BME/ECE 386 students,

Search the FDA database (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm) for a device recall topic. Email Buma your proposed topic for clearance/approval.

As you write your ethics paper (≥ 4 pages), remember that it should tell a good story.

0) **Abstract**: The abstract is short, and gives the main points -- sort of a news flash.

1) **Introduction**: Your intro should provide background info about the company, the device (e.g. what it does), the disease/condition being treated. Briefly describe why the device was recalled and mention if there was any controversy involved (e.g. device problems were ignored for years) and whether it was resolved.

2) **Technical**: Elaborate on the engineering details of the device operation and what went wrong (e.g. wires shorted out, plastic material cracked). Do not worry if you cannot provide all of this info if your references lack these details.

3) **Events**: Then describe the sequence of events (e.g. a timeline), such as when device problems occurred, news releases, more device problems, when the recall was made, details of the recall (particular model number, number of recalled devices, reason for recall, etc.) Remember that the company, not the FDA, issues a recall. So the company website may have additional info about number of recalled devices, specific models, etc. If the number of recalled devices cannot be determined, then just say so in your paper.

4) **Decision Making Process**: Now comes the creative writing part. Make hypothetical arguments for all five members of the decision making committee. Who voted for a recall? Who didn't? Whenever possible, your arguments should be consistent with any information gleaned from your references. Feel free to add extra drama (e.g. Dr. X was horrified by Mr. Y's complete disregard for ....). Release your inner screenwriter!

5) **Analysis:** Now take a step back and analyze the company's actual response. Based on your hypothetical arguments, who prevailed in the decision-making committee?

6) **Conclusions**: The last part of the paper should explain if you agree or disagree with the company and FDA responses? If not, how would you have handled the situation?

7) **References**: No specific format is required, but obviously include reasonable info (e.g. website, author, title, date).