

Review Article

Review of new medical devices approvals by USFDA during the period of 2010 to 2014

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ABSTRACT

Medical devices are health care products distinguished from drugs for regulatory purposes in most countries based on mechanism of action. Unlike drugs, medical devices operate via physical or mechanical means and are not dependent on metabolism to accomplish their primary intended effect. Developing new medical devices requires clinical investigations and approval process goes through similar process like drugs. Medical device approvals in the period of 2010 to 2014 were searched from USFDA website. Disease burden data in the similar period was searched from centers for disease control and prevention website. Collected data was analyzed to know number of approved devices, top therapy areas, and mechanism of action of these devices. Out of a total of 200 medical devices approvals in the time period of 2010 to 2014, maximum number of devices (51; 25.5%) were approved in the year 2011, cardiovascular (78; 39%) was the top therapy area. Highest number (180; 90%) of approved medical devices belonged to the category III and maximum number (73; 36.5%) of approved medical devices had “mechanical” mechanism of action. The top 3 causes of deaths in USA during 2010 to 2014 were heart disease, cancer and followed by respiratory infection. There was a match between the top diseases and the medical device approvals for top 2 diseases in USA i.e. heart disease, and cancer. With respect to respiratory infections and ailments which was the 3rd leading cause of death only one device was approved out of 200 approvals in total.

Keywords: Medical devices, USFDA, Approvals, Disease burden, USA

INTRODUCTION

As defined by WHO, medical devices are defined as “any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purposes such as for diagnosis, prevention, monitoring, treatment or alleviation of disease, or an injury or for investigation, replacement, modification, or support of the anatomy or of a physiological process or for the purpose of supporting or sustaining life, or control of conception.

This broad definition of medical devices encompasses literally tens of thousands of different types of health care products, including in vitro diagnostics.¹ Medical devices are health care products distinguished from drugs for regulatory purposes in most countries based on mechanism of action. Unlike drugs, medical devices operate via physical or mechanical means and are not dependent on metabolism to accomplish their primary intended effect.²

Medical gadgets such as clinical thermometer, spectacles, hypodermic needle, X-ray imaging, cardiac pacemaker play a significant role in our lives, many of which so

obvious that we sometimes take them for granted.³ In 1816 first stethoscope was invented by French physician René Laennec, followed by hypodermic syringes discovered independently by Charles Gabriel Pravaz and Alexander Wood in 1853. In the mid-19th century, ophthalmoscope (for viewing living retinas inside people's eyes) was invented by Hermann von Helmholtz, followed by discovery of the x-ray by Wilhelm Röntgen in 1895. Coolidge tube for x-ray machines was invented by William D. Coolidge in 1913, and first widely used iron lung was invented by Philip Drinker and Louis Agassiz Shaw Jr in 1928. Early 1950s saw mechanical heart valve invention by Charles Hufnagel, followed by development of heart monitors, pacemakers and defibrillators by Paul M. Zoll. In 1962 cryoprobe for cataract surgery was invented by Charles Kelman. In late 1970s there was invention of first full-body MRI by Raymond Vahan Damadian.⁴

The medical device industry is one of the biggest industries in healthcare, driven by innovation and new technologies. The last decade has seen an unprecedented growth in innovative and improved technologies, which has led to the development of state-of-the-art medical devices and catalyzed growth and advancement in the healthcare industry. As shown in Figure 1. The US medical device industry is the global leader with sales of around \$136 billion, which represents approximately 45% of the global market. Europe and China are the second and third largest medical device markets, respectively.⁵

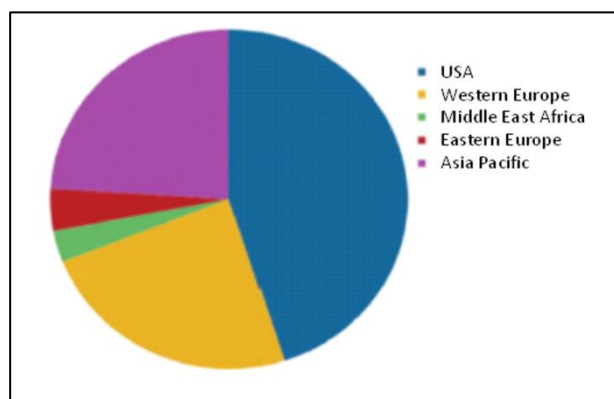


Figure 1: Geographic segmentation of medical device market.⁵

Developing new medical devices requires clinical investigations. Further, testing the new medical devices through clinical trials presents different challenges in the trial design and conduct compared to the clinical studies of pharmaceuticals. For example, clinical outcomes observed in medical device studies are influenced not only by the product under evaluation and the patient, but also by the skill and discretion of the user, who is typically a health care professional but may be the patient. The impact of this third parameter—the medical device user—is a variable unique to medical device

studies and can be responsible for the greatest degree of variability in the clinical outcomes. United States Food and Drug Administration's (USFDA) Center for Devices and Radiological Health (CDRH) is responsible for regulating firms who manufacture, repackage, relabel, and/or import medical devices sold in the United States. The basic regulatory requirements that manufacturers of medical devices distributed in the U.S. must comply are as follows: a. establishment registration, b. medical device listing c. premarket notification 510 (k), unless exempt, or premarket approval (PMA), d. Investigational Device Exemption (IDE) for clinical studies, e. quality system (QS) regulation, f. labelling requirements and specific medical device reporting.⁶

The US Food and Drug Administration (USFDA) has established classifications for different types of devices and grouped them into 16 medical specialties. Each of these types of device is assigned to one of the three regulatory classes based on the level of control necessary to assure the safety and effectiveness of the device.⁷ The three classes and the requirements which apply to them are: Class I - general Controls, Class II general Controls and special Controls, Class III general controls and premarket approval. Device classification depends on the intended use of the device and also upon indications for use. For example, a scalpel's intended use is to cut tissue. A subset of intended use arises when a more specialized indication is added in the device's labeling such as, "for making incisions in the cornea". In addition, classification is risk based, that is, the risk the device poses to the patient and/or the user is a major factor in the class it is assigned. Class I includes devices with the lowest risk and Class III includes those with the greatest risk. All classes of devices are subject to general Controls. General Controls are the baseline requirements of the Food, Drug and Cosmetic (FD&C) Act that apply to all medical devices, Class I, II, and III.⁷

We reviewed approved medical devices by USFDA in the time span of 2010 to 2014 and also the leading causes of death in the same period in USA.^{8,9} This study would help to gain understanding of a co-relation between top diseases and medical device approvals if any.

METHODS

The search strategy for the approved medical devices was as shown in the Figure 2. The regulatory approval process of medical devices in USA was searched from USFDA website. USFDA has specific webpage for medical devices. This webpage provides the detailed guidelines and overview of medical device approval process in USA.

In the second stage USFDA website was searched for approved devices in the time period of 2010 to 2014. All the approved devices in this time period were grouped under "recently approved devices" category. Yearly approvals and details about approved devices were

searched and noted down for each year (2010 to 2014). At a later stage collected data was classified by number of approvals, category of approved devices, and mechanism of approved devices for each year. At third step, from the collected data, search was done to find a device which has modifications / changes and approvals for these changes on USFDA website in the period of 2010 to 2014. Based on the result, detailed information about this device was obtained from USFDA website, PubMed database and device manufacturer website.

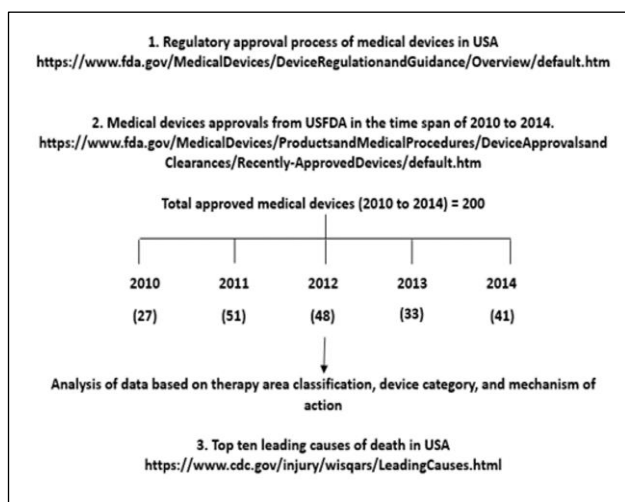


Figure 2: Data search strategy.

The search strategy for disease burden was as shown in Figure 2. Top ten leading causes of death in USA were searched from CDC (Centers for Disease Control and Prevention) web site. <https://www.cdc.gov/injury/wisqars/LeadingCauses.html>

RESULTS

As evident from Figure 2, search on USFDA website resulted in a total of 200 medical devices approvals in the time period of 2010 to 2014. Maximum numbers of devices (51; 25.5%) were approved in the year 2011, whereas the lowest numbers (27; 13.5%) of approvals were seen in the year 2010 as shown in Figure 3. The top 3 therapy areas of approved medical devices from 2010 to 2014 were – cardiovascular (78; 39%), followed by cancer (36; 18%), and gastrointestinal (25; 12.5%) as seen in Figure 4. Highest number (180; 90%) of approved medical devices (Figure 5) belonged to the category III. In the year 2012 maximum numbers of category III devices (52; 26%) were approved. As shown in Figure 6, maximum number (73; 36.5%) of approved medical devices had “mechanical” mechanism of action, followed by “biochemistry” (45; 22.5%) and “chemical” (29; 14.5%) mechanism of action.

As evident from Table 1, the top 3 causes of deaths in USA were heart disease, cancer and respiratory infection in the same order.

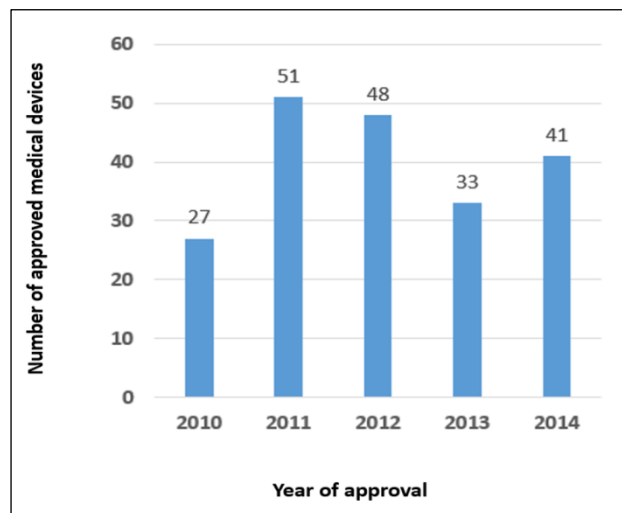


Figure 3: Medical devices approvals from 2010 to 2104.

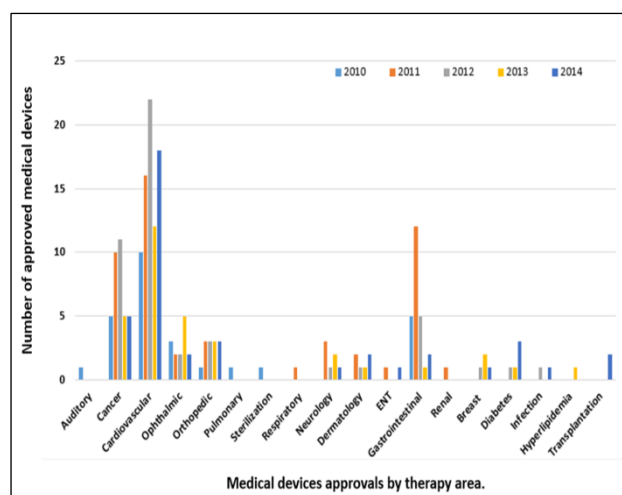


Figure 4: Medical devices approvals from 2010 to 2104.

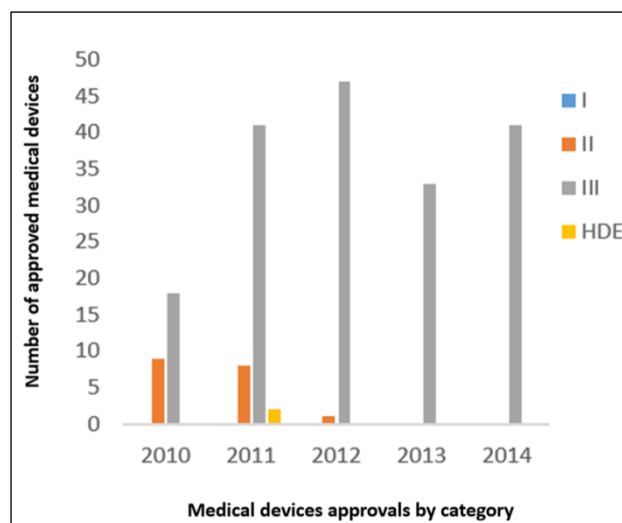


Figure 5: Medical devices approvals by category.

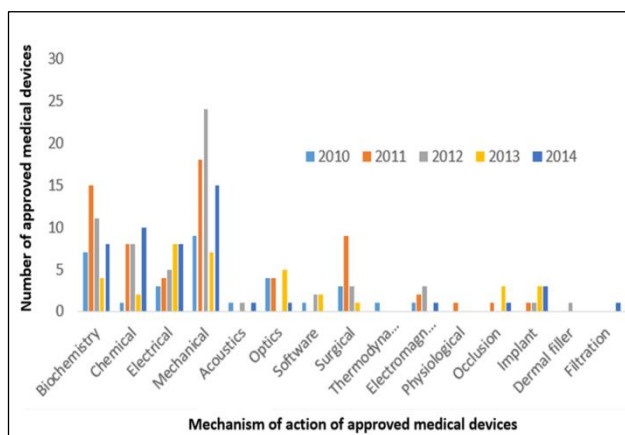


Figure 6: Approved medical devices classified by mechanism of action.

Table 1: Top causes of deaths in USA.

Rank	2010	2014
1	Heart Disease, 597,689	Heart Disease 614,348
2	Malignant Neoplasms, 574,743	Malignant Neoplasms, 591,699
3	Chronic Low Respiratory Disease, 138,080	Chronic Low Respiratory Disease, 147,101
4	Cerebrovascular, 129,476	Unintentional injury, 136,053
5	Unintentional injury, 120,859	Cerebrovascular, 133, 103
6	Alzheimer’s Disease, 83,494	Alzheimer’s Disease, 93,541
7	Diabetes Mellitus, 69,071	Diabetes Mellitus, 76,488
8	Nephritis, 50,476	Influenza and Pneumonia, 55,227
9	Influenza and Pneumonia, 50,097	Nephritis, 48,146
10	Suicide, 38,364	Suicide, 42,773

DISCUSSION

Medical device approvals increased by almost 100% from 2010 to 2011 (27; 2010, 51; 2011). After that there was de-growth in 2012 (48 approvals) and 2013 (33 approvals). While in 2014 device approvals showed increase (41) as compared to 2013.

Price Water House Coopers reported that the approval process was a major source of frustration in 2010 when approval rates dropped as low as 59%.¹⁰ Medical device manufacturers responded by advocating for approval pathway reform legislation. This advocacy led to approval pathway reforms in the 2012 FDA Safety and Innovation Act. This led to increase in approval rates. In addition to higher approval rates, the FDA reported a significant decrease in the average time for FDA

decisions on device applications. The average time for an FDA decision on a device application declined from an average of 432 days in 2013 to a 14-year low of 262 days in 2014. The improvement in the FDA regulatory process may encourage new investment in the medical device industry in the U.S., especially by companies and investors who have traditionally favored Europe’s less stringent regulatory approval process.¹⁰

CONCLUSION

There was a match between the top diseases and the medical device approvals for top 2 diseases in USA i.e. Heart disease, and Cancer. With respect to respiratory infections and ailments which was the 3rd leading cause of death only one device was approved out of 200 approvals in total. USA is considered as the most developed top world economy and can afford to support medical research. The pharmaceutical industry must consider the disease burden and develop medical devices supporting the treatment for the top diseases.

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Ethical approval: Not required

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