

## FDA Regulation of Medical Devices and Medical Device Reporting

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### Abstract

There are three main stakeholders in medical device regulation: people in industry, regulators and practitioners. A medical device report is filed after a device-related adverse event occurs. Studies show that while most medical device reports begin with practitioner observations, people in industry file 97% of reports and practitioners file 3% of reports. The objectives of this article are to identify the major areas of focus in medical device regulation according to industry, regulators, and practitioners, and to investigate the feasibility of increased practitioner participation in medical device reporting. The author interviewed 5 industry, 5 regulators, and 6 practitioners. The stakeholders' views were influenced by their personal distribution on the importance of outcomes such as cost, speed, safety and effectiveness. Industry, regulators and practitioners' main perspectives were that medical device regulation is inconsistent and unpredictable, and that the US medical device industry is lagging behind Europe. Individual stakeholder goals were not aligned and caused bias resulting in a varied depiction of FDA regulation of medical devices. A practitioner-focused survey on medical device reporting was sent to 1567 practitioners in the University of Pennsylvania Health System. 340 survey responses showed that 46% of practitioners have witnessed a medical device failure, but only 19% have ever filed a medical device report. The survey results revealed that practitioners do not currently have enough experience or knowledge about medical device reporting to participate effectively and positively impact postmarket surveillance.

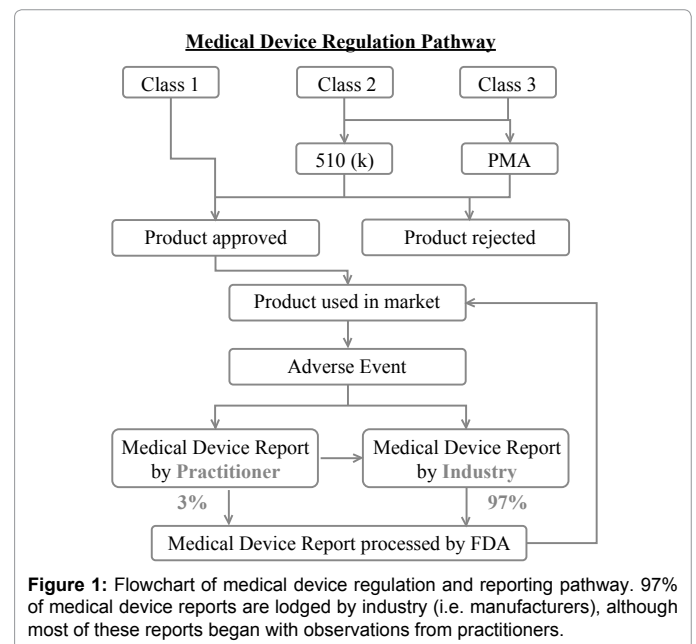
**Keywords:** Medical device; FDA regulation; Device regulation

### Introduction

The field of medical device regulation has three main stakeholders: industry, regulators and practitioners. Industry consists of medical device companies that manufacture and sell medical devices. Regulators include both governmental and non-governmental affiliated regulators. These can be government officials who are employed by the FDA to regulate medical devices, risk management teams at academic institutions that create medical devices, watchdog organizations, executives involved in the public policy sector of medical devices and other executives who act as a liaison between the FDA and an organization that creates but does not sell medical devices. Practitioners are doctors, nurses, and technicians who handle medical devices that are available on the market. Practitioners administer these medical devices to patients. Industry, regulators and practitioners' viewpoints significantly influence the creation of new medical device regulation. It is the FDA's responsibility to ensure that medical device regulation best serves industry, regulators and practitioners while approving medical devices that are safe and effective. This study aims to identify the prevalent and overlapping viewpoints industry, regulators and practitioners hold regarding medical device regulation.

The general medical device regulation process, as shown in Figure 1, begins with the classification of medical devices into one of three classes: Class I (non-risky devices such as gloves, bandages), Class II (moderately risky devices such as infusion pumps and stents), and Class III (risky devices such as defibrillators, pacemakers). Once classified, the medical device must be submitted through either a 510(k) approval process, for devices that use a predicate technology, or the more rigorous premarket approval (PMA) process, for devices that use a novel technology that has not been proven safe and effective beforehand. In general, the PMA process is significantly more time and resource intensive than the 510(k) process, requiring additional clinical trials to prove the device's safety, effectiveness and intended use. Once approved, the medical device enters the market. If and when an adverse event occurs, a medical device report must be sent to the FDA. An adverse event is classified as either a device-related serious injury or a device-related death. A medical device report can be lodged by anyone, including the general public, but the manufacturer of the medical device is mandated by the FDA to report the adverse event.

These mandatory reports from manufacturers account for 97% of the total reports lodged [1]. The FDA then processes the report and decides on the next course of action: recalling the device, reclassifying it, ordering a redesign from the manufacturer or other.



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The medical device reporting system is the principal means by which the FDA monitors the safety and effectiveness of a device after approval [2]. It is a passive system, relying on practitioners to correctly identify the occurrence of a device-related adverse event and to initiate a report through to the manufacturer and/or the FDA [3]. Approximately 80,000 to 120,000 device-related adverse event reports are filed annually [4]. Of these, roughly 5,000 reports are received through MedWatch, the FDA's medical device report database for health institutions [4]. Of concern, a study by the General Accounting Office concluded that only 0.5% of all device-related adverse events are reported to the FDA [1]. Recently, the FDA has expressed interest in improving the current medical device reporting system. Among the initiatives: modernizing its adverse event reporting and analysis, increasing the number of medical device reports received electronically, developing a mobile app for adverse event reporting to facilitate the submission of voluntary reports by health care providers and patients [5].

The current standard among practitioners is not to report. When a practitioner lodges a report, liability and legal concerns that can be traced directly back to the practitioner are raised. Further, the immediate reaction from the manufacturer when a practitioner initiates a report is to place blame on the practitioner's human error instead of on a possible medical device failure [6]. Instead, practitioners choose to bring problems to front by conducting research and publishing a study proving the medical device failure [6]. This can take a year or two at which point, the device may have already be taken off the market. This study aims to investigate the feasibility of increased practitioner participation in medical device reporting.

## Methods

### Interviews

For this study, preliminary interviews were conducted to identify major areas of investigation in the medical device regulation field. These were done in person, when possible, and over the phone. Each interviewee was asked a standardized set of questions using the same script to limit the interviewer's influence on the responses. Interviewees were asked to describe their previous experience with medical devices, whether they identified as industry, regulator or practitioner, and to describe concerns they had with the current regulation of medical devices and medical device reporting in the United States. Industry, regulators, and practitioners were identified as main stakeholders in the medical device field. In total, five industry experts, five regulators, and six practitioners were interviewed. These numbers were purposely balanced to limit bias and ensure the responses reflected a well-rounded view of medical device regulation. The emphasis on medical device reporting was to allow for preliminary investigation for the practitioner-focused survey that supplemented the interview in this study.

### Survey development

Mandatory reports from institutions and manufacturers account for about 97% of the medical device reports, although most of these reports began with observations from healthcare practitioners [1]. Of the reports made by practitioners, it was estimated that nurses were the most frequent reporters (25% of reports) and physicians rarely reported events (8% of reports) [7]. Literature identified medical device reporting as an area for improvement in medical device regulation, in particular with regard to practitioners since it was observed that although practitioners were usually the source of information for adverse event reports, they rarely lodged the actual report. This survey aimed to investigate the feasibility of enhancing healthcare practitioner

participation in medical device reporting and by doing so, increasing overall medical device reporting. As such, this survey focused on medical device reporting from the perspective of practitioners. Participants were limited to practitioners of the University of Pennsylvania Health System.

Before creating the survey, the author was certified by the International Review Board of the University of Pennsylvania (IRB) to conduct research. IRB enforced provisions that protected physicians' privacy restricted the survey's scope of questioning. To maximize response rates, the survey was limited to six concise questions and an option to enter a raffle for a gift card at the end of the survey was utilized. Questions were specifically formulated to assess the knowledge and experience of practitioners regarding medical device reporting. A standardized recruitment email was used for all surveys. The survey was created and managed using Qualtrics, a survey tool. The survey was then submitted and later, approved by the IRB.

### Survey administration

Survey participants were limited to healthcare practitioners of the University of Pennsylvania Health System. The survey was circulated via Department Chairs using a pre-approved recruitment email. No private information was collected from practitioners, with the exception of practitioners' e-mail addresses that were entered optionally at the end of the survey for a raffle. These e-mail addresses were not matched to responses. Participants were not otherwise compensated for their participation. Results were analyzed using Qualtrics after a two-month data collection period.

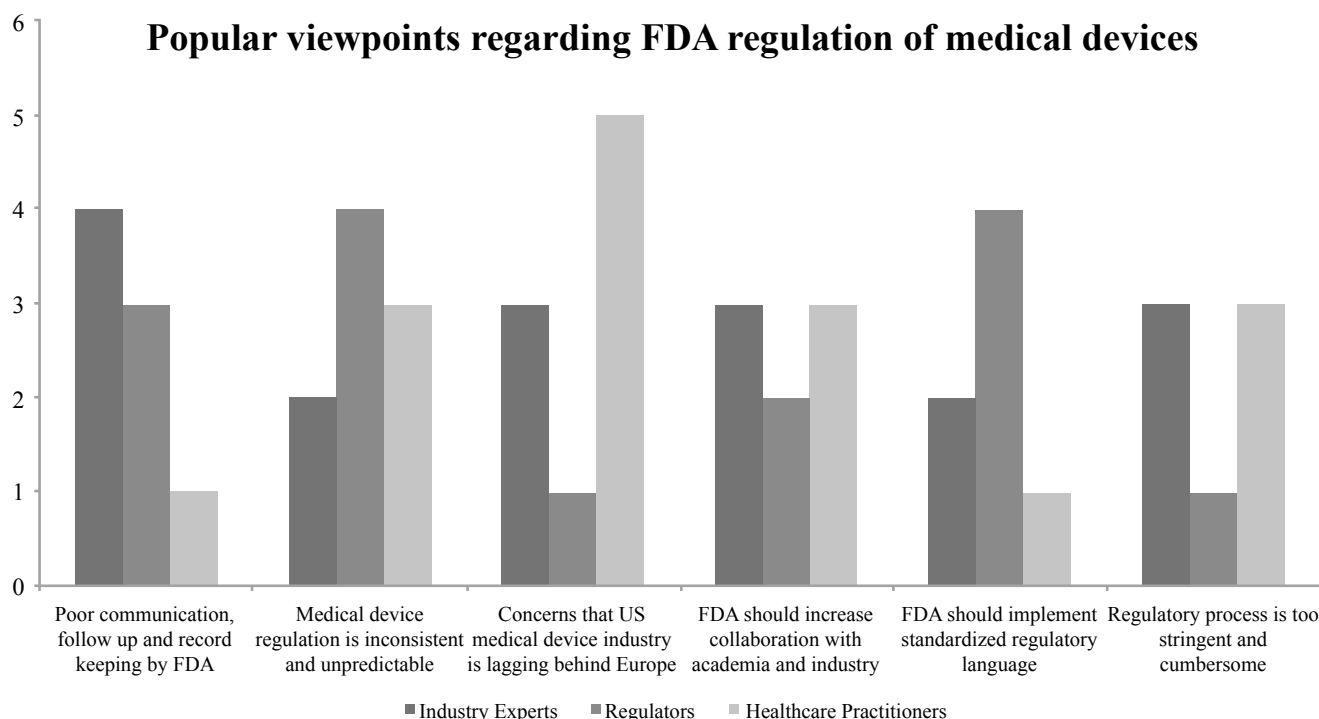
## Results

### Qualitative interview results

Of the sixteen people interviewed, there were five industry experts, five regulators and six healthcare practitioners. It is important to note that qualitative results from these interviews were derived completely from the interviewees and were not guided or suggested by the interviewer. The interviewees identified six popular viewpoints regarding FDA regulation of medical devices (in descending order):

- (1) concerns that the United States medical device industry is lagging behind Europe (56%),
- (2) medical device regulation is inconsistent and unpredictable (56%),
- (3) poor communication, follow up and record keeping by the FDA (50%),
- (4) FDA should increase collaboration with academia and industry (50%),
- (5) FDA should implement standardized regulatory language (44%), and
- (6) the medical device regulatory process is too stringent and cumbersome (44%).

Certain issues appeared more important to particular stakeholders as shown in Figure 2 below. Qualitative data from the interviews showed that industry experts were most concerned about the FDA's poor communication, follow up and record keeping (4/5), regulators were most interested in the implementation of a standardized regulatory language (4/5) and the inconsistent and unpredictable nature of medical device regulation (4/5), whereas practitioners were most concerned that the medical device industry in the US was losing out to Europe (5/6).



**Figure 2:** Popular viewpoints regarding FDA regulation of medical devices gathered from interviews conducted with industry experts, regulators and healthcare practitioners.

Additional viewpoints were (in descending order): the need for standards to allow for easy reclassification of devices registered under PMA to 510(k) (38%), congress and budget concerns (31%), FDA and CMS are disjoint and should be aligned (25%), postmarket surveillance is lacking and should be streamlined with premarket approval (25%), FDA regulation is viewed as not stringent enough (25%), clinical studies required for FDA approval are poorly constructed (19%), the challenges posed by hybrid drug-device products (19%), and FDA regulation is viewed as quick, straightforward and satisfactory (19%).

Interviewees were also asked to share their perspectives regarding medical device reporting. Overall, it appeared as though practitioners did not have any prominent views on medical device reporting as observed by their limited input during interviews. The main viewpoint that arose from the interviews regarding medical device reporting was that the current medical device reporting system requires more sophisticated data mining techniques, use of standardized language and unique device identifiers to operate more effectively (50%). This viewpoint was unanimously supported by regulators (5/5). A secondary viewpoint was that manufacturers should continue to submit the majority of medical device reports to the FDA – a view that was shared by four industry experts, three practitioners, but no regulators (44%).

Other perspectives regarding Medical Device Reporting were (in descending order): practitioners should be educated on medical device reporting practices (31%), legal protection for physician reporting (25%), mandated return of faulty products to manufacturers to allow for better troubleshooting (13%), current medical device reporting practices are satisfactory (13%), and a lack of communication between the FDA, industry and practitioners (13%). A comprehensive listing of results is noted in Table 1.

## Survey results

A total of 1567 surveys were sent to healthcare practitioners at the University of Pennsylvania Health System via respective Department Chairs. Of these, 340 survey responses were collected, giving a response rate of 21.7%. The survey results are summarized in Table 2. The survey results showed that an overwhelming majority of practitioners did not know how to report a medical device failure (62%). There was a relatively even split of practitioners who had witnessed a medical device failure, 46% had witnessed a medical device failure versus 54% who had not. However, only 19% of practitioners had ever reported a medical device failure. The majority of practitioners who had reported medical device failures stated that they reported 76-100% of medical device failures (60%). Practitioners who had reported medical device failures (19%) were undecided when judging their experiences with the process with 8% 'very dissatisfied', 8% 'dissatisfied', 14% 'somewhat dissatisfied', 34% 'neutral', 6% 'somewhat satisfied', 23% 'satisfied' and 5% 'very satisfied'.

## Discussion

### Medical device regulation

The interview results showed that the main areas of focus in medical device regulation were (in descending order): (1) concerns that the United States medical device industry is lagging behind Europe (56%),

(2) medical device regulation is inconsistent and unpredictable (56%),

(3) poor communication, follow up and record keeping by the FDA (50%),

(4) FDA should increase collaboration with academia and industry (50%),

	Question	Response	%
1	Have you ever used a medical device?		
	Yes	270	79%
	No	70	21%
2	Do you know how to report a medical device failure?		
	Yes	129	38%
	No	211	62%
3	Have you ever witnessed a medical device failure?		
	Yes	155	46%
	No	185	54%
4	Have you ever reported a medical device failure?		
	Yes	63	19%
	No	277	81%
5	What percentage of medical device failures have you reported?		
	0-25	17	27%
	26-50	6	10%
	51-75	2	3%
	76-100	38	60%
6	How satisfied were you with the medical device reporting process?		
	Very Dissatisfied	5	8%
	Dissatisfied	5	8%
	Somewhat Dissatisfied	9	14%
	Neutral	22	34%
	Somewhat Satisfied	4	6%
	Satisfied	15	23%
	Very Satisfied	3	5%
	Survey analytics		
	Number of surveys sent		1567
	Number of responses collected		340
	sssResponse rate		21.7%

**Table 1:** Summary of survey results from practitioners at the University of Pennsylvania health system.

(5) FDA should implement standardized regulatory language (44%), and

(6) the medical device regulatory process is too stringent and cumbersome (44%).

Poor communication, follow up and record keeping by the FDA is a direct result of a secondary concern for budget and congress cuts. The FDA is aware of this concern as shown by two reports published in August 2010 that specified issues regarding medical device premarket approval programs and proposed potential actions to address each situation [8]. The issues outlined include: very high reviewer and manager turnover at CDRH, insufficient training for staff and industry, insufficient oversight by managers, CDRH's rapidly growing workload due to the increasing complexity of devices and submissions for review, unnecessary or inconsistent data requirements, and insufficient guidance for industry and FDA staff – all factors tied to the main viewpoint of poor communication, follow up and record keeping by FDA, which in turn is a direct result of budget cuts. The report goes on to suggest an increase in user fees to combat this issue since stable funding is a key component to FDA and industry success in bringing safe and effective devices to market quickly and efficiently. The FDA charges much smaller user fees to review medical devices than it does to review drugs. In 2010, the FDA charged a fee of \$4,007 for a 510(k) submission (and only half that amount for small companies) and \$217,787 for a PMA (one-quarter that amount for small companies) in comparison to \$702,750-\$1,405,500 for drug applications [9]. By

increasing user fees for devices, the FDA may have a more stable source of funding than Congress can presently provide and as such, may be able to more effectively regulate medical devices.

Another main concern is that medical device regulation is inconsistent and unpredictable (56%). This is a concern that is of particular importance to regulators (4/5) and is intrinsically tied with the need for standardized regulatory language (4/5 of regulators, 44% of total). The inconsistency in medical device regulation can be partially attributed to the ever-changing field of medical devices. As technology advances, regulating devices will become increasingly difficult as the present constructs blur and lose relevance. Hence, to keep up with this fast-paced industry, medical device regulation must accommodate such advances and regulate accordingly while maintaining a standardized basis to prevent confusion. Further, a standardized regulatory language that is easily understood by industry, regulators and practitioners would be useful in facilitating transparency and increased collaboration among the three main stakeholders (50%).

Increased collaboration among industry, regulators and practitioners (50%) could also result in more effective medical device regulation that fulfills more collective goals of the three stakeholders. The interview results revealed that there was no single issue that was a shared major concern for the three stakeholders. Industry's major perspectives on medical device regulation were (in descending order): poor communication, follow up and record keeping by FDA (4/5),

1	Concerns regarding FDA regulation of medical devices	I	R	P	Total	%
	Medical device regulation is inconsistent and unpredictable	2	4	3	9	56.3%
	Concerns that US medical device industry is lagging behind Europe	3	1	5	9	56.3%
	Poor communication, follow up and record keeping by FDA	4	3	1	8	50.0%
	FDA should increase collaboration with academia and industry	3	2	3	8	50.0%
	FDA needs standardized regulatory language	2	4	1	7	43.8%
	Regulatory process is too stringent and cumbersome	3	1	3	7	43.8%
	FDA needs standards for reclassification of PMA to 510K for new technologies	2	1	3	6	37.5%
	Congress and budget concerns, FDA is understaffed and undertrained	3	2	0	5	31.3%
	FDA and CMS are disjoint	2	1	1	4	25.0%
	Pre and post market surveillance is lacking	0	3	1	4	25.0%
	FDA regulation is not stringent enough	0	3	1	4	25.0%
	Hybrid drug-device products pose challenges	0	3	0	3	18.8%
	FDA regulation is quick, straightforward and satisfactory	2	0	1	3	18.8%
	Poorly designed clinical studies	0	3	0	3	18.8%
	Concerns regarding Medical Device Reporting (MDR)					
	MDR requires data mining, standardized language and unique device identifiers	2	5	1	8	50.0%
	Manufacturers should continue reporting directly to FDA	4	0	3	7	43.8%
2	Physicians should be educated on MDR	1	2	2	5	31.3%
	Physician reporting should be legally protected	0	2	2	4	25.0%
	Legislation should mandate return of faulty product to manufacturer	1	1	0	2	12.5%
	Current MDR practices are satisfactory	1	0	1	2	12.5%
	Lack of communication among FDA, manufacturer and physician	0	1	1	2	12.5%

**Table 2:** Complete results from qualitative interviews.



concerns that the US medical device industry is lagging behind Europe (3/5), and to increase FDA collaboration with academia and industry (3/5). Regulators' major perspectives on medical device regulation were (in descending order): medical device regulation is inconsistent and unpredictable (4/5), and standardized regulatory language should be implemented (4/5). Practitioners' main perspective on medical device regulation was that the US medical device industry is lagging behind Europe (5/6). These results suggest that each individual stakeholder group is primarily concerned with fulfilling their own goals and not in the achieving a shared set of goals – which may be beneficial for medical device regulation in the long term.

The issue that the US medical device industry is lagging behind Europe (56%) can be viewed as a result of another popular view that US medical device regulation is too stringent (44%). Several studies have attempted to cross compare the US and European medical device regulation to determine a clear winner for successful medical device regulation in terms of delivering safe, effective medical devices in a timely, economical manner. Due to the subjective nature of medical device regulation, the results vary considerably depending on the variables chosen for analysis. According to Makower et al. [10], 75% of survey respondents rated their regulatory experience in the EU excellent or very good versus 16% of respondents for the same ratings in the US. The survey data also revealed that the medical devices represented in the survey were available to patients in the US a full two years after they entered the European market [10]. However, Basu and Hassenplug found that the public reimbursement (CMS) process for medical devices in the US was either as long, when compared to Italy and Britain, half as long, when compared to France, or less than a third as long, when compared to Germany [11]. The US was the obvious leader in time to market entry according to Basu and Hassenplug [11]. Another study quantitatively assessed medical device regulation in the US and Europe by statistically analyzing several key studies and found that it remains unclear whether the US or European approach achieves better outcomes [12]. Multiple stakeholders whose perspectives vary according to how they individually prioritize factors in medical device regulation further complicate this finding [12].

The interview results reflect these conflicting stakeholder viewpoints where the majority of physicians (5/6) supported the view that the US medical device industry is lagging behind Europe, whilst a minority of regulators (1/5) believed it was true. In actuality, the majority of the regulators (3/5) believed that current medical device regulation is too relaxed, especially when compared to drug regulation. To contrast, most of industry said that medical device regulation is too stringent (3/5). Thus, it is indeterminate whether US medical device regulation is lagging behind Europe and whether US medical device regulation is too stringent.

### Medical device reporting

Interview results revealed that the two focus areas with regard to medical device reporting are: medical device reporting requires data mining, standardized language and unique device identifiers, and that manufacturers should continue to serve as the main reporter to the FDA. Data mining, standardized language and unique device identifiers is a popular concern that has been addressed as necessary and forthcoming by the FDA in the upcoming overhaul of the medical device reporting system [5]. Currently, medical device reporting is largely conducted by industry, filing 97% of the reports [1], although the report is usually initiated by a practitioner who first notices the adverse event and thus, is more knowledgeable of the incident [3]. The survey was designed to assess practitioners' familiarity with medical device reporting and with

those results, the feasibility of increased practitioner participation in medical device reporting.

The response rate for the survey was 21.7%. Participants were limited to UPHS practitioners. This is a potential bias in the survey results since UPHS is a top tier health system and so, may be exposed to riskier diseases, more experimental devices and thus, increased frequency in device-related adverse events. The survey results revealed that 38% of practitioners know how to report a medical device failure. 46% of practitioners have witnessed a medical device failure before, but only 19% of practitioners have ever reported a medical device failure. This low level of reporting could be due to a variety of reasons including but not limited to: the current system does not incent practitioners to participate since it exposes the practitioner to liability and legal concerns [3], practitioners do not have the time to report, the standard in the medical community is not to report [6]. The practitioners who did report medical device failures mostly reported 76-100% of observed medical device failures (60%) and experienced varying levels of satisfaction with the reporting process.

These results reveal that practitioners have limited awareness regarding medical device reporting. It is difficult to ascertain the effectiveness of physician medical device reporting without first educating practitioners about medical device reporting. Therefore, it is presently indeterminate but unlikely that increased practitioner participation in the medical device reporting process will add value to the postmarket surveillance process. The feasibility of increased practitioner participation is improbable unless practitioners' understanding of the medical device reporting process is first enhanced by other initiatives.

### Directions and Considerations for Future Work

There were only three main stakeholders identified in this study when in actuality, the field of medical device regulation includes many other external stakeholders. Future work could include payers, such as insurance companies, and/or patients. It would however be difficult to include patients in an investigative study regarding medical device regulation since their knowledge on the issues at hand would be limited. For this reason, patients were excluded from this study and instead, supplemented with practitioners who could potentially act as their advocates. The effect of reimbursement concerns from payers would provide a more representative view of the field of medical device regulation.

The study was limited by small sample sizes for both the survey and interviews. For future work, the interviewee sample group should include: all major medical device companies, prominent governmental and non-governmental organizations, and practitioners in the riskier medical device fields. Survey participants should include practitioners at a variety of health systems to limit the bias that can occur within a single type of health system. These health systems should support a range of medical device riskiness; differ in size and funding etc. If possible, sample sizes should be maximized to increase consistency within the results.

IRB provisions protected practitioners' personal information, thereby limiting the scope of survey questioning. This was further constrained by survey length, which was minimized to increase the number of responses. A more comprehensive survey that includes detailed definitions of regulatory terms such as, "medical device failure" and "adverse event" would reduce any ambiguity and restrict assumptions. It would also be beneficial to include more specific questions that investigate the impact of increased practitioner participation on postmarket surveillance.

## Conclusions

Collectively, industry, regulators and practitioners' main perspectives on medical device regulation are: medical device regulation is inconsistent and unpredictable (56% total, 2/5 of industry, 4/5 of regulators, 3/6 of physicians) and concerns that the US medical device industry is lagging behind Europe (56% total, 3/5 of industry, 1/5 of regulators, 5/6s of physicians). However, these two concerns were not strongly supported by all three stakeholders. Most of the main issues raised received polarized feedback from the stakeholders. This showed that perspectives on FDA regulation of medical devices varied based on stakeholders' personal weight on the importance of outcomes such as cost, speed, safety and effectiveness. It can be inferred that industry, regulators and practitioners' definitions of successful medical device regulation are not aligned.

38% of practitioners surveyed stated that they knew how to report a medical device failure. Although 46% of practitioners have witnessed a medical device failure, only 19% have ever filed a report. Presently, it appears as though practitioners are not sufficiently aware or knowledgeable of the medical device reporting system to actively participate. It is necessary for practitioners to be further educated on medical device reporting before their participation can be assessed with regard to impact on postmarket surveillance. Currently, it is indeterminate but unlikely that increased practitioner participation will add value to postmarket surveillance.

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