Development and Regulation of Innovations: In the Current State of Facts vs. Public Opinions, the Truth Does Not Always Prevail

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Over the last several years, the medical device industry along with the perceived role of FDA's oversight has come under public scrutiny. Documentaries such as The Bleeding Edge and nightly news specials that regularly feature adverse events related to medical devices without scientific, clinical, and regulatory peer review is causing the general public question the integrity of both the industry and the regulatory process. This is advanced further by criminal charges raised against medical device companies, such as Theranos, whose leaders have been alleged to mislead the public into believing the existence and reliability of their technology. It is the responsibility of the medical device industry and the regulating bodies responsible for providing oversight to demonstrate that the respective medical device technology provides access to safe, effective solutions that improve health and quality of life.

In this presentation, we will first review the lessons learned from the current medical device regulatory landscape and how the media has affected public opinion around this. We will discuss the role and portrayal of the FDA as it pertains to currently existing and/or historical medical device technologies. Case studies will discuss the media portrayals of FDA's decision to end the Alternative Summary Reporting (ASR) of adverse events and the newly evolving area of medical device cybersecurity risks. Case studies of recent indictments, such as Acclarent and Theranos, will be discussed along with the corresponding significance of regulations, guidance, and technology standards. The presentation will also discuss how the FDA Manufacturer and User Facility Device Experience (MAUDE) database, while used to monitor device performance by the FDA, has been used by some to propagate incomplete, inaccurate, and unverified information.

Next, we will discuss prospective outlooks of the industry in which we will examine newer areas of interest such as human cells, tissues, and cellular and tissue-based products, which include stem cell therapies and tissue-engineered medical products. Information regarding which regulatory bodies currently provide oversight, how these regulations and guidelines compare to those currently in place for medical devices, and examples of how public opinion has been falsely swayed due to direct-to-consumer marketing and misconceptions of how the technology works will be reviewed. We will examine the importance of robust processes to assure safety and effectiveness, while promoting the advancement of new beneficial technologies.

Now more than ever, it is crucial to highlight how the medical device industry operates and is regulated. Showcasing policies implemented, actions taken, and research conducted to counteract any misguided public perceptions may be the beginning step to addressing any of the public's concerns.