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Southern DAILY

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Exclusive: Merck anti-baldness drug Propecia has long trail of suicide reports, records show



(Reuters) - Newly unsealed court documents and other records show that Merck & Co and U.S. regulators knew about reports of suicidal behavior in men taking the company's anti-baldness treatment Propecia when they decided not to warn consumers of those potential risks in a 2011 update of the popular drug's label.

FILE PHOTO: A bottle of Propecia is seen on a pharmacy shelf in New York City, U.S., August 8, 2019. REUTERS/Zachary Goelman

Internal records from Merck were made public in late January, when a federal magistrate in Brooklyn, New York, granted a 2019 Reuters motion to unseal 11 documents filed in years of litigation alleging Propecia caused persistent sexual dysfunction and other harmful side effects.

Since the 2011 decision on the warning, the FDA has received more than 700 reports of suicide and suicidal thoughts among people taking Propecia or generic versions of the drug. Those included at least 100 deaths. Before that, in the first 14 years the drug was on the market, the agency received 34 such reports, including 10 deaths.

Annual U.S. prescriptions of finasteride, as the drug is known, for hair loss increased to over 2.4 million in 2020, more than double the number in 2015, according to health data company IQVIA.

European and Canadian regulators, citing similar reports among men taking finasteride, require a warning of suicidal thoughts on the label, though they note that research has

not proved that the drug causes such thoughts. To this day, the U.S. label contains no mention of suicide or suicidal thoughts.

As early as 2009, Merck knew of more than 200 reports of depression, including suicidal thoughts, in men taking Propecia, according to an internal "risk management" assessment from that year. The company decided there were too few reports of serious depression and suicidal behavior and not enough specifics about those cases to warrant more than "routine" monitoring of safety data.

In 2011, two years after the Merck risk analysis, the FDA was weighing a company request to add "depression" to the drug's label as a potential risk, with no warnings related to suicide. FDA analysts disagreed about adding a warning related to suicide, according to previously unreported government documents. But the regulator ultimately agreed with Merck's request on the grounds that the number of suicides was lower than one would expect in this group of patients.

CALLS FOR TRANSPARENCY

Some medical researchers and patient advocates said Merck and the FDA have left American consumers in the dark about potentially life-threatening dangers associated with finasteride.

"No family should ever have to learn about this after the fact," said Kim Witzak, a consumer advocate who serves on an FDA advisory panel for psychiatric drugs. She has called drug companies and regulators to issue stronger warnings after her husband died from suicide in 2003 five weeks after being

prescribed an antidepressant for insomnia. Merck "had an opportunity to put suicide on the label, but they didn't want to do that because it's all about sales."

Michael Irwig, an endocrinologist and Harvard Medical School faculty member whose own research has found possible links between finasteride and suicidal behaviors, said Merck's handling of the risk analysis and the FDA's inaction keep critical information from the public. Merck "definitely should have provided a more complete picture," Irwig said. In a statement to Reuters, Merck said that "the scientific evidence does not support a causal link between Propecia and suicide or suicidal ideation and these terms should not be included in the labeling" for the drug. "Merck works continuously with regulators to ensure that potential safety signals are carefully analyzed and, if appropriate, included in the label for Propecia."

Merck has said in past statements that Propecia has been prescribed safely to millions of men since the late 1990s. It also has argued in court that "premature hair loss itself, the very condition for which Propecia is prescribed, is associated with low self-esteem, poor body image, and depression."

In a statement, FDA said it "continues to monitor postmarketing safety data for Propecia." Overall, the agency noted that the presence of a report in the FDA database "does not mean the drug caused the adverse event" and medical problems may stem from the "underlying disease being treated, caused by some other drug being taken concurrently, or occurred for other reasons."

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WEA LEE'S GLOBAL NOTES

02/03/2021

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President Condé's New Book

Today I received two copies of the President of Guinea's new book, "A Vision For Africa."

President Alpha Condé spent his whole life in a political battle for democracy during which he underwent exile and imprisonment. He is the first democratically elected president in Guinea since 2010. In power, he has promised to develop the country. As a university professor, he became a statesman and continued his long journey in service to his country.

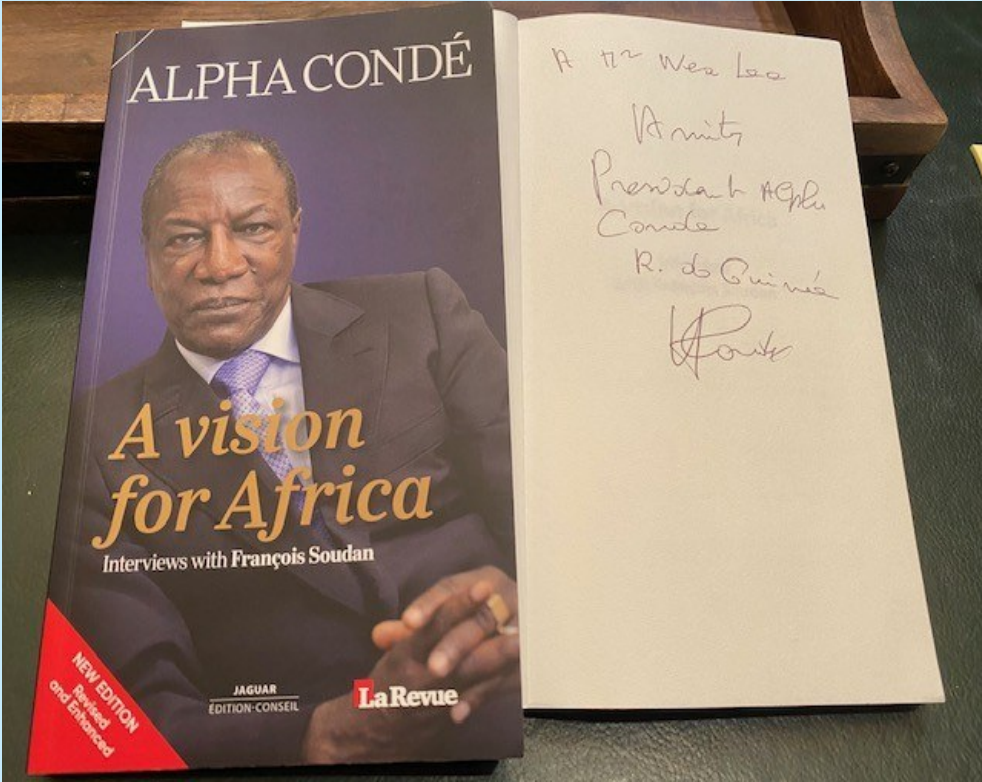
Guinea is a country in West Africa bordered on the west by the Atlantic Ocean. Natural resources are plentiful. In addition to its hydroelectric potential, the country possesses a large portion of the

world's bauxite and significant amounts of iron, gold and diamonds.

To serve the people who want to invest in Guinea, The First Guinea Investment Forum will be held on Feb. 24 to 27. This is the first transactional platform for key investment actors. The Guinea government as well as national, regional and international actors will join the event.

The priority of investments including Agriculture, Energy, Infrastructure, Mining and the digital economy will be discussed.

As President Condé said in his welcome message, "I give you the reassurance of my government in the security and profitability of your investments within



the framework of a win-win partnership. As Honorary Consul of Guinea In Houston,

ton, I am inviting you and your friends to join this forum to explore the opportunities in the Republic of Guinea.



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BUSINESS

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Vaccine Delivery Chaos May Undermine Second Shot Doses



Illustration: Sarah Grillo/Axios

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

Some of the same problems that have plagued the coronavirus vaccine rollout could also make it harder for people to get the second dose of the vaccines.

Why it matters: The two vaccines authorized so far both require two shots to reach the full potential of their protection, and those second shots need to happen within a specific window of time — putting extra pressure on a system that's already struggling to work out its kinks.

What's next: This week will be "when we're really starting to scale up to the second dose...the challenge is going to be about the availability of inventory and scheduling," Louisville Mayor Greg Fischer said in an interview.

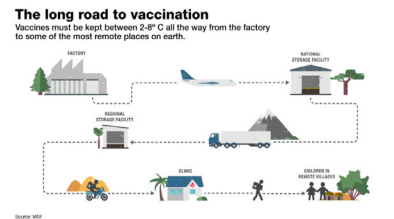
• "Unlike the first dose, you've gotta get the second dose within that time window, so there's a little more criticality to it," he added.

The problem: Some states say they don't have enough visibility into how many doses of vaccine they are getting from the federal government, and when.

• "You need to have information on that entire supply chain," said Celine Gounder, a professor at NYU Grossman School of Medicine. "Forget second doses, we just don't know where doses are."

• "You need to have visibility three to four

weeks in advance to make sure you have that dose in hand, on time, for those patients who are coming back for a second dose," said Jessica Daley, a vice president at Premier Inc., which works with health systems across the country.



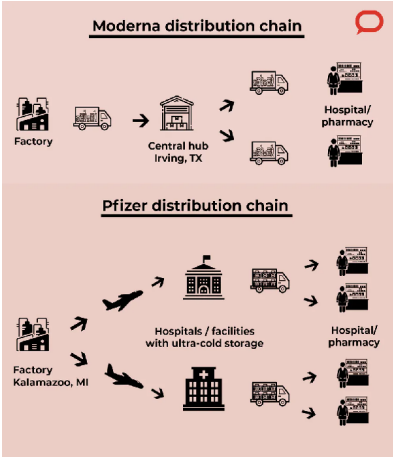
Between the lines: When vaccinating health system employees, "we know them, we can account for them, and it's a finite number. But when it gets to the community, its magnitude is multiple, multiple times" that, said Scott Evans, CEO of Sharp Grossmont Hospital.

Where it stands: Nationally, about 8% of the population has received at least one dose of the vaccine, and less than 2% have received both shots, per Bloomberg.

• The Biden administration isn't holding doses in reserve for people's second shots — it's shipping everything it can right away, trying to give as many people as possible at least some protection. Second doses will come from new supplies,

although some providers and health departments are withholding second doses themselves.

• Once someone receives the first dose of the vaccine, they have six weeks to get the second, per the Centers for Disease Control and Prevention's recommendations. **Scheduling** is also an issue. States and localities that used Eventbrite or other first-come, first-served systems may not have an easy way to guarantee appointments for second doses. "Things as simple as making appointments and calling people to come back and remind them to take their second dose — we don't have the infrastructure," Gounder said. **The other side:** Some health officials and providers feel confident that they'll be able to make the second dose process run smoothly.



• This often comes down to being able to successfully pull off the little things, like differentiating online between first dose appointments and second dose appointments or scheduling second dose appointments at the same time patients receive their first dose. **The bottom line:** We don't know what will happen if millions of Americans fail to receive their second shot in a timely manner. But at this point in the pandemic, we can little afford to figure it out the hard way.

Related

New Variants Driving Virus Fears: Poll

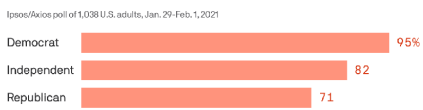
Americans are deeply worried about new strains of the coronavirus — prompting some to double-mask and many to tem-

per expectations about life getting back to normal — according to the latest installment of the Axios/Ipsos Coronavirus Index. The big picture: Fears have eased substantially around sending children back to school, our national survey found. But there's growing anxiety about the virus changing and the implications for the nation's health, economy and society.

• 83% of Americans say they're concerned about new strains that may be more transmissible — with about one-third of that group saying they're "extremely" concerned.

• Only 26% expect life to return to pre-COVID normal in the next six months; 30% predict it will be more than a year; and 8% say "never."

Percent concerned about new COVID-19 strains



Data: Axios/Ipsos survey; Chart: Axios Visuals

Why it matters: The findings suggest that Americans across partisan lines are increasingly attuned to the science around the virus — and that they don't expect vaccines or the new administration under President Biden to bring instant fixes.

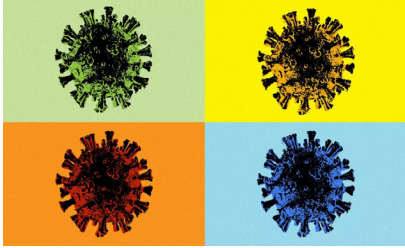
• Six in 10 say they have watched or read news coverage about vaccinations in their community. **What they're saying:** "I'm reading this as, 'What is Biden's window to get this under control?'" said pollster Chris Jackson, senior vice president for Ipsos Public Affairs. Jackson said he'd expected to find three-to-six-month windows of patience, but that Americans seem to be prepared for a longer slog. "At least at the moment, people aren't really expecting it to get under control until six months to a year from now."

What we're watching: Since late August — the last time we asked this question — Americans have grown more comfortable with the idea of schools re-opening in their communities.

• 59% saying they have some level of concern, down from 74%, and only one-third now feel extremely or very concerned, down from half.

• There are still big partisan differences,

with Democrats about twice as worried as Republicans.



By the numbers: A small but significant share of Americans — 15% — who skew older and Democratic say they're wearing two masks at once, either sometimes or all of the time, when they leave home.

• When it comes to life returning to pre-COVID "normal," Republicans are the most likely by far to expect it within six months. But optimists are a minority even in the GOP: 84% of Democrats, 73% of independents and 63% of Republicans say a return to normal will take longer.

• Concerns about new strains of coronavirus are far more bipartisan: 95% of Democrats, 82% of independents and 71% of Republicans. (Courtesy axios.com)



Editor’s Choice



The SpaceX Starship SN9 explodes into a fireball after its high altitude test flight from test facilities in Boca Chica, Texas. REUTERS/Gene Blevins



Newly confirmed Transportation Secretary Pete Buttigieg is embraced by his husband Chasten Buttigieg after being ceremonially sworn as Vice President Kamala Harris watches with her hand on her heart at the White House. REUTERS/Kevin Lamarque



President Joe Biden and first lady Jill Biden pay their respects to late Capitol Police Officer Brian Sicknick, who died on Jan. 7 from injuries he sustained while protecting the U.S. Capitol during the Jan. 6 attack on the building, as he lies in honor in the Rotunda of the U.S Capitol in Washington. Erin Schaff/Pool



Municipal health workers travel on a boat along the Solimoes river banks, where Ribeirinhos (river dwellers) live, to administer the AstraZeneca/Oxford vaccine for the coronavirus, in Manacapuru, Amazonas state, Brazil, February 1.



A demonstrator clashes with a police shield at a rally in solidarity with farmers protesting against farm laws, in New Delhi, India. REUTERS/Anushree Fadnavis



A woman places her hand on a mural of late record-breaking centenarian Captain Tom Moore, who died on Tuesday, in Two Gates, Tamworth, Britain. REUTERS/Jason Cairnduff



Indian Air Force (IAF) Sarang helicopter team performs during the “Aero India 2021” air show at Yelahanka air base in Bengaluru, India. REUTERS/Samuel Rajkumar



Sledders enjoy the snow during a snow storm in the Brooklyn borough of New York City. REUTERS/Brendan McDermid

An Easy-To-Use Test Will Soon Be Available To All Americans, Per White House Covid-19 Adviser Andy Slavitt

U.S. Strikes \$230 Million Deal For Over-The-Counter Covid Tests



“Making easier-to-use tests available to every American is a high priority with obvious benefits,” White House Covid-19 adviser Andy Slavitt told reporters. Ellume’s self-administered rapid coronavirus test.

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

The Biden administration announced a \$230 million deal to ramp up production of the country’s first over-the-counter, at-home Covid-19 test. “These are over-the-counter, self-performed test kits that can detect Covid with roughly 95 percent accuracy within 15 minutes,” Andy Slavitt, the White House senior adviser for Covid-19 response, told reporters on Monday. The Food and Drug Administration granted an emergency use authorization in December for Ellume’s tests, which are expected to cost about \$30 each. “Ellume has been ramping up manufacturing and will ship 100,000 test kits per month to the U.S. from February through July,” Slavitt said. “That’s good, but it’s obviously not where we will need to be.”



Employees work on the production line of a Covid-19 coronavirus home test unit that has been granted an Emergency Use Authorization by the U.S. Food and Drug Administration (FDA), at the production facility of Australian digital diagnostics company Ellume in Brisbane on Dec. 21,

2020. (Photo/Patrick Hamilton / AFP - Getty Images)

The \$230 million deal the departments of Defense and Health and Human Services struck with Ellume will allow the company “to scale the manufacturing base and capacity of this easy-to-use test,” Slavitt said. “Thanks to this contract, they’ll be able to scale the production to manufacture over 19 million test kits per month by the end of this year, 8.5 million of which are guaranteed to the U.S. government.” The test by Ellume, an Australian digital diagnostics company, does not require sending samples to a lab, is similar to how at-home pregnancy tests work, and is “appropriate for people ages 2 and older,” Slavitt said. He said the test uses a “mid-turbinate nasal swab,” which is less invasive than the original deep nasal swabs used at the beginning of the outbreak.



The antigen test involves collecting a sample with a nasal swab that users then place into a Bluetooth-connected analyzer that syncs with a smartphone app. “After you take the swab, you put the sample into a digital analyzer, which will send a result to your smartphone in about 15 minutes,” Slavitt said. He called the news “exciting,” and said he hoped the price would come down when there are more tests in production. (Courtesy nbcnews.com)

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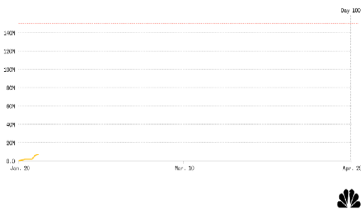
Biden Pledged 150 Million Covid Vaccinations In 100 Days. Only 130 Million-Plus Total Covid-19 Vaccination Shots To Go. On Jan. 25, President Joe Biden upped

his Covid-19 vaccination goal to 150 million shots in arms in his first 100 days in office. Then Jan. 26, shortly after this article was first published, Biden backed away from 150 million and restated his 100 million goal. In the days and weeks before entering office, he said his goal was 100 million vaccinations.



People wait in line to be vaccinated at a vaccination station in an empty department store in California, on Jan. 21. President Joe Biden pledged 150 million vaccinations in 100 days, starting Jan. 20. NBC News has tracked the progress made and the time that’s left to meet the administration’s goal. (Photo/Mike Blake / Reuters)

President Joe Biden pledged 150 million vaccinations in 100 days
Since Jan. 20 there have been more than 7 million total vaccinations.



1,355,451 doses per day average, past seven days 1,552,153 doses per day necessary to reach 150 million. 86 days left to reach the goal.

While Biden’s chief of staff had called the 100 million goal “ambitious,” the vaccination rate necessary to reach the mark is not much higher than what the rate was Jan. 20. The Biden administration has until the end of the day April 29 to reach the target. Use this graphic to follow whether the country is on track to reach the admin-

istration’s goal. Note that total vaccinations given — as in first and second shots, both shots counting individually — are what’s being counted. This is not the same as full vaccinations, which are first and second shots counted as one. Biden specifically mentioned shots in arms in his statements about the goal. (Courtesy nbcnews.com)



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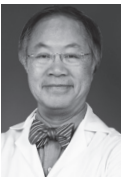
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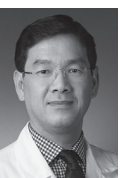
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