

## Regulation of Medical Technologies

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In the past few decades, technological advancements have been proceeding at an unprecedented rate and have pushed medicine into an information era. Headline after headline features medical technologies such as microsensors, brain-machine interface, 3D printing, and numerous health-oriented cell phone applications. In non-health related areas, regulations are often sacrificed to encourage innovation. For example, artificial intelligence robotics is not regulated by the government, and a humanized robot named Sophia has recently been granted citizenship by Saudi Arabia. However, health-related technologies have been subject to more governmental, even intergovernmental, regulations. Although some argue that government regulation of medical technologies can stifle creativity, discourage innovation, and hinder productivity, all medical technologies, including portable personal medical devices, need to be regulated to protect the users and to help improve the technologies.

Debates about regulations have never been limited to healthcare. Financial groups and scholars have been calling for laissez-faire since the 17th century. However, as pointed out in Richard Posner's *A Failure of Capitalism*, financial crises and depression can be largely attributed to free-market capitalism and the lack of government interference (Posner, 2009). Health-related crises, such as outbreaks, pandemics, and a collective loss of trust in public health, pose far more catastrophic challenges for mankind than financial crises.

Medical devices that pose little potential risk to users should be subject to minimal regulations but not be completely exempt from regulatory processes. As regulations often involve an application-approval process, they unavoidably deter the commercialization of new inventions. If device failure does not affect the well-being of the user, tight regulation would add financial burden and discourage innovations, as well as prolong the suffering of people who could potentially benefit from the innovations. The Coping Coach game, created through a research effort led by Dr. FK Winston, a professor at the Children's Hospital of Philadelphia, is an example of an interactive e-Health video game that is not regulated or required to be regulated by the Food and Drug Administration (FDA) in the U.S. Based on evidence regarding "etiology of traumatic stress, risk and protective pathways, and effective interventions for trauma and anxiety in children," Coping Coach aims to prevent, and help children to

recover from, Posttraumatic Stress Symptoms after traumatic events through a role-play game. The game requires the user to interact with the game through progressive modules and learn to identify, communicate, and cope with emotions. The website which presents the game also provides information to parents regarding how and when to seek professional help. A randomized controlled trial of Coping Coach is currently ongoing (Marsac, 2013). Failures within the game, such as loss of stored data or accidental exit from the game, will not physically harm the users' health, and the emotional risk of such failures is minimal. Coping Coach is an example of a low-risk medical device. For any medical device that poses little risk for users, regulations do not need to be extensive. However, government regulation is essential to protect consumer rights. In combination with light regulation, competition in the free market will drive out the ineffective products. However, if the devices are not studied through randomized controlled trials and statistically proven to be effective, a variety of methods should be used to ensure effective treatments.

Medical technologies that require trainings to ensure safety or pose high risks in case of malfunctioning should be under strict regulations. Small personal medical devices should especially be regulated due to the lack of professional supervision, and because users' fear towards device malfunctioning can also cause serious psychological side effects. Also, these devices are often acquired to provide long-term continuous life support, and thus a failure of the devices can be life-threatening. In the case of severe sleep apnea, a life-threatening condition as described by Dr. RJ Schwab, a professor at the Hospital of the University of Pennsylvania, personal breathing assistance is often required. The minimally invasive way to alleviate symptoms of sleep apnea is through treating chronic hypoventilation using Bilevel Positive Air Pressure (BiPAP), which helps to normalize breathing for people who have problems with exhalation or chest pain using Continuous Positive Air Pressure therapy, the most common treatment for sleep apnea (Kim, 2014). Philips Respironics BiPAP AVAPS is a device that treats sleep apnea based on BiPAP. Even though parts of the device do not require FDA approval, the whole device required FDA approved ("Phillips Respironics BiPAP A4 Ventilatoray Support System. Premarket Notification 510(K) Summary," 2012), since the users depend on it to breath, causing its failure to be life-threatening. Sleep apnea can also be treated with an implantable breathing aid, which is a more invasive method. Inspire® is a company that produces breathing aids that monitor and utilize the user's unique breathing pattern to stimulate airway muscles to keep the airway open when needed ("How Inspire therapy works"). The device was subject to extensive testing, and it took almost two years for the FDA to approve the device ("FDA Approves Inspire® Upper Airway Stimulation (UAS) Therapy for Obstructive Sleep Apnea," 2014). Since the user's life depends on the precise electric

stimulation it delivers, regulation of the device is necessary to protect users' safety.

Without regulation or reinforcement of regulations, life-dependent medical technologies can jeopardize numerous people's well-beings. For example, the commercialization of OtisKnee without FDA approval has had irreparably negative impacts on a number of individuals whose knee replacement operations incorporated OtisKnee. The company, Otis Med, claimed that OtisKnee could provide 'custom fit' for patients and guide the surgeons during total knee replacement so that each patient's own bone and ligament could be maximally preserved. The devices were used in surgery without an FDA approval and have caused numerous misalignments and failed operations that could only sometimes be revised with complex surgery (Allen, 2015). Exemption from the FDA's pre-market requirements is meant to drive innovation. Unfortunately, Otis Med falsely marketed their device to physicians and other potential purchasers as exempted from FDA's pre-market requirements, resulting in irreversible damage to the users.

OtisKnee and Respironics BiPAP AVAPS represent high-risk devices among medical devices. For any medical device with a high-risk profile, unregulated commercialization can cause serious harm, including but not limited to, prolonged pain, financial burden, and depression (Fetters, 2015; J., 2017). Even if device failure does not have negative physiological impacts, ineffective devices can cause irreversible impairments due to surgical side effects, since many procedures such as implantation cannot be easily revised, which puts patients under excessive risk of infection and prolonged recovery. Furthermore, regulation of health-related technologies should not be compared to that of non-health related ones due to differences in the severity of the consequences. Especially in the competitive business environment today, where many companies rush to release products to gain a critical time advantage over their competitors rather than prioritize consumer safety, the potential risk posed by health technologies must be regulated by the government to protect the users.

In addition to protecting physical well-being, regulation also protects the privacy of personal medical information. 23andMe is a private genomics and biotechnology company that provides personal genomic testing devices and estimation of predisposition for a range of traits and conditions ("23andMe"). Their devices failed to obtain FDA approval, mainly due to lack of data that validates the device for intended uses, concerns about public health issues and irrational decision-making based on inaccurate results from the device (*Inspections, compliance, enforcement and criminal investigations-23andMe, Inc. 11/22/13, 2013*). Regulation also protects personal health information from being accessed for commercial use. Improper or non-existent regulation of health information can be the root cause of privacy issues in healthcare. In the information age, protecting health information is equally important as protecting health. FDA oversight can facilitate data protection in

healthcare and be a driver for perfecting genomic testing and trait identification technologies.

Through the above examples of low- and high-risk medical devices, it is clear that the healthcare domain should not be exempt from regulatory oversight. The degree of regulation on a device should be based on the level of control necessary to ensure safety: the higher the risk, the more extensive the regulations should be. Many drawbacks of regulations in healthcare can be avoided if the developers, regulatory agencies, and the government cooperate. The regulatory agencies should expedite the approval process for medical devices similar to the pre-certification program for digital medical software, and the government should increase funding in medical technology research and development (Maliyil, 2014). Hopefully, one day, regulatory agencies' monitoring will keep pace with innovation, and the agencies will always represent the best interests of the general public.

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