Medical Devices and IVDs: Regulatory Challenges of Advertising and Promotion

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Moderated by Michael Swit, Principal, Law Offices of Michael A. Swit

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Basics of FDA Regulation of Device & IVD Advertising

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Who Has Jurisdiction …

- **Restricted Devices**
  - Labeling -- FDA
  - Advertising – FDA
- **"Unrestricted Devices"**
  - Labeling -- FDA
  - Advertising – Federal Trade Commission

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Who Has Jurisdiction …

- **Internet – is it labeling or advertising?**
  - Eye of beholder?
  - FDA has asserted that it can regard as labeling web sites for products such as OTC drugs and dietary supplements that the agency does NOT have jurisdiction over advertising

Restricted Devices -- Misbranding

- **<u>Section 502(q)</u> --** In the case of any restricted device distributed or offered for sale in any State, if :
  - (1) its ***advertising is false or misleading in any particular***, or
  - (2) it is sold, distributed, or used in violation of regulations prescribed under section 520(e) of this title [i.e., a regulation restricting sale of device]

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Brief "Statement" for Restricted Devices – Section 502(r) and Advertising

- ***Device is Misbranded …*** unless the manufacturer, packer, or distributor thereof includes in all ***advertisements and other descriptive printed matter*** issued or caused to be issued by the manufacturer, packer, or distributor with respect to that device
  - (1) a true statement of the device's established name as defined in subsection (e) of this section, printed prominently and in type at least half as large as that used for any trade or brand name thereof, and
    - *….continued …*

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Section 502(r) – Device "Brief Statement" …

- (2) a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications and,
  - in the case of specific devices made subject to a finding by the Secretary after notice and opportunity for comment that such action is necessary to protect the public health, a full description of the components of such device or the formula showing quantitatively each ingredient of such device to the extent required in regulations which shall be issued by the Secretary after an opportunity for a hearing.

• *.. continued …*

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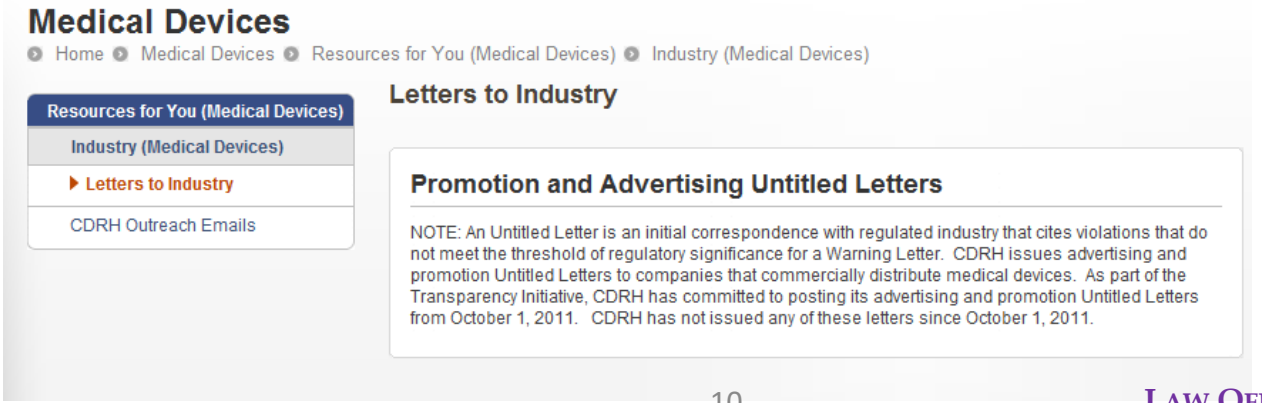
502(r) – Devices "Brief Statement"

- Except in extraordinary circumstances, ***no regulation issued under this paragraph shall require prior approval*** by the Secretary of the content of any advertisement and no advertisement of a restricted device, published after the effective date of this paragraph shall, with respect to the matters specified in this paragraph or covered by regulations issued hereunder, be subject to the provisions of sections 12 through 15 of the FTC Act.
- This paragraph shall not be applicable to any printed matter which the Secretary determines to be labeling as defined in section 321(m) of this title.

Device Advertising Regulations

- Marketed Devices –*<u>no</u>* separate device advertising regulations as in 21 CFR 202.1
- Center for Devices & Radiological Health (CDRH), compared to its drug counterparts -- relatively inactive in ad enforcement –



Device Advertising – Warning Letters …

- **Warning Letters – just 27 between 2001 and today**
- **Source: Warning Letter search: "device advertising" and "device promotion"**
  - http://www.accessdata.fda.gov/scripts/warningletters/wlSearchResult.cfm?webSearch=true&qryStr=device+advertising

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Devices – Intended Uses

- **"Ordinarily, intended use is determined by reference to 'labeling' or promotional claims; only in rare cases might it be necessary to infer intended use from other types of information."**
  - Source: ODE Blue Book Memorandum #K86-3 entitled *Guidance on the Center for Devices and Radiological Health's Premarket Notification Review Program* ***[Hot Link]***
- **Issue** – relative to off-label promotion issues
- **FDA** – can inhibit off-label use, via statute, in clearing a 510(k) under Section 513(i)(1)(E), which provides …
  - ***… continued …***

513(i)(1) (E) – 510(k) Restrictions on Off-Label Promotion

- **Sub-sub paragraph (i) -- FDA --** may require a statement in labeling that provides appropriate information regarding a use of the device not identified in the proposed labeling if, after providing an opportunity for consultation with the person who submitted such report, the Director determines and states in writing—
  - (I) that there is a reasonable likelihood that the device will be used for an intended use not identified in the proposed labeling for the device; and
  - (II) that such use could cause harm.

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513(i)(1)(E) – 510(k) -- Off-Label Restrictions …

- (ii) Such determination shall—
  - (I) be provided to the person who submitted the report within 10 days from the date of the notification of the Director's concerns regarding the proposed labeling;
  - (II) specify the limitations on the use of the device not included in the proposed labeling; and
  - (III) find the device substantially equivalent if the requirements of subparagraph (A) are met and if the labeling for such device conforms to the limitations specified in subclause (II).
- (iii) The responsibilities of the Director under this subparagraph may not be delegated.

Questions?

- ***Call or e-mail:***

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About Your Speaker

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FDA Regulation of Advertising of Diagnostics, RUO Products, and Laboratory Developed Tests

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The Diagnostic Playing Field

- **"Pure" In Vitro Diagnostics – PMA or 510(k)**
- **Laboratory Developed Tests (LDTs) – CLIA regulated**
- **RUO products**
  - FDA: "diagnostic in training" –
    - **21 CFR 809(c)(2)(i)** -- For a product [in vitro diagnostic] in the laboratory research phase of development, and not represented as an effective in vitro diagnostic product, all labeling bears the statement, prominently placed: "For Research Use Only. Not for use in diagnostic procedures."
  - But – if intended use is not diagnostic, how can it be a diagnostic?

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Distinguishing RUO vs. Clinical/Diagnostic Claims

RUO Claims – General Principles

- **Focus on the use of the product for research**
  - ***Use***:
    - Statements that refer to discovery or further development of novel and fundamental medical knowledge related to human disease and conditions.
      - ***Caveat***: statements should accurately reflect the current state of research and, if possible, will be supported by citing to specific peer-reviewed publications.
    - ***Future looking statements*** – it is acceptable to talk about using an RUO product to diagnose disease ***if*** … you make clear that you are talking about doing so in the future.
      - ***Example***:
        - » "With ***CancerRUO*** as a building block, oncologists may soon have new diagnostics for previously undetectable cancers."

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RUO Claims – General Principles …

- **Focus on use of the product for research**
  - ***Eliminate*:**
    - statements that could be construed to mean that the product can be used to screen for, cure, mitigate, treat, or diagnose any disease or disorder in humans.

Examples:

- "With ***CancerRUO***, Dr. Swanson diagnosed chronic myeloid leukemia in a 50-year old Baltimore woman."
- "Sequencing on a ***SanzoSeq*** can allow you to more cheaply detect infectious diseases in your patients."

- clinical performance claims, clinical information, product names, or descriptors that claim or suggest that the product can be used in a clinical investigation, for any clinical diagnostic use, or to manage human health.

Example:

- "**DiagSeq™**, the new palm size next-generation sequencer for diagnosing your patients." – ***what 3 things are not RUO here?***

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RUO Claims – General Principles …

- **Focus on use of the product for research**
  - ***Eliminate:***
    - Statements that suggest that clinical laboratories can validate the product through their own procedures and offer the product for diagnostic use as an LDT
    - "Clinical" statements such as:
      - Clinical interpretative information
      - discussion of clinical significance
      - other indications of clinical applicability

IN SHORT, avoid the word "clinical"

- Statements regarding the ***sensitivity or specificity*** of an assay. Those terms are considered to be diagnostic in nature.
- You may comment on the analytical performance of an RUO assay.

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RUO – Acceptable Claims

- **Research or research use**
  - "clinical research" is acceptable if both words are used together and the context makes clear that it is not for IUO/investigational or IVD/diagnostic purposes.
- **Feasibility**
- **Analytical performance**
- **Scientific or analytical terminology.**

  Examples:

  Variants

  CNVs

  SNPs
- **Subject (*not* "patient")**

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RUO – Acceptable Claims …

- **Verbs:**
  - Analyze
  - Assess
  - Explain
  - Research
  - Review
  - Study
  - Capture
  - Detect – ***but only with*** a genetic/non-disease term such as "variant" or "indel"

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RUO – Unacceptable Claims

- **Clinical**
- **Diagnostic**
- **Patient**
- **Actionable**
- **Sensitivity and Specificity**
  - these terms used without "analytical" imply clinical measures determined by a well-controlled clinical study
- **Verbs – especially if used with any disease or disorder name (but, acceptable, if used with "variant, SNP, indel"):**
  - Detect -- Monitor -- Target
  - Manage -- Identify
  - Diagnose -- Screen

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The RUO Statement

- **<u>FDA Regulations</u> – must be "prominently placed" on all RUO labeling**
- **<u>Recommendation</u>: Must appear any time a RUO product is**
  - Named
  - Pictured, or
  - "Otherwise depicted" (e.g., screenshot from an RUO software)
  - Obviously being discussed
- **<u>Full statement</u> -- to be used always in Ad/Promo:**
  - "For Research Use Only. Not for use in diagnostic procedures."
    - Punctuated and capitalized precisely as above
    - "RUO" or "For Research Use Only" – not acceptable

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IVD Claims – General Principles

- ***Must be "on-Label"*** **-- all statements made about IVD products must:**
  - Be consistent with the product's cleared or approved labeling; ***and***
  - Not go beyond that labeling.
    - **Note:** Verbatim use of the product's intended use statement is required.
    - ***Example:*** if an IVD is regulated by FDA for "screening" only, you can't say "diagnose"
- ***Must include this statement:***
  - **"For *In Vitro* Diagnostic Use"**

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IVD Claims – Unacceptable Claims

- ***Off-label claims –***
  - any safety, effectiveness or other claim that either is clearly ***not already in the labeling*** for the product ***or expands*** an existing claim beyond that which is in the labeling, including use with an instrument that is not clearly in the product labeling.
- **Adding, deleting, or changing process steps relating to a Dx product.**
- **Claims that go beyond the capabilities of our products**

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IVD Claims – Unacceptable Claims

- ***Lacking Fair Balance*** – FDA expects that risk and benefit information for medical devices be presented in a balanced fashion and devotes great attention to reviewing Ad/Promo to ensure industry Ad/Promo reflects such balance.
  - **2009** -- FDA issued a guidance document that captures the agency's views of what constitutes "fair balance" in promotional copy and labeling.
  - Marketers should review the guidance with care as compliance with it best assures that FDA will not raise questions on how an Ad/Promo piece for a diagnostic balances risk and benefit.
  - The guidance can be accessed at: *http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm155480.pdf*

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LDT Claims – General Principles

- ***Must be "on-Label" --*** **all statements must be:**
  - consistent with the product's labeling; ***and***
  - may not go beyond the use developed under the appropriate regulations or standards governing the LDT.
- **Example:**
  - Verifi® LDT -- the following statement appears in conjunction with the first mention of Verifi in an Ad/Promo piece:

The Verifi® test was developed by, and its performance characteristics were determined by Verinata Health, Inc. (VHI), a wholly owned subsidiary of Illumina, Inc. The VHI laboratory is CAP-accredited and certified under the Clinical Laboratory Improvement Amendments (CLIA) as qualified to perform high complexity clinical laboratory testing. It has not been cleared or approved by the U.S. Food and Drug Administration.

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LDT Claims – Acceptable

- Exact definition and indication of the test
- Actual data generated using the test
- May compare to other laboratories LDT's with same indications (e.g., compare validation studies) so long as the comparisons are accurate and adequately substantiated (per FTC standards)

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Companion Diagnostics -- Logistics

- **Coordination – is key with drug/biologic maker to whom you are the companion**
  - Joint review committee/processes – nail these down in the future
  - Plan for challenges

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Questions?

- ***Call or e-mail:***

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CDSS, PDSS, and other devices subject to FDA enforcement discretion

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Presented by: Jeff Gibbs, Director, Hyman Phelps & McNamara, and Chair, FDLI Board of Directors

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Unregulated Products

- Software products excluded under 21st Century Cures (e.g., CDSS, MDDS, EHRs)
- Patient decision support software
- Low-risk mobile medical apps
- Certain microneedling products
- Multifunction products

Basic Ad/Promo Tenets

- Although not actively regulated by FDA as devices, the same basic advertising and promotion considerations still apply
  - Cannot be false or misleading
  - Claims must be on-label with unregulated intended use
  - Claims must be adequately substantiated (e.g., by competent and reliable evidence)

One Additional

- **Be transparent**
  - Regarding intended use/product operation
  - Regarding regulatory status
- Claims can appear to create new uses or cause an otherwise unregulated product to fall outside an exemption

Example

- A software product that is revolutionizing patient diagnosis
  - This product could be a complex black box algorithm subject to FDA regulation
  - Or a simple EHR search tool that allows a physician to more efficiently search for and synthesize information to make a diagnosis

Include Key Details

- Reference key inclusion criteria
- For example, CDSS
  - Intended user
  - Intended use
  - Software inputs
  - Makes a recommendation
  - Basis for the recommendation

Multiple Uses

- Clear separation between the regulated and unregulated applications
  - Physical pages
  - Colors
  - Headers
- Merging two or more uses can cause confusion

FAQs and Disclaimers

- Not required but can be nice to have
- Can help to clarify a product's regulatory status
- Will not help if claims go beyond the bounds of a regulatory exemption

Questions?

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Recent FDA Actions Regarding Advertising/Promotion of Medical Devices

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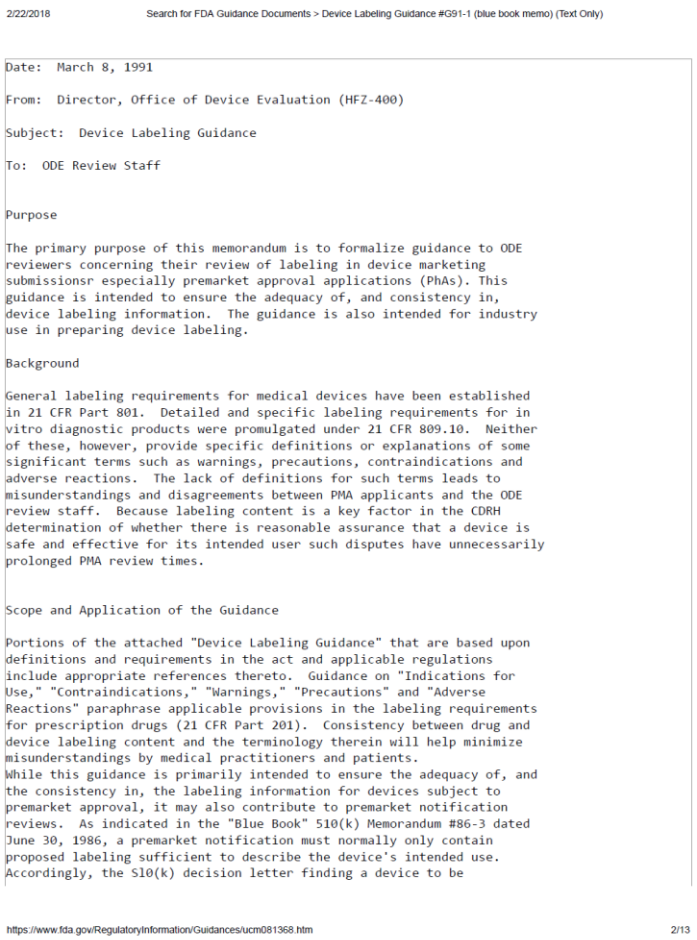
CDRH Guidance on Labeling is Limited

- 1989 Guidance

And this…

- 1991 Blue Book Memo



Date: March 8, 1991

From: Director, Office of Device Evaluation (HFZ-400)

Subject: Device Labeling Guidance

To: ODE Review Staff

Purpose

The primary purpose of this memorandum is to formalize guidance to ODE reviewers concerning their review of labeling in device marketing submissionsr especially premarket approval applications (PhAs). This guidance is intended to ensure the adequacy of, and consistency in, device labeling information. The guidance is also intended for industry use in preparing device labeling.

Background

General labeling requirements for medical devices have been established in 21 CFR Part 801. Detailed and specific labeling requirements for in vitro diagnostic products were promulgated under 21 CFR 809.10. Neither of these, however, provide specific definitions or explanations of some significant terms such as warnings, precautions, contraindications and adverse reactions. The lack of definitions for such terms leads to misunderstandings and disagreements between PMA applicants and the ODE review staff. Because labeling content is a key factor in the CDRH determination of whether there is reasonable assurance that a device is safe and effective for its intended user such disputes have unnecessarily prolonged PMA review times.

Scope and Application of the Guidance

Portions of the attached "Device Labeling Guidance" that are based upon definitions and requirements in the act and applicable regulations include appropriate references thereto. Guidance on "Indications for Use," "Contraindications," "Warnings," "Precautions" and "Adverse Reactions" paraphrase applicable provisions in the labeling requirements for prescription drugs (21 CFR Part 201). Consistency between drug and device labeling content and the terminology therein will help minimize misunderstandings by medical practitioners and patients.
While this guidance is primarily intended to ensure the adequacy of, and the consistency in, the labeling information for devices subject to premarket approval, it may also contribute to premarket notification reviews. As indicated in the "Blue Book" 510(k) Memorandum #86-3 dated June 30, 1986, a premarket notification must normally only contain proposed labeling sufficient to describe the device's intended use. Accordingly, the S10(k) decision letter finding a device to be

Labeling is Advertising

- Labeling regulations require device description, intended use, instructions for use
- PMA (pre-approval)
- 510(k): draft prior to clearance (21 CFR 807.87(e))
- Post-marketing, FDA relies on
  - Websites
  - YouTube
  - Professional society meetings
  - Brochures, advertisements, training materials
  - Trade complaints
  - Inspections
  - “FDA has learned….”

CDRH Warning Letter Review

YEAR	QSR	Labeling	MDR	Sect. 522	BIMO	TOTAL (%)
2018 (Aug)	12	2	1	3	1	19/320 (6)
2017	25	7	1	0	3	36/600 (6)

Violations in WLs Related to Labeling

- Marketing without clearance or approval
- Claims not cleared/approved
- Exceeding the limits of a 510(k) exemption
- Significant modification w/out clearance
- Change to the IFU

Exceeding the Limits of a 510(k) Exemption

- **HOSPIMED** WL 7/20/17
- Rectal balloon used to “immobilize the prostate in patients undergoing radiation therapy.”
- “Although there is a 510(k) exemption for manual gastroenterology-urology surgical instruments and accessories under 21 CFR 876.4730, your device is not exempt because it is intended for a use different from those of legally marketed devices in this generic category. *Generic devices of this type are intended to be used for gastroenterological and urological surgical procedures*.”
- FDA examined website and brochures at professional society meeting
- FDA claims promotion of a specific use exceeds the generic intended use.

Claims Beyond Cleared Indication for Use

SyncThink WL 7/31/17

- EYE-SYNC cleared for viewing, recording, analyzing eye movements
- “your firm’s promotion of the device provides evidence that it is intended for cognitive assessment/testing of concussions and head trauma…”
- FDA relied on company website

Dynavision WL 9/5/17: reaction time clearance w/similar uncleared therapeutic and diagnostic claims

Change to IFU

- **Magellan Diagnostic** WL 10/23/17
  - Only CLIA-waived POC test for lead poisoning
  - Postmarket performance led to field corrective actions and *a change to IFU*
  - FDA investigation determined that change was significant, and required new 510(k)
  - FDA and CDC issued safety alerts and recommend considering repeat testing
- **Becton Dickinson** also affected. WL 1/11/18
  - K2EDTA blood collection tubes, cleared in *1996, 1997, 1998*
  - Changes to stopper were made without a new 510(k)
  - Root cause of Magellan test inaccurate results alleged to be contamination from stopper components

Marketing Without Clearance or Approval

- **Opternative** WL 10/30/17
- On-line eye exam mobile app
- In addition to the website, FDA references a previous meeting in which the company was told a submission is required prior to marketing.*
- This device was subject to a trade complaint.

*"On June 15, 2016, during a meeting held at our Agency, your firm was notified by the Office of Compliance and the Office of Device Evaluation that the On-Line Opternative Eye Examination Mobile Medical App device requires a premarket submission in order to allow the Agency to evaluate its safety and effectiveness."

AMERICAN OPTOMETRIC ASSOCIATION
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April 4, 2016

Via Courier

Robin Newman, MSN, EdD
Director, Office of Compliance
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
WO66-3521
Silver Spring, MD 20993-0002

Re: Opternative: Marketing of Unapproved and Uncleared Ophthalmic Device

Dear Dr. Newman:

The American Optometric Association (AOA) submits this complaint concerning a new medical device marketed by Opternative, Inc. (Opternative). The device is marketed directly to

Take Aways from WL Review

- Why these products?
  - Serious public health concerns (lead poisoning in children; diagnosis of concussion)
  - Trade complaint (eye exam)
  - Random (rectal balloon)
- Judgment calls
  - What is a “significant” change (IFU; intended use)
  - Translating a cleared indication to promotional literature can be a challenge (esp. for OTC product)
- We see coordination between OC and ODE
  - Opternative; Magellan/BD

A Closer Look:
Direct to Consumer Advertising

Jennifer A Henderson

Partner, Hogan Lovells US LP

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DTC Advertisements

- Disseminated directly to a general public consumer audience
- May be disseminated via different mediums:
  - broadcast on TV or radio
  - published in journals, newspapers, magazines, or similar publications
  - Internet (?)
- DTC Ads should generally be:
  - Consistent with the cleared/approved indications for use
  - Truthful and non-misleading
  - Present material facts about the benefits and risks
  - Balanced in the presentation of risks and benefits
  - Presented in language understandable to the target audience

DTC Advertisements – Restricted Devices

- Restricted device advertising must also include:
  - A true statement of the device's established name, if any, printed prominently and in type at least half as large as the trade/brand name; [21 U.S.C.§352(r)(1)] and
  - A "brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications" [21 U.S.C.§352(r)(2)]

Consumer-Focused Devices → DTC Promo

- Historically, DTC broadcast ads used less frequently by medical device firms as compared to pharma
- Explosion in Digital Health products and DTC diagnostic tests
  - Mobile Medical Apps
  - Wearables (KardiaBand, Apple Watch with new features)
  - DTC genetic health risk tests
- As devices become more consumer-focused, promotion and advertising will naturally trend towards direct-to-consumer
  - Ex. DTC TV Ads for Watchman in limited jurisdictions (2017)
    - Permanent cardiac implant to prevent blood clots that can trigger strokes
  - Ex. DTC Newspaper, TV and Radio Ads for Cologuard (2016)
    - DTC DNA assay for colon cancer

Caution: Is it an Advertisement?

- Why does it matter?
  - Dictates whether FDA or FTC regulates
    - FDA regulates labeling and advertising of restricted devices
    - FTC has primary jurisdiction over advertising of non-restricted devices (FDA can consider non-restricted device ads in assessment of intended use)
- FDA has not clearly defined what is an advertisement as it relates to the Internet
  - Only certain types of Internet platforms?
  - Paid search ads, sponsored links, banner ads?

- Can be a challenge for non-restricted devices in assessing what entity has jurisdiction and what requirements/standards apply

Caution: FDA Enforcement

- DTC restricted device ads are closely scrutinized by FDA
  - Concerns about misleading a lay audience

- FDA enforcement action for restricted device ads
  - Series of Warning Letters regarding DTC TV and Billboard Ads for LapBand (2011/2012)
    - Notably, WLs directed at the user facilities/clinics for ads that failed to disclose risks
  - Series of Warning Letters regarding DTC Ads for LASIK (2012)
    - Again, WLs directed to the surgery centers for ads that failed to disclose risks

- Noteworthy in that these actions signal FDA's willingness to reach beyond manufacturers
  - Also presents a unique consideration for manufacturers, given potential negative repercussions of such enforcement due to third party ads

Caution: FTC Enforcement

- FTC has been active in enforcement of consumer-directed medical device ads found to be deceptive, false/misleading
  - Ex. Melanoma detection apps (FTC v. Lasarow et al; 2015)
    - Ads claimed that they could detect symptoms of melanoma and asses cancer risk from pictures taken with smartphone camera
    - FTC found the ads to be deceptive and lacking appropriate scientific evidence to support claims
    - Companies settled; fines paid
  - Ex. Brain-Pad, Inc., C-4375 (Aug. 16, 2012) (challenging unsubstantiated claims that company's mouth guards reduced the risk of sports-related concussions)

- Increased FTC enforcement for non-restricted device ads?
  - More and more consumer-focused digital health devices and home-based tests
  - General direction of deregulation in the Digital Health and General Wellness spaces

Caution: Other Causes of Action

- Competitors can take issue with DTC Ads
  - Not necessarily limited to trade complaints or cease and desist letters
- Ex. Litigation around DTC ads for a non-restricted home pregnancy test with a "weeks estimator" function
  - Competitor filed suit under Lanham Act claiming TV and website ads mislead consumers that estimator was comparable to using traditional method of measuring how many weeks pregnant
  - Years of litigation resulted in finding that ads confused consumers and manufacturer exploited this
  - Separate trial held to assess damages in 2017, awarding competitor almost $10 million in lost profits using a "market share allocation" approach
- Bottom Line: Lanham Act suits can involve years of litigation and very large damage awards for misleading advertising (without mentioning another product)

Summing Up

- DTC Advertising in the medical device space is likely to increase as devices become more consumer-focused, but it raises particular challenges
  - FDA/FTC jurisdictional split
    - Differing standards
  - Lack of clear delineation between labeling and advertising
    - Internet platforms raise many questions
  - Lack of device specific guidance on DTC Ads for restricted devices
    - Draft Guidance: Consumer-Directed Broadcast Advertising of Restricted Devices (February 10, 2004) – withdrawn in 2012 and not replaced
  - Potential for Lanham Act suits for DTC Ads

- Underscores importance of understanding the regulatory status of your device, type of promotion at issue, which entity has primary jurisdiction and the applicable regulatory standards at play

Questions?

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