

Lecture 15: Medical Device Regulations

0. Review

1. History of Device Legislation

2. Federal Agencies

3. Medical Device Approval Process

4. Ethics Assignment

Optional Reading:

PDF about Medical Device Regulations
(see course website)

• Today:
HW6 ←
Quiz
next Tue

• Ellis Field Trip
Mar 10!

• Lab 6 report due Mar 6
• Lab Practical next week
→ see course website for assignment

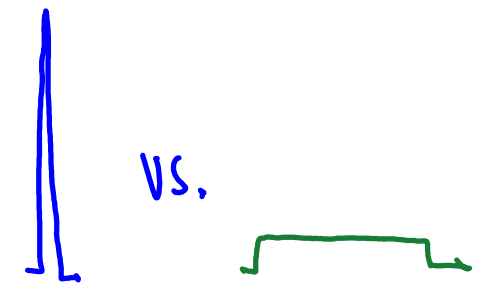
• Exam #2 Thu (Mar 5)
→ Course website has PreLab +
HW solns, 2019 exam + solns

• Team Presentations Mar 10 + 12

• Ethics assignment due Mar 13
→ see FDA website for device
recall database
⇒ Email topic to Burma
(no duplicate device types)

0. Review

• Pulse Duration



• Current Thresholds

★ Major cause of death due to electric shock



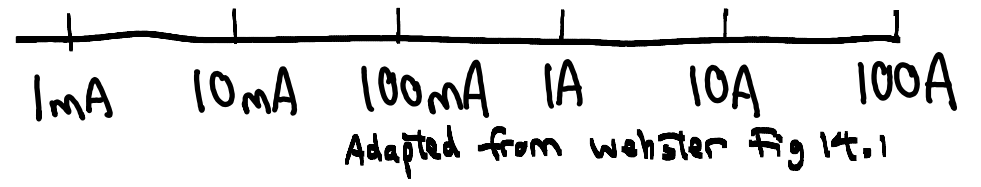
Ventricular Fibrillation

• Burns, injury
• Sustained myocardial contraction

Respiratory paralysis, Fatigue, Pain

Let-Go Current

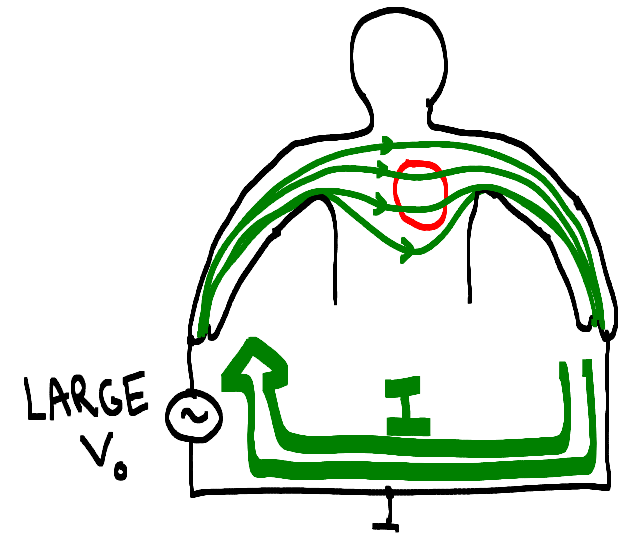
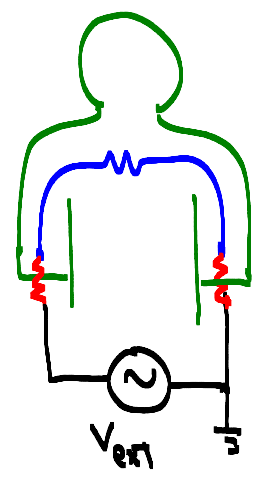
Threshold of perception



MACRO SHOCK

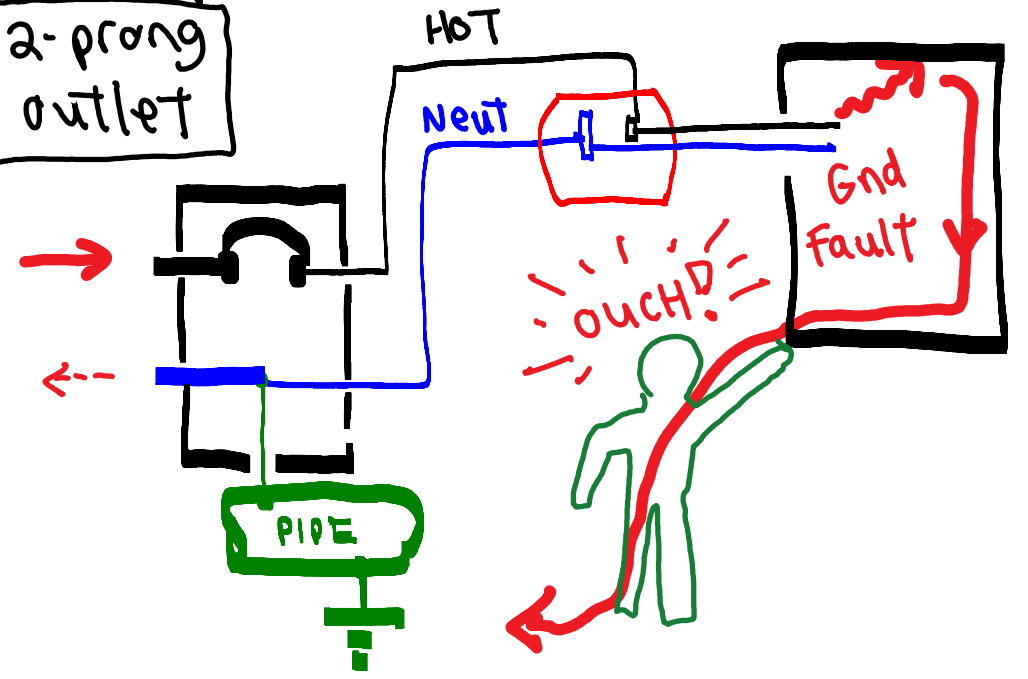
• High voltage on skin

[Dry vs. Wet]

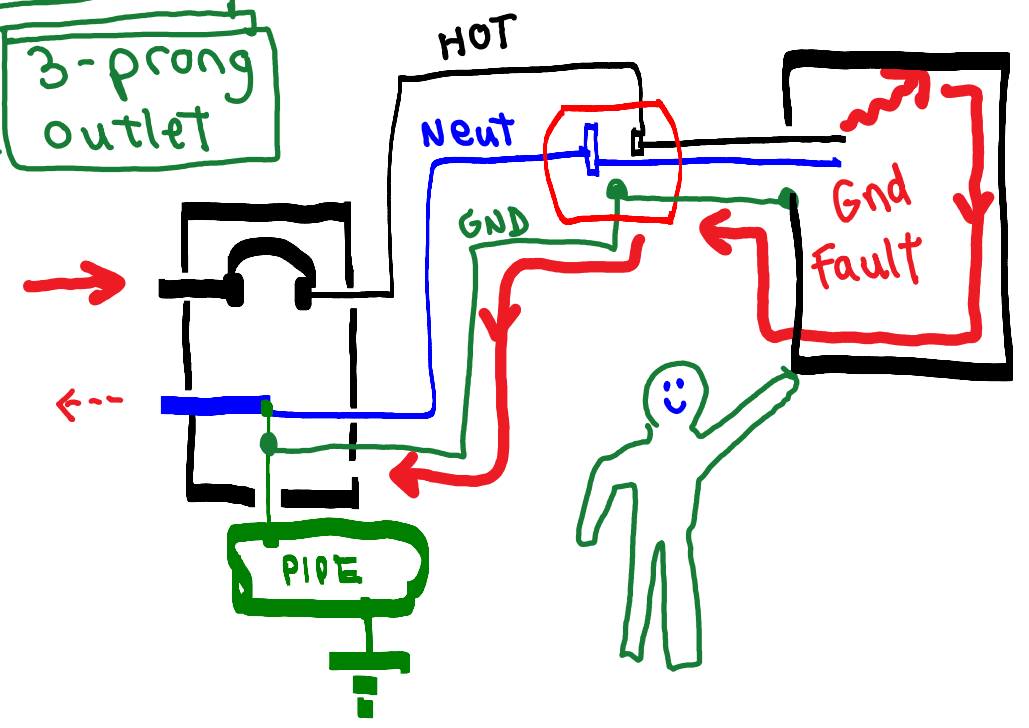


★ Proper grounding to minimize hazard due to ground faults!

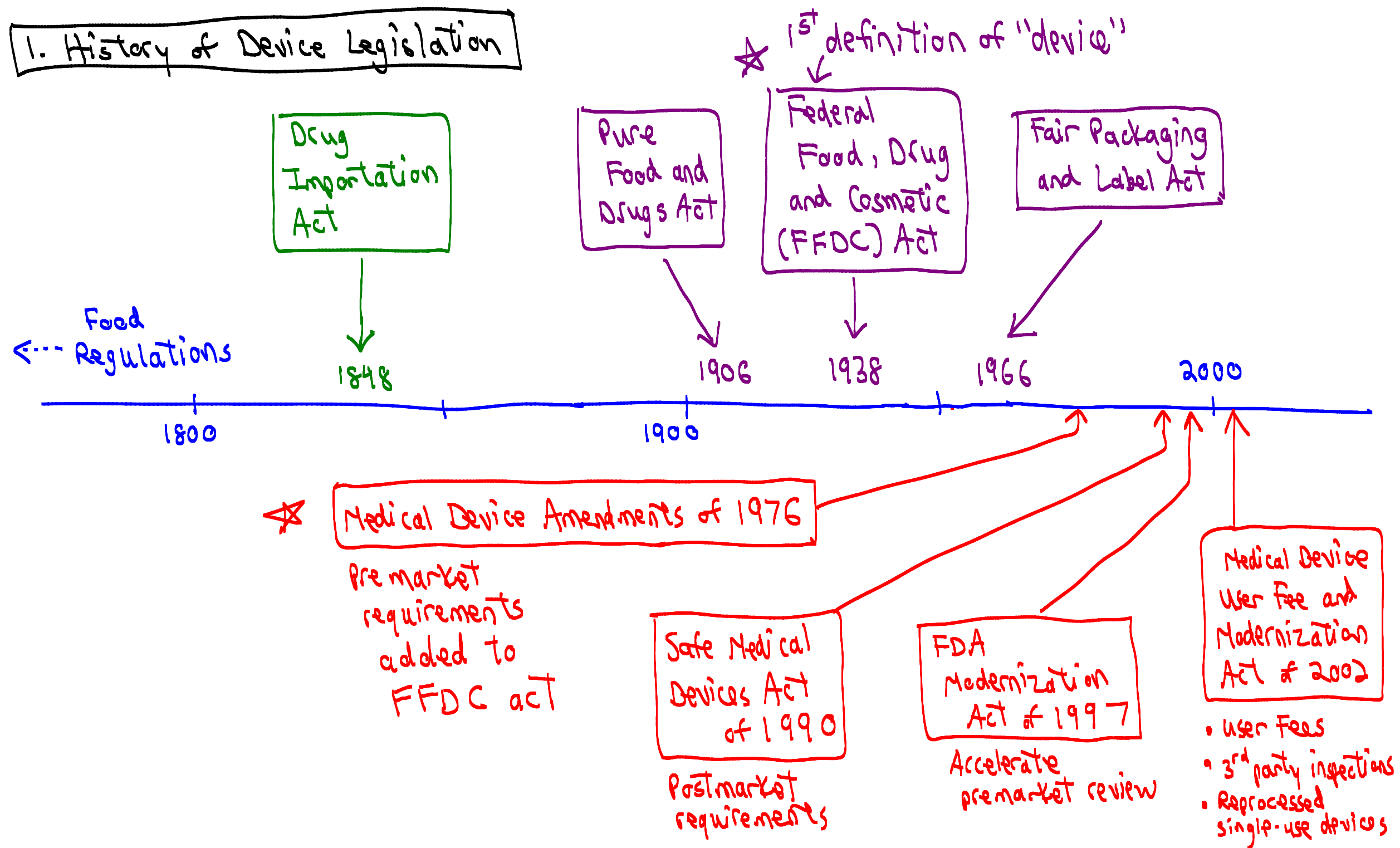
2-prong outlet



3-prong outlet



1. History of Device Legislation



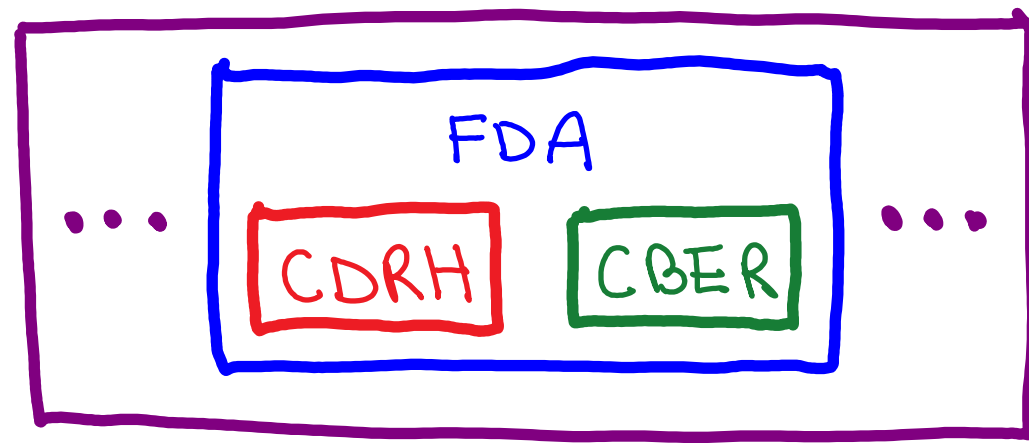
2. Federal Agencies

- Most medical devices sold in the U.S. must be reviewed by the Food + Drug Administration (FDA)



DHHS ← (15.2)

Dept of Health + Human Services



CDRH = Center for Devices and Radiological Health

CBER = Center for Biologics Evaluation and Research

Funded by:

- ① Congressional appropriations

② User Fees

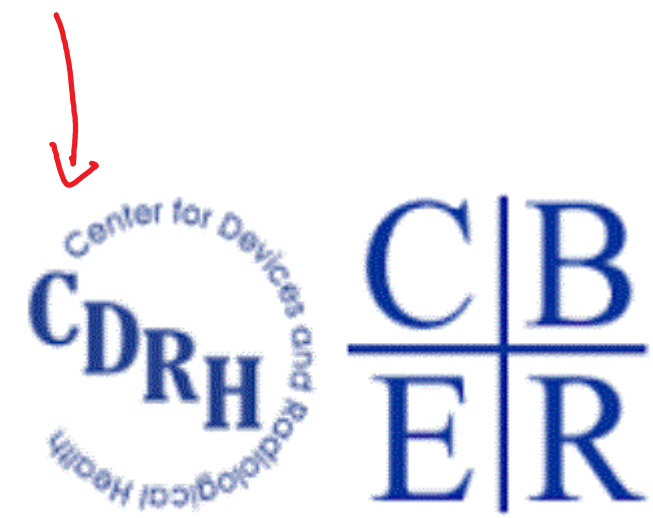
↑
Paid by manufacturer!

Regulate medical device firms:

- Surgical instruments
- Implantable devices
- Diagnostic equipment
- Clinical lab tests
- Radiation emitting electronic products

Regulate medical device firms for blood testing

- Collection
- Processing
- Testing
- Manufacture
- Administration



- Definition of a "medical device":

Section 201(h) of the FDCA Act of 1938 defines a medical device as:

Form of
the device →

an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is —

Purpose →
of the
device

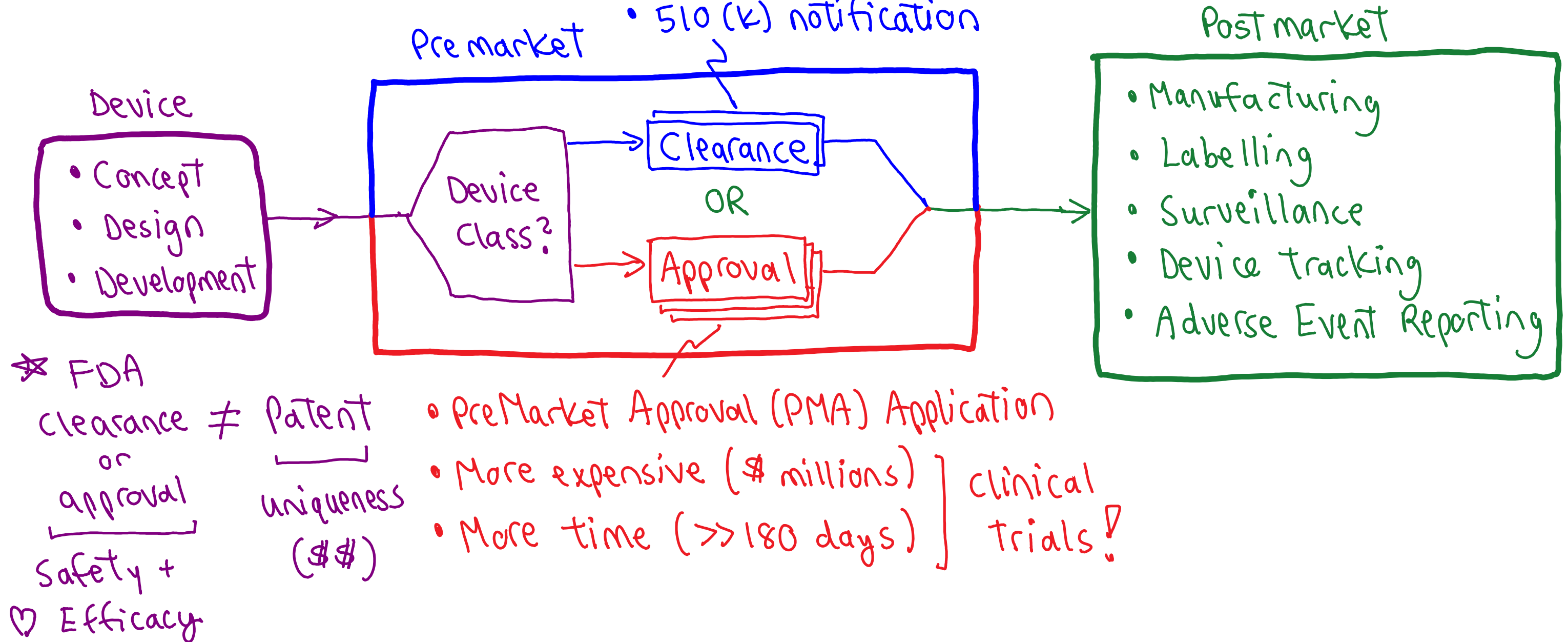
- (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
- (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- (3) intended to affect the structure or any function of the body of man or other animals, and

Device
≠ Drugs. →

which 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 for the achievement of its primary intended purposes.

3. Medical Device Approval Process

- Less expensive
- Less time (~60-90 days)
- 510(k) notification



- Device Classification: Based on level of risk to patient

CLASS 1

- Low Risk (~55% of all devices)

Ex: Elastic bandage

- Many exempt from 510(k) notification

- General Controls

[Establishment registration,
Device listing, labeling,
Good Manufacturing Practice (GMP)]

CLASS 2

- Medium Risk (~40%)

Ex: Powered Wheelchair

- 510(k) Notification ←

- General Controls clearance

↗ Special Controls

↗ Device specific
Additional labeling
Performance Standards

CLASS 3

- High Risk (~5%)

Ex: Heart Valve

- PMA application

[Life supporting +
life sustaining devices]

- General controls

+
Premarket Approval

• 510(k) Notification

→ Required for moderate risk devices that are NOT exempt from premarket review

Traditional 510(k)

For "routine" devices that meet certain qualifications →

Abbreviated 510(k)

Modify a previously FDA cleared device →

Special 510(k)

For non-predicate devices that are NOT high risk →

De Novo 510(k)

Must demonstrate

substantial equivalence
to a predicate device

[Code of Federal Regulations
has list of >1700 devices
from before 1976]

Does NOT require

- clinical studies
- Manufacturing inspections
- Postmarket studies

• Premarket Approval (PMA) Application ← New and/or high-risk devices

↳ FDA approval means sufficient scientific evidence has shown the device to be safe + effective for its intended use

- ↑
- Device function
 - physiological purpose

What does it do?

(e.g. Thermometer measures temp)

- Disease/condition
- Patient population
- Clinical settings

How/when
is it used?

(e.g. Fever, hypothermia)

★ PMA must contain

- Clinical data
- Description of significant physical + performance characteristics

• Indications of Use

- Marketing history (U.S. and foreign)
- Proposed Labeling
- Manufacturing Process

- Post-Approval Requirements

A. Labeling

All FDA approved or cleared medical devices require proper labeling to inform the user of how to use the device in a safe + effective manner.

→ Label on product itself

→ Includes advertising { Posters
Pamphlets
Brochures
etc.

B. Manufacturing

Devices must be produced in accordance with Good Manufacturing Practice (GMP)

↑ included in Quality System Regulation (QSR)

★ Manufacturer has great flexibility in designing manufacturing process that complies with GMP.

• Postmarket Surveillance:

- Safety + Efficacy Data must be gathered for
 - ① Permanent implants
 - ② Supporting or sustaining life
 - ③ Present a potential serious risk

★ Medical Device Reporting (MDR): identifies and monitors significant adverse events involving medical devices

↑
user facilities (e.g. hospitals)
must report device concerns
to FDA and manufacturer
within 10 days.

• Compliance + Enforcement: CDH has an Office of Compliance

NOTE: Device is recalled
by the manufacturer,
not the FDA?

↳ Warning Letter
⋮



Product Recall
⋮

4. Ethics assignment

- Short Paper (≥ 4 pages)  11 pt font, Times New Roman
1.5 line spacing, 1-inch margins

- Case Study $\leftarrow$ device recall within past 10 years (preferred)

① Title + Author: Similar format to Lab Report

② Abstract: Brief summary (~5 to 7 sentences)

③ Introduction: More detailed summary about the device recall

e.g. Device, Problem, Company, Recall date, # of recalled units

④ Technical: Engineering details of device failure

⑤ Events: How was the problem discovered?

How did the company handle the situation?

How did the FDA handle the situation?

How did the physicians + patients handle the situation?

(More...) $\downarrow$

☆ ⑥ Decision Making Process : Describe some hypothetical arguments made by the following members of a company's decision-making committee

↗
 Think outside
 the "engineering
 box"

- Finance Officer Recall costs, Lawsuit costs
- VP of Market Development Sales, market share, competitors
Product availability
Reputation
Relationship with physicians

the customer →

- Physician Patient welfare
Workload of medical staff
Malpractice + reputation

End user →

- Patient Advocate Safety, rights, peace of mind

- Major Investor Value of portfolio

(More ...) ↘

⑦ Analysis: which committee members prevailed?
Did the situation change with time?
How well did the FDA do its job?

⑧ Conclusions: Was the company response appropriate?
Was the FDA response appropriate?

⑨ References: Articles, websites, etc.

★ Assignment is adapted from:

"Teaching Biomedical Engineering Ethics: A Case Based Approach"

S. Lewis, W. Van Hout, A. Huang-Saad

40th ASEE/IEEE Frontiers in Education Conference (2010)

- FDA has database for medical device recalls!

Medical Device Recalls

The FDA posts summaries of information about the most serious medical device recalls. These products are on the list because there is a reasonable chance that they could cause serious health problems or death.

Use the yearly lists to find information about Class I medical device recalls and some Class II and III recalls of interest to patients. The links give details about what to do if you own or use one of these products. If you wish to find information on a recall, or a correction or removal action that has not yet been classified, you can search the [Medical Device Recalls Database](#).

Please note that the FDA lists medical device recall notices by the date that it posts the recall rather than the recall initiation date. You can find the date that

Medical Device Recalls

This database contains Medical Device Recalls classified since November 2002. Since January 2017, it may also include correction or removal actions initiated by a firm prior to review by the FDA. The status is updated if the FDA identifies a violation and classifies the action as a recall and again when the recall is terminated. FDA recall classification may occur after the firm recalling the medical device product conducts and communicates with its customers about the recall. Therefore, the recall information posting date ("create date") indicates the date FDA classified the recall, it does not necessarily mean that the recall is new. [CBER recall information is available here.](#) [More about Medical Device Recalls](#)

Search Database

Product Name Product Code In Vitro Devices ☐

Recall Class PMA/510(K) Number

Recall Date to Recall Number

Other Databases

- 510(k)s
- De Novo
- Medical Device Reports (MAUDE)
- CDRH Export Certificate Validation (CECV)
- CDRH FOIA Electronic Reading Room
- CFR Title 21
- CLIA
- Device Classification
- FDA Guidance Documents
- Humanitarian Device Exemption
- Medsun Reports
- Premarket Approvals (PMAs)
- Post-Approval Studies
- Postmarket Surveillance Studies
- Radiation-Emitting Products

- Example of a particularly controversial device recall...

Case Study: (2005) Defibrillator made by the Guidant Corporation

June 18, 2005

Citing Flaws, Maker Recalls Heart Devices

By BARRY MEIER

(From NY Times)

The Guidant Corporation said yesterday that it was recalling about 29,000 implanted heart devices because of flaws that might cause them to short-circuit when they are supposed to deliver a potentially life-saving shock.

The recall, which comes at the urging of the Food and Drug Administration, involves three models of defibrillators made by Guidant. In the case of one model, the Ventak Prizm 2 DR Model 1861, Guidant did not tell doctors for more than three years that it was prone to electrical failure because of a design flaw. The company also disclosed yesterday for the first time that two other Guidant units had also repeatedly short-circuited.

- Problem: Recalled models may short circuit when they are supposed to deliver a potentially life-saving electrical pulse to an erratically beating heart.
- Controversy²: • For one particular model (Ventak Prizm 2 DR Model 1861), Guidant did not tell doctors for 3 years about the potential flaw.

- Technical details: The polyimide wire insulation in the non-sealed header unit can deteriorate when exposed to body fluids.
- Company Response: Guidant has insisted it did nothing wrong. It submitted the necessary reports to the FDA. It believes the risks of complications during surgical replacement outweigh the risk of device malfunction.
- Some things to ponder :
 - ① No device is 100% safe and effective
 - ② what is appropriate balance between product availability + public safety?
 - ③ when do manufacturers or the FDA have a duty to disclose any evidence of a potential problem with a product?
 - ④ who should determine "acceptable risk" to a patient, especially if the patient has no alternative treatment?
 - ⑤ was there any premarket evidence of potential device problems?