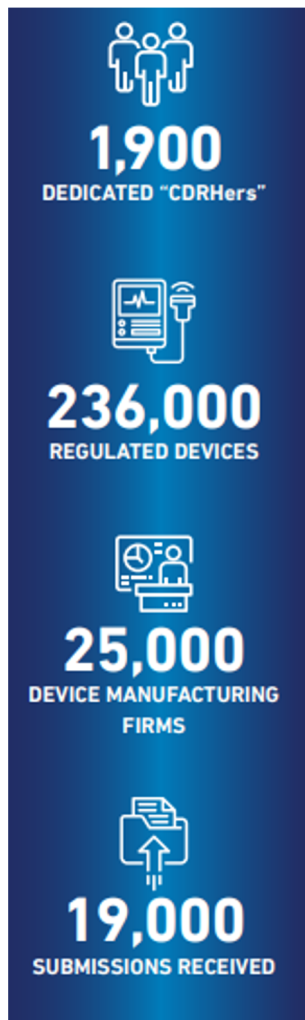

Following FDA guidelines for Fruitful and Long Lasting Partnerships: Advice for Startups

Courtney Williamson, PhD
CEO, AbiliLife

Elora Gupta, PhD
Advisor, Swartz Center for Entrepreneurship

We Became Involved With Regulatory & Reimbursement Out Of Necessity

- Elora's history
 - Drug and Device industry, Global Regulatory Strategy
 - Notables: Eliquis (drug ~10B annual sales), Abilify MyCite (first drug with sensor with FDA Press Release)
 - Translating industry learnings to CMU medical product startups
- Courtney's history
 - Personal need
 - Novel technology
 - CMU alum
- How we met
 - Through Olympus and a personal connection (Elora's daughter)
 - Working together since 2016
 - Joint Swartz presentations since 2017



What is 'Regulatory'



Mission: **Protect** and **Promote** public health by ensuring the safety, efficacy, and security of medical products

CDRH (Center for Devices and Radiological Health) for medical devices

CDER, CBER, CFSAN, CVM....

2021 Pandemic Response



What is 'Reimbursement'

- Medicare
 - Federal health insurance program (65+, people with disabilities, end-stage renal disease)
 - Department of Health and Human Services (HHS)
- Commercial insurance
 - Policies provided by nongovernmental entities (i.e. UPMC, Cigna, Highmark)
- Reimbursement is a major part of an entrepreneur's go-to-market strategy

What Do These Companies Have In Common?

theranos



Whole Leaf

INVISIMART

FDA Warning Letters

FDA inspector slams Theranos for poor quality management

Theranos didn't document quality audits, and there's no way for customers to complain

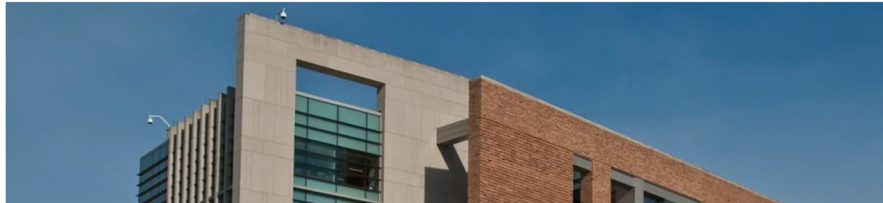
By [Elizabeth Lopatto](#) and [Arielle Duhaime-Ross](#) | Oct 27, 2015, 1:50pm EDT

Source [FDA](#) and [FDA](#)

[f](#) [t](#) [s](#) SHARE

Owlet pulls baby-monitoring Smart Sock from market after FDA warning

by Andrea Park | Nov 29, 2021 3:55pm



Fraudulent Coronavirus Disease 2019 (COVID-19) Products

[f](#) Share [t](#) Tweet [in](#) LinkedIn [e](#) Email [p](#) Print

The U.S. Food and Drug Administration is issuing [warning letters](#) to firms for selling fraudulent products with claims to prevent, treat, mitigate, diagnose or cure [coronavirus disease 2019 \(COVID-19\)](#). We are actively monitoring for any firms marketing products with fraudulent COVID-19 prevention and treatment claims. The FDA is exercising its authority to protect consumers from firms selling unapproved products and making false or misleading claims, including, by pursuing warning letters, seizures, injunctions or criminal prosecutions against products and firms or individuals that violate the law.

FDA NEWS RELEASE

FDA warns 15 companies for illegally selling various products containing cannabidiol as agency details safety concerns

Violations include marketing unapproved new human and animal drugs, selling CBD products as dietary supplements, and adding CBD to human, animal foods

[f](#) Share [t](#) Tweet [in](#) LinkedIn [e](#) Email [p](#) Print

For Immediate Release: November 25, 2019

Content c
01/07/202

What are FDA Warning Letters?

For **MISBRANDED** and **ADULTERATED** PRODUCTS

Medical claims (diagnose, cure, mitigate, treat, prevent, affect structure or function of body) that have **not been substantiated per FDA standards**

Penalties start from warning letters (public posting)

If not addressed in a timely manner - cease and desist

Civil and criminal penalties

Why do Companies Take the Risk?

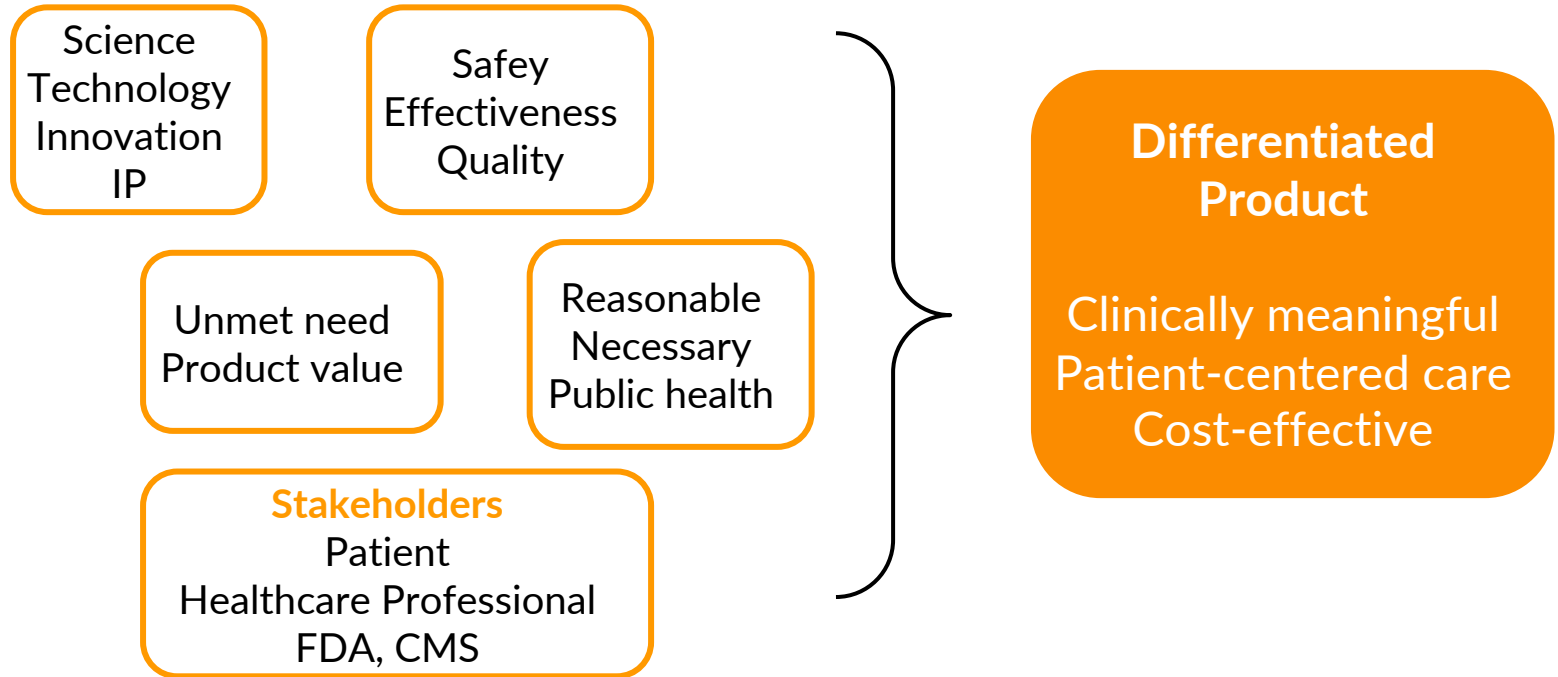
- They are compelled by investors to go-to-market quickly
- Many are ill-informed about what and how the FDA regulates
- Intentional focus on profit before safety, efficacy and quality standards

What Is Regulated?

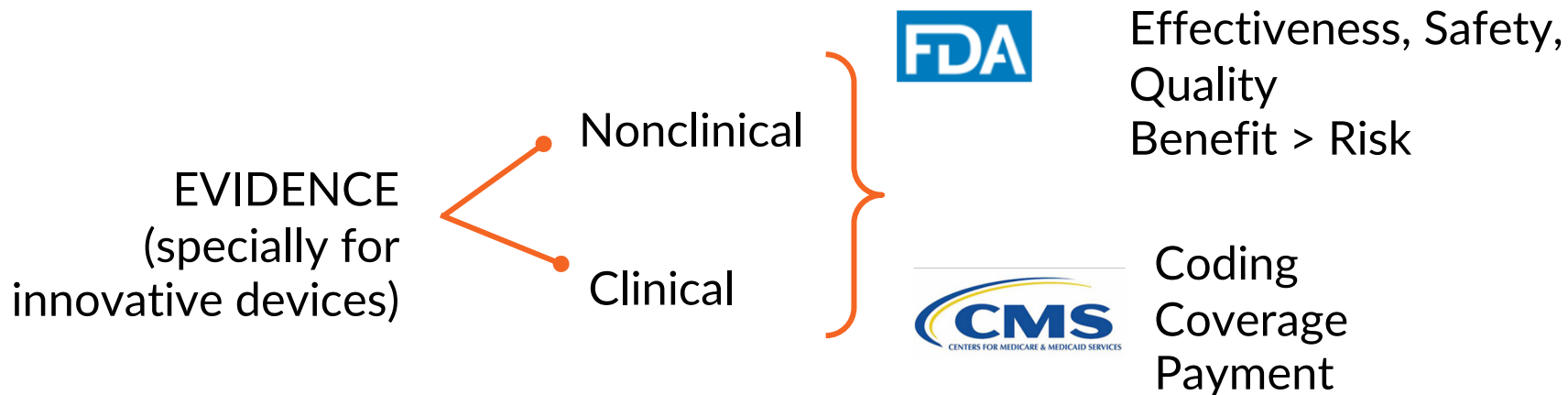


Jeopardy ≠ Medical condition

A well-differentiated product is based on its claims



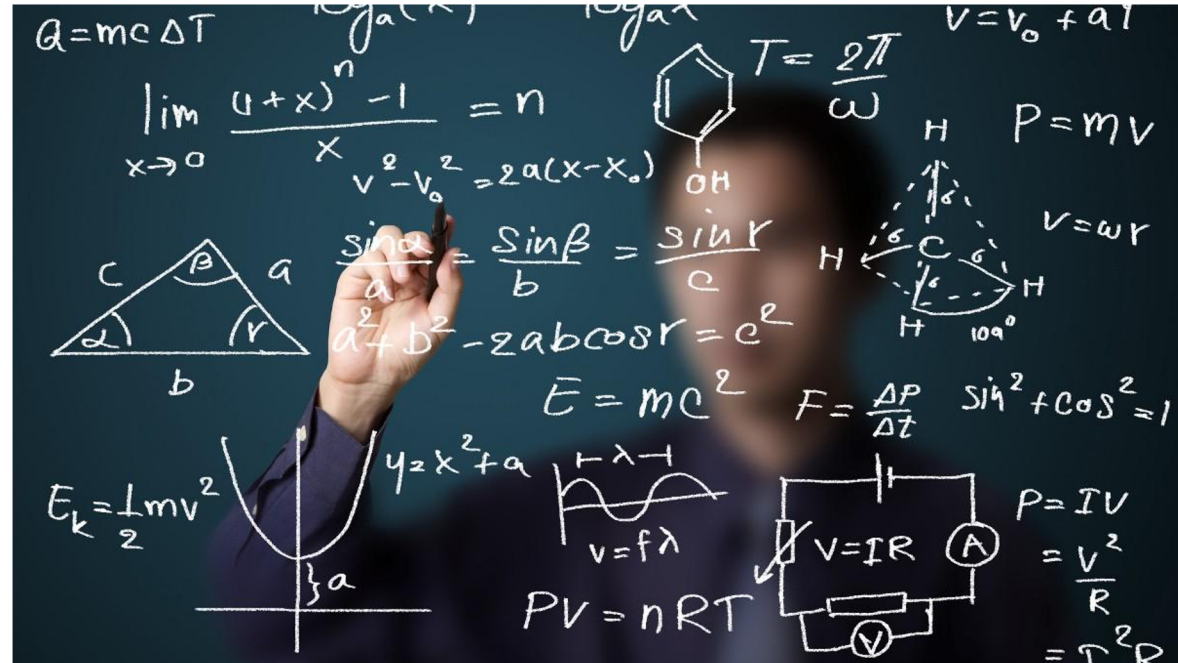
It's about the evidence to support claims and obtaining that in an **efficient manner**



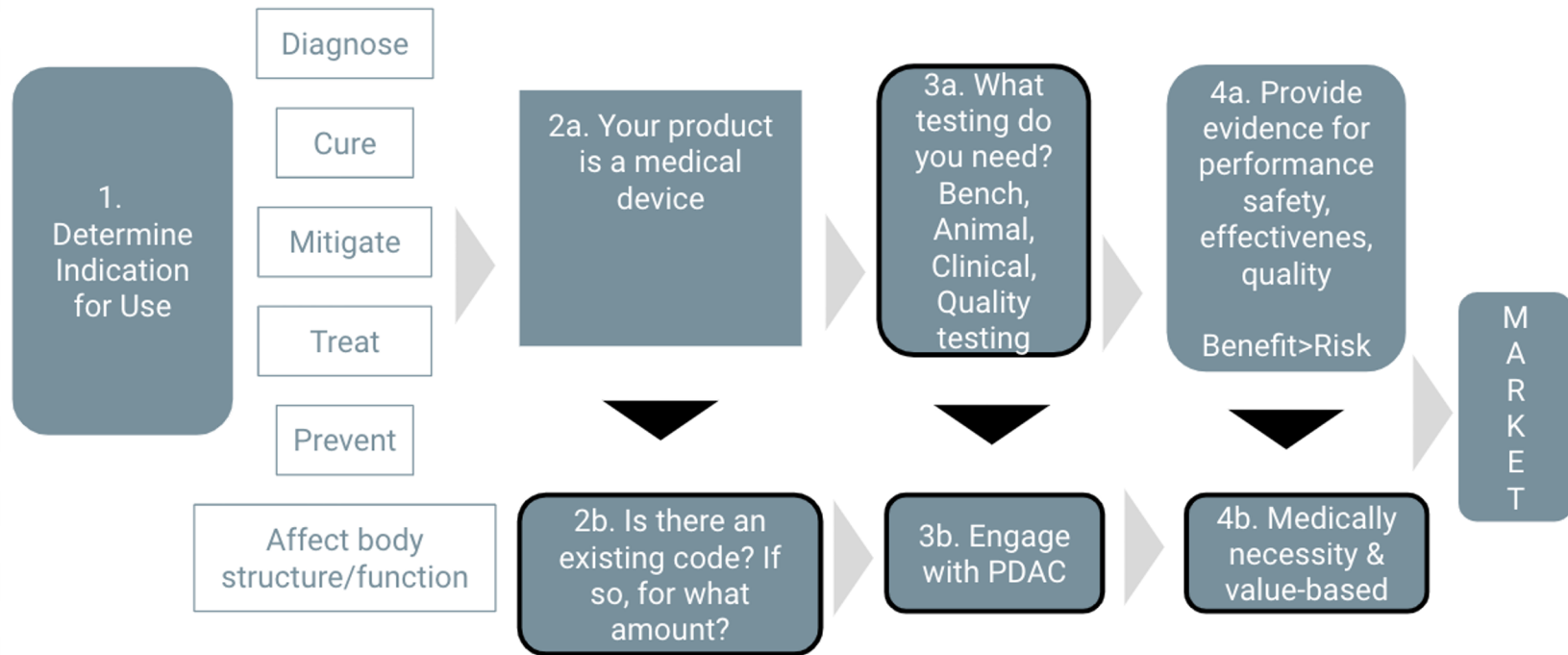
Could My Product Be Regulated?

Interactive Workshop

Calculating Probability Of Success



PDRRS: Probability of Development, Regulatory, Reimbursement
Success



Entrepreneur Action Items

Do your homework

- Identify your patient demographic and unmet medical need
- Work through the decision tree
- Learn from existing FDA and CMS resources (see next slide)
- Contact Division of Industry and Consumer Education (DICE)
- Find an existing CMS code (if applicable)

Prepare for FDA Pre-Sub

Not DIY - engage with regulatory advisor

Evaluate reimbursement implications in parallel

Engage early and consistently throughout product development

Entrepreneur Resources: Get started

FDA

- CDER/CDRH Learn
- druginfo@fda.hhs.gov
- DICE@fda.hhs.gov
- FDA Guidance page
- FDA public workshops
- CFR Title 21

CMS

- PDAC-Medicare Contractor for Pricing, Data Analysis and Coding
- Noridian
- CGS
- Innovator's guide



***INNOVATORS'
GUIDE TO
NAVIGATING
MEDICARE***

[Food](#)

[Drugs](#)

[Medical Devices](#)

[Radiation-Emitting Products](#)

[Vaccines, Blood, and Biologics](#)

[Animal and Veterinary](#)

[Cosmetics](#)

[Tobacco Products](#)

...continuation of FDA's Mission statement

'...FDA is responsible for **advancing the public health** by helping to **speed innovations** that make medical products **more effective, safer, and more affordable** and by helping the public get the **accurate, science-based information** they need to use medical products and foods to **maintain and improve their health**....

Questions?