

# **FDA Impact on U.S. Medical Technology Innovation: A Survey of Over 200 Medical Technology Companies**

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*Note: All figures and tables have been compiled by the authors from survey data unless otherwise cited.*

# Executive Summary

## Overview

Over the past few years, the manner in which the U.S. Food and Drug Administration (FDA) is executing its authority over the regulation of medical devices in the U.S. has been called into question. While some have claimed that current regulatory requirements are lax and harming patients, independent analysis has demonstrated that the current system does an exceptional job of protecting patients.<sup>1</sup> However, with regard to the agency's objective of promoting the public health through new innovations, there are increasing concerns from patients, physicians, and innovators that the FDA is falling short. Until now, little (if any) data has been produced to either validate or refute these concerns.

The purpose of this study was to address the need for data that could be used to evaluate the impact of U.S. medical device regulation on innovation and patients. The authors initiated the study in summer 2010 so that the results could be used to inform discussions underway within the FDA and the Institute of Medicine (IOM).

The U.S. regulatory system uses a combination of processes before a product is available to patients (referred to as the premarket period) and after a product has been cleared/approved for market (referred to as the postmarket period) to ensure patient safety and product effectiveness. The study, which took the form of a survey, focused exclusively on assessing premarket regulatory processes. It was used to help determine if concerns about the efficiency of current U.S. regulatory processes were isolated or widespread across the medical technology ("medtech") industry. It was also designed to identify where the greatest deterrents to innovation exist within U.S. premarket regulatory processes and the costs (in time and dollars) these issues place on U.S. medtech companies. This report summarizes the results of the study and explores the implications of the data on patients, innovators, the U.S. medtech industry, and the economy at large.

Responses from 204 unique companies are reflected in the study data. This number represents approximately 20 percent of all public and venture-backed medical device manufacturers in the U.S. that are focused on bringing innovative new technologies to market to improve the public health (e.g., devices used to treat hypertension, obesity). Survey participants were asked about their experiences in working with the FDA, as well as their experiences working with European regulatory authorities so that comparisons could be made between aspects of the two dominant regulatory systems that assure the safety of innovative technology in the global marketplace.

## Results

In general, survey respondents viewed current U.S. regulatory processes for making products available to patients (the premarket process) as unpredictable and characterized by disruptions and delays. For example, 44 percent of participants indicated that part-way through the

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<sup>1</sup> Ralph Hall, "Using Recall Data to Assess the 510(k) Process," Public Health Effectiveness of the FDA 510(k) Clearance Process: Workshop #2, Institute of Medicine, Washington, D.C., July 2010.

premarket regulatory process they experienced untimely changes in key personnel, including the lead reviewer and/or branch chief responsible for the product's evaluation. A total of 34 percent of respondents also reported that appropriate FDA staff and/or physician advisors to the FDA were not present at key meetings between the FDA and the company. Factors such as these make the U.S. premarket regulatory process inefficient and resource intensive.

The above factors also contribute to significant delays in navigating FDA regulatory processes. Survey respondents reported that the premarket process for 510(k) pathway devices (of low- to moderate-risk) took an average of 10 months from first filing to clearance. For those who spoke with the FDA about conducting a clinical study for their low- to moderate- risk device before making a regulatory submission, the premarket process took an average of 31 months from first communication to being cleared to market the device. In contrast, respondents said it took them an average of 7 months in Europe from first communication to being able to market the same (or equivalent) device.

For higher risk devices seeking premarket approvals (on the PMA pathway), responding companies indicated that it took an average of 54 months to work with the FDA from first communication to being approved to market the device. In Europe, it took an average of 11 months from first communication to approval.

The FDA compared unfavorably to European regulatory authorities in other ways, as well:

- **Predictability** – 85 percent of respondents considered EU authorities to be highly or mostly predictable, while only 22 percent gave the FDA the same ratings.
- **Reasonableness** – 91 percent of respondents rated EU authorities as highly or mostly reasonable compared to just 25 percent for the FDA.
- **Transparency** – 85 percent found the processes and decisions of the EU authorities to be highly or mostly transparent compared to 27 percent for the FDA.
- **Overall Experience** – 75 percent of respondents rated their regulatory experience in the EU excellent or very good. Only 16 percent gave the same ratings to the FDA.

The survey data also showed that the average total cost for participants to bring a low- to moderate-risk 510(k) product from concept to clearance was approximately \$31 million, with \$24 million spent on FDA dependent and/or related activities. For a higher-risk PMA product, the average total cost from concept to approval was approximately \$94 million, with \$75 million spent on stages linked to the FDA. (These estimates do not include the cost of obtaining reimbursement or any sales/marketing-related activities.) Survey respondents confirmed that they are able to make their products available to patients faster and at a significantly lower cost in markets such as Europe. For U.S. companies, these mounting costs are unsustainable in a venture-backed industry where less than 1 out of four medtech start-ups succeed, 50 percent of all reported exits<sup>2</sup> are less than \$100 million, and the total pool of available investment capital is declining.

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<sup>2</sup> The term “exit” refers to a liquidity event (usually an acquisition or initial public offering) that potentially allows investors to realize a return on their invested capital.

Perhaps most importantly, the survey revealed that the suboptimal execution of FDA premarket regulatory processes has a significant, measureable cost to U.S. patients in the form of a *device lag*. Respondents reported that their devices were available to U.S. citizens an average of two full years later than patients in other countries, due to delays with the FDA and/or company decisions to pursue markets outside the U.S. before initiating time-consuming, expensive regulatory processes in their own country.<sup>3</sup> In some cases, this device lag reached up to 70 months (nearly six years).

## **Implications**

Unpredictable, inefficient, and expensive regulatory processes put the U.S. at risk of losing its global leadership position in medtech innovation. Data from the survey clearly indicate that European regulatory processes allow innovators to make new medical technologies available to patients more quickly and at a lower cost. The reasonable question has been raised whether greater regulatory efficiency in the EU has been achieved at the expense of patient safety. However, no information is currently available to suggest that patient safety in Europe has been compromised. If the same devices become available in U.S. following their European approval only after extensive delays and additional costs are accrued, we must evaluate whether U.S. premarket regulatory processes are truly contributing to the advancement and promotion of the public health, or if they are actually restraining it.

Under current FDA processes, millions of U.S. patients are being denied or delayed access to leading medical devices that are first (or exclusively) brought to market in other countries. Fewer medical device start-ups are being launched in the U.S. as investment capital in the industry continues to move to other sectors. And, innovators and medical device companies are relocating to other countries in greater numbers, taking valuable jobs and tax revenue with them. Regulators and innovators must work together to reverse these troubling trends. To truly promote the public health, the FDA must impose reasonable regulatory requirements on new innovations, implement more balanced requirements for premarket and postmarket clinical data, and go back to leveraging market forces to reward technology that presents the greatest value to patients. Only then will the most effective advances in medical care be developed and provided promptly to American patients; and only then will the public health and our economy be best served.

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<sup>3</sup> In this context, availability refers to having achieved regulatory clearance/approval to legally market the device; it does include commercialization activities, such as reimbursement or distribution.

## Background

In 1976, when the U.S. Congress passed the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act, it established a new organization with the FDA that is known today as the Center for Devices and Radiological Health (CDRH). The Center has a two-fold mission to both *protect* and *promote* the public health when it comes to the use of medical technologies. However, over the last two years, representatives from the medtech industry have reported that the FDA is becoming less predictable, transparent, and reasonable while, at the same time, its requirements for demonstrating the safety and effectiveness of new devices continue to increase. To better understand if CDRH's current approach toward device regulation effectively balances the two imperatives reflected in its mission, or if the Center has become so cautious that its policies are denying patients timely access to the latest technologies and negatively affecting innovation in the industry, a systematic evaluation of the regulatory oversight process was needed. These factors motivated the initiation of the study described in this report.

## The Industry

The medtech industry plays an important role in the lives of patients around the world. In this context, medtech refers to medical devices intended for use for therapeutic and diagnostic purposes. Together with other segments of the larger health care sector, medtech companies have contributed to dramatic improvements in health. For example, from 1980 to 2000, new diagnostic and treatment paradigms helped drive an increase in U.S. life expectancy of more than three years, a 16 percent decrease in annual mortality rates, and a 25 percent decline in disability rates for the elderly.<sup>4</sup> During this period, mortality from heart attacks was nearly cut in half. Mortality also declined by more than 30 percent for strokes and by over 20 percent for breast cancer.<sup>5</sup>

The U.S. medtech industry also has an essential role in the U.S. economy. In 2006, companies in the field shipped products valued at \$123 billion and paid \$21.5 billion in salaries.<sup>6</sup> The industry directly employed more than 357,000 individuals and indirectly accounted for another 1.6 million jobs (each direct medtech position generates 4.47 additional jobs in the national economy).<sup>7</sup> Employees in the medtech field earn above average wages—approximately \$60,000 per year—because the industry requires and attracts a highly skilled and educated workforce.<sup>8</sup> New medical technologies also have the potential to drive down costs in a world of escalating healthcare expenditures.

Internationally, the U.S. is the largest global consumer of medical devices. However, it is also the world's leading producer. The country achieved this leadership position through decades of

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<sup>4</sup> "The Value of Investment in Healthcare," MEDTAP International, 2004, [www.aha.org/aha/content/2004/PowerPoint/ValuePresentation.ppt](http://www.aha.org/aha/content/2004/PowerPoint/ValuePresentation.ppt) (October 2, 2010).

<sup>5</sup> Ibid.

<sup>6</sup> "State Impacts of the Medical Technology Industry," The Lewin Group, 2007, [http://www.ihif.org/files/State%20Impacts%20of%20the%20Medical%20Technology%20Industry\\_%23436092%200\\_3\\_.pdf](http://www.ihif.org/files/State%20Impacts%20of%20the%20Medical%20Technology%20Industry_%23436092%200_3_.pdf) (October 26, 2010), p. 1.

<sup>7</sup> Ibid., p. 12.

<sup>8</sup> Ibid., p. 4.

strong, sustained investments in research and development (R&D) by U.S. medical device companies and the venture capital community that backs them. As a result, the medtech field is among a limited number of industries in which the U.S. maintains a trade surplus. In 2007, the total medtech trade surplus was estimated at \$5.4 billion.<sup>9</sup>

Traditionally, innovation in the medtech industry has been driven by small, entrepreneurial companies with a passion for discovering safer, more effective ways to diagnose and treat patients. Although a number of major device manufacturers exist, more than 80 percent of medtech companies have fewer than 50 employees.<sup>10</sup> These small starts-ups are the engine that fuels the development of innovative new devices, which are often acquired by the larger companies as they mature. Through the combined efforts of both small and large medtech companies alike, R&D investment in the industry more than doubled during the 1990s, and it continues to outpace the R&D investment of companies in other U.S. manufacturing industries by an average of twice as much.<sup>11</sup>

## **The FDA**

Within the FDA, CDRH has two primary regulatory pathways that medical devices can take to get to market. The Center uses the premarket approval (PMA) pathway to evaluate and approve technologies that are truly novel and pose a high potential risk to the patients using them. For low to medium risk devices, it employs the premarket notification or 510(k) process. Regardless of whether a device must follow the 510(k) or PMA pathway, the FDA has the ability to request that a company provide clinical data to support clearance or approval. This data often requires an allowance by the FDA to perform clinical trials in the U.S., which is known as an investigational device exemption (IDE).

Early in the implementation of section 510(k) of the Medical Device Amendments, it was well recognized that the 510(k) pathway to market could efficiently facilitate the availability of new technologies that have the same intended use as legally marketed devices without creating an undue regulatory burden. This approach was meant to allow companies to build upon established clinical and scientific evidence of safety and effectiveness to more rapidly iterate and improve the innovations available to patients. Not surprisingly, the 510(k) process is more widely used than the PMA pathway. In 2009, for example, CDRH approved just 15 original PMA submissions while it cleared approximately 3,000 products under a 510(k).<sup>12</sup>

As it shepherds technologies through these two pathways, the FDA must balance the imperative of assuring the safety, effectiveness, and quality of commercially available medical devices with its mission of fostering innovation by providing companies with a timely, predictable route to

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<sup>9</sup> “Medical Technology and Venture Capital: A Fruitful Yet Fragile Ecosystem,” MDMA and NVCA, June 2009, <http://www.medicaldevices.org/node/656> (October 2, 2010).

<sup>10</sup> Ibid.

<sup>11</sup> “Medical Devices Industry Assessment,” International Trade Administration, 2009, <http://www.ita.doc.gov/td/health/Medical%20Device%20Industry%20Assessment%20FINAL%20II%203-24-10.pdf> (October 2, 2010).

<sup>12</sup> Calculated from FDA data available at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm> and <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm> (October 22, 2010).

market. In recent years, some politicians, members of the press, and consumer groups have criticized the FDA for not adequately addressing the safety of medical devices, particularly those cleared through the 510(k) pathway. These concerns have persisted despite a lack of evidence that both the 510(k) and PMA pathways are not fulfilling their intended purpose of protecting patients. In fact, despite the anecdotal examples reported in the media, there is compelling evidence to the contrary. For example, one recent study demonstrated that only about four-tenths of one percent of all 510(k) and PMA devices that were cleared/approved by the FDA from 2004 to 2009 have been associated with have a Class I<sup>13</sup> recall.<sup>14</sup> (Recalls are an indicator of major device problems that have the potential to negatively affect patient safety and/or device effectiveness.) Such results demonstrate that serious device-related safety problems are extremely rare. Also, the data show that the majority of these rare postmarket events stem from issues relating to quality systems and manufacturing processes and not issues that would have been most effectively detected through more expansive premarket data requirements.

Despite this evidence, the FDA's clinical data requirements continue to rise. While the agency historically used the postmarket period to continue accruing data regarding device safety and effectiveness (allowing the market to determine the value of a medical device), it is increasingly demanding that this kind of large-scale clinical data be provided during the premarket period. When it comes to premarket data requests for new products, medtech innovators say they face more uncertainty regarding the FDA's expectations, and that bench, animal, and clinical testing requirements are mounting without clear justification or benefit. Even more troubling are an increasing number of examples from industry representatives that FDA reviewers are requesting esoteric scientific testing, or posing questions that are not reasonably answerable, sometimes at great expense and with little relevance to safety and effectiveness. Moreover, medtech innovators have reported that the FDA is becoming less predictable and increasingly inefficient in its premarket review role. Stakeholders maintain that the CDRH, over the last several years, has become even less transparent in how it makes decisions, as well as slower in responding to inquiries and regulatory submissions. The degree to which these reports represent isolated incidents versus a general trend was unknown prior to the completion of this study.

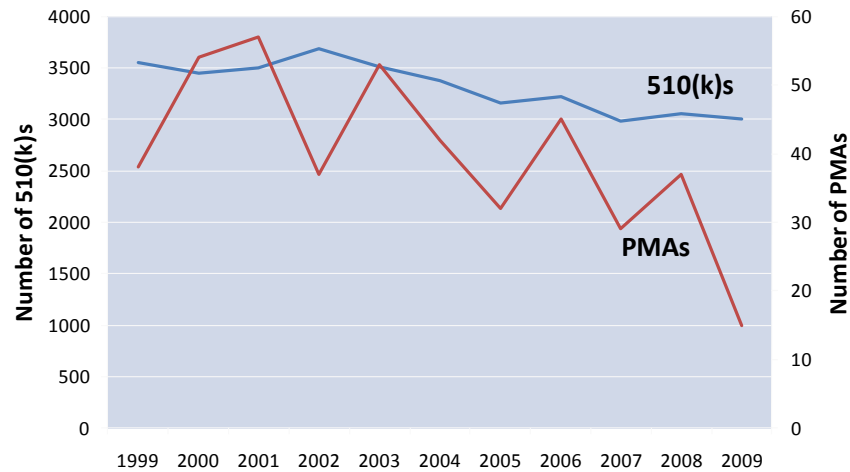
According to device companies, these changes have created nearly insurmountable barriers to medtech innovation in the U.S., with no apparent off-setting public health benefit. The current regulatory environment is particularly challenging for start-up companies, which have historically played a key role in driving innovation, because of their limited financial resources. As a result, regulatory submissions for innovative new medical devices have been declining in the U.S. over the last several years. Clearances/approvals are also trending downward (as shown in **Figure 1**). In an era of greater scientific knowledge and technology advancements than any other time in history, one must question what forces are driving medical technology innovation in a downward direction.

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<sup>13</sup> A Class I recall is the most serious type of FDA recall because the problem for which the device has been recalled may result in major injuries or death.

<sup>14</sup> Hall, op. cit.

**Figure 1 – 510(k) Clearance and PMA Approvals (1999-2009)**



Source: Calculated from FDA PMA approval and 510(k) clearance data.<sup>15</sup>

In 2009, CDRH launched two working groups to evaluate: (1) the 510(k) program, and (2) how the Center uses scientific data to support its regulatory decision making. Similarly, the IOM convened a committee at the FDA’s request to assess the effectiveness of the 510(k) process. As these groups gather information, formulate recommendations, and solicit public comment, objective data must be considered that bears on the role of the FDA in protecting the public health and the adequacy of the agency’s regulatory processes (as noted above). Until now, there has been little systematic information to validate or disprove the anecdotal reports of the deleterious effects that FDA regulation has on U.S. patient access to new medical technology, device innovation in the country, and America’s medtech leadership position in the world.

The purpose of this study was to gather quantitative and qualitative data from a representative subset of medtech companies to elucidate the impact of the FDA’s current regulatory practices on medical technology innovation and the advancement of public health so that Congress, the FDA, and the IOM would have more information to consider in their evaluations.

<sup>15</sup> Calculated from FDA data available at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm> and <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm> (October 22, 2010). It was not possible to calculate the percentage change in clearances/approvals from year to year because data regarding the total number of 510(k) and PMA *submissions* is not made publicly available by the FDA.

## Study Methodology

To obtain a more systematic understanding of the perceptions and experiences of medtech companies in dealing with the FDA, the study authors designed a survey. This survey was created to collect information from medtech industry executives about the how U.S. and European premarket regulatory processes compare, the cost and time to navigate the U.S. premarket regulatory processes, and what aspects of the U.S. premarket regulatory processes are most challenging to innovators.

Input on the questions was requested from MDMA, NVCA, and a variety of relevant state associations including the California Healthcare Institute (CHI), MichBIO, MassBIO, PA BIO, Life Science Alley (Minnesota), MedTech (NY), Colorado Bioscience Association, Florida Medical Manufacturers' Consortium, and Washington Bio. Feedback was also solicited from the FDA, with several CDRH leaders providing input.

Once the questionnaire was developed, participants were recruited through two primary channels. MDMA sent the survey to its 260 members. NVCA also distributed the questionnaire to 211 of its members—venture capital firms with a presence in the life sciences field. These firms were then asked to pass it along to the medtech companies in their investment portfolios. If all of the medtech portfolio companies had been sent the survey, it would have reached approximately 750 potential participants.

Medtech companies were given two options for participating in the survey: they could respond to the questions via an in-person or telephone-based interview; or they could provide their answers electronically by entering them into a web-based form. The online form included a slightly smaller subset of the most relevant survey questions, so it was quicker to complete.

During the data collection period, 100 phone interviews were conducted, primarily with MDMA members. In total, 95 MDMA members expressed interest in taking the survey, but only 80 could be scheduled for a phone interview (for a 31 percent MDMA participation rate). Another 20 companies heard about the survey through other mechanisms (e.g., the state associations listed above) and also participated via phone.

Participants reached through NVCA responded via the online survey. In total, 176 companies completed the web-based questionnaire, but only 131 provided trackable data (meaning, it allowed independent verification of their identities and qualifying answers). Out of a possible 750 portfolio companies, this resulted in a 17 percent NVCA response rate.

Duplicate entries from MDMA and NVCA members were eliminated, leaving responses that represented experiences for 213 unique products from 204 companies. A small number of companies were permitted more than one response if their regulatory experiences varied significantly for two different products, or if more than one department responded within a larger medtech organization. However, the vast majority of the companies in the survey were small, early-stage entities, focused on a single product family.

In terms of characterizing the respondents, 90 percent were private companies; 10 percent were publicly-held. The majority were venture-backed and considered to be small in size (median = 33 employees). When interacting with the FDA, 55 percent had completed a traditional 510(k) for a low- to moderate-risk device; 32 percent went through the PMA process for a higher-risk device; and 13 percent navigated other regulatory pathways (special 510(k)s, de novo 510(k)s, or for humanitarian use devices). A comparison of the survey participants to U.S. medtech industry data published in Ernst & Young’s 2010 “Pulse of the Industry: Medical Technology Report,” is shown in **Table 1**.

**Table 1 – Comparison of Industry Versus Participant Demographics**

<b>U.S. Industry</b>	<b>Participants</b>
1,023 public and venture-backed medtech companies	204 public and venture-backed medtech companies
>50 percent of companies in California, Minnesota, and Massachusetts	>50 percent of companies in California, Minnesota, and Massachusetts
Largest specialties within the market are cardiovascular, orthopedics, and non disease-specific	Largest clusters of participants are from orthopedics, cardiovascular, and general and plastic surgery

Source: U.S. industry data drawn from Ernst & Young’s “Pulse of the Industry: Medical Technology Report,” 2010.

While there are more than 16,000 “medical device companies” registered with the FDA, this figure includes thousands of organizations that supply components to device manufacturers, sterilization service companies, contract laboratories, and other non-product producing enterprises. Of the total, 4,776 are categorized as medical device manufacturers, yet an unknown number are defunct or never produced products. Larger companies in this grouping may also have multiple registrations per entity. In addition, over the past few years, only a minority of these companies filed premarket submissions with the FDA. Thus, this larger FDA-registered group does not represent a reasonable denominator to assess the study subset.

In contrast, the medtech companies included in the Ernst & Young profile are product-driven medical device manufacturers actively working on bringing innovative new medical technologies to market (i.e., those smaller companies that represent the medtech innovation engine). This subset more closely mirrors the population the study was designed to reach. If one considers these 1,023 medtech companies as the target population for the survey, approximately 20 percent of U.S. medtech industry innovators responded to the survey (204 unique companies).

After the study was conducted, the survey, survey database, and study analyses were submitted to PricewaterhouseCoopers LLP to ensure their integrity and verify the way in which the study’s results were calculated. PricewaterhouseCoopers did not assess the study methodology, but focused solely on assuring that the data collection was accurate and that the results were calculated and presented properly. The data summarized in this report reflects these verified study results.

All of the medtech companies that participated in the study were assured that their responses would be kept confidential. For this reason, we can only present study results in an aggregated format so that company-specific information is not revealed. Examples included in this report reflect the actual experiences of specific medtech companies without details that would compromise the confidentiality of individual participants.

## Study Limitations

While the data from more than 200 companies provide a compelling look at current U.S. regulatory practices and their effect on innovation in the medical device industry, there are some potential limitations to the study.

First, there may be selection biases within the sample. MDMA, NVCA, and state association members were the only companies formally invited to participate in the study. Public and venture-backed medtech companies are more likely to develop novel technologies that may be most impacted by the current FDA environment.

Additionally, participation was voluntary. This could mean that companies with issues to report may be more likely than others to respond to the survey; however, we also know that some companies with complaints were unwilling to participate. A number of companies indicated that they would not respond due to fear of retribution from the FDA (despite assurances we would maintain their confidentiality). Others said they were too busy. The remaining companies had other reasons for not participating that are unknown to the authors.

Beyond this, other sources of potential bias may exist. Specifically, some of the study authors have either direct or indirect industry affiliations. Moreover, survey participants themselves may be subject to certain biases based on their personal experiences with the FDA and their business interests within the industry being studied.

Lastly, the representative “n” for each question varies across the survey for several reasons:

- Some questions were designed to apply only to certain subsets of the survey respondents (e.g., specific questions were asked only of those companies that had pursued a 510(k), or required an IDE, or sought a CE mark, etc.).
- Survey responses collected via the 100 telephone interviews used a more expansive, detailed questionnaire, whereas the “online” survey was shorter and more focused.
- In some cases, respondents could not reply to all questions due to a lack of information. In other cases (particularly with the online survey), they may not have completed all fields and no explanation was provided. When this occurred, missing responses were excluded from the sample for those questions.

Despite these potential limitations, this study is among the first to attempt to provide a representative view of the medtech industry’s experiences in the current FDA environment. It significantly advances the available data that can be used to help assess regulatory impact on innovation in the U.S. medical device industry and the ability of U.S. companies to make progress toward affording American citizens access to the best technology under today’s regulatory conditions. It is also the first coordinated effort by MDMA, NVCA, and a majority of the medtech state associations.

## Study Results

Results from the survey are summarized below in four primary sections: (1) efficiency of U.S. regulatory processes and how they compare to the EU, (2) perceptions of FDA performance relative to European regulatory authorities, (3) cost to medtech companies, and (4) cost to U.S. patients.

### Efficiency of U.S. Regulatory Processes and How They Compare to the EU

The FDA and European regulatory authorities both have a solid track record of ensuring the overall safety and effectiveness of the devices that are made available within their jurisdictions. However, survey respondents reported that the FDA's current practices are less efficient than the agency's European counterparts. The general efficiency of regulatory processes can be measured by the time it takes to accomplish key milestones, as well as the presence (or lack) of process disruptions.

In terms of process disruptions, the survey explored problems that could contribute to inefficiencies and delays. For example, 44 percent of participants indicated that part-way through the regulatory process they experienced untimely changes in key personnel, including the lead reviewer and/or branch chief responsible for the product's evaluation. In these cases, companies experienced a significant setback having to retread ground that had already been covered. In addition to the delays caused by a lack of continuity in a review team, new reviewers may have different expectations, which can lead to inconsistencies, frustration, and additional resource demands.

A total of 34 percent of respondents also reported that appropriate FDA staff and/or physician advisors to the FDA were not present at key meetings. For instance, representatives from several companies reported that non-practicing physicians were brought in to work as consultants to augment the FDA reviewers evaluating their devices. The concern in these cases was that the physicians were not familiar with current treatment paradigms and the companies had to spend time discussing recent advancements in the field. Different challenges arose when physicians without the appropriate background or training were assigned work on a review team (e.g., an ophthalmologist called in to assess a cardiovascular device).

From a timing perspective, the CDRH's Office of Device Evaluation (ODE) reported in its FY2009 fiscal year performance report that the "average FDA review time" for a 510(k) was just over two months (63 days). The "average total elapsed time from receipt to final decision" was more than 3 months (98 days).<sup>16</sup> However, these FDA-reported averages likely underestimate the actual time required to achieve 510(k) clearance for several reasons. First, the FY2009 cohort is still incomplete due to an unknown number of decisions on 2009 submissions that are still pending within the agency. Second, the FDA has no established way of tracking the true timing

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<sup>16</sup> "Annual Performance Report," Office of Device Evaluation, Fiscal Year 2009, <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM223893.pdf> (October 4, 2010), pp.8-9.

of the process for an individual company or product as it navigates the regulatory/clinical process; the agency simply reports on the average time a file is open in its offices for a particular type of request (IDE, 510(k), PMA, etc.). This practice can potentially be misleading. With FDA limiting the number of attempts that companies have to demonstrate substantial equivalence in the confines of a single 510(k), requesting 510(k)s be voluntarily withdrawn, and deleting 510(k)s based on the passage of time, average review times have limited value. Fundamentally, the more relevant metric for patients and the industry is how long it takes for a new product to navigate the entire regulatory process until it is cleared or approved for market. The survey tried to quantify this data and how timing in the U.S. compares to timing in Europe.

When measuring comparative review times for the FDA and European regulatory authorities among survey respondents, two starting points were considered. If the filing of a formal submission for clearance or approval was the initiating event for the first interaction between a company and a regulatory body, the date of “first filing” was used as the index date. For most simple, low-risk products (e.g., 510(k)s), companies commonly make a regulatory submission prior to interacting with the regulatory body. However, in a majority of cases, companies either communicate with the regulatory bodies and/or file other documents with the regulatory body (e.g., requesting a pre-IDE meeting to discuss the design of a possible clinical trial, or filing an IDE). In such cases, the date of “first communication” was used as the index. In all cases, products likely to require clinical trials initiated their regulatory process with a communication either alone or in combination with a formal filing. Either way, the earliest interaction between company and regulatory body was used as the starting point for evaluating U.S. and European review timelines relative to one another.

According to the survey, U.S. companies that navigated the 510(k) pathway stated that it took them an average of 10 months from first filing to clearance.<sup>17</sup> Responses from those who had communicated with the FDA prior to making a 510(k) submission indicated that the total elapsed time from first communication to clearance (including any pre-IDE<sup>18</sup> or IDE related interactions) was an average of 31 months. (Note that a relatively small subset of respondents (n = 15) is reflected in this data point because most companies do not have contact with the FDA prior to making a 510(k) submission.) In contrast, survey participants found their interactions with regulatory officials in Europe to be much more timely. On average, they said it took 7 months from first communication to the time that CE mark certification was awarded.<sup>19</sup> A comparison of U.S. and EU timelines is shown in **Figure 2**.

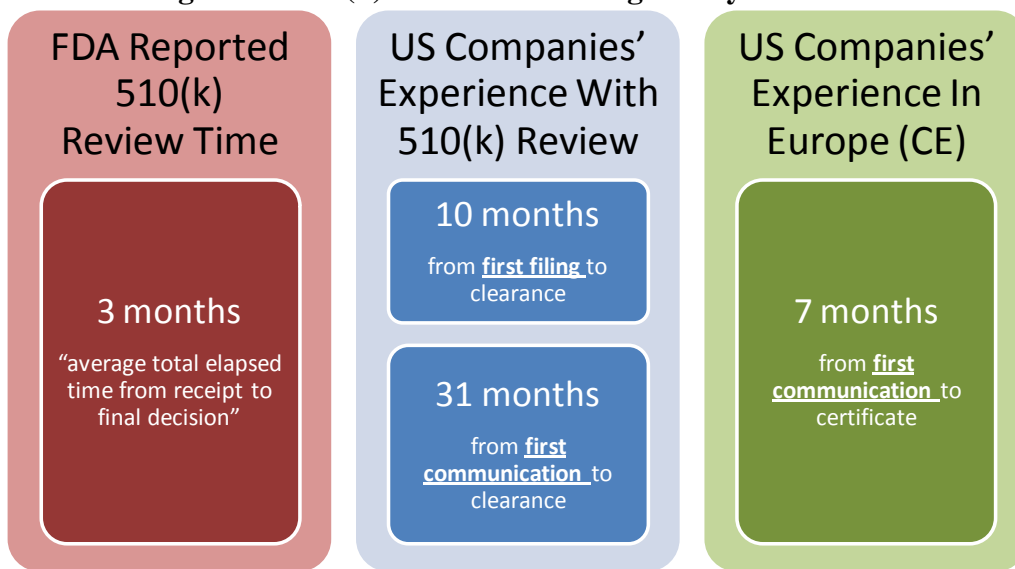
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<sup>17</sup> First filing refers to the point at which a formal submission is made to the FDA.

<sup>18</sup> The “pre-IDE” program includes pre-submission meetings used to discuss premarket requirements that are not related to clinical studies and IDE requirements.

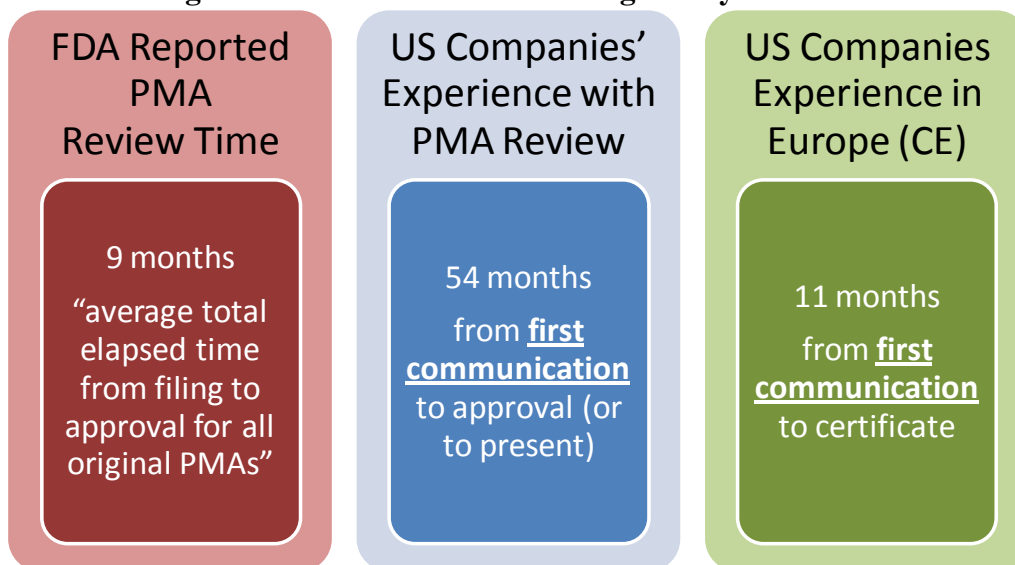
<sup>19</sup> In the European Union, a CE mark is awarded to indicate regulatory approval.

**Figure 2 – 510(k) and CE Mark Regulatory Timelines**



Survey respondents reported similar experiences with the PMA pathway. In its fiscal year 2009 annual performance report, the ODE stated that its “average total elapsed time from filing to approval for all original PMAs” was just over 9 months (284 days).<sup>20</sup> However, survey participants indicated that it actually took them an average of 54 months to work with the FDA from first communication to approval (or until the time of the survey, if the review was still in progress). In Europe, an equivalent product review took an average of 11 months from first communication to CE mark certification (as shown in **Figure 3**).

**Figure 3 – PMA and CE Mark Regulatory Timelines**



<sup>20</sup> “Annual Performance Report,” p.5.

For products requiring an IDE,<sup>21</sup> the ODE reported that the “average review time” was 27 days in fiscal year 2009 and that 99 percent of all original IDE decisions were issued in 30 days.<sup>22</sup> However, according to participants in the survey, the average time required to obtain an IDE was nearly 14 months. The FDA’s data indicates that just 56 percent of IDE submissions are approved in the first review cycle. In the remaining 44 percent of cases, the agency requests additional information from the submitting companies, necessitating extended review times.<sup>23</sup> The FDA may also count “conditional approvals” as IDE approvals, even though many studies cannot commence because of the additional conditions that the FDA imposes. Similarly, the FDA may count approvals of feasibility studies as IDE approvals, even if a feasibility study was not proposed. Finally, some IDEs are withdrawn at the FDA’s suggestion, or they are converted to pre-IDEs. According to ODE data, the average review time for pre-IDE submissions was 92 days in FY2008 but jumped to 156 days (more than five months) in FY2009.<sup>24</sup>

Survey respondents said that many delays were linked to clinical trial-related disagreements with the FDA regarding the definition of primary efficacy endpoints (27 percent), the definition of primary safety endpoints (15 percent), and other factors such as the use of historical controls (8 percent), size of the trial (12 percent), statistical techniques (6 percent), and/or the need for randomization (5 percent). Once an IDE was obtained, it took respondents an average of 21 months to conduct a pivotal trial that was designed to satisfy the FDA’s requirements with no assurance of the adequacy of the FDA-mandated study design.

### **Perceptions of FDA Performance Relative to European Regulatory Authorities**

In addition to issues related to the efficiency of the regulatory review process, survey respondents perceived that there were other important differences between the FDA and European regulatory authorities in the area of clinical, engineering, and statistical competence, predictability, reasonableness, and transparency. Overall, the FDA was perceived to be less efficient in performing premarket reviews relative to its European counterparts.

When asked about the knowledge of reviewers, survey participants found 88 percent of EU reviewers to be highly or mostly competent in their *clinical competence* compared to just 47 percent of U.S. reviewers. Similarly, 91 percent of EU reviewers were considered to be highly or mostly proficient in terms of their *engineering competence* compared to 52 percent in the U.S. Additionally, 79 percent of EU reviewers were believed to be highly or mostly *competent in statistics* versus 60 percent in the U.S.

The survey results were similar in the area of *predictability*, with 85 percent of respondents considering EU regulatory authorities to be highly or mostly predictable. By comparison, only 22 percent gave the FDA the same ratings (see **Figure 4**). The majority of survey participants

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<sup>21</sup> An IDE allows an innovator or company to use a device in human clinical trials in the U.S. prior to its regulatory clearance/approval.

<sup>22</sup> “Annual Performance Report,” p.10.

<sup>23</sup> Ibid.

<sup>24</sup> Ibid., p. 12.

believed the agency to be somewhat predictable (25 percent), mostly unpredictable (22 percent), or very unpredictable (31 percent).

Respondents also found EU regulatory authorities to be more *reasonable*. A total of 91 percent of respondents rated them as highly or mostly reasonable compared to just 25 percent for the FDA (see **Figure 5**).

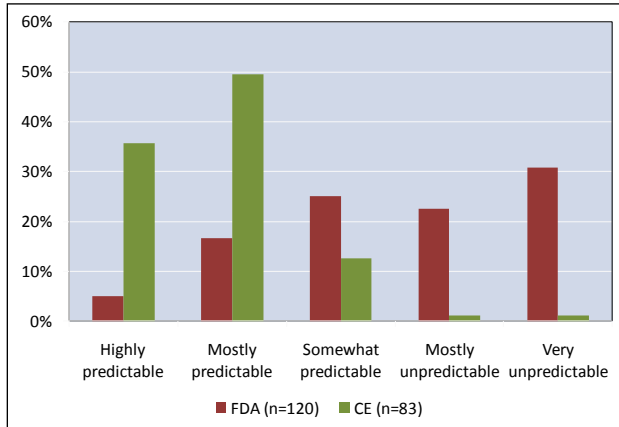
In terms of *transparency*, 85 percent found the processes and decisions of the EU authorities to be highly or mostly transparent compared to 27 percent for the FDA (see **Figure 6**).

Finally, survey participants rated EU regulatory authorities better overall, as shown in **Figure 7**. A full 75 percent rated their overall regulatory experience in the EU excellent or very good, while only 16 percent gave the same scores to the FDA.

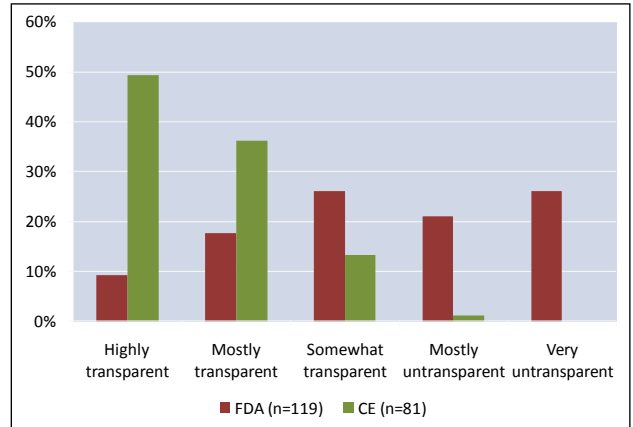
Beyond these direct comparisons, 93 percent of participants in the study agreed or strongly agreed that FDA has become more risk-averse toward new products in the last decade. Specifically, medtech executives and entrepreneurs who started companies and/or took devices through the regulatory process in the late 1990s and early 2000s stated that the agency now seems to be more risk averse and hesitant to make decisions, which could create delays and make the process less predictable and more costly. Additionally, 81 percent of respondents agreed or strongly agreed that the FDA has a particularly difficult time dealing with truly novel technologies (e.g., drug/device combinations and others PMA products). Finally, 66 percent expressed frustration that changes at the FDA had some negative impact or a strong negative impact on the progress of their companies on the way to market.

## Survey Respondent Ratings of FDA and EU Regulatory Performance

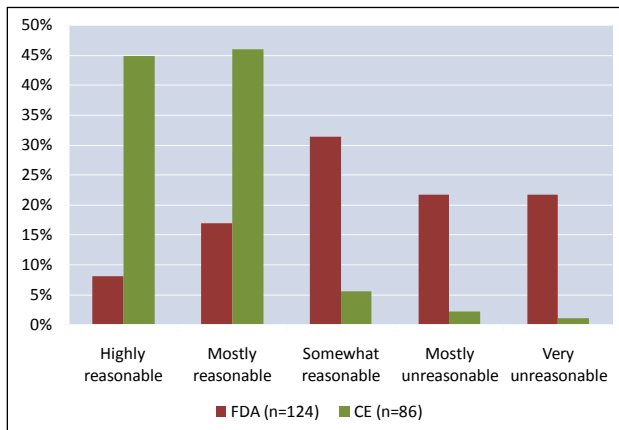
**Figure 4**  
**FDA Versus EU – Predictability**



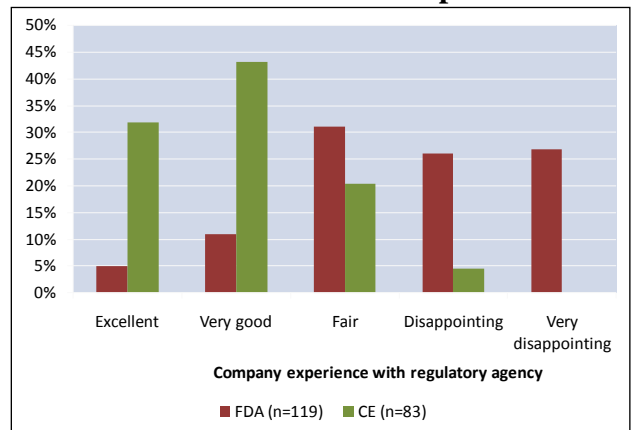
**Figure 6**  
**FDA Versus EU – Transparency**



**Figure 5**  
**FDA Versus EU – Reasonableness**



**Figure 7**  
**FDA Versus EU – Overall Experience**



## The Cost to Medtech Companies

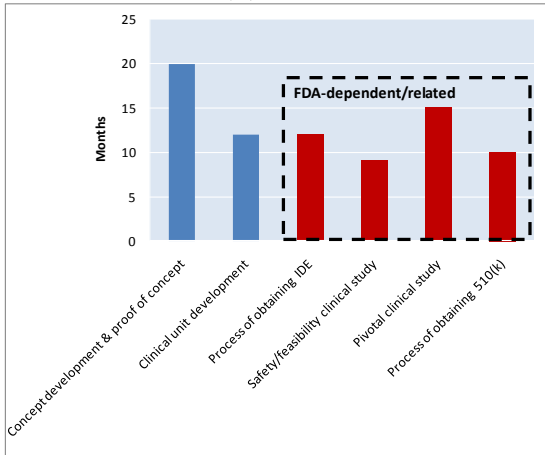
Inefficient regulatory processes can be devastating to medtech companies because so many of them are smaller start-ups without the cash flows or reserves to endure costly delays. In the survey, participants were asked calculate the amount of time (in months) they spent on critical stages in the medtech product development cycle for products taking the 510(k) pathway, as shown in **Figure 8**. Then, they were asked to estimate their average monthly expenditures during each stage, as shown in **Figure 9**. Data from the survey respondents was then used to calculate the total average expenditure to navigate each medtech development stage, as shown in **Figure 10**). The same three questions were asked for products on the PMA pathway, as shown in **Figures 11** through **13**.

When clinical or other data is reasonably required and regulatory processes work efficiently, companies must assume these costs as a hurdle for access to any market. However, if additional costs are incurred due to FDA inefficiencies and/or unreasonable delays, products could become prohibitively more expensive to bring to market in the U.S. For example, according to the survey data, every additional month a company spends attempting to obtain an IDE costs nearly \$400,000 per month for a 510(k) product and more than \$750,000 for a PMA product. Every additional month working through the 510(k) or PMA process itself costs more than \$520,000 and \$740,000 per month, respectively. These high expenditure levels may help drive higher prices for medical technologies when they finally reach the market. Thus, FDA-related delays directly contribute to increased health care costs in the United States.

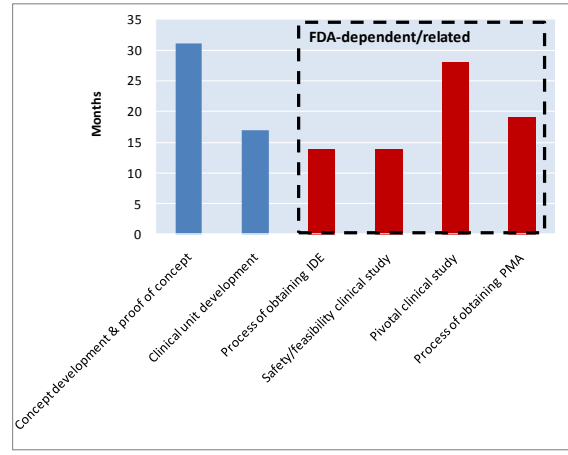
The survey data also revealed that the average total cost for participants to bring a 510(k) product from concept to clearance was approximately \$31 million, with \$24 million spent on FDA dependent and/or related activities. For a PMA, the average total cost from concept to approval was \$94 million, with \$75 million spent on stages linked to the FDA. (Note that these estimates do not include the cost of obtaining reimbursement approval or any sales/marketing-related activities.) The magnitude of these figures confirms the likelihood that the companies that self-selected to participate in the survey were most likely those companies working on innovative, new medical technologies that required clinical data to get through the FDA rather than those seeking relatively simple extensions to low-risk, ubiquitous product lines already in existence.

## Impact of FDA Delays in Terms of Time and Cost

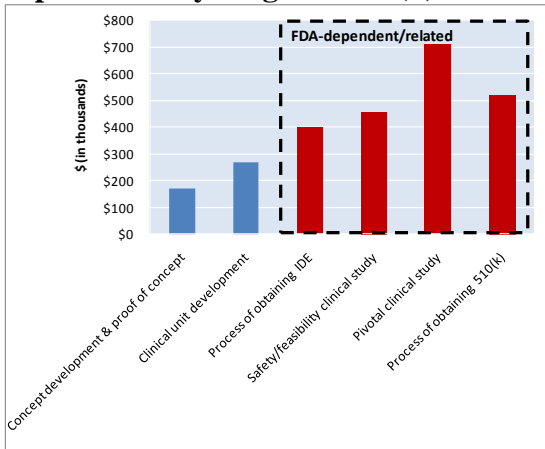
**Figure 8 – Average Time by Stage for 510(k) Product**



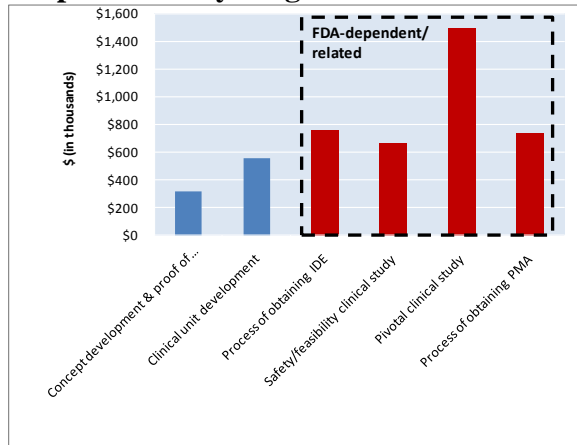
**Figure 11 – Average Time by Stage for PMA Product**



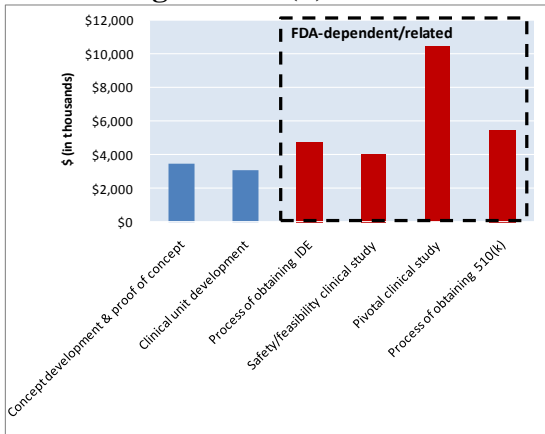
**Figure 9 – Average per Month Expenditure by Stage for 510(k) Product**



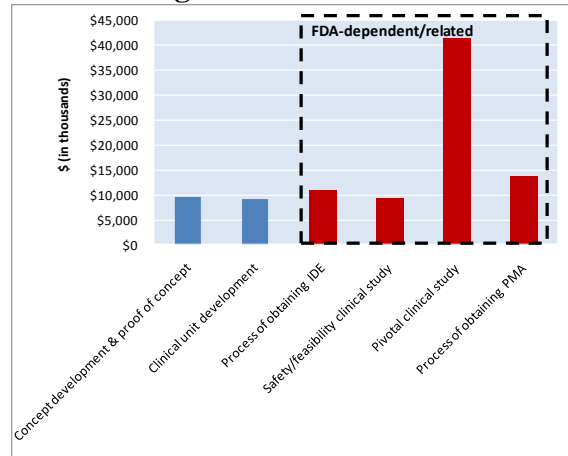
**Figure 12 - Average per Month Expenditure by Stage for PMA Product**



**Figure 10 – Average Total Expenditure by Stage for 510(k) Product**



**Figure 13 – Average Total Expenditure by Stage for PMA Product**



## **The Cost to U.S. Patients**

Importantly, suboptimal regulatory processes can also have a cost to patients that is much more significant than the additional dollars companies must spend to get their products to market. While U.S. citizens used to be the first to gain access to innovative new technologies, they now face a *device lag*. Stated another way, U.S. citizens gain access to new U.S.-made medical technologies later than patients in other countries.

On average, the products represented in the survey were available to patients in the U.S. a full two years *after* they were available to patients in Europe (range = 3 to 70 months later). In some cases, respondents said they initiated their regulatory processes within and outside the U.S. at the same time, but received clearance/approval in the U.S. much later. In anticipation of long, expensive FDA reviews, others said they decided to seek or obtain European approval first in an effort to generate sales overseas that could help fund their U.S. regulatory efforts. Alternatively, some companies reported that they were now setting up operations overseas and developing strategies that do not rely on the U.S. market, despite the fact that it remains the world's largest and most commercially lucrative device market.

Based on the prevalence of the diseases addressed by the companies in the study, this means that millions of Americans do not have access to the latest, most innovative medical technologies. Responding companies reported long delays for U.S. approvals relative to Europe for products offering significant advances for treating or diagnosing highly prevalent conditions such as heart disease, lung disease, obesity, and arthritis. The study data clearly paints a grim picture for patients, as well as medtech innovators relative to the challenges they face as they approach the regulatory stage(s) of their product development process in the United States.

## Discussion

Since the Medical Device Amendments were enacted nearly 35 years ago, medtech regulation has often been described as a pendulum that swings between risk-tolerant and risk-averse regulatory oversight. Over the last two years, the FDA seems to be in the midst of yet another swing toward more risk-averse practices. The forces that drive these oscillations are powerful and deeply rooted in the culture of FDA, as well as in the shifting expectations imposed on the agency by the administration in charge at any particular time. Patients, the public, the media, medtech employees, the scientific community, practicing physicians, and politicians—for better or for worse—all play a role in influencing the FDA's position.

The agency's challenge is clearly to anchor its policies in the position that best serves the public health and is devoid of significant shifts from political influence. The FDA's target is to balance its activities at a some point between the two extremes. However, because some of the stakeholders listed above often have limited or no information about other stakeholders' activities, striking an appropriate balance can be difficult—particularly when prevalent beliefs and behaviors are based on perceptions, headlines, and anecdotes rather than actual data.

This survey attempts to bring forward data that can be used to help inform the discussions currently underway at the FDA and within the IOM regarding the best path forward for medical device regulation. While the challenges we face today are complex and multivariate, and many questions still remain, our hope is that the results of the study will help regulators and innovators work together to achieve a balance that ultimately serves the best interests of patients and the U.S. economy at large.

One of the primary objectives of the survey was to determine if the concerns raised by representatives of the medtech industry regarding the changing environment at the FDA were relatively widespread, or simply the complaints of a vocal minority. The results clearly demonstrate that inefficiencies, delays, and the mounting costs of the U.S. regulatory process are being felt widely across innovators in the industry.

Through the study, we also hoped to shed light on where the greatest problems exist. The data point to troubling inefficiencies caused by reviewer turnover, inconsistent quality and participation of expert advisors, and excessive delays, particularly compared to the FDA's European regulatory counterparts. Participants were asked about their experiences with European regulatory authorities so that comparisons could be made between aspects of the two dominant regulatory systems that assure the safety of innovative technology in the global marketplace.

The study revealed that it takes significantly longer to navigate U.S. regulatory processes than it does to complete European approvals for the same products. Respondents also shared a relatively widespread perception that the FDA has become less reasonable, transparent, and predictable as compared to Europe's regulatory authorities. In combination, these factors had a significant effect on respondents' overall experience with the FDA. More than half of all survey participants said they found their interactions with the agency to be disappointing or very

disappointing. These results suggest that the agency is not actively partnering with medtech employees to work toward mutually satisfactory results and the benefit of health care in the U.S.

Finally, the study sought to quantify the costs of regulatory inefficiencies and other delays on patients and companies in the medtech industry. What we learned is that there is a device lag—innovative new medical technologies are becoming available to U.S. patients an average of two years later than patients in Europe (in some cases, the device lag is up to almost six years).<sup>25</sup> The true cost of this lag is difficult to estimate, but one can hypothesize that millions of patients may not be afforded the opportunity to benefit from the best possible care as they await better or different treatments that are commonly being used in other countries. With no available evidence to suggest that the safety of these devices is being substantially improved as they navigate the U.S. regulatory process (relative to Europe), it is reasonable to question whether the lengthy and expensive FDA process is truly protecting patient health, or more simply delaying patient access to new therapies that are available years earlier in other geographies.

The study documented, in time and dollars, what it takes to navigate the core steps in the regulatory process on the way to market in the U.S. Obtaining an IDE, a 510(k), and/or a PMA is both expensive and time consuming. However, the time and cost associated with conducting the types of pivotal clinical trials increasingly required by the FDA is particularly alarming. As data requirements from the FDA have risen, the complexity of the requested studies, as well as the number of patients for which data are required, is proving to be prohibitive to medtech innovators and investors alike.

To help us better understand the implications of the survey data to U.S. patients, innovators, investors, medtech employees, and the economy at large, we shared the findings with a patient (Marti Conger), three innovators (Robert Fischell, Rodney Perkins, and Paul Yock), three medtech investors (Ryan Drant, Ross Jaffe, and Hank Plain), and a medtech industry observer (David Cassak). Their perspectives are reflected in the discussion below.

## **Implications to Patients**

As noted, one of the most troubling outcomes of the survey is that U.S. patients are increasingly less likely to be the first to have access to innovative new medical technologies, even when those devices are invented in the U.S. As medtech innovators and employees anticipate time-consuming, expensive FDA regulatory processes, a growing number are taking their devices elsewhere before making them available to American patients. One effect of this trend is that the U.S. is losing its position as the leading provider of medical care. “Our world famous U.S. hospitals are not receiving as many patients from all over the world because the most advanced health care is not being practiced in the United States because of the FDA,” stated Dr. Robert Fischell, a serial inventor and founder of multiple medical device companies.

Another effect is that U.S. patients are being forced to pursue leading-edge devices and their associated procedures overseas. As Ryan Drant, a general partner with venture capital firm NEA, put it:

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<sup>25</sup> As noted, availability refers to having achieved regulatory clearance/approval to legally market a device.

Frankly, it's a tragedy. Some of these devices are safely and effectively on the market in Europe for five years before the FDA will even allow them to be used in U.S. clinical trials. The thought that people have to decide whether to forego some potentially lifesaving technology or fly to Europe and figure out some way to pay for it out of pocket, I find very troubling.

Marti Conger became a patient activist, lobbying the FDA for changes in its regulatory practices, after she faced a similar situation. Conger, who was severely debilitated by cervical disc disease, was forced to travel to England to receive the treatment she and her doctor believed would provide the best results. "I couldn't believe I couldn't get the best treatment in my own country," she said. "Finally, I decided my only solution was to find a foreign surgeon with expertise implanting the devices my physician and I deemed most appropriate—even though the devices were made 40 miles from my U.S. home." Conger paid for her surgery with money from her small savings, as well as gifts and loans.

Conger considered herself a voice for millions of U.S. patients who, in her words, "are needlessly suffering, deteriorating, and sometimes dying while they wait for the FDA"—even though the products they need are sometimes widely available out-of-country and with proven track records. "I appreciate [the FDA's] need to protect patients," she said. However, "'absolute assurance' is not a reasonable expectation, as no two bodies are the same. Verify that the product is safe and will function as designed, and then let the patient and doctor make the decision." Conger is lobbying the FDA to accept the regulatory findings of other, trusted nations with strong safety track records (e.g., Europe, Australia, and Japan) or, at a minimum, to "fast track" products that have been cleared/approved in these countries and then monitor them through postmarket studies.

Ross Jaffe, managing director of Versant Ventures, raised an important question for the FDA. "In trying to protect us from things that might not be safe, are we missing out on products that could be very effective?" he asked. By attempting to eliminate safety risks to patients, it is possible that the agency is inadvertently limiting the patient benefits that new technologies can deliver. To truly act in the best interest of patients and the public health, a more holistic perspective is needed. Safety is one important consideration, but there are other equally critical factors to consider. For instance, regulators must take into account the value associated with providing innovative treatments to patients who otherwise might not have any remaining, acceptable options.

### **Implications to U.S. Medtech Innovators, Investors, and Employees**

Since 2008, total annual venture investment in the medtech field has declined by \$1 billion.<sup>26</sup> One reason for this dramatic decrease is the global economic downturn, which began in 2008 and intensified in 2009. However, innovators and medtech investors report that there are other factors contributing to this decline, including the changes that have occurred in the U.S. regulatory environment over the last several years.

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<sup>26</sup> According to data provided by NVCA.

Less transparent and predictable regulatory processes discourage investors from putting their money into medtech companies. This effect is amplified during an economic downturn when less overall capital is available to medtech venture capitalists and the start-ups they fund. Dr. Paul Yock, a renowned innovator and the director of Stanford University's Program in Biodesign, explained the phenomenon:

The development of a new technology of any type is a difficult and fragile process, and the development of a medical technology is a more fragile process still. A major reason for that is regulation. There's a balance that we've gotten reasonably right over the years with being careful about innovation but not stifling it with regulation. But now we have a much more conservative approval process, combined with an economic crunch. Unfortunately for innovators, those two factors can come together to take the gas out of innovation.

Multiple investors confirmed that the escalating cost of bringing medical devices to market is causing funds to flow out of the medtech sector and into other industries where regulation potentially does not exist (or is not perceived as such a significant barrier). As the survey showed, the average cost of taking a product through 510(k) clearance is \$31 million, and the average cost of getting a product through PMA approval is \$94 million (excluding reimbursement and sales/marketing activities). Hank Plain, a partner with Morgenthaler Ventures, pointed out how much these costs have increased:

When I first started as an entrepreneur in the early 1990s, the amount it took to get a product all the way through a PMA was \$30-40 million dollars, which is now what it takes to do a 510(k). So we're seeing a doubling of the cost in a tighter economic environment and with less money available in venture capital.

Historically, investment returns in the device industry are relatively small compared, for example, to those in the biotech and pharmaceutical industries. According to data from the Windhover Strategic Transactions database, approximately 50 percent of medical device exits (for which values were reported) are under \$100 million; 75 percent are under \$150 million.<sup>27</sup> In cases where the cost of getting to market approaches the average exit value, and given the fact that only four out of every 10 medical technology investments is considered successful,<sup>28</sup> the medtech funding equation under these regulatory conditions is crossing into a domain that is no longer viable.

Importantly, as the survey quantified, FDA-dependent product development stages account for a full 77 percent of the cost of bringing a 510(k) product to market and 79 percent for a PMA, so the effect of regulation on this issue should not be underestimated. As David Cassak, managing director of Windhover Information, described:

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<sup>27</sup> Data provided by David Cassak, managing director of Windhover Information.

<sup>28</sup> According to data provided by NVCA.

We've already hit that point where innovators and investors look at the regulatory pathway and say, 'This new technology could be meaningful and could be helpful to patients, but we just can't even take a chance on it.'

Stated another way, the burden of an increasingly difficult and costly regulatory path is not just felt by the companies that are ultimately able to bring their technologies to market. This burden can actually serve as a deterrent that keeps innovators from developing their good ideas into company-backed products. As the rate of FDA submissions continues to decline, patients are being negatively impacted as they are denied the opportunity to experience the life-enhancing benefits of technologies that are never developed into products that can be brought to market.

At the same time that potential rewards in the industry have diminished with rising regulatory costs and approval timelines, medtech risks have also increased. Uncertainty about FDA expectations has become so great that the regulatory process is often characterized as a "moving target." "In our business, what we like to do is try to manage risk," explained Drant. "If you're aware of what a risk is, you can oftentimes manage it adequately and appropriately. But if the FDA keeps moving the goalpost, it's incredibly hard to manage that risk."

Medtech innovators require greater transparency and predictability from the FDA to help bring the risk/reward equation back into alignment. Jaffe commented:

The key issue in my mind is to have a system that can be more efficient, consistent, and predictable in the regulation of devices. That involves having better training of reviewers, better, more up-to-date clinical experts at the FDA who understand the state of the art in what's going on within a specialty, and a process of open and frequent communication between companies and the FDA so we can resolve issues in a reasonable way and move products forward more quickly.

Innovators also expressed the desire to be able to meet with the FDA at the start of a medtech product development project, agree on a meaningful clinical trial strategy, and then execute against it with some reasonable assurance that the agency would honor its agreement. Without such changes, the best and brightest talent in the field will potentially start moving to other technology domains, as venture investors are doing, which could ultimately lead to fewer life-enhancing or life-saving devices being developed to meet patient needs.

### **Implications to the U.S. Economy**

Until recently, device innovation has largely been a U.S. phenomenon—the most important new technologies were invented here, and commercializing them in the sizable U.S. market was at the core most medtech company strategies. However, as medtech hurdles have climbed and available funding has declined, device companies are considering alternative strategies that are less U.S.-dependent. Unfortunately, as described, this means that many new technologies are reaching U.S. patients later than patients in other geographies. It also suggests that the United States is at risk of losing its premier position at the center of the global medtech innovation

ecosystem. As this epicenter shifts, the U.S. economy will be negatively impacted as jobs are moved overseas.

According to Plain, “Every company that I’m involved with now has a European strategy. Ten years ago, many of those companies would have been 100 percent focused on the U.S. for their clinical trials and their product launches. But now what we’re seeing is that it’s completely reversed—Europe is the first area of focus and, in some cases, it’s the only focus.” As medtech companies begin targeting patients and markets outside the U.S., the value of the products they produce and the jobs they create will follow. As Dr. Rodney Perkins, a clinical professor of surgery at Stanford University and a founder of multiple medical device companies, pointed out, “In previous decades, we shipped manufacturing jobs offshore. Now we’re shipping knowledge worker jobs abroad. Once you export innovation jobs, those jobs won’t come back. We need to balance adequate regulatory scrutiny with the rapidly increasing innovation cycle.”

Despite the fact that U.S. politicians are calling for increased innovation and the high-quality, high-salary jobs associated with innovative industries, survey respondents verified in their comments that medtech jobs are moving offshore. For instance, one participant reported that his device company had recently set up overseas operations, firing 19 employees in the U.S. and hiring 12 in Europe. Next, the company planned to shut down its U.S. production facility and move another 30 to 40 manufacturing jobs to Europe. In this particular example, all future growth was also planned overseas. Keeping in mind that every direct medtech job is indirectly responsible for another 4.47 jobs in the national economy,<sup>29</sup> the effect on U.S. employment could be sizable.

While the needs of an industry or the economy at large should never be prioritized over patient safety, it is not clear that the current regulatory obstacles to U.S. market entry truly contribute to the protection and promotion of public health. Given the dire economic condition of the U.S., the trend toward creating exceptional barriers for one of the few remaining industries in which our country is still a leader should be a significant cause for concern.

## **Looking Forward**

Our nation currently faces unprecedented challenges in almost every sector of the economy. However, to individual citizens, nothing is more important than their own health and welfare, as well as the health and welfare of their families. Regulators and innovators have an important responsibility to protect and advance public health, and to maintain the balance between risks and benefits for the patients they serve. In doing so, the patient must remain first and foremost in our minds at all times. Patients can be harmed if unsafe medical technologies reach the market, but they are also harmed when important innovations are not available to treat their medical conditions.

The data presented in this report present a troubling picture of the state of medical device regulation (and its effect on innovation and the advancement of public health) under current FDA

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<sup>29</sup> See “State Impacts of the Medical Technology Industry,” *op. cit.*, p. 12.

policies and practices. The survey results also indicate that the pendulum may have swung too far in one direction and balance again needs to be restored.

As noted, the changes at the FDA that have transpired over the last several years (and that have accelerated in the last two years) have largely been driven by perceived safety concerns. Yet, other than isolated examples and anecdotes, no definitive data has been presented to justify such significant and sweeping adjustments. During this period, regulatory processes in Europe have remained relatively constant, making them a valuable comparator for our own regulatory performance in the U.S. It is clear from the data that the European regulatory process is more predictable, reasonable, and transparent. This system also allows companies to make safe and effective new medical products available to patients more quickly, and at a lower cost. The reasonable question has been raised (and requires an answer) whether greater regulatory efficiency in the EU has been achieved at the expense of patient safety. However, no information is available to date to suggest that patient safety in Europe has been compromised. If the same devices become available in U.S. following their European approval only after extensive delays and additional costs are accrued, we must evaluate whether the U.S. premarket regulatory process is truly contributing to the advancement and promotion of the public health, or if it is actually restraining it.

Today, as we face substantial concerns regarding the cost of healthcare, we also must acknowledge that a substantial number of important patient needs still remain unaddressed. A solution to both of these problems cannot be achieved by delaying new innovations and cost-effective treatments. To truly promote the public health, the FDA must impose reasonable regulatory requirements on new innovations, implement more balanced requirements for premarket and postmarket clinical data, and go back to leveraging market forces to reward technology that presents the greatest value to patients. Only then will the most effective advances in medical care be developed and delivered promptly to American patients; and only then will the public health and our economy be best served.

## Disclosures

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The study was conducted by Dr. Josh Makower and Aabed Meer. Makower is employed as a Venture Partner at NEA, the CEO of ExploraMed Development, and a Consulting Professor at Stanford University. He also serves on the board or as a consultant to several medical device companies. Aabed Meer is a student at Stanford University pursuing an MD and an MBA concurrently. He worked as a summer associate to conduct the study. Lyn Denend, a research associate at Stanford University, was hired to assist in developing this report.

PricewaterhouseCoopers LLP independently verified the data and analysis presented in the report. The views expressed in the Discussion section reflect the perspectives of the authors, the study participants, and select medtech industry representatives who were interviewed by the authors after reviewing the study results.