Lecture 15: Medical Device Regulations

0. Review
1. History of Device Legislation
2. Federal Agencies
3. Medical Device Approval Process
4. Ethics Assignment

- Today:
  - HW6
  - Quiz next Tue
- Ellis Field Trip Mar 10!

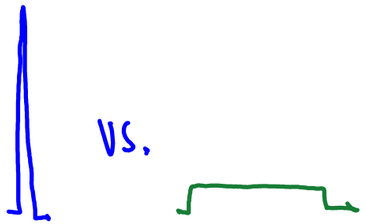
Optional Reading:

PDF about Medical Device Regulations (see course website)

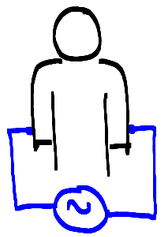
- Lab 6 report due Mar 6
- Lab Practical next week
  - → See course website for assignment
- Exam #2 Thu (Mar 5)
  - → Course website has PreLab + HW solns, 2019 exam + solns
- Team Presentations Mar 10 + 12
- Ethics assignment due Mar 13
  - → See FDA website for device recall database
  - ⇒ Email topic to Burna (no duplicate device types)

0. Review

- Pulse Duration



- Current Thresholds



60 Hz
1 to 3 sec

★ Major cause of death due to electric shock

→ Ventricular Fibrillation

- Burns, injury
- Sustained myocardial contraction

Respiratory paralysis, Fatigue, Pain

Let-Go Current

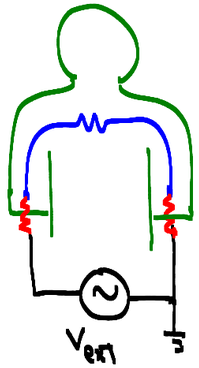
Threshold of perception

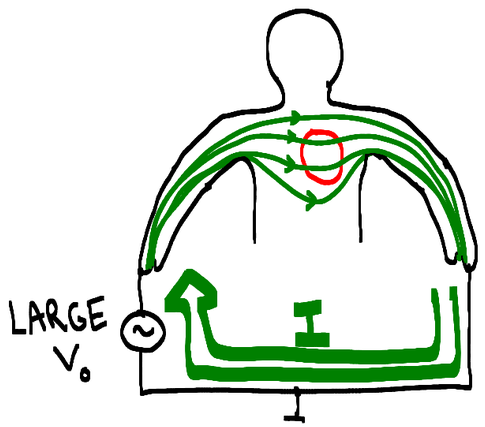
Adapted from Webster Fig 14.1

MACRO SHOCK

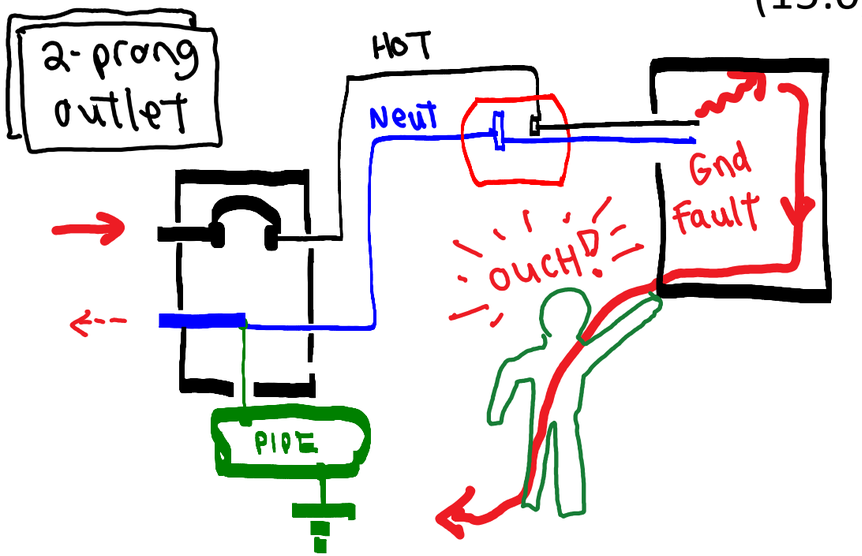
- High voltage on skin

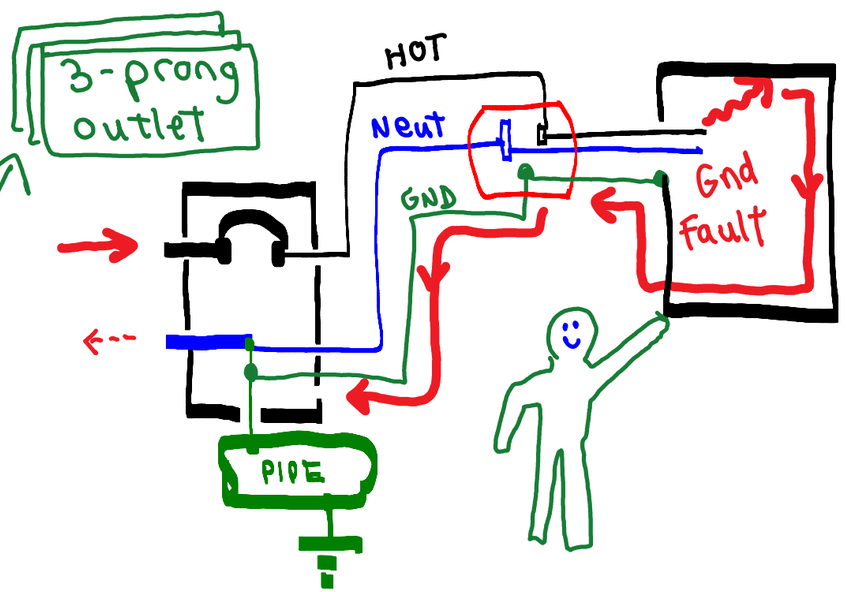
[Dry vs. Wet] ↑



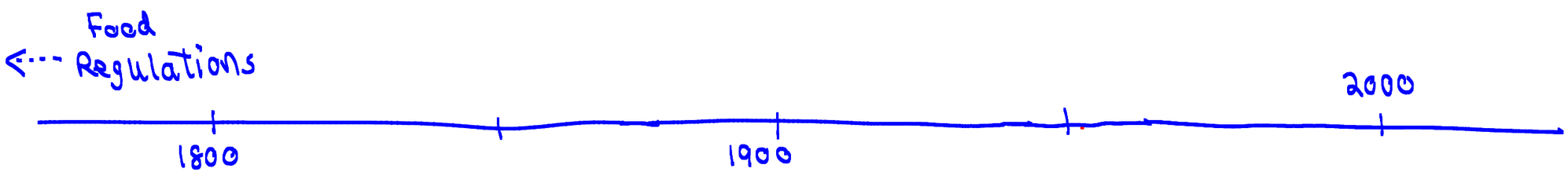


★ Proper grounding to minimize hazard due to ground faults!





1. History of Device Legislation



2. Federal Agencies

- Most medical devices sold in the U.S. must be reviewed by the

- Definition of a "medical device":

Section 201(h) of the FFDC Act of 1938 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 —

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

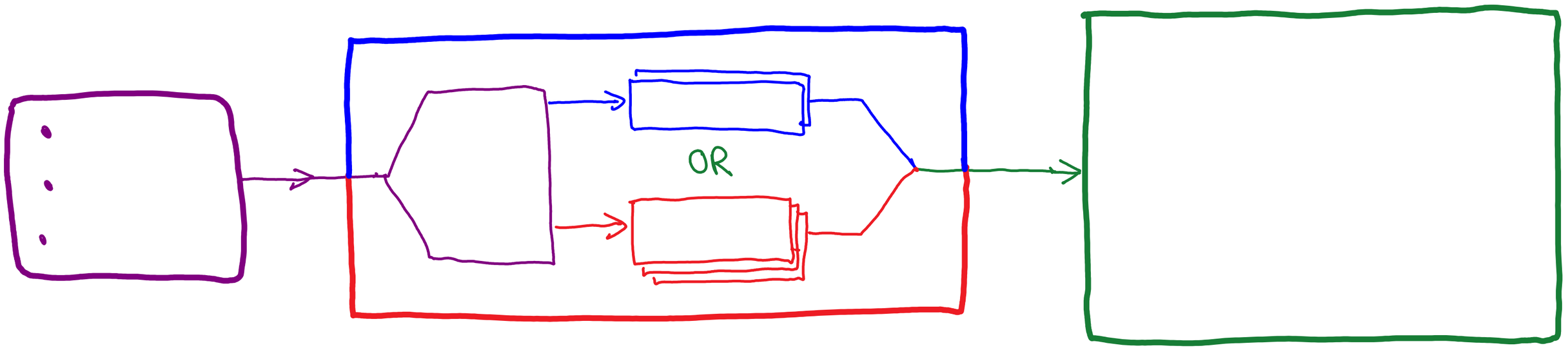
(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and

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

(15.4)



- Device Classification: Based on level of risk to patient

CLASS 1

- Low Risk

  Ex:

- Many

- General

CLASS 2

- Medium Risk

Ex:

-

- General

  Special+

CLASS 3

- High Risk

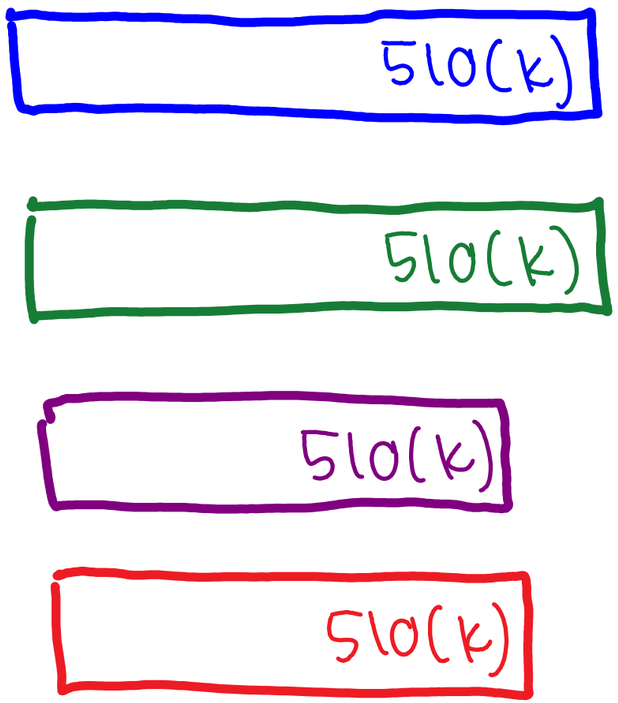
Ex:

-

- General

- 510(k) Notification

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



- Premarket Approval (PMA) Application

↳ FDA approval means sufficient _____ has shown the device to be _____

_____

✡ PMA must contain

- Post-Approval Requirements

A. Labeling

All FDA a ved or cleared medical devi labeling to

B. Manufacturing

Devices must be produced in accordance with

- Postmarket Surveillance:
  - Safety + Efficacy Data must be gathered for { ① ② ③

- Compliance + Enforcement: CDRH has an _____

4. Ethics assignment

- Short Paper (≥ 4 pages) ← 11 pt font, Times New Roman; 1.5 line spacing, 1-inch margins
- Case Study ← 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...) ↴

⭐ 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?

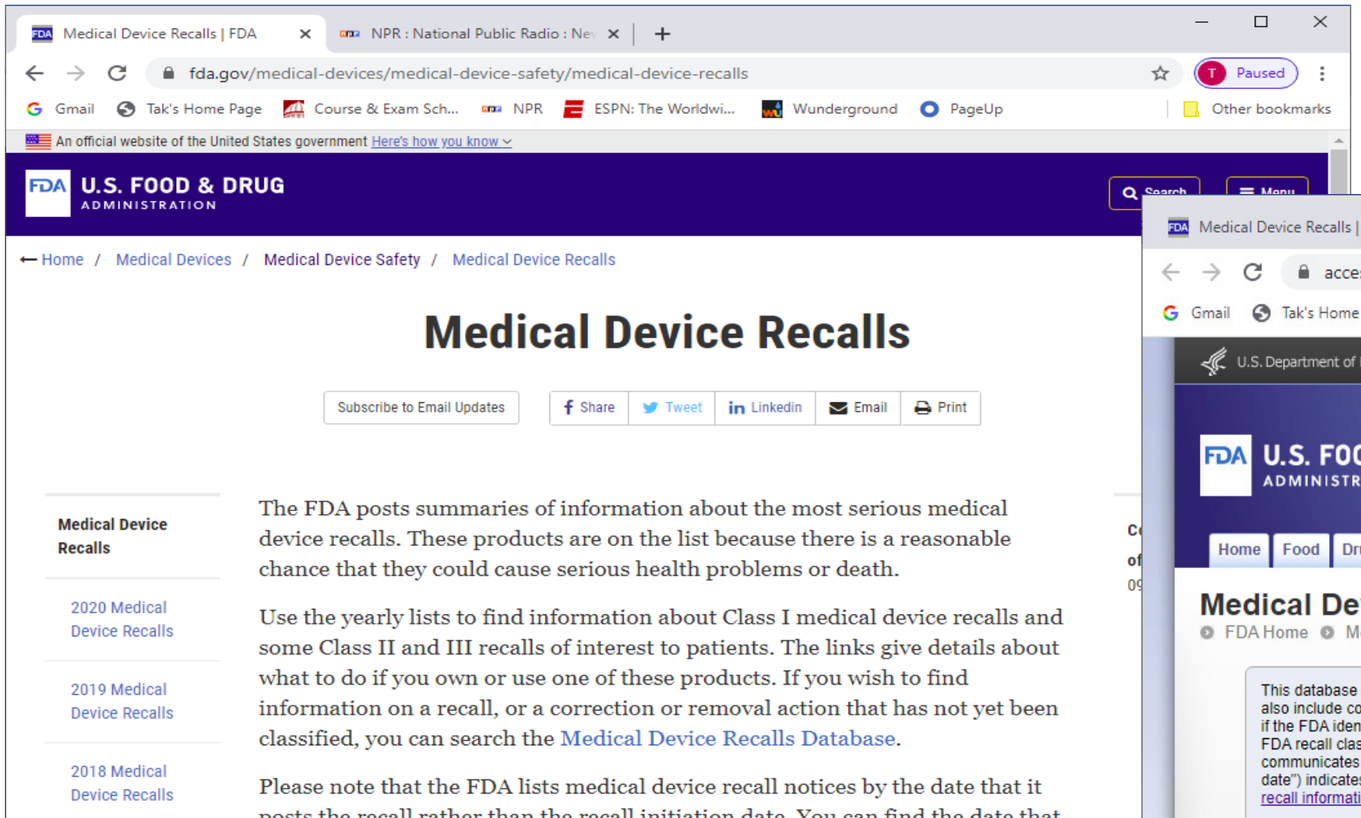
⑧ Conclusions: Was the company response appropriate?
Was the FDA response appropriate?

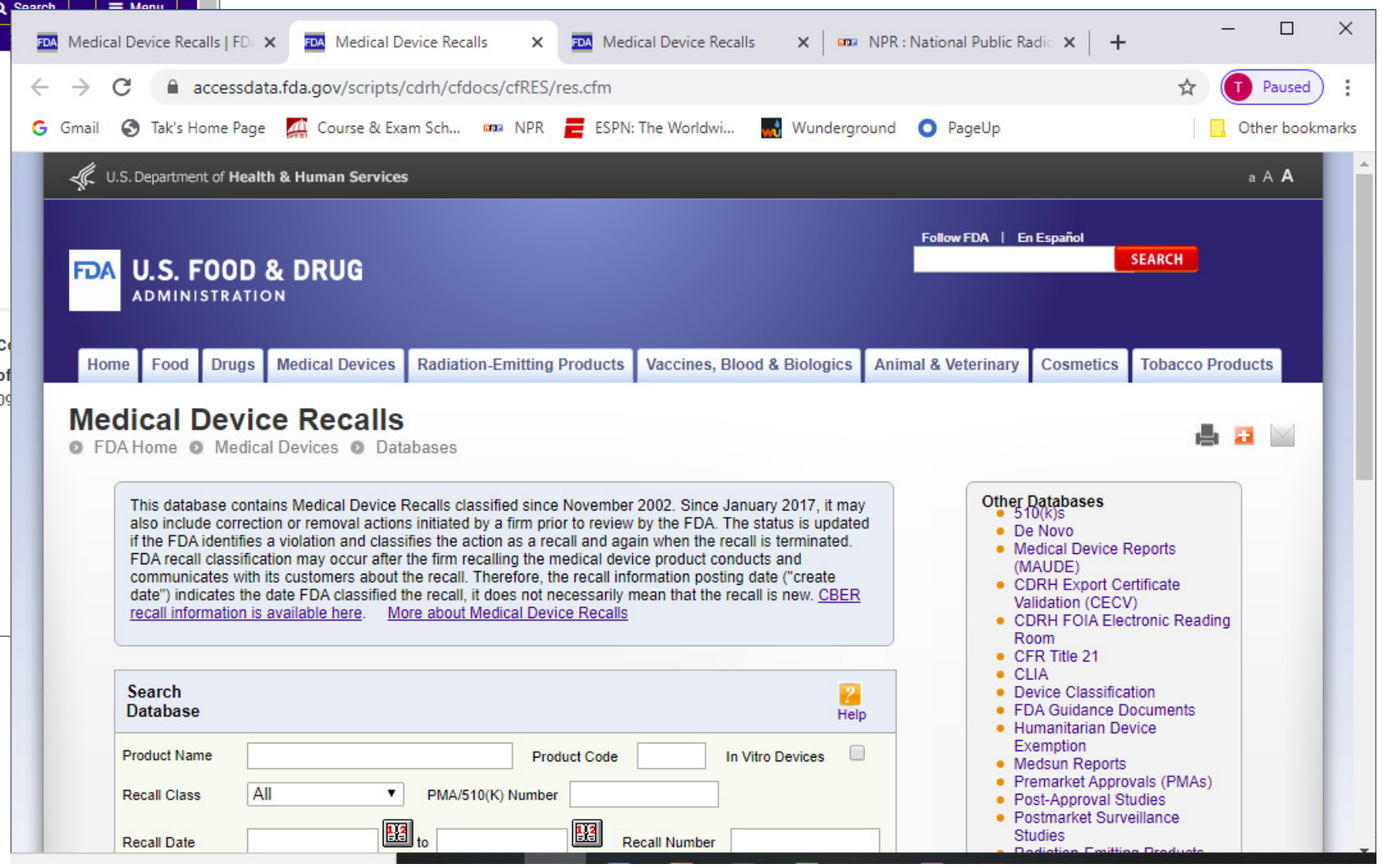
⑨ References: Articles, websites, etc.

☆ 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!





- 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.

- Controversy?
  - 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?