Report to Congress

Postmarket Device Safety-Related Communications

(Consolidated Appropriations Act, 2023 (P.L. 117-328))

Executive Summary

The Center for Devices and Radiological Health (CDRH) in the Food and Drug Administration (FDA) is charged with protecting and promoting the public health and ensuring that the over 238,000 different types of medical devices CDRH regulates are safe and effective for patients in the United States.

FDA strives to provide current information concerning the benefits and risks of marketed medical devices to health care providers, patients, and consumers so that they can make informed treatment and diagnostic decisions. When a device safety risk is identified, CDRH may address the identified risk through a variety of methods, including sharing information with health care providers, patients, and caregivers. From January 1, 2022, through December 31, 2022, CDRH issued 45 safety-related communications, including 30 Medical Device Safety Communications (see https://www.fda.gov/medical-devices/medical-device-safety/safety-communications) and 15 Letters to Health Care Providers (see https://www.fda.gov/medical-devices/medical-device-safety/letters-health-care-providers). Of the 45 safety-related communications issued in 2022, 23 provided new information about device safety, eight provided new information about recalls that had resolved the problem (e.g., the device was removed from the market), and 14 provided updates to previous communications issued by CDRH.

The most recent safety-related communications released by CDRH can be found on CDRH's Medical Device Safety website (https://www.fda.gov/medical-devices/medical-device-safety).

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Acronym List

CDRH	Center for Devices and Radiological Health
FDA	Food and Drug Administration
MDR	Medical Device Reports

Background

According to its mission statement (https://www.fda.gov/about-fda/what-we-do#mission), the Food and Drug Administration (FDA)

> is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation. FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.

FDA is composed of several Offices and Centers, including the Center for Devices and Radiological Health (CDRH). CDRH is charged with protecting and promoting the public health and ensuring that the over 238,000 different types of medical devices it regulates are safe and effective for patients in the United States.[1]

CDRH strives to ensure that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. To do so, FDA conducts postmarket surveillance. New information about a device's safety, such as reports of unexpected adverse events, may become available once a device is more widely distributed and used under real-world conditions (e.g., in routine clinical practice, in the home setting, in broader patient populations, and by a broader range of clinicians). In these real-world settings, new safety concerns may be identified. When a device safety risk is identified, CDRH may address the identified risk through a variety of methods, including sharing information with health care providers, patients, and caregivers.

Within the scope of CDRH's activities to promote and protect the public health, CDRH utilizes communication measures to inform health care providers and the public regarding changes in the safety of or the identification of previously unknown risks associated with the use of a given marketed medical device or device type. These communication measures involve communicating with the public about safety concerns; the intent of these public communications is to provide health care providers, patients, and consumers with access to the most current information concerning the performance and potential benefits and risks of marketed medical devices so that they can make informed decisions about their treatment and diagnostic options.

Under section 3307(b) of the Consolidated Appropriations Act, 2023 (P.L. 117-328), the Secretary of Health and Human Services has been charged with the following:

[1] Although medical devices provide great benefits to patients, they also present risks. FDA's public health responsibilities span the life cycle of medical devices and, at every stage, FDA must make well-supported regulatory decisions, taking into account the totality of the evidence, to determine whether the benefits outweigh the risks.

> Not later than September 30, 2023, and biennially thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, and publish on the website of the Food and Drug Administration, a report on the number of postmarket device signals communications issued by the Secretary, the sources of data for such signals, and how such signals were revised or resolved.

This report is in response to that charge.

II. Safety-Related Communications (January 1, 2022 – December 31, 2022)

A. Sources of Data

To ensure the safety and effectiveness of devices once they are on the market, CDRH continues to monitor for and address device safety risks. CDRH uses a multifaceted approach that relies on various methods and techniques under its current authorities. For example, CDRH monitors reports of adverse events and other problems with medical devices from a variety of sources, including, but not limited to, medical device reports (MDRs), which are reports of certain adverse events and device malfunctions; reports from MedSun, which is an adverse event reporting program (see https://www.fda.gov/medical-devices/medical-device-safety/medsun-medical-product-safety-network); data from mandated postmarket studies; clinical trials or data published in scientific literature; and epidemiological research, including evaluations of administrative databases, health care claims data or registries, and inquiries or investigations from global, federal, or state health agencies. In addition, CDRH seeks information from, or consults with, stakeholders such as external clinical or scientific experts, patients, industry, and other governmental and regulatory agencies.

The safety-related communications issued by CDRH during calendar year 2022 are supported by information from the following items:

- Advisory committee meetings;
- Complaints and allegations;
- Device authorizations;
- Device shortages and supply chain concerns;
- Inspections of device establishments for compliance with quality system and other applicable requirements;
- Laboratory evaluations;
- Manufacturer reports of corrections and removals;
- MDRs;
- Post-approval study results;
- Postmarket surveillance study (also referred to as “522 study”) results;
- Regular monitoring of the marketing of unauthorized, unapproved, or uncleared diagnostic tests (e.g., COVID-19 tests), including reports of problems with test performance or results;
- Review of the scientific literature; and
- Updates to product labeling.

B. Types of Communications

CDRH addresses device safety risks in a variety of ways, such as through product recalls and safety-related communications. CDRH uses the following two types of safety-related communications to inform the public of problems or potential problems with devices that are on the market: Medical Device Safety Communications and Letters to Health Care Providers. First, CDRH uses Medical Device Safety Communications to describe FDA's current analysis of issues, which include specific regulatory approaches and clinical recommendations for patient management. Second, CDRH posts Letters to Health Care Providers to provide information for health care providers about the safe use of medical devices in medical facilities.

From January 1, 2022, through December 31, 2022, CDRH issued 45 safety-related communications, including 30 Medical Device Safety Communications (see https://www.fda.gov/medical-devices/medical-device-safety/safety-communications) and 15 Letters to Health Care Providers (see https://www.fda.gov/medical-devices/medical-device-safety/letters-health-care-providers). Of these 45 safety-related communications issued in 2022:

- Twenty-three provided new information about device safety (Appendix A);
- Eight provided new information about device safety recalls that had resolved the problem (e.g., the device was removed from the market) (Appendix B); and
- Fourteen provided updated information about device safety to previous communications issued by CDRH (Appendix C), including four that provided updated information to safety-related communications issued by CDRH in 2022 and ten that provided updated information to safety-related communications issued by CDRH prior to 2022.

CDRH takes regulatory or enforcement actions to resolve postmarket problems when appropriate. Generally, CDRH has many avenues it can take to resolve these problems, including:

- Requesting or requiring the manufacturer to remove the device from the market;
- Issuing public communications;
- Conducting inspections;
- Sending advisory action letters to manufacturers and firms marketing the device;
- Issuing guidances;
- Developing standards regarding a particular device area;
- Requiring postmarket surveillance studies; and
- Upclassification of a device (e.g. reassignment to Class III).

In some cases, CDRH determines that no action is required.

Sources Utilized for This Report

The following publicly available sources were utilized in preparing this report:

- Medical Device Safety (https://www.fda.gov/medical-devices/medical-device-safety)
- 2022 Safety Communications (https://www.fda.gov/medical-devices/safety-communications/2022-safety-communications)
- 2022 Letters to Health Care Providers (https://www.fda.gov/medical-devices/letters-health-care-providers/2022-letters-health-care-providers)
- Medical Device Safety Action Plan: Protecting Patients, Promoting Public Health (https://www.fda.gov/about-fda/cdrh-reports/medical-device-safety-action-plan-protecting-patients-promoting-public-health)
- CDRH 2022 Annual Report (https://www.fda.gov/about-fda/cdrh-reports/cdrh-2022-annual-report)

Conclusion

At every stage of a device's life cycle, CDRH maintains a robust program for evaluating its safety. Ensuring the safety of medical devices on an ongoing basis includes having a vigilant postmarket surveillance system for the timely identification of new or increased safety concerns, sharing timely public communications/notifications about safety concerns when warranted, and addressing concerns through a variety of methods.

The Medical Device Safety Action Plan: Protecting Patients, Promoting Public Health (https://www.fda.gov/media/112497/download) outlines a vision for how CDRH can continue to enhance its programs and processes to ensure the safety of medical devices throughout the total product life cycle. These programs and processes include providing for the timely communication and resolution of new or increased safety issues and advancing innovative technologies that are safer, are more effective, and address unmet needs.

CDRH strives to provide current information concerning the benefits and risks of marketed medical devices to health care providers, patients, and consumers so that they can make informed treatment and diagnostic decisions. The most recent safety-related communications released by CDRH can be found on CDRH's Medical Device Safety website (https://www.fda.gov/medical-devices/medical-device-safety).

Appendix A – CDRH's 2022 Safety Communications and Letters to Health Care Providers That Provided New Information About Device Safety

Date	Communication	Type
11/03/2022	Do Not Use Infant Head Shaping Pillows to Prevent or Treat Any Medical Condition: FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/do-not-use-infant-head-shaping-pillows-prevent-or-treat-any-medical-condition-fda-safety)	Safety Communication
10/31/2022	Reuse Tracheostomy Tubes or Switch to Appropriate Alternatives During Shortage: FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/reuse-tracheostomy-tubes-or-switch-appropriate-alternatives-during-shortage-fda-safety-communication)	Safety Communication
09/08/2022	Breast Implants: Reports of Squamous Cell Carcinoma and Various Lymphomas in Capsule Around Implants: FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/breast-implants-reports-squamous-cell-carcinoma-and-various-lymphomas-capsule-around-implants-fda)	Safety Communication
09/06/2022	Certain Philips Respironics Masks for BiPAP, CPAP Machines Recalled Due to Safety Issue with Magnets That May Affect Certain Medical Devices: FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/certain-philips-respironics-masks-bipap-cpap-machines-recalled-due-safety-issue-magnets-may-affect)	Safety Communication
08/29/2022	Certain Philips Respironics BiPAP Machines Recalled Due to a Plastic Issue: FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/certain-philips-respironics-	Safety Communication

	bipap-machines-recalled-due-plastic-issue-fda-safety-communication)	
08/11/2022	At-Home COVID-19 Antigen Tests-Take Steps to Reduce Your Risk of False Negative: FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/home-covid-19-antigen-tests-take-steps-reduce-your-risk-false-negative-results-fda-safety)	Safety Communication
07/20/2022	Do Not Use Ultraviolet (UV) Wands That Give Off Unsafe Levels of Radiation: FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/do-not-use-ultraviolet-uv-wands-give-unsafe-levels-radiation-fda-safety-communication)	Safety Communication
07/15/2022	For Monkeypox Testing, Use Lesion Swab Samples to Avoid False Results: FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/monkeypox-testing-use-lesion-swab-samples-avoid-false-results-fda-safety-communication)	Safety Communication
06/28/2022	Do Not Use Baby Neck Floats Due to the Risk of Death or Injury: FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/do-not-use-baby-neck-floats-due-risk-death-or-injury-fda-safety-communication)	Safety Communication
04/19/2022	Genetic Non-Invasive Prenatal Screening Tests May Have False Results: FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/genetic-non-invasive-prenatal-screening-tests-may-have-false-results-fda-safety-communication)	Safety Communication
03/18/2022	Use and Store At-Home COVID-19 Tests Properly to Avoid Potential Harm: FDA Safety Communication	Safety Communication

	(https://www.fda.gov/medical-devices/safety-communications/use-and-store-home-covid-19-tests-properly-avoid-potential-harm-fda-safety-communication)	
03/14/2022	FDA Warns Against Use of Renuvion/J-Plasma Device for Certain Aesthetic Procedures: FDA Safety Communication (https://public4.pagefreezer.com/browse/FDA/10-05-2023T14:26/https:/www.fda.gov/medical-devices/safety-communications/fda-warns-against-use-renuvionj-plasma-device-certain-aesthetic-procedures-fda-safety-communication)	Safety Communication
02/08/2022	Potential Risk of Strangulation in Children Who Use Enteral Feeding Delivery Sets - FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/potential-risk-strangulation-children-who-use-enteral-feeding-delivery-sets)	Safety Communication
12/02/2022	Getinge Maquet/Datascope Intra-Aortic Balloon Pump (IABP) Shortage - Letter to Health Care Providers (https://www.fda.gov/medical-devices/letters-health-care-providers/getinge-maquetdatascope-intra-aortic-balloon-pump-iabp-shortage-letter-health-care-providers)	Letter to Health Care Provider
10/31/2022	Consider Alternatives for MRI-Guided Breast Biopsy Grid Plates Due to Shortage - Letter to Health Care Providers (https://public4.pagefreezer.com/browse/FDA/07-06-2023T13:28/https:/www.fda.gov/medical-devices/letters-health-care-providers/consider-alternatives-mri-guided-breast-biopsy-grid-plates-due-shortage-letter-health-care-providers)	Letter to Health Care Provider
09/08/2022	Abbott MitraClip Device: Potential for Clip Lock Malfunctions - Letter to Health Care Providers (https://www.fda.gov/medical-devices/letters-health-care-providers/abbott-mitraclip-device-potential-clip-lock-malfunctions-letter-health-care-providers)	Letter to Health Care Provider

09/06/2022	Certain Philips Respironics Masks for BiPAP, CPAP Machines Recalled Due to Safety Issue with Magnets That May Affect Certain Medical Devices: Letter to Health Care Providers (https://www.fda.gov/medical-devices/letters-health-care-providers/certain-philips-respironics-masks-bipap-cpap-machines-recalled-due-safety-issue-magnets-may-affect)	Letter to Health Care Provider
06/02/2022	Illumina Cybersecurity Vulnerability May Present Risks for Patient Results and Customer Networks: Letter to Health Care Providers (https://www.fda.gov/medical-devices/letters-health-care-providers/illumina-cybersecurity-vulnerability-may-present-risks-patient-results-and-customer-networks-letter)	Letter to Health Care Provider
04/28/2022	Potential for Internal Pump Malfunction in the Medtronic HVAD System – Letter to Health Care Providers (https://www.fda.gov/medical-devices/letters-health-care-providers/potential-internal-pump-malfunction-medtronic-hvad-system-letter-health-care-providers)	Letter to Health Care Provider
04/27/2022	Potential Risk of Airway Obstruction When Using Certain Electromyogram Endotracheal Tubes – Letter to Health Care Providers (https://www.fda.gov/medical-devices/letters-health-care-providers/potential-risk-airway-obstruction-when-using-certain-electromyogram-endotracheal-tubes-letter-health)	Letter to Health Care Provider
04/11/2022	Intended Use of Imaging Software for Intracranial Large Vessel Occlusion - Letter to Health Care Providers (https://www.fda.gov/medical-devices/letters-health-care-providers/intended-use-imaging-software-intracranial-large-vessel-occlusion-letter-health-care-providers)	Letter to Health Care Provider
03/21/2022	Prefilled Saline Flush Syringe Conservation Strategies - Letter to Health Care Personnel (https://public4.pagefreezer.com/browse/FDA/23-03-2022T15:36/https:/www.fda.gov/medical-devices/letters-health-care-providers/prefilled-	Letter to Health Care Provider

	saline-flush-syringe-conservation-strategies-letter-health-care-personnel)	
02/28/2022	FDA Advisory Panel Recommendations on Lifelong Surveillance and Long-Term Postmarket Data Collection for Patients with AAA Endovascular Aortic Repair - Letter to Health Care Providers (https://www.fda.gov/medical-devices/letters-health-care-providers/fda-advisory-panel-recommendations-lifelong-surveillance-and-long-term-postmarket-data-collection)	Letter to Health Care Provider

Appendix B – CDRH's 2022 Safety Communications and Letters to Health Care Providers That Provided New Information About Device Safety Recalls That Resolved the Problem

Date	Communication	Type
01/11/2022	Stop Using LuSys Laboratories COVID-19 Tests: FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/stop-using-lusys-laboratories-covid-19-tests-fda-safety-communication)	Safety Communication
01/28/2022	Stop Using Empowered Diagnostics COVID-19 Tests: FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/stop-using-empowered-diagnostics-covid-19-tests-fda-safety-communication)	Safety Communication
02/04/2022	Do Not Use E25Bio COVID-19 Tests: FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/do-not-use-e25bio-covid-19-tests-fda-safety-communication)	Safety Communication
03/01/2022	Do Not Use Certain Celltrion DiaTrust COVID-19 Tests: FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/do-not-use-certain-celltrion-diatrust-covid-19-tests-fda-safety-communication)	Safety Communication
03/01/2022	Do Not Use Certain ACON Flowflex COVID-19 Tests: FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/do-not-use-certain-acon-flowflex-covid-19-tests-fda-safety-communication)	Safety Communication
03/01/2022	Do Not Use SD Biosensor STANDARD Q COVID-19 Ag Home Tests: FDA Safety Communication	Safety Communication

	(https://www.fda.gov/medical-devices/safety-communications/do-not-use-sd-biosensor-standard-q-covid-19-ag-home-tests-fda-safety-communication)	
05/10/2022	Do Not Use Skippack Medical Lab SARS-CoV-2 Antigen Rapid Test: FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/do-not-use-skippack-medical-lab-sars-cov-2-antigen-rapid-test-fda-safety-communication)	Safety Communication
10/25/2022	Do Not Use Certain Mighty Bliss Electric Heating Pads Due to Risk of Injury: FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/do-not-use-certain-mighty-bliss-electric-heating-pads-due-risk-injury-fda-safety-communication)	Safety Communication

Appendix C – CDRH's 2022 Safety Communications and Letters to Health Care Providers That Provided Updated Information—in Reference to Previous CDRH Communications—About Device Safety

Date	Communication	Type
01/13/2022	Update on Risk of Type III Endoleaks with Use of Endologix AFX Endovascular AAA Graft Systems - FDA Safety Communication (https://public4.pagefreezer.com/browse/FDA/06-07-2023T14:46/https://www.fda.gov/medical-devices/safety-communications/update-risk-type-iii-endoleaks-use-endologix-afx-endovascular-aaa-graft-systems-fda-safety)	Safety Communication
04/05/2022	Use Duodenoscopes with Innovative Designs to Enhance Safety: FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/use-duodenoscopes-innovative-designs-enhance-safety-fda-safety-communication)	Safety Communication
06/02/2022	UPDATE: FDA Updates Recommendations for the Use of Renuvion/J-Plasma Device for Certain Aesthetic Procedures: FDA Safety Communication (https://public4.pagefreezer.com/browse/FDA/30-06-2023T13:23/https:/www.fda.gov/medical-devices/safety-communications/update-fda-updates-recommendations-use-renuvionj-plasma-device-certain-aesthetic-procedures-fda)	Safety Communication
06/30/2022	UPDATE: Mammography Problems at Capitol Radiology, LLC, doing business as Laurel Radiology Services in Laurel, Maryland: FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/update-mammography-problems-capitol-radiology-llc-doing-business-laurel-radiology-services-laurel)	Safety Communication

07/21/2022	UPDATE: Use of Renuvion/J-Plasma Device for Certain Aesthetic Procedures: FDA Safety Communication (https://public4.pagefreezer.com/browse/FDA/28-07-2023T13:45/https:/www.fda.gov/medical-devices/safety-communications/update-use-renuvionj-plasma-device-certain-aesthetic-procedures-fda-safety-communication)	Safety Communication
09/15/2022	Pulse Oximeter Accuracy and Limitations: FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/pulse-oximeter-accuracy-and-limitations-fda-safety-communication)	Safety Communication
11/17/2022	UPDATE: Certain Philips Respironics Ventilators, BiPAP Machines, and CPAP Machines Recalled Due to Potential Health Risks: FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/update-certain-philips-respironics-ventilators-bipap-machines-and-cpap-machines-recalled-due)	Safety Communication
12/06/2022	Update on Endologix AFX Endovascular AAA Graft Systems and Risk of Type III Endoleak: FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/update-endologix-afx-endovascular-aaa-graft-systems-and-risk-type-iii-endoleak-fda-safety)	Safety Communication
12/22/2022	Certain Reworked Philips Respironics Trilogy 100/200 Ventilators Recalled Due to Potential for Silicone Foam Adhesion Failure and Residual PE-PUR Foam Debris: FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/certain-reworked-philips-respironics-trilogy-100200-ventilators-recalled-due-potential-silicone-foam)	Safety Communication
01/19/2022	UPDATE: Blood Specimen Collection Tube Conservation Strategies - Letter to Health Care and Laboratory Personnel (https://public4.pagefreezer.com/browse/FDA/24-	Letter to Health Care Provider

	01-2022T16:04/https:/www.fda.gov/medical-devices/letters-health-care-providers/update-blood-specimen-collection-tube-conservation-strategies-letter-health-care-and-laboratory)	
04/04/2022	UPDATE: Change in Reprocessing Methods with Certain Karl Storz Urological Endoscopes - Letter to Health Care Providers (https://www.fda.gov/medical-devices/letters-health-care-providers/update-change-reprocessing-methods-certain-karl-storz-urological-endoscopes-letter-health-care)	Letter to Health Care Provider
09/16/2022	Update: Recommendations for Certain Medtronic Electromyogram Endotracheal Tubes and Risk of Airway Obstruction – Letter to Health Care Providers (https://www.fda.gov/medical-devices/letters-health-care-providers/update-recommendations-certain-medtronic-electromyogram-endotracheal-tubes-and-risk-airway)	Letter to Health Care Provider
10/28/2022	Potential Risk of Exposure to Toxic Compounds When Using Certain Hemodialysis Machines Manufactured by Fresenius Medical Care – Letter to Health Care Providers (https://www.fda.gov/medical-devices/letters-health-care-providers/potential-risk-exposure-toxic-compounds-when-using-certain-hemodialysis-machines-manufactured)	Letter to Health Care Provider
12/05/2022	UPDATE: Impella RP System Post-Approval Study Results and Updated Labeling - Letter to Health Care Providers (https://www.fda.gov/medical-devices/letters-health-care-providers/update-impella-rp-system-post-approval-study-results-and-updated-labeling-letter-health-care)	Letter to Health Care Provider

This report was prepared by FDA's Office of Product Quality in the Center for Devices and Radiological Health. For information, please contact:

U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

This report is available on FDA's home page at https://www.fda.gov/.