts)
  - Some overlap between “advertising” and “labeling”

Sources of FDA Requirements

- Statutes and Regulations
  - FDCA § 502 (21 USC § 352)
  - FDA regulations at 21 C.F.R. Part 202
- FDA Guidance
  - The FDCA and FDA regulations provide a general framework for the agency's approach to regulating advertising and promotion
  - The details of FDA's approach to regulation, however, are largely embodied in non-binding "guidance documents," many of which are in draft form
- Warning & Untitled Letters
  - Past letters are instructive, but with the caveat post-CFL guidance that the substantiation standard FDA applies has changed

Sources of FDA Requirements (cont.)

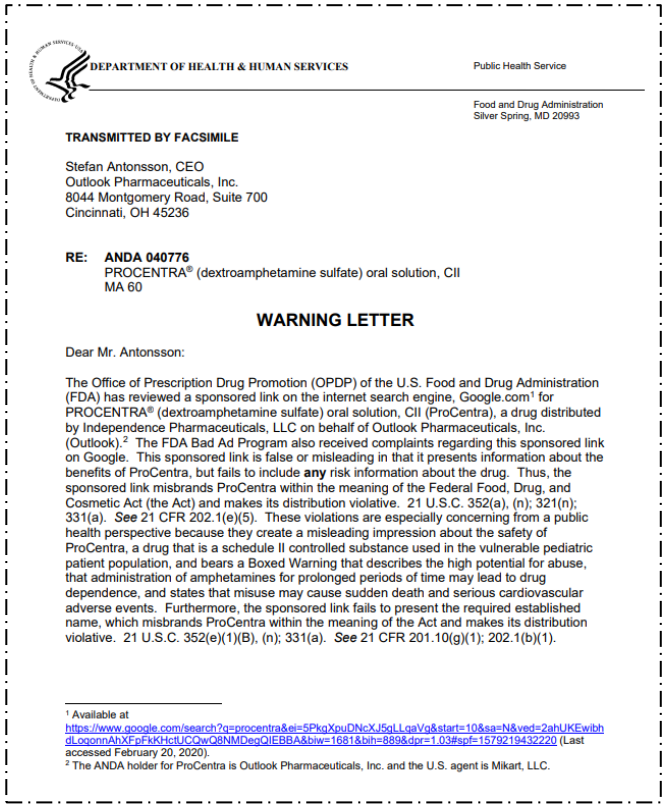
- Key FDA guidance documents include, e.g.:
  - Guidance for Industry: Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products - Questions and Answers (DRAFT) (2020)
  - Medical Product Communications that are Consistent with the FDA-Required Labeling (2018)
  - Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities (2018)
  - Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer Promotional Labeling and Advertisements (DRAFT) (2018)
  - Distributing Scientific and Medical Publications on Unapproved New Uses (DRAFT) (2014)
  - Internet/Social Media Platforms with Character Space Limitations (DRAFT) (2014)
  - Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation (DRAFT) (2014)
  - Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices (DRAFT) (2011)
  - Presenting Risk Information in Prescription Drug and Medical Device Promotion (DRAFT) (2009)
  - Industry-Supported Scientific and Educational Activities (1997)

Submitting Materials to FDA

- Promotional materials for accelerated approval products require pre-submission to FDA (21 CFR 601.45; 21 CFR 314.550)
  - Rationale for pre-submission requirement:
    - Especially sensitive benefit/risk balance
    - Limited data may make physicians and patients especially vulnerable to misleading promotion
  - Launch materials to be used within first 120 days must be submitted prior to approval
  - Non-launch materials must be submitted at least 30 days prior to dissemination
- Companies may voluntarily submit materials to OPDP/APLB for advisory comments (21 CFR 202.1(j)(4))
- All promotional materials must be submitted to FDA a the time of first use on FDA Form 2253 (21 CFR 601.12(f)(1); 21 CFR 314.81(b)(3)(i))

FDA Enforcement: Warning and Untitled Letters

- FDA's Office of Prescription Drug Promotion ("OPDP") may issue warning and untitled letters citing identified promotional violations
- Warning letters
  - Only issued for violations of "regulatory significance"
    - "Significant violations" are those that may lead to enforcement action if not promptly and adequately corrected
  - All warning letters posted on FDA website
  - May require corrective advertising / recall of violative materials
- Untitled letters
  - Violations do not meet threshold of "regulatory significance" for a warning letter
  - Many (but not all) untitled letters posted on FDA website



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

TRANSMITTED BY FACSIMILE

Stefan Antonsson, CEO
Outlook Pharmaceuticals, Inc.
8044 Montgomery Road, Suite 700
Cincinnati, OH 45236

RE: ANDA 040776
PROCENTRA® (dextroamphetamine sulfate) oral solution, CII
MA 60

WARNING LETTER

Dear Mr. Antonsson:

The Office of Prescription Drug Promotion (OPDP) of the U.S. Food and Drug Administration (FDA) has reviewed a sponsored link on the internet search engine, Google.com[1] for PROCENTRA® (dextroamphetamine sulfate) oral solution, CII (ProCentra), a drug distributed by Independence Pharmaceuticals, LLC on behalf of Outlook Pharmaceuticals, Inc. (Outlook).[2] The FDA Bad Ad Program also received complaints regarding this sponsored link on Google. This sponsored link is false or misleading in that it presents information about the benefits of ProCentra, but fails to include **any** risk information about the drug. Thus, the sponsored link misbrands ProCentra within the meaning of the Federal Food, Drug, and Cosmetic Act (the Act) and makes its distribution violative. 21 U.S.C. 352(a), (n); 321(n); 331(a). *See* 21 CFR 202.1(e)(5). These violations are especially concerning from a public health perspective because they create a misleading impression about the safety of ProCentra, a drug that is a schedule II controlled substance used in the vulnerable pediatric patient population, and bears a Boxed Warning that describes the high potential for abuse, that administration of amphetamines for prolonged periods of time may lead to drug dependence, and states that misuse may cause sudden death and serious cardiovascular adverse events. Furthermore, the sponsored link fails to present the required established name, which misbrands ProCentra within the meaning of the Act and makes its distribution violative. 21 U.S.C. 352(e)(1)(B), (n); 331(a). *See* 21 CFR 201.10(g)(1); 202.1(b)(1).

[1] Available at https://www.google.com/search?q=procentra&ei=5PkqXpuDNcXJ5gLLqaVg&start=10&sa=N&ved=2ahUKEwibhdLogonnAhXFpFkKHctUCQwQ8NMDegQIEBBA&biw=1681&bih=889&dpr=1.03#spf=1579219432220 (Last accessed February 20, 2020).
[2] The ANDA holder for ProCentra is Outlook Pharmaceuticals, Inc. and the U.S. agent is Mikart, LLC.

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Test Your Knowledge

Which of the following is not permitted when promoting a biological product?

A. Comparative claims against other drugs
B. Discussion of data from a real-world study
C. Promoting an unapproved use of the product
D. All of the above
E. None of the above

Basic Promotional Requirements

- Promotional claims **must**:
  1. Not be false or misleading
  2. Have “fair balance” and not minimize risk
  3. Be substantiated
  4. Not discuss unapproved (“off-label”) uses
- FDA generally takes the position that failure to satisfy these requirements cannot be cured by disclaimers or other disclosures

Misbranding

- A drug is misbranded if (among other things):
  - Its labeling lacks adequate directions for use
    - Adequate directions for use are limited by regulation to a drug's intended use 21 C.F.R. § 201.5
    - If the manufacturer offers the drug for an unapproved intended use, the labeling will lack adequate directions for use
  - Its advertising does not provide a true statement of material facts, including the "brief summary"
  - Its labeling is false or misleading
    - Failure to disclose material facts can be misleading
    - Does not include required information with sufficient prominence

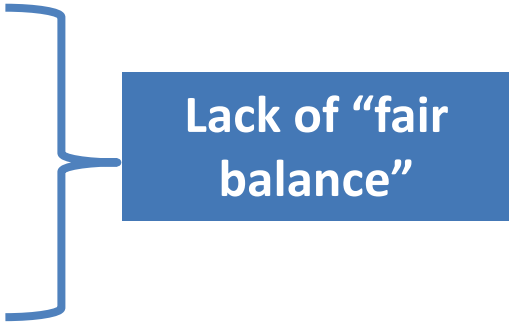
21 U.S.C. § 352

Presenting Risk Information

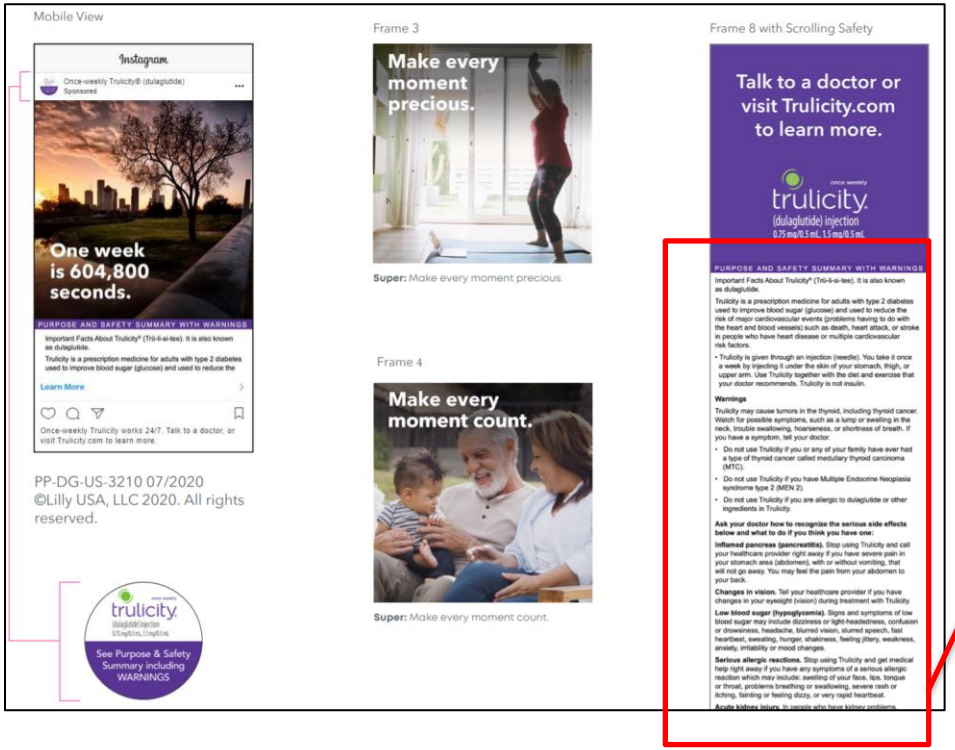
- "Fair balance" requirement (21 CFR 202.1(e)(5)(ii)):
  - Claims cannot be lacking in **fair balance**
  - Fair balance requires presentation of the bad with the good
  - Format of the presentation counts
- Labeling and advertising also may not minimize the risks with the drug

Presenting Risk Information

- What types of things minimize risk with a drug?
  - Failure to present pertinent risk information
  - Insufficient emphasis on risk compared with emphasis on effectiveness claims
  - Insufficient prominence or readability
  - Presenting risks as a potential benefit
  - Downplaying severity or frequency of risk



Presenting Risk Information: Enforcement Example



"The post prominently presents benefit claims . . . emphasized by colorful, compelling, and attention-grabbing fast-paced visuals that take up the majority of the post in a video with frequent scene changes, busy scenes, and large-moving superimposed text . . . In contrast, the risk information is in a small window relegated to the bottom of the post and is presented using fast-paced, scrolling, small font that is difficult to read and cannot be adequately processed or comprehended by consumers. ."

Untitled Letter to Eli Lilly (1/19/22)

Presenting Risk Information: Enforcement Example

- Eton Pharmaceuticals, Aug. 2021
- Untitled Letter re: Alkindi Sprinkle (hydrocortisone) oral granules
- Issue: Sponsored link (1) included efficacy information (product indication and other benefits) without presenting any information on risk
  - FDA noted this was especially concerning from a public health perspective, given that the product is "used in a vulnerable pediatric patient population, and may cause serious adverse reactions such as adrenal crisis, infections, and growth retardation, among others"

Substantiation

- Promotional claims must be adequately substantiated to avoid being considered false or misleading
- Type/strength of substantiation necessary to support a claim varies depending on the type of claim:
  - Safety and efficacy claims
  - Usability and functionality claims
  - Fixed product attribute claims
- In general, claims may be made if they are:
  - Consistent with the approved labeling
  - Appropriately substantiated

Substantiation Standard

- FDA has historically required claims of safety and effectiveness to be supported by "substantial evidence" (defined as "adequate and well-controlled investigations")
- In guidance finalized in 2018 (the "CFL" Guidance), FDA relaxed this standard for claims consistent with the label, adopting a substantiation standard of "scientifically appropriate and statistically sound"
  - Flexible standard potentially met by "a variety of types of studies and analyses"
  - No study design, data source, etc. expressly deemed off limits, but:
    - Cannot base on "speculation or belief" or a "poorly designed or conducted study or analysis"
    - Cannot overstate the findings or the conclusions that can be drawn
- Context and limitations of data/analyses must be clearly disclosed to ensure communication is not misleading

Guidance for Industry: Medical Product Communications that are Consistent with the FDA-Required Labeling (2018)

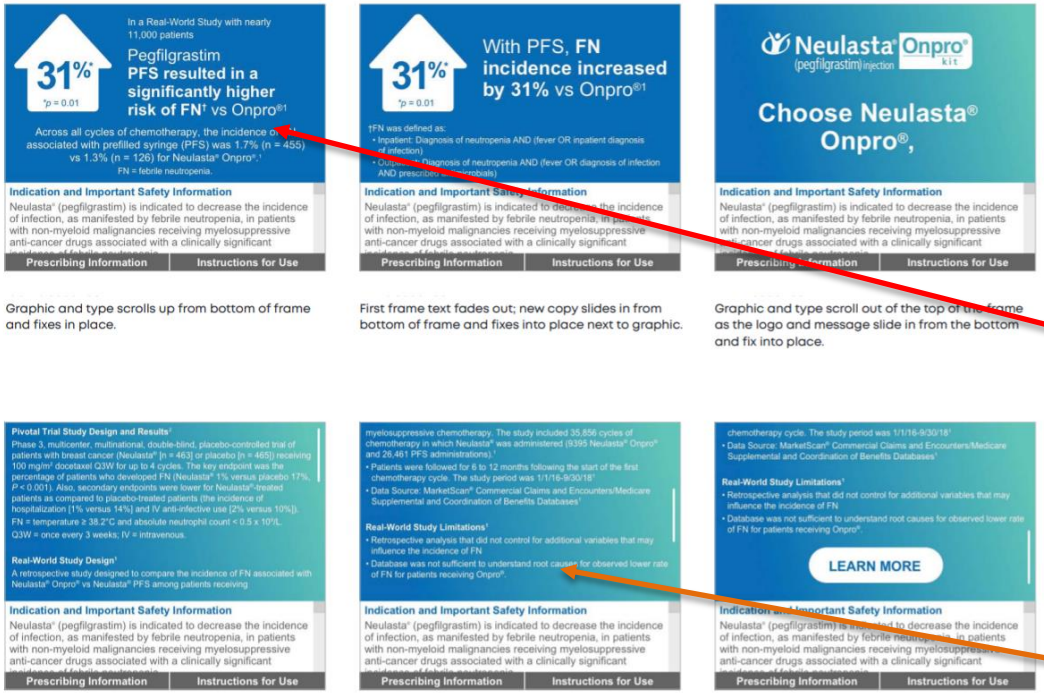
Substantiation Standard (cont.)

- CFL guidance applies to "promotional communications" that are consistent with labeling under 3-factor test:
  - #1: Are the conditions of use described in the communication consistent with the product labeling?
  - #2: Does the communication alter the risk-benefit profile of the product in such a way that may result in increased harm to health?
  - #3: Does the product labeling enable the product to be used safely and effectively for the conditions of use described in the communication?

Guidance for Industry: Medical Product Communications that are Consistent with the FDA-Required Labeling (2018)

Substantiation: Enforcement Example

Animated Banner



"These claims and presentations create a misleading impression regarding the benefit of the product by stating that there is a statistically significant higher risk of febrile neutropenia (FN) when pegfilgrastim is administered via the prefilled syringe (PFS) compared to the Onpro on-body injector (OBI). However, the multiple limitations of the cited study2 preclude the drawing of such conclusions regarding the comparative risk of febrile neutropenia (FN) in patients taking pegfilgrastim depending on delivery method"

"We note that two limitations to the study are presented in frames seven and eight under the header "Real-World Study Limitations." The presentation of two major deficiencies of the study design does not mitigate the misleading claims and presentations in the banner"

Untitled Letter to Amgen (7/7/21)

Substantiation: Enforcement Example

It literally works within, for me, 15 minutes

I was given Nurtec ODT, I tried it, it was a gamechanger . . . other medications would give me rebound headaches, and this one doesn't

Untitled Letter to Biohaven (3/8/21)

Test Your Knowledge

Which of the following is potentially consistent with the FDA-required labeling under the CFL guidance?

A. A biologic indicated for use in Rheumatoid Arthritis in adults is promoted for use in pediatric patients

B. A biologic with dosing instructions to titrate to 2 mL/day as tolerated is marketed with information on restricting dose to 1.5 mL/day in patients with side effects

C. Data from a study in any line of treatment is shared for a biologic indicated for use as a third-line or later treatment

D. All of the above

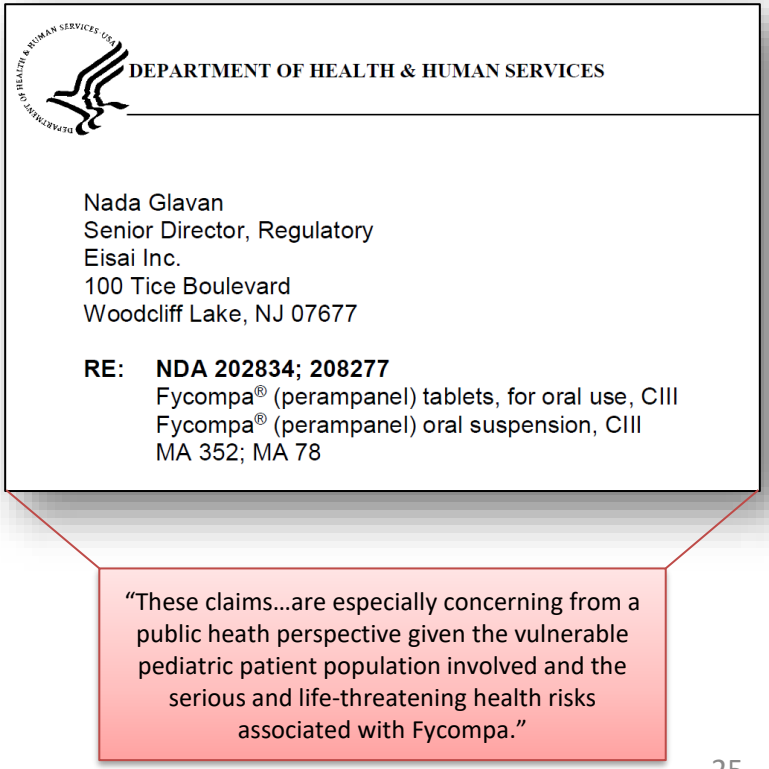
E. None of the above

Off-Label Promotion

- Off-label promotion includes promoting a drug or device for an ***intended use*** that is not approved by FDA
- Examples:
  - Different disease state or condition
  - Different patient population than is covered by the label
  - Different dosing regimen
  - Different surgical procedure
- Products promoted off-label may be considered “adulterated” and “misbranded” under the FDCA
  - Potential criminal penalties
- Practice of medicine exception:
  - While manufacturers may not promote a product for off-label use, FDA does not regulate how end users deploy the product in the practice of medicine

Off-Label Promotion: Enforcement Example

- **Eisai Inc., Oct. 2018**
- **Untitled Letter re: Fycompa based on complaint submitted to OPDP Bad Ad Program**
- **Issue:**
  - Sales representative made **oral statements** intending to promote the drug for **off-label uses** (including patients younger than the approved patient population)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Nada Glavan
Senior Director, Regulatory
Eisai Inc.
100 Tice Boulevard
Woodcliff Lake, NJ 07677

RE: **NDA 202834; 208277**
Fycompa® (perampanel) tablets, for oral use, CIII
Fycompa® (perampanel) oral suspension, CIII
MA 352; MA 78

"These claims…are especially concerning from a public heath perspective given the vulnerable pediatric patient population involved and the serious and life-threatening health risks associated with Fycompa."

First Amendment Considerations

- Traditionally, scientific speech received greater protection than commercial speech
- FDA and DOJ argued that drug and device manufacturers' commercial speech was subject to limited First Amendment protection
- Recent court decisions raise important questions about FDA's ability to regulate truthful and non-misleading manufacturer speech, even if off-label, e.g.:
  - *Sorrell v. IMS Health, Inc.* (U.S. 2011)
  - *United States v. Caronia* (2d Cir. 2012)
  - *Amarin Pharma, Inc. v. FDA* (S.D.N.Y. 2015)
  - *U.S. v. Vascular Solutions, Inc.* (W.D. Texas 2016)
  - U.S. v. Facteau & Fabian (D. Mass. 2016)

First Amendment Considerations (cont.)

- First amendment jurisprudence in this area is continuing to evolve, and much remains uncertain until there are further court rulings in this area
  - Opinions of circuit/district courts may not be persuasive in other jurisdictions
  - DOJ settlements involving off-label promotion have continued since this line of cases
- Key point: older warning and untitled letters may not always reflect FDA's current approach to claims in advertising and promotion in light of First Amendment developments (and newer FDA guidance)

DTC Communications: General Principles

- General Rules
  - DTC advertising must satisfy all the requirements of prescription drug advertising more generally, including:
    - Truthful and not misleading
    - Fair balance
  - Communicate all relevant information
  - Consumer friendly language
  - Consider relevant FDA guidance
    - 2015 draft guidance on disclosing risk information in DTC ads
    - 2018 draft guidance provides recommendations for presenting quantitative efficacy and risk information to consumers
- DTC communications in general are subject to higher degree of scrutiny

DTC Television Advertisements

- Major Statement in broadcast ads (21 C.F.R. §202(e)(1))
  - DTC television and radio advertising for prescription drugs must contain a "major statement" disclosing major side effects and contraindications
  - The "major statement" must be presented in a "clear, conspicuous, and neutral manner" (21 U.S.C. § 352(n))
- Major statement must be accompanied by "adequate provision" for dissemination of approved or permitted package labeling
  - 1999 FDA guidance outlines the following components of "adequate provision":
    1. Disclosure of a toll-free telephone number for consumers to call for the approved package labeling
    2. Reference to a mechanism to provide labeling to consumers with restricted access to sophisticated technology (e.g., concurrent advertisement in a print periodical)
    3. Disclosure in the advertisement of an web address that provides access to the package labeling
    4. Disclosure in the advertisement that pharmacists, physicians, or other healthcare providers may provide additional product information to consumers

PhRMA Guiding Principles on DTC Advertising About Prescription Medicines

- Based on the premise that DTC campaigns should be accurate, balanced, and helpful to consumers
  - Voluntary participation by drug companies
  - Revised in 2018 to incorporate price disclosure for DTC TV ads
- Principles:
  - No promotion of unapproved uses
  - Inclusion of adverse event reporting information
  - Guidelines for actors and celebrity endorsers
  - Voluntary submission of DTC television ads for FDA pre-review
  - Restrictions for ads containing adult-oriented content
  - Prominence of Risk & Safety Information
  - Educating healthcare professionals prior to launching a DTC campaign
  - Moratorium on DTC ads for newly approved prescription drugs

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Biosimilars Promotion

- FDA released draft guidance in February 2020 addressing labeling and promotion of biosimilars
- General framework for prescription drug promotional requirements (e.g., the requirement that advertising and labeling must be truthful and non-misleading) forms the basis for the agency's biologic product-specific recommendations
- Draft guidance was released on the same day as a joint FDA/FTC statement on biosimilars describing how the agencies will work together to "promote competitive markets for biologic products and to take appropriate steps to address false or misleading statements and promotional communications by biologic manufacturers"

FDA, Draft Guidance for Industry: Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products - Questions and Answers (2020)

Biosimilars Promotion (cont.)

- **Key principles contained in the biosimilar promotion draft guidance:**
  - Promotional materials should accurately identify the product described in the materials
  - Refer to the biosimilar labeling when assessing what information or data about the reference product should be included in promotional materials
  - Information and data from studies to support biosimilarity may be used in promotion even though not typically included in the label
  - Carefully evaluate comparisons of biosimilars and reference products to ensure not false or misleading
    - Comparative study data may be presented consistent with FDA's CFL Guidance
    - Avoid presentations that create the impression that there are clinically meaningful differences between the reference product and biosimilar, or that the products are not highly similar
    - Avoid suggesting that a biosimilar product is interchangeable if it has not been licensed as interchangeable; similarly, because a biosimilar is not required to be identical to the reference product, do not represent that a reference product is safer or more effective than a biosimilar that has not been licensed as interchangeable

FDA, Draft Guidance for Industry: Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products - Questions and Answers (2020)

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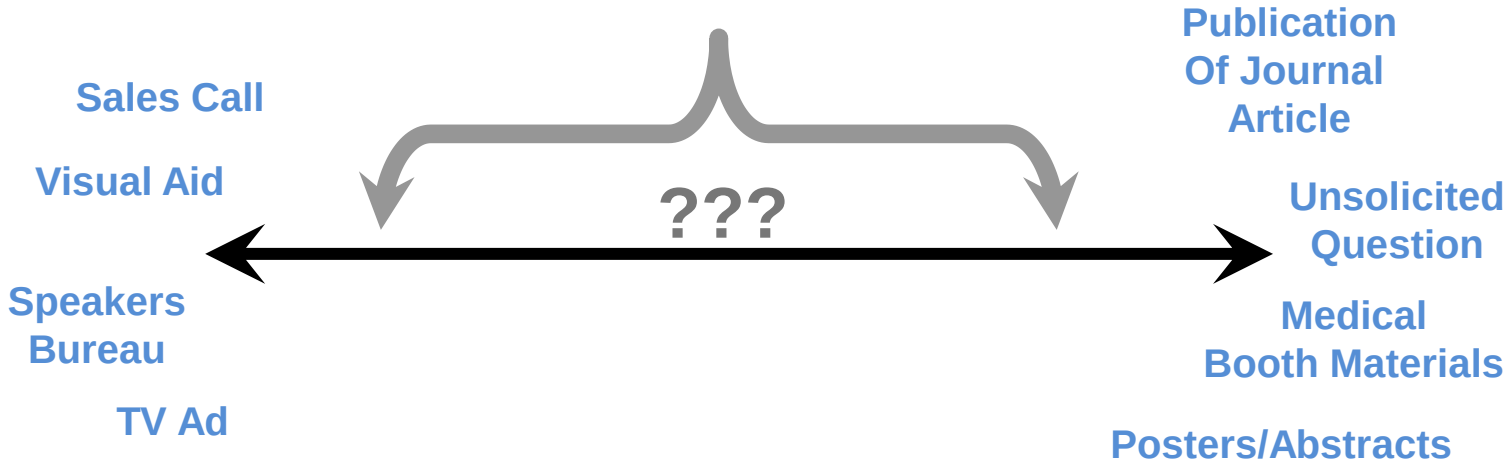
Scientific Exchange

- FDA recognizes it cannot, and should not, regulate core scientific speech—aka, "scientific exchange"
  - What is or is not scientific exchange is a moving target – there are few clear answers
    - FDA does not expressly define either "promotion" or "scientific exchange"
  - In general, scientific exchange should
    - Be truthful and non-misleading
    - Contain no claims of safety or effectiveness
    - Disclose that the product or use is not approved by FDA
  - FDA has recognized certain specific safe-harbors for off-label and preapproval communications (e.g., responses to unsolicited requests, dissemination of reprints), but scientific exchange is broader than this

Scientific Exchange vs. Promotion



Unsolicited Requests: FDA Draft Guidance

- FDA issued draft guidance in 2011 recognizing a safe harbor for responses to unsolicited requests
- Appropriate handling of unsolicited requests depends on
  - Characteristics of the request / response
  - Execution of the response
- Considerations for responses:
  - Tailored to answer only the question asked
  - Truthful, non-misleading, accurate, and balanced
  - Non-promotional in tone
  - Certain recommended disclosures

Unsolicited Requests: FDA Draft Guidance (cont.)

- Guidance distinguishes between “public” and “non-public” requests
- Responses to non-public requests:
  - Tailored to answer only the question asked
  - Truthful, non-misleading, accurate, and balanced
  - Non-promotional in tone
    - Responses should be generated by medical/scientific personnel, not sales/marketing personnel
  - Certain recommended disclosures
- Responses to public requests
  - Request must be specific to company’s named product
  - Response cannot contain substantive off-label information
    - Convey that question involves unapproved use
    - Provide contact info for medical department

Distributing Scientific and Medical Publications

- FDA draft guidance issued in 2014 addressing distribution of off-label scientific and medical publications
  - Covers proactive distribution of: journal articles (reprints), reference texts, clinical practice guidelines (CPGs)
- Reprints, reference texts, and CPGs should be:
  - Accompanied by the approved or cleared labeling
  - Accompanied by a comprehensive bibliography and disclosures
  - Disseminated with representative contrary articles
  - Distributed separately from promotional material

Distributing Scientific and Medical Publications (cont.)

- Reprints, reference texts, and CPGs should not be
  - Edited or significantly influenced by the manufacturer or anyone with a financial relationship with the manufacturer
  - Marked, summarized or characterized in any way by the manufacturer
  - Discussed in a promotional visit
  - Attached to specific product information other than the approved/cleared labeling
- Note that reprints are covered only if they report on “significant” clinical investigations or non-clinical research

Investor Communications

- Investor communications include oral and written communications intended for dissemination to the financial community (e.g., SEC filings, press releases, investor calls)
- The "scientific exchange" regulation permits non-promotional dissemination of "scientific findings in scientific or lay media" and would allow, e.g., press releases announcing results from pivotal clinical trials
  - FDA stated in the preamble to the proposed rule on intended use that SEC filings containing required disclosures of development activities or potential or actual sales for an unapproved use would not by themselves provide evidence of an off-label intended use (85 FR 59736 (Sept. 23, 2020))
- To qualify as scientific exchange, investor communications should:
  - Use factual language focused on study design/results, rather than promotional language
  - Be truthful and nonmisleading
    - Disclose relevant limitations of analyses or data (e.g., interim, post-hoc) and information on adverse events, tolerability
  - Not include conclusions about safety or efficacy
  - Clearly state that the product is investigational

Investor Communications (cont.)

- FDA has asserted jurisdiction to regulate industry press releases and investor communications that are promotional in nature (e.g., make claims of safety or effectiveness)
  - FDA has issued warning and untitled letters for both investigational and marketed products based on investor communications, e.g.:
    - Cornerstone Therapeutics (2012) – untitled letter citing press release for unsubstantiated superiority claims
    - Salix Pharmaceuticals (2012) – untitled letter citing CEO podcast interview as preapproval promotion
  - Frequency of enforcement relating to press releases has decreased over the years, but nevertheless remains a risk

Test Your Knowledge

Which of the following may qualify as scientific exchange?

A. A response to an unsolicited request that is off-label
B. Sharing an off-label journal article
C. An investigator from a company study presenting a poster at a scientific conference
D. All of the above
E. None of the above

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False Claims Act: Overview

- The False Claims Act
  - FCA claims frequently brought in addition to FDCA claims
  - Establishes civil penalties for the knowing or reckless submission of a false or fraudulent claim for payment to the U.S. Government, or the causing thereof
    - Penalties are $5,500 to $11,000 per claim, plus treble damages, costs, and attorneys' fees
  - FCA violators can be excluded from participation in federal health care programs
  - The statute's qui tam provision authorizes private parties to sue on behalf of the government and recover from between 15-30% of any penalty

False Claims Act: Overview (cont.)

- FCA cases against pharmaceutical companies have been predicated on
  - FDA violations
    - Promotional Violations (e.g., off-label promotion)
    - Good Manufacturing Practices
    - Adverse Event Reporting
  - AKS violations
- Numerous FCA cases have been initiated by qui tam actions, resulting in civil and criminal settlements and pleas by corporations and individuals
- In general, these have focused on off-label promotion and anti-kickback statute violations

Anti-Kickback Statute

- Federal law imposes criminal penalties on individuals and entities that knowingly and willfully offer, pay, solicit or receive payments of “remuneration” in exchange for business for which payment may be made under federal or state healthcare programs
- Certain marketing practices can be viewed as “remuneration”
  - Lavish gifts
  - Expensive meals
  - Entertainment (e.g., golf)
  - Travel to exotic locales
- Claims can be brought by doctors, employees, etc.

Anti-Kickback Statute (cont.)

- The law is so broadly written that almost any relationship between a manufacturer and an institutional provider or its affiliated practitioner could implicate the anti-kickback statute
- Protection exists for certain payments that meet listed “safe harbors”
  - E.g., purchasing services pursuant to written contract at fair market value compensation

Sunshine Act

- Federal Open Payments law requires applicable manufacturers to track and report to CMS **Transfers of Value** (TOVs) made to or at the direction of physicians and teaching hospitals
- Report is due annually, every **March 31**, for the preceding calendar year
- CMS **publishes** the data on https://openpaymentsdata.cms.gov/
- "**Transfer of Value**" is broad; can include meals, consulting payments, charitable donations, journal reprints, etc.
- States have passed similar laws expanding the obligation to track and report TOVs made to other types of healthcare professionals

Who Else Is Watching?

- Competitors
  - National Advertising Division cases
  - Lanham Act lawsuits
  - Complaints to FDA/DOJ/States
- Consumers/Patients
  - Class action product liability lawsuits
- States
  - Actions pursuant to consumer protection statutes

Questions