FDA Approves First COVID-19 Vaccine

Today, the U.S. Food and Drug Administration approved the first COVID-19 vaccine. The vaccine has been known as the Pfizer-BioNTech COVID-19 Vaccine, and will now be marketed as Comirnaty (koe-mir'-na-tee), for the prevention of COVID-19 disease in individuals 16 years of age and older. The vaccine also continues to be available under emergency use authorization (EUA), including for individuals 12 through 15 years of age and for the administration of a third dose in certain immunocompromised individuals.

"The FDA's approval of this vaccine is a milestone as we continue to battle the COVID-19 pandemic. While this and other vaccines have met the FDA's rigorous, scientific standards for emergency use authorization, as the first FDA-approved COVID-19 vaccine, the public can be very confident that this vaccine meets the high standards for safety, effectiveness, and manufacturing quality the FDA requires of an approved product," said Acting FDA Commissioner Janet Woodcock, M.D. "While millions of people have already safely received COVID-19 vaccines, we recognize that for some, the FDA approval of a vaccine may now instill additional confidence to get vaccinated. Today's milestone puts us one step closer to altering the course of this pandemic in the U.S."

Since Dec. 11, 2020, the Pfizer-BioNTech COVID-19 Vaccine has been available under EUA in individuals 16 years of age and older, and the authorization was expanded to include those 12 through 15 years of age on May 10, 2021. EUAs can be used by the FDA during public health emergencies to provide access to medical products that may be effective in preventing, diagnosing, or treating a disease, provided that the FDA determines that the known and potential benefits of a product, when used to prevent, diagnose, or treat the disease, outweigh

the known and potential risks of the product.

FDA-approved vaccines undergo the agency's standard process for reviewing the quality, safety and effectiveness of medical products. For all vaccines, the FDA evaluates data and information included in the manufacturer's submission of a biologics license application (BLA). A BLA is a comprehensive document that is submitted to the agency providing very specific requirements. For Comirnaty, the BLA builds on the extensive data and information previously submitted that supported the EUA, such as preclinical and clinical data and information, as well as details of the manufacturing process, vaccine testing results to ensure vaccine quality, and inspections of the sites where the vaccine is made. The agency conducts its own analyses of the information in the BLA to make sure the vaccine is safe and effective and meets the FDA's standards for approval.

Comirnaty contains messenger RNA (mRNA), a kind of genetic material. The mRNA is used by the body to make a mimic of one of the proteins in the virus that causes COVID-19. The result of a person receiving this vaccine is that their immune system will ultimately react defensively to the virus that causes COVID-19. The mRNA in Comirnaty is only present in the body for a short time and is not incorporated into – nor does it alter – an individual's genetic material. Comirnaty has the same formulation as the EUA vaccine and is administered as a series of two doses, three weeks apart.

"Our scientific and medical experts conducted an incredibly thorough and thoughtful evaluation of this vaccine. We evaluated scientific data and information included in hundreds of thousands of pages, conducted our own analyses of Comirnaty's safety and effectiveness, and performed a detailed assessment of the manufacturing processes, including inspections of the manufacturing facilities," said Peter Marks, M.D., Ph.D., director of FDA's Center for Biologics Evaluation and Research. "We have not lost sight that the

COVID-19 public health crisis continues in the U.S. and that the public is counting on safe and effective vaccines. The public and medical community can be confident that although we approved this vaccine expeditiously, it was fully in keeping with our existing high standards for vaccines in the U.S."

FDA Evaluation of Safety and Effectiveness Data for Approval for 16 Years of Age and Older

The first EUA, issued Dec. 11, for the Pfizer-BioNTech COVID-19 Vaccine for individuals 16 years of age and older was based on safety and effectiveness data from a randomized, controlled, blinded ongoing clinical trial of thousands of individuals.

To support the FDA's approval decision today, the FDA reviewed updated data from the clinical trial which supported the EUA and included a longer duration of follow-up in a larger clinical trial population.

Specifically, in the FDA's review for approval, the agency analyzed effectiveness data from approximately 20,000 vaccine and 20,000 placebo recipients ages 16 and older who did not have evidence of the COVID-19 virus infection within a week of receiving the second dose. The safety of Comirnaty was evaluated in approximately 22,000 people who received the vaccine and 22,000 people who received a placebo 16 years of age and older.

Based on results from the clinical trial, the vaccine was 91% effective in preventing COVID-19 disease.

More than half of the clinical trial participants were followed for safety outcomes for at least four months after the second dose. Overall, approximately 12,000 recipients have been followed for at least 6 months.

The most commonly reported side effects by those clinical trial participants who received Comirnaty were pain, redness

and swelling at the injection site, fatigue, headache, muscle or joint pain, chills, and fever. The vaccine is effective in preventing COVID-19 and potentially serious outcomes including hospitalization and death.

Additionally, the FDA conducted a rigorous evaluation of the post-authorization safety surveillance data pertaining to myocarditis and pericarditis following administration of the Pfizer-BioNTech COVID-19 Vaccine and has determined that the data demonstrate increased risks, particularly within the seven days following the second dose. The observed risk is higher among males under 40 years of age compared to females and older males. The observed risk is highest in males 12 through 17 years of age. Available data from short-term follow-up suggest that most individuals have had resolution of symptoms. However, some individuals required intensive care support. Information is not yet available about potential long-term health outcomes. The Comirnaty Prescribing Information includes a warning about these risks.

Ongoing Safety Monitoring

The FDA and Centers for Disease Control and Prevention have monitoring systems in place to ensure that any safety concerns continue to be identified and evaluated in a timely manner. In addition, the FDA is requiring the company to conduct postmarketing studies to further assess the risks of myocarditis and pericarditis following vaccination with Comirnaty. These studies will include an evaluation of long-term outcomes among individuals who develop myocarditis following vaccination with Comirnaty. In addition, although not FDA requirements, the company has committed to additional post-marketing safety studies, including conducting a pregnancy registry study to evaluate pregnancy and infant outcomes after receipt of Comirnaty during pregnancy.

The FDA granted this application Priority Review. The approval was granted to BioNTech Manufacturing GmbH.

Three New Bedford vaccination clinics open from Aug. 20-22

New Bedford, Massachusetts—COVID-19 vaccination clinics are planned for the next several days in New Bedford. No appointment is needed at these walk-up clinics. All New Bedford residents receiving their first dose will receive a $20 Dunkin' gift card.

Friday, August 20:
Kruger Lot – 2:00 p.m. to 8:30 p.m.
Market Basket – 5:00 p.m. to 8:00 p.m.

Saturday, August 21:
Fisherman's Memorial (Between Pier 3 and State Pier) – 10:00 a.m. to 8:30 p.m.
Wings Court – 10:00 a.m. to 8:30 p.m.

Sunday, August 22:
Fisherman's Memorial (Between Pier 3 and State Pier) – 11:00 a.m. to 7:00 p.m.
YMCA lawn – 11:00 a.m. to 7:00 p.m.

COVID Booster Shots to Start in September

By Katie Lannan
State House News Service

The federal government plans to begin making COVID-19 booster shots available next month to adults who have already received both doses of a Moderna or Pfizer vaccine, an announcement Gov. Charlie Baker indicated came without advance guidance for states.

Baker said plans for a booster program did not come up in a regular Tuesday call between governors and Biden administration officials "on all things vaccines and all things COVID."

"First time I heard about it was when I got home last night and saw the news," he said during a GBH Radio interview. "So, I have no guidance, alright, even though we spent an hour on the phone yesterday with all of the people who probably knew something about what this is all about, which really bums me out."

Baker described himself as an "enthusiastic supporter of a booster program" and said that once Massachusetts has more information about timing and other details, the state will "move very aggressively to make sure that those who are eligible to get boosters get them."

"I think it's really important that we do it, especially based on some of the studies that have come out of other countries that are farther ahead of us with respect to vaccines," he said.

During a White House COVID-19 Response Team briefing Wednesday, top health officials said that while the three vaccines used in the United States are highly effective at reducing risks of severe disease, hospitalization and death from the coronavirus, data show that levels of protection against infection decrease over time. Booster shots, they said, extend the protection.

The Biden administration's plan calls for the booster program to begin the week of Sept. 20, pending an independent

evaluation by the Food and Drug Administration and dose recommendations from a Centers for Disease Control advisory panel.

Fully vaccinated adults age 18 and up would become eligible eight months after receiving their second doses of a Pfizer or Moderna vaccine.

“The plan ensures that people who were fully vaccinated earliest in the vaccination rollout will be eligible for a booster first,” Surgeon General Vivek Murthy said. “This includes our most vulnerable populations, like our health care providers, nursing home residents and other seniors.”

The first COVID-19 vaccines in Massachusetts were administered last December. With the vaccine supply constrained at the time, the first waves concentrated on health care workers at the front lines of the pandemic, then the residents and workers of long-term care facilities, first responders and other populations deemed at higher risk of contracting the virus.

More than 4.4 million people in Massachusetts are now fully vaccinated, according to the latest Department of Public Health figures. That includes 4,131,001 who got the Pfizer and Moderna shots, and another 296,222 who received the single-dose Johnson & Johnson vaccines.

Murthy said recipients of the J&J vaccines, which were not administered in the U.S. until March 2021, will likely need boosters as well. He said to expect more data on those shots in coming weeks, and that officials will keep the public informed of J&J booster plans.

Jeff Zients, the White House coronavirus response coordinator, said the federal government will work “very closely” with governors and states to make sure there are enough vaccination sites, and that the Federal Emergency Management Agency “stands ready to help in any way.”

“Thanks to the aggressive actions we have taken to establish our vaccination program, it will be just as easy and convenient to get a booster shot as it is to get a first shot today,” he said. “We have enough vaccine supply for every American, and you’ll be able to get a booster at roughly 80,000 places across the country, including over 40,000 local pharmacies.”

Like the initial vaccines, the boosters will be free regardless of immigration or health insurance status, Zients said.

Sen. Ed Markey applauded the Biden administration for its booster decision, calling vaccines “our best tool for combating COVID-19.”

“As we continue to combat COVID-19 here at home, we cannot forget that no one is safe until everyone is safe from COVID-19. The risk of mutating variants will continue to serve as a threat to all of humanity if we do not mobilize a swift and robust response that extinguishes this virus from all corners of our globe,” Markey said in a statement. “That means working with our international partners on efforts to increase global production of COVID-19 vaccines, share pandemic resources, construct minimum infrastructure required to deliver vaccines globally, and coordinate inoculation campaigns aimed at those most vulnerable. We have no time to spare.”

Algae bloom detected in

Sassaquin Pond; humans and pets should avoid contact with pond water

An algae bloom has been detected at Sassaquin Pond, and residents and pets are advised to avoid direct contact with the water including wading or swimming until lab results can rule out the presence of dangerous bacteria.

Cyanobacteria occurs naturally in fresh water, mostly in late summer and early fall in Massachusetts. Under certain conditions, a concentrated area of cyanobacteria can produce toxins that can cause illness in humans and illness or fatalities in dogs and pets.

The New Bedford Health Department laboratory and state Department of Public Health laboratory are analyzing the results of water samples from Sassaquin Pond to detect its quality. Until an announcement is made, residents and pets are advised to remain out of the water at Sassaquin Pond.

More information about naturally occurring algae blooms can be found here: https://www.mass.gov/info-details/harmful-algae-blooms-in-freshwater-bodies.

More Than 1,000 in Massachusetts Died of Opioid

Overdoses in Six Months

By Katie Lannan
State House News Service

Preliminary Department of Public Health data show 1,038 people died of opioid overdoses in the first six months of this year, an estimated 5 percent decrease from the same time period in 2020.

The preliminary data, presented by Acting DPH Commissioner Margret Cooke at a Public Health Council meeting Wednesday, includes both confirmed deaths and those estimated through a modeling process.

Cooke said the rate of opioid overdose deaths in Massachusetts increased 5 percent from 2019 to 2020, landing at 30.2 deaths per 100,000 residents or slightly below the 2016 peak of 30.6.

She said overdose deaths "have remained relatively stable" since 2016 despite a rise in the presence of the powerful synthetic opioid fentanyl, which in 2020 was recorded in 92 percent of fatal overdoses where a toxicology screen occurred.

Previously released quarterly, the state's opioid data is now published online twice a year, with the next report due in November. In May, the DPH reported a total 2,104 confirmed and estimated opioid deaths in 2020. Cooke's presentation Wednesday showed 1,089 confirmed and estimated deaths in the first six months of 2020.

Leigh Simons Youmans, the senior director of health care policy at the Massachusetts Health and Hospital Association, said the figures discussed Wednesday "demonstrate that the opioid crisis in Massachusetts is still just that: a crisis." She encouraged people to "check in with those in their lives who may be battling substance use disorders and help them find the resources they need."

“Our healthcare leaders and front-line providers continue to report that the virus has been a driver for substance use and personal mental health crises – particularly among people of color and individuals living in underserved areas,” she said in a statement.

Data presented to the council showed that confirmed opioid overdose death rates “increased significantly” for Black non-Hispanic males between 2019 and 2020, while decreasing for white non-Hispanic males. The overdose death rate for women rose in 2020, and the increase was higher for Hispanic and Black non-Hispanic women than for white non-Hispanic women.

Cooke said the Bureau of Substance Addiction Services plans to invest $40 million over the next four years “specifically for expanding access and enhancing services for Black, Indigenous and people of color communities.”

Dr. Edward Bernstein, a gubernatorial appointee to the Public Health Council and emergency medicine professor at the Boston University School of Medicine, asked during the meeting what the state has learned about the most effective practices for addressing opioids.

“I get letters from the Black community saying, you know, we’ve tried all this, what’s going to change?” he said.

Bernstein said access to mental health services, housing, jobs and education are all “key elements” and advocated for an approach that goes beyond public health alone to also involve community engagement.

Cooke said she agreed and that the state is “putting significant dollars” into a housing-first program that has been “seeing some great success.”

Massachusetts Health Officials Report Death Rate Among Fully Vaccinated Individuals

Chris Lisinski
State House News Service

One hundred of the nearly 4.3 million people fully vaccinated in Massachusetts have died of COVID-19, a rate of 0.002 percent, according to state data on breakthrough cases published Tuesday. The Department of Public Health tracked a cumulative 7,737 confirmed COVID-19 infections among those fully vaccinated in the Bay State as of Saturday, July 31, representing 0.18 percent of the immunized population.

Saturday's cumulative count reflects an increase of 1,364 breakthrough cases over July 24. That accounts for a bit more than 30 percent of all new cases confirmed in the one-week span. Since the first residents became fully vaccinated in January, DPH has counted 395 immunized residents hospitalized with COVID-19 cases and 100 who died from the virus. Those numbers include 34 new breakthrough hospitalizations and nine additional deaths among those fully vaccinated tracked in the past week.

Overall case numbers have been on the rise in Massachusetts and nationwide for weeks as the more infectious Delta variant spreads, including among those who are fully vaccinated, but health experts have repeatedly stressed that vaccinations reduce the risk of serious injury or death in the rare breakthrough cases. DPH previously released data on

breakthrough infections in response to records requests, and on Tuesday it published those figures for the first time as part of the vaccination report it releases every weekday. The department said it plans to continue including updated breakthrough numbers in Tuesday vaccination reports.

Fort Taber Park and New Bedford beaches closed Friday, July 9 due to tropical storm warning

Fort Taber Park and New Bedford’s beaches will be closed on Friday, July 9 due to the Tropical Storm Warning in effect for the Greater New Bedford area.

Rain along with winds of 8 to 13 miles per hour, with wind gusts as high as 43 miles per hour, are expected close to 3:00 a.m. Friday into the daytime hours. Residents are advised to safely contain lawn furniture or outdoor items, and ensure pets are inside during the storm.

A Flash Flood Watch is also in effect for the area from 12:00 a.m. midnight until 4:00 p.m. on Friday, July 9.

FDA grants accelerated approval for Alzheimer’s drug made in Massachusetts

Today, the U.S. Food and Drug Administration approved Aduhelm (aducanumab) for the treatment of Alzheimer’s, a debilitating disease affecting 6.2 million Americans.

Aduhelm was approved using the accelerated approval pathway, which can be used for a drug for a serious or life-threatening illness that provides a meaningful therapeutic advantage over existing treatments. Accelerated approval can be based on the drug’s effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit to patients, with a required post-approval trial to verify that the drug provides the expected clinical benefit.

“Alzheimer’s disease is a devastating illness that can have a profound impact on the lives of people diagnosed with the disease as well as their loved ones,” said Patrizia Cavazzoni, M.D., director of the FDA’s Center for Drug Evaluation and Research. “Currently available therapies only treat symptoms of the disease; this treatment option is the first therapy to target and affect the underlying disease process of Alzheimer’s. As we have learned from the fight against cancer, the accelerated approval pathway can bring therapies to patients faster while spurring more research and innovation.”

Alzheimer’s is an irreversible, progressive brain disorder that slowly destroys memory and thinking skills, and eventually, the ability to carry out simple tasks. While the specific causes of Alzheimer’s disease are not fully known, it is characterized by changes in the brain—including amyloid plaques and neurofibrillary, or tau, tangles—that result in loss of neurons and their connections. These changes affect a

person’s ability to remember and think.

Aduhelm represents a first-of-its-kind treatment approved for Alzheimer’s disease. It is the first new treatment approved for Alzheimer’s since 2003 and is the first therapy that targets the fundamental pathophysiology of the disease.

Researchers evaluated Aduhelm’s efficacy in three separate studies representing a total of 3,482 patients. The studies consisted of double-blind, randomized, placebo-controlled dose-ranging studies in patients with Alzheimer’s disease. Patients receiving the treatment had significant dose-and time-dependent reduction of amyloid beta plaque, while patients in the control arm of the studies had no reduction of amyloid beta plaque.

These results support the accelerated approval of Aduhelm, which is based on the surrogate endpoint of reduction of amyloid beta plaque in the brain—a hallmark of Alzheimer’s disease. Amyloid beta plaque was quantified using positron emission tomography (PET) imaging to estimate the brain levels of amyloid beta plaque in a composite of brain regions expected to be widely affected by Alzheimer’s disease pathology compared to a brain region expected to be spared of such pathology.

The prescribing information for Aduhelm includes a warning for amyloid-related imaging abnormalities (ARIA), which most commonly presents as temporary swelling in areas of the brain that usually resolves over time and does not cause symptoms, though some people may have symptoms such as headache, confusion, dizziness, vision changes, or nausea. Another warning for Aduhelm is for a risk of hypersensitivity reactions, including angioedema and urticaria. The most common side effects of Aduhelm were ARIA, headache, fall, diarrhea, and confusion/delirium/altered mental status/disorientation.

Under the accelerated approval provisions, which provide

patients suffering from the disease earlier access to the treatment, the FDA is requiring the company, Biogen, to conduct a new randomized, controlled clinical trial to verify the drug's clinical benefit. If the trial fails to verify clinical benefit, the FDA may initiate proceedings to withdraw approval of the drug.

Aduhelm was granted Fast Track designation, which seeks to expedite the development and review of drugs that are intended to treat serious conditions where initial evidence showed the potential to address an unmet medical need.

Aduhelm is made by Biogen of Cambridge, Massachusetts.

Vaccines available this weekend at Seabra, Madeira Field, and Buttonwood Park, no appointment needed

New Bedford, Massachusetts—COVID-19 vaccination clinics are planned for this weekend in New Bedford.

No appointment is needed at the walk-up clinics. All New Bedford residents receiving their first dose will receive a $20 Dunkin' gift card. Pfizer vaccines will be given at the Seabra and Buttonwood Park locations. JNJ Vaccine will be given at the Southcoast / Madeira field location.

-Seabra Foods, 41 Rockdale Avenue –Saturday,June 5 from 9:00 a.m. to 1:00 p.m., operated by CIC Health with the New Bedford Health Department.

The first 20 New Bedford residents getting their first dose will receive a $50 Seabra gift card.

-Madeira Field, 88 Tinkham Street –Saturday,June 5 from 9:00 a.m. to 2:00 p.m.,operated by Southcoast Health.

-Buttonwood Park (near Lawler Branch Library) –Sunday, June 6 from 9:00 a.m. to 4:00 p.m.,operated by CIC Health with the New Bedford Health Department.The New Bedford Health Department's site at Andrea McCoy Recreation Center will be open on Monday, June 7 from 9:00 a.m. to 4:00 p.m. for walk-in vaccination

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Joint simulations at St. Luke's Hospital bring teams together to 'Stop the Bleed'

The St. Luke's Hospital Emergency Department, Trauma team, and area first responders, along with medical professionals across the country, recently took part in Stop the Bleed Day during National Trauma Awareness Month to emphasize the importance of using tourniquets and other bleeding-control methods in emergency situations to stop life-threatening bleeds quickly.

The Stop the Bleed campaign is a collaborative effort initiated by the Department of Homeland Security and the American College of Surgeons with a goal of sharing essential knowledge and conducting training programs about controlling bleeding from serious injury. Stop the Bleed equips and empowers bystanders to help in a fast-moving situation before emergency services can arrive on scene.

“The program is a fantastic thing, and I’m glad we’re doing it. It can really make a difference,” said Dr. Brandon Fumanti, a Trauma Physician at St. Luke’s Hospital. “If people in the community can learn to stop bleeding and get patients to the Trauma Center, it can save a lot of lives.”

Throughout May 20, starting at 5am, each Emergency Department shift participated in a fast-paced Stop the Bleed simulation.

“We want to make sure that our community and all team members know how to perform life-saving measures to stop bleeding,” said St. Luke’s Trauma Program Manager Stephanie Smith-Raby.

“This program helps team members exercise their skills in a simulation and to practice activating our trauma response in these types of situations.”

The St. Luke’s Trauma Center remains on track to earn a Level II Trauma Center verification and designation later this year. Currently, St. Luke’s has a full trauma team onboard, with trauma surgeons and staff available 24/7, as Southcoast Health continues on the path to full verification from the American College of Surgeons and designation from the Commonwealth of Massachusetts.

A Level II Trauma Center is equipped to treat any type of trauma patient and has the same clinical capabilities as a Level I center. Unlike a Level I center, it is not required to conduct research or have residency programs.

Traumatic injuries remain the leading cause of death for individuals up to the age of 45, according to the Centers for Disease Control and Prevention. Becoming a Level II Trauma Center will enable St. Luke’s to treat patients who have suffered traumatic injuries as a result of accidents and other life-threatening events. This will benefit the patient, their loved ones, and emergency services, all of whom will not have to travel to Boston or Providence for definitive care.

“The closest Trauma Center is Rhode Island Hospital, a 30- to 45-minute drive away,” said Dr. Theodore Delmonico, a Trauma Surgeon at St. Luke’s Hospital. “Not only is a long drive dangerous for a very sick patient and difficult for their family, but it also takes that ambulance out of commission for a few hours. In the New Bedford region, there are limited ambulances available, so it would be beneficial to keep them close to the community.”

In a trauma situation, patients often find themselves in a race against time. Receiving high-quality medical care quickly and close to home is essential. Through programs like Stop the

Bleed and other injury-prevention initiatives and requirements, Southcoast Health and St. Luke’s are striving to achieve Level II Trauma Center verification and designation to provide critical, timely care to those who need it most – during the moments that matter most.