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[Case Study Paper] Teaching Medical Device Ethics Through Film and Reflection: A Student-Led Approach

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Engineering Ethics Case Study Paper: Teaching Medical Device Ethics Through Film and Reflection: A Student-Led Approach

Motivation

Medical device innovation is advancing faster than regulatory systems can keep up, creating ethical and safety challenges that future engineers must navigate. This case study activity introduces students to those realities and encourages them to consider the ethical and regulatory challenges they are likely to face as professionals. To address this gap, a classroom activity was developed around the non-fiction film *The Bleeding Edge*, a 2018 documentary by Kirby Dick and Amy Ziering [1]. This documentary film exposes the human and systemic consequences of the medical device industry's drive for innovation and profit. The activity engages students in examining real-world ethical dilemmas related to medical device approval, safety, and commercialization, emphasizing the complex balance between technological progress and public welfare.

Introduction

In the field of biomedical engineering, the drive for innovation often clashes with the rigorous demands of safety and regulation. For engineering educators, the challenge lies in helping students move beyond abstract ethical theories to an understanding of the real-world pressures they will face in industry. The complexity of the medical device landscape, characterized by rapid technological advancement, high profit margins, and intricate and flawed regulatory pathways, provides a fertile ground for ethical analysis.

One of the most challenging aspects in analyzing an ethical problem is the initial identification of the issues. Typically, the case studies used in classrooms tend to limit student's opportunities to develop generalizable skills for identifying relevant ethical cases in unexpected situations and scenarios [2]. Movies can show realistic situations in a way that is engaging and relatable for engineering students [3]. When used in a course, movies can give students a chance to identify and talk through the different factors that shape ethical situations [4]. Movies can enable students to develop speculative design, with the critical thinking and ethical reasoning skills necessary to navigate the challenges of emergent technologies in professional practice, and which can be adapted to any engineering discipline [5]. Previous work has explored both fictional and non-fictional films in ethics education [6]. In the case study presented here, a non-fictional film is used to ground ethical discussion in real world events.

The case study was developed as a module for use in the senior capstone course for biomedical engineering students. The Bleeding Edge investigates the $400 billion medical device industry, and highlights the systemic failures that have allowed flawed devices, such as the Essure permanent birth control device and cobalt-chrome hip replacements, to cause significant patient harm. By exploring these scenarios, students are forced to confront the "bleeding edge" of technology, where the benefits of innovation are weighed against potential catastrophic risks to human health. Importantly, most students entering this course have had limited formal exposure to ethical theory or structured ethics coursework, making this module an early and meaningful entry point into ethical reasoning as professional engineers.

Relevant Ethical Frameworks

Two ethical frameworks were identified to be relevant to this case study: 1) ABET, and 2) Ethics of Care. Framing the activity within these established perspectives provides structure for analyzing the outcomes and highlights how students engaged with professional responsibility, systems thinking, and empathy in meaningful ways.

Ethical Framework 1: ABET Student Outcome 4

This case study lines up with ABET Student Outcome 4, which focuses on *recognizing ethical and professional responsibilities in engineering and making informed decisions that consider global, economic, environmental, and societal impacts* [7]. The student discussions and reflections which students complete after viewing the film speak directly to these areas and can be summarized as follows:

- **Economic:** Students analyze the profit motives driving corporations to rush devices to market.
- **Societal/Global:** The activity highlights how regulatory loopholes, mainly the FDA's 510(k) pathway, impact public health on a mass scale.
- **Ethical Responsibility:** By witnessing the testimony of injured patients, students are challenged to recognize that their professional responsibility extends beyond technical compliance to ensuring patient safety.

Ethical Framework 2: Ethics of Care

This module aligns with the Ethics of Care framework, *which highlights relational interdependence, empathy, and responsiveness to the needs of others* [8]. The Bleeding Edge works especially well for this approach because it shows testimony of people harmed by medical devices. Unlike a typical textbook case, the film asks students to practice attentiveness, a core idea in ethics of care, by listening to personal accounts of engineering failures. Moving from abstract scenarios to direct human stories helps students better grasp the real human impact of engineering decisions.

Activity Design and Implementation

This "flipped classroom" module consists of three distinct steps: Preparation, Peer-Led Discussion, and Reflection. The steps are detailed below.

Step 1: Pre-Class Preparation (at-home)

To cover a wide range of topics without repetition, the class is divided into pairs, with each pair focusing on a different topic. Students watch The Bleeding Edge on their own before class, and take notes on the theme they were assigned, so that they watch with purpose instead of passively. Those topics include the following:

- **The 510(k) Loophole and Predicate Devices**: Investigate "grandfathering" of devices, where devices are approved based on "substantial equivalence" to older devices rather than through updated rigorous clinical trials [9].
- **Conflicts of Interest**: Examine the relationships between doctors, regulators, lobbyists (former regulators), and device manufacturers.
- **Innovation vs. Safety**: Analyze the pressure to be "first to market" and how it compromises testing protocols.

- **Women's Health**: Explore gender-specific device risks and why women's health concerns are often overlooked.
- **Patient Advocacy and Adverse Events**: Focus on the role of patients (particularly women) in identifying and reporting systemic failures when regulators fail to do so.
- **Regulatory Agencies and Procedures**: Understand FDA regulatory pathways, oversight mechanisms, and regulatory gaps [10].
- **Lobbying**: Examine industry influence on policy and regulation.
- **Whistleblowers**: Analyze the role of insiders who expose safety concerns.

Step 2: Peer-Led Discussion (in-class)
Each pair leads a 5-to-8-minute discussion on their theme, taking ownership of the ethical analysis. The instructor mainly observes and keeps the session on track, while students guide the conversation and take responsibility for the discussion. For example, the pair focused on the 510(k) pathway might explain how the process works and then ask a question like, "*Is it ethical for the FDA to approve high risk implants without human trials simply because they resemble a device approved decades ago?"* The rest of the class responds to the question.

Step 3: Individual Reflection (in-class, or after class)
Following the discussion, students submit written reflections to the following three prompts:
1. *Summarize the key points from your assigned topic: The Bleeding Edge film reveals a lot of the issues with medical device development, commercialization, and utilization. How would you summarize the sub-topic you were assigned?*
2. *What are your 3 key takeaways from watching the film?*
3. *Role of Biomedical Engineers: As biomedical engineers, what should your role be to address/avoid/prevent the issues raised in the film?*

Assessment

Thematic analysis was conducted on student reflections from three offerings of the activity, focusing on Reflection Topic 3 above: *"the role of biomedical engineers in ethics"* [11-12]. The dataset included 33 reflections collected from senior capstone courses offered in the summer semesters of 2022, 2023, and 2024. Results from the analysis indicate high levels of student engagement and thoughtful reflection. Key themes are summarized below.

Key Themes in Student Reflections:

1. **Development of Empathy:** Consistent with the Ethics of Care framework, students cited the patient stories as the most impactful element. The visual medium helped illustrate empathy and human suffering.
2. **Complexity of Engineering Ethics:** Students recognized that ethical failures often result from a combination of lobbying, regulatory weakness, and corporate culture, rather than just individual malice and moved beyond "good vs. bad" thinking to appreciate the systemic complexity and impact of the industry.
3. **Awareness of Regulatory Gaps:** Many students were surprised and concerned by the 510(k) process. One student noted, *" device companies prioritized large profit margins and the use of the 510(k) approval process as a way to avoid intensive testing in humans".*

Discussion

After watching The Bleeding Edge and completing the follow-up activities, students demonstrated increased awareness of the role of ethics in biomedical engineering. Their discussion and reflection comments suggest that the film helped them connect ethical concepts to real world consequences. This shift indicates that students began to internalize ethical principles. The vivid accounts of patient harm appear to have grounded their empathy. Key insights are presented next, together with quotes from student reflections highlighting each of the themes:

Students Put Patient Welfare First

The strongest theme was prioritizing patient safety, even when it conflicts with timelines or profits. Students often framed this personally, asking whether they would trust using a device in themselves or a loved one. Many emphasize that engineers serve patients just as much as clinicians do.

- "*When they start to put the profit above the patients, is when bad things can happen. This unethical behavior… leads to patient harm.*"
- "*If I wouldn't recommend the medical device for my family, then there is no way I should be okay with allowing something to be on the market with known faults that may harm them."*

They Took Testing and Integrity Seriously

Students felt that meeting minimum regulatory requirements is not enough. They called for strong verification and validation, especially for implantable or high-risk devices, and pointed to the dangers of cutting corners or ignoring concerns. They argued that engineers must go beyond baseline standards, resist pressure to alter data, and demand solid evidence before devices reach patients. Technical rigor becomes an ethical responsibility, not just a procedural task.

- "*Even if federal and regulatory guidelines do not require substantial testing, we should perform vigorous testing to ensure that patients are not negatively impacted.*"
- "*We should make sure our devices are thoroughly tested before being used on patients… the product should pass with flying colors on all aspects of testing before entering the market.*"

They Questioned Regulatory Systems

Students showed awareness of how regulatory processes affect safety, raising concerns about 510(k) equivalence, oversight, and loopholes. They began to see device failures as signs of broader system issues rather than isolated mistakes. Instead of treating regulation as rules to follow, they argued that engineers should engage critically with approval processes and speak up about needed improvements.

- "*Given that the FDA can't be trusted to complete further testing or deny approval based on lack of data, my role is to gather the necessary information and possible side effects…*"
- "*Ideally… the main goal would be to ensure that FDA approval isn't bypased by loopholes such as the 501k and to ensure that over time, no adverse effects show themselves as life threatening…*"

They Emphasized Speaking Up and Being Transparent

Students recognized their own responsibility to raise concerns, question decisions, and, act as whistleblowers. Because engineers are closest to technical details, they may be the first to see risks. Staying silent in the face of known problems was widely viewed as an ethical failure. They also stressed honest communication about risks and the importance of not downplaying data.

- "*If I witness any kinds of issues in the company, it is my responsibility to say something.*"
- "*We need to be the whistleblowers that legally raise concerns about the safety of our products… without us, there is no product in the first place.*"

They Saw Ethics as a Lifecycle Responsibility

Students came to see that responsibility does not end at product approval. They described a duty to monitor devices over time, respond to complaints and recalls, and revisit testing and quality processes. Ethics, in their view, extends across the full lifecycle of real-world device use.

- "*Making sure that the device is still working properly and not causing harm even after it is approved should be a part of our job as engineers.*"
- "*This means constant updating of safety procedures and testing of equipment as well as periodic follow up on longer term devices to ensure that the suggested life span… is accurate and safe.*"

They Understood Engineering as a Team Effort

Finally, students recognized that biomedical engineering (BME) happens within a network of clinicians, regulators, patients, manufacturers, and multidisciplinary teams. They emphasized collaboration and saw themselves as part of a larger system responsible for patient well-being, not as isolated designers.

- "*BMEs… understand the functions of the human body and how different products… would interact… Our job is to protect the patients who aren't well educated in this field…*"
- "*We should be collaborating with the FDA to strengthen approval guidelines, ensure transparency, and promote accountability.*"

Integrating Thematic Findings with Ethical Frameworks

Taken together, these themes align closely with the ethical frameworks introduced earlier and help clarify the impact of the module. The findings fully align with ABET Student Outcome 4, which focuses on recognizing ethical and professional responsibilities and making informed decisions that consider economic and societal impacts. Students were not just pointing out problems. They were describing what they would do as engineers. That shift toward personal ownership aligns directly with the intent of ABET Student Outcome 4. Students' critiques of profit driven decisions show awareness of economic pressures on engineers in commercial settings. Their concerns about regulatory gaps, especially the 510(k) pathway, demonstrate understanding of large-scale public health consequences. Their emphasis on speaking up, resisting pressure, and going beyond minimum compliance reflects a growing sense of professional responsibility rather than simple rule following.

The themes also connect clearly to the Ethics of Care framework. . The patient stories appeared to deepen empathy and move students beyond abstract thinking. Students asked whether they would trust a device in themselves or someone they love. Their focus on transparency, whistleblowing, and long-term responsibility reflects attentiveness and responsiveness to human harm, both central to care based ethics.

Conclusion

This case study shows how film, peer led discussion, and reflection can create an engaging and effective way to expose students to ethics while building students' awareness of the real-world challenges engineers face. Using the non-fiction film The Bleeding Edge gave students a more personal and empathetic understanding of professional responsibility, something that can be hard to achieve through traditional instruction alone.

Student reflections suggest that the film and discussions pushed them to think more critically about the systems behind medical innovation. Many described a clearer understanding of how regulation, commercialization, profit, and ethics intersect, along with deeper empathy for

patients affected by device failures. Grounding ethical questions in real patient experiences and regulatory breakdowns made ethics feel immediate rather than abstract.

Notably, most students had limited prior exposure to formal ethical theory, yet their reflections aligned with both professional responsibility and care-based frameworks. This suggests that using real patient narratives and real system failures can help students develop meaningful ethical reasoning, even without explicit theoretical instruction.

In summary, in this case study, a non-fictional documentary was chosen to ground the discussion in documented real-world events. The same structure could also be used with fictional films that explore ethical dilemmas. This flexibility, combined with the power of storytelling to connect ethical principles to professional practice, makes the approach both practical and meaningful.

The approach presented here is highly transferable across engineering disciplines. Because it relies on widely available films, small group discussions, and guided reflection rather than specialized equipment or discipline specific content, it can be implemented with minimal changes in almost any engineering course. Instructors can adapt the activity by selecting films relevant to their field while keeping the same peer led discussion and reflection structure, and examples are provided in [4].

IRB Statement on Data Usage

The data utilized in this study was anonymized and aggregated and was deemed as “exempt” by our university’s IRB committee.

References

[1]. K. Dick and A. Ziering, *The Bleeding Edge* [Film]. Los Gatos, CA, USA: Netflix, 2018.

[2] C. Bertha, “How To Teach An Engineering Ethics Course With Case Studies.” *ASEE Conferences, Louisville, Kentucky, 2010.* doi: 10.18260/1-2--16501. https://peer.asee.org/16501

[3] M. M. Bevilacqua, “Engaging Undergraduate Students in Ethical Thinking Through Fun and Movies.” *ASEE Conferences, Montreal, Quebec, Canada, 2025.* doi: 10.18260/1-2--56370. https://peer.asee.org/56370

[4] K. Bliley, E. Mowry, A. Gray, J. Collins, C. Mathieson, and S. Brophy, “Bme Goes To The Movies: Developing Ethical Perspective In Bioengineers.” *ASEE Conferences, Montreal, Canada, 2002.* doi: 10.18260/1-2--10810. https://peer.asee.org/10810

[5] C. M. Kim, “Preparing Ethical Engineers for the Future: Integrating Modern Case Studies and Design Fiction in Biomedical Engineering Ethics.” *ASEE Conferences, Montreal, Quebec, Canada, 2025.* doi: 10.18260/1-2--57064. https://peer.asee.org/57064

[6] S. J. Hitt and T. T. Lennerfors, "Fictional Film in Engineering Ethics Education: With Miyazaki’s The Wind Rises as Exemplar," *Sci. Eng. Ethics,* vol. 28, *(5),* pp. 44, 2022.

[7] ABET, *Criteria for Accrediting Engineering Programs, 2025–2026*. Baltimore, MD, USA: ABET, 2025. [Online] https://www.abet.org/wp-content/uploads/2024/11/2025-2026_EAC_Criteria.pdf

[8] E. Ramvi, I. Hellstrand, I.B. Jensen, B.H. Gripsrud, B. Gjerstad. “Ethics of care in technology-mediated healthcare practices: A scoping review.” *Scand J Caring Sci. 2023* Dec;37(4):1123-1135. doi: 10.1111/scs.13186. Epub 2023 Jun 5. PMID: 37272481.

[9] FDA, *“Premarket Notification 510(k),”* U.S. Food and Drug Administration, 2024. [Online]. Available: https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k

[10] U.S. Food and Drug Administration, *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]—Guidance for Industry and Food and Drug Administration Staff*. Silver Spring, MD, USA: U.S. Food and Drug Administration, 2014. [Online]. Available: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k

[11] E. P. Douglas, "Beyond the interpretive: Finding meaning in qualitative data," *ASEE conferences, Columbus, OH, USA, June 2017.*

[12] V. Braun and V. Clarke, "Using thematic analysis in psychology," *Qual. Res. Psychol.,* vol. 3, no. 2, pp. 77–101, 2006.