

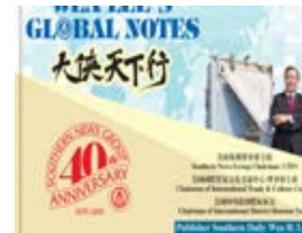


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Mr. Lee's Commentary and Dairy



Inside C2

# Southern DAILY

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## FDA faults quality control at Lilly plant making Trump-touted COVID drug



FILE PHOTO: The logo of Lilly is seen on a wall of the Lilly France company unit, part of the Eli Lilly and Co drugmaker group, in Fegersheim near Strasbourg, France, February 1, 2018. REUTERS/Vincent Kessler/File Photo

(Reuters) - U.S. drug inspectors uncovered serious quality control problems at an Eli Lilly and Co pharmaceutical plant that is ramping up to manufacture one of two promising COVID-19 drugs touted by President Trump as "a cure" for the disease, according to government documents and three sources familiar with the matter.

The Lilly antibody therapy, which is experimental and not yet approved by regulators as safe and effective, is similar to a drug from Regeneron Pharmaceuticals that was given to the president during his bout with COVID-19.

Trump, who credits the Regeneron drug with speeding his recovery, has called for both therapies to become available immediately on an emergency basis, raising expectations among some scientists and policy experts that the administration will imminently release an Emergency Use Authorization (EUA) for the drug. The president's push is key to his efforts to convince voters he has an answer to the pandemic that has killed more than 215,000 Americans.

But the findings by the U.S. Food and Drug Administration inspectors at the Lilly manufacturing facility, which have not been disclosed previously, could complicate the drugmaker's bid for a so-called emergency use authorization (EUA) from the federal agency, two of the sources and two outside legal experts told Reuters. That's because U.S. law generally requires compliance with manufacturing standards for authorization of a drug.

The three sources who spoke to Reuters requested that their names be withheld so they could speak freely without fear of retaliation.

Inspectors who visited the Lilly plant in Branchburg, New Jersey, last November found that data on the plant's various manufacturing processes had been deleted and not appropriately audited, government inspection documents show.

"The deleted incidents and related audit trail were not reviewed by the quality unit," the FDA inspectors wrote. Because the government inspection documents reviewed by Reuters were heavily redacted by the FDA it was not possible to see the inspectors' more specific findings.

Following its November inspection, the FDA classified the problems as the most serious level of violation, resulting in an "Official Action Indicated" (OAI) notice.

That "means that the violations are serious enough and have a significant enough impact on the public health that something needs to be fixed," said Patricia Zettler, a former associate chief counsel at the FDA who is now a law professor at Ohio State University.

Separately, Lilly said on Tuesday it had paused its clinical trial for the COVID drug in hospitalized patients "out of an abundance of caution" over a potential safety concern. The company did not release information on what the problem was

and declined to say how the news might affect their EUA request.

In response to Reuters' questions on Monday about the manufacturing issues, Lilly confirmed the OAI notice but declined to provide details on what prompted the FDA action. The drugmaker said it has launched a "comprehensive remediation plan," has increased staffing at the site and was working "aggressively" to address all concerns raised during the inspection.

The data deletions cited by the FDA, Lilly said, were not related to production of the drug. "These findings do not impact product quality or patient safety, as outlined in a detailed assessment submitted to FDA," the company's statement said. "Lilly continues to provide updates to the FDA on progress towards completion of our detailed plan."

The drugmaker declined to provide a copy of the assessment it gave the FDA. The FDA did not respond to requests for comment. The White House declined to comment.

One of the sources told Reuters that Lilly employees had complained about problems at the plant, including insufficient staffing and falsified records tracking whether workers had followed FDA manufacturing standards.

Lilly said the FDA has not made any findings of falsification at the site.



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WEA LEE'S GLOBAL NOTES

10/13/2020

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COVID-19 DASHBOARD ROUND-UP 10/14/20



Rafael Nadal lifts the winning French Open trophy in Paris – the city has been put on maximum alert as COVID cases rise. (Photo/REUTERS/Charles Platiau)

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

This COVID-19 Dashboard Round-up brings you a selection of the latest news updates on the coronavirus pandemic, as well as tips and tools to help you stay informed and protected.

Top stories: Cases in India top 7 million; China to test city of 9 million; record daily rise in Russia and how the second wave is hitting Western Europe.

How COVID-19 Is Affecting The Globe

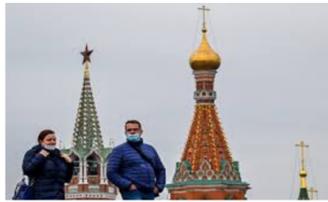
Confirmed cases of COVID-19 have now passed 37.4 million globally, according to the Johns Hopkins Coronavirus Resource Center. The number of confirmed deaths stands at over 1.07 million. In the US, confirmed cases have risen to 7,694,865, according to the Centers for Disease Control and Prevention (CDC), an increase of 53,363 cases from its previous count. The number of deaths rose by 577 to 213,614.



Confirmed cases of COVID-19 have now passed 37.4 million globally.

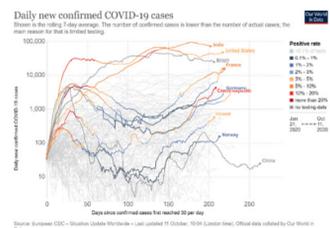
President Donald Trump said on Sunday he had fully recovered from COVID-19 and was not an infection risk for others. "I'm in great shape," he told Fox News. Cases in India have now topped 7 million, after the health ministry reported 74,383 new infections in the previous 24 hours. A rise in infections in southern states is offsetting a drop in western regions. Asia-Pacific countries including Singapore, Australia and Japan are easing some international travel restrictions as coronavirus cases slow. China's

Qingdao City will conduct COVID-19 tests for its population of more than 9 million people over five days, after new cases appeared linked to a hospital treating imported infections. Deaths in Brazil have passed 150,000. It has the second highest death toll after the US. Confirmed cases stand at more than 5.09 million. Record daily increases in Russia Russia has recorded a new record increase in daily cases, pushing the world's fourth highest infection tally towards 1.3 million, reports Reuters.



The country's coronavirus taskforce recorded 13,634 new cases in the last 24 hours, including 4,501 in Moscow. The death toll now stands at 22,597. The capital has been the hardest-hit area. It has opened two temporary hospitals and ordered businesses to have at least 30% of staff working remotely. In August, Russia became the first country to grant regulatory approval for a COVID-19 vaccine. Large-scale trials had not been completed, which caused concern among some in the global scientific community. About 400 high-risk patients have received jabs, according to the health ministry, but the vaccine is not yet in general circulation.

Cases spike in Western Europe as second wave hits.



How COVID-19 cases are rising in European countries. Image: Our World In Data.

A second wave of coronavirus infections is sweeping across much of Europe, while countries seek to bring in new restrictions without further damaging economies. France recorded a one-day record number of cases on 10 October, with 26,896 infections. It comes just days after the capital city of Paris was put on maximum alert, with all bars closing but restaurants allowed to remain open. Ireland also recorded a record daily increase over the weekend – with 1,012 new cases of COVID-19, almost double the average for the past week. Chief Medical Officer Tony Holohan said he was "very worried about the numbers we are seeing and how quickly they are deteriorating." Italy is preparing fresh nationwide restrictions, including on private parties, in response to a recent spike in new coronavirus cases, Health Minister Roberto Speranza said on Sunday.

Meanwhile, England's deputy chief medical officer Prof Jonathan Van-Tam warned the UK had reached a "tipping point". More than 15,160 people tested positive for coronavirus on 10 October, reports the BBC – an increase of more than 1,300 on the previous day.



British Prime Minister Boris Johnson Prime Minister Boris Johnson is expected to announce a three-tier local lockdown system which would see regions under different restrictions, depending on the severity of cases. An aide to Chancellor Angela Merkel said Germany should continue capping the number of people allowed at gatherings and clamp down on unnecessary travel as it battles rising coronavirus infections.

"We must be a bit stricter in places where infection chains spread mostly, which is parties and, unfortunately, also travel," the chancellor's chief of staff, Helge Braun, told public broadcaster ARD. (Courtesy weforum.org)

Latest Updates From The CDC CDC forecasts coronavirus death toll to hit 233,000 by the end of the month with as many as 6,800 new fatalities in the last week of October alone

The CDC's national ensemble forecast uses 41 different independent models to create its own prediction. The national ensemble predicts a total of 224,000 to 233,000 COVID-19 deaths will be reported by October 31.



It also predicts 2,800 to 6,800 new deaths will likely be reported during the week ending October 31. More than 7.7 million Americans have already tested positive for the virus; the death toll stands at 214,573. More than 56,000 new cases were reported across the US Thursday; the highest daily spike since August.



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# Editor's Choice



A demonstrator clashes with the riot police during a protest march by Mapuche Indian activists against Columbus Day in downtown Santiago, Chile. REUTERS/Ivan Alvarado



U.S. President Donald Trump throws a face mask from the stage during a campaign rally, his first since being treated for the coronavirus, at Orlando Sanford International Airport in Sanford, Florida. REUTERS/Jonathan Ernst



Biden supporters gather outside of a campaign event held by Biden in Cincinnati, Ohio, October 12. REUTERS/Megan Jelinger



A person dressed up as Spider-Man sits next to cab as taxi drivers hold a protest against ride-hailing apps such as Uber, Cabify and Didi at Angel de la Independencia monument, in Mexico City. REUTERS/Edgard Garrido



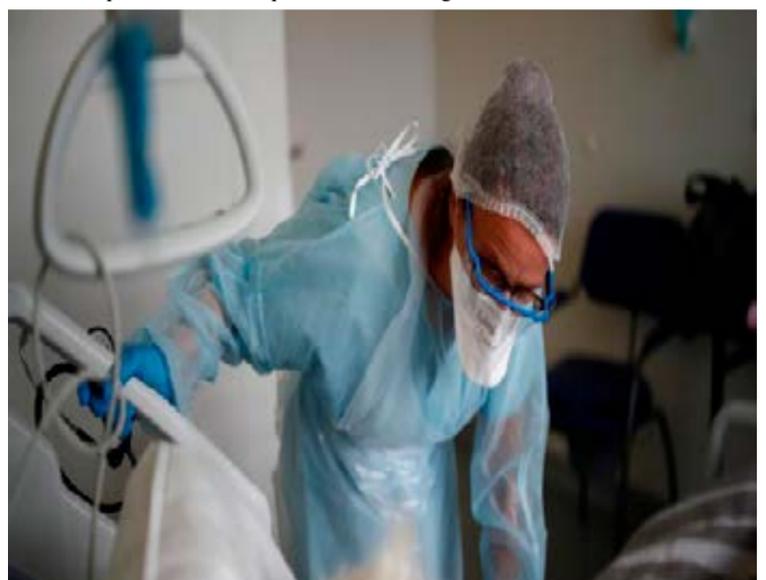
Iyana Sells, 9, plays on her street which is still lined with debris from Hurricane Laura the day after Hurricane Delta swept through Lake Charles, Louisiana. REUTERS/Kathleen Flynn



Judge Amy Coney Barrett's husband Jesse Barrett sits with some of their seven children as they attend his wife's Senate Judiciary Committee hearing on her nomination to serve as an associate justice on the U.S. Supreme Court on Capitol Hill in Washington. REUTERS/Leah Millis/Pool



Texas A&M Aggies fans cheer during a scoring drive in the second quarter against the Florida Gators at Kyle Field in College Station, Texas. Scott Wachter-USA TODAY Sports



A doctor, wearing a protective mask and a protective suit, works in a pulmonology unit at the hospital in Vannes, where patients suffering from the coronavirus are treated, France. REUTERS/Stephane Mahe

**11 States Set Records For New COVID-19 Cases**  
**WHO Discourages Lockdowns**  
**As U.S. Hospitalizations Climb**



Dr David Nabarro from the WHO appealed to world leaders yesterday, telling them to stop 'using lockdowns as your primary control method' of the coronavirus. (Photo / Getty Images)

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

A World Health Organization doctor has walked back the organization's original Covid-19 stance, calling for world leaders to stop locking down their countries and economies as a "primary control method." Dr. David Nabarro from the WHO appealed to world leaders yesterday, telling them to stop "using lockdowns as your primary control method" of the coronavirus. He also claimed that the only thing lockdowns achieved was poverty – with no mention of the potential lives saved. "Lockdowns just have one consequence that you must never ever belittle, and that is making poor people an awful lot poorer," he said. "We in the World Health Organisation do not advocate lockdowns as the primary means of control of this virus," Dr Nabarro told The Spectator. "The only time we believe a lockdown is justified is to buy you time to reorganise, regroup, rebalance your resources, protect your health workers who are exhausted, but by and large, we'd rather

not do it."



WHO Director-General, Dr Tedros Adhanom Ghebreyesus, wearing a mask to protect against coronavirus. (Photo / AP)

Dr Nabarro's main criticism of lockdowns involved the global impact, explaining how poorer economies that had been indirectly affected. "Just look at what's happened to the tourism industry in the Caribbean, for example, or in the Pacific because people aren't taking their holidays," he said. "Look what's happened to smallholder farmers all over the world ... Look what's happening to poverty levels. It seems that we may well have a doubling of world poverty by next year. We may well have at least a doubling of child malnutrition." Melbourne's lockdown has been hailed as one of

the strictest and longest in the world. In Spain's lockdown in March, people weren't allowed to leave the house unless it was to walk their pet. In China, authorities welded doors shut to stop people from leaving their homes. The WHO thinks these steps were largely unnecessary. (Courtesy www.nzherald.co.nz)

**Related**  
**U.S. Reports More Than 50K COVID-19 Cases For Third Straight Day; 9 States Set Record**

For the first time since mid-August, the U.S. has recorded its third consecutive day of more than 50,000 new COVID-19 cases as forecasters predict a death total as high as 233,000 by the end of the month. At least 57,420 new infections were reported across the country on Friday, bringing the total U.S. infections to over 7.6 million as of Saturday, according to data collected by Johns Hopkins University. There were 56,191 new cases Thursday and 50,341 reported on Wednesday. Meanwhile, a forecast by the Centers for Disease Control and Prevention hat combines data from nearly 40 independent models predicts U.S. deaths from COVID-19 could hit 233,000 by the end of the month. To date, over 213,800 people have died from COVID-19 in the U.S., according to Johns Hopkins.

"This week's national ensemble forecast indicates an uncertain trend in new COVID-19 deaths reported over the next four weeks and predicts that 2,800 to 6,800 new deaths will likely be reported during the week ending October 31," the CDC said on its website Thursday.



A worker sanitizes the floor of a shopping mall reopened after the government eased a nationwide lockdown imposed as a preventive measure against the Covid-19 coronavirus, in Chennai on September 1, 2020.

As the holidays approach and cold weather sets in, the statistics will likely get bleaker. "It's important for all of us to not let our guard down during Thanksgiving," Dr. Deborah Birx of the White House Coronavirus Task Force

said Friday at a media briefing in Cambridge, Massachusetts. "We see that from the High Holy Days, people are just yearning to be together." Coronavirus hospitalizations were continuing a dangerous trend in the United States while Brazil and India each reached ominous milestones as the global pandemic showed little sign of retreat Sunday. Hospitalizations, which peaked at nearly 60,000 across the nation in July, had fallen by more than half last month. But since dipping below 29,000 on Sept. 20, the number of people being treated in hospitals each day has crept higher, to almost 35,000. A USA TODAY analysis of Johns Hopkins data through late Saturday shows 11 states set records for new cases for a seven-day period – Alaska, Colorado, Indiana, Minnesota, Missouri, Montana, Nebraska, New Mexico, North Dakota, South Dakota and Utah. Some governors are unmoved by the data. South Dakota is experiencing an increase in daily cases, hospitalizations and even deaths, but Gov. Kristi Noem has stressed that South Dakota's hospital capacity has not been strained by the pandemic.



A nurse shows a COVID-19 vaccine produced by Chinese company Sinovac Biotech at the Sao Lucas Hospital, in Porto Alegre, southern Brazil on August 08, 2020. - The vaccine trial is being carried out in Brazil in partnership with Brazilian Research Institute Butanta.

"I always knew that South Dakota could be an example to the nation," Noem said in a recent statement lauding her state's efforts. "I never expected that such an example would be set in the midst of a global pandemic."

Nationwide, a fourth consecutive day of more than 50,000 new COVID-19 cases represents a streak not seen in two months. The U.S. has now reported more than 7.7 million cases and almost 215,000 deaths since the first U.S. case was confirmed Jan. 21. Record numbers of deaths over a seven-day period were reported Saturday in Kansas and North Dakota.

"Our state's robust testing capacity, combined with North Dakotans' commitment to personal responsibility, can continue to help slow the

spread of COVID-19 in our communities," Gov. Doug Burgum said in a tweet. Bill Gates, co-founder of Microsoft and benefactor of the Gates Foundation, warns that the nation must be ready for "lots of additional deaths" if COVID-19 testing does not improve. "Testing results don't come back within 24 hours (and) we reimburse for these worthless things," Gates said on NBC's "Meet the Press." "We are running the worst testing system, in terms of who gets access to it, of any country."



People walk among the Spanish flags placed in memory of coronavirus (COVID-19) victims in Madrid, Spain, Sunday, Sept. 27, 2020. An association of families of coronavirus victims has planted what it says are 53,000 small Spanish flags in a Madrid park to honor the dead of the pandemic.

**World Battles The Virus**  
The world is not faring much better in its battle with the virus.

British Prime Minister Boris Johnson is expected to unveil tougher restrictions Monday, including a three-tier system based on severity of cases in each region of England. Graham Medley, professor of infectious disease modelling at the London School of Hygiene & Tropical Medicine and the director of the Center for the Mathematical Modelling of Infectious Diseases, warned that "thousands will die" unless Britain can alter the trajectory of the disease.

"We are clearly in a difficult position," Medley tweeted. "The level and rise of infections, admissions and deaths puts us in a similar position to early March. (But) we know the harms that 'lockdown' will bring. Very, very hard choices."

Dr. David Nabarro, the World Health Organization's special envoy on COVID-19, urged world leaders this week to stop "using lockdowns as your primary control method" for blunting a virus surge. (Courtesy usatoday.com)

**廣告**  
**Daily News**



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