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Editorial: Vaccine can be harmful: Side effects and clinical trial errors

Why every nation is in hurry to release COVID-19 drug/vaccine despite many concerns?

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Editorial

Why every nation is in hurry to release COVID-19 drug/vaccine despite many concerns?

by Kamal Pratap Singh, kamal9871@gmail.com

Despite various questions about effectiveness, safety and availability there seems a hurry to release COVID treatment by individuals, scientists, organizations and Nations. There are numerous examples of failures like Solidarity trial candidates – remdesivir, hydroxychloroquine, lopinavir/ritonavir and interferon, AstraZeneca's Calquence, Novartis' Ilaris, Sanofi & Regeneron's Kevzara, Eli Lilly antibody drug, Roche's Actemra, Glenmark's Favipiravir, Biocon's Itolizumab, Patanjali's Coronil and many many more. In this article we are discussing how the organizations came up with magical treatment and how these products were criticized and soon vanished from the news headlines, even though there was urgent need of treatment. We will also take a look at the aspects of pharma profiteering and lobbying, based on the many reports that signifies pharma/healthcare profiteering and lobbying that was aimed at financial gains in this COVID pandemic.

In a CBS interview, Fauci first suggested that the British regulators had failed to scrutinise the data carefully enough and had waved the vaccine through. Later he apologized for casting doubt over UK's approval of Pfizer vaccine. Source: https://www.firstpost.com

Bullet points

- Several drugs have been given approval without any concrete studies and have been challenged
- Death rate is not significant and it is lowest in a densely country populated like India
- People have come out without any measure but transmission has not seen
- Many countries like new Zealand and Australia have reduced their COVID-19 transmission to zero without any drug/vaccine

There are many aspects to see how all this is working but let's first take a look that what and how different COVID treatments came into picture and how they progressed or vanished.

COVID 19 drugs approved till now (Major ones)

On March 13, 2020 for the first time news reports appeared about China's National Medical Products Administration had approved Fujifilm's Favilavir (Favipiravir), an anti-viral drug as a treatment against coronavirus. This was the first time too when scientific but non-evidence based headline came into prevalence. The drug was touted as the first approved coronavirus drug, while clinical trials were still ongoing in Shenzhen, Guangdong province, when subjects involving 70 patients reportedly showed treatment efficacy with very little side effects but no effects on disease were discovered. (Source: https://www.hospimedica.com/covid-19/articles/294781247/fujifilms-antiviral-becomes-first-approved-drug-to-treat-coronavirus-in-china.html)

In March, the US president used a press conference to promote the use of hydroxychloroquine(HCQ), a common existing anti-malaria drug, to treat COVID-19, saying: "I sure as hell think we ought to give it a try." Trump was influenced by a widely publicized study in France where 40 coronavirus patients were given HCQ, with more than half experiencing the clearing of their airways within three to six days. (https://www.statnews.com/2020/03/20/trump-coronavirus-drug-just-a-feeling/)

The first French scientist Didier Raoult who proposed HCQ was heavily criticized several times for this act (https://www.sciencemag.org/news/2020/03/insane-many-scientists-lament-trump-s-embrace-risky-malaria-drugs-coronavirus).

At the same time Food and Drug Administration (FDA) provided hydroxychloroquine with an "emergency use authorization" to use on coronavirus patients in some circumstances. Some experts in India too have criticised the endorsement of HCQ by India's top health research body for use on COVID-19 patients and healthcare workers without proper evidence that proves the drug's ability to reduce the viral load (https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31180-6/fulltext).

Now it has been proved that HCQ do not provide any better experience in COVID-19 patients (https://www.nejm.org/doi/full/10.1056/NEJMoa2023184)

Another most popular earliest drug Gilead's antiviral drug Remdesivir, intravenously administered in hospitals, was declared to be the first treatment to show improvement in COVID-19 trials. On around 1st May it was approved for emergency use in severely-ill patients in the United States, India and South Korea, and has received full approval in Japan even after drug failed its first randomised clinical trial according to draft documents published by the World Health Organization. Now various studies have published showing no effect on COVID patients (https://www.nejm.org/doi/full/10.1056/NEJMoa2023184)

Leader turned scientist Donald Trump again had been lambasted by the medical community after suggesting research into whether coronavirus might be treated by injecting disinfectant into the body. He also appeared to propose irradiating patients' bodies with UV light, an idea dismissed by a doctor at the briefing later. Needless to say that this was the height of creating panic, several patient were admitted in hospital after drinking alcohol and sanitizers. https://www.bbc.com/news/world-us-canada-52407177

On March 30, 2020 French pharmaceutical company Sanofi and Regeneron initiated trials around the world to determine whether Kevzara (repurposed) has the potential to play a role in addressing the COVID-19 global health crisis. In October report were published about its failure, the drug typically used for rheumatoid arthritis have produced adverse reactions in some

patients, including pneumonia and even death.

In most hurry Moderna's researchers rush to test coronavirus vaccine in people without knowing how well it works in animals "I don't think proving this in an animal model is on the critical path to getting this to a clinical trial," said Tal Zaks, chief medical officer at Moderna, a Cambridge, Mass.-based biotech that has produced a COVID-19 vaccine candidate mRNA-1273 at record speed. He told STAT that scientists at the National Institutes of Health are "working on nonclinical research in parallel." Meanwhile, the clinical trial started recruiting healthy participants in the first week of March. However, the vaccine by Moderna and Vaccine Research Center could start phase one clinical trials in April. (https://www.statnews.com/2020/03/11/researchers-rush-to-start-moderna-coronavirus-vaccine-trial-without-usual-animal-testing/)

US biopharma company Altimmune, a clinical stage biopharmaceutical company announced that it is working on an intranasal coronavirus vaccine, which is being developed based on a vaccine technology platform similar to NasoVAX, the influenza vaccine developed by Altimmune. There is no update since then about their product and any results of clinical trial. (https://clinicaltrials.gov/ct2/show/NCT04442230)

On April 10, 2020, the U.S. Food and Drug Administration issued an emergency use authorization for a blood purification system to treat patients 18 years of age or older with confirmed Coronavirus Disease 2019 (COVID-19) admitted to the intensive care unit (ICU) with confirmed or imminent respiratory failure. (https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-blood-purification-device-treat-covid-19)

On April 3, 2020 Bharat Biotech and the US-based FluGen along with virologists at the University of Wisconsin-Madison began the development and testing of a unique vaccine against covid-19 called CoroFlu Speaking to Business Today- a newspaper, Chairman and Managing Director of Bharat Biotech Krishna M Ella said a lot depends on the approval process. "If the government acts fast on it and treats it as a national emergency, it should be possible to get the vaccine out in about eight months. (https://www.thehindu.com/sci-tech/science/bharat-biotech-set-to-develop-and-test-vaccine-for-covid-19/article31244845.ece .)

Ella believes the process could be faster in India as CoroFlu is being built on the backbone of FluGen's flu vaccine candidate known as M2SR. "M2SR is proven in phase 2 human challenge studies, so it can fastrack the project," he said. No news of any further developments of CoroFlu came afterwards but another candidate of Bharat Biotech secured regulatory approval from the DCGI to advance its COVID-19 vaccine candidate, COVAXIN, into human clinical trials.

Before this Bharat Biotech said it is leading a project to develop human monoclonal antibodies as therapy for COVID-19 infections. The project was sanctioned by the Council of Scientific and Industrial Research (CSIR) under its flagship programme, New Millennium Indian Technology Leadership Initiative. https://www.financialexpress.com/industry/bharat-biotech-to-lead-monoclonal-antibodies-project-for-covid-19-therapy/1953143/ This project was a collaboration between NCCS, Pune; IIT, Indore, and PredOmix Technologies but no progress has seen so far for antibody technology or any vaccine out of this. https://www.financialexpress.com/industry/bharat-biotech-to-lead-monoclonal-antibodies-project-for-covid-19-therapy/1953143/

In an article by The Lancet published on April 30, Bacille Calmette-Guérin vaccine (BCG) was proposed as COVID-19 cure. It wrote, in addition to its specific effect against tuberculosis, the BCG vaccine has beneficial nonspecific (off-target) effects on the immune system that protect against a wide range of other infections and are used routinely to treat bladder cancer. This has led to the suggestion that vaccination with BCG might have a role in protecting health-care workers and other vulnerable individuals against severe coronavirus disease 2019 (COVID-19). No fresh report was seen which connects COVID-19 and BCG.

The two big international multidrug trials were launched one after another to see if the combination of drugs can prove to be effective against COVID-19. The first trial was launched on 23 April 2020 by WHO and called "Solidarity Trial" for COVID-19 treatments, it was officially launched in Indonesia. The Indian Council for Medical Research (ICMR) has

TABLE 1: Drugs which gain popularity during COVID-19 pandemic

Note: The results and updates are highly dynamic because of actions of companies, FDA, EUA, DCGI etc. The data was last accessed on 15/12/2020

S.No.	Drug/therapy	Company	Status as on	Source
1	Calquence	AstraZeneca	Failed in Phase II, 12 Nov	https://www.fiercepharma.com/pharma/az-s-calquence-fails-covid-19-study-hospitalized-patients-joining-list-repurposed-drugs-have
2	Favilavir (Favipiravir)	Glenmark	Ongoing, Phase III trial, 24th November	https://www.clinicaltrialsarena.com/news/glenmark-favipiravir-covid-19/
3	Hydroxychloroquine with Ivermectin	Didier Raoult, Donald Trump	failed	https://www.nejm.org/doi/full/10.1056/NEJMoa2023184
4	Remdesivir	Gilead's	failed	https://www.nejm.org/doi/full/10.1056/NEJMoa2023184
5	Disinfectants	Donald Trump	failed	Due to general sense of people
6	Kevzara	Sanofi and Regeneron	failed	https://in.reuters.com/article/us-health-coronavirus-sanofi/sanofi-says-kevzara-drug-fails-as-possible-covid-19-treatment-idINKBN25S3R4
7	mRNA-1273	Moderna and Pfizer	No result posted yet	https://clinicaltrials.gov/ct2/show/NCT04283461
8	NasoVAX	Altimmune	No result posted	https://clinicaltrials.gov/ct2/show/NCT04442230
9	blood purification system	USFDA	No result posted	https://clinicaltrials.gov/ct2/show/NCT04478539
10	CoroFlu	Bharat Biotech and FluGen	No result posted	NONE
11	human monoclonal antibodies	Bharat Biotech/OTHERS	No result posted	https://clinicaltrials.gov/ct2/show/NCT04354766
12	Covaxin	Bharat Biotech	Ongoing	NONE
13	ChAdOx1 nCoV-19	Oxford University	No result posted	https://clinicaltrials.gov/ct2/show/NCT04536051
14	AZD1222	Oxford/AstraZeneca	No result posted	https://clinicaltrials.gov/ct2/show/NCT04516746
15	convalescent plasma	Max Healthcare	Failed	DOI: 10.1056/NEJMoa2031304
16	BCG	OTHER	No result posted	https://www.clinicaltrials.gov/ct2/show/NCT04347876
17	Solidarity Trial – Dexamethasone, Colchicine, Tocilizumab, Convalescent plasma, REGN-COV2, Aspirin	WHO	Failed	https://www.nejm.org/doi/full/10.1056/NEJMoa2023184

18	Recovery trial - Lopinavir and Ritonavir, Dexamethasone, Azithromycin, Hydroxychloroquine, Tocilizumab, REGN-COV2, Convalescent plasma	UK	Failed	https://www.recoverytrial.net/results
19	Ivermectin and Doxycycline	Bangladesh	No result posted	https://clinicaltrials.gov/ct2/show/NCT04551755
20	Coronil	Patanjali Ayurveda	Failed	https://www.newindianexpress.com/nation/2020/jul/15/did-coronil-violate-clinical-trial-norms--doctors-experts-seek-mci-intervention-2170133.html
21	Itolizumab	Biocon	Failed	https://science.thewire.in/health/icmr-balram-bhargava-biocon-kiran-mazumdar-shaw-itolizumab-mortality-phase-2-trials/

Other suggested COVID treatments drugs: Tamiflu, Actemra, stem cell technology, Coronavir, Avifavir, oseltamivir, Kaletra, Bemcentini, Medi3506, Zilucoplan, Heparin etc.

also fast tracked the roll out of the global 'Solidarity Trial' launched by the WHO to help find an effective treatment for COVID-19. Nine hospitals were given approval to conduct randomised controlled clinical trials under the WHO's 'Solidarity Trial' to find an effective treatment. The drugs/therapies to be investigated through the study were:

1. Low-dose Dexamethasone
2. Colchicine
3. Tocilizumab
4. Convalescent plasma
5. REGN-COV2
6. Aspirin

According to a Nature Biotechnology article published on 11 May 2020 which called it the world's biggest trial of drugs to treat COVID-19 patients was set up in the UK (https://www.nature.com/articles/s41587-020-0528-x).

The study was jointly funded between UK Research and Innovation (UKRI) and the NIHR - and is sponsored by University of Oxford. The Recovery trial has recruited over 5,000 patients in 165 NHS hospitals. The drugs/therapies to be investigated through the study were:

- Lopinavir-Ritonavir (commonly used to treat HIV)
- Low-dose Dexamethasone (now only recruiting children)
- Azithromycin (a commonly used antibiotic)
- Hydroxychloroquine (an antimalarial drug)
- Tocilizumab (an anti-inflammatory treatment given by injection)
- REGN-COV2
- Convalescent plasma

On May 30, doctors in Bangladesh declared that the combination of Ivermectin and Doxycycline is an effective treatment against COVID-19, with patients recovering within four days. Ivermectinis an anti-parasite drug, while doxycycline is an antibiotic. Subsequently, Max Hospital registered a trial to study the effectiveness of Ivermectin with 'standard of care treatment versus standard of care treatment for COVID-19 cases'. Another trial, registered by the Department of Medicine of Lady Hardinge Medical Col-

lege in Delhi studied the effects of anti-malarial drug hydroxychloroquine, ciclesonide, a drug used to treat asthma, and Ivermectin in the treatment of moderate COVID-19 illness.

Later WHO provided advisory that Antibiotics work only against bacteria, not viruses. COVID-19 is caused by a virus, and therefore antibiotics should not be used for prevention or treatment. (https://www.who.int/emergencies/diseases/novel-coronavirus-2019/advice-for-public/myth-busters?gclid=EAIaIQobChMIhe6un7PP7QIVrINLBR1_GwSEEAAYASAAEgKqtPD_BwE#antibiotics)

In India, on June 30, one company known as Patanjali Ayurveda released a drug named Coronil without any approval of ICMR and claimed in Big Sponsored News & Ads that "We have prepared the first Ayurvedic-clinically controlled, research, evidence and trial based medicine for COVID-19. We conducted a clinical case study and clinical controlled trial, and found 69% patients recovered in 3 days and 100% patients recovered in 7 days and it treats Coronavirus". Several media houses kept running news for days in favour of coronil but later due to public outrage Patanjali and Baba Ramdev with his allies Balakrishnan retracted from their statement and claims and released a statement that the coronil just boost their immunity which will help people fight diseases like coronavirus, it has not made or shipped any medicine called 'Corona Kit'. It also denied claims of calling the new medicine a "cure" for coronavirus, however a full video is available to see what he has said. https://www.youtube.com/watch?v=q8ko7kKboy0

On Jul 13 2020, Bengaluru based biotech major Biocon announced that its drug Itolizumab priced at Rs 8,000 per vial, which will hit the market as ALZUMAb, has received permission from the Drugs Controller General of India for use in moderate to severe COVID-19 patients. "It is the first novel biological therapy to be approved by the DCGI for treating patients with moderate to severe Covid-19 complications," the executive chairperson of the company Kiran Mazumdar Shaw said at a press conference. Itolizumab, drew sharp scrutiny. The critics pointed to the small size of the clinical trial enrolling a total of 30 hospitalised COVID-19 patients , exemption of Phase-3 trial, use of the drug as off-label for COVID-19, and making claims to the press before data is published in a peer-reviewed journal. Later, ICMR Director-General Balram Bhargava said there is not enough evidence from clinical trials that the drugs Itolizumab and Tocilizumab reduce mortality in COVID-19 patients. (https://www.newindianexpress.com/nation/2020/jul/25/covid-19-task-force-not-in-favour-of-itolizumab-for-treatment-says-evidence-inconclusive-2174698.html)

On 19 Jul 2020, DCGI pulls up Glenmark for false claims, first over trials result and overpricing of COVID-19 drug FabiFlu (Favipiravir). It said that it has been mentioned in representation that Glenmark drug is effective in co-morbid conditions like hypertension, diabetes, whereas in reality, as per protocol summary, this trial was not designed to assess the FabiFlu in co-morbid conditions." Lok Nayak Hospital in Delhi, India had barred the use of Favipiravir in its hospital due to certain side-effects like loss of appetite, nausea and potential risk to liver, and cardiac functioning. (https://www.nationalheraldindia.com/india/delhis-ln-hospital-to-discontinue-anti-viral-drug-favipiravir-for-covid-19-treatment)

What's next in COVID-19 treatment regime?

There are now hundreds of candidates in the market ready to launch in the market. All these news are floating around but none of them has shown any magical effect on patients like any drug does. There are many existing players in the market like Pfizer, Bharat Biotech and Serum Institute India who are front runner in India whereas Pfizer is leading the world after grabbing support from two countries.

Before going further it is also to be shown that all these statements were followed by high profile deals among different govt and private organizations but none of the vaccine and its manufacturers have shown any immediate safe effect.

So we have seen how different individuals and organization laid emphasis on the need of treatment without

TABLE 2. **Retracted COVID-19 Studies related to COVID treatment and prevention**

(Source: Retraction Watch)

S.No.	Retracted COVID-19 Studies	Intervention Questioned
1	"Effectiveness of Surgical and Cotton Masks in Blocking SARS–CoV-2: A Controlled Comparison in 4 Patients," published on April 6, 2020 in the Annals of Internal Medicine, retracted on June 1, 2020.	Masks
2	"Hydroxychloroquine plus azithromycin: a potential interest in reducing in-hospital morbidity due to COVID-19 pneumonia (HI-ZY-COVID)?" preprint published on medRxiv, May 11, 2020, withdrawn on May 20, 2020. Our coverage here.	Hydroxychloroquine and azithromycin
3	"Hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19: a multinational registry analysis," published in The Lancet on May 22, 2020, subjected to an expression of concern on June 2 ,and retracted on June 4.	Hydroxychloroquine
4	"Cardiovascular Disease, Drug Therapy, and Mortality in Covid-19," published in the New England Journal of Medicine on May 1, 2020, subjected to an expression of concern on June 2, and retracted on June 4.	ACE inhibitors
5	"Corona Virus Killed by Sound Vibrations Produced by Thali or Ghanti: A Potential Hypothesis," published in Journal of Molecular Pharmaceuticals and Regulatory Affairs, dates of publication and retraction unknown.	Sound Vibrations: Thali or Ghanti
6	"COVID-19 Emergency Responders in FDA's Center for Drug Evaluation and Research," published sometime after April 6, 2020 in Journal of the American Pharmacists Association, date of retraction unknown.	Other
7	"Ivermectin in COVID-19 Related Critical Illness," posted in April 2020 on SSRN, retracted sometime in May. Reporting from The Scientist here.	Ivermectin
8	"Usefulness of Ivermectin in COVID-19 Illness," posted on April 19, 2020 on SSRN, retracted sometime thereafter.	
9	Patterns of COVID-19 Mortality and Vitamin D: An Indonesian Study, published on SSRN on April 30, 2020. Retraction date unknown. (Hat tip to HealthNerd)	Vitamin D
10	"Chloroquine or hydroxychloroquine for COVID-19: why might they be hazardous?" published in The Lancet May 22, 2020, retracted and replaced July 9, 2020. Our coverage here.	hydroxychloroquine
11	"Treatment Response to Hydroxychloroquine, Lopinavir/Ritonavir, and Antibiotics for Moderate COVID 19: A First Report on the Pharmacological Outcomes from South Korea" medRxiv preprint posted May 18, 2020, and withdrawn June 14, 2020.	Hydroxychloroquine, Lopinavir/Ritonavir, and Antibiotics
12	"SARS-CoV-2 was Unexpectedly Deadlier than Push-scooters: Could Hydroxychloroquine be the Unique Solution?" published on August 15, 2020 in Asian Journal of Medicine and Health, retracted August 16, 2020. Our coverage here.	Hydroxychloroquine
13	"Decrease in Hospitalizations for COVID-19 after Mask Mandates in 1083 U.S. Counties," medRxiv preprint posted on October 23, 2020 and withdrawn on November 4, 2020.	Mask

studying the importance and safety, Thanks to scientific watchdogs like RETRACTION WATCH and ELIZABETH BIK that these miraculous drugs could not pull out money - out of pocket of general public or could save lives of them by boycotting these respective fake studies. TABLE 2.

Now the questions arise as why everyone wants to push a vaccine in the market when the transmission has slowed down and this can be seen worldwide for ex; the political rallies of Trump and BJP govt in India and farmers' protest when many individuals could be seen to avoid social distancing and preventive measures like masks. Though they can be accounted for the violation of emergency protocols but the science that comes out from this cannot be avoided. This science shows us that the transmission is not occurring either because virus has lost its virulence or it has become common like all other viruses that exist around us feom centuries.

A regular update of data on COVID-19 deaths by the Centers for Disease Control and Prevention has prompted a groundswell of claims that only a fraction of people have actually died directly from the novel coronavirus. The report stated, "For 6% of deaths, COVID-19 was the only cause mentioned. For deaths with conditions or causes in addition to COVID-19, on average, there were 2.6 additional conditions or causes per death." (https://www.usatoday.com/story/news/factcheck/2020/09/01/fact-check-cdcs-data-covid-19-deaths-used-misleading-claims/5681686002/)

So what can be the possible reason(s) for a Coronavirus push?

They reasons are aided by a confluence of many factors. A new method of developing vaccines was already waiting to be tested (for MERS), with the coronavirus a perfect target. Sky-high infection rates accelerated the pace of clinical trials, the most time-consuming part of the process. And the government was willing to spend whatever it took, eliminating financial risks and bureaucratic roadblocks and allowing mass production to begin even before the trials were done.

Healthcare profiteering and Pharma Lobbying

This biological pandemic has not only skyrocketed the share of companies which were/are providing COVID Healthcare solution but also attracting huge funding from public and private organizations.

Firstly, government promoted sanitizers and masks with a lot of enthusiasm, later when people got habitual of sanitizers, pharma companies raised and almost doubled and tripled the price of sanitizers in the market, lot of fake sanitizers also arrived in the market to fulfil the demand and need. Allmed Medical Products Co. makes just about any kind of gauze product imaginable. It also produces surgical masks, and its export-quality products were much sought-after in China those days. Chairman Cui Jinhai, who founded the company based in Hubei province at the epicenter of the coronavirus outbreak, is leading the way among tycoons in China's medical and biotech industries who have added more $17 billion in stake value even as global markets plunge, according to the Bloomberg Billionaires Index. Shares of Guangzhou Wondfo Biotech Co., a developer of rapid-test kits and antibody tests, have gained more than 40% this year, making president Li Wenmei and his wife Wang Jihua a billionaire couple. Wang is the chairman. (https://www.msn.com/en-in/money/news/the-coronavirus-is-creating-new-medical-and-biotech-billionaires/ar-BB118uzT)

The Global Pharma Lobby around the world are making multiple announcements for development of their vaccines and have been running into a rat race of manufacturing the drugs/vaccine as well as its human trials, but the facts behind this rat race of making fool of the common man and digging out the money from the common man's pocket in the name of Vaccine and saving their life from this Global Pandemic is far more different from what is shown. People have become so much annoyed, frustrated, irritated with the loss of life, money, job, health & lockdown and its overall impact on the economy that they are now ready to buy anything and everything in the name of safety and to end this all.

According to researchers' team from Brigham Young

University in Provo, Utah found that companies making drugs and vaccines for COVID-19, accounted for one-fourth of all lobbying funds in the first quarter of 2020. (https://www.dailymail.co.uk/health/article-8620057/Big-Pharma-spent-nearly-250-million-lobby-lawmakers-amid-coronavirus-pandemic.html)

For the study, published in the Journal of General Internal Medicine, the team looked at lobbying expenditures in the fourth quarter of 2019 and the first quarter of 2020. Results showed that lobbying spending hit $248.4 million between January 1 and March 31, and 357 new lobbyist registrations were filed during this period. Researchers found the biggest increases came from the pharmaceutical industry, making up 16 of the top 30 healthcare organizations in lobbyist spending.

Illinois-based AbbVie Inc's spending soared by 155 percent whole Novartis International AG, based in Switzerland, increased its lobbyist spending by 259 percent this year over last year. Biogen Inc, headquartered in Cambridge, Massachusetts, increased its lobbyist spending by 344 percent.

London-based AstraZeneca Plc spent $780,000. The U.S. government committed as much as $1.2 billion to Astra in May to help make the potential vaccine it's developing with the University of Oxford.

Moderna Inc. spent a company record $70,000 on lobbying in the second quarter, up from the $10,000 it spent in the same period a year ago. The Cambridge, Massachusetts-based biotech firm has also surged in trading this year and received backing from Operation Warp Speed.

Novavax Inc. disclosed lobbying the White House and Vice President Mike Pence's office through an outside lobbying consultant, Faegre Drinker Biddle & Reath LLP. Among its lobbyists at the firm were former Republican Representative Luke Messer, who succeeded Pence in the House of Representatives when the latter became Indiana's governor. The company had no products on the market but announced on July 7 it would receive $1.6 billion from the U.S. for its vaccine development process, the largest amount yet from Operation Warp Speed. Those funds will allow Novavax to conduct advanced human studies and establish manufacturing to deliver 100 million doses as soon as late 2020, the company stated at that time.

Abbott Laboratories, which has received emergency use authorization from the U.S. for both virus tests and antibody tests, spent $930,000, up 16% from the previous year. The company has been selling tests at a clip, although it has tried to counter concern about the false negative rate on one of its offerings.

Corporate Europe Observatory had also uncovered dozens of documents via freedom of information requests – including minutes from weekly calls between pharma and the Commission held during the pandemic – which reveal how the industry is putting profit before an effective pandemic response. The pharmaceutical industry initially used its special access to lobby against joint procurement of treatments in Europe, a tool intended to avoid member states competing for drugs and thus driving up prices. It has also used arguments that pit rich countries against each other (whilst leaving the ones with limited resources behind) to win lucrative advance purchase agreements for potential new vaccines, without the needed public interest conditions in place.

Another study at around 21st July 2020 in the Mint found that Gilead Sciences Inc. reported $1.26 million in lobbying spending in the three months ending June 30, 2020, according to a disclosures with the U.S. Congress. That was up 17% from a year ago and came as U.S. officials in May issued an emergency use authorization for Gilead's remdesivir as a treatment for Covid-19 after a trial found it speed recovery by about four days in hospitalized patients. Gilead donated remdesivir to hospitals through June, but the company announced at the close of that month its plans to charge $390 a vial, or $2,340 for a five-day regimen, for direct government purchases by the U.S. or other developed countries.

South Africa and India have lodged a proposal at the World Trade Organization -WTO to suspend international patent laws for an extended period, allowing countries to produce their own versions of patented medicines, treatments and protective equipment without being held to ransom by the corporations which own those patents. Despite gaining broad support from around the world, Big Pharma howled in protest. Pfizer called it "nonsense".

British companies working on coronavirus treatments, AstraZeneca and GSK, refused to participate, backed by the British government which tried to water down the proposals. (https://www.aljazeera.com/opinions/2020/10/18/big-pharma-is-not-going-to-help-the-world-defeat-covid-19)

It is evident from the following statements that how much money can be involved in this whole pandemic. On vaccines only, Tedros said, $4.3 billion is needed immediately to lay the groundwork for mass procurement and delivery of vaccines and a further $23.9 billion is required for 2021. That total, Tedros said, is less than one-half of 1 percent of the $11 trillion in stimulus packages announced so far by the Group of 20, the world's richest countries.

Politicization of vaccine

The politicization of vaccines, not just in the case of COVID-19 but also with regard to measles and many other diseases, is a key problem of public health where social science is essential for understanding the problem of persuasion," said Saad B. Omer, director of the Yale Institute for Global Health and a co-author of the study which measured the effects of the timing of a vaccine approval relative to the U.S. elections and the influence of vaccine endorsements by President Donald Trump, U.S. Speaker of the House Nancy Pelosi, and Dr. Anthony Fauci. (https://news.yale.edu/2020/10/27/politics-affect-public-buy-covid-19-vaccine-study-shows)

The rumours are highly demanding that even presidents have to come forward to say that vaccine is not politicised, President-elect Joe Biden sought to instill public confidence in a coronavirus vaccine that could soon be available, insisting that its safety and effectiveness is being evaluated without political influence amid reports that President Donald Trump's administration was pressuring the Food and Drug Administration for emergency authorization. (https://edition.cnn.com/2020/12/11/politics/joe-biden-coronavirus-vaccine/index.html)

The COVID-19 vaccine, nowhere on the horizon, was in the eye of a political storm, with the BJP promised to provide free shots to the over 10 crore population of Bihar as part of its election manifesto, and the Opposition deriding this as 'vaccine politics'. On the heels of the BJP, one of its supporters, the AIADMK government in Tamil Nadu, offered to administer the vaccine to all, again free of cost. The announcement created a political storm. (https://www.theweek.in/news/india/2020/10/25/first-promised-in-bihar-a-non-existent-covid-vaccine-sparks-political-melee-across-india.html)

Conclusion:

Though it is not open in a country like India but US reports have shown that Pharma companies have spent their dollars on lobbying. Similarly huge funding was given to many companies for COVID-19 purposes. Still many pharma companies are trying to get funding, to get their products approved through various regulatory agencies and also govt contracts to supply vaccine. And lastly, the various political and otherwise gathering have provided an excellent research ground to show that Coronavirus transmission is not occurring now. The so-called vaccines claimed by pharma lobby around the world would provide with the active immunity against the disease, but as per one report of WHO and several mainstream media houses around the world, it has been observed that there are several cases where a person who has been infected by Coronavirus COVID-19 diseases once has been re-infected again even after getting treated and getting healthy. In other words, a person can be infected with coronavirus COVID-19 disease again and again no matter how strong his immunity has been developed. If this point is taken into the consideration, even if the global pharma lobby is successful in making the vaccine, it will not be as successful in preventing the COVID-19 disease as claimed by the large pharma companies around the world and the patients have to take vaccine more than once or everytime. In light of above statements now it is duty of everyone to think about what we need or what don't.

Note: These are author's personal views, Biotech Express and its Editors are not responsible for any of the content of this article. This article does not endorse any treatment for COVID-19.

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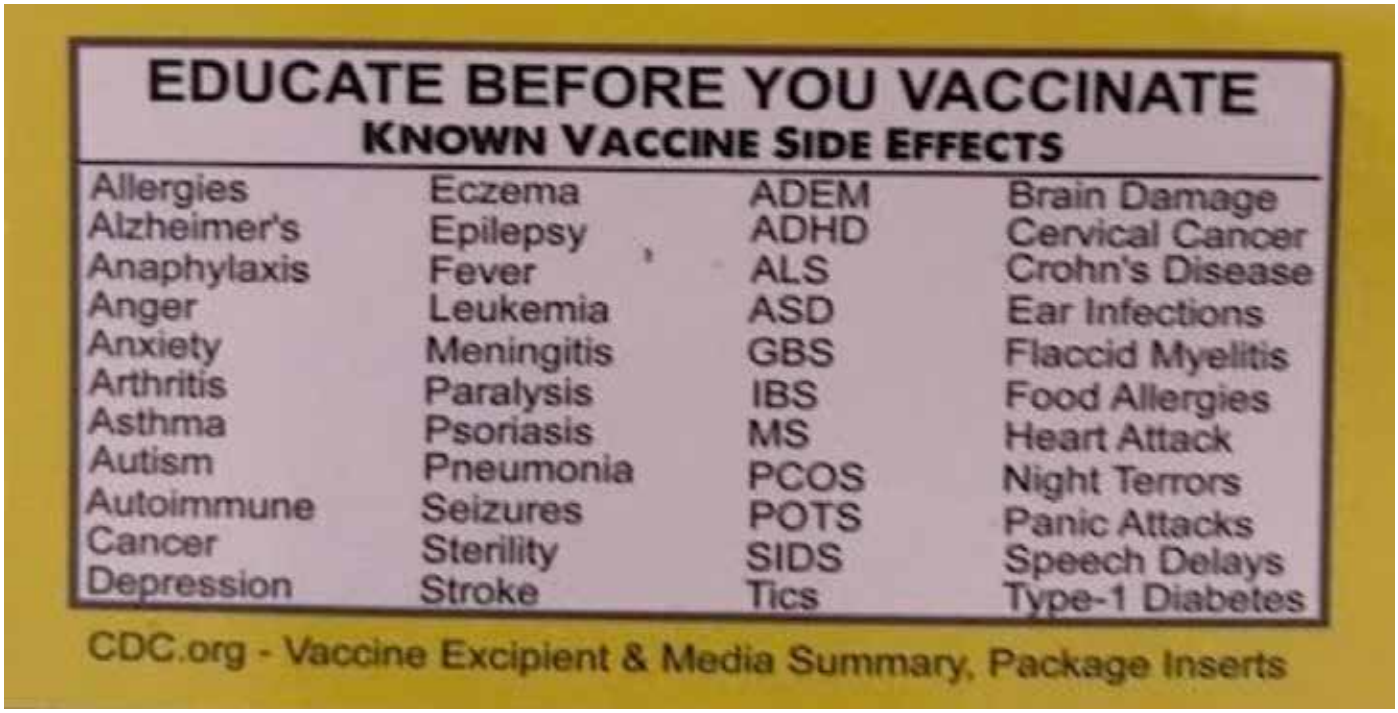
Editorial

Vaccine can be harmful: Side effects and clinical trial errors

by Dr Seema P Upadhaye



While we have a lot of promising COVID-19 vaccine candidates ready to roll out in the earliest timeline possible, this is the first time that a vaccine for such a novel infection has been developed in such an accelerated manner. That also leaves space for a lot of trial errors and side effects we might be exposed to, once the vaccination drives start.

Experts pointed out that the lack of transparency in releasing crucial information and data could lead to stricter scrutiny by regulators in many countries and mistrust among people.

Vaccines, though they are designed to protect from disease, can cause side effects, just as any medication can. Most side effects from vaccination are mild, such as soreness, swelling, or redness at the injection site. Some vaccines are associated with fever, rash, and achiness. Serious side effects are rare, but may include seizure or life-threatening allergic reaction which can persist to next human generations as well.

The possible Moderate to Severe Problems of vaccination includes:

– Serious eye infection, or loss of vision, due to spread of vaccine virus to the eye.

– Rash on entire body (as many as 1 per 4,000).

– Severe rash on people with eczema (as many as 1 per 26,000).

– Encephalitis (severe brain reaction), which can lead to permanent brain damage (as many as 1 per 83,000).

– Severe infection beginning at the vaccination site (as many as 1 per 667,000, mostly in people with weakened immune systems).

– Death (1-2 per million, mostly in people with weakened immune systems).

https://www.cdc.gov/vaccines/vac-gen/side-effects.htm

Historical incidents of side effects of vaccines

In 1955, some batches of polio vaccine given to the public contained live polio virus, even though they had passed required safety testing. Over 250 cases of polio were attributed to vaccines produced by one company: Cutter Laboratories.

From 1955 to 1963, an estimated 10-30% of polio vaccines administered in the US were contaminated with simian virus 40 (SV40). The virus came from monkey kidney cell cultures used to make polio vaccines at that time. Most of the contamination was in the inactivated polio vaccine (IPV), but it was also found in oral polio vaccine (OPV).

An increased risk of narcolepsy (a chronic sleep disorder) was found following vaccination with Pandemrix, a monovalent 2009 H1N1 influenza vaccine that was used in several European countries during the H1N1 influenza pandemic. This risk was initially found in Finland, and then some other European countries also detected an association. Pandemrix manufactured by GlaxoSmithKline in Europe was specifically produced for pandemic 2009 H1N1 influenza. Pandemrix was never licensed for use in the United States.

In 1998, the FDA approved RotaShield vaccine, the first vaccine to prevent rotavirus gastroenteritis. Shortly after it was licensed, some infants developed intussusception (rare type of bowel obstruction that occurs when the bowel folds in on itself) after being vaccinated. The Advisory Committee on Immunization Practices (ACIP) withdrew its recommendation to vaccinate infants with RotaShield® vaccine, and the manufacturer voluntarily withdrew RotaShield from the market in October 1999.

https://www.cdc.gov/vaccinesafety/concerns/concerns-history.html

What we know for current COVID-19 vaccine? Side effects and trial error

In case of COVID-19 vaccine, recent findings are coming from under trial vaccines. It is irrelevant to discuss about phases of trials here because the vaccine which had lost its charm are not in the race of COVID-19 cure. There are 3-4 front runners in the race against COVID-19 but these have also reported moderate to serious side effects. And where the numbers of participants are less as compared to other regular trial, it should not be neglected while vaccinating billions of people around the globe.

According to Moderna's COVID-19 vaccine trial, involving some 23,000 volunteers most side effects reported during its clinical trials were mild to moderate, but some were classified as "Grade 3", or severe. The independent board that conducted the interim analysis of Moderna's huge trial found that severe side effects included fatigue in 9.7% of participants, muscle pain in 8.9%, joint pain in 5.2%, and headache in 4.5%. According to an article by Science magazine, a computational biologist Luke Hutchison who volunteered for a trial of Moderna's COVID-19 vaccine after the second injection, his arm swelled up to the size of a "goose egg," Hutchison says. He can't be sure whether he got the vaccine or placebo, but within a few hours, Hutchison, who was healthy and 43, was

beset by bone and muscle aches and a 38.9°C fever. "I started shaking. I had cold and hot rushes," he says. "I was sitting by the phone all night long thinking: 'Should I call 911?'"

In the Pfizer/BioNTech COVID-19 vaccine trial which involved 40,000 volunteers, severe side effects included fatigue (3.8%) and headache (2%). After Britain began administering the Pfizer/BioNTech vaccine, British health authorities said two patients had suffered adverse reactions. Four cases of Bell's palsy - a facial paralysis that is often temporary - were observed among 18,000 volunteers over two months in the Pfizer/BioNTech trial. There were eight cases of appendicitis in those who were administered the vaccine, double the amount for those who received the placebo, but the FDA put this down to a statistical coincidence, unrelated to the vaccine. https://www.nst.com.my/world/world/2020/12/648984/what-we-know-about-covid-19-vaccines-and-side-effects

The Oxford/AstraZeneca COVID-19 vaccine trial was voluntarily put on hold at one stage to investigate why one participant - out of many thousands - had died. It restarted once it was clear it was not related to the vaccine. One patient who received the Oxford AstraZeneca jab had a "serious side effect possibly related" to the injection, according to the data in The Lancet. The patient suffered from transverse myelitis, a rare neurological condition that causes inflammation of the the spinal cord.

Jaseem (name changed to protect identity) from India said that he had a hard time getting back on his feet after he was diagnosed with 'Acute Neuro Encephalopathy' (means damage or disease that affects the brain), a sudden neurological dysfunction affecting the brain. According to his family, he could not recognise them, experienced mood swings and could not carry out daily work on his own. He claims it was the result of an extreme side-effect of the COVID-19 vaccine that he was administered on October 1 as part of the trial by the Pune-based pharmaceutical giant, Serum Institute of India Private Limited which is sponsoring Oxford/AstraZeneca COVID-19 vaccine trial in India. Responding to this volunteer's allegations, the Serum Institute, in turn, threatened him with a Rs 100 crore suit to "safeguard the reputation of the company.

https://www.cnbctv18.com/healthcare/covid-19-vaccine-serum-institute-files-rs-100-cr-suit-against-volunteer-experts-seek-transparency-7601091.htm

Also, during the clinical trials of AstraZeneca COVID-19 vaccine, some participants were mistakenly given half a dose rather than a full dose in their first round of shots, according to BBC News. Still, the trial continued and the researchers discovered those given the weaker dosage produced a better immune response. Some experts have criticized the fact that AstraZeneca combined the efficacy results from what's essentially two different trials and say the company will need to conduct another trial properly evaluating the effectiveness of the half-dose full-dose regimen. Small mistakes are common, but giving thousands of participants the wrong dose unintentionally is not a common mistake. Time will tell whether this particular mistake leads to a discovery, but at this point in time there is a lot of uncertainty around the findings," said Dr. Philip Smith, an assistant professor in the department of kinesiology and health at Miami University in Ohio. It has also come out that the trial participants, based on which the early results have been released, consisted of very few elderly individuals among whom the efficacy of the potential vaccine was found to be lower than other groups, but this information was not made public. https://www.newindianexpress.com/nation/2020/nov/26/covid-19-vaccine-by-astrazeneca-oxford-sparks-controversy-amidst-concerns-that-crucial-information-w-2228486.html

Vaccines generally work better in younger people, says Hunter. Neither AstraZeneca nor Oxford released full details of the age profiles of the volunteers in both trials except to say that all were 18 or over. Another wrinkle is that the volunteers were all healthy or had "stable underlying medical conditions". That may mean that the results don't reflect how the vaccine will perform among vulnerable groups such as people with serious health problems.

The results of the early trials of the Sputnik V vaccine

were published in *The Lancet Study* on September 4, no serious adverse effects were reported. However, the results have been criticised by several scientists around the world, including a group of researchers who wrote an open letter against the published trial results of Sputnik V. In this letter, they have highlighted that the data appears to be duplicated, while also arguing that the paper presents its results only as box plots—a method for graphically depicting groups of numerical data through their quartiles—without providing a detailed breakdown of the data. "We believe that poor methodology, study design flaws, errors in data analysis, and a poor description of the study call into question the main conclusions about the safety and efficacy of the vaccine," Vlassov and his colleagues, members of the Russian Society of Specialists in Evidence Based Medicine, wrote.

https://www.themoscowtimes.com/2020/12/10/gross-violation-in-open-letter-russian-scientists-criticize-lack-of-vaccine-data-a72311

Further, Konstantin Andreev, who studies viral respiratory infections at Northwestern University at Evanston, Illinois, USA, stated: "To see such similar data patterns between unrelated measurements is really not likely. These discrepancies are not minor." Other experts have urged the Russian authors to publish the underlying, supplementary data as well, just like the pharmaceutical company did when publishing the results of their vaccine trials.

Amid the controversy, The Lancet, in a statement, invited the authors of the Russian vaccine study to respond to the questions raised by Enrico Bucci open letter. However, Denis Logunov, the Russian paper's lead author, told the Russian media that he has no intention of responding to the letter. He also denied the errors highlighted in the letter, and stated that the measured antibody levels were "exactly as they were presented".

https://www.moneycontrol.com/news/coronavirus/covid-19-vaccine-bharat-biotechs-covaxin-reported-adverse-event-during-phase-1-trials-trials-not-halted-6144331.html

Recently questions have been raised on Bharat Biotech's COVAXIN too when Haryana health minister, Anil Vij, who was given a trial dose of corona vaccine, Covaxin, has been tested positive for the Covid-19. On November 20, he was administered a dose of Covaxin at a hospital in Ambala, as part of its third phase trial, according to his twitter post.

Conclusion

In the long term as these COVID-19 vaccines are new, scientists do not know for certain the potential long term side effects which can pose long term side effects which can pose danger to entire humankind, may not just existing generation but to coming generations as well. Thus, long term studies in large different ethnic groups are required to make a final conclusion before giving EUA or authorization as given by FDA, WHO, European Union etc. We have seen loopholes in existing system of FDA and EU when they approved certain medications without any sufficient evidences and later these studies were challenged and retracted. All these incidences not only can decrease trust of general public in such authorities but can also make people's life miserable if any serious side effect succumb the public at large.

CHALLENGES & OPPORTUNITIES IN MEDICAL DEVICES INDUSTRY

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Dr. Sharma holds a Master's degree in Veterinary Sciences. He has experience working as an animal model specialist for infectious diseases at HCV, Singapore, and also for anti-Cancer drug discovery at Forma Therapeutics. He recently worked on Preclinical medical device testing at Innoheart Singapore and currently holds the position of Medical device Preclinical models specialist at PBS, India. Dr. Sharma has had hands-on experience for Cath lab, Echo and OCT, for Cardiothoracic and vascular interventional surgeries in Large Animals(Swine), and also on Statistical Softwares. He is also skilled in Large animal preclinical cardiovascular device models.

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Featured News

Are Bill Gates's Billions Distorting Public Health Data?

DECEMBER 11, 2020

In the early days of the pandemic, the IHME projected a far less severe outbreak than other models, which drew the attention of Donald Trump, who was eager to downplay the danger. At a March 31 press briefing, the White House's coronavirus response coordinator, Debbie Birx, with the president at her side, used IHME charts to show that the pandemic was rapidly winding down.

""Throughout April, millions of Americans were falsely led to believe that the epidemic would be over by June because of IHME's projections," the data scientist Youyang Gu noted in his review of the institute's work. "I think that a lot of states reopened based on their modeling."

The institute's uncanny resilience, unconventional methods, and media savvy have long made it controversial in the global health community, where scholars have watched its meteoric rise over the past decade with a mix of awe and concern. Years before Covid, the IHME gained outsize influence by tracking hundreds of diseases across the planet and producing some of the most cited studies in all of science.

But it has also spawned a legion of detractors who call the IHME a monopoly and a juggernaut and charge the group has surrounded itself with a constellation of high-profile allies that have made it too big to peer review, the traditional method of self-regulation in science. Fueled by more than $600 million in funding from the Bill & Melinda Gates Foundation—a virtually unheard-of sum for an academic research institute—the IHME has outgrown and overwhelmed its peers, most notably the World Health Organization (WHO), which previously acted as the global authority for health estimates.

Today the IHME's sprawling estimates have become the gold standard for understanding an increasingly broad array of topics related to health and development—particularly in the data-poor developing world, where record keeping is sparse. Its website offers interactive maps that allow users to drill down to virtually any village in sub-Saharan Africa, for example, to find out how many years of education people

have; how malaria, HIV, and lower respiratory infections are changing over time; who has access to piped water; or how many men are circumcised. These estimates—educated guesses, really—help guide billions of dollars in aid spending and tell health ministers, charities, researchers, and journalists where things are getting better or worse.

"In a relatively short period of time, the IHME has exerted a certain kind of hegemony or dominance on global health metrics production," says Manjari Mahajan, a professor of international studies at the New School. "It's a kind of monopoly of knowledge production, of how to know global health trends in the world. And that produces a concentration of…power that should make anybody uncomfortable."

Critics say this monopoly power can be seen in the ways the IHME appears to play by a different set of rules from the rest of the scientific community. Many describe its estimates as a black box. "It's quite impossible to criticize or indeed comment on their methods, since they are completely opaque," says Max Parkin, from the International Network for Cancer Treatment and Research.

Despite such criticisms, the IHME's dominion keeps expanding—thanks in large part to Richard Horton, the editor in chief of The Lancet, who has put the credibility of the famed medical journal behind it, publishing more of the institute's studies than any other periodical. While most scholars are lucky to publish one research article in The Lancet during a decades-long career, the IHME's Murray has published more than 100.

The relationship between The Lancet and the institute was further underscored last year when Murray nominated Horton to receive the $100,000 Roux Prize from the IHME. It was a striking conflict of interest that raised eyebrows among scholars but virtually no public criticism. Challenging Horton could mean foreclosing on future publishing opportunities in a leading journal.

Some experts are also reluctant to criticize the IHME for fear of upsetting the Gates Foundation, one of the most important funders in global health and academic research more generally. According to the Web of Science database, more than 20,000 academic papers cite funding from the Gates Foundation, which has poured over $8 billion into universities in the past two decades, according to The Nation's analysis of its charitable giving. Scholars have even used the term "the Bill chill" to describe their reluctance to bite the hand that feeds them.

"We are receiving millions of dollars for our polio campaign in Afghanistan and Pakistan from the Gates Foundation. We cannot jeopardize that campaign. Publicly criticizing the work of the IHME could potentially alienate the Gates Foundation," one UNICEF official, who asked for anonymity, admitted to Mahajan in a study she published in 2019.

"Who is making such criticism, and where has the criticism been published or stated publicly?" an IHME spokesperson responded when asked about the institute's controversial reputation. After The Nation forwarded several scholarly reviews, the institute struck a different tone: "This criticism is not new.… Part of the process over the past 12 years of creating a leading source of global health data is reckoning with criticism. IHME welcomes it and other critiques as one aspect of improving the Institute's work."

The 2015 book Epic Measures: One Doctor. Seven Billion Patients, by Jeremy M. Smith, describes Murray's approach to health estimates as an extension of his medical training. Instead of treating individual patients, he's diagnosing the globe, using Big Data to show governments and aid groups which diseases need the most attention and money.

Based on Murray's estimates, Gates saw an opportunity to make a big impact, and his foundation went on to donate almost $40 billion to global health and development, becoming one of the most powerful political actors in the field.

Note: The complete article was appeared on website of THE NATION on December 3, 2020 and author Tim Schwab is a freelance journalist based in Washington, D.C., whose investigation into the Gates Foundation was part of a 2019 Alicia Patterson Foundation fellowship.

COVID-19 Antibody Discovery Company Preps for Massive $391 Million IPO

Dec 07, 2020

Having already raised $105 million in a Series B in May, Canadian R&D engine AbCellera is gearing up for a massive $391 million IPO. Offering 23 million shares priced between $14 and $17 each, this IPO will be the biggest debut on record for a Canadian biotech, if successful.

AbCellera's rise to world-renown happened this year when a partnership with Eli Lilly to find the human antibody bamlanivimab secured Emergency Use Authorization (EUA) with the Food and Drug Administration (FDA) to treat COVID-19 patients. Bamlanivimab is a monoclonal antibody therapy for people who have mild-to-moderate symptoms. One million doses are anticipated to be manufactured by the end of the year.

The company's AI-powered antibody discovery platform speeds the otherwise lengthy and grueling process by analyzing the database of natural immune systems to find antibodies that can be developed into drugs. The promise to partners is to "move quickly. Reduce cost. Tackle the toughest problems in drug development."

Since the company's partnership with Lilly was announced, AbCellera has seen support from PayPal founder and tech/life sciences investor Peter Thiel. His support secured him a seat on AbCellera's board of directors. Additional backers include German entrepreneur Christian Angermayer, the Bill & Melinda Gates Foundation, Viking Global Investors and healthcare investment firm OrbiMed Advisors LLC.

AbCellera also got a boost from the Canadian government with a $175.6 million grant from the Innovation, Science and Economic Development Canada's Strategic Innovation Fund in May.

Incyte and Novartis' Jakafi (Ruxolitinib) fails to reduce COVID-19 associated Cytokine Storm Complications

DECEMBER 4, 2020

Incyte and Novartis announced a Phase III study of Jakafi (ruxolitinib), a first-in-class JAK1/JAK2 inhibitor, failed to hit endpoints as a treatment for patients 12 and up with COVID-19 associated cytokine storm.

This morning, the two companies said treatment with the JAK inhibitor plus standard-of-care (SoC) in the late-stage RUXCOVID study did not prevent complications in patients with COVID-19 associated cytokine storm. There was no reduction in severe complications, including the need for mechanical ventilation and death. In the trial, the proportion of patients who died, or required mechanical ventilation due to respiratory failure or ICU care by Day 29, was 12% for Jakafi and SoC compared to 11.8% for placebo plus SoC.

Additionally, Novartis and Incyte said Jakafi and standard-of-care treatment failed to show a clinically relevant benefit observed among secondary and exploratory endpoints, including mortality rate by Day 29 and time to recovery.

Incyte and Novartis initiated their Jakafi study in the spring, when COVID-19 was running rampant across parts of Europe and Asia, and was also in its early days of outbreak in the United States. The companies said they intend to conduct a comprehensive analysis of the Phase III RUXCOVID study.

John Tsai, Novartis' CMO and Global Head of Drug Development, also expressed his disappointment in the study's failure.

Boston Biogen Superspreader Conference Led To Over 300,000 Covid-19 Coronavirus Cases

Dec 09, 2020

UK regulators stated today that they have received two reports of potential allergic reactions linked to the COVID-19 vaccine from Pfizer and BioNTech, according to the Associated Press. The individuals who received the vaccine were a part of Britain's coronavirus vaccination program.

Dr. June Raine, head of the UK's medical regulatory agency, revealed the news while testifying to a Parliamentary committee on Wednesday. She stated that researchers are still looking into the two alleged reports of allergic reactions, and that clinical trials did not initially reveal these reactions to be a potential problem. Now, regulators are claiming that individuals who have a history of serious allergic reactions should not receive the vaccine.

The news comes after data released on Tuesday showed that out of Pfizer's 44,000 trial volunteers, there were no participants with a "history of severe adverse reaction associated with a vaccine and/or severe allergic reaction to any component of the study intervention(s)."

Pfizer and BioNTech announced in early November that their Phase III study data showed the vaccine was more than 90% effective in preventing COVID-19 in participants who had not been previously infected. The trial enrolled more than 43,000 subjects at the time, 42% of whom had diverse backgrounds. At the time, no serious safety concerns were reported.

Anthony Fauci will continue as Chief Medical Adviser in the Biden administration

Dec 4, 2020

Anthony Fauci, a top U.S. infectious disease expert, said on Friday that he has accepted President-elect Joe Biden's offer to be his chief medical adviser. The confirmation came a day after Biden disclosed he has asked Fauci to be his chief medical adviser and part of his administration's COVID-19 response team.

Fauci has served on the White House coronavirus task force for months, advising the Trump administration on Covid-19 policy and publicly exhorting Americans to follow health guidelines.

Before the election, Biden had repeatedly vowed to keep Fauci onboard and listen to his advice if he wins. His campaign used this as a point of contrast with Trump, who has doubted Fauci's advice and openly flirted with firing him.

Chief medical advisor is not a standard position in most administrations, but Trump gave the same title to former White House physician Ronny Jackson in February 2019. Jackson, who has faced accusations of mishandling drug prescriptions, left the role less than a year later and successfully ran for a U.S. House seat in Texas last month.

UK Investigates Reports of Allergic reactions to Pfizer-BioNTech COVID-19 Shot

Dec 09, 2020

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COVID-19 Vaccine Shelved After False HIV Positives Affirms Need for Multiple Vaccines

Dec 11, 2020

Anthony Fauci, a top U.S. infectious disease expert, A COVID-19 vaccine being developed by CSL Ltd., and the University of Queensland was scrapped this week after numerous vaccine recipients reported receiving false positives on certain HIV tests, according to the Wall Street Journal. The Australian government had originally agreed to buy 51 million doses of the product, v451. Australian Health Department Secretary Brendan Murphy told the Journal that the country can take its time, as it has relatively controlled the virus.

V451 utilized molecular clamp technology, which prevents spike proteins on the coronavirus from uncoiling. Those who receive the vaccine presumably develop antibodies to the coiled shape. However, v451 involved the use of an HIV protein, resulting in false positives on tests. The researchers behind the vaccine say it will take another year to re-engineer the vaccine and resolve the issue. If v451 were to roll out, regardless, HIV-testing procedures would need to change significantly. Authorities ultimately decided that it was not worth progressing the vaccine to an advanced clinical trial.

Australian Prime Minister Scott Morrison said today that Australia has since increased its orders for two vaccines that are still under consideration. One of the products, which stems from Oxford University and AstraZeneca, is being produced by CSL in Australia to limit supply chain risks. Australian Health Minister Greg Hunt says the country has access to more than 140 million doses.

AstraZeneca Dives into Rare Diseases With $39 Billion Acquisition of Alexion

Dec 14, 2020

AstraZeneca announced it is acquiring Alexion Pharmaceuticals for $39 billion. Alexion shareholders will get $60 in cash and 2.1243 AstraZeneca American Depositary Shares (ADS), with each ADS worth half of an ordinary AstraZeneca share. The deal otherwise comes to about $175 per share.

The deal has been approved by both companies' boards and is expected to close in the third quarter of 2021.

AstraZeneca's focus has been on oncology, cardiovascular, renal and metabolism and respiratory diseases. It has also increased its immunology research-and-development efforts associated with immune-mediated diseases.

Alexion's focus is on complement inhibition. Complement is a part of the human immune system, and its focus has been on a range of immune-mediated rare diseases caused by abnormal activation of the complement system. Alexion's branded products include Soliris (eculizumab), a first-in-class anti-complement component 5 (C5) monoclonal antibody. It is approved in several countries for paroxysmal hemoglobinuria (PNH), atypical hemolytic uremic syndrome, generalized myasthenia gravis and neuromyelitis optica spectrum disorder. Another branded product is Ultomiris (ravulizumab), a second-generation C5 monoclonal antibody.

Soliris brought in about $4 billion in revenue in 2019. Ultomiris was in 2019 and brought in $338.9 million. Other marketed products include Strensiq (asfotase alfa) and Kanuma (sebelipase alfa).

UK clears Pfizer's COVID vaccine, first in the world

Dec 02, 2020

The UK today became the first country to approve the Covid-19 vaccine developed by Pfizer Inc and its German partner BioNTech SE. The vaccine will be available in Britain from next week, according to a statement from the U.K. government. The emergency authorization clears the way for the deployment of a vaccine that's expected to play a significant role in the global effort to halt the coronavirus.

"The government has today accepted the recommendation from the independent Medicines and Healthcare products Regulatory Agency (MHRA) to approve Pfizer-BioNTech's COVID-19 vaccine for use. This follows months of rigorous clinical trials and a thorough analysis of the data by experts at the MHRA who have concluded that the vaccine has met its strict standards of safety, quality and effectiveness," the UK government said in a statement.

The U.K. has ordered enough doses of the two-shot Pfizer-BioNTech vaccine to immunize 20 million people. The companies also have deals to supply hundreds of millions of shots to Europe, the U.S., Japan and elsewhere.

Zydus Cadila gets DGCI nod for phase 3 clinical trials of COVID-19 therapy

Dec 04, 2020

Drug firm Zydus Cadila on Friday said it has received the approval from the Drugs Controller General of India (DCGI) to start phase 3 clinical trials with its biological therapy PegiHep in COVID-19 patients.

The company had completed the phase 2 clinical trials with PegiHep last month.

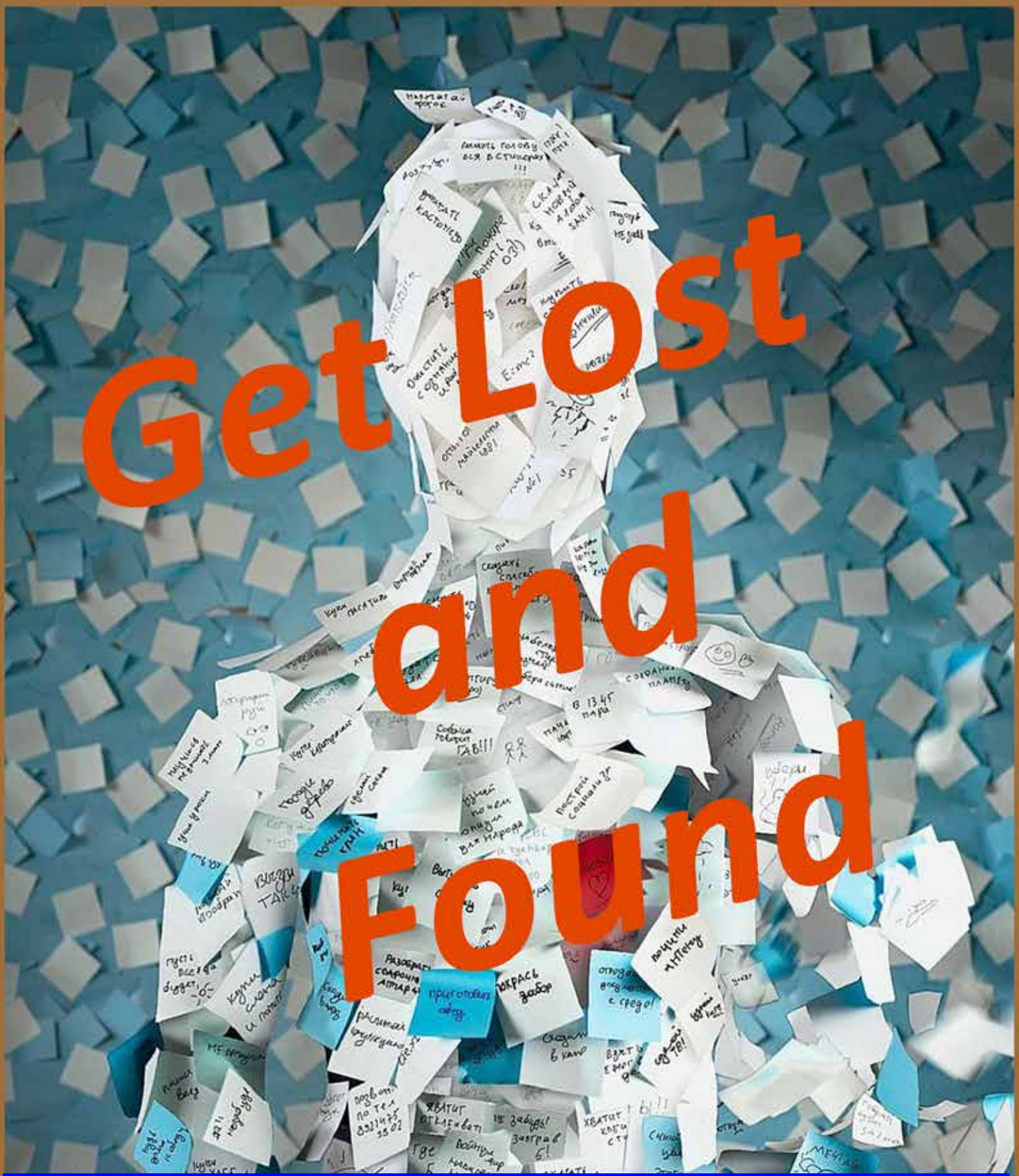
In a regulatory filing, Zydus Cadila said it has received approval from the DCGI to start the phase 3 clinical trials in COVID-19 patients with its biological therapy Pegylated Interferon alpha-2b or PegiHep.

The trials, which will commence in December, will be conducted on 250 patients across 20-25 centres in India, according to the filing.

Sharvil Patel, Managing Director of Cadila Healthcare Ltd, said, "we are encouraged by the results of phase 2 study of Pegylated Interferon alpha 2-b which has shown the potential to reduce virus titres when given earlier in the disease.

"Our efforts are to look at possible treatment options to fight COVID-19 which are safe, can be administered easily and also reduce the disease burden".

Further, the company said it is conducting a similar phase 2 trial in Mexico and is also working with the US Food and Drug Administration (USFDA) to open an Investigational New Drug (IND) application for PegiHep in order to initiate appropriate clinical trials in the US.



Biotech Express magazine put forward all the news and articles related to biotechnology in front of its diverse audience. Since Biotechnology is amalgamation of different branches of science, we also try to include updates from several disciplines. This magazine would like to take you near the greatest people from field through interviews which will surely help to carve out the decision process by knowing nitty-gritty of the field.

Haryana Minister, Who Participated In Bharat Biotech COVID Vaccine Trial, Tests Positive

Dec 6, 2020

Anil Vij was last month administered a trial dose of a coronavirus vaccine as part of the third phase trial of Bharat Biotech's Covaxin.

Barely two weeks after being administered a trial vaccine shot of Bharat Biotech's Covaxin, Haryana's Health Minister Anil Vij Saturday tested positive of the novel coronavirus. The 67-year-old BJP veteran is diabetic, and had recently undergone a surgery for a thigh bone fracture. He had volunteered to participate in the vaccine's human phase trials, in which over 25,000 persons were administered trial doses.

On November 20, Mr Vij, who is also Haryana's Health Minister, participated in the third phase trial of Bharat Biotech's Covaxin. He had earlier announced on Twitter that he will be the first volunteer in his state for the vaccine trials.

After getting Covaxin's trial shot for Covid-19, Vij had said: "It is a matter of pride for every Indian that Bharat Biotech is coming up with an indigenous vaccine for COVID-19. I had volunteered to become one of the participant for the third phase so that people shed their fears and come forward to volunteer. With this, the entire process of developing the vaccine shall be expedited.

Health minister's statements have created conflict toward vaccine safety, efficacy because trial has to be confidential. Vij participated in a double-blind trial which means the investigators, the participants and the company are not aware of who is assigned to which group. If Vij received the placebo, then he would not have had any protection against the virus to begin with. However, if he received the vaccine, his subsequently contracting COVID-19 needs to be seen against factors such as the trial-dose-regimen and vaccine efficacy.

Expert committee of CDSCO has sought more data from Serum Institute and Bharat Biotech on their vaccine trials

Dec 11, 2020

An expert committee of the Central Drugs Standard Control Organisation (CDSCO) on Dec 9 sought additional safety and efficacy data for COVID-19 vaccine candidates of Serum Institute and Bharat Biotech, after deliberating upon their applications seeking emergency use authorisation for the shots, official sources said.

The application by the Indian arm of US pharmaceutical firm Pfizer was not taken up for deliberation on Wednesday as the firm sought more time for making presentation before the committee, they said.

While considering Serum Institute's application, the subject expert committee (SEC) of the CDSCO is learnt to have asked for updated safety data of phase-2 and phase-3 clinical trials in the country, immunogenicity data from the clinical trial in the UK and India, along with the outcome of the assessment of the UK Medicines and Healthcare products Regulatory Agency (MHRA), sources said.

As for Hyderabad-based Bharat Biotech, after detailed deliberations, the SEC recommended that the firm should present the safety and efficacy data from the ongoing phase-3 clinical trial in the country for further consideration, the source said.

Bharat Biotech had applied to the Drugs Controller General of India (DCGI) for emergency use authorisation for its indigenously developed COVID-19 vaccine Covaxin on December 7, while Pune-based Serum Institute sought the nod for the Oxford COVID-19 vaccine, Covishield, on December 6.

Health Ministry Does Not Know Where COVID Vaccine Expert Group's Records Are, revealed RTI

Dec 9, 2020

The Union health ministry has said in response to an RTI application that it does not know where records related to agenda circulated in meetings of the National Expert Group on Vaccine Administration for COVID-19 (NEGVAC) are held.

Venkatesh Nayak of the Commonwealth Human Rights Initiative had approached the ministry seeking details of the constitution and working of the expert group such as dates of meetings, a copy of the detailed agenda circulated in relation to every meeting, presentations made before its members, and material it had shared with the Ministry of External Affairs (MEA). Nayak had also sought to know the amount of sitting fees and every other remuneration or allowances payable to the chairperson and every member of the expert group and the amount of sitting fees and every other remuneration or allowances actually paid to them.

Nayak filed an appeal before a senior official in the ministry challenging the order of the CPIO. The official ruled that the CPIO does not have information and does not know where the information can be. The application was also transferred to the Indian Council of Medical Research (ICMR) and the MEA. The ICMR said it does not have information sought by Nayak. On the NEGVAC material shared with it, the MEA cited exemption clause of national security and related issues to deny the records. Nayak said both the CPIO and the first appellate authority not knowing about the physical location of NEGVAC's papers despite the Ministry of Health and Family Welfare (MoHFW) servicing this body is "truly perplexing".

"How can people's meaningful participation be ensured if the MoHFW does not place in the public domain details of NEGVAC's working. There is a statutory requirement of proactive information disclosure under Sections 4(1)(c) and 4(1)(d) of the RTI Act about NEGVAC's working. MoHFW and other public authorities involved in the vaccination roll-out plan have a statutory duty to make all facts and figures public along with the underlying reasoning for their decisions and actions under these provisions," Nayak said.

He said he would approach the Central Information Commission to challenge "the actions and omissions of MoHFW and MEA".

Oxford and Serum Institute of India (SII) vaccine has serious adverse effects?

Dec 01, 2020

Chennai-based volunteer served a Rs 5 crore compensatory legal notice to the Serum Institute of India (SII) against the neurological complications he claimed to have developed after being administered a test dose of Oxford-AstraZeneca 'Covishield' vaccine for coronavirus.

The 40-year-old volunteer, who works as a business consultant, had, in the legal notice, stated that he "must be compensated, in the least, for all the sufferings that he and his family have undergone" because the candidate vaccine was not safe.

The participant has been diagnosed with acute neuro encephalopathy, which he alleged was a side-effect of the 'Covishield' shots he took on October 1.

He also sought to cancel the approval for its testing, 'manufacture and distribution', failing which he said he would take legal action against the institute. Along with the SII, a legal notice was also served to the Indian Council of Medical Research and Sri Ramachandra Institute of Higher Education and Research – other avenues involved in the development and production of the Covid-19 vaccine candidate.

Dismissing the participant's claim, the institute has said that allegations made by the Chennai participant are "malicious and misconceived" and the Pune-based pharma giant countered with a demand of Rs 100 crore as damages to its reputation.

Lawyers representing Chennai-based volunteer of the Oxford Covishield COVID-19 vaccine trial said that the Pune-based Serum Institute of India (SII) was attempting to intimidate their client. "Our client states that the severe trauma he went through from 11th October 2020, because of the "Acute Neuro Encephalopathy" that he suffered, is an extreme side-effect of the test vaccine that he took on 1st October 2020," said the legal notice issued by NGR Prasad & R Rajaram Advocates, on behalf of the participant. "Our client's wife states that he is still not stable, has severe mood swings, has problems with comprehending and focusing on things, and is finding it difficult to even do simple routine things like making online payments, leave alone focusing on work-related matters," it explains.

"Exactly What Does PM Stand By?": Rahul Gandhi's Dig On 3 Vaccine Quotes

Dec 03, 2020

Congress leader Rahul Gandhi today attacked the centre over its statement that it had never spoken about inoculating everyone with the COVID-19 vaccine in his latest attack on the government amid the pandemic which has affected 95.3 lakh people in the country. Taking to twitter, the former Congress president cited the differences in statements of the Prime Minister Narendra Modi, the government and the BJP on the anticipated vaccine for the COVID-19 as he asked "exactly what does the prime minister stand by".

The centre on Tuesday said there may not be a need to vaccinate the country's entire population against COVID-19 if a critical mass of people are given a shot to break the chain of virus transmission, and made it clear it had never spoken about inoculating everyone.

"I just want to make this clear that the government has never spoken about vaccinating the entire country. It's important that we discuss such scientific issues based on factual information only and then analyse it," Health Secretary Rajesh Bhushan had said.

Last month the BJP was criticised after Union Minister Nirmala Sitharaman, while launching the party's manifesto for the Bihar election, promised "free coronavirus vaccination for all".

The announcement was met with shock and indignation by opposition leaders, leaving the BJP fending off allegations that it was using the promise of a vaccine - for an infectious and fatal illness that has already killed over 1.21 lakh in India alone - for its political agenda.

Pfizer's COVID-19 vaccine may not be needed, says Harsh Vardhan

Union health minister Harsh Vardhan has reiterated that India may not require Pfizer's vaccine against coronavirus disease (Covid-19), with other vaccine candidates being tested in the country showing promising results in safety trials so far.

According to media reports, the health minister said that it did not make sense to consider the Pfizer-BioNTech's vaccine as even the US regulatory authority had not yet granted approval to the vaccine. And even if the approvals are granted, the manufacturer would first attempt to cater to its local population before supplying the vaccine to other countries, he said.

India has at least five vaccine candidates against Covid-19 under human trial, of which three vaccine candidates are undergoing advanced phase 2/3 clinical trials to establish safety and efficacy.

The government is in talks with developers and manufacturers of all potential Covid-19 vaccine candidates for procurement of their product. According to the health minister, the government will start the immunisation process in a phased manner. In the first phase it is looking at vaccinating 250-300 million people by July of next year, for which it aims to procure around 500 million vaccine doses as most vaccines follow a two-dose regimen.

"As for following up on the progress made on vaccine research, the government is continuously in talks with the parties involved. However, the actual procurement process will begin the day any of these vaccines gets regulatory approvals. So far, none of these vaccines has secured emergency use authorization (EUA) so there is no question yet of vaccine procurement," Union health secretary, Rajesh Bhushan, told HT.

FDA Issued Emergency Use Authorization for Second COVID-19 Vaccine

Dec 18, 2020

The U.S. now has two COVID-19 vaccines that are safe and effective enough for the public.

On Dec. 18, the Food and Drug Administration issued an emergency use authorization (EUA) for a COVID-19 vaccine made by Moderna, a biotech company based in Massachusetts.

The decision followed an overwhelming 20 to zero vote, with one abstention, in favor or authorizing the vaccine by an FDA vaccine advisory committee on Dec. 17.

"This evening the FDA granted the second emergency use authorization for a COVID-19 vaccine," Dr. Stephen Hahn, commissioner of the FDA, said during a media briefing announcing the decision. "This is another crucial step in the fight against a global pandemic causing vast numbers of hospitalizations and deaths in the United States every day. The transparency around our review of the Moderna COVID-19 vaccine should reassure the public that this vaccine met the FDA's rigorous standards for quality, safety and efficacy. As with any decision made by the FDA this authorization was fixed solely by science and data."

In its EUA for the Moderna shot, the FDA, as it did with the Pfizer-BioNTech vaccine, added a warning to providers that people with known allergies to components of the vaccine should not get the shot; a handful of reports of allergic reactions, some of them severe, have occurred in people who have been vaccinated with the Pfizer shot so far.

Covid vaccine can turns you into a crocodile?: Brazilian President's remarks

Dec 20, 2020

"In the Pfizer contract, it's very clear: 'we're not responsible for any side effects.' If you turn into a crocodile, it's your problem," he said, according to news agency AFP.

Brazilian President Jair Bolsonaro has cautioned his citizens that his government won't be responsible if the Pfizer/BioNTech vaccine turns people into "crocodiles" or make women bearded as a side-effect, leaving netizens baffled.

Bolsonaro, who had tested positive for coronavirus after months of undermining the pandemic shared Brazil's vaccine distribution plans recently, saying that inoculations would eventually be provided free of charge "for everyone who wants it," while insisting that he has chosen not to be vaccinated.

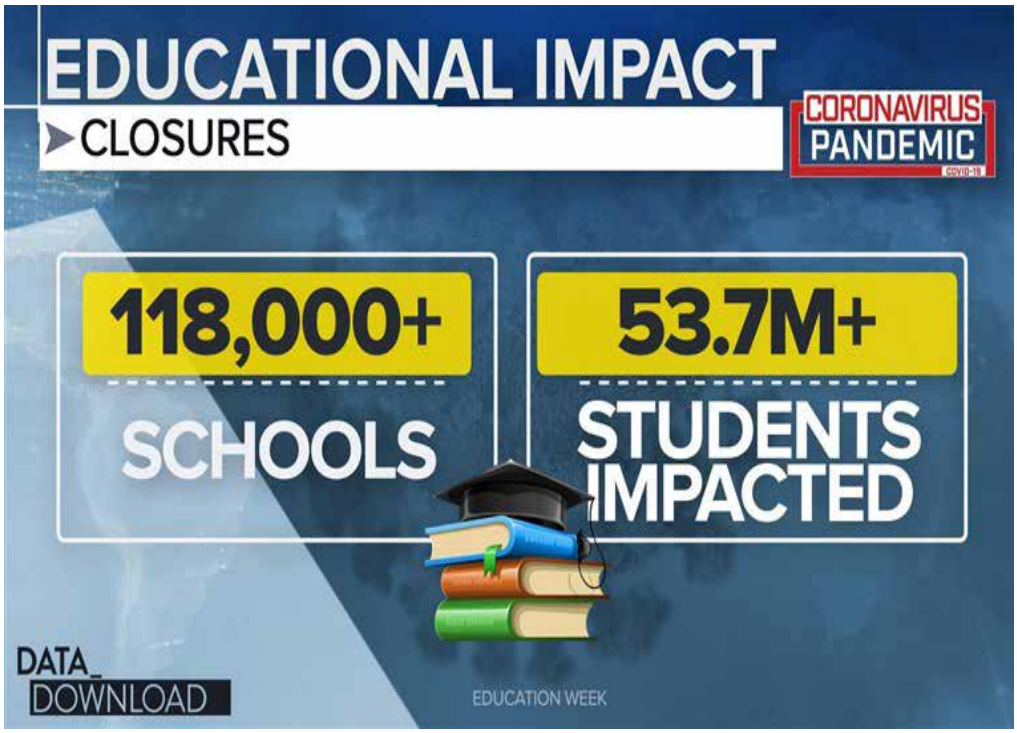
"If you become superhuman, if a woman starts to grow a beard or if a man starts to speak with an effeminate voice, they will not have anything to do with it," he added for the vaccine that is already being used in the United States and Britain.

"Some people say I'm giving a bad example. But to the imbeciles, to the idiots that say this, I tell them I've already caught the virus, I have the antibodies, so why get vaccinated?" he said in his defence.

Bolsonaro's statements are particularly alarming as Brazil's death toll stands at 185,687, which is second only to the United States, the worst-hit nation both in terms of the total number of cases and deaths.

Research Highlights

Coronavirus study that found US school closures cut life expectancy criticised by epidemiologist



A study that found US school closures during the Covid-19 pandemic cut the life expectancy of each child in primary school by an average of three months contains "critically flawed assumptions" and "clear mistakes in study design", according to a rebuttal led by an Australian epidemiologist.

The study, published in the Journal of the American Medical Association on 12 November, was widely shared on social media including by scientists, doctors and policymakers and was covered in dozens of news stories.

The researchers calculated the years of life lost that might be attributable to school closures, and compared that to the years of life lost attributed to the first months of the pandemic.

The study found a total of 5.5m life years would be lost due to school closures, higher than that directly attributable to COVID-19. This was determined by calculating the impact of missing days of school on educational attainment. The researchers linked this to an estimate of a 25% reduction in relative risk of death for each year of schooling, because education is associated with better health outcomes. The researchers then used these assumptions to estimate years of life lost that would be associated with school closures.

The researchers concluded there was "a 98.1% probability that school opening would have been associated with a lower total YLL [years of life lost] than school closure".

An epidemiologist with the University of Wollongong, Gideon Meyerowitz-Katz, and a demographer with the University of Southern Denmark, Dr Ilya Kash-

nitsky, last week published a response to the study, describing it as "filled with errors".

"This study has received enormous public attention, and its results immediately appeared in discussions of public health policies around schools worldwide," they wrote.

"The authors suggested a causal chain that consists of two highly questionable links: (1), missing school is linked to overall educational attainment, and, (2), attainment is then linked to the length of life. The first link relies entirely on a single Argentinian study … of the long-term effects of teacher strikes on educational attainment of children who attended school during this time.

"My co-author and I are not saying that school closures are necessarily a good thing," Meyerowitz-Katz said. "What we're saying is that this study can't provide evidence [that they are harmful]. The numbers that they've presented in part of their model are mathematically impossible. Given the procedure they claim to have used, they're also wrong."

He and Kashnitsky have called on the journal to correct or retract the paper. Scientists have warned about an influx of scientific papers throughout the COVID-19 pandemic, as medical journals rush to publish new information about the virus.

The lead author of the JAMA schools paper, Dr Dimitri Christakis, is director of the Seattle Children's Research Institute's centre for child health in the US and told Guardian Australia his paper had been "through rigorous peer review," pointing out that the criticisms of the study had not. He also referred to the disclaimer on the site on which Meyerowitz-Katz and Kashnitsky had posted their criticisms, which states: "Caution: Preprints are preliminary reports of work that have not been certified by peer review. They should not be relied on to guide clinical practice or health-related behavior and should not be reported in news media as established information."

Christakis did not address the criticisms of the paper, but said Meyerowitz-Katz and Kashnitsky "have so far refused to engage in the normal process of scientific discourse which is to submit a letter/comment to the journal for a response, or to conduct their own peer-reviewed work".

The Journal of the American Medical Association did not respond to a request from Guardian Australia for comment. However, Meyerowitz-Katz said the journal editors told him that any concerns could be outlined by leaving a comment on the Christakis paper in the journal online.

Source: Guardian News & Media Limited

COVID-19 pneumonia paper earns expression of concern — for being similar to a pre-pandemic article

December 3, 2020

Researchers in China have received an expression of concern for a recent paper on COVID-19 pneumonia after editors were alerted to suspicious similarities between the tables in the article and those in a 2018 study by members of the same group.

The article, "Lung ultrasound score in establishing the timing of intubation in COVID-19 interstitial pneumonia: A preliminary retrospective observational study," appeared in early September in PLOS ONE. Led by Xiao Lu, the authors were affiliated with the Department of Emergency Medicine at Zhejiang University School of Medicine, in Hangzhou.

The authors appear to have been submitting problematic data, as well as overlapping text, to several journals, according to one editor who spotted unlikely patterns in their results and raised alarms. But the re-

searchers say the flaws resulted from lack of record-keeping rather than misconduct.

According to the expression of concern, which is dated Nov. 30, 2020: Following the publication of this article [1], concerns were raised regarding the similarity between results reported in Table 1 and Table 2 in this article, and results in an article previously published in the Journal of Intensive Care Medicine [2]. Specifically,The BMI and SOFA scores reported in Table 1 of [1] are identical to the BMI and SOFA scores reported in Table 1 of [2] despite describing different study populations.

The reported P value for the gender division parameters in Tables 1 of both articles [1, 2] is identical.

The Respiratory rate and the PaCO2, mmHg scores reported in Table 2 of [1] are identical to the T1 (Initial EICU presentation 2 hours) Respiratory rate and the PaCO2, mmHg scores reported in Table 2 of [2] despite describing different study populations.

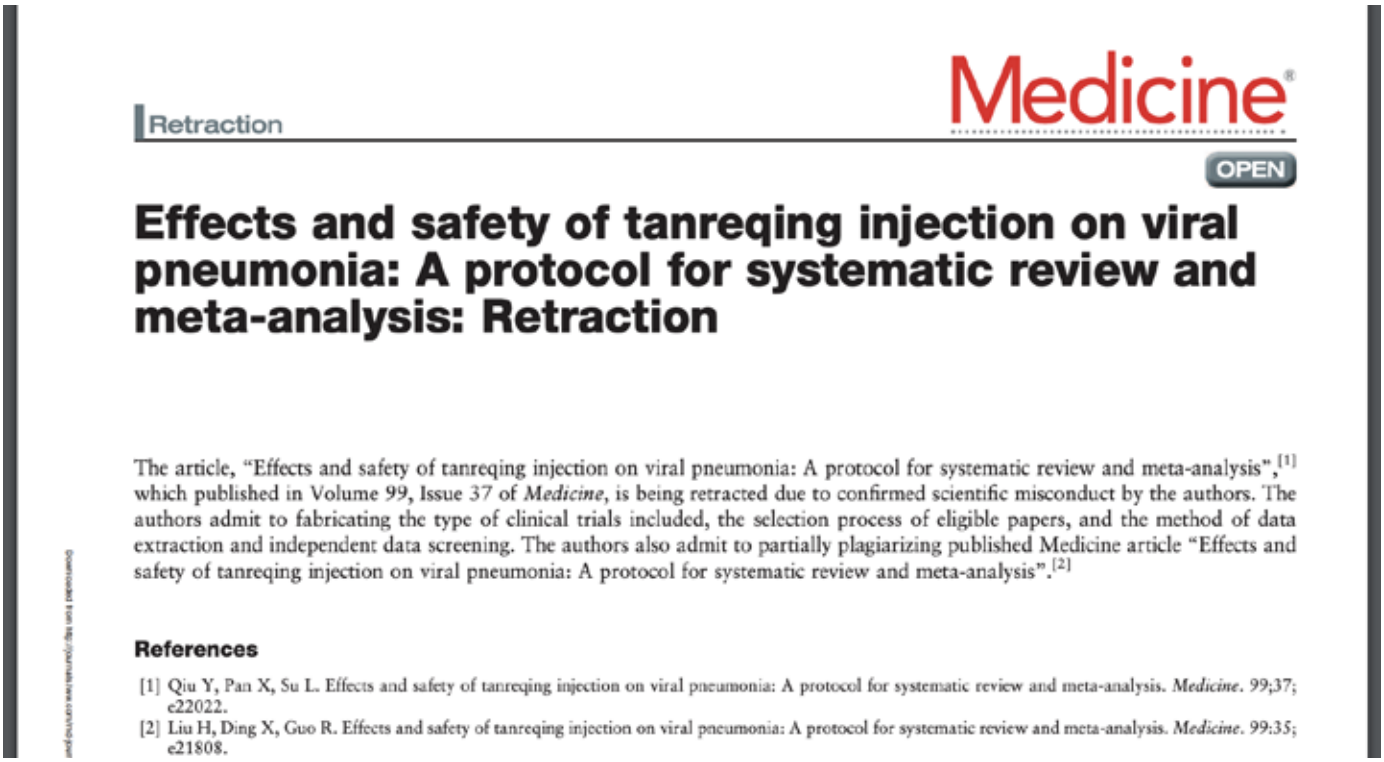
The Pulse rate reported in Table 2 of [1] is more similar to the Pulse rate reported in Table 2 of [2] than would be expected from independent studies.

The corresponding author agrees there are similarities between the data reported in these articles [1, 2] and indicated they are checking the underlying data.

PLOS ONE is currently reassessing the article and following up on the above issues in accordance with COPE guidance and journal policies. Meanwhile, the PLOS ONE Editors issue this Expression of Concern.

The JICM paper, on which Lu also is first author, is titled "Bedside ultrasound assessment of lung reaeration in patients with blunt thoracic injury receiving high-flow nasal cannula oxygen therapy: a retrospective study."

In response to an email request for comment, Lu told us:
we do find there are some similarities between the data reported in the paper and my another article 2018 Journal Of Intensive Care Medicine article. We will check all the data and find the reasons. As the information in our paper, the patients were conducted in one makeshift ICU in Wuhan,and our medicial team was support to built this ICU and treat the patients there. We do use the LUS [lung ultrasound] to check the patients everyday and it was also proved to be a useful tool. However the LUS of the patients



Retraction

Medicine

OPEN

Effects and safety of tanreqing injection on viral pneumonia: A protocol for systematic review and meta-analysis: Retraction

The article, "Effects and safety of tanreqing injection on viral pneumonia: A protocol for systematic review and meta-analysis",[1] which published in Volume 99, Issue 37 of *Medicine*, is being retracted due to confirmed scientific misconduct by the authors. The authors admit to fabricating the type of clinical trials included, the selection process of eligible papers, and the method of data extraction and independent data screening. The authors also admit to partially plagiarizing published Medicine article "Effects and safety of tanreqing injection on viral pneumonia: A protocol for systematic review and meta-analysis".[2]

References

[1] Qiu Y, Pan X, Su L. Effects and safety of tanreqing injection on viral pneumonia: A protocol for systematic review and meta-analysis. *Medicine*. 99;37; e22022.
[2] Liu H, Ding X, Guo R. Effects and safety of tanreqing injection on viral pneumonia: A protocol for systematic review and meta-analysis. *Medicine*. 99:35; e21808.

were not recorded in the original documen [sic], and the original documens of the patients were just left in that makeshift ICU and had not been preservation by us. We just record patients information in the word files as we finished our job in Wuhan. We could check the info recoeded [sic] in our word files. May be the problem was in the file.

We do not deny the questionable points of these data, espesilly [sic] the patient characteristics at baseline; but we didn't deliberately fake it or copy the data as we do the study before. I will be responsible for this as the first and Corresponding author.

John Loadsman, the chief editor of Anaesthesia and Intensive Care, told us the problems don't end there:

The first author (corresponding on the PLoS One paper) submitted a third paper to my journal reporting a study of 98 patients (49 per group). It was about using two forms of non-invasive ventilatory support to prevent extubation failure, so quite a different study to the previous publications. Nevertheless, and as with the PLoS One paper, many of the means, standard deviations and p-values in both the demographic and results tables were identical to those in the other two papers. I noticed the problem with the data after our astute SAGE Peer Review Manager brought potential text similarity issues to my attention. I understand investigations by the other two journals are ongoing.

Loadsman noted that all three articles acknowledge the help of an editing services outfit called LetPub, which has offices in the United States, Europe, South America and Asia.

Clark Holdsworth, the research communications manager at LetPub's parent company, Accdon, said problems with the articles his firm works on "always disappointing to see," but added that LetPub doesn't get involved in the production of tables:

This manuscript came to us for our standard language editing service and would have been edited for spelling, punctuation, and grammar. We are only able to provide editorial support, so we do not produce figures or tables. Essentially, these projects go through the same thorough copy editing performed by most journals prior to publication.

Regarding figure editing, the editor responsible for the manuscript receives them as a PDF for reference only. In the event of a typo contained within the figures, the editor would simply specify the correction in a comment, for the author to revise themselves in whichever software they used for generating the figure. Regarding table editing, tables are available to the editor in the Word document and the editor revises these for spelling, punctuation, and grammar, unless the author specifically requests for us to exclude them from the scope of editing, in which case the editor still receives them for reference. As you might imagine, our revisions to tables are found in the title, legend, and column/row headings.

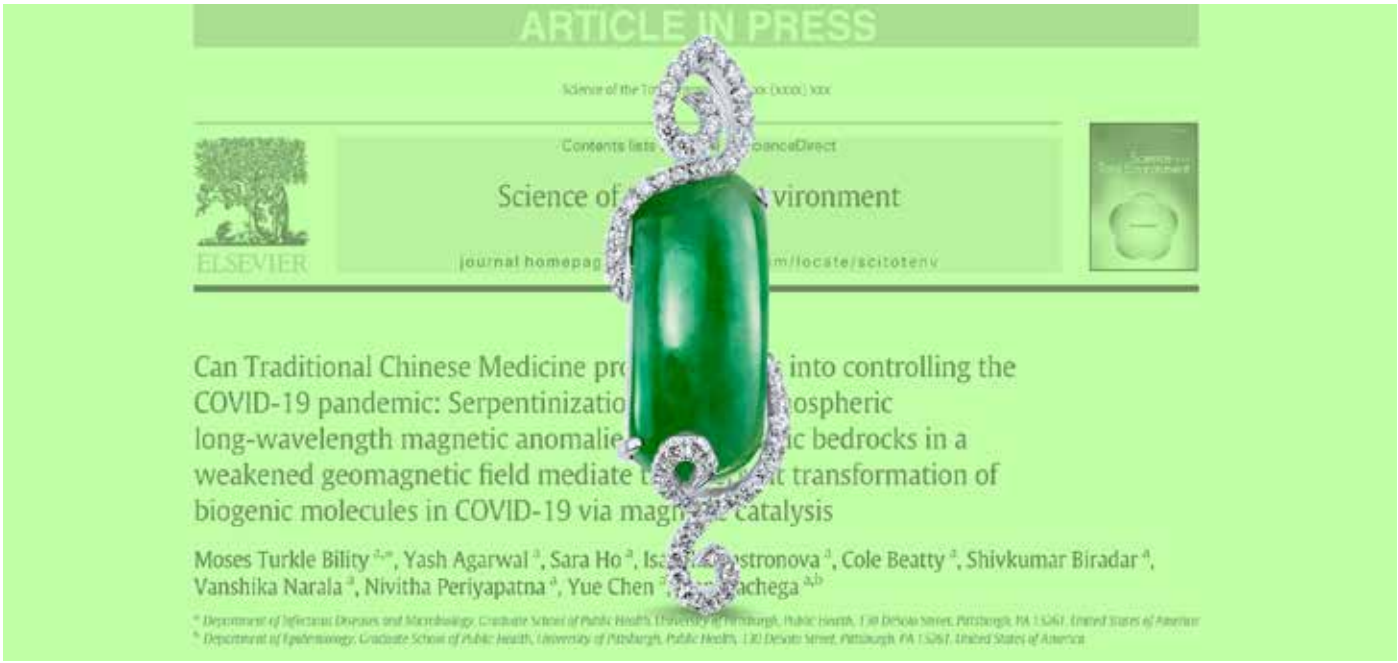
By our count, the EoC marks the fourth such notice for COVID-19 articles. Another 44 have been retracted or temporarily retracted.

Source: Retraction Watch

Prof Said Jade Amulets May Block COVID—and Became a Science Supervillain

Nov. 29, 2020

Scientists have started sounding the alarm over a strange new theory circulating online about the novel coronavirus. Basically, it argues that the coronavirus may not really be all that novel. Instead, the thinking goes, it could be an ancient virus hidden in our DNA that does not directly make people sick—until shifts in Earth's geomagnetic field create a cascade of effects that ultimately activate that latent genetic code and cause COVID-19.



The wildest part: Thanks to its own unique geomagnetic properties, the theory maintains, "nephrite-jade amulets, a calcium ferromagnesium silicate, may prevent COVID-19." In other words, you may be able to wear a physical piece of armor to ward off the deadly illness.

Unlike the bogus far-right conspiracy theories about COVID-19 and other diseases that have percolated over the years, this idea did not emerge from some secretive digital fringe. Instead, it originated in a peer-reviewed article in Science of the Total Environment (SOTE), a reputable academic journal, thanks in part, its authors claim, to funding "through grants from the United States National Institutes of Health." (The National Institutes of Health did not respond to a request for comment for this story.)

Its primary author, Moses Bility, is—or at least was—a respected assistant professor of infectious diseases and microbiology at the University of Pittsburgh. Suffice to say he has come under withering attack from others in his field and beyond over the article, and SOTE has temporarily withdrawn the paper—although the journal has not (yet) retracted it.

"I am not sure who peer-reviewed it, but this paper should not have passed," Elisabeth Bik, a microbiologist and scientific integrity watchdog, told The Daily Beast.

She and other skeptical expert readers argue that the paper drastically mischaracterizes or misunderstands many of the diverse concepts and studies it draws upon, as well as many clinical observations on the nature of COVID-19.

It also contains some basic errors.

"For instance, right at the start, he talks about 'thoracic organs, namely the lungs and kidneys,'" noted Jonathan Jarry, a former United States Armed Forces biological scientist and current science communicator for McGill University. "The kidneys are not thoracic organs. They're in the abdomen."

Bility, who is Black, believes his article got through peer review because his theory is sound, if provisional, and that he is the victim of a prejudiced digital mob that doesn't understand his research or respect him. Every other scientist The Daily Beast canvassed for this story believes his paper got through because of flaws in the peer-review process that occasionally give an aura of academic rigor to pure nonsense.

They also believe that his paper's contents could bol-

ster conspiracy theories that deny the value of basic public health measures like mask wearing, as well as pseudoscience hucksters eager to move some jade. That its inclusion in a legitimate journal could lead people to doubt the rigor of every other academic article, ultimately eroding faith in science as a whole. And that any efforts to get it removed in the name of scientific integrity will convince conspiracy theorists that the establishment is trying to suppress uncomfortable truths and free thought.

"I expected people to be hesitant about this idea," Bility told The Daily Beast. "It's a new idea."

What he did not expect was for his paper to be this controversial. He claims that some critics have called, in emails to his colleagues, for the university to take disciplinary action against him, or to fire him.

When asked if the University of Pittsburgh had received any complaints or concerns about Bility related to this paper, a representative did not address that question and instead told The Daily Beast, "The paper has been retracted… The University of Pittsburgh remains committed to supporting the academic freedom of all of our faculty members." (The paper has not, in fact, been retracted.)

Bility has actually been openly developing the core ideas behind the paper—a grand new hypothesis meant to address perceived flaws in the germ theory of disease through the novel application of (his self-taught understandings of) fields like quantum physics—for years.

Another paper related to this overarching theory, posted at the start of 2020, claimed Stonehenge was potentially a "state-of-the-art Neolithic European public health complex" built to protect people from geomagnetic fluctuation-related illness and "mega-death." Mike Pitts, a Stonehenge excavator and expert, told The Daily Beast that article "overstated or misinterpreted" most of the archaeological theories and evidence it hinged on. He also said it "contains one of the most nonsensical sentences I've ever read about Stonehenge—and I've suffered quite a few."

The seeds of Bility's COVID-19 paper originated last fall, he said, when his lab observed a strange lung illness in some of their rats, which he thought resembled the outbreak of a lung condition among people who used e-cigarettes and other vaporizers. He did not buy conventional explanations for the origin and end of that outbreak. So he posted a paper proposing that this vaping lung condition and the disease he saw in his rats were triggered by—and ebbed and flowed with—shifts in the geomagnetic field.

Source: https://www.thedailybeast.com/moses-bility-at-university-of-pittsburgh-said-jade-amulets-may-block-coronavirus-and-became-science-pariah

Public health journal "seeking further expert advice" on January paper about COVID-19 PCR testing by high-profile virologist

After a petition from nearly two dozen people in Europe, the United States and Asia, a public health journal says it is investigating an article it published last January about a way to detect the virus that causes COVID-19.

The paper, "Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR," appeared in Eurosurveillance. It was received on January 21 and accepted on January 22, a remarkably quick turnaround under normal circumstances, although not unheard of during the pandemic. It has been cited well over 800 times, according to Clarivate Analytics' Web of Science.

The senior author of the work was Christian Drosten,

of the Charité University Hospital in Berlin, who became something of a celebrity virologist — the Anthony Fauci of Germany — in the early days of the pandemic. As Science reported in late April, Drosten's podcast, Coronavirus Update, became the most popular podcast in Germany, garnering more than 1 million downloads per episode.

But, as with Fauci in the United States, Drosten has become a target of criticism, largely from political conservatives, who complain that what they consider to be flawed science is informing economically damaging policies. An article in May in Bild, a right-wing tabloid, accused Drosten of having "worked dishonestly," and peddling "false conclusions" about the infectivity of the SARS-Co-V2 virus. But the newspaper apparently only gave him an hour to respond to their questions.

As Bloomberg reported in September, Drosten's handling of the Bild story earned him hero status on social media:

A German model proposed to him on Twitter, demanding a response within the hour or else she'd assume they're engaged. ZSK, a punk band in Berlin, released a song called I Have Better Things to Do. The accompanying music video features a cartoon Drosten angrily throwing away a cellphone with Bild on its screen and blasting viruses with laser beams shooting out of his eyeballs.

The petition doesn't call Drosten dishonest. But it does demand that Eurosurveillance retract his group's paper for a litany of "scientific and methodological blemishes," which it enumerates in detail (10 points, to be precise). The second author of the petition, Bobby Rajesh Malhotra, described what he called "the very specific behavioral-patterns, underlying market-architecture, fraudulent scientific methods, orthodox rituals of the vast pharma-wasp nest set around the queen wasp Christian Drosten" in a 124-tweet thread in October.

Central to the group's claims is the notion that Drosten and colleagues failed to prove that PCR testing can identify the SARS-Co-V-2 virus. The result, they claim, has been:

worldwide misdiagnosis of infections attributed to SARS-CoV-2 and associated with the disease COVID-19. We are confronted with stringent lockdowns which have destroyed many people's lives and livelihoods, limited access to education and these imposed restrictions by governments around the world are a direct attack on people's basic rights and their personal freedoms, resulting in collateral damage for entire economies on a global scale.

The statement from Eurosurveillance reads:

We have recently received correspondence regarding a paper published this year, questioning both the content and the editorial procedures used to evaluate the article prior to publication. We can assure our readers and authors that we take comments relating to scientific content, the processing of articles and editorial transparency seriously.

All articles published by the journal are peer-reviewed by at least two independent experts in the field (or at least one in the case of rapid communications). The article in question was also peer-reviewed by two experts on whose recommendation the decision to publish was made.

Eurosurveillance is seeking further expert advice and discussing the current correspondence in detail. We will, according to our existing procedures, evaluate the claims and make a decision as soon as we have investigated in full. In the meantime, it would be unfair to all concerned to comment or discuss further until we have looked at all the issues.

Source: Retraction Watch

CSIR-Central Drug Research Institute, Lucknow
Council of Scientific and Industrial Research
Sector 10, Jankipuram Extension, Sitapur Road,
Lucknow – 226 031, Uttar Pradesh, India

SCIENTIST RECRUITMENT-2020

Advertisement No 10/2020

URL for Online Application: https://recruit.cdri.res.in

OR

Access link 'SCIENTIST RECRUITMENT-2020' on https://cdri.res.in

Start Date for Registration for Online Application:	Saturday, 5 December, 2020, 10:00 Hrs IST
Last Date for Registration & Submission of Online application:	Friday, 15 January, 2021, 23:59 Hrs IST
Last date of Receipt of physical copy of application at CDRI:	Monday, 1 February, 2021, 17:30 Hrs IST

A unique opportunity for research career in Science & Technology in the area of Drugs, Pharmaceuticals and Biomedical Research

CSIR-Central Drug Research Institute, Lucknow, a premier Institute under Council of Scientific and Industrial Research (CSIR), is involved in multidisciplinary R&D programs of both basic and applied nature. CSIR-CDRI is a pioneer biomedical research organization in India and has the infrastructure and expertise to develop a drug from concept to commercialization. In the year 2012, CSIR-CDRI shifted to its state of the art new campus, which has been set up with a vision to serve as a Nodal Center of CSIR in new drug discovery and development. Spread across ~61 acres, it houses an R&D Complex, Support Services, Guest House, Hostel and Staff Quarters. Please visit http://www.cdri.res.in for further information.

With the aim to expand and strengthen the areas of Neurobiology, Virology, Parasite Biology, Endocrinology, Human Genetics, Analytical Biochemistry, Computational Chemistry, Medicinal Process Chemistry, Statistics, IPR & HR Management, the Institute is looking for enthusiastic, talented young researchers / professionals with brilliant academic record, proven scientific achievements and zeal to conduct research as per the mandate of the Institute aligned with National Missions. Due weightage will be given to the candidates involved in the product development/ technology innovation/applied technology / translation research. The positions offer exciting opportunities for career growth as per the Flexible Complementing Scheme for Scientists.

Applications are invited from motivated young Indian Nationals with requisite qualification and experience for the following posts as per the details given below. The emoluments and age limit for various posts as per norms is summarized as below: -

Designation	No. of Posts	Pay Level	Basic	*Total Emoluments	**Upper Age Limit not exceeding (as on 15/01/2021)
Scientist	**06** [UR-3; SC-1; OBC-1; EWS-1] & **02** PwD (OH/HH/VH) Backlog Posts	11	Rs. 67700/-	Rs. 94,720/-	32 years
Senior Scientist	**08** UR/Lateral Entry	12	Rs.78800/-	Rs. 1,08,928/-	37 years
Principal Scientist	**01** UR/Lateral Entry	13	Rs.123100/-	Rs. 1,59,744/-	45 years

UR: Unreserved; SC: Scheduled Caste; OBC: Other Backward Class; EWS: Economically Weaker Section;
*** Approximate total emoluments on minimum of scale including House Rent Allowance in Lucknow City.**
****Please see age relaxation under Relaxation column.**

वैऔअप–केन्द्रीय औषधीय एवं सगंध पौधा संस्थान
CSIR-Central Institute of Medicinal & Aromatic Plants
CSIR-CIMAP
Diamond Jubilee Year (1959-2018)
60 years of dedicated service towards farmers empowerment

CIMAP Scientist & Technical Posts Recruitment

(A): Scientist Posts (Entry Level)
Post I - Name of the Job: Scientist (Computational Biology and big data analysis)
Post II - Name of the Job: Scientist (Pathway elucidation and Engineering)

(B): Senior Scientist Posts (Lateral Level)

Post III - Name of the Job: Senior Scientist (Biochemistry)
Post IV - Name of the Job: Senior Scientist (Project Planning and Management)
Post V - Name of the Job: Senior Scientist (Plant Tissue Culture)

How to Apply for CIMAP Scientist & Technical Posts:

a) Eligible and interested applicants are required to fill the application ON-LINE by accessing the web-site https://www.cimap.res.in.

The datelines for the above-mentioned stages of application are as follows:

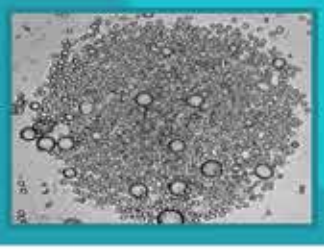
Last date for registration and applying for Online application: Thursday, 21st January 2021; 23:59 Hrs. IST
Last date for Fee Submission at Bank Payment Gateway Online/Offline: Wednesday, 27th January 2021; 16:00 Hrs. IST
Last date for Submission of Online Application in the Recruitment Portal: Friday, 05th February 2021; 23.59Hrs. IST
Last date for Receipt of physical copy (hardcopy/printout) of the submitted application at CIMAP, Lucknow: Monday, 22nd February 2021; 17:30Hrs. IST
e) Applicants are required to pay application fee Rs.100/- only based on 'Fee Payment Procedure' available on the web site. The candidates belonging to SC/ST/Women/ PWD/Abroad applicants and regular employees of CSIR are exempted from payment of application fee.
f) The Printout of the application, generated after online submission, duly accompanied by self-attested copies of the requisite certificates/mark sheets of date of birth, educational qualifications, experience, and community certification, if any, addressed to the " Controller of Administration, CSIR-Central Institute of Medicinal and Aromatic Plants, Post Office-CIMAP, Lucknow-226015 " must reach this office by speed post/registered post on or prior to 22.02.2021. Candidates applying for greater than one post must send separate application for each post indicating the Code No. of the post.

TRANSTOX BIO

PRIMARY HUMAN DERIVED STEM CELLS FOR PREDICTIVE PLATFORMS

Trans-MSC is Human derived primary pluripotent stem cell aggregate model that can predict test chemical's safety and preclinical prognosis

Trans-HSC is Human derived primary hematopoietic stem cell aggregate model that can predict test chemical's safety and preclinical prognosis



FEATURES:

- Stem cell aggregates are either stromal or hematopoietic in nature
- Test readouts are 100% relevant to humans
- Tests performed can be robust, specific, sensitive, and reproducible
- Suitable for both low throughput and high throughput screening
- Suitable for cell based modelling
- Primary in nature; Not transformed; Not genetically modified
- Customized units
- Ready to use; Can be maintained at -80^{0}C till use

Primary cell solutions
Certificate of Analysis

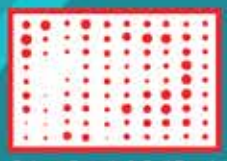
Trade Name:	Trans-MSC
ID:	Trans-MSC14/R
Cells Harvested Date	
Biosafety Level	1
Organism	Homo sapiens (Human)
Growth properties:	Adherent
Morphology	Spindle Shaped, fibroblast like
Volume/Vial:	5ml (2.3 million cells / 1ml)
No: of Vials	As required
Viability	≥92%
Population Doubling Capacity:	≥ 10 in complete growth medium and support differentiation
Shipped	Frozen
Storage	Liquid nitrogen or for short term storage at -80°C
Quality Assurance:	
Testing	Tested for CD73, CD90, CD105, CD34, and CD45, Primary cells display normal karyotype as assessed by G-banding of 20 metaphase cells.
Sterility Tests	Bacteria & Yeast : Negative Mycoplasma: Negative Endotoxin: Negative

Trans-MSC + Test compound

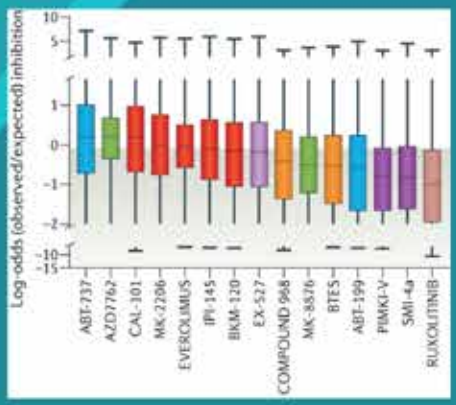
Colormetric Assays

Turbidity Measurements

Cell Marker Expression



Colony Growth & Cell Death



Use Case

- Acute Toxicity
- Chronic Toxicity
- Repeat Dose Toxicity
- Ic50
- Carcinogenicity
- Mutagenicity
- Draize Test
- Developmental Toxicity

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Contact: aarthi.k@transtoxbio.com,sindhu.b@transtoxbio.com

International Conference on Biotechnology for Sustainable Agriculture, Environment and Health

XVII Convention of BRSI

(BAEHS-2021)

ISSN: 2454-6968
RNI No. UPENG/2013/54102

April 4-8, 2021 Jaipur

Details: http://brsi2020jaipur.in/

Conference will be held in Hybrid mode (Physical and Virtual)

The event will be jointly organized by the MNIT, Jaipur; CDC India, Jaipur, BISR, Jaipur and NIT-Uttarakhand in association with the International Solid Waste Association (ISWA), The Institute of Chartered Waste Managers (ICWM) and B Lal Institute of Biotechnology, Jaipur. This will be supported by the International Bioprocessing Association, France; Centre for Energy and Environmental Sustainability (CEES)-India and Amity University, Jaipur. The event will be held at BISR, Jaipur. Prof TP Singh, Prof AB Gupta and Dr Vivek Agarwal are conference chairs. Dr V Vivekanand is the convener of BAEH-2020 and Dr P Binod, COE, BRSI; Dr Krishna Mohan, BISR, Jaipur and Dr B Lal, BIB, Jaipur, Dr Rakesh Kumar Mishra, NIT-Uttarakhand are its co-conveners. Details can be found at http://brsi2020jaipur.in/