Fundamentals of Digital Health Regulation:
Successfully Navigating Your Product Through FDA

November 9, 2021 | Virtual

Agenda

All times are in Eastern Time

11:00–11:05 AM **Welcome and Course Overview**
Laura Brown, Director, Educational Programs, FDLI

11:05 AM–12:00 PM **I. Is My Digital Health Product a Medical Device Regulated by FDA?**

Shelby Buettner, Principal Legal Counsel, Medtronic
M. Jason Brooke, Attorney & Managing Member, Brooke Consulting, LLC

A special thank you to Laura Bailis, Associate Corporate Counsel, Google, for her contributions to the content of this presentation

Not all digital health products in the healthcare space meet the definition of a "device." We'll use examples to help understand the definition and how it applies to different use cases for software.

A. Definition of Medical Device

1. Federal Food, Drug, and Cosmetic Act Definition
    i. Intended use
    ii. FDA's risk-based approach to regulating medical devices, generally
2. Regulation of Software & 21st Century Cures Act (2016) Software Carve-Outs
    i. Software Function Intended for Administrative Support of a Health Care Facility
    ii. Software Function Intended for Maintaining or Encouraging a Healthy Lifestyle
    iii. Software Function Intended to Serve as Electronic Patient Records
    iv. Software Function Intended for Transferring, Storing, Converting Formats, Displaying Data and Results
    v. Clinical Decision Support Software Function
    vi. Software with Multiple Functions

B. Agency Enforcement Discretion

1. What is enforcement discretion?
2. FDA's process for issuing guidance documents ("Good Guidance Practices")

3. FDA guidance documents related to Digital Health

12:00–12:15 PM	**Break**

12:15–1:15 PM	**II. What Regulatory Pathway Applies to My Digital Health Product? What Are Other Relevant Considerations?**

Jeffrey K. Shapiro, Director, Hyman, Phelps & McNamara, PC

If a digital health product is regulated by FDA as a "device," there are typically two threshold questions: (1) which regulatory pathway applies? And (2) what data are required to market the product? This section will highlight important considerations to keep in mind when answering these questions.

A. Device Classification and Pathways

1. Framework for Device Regulation
    i. Device Classifications and Regulatory Pathways
    ii. How to Determine the Classification of Your Device
2. Devices Exempt from Premarket Review
    i. Limitations on Exemption - The ".9" regulations
    ii. Documenting the Self-Determination of classification
    iii. General Controls
3. The 510(k) Pathway
    i. Substantial Equivalence
    ii. Predicate Devices
    iii. Content Requirements
    iv. Use of Standards in a 510(k)
    v. Changing/modifying a "cleared" device
4. Other Premarket Pathways
    i. The De Novo Classification Request Pathway
        a. When is the De Novo Pathway Used?
    ii. Premarket Approval Application (PMA) Pathway
        a. PMA Content and Approval Process
        b. PMA Supplements
    iii. The Emergency Use Authorization (EUA) Pathway

B. Working with FDA

1. The Process for:
    i. Classifications and Reclassifications
    ii. Q-Submission Program
2. 513(g) Requests

C. Agency Initiatives and Areas of Focus Involving Digital Health Products (At a Glance)

1. Software Pre-Certification Pilot Program
2. Artificial Intelligence and Machine Learning Software
3. Cybersecurity Considerations
4. Medical Device Development Tool (MDDT) Program

D. Other Considerations

1. Clinical Investigations
    i. Investigational Device Exemption (IDE)
2. FDA User Fees and Review Timelines
3. Combination Products
    i. Definition
    ii. Primary Mode of Action
4. Unique Considerations for Pharmaceuticals
    i. Companion Products
    ii. Compliance Aids
5. Telehealth
6. Reimbursement Considerations
    i. Use of Real-World Evidence for Reimbursement

E. International Regulation

1. EU Medical Device Regulation (MDR)

1:15–1:45 PM **Break**

1:45–2:45 PM **III. What Post-Marketing Issues Should I Be Considering?**

Christine P. Bump, Principal, Penn Avenue Law & Policy

Medical device manufacturers and other stakeholders involved in the distribution of these products must follow certain requirements. This section will describe the different FDA requirements that generally apply, utilizing practical examples and case studies.

A. Registration and Listing

1. Who Must Register?
2. How and When to Register/List?
3. Updates to Registrations/Listings

B. Modifications to a Device

C. Labeling Requirements

1. Instructions for Use
2. Unique Device Identification System

D. Quality System Regulation: Key Principles for Software

1. Quality System Principles – High Level
2. Quality System – Significant Requirements
    i. Management Controls
    ii. Software Design Controls
    iii. Quality Audit and Personnel
    iv. Complaint Handling
    v. Corrective and Preventive Action (CA/PA)

vi. Records, Documents, and Change Control

E. Third Parties in Manufacturing and Quality Operations

1. Contract Manufacturers and Quality Agreements
2. Specification and Software Developers
3. Supplier Controls

F. Adverse Events/ Product Problems

1. Complaint Handling
2. Medical Device Reporting
3. Recalls and Reports of Corrections and Removals
4. Safety Communications and Letters to Healthcare Providers

G. Enforcement and Compliance

1. Prohibited Acts and Penalties
2. FDA Inspection
3. FDA Enforcement Options
    i. Untitled Letter/ Warning Letter
    ii. Seizure
    iii. Injunction/Consent Decree
    iv. Criminal Prosecution
4. Other Enforcement/Remedial Possibilities

2:45–3:00 PM **Break**

3:00–3:45 PM **IV. What Advertising and Promotion Requirements Apply?**

Kyle Y. Faget, Partner, Foley & Lardner LLP

This section will describe regulations concerning advertising and promotion of digital health products. Examples and case studies will clarify the requirements.

A. FDA and FTC Authority

1. "Label" and "Labeling"
2. Promotion and Advertising
    i. FDA and FTC Jurisdictions
    ii. Restricted Devices

B. Fundamental Requirements

1. Truthful and Not Misleading
2. Adequate Directions for Use
3. FTC's standard for digital health advertising
    i. Substantiation
4. Consumer Testimonials, Social Media, and other Issues

C. Preapproval Communications – What Can I Say About My Product Before Clearance/Approval

1. Trade Shows

2. Press Releases

3:45 PM **Course Adjournment**

FDLI would like to thank Curriculum Advisor Shelby Buettner, Principal Legal Counsel, Medtronic *for her help in planning this course and for her assistance and support of FDLI's Educational Programs.*