Julie Karand, University of Delaware
juliek@udel.edu

Using Informational Comedy in 510k Discussion

When to use this: This activity encourages ethical discussion surrounding current medical device regulations. It can be used in any classroom, from a first-year Introduction to BME course to a BME elective for upperclassmen and early graduate students.

Activity Prep (before or during class): Students watch an edited, 10-minute clip from “Last Week Tonight with John Oliver: Medical Devices” from 2019. Optional pre-reading on the Morcellation Debate, a case study on the impact of the 510k process.

Unedited Last Week Tonight episode: https://www.youtube.com/watch?v=-tIdzNlExrw
note video editing is important due to some inappropriate content in full video
Morcellation Debate paper: https://pubmed.ncbi.nlm.nih.gov/31881092/

In-Class Discussion: Students are put into groups, each with a different role (see below) to focus the discussion. Use 5 groups for small class sizes, and 10 groups for large classes (half teams pro-status quo, half teams anti-status quo). Teams make arguments for or against the current device regulation system based on their role.

1. Market Development: focus on sales, product availability, relationships with physicians
2. Finance Office: consider costs of recall, financial liability of lawsuits, value of portfolio
3. Physicians: worked about safety, malpractice, workload of staff, reputation, patient health
4. Patient Advocate: interested in the end user, safety, rights, peace of mind
5. Quality Control: focus on product consistency, impacts to manufacturing, reputation

Full class discussion prompts:

1. Are there any benefits to the current system? What would happen without this system? Who benefits from it most? What kind of devices benefit from it most?
2. Is the FDA's definition of "substantial equivalence" specific enough to prevent device related disasters? Do you think "substantial equivalence" can hinder innovation?
3. Are there any concerns about outdated predicates? What standards should be set in order for a predicate to qualify for a 510k?
4. What can we learn from the Morcellation Debate and the provided case study?

Final class conclusion: What legislative, regulatory, or administrative changes do you recommend to achieve the goals of the 510k process?

At-Home Reflection Questions: Submitted individually within one week.

1. Does the current 510k process currently protect patients and promote innovation in support of public health? If not, what legislative, regulatory, or administrative changes do you recommend to achieve the goals of the 510k process optimally? Please be specific.
2. Which hypothetical role (listed below) could make the best argument for maintaining the status quo? Make that argument from their perspective. Roles: Market Development, Finance Office & Investors, Physicians, Patient Advocate, Quality Control
3. Which hypothetical role could make the best argument for an overhaul of the current system? Make that argument from their perspective.
4. Do you believe that the fact that the US has a for-profit health care system impacts these types of regulatory decisions? Provide at least one specific example in your explanation that goes beyond what you read in the case study.
5. How can we best educate others about how products that are implanted into the body are regulated? Consider how we can inform physicians, patients, and biomedical engineers.