REVA Pharma
Caring for Healthier Lives

NEWS LETTER
For Private Circulation only

# FDA Chief Refuses To Back Trump's Vaccine Prediction


The head of the US drugs regulator has cast doubt on President Donald Trump's prediction that a Covid-19 vaccine will be ready this year. "I can't predict when a vaccine will be available," US Food and Drug Administration (FDA) Commissioner, Dr Stephen Hahn, said.

Dr Hahn said vaccine development would be "based upon the data and science". A vaccine would train people's immune systems to fight the virus, so they do not become sick. Dr Hahn, a member of the White House coronavirus task force, was asked about the timeframe after President Trump suggested that a "vaccine solution" to the pandemic would be ready "long before the end of the year". "I want to send our thanks to the scientists and researchers around the country, and even around the world, who are at the forefront of our historic effort to rapidly develop and deliver life-saving treatments and ultimately a vaccine," Mr Trump said during his Independence Day address at the White House.

"We are unleashing our nation's scientific brilliance and we'll likely have a therapeutic and/or vaccine solution long before the end of the year."

**Coronavirus vaccine: When will we have one?**

The president has been criticised for his comments on vaccines and treatments during the coronavirus epidemic, which has claimed the lives of almost 130,000 people in the US. In recent days, infections have been rising at a record rate in western and southern states, bringing the total to more than 2.8 million nationwide.

The head of the World Health Organization (WHO), Dr Tedros Adhanom Ghebreyesus, warned in June that scientists may never be able to create an effective vaccine against the coronavirus. "The estimate is we may have a vaccine within one year," the WHO chief said. "If accelerated, it could be even less than that, but by a couple of months. That's what scientists are saying." Other experts have suggested a Covid-19 vaccine will not be available until at least mid-2021.

**What did Dr Hahn say?**

In an interview with ABC News on Sunday, FDA chief Dr Hahn said "we are seeing unprecedented speed for the development of a vaccine", but did not elaborate on a timeline for its availability. "Our solemn promise to the American people is that we will make a decision based upon the data and science on a vaccine, with respect to the safety and effectiveness of that vaccine," he said. In another interview with CNN, Dr Hahn said he would not comment on Mr Trump's assertion that 99% of Covid-19 infections were "totally harmless". "I'm not going to get into who is right and who is wrong," he said of Mr Trump's remark, also made in his Independence Day speech. The global fatality rate among Covid-19 patients is estimated to be relatively low, differing from country to country. In March the head of the WHO said about 3.4% of reported Covid-19 cases had been fatal globally. While most patients with Covid-19 have mild or moderated symptoms, around 20% require oxygen, according to the WHO.

**What progress has been made on a vaccine?**

A vaccine would normally take years, if not decades, to develop, but scientists across the world are doing their best to fast-track efforts. There are around 120 vaccine programmes currently under way. Oxford University and Imperial College London have both started human trials. US health officials have expressed cautious optimism that a vaccine will be in production by the end of 2020 or early 2021.

Earlier this week, the US's top infectious diseases expert, Dr Anthony Fauci, said the safety and effectiveness of a vaccine against Covid-19 should be known by "early winter". Dr Fauci said trials of various vaccines would be entering the latter stages of the testing process this month. "We may be able to at least know whether we are dealing with a safe and effective vaccine by the early winter, late winter, beginning of 2021," said Dr Fauci, the director of the National Institute of Allergy and Infectious Diseases. (Source: BBC)

# Coronavirus: Russian Spies Target Covid-19 Vaccine Research


Russian spies are targeting organisations trying to develop a coronavirus vaccine in the UK, US and Canada, security services have warned.

The UK's National Cyber Security Centre (NCSC) said the hackers "almost certainly" operated as "part of Russian intelligence services".

It did not specify which organisations had been targeted, or whether any information had been stolen. But it said vaccine research had not been hindered by the hackers. Russia has denied responsibility.

"We do not have information about who may have hacked into pharmaceutical companies and research centres in Great Britain. We can say one thing - Russia has nothing at all to do with these attempts," said Dmitry Peskov, a spokesman for President Putin, according to the Tass news agency.

The warning was published by an international group of security services:

- the UK's NCSC
- the Canadian Communication Security Establishment (CSE)
- the United States Department for Homeland Security (DHS) Cyber-security Infrastructure Security Agency (CISA)
- the US National Security Agency (NSA)

One expert said it was "plausible" that, despite the Kremlin's denials, Russian spies were involved.
"The received wisdom is that in cyber-space, attribution is difficult but not impossible," commented Emily Taylor from the Chatham House think tank.

"Usually the security services are much more hedgy in their language if they think there is any doubt.
"Cozy Bear [the named group] has been implicated in past cyber-attacks and has left quite a trail, and there are fairly good links to the Russian state itself."

In recent years, Western security agencies have become more willing to call out hackers targeting companies and organisations in their countries in the hope it will deter them. But the latest accusations are more unusual since officials are directly pointing the finger at Russian spies rather than talking generally about "state-backed hackers" or using other more cautious references.

And they are also challenging them over targeting something that the general public recognises as being highly sensitive - coronavirus vaccine research - rather than simply some company or government department's information. However, on another level we should not be too surprised by the claim.

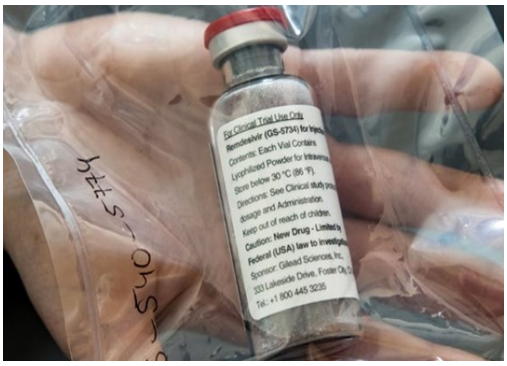
Understanding vaccine research and other details about the pandemic has become a top target for intelligence agencies around the world and many others, including Western spies, are likely to be active in this space.

The UK, US and Canadian agencies said the hackers had exploited software flaws to get access to vulnerable computer systems, and had used malware called WellMess and WellMail to upload and download files from infected machines. They are also said to have tricked individuals into handing over login credentials with spear-phishing attacks.

Phishing emails are designed to trick the recipient into handing over their personal information Spear phishing is a targeted and personalised form of the attack, designed to trick a specific individual. Often the email appears to come from a trusted contact, and may include some personal information to make the message seem more convincing.

But one cyber-security expert said the Russians were unlikely to be the only ones involved in such a campaign. "They have lots of people, we have lots of people, the Americans have even more people, as do the Chinese," commented Prof Ross Anderson from the University of Cambridge's Computer Laboratory. "They are all trying to steal this kind of stuff all the time." (Source: BBC)

## Mylan Pharma To Launch Remdesivir In India At Rs 4,800 Per 100 mg Vial



Bengaluru: Drugmaker Mylan NV said on Monday it would launch its generic version of Gilead Sciences Inc's COVID-19 treatment remdesivir in India this month at 4,800 rupees ($64.31) per 100 mg vial, as infections surge in the world's third worst-hit country.

The Drug Controller General of India (DCGI) approved Mylan's remdesivir version, to be called Desrem, for the treatment of suspected or laboratory confirmed severe incidences of COVID-19 in adults and children, the company said in a statement.

Mylan's version comes after two drugmakers, Cipla Ltd and privately-held Hetero Labs Ltd, launched their generic versions of the drug. Cipla will price its version, Cipremi, at less than 5,000 rupees, while Hetero has priced its version, Covifor, at 5,400 rupees.

Gilead has priced remdesivir at $2,340 per patient for wealthier nations. It has agreed to send nearly all of its supply of the drug to the United States over the next three months, stirring concerns about availability elsewhere.

Remdesivir is in high demand after the intravenously-administered medicine helped to shorten hospital recovery times in a clinical trial. On Friday, it got conditional approval from the European Commission for use in severe COVID-19 patients.

Mylan said it was working toward expanding emergency use access for patients in the 127 low- and middle-income countries where it is licensed by Gilead Sciences to do so. Gilead has signed licensing agreements with Dr. Reddy's Laboratories Ltd, Jubilant Life Sciences Ltd, Syngene International Ltd and Zydus Cadila, listed as Cadila Healthcare Ltd, to make and sell remdesivir. Cases of the novel coronavirus in India stood at 697,413 on Monday, health ministry data showed, while the death count stood at nearly 20,000. (Source: NDTV)

## Eli Lilly Tests Antibody Drug to Halt Covid-19 Spread in US Nursing Homes

Eli Lilly and Co said on Monday it started a late-stage trial testing whether one of its experimental Covid-19 antibody treatments can prevent the spread of infections in residents and staff at US nursing homes. The Indianapolis-based drugmaker said it dosed the first participant in the placebo-controlled trial at a nursing home in Illinois.

LY-CoV555, which is being developed in partnership with Canadian biotech firm AbCellera, is already being studied as a treatment in patients who have contracted the disease. The nursing home trial will test whether it works prophylactically. The Phase III trial is expected to enrol up to 2,400 participants who live or work at facilities that have had a recently diagnosed case of Covid-19.

Lilly is also developing other potential antibody treatments for Covid-19, but has prioritised manufacturing LY-CoV555, Chief Scientific Officer Daniel Skovronsky said. The company hopes to have over one lakh doses available by year-end, he said. “If it works, that’s not enough. Doses will have to be prioritised to patients that need it the most,” Skovronsky said in an interview, noting that preventing spread in nursing homes is one scenario that would likely be prioritised.

The elderly are at particularly high risk for the disease that has claimed more than 6.9 lakh lives globally. If the drug proves effective, Skovronsky said Lilly hopes to manufacture around 10 lakh doses by the end of 2021. The nursing homes trial is being conducted in partnership with several long-term care networks across the country, as well as the US National Institute of Allergy and Infectious Diseases.

To speed the study, the company has created mobile research units including retrofitted recreational vehicles that can be deployed in response to coronavirus outbreaks at nursing homes across the United States. LY-CoV555 belongs to a class of drugs known as monoclonal antibodies, which are among the most widely used biotechnology medicines. Regeneron Pharmaceuticals Inc and other drugmakers are testing similar treatments against Covid-19.

Last week, Lilly told investors that LY-CoV555 had moved into mid-stage trials as a treatment and that late-stage trials would begin in the coming weeks.

Skovronsky said that the earliest data to be released would likely come from a Phase II study in patients with Covid-19 who have not been hospitalised. Because that study is based on measuring patients’ viral load — the amount of virus detectable in the blood — rather than preventing hospitalisations or deaths, the data could be released a few weeks after enrolment for the trial closes, he said.

That data, however, might not be enough for the company to receive US emergency use authorisation for the drug, Skovronsky said, noting that the company may still have to show it can reduce hospitalisations or other risks to assure regulators. (Source: Business Line)

## Coronavirus: UN Makes Record $10.3bn Appeal for Pandemic Fight

The United Nations is making an appeal for $10.3 billion (£8.2 billion) to help fight the coronavirus pandemic, its largest ever fundraising call. The UN says up to 265 million people could face starvation by the end of the year because of the impact of Covid-19.

The money will be for used for low income and fragile countries. The UN warned that failure to act could undo decades of development. It initially asked for $2 billion in its first coronavirus appeal in March.

The coronavirus pandemic is having a huge impact on the world's poorest, the BBC's Imogen Foulkes reports from Geneva. This revised appeal is a record, but, the UN says, wealthy countries have thrown away the financial rule book to protect their own economies, and must now do the same for poorer nations.

If they do not, the UN warns, the world faces a series of crises, with millions pushed into starvation. Millions of migrant workers laid off under lockdown cannot send money home, vaccination programmes for childhood diseases are on hold, and countries already enduring years of conflict are ill equipped to handle Covid-19. In Yemen, a quarter of all those confirmed to have had the virus have died from it, five times the global average. Fourteen charities - including Oxfam, Christian Aid, Islamic Relief and the British Red Cross - will join together to ask the British public to donate. There have been more than 13 million confirmed Covid-19 cases so far globally and nearly 600,000 people have died. (Source: BBC)

## Oxford Covid-19 Vaccine Shows Positive Results, Indians are Already Lining Up With Memes


As news of the Oxford vaccine working positively started circulating, Indians started lining up on Twitter to be 'next in line' to get it on a mass scale - by celebrating it with memes. Oxford University's Phase-1 and Phase-2 trials on their Covid-19 vaccine showed that there was no major adverse reaction and it induced a strong antibody and T cell immune response among participants.

The vaccine triggered a T-Cell response within 14 days of vaccination and an antibody response within 28 days, a paper published in The Lancet journal said. A T cell response refers to the attack of the white blood cells on the cells that are infected with the SARS-CoV-2 virus, the University of Oxford said. The paper in The Lancet was much anticipated as the Oxford University's experimental vaccine has been touted as one of the front-runners among over 20 vaccine candidates that have entered the human trial stage.

A phase-I trial typically enrolls healthy volunteers to test the safety of the vaccine. The Oxford team though tried to look at both safety and efficacy of the experimental vaccine on the participants. Participants showed detectable neutralising antibodies, which have been suggested by researchers as important for protection, the University said. The strongest response was noted among those who received two doses of the vaccine. As news of the vaccine working being positive started circulating, Indians started lining up on Twitter to be 'next in line' to get it on a mass scale - by celebrating it with memes. (Source: TV 18)

## Indian Pharmacopoeia Drops Redundant' Toxicity Test On Animals for Human Vaccines

Human vaccines will no longer require an "abnormal toxicity test" done on small animals before a batch of the product is released, provided manufacturers adhered to the country's Good Manufacturing Practices (GMP) norms. The development follows a recent amendment to the Indian Pharmacopoeia (IP) and will give a lease of life to several guinea pigs and mice who are put through these tests. The IP is a compilation of official standards of drugs being made or marketed in India, brought out by the Indian Pharmacopoeia Commission, an autonomous institution under the Health Ministry.

Explaining why abnormal toxicity tests had been dropped in other parts of the world as well, a note from People for the Ethical Treatment of Animals (PETA) said, "In the test, animals are injected with a vaccine, and if none of them die, the batch is deemed safe. Animals who don't die during the experiment are killed afterwards. Extensive reviews of historical data from the abnormal toxicity test have shown that compliance with good manufacturing practices is superior to the use of animals for controlling and detecting batch contamination." Dipti Kapoor, PETA's India Science Policy Adviser, told *Business Line*, the country had already moved in the direction of removing this toxicity test from the general requirements of the IP monographs. But the impact was missing since individual monographs still required it, and the latest IP amendment drops this requirement from individual monographs of the human vaccines as well. The move came into effect from July 22, she said, when the IP amendment was published.

Eliminating this test would not affect the safety or quality of the product being released, provided GMP norms were followed, Kapoor said, adding that these tests had already been dropped from requirements in Europe, the United States and norms outlined by the World Health Organisation. The vaccines impacted by the move included, Diphtheria and its combination vaccines, Hepatitis A, Influenza, Rabies, Japanese Encephalitis, Typhoid, Measles-Rubella, etc, she pointed out. (Source: Business Line)