

EXECUTIVE SUMMARY
FOR THE PATIENT
ENGAGEMENT ADVISORY
COMMITTEE MEETING

Medical Device
Recalls:
Patient-Focused
Communications

October 6, 2021

PEAC Executive Summary– Medical Device Recalls

Table of Contents

Introduction 3

Basics of Recall Communications..... 4

 FDA’s Recall Communications..... 6

Table 1. Medical Device Recalls in 2020 6

 Other Ways Patients May Learn of Recalls..... 8

Table 2. Public Recall Communications from FDA and Manufacturers 10

Concerns and Questions about Recall Communications..... 11

Understanding Benefit-Risk Assessments..... 12

How to Best Communicate Recalls..... 16

Figure 1. FDA Recall Summary Template..... 17

Additional Information 19

Updating Information..... 20

Simplifying Communications 20

Reaching the Digitally Underserved 22

Learning from Other Agencies 23

Limitations 24

Conclusion 25

Disclaimer: This Executive Summary is for discussion purposes only and does not represent draft or final guidance. It is not intended to propose or implement policy changes regarding communication of recall information.

Introduction

The FDA currently regulates more than 190,000 different medical devices. Many of these devices are important to diagnosing and treating illness and injury and bring enormous benefits to patients. But medical devices can also present risks. We at the FDA take seriously our role in communicating about both the benefits and risks of medical devices, to support an informed public and strong health care system.

Once a product is available on the market for widespread use, unexpected issues can sometimes lead to a recall. Some examples include manufacturing problems, flawed designs, or new and unexpected risks that could potentially make the medical device more harmful. In some of these situations, recalling that product—removing it from the market or correcting the problem—can be the most effective means for protecting the public. Sometimes a company discovers a problem and recalls a product on its own. Other times a company recalls a product after FDA raises concerns. FDA's role is to oversee a company's strategy and assess whether it is effective. Information about the recall is communicated to affected customers, and sometimes the public, in different ways.^{1,2}

The FDA wants to make sure the communications the public receives about medical device recalls reflect the needs and interests of patients. Communicating recall information to patients can be challenging. Recalls can involve complex issues, processes and decisions. Messages need to clearly convey relevant information to the right people at the right time. It is important for patients to understand whether a recall impacts them, what they need to do to minimize risks related to recalled devices, and where to go if they have questions. To that end, the agency is engaging with patients, health care providers, manufacturers and others in the medical device community to identify opportunities to provide information about recalls more clearly and effectively, in a timely fashion, and in ways that are relevant and of most benefit to patients.

¹ FDA. *Recalls, Corrections and Removals (Devices)*. Available at: <https://www.fda.gov/medical-devices/postmarket-requirements-devices/recalls-corrections-and-removals-devices> (accessed September 7, 2021).

² 21 CFR Part 7, Subpart C – Recalls (Including Product Corrections)—Guidance on Policy, Procedures, and Industry Responsibilities. Available at: https://www.ecfr.gov/cgi-bin/text-idx?node=sp21.1.7.c&rgn=div6#se21.1.7_149

Basics of Recall Communications

The FDA and the medical device industry share responsibility for informing the public about medical device risks. All medical device recalls are listed in the FDA's [Medical Device Recalls](#)³ database and [Enforcement Report](#).⁴ For recalls which pose the most serious risks to health, the FDA's [Yearly List of Medical Device Recalls](#)⁵ summarizes key information about the recall, including where to go for more information. In some cases, the FDA will also issue a [Safety Communication](#)⁶ or [Letter to Health Care Providers](#)⁷ to raise public attention about the risks of using a recalled device. But other information about risks often comes from manufacturers because they may be best positioned to quickly communicate relevant information. The manufacturer of a medical device that is being recalled might send out general communications to the public.⁸ It might also send out more targeted communications to customers affected by the recall, as well as to patients, caregivers, and health care professionals.

It is important to note that medical device recalls are usually conducted voluntarily by the manufacturer. Less commonly, a manufacturer or importer may fail to voluntarily recall a medical device that is a risk to health. In these rare cases, the FDA may issue a mandatory recall order to the manufacturer or importer and require them to report their compliance.⁹ Sometimes a medical device recall means that you should stop using the product or return it to the company. Other times it means the medical device needs to be checked, adjusted, or fixed. For example, a study of five years of orthopedic medical device recalls found that packaging errors were more common than design flaws or manufacturing issues.¹⁰ These could potentially be resolved in the field by sending updated labeling rather than returning the product to the company.

Manufacturers are responsible for ensuring their direct customers receive information about recalls.^{11,12} These customers typically include hospitals and health care providers, or sometimes

³ FDA. *Medical Device Recalls*. Available at:

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm> (accessed September 2, 2021).

⁴ FDA. *Enforcement Reports*. Available at: <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports> (accessed September 2, 2021).

⁵ FDA. *2021 Medical Device Recalls*. Available at: <https://www.fda.gov/medical-devices/medical-device-recalls/2021-medical-device-recalls> (accessed September 2, 2021).

⁶ FDA. *2021 Safety Communications*. Available at: <https://www.fda.gov/medical-devices/safety-communications/2021-safety-communications> (accessed September 2, 2021).

⁷ FDA. *Letters to Health Care Providers*. Available at: <https://www.fda.gov/medical-devices/medical-device-safety/letters-health-care-providers> (accessed September 2, 2021).

⁸ If so, FDA may post company press releases or other public notices about recalls that may potentially present significant risks to consumers or users of the product at <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts> (accessed September 2, 2021).

⁹ FD&C Act § 518(e) and 21 CFR Part 810.

¹⁰ Vajapey SP, Li M. *Medical Device Recalls in Orthopedics: Recent Trends and Areas for Improvement*. *J Arthroplasty*. 2020 Aug;35(8):2259-2266.

¹¹ 21 CFR 7.42 and 7.49.

¹² FDA. *Product Recalls, Including Removals and Corrections*. Available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/product-recalls-including-removals-and-corrections>.

distributors who serve providers, unless it is a direct-to-consumer device. In most cases, manufacturers do not directly reach out to patients because they do not have a good way of knowing who those patients are or how to contact them. Doing so is generally left to health care providers. For direct-to-consumer devices, some manufacturers include registration cards which consumers can fill out online or by mail. If that medical device is later recalled, the manufacturer can more easily notify consumers who have registered.

Manufacturers are encouraged to follow best practices¹³ when faced with a recall. This includes tracking all customers who might have to be notified, including how to reach the best contact at each customer. In addition, tracking the individual components in medical devices makes it easier to identify and replace flawed components. It is also important to establish a procedure for separating out and fixing or destroying recalled medical devices returned to the manufacturer.

When an implanted medical device (for example, an artificial hip) has the potential to fail unexpectedly, companies often tell doctors to contact their patients to discuss the risk of removing the medical device compared to the risk of leaving it in place.¹⁴ Hospitals, physicians and other health care providers are supposed to follow best practices to help ensure that patients are notified and to prevent additional recalled medical devices from being used. These practices include appointing a recall coordinator at hospitals, explaining to patients who will be receiving implantable medical devices that there are risks that flaws will be discovered later, and proactively monitoring FDA communications for recall notices.¹⁵

These and all recall communications practices and efforts will be greatly enhanced by the ongoing implementation of the FDA's Unique Device Identification (UDI) system.^{16,17} The UDI system involves placing a human- and machine-readable code on most medical devices, so that the FDA, manufacturers, health care providers, patients and others can more easily identify medical devices. This system may also facilitate rapid identification of medical devices affected by a recall and help health care providers and patients get the information they need.

¹³ FDA provides industry with numerous resources and best practices for conducting recalls of all regulated products, including resources specific to medical device recall communications. *Industry Guidance for Recalls*. Available at: <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls>.

¹⁴ FDA. *What is a Medical Device Recall?* Available at: <https://www.fda.gov/medical-devices/medical-device-recalls/what-medical-device-recall> (accessed September 2, 2021).

¹⁵ Magennis Healy E, Braender LJ, and Zalewski TA. *A Provider's Guide to Managing a Medical Device Recall*. Available at: <https://sitecoreadmin.daypitney.com/professionals/z/~/-/media/359cceb7490942f5897229b982c70a00.ashx> (accessed September 5, 2021).

¹⁶ FDA. *Benefits of a UDI System*. Available at: <https://www.fda.gov/medical-devices/unique-device-identification-system-udi-system/benefits-udi-system> (accessed September 5, 2021).

¹⁷ Pew Charitable Trusts. *How Medical Device Identification Supports High-Quality Healthcare (video)*. Available at: <https://www.youtube.com/watch?v=A3CS8pfTmb4> (accessed September 7, 2021).

FDA’s Recall Communications

The FDA provides oversight and guidance to manufacturers about how to communicate publicly about recalls.¹⁸ But sometimes the FDA will issue its own communications based on a number of factors including: the seriousness of the medical device issue, the urgency of communication, and the effectiveness of the manufacturer’s communication. An example is the Letter to Health Care Providers that the FDA issued about [certain needles and syringes](#).

There are several types of communications that the FDA may issue in association with a medical device recall. Among these FDA communications, roughly in the order in which they are most likely to appear, are the following:

- Listings of all recalls in an FDA database, accessible to the public through its website
- Listing of manufacturers’ public recall notices and press releases
- FDA recall summaries, posted on the FDA website
- Email notifications to subscribers of particular agency email lists
- Social media posts
- Letters to health care providers
- The FDA’s press releases distributed to news organizations

Some time after the manufacturer notifies their customers, the FDA completes the analysis required to “classify” the recall—that is, determining how serious a risk the recalled medical device poses to human health. If the risk to health is serious, the recall is deemed a Class I recall. However, a large majority of medical device recalls are less likely to pose a serious hazard. In those cases, the action is deemed a Class II or III recall.

In 2020, there were 1,078 medical device recalls, most of which were Class II (**Table 1**).¹⁹

Table 1. Medical Device Recalls in 2020

Recall Classification	Relative Degree of Risk ²⁰	Number of Medical Device Recalls in 2020
Class I	Reasonable chance that a product will cause serious health problems or death	41
Class II	May cause a temporary or reversible health problem or where there is a slight chance that it will cause serious health problems or death	994
Class III	Not likely to cause any health problem or injury	43

¹⁸ FDA. *Public Warning and Notification of Recalls Under 21 CFR Part 7, Subpart C*. Available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/public-warning-notification-recalls-under-21-cfr-part-7-subpart-c>.

¹⁹ FDA. *Enforcement Reports*. Available at: <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports> (accessed September 2, 2021).

²⁰ 21 CFR 7.3(m).

All medical device recalls are described in the FDA's [Medical Device Recalls](#) database and [Enforcement Report](#). These can be accessed and searched by the public on the FDA website. Also, anyone can [register](#) to receive daily or weekly email notifications of new and updated recalls posted to the Enforcement Report. These sources contain:

- Details about the medical device, the reason for the recall and which medical devices are affected.
- Manufacturer contact information.
- Actions taken by the manufacturer to notify customers.
- Details about the quantity of medical devices in distribution worldwide.

For some recalls, particularly Class I and higher-priority Class II recalls, the FDA will also post summaries of key information to [Yearly List of Medical Device Recalls](#) on the FDA website. In 2020, 33 such notices were posted.²¹ These notices provide:

- A summary of information about the medical device, the reason for the recall, and which medical devices are affected.
- Recommended actions for health care providers, facilities, and impacted patients, among others.
- How to contact the manufacturer for additional information.
- Links to additional resources, including manufacturer public recall notices and the FDA *Medical Device Recalls* database listings.

In addition, the FDA in some instances will issue a [Safety Communication](#) or a [Letter to Health Care Providers](#). These communications further alert the public that a recalled medical device presents an urgent, serious, or widespread hazard to health, and provides further instructions on what to do. Some examples:

- [Stop Using Innova Medical Group SARS-CoV-2 Antigen Rapid Qualitative Test: FDA Safety Communication](#)
- [Stop Using Lepu Medical Technology SARS-CoV-2 Antigen and Leccurate Antibody Tests: FDA Safety Communication](#)
- [Zoll LifeVest 4000 Wearable Cardioverter Defibrillator - Potential Lack of Treatment \(Shock\) Delivery Due to Device Failure: FDA Safety Communication](#)

Sometimes the FDA determines there may be particular urgency in notifying the public about a recall before formally classifying the recall. In those cases, the agency may issue a *Safety Communication* or *Letter to Health Care Providers* earlier in the recall process. Some examples of *Safety Communications* that were issued before the recall was classified:

- [Stop New Implants of the Medtronic HVAD System – Letter to Health Care Providers](#)

²¹ FDA. *2020 Medical Device Recalls*. Available at: <https://www.fda.gov/medical-devices/medical-device-recalls/2020-medical-device-recalls> (accessed September 2, 2021).

- [Philips Respironics Recalls Certain Continuous and Non-Continuous Ventilators, including CPAP and BiPAP, Due to Risk of Exposure to Debris and Chemicals](#)
- [Allergan Recalls Natrelle Biocell Textured Breast Implants Due to Risk of BIA-ALCL Cancer](#)
- [RVO 2.0, Inc. Recalls Raindrop Near Vision Inlay Due to Risk of Increased Risk of Corneal Haze](#)

The FDA typically uses email and social media to further share and promote information about a Class I medical device recall to the public and to potentially impacted stakeholders. But it usually does so only when the recalled medical device is widely used or affects particular stakeholder communities. Medical devices purchased directly by patients over-the-counter are a key example.

For these more widely promoted communications about medical device recalls, CDRH sends a targeted email to the roughly 115,000 subscribers to the CDRH [Medical Device Safety and Recalls email list](#), and to the roughly 60,000 subscribers to its [Consumer Info for Medical Devices email list](#). The email states: “**The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.**” CDRH then posts a tweet about the Class I medical device recall on the CDRH Twitter account [@FDADeviceInfo](#), which currently has about 95,000 followers. (Tweets may of course have reach beyond the follower base, via retweets.) CDRH also collaborates with others at the FDA to issue an email alert to subscribers to the FDA [MedWatch email list](#) (roughly 360,000 subscribers) and MedWatch Twitter account (which currently has about 53,000 followers). Those alerts are also listed on the FDA [MedWatch webpage](#), and are searchable by anyone in the public.

Other Ways Patients May Learn of Recalls

While the number of subscribers listed above may seem large to some, it reflects only a small subset of the general public that directly receives FDA communications. That means the FDA communications about a recall may not reach patients and others potentially impacted by a recall. Instead, patients and other members of the public may commonly learn about recalls through other sources, including the following:

- Notices issued by manufacturers directly to their customers
- Conversations with or notifications from health care providers
- News reports or other accounts in print, trade or online media
- Social media from non-FDA sources (Facebook, Twitter, YouTube, blogs, etc.)
- Word of mouth (relatives, friends, colleagues, etc.)

As a result, the FDA may have relatively little control over what patients hear about a recall. That includes how the information is interpreted and framed, the perceptions patients have about how

the recall might impact them, what actions they might consider, and other aspects of the recall. Patients may end up making important health decisions based on information about a recall that is biased, incomplete, misleading, or simply false.

Even patients and others in the public who do happen to read a communication from the FDA about a recall that impacts them may not come away with a clear sense of how they are affected and what actions might be appropriate for them to take. That is because many of the FDA communications are not specifically or uniquely targeted for patients who have or are considering use of the medical device. Thus, these communications may not clearly convey the information that is most relevant to them in a form and in language that makes the information easy to consume and understand. (The above-referenced [communications guidance](#) document offers some direction to the FDA staff aimed at producing clearer communications.)

There are several types of public communications that the FDA or manufacturers may issue about a medical device recall. They are listed in **Table 2**, approximately in order from most (FDA Enforcement Report) to least (FDA press announcements) commonly used.

Table 2. Public Recall Communications from FDA and Manufacturers

Title	Source	Description	Timing
<u>FDA Enforcement Report</u>	FDA	Report including all recalls monitored and classified by FDA, and occasionally include some recalls initiated by a firm prior to review by the FDA	Database updated daily, with weekly report of new items and changes
<u>Medical Device Recalls Database</u>	FDA	Database of all medical devices recalls classified since November 1, 2002, and occasionally include some recalls initiated by a firm prior to review by the FDA.	Updated daily
<u>FDA Recall Summaries, posted in an FDA list</u> ²²	FDA	Public summaries of information about the most serious medical device recalls	Updated frequently, as items become available
Notifications and press releases from manufacturers	Manufacturers	Public communication from manufacturers to raise awareness about certain recalls	Varied depending on the urgency of notification ²³
<u>Manufacturer recall notices, posted on an FDA website list</u>	FDA	Manufacturer public notifications posted by FDA for public awareness	Updated frequently, as items become available
Social media posts	FDA, Manufacturers	Public communication to raise awareness about certain recalls on various social media platforms	Varied depending on the urgency of notification
<u>Letters to Health Care Providers and Safety Communications</u>	FDA	Public communication to raise awareness about certain recalls targeted to specific groups	Varied depending on the urgency of notification
<u>FDA press announcements distributed to news organizations and posted on the FDA website</u>	FDA	Public communication to raise awareness about certain recalls through news organizations	Varied depending on the urgency of notification

²² Limited to recalls that may potentially present a significant or serious risk to the consumer or user of the product.

²³ While timeframes vary on a case-by-case basis depending on the recall and device issues, manufacturers should generally issue a public warning within 24 hours of receiving FDA's request to do so. For more information, see: Final guidance "Public Warning-Notification of Recalls Under 21 CFR Part 7, Subpart C" available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/public-warning-notification-recalls-under-21-cfr-part-7-subpart-c>.

Concerns and Questions about Recall Communications

It is important to consider what the effects of communications might be on patients and others potentially impacted by a recall. This concern is particularly true when communications lack prompt, accurate, useful, and easily understood directions or suggested actions to take. Without this additional information, patients may not understand how they might be impacted and if so, what they should do about it. Here are some of the possible problems that might be caused or exacerbated by inadequate communications of recalls to patients and their family members:

- They might overreact to the recall, experiencing undue stress, and stopping use of the product or insisting on its removal when doing so is not medically advisable.
- They might underreact, ignoring the recall or failing to contact their health care provider, when there is good reason to consider taking action.
- They might become inappropriately convinced of a particular course of action that conflicts with their health care provider's advice.
- They might misunderstand the scope of a recall to be broader than it is. For example, they might confuse a recall of certain lots of a medical device with a larger problem with all units of that model. They might even assume it applies to all medical devices made by that manufacturer, or to all medical devices of that type made by any manufacturer. As a result, they may reject the use of some medical devices that may in fact be beneficial to them.

Any of these problems might lead to worse health outcomes for patients than if they received more clear communications about recalls.

The FDA is interested in how to issue more effective recall communications specially intended to be read more widely by patients and others in the public that might be affected. This could include creating new types of communications or modifying existing communications specifically with patients and the public in mind. What are some of the considerations that should guide the content of these patient-focused communications?

That question leads to a more basic question: What are the proper goals of the FDA communications to the public about recalls?

The FDA's over-arching goal in communicating recall information to the public is to protect public health—a key pillar of the Agency's mission. But what other goals should FDA aim to accomplish with recall communications?

- To minimize harms related to recalled medical devices
- To be completely transparent about, and provide the fullest information on, the factors and processes behind the recall
- To provide the most easily understood summaries of information

- To drive home the points that may have the most impact on patient decisions
- To reach the widest possible audience
- To best prepare patients to discuss the recall with their health care providers

These may all each be worthy goals, but there are likely to be tradeoffs and conflicts among some of them. For example, providing full transparency can result in longer, less easily understood communications. Patients might be less likely to read that sort of document than one that leaves out some information in favor of emphasizing a few simple points. Clearly providing lots of technical and administrative details for general transparency purposes may not address the information needs of patients.

Recalls often involve complex decision-making and processes for industry, the FDA, hospitals and clinicians. As a result, information about a recall can include a great deal of technical and administrative information. It can also include uncertainty, such as when there is a lack of data. There may also be uncertainty about the factors a person might consider in determining whether available alternatives are adequate. These complexities make it even more challenging to clearly communicate recall information. The following section outlines some of the factors behind recall decisions, and what can make them particularly complicated.

Understanding Benefit-Risk Assessments

When the FDA makes decisions about whether or not a new medical device is appropriate for initial sale in the United States, it weighs the benefits of using the medical device against any risks of using the medical device. Once a medical device is marketed for sale and is in use, the FDA may determine that the medical device benefit-risk profile has changed. That may happen as new information becomes available about manufacturing defects, the medical device design or performance, or how it is being used. That changing profile is critical to determining whether or not a product should be recalled.²⁴

At the FDA, a medical product recall is defined as “a firm's removal or correction of a marketed product” that the FDA considers “nonconforming,” which usually means the product is flawed, or its marketing in some way violates FDA regulations. Note that a manufacturer can sometimes meet the requirements of a recall without removing the product from the market. It usually does so by repairing, modifying or inspecting the products that are out in the market or updating their labeling.²⁵ Also note that not all products removed from the market are “recalled.” For example,

²⁴ FDA. *Factors to Consider Regarding Benefit-Risk in Medical Device Product Availability, Compliance, and Enforcement Decisions*. Available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/factors-consider-regarding-benefit-risk-medical-device-product-availability-compliance-and>.

²⁵ For more information on policy around non-removal recalls, see “Corrections and Removals - 21 CFR 806” in <https://www.fda.gov/medical-devices/postmarket-requirements-devices/recalls-corrections-and-removals-devices>.

products may be removed through normal stock rotation practices and routine equipment adjustments and repairs.

The most important reason for a recall is a risk to health. The FDA defines “risk to health” this way: A reasonable probability that use of, or exposure to, the product will cause serious adverse health consequences or death; or that use of, or exposure to, the product may cause temporary or medically reversible adverse health consequences, or an outcome where the probability of serious adverse health consequences is remote.²⁶

The FDA classifies medical device recalls based on the level of risk to health that the recalled devices may pose to users, as described in **Table 1**.

- Class I recalls represent the highest level of risk. For example, a flaw that causes a potential failure in an implanted medical device that helps the heart pump.
- Class II recalls represent the middle level of risk. For example, a higher-than-expected risk of early failure in an artificial hip joint.
- Class III recalls represent the lowest level of risk. For example, an imaging medical device display screen having incorrect brightness settings.

The FDA relies on a combination of quantitative and qualitative information to make classification decisions. The information might include projected medical device failure rates, past agency experience with similar medical devices, and clinical judgment. Common reasons for medical device recalls include:

- General medical device failure, or failure of a specific component, such as a resistor or capacitor.
- Design flaws, including human factors issues.
- Inadequate instructions for use.
- The manufacturer’s failure to provide the FDA with required information, or otherwise obtain required FDA authorizations, prior to marketing the product.
- Package integrity problems for medical devices marketed as sterile—for example, pinholes in the device wrapping.

The calculation of benefits and risks can be complicated. Commonly considered benefits include:

- The degree to which the medical device helps patients experience clinical improvements, lower risks, receive a more accurate diagnosis, or undergo shorter procedures, and the likelihood that patients will experience those benefits.
- How long the benefit can be expected to last.
- Improvements that benefit health care professionals or caregivers, such as shorter procedural times, and better training.

²⁶ 21 CFR 806.2(k).

Commonly considered risk factors include:

- Deaths and serious injuries and impairments attributable to the use of the medical device, or the need for medical intervention to prevent such harms.
- Adverse health events and complications that don't rise to the level of possible death or serious injury—for example, a diagnostic medical device that provides unexpectedly unreliable results, leading to patient overtreatment or undertreatment.
- Medical device malfunction or underperformance, even when adverse health events do not result. An example might be a diagnostic medical device that provides unreliable results, though those false results do not result in treatment decisions that adversely impact health.
- Risks that impact health care professionals or caregivers, such as the need to invest extra time and training in the use of the medical device without deriving any benefit from that investment.

The FDA also considers that patients might prefer continuing to use a nonconforming medical device for various reasons.

It might be possible to communicate many of these factors to patients in ways that are understandable, and that help them make decisions about what actions to take in response to a recall. But other information related to medical device recalls may be more difficult to clearly communicate to patients.

For example, sometimes medical devices that have no manufacturing defects are recalled when postmarket data show higher-than-anticipated risk for the medical device. On the other hand, some of these medical devices may not have to be recalled if they can be made safer or more beneficial by changing the way the medical device is used by providers or patients. For example, it may be a matter of communicating the risks of off-label use of the medical device to promote using the medical device as intended and authorized. The FDA may also seek alternatives to a recall out of concern that it could lead to a market shortage of a medical device that may be medically necessary for some patients.

Some questions to consider: Is it important to communicate these sorts of more complex, subtle issues impacting recalls to patients? If so, how might that be done in clear, helpful ways that don't confuse more than clarify?

Another complication is the fact that different stakeholders may judge the benefits and risks of a medical device in different ways. The FDA relies heavily on the clinical expertise of health care providers to help determine and weigh medical device benefits and risks. This includes clinical experts at the FDA, on its advisory committees, through [MedSun: Medical Product Safety](#)

[Network](#)²⁷ and through the [Network of Experts Program](#).²⁸ The agency is also interested in understanding the unique perspectives that patients bring that can influence a benefit-risk assessment. This includes the role the medical device plays in their day-to-day lives, how they perceive the pros and cons of the medical device, how the medical device impacts their sense of wellness, and different patients' tolerance for the risk of harm. Patient perspectives might vary widely across the patient population and may be influenced by certain situations and conditions. For example, a patient who has a more severe form of a disorder addressed by the medical device or who has easy access to health care providers may have a different perspective on the benefits and risks than another patient with mild disease or limited access to providers. (Further information about how the FDA solicits and enlists patient perspectives and other data can be found in the [PMA BR Guidance](#)²⁹ pages 12-13, [510\(k\) BR Guidance](#)³⁰ pages 16-17, [IDE BR Guidance](#)³¹ pages 15-16, and [Compliance and Enforcement BR Guidance](#)³² pages 13-14.)

Uncertainty is another challenge. Some medical devices are used by relatively small numbers of patients, which means data on medical device usage may be limited. The result may be a relatively high level of uncertainty around the benefit-risk profile, and thus in some cases around recall decisions. Different patients may interpret a given level of uncertainty in very different ways. In some cases, for example, they may ignore the high level of uncertainty attached to a recall decision, and in other cases see a moderate level of uncertainty as completely undercutting a recall decision. These patient perspectives about uncertainty might also inform FDA decisions about recalls, and especially decisions about how recalls are communicated. (Additional information on the issue of uncertainty and patient perspectives can be found in the [Uncertainty BR Guidance](#)³³ pages 9, 11 and 16.)

²⁷ FDA. *MedSun: Medical Product Safety Network*. Available at: <https://www.fda.gov/medical-devices/medical-device-safety/medsun-medical-product-safety-network> (accessed September 9, 2021).

²⁸ FDA. *Network of Experts Program: Connecting the FDA with External Expertise*. Available at: <https://www.fda.gov/about-fda/center-devices-and-radiological-health/network-experts-program-connecting-fda-external-expertise> (accessed September 9, 2021).

²⁹ FDA. *Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications*. Available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/factors-consider-when-making-benefit-risk-determinations-medical-device-premarket-approval-and-de>.

³⁰ FDA. *Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications (510(k)) with Different Technological Characteristics*. Available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/benefit-risk-factors-consider-when-determining-substantial-equivalence-premarket-notifications-510k>.

³¹ FDA. *Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions*. Available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/factors-consider-when-making-benefit-risk-determinations-medical-device-investigational-device>.

³² See Footnote 24.

³³ FDA. *Consideration of Uncertainty in Making Benefit-Risk Determinations in Medical Device Premarket Approvals, De Novo Classifications, and Humanitarian Device Exemptions*. Available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/consideration-uncertainty-making-benefit-risk-determinations-medical-device-premarket-approvals-de>.

The FDA also tries to consider broader benefit-risk questions surrounding what patients might do in the face of a recall. That is especially true in relation to the availability of suitable alternative products. For example, some patients might choose to continue to use a nonconforming medical device that has been recalled, perhaps because they are not aware of the availability of suitable alternatives. Others, meanwhile, might choose to stop using a medical device without first giving much thought to whether there are alternatives that are suitable for their needs. (Additional information on how recalls impact patients are in the [Compliance and Enforcement BR Guidance](#)³⁴ pages 13-14.) In addition, patients may choose to continue using a nonconforming medical device because they cannot access available alternatives due to insurance coverage policies, cost, clinical advice, or other reasons.

How to Best Communicate Recalls

In considering the FDA's current recall communications practices from patients' perspectives, a number of questions arise:

- Where do patients find recall information?
- To what extent are patients inadequately informed due to challenges identifying impacted patients and reaching them directly with targeted communications?
- Do current communications adequately help patients identify whether they are impacted by a recall?
- Does the FDA's classification and other terminology impact patients' ability to clearly comprehend recalls and decide what to do?
- What are reasonable goals and expectations for communicating updates of recall information to patients?

As discussed above, patients may be more likely to receive information about recalls from manufacturers, health care providers, the press, social media, and other sources, before they read an FDA-issued communication about the recall. Patients who do not come to the FDA website, subscribe to a relevant FDA email list, or follow FDA social media posts, may never see an FDA communication about the recall.

Still, some patients do see these FDA communications. What's more, the FDA in some cases has some influence over what manufacturers and others may have to say about recalls. Thus, it is well worth asking: What information would be most appropriate to include in patient-focused recall communications, regardless of the source?

Currently, the FDA posts a public notice for nearly all Class I recalls, and for significant Class II or III recalls of interest to patients. These are posted on the FDA website under lists sorted by year, such as [2021 Medical Device Recalls](#).³⁵ These recall summaries include certain basic information, as listed on the following template (**Figure 1**):

³⁴ See Footnote 24.

³⁵ See Footnote 5.

Figure 1. FDA Recall Summary Template.

Title: [Company Name] **Recalls** [Recalled Product] [Reason for Recall]

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these medical devices may cause serious injuries or death.

Recalled Product (Include the following information)

Product Names: Name and Version (if applicable)

Product Codes

Model Numbers:

Manufacturing Dates: Month Day, Year to Month Day, Year

Distribution Dates: Month Day, Year to Month Day, Year

Medical Devices Recalled in the U.S.: Number of products

Date Initiated by Firm: Month Day, Year

Medical Device Use

Utilizing clear communication best practices, provide a description of the device's intended use.

If available, include photo of device.

Reason for Recall

Utilizing clear communication best practices, provide a reason for the recall. This section should be approximately one to two short paragraphs, which include a brief description of the product's use and the specific issues/concerns described in the recall documents.

On a separate line, add: *The use of affected product may cause serious adverse health consequences, including X (add specific examples of possible injuries that may occur) and death.*

Also, include a sentence about any reported injuries or death. *For example: "There have been x reported injuries. There have been no reports of death."*

Who May be Affected

Include categories of device users for the recalled device and others who may need to know the information.

-- *Template is Continued on Next Page* --

-- Template Continued from Previous Page --

What to Do

This section should include actions that users of the device should take in response to the recall that was included in the customer letter the company sent. This information is often included in the company's press release, or in Urgent Medical Device Recall Notifications sent by the company.

For example: "On [Date], [Company Name] sent all affected customers an Important Medical Device Advisory. The letter requested customers to: <then list out bullets underneath>"

Contact Information

"Customers in the U.S. with questions about this recall should contact [Company Name] at [phone number]."

Full List of Affected Devices (if applicable)

"A complete list of affected devices is available in the [Medical Device Recalls database](#)."

Additional Resources:

Medical Device Recall Database Entry (link to the [Medical Device Recalls database](#) entry)

FDA Press Release (If available)

FDA Safety Communication (If available)

Firm Press Release (If available)

Firm Recall/Correction Letter (If available)

Firm Recall Web Page (If available)

Firm Related Recall (If available)

Related FDA recall classification notices (If available)

How do I report a problem?

Health care professionals and consumers may [report adverse reactions or quality problems](#) they experienced using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program using an online form, regular mail, or FAX.

Whatever their merits, such summaries may not succeed in clearly conveying to patients what they might most want to know about a recall. Among the key pieces of information patients may want to learn:

• Does this recall affect me?

Patients may have trouble determining if their medical devices are affected based on lot numbers, distribution dates, or other information normally provided in notices. Perhaps other

types of information would be helpful, such as including an image of affected devices, or suggesting other ways to find identifying information, who to contact for help in determining whether a patient's device is impacted, and how best to proceed if the patient cannot determine whether a device is impacted. For example, in some cases it may be best to assume that a device is impacted, and in other cases the opposite may be true.

• ***Why should I be concerned about the medical device, and how concerned should I be?***

Merely listing a medical device defect and the potential harm may offer little insight from the patient's point of view. There may be other ways to best communicate the considerations that could help patients determine how urgently to react to a recall, and the level of risk they may face if they do not take action.

• ***What should I do?***

It is critical to clearly spell out any urgently required patient actions, such as to immediately stop using a medical device. But it may also be helpful to patients to spell out other steps the patient could take. Such steps might help patients reduce the risk of harm, assess personal risks and benefits, seek out alternative medical devices or treatments, and learn more about how to decide on the best course of action.

In many instances, and especially for implanted medical devices, encouraging the patient to contact a health care provider makes sense. But it's important to recognize that some health care providers may themselves be unclear about the considerations surrounding a recall. More importantly, many patients may be unwilling or unable to consult with a provider or may not have trusting relationships with their providers. These problems can be particularly challenging in underserved populations. Thus, understanding how patients and providers work together to reach decisions, and how likely patients are to have access to a trusted provider would cast more light on these questions.

Additional Information

Beyond these key points, patients may want to see different amounts of detail about the recall and the FDA or manufacturer's decision to initiate it. For example:

- **Information about uncertainties.** The FDA generally assumes risk is higher when uncertainties exist which can be due to insufficient data. Patients might prefer to be told about these assumptions, if the uncertainties are clearly defined. Explaining uncertainties can also prepare patients to better understand that the situation is evolving, and may be updated at a later time.

- **Reassurance about non-impacted medical devices and low risks.** Some patients might appreciate having the things they do not need to worry about spelled out. That might include the models and devices that are not in any way affected by the recall (including pictures for easier identification), or ones in which risks are known to be low.

The potential downside to providing more detailed information is that some patients may be more comfortable with short, simple, clear notices that provide only a few key points in relatable terms. The presence of additional material that addresses more complex considerations may leave them feeling confused or overwhelmed, or may cause them to neglect reading the notice altogether. One possible solution might be to present a simplified document with key points only, while offering a link or other access to a more detailed document clearly labeled as providing additional information.³⁶

Updating Information

After a recall is underway, and the initial round of communications have been issued, it may be appropriate to try to provide patients updated information on the recall. In some cases, doing so could be extremely helpful or even critical. For example, if it later comes to light that more lots or models than realized early in a recall are affected by a flaw that poses a serious health hazard, getting that updated information to patients could be a matter of life and death.

Updated recall information could in theory get to patients in much the same way as the original recall information got to them. But there are currently no formal or special mechanisms for ensuring updates are communicated. As a result, it is possible that important updates for patients are not getting the attention they may deserve. By the same token, patients themselves may be less likely to watch out for, make a point of reading, or seek out updated information. That is because they may be under the possibly false assumption that such information is not going to significantly change their own situations.

Are new mechanisms needed to ensure that important updates are likely to make their way to patients? And if so, what sorts of updated information should be included? Selectivity would probably be essential: Bombarding patients with a stream of detailed updates that have little significance to them would likely become background noise in which critical updates might be lost.

Simplifying Communications

It is essential to provide patients with access to timely information that is as clear, simple to understand, and easy to act on as possible. Currently, the FDA's communications about recalls

³⁶ CDC. *CDC Clear Communication Index*. Available at: <https://www.cdc.gov/ccindex/pdf/ClearCommUserGuide.pdf> (accessed September 8, 2021).

are written for a variety of audiences, including patients, caregivers, health care providers, and other external stakeholders. The FDA aims to ensure all communications use plain language and clear communication best practices, including displaying the information in an easy-to-read fashion. The goal is for readers to understand the content the first time they read it, increasing the chance that patients understand what to do in response to a recall. That means getting the point across quickly without using unnecessary words or technical jargon. Still, the need to present health care providers and other stakeholders with the detailed information they require to make sound decisions about a recall probably requires including more complex information than if the communication were aimed specifically at a patient population.

The Department of Health and Human Services emphasizes the need for simplified information, given low health literacy rates in the U.S. ³⁷ [According to the 2003 National Assessment of Adult Literacy](#), 88% of U.S. adults lack proficiency in understanding health information, and more than a third of them would have trouble following directions on a prescription label or carrying out other common health tasks.³⁸ Nearly half the population has limited abilities navigating the health care system and understanding probability and risk.³⁹

Even those with advanced general literacy skills may have trouble consuming health information, given the complexity and rapid progress of medical science. Regardless of literacy level, technical, or bureaucratic language can make information hard to digest. Additionally, patients facing a possible medical device recall may in some cases be experiencing relatively high levels of stress. That may be because of the recall, because of their medical condition, or for other reasons. Regardless of the cause, stress can further strain the ability to process information.⁴⁰

The need for simple communications is underscored by the fact that Americans increasingly read the news on a mobile device, compared to a desktop or laptop computer.⁴¹ Fifty-seven percent of Americans often read news on their mobile device, compared to 30% who use a desktop or laptop computer.⁴² Metrics for mobile access to the FDA safety communications

³⁷ AHRQ. *America's Health Literacy: Why We Need Accessible Health Information*. Available at: <https://www.ahrq.gov/sites/default/files/wysiwyg/health-literacy/dhhs-2008-issue-brief.pdf> (accessed September 2, 2021).

³⁸ These figures are based on a 2003 study, but more recent studies suggest literacy has not been changing significantly over time. National Center for Education Statistics. *National Assessment of Adult Literacy (NAAL) - Health Literacy - Highlights of Findings*. Available at: https://nces.ed.gov/naal/health_results.asp (accessed on September 8, 2021).

³⁹ MK Paasche-Orlow, RM Parker, JA Gazmararian, et al. *The prevalence of limited health literacy*. *J Gen Intern Med* 2005;20:175-84.

⁴⁰ Annual Review of Public Health. *Risk Communication for Public Health Emergencies*. Available at: <https://www.annualreviews.org/doi/full/10.1146/annurev.publhealth.28.021406.144123> (accessed September 1, 2021).

⁴¹ Pew Research Center. *Americans favor mobile devices over desktops and laptops for getting news*. Available at: <https://www.pewresearch.org/fact-tank/2019/11/19/americans-favor-mobile-devices-over-desktops-and-laptops-for-getting-news/> (accessed September 3, 2021).

⁴² See Footnote 41.

show that, depending on the topic, most visitors use mobile devices to read the information.⁴³ The use of mobile devices to read recall information makes it important to provide brief paragraphs and short titles that are easier to read on a smaller screen.⁴⁴

The FDA also faces challenges with communicating to individuals who do not speak English as their first language. The 2017 results of the [American Community Survey](#) of over 120 million households found over five million households were a limited English-speaking household. Over three million of those spoke Spanish as their first language, with over two million speaking other languages.⁴⁵ Simply translating health information into someone's native tongue does not guarantee it will be understandable. Health information for people with limited English proficiency needs to be communicated plainly in their primary language, using words and examples that make the information understandable and relatable in their native language. Currently, the FDA does not always translate the material it distributes in languages other than English.

Reaching the Digitally Underserved

Like other government entities, the FDA relies heavily on digital distribution mechanisms to distribute and amplify communications about safety concerns. All safety communications are posted to FDA's website and are then distributed through email distribution lists (to which individuals have subscribed) as well as social media. These messages are amplified by other digital means, such as articles in digital media, email sharing, and social sharing.

Despite the overall widespread use of digital communications, the access to or use of online resources varies considerably among different target audiences. According to a Pew Research Center analysis of 2021 survey data, 7% of U.S. adults age 18 and older do not use the internet.⁴⁶ The analysis found that internet non-adoption is linked to several demographic variables, including age, household income, educational attainment, and community type.

Among the groups significantly less likely to be online:

- Older adults, particularly adults over the age of 65 years
- Adults with a household income of less than \$30,000

⁴³ FDA. *Communicating Cybersecurity Vulnerabilities to Patients: Considerations for a Framework*. Available at: <https://www.fda.gov/media/143000/download> (accessed September 3, 2021).

⁴⁴ See Footnote 43.

⁴⁵ United States Census Bureau. *Household Language: 2017 American Community Survey 1-Year Supplemental Estimates with a Population Threshold of 20,000 or More*. Available at <https://data.census.gov/cedsci/table?text=C16002&hidePreview=true&tid=ACSDT1Y2017.C16002&tp=true> (accessed September 7, 2021).

⁴⁶ Pew Research Center. *7% of Americans don't use the internet. Who are they?* Available at: <https://www.pewresearch.org/fact-tank/2021/04/02/7-of-americans-dont-use-the-internet-who-are-they/> (accessed Sept. 1, 2021).

- Adults with a lower level of educational attainment, particularly adults with a high school education or less
- Adults who live in rural areas

These groups may need specially targeted safety communications that take into account their lack of online use or access.

The FDA uses available metrics to determine the reach of its communications on FDA's website. These metrics include how many people viewed an FDA webpage, such as a safety communication, the amount of time they spend viewing the content, and which country they are in at the time. But data on variables such as demographics are not currently available. Likewise, FDA can measure email and social media reach, including how many people opened the email or liked a Tweet. But specific feedback on a page is not currently assessed. An agency-wide voice of the customer (VOC) survey is being implemented on FDA's website, and there may be opportunities to use that system to get patient feedback on FDA's safety communications. Other techniques that have been used to evaluate the effectiveness of communications include:

- Surveys
- Evaluations from risk communication experts
- Message testing
- Usability testing of content and navigation
- User data on interactions with the safety communication

Learning from Other Agencies

Recalls are not unique to medical devices or products regulated by FDA. Other industries face similar challenges effectively reaching their target audience with relevant information that makes it clear what to do in response to a recall. It may be valuable to look to agencies that oversee the automotive and consumer product industries, for example, to leverage effective communication practices and lessons learned. The National Highway Traffic Safety Administration analyzed recalls of motor vehicles to identify common traits of effective "recall campaigns." These include:

- Direct and plain language about the risk
- Current contact information
- An escalation strategy that includes multi-channel and multi-touch approaches
- Conspicuous use of the manufacturer's brands or logos on recall material
- An approach that considers demographics, what barriers exist to obtaining the repair, and a plan that mitigates those barriers
- An execution strategy that best leverages the power, knowledge, and relationships of the manufacturer's network⁴⁷

⁴⁷ NHTSA. *Tips for Increasing Recall Completion Rates*. Available at: <https://www.nhtsa.gov/vehicle-manufacturers/tips-increasing-recall-completion-rates> (accessed September 9, 2021).

Similarly, the Consumer Product Safety Commission (CPSC) held a workshop in 2017 to “explore and develop proactive measures that CPSC and stakeholders can take to improve recall effectiveness.” The CPSC noted that direct notice recalls have proven to be the most effective and improved product registration methods could lead to higher consumer participation.⁴⁸

Limitations

No matter how much the FDA improves its notifications about recalls, they might not have the needed impact on patients who have already made up their minds about recalls that affect them. Patients might quickly form opinions and make decisions about a recall based on what they’ve heard from manufacturers and other non-FDA sources. One question to explore is whether the FDA can find new ways to collaborate with other information sources to support clear and consistent information and avoid confusing or misleading differences.

The case of the 2011 Class I recall of heart-defibrillator leads from Riata provides an example of the challenges faced by the FDA, patients, health care providers and manufacturers when communicating about a recall. It was a complex decision as to whether it was medically advisable to surgically remove these leads, which are wires than run from an implanted electronic device to the heart.^{49,50} It was a decision that required weighing the risk of surgery versus the risk of the leads causing a potentially fatal short circuit in the heart. In addition, these factors had to be considered along with the specific situation for the individual patient. These sorts of decisions are properly made by patients in close consultation with their health care providers. The FDA does not make medical recommendations or otherwise interfere in the practice of medicine. For these reasons, many recall communications by manufacturers or by the FDA have historically been directed primarily to health care providers and hospitals rather than patients.

Similarly, manufacturer recall communications typically go out only to health care providers and hospitals, and in some select cases distributors. In some situations, FDA will request the recalling manufacturer to directly notify affected medical device users or patients. However, it can be challenging for manufacturers or the FDA to identify specific users and patients with a recalled device. This results in practical limitations on the effectiveness of FDA’s request. Still, it

⁴⁸ CPSC. *Recall Effectiveness Workshop Report*. Available at: https://www.cpsc.gov/s3fs-public/Recall_Effectiveness_Workshop_Report-2018.pdf?R1VyLltrl8M_id.2vkAkIHozjaSCab (accessed September 9, 2021).

⁴⁹ Barrett CD, Danik SB. The Riata lead recall—More data, but do we now know what we need to know? *Heart Rhythm* 2013;10(12): 1783-1784. Available at: [https://www.heartrhythmjournal.com/article/S1547-5271\(13\)01073-4/fulltext](https://www.heartrhythmjournal.com/article/S1547-5271(13)01073-4/fulltext) (accessed September 1, 2021).

⁵⁰ Gwag HB, Hwang JK, et al. The Incidence of Riata Defibrillator Lead Failure: a Single-Center Experience. *J Korean Med Sci*. 2017; 32(10): 1610-1615. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5592174/> (accessed September 1, 2021).

may be worth examining the criteria the FDA applies for making this request of manufacturers, and more generally for exerting influence over manufacturer communications and even communicating in place of or in parallel with manufacturers.

Media coverage can also have more influence on patients than FDA communications. There are obvious and necessary limitations to the FDA's ability to influence this coverage. But there may be opportunities to engage members of the media more effectively, so that their reporting on recalls includes highlighting information that is helpful to patients. To that end, insights into what patients read and how they are influenced by and react to media accounts of recalls would be useful.

Conclusion

The challenges and limitations discussed above affect how much the FDA can do to reach patients with recall communications that are ideally suited to their differing needs. However, the FDA would like to identify opportunities to enhance the way it provides information about recalls clearly and effectively, in a timely fashion, and in ways that are relevant and beneficial to patients. FDA seeks to learn more about patient perspectives on these issues, and the role industry, health care providers and others in the medical device community play in effective recall communication. These insights will be a highly valuable resource in promoting and protecting public health.