

**Medical Devices:
Saving Lives, But Is It in Time?**

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Executive Summary

The United States takes pride in providing the most advanced and lifesaving medical care. Most of the medical care that constitutes advanced technology can usually be classified as a medical device. Devices range from a tongue depressor to a MRI machine and all devices in between. Medical devices provide an innovative alternative to the current practices ideally more efficiently, effectively, and are less invasive.

In order to deliver this life saving technology and ensure public safety, each device is subject to Food and Drug Administration (FDA) inquiry and approval. The time for review and approval has become increasingly delayed causing loss in revenues, frustration, declines in growth, and finally delayed care for the patients. The fundamental problem of lengthy review times can be attributed to inefficient methods within the FDA review process.

Currently the United States earned \$44 billion in revenue; however, our dominance of the world market share is decreasing while our competitors are increasing. In 1980 the U.S. held 60 percent of the market share, yet currently holds only 41 percent of the total market.

The medical device industry is becoming an increasingly large industry. The frontier of this industry provides an opportunity for the U.S. to demonstrate its achievement and technological superiority. Thus, in order to facilitate effective reform, the FDA and industry must continue to explore changes in current regulations and new technological development to make the system more effective and to maintain an economic advantage. In particular, current procedures for pre-market approval, post-market surveillance, third party review options, device tracking and reporting methods, use of international standards, and performance standards need a thorough examination. Litigation and legal concerns of the material supply industry also affect the medical device industry.

The medical device industry's own suggestions for reforms resemble the European model. The industry calls for a more extensive and organized third party review system as well as an increased use of international standards, clearer FDA guidelines, enhanced communication during the review process, and standards for self declaration of Class I devices. Congress is trying to instigate reform while keeping peace within the political system which can prove tiresome. Pending legislation calls for some expansion of third party review systems, enhanced communication guidelines, and expanded humanitarian use of some devices. FDA is proposing to focus on more intensive time consuming review applications. This shift in staff attention would allow a more efficient process for approving a product starting from the investigational device exemption stage. FDA is also considering expanding the use of international standards and some third party review.

Reform is desperately needed. Restructuring of the FDA, the establishment of clear guidelines and standards, as well as further development of the third party review system are the best possible pathways. In addition, the U.S. must prioritize exploring options of financial incentives to maintain and develop the device business on U.S. soil to reassert our dominance in an industry where there are no easy or straight forward answers.

Issue Background of Medical Device Reform

The United States prides itself on its ability to be technologically superior as well as provide the public with state of the art technology and a higher standard of living. This country also takes pride in providing the most advanced and lifesaving medical care. The medical system seeks to offer patients access to cutting edge treatments and technology. This technology will hopefully provide quality care in a less painful way than other techniques. Most of the medical care treatments that constitute advanced technology can usually be classified as a medical device.

Definition of a Medical Device

Medical devices provide life saving or enhancing technology. They also represent a new manufacturing industry that has not matured or been fully cultivated, thus offering a new market for revenue and employment. Medical devices are defined as any device used for a medical purpose that does not involve chemical interaction as a primary means of delivery. Devices include tongue depressors to MRI machines and all other devices in between. Medical devices can provide an innovative alternative to the current practices ideally more efficiently, effectively, and are less invasive. Yet at all times safety of the American public and others is first priority. In order to deliver this life saving technology and ensure the public's safety, each device is subject to Food and Drug Administration (FDA) inquiry and approval.

History of Medical Devices

The FDA in the 1930's began to review and approve pharmaceuticals used throughout the nation. The country felt there was a need to ensure that the food supplies used by the country as well as the items used within the medical community were safe for consumption. The United States sought to protect its citizens from unnecessary harm as well as hold suppliers responsible for their products.

As the medical community grew and changed, more technology was developed and used in medical applications. This new technology included medical devices. Thus issues arose surrounding the use and safety of these new devices used to deliver quality medical care.

The medical device regulations began in 1976. This was the first time Congress extended the responsibilities of the FDA to regulate medical devices. Prior to 1976 devices were unregulated formally. No clinical evidence was required to be submitted to the FDA in order to ensure the safety of the American public. The medical device industry brought many new issues such as post market monitoring and clinical trial issues to the table thus further amendments and changes in regulation were made along the way.

The next major set of reform amendments was in 1990 with the Safe Medical Device Act re vestly d]¶Ò²àed user facilities, such as nur____nn_ÀO«ž__ :đđÆJ

_____ (Different from those associated with pharmaceutical regulations. Medical devices pose a particular risk since many devices are implanted in or extensively interact with the body. FDA for many years has regulated drugs, but it has been only recently that they have taken the official role of approving medical devices. Clinical trials are much more straight forward in pharmaceutical approval. In drug approval there is a test group and a contnd Methods of Application Review

“FDA’s Center for Devices and Radiological Health is responsible for ensuring the safety and effectiveness of medical devices and eliminating unnecessary human exposure to man-made radiation from medical occupational and consumer products. The center accomplishes its mission by:

- reviewing requests to research or market medical devices
- collecting analyzing and acting on information about injuries and other experiences in the use of medical devices and radiation-emitting electronic products
- setting and enforcing good manufacturing practice regulations and performance standards for radiation-emitting electronic products and medical devices
- monitoring compliance and surveillance programs for medical devices and radiation-emitting electronic products providing technical and other non-financial assistance to small manufacturers of medical devices.”¹

The FDA has set up stringent guidelines and categories for approval and the data required for such decisions. Since data and clinical trials are not as straight forward as in the pharmaceutical industry, bench, animal, and clinical data is required and extensively scrutinized. Industry often spends a great amount of time with administrative nuances due to the detailed and rigorous application process. Also the review process is time consuming for the FDA. The time for review and approval has become increasingly delayed, for some devices one can expect between 414 to 984 days, causing loss in revenues, declines in growth, frustration, and finally delayed care for the patients.²

Issue Participants

Many parties are involved in the elaborate approval process as well as affected by the outcome of the FDA’s actions and decisions. Industry has already established associations to represent and defend their interest. Groups such as The Health Industry Manufacturers Association (HIMA) and The Medical Device Manufacturers Association (MDMA) have formed due to issues of regulation. FDA’s role is to ensure the safety of the American public from products that could be potentially dangerous, while it is congress’s role to oversee and monitor the activity of FDA. Thus Congress holds a stake in determining the guidelines and budget of the FDA. Finally it is patients and their families that hold the largest concern in the medical device industry. Their lives will be the ones saved or enhanced by these products and clinical trials. It will be their lives who are put in danger by a faulty product or a delayed approval of a product due to administrative concerns.

Benefits and Problems of Devices

In the beginning the FDA review process had little problems. The United States served as the world leader of global market shares of the device industry for most of the last two decades. This dominance provides us with great export options and new revenue. This industry also offers new opportunities for employment and American benefit. And most importantly it ensures that Americans receive the best and most innovative care on the market first. Americans can also receive advanced treatment through clinical trials thus retaining vital access to cutting edge products which can save and enhance lives.

However with increased delays and bureaucratic technicalities our dominance has slowly slipped away. Today there are over 100 products currently available in Europe that are not available here in the U.S. . For example European doctors repair abdominal aortic aneurysms with Stent grafts^① which have saved 25,000 lives, prevented 3000 strokes, and prevented 10,800 heart attacks annually. Companies like Medi-Tech, Inc. a Boston Scientific Corporation, has manufactured the Stecker Stent. This soft flexible stent is easier to place in tortuous anatomy has increased visibility. These stents has been available in Europe and Japan since 1990 yet has no plans for U.S. introduction due to extensive FDA review process.³ This is just one such example of a device which Americans do not have access to. There are many lives that can be saved by products that are not available here. In addition new technologies often prove cost effective; if 48,000 annually who require treatment would have otherwise been treated by a more invasive surgery could have saved \$16,000 procedure saving annually \$768 million in total costs.⁴

Regulatory issues concerning devices are vastly different from those associated with pharmaceutical regulations. Medical devices pose a particular risk since many devices are implanted in or extensively interact with the body. FDA for many years has regulated drugs, but it has been only recently that they have taken the official role of approving medical devices. Clinical trials are much more straight forward in pharmaceutical approval. In drug approval there is a test group and a control group. Blood samples can be taken to monitor effects. Although it may take a considerable amount of time for a drug to reach the market often their data collection process and trial phases are much more straight forward than the device approval process.

Device clinical trials involves no real control group and can pose a greater risk than drugs in some cases. Also during pharmaceutical trials more data can be taken and thus safety, efficacy and reliability concerns are easier to demonstrate. The number of patients available for a device clinical trial is usually smaller and costs of the device clinical trial is usually much larger. Medical insurance companies and plans such as Medicare are less likely to cover the cost and consider the trial device a medical treatment. The lack of companies to pay for the trial limits the number of patients eligible for the clinical trial. Finally there are issues of rejection and long term failure problems which are not associated with pharmaceuticals.

^① Stents grafts are artificial prosthesis, placed inside the aorta and secured with a stent or other attachment device to create a new lining for the diseased aorta.

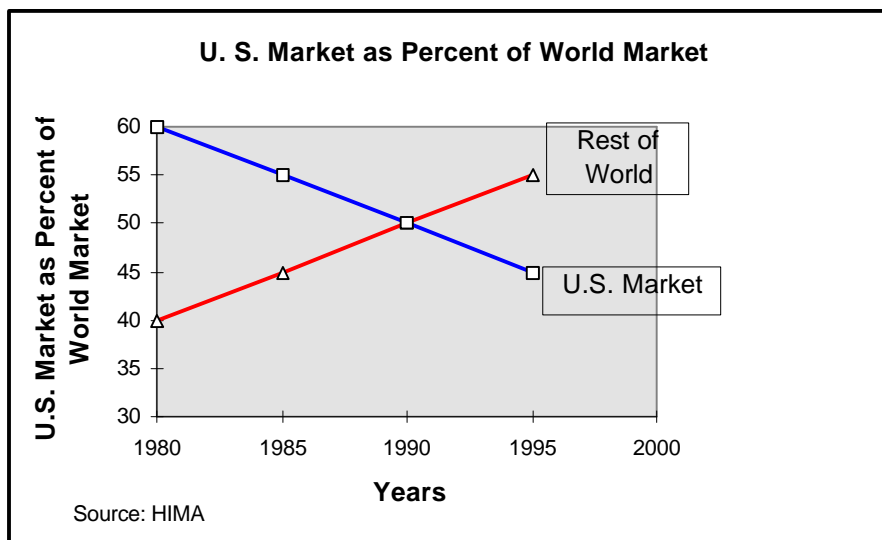
Clinical trials are not the only monetary concern for industry. In order to conduct research and provide advanced technology they must make profit from device sales. Long delays in approval can prove financially draining. Many companies turn to Europe for both market and clinical trials. If the market abroad continues to prove financially attractive, many businesses may decide to locate their operations and hire their employees abroad. A move overseas means Americans will not only lose employment opportunity they will also not have the same first priority access to cutting edge technology.

Europe's Influence on the Industry

Europe and other overseas locations are attractive for several reasons. Europe offers less delays in approval, easier and less expensive clinical trials, and a decrease in shipping costs. These device companies may target other countries as their primary market and the U.S. as their secondary market. Already, according to the Wilkerson Report of 1995, "more than 60 percent of medical device companies plan to market off-shore products that are not available in the U. S. More than 90 percent of these companies cited U.S. product review requirements as the reason for introducing products overseas first. These companies must generate early cash flow from European markets in order to fund the more costly and time consuming approval and commercialization requirements in the U.S."⁵

Market Size

According to a HIMA study released in 1995, the world market for medical devices was valued at \$93 billion. The United States in 1980 held 60 percent yet has declined in dominance to 41% in 1993. The U.S.'s dominance is decreasing while their competitor's influence is increasing. For fiscal year 1996 according to the Department of Commerce there was \$44 billion in sales and \$5.1 billion export manufacturing surplus. Currently the market employs 267,000 employees in 8,000 companies.⁶



Graph Illustrating the Decline in Dominance of the World Market Share by the U.S. according to HIMA from the Wilkerson Report

Due to delays in approval of products as well as cost containment measures prices have been driven down thus retarding the growth of the industry. This frontier of the medical device industry is a large industry for the U.S. to demonstrate its achievement and technological superiority. Thus in order to enhance situations in the U.S. reform within the FDA and industry, new development and changes in regulations must be approached to make the system more effective and maintain economic advantage.

Key Concerns of Current Medical Device Regulation

The fundamental problem that faces the medical device market is the long delays in approval of new devices. The diminishing dominance of the world market share as well as the declines in growth are symptoms of the lengthy FDA approval process. FDA actions have been characterized by some members of Congress as detrimental and horribly inefficient. These long delays are attributed to the inefficient methods and requirements of FDA review process. Congress has identified areas in need of reform. These areas include current procedures for pre-market approval, post market surveillance, third party review options, device tracking and reporting methods, use of international standards, and performance standards.

Another area impacting the medical device industry is litigation and legal concerns that involves the material supply industry. Medical device tort reform that limits harm to manufactures and protects material suppliers is vital. If liability can be traced back to the company providing the material used in the medical device and prevent the materials from being available, the industry will be severely limited and set back in advancement. Litigation and tort reforms are avenues of changes that help the advancement of the industry. Reform is vital for saving lives and protecting the device industry but we must not lose sight of the safety of the American public. In no way can the jeopardy of our nation's patients be sacrificed for the sake of industry.

510 (k) Application Issues

The FDA process has three avenues of entry for approval of a device. One method is the 510(k) application, in which a new device is "substantially equivalent" to a device that is currently on the market. These applications do not mandate as much clinical trial data or stringent requirements as a pre-market approval application. The time to review set aside by Congress for such a device is 90 days. According to a 1994 GAO study, mean review time for a 510(k) device was 166 days and the median 152 days, nearly twice of the required time period set by Congress. This time for review was an increase from the 80-90 days during 1989-1991. At the time of the study, 13 percent of the cases were still open.

There is a safety issue of concern for the 510(k)s which account for about 90 percent of the applications.⁷ Some products have been modernized electronically yet are still considered substantially equivalent to a previous device. Tests are not always performed to discover if the modernization of the device has a profound effect or not.

PMA Application Issues

Another avenue for review and area for reform is through the Pre-market Approval application. This application is extensive and requires large amounts of bench, animal, and clinical trial data. The clinical trials also have extensive requirements and cost a sizable amount of money. The time required for review by Congress is 180 days. However according to its 1993 study, the GAO found the median time for a PMA approval was 804 days more than 4 times the required amount set forth by Congress. The implications of the mean and median data collected are less clear since 1994; then 81 percent of the applications remained open.⁸ This amount of time can tie up not only industry's time and resources it also burdens the FDA. There has been a decrease in the number of submissions of PMA's from 84 in 1989 to 43 in 1994 due to setbacks and extensive demands.⁹

The final approval application is an investigational device exemption (IDE) that is not to be used as a proven medical treatment option. The Congress required that 30 days be used for review. According to the GAO this review time has remained constant at 30 days. Data gathered from the use of IDE's can be very valuable for using throughout the approval process in an efficient way could prove very beneficial.

Third Party Review Issues

The FDA further breaks down devices into three categories, Class I, Class II and Class III devices. Class I is the least invasive or dangerous device; tongue depressors fall into this category. Class III devices are the most dangerous and risky devices including pacemakers, artificial heart valves, and heart-lung machines. These devices usually require the most review time. FDA is testing a pilot for third parties to review Class I and Class II devices, allowing the FDA to spend more time reviewing Class III devices.

Third party review[®] is an interesting and somewhat controversial topic in review reform. The political climate surrounding this issue is divided as is industry. Republican efforts are emphasizing third party review to increase the free market climate. The Democrats wish for FDA to control the review process and are not as favorable of third party review. The FDA also has issues that must be worked on in order for the third party review to be successful. Currently there are not enough devices classified as eligible for third party review to make it appealing to industry. Thus industry is not willing to spend the money for third party review. However third party review is part of what has made the European market successful.

Comparison of European and U.S. Review processes

The European review and device approval system is organized very similarly to the U.S. with a few exceptions. The Europeans have no category of "substantially equivalent". The Europeans manufacturers do not have to prove a device's efficacy. Not having to prove efficacy means each device is reviewed for safety and to ensure it performs the function the manufacturer has stated. They do not require data that

[®] Third Party Reviews refers to independent agencies who have no ties to industry and are invested with the power to review a medical device application just as FDA does.

proves it is an effective means treatment. In addition their Class I devices since they pose little danger can be self declared by the manufacturer that they meet safety requirements. Their regulating agency also relies heavily on third party review for all classes of devices; thus saving time in the review process and spending more time reviewing these third party agencies to ensure all reviews are consistent and safe. The European community is also forming a uniform system for all 12 member countries to increase efficiency.

In addition to more efficient means of review, the European community has also set up a more defined set of guidelines for post-market surveillance that are less burdensome. The U.S. in 1990 and 1992 passed a set of amendments and acts requiring more facilities to report incidents of injury and death associated with devices. Yet still today, FDA has not come up with a clear consistent set of guidelines for reporting incidents in such a way that is useful for post-market maintenance. Currently only large facilities are reporting and projections are made from these reports; however, the forms and requirements are not straight forward, and often it takes FDA considerable time to decipher the report and contact the facility for all required information.¹⁰ Delays in reporting and post-market surveillance undermines the safety checks of device regulation. Delays prevent devices that would require more review to slip through with more possibility of death or injury resulting.

Current legislation proposed by Congress would impose a time limit on manufactures to “submit a plan to the Secretary within 60 days of receiving notification by the Secretary of Health and Human Services.”¹¹ Also the surveillance period by the manufacturer can not exceed 18 months. These time limits would provide a greater assurance of safety for a product once it is on the market. FDA is housed under the Department of Health and Human Services, thus all approval is handled by the FDA Administrator but is the responsibility of the Secretary of the Department. Congress is also considering amendment to the current U.S. code to require a manufacturer to adopt a method of tracking a Class II or Class III device. This amendment is specifically targeted at devices intended to be implantable or life sustaining used outside a device user facility in order to detect problems before they can cause great harm.¹²

One final aspect that enables the European community to be more efficient is their use of internationally recognized standards. Even though the FDA takes part in developing over 400 international standards, in the domestic review however they use less than 100 of them. Creating a more uniform set of review practices could greatly aid the industry. The review time could be lessened and industry could have a more clear set of guidelines to adhere to preventing delays and miscommunication during the process. Although there are many areas that are successful in the European System, it must be noted the health care structure in Europe is constructed and run differently than in the U.S..

Policy Alternatives for Reform of Current Regulations

Legislative Options

Current legislation in the Senate is proposed by Senator Jeffords (R-VT). Jeffords is known for balanced legislation and his willingness to compromise. S-830, Food and Drug Administration Modernization and Accountability Act of 1997, involves more issues than medical devices and is not as bold as the H. R.-1710, Medical Device Regulatory Modernization Act of 1997, proposed by Representative Joe Barton (R-TX). The Senate bill is divided into 8 titles with titles 2-6 targeted at the medical device industry. These are the objectives and subsections that are proposed by legislation efforts by the Congress:

- *Increasing access to expertise and resources.* - The amendment calls for interagency collaboration with NIH and science based government facilities. A sense of cooperation regarding global harmonization efforts including working out agreements with the Secretary of Commerce and other foreign governments is also mandated. Contracts for expert review, accredited party review, and device performance standards all of which can expedite the review process and increase efficiency are also proposed.
- *Improving collaboration and communication.* - This section requires a collaborative effort in the review process and determinations of device data requirements. These measures will reduce the down time during the review process making for less time lost and less misunderstandings in expectations and requirements between FDA and industry.
- *Improving certainty and clarity of rules.* - This section carries many initiatives to improve the review process in a variety of ways. 1. policy statements and product classifications which limit the time and set standards for product classifications and categories. 2. Use of data relating to pre-market approval also reducing time lost and allows for use of data that is relevant and useful. 3. Consideration of labeling claims for product review. This subsection requires the Secretary to only consider labeled uses in the review and not other possible uses of the device. 4. Definition of a day for review purposes and certainty of time frames have been drafted to ensure the time limit is held to and that industry is in clear understanding of the definition of the time frame and how it should not be violated. 5. Limitations on initial classification determinations, 6. Clarification with respect to general use and specific use of the device. 7. Clarification of the number of required clinical investigations for approval and prohibited acts. These amendments define the action of the Secretary of Health and Human Services for the various areas and ensures timely fair regulations.
- *Improving accountability* - Minor modifications, environmental impact review, exemption of certain class devices from pre-market notification requirements, review of class I and II devices and evaluation of automatic class III designations, and Secretary's of Health and Human Services and (FDA Administrator's) discretion to track devices and conduct post market surveillance are all proposed. These provisions are designed for better balance and safety checks in the process of classification and post marketing reviews.¹³

H.R.1710 expands and calls for more bold action and review measures. In addition to the above provisions which are very similar to those in this bill, they also call for investigational device exemptions, more defined accreditation of accredited third parties, expanding humanitarian use of devices and device tracking methods. Whether or not these bills are passed is very questionable. Debates on third party review seem to be a controversial issue for the parties. Senator Kennedy (D-MA) is opposed to the third party system and seems unwilling to compromise on this issue. Despite debates these bills represent current thought of Congress.

FDA Options

The FDA has raised certain concerns for the proposals in S.830. They are concerned that proposed changes are burdens and do not promote public health. Also the third party review of device expansion may not ensure the safety that is in the public's interest. In addition FDA feels changes in approval standards for devices would limit their authority to evaluate clinical outcomes for devices. FDA is also concerned about the expanded access to investigational therapies that would be available with appropriate protections. Also they are concerned that device modifications would allow manufacturing changes that affect a devices safety and effectiveness adversely.¹⁴ Instead the FDA has proposed some internal reengineering efforts.

First the FDA recognizes the need for reform particularly in the PMA device arena. They propose to move personal from the 510(k) evaluations of less risky devices and devote more time to the PMA approval process. They also propose to increase personnel assigned to class or tier III 510(k) devices to ensure safety requirements are met. Then limiting the time spent by FDA on less risky tier I 510(k) devices. FDA is considering implementing some of the following four options for lessening the regulation burden:

- Consensus standards by international groups such as International Organization of Standardization,
- Design controls that adhere to regulations,
- Third party review involvement, and
- Exemption of more devices from the review process entirely.¹⁵

The FDA has also initiated negotiations with the European Community to establish standards and agreements for review. The agreement calls for inspections of facilities to check for compliance in good manufacturing practices and quality system requirements. The agreement also calls for FDA to provide written guidance on product testing requirements to assure consistency for review. These written guidance standards are also advantageous for domestic regulation clarity. In addition after a 3 year transition period there would be a consensus decision on which notified bodies overseas have demonstrated proficiency to conduct reviews. Also these agreements provide for pre-market review of low and medium risks devices allowing for applications to review against U.S. requirements and submit reviews to FDA for final action. These agreements would streamline the review processes as well as save expenses on overseas inspections annually.¹⁶

FDA has also set forth changes for post-market review and inspections. The policy alternatives they are considering for post-market review are adding summary reporting alternatives. These summaries would provide adequate information for the FDA to pursue a problem they already recognize without having to screen so many individual reports. They are also considering electronic data interchange in order to speed screening and save encoding requirements. FDA is seeking denominator data on device usage in order to judge the significance of a medical device report through a pilot program FDA has launched. For inspection purposes the FDA is considering third party agencies to inspect manufacturing facilities.

The FDA reengineering efforts set forth and Product Development Protocol projects are aimed at reducing the resources and time to review for devices without compromising the safety of the American public. The product development goals include: providing a process that will allow FDA to effectively regulate class III products from initial development through even eventually replacement by more advanced products, reduce required resources and time to review and approve new class III devices, and ensure overall safety and efficacy concerns are not overlooked.¹⁷

FDA's opinion and views on reform options are not easily accessible, nor is the agency itself. Communication between industry, the public, and FDA should be improved. Clearer requirements and views should be expressed to achieve better interactions and an improved image. More accessibility to FDA's goals and motivations would enhance reform, negotiations, and cooperation between industry, Congress, the public and FDA.

Industry Options

In addition to FDA and congressional legislation, industry has their own suggestions and policy alternatives to enhance and renovate the current regulatory system that will hopefully provide a better climate for medical device development. The industry feels in order to streamline the process and ensure safety FDA should make the following changes.

- First FDA should focus the scope of pre-market review to ensure the devices are safe and perform what they are labeled. Industry feels that FDA should not be a medical gate keeper and be responsible for recommendations on effectiveness or what devices is appropriate for a given situation. Industry feels FDA should only guarantee safety and labeled use not other responsibilities.
- FDA should build on the use of experts outside the agency for evaluations.
- FDA should use international and national standards for comparisons of performance and safety.
- FDA should bring down review times for lifesaving and supporting devices.¹⁸

HIMA believes certain steps such as setting milestones for the review process, making the review process more interactive, eliminating reviews of low risk Class I devices and modifications as well as refining the product classification process will enable the FDA to streamline the review process so it is more effective. Finally industry feels the third party review process should be expanded. Establishing review standards, conflict-of-interest rules, and clear criteria for evaluating medical devices

would aid in an effective process of third party review. In addition industry feels FDA should conduct on going oversight and review of accredited agencies to ensure safety and consistency in reviewing. Device manufactures also emphasize FDA has the final authority to review all applications. Industry feels that if all of the suggestions stated were adhered to the third party review process would be effective as well as safe and could be expanded to include more devices.²⁰

Recommendations

Through the analysis of FDA, industry, and Congressional policy stances as well as the European system, it is imperative that regulation be reformed soon. The American public will always have access to quality medical treatment and devices; however, the American public is losing its first access priority and opportunity due to long delays in approval. The lengthy review time is attributed to inefficient methods and requirements set forth by the FDA. Also the FDA's inability to effectively convey their views and stances on issues compared to the strong cohesive message by industry creates a weak disheveled image which is detrimental to FDA's cause.

Device manufactures are looking to the European market for first introduction as well as clinical trial avenues. The more incentives offered by the European community causes companies to shift their growth and development overseas and use the U.S. as a secondary launching market. The medical device industry generates \$44 billion, yet our world dominance is diminishing. Thus productivity is diminishing and companies are cutting back on employment and research and development and shifting these opportunities overseas.

Investors are not seeing a quick turn around on their money and are not as willing to put forth the capital on these investments. The American public is facing a shrinking industry that has not reached its full potential; thus, losing not only revenue and employment opportunities they are also losing timely access to new innovative products.

FDA internal structure and application requirements seem to be first places in which reform should start. If the FDA would set up more defined guidelines for review, quality systems, and good manufacturing practices. Secondly a system set up for oversight and evaluations of third parties time could be saved and the review process could be much more effective. The method of third party review is a very effective viable option overseas. Third party reviewers must be regulated as heavily as devices; however, if more devices were up for third party review, then the process could be expedited considerably. Also the exemption of certain low risk devices from review would also be an effective measure. These devices would be self proclaimed by already set standards and accountable however they would not tie up FDA resources that could be placed else where.

In addition, the use of international standards would be a very effective step in setting clarity as well as participating more extensively in the global market which offers a great source of opportunity. Clear guidelines by the FDA in the application process as well as reporting and post market surveillance issues are imperative for an efficient process. Better avenues for communication could also prove beneficial for industry and clear up misunderstandings that delay the process. Finally incentives that

might be offered by the government and helpful guidelines and standards for exporting would also provide a place for industry to remain on domestic soil and thus contribute to the economy and employment sector.

Lastly biotechnology companies should be encouraged to participate in programs such as ATP that offer funding and start up options to increase productivity if other investors are not available. Improvements such as these would guarantee the American health system would remain the first market for new devices that can be life saving and enhancing.

Acronyms

FDA - Food and Drug Administration

HIMA - Health Industry Manufacturers Association

MDMA - Medical Device Manufacturers Association

NIH - National Institutes of Health

PMA - Pre-market Approval (classification of a device)

IDE - Investigational Device Exemption

GAO - General Accounting Office

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- ¹⁹ “Process Improvements” www.himanet.com/new/mediakits/fdareform/process.html
- ²⁰ “FDA Accredited Scientific Organizations”www.himanet.com/news/mediakits/fdareform/accreditedorgs.html