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I. FDA Device Approvals

Abbott Receives FDA Clearance for New Cardiac Mapping System to Improve How Doctors Treat Abnormal Heart Rhythms

On January 12, 2022, Abbot received FDA clearance for the EnSite X EP System with EnSite Omnipolar Technology (OT), a new cardiac mapping platform. It is designed to help physicians better treat abnormal heart rhythms, also known as cardiac arrhythmias. Designed with input from electrophysiologists from around the world, the system creates highly detailed three-dimensional maps of the heart to help physicians identify and then treat areas of the heart where abnormal rhythms originate. [FN2]

Millions of Americans are affected by abnormal heart rhythms caused by breakdowns in the electrical pathways of the heart. Left untreated, these breakdowns can lead to erratic heartbeats or cause the heart to beat too fast or too slow, which can dramatically impact a patient's health. Atrial fibrillation (AFib), the most common arrhythmia the EnSite X EP System with EnSite OT can help treat, is a condition in which the heart's chambers are out of sync, causing them to beat in a rapid and chaotic fashion. In some cases, untreated arrythmias like AFib may eventually lead to heart failure or stroke.

Increasingly, physicians are turning to cardiac ablation to treat cardiac arrhythmias because -unlike medication - the therapy treats the condition at the source by disrupting the area of the heart generating abnormal heart beats. Cardiac mapping is critical to successful ablation therapy because highly precise, accurate and detailed images of the heart allow physicians to determine the best location to deploy therapy safely and effectively.

Traditional mapping systems use either unipolar or bipolar measurement principles. While unipolar measurements have multiple advantages, including direction and speed, bipolar measurements provide local signal measuring to pinpoint areas of concern. The EnSite X System with EnSite OT brings the best of both measurement principles together to maximize data collection.

FDA Grants Expanded Indication for Abbott's CardioMEMS HF System

On February 23, 2022, Abbott announced the FDA approved an expanded indication for the company's CardioMEMS HF System to support the care of more people living with heart failure. With the expanded indication, an additional 1.2 million US patients are now eligible to benefit from advanced monitoring with the CardioMEMS sensor, which marks a significant increase over the current addressable population. The sensor provides an early warning system enabling doctors to protect against worsening heart failure. [FN3]

The CardioMEMS sensor is a paperclip-sized device that, once placed in the pulmonary artery during a minimally invasive procedure, monitors for pressure changes that indicate worsening heart failure. The sensor wirelessly transmits daily pressure readings to a patient's clinical team ? allowing physicians to make therapy changes to combat progression to later-stage heart failure while empowering the patient to manage their condition from virtually anywhere.

The CardioMEMS HF System was initially approved in 2014 for use in New York Heart Association (NYHA) Class III heart failure patients with a prior heart failure hospitalization within the last year. The new indication allows the CardioMEMS sensor to be used by people living with Class II heart failure and for patients who undergo a blood test showing elevated levels of biomarkers known as natriuretic peptides, which indicate worsening heart failure.

FDA Authorizes First COVID-19 Diagnostic Test Using Breath Samples

On April 14, 2022, the FDA issued an emergency use authorization (EUA) for the first COVID-19 diagnostic test that detects chemical compounds in breath samples associated with a SARS-CoV-2 infection. The test can be performed in environments where the patient specimen is both collected and analyzed, such as doctor's offices, hospitals and mobile testing sites, using an instrument about the size of a piece of carry-on luggage. The test is performed by a qualified, trained operator under the supervision of a health care provider licensed or authorized by state law to prescribe tests and can provide results in less than three minutes. [FN4]

'Today's authorization is yet another example of the rapid innovation occurring with diagnostic tests for COVID-19," said Jeff Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health. 'The FDA continues to support the development of novel COVID-19 tests with the goal of advancing technologies that can help address the current pandemic and better position the U.S. for the next public health emergency."

The InspectIR COVID-19 Breathalyzer uses a technique called gas chromatography gas mass-spectrometry (GC-MS) to separate and identify chemical mixtures and rapidly detect five Volatile Organic Compounds (VOCs) associated with SARS-CoV-2 infection in exhaled breath.

FDA Permits Marketing for New Test to Improve Diagnosis of Alzheimer's Disease

On May 4, 2022, the FDA permitted marketing for the first in vitro diagnostic test for early detection of amyloid plaques associated with Alzheimer's disease. The Lumipulse G #-Amyloid Ratio (1-42/1-40) test is intended to be used in adult patients, aged 55 years and older, presenting with cognitive impairment who are being evaluated for Alzheimer's disease and other causes of cognitive decline. [FN5]

'The availability of an in vitro diagnostic test that can potentially eliminate the need for time-consuming and expensive PET scans is great news for individuals and families concerned with the possibility of an Alzheimer's disease diagnosis," said Jeff Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health. 'With the Lumipulse test, there is a new option that can typically be completed the same day and can give doctors the same information regarding brain amyloid status, without the radiation risk, to help determine if a patient's cognitive impairment is due to Alzheimer's disease."

According to the National Institutes of Health, more than six million Americans, most age 65 or older, may have dementia caused by Alzheimer's disease, a brain disorder known to slowly destroy memory and thinking skills, and, eventually, the ability to carry out the simplest tasks. In most people with Alzheimer's disease, clinical symptoms first appear later in life.

Alzheimer's disease is progressive, meaning that the disease gets worse over time. Early and accurate diagnosis is important to help patients and caregivers with planning and early treatment options. There is an unmet need for a reliable and safe test that can accurately identify patients with amyloid plaques consistent with Alzheimer's disease. While amyloid plaques can occur in other diseases, being able to detect the presence of plaque, along with other evaluations, helps the doctor determine the probable cause of the patient's symptoms and findings. Prior to today's authorization, doctors used positron emission tomography (PET) scans, a potentially costly and cumbersome option, to detect/visualize amyloid plaques in a patient's brain, often years before clinical symptom onset, to aid in diagnosing Alzheimer's disease.

The FDA permitted marketing of the Lumipulse G ?-Amyloid Ratio (1-42/1-40) to Fujirebio Diagnostics, Inc.

FDA Authorizes First COVID-19 Test Available without a Prescription That Also Detects Flu and RSV

On May 16, 2022, the FDA authorized the Labcorp Seasonal Respiratory Virus RT-PCR DTC Test for use without a prescription by individuals with symptoms of respiratory viral infection consistent with COVID-19. This product is the first direct-to-consumer (non-prescription) multi-analyte COVID-19 test authorized by FDA and allows an individual to self-collect a nasal swab sample at home and then send that sample to Labcorp for testing. The test can identify and differentiate multiple respiratory viruses at the same time, detecting influenza A and B, commonly known as the flu, respiratory syncytial virus, commonly known as RSV, along with SARS-CoV-2, the virus that causes COVID-19. Results are delivered through an online portal, with follow-up from a health care provider for positive or invalid test results. [FN6]

'While the FDA has now authorized many COVID-19 tests without a prescription, this is the first test authorized for flu and RSV, along with COVID-19, where an individual can self-identify their need for a test, order it, collect their sample and send it to the lab for testing, without consulting a health care professional," said Jeff Shuren, M.D., J.D., director of FDA's Center for Devices and Radiological Health. 'The rapid advances being made in consumer access to diagnostic tests, including the ability to collect your sample at home for flu and RSV without a prescription, brings us one step closer to tests for these viruses that could be performed entirely at home."

This home sample collection kit can be purchased online or in a store without a prescription. The samples can be self-collected by individuals ages 18 years and older, self-collected by individuals 14 years and older with adult supervision, or collected with adult assistance for individuals 2 years and older. This will enable consumers to more easily determine whether they may be infected with COVID-19, flu, or RSV, which can aid in determining if self-isolation (quarantine) is appropriate and to assist with health care decisions after discussion with a health care professional.

U.S. Over-the-Counter Hearing Aids Now Available

On October 17, 2022, most major U.S. retailers began selling lower-cost hearing aids without a prescription or medical exam as final federal administration rules [FN7] became effective.

The FDA in August approved the sale of over-the-counter hearing aids, allowing millions of Americans to buy hearing aids without seeing an audiologist and potentially saving individuals thousands of dollars. [FN8]

The rules apply to hearing aids for people with mild to moderate hearing loss. The aids will be available directly from stores or online without medical exams, a prescription or audiologist fitting adjustment.

White House National Economic Council director Brian Deese said in August the government estimated the rule will save consumers about $2,800 per pair of hearing aids and could help 'tens of millions of Americans.'

In 2017, Congress passed legislation requiring the FDA to create a category of over-the-counter hearing aids, but it was not fully implemented. In June 2021, President Joe Biden signed a broad competition executive order that instructed the Health and Human Services Department to 'promote the wide availability of low-cost hearing aids.'

II. Warnings, Recalls and Suspensions

FDA Says Empowered Diagnostics Recalling COVID-19 Tests

On January 28, 2022, the FDA issued a warning for people to stop using the Empowered Diagnostics CovClear COVID-19 Rapid Antigen Test and ImmunoPass COVID-19 Neutralizing Antibody Rapid Test. These tests were distributed with labeling indicating they are authorized by the FDA, but neither test has been authorized, cleared, or approved by the FDA for distribution or use in the United States. The FDA is concerned about the potentially higher risk of false results when using unauthorized tests. [FN9]

The FDA indicated that Empowered Diagnostics is recalling the CovClear COVID-19 Rapid Antigen Test and the ImmunoPass COVID-19 Neutralizing Antibody Rapid Test, and the FDA has identified this issue as a Class I recall, the most serious type of recall.

Philips Respironics Recalls Certain Trilogy EVO Ventilators for Potential Health Risks from PE-PUR Foam

On January 26, 2022, the FDA classified an expanded recall of certain ventilators by Philips late last year as Class 1, or the most serious type, saying they could lead to injuries or death. [FN10]

Phillips initiated the recall of 215 Trilogy Evo ventilators and 51 repair kits in the United States in December due to potential health risks from a type of foam used in the devices.

A Philips supplier incorrectly used polyester-based polyurethane (PE-PUR) sound abatement foam, a non-conforming material, in the muffler assembly of the affected Trilogy Evo ventilators. The issue was identified during lab testing of the Trilogy Evo ventilator. The Trilogy Evo ventilators with non-conforming foam were distributed to customers in the United States and Korea. There have been no reported injuries or death to date.

FDA Orders Philips Respironics to Notify Patients Regarding the Recall of Certain Breathing Assistance Machines

On March 10, 2022, the FDA issued a notification order to Philips Respironics requiring the company to notify patients and others of the company's June 14, 2021, recall of certain Philips Respironics ventilators, continuous positive airway pressure (CPAP) and bilevel positive airway pressure (BiPAP) machines, and the unreasonable risk of substantial harm to the public health posed by the degradation of the polyester-based polyurethane (PE-PUR) sound abatement foam used in those products. The FDA has determined that this order is necessary to eliminate the unreasonable risk of harm posed by the recalled products, because the company's notification efforts to date have been inadequate. [FN11]

'The FDA has heard the frustration expressed by patients and durable medical equipment suppliers who are unaware of the recall and have received insufficient information on their next steps regarding the recall process," said Jeff Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health. 'Taking this action today enables the FDA to mandate that Philips Respironics improve its communication about the recall and the serious risk posed by the foam used in the recalled products with patients and the public and to ensure that individuals who rely on these essential devices are receiving the important information they need from the company."

The FDA is ordering Philips Respironics to notify all device users, durable medical equipment (DME) suppliers, distributors, retailers, and health care providers who prescribe the products about the recall and the health risks posed by the foam used in the recalled products. The order also directs Philips to maintain language to patients regarding the risk of using ozone cleaners on the recalled devices on their main webpage for the recall, and to provide instructions for device users to register their devices on the Philips website.

Along with these actions, the FDA recommends additional measures Philips can take to better communicate with the public regarding the recall. Specifically, the FDA recommends that Philips provide monthly updates to device users who register their devices on the Philips website that include information on expected time for replacement and current rate of replacement of recalled devices. The FDA also recommends that Philips provide detailed information to device users, DME suppliers, distributors, retailers, and healthcare providers on the replacement process.

CAR-T drugs work by harvesting a patient's own disease-fighting T-cells, genetically engineering them to target specific proteins on cancer cells and replacing them to seek out and attack cancer.

FDA Warns of Risks Associated with Non-Invasive Prenatal Screening Tests

On April 19, 2022, the FDA published a safety communication warning patients and health care providers about the risks of false results with genetic non-invasive prenatal screening (NIPS) tests, sometimes called noninvasive prenatal testing or tests (NIPT). Results from NIPS tests can provide information about the possibility of a fetus having certain genetic abnormalities that could result in a child being born with a serious health condition.

While health care providers widely use NIPS tests, none have yet been authorized, cleared, or approved by the FDA. The accuracy and performance of NIPS tests have not been evaluated by the FDA and these tests can give false results, such as reporting a genetic abnormality when the fetus does not actually have one. NIPS tests are screening tests, which means the NIPS test may only tell you the risk of the fetus having certain genetic abnormalities. They are not diagnostic tests, which are generally used to more definitively confirm or rule out a suspected genetic abnormality.

The FDA is aware of reports that patients and health care providers have made critical health care decisions based on results from these screening tests alone and without additional confirmatory testing. Specifically, pregnant people have ended pregnancies based only on the results of NIPS tests. Without confirming the results with a diagnostic test, there is no way to know whether the fetus actually had the genetic abnormality reported by the screening test. The FDA is aware of cases where a screening test reported a genetic abnormality and a confirmatory diagnostic test later found that the fetus was healthy.

Given the increased use of these tests and concerns raised in recent media reports, the FDA is providing this information to educate patients and health care providers and to help reduce the inappropriate use of NIPS tests. The FDA recommends that patients discuss the benefits and risks of NIPS tests with a genetic counselor or other health care provider before deciding to get these tests. Patients should also discuss the results of NIPS tests with a genetic counselor or other health care provider before making any decisions about their pregnancy. Health care providers should be aware of the risks and limitations of using these screening tests and should not use the results from these tests alone to diagnose chromosomal (genetic) abnormalities or disorders.

FDA Provides Updated Information on Philips Ventilator Recall

On May 19, 2022, the FDA updated the web page [FN12] on the Philips Respironics Ventilator, BiPAP Machine, and CPAP Machine Recalls with new data on device reports and patient deaths.

Philips Respironics voluntarily recalled certain ventilators, bi-level positive airway pressure (also known as Bilevel PAP, BiPAP, or BPAP) machines, and continuous positive airway pressure (CPAP) machines in June 2021 due to potential health risks. The polyester-based polyurethane (PE-PUR) foam used in these medical devices to lessen sound and vibration can break down. If the foam breaks down, black pieces of foam, or certain chemicals that are not visible, could be breathed in or swallowed by the person using the device.

According to the FDA's notice, the agency received more than 21,000 medical device reports (MDRs), including 124 reports of death, associated with the PE-PUR foam breakdown or suspected foam breakdown in Philips Respironics' ventilator devices between April 2021 and April 30, 2022.

The MDRs received by FDA included both mandatory reports from Philips and voluntary reports from healthcare professionals, consumers and patients. The MDRs reported a wide range of injuries, including cancer, pneumonia, asthma, other respiratory problems, infection, headache, cough, dyspnea (difficulty breathing), dizziness, nodules, and chest pain.

Philips submitted 30 MDRs between 2011-April 2021 that they identified as associated with the PE-PUR foam breakdown. Eight of those reports were from the U.S. There were no reports of patient injury or death among those 30 MDRs. The FDA acknowledged the limitations of its MDR passive surveillance system, indicating that it only comprises one of its post-market surveillance data sources.

The FDA said the MDR system is limited in its effectiveness because the incidence, prevalence or cause of an event cannot typically be determined from the reporting system alone due to the under-reporting of events, inaccuracies in reports, lack of verification that the device caused the reported event and lack of information about the frequency of device use.

The FDA continues to review and assess the MDRs and will keep the public informed as new information becomes available.

FDA Updates Recall Information on Medtronic's HeartWare Ventricular Assist Device (HVAD) System

On June 3, 2021, the FDA issued a letter [FN13] to health care providers stating that Medtronic has stopped the sale and distribution of the HeartWare Ventricular Assist Device (HVAD) System. Medtronic stopped the sale and distribution of the HVAD system because the increased risk of mortality and neurological adverse events in patients using the device, and a malfunction where the device may fail to restart. Both problems may lead to serious injuries or death.

The following is a timeline and summary of the significant activities by the FDA since June 2021:

• On August 12, 2021, the FDA issued a recall notice [FN14] indicating the FDA classified the June 3, 2021 actions to stop the sale and distribution of the HVAD System as Class 1.

• On April 28, 2022, the FDA issued a letter [FN15] to health care providers to alert health care providers to the possibility that patients who have the Medtronic HVAD System and appear to present with pump thrombosis may have a weld defect in the internal pump causing the pump to malfunction.

• On June 10, 2022, The FDA issued a recall notice [FN16] indicating the FDA classified the April 2022 recall related to actions to alert healthcare providers to a possibility of a weld defect in the internal pump as Class 1.

• On June 23, 2022, The FDA issued a recall notice indicating the FDA classified the May 2022 recall related to a welding defect affecting internal HVAD Battery components from a single lot as Class 1.

The FDA continues to work with Medtronic to ensure the health and safety of device users, and to update the public as new information becomes available.

American Contract Systems Recalls COVID Test Kits Nonsterile and Clean Catch Urine Kits for Risk of False Results

On July 14, 2022, the FDA identified a recall for the American Contract Systems (ACS) COVID Test Kit Nonsterile and Clean Catch Urine Kit. The FDA has identified this as a Class I recall, the most serious type of recall. [FN17]

ACS is recalling the COVID Test Kit Nonsterile and Clean Catch Urine Kit products because they were assembled in an uncontrolled facility by people without proper training. As a result, the company is unable to verify that the kits will perform as expected. These kits have the potential to give false negative or false positive results or lead to misinterpretation of test results.

Use of these affected products could cause serious adverse health consequences and death.

The company has not received any complaints or reports of injuries or deaths associated with the use of these kits.

Smiths Medical Recalls Certain Medfusion 3500 and 4000 Syringe Infusion Pumps for Software Issues That May Impact Infusion Delivery

On July 20, 2022, the FDA identified a recall for the Smiths Medical Medfusion 4000 and 3500 Syringe Infusion Pumps. The FDA has identified this as a Class I recall, the most serious type of recall. [FN18]

Smiths Medical Medfusion 4000 and 3500 Syringe Infusion Pumps are used to give fluids to patients in precisely controlled amounts. They deliver blood or blood products, lipids, drugs, antibiotics, enteral feedings and other therapeutic fluids through infusion tubing into a patient's vein or through other cleared routes of administration. Syringe pumps are primarily used in the neonatal and pediatric populations or in operating rooms and intensive care units for the adult population.

Smiths Medical is recalling Medfusion 3500 and 4000 Syringe Infusion Pumps for eight software malfunctions that affect different serial numbers and software versions. These malfunctions may cause serious harm or death to patients from under- or over-infusion, or delays in the delivery of critical medications to patients.

Smiths Medical states there have been a total of 7 serious injuries and one death reported related to these issues.

FDA Issues Safety Alert for Squamous Cell Carcinoma and Various Lymphomas in Scar Tissue around Breast Implants

On September 8, 2022, the FDA issued a safety communication [FN19] informing patients and providers about reports of squamous cell carcinoma (SCC) and various lymphomas located in the capsule or scar tissue around breast implants. After an initial extensive review, The FDA believes that the risk of SCC and other lymphomas occurring in the tissue around breast implants is rare. However, in this case, and when safety risks with medical devices are identified, wanted to provide clear and understandable information to the public as quickly as possible.

In some reported cases, patients were diagnosed years after having breast implants and presented with findings such as swelling, pain, lumps or skin changes. These emerging reports of lymphoma in scar tissue are different from Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL), which the FDA began communicating about as a potential risk more than a decade ago.

Looking ahead, the FDA will soon complete a thorough literature review and continue our partnership with the American Society of Plastic Surgeons as we work to identify ways to collect more detailed information regarding patient cases where cancer in the breast implant capsule has been reported. As we learn more about these cases, we hope to better understand the patient risk and communicate findings to the public.

III. Other Developments

FDA Grants Marketing Authorization for Inferior Vena Cava Filter Removal Device

On December 21, 2021, the FDA authorized marketing of the first laser-based device for the removal of Inferior Vena Cava (IVC) filters. The device is designed for patients who have an IVC filter, a small cage-like device inserted into the largest vein in the body to capture blood clots and prevent them from traveling to the lungs. The new device, called the Philips CavaClear Laser Sheath, is intended for the removal of tissue to facilitate detachment of an IVC filter during retrieval when previous methods of removal have failed.

'To date, there have been limited options for the successful removal of chronically embedded IVC filters, as they can be difficult to retrieve due to potential complications associated with the complex procedure," said Bram Zuckerman, M.D., director of the Office of Cardiovascular Devices in the FDA's Center for Devices and Radiological Health. 'Today's action by the FDA will provide physicians with an important tool for the safe removal of IVC filters and potentially help reduce complications for patients. It also demonstrates FDA's commitment to leveraging real world evidence where appropriate to evaluate device safety and effectiveness."

IVC filters are commonly used to treat patients who are at risk for pulmonary embolism (a blood clot in the lungs) when treatment with blood thinners cannot be used or is ineffective. While some IVC filters are left in place permanently, the FDA issued a safety communication in 2014 Disclaimer based on reports of adverse events associated with IVC filters and recommended that implanting physicians consider removing the filter as soon as blood clots are no longer a risk for the patient.

The FDA granted the marketing authorization to Philips.

FDA Statement on Medical Device User Fee Amendments (MDUFA)

On March 22, 2022, the FDA released a statement of an agreement on proposed recommendations for the fifth reauthorization of the medical device user fee program. Under the new agreement, the FDA would be authorized to collect at least $1.78 billion in user fees over five years, plus additional funding, for a total of up to $1.9 billion to further improve performance if specified goals are met. This funding would provide critical resources to the FDA medical device review program. The proposed recommendations have been posted on the FDA website and will be published in the Federal Register for public comment. Additionally, the MDUFA V public meeting will be held virtually April 19, 2022, to provide the public an opportunity to learn more about and provide their views on the proposed recommendations. The final recommendations are scheduled to be delivered to Congress in April 2022, after FDA considers public input on the proposed recommendations and revises them as necessary. [FN20]

'The agreement underscores the continued commitment by the FDA and medical device industry to prioritize innovation and increase patient access to safe and effective medical devices," said Jeffrey Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health. 'In addition, MDUFA V represents a substantial investment in the future of the agency's medical device program and would provide for important improvements, including new hiring targets, greater engagement with developers of innovative technologies based on lessons learned from the pandemic, broadened international harmonization efforts and expanded opportunities to ensure patient perspectives are an integral part of medical device development."

FDA Issues Guidance Regarding Electromagnetic Compatibility (EMC) of Medical Devices

In June, the FDA issued the final guidance, 'Electromagnetic Compatibility (EMC) of Medical Devices: Guidance for Industry and Food and Drug Administration Staff," [FN21] .

This guidance document provides the FDA's recommendations on testing to assess the electromagnetic compatibility of medical devices and information to include in the labeling. This guidance applies to medical devices, including in vitro diagnostics, and accessories that are electrically powered or have functions or sensors that are implemented using electrical or electronic circuitry. The recommendations are intended to promote consistency and facilitate efficient review of electromagnetic compatibility in device submissions.

The final guidance takes effect June 6, 2023 for in vitro diagnostics, and August 5, 2022 for all other devices.

FDA Finalizes Historic Rule Enabling Access to Over-the-Counter Hearing Aids for Millions of Americans

On August 16, 2022, the FDA issued a final rule [FN22] to improve access to hearing aids which may in turn lower costs for millions of Americans. This action establishes a new category of over-the-counter (OTC) hearing aids, enabling consumers with perceived mild to moderate hearing impairment to purchase hearing aids directly from stores or online retailers without the need for a medical exam, prescription or a fitting adjustment by an audiologist. [FN23]

The rule is expected to lower the cost of hearings aids, furthering the Biden-Harris Administration's goal of expanding access to high-quality health care and lowering health care costs for the American public. It is designed to assure the safety and effectiveness of OTC hearing aids, while fostering innovation and competition in the hearing aid technology marketplace.

This action follows President Biden's Executive Order [FN24] on Promoting Competition in the American Economy, which called for the FDA to take steps to allow hearing aids to be sold over the counter and set a swift 120-day deadline for action, which the FDA met. In 2017, Congress passed bipartisan legislation requiring the FDA to create a category of OTC hearing aids, but it was not fully implemented until now. Consumers could see OTC hearing aids available in traditional retail and drug stores as soon as mid-October when the rule takes effect.

'Reducing health care costs in America has been a priority of mine since Day One and this rule is expected to help us achieve quality, affordable health care access for millions of Americans in need," said Health and Human Services Secretary Xavier Becerra. 'Today's action by the FDA represents a significant milestone in making hearing aids more cost-effective and accessible."

The OTC category established in this final rule applies to certain air-conduction hearing aids intended for people 18 years of age and older who have perceived mild to moderate hearing impairment. Hearing aids that do not meet the requirements for the OTC category (for example, because they are intended for severe hearing impairment or users younger than age 18) are prescription devices.

This rule is effective October 17, 2022.

FDA, Veterans Health Administration Collaborate to Help Accelerate Medical Device Innovation and Advancement of Care

On September 28, 2022, the FDA and the Veterans Health Administration (VHA) announced a collaboration [FN25] intended to help accelerate American medical device innovation to further improve and benefit public health. Veteran Affairs' VA Ventures Innovation Institute, located in Seattle, will host up to 12 FDA staff to foster robust collaborations between the two agencies. The FDA staff will focus on the regulatory science — the science for evaluating the benefits and risks of new products — while VA staff will provide clinical context for test development and provide hands-on training and other immersive experiences for innovators wishing to utilize the tools. [FN26]

Together, the organizations will work toward developing and disseminating new tools designed to test the safety and effectiveness of medical devices and emerging technologies. These ‘off-the-shelf” testing tools will provide innovators with straightforward, reproducible and cost-effective testing methods throughout the product development cycle. Providing standardized tests can help streamline the regulatory evaluation process, accelerating the time it takes for products to reach patients by increasing predictability in the product development process. This effort may also reduce risks for early innovators that might not have access to more elaborate testing systems.

'Both the FDA and VA need to stay at the forefront of new medical technology development, and the science of evaluating new technology. This strategic alignment between our organizations creates a unique environment to achieve shared objectives for accelerating patient access to safe, innovative and effective medical devices,” said Jeff Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health. ‘We are eager to gain valuable insight from VHA clinicians and scientists using a real-world perspective, and we look forward to working with our federal colleagues to help ensure Veterans and all Americans have access to the most innovative medical solutions and technologies to improve their health and quality of life.”

'By working side by side, VA and FDA will leverage our combined strengths and expertise to bring the most promising health care technology innovations to Veterans ? and Americans at large ? faster than ever before,” said Dr. Shereef Elnahal, VA's Under Secretary for Health. ‘Additionally, the co-location in Seattle will allow us to tap into important health care-adjacent technology markets. We look forward to working closely with the FDA to improve the health and wellness of Veterans and all Americans.”

Collaborative efforts between the VHA and FDA will initially focus on interoperable systems which can exchange health information automatically for the diagnosis and treatment of patients. An increasing number of medical devices, such as ventilators and fluid resuscitation systems, will be controlled autonomously based on inputs from a variety of sensors. Ensuring appropriate function of both the sensors and the systems is a vital goal for this emerging and exciting area. Future areas of the collaboration will include the development of test methods for devices that can be used at a distance through, for example, 5G networks. These devices have the potential to enhance medical treatment for patients in remote and underserved populations.

FDA Finalizes Guidances on Medical Device Post-Approval Studies and Postmarket Surveillance

On October 7, 2022, the FDA released two final guidances to assist manufacturers of moderate- to high-risk medical devices to comply with the agency's postmarket surveillance requirements and to better understand the agency's expectations for conducting post-approval studies of these products. [FN27] The final guidance documents are entitled ‘Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act“ [FN28] and ‘Procedures for Handling Post-Approval Studies Imposed by Premarket Approval Application Order” [FN29]

These guidance documents are intended to facilitate and set expectations for timely initiation and completion of certain studies fulfilling postmarket surveillance requirements and of Post-Approval Studies (PAS), respectively. Additionally, these guidance documents are intended to increase transparency to stakeholders on FDA's approach to the issuance and tracking of postmarket surveillance orders and of PAS requirements.

The final guidance ‘Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act” is intended to update and replace the guidance issued in May 2016; the final guidance ‘Procedures for Handling Post-Approval Studies Imposed by PMA Order” is intended to update and replace the guidance issued in June 2009.

The procedures guidance provides recommendations on the format and content of PAS submissions as a condition of premarket approval (PMA) and is intended to help facilitate reviews of these PAS protocols.

The postmarket surveillance guidance addresses FDA's interpretation of postmarket surveillance orders under section 522 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) with respect to certain Class II or Class III medical devices.

FDA Recommends Health Care Providers Consider Alternatives for MRI-Guided Breast Biopsy Grid

On October 31, 2022, the FDA recommended that health care providers discuss alternative options for Magnetic Resonance Imaging (MRI)-guided breast biopsy procedures with patients if a facility is unable to perform the biopsy due to a shortage of Philips Invivo MRI breast biopsy grid plates and other Philips Invivo MRI disposables. [FN30]

On September 29, 2022, Philips issued a communication on its website informing customers of shipment delays and shortages of certain products in its portfolio of MRI coil disposables and have instructed customers to contact Philips directly with questions or for assistance.

The FDA is aware of the shortage and has worked with Philips to resume deliveries and to prioritize shipments to facilities in regions that have no alternative imaging centers where these procedures can be performed. Imaging facilities notified the FDA of this shortage in July 2022, and we have been working with Philips to identify potential contributing factors and mitigation strategies. The shortage is estimated to continue through the end of 2022.

The FDA continues to monitor the current situation and will continue to keep health care providers and the public informed if new or additional information becomes available.

[FN2]

. 1/12/22 Reuters News 14:07:49

[FN3]

. 2022 WLNR 5598572

[FN4]

. 2022 WLNR 12007254

[FN5]

. 2022 WLNR 14139211

[FN6]

. 2022 WLNR 15472401

[FN7]

. 87 FR 50698

[FN8]

. 10/17/22 Reuters News 09:00:00

[FN9]

. 2022 WLNR 2897718

[FN10]

. 2022 WLNR 2659844

[FN11]

. 2022 WLNR 7496203

[FN12]

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