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or contact
John Robbins 281-965-6390
Jun Gai 281-498-4310

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Publisher: Wea H. Lee
President: Catherine Lee
Editor: John Robbins

Address: 11122 Bellaire Blvd., Houston, TX 77072
E-mail: News@scdaily.com

Inside C2

Thursday, December 02 2021|

Omicron rapidly dominating in South Africa, U.S. reports first case

JOHANNESBURG/WASHINGTON, Dec 1 (Reuters) - Heavily mutated Omicron is rapidly becoming the dominant variant of the coronavirus in South Africa less than four weeks after it was first detected there, and the United States on Wednesday became the latest country to identify an Omicron case within its borders.
The first known U.S. case was a fully vaccinated person in California who returned to the United States from South Africa on Nov. 22 and tested positive seven days later.
The infected person had mild symptoms and was in self-quarantine, Dr. Anthony Fauci, a top U.S. infectious disease official, told reporters at the White House.

Late on Tuesday, airlines in the United States were told to hand over the names of passengers arriving from parts of southern Africa hit by Omicron, according to a U.S. Centers for Disease Control and Prevention letter seen by Reuters.

Key questions remain about the new variant, which has been found in two dozen countries, including Spain, Canada, Britain, Austria and Portugal. The UAE reported its first case on Wednesday, the second Gulf country after Saudi Arabia.

Early indications suggesting Omicron may be markedly more contagious than previous variants have rattled financial markets, fearful that new restrictions could choke off a tentative recovery from the economic ravages of the pandemic.
South Africa's National Institute for Communicable Diseases (NICD) said early epidemiological data suggested Omicron was able to evade some immunity, but that existing vaccines should still protect against severe disease and death.

It said 74% of all the virus genomes it had sequenced last month had been of the new variant, which was first found in a sample taken on Nov. 8 in Gauteng, South Africa's most populous province.

The number of new cases reported in South Africa doubled from Tuesday to Wednesday.

World Health Organization epidemiologist Maria van Kerkhove told a briefing that data on how contagious Omicron was should be available "within days."

BioNTech's CEO said the vaccine it makes in a partnership with Pfizer (PFE.N) was likely to offer strong protection against severe disease from Omicron.

"The World Health Organization classified Omicron as a "variant of concern," due to the number of mutations that might help it spread or evade antibodies from prior infection or vaccination

The president of the European Union's executive Commission said there was a "race against time" to stave off the new variant while scientists establish how dangerous it is. The EU brought forward the start of its vaccine rollout for five-to-11-year-olds by a week to Dec. 13.

"Prepare for the worst, hope for the best," Ursula von der Leyen told a news conference.
A woman gets vaccinated against the coronavirus disease (COVID-19) through a window outside a doctor's practice, in the district of Friedrichshain, Berlin, Germany December 1, 2021. REUTERS/ Annegret Hilse
She said that full vaccination and a booster shot provided the strongest possible protection, according to scientists - a view echoed by Fauci.

But WHO emergencies director Mike Ryan criticized developed countries pushing booster shots for large parts of their fully vaccinated populations when vulnerable people in many poorer regions had had no vaccination at all.

"There is no evidence that I'm aware of that will suggest that boosting the entire population is going to necessarily provide any greater protection for otherwise healthy individuals against hospitalization or death," he said.

Britain and the United States have both expanded their booster programs in response to the new variant.

The WHO has noted many times that the coronavirus will keep producing new variants for as long as it is allowed to circulate freely in large unvaccinated populations.

An upsurge in new coronavirus variants and poor access to vaccines in developing countries threaten a full recovery from the COVID-19 pandemic.
An upsurge in new coronavirus variants and poor access to vaccines in developing countries threaten a full recovery from the COVID-19 pandemic.
TRAVEL RESTRICTIONS

Some 56 countries were reportedly implementing travel measures to guard against Omicron as of Nov. 28, the WHO said.

U.N. Secretary-General Antonio Guterres slammed what he called "travel apartheid."

"Blanket travel bans will not prevent the international spread and they place a heavy burden on lives and livelihoods," the WHO said, while advising those who were unwell, at risk or 60 years and over and unvaccinated to postpone travel.

The United States has barred nearly all foreigners who have been in one of eight southern African countries.

Hong Kong added Japan, Portugal and Sweden to its travel restrictions. Malaysia temporarily barred travelers from eight African countries and said Britain and the Netherlands could join the list.

Fitch Ratings said it had lowered its global air passenger traffic forecasts for 2021 and 2022.

"It feels a little bit like we are back to where we were a year ago," said Deidre Fulton, a partner at consultancy MIDAS Aviation, at an industry webinar. "And that's not a great prospect for the industry and beyond."

Fauci said it could take two weeks or more to gain insight into how easily the variant spreads from person to person, how severe the disease is that it causes, and whether it can bypass the protections provided by vaccines currently available.

WEA LEE'S GLOBAL NOTES

12/01/2021

Wea H. Lee
Wealee@scdaily.com
Chairman of International District Houston Texas
Publisher Southern Daily Wea H. Lee
Southern News Group Chairman / CEO
Chairman of International Trade & Culture Center
Republic of Guiana Honorary consul at Houston Texas

New Covid Variant Rises Again

President Biden announced new U.S. travel restrictions from South Africa and seven other countries to contain the threat from the newly detected Omicron Covid–19 variant.

The travel ban alone may offer little comfort to Americans which set a new travel record on the eve of Thanksgiving Day.

Canadian officials confirmed the country's first two cases of the Omicron variant in Ottawa. Germany and the United Kingdom also confirmed cases within their borders. The UK has mandated face covering in shops and on public transport.

Dr. Paul Burton of Moderna Corporation said in an interview that we should brace for several weeks of uncertainty as scientists and vaccine manufacturers investigate the transmissibility of the new variant, the level of illness that causes and whether the antibodies produced in response to the current vaccines will be effective in thwarting it.

Scientists are concerned that the new variant has more than 30 mutations as a part of the virus raising fear that the protection offered by vaccines currently available would not be enough.

The Biden administration's biggest challenge may be the ongoing stubborn resistance among the approximately 60 million American adults who remain unvaccinated.

We sincerely want to urge all people to get vaccinated to simply protect yourself and your loved ones.

We also want to urge world leaders to work together to fight against this new threat.

Southern DAILY Make Today Different

Editor's Choice

Parents walk away with their kids from the Meijer's parking lot where many students gathered following an active shooter situation at Oxford High School in Oxford, Michigan. Eric Seals-USA TODAY NETWORK

A man takes a picture of one of the ships that have been grounded on the shores of the Marmara Sea after extreme winds drove them off their moorings, in Istanbul's Maltepe district, Turkey. REUTERS/ Umit Bektas

A restoration company vehicle sits in a flooded field after rainstorms lashed the western Canadian province, triggering landslides and floods, shutting highways, in Abbotsford, British Columbia, Canada. REUTERS/Jennifer Gauthier

A visitor holds a weapon at the Egyptian stand at Egypt Defence Expo (EDEX), showcasing military systems and hardware, in Cairo, Egypt. REUTERS/Mohamed Abd El Ghany

Ghislaine Maxwell listens as defense attorney Bobbi Sternheim gives her opening statement at the start of Maxwell's trial on charges of sex trafficking, in a courtroom sketch in New York City. REUTERS/Jane Rosenberg

An anti-abortion rights activist holds a baby doll during a protest outside the Supreme Court building, ahead of arguments in the Mississippi abortion rights case Dobbs v. Jackson Women's Health, in Washington. REUTERS/ Jonathan Ernst

Southern DAILY Make Today Different

BUSINESS

COVID-19 In The U.S. Update

CDC Panel Endorses COVID-19 Vaccine Boosters For All Adults

Compiled And Edited By John T. Robbins, Southern Daily Editor

A key outside advisory group to the Centers for Disease Control and Prevention (CDC) has endorsed the use of COVID-19 booster shots for all adults, a one-size-fits-all approach designed to simplify eligibility. If CDC Director Rochelle Walensky signs off on the broader use, as expected, the extra shots will be available immediately to all adults, as long as they are six months past the final dose of a Pfizer or Moderna vaccine, or two months after a Johnson & Johnson dose.

The recommendation from the panel comes just hours after the Food and Drug Administration (FDA) authorized both Pfizer and Moderna's booster shots for everyone over the age of 18.

Pfizer applied to the FDA earlier this month for an expansion of the emergency authorization for its booster shot to make it available to anyone 18 or older. Moderna announced just this week that it too had asked the FDA to allow its booster to be given to all adults.

Boosters for everyone has always been the Biden administration's goal, but until now federal health authorities have stopped short of such a policy, and instead recommended boosters for only specific populations — those over age 65, anyone at high risk because of work or where they live, or those with an underlying medical condition.

The primary COVID-19 vaccination continues to provide good protection against severe disease and death, even as effectiveness against milder infection has waned. But cases have been steadily rising across the country, and authorities have said they want to stave off another winter surge.

The current recommendations, while fairly broad, have caused confusion. While people over the age of 65 are most at risk from waning vaccine immunity, fewer than 40 percent of them have received a booster, according to CDC data.

"The current guidelines, though well-intentioned and thoughtful, generate an obstacle to uptake of boosters. In pursuit of precision, they create confusion," Nirav Shah, president of Association of State and Territorial Health Officials, told the panel.

The panel did not make a distinction in their recommendation between the two types of mRNA vaccines, despite the potential for increased risk of myocarditis — a type of heart inflammation — in young men after receiving Moderna's vaccine.

CDC officials told the panel it's too early to draw conclusions on the risk of myocarditis after the third dose of mRNA vaccines, because teens and younger adults haven't yet been boosted in large enough numbers.

Several other countries have discouraged use of the Moderna vaccine in people younger than 30 because of that risk.

Gottlieb Says He Expects The CDC Will Consider 'Fully Vaccinated' As Including Boosters

Former Food and Drug Administration Commissioner Scott Gottlieb

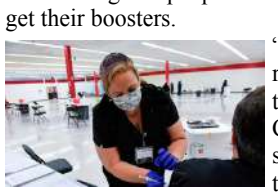
Former Food and Drug Administration Commissioner Scott Gottlieb said on Sunday that he expects the Centers for Disease Control and Prevention (CDC) to consider Americans "fully vaccinated" when they receive a booster shot, adding that recommendations to change it would likely not happen this year.

"Should the CDC say you need a booster to be considered fully vaccinated?" "Face the Nation" moderator Margaret Brennan asked Gottlieb on CBS.

"I think at some point they're going to, but not this year," Gottlieb answered.

"I think eventually this will be considered the three-dose vaccine, but I would be hard pressed to believe CDC is going to make that recommendation any time soon, in part because of this debate about whether or not younger people who are less risk should be receiving that third dose in states where governors are looking to do this, and I think some local communities will do it," he added.

Gottlieb was also asked about CDC saying last week that all American adults could get a booster shot while specifically recommending that people over the age of 50 get their boosters.



"I think the reluctant nature by which CDC has been stepping into this debate reflects a broader ambivalence or a broader debate happening in a public health community about whether the vaccines should be used as tools to protect people from bad outcomes from COVID, or whether they should be used as tools to try to end the pandemic and control transmission," Gottlieb said.

CDC Director Rochelle Walensky late last week signed off on a recommendation from a CDC advisory panel to broaden eligibility of the COVID-19 booster to all American adults. The advisory panel had also recommended that those over the age of 50 should get their booster shot.

Fauci Hopes COVID-19 Booster Increases Durability To Not Need It Regularly

President Biden's chief medical adviser Anthony Fauci said on Sunday that he hopes COVID-19 boosters will increase vaccine durability so that "you will not necessarily need it" every six months or year.

"We would hope - and this is something that we're looking at very carefully - that that third shot with the mRNA not only boosts you way up but increases the durability so that you will not necessarily need it every six months or a year," Fauci said during "This Week" on ABC.

President Biden's chief medical adviser Anthony Fauci

"We're hoping it pushes it out more. If it doesn't, and the data show we do need it more often, then we'll do it," he added.

Centers for Disease Control and Prevention (CDC) Director Rochelle Walensky signed off on a CDC advisory panel's recommendation to increase eligibility for booster shots to all American adults. The decision means that all adults who are at least six months out since receiving their second shot of the Pfizer or Moderna vaccines are now able to get their third shot of the COVID-19 vaccine.

"Booster shots have demonstrated the ability to safely increase people's protection against infection and severe outcomes and are an important public health tool to strengthen our defenses against the virus as we enter the winter holidays. Based on the compelling evidence, all adults over 18 should now have equitable access to a COVID-19 booster dose," Walensky said in a statement regarding the news.

The decision comes only weeks after children as young as 5 years old became eligible to get COVID-19 vaccine, much to the relief of parents and health officials seeking to have their kids inoculated in time for holiday gatherings.

Despite widespread vaccine availability, however, it has not stopped the U.S. from passing the grim milestone last week of recording more COVID-19 deaths in 2021 than last year. (Courtesy thehill.com)

OSHA Suspends Enforcement Of COVID-19 Vaccine Mandate For Businesses

The Occupational Safety and Health Administration (OSHA) is suspending enforcement of the Biden administration's COVID-19 vaccine mandate for large private businesses after a federal appeals court upheld a stay on it last week.

OSHA said in a statement published on its website Friday night that while it is confident in its power to protect workers amid the pandemic, it is suspending activities related to the mandate, citing the pending litigation.

"The court ordered that OSHA 'take no steps to implement or enforce' the ETS [Emergency Temporary Standard] 'until further court order.' While OSHA remains confident in its authority to protect workers in emergencies, OSHA has suspended activities related to the implementation and enforcement of the ETS pending future developments in the litigation," OSHA said.

OSHA® Occupational Safety and Health Administration

President Biden announced in September that the administration was rolling out a new rule that would require all private employers with 100 or more employees to mandate vaccines or weekly testing for all personnel, a guideline that has the potential to impact nearly 80 million workers. Earlier this month the administration set Jan. 4 as the deadline for qualifying private employers to start mandating the vaccine or requiring weekly testing. The rule was developed by OSHA.

In a 22-page ruling last week, the 5th U.S. Circuit Court of Appeals wrote that the administration's COVID-19 vaccine and testing mandate was "fatally flawed" and ordered that OSHA not enforce the requirement "pending adequate judicial review" of a motion for a permanent injunction.

The court said OSHA should "take no steps to implement or enforce the mandate until further court order." (Courtesy thehill.com)

COMMUNITY

A Daily Pill To Treat COVID-19 Could Be Just Months Away, Scientists Say

Results of trials on a daily pill to treat COVID-19 could be available within months.(Image/Unsplash/Halacious)

Key Point

- ***At least three antivirals for COVID are in clinical trials.***
- ***An early trial of 202 participants last Spring showed that molnupiravir rapidly reduced the levels of infectious virus.***
- ***Antivirals are already essential treatments for viral infections, including hepatitis C and HIV.***
- ***The drugs work by interfering with the virus's ability to replicate in human cells***

Compiled And Edited By John T. Robbins, Southern Daily Editor

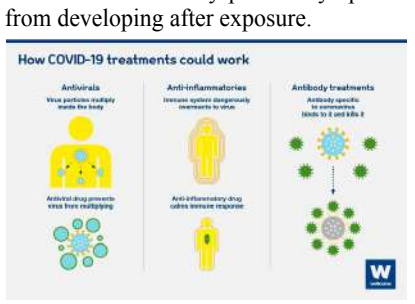
Within a day of testing positive for Covid-19 in June, Miranda Kelly was sick enough to be scared. At 44, with diabetes and high blood pressure, Kelly, a certified nursing assistant, was having trouble breathing, symptoms serious enough to send her to the emergency room. When her husband, Joe, 46, fell ill with the virus, too, she really got worried, especially about their five teenagers at home: "I thought, 'I hope to God we don't wind up on ventilators. We have children. Who's going to raise these kids?"

But the Kellys, who live in Seattle, had agreed just after their diagnoses to join a clinical trial at the nearby Fred Hutch cancer research center that's part of an international effort to test an antiviral treatment on the unvaccinated that could halt Covid early in its course.

By the next day, the couple were taking four pills, twice a day. Though they weren't told whether they had received an active medication or placebo, within a week, they said, their symptoms were better. Within two weeks, they had recovered.

"I don't know if we got the treatment, but I kind of feel like we did," Miranda Kelly said. "To have all these underlying conditions, I felt like the recovery was very quick."

The Kellys have a role in developing what could be the world's next chance to thwart Covid: a short-term regimen of daily pills that can fight the virus early after diagnosis and conceivably prevent symptoms from developing after exposure.



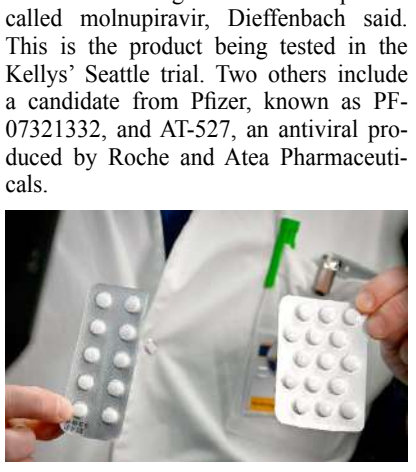
"Oral antivirals have the potential to not only curtail the duration of one's Covid-19 syndrome, but also have the potential to limit transmission to people in your household if you are sick," said Timothy Sheahan, a virologist at the University of North Carolina-Chapel Hill who has helped pioneer these therapies.

Antivirals are already essential treatments for other viral infections, including hepatitis C and HIV. One of the best known is Tamiflu, the widely prescribed pill that can shorten the duration of influenza and reduce the risk of hospitalization if given quickly. The medications, developed to treat and prevent viral infections in people and animals, work differently depending on the type. But they can be engineered to boost the immune system to fight infection, block receptors so viruses can't enter healthy cells, or lower the amount of active virus in the body.

At least three promising antivirals for Covid are being tested in clinical trials, with results expected as soon as late fall or winter, said Carl Dieffenbach, director of the Division of AIDS at the National Institute of Allergy and Infectious Diseases, who is overseeing antiviral development.

"I think that we will have answers as to what these pills are capable of within the next several months," Dieffenbach said.

The top contender is a medication from Merck and Ridgeback Biotherapeutics called molnupiravir, Dieffenbach said. This is the product being tested in the Kellys' Seattle trial. Two others include a candidate from Pfizer, known as PF-07321332, and AT-527, an antiviral produced by Roche and Atea Pharmaceuticals.



They work by interfering with the virus's ability to replicate in human cells. In the case of molnupiravir, the enzyme that copies the viral genetic material is forced to make so many mistakes that the virus can't reproduce. That, in turn, reduces the patient's viral load, shortening infection time and preventing the kind of dangerous immune response that can cause serious illness or death. So far, only one antiviral drug, remdesivir, has been approved to treat Covid. But it is given intravenously to patients ill enough to be hospitalized, and is not intended for early, widespread use. By contrast, the top contenders under study can be packaged as pills.

Sheahan, who also performed preclinical work on remdesivir, led an early study in mice that showed that molnupiravir could prevent early disease caused by SARS-CoV-2, the virus that causes Covid. The formula was discovered at Emory University and later acquired by Ridgeback and Merck.

Clinical trials have followed, including an early trial of 202 participants last spring that showed that molnupiravir rapidly reduced the levels of infectious virus. Merck chief executive Robert Davis said this month that the company expects data from its larger phase 3 trials in the coming weeks, with the potential to seek emergency use authorization from the Food and Drug Administration "before year-end."

Pfizer launched a combined phase 2 and 3 trial of its product Sept. 1, and Atea officials said they expect results from phase 2 and phase 3 trials later this year.

If the results are positive and emergency use is granted for any product, Dieffenbach said, "distribution could begin quickly."

That would mean millions of Americans soon could have access to a daily orally administered medication, ideally a single pill, that could be taken for five to 10 days at the first confirmation of Covid infection.

"When we get there, that's the idea," said Dr. Daniel Griffin, an infectious diseases and immunology expert at Columbia University. "To have this all around the country, so that people get it the same day they get diagnosed."

Once sidelined for lack of interest, oral antivirals to treat coronavirus infections are now a subject of fierce competition and funding. In June, the Biden administration announced it had agreed to obtain about 1.7 million treatment courses of Merck's molnupiravir, at a cost of $1.2 billion, if the product receives emergency authorization or full approval. The same month, the administration said it would invest $3.2 billion in the Antiviral Program for Pandemics, which aims to develop antivirals for the Covid crisis and beyond, Dieffenbach said.

The pandemic kick-started a long-neglected effort to develop potent antiviral treatments for coronaviruses, said Sheahan. Though the original SARS virus in 2003 gave scientists a scare—followed by Middle East respiratory syndrome, or MERS, in 2012—research efforts slowed when those outbreaks did not persist.

"The commercial drive to develop any products just went down the tubes," said Sheahan.

Widely available antiviral drugs would join the monoclonal antibody therapies already used to treat and prevent serious illness and hospitalizations caused by Covid. The lab-produced monoclonal antibodies, which mimic the body's natural response to infection, were easier to develop but must be given primarily through intravenous infusions. The federal government is covering the cost of most monoclonal products at $2,000 a dose. It's still too early to know how the price of antivirals might compare.

Like the monoclonal antibodies, antiviral pills would be no substitute for vaccination, said Griffin. They would be another tool to fight Covid. "It's nice to have another option," he said.

One challenge in developing antiviral drugs quickly has been recruiting enough participants for the clinical trials, each of which needs to enroll many hundreds of people, said Dr. Elizabeth Duke, a Fred Hutch research associate overseeing its molnupiravir trial. Participants must be unvaccinated and enrolled in the trial within five days of a positive Covid test. Any given day, interns make 100 calls to newly Covid-positive people in the Seattle area—and most say no.

"Just generally speaking, there's a lot of mistrust about the scientific process," Duke said. "And some of the people are saying kind of nasty things to the interns."

If the antiviral pills prove effective, the next challenge will be ramping up a distribution system that can rush them to people as soon as they test positive. Griffin said it will take something akin to the program set up last year by UnitedHealthcare, which sped Tamiflu kits to 200,000 at-risk patients enrolled in the insurer's Medicare Advantage plans. Merck officials predicted the company could produce more than 10 million courses of therapy by the end of the year. Atea and Pfizer have not released similar estimates.

Even more promising? Studies evaluating whether antivirals can prevent infection after exposure.

"Think about that," said Duke, who is also overseeing a prophylactic trial. "You could give it to everyone in a household, or everyone in a school. Then we're talking about a return to, maybe, normal life." (Courtesy weforum.org)