

# Ethics After Hours



## **The Bleeding Edge**

*Documentary*

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### **Summary<sup>1</sup>**

Medical devices can save lives, help us live longer, and improve our quality of life. In *The Bleeding Edge*, Kirby Dick, Amy Ziering and Amy Herdy explore how lax regulations, corporate cover-ups and the drive for profit in the medical device industry may put patients at risk. The program features cases where medical devices such as Essure (a permanent birth control device), vaginal mesh, the DaVinci Surgical System, and chrome-cobalt hip-replacements have caused irrevocable harm to patients.

Director: Kirby Dick

Producer: Amy Ziering and Amy Herdy

Released: April 21, 2018

Available on Netflix

Duration: 1 hours 40 Mins.

### **Discussion questions:**

- What was your initial reaction to this documentary?
- In your opinion, what are the ethical responsibilities of the medical device industry, the medical community, and the government in ensuring patient safety regarding medical devices through approval, usage guidelines, and reporting of adverse events?
- Should health care providers be better educated about the approval processes for drugs and medical devices?
- According to the documentary, pre-market approval (PMA) for medical devices requires only one clinical trial or study.
  - Did it surprise you that the approval for medical devices requires fewer steps than the approval of new drugs?
  - Discuss various reasons for this difference in approval process. Do you believe that it is justified?
- What type of regulatory and non-regulatory measures do you think could help alleviate the problems around patient safety outlined in the documentary?

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<sup>1</sup> This summary is adapted from Wikipedia [https://en.wikipedia.org/wiki/The\\_Bleeding\\_Edge](https://en.wikipedia.org/wiki/The_Bleeding_Edge) and Netflix's website.