Comparative Analysis of Regulatory Frameworks

A comparative study of Medical Device Regulations in the US and the EU.

ABSTRACT

This paper presents a comparative analysis of medical device regulations in the United States, European Union, and Canada. By examining the unique regulatory frameworks of these regions, the study identifies key similarities, differences, and opportunities for improvement. The analysis emphasizes the critical role of regulation in ensuring patient safety and effective healthcare delivery. It also highlights the importance of global harmonization and collaboration to advance healthcare standards worldwide.

kanneganti.r@northeastern.edu

Legal Issues International Regulations

ABSTRACT:

A comparative analysis of medical device regulations in various countries can provide valuable insights for stakeholders in the industry. Examining the specific frameworks of various regions can highlight similarities, differences, and potential areas for improvement. Medical device regulation is a critical component of ensuring patient safety and the efficacy of healthcare interventions around the world. This paper compares regulatory frameworks for medical devices in three countries: the United States, the European Union, Canada. This study highlights the importance of harmonization efforts and collaborative initiatives in improving global healthcare standards.

INTRODUCTION:

Medical devices play an important role in modern healthcare, ranging from simple tools to complex technologies that diagnose, monitor, and treat a variety of medical conditions. However, ensuring the safety and efficacy of these devices necessitates strong regulatory frameworks that can adapt to technological advances and changing healthcare needs. International organizations have been established, such as the International Medical Device Regulators Forum (IMDRF) and the Asian Harmonization Working Party (AHWP). IMDRF, established in 2011, facilitates discussions on harmonizing global medical device regulations. To ensure the safety and effectiveness of medical devices, strict risk-based regulations must be implemented. Furthermore, certification procedures for various specifications must be followed. However, the diversity and innovation of medical devices pose a challenge to current regulatory frameworks. Medical device regulations are constantly being updated to protect public health and encourage the use of high-quality, effective technologies. The study aims to provide an informative review of medical device regulatory frameworks in the US, Europe, and Canada by taking cases on

Clinical Investigation, Pre-Market Approval and Post market Monitoring data.

CASE STUDY I:

In the US:

Dalkon Shield IUD:

- Dalkon Shield IUD was an intrauterine device (IUD) that was manufactured and marketed by A.H. Robins Company from 1971 to 1974. This IUD was invented by physician Hugh Davis and electrical engineer Irwin Lerner. They published an article with the claims of the product being modern, Superior performance and being a first-choice method. This IUD was responsible for numerous reports of inflammatory pelvic infections, uterine perforations, spontaneous septic abortions, and at least four deaths.
- A.H. Robins Company This IUD was invented by physician Hugh Davis and electrical engineer Irwin Lerner. They published an article with the claims of the product being modern, Superior performance and being a first-choice method.
- The Dalkon shield was not subjected to the extensive testing required by the FDA because it was not a drug. But, Many studies revealed that the pregnancy rate was much higher than previously thought, with some estimating it at 5.5 percent or even higher.
- The FDA requested that it be removed from the market, but a formal recall was never issued. The A.H. Robins Company discontinued selling the device in 1974, and manufacturing ended in 1976.

In the EU:

PIP Breast Implant Scandal:

- PIP (Poly Implant Prothèse) silicone breast implants scandal, in which a French manufacturer used industrial silicone to produce the medical device for ten years.
- In March 2010, French Agency for the safety of Health Products (AFSSAPS) announced the withdrawal from the market of silicone breast prostheses manufactured by the French company Poly Implant Prothèse - PIP, due to the use of non-homologated silicone gel. Non-homologated silicone gel did not pass the required biocompatibility tests.
- The PIP scandal became public in 2011 after the death of a middle-aged PIP recipient in Marseille who was diagnosed with anaplastic large-cell lymphoma (ALCL), a rare type of cancer. PIP's owner, Jean-Claude Mas, was eventually sentenced to four years in prison and fined 75,000 euros for aggravated fraud.

Cases Illustrating The Impact:

1. Importance of Pre-Market Testing: The Dalkon Shield case highlights the importance of rigorous pre-market testing for medical devices. The Dalkon Shield IUD was rushed to market without adequate testing, and this led to serious health problems for many women.
2. Patient Safety: The Dalkon Shield case underscores the importance of patient safety in the development and marketing of medical devices. Manufacturers have a responsibility to ensure that their products are safe and effective before they are made available to the public.

3. Stricter Material Requirements: Regulatory bodies worldwide tightened regulations governing the materials used in medical device manufacturing. This included stricter controls on sourcing, composition, and testing of materials like silicone used in implants.

4. Enhanced Surveillance: Post-market surveillance programs were strengthened to actively monitor the safety and performance of medical devices once they reach patients. This allows for earlier detection of potential issues and faster intervention, if necessary.

CASE STUDY II:

In the US:

Essure Permanent Birth Control:

- Essure is a permanent birth control device designed for women seeking long-term contraception without undergoing surgery. It consists of small, flexible coils made of nickel-titanium alloy and polyester fibers.

- The Essure procedure involves the insertion of these coils into the fallopian tubes through the cervix and uterus. Over several months, scar tissue forms around the coils, blocking the tubes and preventing sperm from reaching the eggs.

- Essure has been associated with various reported adverse effects, including chronic pelvic pain, migration of the device, perforation of the fallopian tubes. Reports of these complications prompted significant public concern and led to regulatory actions, including an FDA investigation and hearings. In 2018, the FDA restricted sales of Essure

and required Bayer, the manufacturer, to add a black box warning to the product labeling.

In the EU:

Pelvic Organ Prolapse (POP)

- Pelvic mesh implants, also known as transvaginal mesh implants or pelvic organ prolapse (POP) mesh implants, have been used in the European Union (EU) for the treatment of pelvic organ prolapse and stress urinary incontinence in women. These are are surgically implanted through the vagina to reinforce or support the pelvic floor structures.

- Some women who have received pelvic mesh implants have reported debilitating and life-altering complications, prompting a backlash against the devices and calls for increased regulation and oversight. Reports of adverse events and complications associated with pelvic mesh implants have raised serious questions about their safety and efficacy.

- To address safety concerns, regulatory authorities in the EU, including the European Medicines Agency (EMA) and national competent authorities have taken various actions. Several EU countries have suspended or restricted the use of certain types of pelvic mesh implants.

Cases illustrating the impact:

1. Public Awareness: Legal battles brought attention to potential health risks associated with Essure, which may have influenced women's decisions about the device.

2. Research Focus: The legal issues surrounding Essure may have steered research towards better understanding long-term complications and alternative permanent birth control methods.

3. Improved Standards of Care: Development of more standardized and evidence-based guidelines for management.

4. Regulatory Changes: Cases with evidence of serious complications can lead regulatory bodies in the EU and US to re-evaluate the safety and efficacy of treatments. This involves stricter approval processes for new devices or restrictions.

CASE STUDY III:

In the US:

Kugel Mesh Hernia Repair Products:

- The Kugel Mesh Hernia Repair Products case concerned a medical device manufactured by C.R. Bard, Inc. The device, which was used in hernia repair surgeries, was made up of a flexible, composite mesh patch that reinforced weakened tissue.

- However, numerous reports emerged of complications associated with the Kugel Mesh, including bowel perforation, chronic pain, and migration of the device.

- Bard finally recalled more than 137,000 of the devices between 2005 and 2007. A defective part in some of the meshes could break and puncture internal organs or tissues.

In the EU:

metal-on-metal hip implants:

- Metal-on-Metal hip implants, such as those manufactured by DePuy Orthopaedics, a subsidiary of Johnson & Johnson. Metal-on-metal hip implants were designed to provide durability and longevity compared to traditional hip implants made of other materials, such as ceramic or polyethylene.

- Concerns arose when patients began experiencing complications associated with these implants, including metallosis (metal poisoning), tissue damage, implant loosening, and device failure. The European Commission requested the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) to assess the safety of MoM implants in 2010.
- The SCENIHR concluded that MoM implants posed a higher health risk compared to alternative bearing surfaces. Individual EU member states also took action. Some countries, like the UK, implemented national registries to monitor MoM implant performance and patient outcomes.

Cases illustrating the impact:

1. Tighter Oversight of Manufacturing and Quality Control: Regulatory agencies have implemented stricter oversight of medical device manufacturing and quality control processes to ensure compliance with regulatory standards and specifications.
2. Updated Guidance Documents and Labeling Requirements: Regulatory agencies have developed updated guidance documents and labeling requirements for medical devices, including hernia repair meshes, to provide clearer instructions and information to healthcare providers and patients. These documents may include recommendations for device selection, implantation techniques, patient monitoring, and follow-up care to minimize the risk of complications and improve patient outcomes.
3. Revision of Medical Device Regulations (MDR): Stricter requirements for the assessment of medical devices' safety and performance, as well as enhanced post-market surveillance and vigilance measures. These changes are intended to improve the overall safety and

reliability of medical devices, including hip implants.

4. Improved Transparency and Reporting: Regulatory changes introduced measures to enhance transparency and reporting of adverse events associated with hip implants and other medical devices. Manufacturers are required to promptly report adverse events and safety concerns to regulatory authorities, healthcare providers, and patients, and to take appropriate corrective actions to mitigate risks.

REFERENCES:

- Chien, C. H. C., Chen, Y. J. C., Chiou, C. M., Huang, Y. W., Tu, P. W., & Lee, Y. C. (2016). *A Comparative Study of Medical Device Regulations: US, Europe, Canada, and Taiwan* (pp. TherapeuticInnovation&RegulatoryScience2018, Vol.52(1)62-69). Sagepub.com.
- (n.d.). *The regulation of medical devices: A comparative study of American and EEC Law*. University of Georgia Tech. https://digitalcommons.law.uga.edu/stu_llm/298/
- (n.d.). *Dalkon Shield birth control device*. Encyclopedia Britannica. https://www.britannica.com/science/Dalkon-Shield
- (2023, October 15). *Comparison of the international regulations for medical devices–USA versus Europe*. Science Direct. https://www.sciencedirect.com/science/article/pii/S0020138323005946
- (2015, October 15). *He Poly Implant Prothèse breast prostheses scandal: Embodied risk and social suffering*. Science Direct. Retrieved March 22, 2024, from https://www.sciencedirect.com/science/article/pii/S0277953615302070
- Sheffield, S. (2015). The Controversy Over Essure Birth Control (pp. Volume4, IssueNo.2). Tulane University.

- (2019, December 23). *Metal implant advice -Hip replacement Contents*. NHS. Retrieved March 22, 2024, from https://www.nhs.uk/conditions/hip-replacement/metal-implants/
- (2023, September 5). *Essure Permanent Birth Control*. Drug Watch. Retrieved March 22, 2024, from https://www.drugwatch.com/essure/
- (2020, October 31). *The international discussion and the new regulations concerning transvaginal mesh implants in pelvic organ prolapse surgery*. NIH. Retrieved March 22, 2024, from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7497328/
- (2023, September 5). *Kugel Patch*. Drug Watch. Retrieved March 22, 2024, from https://www.drugwatch.com/hernia-mesh/kugel-patch/
- (2019, September 30). *Metal-on-Metal Hip Implants*. FDA.gov. Retrieved March 22, 2024, from https://www.fda.gov/medical-devices/implants-and-prosthetics/metal-metal-hip-implants
- (2012, October 23). *Faulty hip implant shows up failings of EU regulation*. TheBMJ. Retrieved March 22, 2024, from https://www.bmj.com/content/345/bmj.e7163