

Advertising and Promotion of Medical Devices

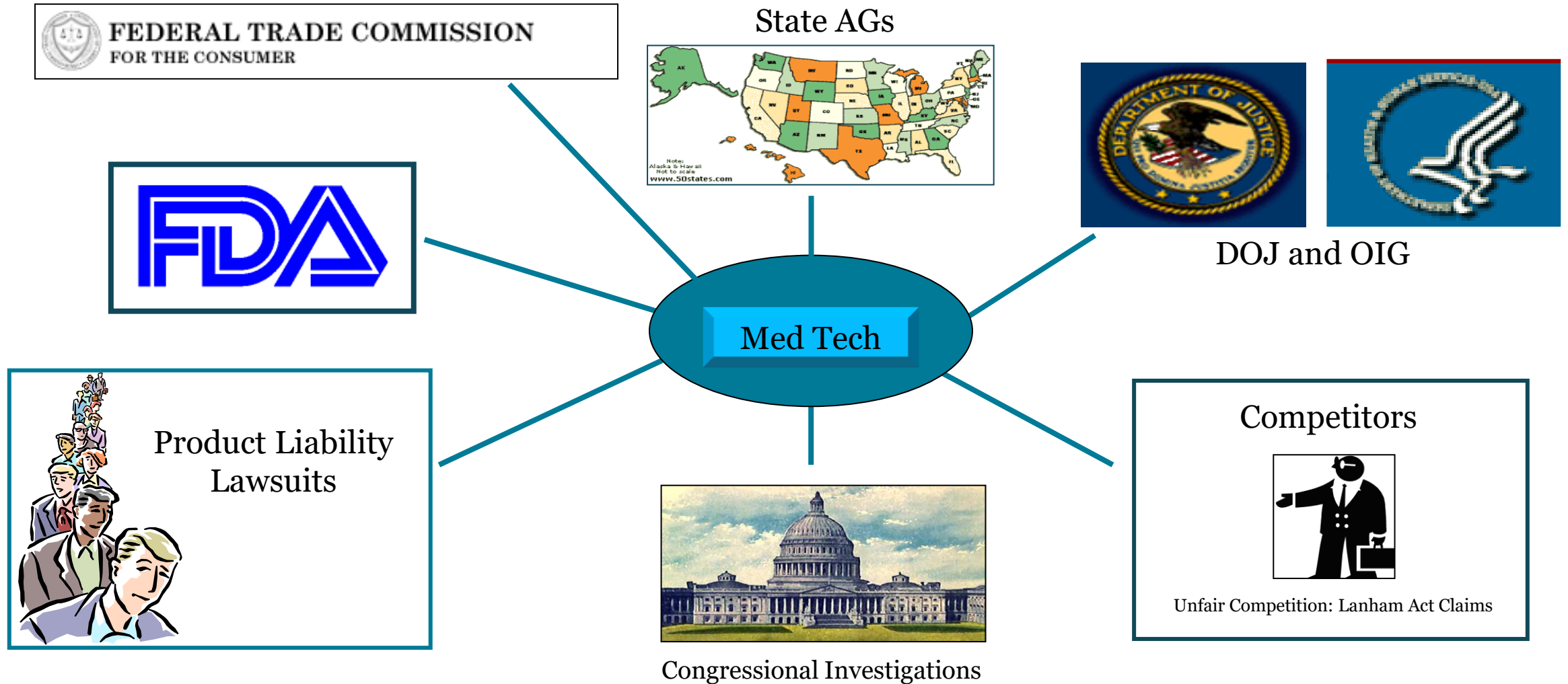
Scott D. Danzis
April 2022

COVINGTON

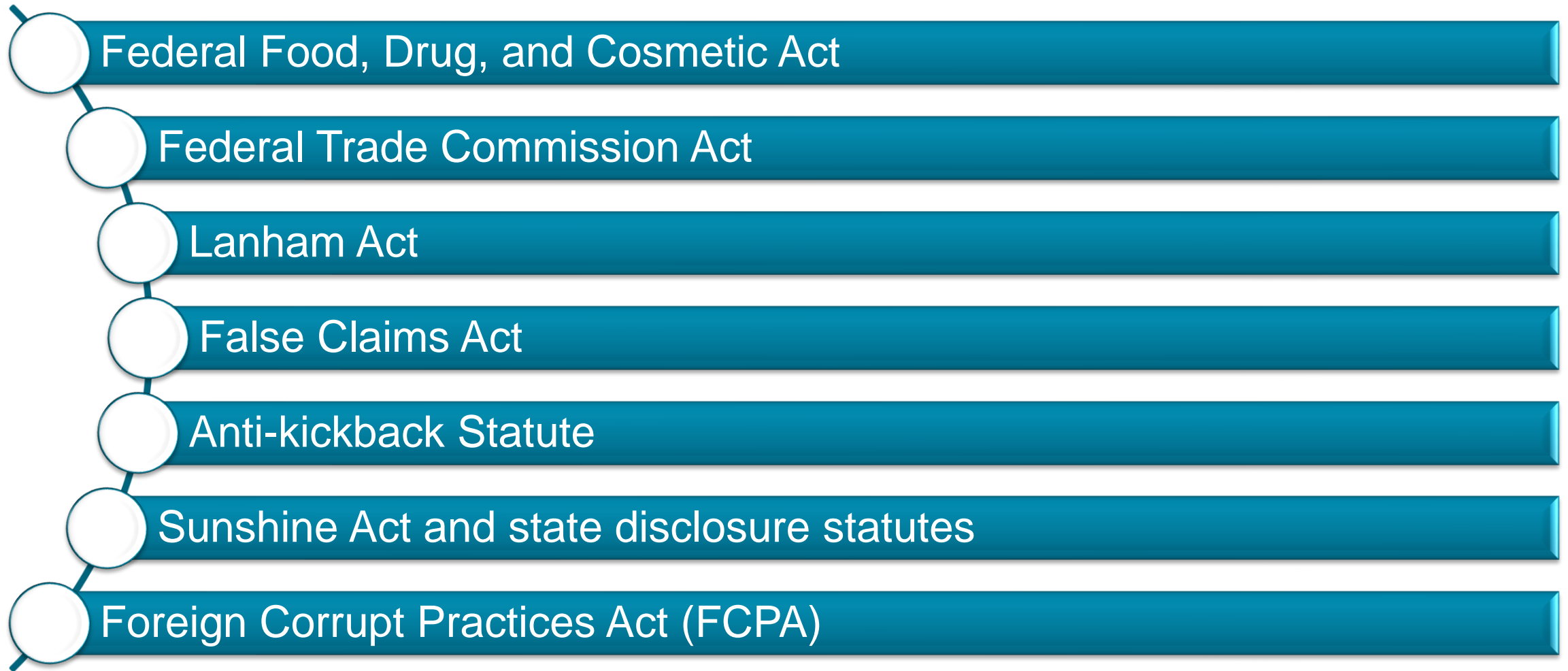
BEIJING BRUSSELS DUBAI FRANKFURT JOHANNESBURG LONDON LOS ANGELES
NEW YORK PALO ALTO SAN FRANCISCO SEOUL SHANGHAI WASHINGTON

www.cov.com

Promotion Enforcement Landscape



Key Statutes Impacting Promotional Activities



Who Regulates?



Labeling

Advertising of restricted devices

Other promotional communications
(including others speaking on company
behalf) can be evidence of "intended use"

Advertising of non-restricted devices

Labels, Labeling, Advertising

Labels

FDCA 201(k)

Display of written, printed, or graphic matter upon the immediate container of any article.



Labeling

FDCA 201(m)

Written, printed, or graphic material which:

- “Accompanies” the device
- Supplements or explains the product
- Is disseminated by the manufacturer

Includes brochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house newsletters, letters, PowerPoint presentations, etc.

Advertising

21 C.F.R. 202.1(l)(1) (drug regs)

Advertising is media-based materials such as:

- Magazines
- Newspapers
- Professional journals
- Radio and TV commercials

Internet, Social Media

Federal Food, Drug and Cosmetic Act (FDCA)

Misbranding

FDCA § 502

- Labeling is false or misleading
- Labels/labeling lack required information or prominence
- Failure of labeling to include “adequate directions for use” for all intended uses of device
- Failure to include information required for advertising of restricted devices
- If device lacks a 510(k) for an intended use, and a 510(k) is needed

Adulteration

FDCA § 501

- If device lacks a PMA for an intended use, and a PMA is needed.
- If device is approved under a PMA and lacks an investigational device exemption (IDE) for an investigational use.

Federal Trade Commission Act

- FTC regulates advertising of non-restricted medical devices
- Relevant provisions of FTC Act:
 - Section 5: Prohibits “unfair or deceptive acts or practices”
 - Section 12: Prohibits dissemination of any “false advertisement” likely to induce the purchase of devices, drugs, cosmetics, food, or services
 - Section 15: Defines “false advertisement” as ad that is misleading in a material respect

Overview of Promotion Requirements

Claims must be Truthful and Not Misleading

- Express & Implied Claims
- Omissions

Claims must be Substantiated

- Need “valid scientific evidence” supporting claims
- Evidence required may vary based on the claim and device characteristics, other factors

Claims must be “On-Label”

- Approved in a PMA
- Cleared in a 510(k)
- Consistent with Exemption from 510(k)

Claims = statements regarding the actual or comparative safety, effectiveness or performance of a device

Pre-Approval Communications

Display of 510(k)-Pending Devices

- FDA policy (CPG § 300.600) going back to 1978:

Although a firm may advertise or display a device that is the subject of a pending 510(k) -- in the hope that FDA will conclude that the device is substantially equivalent to a pre-amendments device -- a firm may not take orders, or be prepared to take orders, that might result in contracts of sale for the device unless limited to research or investigational use.

- Based on this language, a practice has emerged to display or advertise a device that is the subject of a submitted (or filed?) 510(k)

Check out our next-generation MRI!!

~~Safe and Effective!~~



~~Place your Order Now!~~

Pending 510(k) clearance, not available for sale within the United States

FDA Guidance (June 2018)

- “FDA does not intend to object to” communications about “health care economic information (HCEI)” with “payors, formulary committees, and similar entities” about products in development, which may include:
 - Product information and indication sought;
 - Endpoints and populations studied, and factual presentations of results from clinical or preclinical studies (i.e., no characterizations or conclusions should be made regarding the safety or effectiveness of the product”);
 - Anticipated timeline for FDA action;
 - Product pricing information and planned outreach/marketing strategies;
 - Product-related programs/services (e.g., patient support programs).
- Must also:
 - Include a clear statement that product is under investigation;
 - Provide information on stage of product development;
 - Follow up when information becomes outdated.

To Whom May Such Information be Provided?



Entities and persons making purchasing decisions for a population

“[P]ublic and private sector payors, formulary committees... technology assessment committees, ... third party administrators, and other multidisciplinary entities that, on behalf of health care organizations, review scientific and/or technology assessments to make drug or device selection or acquisition, formulary management, and/or coverage and reimbursement decisions on a population basis.”



HCPs making prescribing decisions and/or consumers

“[T]his guidance does not apply to ... other audiences, such as health care providers who are making individual patient prescribing decisions or consumers (e.g., dissemination directed toward prescribers or consumers via a public website).”



HCPs that have multiple roles

“This is not meant to suggest that individuals who have multiple roles, such as a health care professional who serves on a formulary committee and also provides care for individual patients, would not fall within the scope of the appropriate audience for this guidance when they are carrying out their professional responsibilities for selection of drugs for coverage or reimbursement for a payor, formulary committee, or similar entity.”

Comparative and General v. Specific Claims

Comparative and Superiority Claims

- Comparative claims explicitly or implicitly compare two or more devices

“best in
class”

“performed
better than
...”

“optimal”

“most
advanced”

- A claim can be comparative even if no other device is expressly discussed
- Presenting contrasting data is comparative claim even if no express comparative statements are made
- FDA regulations that a device can be misbranded through false or misleading comparisons to other products (see 21 C.F.R. § 801.6)

Comparative Claims

- Comparative claims (e.g., safety, effectiveness) require head-to-head studies
 - FDA has repeatedly stated this principle in Warning Letters to drug and device companies.
- In some cases, comparison of published performance or technical specifications may be defensible:
 - *E.g.*, IFU to IFU comparisons of objective information (e.g, stent lengths or published tensile strengths for an implant).
 - Such comparison should not be made if the test methods used for the two products were known to be materially different.
 - Such comparisons cannot be used to imply or claim a comparative advantage in terms of clinical performance.
- Even if a comparison is appropriately substantiated, other standards apply, including requirement to be consistent with labeling.

Curatronic Warning Letter (Jan. 2013)

“The BioMove 5000 is not only the best Stroke Rehabilitation system in the world but also the easiest stroke therapy device for use by the stroke survivor.”

“If the stroke survivor hardly has any movement left, the BioMove 5000 Pro device is the right choice as it is able to measure very weak EMG signals with its superior EMG detector and signal processing system.”



FDA: Comparative claims regarding the device being the best and easiest stroke rehabilitation system in the world require clinical data and a new 510(k)

General v. Specific Use

- 510(k) clearance for a general use does not necessarily mean the device is cleared for a specific indication
- Key is interpreting intended scope of clearance and
 - Risks inherent in specific use
 - Knowledge base
 - Public health impact

Guidance for Industry on General/Specific Intended Use

Introduction

This guidance¹ document identifies the general principles that will be considered by the Food and Drug Administration (FDA) in determining when a specific indication for use is reasonably included within a general indication for use of a medical device² for purposes of determining substantial equivalence under Section 513(f) or Section 520(l) of the Federal Food, Drug and Cosmetic Act (the Act). This guidance is issued in accordance with new Section 513(i)(1)(F) of the Act, which was added by Section 206 of the Food and Drug Administration Modernization Act of 1997 (FDAMA).

There are a number of reasons medical device manufacturers may seek to add a specific indication for use to a general use of a legally marketed predicate device. In some cases, technology may drive a manufacturer's decision to request the addition of a specific indication for use; "minor" technological changes to a device may make it more applicable to one specific indication for use and less applicable to other uses. Alternatively, a new competing device may enter the market with a specific claim resulting in a potential loss of market share for the device without that claim. Sometimes the identification of a specific intended use is the result of the evolution of medical practice once a device is marketed. When the medical community adopts a specific indication for use as routine practice, manufacturers and physicians want that specific indication for use to appear on the labeling for both liability and reimbursement purposes.

Purpose

The purpose of this document is to help medical device manufacturers understand the principles used by FDA to determine whether the addition of a specific indication for use to a medical device cleared for marketing with a general indication for use could trigger the need for a PMA. The guidance is intended to help manufacturers answer the following questions: Under what circumstances is a device with a new, specific indication for use likely to be found

¹ This document is intended to provide guidance. It represents the Agency's current thinking on the above. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

² Please note that the addition of a specific use to a device may result in a product that is considered a combination product or otherwise requires input from other FDA Centers as presented in the intercenter agreements effective October 31, 1991. In such cases, regulatory issues not addressed in this document may apply.

FDA Guidance Examples – Diagnostic Ultrasound

Ultrasound Device 510(k)-Cleared with general indication: evaluation of soft tissue

Specific claim

Aid in differentiation of benign from malignant breast lesions

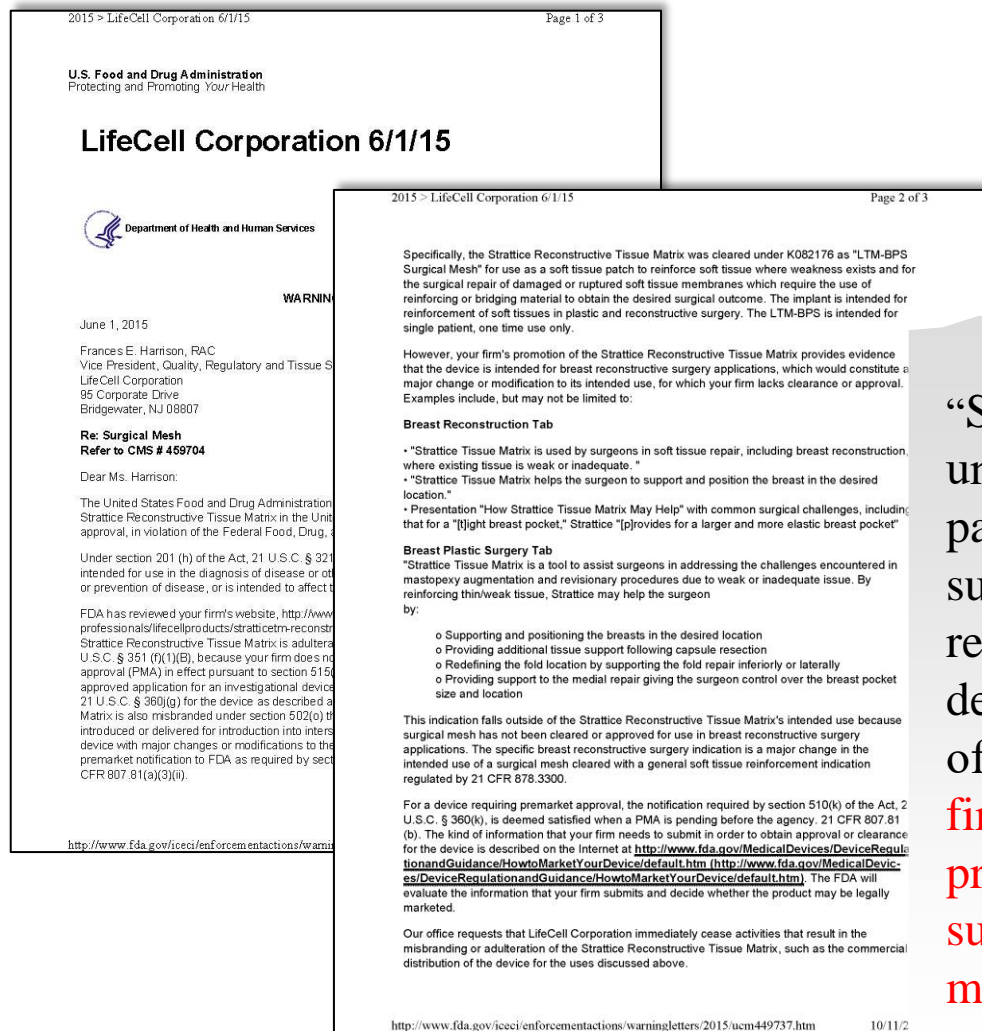
- Specific indication is not substantially equivalent to general indication.
 - Risk: Risk of false negatives leading to postponement of breast biopsy is far greater than risk of false negatives in general ultrasound studies
 - Public health: Breast cancer is a leading cause of morbidity/mortality in US, any change in the management paradigm for suspicious lesions may have a profound impact on public health.

Specific claim

Discrimination of small soft tissue parts (e.g. tendons, nerves)

- Specific indication is substantially equivalent to general indication
 - Risk: Specific indication is simply a statement of the types of anatomical detail that can be evaluated with ultrasound technology.

Warning Letter: Inappropriate Specific Claims



“Specifically, the Strattice Reconstructive Tissue Matrix was cleared under K082176 as ‘LTM-BPS Surgical Mesh’ for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes which require the use of reinforcing or bridging material to obtain the desired surgical outcome. The implant is intended for reinforcement of soft tissues in plastic and reconstructive surgery. ... However, **your firm's promotion of the Strattice Reconstructive Tissue Matrix provides evidence that the device is intended for breast reconstructive surgery applications, which would constitute a major change or modification to its intended use, for which your firm lacks clearance or approval.**”

Promotion Using Social Media

Social Media Regulatory Challenges

- Statute and regulations drafted for traditional print materials

(l)(1) Advertisements subject to section 502(n) of the act include advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems.

(2) Brochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug and references published (for example, the "Physicians Desk Reference") for use by medical practitioners, pharmacists, or nurses, containing drug information



- Interacting on social media:

- Same general rules apply – cannot promote via social media what would not be appropriate in other forums
 - Company responsible for content that it adopts or endorses through social media, e.g., liking, reposting
- FDA enforcement with respect to social media has ramped up in recent years

Responsibility for Social Media Content

2014 “Misinformation” Draft Guidance clarifies the types of content for which a company is “responsible”

A firm is responsible for communications that are owned, controlled, created, “influenced,” or affirmatively adopted or endorsed by the firm.

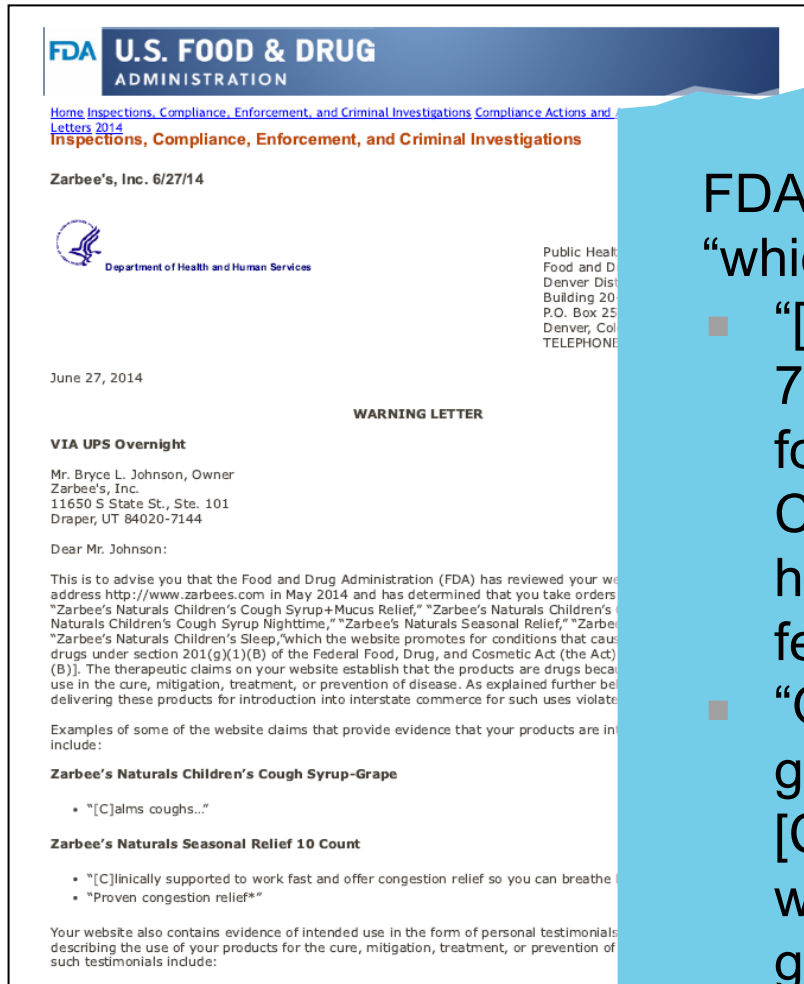
- Internet and social-media content made by the company or its agent
- Discussion hosted on company website with comments moderated by company

A firm is not responsible for user-generated content (UGC) that is independent

Even if posted on company owned site, if firm has no control over content

Content for which the company is responsible must comply with regulatory requirements

Warning Letter: Adoption of Inappropriate Statements



FDA cited user testimonials on company's Facebook page "which are endorsed or promoted by [the company]" including:

- "[Company] 'liked' the following comment made on January 7, 2014: 'I've been battling either bronchitis or pneumonia for the last 18 days and have tried everything...your Children's Cough Syrup and mucus relief got rid of...my hoarsness [sic]...[m]y throat and chest are beginning to feel so much better...'"
- "On January 6, 2014: '...It is the best thing for my granddaughters bronchitis.' On January 7, 2014: [Company] commented 'Vivian, we switched that item out with our Children's Nighttime Cough Syrup which works great!!!' on this claim."

Correcting Third-Party “Misinformation”

- A firm may choose to correct third party misinformation, but it is not required to do so
- Corrective information should be:
 - Limited and tailored to correcting the misinformation
 - Non-promotional in tone and presentation
 - Accompanied by FDA-approved labeling
 - Accurate and supported by appropriate evidence
 - Made by firm representative with disclosure of affiliation
- Firms should clearly identify the particular piece of misinformation and the portion of the forum it is correcting

Guidance for Industry

Internet/Social Media Platforms:
Correcting Independent Third-Party
Misinformation 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 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*.

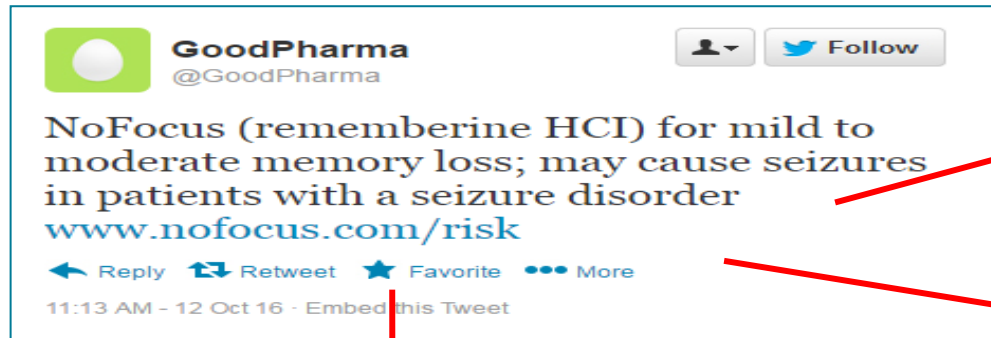
For questions regarding this draft document, contact (CDER) Julie Chronis at 301-796-1200; (CBER) Office of Communication, Outreach and Development at 800-835-4709 or 240-402-7800; (CVM) Thomas Moskal at 240-276-9300; or (CDRH) Deborah Wolf at 301-796-5732.

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

June 2014
Advertising

“Character-Space-Limited Platforms” Guidance

- Draft guidance applies to platforms like Twitter and “sponsored links” on search engines (Google, Yahoo) that have limited space
- Does not cover product websites, online banners, or reminder advertising



Benefit info must be accurate and non-misleading

Include both benefit and most serious risks within the communication, in comparably prominent manner

Direct hyperlink to more complete discussion of risk information: link to a safety info page, not a promotional page

- Products with complex indications or extensive serious risks may not be able to use such platforms in “meaningful ways”

Warning Letter: Lack of Safety Information

- Presentation of risk information in Facebook share widget

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
Washington, MD 20593

Home - Tasigna (nilotinib) 200mg capsules
<http://www.us.tasigna.com/hcp/index.jsp>

Tasigna (nilotinib) is used to treat a type of leukemia called Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML)

1 of 3 Choose a Thumbnail
☐ No Thumbnail

The posted shared content available from several of the Tasigna product web pages makes representations or suggestions about the efficacy of Tasigna, but fails to communicate any risk information. For example, the posted shared content from the “Facebook Share” widget on the healthcare professional home page for Tasigna consists of the following claims:

by Novartis and, although Facebook users can add additional comments that are displayed separately from the Tasigna information, the shared content cannot be modified by Facebook users who use this Facebook Share social media widget. We also note multiple Tasigna web pages contain widgets that allow users to share content via other social media applications offered via the “Share This” tool (<http://sharethis.com>). Some of the content available to share through these other social media applications raise similar issues to those discussed in this letter.

Testimonials and Endorsements

Testimonials/Endorsements

- FDA is usually skeptical of testimonials and endorsements
 - Testimonials are often “inherently misleading” and “not balanced” because “only patients [and physicians] with good outcomes . . . have testimonials”
(Deborah Wolf, CDRH)
- Testimonials should not go beyond the safety and efficacy demonstrated in labeling
 - Portrayals should reflect the typical patient/user experience
 - Claims should not be exaggerated
 - Claims should be balanced and disclose risks of the product
- Disclaimers like “individual results may vary” or “risks include....” are not sufficient to mitigate the misleading nature of testimonials



Testimonials/Endorsements

- In May 2015, FTC issued updated guidelines regarding testimonials/endorsements
 - “Testimonials claiming specific results usually will be interpreted to mean that the endorser’s experience reflects what others can also expect. Statements like ‘Results not typical’ or ‘Individual results may vary’ won’t change that interpretation.”
- That leaves advertisers with two choices:
 - Have adequate proof to back up the claim that the results shown in the ad are typical, or
 - Clearly and conspicuously disclose the generally expected performance in the circumstances shown in the ad



Warning Letter: Inappropriate Patient Testimonial



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Larry Downey
Executive Vice President, US Branded Pharmaceuticals
Teva Pharmaceuticals USA
c/o Teva Neuroscience, Inc.
901 East 104th Street, Suite 900
Kansas City, MO 64131

RE: NDA# 020622
COPAXONE[®] (glatiramer acetate injection) solution for
MA #762

WARNING LETTER

Dear Mr. Downey:

The Office of Prescription Drug Promotion (OPDP) of the U.S. Food and Drug Administration (FDA) has reviewed 2011 AAN Professional Exhibit Panels "A" (COP112014807/110193) (2011 AAN Exhibit Panels G) for Copaxone (glatiramer acetate injection) solution for subcutaneous injection (Copaxone), subcutaneous injection (COPAXONE[®]) (Teva) under cover of Form FDA-2253, as well as the "Te" (COP110006303/110312), "David Kyle" webpage (COP100006324/102245) for Copaxone.¹

These promotional materials are false or misleading because they present unsubstantiated claims, broaden the indication of Copaxone, omit important risk information associated with the drug, present unbalanced information, and omit material facts. Thus, the 2011 AAN Professional Exhibit Panels "A" (COP112014807/110193) (2011 AAN Exhibit Panels G) for Copaxone (glatiramer acetate injection) solution for subcutaneous injection (Copaxone), subcutaneous injection (COPAXONE[®]) (Teva) under cover of Form FDA-2253, as well as the "Te" (COP110006303/110312), "David Kyle" webpage (COP100006324/102245) for Copaxone, are in violation of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), 21 U.S.C. 352(a), (n), 321(n), (e)(5); (e)(6)(i), (ii), (iv), (xviii) & (e)(7)(i). These violations are

"...the patient testimonials misleadingly broaden the indication and overstate the efficacy of Copaxone. . . . Copaxone is **not** indicated for slowing, preventing or reversing physical disability associated with RRMS. Moreover, FDA is not aware of substantial evidence or substantial clinical experience supporting the implication that Copaxone treatment will result in the magnitude of effects as described in the above patient testimonials. . . . The personal experiences of 'Team Copaxone' patients . . . do not constitute substantial evidence to support such claims and presentations. If you have data to support these claims, please submit them to FDA for review."

Warning Letter: Influencers Held to Same Standard



kimkardashian

FOLLOWING

464k likes

1w

kimkardashian OMG. Have you heard about this? As you guys know my #morningsickness has been pretty bad. I tried changing things about my lifestyle, like my diet, but nothing helped, so I talked to my doctor. He prescribed me #Diclegis, I felt a lot better and most importantly, it's been studied and there was no increased risk to the baby. I'm so excited and happy with my results that I'm partnering with Duchesnay USA to raise awareness about treating morning sickness. If you have morning sickness, be safe and sure to ask your doctor about the pill with the pregnant woman on it and find out more www.diclegis.com; www.DiclegisImportantSafetyInfo.com

view all 10,983 comments

imoumaima @youssefchorfi

flawlessfashionstore ldk if shes getting paid for this and do not care. But it is safe for mom & baby. I called my doctor because i couldn't even keep water down.



Add a comment...



☒ Efficacy claims

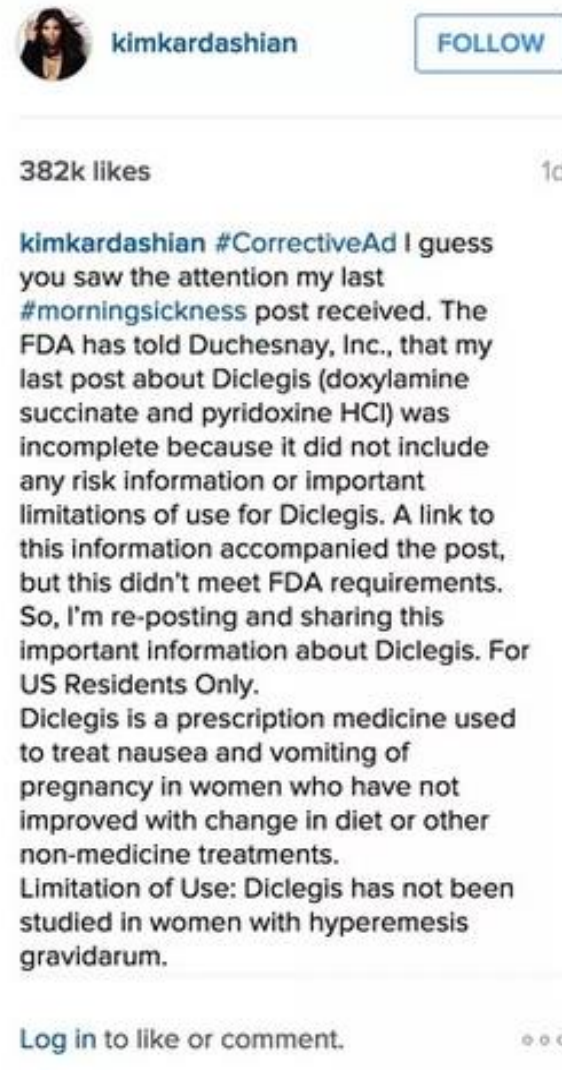
☒ Important Safety Information

☐ Risk information

☐ Material facts

Bottom Line: post implies that product is safer than has been demonstrated

FDA-Mandated Corrective Ad



#CorrectiveAd

Original post deleted and new post complied with FDA's corrective advertising requirements, including Important Safety Information

Endorsements: Experts

- Whenever an advertisement represents, directly or by implication, that the endorser is an expert, the endorser must actually have such expertise.
- Endorsement must be supported by an actual evaluation of the product
 - Evaluation must have been at least as extensive as someone with the same degree of expertise would normally need to conduct in order to support the conclusions presented in the endorsement.

Warning Letter to manufacturer of a vascular hemostasis device

“[A] testimonial by one of the physicians on your web site . . . states, *Our overall complication rates (major and minor) with VasoSeal have been extremely low--1.25%.* These statements essentially contradict the complication rates identified in the approved labeling and approved instructions for use.”

Material Connections

- “Material connections” between endorser and company must be clearly and conspicuously disclosed as part of endorsement
- Material connection could be:
 - Monetary payment or financial arrangements (e.g., “ambassadors”)
 - Free product with expectation that endorser will discuss product
- Material connections also impact whether company is “responsible” for content of testimonial or endorsement
 - Company is responsible for content controlled or “influenced” by the firm (e.g., via financial arrangements)
 - Company is also responsible for content it adopts or endorses (e.g., reposts, retweets, likes, etc.)

Off-Label Communications

The “Off-Label” Paradigm



Physicians may use cleared/approved drugs and devices for unapproved/uncleared uses

The approved labeling may lag behind medical science

Off-label use may be accepted medical practice, supported by literature, and reimbursed by federal health care programs



BUT, companies may not promote an off-label use.

Off-label promotion can trigger FDA Warning Letters, DOJ investigations, settlements, collateral lawsuits, and criminal prosecutions

In FDA’s traditional view, it does not matter if the off-label information is truthful and accurate, or whether the off-label use is a safe and effective use of the drug or device – if it is off-label promotion, it can trigger enforcement

Traditional Areas of Communications re Unapproved Uses

Answering Questions

May respond to “unsolicited” requests, even if the response requires the company to share off-label information (Draft Guidance, Dec. 2011):

- Initiated by persons that are completely independent of the company
- Not “prompted” in any way
- Public v. Private unsolicited requests

Off-Label Communications: What's Happened?

09-5006-cr
United States v. Caronia

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

August Term 2010

(Argued: December 2, 2010 Decided: December 3, 2012)

Docket No. 09-5006-cr

UNITED STATES OF AMERICA,
Appellee,

v.

ALFRED CARONIA,
Defendant-Appellant.

Before:
RAGGI, LIVINGSTON, and CHIN, *Circuit Judges.*

Appeal from a judgment of the United States District Court for the Eastern District of New York (Eric N. Vitaliano, J.) convicting defendant-appellant Alfred Caronia of conspiracy to introduce a misbranded drug into interstate

The Clerk of the Court is directed to amend the official caption in accordance with the above.

United States v. Caronia
(2nd Cir. 2012)

Case 1:15-cv-03588-PAE Document 73 Filed 08/07/15 Page 1 of 71

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

AMARIN PHARMA, INC., DR. JONATHAN HERBST, DR. ERIC RISHE, DR. PETER GOTTESFELD, and DR. RALPH YUNG,
Plaintiffs,

-v-

UNITED STATES FOOD & DRUG ADMINISTRATION, UNITED STATES OF AMERICA, STEPHEN OSTROFF, M.D., and SYLVIA MATTHEWS BURWELL,
Defendants.

PAUL A. ENGELMAYER, District Judge:

In *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012), the Court of Appeals for the Second Circuit vacated a pharmaceutical sales representative's conviction for conspiring to introduce a misbranded drug into interstate commerce, in violation of 21 U.S.C. §§ 331(a) and 333(a)(1). The conviction was based on Caronia's having promoted a drug for "off-label use," that is, a use other than the one approved by the U.S. Food and Drug Administration (the "FDA"). Caronia's conduct to promote the off-label use, however, had consisted solely of truthful and non-misleading speech. The Second Circuit held that, to avoid infringing the First Amendment, the misbranding provisions of the Federal Food, Drug and Cosmetic Act (the "FDCA") must be construed "as not prohibiting and criminalizing the truthful off-label promotion of FDA-approved prescription drugs" where the off-label use itself is lawful. 703 F.3d at 168.

This case grows out of the decision in *Caronia* and involves the same misbranding provisions. Plaintiff Amarin Pharma, Inc. ("Amarin") manufactures a triglyceride-lowering drug, Vascepa. The

USDC SDNY
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DOC #:
DATE FILED: 8/7/15

15 Civ. 3588 (PAE)
OPINION & ORDER

Amarin Pharma. v. FDA
(S.D.N.Y. 2015)

Case 1:15-cv-07055-RA Document 16 Filed 09/09/15 Page 1 of 31

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

PACIRA PHARMACEUTICALS, INC.,
DR. LOREN J. HARRIS, and DR. JOSEPH W. BELL,
Plaintiffs,

v.

UNITED STATES FOOD & DRUG ADMINISTRATION; UNITED STATES OF AMERICA; DR. STEPHEN OSTROFF, in his official capacity as Acting Commissioner of Food and Drugs; UNITED STATES DEPARTMENT OF HEALTH & HUMAN SERVICES; and SYLVIA MATHEWS BURWELL, in her official capacity as Secretary of the Department of Health & Human Services,
Defendants.

Civil Action No. 15-cv-7055-RA

MEMORANDUM OF LAW IN SUPPORT OF
MOTION FOR PRELIMINARY INJUNCTION

Pacira Pharma. v. FDA
(Settled 2015)

Case No. SA-14-CR-926-RCJ
United States District Court, W.D. Texas, San Antonio Division.

United States v. Vascular Solutions, Inc.

181 F. Supp. 3d 342 (W.D. Tex. 2016)
Decided Jan 27, 2016

ROYCE C. LAMBERTH, United States District Judge

343 *343

Bud Paulissen, Christina Laura Playton, United States Attorney's Office, San Antonio, TX, Charles John Biro, Michael S. Blume, Timothy T. Finley, U.S. Department of Justice, Washington, DC, for Plaintiff.

Christopher L. Peele, The Ashcroft Law Firm, Johnny K. Sutton, Ashcroft Sutton Ratcliffe, LLC, Austin, TX, Jeffrey S. Bucholtz, John C. Richter, Michael R. Panze, Robert K. Hnr, King & Spalding LLP, Washington, DC, Dulce J. Foster, John W. Lundquist, Kevin C. Riach, Fredrikson & Byron, P.A., Minneapolis, MN, John E. Murphy, Attorney At Law, San Antonio, TX, for Defendants.

MEMORANDUM AND ORDER

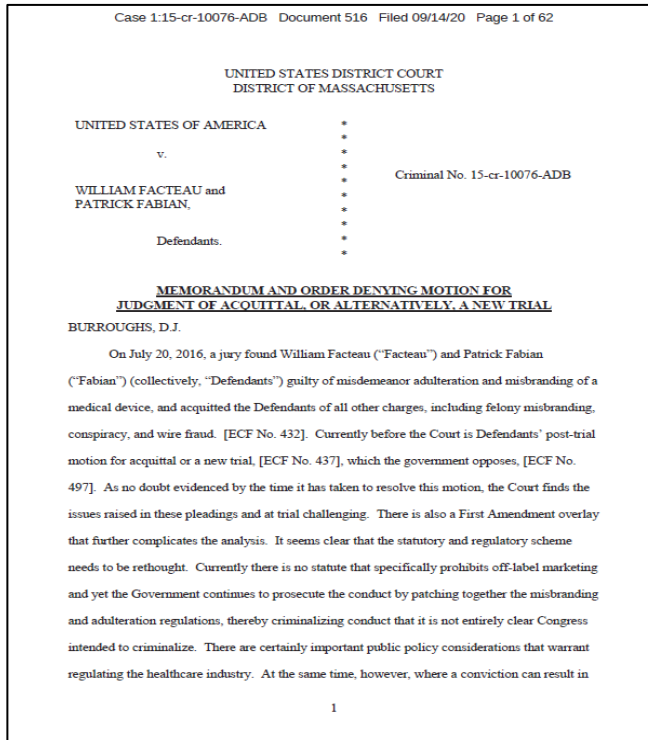
ROYCE C. LAMBERTH, United States District Judge

This case comes before the Court on defendants' Motion [158] in Limine to Set Ground Rules for Trial Regarding the First Amendment, the government's response thereto, and defendants' reply in support thereof, as well as defendants' Motion [160] to Exclude Evidence of the Company's Subjective Intent to Market the Vari-Lase Device, the government's response [181] and defendants' reply [192] thereto. Upon consideration of these filings, the applicable law, and the entire record in this case, defendants' motions are **DENIED** for the reasons set forth below.

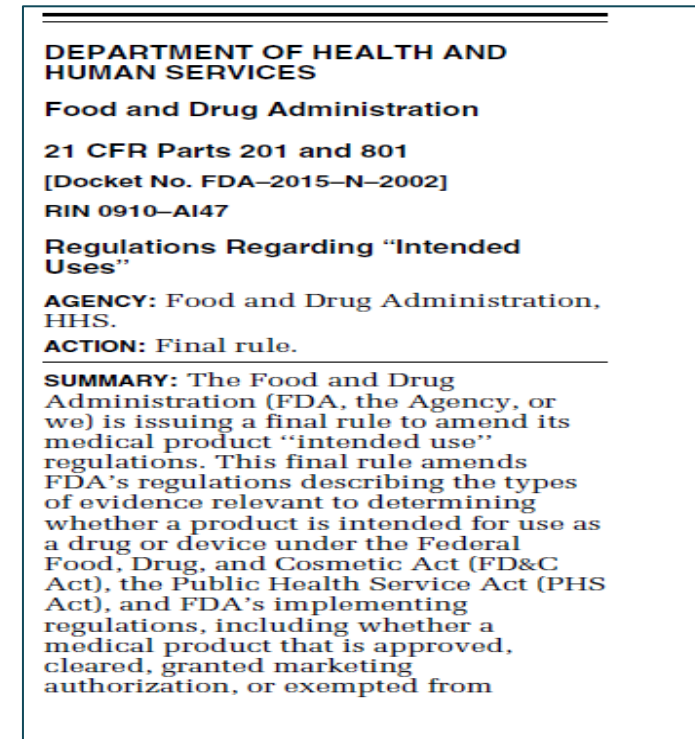
United States v. Vascular Solutions (W.D. Tex 2016)

Increasing consensus that truthful, non-misleading off-label promotion is protected by First Amendment

But ... not so fast?



United States v. Facticeau
(D. Mass 2020)



FDA Final Rule Amending Regulations
on Intended Use (August 2, 2021)

Recent developments reflecting traditional FDA views on off-label issues.

Off-Label Communications: Where are we today?



The "law of the land" has not changed



Premature for firms to revise their promotional policies

- Court decisions and settlements are very case-specific and should not be applied more broadly
- FDA and DOJ have continued to pursue cases and open new investigations



But, certain core precepts are being successfully challenged, which could, in the future, lead to more leeway on what has historically been considered impermissible, off-label promotion



FDA could issue guidance in future on key aspects of off-label promotion (e.g., scientific exchange)

Questions?