FDA Regulatory Considerations for Beauty, Wellness, and AI-Enabled Devices

TOPIC 1: FDA REGULATORY CONSIDERATIONS FOR BEAUTY & WELLNESS DEVICES

1. **Stakeholders – Medical Device Labeling & Advertising**

- Food and Drug Administration (FDA) has primary jurisdiction over the safety and labeling of medical devices, along with foods, drugs, cosmetics: Enforcement authority generally over the manufacturer/distributor whose name is on the product label.
- Federal Trade Commission (FTC) has primary jurisdiction over advertising of virtually all products (with limited exceptions for Rx drugs and restricted devices): Enforcement authority over all parties responsible for the marketing and advertising of products
- State AGs: Investigate safety, quality, labeling and advertising issues. May capture a variety of parties in the chain of supply depending on the issue.
- Class Action Plaintiffs: May file private lawsuits under product liability claims and state consumer protection laws over all parties in the supply chain

2. **Product Classification**

- When is a Beauty Device a "Medical Device"?
  - It is a broad definition!
  - Section 201(h) of the Federal Food, Drug and Cosmetic Act (FDCA)
  - A medical device is "… an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including **any component**, part, or accessory, which is….
    - intended for **use in the diagnosis of disease or other conditions**, or in the **cure, mitigation, treatment, or prevention** of disease, in man or other animals, or
    - intended to **affect the structure or any function of the body of man** or other animals…
    - and does **not** achieve its primary intended purposes through **chemical action** within or on the body of man or other animals and which is not dependent upon being **metabolized**
- Example Claims to Impact a "Disease" "Condition" or "Structures/Functions of the Body
  - *Reduce/improve wrinkles and/or acne, rosacea, skin irritation*
  - *Improve hair growth*
  - *Promote collagen production*
  - *Offer pain relief*
  - *Penetrate the skin for cosmetic benefits*
  - *Promote circulation/blood flow*
  - *Improve muscle recovery*
  - *Test or track functions of the body, including: ovulation, blood pressure, heart rate, etc*.
- Classification of Medical Devices
  - **Class I Devices**
    - Low risk

- Generally, no premarket authorization requirements
- Rather, claims simply be consistent with applicable FDA regulation* which…
- Outlines the permitted intended use of the product
- Sets forth any "special controls" necessary to lawfully market the product
- Manufacturer/importer must register facilities and list devices with FDA
- Good Manufacturing Practices (GMP) Obligations, except for rare exemptions
- Adverse Event Reporting
- Mandatory for manufacturer/distributor who's name is on the label
- Voluntary for consumers, healthcare practitioners, third-party retailers
- Examples:
  - Therapeutic Massager (manual and electronic) – 21 CFR 890.5660
  - Sunglasses (non-Rx) – 21 CFR 886.5850
  - Powered heating pad – 21 CFR 890.5710
  - Manual Dermabrasion Devices - 21 CFR 878.4800
  - Motorized Dermabrasion Devices - 21 CFR 878.4820

➢ **Class II / III Devices**

- Moderate & High Risk
- Generally, Class II 510(k) premarket clearance, and Class III PMA approval
- Claims must *closely track* FDA approved/cleared intended use / indications for use*
  - *Should not expand the intended user population*
  - *Should not overstate the indications for use*
  - *Should not minimize relevant risks*
- *Following any special controls set forth in the applicable FDA regulation*
- Manufacturer/importer must register facilities and list devices with FDA
- GMP Obligations (more burdensome than Class I)
- Adverse Event Reporting
- Mandatory for manufacturer/distributor who's name is on the label
- Voluntary for consumers, healthcare practitioners, third-party retailers
- Examples:
  - Microneedling Device (21 C.F.R. 878.4430) – using needles to mechanically puncture and injure skin tissue for aesthetic use
  - Electrosurgical Device for OTC aesthetic use (21 C.F.R. 878.4420) Low level laser System for Aesthetic Use (21 C.F.R. 878.5400) -
  - Ultrasound Stimulator for Aesthetic Use (21 C.F.R. 878.4590) Infrared Lamp (21 C.F.R. 890.5500) – *Hairmax lamps*

        - TENS Device for Aesthetic Purposes (21 CFR 882.5890) LED Device for Acne (21 C.F.R. 878.4810)

- **<u>Carve Out: "General Wellness Products"</u>**
    - Subject to FDA "Enforcement Discretion"
        - Not actively regulated by FDA
        - No FDA Regulatory Obligations
    - Low Risk Devices
        - Non-invasive and Non-implantable
        - No other significant safety risk (i.e., lasers, radiation, heat, introducing energy into the skin)
    - Intended Use to:
        - Sustain or offer general improvement to functions associated with a general state of health (no disease claims at all), or…
        - Promote, track, and/or encourage choice(s), which, as part of a healthy lifestyle, "may help to reduce the risk of" or "may help living well with" certain chronic diseases or conditions (can make limited reference to a disease or condition), only when associations are generally accepted and described in peer-reviewed scientific publications or official statements made by healthcare professional organizations (e.g., high blood pressure, heart disease, type 2 diabetes)
    - General Wellness Intended Use
        - *weight management*
        - *physical fitness, including products intended for recreational use,*
        - *relaxation or stress management*
        - *mental acuity*
        - *self-esteem (e.g., devices with a cosmetic function that make claims related only to self-esteem)*
        - *sleep management*
        - *sexual function*
    - Not Appropriate For General Wellness Use
        - *Needling devices that penetrate beyond the stratus corneum*
        - *A laser product that claims to improve confidence in user's appearance by rejuvenating the skin, as it is not low risk (despite cosmetic claims)*

- **<u>Risk Mitigation Considerations: Questions to Consider re: Scope of FDA Regulation</u>**
    - <u>Intended Use</u>
        - Does the intended use reference any disease state or medical condition (e.g., hair loss, acne, rosacea, pain, skin irritation)? If yes, then likely a regulated device

        - Does the intended use reference any effect on the body (i.e., impact wrinkles, promote collagen production)? If yes, potentially regulated device or a general wellness product depending on functionality/safety considerations
    - Functionality / Safety Considerations
        - Does the product penetrate the skin, beyond minimal exfoliation (e.g., needles)? If yes, then likely a regulated device.
        - Does the product involve use of a laser, LED, infrared light, radiation? If yes, then likely a regulated device (often, Class II)
    - Regulated Devices - Does FDA actively regulate devices of the same intended use/functionality? If yes, then likely a regulated device.

TOPIC 2: ARTIFICIAL INTELLIGENCE AS AN FDA-REGULATED MEDICAL DEVICE

- Rapid Growth of AI/ML in FDA-Regulated Products
    - Medical Device Software Development
        - Digital Health Technologies
        - Clinical Decision Support Software
        - Diagnostic Decision-Making Tools
    - Drug & Biologic Development
        - Clinical trial development & protocols
        - Collection of patient information
        - Data analysis & safety monitoring
    - Note: Challenge for FDA to Keeping Pace with AI/ML Innovations!\
- Medical Device Framework
    - What is a "medical device"?
        - "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article…
        - intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
        - intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action…" See FDCA Section 201(h)
    - Note: Definition includes software as a medical device, depending on its intended use & subject to limited exclusions
- Limitations on Medical Device Regulation
    - 21st Century CURES Act
        - Carves out certain software functions from device definition if intended *only to* display, store, transfer, covert laboratory tests/device data so long as not intended to *analyze/process* such tests/data

        - Carves out '*clinical decision support*' software that supports but doesn't remove HCP decision-making
    - Software as a "General Wellness Products"
        - Must be very low risk to patient and, generally avoid disease claims, only claims to support healthy living (e.g., mobile app to promote healthy sleep management, promote normal stress management)
    - Laboratory-Developed Tests
        - Currently, FDA takes a risk-based approach to regulation
        - October 2023 proposed rule to phase-out enforcement discretion for LDTs
- Challenges for AI/ML in Existing FDA Device Framework
    - Premarket Submissions
        - Device continually changes (including outputs)
        - What is the device?
        - Cybersecurity considerations
        - Validation of algorithms for patient care based on ML (biases, data used to generate ML)
        - Role of HCP and independent clinical decision making
    - Postmarket Obligations
        - Product claims
        - Evaluating whether new marketing submission is required as device changes
        - FDA's current framework which is based largely on "substantial equivalence" for Class II devices, including software
        - Managing cybersecurity
- FDA Policies & Guidance Impacting AI Products
    - FDA Guidance: "*Clinical Decision Support Software*" (Sept. 2022)
        - Incorporates substantial changes to FDA's approach to analyzing whether CDS software is excluded from the statutory definition of "device" under CURES Act
        - In considering whether the product is a device or not, FDA places significant focus on whether the software supports but does not overtake or otherwise remove the ability of the HCP to "independently review" and evaluate basis for software recommendations on clinical diagnosis
    - FDA Draft Guidance: "*Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence /Machine Learning (AI/ML)-Enabled Device Software Functions*" (April 2023)
    - FDA Guidance: "*Content of Premarket Submissions for Device Software Functions*" (June 2023)