# FDA 301-- Case Study of a Mobile Communications Platform

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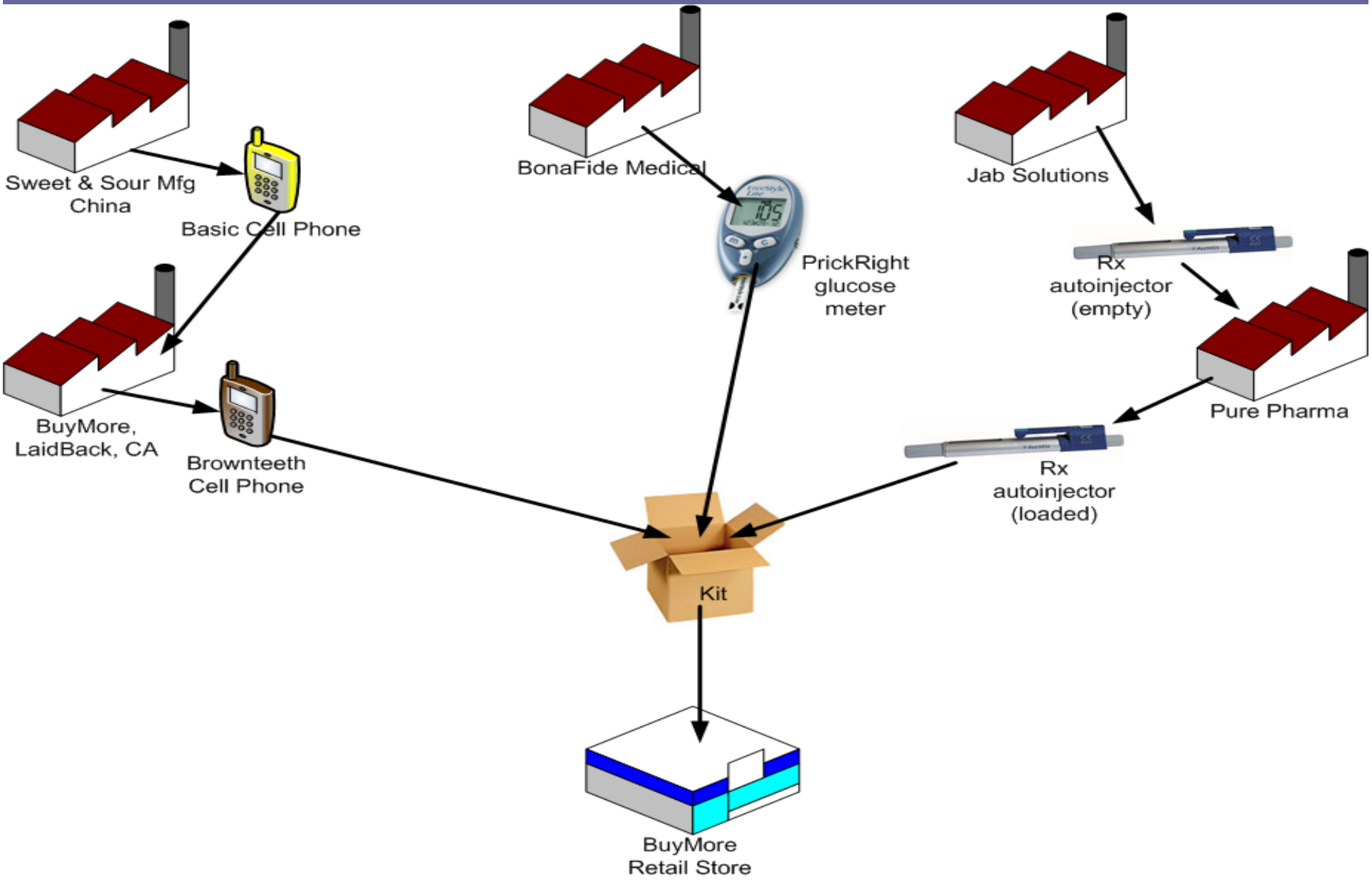
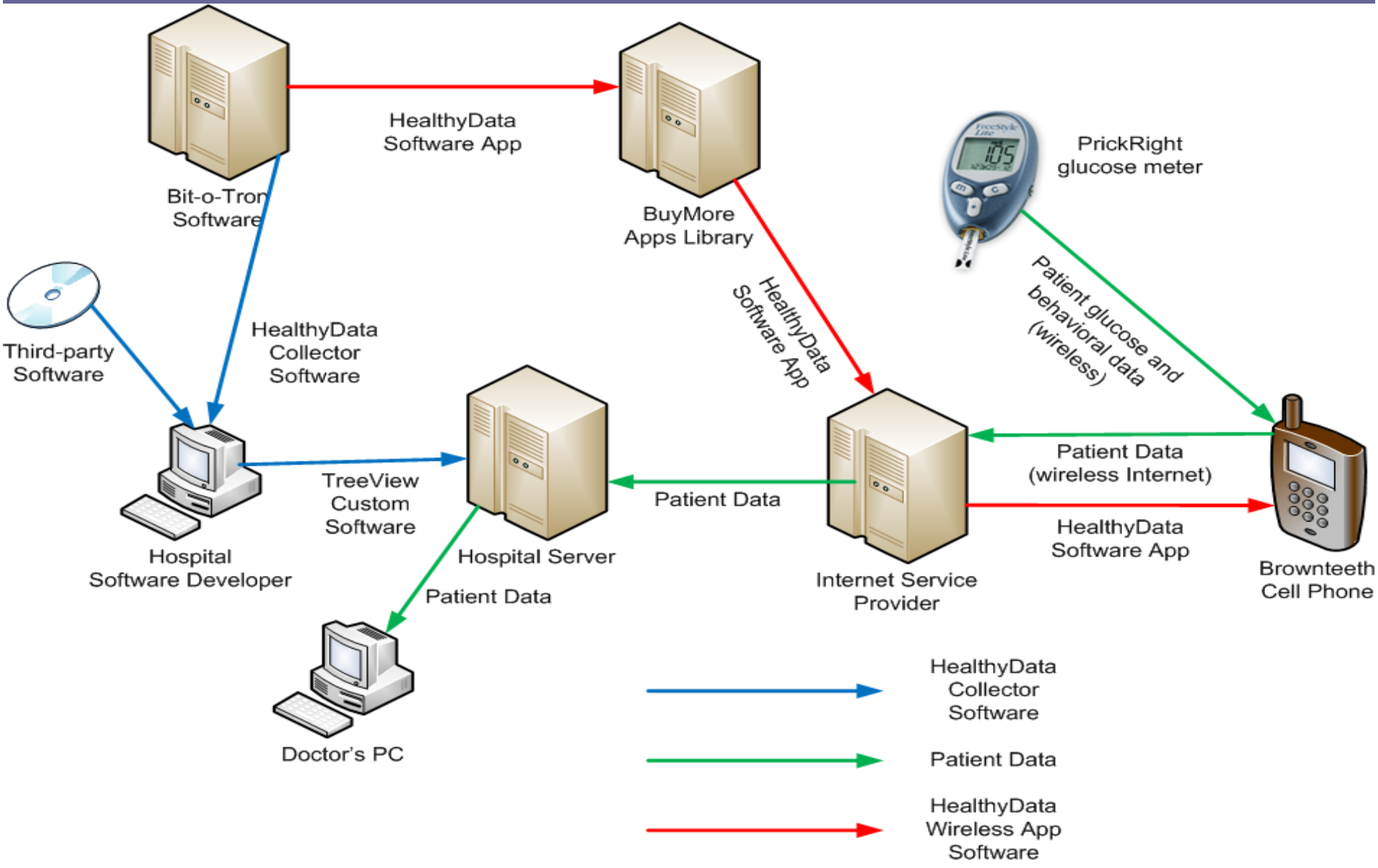
# Kit Manufacturing



# Software Development / Acquisition



# Components and accessories

- *me*Phone smart cell phone and HealthyData software for the phone that allows tracking important information for a person with diabetes, sold separately by BuyMore Electronics.
  - The software is purchased and downloaded from a BuyMore online apps store.
- As initial promotions during the launch:
  - *me*Phone sold together with a compatible PrickRight blood glucose meter as a kit, from the BuyMore
  - *me*Phone sold together with a Rx auto-injector for use with insulin (no drug included) as a kit, from the BuyMore through pharmacies
- No one sells a good, ready-made complete system for doctors to read the data, so Treeview Hospital builds its system through piecing together a variety of off the shelf software that includes one small program designed to accept the data from the HealthyData software, with substantial programming by Treeview required to get the pieces to work together

# Sourcing

- Basic *me*Phone made by a contract manufacturer in China.
- BrownTeeth capability added by BuyMore in its LaidBack, California plant.
- HealthyData software was developed by Bit-o-Tron Software, primarily a maker of video games and other such important software. BuyMore sells the stuff through its online app store.
- PrickRight blood glucose meter is made by BonaFide Medical Company
- The auto-injector is made by Jab Solutions, Inc., under a contract with Pure Pharmaceuticals LLC.
- The kits are co-packaged (shrink wrapped with existing packaging and labeling plus overlay labeling) by the BuyMore.
- Treeview Hospital pieces together software programs made by a wide variety of vendors, including the HealthyDataCollector software from Bit-o-Tron Software

# Marketing claims

- *me*Phone smart cell phone, the HealthyData software and the PrickRight blood glucose meter all bear a (K) which means they are interoperable with all other devices with a (K), according to standards developed by Kintinuum Alliance.
  - Indeed, since that isn't well understood by consumers, the labeling and advertising for each explains that meaning in a coordinated advertising campaign
- The BuyMore also generally promotes the *me*Phone for its cool apps, include a whole slew of health apps such as HealthyData software. The BuyMore's apps store includes the description of the HealthyData software.
- Bit-o-Tron Software promotes its HealthyData software for use with the *me*Phone and the PrickRight blood glucose meter, touting all of the cool things it can keep track of like diet and blood glucose readings and the connectivity features with the doctor, so the doctor can make treatment decisions without the hassle of an appointment/visit.

# Marketing claims

- BonaFide Medical promotes its PrickRight blood glucose meter as linkable to the *me*Phone.
  - Runs a lot of ads showing hip young tan Californians (with diabetes) connecting with their doctors just before engaging in extreme sports like mountain biking down the side of the Grand Canyon, not using a trail, while drinking LighteningJolt.
- Hospitals like Treeview start to promote their remote treatment capabilities, which allow people with diabetes to live normal lives without the hassle of actually seeing their nerdy, curmudgeonly doctors.

# Marketing Tactics

- BuyMore holds a classy program in Aspen, and brings together a range of experts to talk about best practices in managing people with diabetes remotely
- The program is free for some selected thought leaders who can be relied on to talk up the products afterward
- A distinguished physician from Treeview Hospital that BuyMore recruited gives a talk on the *me*Phone's incredibly broad number of uses in health, and on some examples of software applications others have built that are available at the BuyMore on-line store

# Postmarket problems

- Right before mountain biking down the side of the Grand Canyon, a young person connects to his doctor at Treeview, who sees his blood glucose in the normal range.
- The doctor says go for it.
- Turns out the system hiccupped somehow, the person was actually hypoglycemic, and passes out on his way down, tragically crashing into the Colorado River and drowning.
- We can’t recover the devices, which probably are at the bottom of Lake Mead.

# 1. Device Definition

# Background

Same as FDA 201

# Discussion Questions

- Which of the following are medical devices?
  - *me*Phone
  - HealthyData software
  - PrickRight blood glucose meter
  - PrickRight and *me*Phone as a kit
  - An Rx autoinjector
  - *me*Phone sold together with a Rx auto-injector
  - A variety of off the shelf software
  - One small program designed to accept the data from the HealthyData software
  - All that software melded together by Treeview Hospital
- Which are standalone, accessories and components

# 2. Rx Classification

# Background

| | Prescription Device | Restricted Device |
|---|---|---|
| Law | 21 C.F.R. 801.109 | 520(e) of the Act |
| How designated | Checking a box in 510(k) | By regulation (e.g. 21 C.F.R. 801.420 for hearing aids) or by order (e.g. in PMA) |
| Impact | Can only be sold on the order of a qualified health professional | Basically any and all marketing and distribution restrictions are possible: legally very similar to Rx drugs |
| Labeling and promotional labeling | Must include the specified Rx language and more detailed risk information | Must include designated restricted language and any other required content |
| Advertising | FTC rules | FDA Rules |

# Rx vs Restricted Device Distribution

- The role of pharmacies and wholesale device distributers is a matter of state law and each state is different
- Often Rx and restricted devices will be treated the same under state law, and may only be distributed by licensed institutions
- If non Rx devices are packaged with Rx devices, the more restrictive rules will govern
- But mere cross referencing should not “up-regulate” the OTC device
  - Typically the OTC device will have other uses—that’s why it isn’t Rx—that should be sorted out at the time of FDA review

# Discussion questions

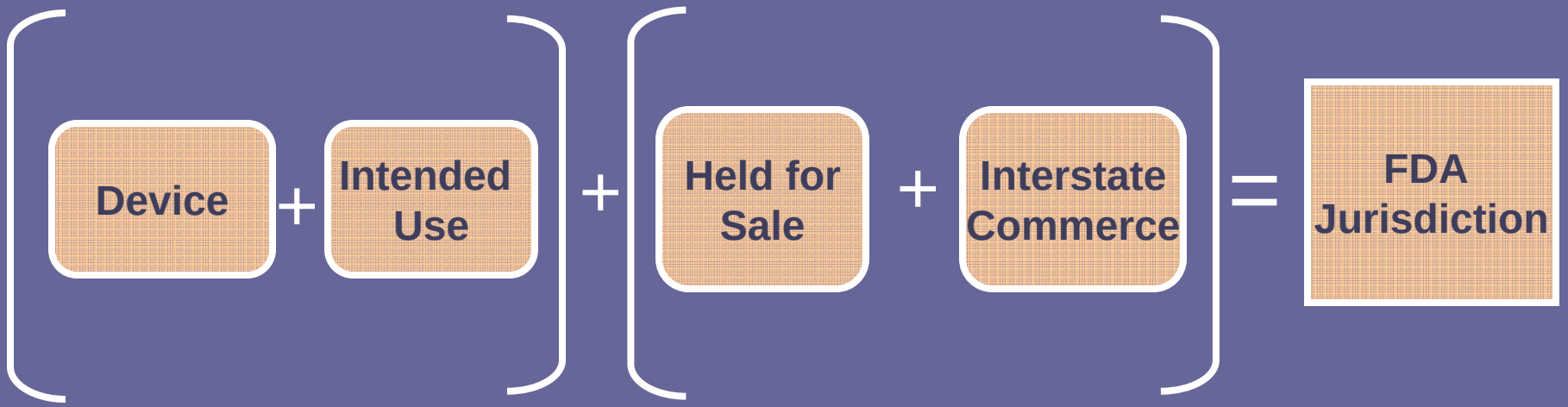
1. Can a company package prescription and non-prescription (OTC) devices without impacting the OTC device?
2. Are there special labeling considerations for these devices?
3. Who is responsible for managing the distribution of the prescription device?

# 3. Who are the manufacturers?

# Background

- It's a tail and dog situation.
  - To figure out if a company is "manufacturing", you first need to figure out if the product is a regulated "medical device."
  - We have already discussed the device definition, so the trick is to figure out when a "device" can be regulated under FDA's jurisdiction.

# FDA Jurisdiction

# Prohibited Acts

FDCA Section 301(k) on "prohibited acts" applies to devices:

1. "Held for sale (whether or not the first sale)
2. After shipment in interstate commerce"

Plus other sections of 301 can apply.

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My mother never saw the irony in calling me a son-of-a-bitch.

Jack Nicholson

# Prohibited Acts

| Requirement | Devices |
| --- | --- |
| "Interstate commerce" requirement | 1. The use of the channels of commerce;<br>2. The instrumentalities of interstate commerce; and<br>3. Those activities having a substantial relation to interstate commerce<br>4. It's presumed for medical devices. |

# Prohibited Acts

| Requirement | Devices |
| --- | --- |
| "held for sale" | ◆ Devices can be held for sale just before they are used in a test (*Hoxsey*)<br>◆ Devices can be held for sale just before they are transferred from the facility that made them to the facility that uses them (*Sene X Eleemosynary*)<br>◆ Simple components can be devices and give FDA jurisdiction. (*CRL)* |

# Bottom Line:

- Imagine if a major hospital bought a pacemaker company and started to produce their own pacemakers for patients at the hospital.
  - FDA would have no problem regulating them
- FDA in fact has announced a major policy in this area: reuse of disposable products.

# On the other hand

- User vs. Manufacturer
  - Healthcare professionals routinely modify devices to fit their needs
  - The law declares no FDA regulation on the practice of medicine. (Sec. 906 of the Act)
  - Notice these concepts are directed at licensed healthcare professionals, and seeks to avoid duplicating state regulation of these professionals
    - IT engineers in a back room may not qualify
  - Issue, it is modifying an already regulated article, or making something out of unregulated articles?

# Further Exceptions

Customized Device Manufacturing

- Key elements
  - Exempt from 510(k)—21 C.F.R. § 807.85(a). A device is exempt from the premarket notification if the device
    - is not generally available in finished form for purchase
    - is not offered through labeling or advertising for commercial distribution
    - is intended solely for use by a physician or dentist (or other specially qualified person)
    - is not generally available to, or generally used by, other physicians or dentists (or other specially qualified persons)
  - Must register and list (21 C.F.R. § 807.20(a)) and comply with GMPs

# Intent Behind Custom Device

- Key is
  - uniqueness of the product
  - usually low volume
- Contact Lens Mfrs. Ass'n, Court noted that the custom device definition: appears to reflect a commonsense congressional judgment that the *design and composition of certain medical devices are so individualized that subjecting them to the usual regulatory controls would be impractical* (and added that such particularly constructed devices are so closely monitored by the prescribing physician that stringent regulation might well be excessive).

# FDA Discretion

- FDA permits manufacturing like activity by provider institutions in special circumstances, for example:
  - Pharmacy that do limited compounding
  - Laboratories that do limited diagnostic test development

# Factors FDA uses to address pharmacy compounding:

1. Compounding of drugs in anticipation of receiving prescriptions, except in very limited quantities in relation to the amounts of drugs compounded after receiving valid prescriptions.
2. Compounding drugs that were withdrawn or removed from the market for safety reasons.
3. Compounding finished drugs from bulk active ingredients that are not components of FDA approved drugs.
4. Receiving, storing, or using drug substances without first obtaining written assurance from the supplier that each lot of the drug substance has been made in an FDA-registered facility.
5. Receiving, storing, or using drug components not guaranteed or otherwise determined to meet official compendia requirements.
6. Using commercial scale manufacturing or testing equipment for compounding drug products.
7. Compounding drugs for third parties who resell to individual patients or offering compounded drug products at wholesale to other state licensed persons or commercial entities for resale.
8. Compounding drug products that are commercially available in the marketplace or that are essentially copies of commercially available FDA-approved drug products.
9. Failing to operate in conformance with applicable state law regulating the practice of pharmacy.

# Discussion Questions

- Can FDA regulate Treeview Hospital that integrates regulated devices and non-regulated data systems?
- Is Treeview Hospital considered a manufacturer in this instance or is this “the practice of medicine”?
- If Treeview is a manufacturer, is it a custom device manufacturer?
- Is this a legitimate area for enforcement discretion?

# 4. Device Clearance and Approval Process

# Devices / Accessories Requiring Approval

- The entire “K” system
  - All devices, accessories and software V&V tested together in all possible combinations
  - Establishment of an FDA-recognized standard for “K” product attributes (brownteeth data communications, fail-safes, error-recovery, etc.)
  - V&V testing of and MTFs for each new **device** added to the K family after initial submission of the K family products
- mePhone+ (mePhone+brownteeth+HealthyData apps S/W)
- Each mePhone+ / device kit
- PrickRight glucose meter
- Rx autoinjector
- TreeView Hospital software

# Manufacturers of Record

| | |
|---|---|
| mePhone+ | BuyMore |
| mePhone+/device kits | BuyMore |
| “K” product family system | BuyMore |
| PrickRight | BonaFide |
| Rx autoinjector | Pure Pharma |
| Hospital software | TreeView |

# Approval Process

- Get the “K” product family approved consisting of the mePhone+, at least one medical device, and the TreeView Hospital software
- Get FDA recognition / approval of the K family data communications standard
- Conduct full V&V testing on any new devices and all combinations of new / old devices every time a device is added to the K family
- Get 510(k) clearances for any new capability devices and use MTF for product changes where the intended use does not change

# Indications for Use Statement

"This product is intended for use with K family devices and software and is not intended for use with other wireless communications or medical device technologies not Kontinuum certified."

# 5. Device GMPs

# Manufacturers of Record

| | |
|---|---|
| mePhone+ | BuyMore |
| mePhone+/device kits | BuyMore |
| “K” product family system | BuyMore |
| PrickRight | BonaFide |
| Rx autoinjector | Pure Pharma |
| Hospital software | TreeView |

# Specification Developers

- HealthyData software — BuyMore
- HealthyDataCollector S/W — TreeView
- K family standard — Kontinuum?

# Contract Manufacturers

- PrickRight bG meter — BonaFide
- RX autoinjector — Pure Pharma

# Medical Devices

| | |
|---|---|
| ◆ mePhone+ | Class II |
| ◆ mePhone+/device kits | Class II |
| ◆ “K” product family system | Class II |
| ◆ PrickRight | Class II |
| ◆ Rx autoinjector | Class III? |
| ◆ Hospital software | Class II |

# Registrations and Listings

- All Manufacturers of Record, Specification Developers, and Contract Manufacturers need to register with the FDA
- All medical devices need to be listed with the FDA
- Each Manufacturer of Record needs to have their own market surveillance, complaint handling, adverse event, reporting and recall systems

# 8. Limits on Promotion and labeling

# Background from 201

# Discussion Questions

- What do you need to know to assess the risk?
- Where does the BuyMore have risk?
- What can they do to moderate the risk?