

# FDA Regulation of Medical Device Advertising & Promotion

FDLI/CDRH Training – March 4, 2021

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# ***Agenda***

- A. Scope of FDA Authority**
- B. Fundamental FDA Rules and Policies for Marketing**
- C. Marketing and Promotion of Unapproved (Investigational) Devices**
- D. Claims Substantiation**
- E. Off-Label Issues**
- F. Direct-to-Consumer (DTC) Advertising**
- G. Monitoring Compliance; FDA and non-FDA Enforcement**
  - i. Internet and Social media**

# Scope of FDA Authority

# Scope of FDA and FTC Authority

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- Under the Federal Food, Drug, and Cosmetic Act (FDCA), FDA has jurisdiction over medical device labeling [21 U.S.C. § 352(a)]
- FDA jurisdiction over advertising is *limited* to prescription drugs and restricted devices (designated as such by FDA, by PMA or regulation)
  - FTC has primary jurisdiction over advertising of all other (non-restricted) medical devices
  - FDA has consistently sought to expand its jurisdiction over advertising (of non-restricted devices) by calling it labeling

# What Are Labeling and Advertising?

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- *Label*: any display of written, printed, or graphic matter on the immediate container of any article, or any such matter affixed to any consumer commodity or affixed to or appearing upon a package containing any consumer commodity.
- *Labeling*: all written, printed, or graphic matter *accompanying* an article at any time while such article is in interstate commerce or held for sale after shipment or delivery in interstate commerce.
  - No physical connection required – must just supplement or explain the article.
  - ***Examples?***
- Advertising is not specifically defined in the FDC Act
  - Can include information in published journals, magazines, other periodicals, newspaper, and advertisements broadcast through media such as radio, television, and telephone communications systems

# FDA versus SEC Expectations

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- SEC: Must give sufficient information to (prospective) shareholders, including about products in development
  - SEC requires a disclaimer of future looking statements, but these often are seen by FDA as pre-approval promotion
- FDA shows some flexibility for corporate information presented to that audience
  - Should be temporary – not enduring (usually 4-6 months is long enough)
  - Prospectus for an IPO should not use overly promotional language and should address things such as risk that FDA will not clear or approve a device, etc.
- *Takeaways:*
  - Apply the truthful, non-misleading standard to avoid liability from either agency
  - Separate section of the website
  - Avoid promotional statements and remove investor materials (8Ks, etc.) from website after short period

# Fundamental FDA Rules and Policies for Marketing

# General Rules of Marketing and Promotion

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- **Golden Rule:** A medical device may be labeled and promoted only for its cleared or approved intended use(s)
  - If 510(k)-exempt, labeling may not exceed the scope of the exemption as outlined by the classification regulation and the legally marketed exempt devices of that type
- ***Which of the following constitute “promotion”?***
  - A. Posting your device’s labeling on a public website*
  - B. Discussing your device’s capabilities on Facebook*
  - C. Objectively answering a doctor’s question about your product’s intended use*
  - D. Displaying a prototype of your product at a trade show*



# Adulteration and Misbranding

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- Devices are adulterated or misbranded when advertising/labeling creates a new intended use that requires premarket notification or approval [FDCA §§ 501(1); 502(o)]
- **Adulteration** means:
  - Lack of premarket approval under FDCA § 515(a)
  - Lack of Investigational Device Exemption (IDE) approval under FDCA § 520(g)
- **Misbranding** means *false or misleading* in any particular [21 USC § 352(a)], such as:
  - Misstatement or omission of material facts
  - Lack of fair balance (risk and benefit information)
  - Lack of adequate directions for use
  - Misleading representation with respect to another device [21 CFR § 801.6]

# Determination of Intended Use

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- Determination of intended use [21 C.F.R. §801.4]:
  - Objective intent – expressions and circumstances
  - All statements by company, written or oral, labeling, advertising, or on website
  - FDA looks at all the surrounding circumstances in determining intended use
- If promoting for a new intended use, FDA may find that the new use requires a new 510(k) notice or a new PMA or PMA Supplement

# Marketing and Promotion of Unapproved Devices

# Investigational Devices

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- **CANNOT** represent the device as safe or effective, or imply that such characteristics have been established;
- **CANNOT** promote or test market the device
- **CAN** disseminate limited information tailored to recruitment of clinical investigators and study subjects
  - Must state the purpose is to recruit investigators or patients, not to make the device generally available
  - Must prominently state: “Caution – INVESTIGATIONAL DEVICE. LIMITED BY FEDERAL (OR U.S.) LAW TO INVESTIGATIONAL USE”
- **CAN** disseminate technical information (*e.g.*, specifications) in an objective, *non-promotional* context

# Devices with a 510(k) Submission Pending

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- Display/promotion at a trade show is permitted under FDA Compliance Policy Guide (CPG) 300.600
  - Only for the intended use that is the subject of the pending 510(k) notice
  - Must include: “Pending 510(k), not available for sale within the United States.”
- Solicitation of purchase orders (commercialization) is prohibited
  - Price information may not be disseminated
  - Customer lists should not be generated
- This policy explicitly calls out devices *after* a 510(k) notice is submitted
- If FDA requires clinical data to support the 510(k) submission, follow the rules for displaying investigational devices instead

# Claim Substantiation

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- **Claim** = any statement tied to a device's intended use and company's purpose for selling it
- FDA may consider a claim false/misleading if not appropriately substantiated
  - Data supporting a claim must be scientifically adequate (*i.e.*, statistically valid sample size, peer-reviewed, etc.), and typically submitted to FDA for formal review
  - “Data on file” may support certain claims for cleared devices, but increasingly disfavored
  - Disclose relevant facts relating to studies to give reasonable basis for assessment
- “Establishment” claims = express or implied statements describing the amount of support for a particular product claim
  - Key rule enforced by multiple agencies: Company must have the form of substantiation alluded to by the claim

# Comparative Claims

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- FDA considers comparative claims inherently misleading, unless based on appropriate head-to-head testing.
  - Includes superiority claims (assertions of better safety, performance, etc.)
  - A device is misbranded if its labeling contains a false or misleading statement about another device
- Clinical comparative claims require head-to-head clinical data support evaluating the devices being compared in a scientifically valid study, where both devices are used for their on-label indications
  - Even where a company is comparing to a prior version of its own device



# Claims about FDA Review Status

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- Language noting 510(k)-cleared status of a device is allowable, unless presented in a way that would be considered misleading by implying:
  - (1) approval;
  - (2) FDA endorsement; or
  - (3) that clearance means anything beyond the fact that the device is legally marketed
- Promotional materials for a PMA-approved device may state “FDA-approved”
- Promotional materials *cannot* refer to a product’s registration and listing status

# Your Turn!

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" products are FDA approved  
Body Composition Analyzer Device.



# Off-Label Issues

# Off-Label Use and Practice of Medicine Exemption

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- FDA has authority over medical device labeling and restricted device advertising; but FDA does not regulate the *use* of devices by physicians
- Under the FDC Act, physicians may use or prescribe a lawfully marketed product for unlabeled uses as part of caring for an individual patient
  - FDA avoids dictating to health care professionals how to practice their craft
  - Where an HCP inappropriately commercializes/promotes, FDA can and has taken enforcement action
- Manufacturers *cannot* promote uncleared/unapproved uses of a device
  - Sales representatives should be trained as to what is and is not within the scope of a device's clearance/approval

# Determining a Product's Intended Use

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- FDA looks at all the surrounding circumstances in determining intended use, including:
  - Objective intent of manufacturer based on totality of expressions and circumstances
  - All statements by company, written or oral, labeling, advertising, or on website
- If promoting for a new intended use, FDA may find that the new use requires a new 510(k) or new PMA or PMA Supplement
- 2018 [guidance](#) on “consistency with labeling” somewhat broadens acceptable claims and evidentiary support for promotion of approved uses that are “consistent” with FDA-required labeling
  - More relevant to PMA-approved devices

# General versus Specific Uses

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- Clearance/approval of a general indication does NOT allow for promotion of more specific indications (*e.g.*, regarding function, target population, etc.)
- Per General/Specific Intended Use guidance, to determine whether a specific use is covered by a general indication, interpret intended scope of the clearance/approval and whether the specific indication raises different/more severe risks
  - For cleared devices, FDA generally sees the Indications for Use statement as the definitive scope of the clearance; for PMA-approved devices, scope is defined by the FDA-approved labeling
  - Data used to support the clearance/approval may be key; language in the submission, approved labeling, and related correspondence may also be important
  - If FDA has communicated to a company that it does not agree with using certain terms or claims, promoting the device along those lines increases risk of enforcement action

# Your Turn – What is “Within the Scope” of Clearance?

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- Hot Dog Patient Warming System is 510(k)-cleared “to prevent or treat hypothermia and to provide warmth to patients”
- ***Can the company include the following on its website?***
  - ❑ “Unlike forced-air, air-free HotDog warming doesn't generate waste heat that can contaminate the sterile field. Hospitals that have switched to HotDog report significant reduction in deep joint infections. For example, a #1 rated hospital in Minnesota experienced an 81% reduction after switching to air-free warming.”
  - ❑ Use has been shown to reduce incidence of hypothermia in several clinical trials
  - ❑ Summary of an article published in a scientific journal, stating that it finds “74% reduction in implant infections” and “Researchers concluded air-free warming is recommended over forced-air warming for orthopedic procedures”

# What is “Within the Scope” of Clearance?

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- *Can the company include the following on its website?*

“Unlike forced-air, air-free HotDog warming doesn't generate waste heat that can contaminate the sterile field. Hospitals that have switched to HotDog report significant reduction in deep joint infections. For example, a #1 rated hospital in Minnesota experienced an 81% reduction after switching to air-free warming.”

✗ Infection reduction is a different intended use from preventing hypothermia, and would require supporting clinical data

Use has been shown to reduce incidence of hypothermia in several clinical trials

✓ Consistent with cleared indications for use; should provide adequate context

Summary of an article published in a scientific journal, stating it finds “74% reduction in implant infections” and “Researchers concluded air-free warming is recommended over forced-air warming for orthopedic procedures”

✗ Infection reduction claim (albeit from third-party); exceeds scope of clearance



# Dissemination of Off-Label Information

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- A few “safe harbors” allow for manufacturers to lawfully disseminate (not promote) truthful, non-misleading information about off-label uses of their medical devices:
  - Proactive dissemination to healthcare providers via FDA’s “Good Reprints” practices guidance
  - Reactive dissemination in response to an unsolicited request from a healthcare provider
  - Sponsorship of independent Continuing Medical Education (CME) events
  - “Scientific exchange”
- Off-label information disseminated via these pathways must be non-promotional, scientifically valid, objective, and fairly balanced
  - FDA does not intend to consider such dissemination as evidence of the manufacturer’s intent to promote a device for off-label use

# Recent First Amendment Case Law

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- Recent 1<sup>st</sup> Amendment cases show a trend of supporting manufacturers' truthful and non-misleading commercial speech, including discussion of off-label uses
  - *United States v. Caronia* (2d Cir. 2012)
  - *Amarin Pharma, Inc. v. FDA* (SDNY Aug. 2015)
  - *Pacira Pharmaceuticals Inc. et al. v. FDA* (SDNY Dec. 2015)
    - Argued that broad indication for which a device was approved reasonably encompassed the specific uses for which it was promoted
  - *U.S. v. Vascular Solutions, Inc. and Howard C. Root* (WD Tex. Feb. 2016)
  - *U.S.A. v. Facteau, et al.* (D. Mass. July 2016)
- Important: Reliance on these cases is still very jurisdiction- and fact-specific.
- Case law also exists that conflict, with, or limits the application of, the above cases

# Recent Developments: FDA “Intended Use” Rule

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- There is a proposed rule to modify the definition of “intended use”
- If finalized, it would delete the last sentence in the current regulation which requires manufacturers to supply adequate labeling covering a new “effective” intended use (an off-label use) when they are aware of it
- Would also clarify that manufacturer knowledge (of off-label use) is only one source of evidence of what the manufacturer’s intent is, while maintaining FDA ability to rely on that as part of the totality of evidence of the intended use

# Payor Guidance

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- June 2018 final guidance on manufacturer communications of health care economic information (HCEI) with payors, formulary committees, and similar
  - FDA defines an audience with appropriate knowledge and expertise to whom firms may provide HCEI, as long as it is “related to” a device’s cleared or approved indication
    - Meaning related to the disease or condition, its manifestation, or symptoms associated with it in the patient population for which it is indicated in the FDA-approved labeling
  - Greater leniency in what is disseminated to this tailored audience (*e.g.*, can discuss expected date of clearance to allow for budgeting)
- FDA stops short of permitting claims regarding unapproved uses, patient populations, doses, and situations that might shift the risk/benefit balance

# Direct-to-Consumer (DTC) Advertising

# DTC Promotion: General Requirements

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- FDA is particularly concerned with promotional materials directed to lay consumers, because they may not have the specialized knowledge or training needed to appropriately utilize the information provided in these materials
- Primary rules generally align with those for promotion of any device:
  - Content must be consistent with the cleared/approved indications for use
  - All content must be truthful, accurate and current (i.e., not false or misleading)
    - Specific claims *and* overall impression
  - Material facts must be revealed
  - Fair balance/presentation of risks and benefits
  - All language used should be understandable to the target audience
- Beyond the general DTC promotional requirements, the FDCA sets forth specific requirements for DTC ads for restricted devices

# DTC Advertising: Testimonials

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- Testimonials utilized by a company are subject to the same requirements as if the company made the statements itself
- Testimonials must be consistent with the device clearance or approval
- Testimonials must represent results that a typical user might expect - can't cherry pick the very best results
  - or must clearly and conspicuously disclose the generally expected performance in the depicted circumstances with adequate substantiation for that representation
  - Not sufficient to use a disclaimer such as “results not typical”
    - *The promotional material must convey fair balance of benefits and risks*
- Numerous other requirements imposed by the FTC

# FTC's Purview: Deceptive or False Advertising

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- The FTC Act prohibits “unfair or deceptive acts or practices” in advertising, including false advertisements (defined as “misleading in a material respect”) likely to induce the purchase of foods, drugs, cosmetics, or devices
  - FTC looks at “representations made or suggested“, and at the extent to which an ad fails to reveal facts material in light of such representations with respect to consequences which may result from use of a product under the conditions prescribed in the ad, *or* under such conditions as are customary or usual
- To substantiate health, safety, or efficacy claims, the FTC generally requires advertisers to possess “competent and reliable scientific evidence”
- If disclosure of information is necessary to prevent an ad from being deceptive, it must be clear and conspicuous, and in appropriate proximity to the claim it modifies



# Monitoring Compliance; FDA and non-FDA Enforcement

## *What's the Risk?* FDA Enforcement Remedies

Inspectional observations (FDA-483s)	Civil monetary penalties
Warning Letters and Untitled Letters	Criminal fines/penalties
Product seizures	Equitable remedies (restitution, disgorgement)
Administrative detention	Criminal prosecution of company/individual
Recalls (voluntary and mandatory)	Corporate integrity agreements
Application Integrity Program	Import alerts
Refusing requests for 510(k) clearance or PMA approval of new products and PMA Supplements	Exclusion from federal health care programs and debarment from government contracts/grants
Injunctions	

Informal outreach (e.g., e-mail, teleconference), questioning promotional practices is fairly common in CDRH's new Total Product Life Cycle model

# *What's the Risk?* Non-FDA Enforcement

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- False Claims Act
  - U.S. Department of Justice (DOJ) has authority to prosecute device manufacturers for off-label promotion
  - Focus on promotional activities that result in submission of improper claims for Medicare/Medicaid reimbursement by healthcare professionals (i.e., for uncleared/unapproved uses of a device)
- FTC enforcement for false or misleading statements and unsubstantiated claims in advertising
- Lanham Act – unfair or deceptive trade practices
- State laws

# Internet / Social Media Issues

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- FDA considers website materials and social media to be labeling
  - Holds companies responsible for their sites just as for other promotional material
  - A company is responsible for information it links to its website
- U.S. vs. OUS marketed products
  - Portal page should direct to U.S. versus OUS sections of website if clearance/approval is not universal
  - Disclaimers regarding U.S. regulatory status are not enough



# Unique Challenges of Social Media Promotion

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- Presenting risk information with space limitations and web page layouts
- Monitoring and responding to adverse events, complaints, customer service concerns generated by users
  - *e.g.*, "@COMPANY Can we talk about #sideeffects from your products? Please? #stillvomiting #nothappy #DRUGxx #FAIL"
- Controlling employees' and representatives' comments and responses
- Need for and extent of monitoring user-generated content on corporate webpages or sites influenced by companies for potential off-label information
- User-generated content can be false, misleading or biased; blogs/comments allow others to influence the message
  - Whether/how to correct third-party "misinformation"
  - Company is not responsible for *truly independent* content generated by users

# Social Media Enforcement

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- Fundamental violations cited are the same as in more traditional platforms
  - Promotion outside scope of clearance
    - Promoting products for unapproved intended uses via links on a company site, search engines, meta-tagging, etc.
  - Promotion without any clearance/approval
  - Misleading presentations, *e.g.*, unbalanced presentation of risks and benefits
- FDA social media enforcement examples
  - “Liking” a Facebook comment about an uncleared/unapproved use (treating cancer)
  - Company website designed such that product lists were brought up if a consumer typed diseases (*e.g.*, “diabetes”) into the product search field (and the product did not have corresponding approval)
  - Sharing and retweeting third-party comments may also be considered endorsement by the company

# Other Promotional Issues

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- Trade shows, scientific forums, detailers
  - FDA monitors these activities and often attends events “in cognito”
- Press Releases
  - FDA permits more information than otherwise typically allowed in labeling, but restrictions still apply
  - Must not state or imply that the device is approved or cleared for intended uses outside of the already cleared or approved indications



## *How will you use the information you received?*

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