# Effects of the Medical Device User Fee and Modernization Act on FDA Review Times for Medical Devices

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**Abstract**

In the United States, the safety and efficacy of medical devices are regulated by the US Food and Drug Administration (FDA), which must successfully navigate a crucial tradeoff between speed and safety in approving applications for new devices. Although a shorter (and potentially less thorough) approval process could benefit patients by resulting in quicker access to potentially life-saving therapies, the potential benefits could be outweighed if a shorter approval process allows more unsafe devices to enter the market. In 2002, Congress passed the Medical Device User Fee and Modernization Act (MDUFA), with the aim of pushing the FDA toward the "speed" side of the tradeoff. The MDUFA levied large user fees on manufacturers of medical devices in exchange for the promise of shorter review times by the FDA. Whether the Act has resulted in shorter review times is unclear. We conducted a regression analysis using data on FDA review times for devices seeking approval between 1991 and 2012 to address this question. During the pre-MDUFA era (1991–2002), review times for new devices fell by 8% annually for device applications submitted for approval under the more stringent process of premarket approval and fell by 4.5% annually for devices submitted under the less stringent premarket notification, or 501(k), process. These trends continued during the initial MDUFA era (2003–2008), as well as during the initial period after the law's reauthorization (2008–2012). Our results suggest that, for the years studied, the MDUFA was associated with a *smaller* annual decline in review times and does not appear to have achieved its intended goal of reducing review times for medical devices.

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**FDA Review Times for Medical Devices**

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## 1. Introduction

In the United States, the safety and efficacy of medical devices are regulated by the US Food and Drug Administration (FDA). Typically, new drugs and medical devices must undergo an approval process by the FDA before they can be marketed to the general public. In its role, the FDA must successfully navigate the tradeoff between speed and safety. A shorter (and potentially less thorough) application approval process could benefit patients by resulting in quicker access to potentially life-saving therapies. In addition, a faster approval process could benefit patients by lowering costs for device manufacturers and therefore consumer prices. These potential benefits could be outweighed, however, if a shorter process allows more unsafe or ineffective therapies to enter the market.

In 2002, Congress passed the Medical Device User Fee and Modernization Act (MDUFA), requiring the FDA to "assess and collect fees from manufacturers for review of medical device applications, with the intent of expediting review of device applications."[1] Under the MDUFA, medical device manufacturers now pay large user fees[a] to the FDA when seeking approval for a new device, with the promise that the FDA will move more quickly in making a decision. Specifically, the MDUFA requires the FDA to meet a series of performance goals, such as making a decision within 320 days for certain types of new device applications. On the whole, the goal of the MDUFA is to push the FDA toward the "speed" side of the speed–safety tradeoff,

[a] The fiscal year 2016 user fee for a premarket application for a medical device is $261,388. User fees for other device applications are set as percentages of the premarket approval fee. See https://www.federalregister.gov/articles/2015/08/03/2015-18907/medical-device-user-fee-rates-for-fiscal-year-2016#h-9.

although with additional resources for the FDA, it is possible that the MDUFA could result in gains in both speed and safety.

The question of whether the MDUFA is a net positive for patients depends on two factors: (1) the benefits that patients receive from quicker access to new medical devices and (2) the potential costs (if present) from new devices that are later found to be harmful to patients. Before we can address this question, we must first establish whether the MDUFA has accomplished its intended goal of shorter application review times for medical devices. Indeed, there are concerns from manufacturers that the MDUFA may not have appreciably reduced review times. In a 2006 report commissioned by the FDA, 70% of device manufacturers included in the study report that the MDUFA has not resulted in meaningful reductions in review times,[2] a concern that persists.[3] These concerns are particularly pressing because the user fees levied by the MDUFA are large and have increased since the law's inception.[4] More importantly, whether the MDUFA has shortened review times has important implications for patient health. For example, one study finds that 47% of drug-eluting stents that were available in the European Union were not available in the United States at the same point in time.[5] Other studies have found that drug approval times are generally longer in the United States than in European countries,[6,7] although one study found the opposite.[8]

In this paper, we use publicly available data from the FDA to examine whether the MDUFA was associated with faster review times for medical devices that began the approval process between 1991 and 2012. Although previous work[3] has documented trends in review times, these analyses do not explicitly evaluate the causal effect of the MDUFA. For example, even if decision times remained inappropriately long after the MDUFA, these analyses do not address the issue of whether the review times would have been even longer had the MDUFA not

been enacted. By contrast, our approach attempts to address the causal effects of the MDUFA on application review times. In addition, our analysis examines a broader set of devices compared to other studies. Because the definition of a medical device is broad, covering routine items such as bandages all the way to invasive implements such as pacemakers, the FDA has implemented several regulatory processes for approving new devices. Previous literature[3] has tended to focus on devices approved under the premarket approval (PMA) submission process, which is reserved for devices posing the highest risk to human health and for which substantial premarket clinical testing is required. In this paper, we examine devices approved under the PMA process and expand our analysis to include devices approved under the less stringent premarket notification, or 510(k), process, which accounts for the vast majority of devices requiring premarket approval. During the time period we examined, manufacturers sought FDA approval through the PMA process for 825 devices and through the 510(k) process for 67,491 devices.

Overall, we find that the MDUFA does not appear to have had a material effect on the FDA's review times for the years studied. During the pre-MDUFA era (1991–2002), review times for medical devices fell 8% annually for PMA applications and 4.5% annually for 510(k) applications. We find that this trend continued during the initial MDUFA era (2003–2008), as well as during the period covered by the law's subsequent reauthorization (2008–2012). Our results suggest that, for the years studied, the MDUFA was associated with a *smaller* annual decline in review times. In summary, the MDUFA does not appear to have achieved its intended goals under either the PMA or the 510(k) process for the years studied here.

This paper is organized as follows. Section 2 provides background on the regulation of medical devices and the MDUFA. Section 3 outlines the methods used for our analysis. Section 4 presents our results. Section 5 provides a brief policy discussion and concluding thoughts.

## 2. Background

The FDA, an agency of the US Department of Health and Human Services, is responsible for ensuring the safety and efficacy of drugs and medical devices. The agency's regulatory authority over devices was established by the Federal Food, Drug, and Cosmetic Act, although the 1938 law only gave the FDA legal authority to challenge existing (already marketed) devices thought to be unsafe.

The Medical Device Amendments of 1976 established core standards and processes for evaluating medical devices. Most critically, the 1976 legislation handed the FDA a legal mandate to review medical devices *before* marketing. The regulation of medical devices is particularly complex because of the broad definition of what constitutes a medical device:[9]

> . . . an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similarly or related article, including a component part, or accessory which is:
>
> - recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
> - intended for the use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
> - intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its intended purposes.[b]

Under this definition, a variety of objects used for patient care—from stethoscopes to pacemakers—count as medical devices, with each requiring a different level of scrutiny. Therefore, the Medical Device Amendments of 1976 classified devices into one of three categories, each with its own regulatory requirements:

- *Class I devices* are devices for which a set of regulatory requirements known as "general controls" are sufficient to ensure safety and effectiveness. Broadly speaking, these

[b] This last criterion separates drugs from medical devices.

controls refer to standards regarding manufacturing and premarket notification. Devices in this category typically pose very small risks to health (e.g., stethoscopes, bandages).

- *Class II devices* are devices for which general controls alone are not sufficient to ensure safety and effectiveness and for which there already exist specific standards ("special controls")—such as specific requirements for performance standards or premarket notification—to ensure safety.
- *Class III devices* are devices for which general and specific controls cannot ensure safety and effectiveness. Devices in this class are typically intended to play a large role in sustaining life or health, are expected to pose substantial risks to patients, or both.

Typically, Class I devices do not require premarket approval by the FDA, but they do require premarket notification. Class II and Class III devices almost always require premarket approval, which can be achieved through one of two regulatory processes. Class II devices are brought to market through the 510(k) process, which requires the manufacturer to demonstrate that the device is "substantially equivalent" to an existing device that has received approval.[c] This process typically requires laboratory testing and perhaps a clinical trial.[5] Class III devices are brought to market through the PMA process, which involves substantial premarket clinical testing.

The overall costs of bringing a new device to market, as well as the costs of regulatory compliance, can be substantial. Makower et al. find that the path to market for a 510(k) medical device costs $31 million, of which $24 million reflects regulatory compliance. A PMA device costs nearly $100 million to bring to market, and $75 million of that cost is for regulatory compliance.[10] In addition, there are substantial costs (such as forgone earnings)

[c] Broadly, then, the 510(k) process is analogous to the process used to approve generic drugs.

associated with delays in bringing a new device to market. Makower et al. note that it takes, on average, 2 years longer to bring a new device to market in the United States than in other developed countries.

In October 2002, the MDUFA was signed into law. Its main goal is to streamline and improve the approval process for medical devices. The MDUFA levies user fees on manufacturers seeking FDA approval for new devices and also mandates performance goals for the FDA regarding application review times. As an overall goal, the law specifies that the FDA should issue a first action within 180 days, and a final decision within 320 days, for devices submitted for approval under the PMA process. The FDA should issue a first action within 75 days, and a final decision within 90 days, for devices submitted under the 510(k) process. The MDUFA also specifies that the FDA should meet these goals for an increasing number of applications over time—in fiscal year (FY) 2005, for 75% of devices submitted under the PMA process, with increases to 90% of devices by FY 2007. Also, the MDUFA initially set user fees at $154,000 for PMA applications and $2,187 for 510(k) applications.[d] However, the MDUFA allowed fees to vary in accordance with inflation as well as revenue targets for the FDA. Because revenue initially failed to meet the targets, device manufacturers saw sharp initial increases in user fees, which reached $239,237 for PMA applications in FY 2005. Although the user fees paid by manufacturers are small relative to the total cost of bringing a new device to market, the fees form a substantial portion—nearly half—of the FDA's budget.[11]

Early reaction to the MDUFA was mixed. Although device manufacturers applauded the overall intent of the MDUFA, many thought the law failed to achieve its intended goal and many were concerned about the sharp initial increases in user fees.[2] The FDA's own data bear out

[d] These amounts were (and are) substantially discounted for small businesses.

some of these concerns. In FY 2006, the proportion of PMA applications that received a decision within 320 days was 81%. Although this value slightly exceeded the target of 80%, it represented a *decrease* from the approximately 90% rates reported for FY 2002–2004.[12]

The MDUFA contained a sunset provision that required its reauthorization after 5 years. The law was renewed as part of the Medical Device User Fee Amendments of 2007 (MDUFAII). As noted previously, in an effort to slow growth in the amount charged for user fees, the 2007 amendments lowered the fees in exchange for other new fees for manufacturers—an establishment fee (an annual levy on each device manufacturer) and a product fee (in essence, an annual levy for each Class III device). In addition, the MDUFAII set slightly more stringent performance goals for the FDA and contained another 5-year sunset provision.[13] The MDUFA was reauthorized a second time as part of the Food and Drug Administration Safety and Innovation Act of 2012. This legislation provides a broader definition of who is required to pay user registration fees, which were projected to raise $595 million over 5 years in exchange for increased performance goals and performance reporting on the part of the FDA.[14]

Whether the MDUFA has been a net positive for patients depends on two factors: the benefits to patients from faster access to new medical devices and the potential costs from unsafe devices released into the market. As a first step in evaluating the MDUFA, it is important to measure whether it has accomplished its stated goals of reducing the FDA's application review times. Indeed, there are concerns that the legislation has failed to do so, particularly since the median approval time for Class III devices has *increased* since 2002.[3] These concerns are particularly salient because the MDUFA is due for another reauthorization in 2017. Moreover, the law has now been in existence for nearly 14 years, so there is a wealth of data available to help understand its effects. Understanding the degree to which the MDUFA has reduced

application review times by the FDA could inform policymakers about ways to modify the law and address any shortcomings during the 2017 reauthorization process.

Although recent work has presented descriptive trends in the FDA's review times,[3] these trends cannot fully address whether the MDUFA has reduced review times. For example, although median review times by the FDA increased from 2002 to 2012, a potential counterargument is that *even larger* increases in review times would have resulted without the MDUFA. Philipson et al.[15] examine whether the 1992 Prescription Drug User Fee Act—the analogue of the MDUFA for pharmaceuticals—is associated with a decrease in the review times for new drug applications. Overall, that study finds that PDUFA was associated with an additional 10% per year decrease in drug review times for drugs undergoing review between 1979 and 2002. In this paper, our goal is to apply methods similar to those of Philipson et al. to estimate the effect of the MDUFA on application review times for new devices.

## 3. Methods

This section outlines our empirical approach, which is based on previous work examining the effect of the Prescription Drug User Fee Acts on drug review times.[15] Section 3.1 describes the data used in our analysis. Section 3.2 describes our empirical approach.

### *3.1. Data*

The data used for this study consist of application review times for all medical devices for which approval by the FDA was sought under the 510(k) or PMA process between January 1, 1991, and December 31, 2012. These data are publicly available from the FDA and for each device include a unique identifier, the date the PMA process began, and the date of the

agency's final decision.[e] In addition, the data report the general therapeutic class for each device (which can be inferred from the FDA advisory committee that reviewed it), as well as whether the device was selected for priority review.[f] Because the data include only devices for which a final decision had been made, we chose December 31, 2012, as the cutoff date because final decisions may not have been made for more recent applications for new devices.

Our initial dataset consisted of 19,471 PMA applications and 81,430 applications submitted under the 510(k) process. We then applied the following exclusion criteria. For 510(k) devices, we excluded devices that received approval through a third party (n = 2,376),[g] although we explored the effect of the MDUFA on these devices in separate subanalyses described below. In addition, we limited our analysis to devices that were classified as having been approved under the "traditional" 510(k) pathway.[h] For PMA applications, the vast majority of applications (n = 18,646) in the FDA data pertain to supplements to an original application, such as a supplement required as a result of changes in the manufacturing process. We excluded most of these supplemental applications and restricted our analysis to applications for new devices and "panel track" supplements. The latter are supplements used to seek approval for substantive changes in a device's design. Our final sample consists of 67,491 applications submitted under the 510(k) process and 825 PMA applications (684 new devices and 141 panel track supplements).

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[e] The data can be downloaded at http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/ for PMAs and http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/ucm089428.htm for 510(k)s.

[f] Devices eligible for priority review are typically novel devices intended to treat life-threatening or otherwise serious conditions. See http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089643.htm#s3.

[g] The FDA now allows an increasing number of Class II devices to be reviewed and approved by a third party. For a list of devices eligible for third-party review, see http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfThirdParty/current.cfm#2.

[h] There are two additional pathways—the "special" 510(k) pathway and the "abbreviated" 510(k) pathway. In essence, the former imposes additional restrictions and requirements relative to the traditional pathway, and the latter provides for an abbreviated process for a small subset of devices.

### *3.2. Empirical Approach*

Our empirical approach closely mirrors the approach used by Philipson et al.[15] In essence, by using the experience of devices submitted for FDA approval during the pre-MDUFA era, we first identified the presence of any secular trends in device review times. We then used a linear regression to examine whether the MDUFA altered this secular trajectory.

We implemented our approach by using a multivariable linear regression in which the dependent variable is the natural log of the number of days elapsed between initiation of the PMA or 510(k) process and the date of the FDA's final decision. We then included a trend variable associated with the year the device was submitted for approval (1996 = 1, 1997 = 2, etc.). This variable represents the initial, pre-MDUFA trend in review times. To estimate the effect of the MDUFA on this trend, we generated two indicator variables: the first variable equals 1 if the device was submitted for approval in the MDUFA era (2003–2007), and 0 otherwise. The second indicator variable (MDUFAII) equals 1 if the device was submitted for approval in the first reauthorization period (MDUFAII: FY 2008–FY 2012), and equals 0 otherwise. It is important to note that MDUFA and MDUFAII officially took effect starting in FY 2002 (October 1, 2002) and FY 2007 (October 1, 2007), respectively. However, to allow for the possibility that the FDA and drug manufacturers may not have reacted immediately to these changes, our indicator variables for whether these laws were in effect were based on the nearest calendar year following the enactment date (January 1, 2003, for MDUFA, and January 1, 2008, for MDUFAII).

We then interacted these indicator variables with our trend variable; the coefficient on the interacted variables describes the extent to which the MDUFA and the MDUFAII each altered the preexisting trend in application review times. As additional controls, we included the

therapeutic class for each device, which we inferred from the FDA advisory committee that reviewed each device. We also included a control for whether the device received priority approval. We performed separate analyses for applications submitted under both the PMA and the 510(k) processes. A more detailed explanation of our approach is given in the appendix.

### *3.3. Subanalyses and Robustness Checks*

In addition to the main analyses described in 3.2, we performed analyses for 510(k) device applications that underwent third-party review. The Food and Drug Administration Modernization Act of 1997 allowed Class I 510(k) applications to be reviewed by a third-party entity, called an "Accredited Person." In 1998, the program was expanded to include Class II devices that are not permanently implantable, life sustaining, or life supporting and those for which clinical data are required. After review, the Accredited Person forwards the review and recommendation to the FDA, and the agency must make a decision within 30 days.[16] The number of 510(k) device applications that underwent review by third parties substantially increased from 0.0468% of devices in 1996 to 11.4% of devices in 2008, falling to 5.89% of devices in 2012. By using the methods described previously, we also examined the effect of the MDUFA on review times for devices undergoing review by a third party.

In addition to the subgroup analyses described previously, we performed two analyses to examine the robustness of our model to alternative specifications. First, we performed the same analyses described previously, except that we used the actual number (as opposed to the natural log) of days as our measure of review time. Second, the analyses described previously examined whether the MDUFA, during the years studied, was associated with a change in secular trends in review times. Another approach would be to examine the average change in review times

associated with the MDUFA directly. For this analysis, we used a linear regression in which the dependent variable is the review time itself. Our model includes controls for therapeutic class (as previously defined) and priority review. The independent variables of interest are indicator variables equaling 1 if the MDUFA or the MDUFAII was in effect and 0 otherwise. In effect, this approach compares the average review times between the pre- and post-MDUFA periods, after adjusting for differences in therapeutic class and new device applications submitted for priority review.

## 4. Results

This section presents the results of our analysis. Section 4.1 presents some descriptive trends in the review times for devices for which approval was sought through the 510(k) and PMA processes. Section 4.2 presents the results of our regression analysis, which examines the extent to which the MDUFA succeeded, during the years studied, in lowering the FDA's application review times.

### *4.1. Descriptive Trends*

Table 1 (page 26) presents descriptive statistics for our sample. The table shows that, during the years 2003–2012, the MDUFA and the MDUFAII had, at best, mixed effects on review times. For PMA applications for new devices, the FDA's average review time was 524.6 days (SE = 21.4) in the pre-MDUFA era, 524.3 days (SE = 32.6) in the MDUFA era, and 535 days (SE = 32.2) in the MDUFAII era. For 510(k) applications, the average review time was 148.1 days (SE = 0.678) in the pre-MDUFA era, 120.8 days in the MDUFA era (SE = 0.962), and 165.4 days (SE = 1.12) in the MDUFAII era.

This mixed effect is also suggested by Figures 1 and 2 (pages 27–28), which present descriptive trends for our sample. Figure 1 shows the mean and median review times for devices submitted for approval under the PMA process during 1991–2012. Figure 2 shows the mean and median review times for applications approved under the 510(k) process during 1991–2012. Qualitatively, both figures suggest that the MDUFA may have done little to improve review times. In the case of PMA applications, Figure 1 shows a general decline in review times during the starting period, with the median review time falling from 885 days in 1991 to 360 days in 2012. However, most of this decline appears to have occurred in the pre-MDUFA era, as the median review time fell from 885 days in 1991 to 323 days in 2002. By contrast, review times *rose* during the MDUFA era of 2003–2007, with the median review time reaching a peak of 661 days in 2007. For applications approved under the 510(k) process, median review times actually increased from 89 days in 1991 to 132 days in 2012. Review times were generally constant in the pre-MDUFA era, with a median of 89 days in 1991 and a median of 85 days in 2002. By contrast, review times were much higher during the post-MDUFA era, with a peak time of 134 days in 2010, falling slightly to 132 days in 2012. It is important to note that these statistics do not take into account such possibilities as differences in the types of devices submitted for approval or the number of devices submitted for priority review, which we address below in our regression analysis.

Figure 3 (page 29) shows the number of devices seeking approval through the 510(k) and PMA pathways for the years 1991–2012,[i] as well as the number of full-time employees assigned by the FDA for device application review. These values were obtained from various sources.[17-20]

[i] Recall that our data are limited to devices that received a final decision from the FDA; the values shown in Figure 3 are the total number of devices for which approval was sought (including devices that may not have received a final decision or that were withdrawn from consideration).

It is important to note that, as a result of the MDUFA, the FDA changed the way it counts the number of new device applications submitted in a given year. Specifically, in the pre-MDUFA years, the agency reported the total number of applications it received. After the MDUFA, the FDA reported the total number of applications that received a decision by the agency and excluded applications that were closed without a decision (e.g., applications that were rejected by the FDA or were withdrawn by the manufacturer). Figure 3 suggests that, for the years studied, the number of new device applications decreased (as in the case of 510(k) applications) or stayed fairly constant (as with PMA applications), whereas the number of full-time FDA employees assigned to application review largely increased. Overall, it appears that, for 2003–2012, the MDUFA resulted in an increase in the number of FDA employees devoted to new device application review.

### *4.2. Regression Analysis*

Figures 1 and 2 qualitatively suggest that the MDUFA may not have reduced review times during 1991–2012, because the actual times were *higher* in the post-MDUFA era. The goal of our regression analysis was to determine whether these initial qualitative impressions withstood closer scrutiny. The results of our analyses for PMA applications are shown in Table 2 (page 30), and our results for 510(k) applications are shown in Table 3 (page 31). These tables present two sets of results. The first ("base model") is a simple regression in which only the trend variables described previously are incorporated. The second ("extended model") incorporates controls for therapeutic class and whether the new device application received priority review by the FDA. Overall, our results are robust to either model specification. For PMA applications, we find that review times fell by 8% per year (Table 2) during the pre-MDUFA period (1991–2002). The

trend was not significantly altered in either the MDUFA period of 2003–2007 or the MDUFAII period of 2008–2012. If anything, the annual decline in review times was *smaller* in magnitude during the MDUFA and MDUFAII periods, although the difference (<0.1% per year) is of little policy significance.[j] Similarly, in the case of 510(k) applications, our results show a 4.52% annual decline in the pre-MDUFA era (Table 3). Again, the annual decline was significantly *smaller* (from a statistical perspective) during the MDUFA and MDUFAII time periods, but the difference (again, <0.1% per year) is of little policy significance.

### *4.3. Subanalyses*

We considered a variety of alternative specifications to our model. First, instead of using the natural log of review times, we considered specifications where we the review times themselves would be used. The results are shown in Tables 2 and 3. Overall, the results remain the same: we find a general downward decline in application review times during the study period that is largely unaffected by the MDUFA. In another specification, we considered a simpler model that examines the effect of the MDUFA on average application review times (Table 4, page 32). We again find that the MDUFA was not associated with any change in review times in the case of PMA applications. For 510(k) applications, our results do suggest a decrease of roughly 34 days ($P = .039$) during the MDUFA era but no change during the MDUFAII era. We caution that the latter set of results was not adjusted for any underlying secular trends.

Finally, we examined the effect of the MDUFA during the same years on review times for 510(k) applications that underwent review by third parties (see Table 5, page 33). Again, we find that both the MDUFA and the MDUFAII had no significant effect on the FDA's review

[j] The difference is statistically significant at the $P < .001$ level.

times. However, our point estimates are large in magnitude, suggesting the possibility that our study was underpowered to find significant effects, particularly given the small number of devices (2,376) in this subsample.

## 5. Conclusions

The MDUFA was enacted in October 2002 with the goal of improving patient health by streamlining the FDA's approval process for applications for new medical devices, thereby allowing patients quicker access to potentially life-saving therapies. Since its inception, the MDUFA has been the subject of some controversy, given sharp increases in user fees charged to device manufacturers during the law's early years, as well as general concerns from industry that the law has not succeeded in lowering the FDA's review times.

Our results confirm these concerns. We find that review times were already declining before the MDUFA and that the MDUFA did nothing to accelerate the decline. Rather, our results suggest the opposite—that, during 2003–2012, the MDUFA actually slowed the decline, although the magnitude of the change is of little practical significance. We conclude that, for the years studied, the MDUFA did not achieve its intended goal of shortening review times for applications for new medical devices.

Why the MDUFA failed to achieve its intended goal is a complex topic. A simple first response could be that the user fees paid by device manufacturers were not allocated toward increasing the FDA's review staff. However, we find that the number of applications for new devices remained fairly constant during our study period, while the number of FDA full-time employees increased. At first glance, then, it appears that the issue is not a lack of agency resources. However, it is possible that the source—in addition to the level—of resources may

influence the FDA's behavior. For example, the agency may feel less pressure to be efficient knowing that it is funded by user fees, compared to being funded out of general appropriations.

One possibility, suggested by the FDA itself, is that increased review times are the result of poorer-quality applications that require additional scrutiny by the FDA and then application revisions by the device manufacturers.[21] Closely related to this possibility is the hypothesis that medical devices have become more complex over time, thereby necessitating longer reviews by the FDA. In assessing this possibility, it is important to note the distinction between two types of review times: (1) the review times reported by the FDA (and used to assess whether it has met its performance goals) and (2) the total amount of time between application submission and a decision date. The difference between the two is that the former stops when the FDA makes a request for more information, even though calendar days obviously continue. If the FDA makes repeated requests from a device manufacturer for revisions and additional information, there may be little or no change in the FDA's reported review time, even as the total time to decision increases. There certainly appears to be support for the notion that the FDA is placing more requirements on device manufacturers. For example, a 2013 report from the US Government Accountability Office finds that, because of time spent gathering additional information for the FDA, the average time to final decision for 510(k) applications increased from 100 days to 161 days between FY 2005 and FY 2010.[22]

An alternative hypothesis is that the FDA has become more cautious or less efficient over time.[23] A recent report details a number of deficiencies in the FDA's medical device review divisions, including excessive staff turnover, a lack of mentoring and succession planning, and a lack of understanding on the part of reviewers about the changing mission of the FDA's device

review divisions. Beyond these systemic challenges, the report notes that the FDA exhibits "inconsistent decision making" including "a lack of transparency in thresholds or requirements used to trigger additional information requests."[24] These problems have persisted despite large increases in staff levels dedicated to device application review.

Our results should be viewed in the context of their limitations. Although our empirical approach considered a wide variety of controls and alternative specifications, pinning down causality is difficult in a situation where there are no obvious controls (given that the MDUFA affected all devices at the same time). Second, the FDA reports data only for device applications for which a decision has been made, so our analysis implicitly excluded applications for which a decision remained outstanding for the periods studied. Still, including those devices would most likely *exaggerate* our findings, because the excluded devices were more likely to have been submitted in later years (i.e., the post-MDUFA era) and the applications for those devices would have tended to have had longer review times.

In summary, patients are better off when they can receive timely access to new medical therapies. Although the MDUFA was enacted with the hope of accomplishing this goal, our analysis suggests that the law had no effect on device applications review times for the years 2003–2012. By contrast, another analysis found that the 1992 Prescription Drug User Fee Act was successful in review times for prescription drugs, and that the faster review times were of tremendous value to patients.[15] Although the same may not necessarily hold for the MDUFA, it seems likely that shorter review times by the FDA for new medical devices could provide similar benefits for patients. For patients to realize these benefits, however, policymakers must ensure that the MDUFA accomplishes its stated goal of reducing review times for new devices. Because our analysis suggests that the MDUFA did not do so over the 2003–2012 period,

policymakers and researchers should enhance their efforts to understand and address why the MDUFA has been unsuccessful in reducing the FDA's review times for applications for new medical devices.

**Appendix**

In this appendix, we outline in more detail the regression models used in our analysis. Our baseline analyses estimate the following regression:

$$ln(review_{it}) = \Gamma X_i + \beta_1 trend_t + \beta_2 trend_t \times MDUFMA_t + \beta_3 trend_t \times MDUFAII_t + \varepsilon_{it}. \quad (1)$$

In equation (1), $i$ indexes the device and $t$ indexes the year. $X_i$ is a vector of device characteristics (its therapeutic class and whether it received priority review by the FDA), and $trend_t$ is a trend variable that captures a linear trend (= 1 for the year 1991, = 2 for the year 1992, etc.). $MDUFMA_t$ is an indicator variable that equals 1 if the MDUFA is in effect and zero otherwise (therefore, it equals 1 in years 2003–2007 and 0 otherwise). $MDUFAII_t$ is an indicator variable that equals 1 if MDUFAII is in effect and 0 otherwise (therefore, it equals 1 in years 2008–2012). $\beta_1$, $\beta_2$, and $\beta_3$ are our coefficients of interest. $\beta_1$ represents the overall secular trend in review times during the sample period, measured in percentage terms. For example, if $\beta_1$ is to equal −0.08, it would suggest an overall decline in review times of 8% annually. $\beta_2$ and $\beta_3$ represent the degree to which this overall trend changed during the MDUFA and MDUFAII eras. For example, if $\beta_2$ is to equal 0.05, it would suggest that—relative to the overall trend—review times increased by 5% annually during the MDUFA era. Or, using the previous example (where $\beta_1 = -0.08$), this would suggest that review times declined by 3% during the MDUFA era (because −0.08 + 0.05 = −0.03).

Our subsequent analyses are variants of equation (1). First, we considered an alternative specification in which the actual review times are used rather than the natural log of review times:

$$review_{it} = \Gamma X_i + \beta_1 trend_t + \beta_2 trend_t * MDUFMA_t + \beta_3 trend_t \times MDUFAII_t + \varepsilon_{it}. \quad (2)$$

Equation (2) is similar to equation (1), except that the dependent variable is now the actual review times, as opposed to the natural log of review times. With this specification, the

interpretation of $\beta_1$, $\beta_2$, and $\beta_3$ remains largely the same, except that the coefficients now express annual changes in *days* (as opposed to percentage changes). For example, if $\beta_1$ were to equal 10, this would suggest that review times fell by 10 days annually.

These two specifications examine the effect of the MDUFA on annual trends in review times. In a final specification, we examine the effect of the MDUFA on the review times themselves:

$$review_{it} = \Gamma X_i + \beta_1 MDUFA_t + \beta_2 MDUFAII_t + \varepsilon_{it}. \quad (3)$$

In equation (3), the trend variable was removed. The coefficients $\beta_1$ and $\beta_2$ now represent the degree (measured in days) to which the average review times in the MDUFA and MDUFAII eras differed from the average review times in the pre-MDUFA era.

Because observations in a given year may be correlated, the standard errors for all our analyses were adjusted for clustering at the year level.

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**Table 1. Sample Characteristics for Devices Seeking Approval, 1991–2012**

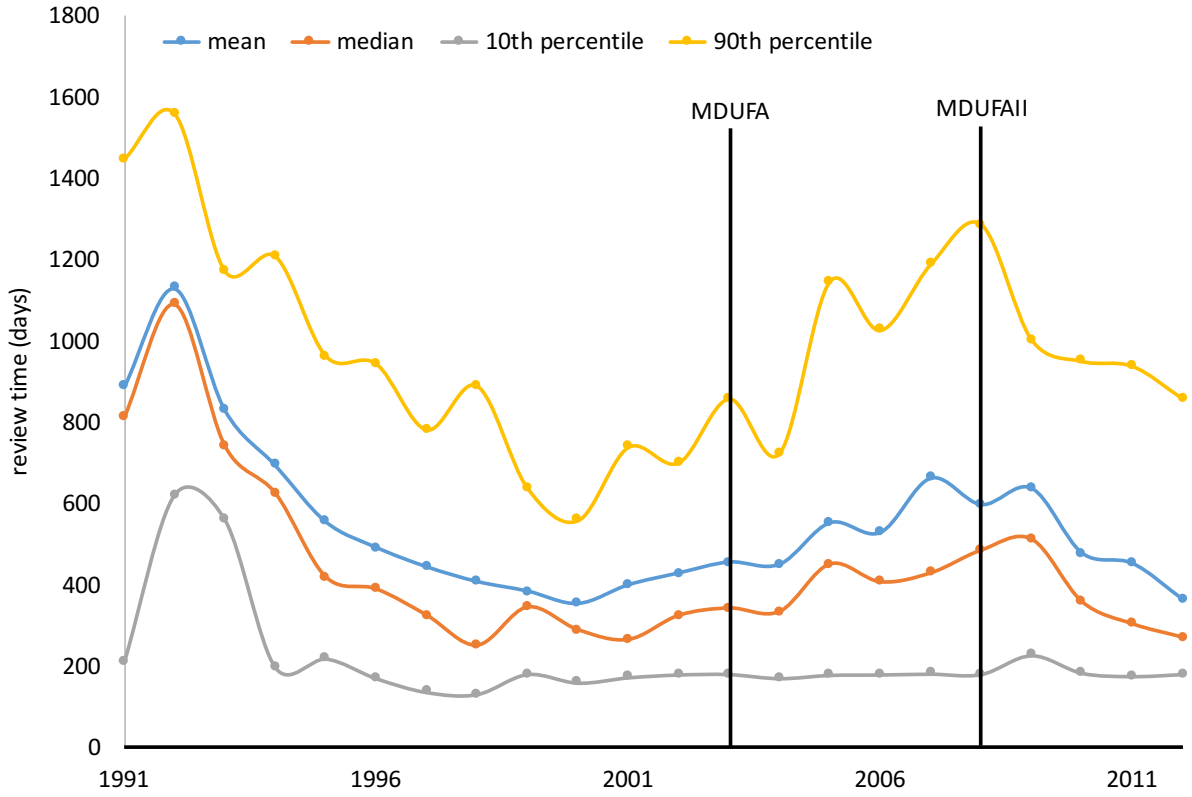
| | Pre-MDUFA (1991–2002) | MDUFA (2003–2007) | MDUFAII (2008–2012) |
|---|---|---|---|
| No. of applications | | | |
| PMA (new applications) | 384 | 169 | 131 |
| PMA (panel track supplement) | 76 | 35 | 30 |
| PMAs receiving priority review | 76 | 24 | 19 |
| 510(k) | 46,222 | 10,797 | 10,472 |
| Average review time (days) | | | |
| PMA (new applications) | 524.6 | 524.3 | 535 |
| | (21.4) | (32.6) | (32.2) |
| PMA (panel track supplement) | 381.9 | 449.6 | 298.8 |
| | (33.1) | (74.9) | (33.2) |
| 510(k) | 148.1 | 120.8 | 165.4 |
| | (0.678) | (0.962) | (1.12) |

Abbreviations: MDUFA, Medical Device User Fee and Modernization Act; MDUFAII, Medical Device User Fee Amendments; PMA, premarket approval.

Note: Standard errors are given in parentheses where applicable.

Sources: Data for PMAs are from the Food and Drug Administration, "PMA Approvals," last updated January 26, 2016, http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/; data for 501(k)s are from the Food and Drug Administration, "Downloadable 501(k) Files," last updated June 6, 2014, http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/ucm089428.htm.

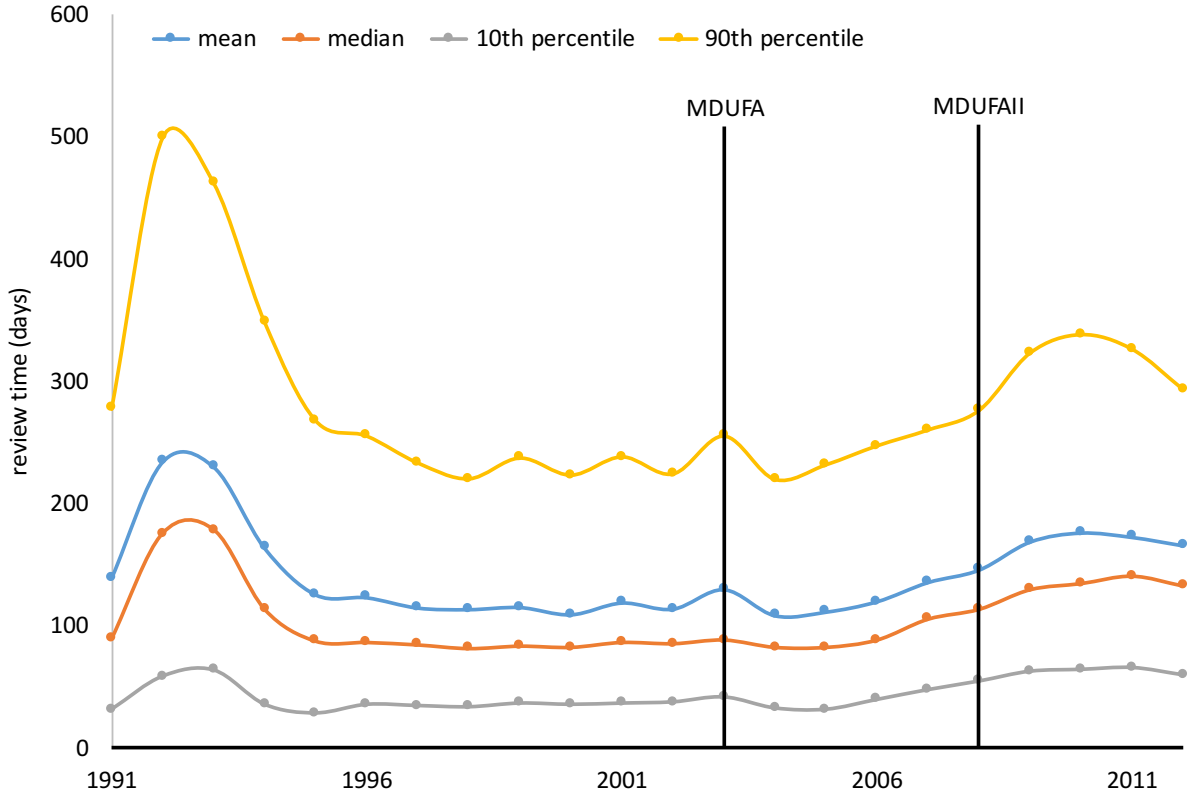
**Figure 1. Annual Mean and Median Review Times for Device Applications Submitted for Approval under the PMA Process, 1991–2012**




Abbreviations: MDUFA, Medical Device User Fee and Modernization Act; MDUFAII, Medical Device User Fee Amendments.

Source: Data are from the Food and Drug Administration, "PMA Approvals," last updated January 26, 2016, http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/.

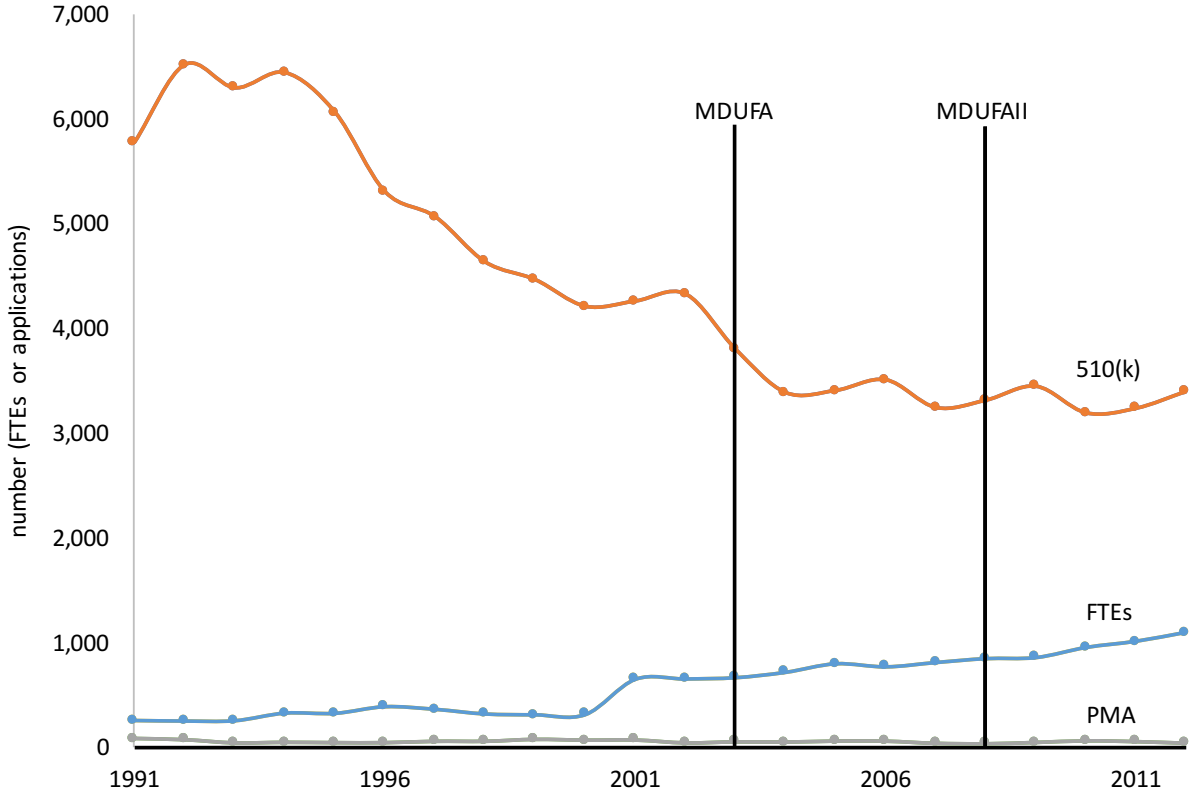
**Figure 2. Annual Mean and Medium Review Times for Device Applications Submitted for Approval under the 510(k) Process, 1991–2012**




Abbreviations: MDUFA, Medical Device User Fee and Modernization Act; MDUFAII, Medical Device User Fee Amendments.

Source: Data are from the Food and Drug Administration, "Downloadable 501(k) Files," last updated June 6, 2014, http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/ucm089428.htm.

**Figure 3. Number of PMA Applications, 510(k) Applications, and FDA Full-Time Employees for Device Application Reviews, 1996–2012**




Abbreviations: FDA, US Food and Drug Administration; FTEs, full-time employees; MDUFA, Medical Device User Fee and Modernization Act; MDUFAII, Medical Device User Fee Amendments; PMA, premarket approval.

Note: The number of submissions in the post-MDUFA era is not completely comparable to the number of submissions in the pre-MDUFA era; see text for details.

Sources: Various congressional and FDA reports.

## Table 2. FDA Review Times for PMA Applications for New Medical Devices

| | ln(review time) | | (review time) | |
|---|---|---|---|---|
| | Base Model | Extended Model | Base Model | Extended Model |
| | (1) | (2) | (3) | (4) |
| Pre-MDUFA trend | −8.03*** | −8.11*** | −46.5*** | −46.0*** |
| (1991–2002) | (1.76) | (1.77) | (11.0) | (10.9) |
| MDUFA trend | 0.0297*** | 0.0283** | 0.167 | 0.161** |
| (2003–2007) | (0.00803) | (0.00788) | (0.0451) | (0.0442) |
| MDUFAII trend | 0.0506*** | 0.0508*** | 0.282 | 0.281*** |
| (2008–2012) | (0.00108) | (0.00106) | (0.0659) | (0.0645) |
| N | 825 | 825 | 825 | 825 |
| $R^2$ | 0.0841 | 0.1384 | 0.0854 | 0.1484 |

* $P < .05$; ** $P < .01$; *** $P < .001$.

Abbreviations: FDA, US Federal Drug Administration; MDUFA, Medical Device User Fee and Modernization Act; MDUFAII, Medical Device User Fee Amendments; PMA, premarket approval.

Note: The value shown for the pre-MDUFA trend is the annual decline in FDA review times in percentage terms (columns 1 and 2) or in days (columns 3 and 4) during the pre-MDUFA time period. For the MDUFA (2003–2007) and MDUFAII (2008–2012) time periods, the value shown is the change in annual decline *relative to the pre-MDUFA* period. For example, the annual percentage decline in review times during the MDUFA period was roughly −8.03 + 0.0297 = −8 percent (column 1) or roughly −46.5 + 0.167 = −46.4 days (column 3). *Base model* refers to our initial regression, which contained only the trend variables described above. *Extended model* refers to a more extensive regression in which we included controls for therapeutic class and whether the application was selected for expedited review. Coefficients for these controls are not shown but are available on request. Standard errors, adjusted for clustering by year, are shown in parentheses.

Sources: Data for PMAs are from the Food and Drug Administration, "PMA Approvals," last updated January 26, 2016, http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/; data for 501(k)s are from the Food and Drug Administration, "Downloadable 501(k) Files," last updated June 6, 2014, http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/ucm089428.htm.

## Table 3. FDA Review Times for 510(k) Applications for New Medical Devices

| | ln(review time) | | (review time) | |
|---|---|---|---|---|
| | Base Model | Extended Model | Base Model | Extended Model |
| | (1) | (2) | (3) | (4) |
| Pre-MDUFA trend | −4.43* | −4.52* | −8.35* | −8.46* |
| (1991–2002) | (1.99) | (2.03) | (3.20) | (3.29) |
| MDUFA trend | 0.0144 | 0.0140 | 0.0247* | 0.0246* |
| (2003–2007) | (0.00706) | (0.00711) | (0.0112) | (0.0114) |
| MDUFAII trend | 0.0440*** | 0.0437** | 0.0680** | 0.0678** |
| (2008–2012) | (0.00120) | (0.0121) | (0.0195) | (0.0197) |
| N | 67,491 | 67,491 | 67,491 | 67,491 |
| $R^2$ | 0.0424 | 0.0917 | 0.0398 | 0.0752 |

* $P < .05$; ** $P < .01$; *** $P < .001$.

Abbreviations: FDA, US Food and Drug Administration; MDUFA, Medical Device User Fee and Modernization Act; MDUFAII, Medical Device User Fee Amendments.

Note: The value shown for the pre-MDUFA trend is the annual decline in FDA review times in percentage terms (columns 1 and 2) or in days (columns 3 and 4) during the pre-MDUFA time period. For the MDUFA (2003–2007) and MDUFAII (2008–2012) time periods, the value shown is the change in annual decline *relative to the pre-MDUFA* period. For example, the annual percentage decline in review times during the MDUFA period was roughly −4.43 + 0.0144 = −4.3 percent (column 1) or roughly −8.35 + 0.0.0247 = −8.3 days (column 3). *Base model* refers to our initial regression, which contained only the trend variables described above. *Extended model* refers to a more extensive regression in which we included controls for therapeutic class and whether the application was selected for expedited review. Coefficients for these controls are not shown but are available on request. Standard errors, adjusted for clustering by year, are shown in parentheses.

Sources: Data for PMAs were from the Food and Drug Administration, "PMA Approvals," last updated January 26, 2016, http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/; data for 501(k)s were from the Food and Drug Administration, "Downloadable 501(k) Files," last updated June 6, 2014, http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/ucm089428.htm.

**Table 4. Effect of the MDUFA on Average Review Times by the FDA for PMA and 510(k) Applications for New Medical Devices**

| | PMA Applications | | 510(k) Applications | |
|---|---|---|---|---|
| | Base Model | Extended Model | Base Model | Extended Model |
| | (1) | (2) | (3) | (4) |
| MDUFA (2003–2007) | 10.4 | 7.71 | −33.6* | −34.1* |
| | (57.0) | (53.6) | (15.2) | (15.5) |
| MDUFAII (2008–2012) | −10.1 | 1.0 | 8.7 | 7.8 |
| | (60.7) | (52.0) | (15.5) | (15.9) |
| N | 825 | 825 | 69,867 | 2,376 |
| $R^2$ | 0.0003 | 0.0676 | 0.0102 | 0.0464 |

* $P < .05$; ** $P < .01$; *** $P < .001$.

Abbreviations: FDA, US Food and Drug Administration; MDUFA, Medical Device User Fee and Modernization Act; MDUFAII, Medical Device User Fee Amendments; PMA, premarket approval.

Note: *Base model* refers to our initial regression, which contained only the trend variables described above. The coefficient shown is the change in review times (measured in days) associated with MDUFA or MDUFAII, relative to the non-MDUFA period. *Extended model* refers to a more extensive regression in which we included controls for therapeutic class and whether the application was selected for expedited review. Coefficients for these controls are not shown but are available on request. Standard errors, adjusted for clustering by year, are shown in parentheses.

Sources: Data for PMAs are from the Food and Drug Administration, "PMA Approvals," last updated January 26, 2016, http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/; data for 501(k)s are from the Food and Drug Administration, "Downloadable 501(k) Files," last updated June 6, 2014, http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/ucm089428.htm.

## Table 5. Effect of the MDUFA on Device Review Times for 510(k) Applications Reviewed by a Third Party

| | ln(review time) | | (review time) | |
|---|---|---|---|---|
| | Base Model | Extended Model | Base Model | Extended Model |
| | (1) | (2) | (3) | (4) |
| Pre-MDUFA trend | 8.16*** | 7.20*** | 3.76* | 3.32* |
| (1991–2002) | (2.25) | (2.03) | (1.39) | (1.29) |
| MDUFA trend | −10.8 | −8.07 | −2.85 | 1.67 |
| (2003–2007) | (11.1) | (10.0) | (6.84) | (6.28) |
| MDUFAII trend | −18.2 | −7.8 | −6.45 | −1.31 |
| (2008–2012) | (22.1) | (19.4) | (13.6) | (12.0) |
| N | 2,376 | 2,376 | 2,376 | 2,376 |
| $R^2$ | 0.0555 | 0.1646 | 0.039 | 0.1189 |

* $P < .05$; ** $P < .01$; *** $P < .001$.

Abbreviations: FDA, US Federal Drug Administration; MDUFAII, Medical Device User Fee Amendments; MDUFA, Medical Device User Fee and Modernization Act.

Note: The value shown for the pre-MDUFA trend is the annual decline in FDA review times in percentage terms (columns 1 and 2) or in days (columns 3 and 4) during the pre-MDUFA time period. For the MDUFA (2003–2007) and MDUFAII (2008–2012) time periods, the value shown is the change in annual decline *relative to the pre-MDUFA* period. For example, the annual percentage change in review times during the MDUFA period was roughly 8.16 −10.8 = −2.6 percent (column 1) or roughly 3.76 − 2.85 = 0.91 days (column 3). *Base model* refers to our initial regression, which contained only the trend variables described above. *Extended model* refers to a more extensive regression in which we included controls for therapeutic class and whether the application was selected for expedited review. Coefficients for these controls are not shown but are available on request. Standard errors, adjusted for clustering by year, are shown in parentheses.

Sources: Data for PMAs are from the Food and Drug Administration, "PMA Approvals," last updated January 26, 2016, http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/; data for 501(k)s are from the Food and Drug Administration, "Downloadable 501(k) Files," last updated June 6, 2014, http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/ucm089428.htm.