FDA 345
mHealth Case Study: The Importance of the Intended Use

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topics

1. US legal and regulatory framework for medical devices
2. The choices: options for staying out of regulated territory
3. The future: dynamic elements of the model
4. Case study: picking the best intended use

I feel like Zsa Zsa Gabor's fifth husband.
I know what I'm supposed to do
but I don't know if I can make it interesting.
Al Gore

device definition

Section 201(h) of the Federal Food, Drug, and Cosmetic Act, defines a medical device as:

> "... an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is ... [either]
>
> 2.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]
>
> 3.intended to affect the structure or any function of the body of man or other animals."

device definition distilled

To be a device, boiled down to its essence there are two criteria:

1. A physical, mechanical product is involved and
2. The product is “intended” for a medical use.

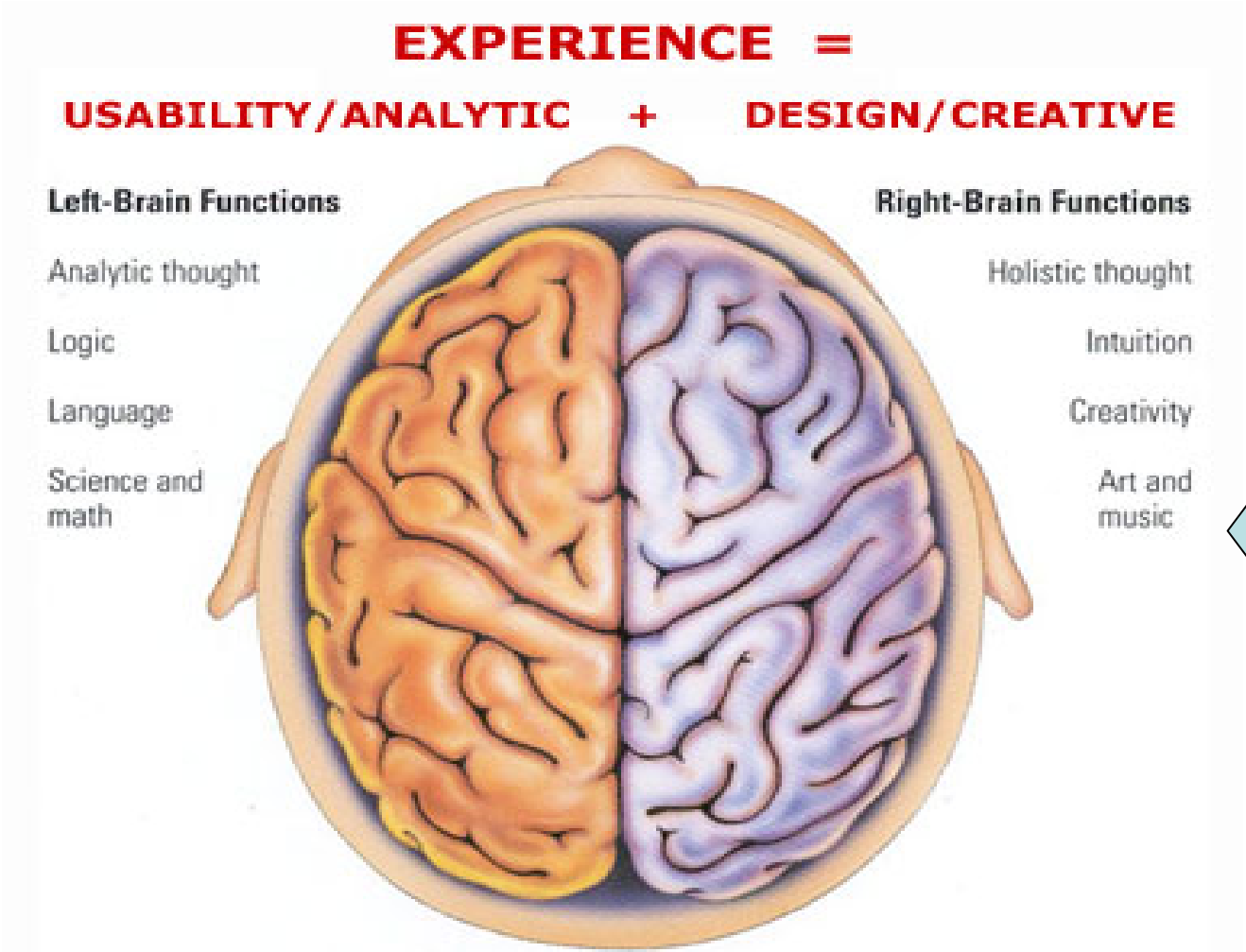
The Ten Commandments contain 297 words.
The Bill of Rights 463 words.
The Gettysburg Address 266 words.
A recent federal directive to regulate the price of cabbage contains 26,911 words.

basic intended use framework

Under 21 CFR 801.4, the words “intended uses” …

refer to the objective intent of the persons legally responsible for the labeling of devices. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. …

for the next two slides



Use this side

Ninespv.wordpress.com

judging intended use

1. Words
   a. External (e.g. labeling, sales lit. advertising, sales pitches)
   b. Internal (e.g. business planning, sales force memos, training programs)
2. Actions, for example
   a. Design features (i.e. uniquely medical features)
   b. Distribution (e.g. medical sales and distribution channels)
   c. Where do you sales people visit?
3. Circumstances (inferences), for example
   a. How legitimate are non medical uses
   b. Actual sales volume

The totality determines the outcome

determining the intended use of a stick

Statements suggesting Popsicle Stick
It’s a popsicle stick
Sterilized to food grade
Kids love it
Makes popsicles last longer

Tastes Great

Statements suggesting Pediatric Tongue Depressor
It’s a Pediatric Tongue Depressor
Sterilized to medical grade
Young patients love it
Narrow enough to access those hard to reach places in a kid’s mouth

Dual Use Products

Product	Medical Use	Nonmedical Use
Massager 890.5660	“treats minor muscle aches and pains”	“relaxation”
Teething ring 872.5550	“soothe gums during the teething process”	“soothe tender gums”?
Mechanical chair with casters, 890.3100	“To assist disabled persons”	Ergonomic office chair
Home humidifiers, 868.5460	“respiratory therapy”	Humidifies the air: But what about: Protect your family and your home from the unhealthy and damaging effects of over-dry air. Dry nose, cracked, itchy skin, and sore throats. Aggravated allergy and asthma symptoms. Painful static shocks. Chipping paint and plaster. Splitting or cracked wood floors, furniture, trim and molding?
Heating pad, 890.5740	“medical purposes that provides dry heat therapy	Heat and relaxation

duties that arise

- If you want to cross the line into the regulated device realm
  - Vigilance in meeting the applicable device requirements
- If you *do not* want to cross the line into the regulated device realm
  - Vigilance in making sure that
    - The company's words and deeds stay true to the unregulated status
    - Circumstances don't too strongly suggest device status

In both cases, senior management is personally responsible for the required vigilance.

types of devices

Element of device definition	Finished Stand alone Parent device	Accessory	Component
Definition	A medical device in finished form, ready to use perhaps with accessories, intended for sale to the end user	An article intended for use in or with a finished medical device, intended for use by the end user	An article intended for use in or with a finished medical device, intended for use by a manufacturer
FDA Clearance required?	Yes, unless exempt from clearance	Yes, unless exempt from clearance	No
GMPs required?	Yes, unless exempt from GMPs	Yes, unless exempt from GMPs	No, but quality must be assured to the satisfaction of the finished device manufacturer

Major FDA Requirements

- Premarket clearance or approval
  - Requirements vary significantly depending on the risk based classification
  - Range from exempt to clinical trials, but in the middle must prove “substantially equivalent”
- Good Manufacturing Practices
  - So-called quality system regulation, similar to ISO 13485
  - Design controls often prove the most demanding hurdle

Other FDA Requirements

- Facility registration
- Product listing
- Investigational device requirements
- Export and import restrictions
- Labeling and advertising requirements
- Tracking, Unique Device Identifiers, and postmarket surveillance

Winter related injuries occur more often in the winter.
-newswoman for WHIZ-TV, Zanesville Ohio

The Risks are Large

- OIG continues to investigate off- label promotion
- State AG Investigations of off-label promotion are on the rise
- Regulators now seem to be targeting device companies

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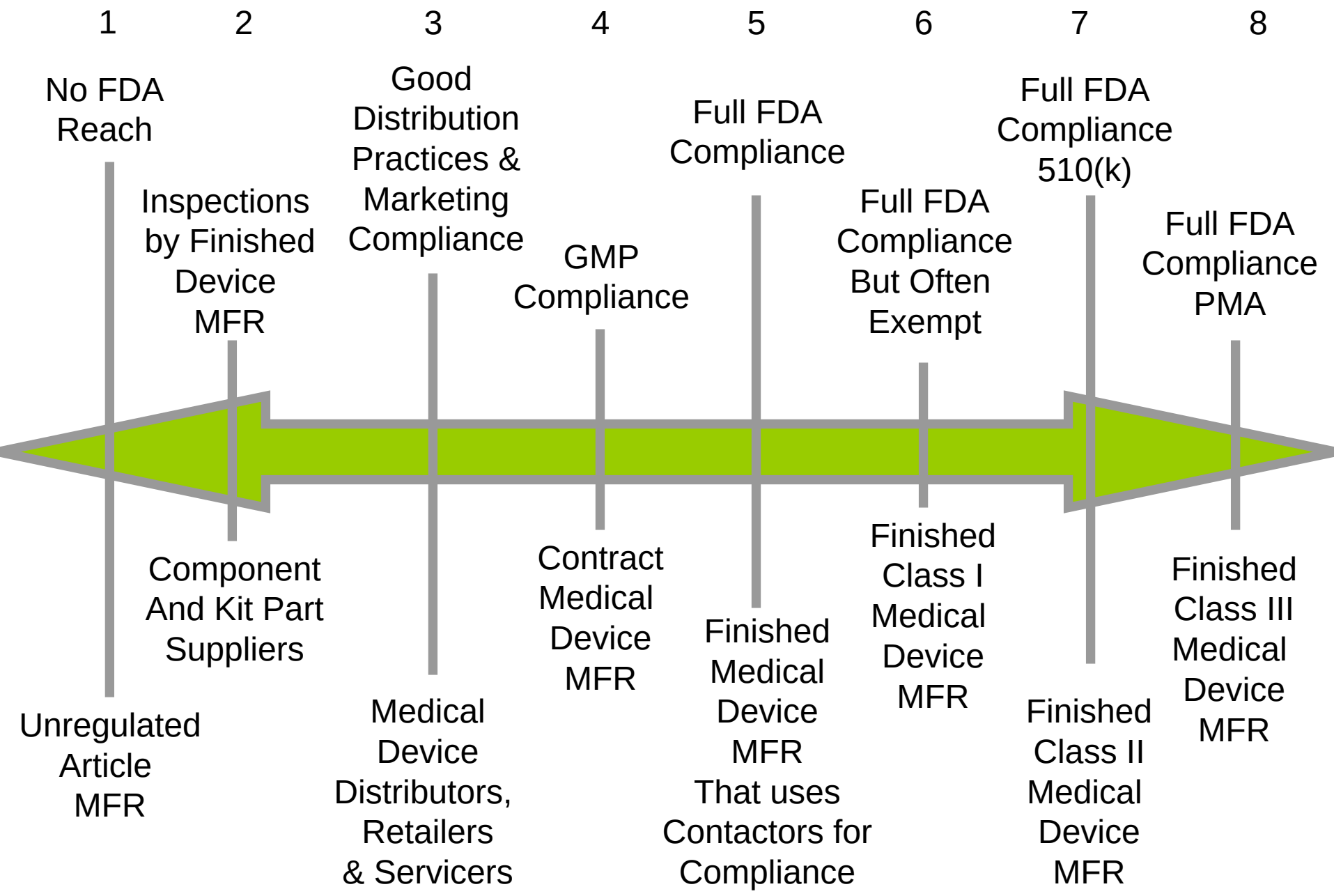
Democracy used to be a good thing, but now it has gotten into the wrong hands.

-Senator Jesse Helms

Continuum of Potential Involvement in the Device Industry



There are at least 4 strategies for avoiding medical device regulatory status

These must be pursued in good faith

The pure and simple truth is rarely pure and never simple.
Oscar Wilde

1. Limit marketing claims and features

- So long as a product has (a) legitimate and (b) material nonmedical uses, the manufacturer can opt for generic claims that do not implicate medical uses
  - Here medical uses includes regulated uses under the Act
  - But would exclude things like general fitness and strictly library or communication functions
- The manufacturer's actions should conform to this neutral stance
- The product also should not have features tailored to a medical use
- The officers and the company should be vigilant in ensuring the avoidance of medical claims

2. Avoid controlling the specs and claims for the final product

- This includes
  - (2) component supplier
  - (4) contract manufacturing
- You can supply a component or subassembly to a finished device manufacturer, and basically avoid all regulatory oversight, but be subject to quality inspections by your customers

2. Avoid controlling the specs and claims for the final product

- You can supply the finished product as a contract manufacturer to a traditional device company (*but not a company merely acting as a distributor [3]*)
  - For contract manufacturing to be available, the finished device manufacturer has to take responsibility for the design and impose that design on its contractor
  - The contract manufacturer is responsible for complying with the quality system regulations to the extent they apply to their operations
- It all comes down to the agreement.

3. Contract out regulatory duties

- The execution of any activity required by the regulations can be contracted out.
  - Regulatory filings
  - Adverse event reporting
  - The design of a quality system
- The responsibility for ensuring compliance may not be contracted out, except for a few very narrow circumstances.
  - Indeed, officers and those within the company with regulatory responsibilities remain personally responsible

4. Sell a service or be a user

- FDA by law regulates products sold in commerce
- Some service providers do work remarkably like product manufacturers, but don’t get regulated by FDA
  - Clinical laboratories
  - Pharmacies
- But they are regulated by others
- Not as simple as converting to leasing, etc.

	FDA Regulated 8	Contract out tasks 5	Component supplier 2	Not regulated 1
Profit margins				
Product life cycle length				
Internal over head costs				
Barriers to entry				

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The voters have spoken—the bastards.

Richard M. Nixon

Jan 25-27 FDA Meeting on Connected Health

- Well-attended by diverse group of about 130 people (device manufacturers, IT vendors, HC providers, researchers, and consultants), plus webcast
- Organized by FDA, Continua Health Alliance and CIMIT: Center for Integration of Medicine and Innovative Technology
- Workshop environment: interactive sessions
- Materials will be posted to the CIMIT website

Process over the 3 days

- Educational presentations on current thinking about connected health and interoperability
- Public panel presentations organized by themes
- Breakout groups for discussion among those with common interests
- Reports back to the group
- Discussion among the sponsors of the path forward

BMT's personal impressions relevant to mHealth

- Very good exchange of information by diverse groups
- FDA now understand clearly both the value proposition for these new technologies, and the issues over which manufacturers have anxiety
- Several Issues emerged

1. The scope of FDA regulation

The circumstances when the following examples might be regulated *directly* (as opposed to simply being part of a system that must be validated):

- Cell phone/smart phone (what functionality/use might cross the line)
  - Automatic data input
  - Data manipulation and analysis
  - Control required
  - Claims made, including consumer vs. medical
  - Method of distribution
- Home hub use case that includes PCs and servers
- Off the shelf software used on a cell phone or PC

2. The level of FDA regulation

- Can home or mobile devices that may be swept into an FDA regulated system be placed in class I and exempted from premarket clearance (on the basis of a favorable risk benefit assessment)
- Can connectivity devices remain in class I even when a class II medical device is added to the system

3. Intended use questions

- How do we cope with intended uses that evolve with new learning/experience? Can we get to market with tool claims that do not claim specific clinical utility?
- Can we just get clearance for a general connectivity claim, without specifying the system?
- Does co packaging or selling items together necessarily change the intended use?

4. Evidence required for clearance

If the medical device manufacturer is responsible for the claimed system, but the components of the system are open-ended—

- How does the company demonstrate substantial equivalence?
- Can the company demonstrate certification to a standard or specification for an interface, rather than validating every possible part of the system.
- Can we come up with a new paradigm for clearing these connected devices that classifies or stratifies these devices based on risk (for example, based on acuity), and does not require the traditional evidence for validating systems designed for low risk/acuity devices.

5. Standards for clearance

Does FDA have any minimum requirements for substantial equivalence for remote monitoring devices or mHealth devices, such as

- Latency
- Human factors design issues
- Limits on appropriate population
- Ability to use open source platform
- Acceptable use environment
- Usability issues
- Protection against interference by other software

Other Issues

6. Design control complexities for open ended system
7. Postmarket challenges for root cause analysis, reporting and remediation
8. Can industry benefit from learning from the collective adverse events

Process

- Not surprisingly, two paths forward
  - Education. Some of the anxiety flows from misunderstandings about FDA, its role and existing rules
  - New FDA guidance to address open questions in a practical, timely way
- Prioritization needs to take place
- Process: Continua volunteered to serve as a forum for discussions, and organize efforts to seek guidance, perhaps through
  - Discussions of case studies or
  - Proposed guidance
  - The difference between a point and a line
- FDA wants to be involved, and is enthusiastic
  - Volunteered to be part of a working group

Get Involved

In Massachusetts it is illegal to keep a mule on the second floor of a building not in a city unless there are two exits.

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One way to make sure crime doesn't pay would be to let the government run it.

Ronald Reagan

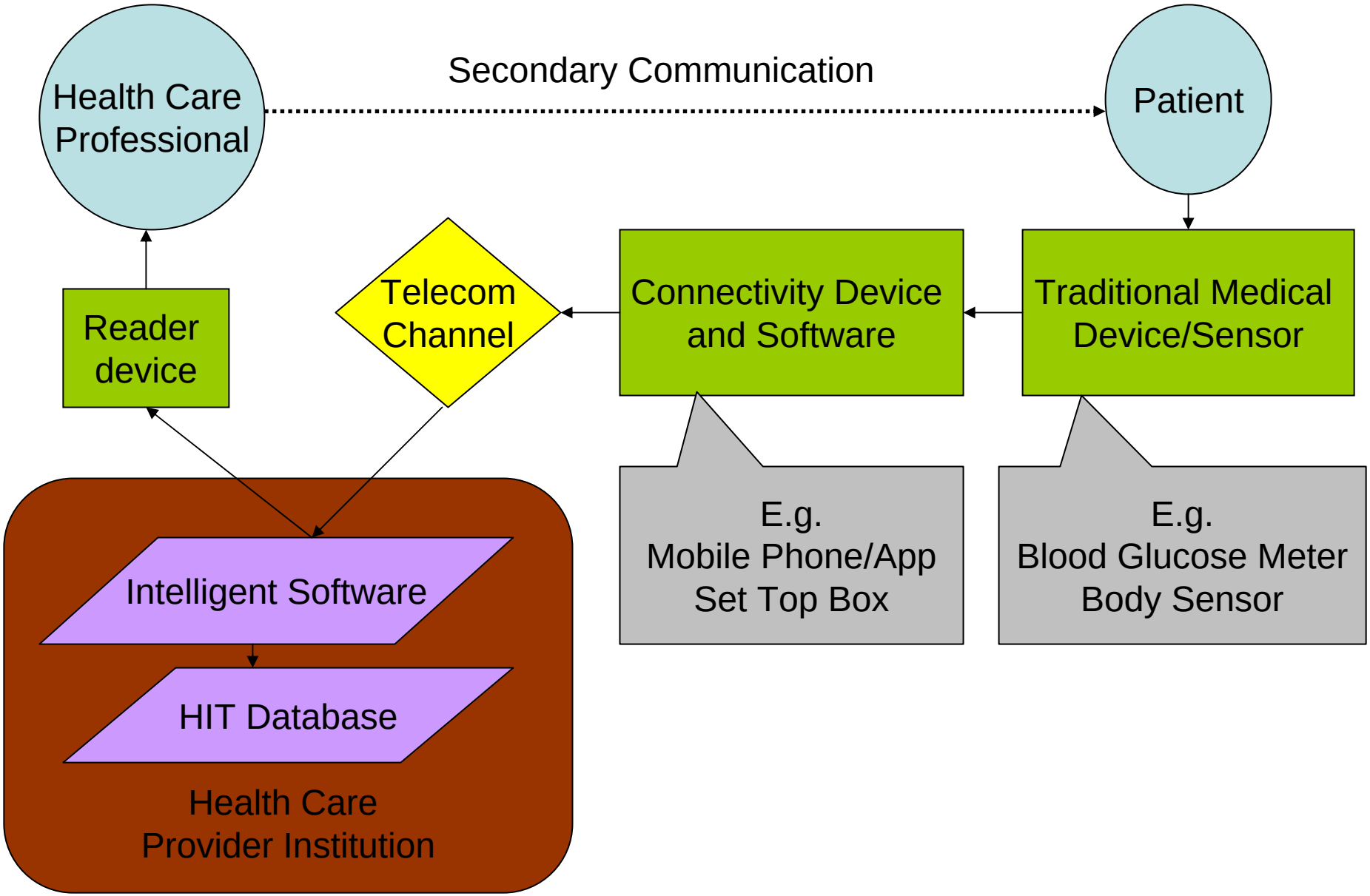
Here's What We're Going to Do

1. The BuyMore VP of Marketing, Brad Thompson, comes to you for advice
2. Colleen Hittle, VP of R&D, will tell you about the company plans so far for a cell phone platform
3. Then Brad will present a range of intended use statements for the phone, and ask you 4 questions about each:
   a. Would the intended use make the phone an FDA-regulated medical device?
   b. What activities might I need to change to conform to that intended use?
   c. If a device, in what class would it be?
   d. If a device, what evidence would I need to develop before I could market it?

Basic Scenario

- BuyMore is considering the development and launch of a cell phone platform
  - designed for connection via Brownteeth technology
  - Can connect to a variety of devices used by people to monitor a chronic disease
- The specific product under development first is targeted at the diabetes population

BuyMore mHealth Model



Products, Components, Accessories

- mePhone SmartPhone
- HealthyData software for tracking important information for a patient who has diabetes
  - Software is downloadable from the BuyMore website for purchase
- DocView is a separate application that works with HealthyData software
  - Enables doctors to read the results collected by the HealthyData software
- PrickRight blood glucose meter
  - Initial device selected by BuyMore for use with the software and mePhone

Products, Components, Accessories, (cont'd)

- BuyMore is considering launching:
  - mePhone and compatible PrickRight blood glucose monitor as a kit
  - mePhone together with a prescription auto-injector for use with insulin as a kit available through pharmacies.
- Treeview Hospital is an interested provider in the Buymore offering, except:
  - The hospital does not like the DocView software, would rather build their own viewing interface using their corporate IT standard SOA software development tools and existing systems

Possible Sales Channels

- Direct to consumer via multiple carriers
  - Support multiple cellular networks
- Handset option for resale through a major telecommunications carrier
  - Carrier just launched healthcare vertical industry organization
- Strategic relationship with major wholesale warehouse club retailer
  - Focus on addressing healthcare needs of members

Sourcing

- PrickRight blood glucose monitor manufactured by Bonafide Medical Company in Minnesota
- Auto-injectors made by Jab Solutions, Inc. under a contract with Pure Pharmaceuticals, Inc.
- Treeview Hospital, if it used the mePhone kit, will utilize their own physician software for reading results, plus customization via their SOA framework to tie it to their internal systems from a variety of vendors

Potential Routes to Market

- Direct to consumers, targeting patients with chronic diseases, beginning with diabetes. Multiple carriers.
- Large mobile network operator handset supplier agreement through their vertical industry BU
- Large hospital chains or insurance companies with disease or wellness management programs
- Major wholesale club warehouse retailer wants private label and or exclusive rights to the bundle

Possible Marketing Claims for Bit-O-Tron Software

- Promote its HealthyData software for use with the mePhone and the PrickRight blood glucose monitor
  - Touts the ability to keep track of diet and blood glucose readings
- DocView software connects the patient data collected by HealthyData
  - Doctors can monitor patient health without having to schedule appointments with them.

Possible Claims for Bona Fide Medical

- Promote the virtues of the PrickRight blood glucose meter linked to the mePhone
  - Maintain an active, energetic, on-the-go lifestyle and still manage your diabetes
- Create an advertising campaign
  - Depicts physically active, youthful actors who happen to have diabetes participating in extreme sports activities

Possible Claims by Treeview Hospital

- Promote their remote monitoring and treatment plans to patients in the community
  - Maintain your health without the hassle of having to meet with a doctor in person
- Promote their way of providing access to this service to other members of the national procurement network of hospitals they are affiliated with
  - Treeview innovation leadership in remote monitoring

Remember the Four Questions

1. Would the intended use make the phone an FDA-regulated medical device?
2. What activities might I need to change to conform to that intended use?
3. If a device, in what class would it be?
4. If a device, what evidence would I need to develop before I could market it?

Possible BuyMore Intended Use Statements for the *me*Phone

- *me*Phone is a smart cell phone, capable of serving all of your communication needs.
- The *me*Phone helps you manage your health
- *me*Phone and all components are marked with a “K”, certifying interoperability through adherence to the Kintinuum Alliance standards
- The *me*Phone’s operating system is ideal for running medical apps and connecting to peripheral devices
  - like glucose meters

More Claims

- Checking your blood glucose level is as easy as checking your email
- Quality, reliability, and durability when it counts; your personal healthcare
- A better life and less disruption from your diabetes through the *me*Phone
- When used with the PrickRight, the *me*Phone can control medication delivery through your insulin pump, and keep your doctor informed

And More Claims

- The *me*Phone is ideal for running the DocView software
- The *me*Phone is specially suited for connecting to the PrickRight.
- The *me*Phone is part of “Healthcare 2.0”
- For those who use the PrickRight, the *me*Phone is ideal for managing your diet and exercise

And Even More Claims

- Being able to connect with your doctor in real time means better management of chronic diseases and fewer trips to the ER
- The *me*Phone is the #1 smart phone platform for healthcare applications in the US; over 50% of healthcare professionals use our phone with a variety of healthcare applications that help them treat patients more effectively and monitor their conditions 24 hours a day from anywhere. The *me*Phone is mobile healthcare at its best!
- NEW! The mePhone now also enables you to have your blood glucose measurements posted directly to almost any personal health record of your choice, through interface applications for the most popular PHR's readily available for download. Pick your PHR, download the app, and set it up, it that's easy.

Now you suggest some

Questions?

Arguing with a lawyer is like
mud wrestling with a pig: after a while
you realize the pig actually enjoys it.

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