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The Future of Dissolvable Electronics in Medicine

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Abstract: *In recent years, there has been a surge in the development of implantable electronics using bioengineered nano-materials, proposing broad implications in preventing and aiding medical ailments, monitoring patient functionality and efficiency in access of patient records. Implanting medical devices made of silk sheets, which can be discretely implanted into the human body, is a recent innovation, first introduced by the Defense Advanced Research Projects Agency ("DARPA") in 2011 and approved by the Food and Drug Administration ("FDA") within one year. Despite their demand by medical professionals to have these products introduced in hospitals across the United States, criticism has followed FDA's decision to implement such products at early testing stages. In particular critics are arguing these devices may go against the health, safety, and confidentiality of patients and others.*

Keywords: medical devices, implants, device regulation, innovation

Introduction

In January of 2011, the FDA met with DARPA to explore methods in monitoring human functioning in terms of "biological responses, drug responses and the physical state of the individual."[1] In response to emerging modern warfare techniques, such as bioengineered pathogens, DARPA and the FDA sought a device that could provide early preventative measures for soldiers in battle.[2] At the time, DARPA was limited to medical electronic devices that showed poor reliability, inadequate data processing, and low overall integrity.[3] Within a year, a team of bioengineers funded by DARPA created a phenomenal device composed of a thin sheet made up of organic, biodegradable substances, allowing for their sustainability.[4]

Biomarkers are in high demand by medical professionals, seeking efficient ways to aid their patients. However, research indicates these products are not ready for human use just yet, and that the FDA and DARPA may be speeding up the process a bit too quickly.[5] The result of this technology has implications for time-released drugs, brain and heart monitoring, and easy patient record access and monitoring.[6] Therefore, healthcare professionals are eager for these devices to enter the market. However, opponents argue that the FDA should give more scrutiny to the medical devices before allowing them to become distributed to the public.[7]

Issue: Safety on Unique Device Identifiers

Furthermore, the FDA Safety and Innovation Act amendments passed in 2012, mandates that "life-sustaining and life-saving devices come into compliance within two years of the rule being finalized."[12] Recent budget cuts and the increasing demand for these devices is the reason why FDA has adjusted the approval time needed for innovative devices to enter the market within only one year after final review.[9] Medical device manufacturers argue against the FDA's regulatory scheme for the use of what they call Unique Device Identifiers ("UDI"), stating "one year isn't enough time and we are asking for two years after the final rule."[10] Opponents argue clinical trials and research studies have yet to determine how large amounts of information such as patient medical history as well as manufacture labeling modifications can be done for these devices.[11]

Recently, the FDA implemented the 510K-approval process in order to quicken the pace at which innovative medial devices enter the market without requiring human testing, generally those foreseen to fall under a "low-risk" category.[12] By using 510K, FDA can assess high-risk devices under more scrutiny before they enter the market.[13] However, since the implementation of this rule, safety issues have arisen regarding medical devices categorized as "low risk." For example, in 2010, the FDA classified the Octopus Nuvo, a heart-stabilizing device, as a "low-risk" device. Later in the year, after being used on patients, the Octopus Nuvo was recalled due to dangers of broken glass.[16] One critic proclaims "some devices classified as low-risk" which "don't get 510K scrutiny" are not "optimized for patient safety." UDIs are one such device that the FDA classify as low-risk and FDA's expedited approval of these products is justified under the 510K approval process. Therefore, these devices have not yet been tested on humans and may pose safety

issues similar to that of the Octopus Nuvo released in 2010.

Public Demand

FDA and DARPA claim that the implementation of these devices can revolutionize many sectors of our nation and the world. That, and the overwhelming demand for their use by the military and hospital professionals is why the FDA seeks to speed up the process.

Gordon Wyden of the Nanotechnology Caucus in 2007 predicted nanotechnology is expected to bring in $2 trillion by 2014.[17] Indeed, it is growing industry with opportunities to increase jobs, help the economy as well as promote security, the environment, and healthcare.[18] Wyden stated in order for this industry to thrive our government must invest in bioengineering companies and facilities for innovation.[19] Currently, the government is working to achieve this goal and the demand for its benefits is similar to what Wyden had previously predicted. These tools propose a wide variety of benefits such as ensuring the existence of cancer cells, indicating impending heart attacks or strokes, detecting Alzheimer's, and locating tumors[20].

However, with such complexity in their function, the FDA must devote time to studying the effects biotechnological devices have on human beings instead of just animals. Biocompatibility is a concern for bioengineering researchers, who believe they are uncertain whether these devices will or will not be rejected by the human body. Despite the uncertainty surrounding the safety of these devices, the FDA insists they are meeting the needs of the professionals and patients by implementing these devices early, but manufacturers and researchers familiar with the design disagree.

Conclusion

Thus, the development of new and complex technological innovations in medical devices calls for a further evaluation of the FDA's regulatory scheme in regards to patient safety. The FDA must ensure to eliminate foreseeable risks of the products before entering the market.

Competing Interests: None reported

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