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Analysis Of Medical Device Reclassification: An Evaluation Of The 515 Program Initiative

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ABSTRACT

Background: The US Food and Drug Administration (FDA) is in charge of regulating medical devices and one key power the FDA has to ensure safety and effectiveness of these devices is risk reclassification. One example of this regulatory power is the 515 Program Initiative, where the FDA was tasked with reclassifying preamendment devices that had never undergone initial rigorous review before entering the market.

Objective: The objective of this thesis project is to characterize the device types reassessed under this program and determine what characteristics the FDA heavily considers when making a risk classification determination.

Methodology: Data was collected on all 23 device types reviewed through this initiative on a variety of characteristics: therapeutic area, implantable, life-sustaining, reclassification mechanism, prior 510(k)s, devices out after reclassification, advisory committee decisions, recalls, and public comments. Additionally, Fisher exact tests were conducted to assess whether these characteristics were associated with final risk classification decisions.

Results: Of the 23 classification rules and orders, 15 called for downclassifications from Class III to Class II or Class I device types and 8 called for devices to remain Class III. Most device types characteristics were not significantly associated with the downclassification decision, except for advisory committee decisions ($P = 0.000$) and reclassification mechanism ($P = 0.000$).

Conclusion: The FDA should consider these key regulatory processes when making reclassification decisions. These findings suggest that the FDA prioritizes certain key players, such as experts within advisory committees, during their decision-making process and that regulatory burdens could both help and hinder the FDA's mission to ensure safety and effectiveness.

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INTRODUCTION

One power under the FDA's authority in order to protect the public from unsafe medical devices is reclassification of medical devices into new risk categories if they pose more or less risk, after these devices have been on the market for some time. One example of this is the 515 Program Initiative, where the FDA was tasked with re-evaluating preamendment devices and their current risk category. But there are concerns over whether the FDA may be downclassifying devices that still pose high levels of risk, raising additional safety concerns. To understand the relative importance of the 515 Program Initiative, I examined key factors that go into the FDA's decision-making process with regards to medical device regulation as a whole.

Medical devices in the US have been regulated since the 1938 Federal Food, Drug, and Cosmetic Act but they were originally regulated under an expanded definition of drugs, rather than a device-specific statute. Despite their inclusion under the 1962 Kefauver-Harris amendments, which first required the use of clinical trials during pre-market review, devices were not required to undergo any clinical trials prior to approval. It was not until 1976, when Congress passed the Medical Device Amendments (MDA), where medical devices were required to undergo a more rigorous pre-market review process.[i]

As established by the MDA, medical devices are now regulated by their risk classification. There are three risk classifications: Class I, low risk; Class II, moderate risk; and Class III, high risk. Only Class III medical devices undergo pre-market approval (PMA), which requires a "reasonable assurance of device safety and effectiveness" involving at least one pivotal clinical trial. Class I and II medical devices are either required to meet general controls or receive clearance through the 510(k) pathway. The 510(k) pathway requires that the new device is "substantially equivalent" to another predicate device(s), which does not require clinical data,

unless the FDA asks for it, which the FDA rarely does.[ii] "Substantial equivalence" is based on similarity to predicates, which are devices that have already been cleared by the FDA, even if these predicate devices have been recalled because of ineffectiveness or safety concerns. Although the 510(k) pathway was intended to regulate only moderate-risk devices, this pathway was temporarily used for preamendment devices that were initially regulated as Class III, with the FDA intending to downclassify them or keep the Class III classification and require PMA applications.

As another safeguard to protect patient safety, the FDA has the authority to request Post-Approval Studies or 522 postmarket surveillance studies. Post-approval studies require the same clinical rigor as PMA studies but occur after approval and can be a condition of devices approved through the PMA pathway.[iii] Similarly, the FDA can require a manufacturer to conduct 522 postmarket surveillance studies of a Class II or III device, based on certain risk and safety criteria.[iv] Both are used to help ensure the safety of riskier medical devices, but not only does the FDA rarely require them but also many of these studies are not completed.[v]

Since 1976, all new devices have been risk classified and reviewed accordingly. But, as there were many devices on the market prior to the creation of the MDA, Congress needed to determine how to reassess those devices, referred to as preamendment devices. These preamendment device types were automatically given a Class III risk designation until further FDA review to assess if these devices warranted a Class III designation or could be downclassified. But despite the need to review these devices, it was a lower priority for the FDA in practice as the FDA still had many preamendment devices to assess.

To facilitate this process of reanalyzing these preamendment devices, as well as to improve the reclassification process to more effectively regulate new devices, the FDA kicked

off the 515 Program Initiative, named after the section of the Food, Drug, and Cosmetic Act (FD&C Act) it draws its power from, which used the agency's rulemaking power to reclassify devices. But in 2012, as part of the Food and Drug Administration Safety and Innovation Act (FDASIA) amended Section 515 of FD&C Act, which originally required the final administrative action to use rulemaking and now has altered it to utilize an administrative order process. More specifically, under FDASIA changes to Section 515, the FDA used a 5-step reclassification process to finalize classification for the devices: (1) review existing scientific information to assess risks and benefits, (2) convene expert advisory panel, (3) issue proposed risk classification, (4) review public comments, and (5) issue final risk classification.[vi] Additionally, to change the classification of the device, the proposed new class needed to have sufficient regulatory controls to provide reasonable assurance of safety and effectiveness for its intended use. As of 2009, 26 medical device regulations still required action. Under the 515 Program Initiative, by the end of 2019, the FDA had finalized their classifications.[vii]

These steps to reclassification are critical because they serve as ways to ensure the FDA is considering the safety and effectiveness considerations from all angles. The expert advisory panel ensures the FDA is in line with recent medical literature and practice of these devices. Similarly, the public comments serve as the FDA's main mechanism to listen to patients and other stakeholders but this could be interesting to evaluate and determine if the FDA listens to specific groups more heavily.

All in all, the 515 Program Initiative is important because it speaks to larger issues within the FDA, e.g., how it goes about reclassifications, regulatory burdens, and how these actions connect to the FDA's greater mission of ensuring patient safety. Most importantly, this program speaks to the FDA's authority and their use of it to compel rigorous evaluation and evidence to

inform practices (both during the premarket and postmarket phases). The results from this program play a large role in whether future devices could be more or less safe when introduced to the market and how this could impact patients. The program is not only representative of many of the FDA's internal activities but it is also the key to understanding the motivations of the FDA with regards to their broader decision-making processes and how well it is carrying out its patient-oriented mission.

The objectives of this thesis are to assess the 515 Program Initiative and characterize the downclassifications of preamendment devices. Moreover, this assessment aims to elucidate the process of FDA-decision making, by analyzing what factors the FDA is considering when deciding whether to downclassify a device. I suspect that a few factors play a key role in whether the FDA decides to downclassify a specific device.

METHODOLOGY

I constructed the sample of device types from all remaining preamendment device types that needed to be reevaluated under the 515 program and were therapeutic devices (not diagnostic), which were pulled directly from the FDA website as making this information publicly accessible is explicitly required in the FDASIA. Ultimately, 23 devices were evaluated for this study.

Downclassifications

For all devices undergoing reevaluation, the FDA could choose to keep them as Class III devices, downclassify to Class II or Class I, or split reclassify them, where the original device type is downclassified but the FDA creates a new device type as an offshoot of the original that is designated as Class III. For the purposes of this paper and its analysis, devices that were split-reclassified will be considered as "downclassified" as well.

Device Type Base Characteristics

Using information from the publicly accessible FDA "Product Classification" database, I was able to classify each device type in the sample by the following characteristics: division of care / therapeutic area, implantable designation (yes / no), life-sustaining designation (yes / no), and whether device type was reclassified via rule or order. A few other characteristics were also evaluated. Pulling from the Post-Approval Studies (PAS) Database, I searched through this database to determine whether any of these device types had PAS/522 requirements. Additionally, to assess whether the device types had devices approved through the 510(k) pathway and had devices out after the reclassification decision, I used the premarket notifications (510(k)s) database and premarket approvals (PMA) database. Advisory committee history was reviewed through a reading of the final rules and orders.

Recall History

In order to characterize each device type's recall history, I used the "Recalls of Medical Devices" database. Using each device type's unique product code, I was able to search through the database and record the number of recalls by level of recall (Class I-III, with Class I being the highest risk recall and Class III the lowest risk recall; this study will only examine Class I and Class II recalls).

Public Comments

For public comments, I was able to pull them by searching each device type's reclassification order / rule using its docket numbers into regulations.gov. After comments were found, they were sorted into categories of where they came from: patient, patient advocacy organization (PAO), health professional, health care association (HCA), academia, device industry, government, or other organizations. For all but one device type, all comments were

read and assessed for whether the comment supported or did not support downclassification. The one device type that did not have all its comments read was due to the high quantity of comments. While most other device types' orders / rules faced a maximum of 300 comments, one device type received 3000 comments. In order to prevent this device type's results from skewing further analysis, I took a random sample of 300 of its comments to characterize its public comments.

Statistical Analysis

First, I used descriptive statistics to characterize the device type sample, to evaluate commonalities among devices that were downclassified and devices that were not downclassified. More specifically, we used descriptive statistics when evaluating all of the device type base characteristics. We looked further into recall rates, before and after reclassification along with the percentage of recalls within each class of recall risks. Similarly, public comments were evaluated overall but also dependent on whether the device was later downclassified.

Second, we then used Fisher exact tests to assess whether any of these factors could predict downclassifications by testing bivariate associations between each of the device type characteristics and whether it was downclassified. Analyses were all performed using Stata version 16.0.

RESULTS

Table 1. Individual device types reviewed under the 515 Program Initiative

Year	Device	Therapeutic Area	Stayed Class III	Downclassified	Split - reclassified
2011	Topical Oxygen	General & Plastic Surgery		x	
	Female Condom	Obstetrics / Gynecology	x		
	Pacemaker Repair or Replacement Material	Cardiovascular	x		
	Ventricular Bypass Device	Cardiovascular	x		
2012	Implantable Pacemaker Pulse Generator	Cardiovascular	x		
	Pacemaker Programmers	Cardiovascular	x		
	Cardiovascular Permanent Pacemaker Electrode	Cardiovascular	x		
2013	Temporary Mandibular Condyle Reconstruction Plate	Dental		x	
	Intra-aortic Balloon and Control System	Cardiovascular			x
	External Counter-pulsating Devices	Cardiovascular			x
2014	Sorbent Hemoperfusion System	Gastroenterology / Urology			x
	Endosseous Dental Implant (Blade-form)	Dental		x	
	Implanted Blood Access	Gastroenterology / Urology		x	
2015	Automated External Defibrillators	Cardiovascular	x		
	Nonroller-type Blood Pump	Cardiovascular			x
	Shortwave Therapy	Physical Medicine		x	
2016	Extracorporeal Circuit & Assessories For Long-term Respiratory/Cardiopulmonary Failure (ECMO)	Cardiovascular		x	
	Hip joint metal/metal semi-constrained, with an uncemented and cemented acetabular component, prosthesis	Orthopedic	x		
	External Pacemaker Pulse Generator (EPPG)	Orthopedic		x	
	External Cardiac Compressor (ECC)	Cardiovascular		x	

	Thoracolumbosacral Pedicle Screw Systems and Semi-Rigid Systems	Orthopedic		x	
2018	Electroconvulsive Therapy Devices	Neurology			x
2019	Cranial Electrotherapy Stimulator	Neurology			x

Table 2. General characteristics of device types reviewed under the 515 Program Initiative

	No. (%)	Downclassified?	*p*-values*
Therapeutic area		15	0.531
Cardiovascular	12 (52.2%)	6	0.193
Dental	2 (8.7%)	2	0.526
Gastroenterology / Urology	2 (8.7%)	2	0.526
General & Plastic Surgery	1 (4.3%)	1	1.000
Neurology	2 (8.7%)	2	0.526
Obstetrics / Gynecology	1 (4.3%)	0	0.348
Orthopedic	2 (8.7%)	1	1.000
Physical Medicine	1 (4.3%)	1	1.000
Implantable			
Yes	8 (34.8%)	4	0.371
No	15 (65.2%)	11	
Life-sustaining			
Yes	2 (8.7%)	2	0.526
No	21 (91.3%)	13	
Reclassification Mechanism			
Final rule	16 (69.6%)	14	0.002
Final order	7 (30.4%)	1	
PAS / 522 Requirements			
Yes	1 (4.3%)	0	0.348
No	22 (95.7%)	15	
Prior 510(k)s			
Yes	21 (91.3%)	15	0.111
No	2 (8.7%)	0	
Devices out after reclassification			
Yes	15 (65.2%)	11	0.371
No	8 (34.8%)	4	
Advisory Committee Decision			
Agrees with final classification	22 (95.7%)	14	0.000
Disagrees with final classification	1 (4.3%)	1	

* *p*-values were derived from Fisher Exact tests.

Of the 23 classification rules and orders, 8 called for the devices to remain Class III device types, 9 called for downclassifications to Class II, and 6 called for split-reclassifications (Table 1). Across the device types, 8 (34.89%) are implantable and only 2 (8.7%) are life-sustaining (Table 2). The most prevalent therapeutic area is cardiovascular, as it made up 12 of the 23 (52.1%) device types. Overall, 21 (91.3%) device types had at least one device approved through the 510(k) pathway and 15 (65.2%) have produced new devices since the final classification announcement (Table 2). Only one device (4.3%) required either PAS or 522 requirements. Additionally, 14 of the 15 devices that were ultimately downclassified faced advisory committee decisions that supported this classification.

Table 3. Recall history and public comments for 515 device types.

	No. (%)	Downclassified?	*p*-values
Recalls		10	1.000
Class I	8 (34.8%)	4	0.371
Class II	15 (65.2%)	10	1.000
Public Comments		13	0.131
Academia	7 (30.4%)	5	1.000
If device received comments	7 (41.2%)		
Device Industry	7 (30.4%)	6	0.345
If device received comments	7 (41.2%)		
Government	1 (4.4%)	0	0.348
If device received comments	1 (5.9%)		
Health Care Associations	7 (30.4%)	5	1.000
If device received comments	7 (41.2%)		
Health professionals	8 (34.8%)	7	0.176
If device received comments	8 (47.1%)		
Other organizations	3 (13.0%)	2	1.000
If device received comments	3 (17.7%)		
Patients	5 (21.7%)	4	0.621
If device received comments	5 (29.4%)		
Patient Advocacy Organizations	16 (69.6%)	12	0.182
If device received comments	16 (94.1%)		

Recalls

Overall, 15 (65.2%) device types have had at least one device face either a Class I or Class II recall. For Class I, 8 devices faced at least one Class I recall, that is 34.7% of all devices and 53.3% of devices that faced at least one recall. For Class II recalls, 15 devices faced at least one Class II recall, that is 65.2% of all devices and 100% of devices that faced at least one recall. Additionally, all 8 devices that faced at least one Class I recall also experienced at least one Class II recall.

Public Comment

17 (73.9%) of device types received at least one public comment. Out of the 8 potential sources for comments, PAOs had the greatest turnout rate, as they commented on classification announcements of 16 (94.1%) devices out of the 17 that received at least one comment. The next highest turnout was in health professionals, by commenting on 8 (47.1%) devices. Then HCAs, academics, and the device industry each commented on 7 devices (41.18%). In similar ranges, patients responded to 5 devices (29.4%) and other non-specified organizations commented on 3 devices (17.7%). Lastly, government entities only commented on 1 device (5.9%). Despite most devices receiving at least one public comment, none of these public comment categories were associated with the final device classification.

Predictors of Downclassification

Most device type characteristics were not significantly associated with final classification decision. Notably, none of the therapeutic areas were associated with downclassifications (P = 0.531) (Table 2). Similarly, whether or not a device type received public comments, both in general and across types of submissions, was not associated with downclassifications (P = 0.131)

(Table 3). Recalls were found not to be associated with downclassifications (P = 0.250; P = 0.448) (Table 3).

But, there were two characteristics that were significantly associated with downclassifications. All final device classifications directly aligned with the advisory committee decisions, as there is a statistically significant association between these (P = 0.000) (Table 2). Similarly, most devices that were classified through final rule stayed Class III, whereas most devices classified through final order were down classified. The classification mechanism was also associated with final device classifications (P = 0.000) (Table 2).

DISCUSSION

This evaluation of the 515 Program Initiative, done by delving into the device reclassifications instigated through this procedure, demonstrates that reclassifications (and, more specifically, downclassifications) are largely device-specific but are decided with heavy influence from key stakeholders and administrative procedures. All 23 device types that were re-assessed through this initiative were assessed on a variety of characteristics and were found to be largely heterogeneous but some associations were found between these characteristics and final classification. Determining these significant associations can lend itself to elucidating important factors to the FDA's decision-making process, which can both positively and negatively impact patient safety.

Most device characteristics were not significantly associated with the final classification decisions but two factors did show potential for being predictors. First, the advisory committee opinion seemed to play a huge role in whether the device type was down classified. For all device types, all advisory committee decisions directly aligned with the final decision to downclassify, except for one device where the FDA specifically indicated the advisory

committee decision was made prior to significant evidence that changed the science base for reclassification. This alignment signifies the key role of advisory committees to not only device classifications but also in FDA decision-making as a whole, as various statutes regarding the FDA requires the FDA to confer with advisory committees before proceeding. This finding is consistent with previous studies evaluating the relationship advisory committee decisions and FDA actions, which confirms that these committee opinions play a large role in FDA decisions.[viii] As this influence is large, this suggests that the FDA may need to more effectively consider and evaluate who ends up on an advisory committee, considering the impact advisory committees have.

Second, whether the device type was downclassified through a final rule or final order playing a role could be telling over the role of regulatory burden on decision-making. The results indicated that more device types that were classified through a final rule were not downclassified than device types classified through a final rule. Given that a final order is easier to pass than a final rule, this indicates that the amount of regulatory scrutiny placed on a device undergoing evaluation plays a role in whether the device gets downclassified or not. This falls in line with previous literature, suggesting that the FDA is overloaded and may take steps to reduce the regulatory burden across the board, in order to increase innovation but potentially at the expense of safety.[ix]

Of note, there were two characteristics that were not significantly associated with the final classification that could signify greater problems within the reclassification process: recalls and public comments. Recalls did not show to be significantly associated with the final classification. This is an area for concern because the FDA has come under criticism for not appropriately handling devices that cause many recalls. As it stands, only a few device types

cause the majority of recalls. Most of those device types tend to be in the cardiovascular therapeutic area; a decent amount of the device types evaluated under the 515 Program Initiative were cardiovascular and were downclassified, despite evidence of recalls. This is particularly of interest because the literature has found that most recalls resulting from cardiovascular medical devices and, more specifically, a small subset of cardiovascular devices, a few of which were downclassified through this initiative.[x] This brings into question how much the FDA may be evaluating the risks of these devices based on real-world evidence.

Public comments also did not play a distinct role in whether the devices were downclassified. Across the spectrum of where the comments came from, none were shown to be significantly associated with the final risk specification. This is consistent with the current literature that regulatory agencies largely listen to comments to enhance their current position rather than alter their decisions dependent on the comments.[xi] Although this is a required component to the regulatory process and the FDA does address significant comments in the final rule and order write-ups, this assessment shows that the public comment portion may serve as an administrative specification rather than playing a role in the FDA's decision-making process.

Additionally, through the characterization of these medical devices, we see that the remaining devices that needed to be evaluated under the 515 Program Initiative are quite diverse. There were not too many similarities across the general characteristics, other than that most were cardiovascular and not life-sustaining, although these characteristics also make up the majority of devices currently on the market. This could again suggest that the FDA must take a considerable amount of time in order to look at these device classification decisions, which may cause the FDA to proceed on the path that leads to the least future regulatory burdens.

Moving forward, these results could provide insight on the FDA's decision-making, especially as it relates to device risk reclassifications, since, at the same time as the creation of the 515 Program Initiative, the FDA also launched changes to Section 513, which made it also easier from a regulatory perspective to reclassify *de novo* devices. That being said, now that the FDA has finished classifying devices under the 515 Program Initiative, it could have more time to dedicate to the *de novo* reclassification process. But these findings should be considered as the FDA approaches reclassifications overall because this is a key power that the FDA has in order to protect the public, in line with its core mission.

This analysis has several limitations worth consideration. First, when assessing public comments, for many of the devices, at least a few comments were blocked from review by regulations.gov or the FDA itself. Therefore, not all comments could be viewed. With some devices only receiving a few comments with half of those blocked, this could have skewed the results. Additionally, one device received over 1000 comments. To ensure that this device's comments would not mask the results of other devices that received fewer comments, a sample of 300 comments were taken for analysis. This could additionally be not as representative of these comments as assessing all comments from this device type. Second, as there were only 26 devices that needed to be reevaluated under the 515 Program Initiative, the sample size was very small. It is difficult to accurately say these results are not simply random. Third, the 515 Program Initiative is special in two respects: it began to tackle a specific problem and that these devices are inherently unique. Congress created this to assist the FDA in their long-term effort to reclassify these devices. The incentives to make this a speedy process may not apply to current or future reclassification efforts by the FDA. These preamendment devices are very different from devices that now come up as *de novo* devices that are seeking reclassification.

All in all, these findings suggest that the FDA prioritizes certain key players, such as experts within advisory committees, during their decision-making process and that regulatory burdens could both help and hinder the FDA's mission to ensure safety and effectiveness. Although the 515 Program Initiative is special in its own right, it gives us much to think about for the future of regulatory bandwidths, how the FDA may choose to review devices, and, most importantly, how FDA decisions may impact patient safety.

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