

# The Cause and Effects of Ethical Violation Nonmaleficence in FDA Approval Processes

## Abstract

The article explores the ethical principle of nonmaleficence within the context of U.S. Food and Drug Administration approval processes, focusing on the violations highlighted in the documentary “The Bleeding Edge.” It examines the FDA’s response to these violations and provides recommendations for improving regulatory practices to prevent future ethical breaches.

**Keywords:** Nonmaleficence, Ethical violations, Approval process, Medical devices, Contraceptive device Essure

## Introduction

Nonmaleficence, derived from the Latin phrase “primum non nocere” meaning “first, do no harm,” is a foundational principle in medical ethics [1]. This principle emphasizes the importance of not causing harm to patients and is crucial in the approval and regulation of medical devices. The FDA’s medical device approval process is governed by several principles, including premarket assessment, premarket notification, post-market assessment, and the principle of not harm [2]. Despite these regulations, the approval process for a contraceptive device Essure revealed significant ethical violations. This article discusses the ethical violations associated with the U.S. Food and Drug Administration’s (FDA) approval of the Essure contraceptive device, as presented in the documentary “The Bleeding Edge.”

## Case Study

Bayer’s contraceptive device, Essure, was approved by the FDA in 2002 [3]. Essure was associated with numerous complications, including pain, bleeding, and even death, and by December 2017, the FDA had received 26,773 reports of adverse effects [3]. The documentary “The Bleeding Edge” highlights several ethical breaches in the approval process, including inadequate testing, false information, conflicts of interest, and lack of post-approval surveillance [4].

## Literature Review

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## FDA’s response

The FDA’s response to the issues with Essure included several key actions [5].

- September 2015: FDA OBGYN Devices panel meeting.
- February 2016: FDA ordered Bayer to conduct a postmarket surveillance study.
- October 2016: Updated labelling information.
- March 2017: Active evaluation due to increased patient reports.

- **April 2018:** Restricted sales of Essure and implemented a patient-doctor discussion checklist.
- **December 2018:** Bayer stopped sales of Essure and revised the post-market study.
- **April 2020:** Publicly available analysis reports.
- **October 2023:** FDA provided the most recent interim results of post-market surveillance.
- **April 2024:** FDA updated web pages with the latest Essure-related problem reports and device removal information.

Led by the FDA, the Centre for Devices and Radiological Health (CDRH) provided recommendations to prevent future ethical violations [2]

- Establishing a robust medical device patient safety net.
- Streamlining and modernizing post-market mitigations.
- Encouraging innovation for safer medical devices.
- Enhancing medical device cybersecurity.
- Integrating premarket and postmarket activities to ensure a Total Product Life Cycle approach to device safety.

Post-market surveillance study for the Essure contraceptive device

Under Section 522 of the Food, Drugs, and Cosmetics (FD&C) Act, the FDA can require manufacturers to perform post-market surveillance [6]. This authority was exercised in the case of the Essure device, leading to a comprehensive study designed to monitor its long-term safety and effectiveness. The interim analyses reported high rates of chronic pain and abnormal bleeding among patients in this ongoing prospective cohort study [6].

## Study Design

- **Type:** Open-label, non-randomized, prospective observational cohort study.
- **Participants:** 340 patients were initially enrolled in the study. After one or two insertion tries, 265 successfully

underwent hysteroscopic sterilization using the Essure device and were considered qualified for the study assessment.

- **Duration:** Initially planned for 3 years, the study was extended to 5 years to gather more extensive long-term data.

## Objectives

- To provide detailed information on the adverse risks associated with the Essure device.
- To identify any complications that might lead to the removal of the device.
- To evaluate potential immune reactions and inflammation through blood testing.

## Key findings from the 2023 interim analysis

- Chronic Lower Abdominal and/or Pelvic Pain: Reported by 14.4% of participants.
- Abnormal Uterine Bleeding: Reported by 21.6% of participants.

## Additional measures

- The study included blood tests to detect biomarkers indicating increased inflammation.
- The FDA aimed to evaluate potential immune reactions to the device, which could contribute to the reported adverse effects.

## Final report

- The study's final report, planned for June 2025, will provide comprehensive data on the Essure device's long-term safety and effectiveness.

These detailed findings and actions underscore the importance of rigorous post-market surveillance to ensure the safety and well-being of patients using medical devices. The extended study period and inclusion of blood tests for biomarkers reflect the FDA's commitment to addressing the complexities of device-related adverse effects and improving regulatory practices.

The findings from the FDA's post-market surveillance

study of the Essure device have several important implications for clinical practice, as recommended by the primary author,

### Enhanced patient counselling

**Informed decision-making:** Clinicians must provide comprehensive information about the potential risks of the Essure device, including the likelihood of chronic pain and abnormal bleeding. This ensures that patients can make well-informed decisions about their contraceptive options.

**Risk Communication:** Clear communication about the risks identified in the study helps build trust between patients and healthcare providers and ensures patients know what to monitor for post-procedure.

### Improved monitoring and follow-up

- **Regular check-ups:** Given the significant rates of adverse effects, healthcare providers must schedule regular follow-up appointments to monitor patients who have received the Essure device.
- **Symptom tracking:** Clinicians should actively track and document any symptoms patients report, such as pelvic pain or abnormal bleeding, to provide timely interventions if necessary.

### Personalized Care

- **Tailored treatment plans:** The findings highlight the need for personalized care plans that consider individual patient factors, such as medical history and potential risk factors for adverse reactions.
- **Alternative options:** For patients at higher risk of complications, clinicians might consider recommending alternative contraceptive methods that have a more favourable safety profile.

### Regulatory and ethical considerations

- **Adherence to guidelines:** Clinicians must stay updated with the latest FDA guidelines and recommendations regarding medical devices like Essure. This includes adhering to any new safety protocols or restrictions imposed by regulatory bodies.
- **Ethical practice:** The ethical principle of

nonmaleficence, or “do no harm,” should guide clinical decisions. The findings underscore the importance of rigorous ethical standards in the approval and post market monitoring of medical devices.

### Advocacy for patient safety

- **Reporting adverse events:** Healthcare providers should encourage patients to report any adverse events and ensure these reports are submitted to the FDA. This helps in the ongoing assessment of device safety and efficacy.
- **Patient education:** Educating patients about the importance of reporting symptoms and adverse effects can lead to better overall outcomes and contribute to the body of knowledge regarding the safety of medical devices.

### Clinical research and training

- **Continued research:** The findings highlight the need for ongoing clinical research to understand medical devices’ long-term effects better. Clinicians should be involved in or support studies that aim to improve patient safety.
- **Professional development:** Healthcare providers should seek continuous education and training on the latest developments in medical device safety and ethical practices to enhance their clinical skills and knowledge.

These implications emphasize the critical role of healthcare providers in ensuring patient safety and upholding ethical standards in clinical practice. By integrating these findings into their practice, clinicians can better protect their patients and contribute to improving medical device regulation and safety.

Patients can take several proactive steps to advocate for their safety, especially when dealing with medical devices or treatments. Here are some critical actions recommended by the primary author.

### Educate yourself

- **Research:** Learn about the medical device or treatment you are considering. Look for information

from reputable sources such as the FDA, medical journals, and trusted healthcare websites.

- **Understand Risks and Benefits:** Ensure you understand the potential benefits and risks associated with the device or treatment.

#### Ask questions

- **Consult Your Doctor:** Ask your healthcare provider detailed questions about the device or treatment, including its safety record, potential side effects, and alternative options.
- **Clarify Doubts:** Do not hesitate to ask for clarification on any medical terms or procedures you do not understand.

#### Seek second opinions

- **Consult another specialist:** If you have any doubts or concerns, seek a second opinion from another healthcare professional to ensure you have all the necessary information to make an informed decision.

#### Report adverse effects

- **Monitor your health:** Keep track of any side effects or complications you experience after receiving a medical device or treatment.
- **Report issues:** Report any adverse effects to your healthcare provider and the FDA. This helps monitor medical device safety and can prevent harm to others.

#### Stay informed

- **Follow:** Stay in touch with your healthcare provider for regular check-ups and updates on your condition.
- **Stay updated:** Keep yourself informed about any new findings or updates related to your device or treatment.

#### Participate in support groups

- **Join communities:** Engage with support groups or online communities of patients with similar conditions or using the same medical device. Sharing experiences can provide valuable insights and support.

#### Advocate for transparency

- **Demand information:** Advocate for transparency from manufacturers and healthcare providers regarding the safety and efficacy of medical devices.
- **Support regulations:** Support policies and regulations that promote patient safety and ethical practices in medical device approval and monitoring.

#### Maintain records

- **Document everything:** Keep detailed records of your medical history, treatments, and any adverse effects you experience. This information can be crucial for your healthcare provider to make informed decisions about your care.

By taking these steps, patients can play an active role in their healthcare, ensuring they receive safe and effective treatments while contributing to improving medical device safety. Patient advocacy organizations play a crucial role in the healthcare system by representing the interests and rights of patients. Here are some critical aspects of their role that includes.

#### Education and awareness

- **Information dissemination:** These organizations provide patients with valuable information about diseases, treatments, and medical devices. They help patients understand their conditions and the available options for managing them.
- **Awareness campaigns:** They run campaigns to raise awareness about specific health issues, encouraging early detection and prevention.

#### Support and resources

- **Emotional support:** Patient advocacy groups offer emotional support through counseling services, support groups, and peer networks. This helps patients and their families cope with the challenges of illness.
- **Practical assistance:** They provide financial aid, transportation services, and assistance navigating the healthcare system.

### Policy advocacy

- **Legislative efforts:** These organizations advocate for policies that protect patient rights and improve healthcare quality. They work with lawmakers to pass legislation that benefits patients.
- **Regulatory input:** They provide input to regulatory bodies like the FDA on drug and device approval issues, ensuring that patient perspectives are considered in decision-making processes.

### Research and data collection

- **Clinical trials:** Patient advocacy groups often collaborate with researchers to promote and facilitate clinical trials. They help recruit participants and ensure that studies address patient needs.
- **Data gathering:** They collect data on patient experiences and outcomes, which can be used to improve healthcare practices and policies.

### Patient empowerment

- **Self-Advocacy training:** These organizations empower patients by teaching them how to advocate for themselves within the healthcare system. This includes how to communicate effectively with healthcare providers and make informed decisions about their care.
- **Rights protection:** They work to protect patient rights, ensuring that patients receive fair treatment and have access to necessary healthcare services.

### Community building

- **Networking:** Patient advocacy groups create communities where patients can connect with others who have similar experiences. This fosters a sense of belonging and mutual support.
- **Events and conferences:** They organize events, workshops, and conferences to bring patients, healthcare providers, and researchers together to share knowledge and experiences.

### Monitoring and accountability

- **Oversight:** These organizations monitor healthcare practices and advocate for accountability in cases of medical errors or unethical practices.
- **Reporting mechanisms:** They provide platforms for patients to report adverse events or unethical behaviour, ensuring that these issues are addressed appropriately.

By fulfilling these roles, patient advocacy organizations help ensure that patients' voices are heard, their rights are protected, and they receive the best possible care. They are essential partners in the healthcare ecosystem, working to improve patient outcomes and quality of life.

## Australian Perspective

Australia has several advocacy organizations that protect and promote various groups' rights and well-being. Here are some notable ones.

### Amnesty international Australia

- **Focus:** Human rights advocacy, including violence against women, Indigenous rights, and refugee protection.
- **Activities:** Research, mobilization, and campaigning to end human rights abuses.

### Human rights law centre

- **Focus:** Legal advocacy to promote fairness, equality, and human rights.
- **Activities:** Legal action, policy solutions, and community support to address injustice and inequality.

### Disability Advocacy Network Australia (DANA)

- **Focus:** Advocacy for people with disabilities.
- **Activities:** Providing contact details for advocacy organizations and supporting individuals to ensure they are treated equally and respectfully.

### Australian human rights commission

- **Focus:** Promoting and protecting human rights in Australia.

- **Activities:** Investigating complaints, conducting public inquiries, and educating on human rights issues.

#### **Australians for Native Title and Reconciliation (ANTaR)**

- Focus: Rights and reconciliation for Aboriginal and Torres Strait Islander peoples.
- Activities: Campaigning, education, and maintaining relationships with Indigenous leaders and communities.

#### **ActionAid Australia**

- Focus: Women's rights and poverty eradication.
- Activities: Supporting women in low-income communities, campaigning for their rights, and addressing structural causes of inequality.

#### **Youth Law Australia**

- **Focus:** Legal rights of children and young people.
- **Activities:** Providing free legal advice, advocating for children's rights, and monitoring human rights violations.

#### **Advocacy Australia**

- **Focus:** Social justice, health, and human rights.
- **Activities:** Providing support services, raising awareness, and advocating for victims of serious crimes and human rights abuses.

These organizations play a vital role in advocating for the rights and well-being of various groups in Australia, ensuring that their voices are heard, and their rights are protected.

## **Conclusion**

The ethical principle of nonmaleficence, which emphasizes "first, do no harm," is a cornerstone of medical ethics and must be rigorously upheld in all aspects of medical

device approval and regulation. The case of the Essure contraceptive device, as highlighted in the documentary "The Bleeding Edge," underscores the critical need for stringent testing, transparent processes, and continuous post-market surveillance to protect patient safety and well-being. The FDA's response to the issues with Essure, including post-market surveillance and regulatory actions, demonstrates the importance of addressing ethical violations promptly and effectively.

Moreover, other examples of ethical violations in medical device approval, such as cobalt poisoning from metal-on-metal hip implants and inadequate delivery by insulin pumps, further illustrate the potential risks when regulatory standards are not strictly enforced. The primary author recommends ongoing investigations and proposed changes to the FDA approval processes, including embracing modern technologies, enhancing post-market safety management, and regulatory flexibility, aim to improve medical devices' overall safety and efficacy.

Healthcare providers play a crucial role in ensuring patient safety by providing comprehensive information, monitoring patients closely, and advocating for patient safety. By integrating these findings into clinical practice, clinicians can better protect their patients and improve medical device regulation and safety.

In conclusion, upholding the principle of nonmaleficence in medical device approval processes is essential to prevent harm and ensure patients' well-being. Continuous improvement in regulatory practices, vigilant post-market surveillance, and ethical clinical practices will help safeguard public health and maintain trust in medical innovations.

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