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Mr. Lee's Commentary and Dairy



Inside C2

# Southern DAILY Make Today Different

Southern Daily News is published by Southern News Group Daily

Publisher: Wea H. Lee  
President: Catherine Lee  
Editor: John Robbins, Jun Gai  
Address: 11122 Bellaire Blvd., Houston, TX 77072  
E-mail: News@scdaily.com

Tuesday October 06, 2020 | www.today-america.com | Southern News Group

## China says U.S. TikTok, WeChat bans break WTO rules



A U.S. flag is seen on a smartphone in front of displayed Tik Tok and WeChat logos in this illustration taken September 18, 2020. REUTERS/Dado Ruvic/Illustration

GENEVA (Reuters) - China said at a World Trade Organization meeting that restrictions by the United States on Chinese mobile applications TikTok and WeChat are in violation of the body's rules, a trade official said.

The Trump administration has ordered download blocks on the two mobile apps and ordered ByteDance, the Chinese owner of TikTok, to sell its operations to a U.S. company, citing national security concerns. However, U.S. judges have questioned the government's case.

A representative for China said at the closed-door meeting on Friday that the measures "are clearly inconsistent with WTO rules, restrict cross-border trading services and violate the basic principles and objectives of the multilateral trading system," a trade official familiar with the matter, who did not wish to be identified, said.

The official said the delegate described the U.S. failure to provide concrete evidence of the reasons for its measures a "clear abuse" of rules.

In the same meeting, the United States defended its actions, saying they are intended to mitigate national security risks, the trade official said. The government has previously said data from American users is being accessed by the Chinese government.

The office of the U.S. Trade Representative had no immediate comment. An official at the Chinese mission to the WTO did not immediately respond to a request for comment.

### 'Don't be afraid' of virus, Trump says as he prepares to leave hospital

WASHINGTON (Reuters) - President Donald Trump said he will leave a military hospital where he is being treated for COVID-19 later on Monday, and urged people not to be afraid of the disease, which has killed more than a million people worldwide and wreaked economic havoc.

Despite a wave of coronavirus infections that has torn through the White House four weeks before the U.S. presidential election, Trump said he was feeling well and would leave the hospital later in the afternoon after a three-day stay.

"I will be leaving the great Walter Reed Medical Center today at 6:30 P.M. Feeling really good! Don't be afraid of Covid. Don't let it dominate your life. We have developed, under the Trump Administration, some really great drugs & knowledge. I feel better than I

did 20 years ago!" he said on Twitter.

Trump, 74, had a high fever and received supplemental oxygen after his blood oxygen levels dropped on Friday, according to his medical team. Doctors have been treating him with a steroid, dexamethasone, that is normally used only in the most severe cases.

"Over the past 24 hours the president's condition has continued to improve," Dr. Sean Conley, the White House physician, told reporters in a briefing outside the hospital in Bethesda, Maryland.

Don't politicize the virus, Pelosi tells Trump  
Trump defends decision to take car ride from hospital  
Trump does not have any respiratory complaints, but Conley said he "may not entirely be out of the woods yet." He added that the

president would be surrounded by world-class medical care around the clock at the White House.

Trump was reluctant to go to the hospital last week and is eager to get out, a source familiar with the situation told Reuters earlier on Monday

Even if discharged, he will need to continue treatment as he is still undergoing a five-day course of an intravenous antiviral drug, remdesivir. The normal quarantine period for anyone testing positive for the novel coronavirus is 14 days.

Trump has frequently downplayed the threat of the pandemic which has infected 7.4 million Americans. In recent days, he released a series of videos to reassure the public he is recovering from the disease caused by the virus.

The coronavirus outbreak around Trump, however, widened on Monday when White House press secretary Kayleigh McEnany said she had tested positive for the virus.

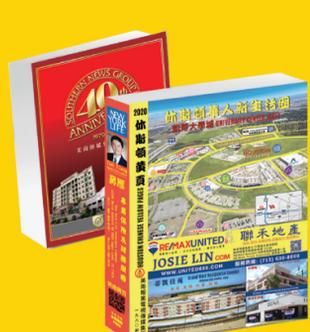
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# BUSINESS

Wear Mask!

## The Secretive Group At The Center Of The Nation's Largest Vaccine Trials



Members of this group hold powerful sway on vaccines.

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

(CNN) A group you've probably never heard of holds powerful sway over which coronavirus vaccines will end up on the market. It's known as the DSMB.

Members of a Data and Safety Monitoring Board are the only ones who get to look under the hood while a trial is ongoing. They know who has been given a Covid-19 vaccine, and who has gotten a placebo. The very doctors running the trials, the pharmaceutical companies that developed the vaccines, and even the US Food and Drug Administration don't know. Armed with that secret, only the DSMB can monitor how safe and effective a vaccine is shaping up to be.

One word from the DSMB, and a trial can be stopped. That's what happened to the AstraZeneca trial in early September after a study participant developed neurological symptoms. Shortly after, it came to light that the same trial had been paused briefly in July for similar reasons. While the vaccine trial resumed in the UK, it is still on pause in the US.

"They're very powerful. They're key guardians of science and safety and are as important if not more important than the FDA," said bioethicist Art Caplan.

### The need for anonymity

Earlier this year, the National Institutes of Health appointed a common DSMB to monitor Covid-19 vaccine clinical trials that are being funded by the

federal government under Operation Warp Speed. This DSMB has 10 to 15 members with specialties including vaccine development, statistics and ethics.



It's not a glamorous or public-facing job. They're paid only a modest honorarium by the NIH -- just \$200 per meeting -- and there are no press conferences, no TV interviews, no fame and no glory. That's because members' names aren't typically revealed while trials are in progress to shield them from external pressures. Caplan, who has served on about 20 DSMBs, said there's a good reason members' names are kept secret.

"You wouldn't want some investor calling a DSMB member and saying 'Hey, how's this clinical trial looking? If you tell me, I'll give you 10% of whatever I make,'" said Caplan.

There's a lot at stake. They scrutinize the data carefully. One word from them, and a vaccine's chances of coming to market could be squashed. Millions of dollars spent on research and development could all be for naught. While there are good arguments for secrecy, Caplan said he disagrees

with the confidentiality that currently shrouds the DSMBs for Covid-19 vaccine candidates.



"We need to know if we can trust the vaccine, so the more transparency the better," Caplan said.

In order to reach population immunity through a vaccine, a large proportion of the US public needs to get vaccinated. But confidence in a potential vaccine is low -- 49% of Americans say they definitely or probably would not get a vaccine if one were available now, according to a recent poll by the Pew Research Center.

"We want to know they're fully independent, that they have no prior relationships with the company. So they're not conflicted in any way," said Dr. Eric Topol, professor of molecular medicine at Scripps Research. "We want to know about their expertise. It's important to know who they are."

**How DSMBs work** The job of the DSMB, as the name suggests, is to monitor the data that comes out of clinical trials. In clinical trials, there can be thousands, or tens of thousands, of study participants. Some are randomly assigned to receive an intervention -- in this case, the vaccine -- and some receive a placebo. The studies are what's called "double-blinded." The participants don't know which they're getting, and neither do the doctors running the trials. If a study volunteer has what appears to be a side effect or "adverse event," the DSMB can look and see if they received the vaccine or the placebo.



"If it was a placebo, then it's one of these random things," Susan Ellenberg, a member of Covid-19-related DSMBs, told CNN's Chief Medical Correspondent Dr. Sanjay Gupta. "If it was the vaccine, it could still have been a random thing. But then people have to write their hands and try and consider how likely is it that the vaccine could cause this kind of event?"

If these events are concerning enough, the DSMB can recommend that the trial be stopped for safety reasons. The stakes are especially high in Covid-19 vaccine trials, which may ultimately be

administered to millions of healthy people -- unlike drug trials intended for those who are already sick and may have few options.

"Even an adverse event that happens as infrequently as one in 10,000 people or one in 20,000 people -- that would be a lot of people who would have a serious adverse event," explained Ellenberg, a professor of biostatistics at the Perelman School of Medicine at the University of Pennsylvania.

At pre-determined intervals, the DSMB also checks on efficacy. If people receiving the vaccine get sick roughly as often as those who get the placebo, that's not a good sign. The board can recommend that the trial be stopped due to "futility." They may also look at the quality of the data, Ellenberg said. If there's missing data, participants who drop out, or if the trial



is being conducted poorly, it's the DSMB that can weigh in.

"Most of the time, a data monitoring committee will say, 'Everything looks fine, keep going,'" Ellenberg said. "But sometimes -- you never know when ... a hard decision is going to have to be made. And that's the value of these committees."

Conversely, if it looks like the vaccine is working exceptionally well, the DSMB may recommend that the study sponsor submit an application to the FDA before the official end of the trial, in order to get it more quickly to market.

**'Thoroughly vetted'** "The people who serve on these committees are thoroughly vetted for conflicts of interest," Ellenberg said.

Members are screened to make sure they don't have a financial interest in the pharmaceutical company that's sponsoring the vaccine trial.

"DSMB members or their family members should have no professional, proprietary, or financial relationship with the sponsoring companies," according to a statement from the National Institute of Allergy and Infectious Diseases, which organized the common DSMB for the Covid-19 vaccine candidates under Operation Warp Speed -- including Moderna, AstraZeneca and Johnson & Johnson. "Selected DSMB members and their family members

were not allowed to work for other companies developing COVID-19 vaccines."



Topol, of Scripps Research, said it's "unprecedented to have a DSMB with that much authority." Typically, each clinical trial has its own DSMB. Such is the case with Pfizer, whose trial is not neither under the common DSMB nor funded by the government. Pfizer's DSMB comprises "a chairperson and 4 additional members that meets on a weekly basis," according to a spokeswoman. Topol considers that small for a trial that aims to enroll up to 44,000 participants. "The trials that I ran always had six or seven at least, sometimes eight or nine," he said. "In large trials, you got to have a bioethicist, virologist, an immunologist, epidemiologist... You have all the critical areas covered."

**Big honor, but no bragging rights** It's a big honor to be named to a DSMB. But it's a no-no to brag about it, as one university recently found out. The university proudly posted that one of its professors was named chair of the DSMB for the government-supported trials of coronavirus vaccines. When CNN called to ask why the professor was publicly identified, the university quickly removed the press release.

"It looks like a staff member shared that news and was unaware that it was not for public consumption," a university spokesperson wrote to CNN. CNN is not revealing the professor's name or the name of the university. Despite the lack of public recognition, fame and glory, Ellenberg says there's plenty of motivation to serve on these boards.

"You feel a great responsibility when you're on these trials," she said. "Everybody's trusting you with these data."

She remains faithful in the DSMB process. If it goes as it's supposed to, "I would take the vaccine myself, and I would recommend that other people take it," she said. Still, downstream from the DSMB, Ellenberg acknowledges "we're in uncharted territory." Last week, President Trump claimed the White House can overrule the FDA's attempt to toughen its Covid-19 vaccine guidelines -- guidelines that could push hopes of a vaccine authorization past Election Day.

"It never occurred to anybody that anybody outside the FDA would try and interfere with that," Ellenberg said. "And I'm hopeful that they won't." (Courtesy cnn.com)

# WEA LEE'S GLOBAL NOTES

10/05/2020

CORONAVIRUS DIARY

## Does The President Follow The Rules?



On Sunday afternoon President Trump left the hospital for a surprise motorcade drive past supporters outside the Walter Reed Military Medical Center where he is being treated for an infection of the coronavirus.

At least two other people, probably agents of the U.S. Secret Service, were seen on video in the vehicle accompanying Trump.

The Trump campaign defended his decision to leave Walter Reed Medical Center and take a short drive to wave to his supporters outside the hospital showing people he is very grateful for all the support they have shown him.

Dr. James Phillips from George Washington University who is an attending physician at Walter Reed Medical Center called the stunt "insanity." He said every single person in the President's vehicle now has to be quarantined for 14 days. They could possibly get sick and die from this action.

The White House Correspondents Association released a statement condemning the White House for not informing the press pool that Trump would be making an appearance outside of the hospital. The statement said, "It is outrageous for the president to have left the hospital even briefly amid a health crisis without a protective pool

present to ensure that the American people know where their president is and how he is doing."

Today the whole world is watching to learn how Trump's health challenge will unfold. Every move and new development in the president's health will be directly related to and affect the security of the world.

As the whole nation is still fighting this horrible disease, according to health experts, by the end of this year we will lose more than 350,000 lives.

We urge President Trump to come up with more serious measures to save lives.



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Publisher Southern Daily Wea H. Lee

# Editor's Choice



A sign displayed in the window of a student accommodation building in Manchester, Britain. REUTERS/Phil Noble



White House Chief of Staff Mark Meadows rubs his head as U.S. Navy Commander Dr. Sean Conley, the White House physician, speaks to the media about President Trump's health, at Walter Reed National Military Medical Center in Bethesda, Maryland. REUTERS/Erin Scott



A Catholic priest sprinkles holy water on a cat at a drive-thru pet blessing on World Animal Day, in Quezon City, Philippines. REUTERS/Eloisa Lopez



A sapper works next to an unexploded BM-30 Smerch rocket allegedly fired by Armenian forces in the fighting over the breakaway region of Nagorno-Karabakh, near the Mingachevir Hydro Power Station in the town of Mingachevir, Azerbaijan. REUTERS/Stringer



Members of a Black militia group called the NFAC hold an armed rally at Parc Sans Souci in Lafayette, Louisiana. REUTERS/Go Nakamura



A general view shows a bridge that collapsed into the Vesubie river, after heavy rainfall hit southern France, in La Bollene-Vesubie, France. REUTERS/Eric Gaillard

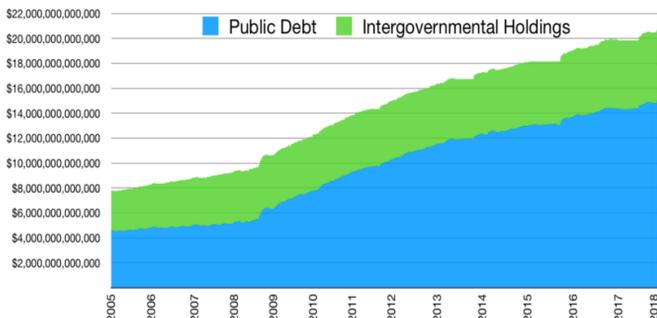


South Sudan's military officer attends a parade before the signing of peace agreement between the Sudan's transitional government and Sudanese revolutionary movements to end decades-old conflict, in Juba, South Sudan. REUTERS/Samir Bol



People enjoy Ipanema beach on the end of the day, which according to local media was the hottest day this year so far, in Rio de Janeiro, Brazil. REUTERS/Ricardo Moraes

Federal Debt Tops \$27 Trillion for First Time National Debt



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

(CNSNews.com) - The US national debt has just reached 120.5 percent of the nation's annual economic output...



It then climbed another trillion dollars in just 35 days, topping \$26 trillion for the first time on June 9.

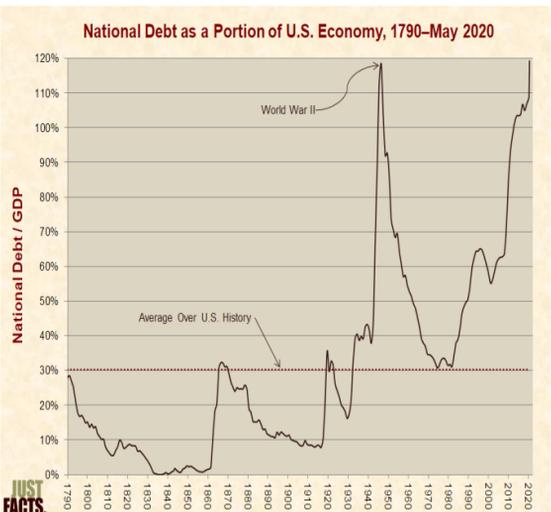
Table III-C of the Daily Treasury Statement for Thursday, October 1, 2020 (shown below) indicates that the total public debt of the federal

Table III-C - Debt Subject to Limit. Columns: Balance Transactions, Closing balance today, Opening balance (Today, This month, Fiscal year).

government rose from a closing balance of approximately \$26,945,391,000,000 on September 30 to a closing balance of approximately \$27,026,922,000,000 on October 1:

TABLE III-C - Debt Subject to Limit. Table with columns for Closing balance today, Opening balance (Today, This month, Fiscal year).

when it reached 118.5 percent. By the end of May, it had reached 119.5 percent, or four times its average over the nation's history:



The debt continued growing in early June and reached 120.5 percent by the 8th day of the month. These debt-to-GDP figures are based on the latest available yearly data from the US Treasury and the US Bureau of Economic Analysis...

COVID Policies Drive National Debt to All-Time Record for Highest Portion of US Economy



Today's unprecedented debt-to-economy ratio includes \$2.5 trillion in new debt since the outset of the COVID-19 pandemic. Over the course of US history, the government's debt-to-GDP ratio has averaged 30.3 percent...

COVID-19 Responses & Impacts

From the day that the World Health Organization declared COVID-19 a pandemic (March 11) through June 8th, the US national debt rose by \$2.5 trillion or 11.5 percentage points of GDP. This was mainly due to: 1. Four federal bills passed to address the pandemic...

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