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BIOTECH EXPRESS

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Adverse Effects of the Pfizer Vaccine Covered Up by the Israeli Ministry of Health

HC asks Mumbai civic body under which law it fined people for not wearing masks

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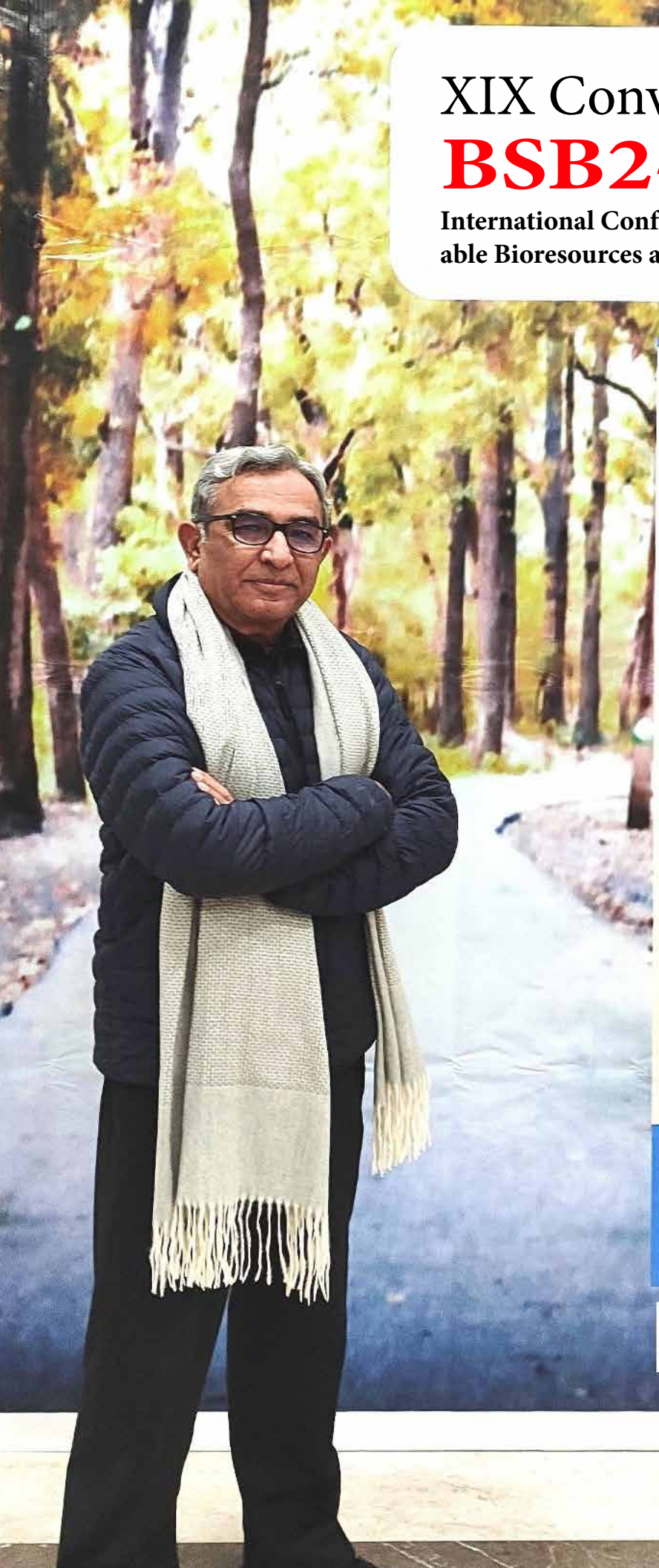
BSB2-2022

International Conference on Biotechnology for Sustainable Bioresources and Bioeconomy (BSB2-2022)



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Prof Ashok Pandey
General Chair, BSB2-2022, Chief Mentor- BRSI,
CSIR-IITR, Lucknow, India

December 7-11, 2022
IIT- Guwahati

Details can be found at
https://www.bsb2iitg2022.in/

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- After a long fight, Delhi HC Directs School to Permit COVID-19 Unvaccinated Teacher to Join Duty
- International Study Shows Pfizer & Moderna Vaccines 'Associated with Increased Risk of Serious Adverse Events'
- Anil Ambani's son lashes out against lockdowns; says it is only about control not health
- US Senator Rand Paul threatens to investigate royalties to Dr Fauci, other officials
- Adverse Effects of the Pfizer Vaccine Covered Up by the Israeli Ministry of Health
- HC asks Mumbai civic body under which law it fined people for not wearing masks

9th International Conference on "Interdisciplinary Approaches in Life Sciences for Translational Research"

November 04th -05th , 2022 (Friday & Saturday)

We welcome your participation in the 9th International Conference on "Interdisciplinary Approaches in Life Sciences for Translational Research". The conference is planned with a motivation to provide an excellent international platform for the academicians, researchers, engineers, industrial participants and innovative students around the world to share their research findings with the global experts and carry their research ideas to next level. Both academia and industries are invited to present their research dealing with defined thrust areas for future developments. We are looking forward for your gracious presence at Invertis University, Bareilly, UP.

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- Bioinformatics
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- Environmental Biotechnology
- Database Management
- Next Generation Sequencing
- Enzyme and Protein Engineering
- Industrial and Manufacturing Biotechnology
- Statistical Methods in Life Sciences
- Drug Development and Clinical Trials
- Bioethics and IPR
- Agriculture Biotechnology

TECHNICAL SESSION

This conference will commence with an introductory Keynote session, Plenary sessions and following awards

- Young Scientist Award
- Best Poster Presentation Award
- Best Oral Presentation Award

CALL FOR ABSTRACT

Research papers/posters are invited from given thrust areas. All abstract should be submitted by email before **October 20, 2022 on** the **registration link** provided below.
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Last Date of submission:	20 October 2022
Last date of registration:	30 October 2022
Date of conference:	04-05 November 2022

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Vaccination, Rising Deaths, And The False Narrative

by Dr Amitav Banerjee, Professor, Department of Community Medicine

A popular corporate-run newspaper recently ran this sensational headline, "Doctors fear those hit by Covid now vulnerable to cardiac issues." The narrative under the headline is scary. It goes on to say that Covid-19 not only killed millions of people, the virus is leaving many more sick and vulnerable to chronic cardiac and nervous system disorders.

The report goes on to describe two cases in young people in Maharashtra who had clotting and heart issues. The first, a 28-year-old who suffered from Covid-19 a year back landed up in hospital with heart issues. He weighed 130kg. The other youngster, 22-years-old, was rushed to a hospital with a large clot in his heart's left lower chamber, which travelled to the artery supplying the lung. His medical history revealed Covid-19 infection a year ago.

What is conspicuous by its absence in the news report is any history of vaccination against Covid-19 in these two cases. Is it deliberate? Why has coronavirus vaccination status become an elephant in the room in such cases? Against the backdrop of these two cases, cherry-picked news reports from the West are discussed expressing concerns about cardiac and neurological disorders post Covid-19 recovery.

Amid all this, one must give credit to a member of the Covid task force of the state who admitted that while in recent times we're seeing young people getting hospitalised with stroke or heart attack, it is not easy to straightaway make a correlation with Covid.

About Dr Amitav Banerjee

Dr Amitav Banerjee, is currently Prof & Head, Department of Community Medicine, Dr DY Patil Medical College, Hospital & Research Centre, Pune. He has served in the Indian Armed Forces from 1978 to 2005. He has eaned zeveral awards like Chief of Army Staff Gold Medal for his paper "Impact of Information Technology on Armed Forces," in the year 1996, Armed Forces Silver Medal for paper on Tribal Malaria in the year 2003, Best Published Paper Award on "Outbreak of Hepatitis E" in the year 2005 among many others.

Dr Amitav has more than 200 papers in peer reviewed Journals. (Citations 2124; h-index 19; i10-index 34) https://scholar.google.co.in/citations?user=CrRdbUYAAAAJ&hl=en. He has been reviewer for reputed Journals including the BMJ & Nature and has awarded Publons Peer Review Award 2017 and also in 2018 as one of the top 1% peer reviewers globally. (https://publons.com/awards/field/?name=Amitav%20Banerjee&asjc=49)

Dr Amitav is a research and publications adviser in Surin University, Thailand. His paper "Population and Samples" is reading material in one of the Research Methods Courses at Stanford University.: http://web.stanford.edu/class/symsys130/ Editor in Chief, Medical Journal of Dr DY Patil Vidyapeeth (Indexed in SCOPUS, DOAJ) Delivered Dr Mapuskar Memorial Oration at 45th National IAPSM and 19th Maharashtra State Level Joint Conference in the year 2018.

Another doctor said in the same news report that younger people who had Covid and have at least one comorbidity are more vulnerable to these complications compared to those without comorbidities.

Strangely, there is no mention of vaccination status against Covid-19. The WHO's chief scientist Soumya Swaminathan, meanwhile, has been talking through the hat. She tweeted, "We need to prepare for large increases in cardiovascular, neurological and mental health disorders in countries affected by the #SARSCoV2# pandemic." For the chief scientist at the WHO, it's a grave omission indeed not to consider the ill-effects of the experimental vaccine, however remote and unlikely that may be.

Such biased news reporting will make the reader attribute all complications to "long Covid," which is increasingly being promoted as an emerging problem. And more disturbingly, it will brush under the carpet any complications due to the experimental vaccines as all adverse events following immunization (AEFI) would be conveniently covered under the blanket of "long Covid."

Let's look at the other end of the spectrum.

A volunteer at an AstraZeneca vaccine trial in late 2020 in Utah, US, Brianne Dressen, narrated her scary experience after receiving the AstraZeneca vaccine shot (marketed as Covidshield in India) as a trial participant. She never had Covid-19 in the past, which was one of the criteria for taking part in the trial.

As a former rock climber, she was seriously incapacitated following the vaccine injury. Her vision and hearing were distorted, she had severe heart rate fluctuations,

DEEP DIVE | 05

WHEN VAX TURNS ADVERSE

While over 2 billion doses of Covid-19 vaccines are administered in India, there have been a few serious adverse events after immunisation. Are there systemic gaps in reporting such cases and obtaining relief?

Types of AEFI

How to Report AEFI

AEFI: Rural vs Urban

ETPrime

severe muscle weakness, and she had a sensation of internal electric shocks. She had to spend most of her time in a darkened room, unable to brush her teeth, or tolerate the touch of her children.

She also found other people who had never suffered from Covid-19 but experienced serious and long-lasting health problems after taking the coronavirus vaccine. Researchers were non-committal. Avindra Nath, clinical director at the National Institute of Neurological Disorders and Stroke who had been leading the investigation on behalf of the National Institute of Health (NIH), US, conceded the association of these disorders with Covid-19 vaccination, but fell short of conceding an "etiological association," implying ignorance whether vaccines directly caused the subsequent health problems.

Such restraint in jumping to conclusions is certainly the right approach in scientific inference. But the same restraint should be used before attributing any short-term adverse event or lingering long-term ill-health to natural infection with Covid.

What dismayed the sufferers of these symptoms post-vaccination was the pullback by the NIH as communications with these patients dwindled by late 2021. There are other red signals. Edward Dowd, author of the book, "Cause Unknown: The Epidemic of Sudden Deaths in 2021 and 2022," has been analyzing data on all mortality since March 2021 after hearing about many anecdotal accounts of vaccine injury.

He found a huge spike in sudden deaths spanning the fall of 2021 to early 2022 in the working age cohort corresponding to the vaccine mandate in the US for workers. People from 25 to 44 years of age experienced a dramatic 84% rise in excess mortality coinciding with mass vaccine mandates – 61,000 Americans died in the period from March 2021 to February 2022.

His findings were corroborated by studying insurance claims. Closer to home, a six-fold increase in heart attacks was observed in Mumbai in the year 2021 as observed by a critical-thinking data analyst from IIT Bombay.

As things stand, there are two contenders for the cause of the unusual health events particularly seen in young people around the world. It may be either be due to a long-term effect of having suffered from Covid-19 or due to the vaccines, or both. A scientific temperament cannot afford to support one over the other without hard evidence.

Regrettably, in the ongoing pandemic, this approach has been found lacking on the part of the WHO, the CDC, and other haloed health research institutions. Eminence-based medicine has taken precedence over evidence-based medicine. Scientists, researchers, academicians and others surrendered the scientific approach and made a beeline for their one minute of fame in the era of 24×7 news channels.

In fact scientists and haloed scientific institutions seem to have gone a step further. They have blatantly ignored hard evidence that could have guided policy and at the same time resolved the issue of whether the short-term and long-term adverse events post-pandemic are due to the natural infection or the vaccines.

In the early days of the pandemic, there was evidence that immunity after recovery from natural infection can perhaps last indefinitely. Subsequently, while studies from Israel established that natural immunity is 13 times more robust than vaccine-induced immunity, the WHO continued to ignore the evidence while recommending mass vaccination for COVID.

The global scientific consensus seems to be on the brink of another major act of omission now, or perhaps, commission. It is relentlessly promoting mass vaccination when most of the people in countries such as India have already experienced the natural infection and therefore are already well protected.

According to the evidence we have so far, vaccinating them wouldn't confer any additional benefit while will subject them to the risk of adverse events, howsoever remote the chances are. More importantly, it is missing out on the opportunity to resolve the dilemma of a sudden spike in deaths among young people across the world – whether they are due to the disease or the vaccine.

Those who have recovered from natural infection need not be vaccinated if we follow the science as well as apply common sense. It is the basic requirement of any experiment to have two different groups. In this case, we have the perfect opportunity to have a group of vaccinated people who have never suffered from the natural infection and the other group of unvaccinated people who have recovered from natural infection.

These groups could have been followed forward in time to compare the short-term and long-term adverse events and provide hard evidence of the cause-and-effect relationship. On the other hand, it appears that there is a desperate attempt to muddy the waters by eliminating the possibility of gathering this hard evidence.

The largest mass experiment in human history is being performed without a control group, reminding us of the public health quackery practised during ancient times – incredible stuff like the bloodletting that killed George Washington, the first president of the US.

Source: EmpireDiaries.com

Event Report: Whale Tank Event

"Venture Capital – Biotech Start-up Connect"

The Federation of Asian Biotech Associations (FABA), which has been offering a platform for academy- industry interactions since 2005 and career guidance, and skill development activities as part of FABA Academy from 2020, launched FABA Entrepreneurship division through organisation of Whale Tank event on 18th and 19th August in association with the leading incubation centres in the country.

The purpose of this event was to attract prospective investments in bio- startups in their growth phase and strengthen India's startup ecosystem. The event received an overwhelming response by the attendees including venture capitalists, pharmaceutical firms, leading incubators, and students. The event witnessed the participation of 200+ audience which included 60 life sciences-based startups, 12 incubation centers, 7 investors and big Pharma and Biopharma industry leaders.

The two-day event witnessed keynote addresses, the panel discussions and fireside chat with successful startups. The startups got a chance to exhibit their technologies/products virtually on both the days. Of these 14 startups were shortlisted to pitch before the investors. The event started with a keynote address on "The Biotech Startup Ecosystem in India: Opportunities and Challenges in Making a Global Impact" by Dr. Renu Swarup, Former Secretary, Dept. of Biotechnology Ministry of Science & Technology, Government of India. She explicitly brought the relevance of an event like 'FABA Whale Tank' for sustaining the growth of startups by bringing together VCs, incubation

centers and industry leaders. She further highlighted the role of startups in linking the academy and industry and driving innovation-led enterprises. Startups are at an ideal position to take the ideas, technologies from academia, validate them and transfer to the industry for commercialization. She concluded the talk by sharing the strategy of connect-converge-collaborate which is the answer to the impactful delivery of startup missions.

The fireside chat with successful startups -Bugworks, String Bio, Pandorum Technologies, Huwel Life Sciences, moderated by Uday Saxena, provided valuable tips for startups, such as how to access international grants at an early stage, the need for start-up teams to include experts in business skills, how to avoid being overly technical when pitching to an investor, how to conduct cold calls and network, and finally, how to explore tie-ups with established Pharma and Biopharma companies for further development and commercialization of their technologies.

Mr. Sanjiv Navangul, MD & CEO, Bharat Serums and Vaccines (BSV) discussed how startups would change biotech's future. His discussion of how emerging technology would change the biotech industry was both informative and inspiring. He mentioned a few promising new startups that piqued his interest, such as those developing nasal vaccinations against COVID-19 and devices for imaging breast cancer which made him excited. As for the intriguing technologies that are emerging in startups, he added that India is on the cusp of a new era of innovative startup ideas. Furthermore, he mentioned that Bharat Serums and Vaccines (BSV) is working to foster an environment conducive to startups.

Through panel discussions, the event also highlighted problems and potential solutions to sustain the ecosystem of incubators. One of the issues raised during the conference was that of the fundamental changes required at the level of incubators to support the growth phase of the successful startups. Another issue raised was the support system required for start-ups working on human subjects in terms of ethical approvals and linkages with hospitals/clinicians, which is missing in most of the incubation centers. How to teach the incubatees about regulatory aspects, legal documentation aspects, and business skills for start-up advancement represented another difficulty that was addressed. In addition, the panelists informed that the startups could benefit a lot from
the regular events hosted by BIRAC on IP, marketing and regulatory issues. Strengthening the network of incubators and start-ups around the nation was another priority.

One of the main goals of this event was to promote the startup ecosystem in the country in healthcare sector and send a clear message to the start-ups on the importance of the teamwork, collaboration with other sectors, being bold and thinking differently, having strong mentors and addressing the problems with the global agenda in mind.

For more information visit, https://biofaba.org.in/

Guestorial

Genome Mapping Techniques and its Application in Aquaculture

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Abstract:

Aquaculture is the fastest growing sector that provides highly nutritious food to mitigate global challenges such as hunger, malnutrition, medicinal therapeutics and human health. In the past few decades, the fisheries sector possesses potential threats of overfishing, anthropogenic activities, germplasm degradation, climate change and disease (viral, bacterial and parasitic). Advance genomics technology such as Next generation sequencing (NGS), Single molecule real-time sequencing (SMRT), Nanopore sequencing, Cas9-assisted targeting chromosome segments (CATCH) and quantum dot and signal amplification by exchange reaction (QD-SABER) were used to assess & prevent these challenges. In the last two decades, 594 fish genomes have been sequenced, which is 1.85% of the total reported fish species (34,000).

Genome mapping technology allows the identification of novel and causal genetic variation, sex determination, disease, biomass prediction (abundance and spawning stock biomass), andgenetic basis performance and trait determination for selective breeding programs.

What is genome mapping?

A genome contains information on all functional and non-functional DNA sequences of an organism.Genome mapping is a technique used to locate genes on a chromosome and measure the distances between them.It includes short DNA sequences regulatory sites that turn genes on and off or the genes themselves. There are two types of the genome mapping

1.Genetic mapping: it shows the location or arrangement of genes and genetic markers along the chromosomes based on how frequently they are inherited together.These maps rely on recombination and crossing over. Numerous DNA-based genetic markers such as restrictionfragment length polymorphism(RFLP), random amplifiedpolymorphic DNA (RAPD), amplified fragment length polymorphism(AFLP), se-

Based on the application and drawbacks leads to the development of the different generation of DNA sequencing platform mentioned below:

1st generation sequencing	2nd generation sequencing	3rd generation sequencing	4th generation sequencing
Sanger sequencing	Pyrosequencing (454 life sciences)	Oxford nanopore technologies (ONT)	In situ sequencing (Hi-C technology)
	Sequence by oligonucleotide ligation and detection (SOLiD)	SMRT pacific Bioscience sequencing (PacBio)	
	Bridge amplification-based sequencing (Illumina)		

quence-tagged site (STS), microsatellitesor simple sequence repeats (SSRs), and single nucleotide polymorphism(SNP) were developed to detect polymorphism between two parental lines.

2.Physical mapping: Physical mapping represents chromosomes and the physical distance between known DNA sequences (including genes) by measuring the number of base pairs (A-T, C-G) between them. Chemically staining andviewing whole chromosomes using techniques such as in situhybridization (ISH), C-banding and fiber-fluorescence in situhybridization (FISH) were used for physical mapping. These are further subdivided into three groups: (a.) Cytogenic maps (chromosomal maps) (b.) Radiation hybrid maps and (c.) Sequence maps.

Based on the application and drawbacks leads to the development of the different generation of DNA sequencing platform mentioned below:

Advance Genome mapping techniques

1. Next generation sequencing (NGS):

NGS works on sequencing by synthesis method and reversible dye-terminators allow for the detection of single bases as they are inserted into DNA strands. It directly uses genomic DNA /complementary DNA libraries for sequencing.It has numerous applications, such as transcription analysis, whole genome sequencing, methylation profiling, small RNA discovery, metagenomics, targeted region sequencing and genome wide analysis of protein-nucleic acid interactions. The basic workflow of the NGS is illustrated below (Fig. 1).

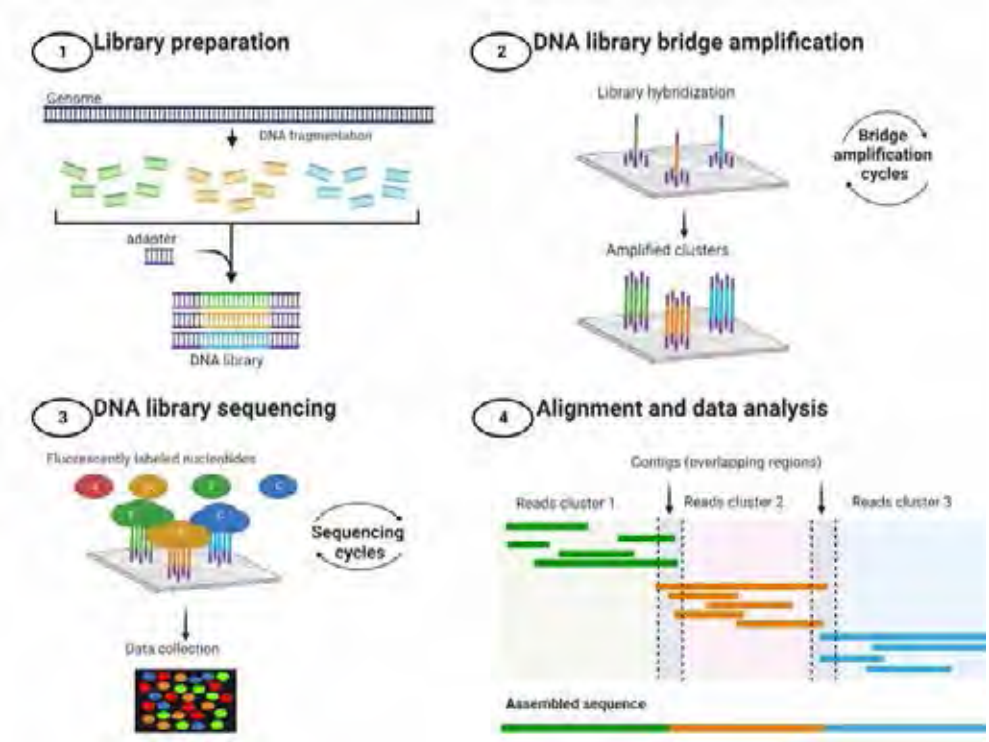

Figure 1. Basic workflow of the NGS

2. Single Molecule Real-Time sequencing (SMRT)

Single molecule real time sequencing allows sequencing from individual DNA molecules without amplifying and fragmenting the target sequence. It works on the sequencing while synthesizing principle. SMRT uses 4-color fluorescence labeled dNTPs and zero-mode waveguides (ZMW) to sequence single DNA molecules whereas the DNA template will be captured by DNA polymerase. Different bases will emit different fluorescent lights during the base pairing phase and the wavelength and peak value of fluorescent light can be used to determine the type of base entering. The phosphate group of dNTPis the place where the fluorescence signal is attached,and when the subsequent dNTP is synthesized, the phosphate group is automatically detached, ensuring detection consistency, accelerating detection, and working with the high-resolution optical detection system for real-time detection. The steps of the SMRT sequencing are presented below (Fig. 2).

- Fluorescent phospholinked labeled nucleotides are introduced into the zero-mode waveguides.
- The base being incorporated is held in the detection volumefor tens of milliseconds, producing a bright flash of light.
- The phosphate chain is cleaved, releasing the attached dye molecule.
- The process repeats.

3. Nanopore sequencing

It's a fourth-generation DNA sequencing technology developed by Oxford Nanopore Technologies Ltd. and is the most powerful method for the rapid generation of long-read sequences.Without PCR amplification or chemical labeling of the samplesingle molecule of DNA or RNA can be sequenced using nanopore sequencing.Single strands of DNA or RNA molecules are passed through a tiny protein channel (nanopore)embeddedin an electrically resistant membrane.The ion current changes as the DNA mol-

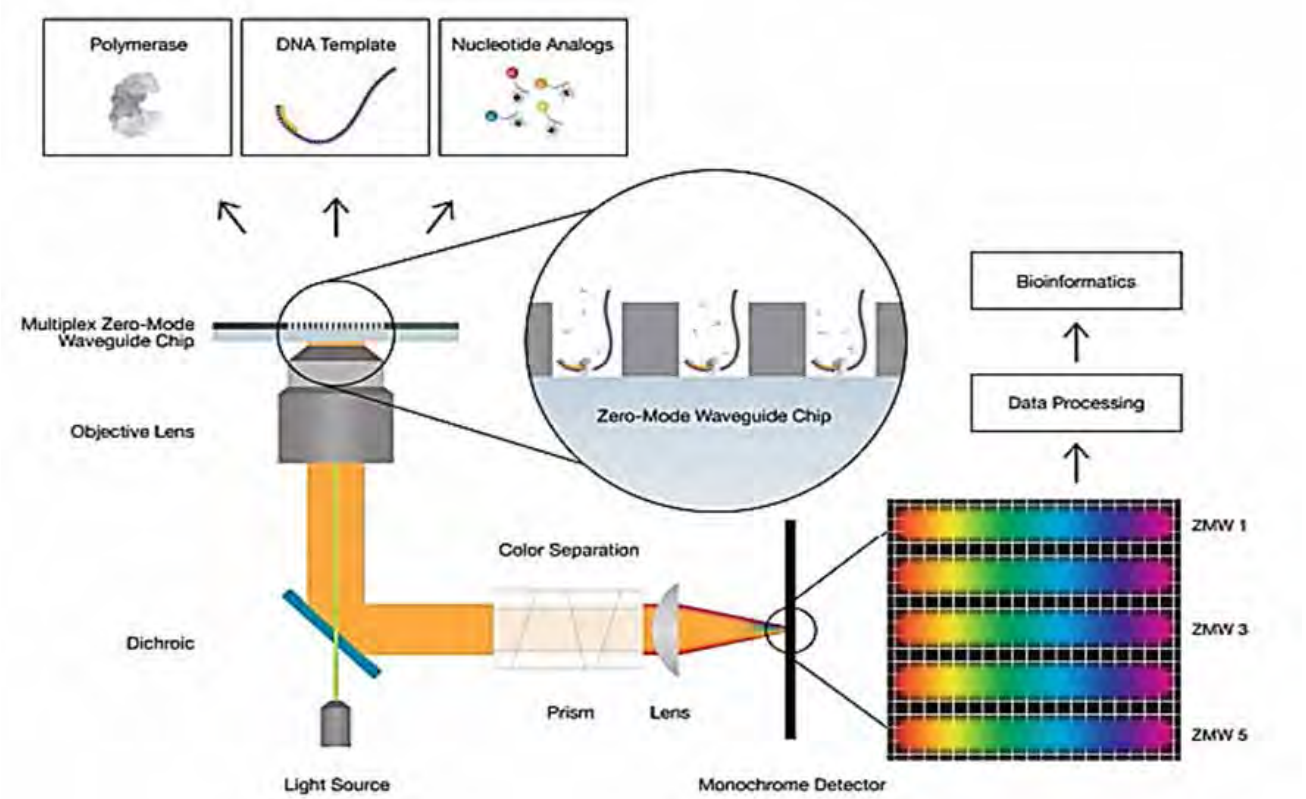

Figure 2. Steps of the SMRT sequencing

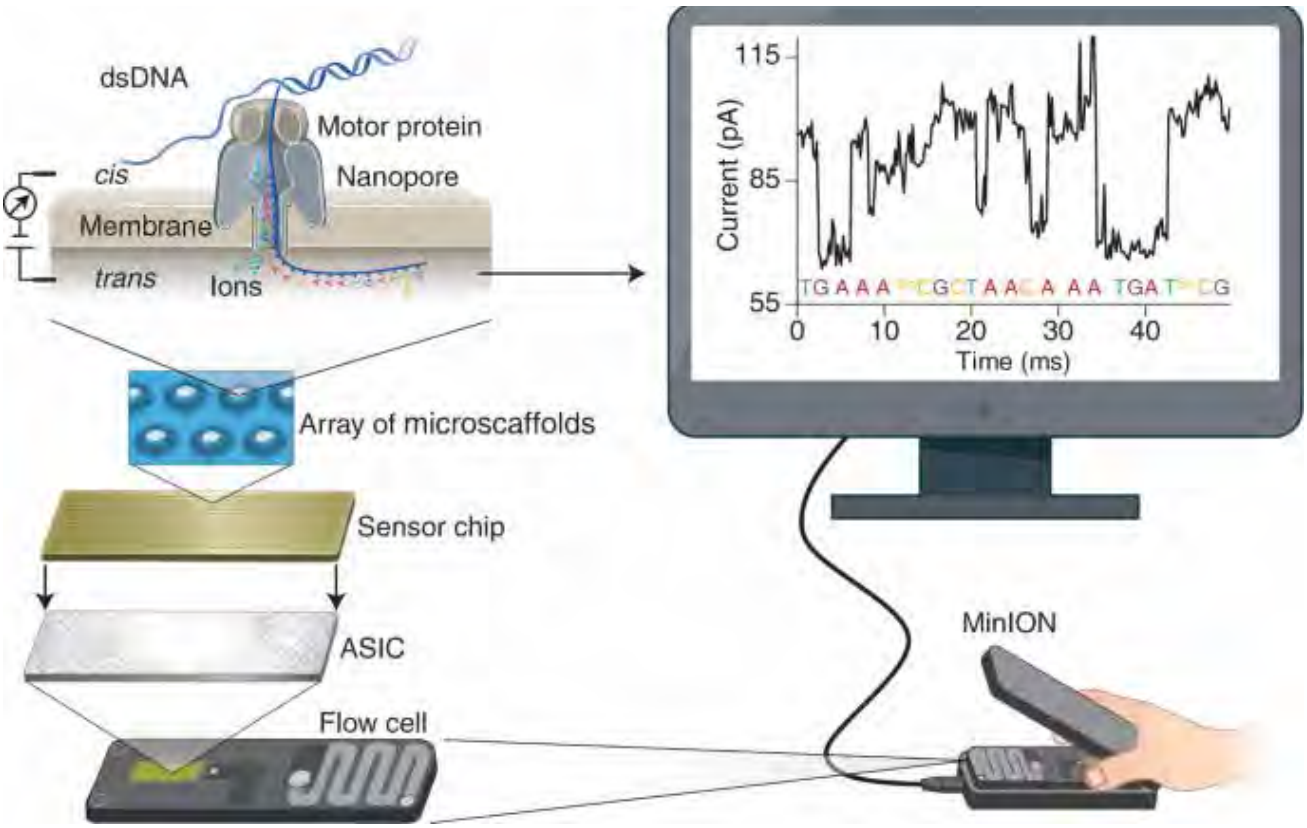

Figure 3. Schematic view of Nanopore Sequencing

ecule moves through the nanopore, which provides information on the sequence and base modifications (Fig. 3).

4. Cas9-Assisted Targeting Chromosome segments (CATCH)

For genetic analysis,enrichment of large genomic fragments was used.Intact moleculesof the target DNA are extracted, enabling for multiscale examination of both short- and long-range data.A Cas9 nuclease is guided to the site of cleavage by the sequence homology of an RNA subunit. This method relies on capturing cells in gel plugs for lysis and their high-molecular weight chromosomal DNA extracted. Then the DNA is digested invitro at two sites flanking the locus of interest using the Cas9 enzyme.Gibson assembly can be used by CATCH to efficiently clone large genomic segments. The workflow of the CATCH technique is illustrated below (Fig. 4).

5. Quantum Dot and Signal Amplification By Exchange Reaction (QD-SABER)

Recruitment of fluorescently labeled detectionoligos to the specific nucleic acid or protein targets, the regulated synthesis of long DNA concatemers from a short primer serves as an effective substrate for multiplexed and amplified signal detection in cells.So, this technology utilizes quantum dots (higher levelof brightness, photostability, and multiplexing) and the adaptability and programmability of DNA nanotechnology (such as signal amplification, and reduced antibody incubation cycles) due to unique optical properties (Fig. 5).

Application ofadvanced Genome mapping techniques

- Assessment and understanding of the molecular mechanism of abundant non-coding element divergence, phenotypic diversity, excessive gene duplications, accelerated coding

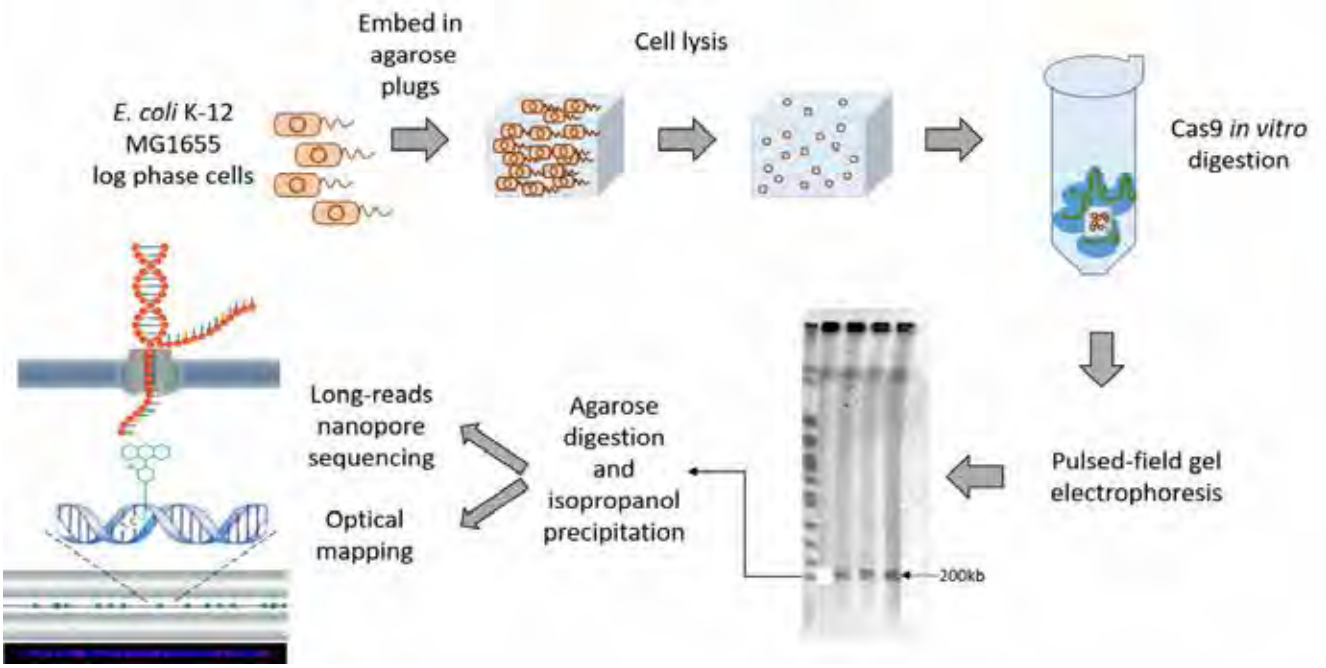

Figure 4. Workflow of the CATCH technique

sequence evolution, expression divergence associated with transposable element insertions, and regulationby novel microRNAs using genome analysis.

- Accurate identification of fish stocks for capture fish management.
- Conservation of fish genetic resources.
- Development of therapeutics based on analysis and comparison of the genome using the immune-related molecular understanding and production of disease-free/resistant fish stock.
- Genomic data is used forhow genetic and environmental factors control the formation and development of morphological traits such as growth and development.
- Whole genome sequencing data is used for the identification of sex determination and sex differentiation of potential aquaculture species.
- Transcriptomic data were utilized for the selective breeding program.
- To understand the biochemical response of fishes to climate change.
- Understanding the interaction between genotype and nutritional profile.

Conclusion

Advance genome sequencing technology have modernized fisheries and aquaculture sciences and practices. Genome sequenced data can be utilized to mitigate upcoming challenges such as disease resistance and climate change, increasing production using selective breeding programs, sexual determination and fisheries resource management. Further, this advance techniques such QD-SABER, CATCH and SMRT could be used for the genome sequencing of non-model fish species.

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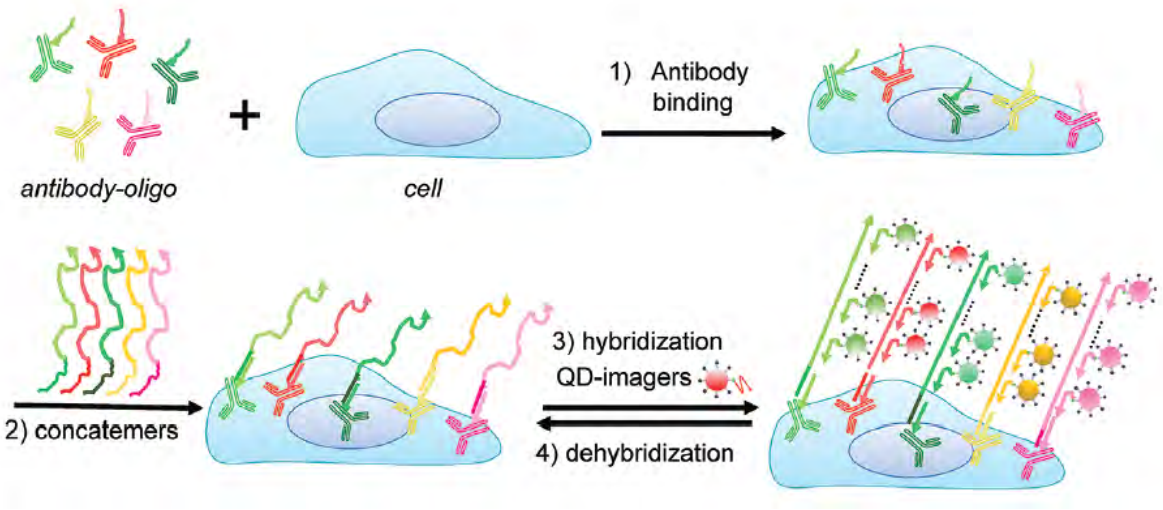

Figure 5. QD-SABER

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Featured Biotech News

Florida Republicans propose labelling WHO terrorist group

September 12, 2022

Lee County Republicans in Florida, USA have introduced several resolutions targeting the WHO. A resolution sponsored by Joe Sansone blasts US President Joe Biden for agreeing to sign the pandemic treaty.

"Back in May, the Biden administration worked with WHO and attempted to amend the treaty granting WHO the power of global Martial law and the ability to force masks, lockdowns, and vaccinations, etc., in the case of a future pandemic," Sansone told Florida Politics.

"Regarding WEF: They are much like a secular end times cult and believe the planet can't sustain the human population and appear to be implementing a controlled demolition of human civilization. Klaus Schwab brags about penetrating governments with graduates of his young global leaders' school in governments around the world."

During May's World Health Assembly, representatives across the world met to discuss the global pandemic treaty.

"In consultation with member states, the secretariat has prepared a proposal for a more equitable, inclusive and coherent global architecture from the various reviews of the global response to the pandemic. The international accord which member states are now negotiating will provide a vital overarching legal framework under which we make ten recommendations in three key areas," said WHO Director-General Dr. Tedros Ghebreyesus.

Asked about whether adopting the resolutions could be seen as taking extremist positions, Martin told Florida Politics the topics — including labelling the WHO a terrorist group — have only been raised.

Fauci admits, I knew 'draconian' lock-downs would harm kids and economy

September 23, 2022

After repeatedly downplaying the impact on children of the COVID-19 lockdowns, Dr. Anthony Fauci justified the mitigation measures at an event while acknowledging they were "draconian."

"Sometimes when you do draconian things, it has collateral negative consequences. Just like when you shut things down, even temporarily, it does have deleterious consequences on the economy, on the school children, you know that," Fauci said at the event, hosted by The Atlantic magazine.

In August, Fauci, President Biden's top health adviser, dismissed concerns about the impact of the lockdowns and school closures on children in an interview on Fox News' "Your World with Neil Cavuto."

"In retrospect doctor, do you regret that it went too far?" Cavuto asked regarding the lockdowns. " … Particularly for kids who couldn't go to school except remotely, that it's forever damaged them?"

"Well, I don't think it's forever irreparably damaged anyone," Fauci replied. He charged that "people selectively … pull things out about me."

Earlier this month, the Department of Education released a report concluding the school shutdowns and the shift to virtual learning led to "the largest average score decline in reading since 1990, and the first ever score decline in mathematics" among the nation's schoolchildren.

Last November, the American Academy of Pediatrics, the American Academy of Child and Adolescent Psychiatry, and the Children's Hospital Association declared that the pandemic-related decline in child and adolescent mental health had become a national emergency.

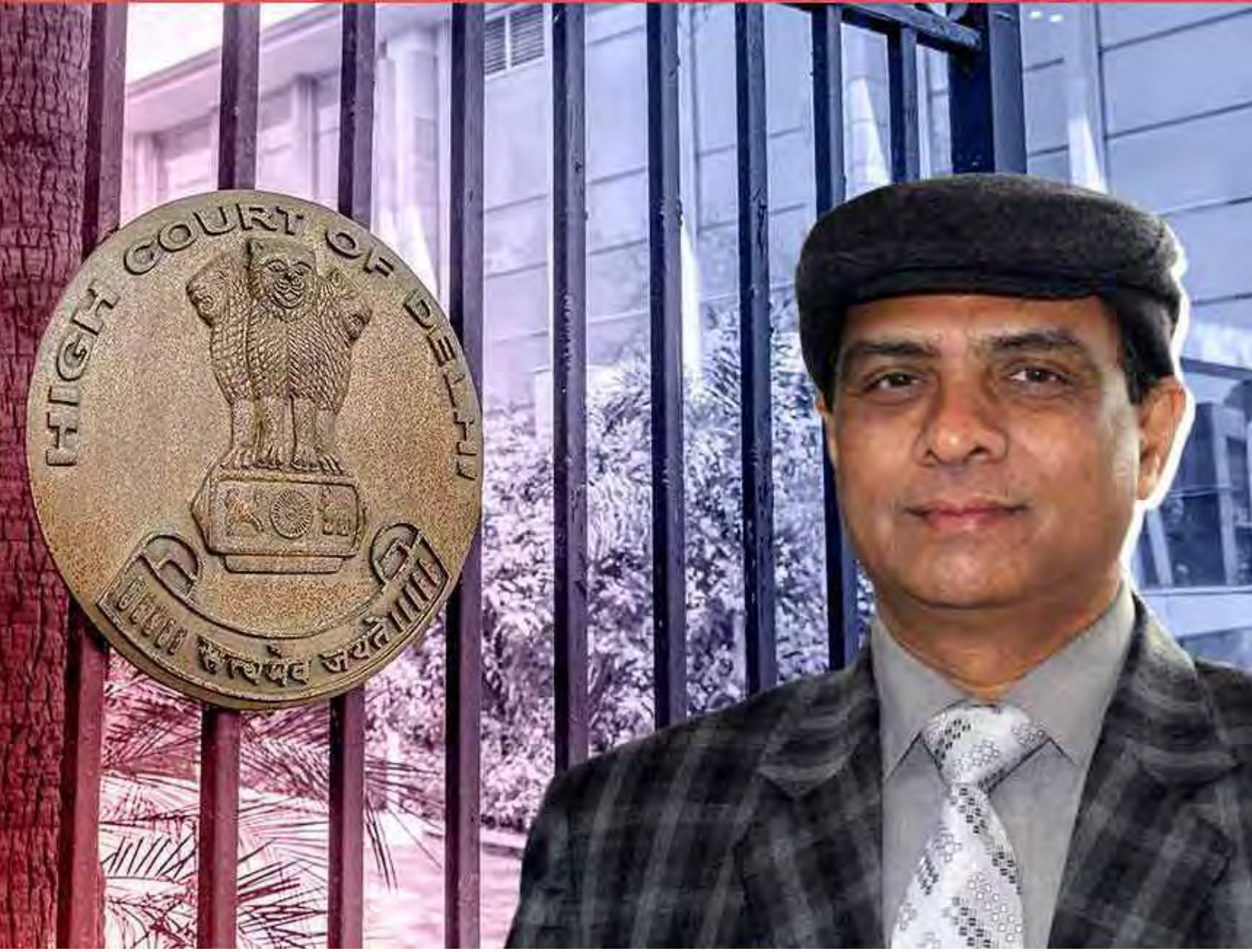
At The Atlantic Festival convention Wednesday, Fauci went on to say "you have to make a balance, when … the only way to stop something cold in its tracks is to shut things down."

Fauci prefaced his response to the question by The Atlantic editor Ross Andersen about the lockdowns by blaming "divisiveness" of "social media" for turning his guidance into controversy.

"When you have a divisiveness in society where every time you say something, you have X number of people with social media looking to attack it, that adds to the understandable confusion when you're dealing with an evolving outbreak," Fauci said.

He argued the "draconian" lockdowns, masking and vaccination was necessary because hospitals were being "overrun."

However, studies have found the lockdowns had no effect on virus spread or deaths while causing a 26% rise in excess deaths among working-age adults.



After a long fight, Delhi HC Directs School to Permit COVID-19 Unvaccinated Teacher to Join Duty

September 23, 2022

The Delhi High Court has allowed an unvaccinated private school teacher to resume his teaching duties after a report of a five-member board constituted by All India Institute of Medical Sciences (AIIMS) stated that the teacher was at a higher risk of developing an allergic reaction to the Covid-19 vaccine as compared to the general population.

A single judge bench of Justice Rekha Palli on September 22 directed a prominent private school in South Delhi to "forthwith permit the petitioner to join his duties". The court further directed the school to "release the balance salary along with all allowances payable to him after deducting 10% from the salary payable for the period between 02.11.2021 till the date of his rejoining duty" and said it should "be paid within a period of six weeks from today".

In March, the court, after taking into account the petitioner's plea that it was only after getting medi-

cal advice that he had decided not to take the Covid-19 vaccination, directed the school to pay 50% of his salary, with effect from February 2022.

The court had also asked the Delhi government to take a considered decision on the petitioner's representation seeking exemption from taking the Covid-19 vaccine.

The Delhi government after reconsideration had directed the petitioner to appear before the "concerned doctor at AIIMS to obtain conclusive medical advice as to whether he could, without any undue risk to his health, take the vaccination for Covid-19".

The plea stated that the petitioner, who is working as a PGT-Chemistry teacher, was suffering from angio immunoblastic T-cell lymphoma (involving B-cell), and was consistently advised by doctors from various medical institutions that his condition may deteriorate if he takes the vaccination as he had in the past suffered serious allergic reactions from various drugs and medications.

As there were various orders passed by the government of NCT of Delhi (GNCTD) and the District Disaster Management Authority (DDMA) making it "mandatory for all teachers to be 100% vaccinated", the petitioner was not allowed to discharge his duties as he has not been able to take the Covid-19 vaccination on account of his medical condition.

The petitioner pointed out that though he was initially granted an exemption by the Delhi government from taking any Covid-19 vaccination, this was unilaterally withdrawn on October 29, 2021.

Delhi HC also directed the school to pay 50% of his salary, with effect from February 2022.

The five-member board from AIIMS, in its report dated September 8, observed, "As per documents provided by…, he is suffering from following medical ailments i.e. Angioimmunoblastic T-Cell Lymphoma currently clinically in remission and not on any immunosuppressive chemotherapy.

He is also suffering from Type 2 Diabetes Mellitus with a history of suspective drug induced maculopapular eruptions and documented urticarial vasculitis/ panniculitis, while on treatment of lymphoma.

Based on careful scrutiny of available records, the board members opined that, in view of his past history of maculopapular drug eruption I urticarial vasculitis/ panniculitis, he may be at higher risk of developing allergic reaction due to Covid vaccination as compared to general population."

Based on this report, the deputy director of education (southwest district) passed an order on September 20, acceding to the petitioner's request for exemption from Covid-19 vaccination "as a special case, with a condition that he shall observe Covid-appropriate behaviour and guidelines, as issued by the appropriate authorities from time to time".

During the course of the hearing, the counsel for the petitioner assured that the "petitioner will ensure that he always wears the mask while in the school premises, and will also observe Covid-19 appropriate behaviour and guidelines".

Kerala HC directs NDMA to frame policy for identifying deaths due to COVID-19 vaccine

September 05, 2022

The Kerala High Court has directed the National Disaster Management Authority (NDMA) to "expeditiously" frame a policy for identifying those who died due to after-effects of COVID-19 immunisation and compensating their dependents. Justice VG Arun directed the NDMA to do the needful as expeditiously as possible within three months of its order dated September 1.

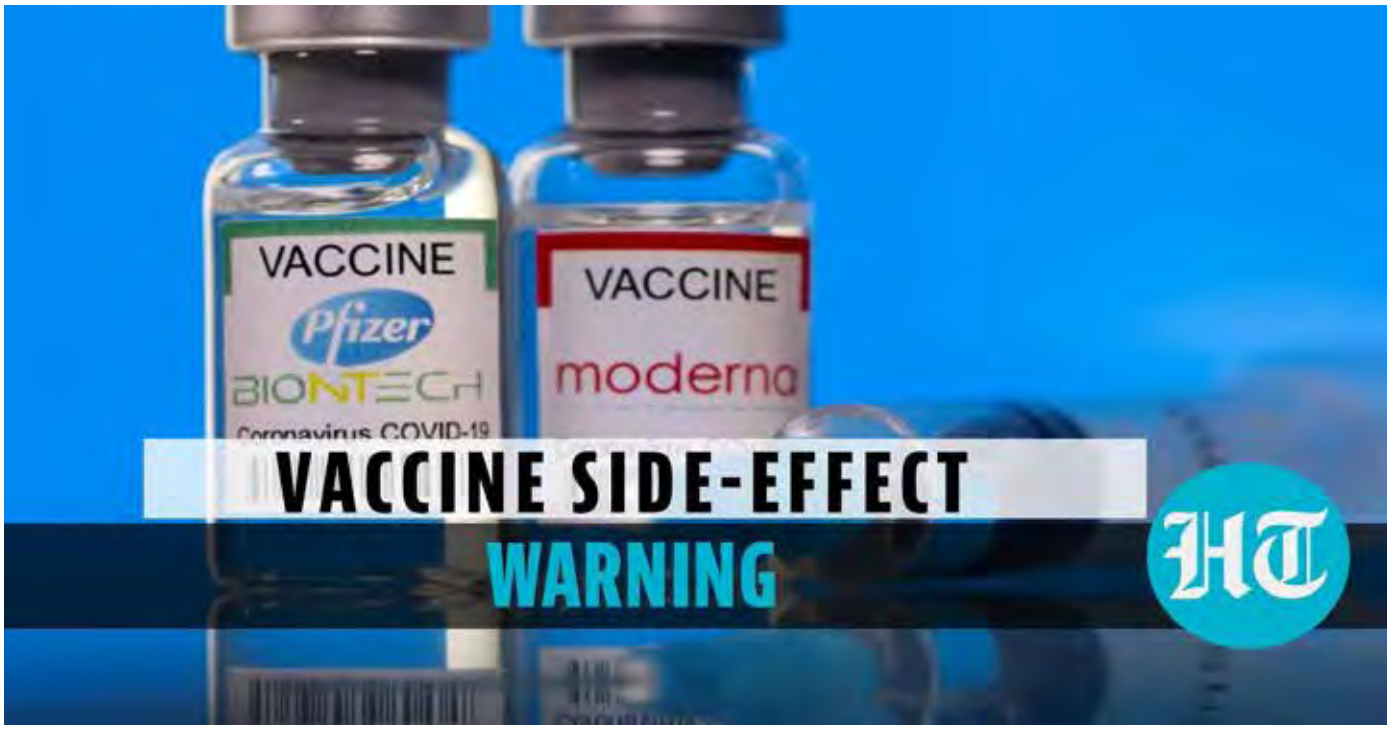
The direction was issued after Justice Arun said that he himself, in his current jurisdiction, has come across three such cases which claimed that a person who had undergone COVID-19 immunisation had succumbed to the after-effects of vaccination. "Therefore, even if the numbers are very few, there are instances where people are suspected to have succumbed to the after-effects of immunisation. In such circumstances, respondents 2 (NDMA) and 8 (Ministry of Health) are bound to formulate a policy for identifying such cases and compensating the dependents of the victim," the court said.

It further directed the NDMA to formulate a policy to identify the cases of death due to the effects of COVID-19 vaccination. "The second respondent (NDMA) is hence directed to formulate policy/guidelines for identifying cases of death due to the after-effects of COVID-19 vaccination and for compensating the dependents of the victim. The needful in this regard shall be done as expeditiously as possible and at any rate within three months."

The court also noted in its order that the documents on record prima facie show that the petitioner's husband died due to adverse events following immunisation. The order came after the Union government informed the court that no such policy has been formulated so far.

The court was hearing the widow's plea seeking a direction to the respondents (Union and state government authorities) to grant her and her children ex-gratia compensation, which was offered to families of those who succumbed to COVID-19.

International Study Shows Pfizer & Moderna Vaccines 'Associated with Increased Risk of Serious Adverse Events'



September 02, 2022

International researchers have found that major Covid-19 vaccines pose an increased risk of "serious adverse events" that surpasses the "risk reduction for Covid-19 hospitalization."

The scientific researchers are from Stanford University, UCLA, Louisiana State University, the University of Maryland School of Pharmacy, Navarre Health Service in Spain, and Bond University in Australia.

https://www.sciencedirect.com/science/article/pii/S0264410X22010283

"We sought to investigate the association between FDA-authorized mRNA COVID-19 vaccines and serious adverse events identified by the Brighton Collaboration, using data from the phase III randomized, placebo-controlled clinical trials on which authorization was based," the researchers state. "We then use the results to illustrate the need for formal harm-benefit analyses of the vaccines that are stratified according to risk of serious COVID-19 outcomes, as well as contextualize the findings against post-authorization observational data."

The scientific findings suggest that the risk-benefit analysis is trending against mass inoculation for Covid-19 due to the 'increased risk of serious adverse events' in examined populations.

"Pfizer and Moderna mRNA COVID-19 vaccines were associated with an increased risk of serious adverse events of special interest, with an absolute risk increase of 10.1 and 15.1 per 10,000 vaccinated over placebo baselines of 17.6 and 42.2 (95% CI -0.4 to 20.6 and -3.6 to 33.8), respectively," the researchers found. "Combined, the mRNA vaccines were associated with an absolute risk increase of serious adverse events of special interest of 12.5 per 10,000 (95% CI 2.1 to 22.9)."

"The excess risk of serious adverse events of special interest surpassed the risk reduction for COVID-19 hospitalization relative to the placebo group in both Pfizer and Moderna trials (2.3 and 6.4 per 10,000 participants, respectively)," the authors add.

Government wrong to 'empower scientists' on Covid lockdowns, says Rishi Sunak

August 25, 2022

Conservative leadership hopeful Rishi Sunak has claimed scientists were handed too much power during the Covid pandemic as he attacked the government's approach to lockdowns.
The former chancellor said he "wasn't allowed to talk about the trade-off" of lockdowns during the early phases of the crisis – condemning the "fear narrative" which drove public messaging.
Mr Sunak suggested Boris Johnson let lockdown go on too long, and claimed the Scientific Advisory Group for Emergencies (Sage) group advising the PM edited its minutes to hide dissenting opinions.
"The script was: 'oh there's no trade-off, because doing this for our health is good for the economy',." Sunak said. He added that if the 'trade-offs had been acknowledged, different decisions would have been made on things like schools.

Sunak said during one meeting he tried to voice his opposition to closing schools, saying he got "very emotional about it". The former chancellor added: "I was like: 'Forget about the economy – surely we can all agree that kids not being in school is a major nightmare.'

As chancellor from February 2020 to July 2022, Mr Sunak established furlough and the Eat Out to Help Out scheme, and has previously questioned the extent of the restrictions imposed to curb the virus.

In his Spectator interview, he said the negative impacts of lockdowns on society were "never part" of internal discussions, adding meetings were "literally me around that table, just fighting".
Ministers were also told not to discuss the potential downsides in interviews, he added.

Asked if more frank discussions would have enabled Britain to avoid lockdowns, he said: "I don't know, but it could have been shorter. Different. Quicker."

FDA Greenlights New COVID-19 Boosters Despite Lack of In-Human Data

September 01, 2022

Paul Offit, M.D., member of the FDA's vaccine advisory committee and vaccine expert at Children's Hospital of Philadelphia, told BioSpace that the data presented in June before the vaccines advisory committee was done the right way. While it increased immunogenicity by 1.5 to 1.75-fold in mice given vaccines targeting BA.1, it was "not likely to be a clinically meaningful benefit" in people, he said.

The FDA authorized new Omicron-specific booster shots developed by Pfizer-BioNTech and Moderna despite a lack of human data.

The new vaccine boosters are bivalent, containing messenger RNA (mRNA) that codes for both the spike protein of the original wildtype Wuhan strain and BA.1 or BA.4 and BA.5, which have identical spike proteins. There are no human data for the boosters, and some experts expressed concern.

In a meeting with the FDA's vaccine advisory committee in June, the companies presented data demonstrating the boosters had side effects like those of the original vaccines, primarily site injection soreness and fatigue. They also stated the boosters elicited strong antibody responses to the original strain and Omicron BA.1, as well as to BA.4 and BA.5, although the response was lower in BA.4 and BA.5 than in BA.1.

Offit also expressed concern over the lack of any human data for either of the bivalent vaccines in humans, which he said could be gathered in about a month. He asserted that the data does not represent a need for booster doses with the bivalent and Omicron-specific vaccines to prevent hospitalization in an otherwise healthy population, but might in the elderly or immunosuppressed.

Influenza vaccines, for example, are reformulated each year and don't undergo new clinical trials unless the vaccine makers significantly modify the way they manufacture the vaccines. However, Offit said, "We've known exactly what the flu shots do since the 1940s. But the mRNA vaccines have only been around for less than two years and we have no data in humans on the bivalent vaccines. We can't assume. The history of medical innovation would suggest we should be cautious."

Still, not all experts are concerned. Leif Erik Sander, M.D., an infectious disease expert at the Charité University Hospital in Berlin, told Science the changes to the mRNA are minor and that an updated vaccine created as quickly as possible is "an ethical issue," adding, "We need to allow people to protect themselves from a virus that we can't fully control."

Covid Vaccines Up to 100 Times More Likely to Cause Serious Injury to a Young Adult Than Prevent It, Say Top Scientists

September 13, 2022

University COVID-19 vaccine mandates are unethical because the vaccines are up to nearly 100 times more likely to cause a person of student age serious injury than prevent him or her from being hospitalised with COVID-19, a new study has concluded.

The study, whose authors include Dr. Kevin Bardosh, a recipient of funding from the pro-vaccination Wellcome Trust led by Sir Jeremy Farrar, and Dr. Tracy Beth Høeg of the Florida Department of Health, presents a risk-benefit assessment of booster vaccines among people of student age and provides five ethical arguments against mandates.

The researchers estimate that 22,000-30,000 previously uninfected adults aged 18-29 must be boosted with an mRNA vaccine to prevent just one COVID-19 hospitalisation. In the study, which is currently undergoing peer-review, the authors analyse CDC and reported adverse event data and find that booster mandates are likely to cause a net expected harm. They estimate that for every COVID-19 hospitalisation prevented in previously uninfected young adults, 18 to 98 serious adverse events will occur, including 1.7 to 3.0 booster-associated myocarditis cases in males, and 1,373 to 3,234 cases of serious injury which interferes with daily activities.

The authors add that given the high level of natural immunity following infection now present in the population, the actual risk-benefit profile is even less favourable.

On the basis of this evidence they argue that university booster mandates are unethical because:

- no formal risk-benefit assessment exists for the age group;
- vaccine mandates may result in a net expected harm to individual young people;
- mandates are not proportionate: expected harms are not out-

weighed by public health benefits given the modest and transient effectiveness of vaccines against transmission;

- U.S. mandates violate the reciprocity principle because rare serious vaccine-related harms will not be reliably compensated due to gaps in current vaccine injury schemes; and
- mandates create wider social harms.

They consider counterarguments, such as a desire for socialisation and safety, and show that such arguments are weak and lack scientific and ethical support.

The authors include Dr. Vinay Prasad of the University of California and Dr. Martin A. Makary and Dr. Stefan Baral of Johns Hopkins University. A previous intervention in February by many of the same authors, published in BMJ Global Health, took a strong ethical stance against vaccine coercion in the form of mandates and passports.

It's been clear for some time that the cost-benefit assessment of the vaccines will not be favourable for young people. But with leading scientists, including some funded by pro-vaccination organisations like the Wellcome Trust, now putting the case in top journals, hopefully the message will get through to politicians and administrators, especially in America, who continue to impose vaccine requirements on young adults.

Michigan State University to Send Plant Seeds to Space

August 31, 2022

Science has done it again. Instead of planting seeds in the ground, Michigan State University scientists are sending them to outer space. The Arabidopsis thaliana seeds inside Michigan State's plant biology laboratories are ready for a first-class flight to infinity and beyond.

"So the seeds that are flown on Artemis 1 from our lab are more nutritious, and they will hopefully be able to give us new knowledge to be able to use in the future to engineer plants for astronauts for long term space exploration," said graduate research assistant Joanne Thomson.

Thomson and distinguished professor of Plant Biology, Federica Brandizzi, are studying how plants respond to flight environments when traveling to space.

"Our goal here is to make sure that we can provide a sustainable environment to humans in other organisms that will live in space. Eventually, we want to have self-sustained environments that can provide nourishment to the astronauts," Brandizzi said.

The seeds will spend six weeks in space inside plastic tubes. When the seeds come home, Brandizzi and Thomson will see how the plants that grew from the seeds perform.

Anil Ambani's son lashes out against lockdowns; says it is only about control not health

September 1, 2022

Anmol Ambani, the eldest son of industrialist Anil Ambani, has lashed out against lockdowns being imposed amid the surge in COVID-19 cases, saying such restrictions do not concern health but control and that they destroy the very backbone of the society and economy.

The 29-year-old former executive director of Reliance Capital Ltd in a series of tweets lambasted the semi-lockdown rules hurting small businesses and daily wage earners.

"Professional 'actors' can continue shooting their films. Professional 'cricketers' can play their sport late into the night. Professional 'politicians' can continue their rallies with masses of people. But YOUR business or work is not ESSENTIAL. Still don't get it?" he said in a tweet.

He had in the past too voiced opposition to such restrictions and retweeted videos and comments denouncing them.

"What does essential even mean? EACH INDIVIDUALS WORK IS ESSENTIAL TO THEM," he said tweeting with hashtag #scamdemic. Lockdowns, he said, are key in "continuing and enabling greatest wealth transfer in human history." "The mistake is that the people think this is simply inefficient governance. it's not. It's a coordinated, thought out set of policies designed to enable a new world order to be brought in," he said.

While Maharashtra has shut all non-essential services through April, the national capital has started night curfew. The specter of another lockdown is now the biggest headwind for local businesses. "These lockdowns were never about and have nothing to do with health," Ambani tweeted. "They destroy the very backbone of our society and economy, from the daily wage workers, self-employed and SMEs to the restaurants and dhabas, fashions and clothing stores."

Lockdowns also destroy and diminish health by closing gyms, sports complexes and playgrounds, he said, adding that exercise, sunlight and fresh air are some of the strongest pillars of good health and strong immunity. "And don't forget the psychological damage this is doing to children who are growing up through this madness and are being programmed to believe this is normal," he said.

Stating that lockdowns worsen inequality, he said shutting down of brick-and-mortar stores benefits digital and e-commerce companies, farmland is corporatised and colonised and data and privacy are sold to new-

लॉकडाउन के खिलाफ अनिल अंबानी के बेटे का जोरदार प्रहार

नई दिल्ली, प्रेट्र : कोरोना संक्रमण के बढ़ते मामलों के बीच शुरू हुए लॉकडाउन के नए दौर के खिलाफ उद्योगपति अनिल अंबानी के बड़े बेटे अनमोल अंबानी ने जोरदार प्रहार किया है। अनमोल ने कहा कि नए प्रतिबंधों का आम लोगों के स्वास्थ्य से कुछ लेना नहीं है, बल्कि इसका मकसद लोगों के जीवन को नियंत्रित करना है। ये पाबंदियां समाज और अर्थव्यवस्था के आधारभूत ढांचे को ध्वस्त कर देंगी।

रिलायंस कैपिटल लिमिटेड के कार्यकारी निदेशक रह चुके 29 साल के अनमोल ने एक के बाद एक ट्वीट में लॉकडाउन जैसे सख्त नियमों की आलोचना की, जिससे छोटे व्यवसाय और दैनिक वेतन भोगियों को नुकसान हो रहा है। अनमोल अंबानी ने एक ट्वीट में कहा, 'पेशेवर अभिनेता अपनी फिल्मों की शूटिंग जारी रख सकते हैं, पेशेवर क्रिकेटर देर रात तक खेल सकते हैं, नेता भारी भीड़ के बीच अपनी रैलियां कर सकते हैं। लेकिन आपका व्यवसाय या कार्य आवश्यक नहीं है। आप उसे नहीं कर सकते।' स्कैमडेमिक हैशटैग के साथ

विरोध

- कहा, अभिनेता शूटिंग और नेता रैलियां कर सकते हैं, आप अपना कारोबार नहीं
- प्रतिबंधों का मकसद आपके जीवन के हर पहलू को नियंत्रित करना, इनका स्वास्थ्य से लेना-देना नहीं

अनमोल ने ट्वीट किया, 'आवश्यक का क्या मतलब है? हर व्यक्ति का काम उसके लिए आवश्यक है।' कहा कि लॉकडाउन मानव इतिहास में धन हस्तांतरण को जारी रखने और सक्षम बनाने में महत्वपूर्ण है। उन्होंने कहा, 'गलती यह है कि लोगों को लगता है कि यह केवल अक्षम शासन है। ऐसा नहीं है। यह एक समन्वित, सोची-समझी नीतियों का सेट है, जिसे एक नई विश्व व्यवस्था को लाने के लिए डिजाइन किया गया है।' अनमोल ने कहा, 'यह स्वास्थ्य के बारे में नहीं है। यह नियंत्रण के बारे में है। मैं समझता हूं कि हम सभी अनजाने में बहुत भयावह योजना में फंसते जा रहे हैं। जो आपके जीवन के हर पहलू को नियंत्रित करने के लिए है।'

age empires.

"This is not about health. This is about control, and I would think most of us are unknowingly and unconsciously falling into the trap of a much larger and very sinister plan," he said. "To control every aspect of your life – A technocracy exactly like China – A totalitarian bio-surveillance fascist state-controlled from the outside."

Anmol, however, said he has faith in India and its people. "That we will resist this global coup and not let our country get colonised even more. All we need to do is wake up to the truth. Stand for love, peace, unity and compassion."

Anmol tweeted about inequalities that lockdowns create. "It's no coincidence that the losses of the common man are gains of the wealthiest," he said, adding that lockdowns accelerate this "wealth transfer."

He later retweeted one Jeremy R Hammond comment that "Note that by their own definition, #lockdown measures including stay-at-home orders and business closures are 'a crime against humanity' and 'an attack on the civilian population.'"

On April 5, he commented on a media report of migrant workers in Mumbai planning to return to their native places after lockdown, saying, "Planned destruction of the economy, livelihoods and lives. This is new age colonisation and very few realise it. Classic IMPERIALISM. Colonisation of your mind, body and soul. Take back your power. Go back to your roots."

On April 2, he said, "the plan is to perpetually keep us in a state of emergency. It seems like this festival week will be used to impose further totalitarian measures. Testing is only being increased to justify more lockdowns and puch the quackcines. Resist."

"The more you listen/obey, propagate the fear, the longer this will carry on," he said on that day.

On March 27, he said, "This lockdown nonsense will keep happening if you don't resist. It's just a control tactic and has nothing to do with your health. 'Cases', which are meaningless in the first place, are being manipulated through CT value and this will be unending till you say NO."

Indian Scientist Wins Global Award for Creating World's First Biofortified Pearl Millet

Dr Mahalingam Govindaraj, an agricultural scientist has won the Norman E Borlaug Award for Field Research and Application 2022. This award is for his efforts to develop a biofortified pearl millet (bajra) that is rich in iron and zinc.

Dr Govindaraj is a Senior Scientist for Crop Development at HarvestPlus and the Alliance of Bioversity International and International Center for Tropical Agriculture (CIAT).

In 2014, he released Dhanashakti, which is the world's first biofortified pearl millet.

Biofortification is a method of breeding crops to increase their micronutrient content. As per a statement by the World Food Prize Foundation, 200 grams of Dhanashakti provides women with more than 80 per cent of the

recommended daily iron allowance, while regular bajra varieties only provide 20 per cent.

More than 120,000 farming households grow Dhanashakti in India today. He has been involved in developing more than ten high-iron and zinc pearl millet varieties. These varieties are also being grown in Kenya, Zimbabwe, Sudan, Niger, Nigeria and Senegal. It is estimated that by 2024, more than 9 million people in India will consume iron and rich bajra, leading to better nutrition.

Hailing from a farming family in Tamil Nadu, Dr Govindaraj's love for farming started at a young age. He was a first-generation graduate.

"I was raised in the south of India where the majority of the crop was rice. My family had been farming for many years; I was the first in my family to go all the way through school and graduate from college. I loved studying science and felt drawn to researching how scientific methods could have a positive impact on agriculture. From the outset, I was fascinated by breeding and genetics and the possibilities of growing crops beyond rice, which could thrive in more challenging environments than the wetlands where I grew up," said Dr Govindaraj

He got his Bachelor of Science degree from the Agricultural College and Research Institute, Killikulam, Tamil Nadu and Master of Science and Doctorate degrees in plant breeding and genetics from Tamil Nadu Agricultural University.

He worked as a CGIAR researcher at the International Crops Research Institute for the Semi-Arid Tropics (ICRISAT) from 2011 until 2021.

While working on Dhanashakti, he also convinced the Indian Council of Agriculture Research (ICAR) to include minimum iron and zinc standards in their national cultivar release policy.

Through his efforts, pearl millet became the first crop in which minimum levels of zinc and iron were mandated in 2018.

He says he is very happy to receive this award as Norman E Borlaug was a big influence on his work. "His work on the importance of local circumstances on major crops motivated my research from the very beginning. I was always very inspired by the quote from Norman E. Borlaug who said: 'Food is the moral right of all who are born into this world'," said Govindaraj

US Senator Rand Paul threatens to investigate royalties to Dr Fauci, other officials

September 14, 2022

Sen. Rand Paul, accused government health officials of taking a wrong approach in evaluating COVID-19 vaccines by failing to take into account people's previous infections.

The Kentucky Republican then implied that there could be a reason for this. Stating that government vaccine committee members have not disclosed what, if any, royalties they have received from companies that make the vaccines, Paul said that if the GOP takes control of the Senate in November's midterm elections they will investigate the matter.

"We've been asking you and you refused to answer whether anybody on the vaccine committees gets royalties from the pharmaceutical companies," Paul said to Dr. Anthony Fauci during a Senate Health, Education, Labor and Pensions Committee hearing. "I asked you last time, and what was your response? We don't have to tell you. We've demanded them through the Freedom of Information Act. And what have you said? We're not going to tell you. But I tell you this, when we get in charge, we're going to change the rules and you will have to divulge where you get your royalties from, from what companies, and if anybody in the committee has a conflict of interest, we're going to learn about it. I promise you that."

Fauci responded by saying that those committees are advisory committees with the Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA), yet Paul keeps asking about him.

Paul responded by saying that Fauci himself has refused to say which companies, if any, gave him royalties, or paid royalties to other scientists.

"They are not my committees," Fauci reiterated, without addressing Paul's claim that Fauci himself has not been transparent.

The discussion of royalties from pharmaceutical companies stemmed from Paul's claim that Fauci and other officials were not following established science because they were ignoring the effects of COVID-19 infections when looking at vaccines. He began his segment by showing an interview Fauci gave in 2004, in which he said

regarding the flu that "the best vaccination is to get infected yourself."

Paul asked Fauci why that same idea does not appear to be reflected in the government's approach to COVID-19.

"Currently, antibody surveys show that 80 percent of children, approximately 80 percent of children, have had COVID, and yet there are no guidelines coming from you or anybody in the government to take into account their naturally acquired immunity," the senator said, adding that death rates from COVID-19 are similar "if not less than that" of the flu.

"So when we look at this, we wonder, you know, why you seemed to really embrace basic immunology back in 2004, how you or why you seem to reject it now," Paul said.

Fauci denied rejecting basic immunology and said he "never denied that there is the importance of the protection following infection." Still, he said the FDA and CDC support the idea that "vaccination following infection gives an added extra boost."

The problem, Paul said, is that "almost none of your studies from the CDC or from the government have the variable of whether or not you've been previously infected." "If you ignore whether they've been infected, you're ignoring a vaccine, basically," he added.

HC asks Mumbai civic body under which law it fined people for not wearing masks

September 20, 2022

The Bombay High Court asked Mumbai's civic body to explain the provisions of law under which it had made masks mandatory and fined people for not wearing them during the COVID-19 pandemic.

A Division Bench of Chief Justice Dipankar Datta and Justice Madhav Jamdar was hearing two petitions seeking a refund of fines collected by the Brihanmumbai Municipal Corporation (BMC) from people who violated the mask rule. The pleas also sought a probe against former Chief Minister Uddhav Thackeray for alleged misappropriation of public funds during purchase of vaccines and for forcing people to get vaccinated during the pandemic.

Maharashtra's counsel S.U. Kamdar informed the court that the Supreme Court had recently noted that the vaccination drive by the Centre was not arbitrary and justified given the pandemic. Therefore, the Thackeray government cannot be questioned and prosecuted for the same.

The court said, "If a notification was issued by the BMC that in order to contain the pandemic, people have to wear masks and a fine would be imposed for not wearing them, then it was for achieving greater good and the court will not interfere."

However, the court also directed BMC to address the court on the Epidemic Diseases Act, under which the government has power to take special measures during an epidemic. The Bench posted the matter for further hearing after two weeks.

Adverse Effects of the Pfizer Vaccine Covered Up by the Israeli Ministry of Health

September 20, 2022

The Israeli MOH had no adverse events reporting system for the entire year of 2021. They commissioned a research team to analyze the reports from a new system implemented on December 2021.

A leaked video reveals that in June, the researchers presented serious findings to the MOH, that indicated long-term effects, including some not listed by Pfizer, and a causal relationship. The Ministry published a manipulative report, and told the public that no new signal was found.

The speaker is Prof. Mati Berkowitz, a pediatric specialist, head of the Clinical Pharmacology and Toxicology unit at Shamir Medical Center, and head of the research team appointed by the Israeli Ministry of Health (IMOH) to examine the safety of the COVID-19 vaccine.

This crucial study was based on a new adverse event reporting system the MOH launched in December 2021 – 12 months AFTER rolling out the vaccines to the public, as the system was implemented in December 2020, as they now officially admit, was dysfunctional and did not allow an analysis of the data.

In an internal Zoom meeting in early June, the recording of which was leaked to the press, Prof. Berkowitz warned MOH senior officials that they should think carefully how to present his study's findings to the public, otherwise they may be sued, since they completely contradict the MOH's claims that serious side effects are rare, short-term and transient.

After analyzing the reports received over a period of 6 months, the research team found that many serious side effects were in fact long-term, including ones not listed by Pfizer, and established causal relations with the vaccine.

Yet, instead of publishing the findings in a transparent manner to the public, the MOH withheld the findings for nearly two months, and when it finally released an official document, it misrepresented and manipulated the findings, minimizing the extent of reports, and stating that no new adverse events ("signals") were found, and that the events that were detected were not necessarily caused by the vaccine, even though the researchers themselves said the exact opposite.

In early June, the researchers presented their findings to MOH senior officials, including Dr. Emilia Anis, head of the MOH's epidemiological department. Here are their main findings and points:

New signals – The research team identified and characterized side effects not listed by Pfizer, including neurological side effects such as hypoesthesia, paresthesia, tinnitus, and dizziness; back pain; and digestive system symptoms in children (abdominal pain).

Long-term events – The research team repeatedly stressed during the discussion that their findings indicate that, contrary to what we were told so far, in many cases, serious adverse events are long-term, last weeks, months, a year, or even more, and in some cases – are ongoing, so that the side effect still lasted when the study was over. These include menstrual irregularities and various neurological side effects, muscle-skeletal injuries, GI problems, and kidney and urinary system adverse events.

Manipulating the numbers – In order to promote the narrative of "rare adverse events," the MOH divided the number of reports received with a denominator of the total number of doses given in Israel for the entire year and a half since the beginning of the vaccine rollout – ~18 million, hiding the fact that they only instituted the system in December 2021, and that the analysis was done on reports received during the 6 months until May 2022, from one small HMO.

This ignores the known fact that such passive reporting systems cover only a fraction of the actual events. That would still be true even if the system was operational throughout the entire vaccination period and used by all HMOs (which of course is not the current case). This manipulation – using the denominator of the total doses, was repeated in each of the categories of the side effects in the report.

Furthermore, it turns out that in order to downplay the rate of reports on menstrual irregularities, the MOH used a denominator of the total number of all adult doses – ~16 million – and thus, absurdly, included men in the equation of how common menstrual irregularities are.

Global implications

The discussion exposed in the leaked video has far-reaching and worrying implications at a global level. While Israel is a relatively small country, it was dubbed "the world's laboratory." The eyes of much of the world were on it, and the FDA and other regulators have repeatedly cited its experience with the vaccine as a basis for policy-making, including for boosters and mandates and much else.

So if Israel did not in fact have a functioning adverse event monitoring system in place and its data was a fiction, and even if when it did launch a proper monitoring system a year too late, with analysis of the system's findings completely ignored and withheld – what was the FDA really relying on? What were all those regulators relying on?

India's GEAC Approves Field Trials of GM Cotton and Maize

September 21, 2022

The confined field trials of genetically modified (GM) herbicide tolerant cotton and maize in India have been approved by the states of Haryana and Karnataka and by the Genetic Engineering Appraisal Committee (GEAC) under the Ministry of Environment, Forest and Climate Change (MoEF&CC).

Following receipt of the No Objection Certificate (NOC) from the Governments of Haryana and Karnataka, the GEAC cleared the proposals submitted by Rallis India Limited to conduct BRL-1 (1st and 2nd year) field trials of two GM stacked cotton (MLS2154 x MLS4301x MLS2531 and MLS2154 x MLS4301) to evaluate resistance against Helicoverpa armigera and Spodoptera litura and tolerance to glyphosate, and GM stacked maize MLS10101 x MLS13621 to evaluate resistance against S. frugiperda and tolerance to glyphosate during 2022-23 and 2023-24 at two trial locations amongst the proposed sites, namely, University of Agricultural Sciences, Dharwad, Karnataka; University of Agricultural Sciences, Raichur, Karnataka; and Chaudhary Charan Singh Haryana Agricultural University, Hisar, Haryana per year was recommended by the committee subject to a number of conditions.

The Review Committee on Genetic Manipulation (RCGM) may issue the permit letters and monitor confined field trials to ensure compliance with prescribed terms and conditions.

For more details, download and read the agenda items in the minutes of the 145th meeting of GEAC on the GEAC website.

IISC researchers develop new method to deliver TB vaccine

September 16, 2022

The new method uses spherical vesicles secreted by bacteria coated on gold nanoparticles which can then be delivered to immune cells.

In the study, immune cells cultured in the lab were treated with OMVs derived from Mycobacterium smegmatis, a related bacterial species that do not cause disease in humans.

Researchers from the Indian Institute of Science (IISc) have designed a new method to deliver a vaccine candidate for tuberculosis (TB). It involves using spherical vesicles secreted by bacteria coated on gold nanoparticles which can then be delivered to immune cells, Bengaluru-based IISc said in a statement on Wednesday.

"This can potentially trigger an immune response and offer protection against the disease," it said. Caused by the bacterium Mycobacterium tuberculosis, TB kills over a million people worldwide every year. The only effective vaccine currently in use is the BCG vaccine. It contains a weakened form of the disease-causing bacterium. When injected into our bloodstream, it triggers the production of antibodies that can help fight the disease.

While the BCG vaccine works well in children, it is not as effective at protecting adolescents and adults, according to the statement. This prompted Rachit Agarwal, Assistant Professor at the Centre for BioSystems Science and Engineering (BSSE), IISc, and his group to develop a potential sub-unit vaccine candidate that contains only parts of the infectious bacterium to stimulate an immune response.

Scientists have earlier developed sub-unit vaccines based on just a handful of proteins from the disease-causing bacteria, but none of them have been effective so far, IISc said. Instead, Agarwal's group decided to use Outer Membrane Vesicles (OMVs), which are spherical membrane-bound particles released by some bacteria, and contain an assortment of proteins and lipids which could induce an immune response against the pathogen.

"They're safer compared to a live bacterium, and since they are membrane-derived, they contain all kinds of antigens," explains Agarwal, the senior author of the paper published in 'Biomaterials Advances'. Sub-unit vaccines typically only contain a limited number of antigens -- bacterial proteins that can elicit an immune response in the host. In contrast, OMVs contain a variety of antigens and can induce a better immune response, according to the researchers. Mycobacterium-derived OMVs are usually unstable and come in different sizes, making them unsuitable for vaccine applications. But the OMVs coated on gold nanoparticles (OMV-AuNPs) by the IISc team were found to be uniform in size and stable, the statement said.

The researchers also found that human immune cells showed higher uptake of OMV-AuNPs than of OMVs or gold nanoparticles alone. "Producing the OMVs is a complex process, and scaling it up was challenging," says Avijit Goswami, a former post-doctoral fellow at BSSE and one of the first authors of the study. "To synthesise OMV-AuNPs, the OMVs and the gold nanoparticles are forced together through a 100 nm filter. The OMVs break up in the process and encapsulate the gold nanoparticles," explains Edna George, a former postdoctoral fellow at BSSE, and co-first author of the study.

In the study, immune cells cultured in the lab were treated with OMVs derived from Mycobacterium smegmatis, a related bacterial species that does not cause disease in humans. In future studies, the team plans to develop gold-coated OMVs derived directly from Mycobacterium tuberculosis and test them on animal models to take the results forward for clinical applications. "Such efforts could open up new avenues for the development of vaccines for other bacterial diseases as well," IISc said.

Mumbai reported average of 98 deaths/day due to heart attack between January-June 2021: RTI report

September 20, 2022

According to the information provided by Brihanmumbai Municipal Corporation's (BMC) public health department, 17,880 deaths due to heart attack were reported from January 2021 to June 2021 (in six months) as compared to 5,633 deaths reported in the year 2020.

The information received from the Right to Information (RTI) application further reveals that in 2019 and 2018, the number of deaths due to heart attack in the city were 5,849 and 8,601 respectively. According to the response given in the RTI, the MIS cell of the health department is still processing the data on the cause of deaths reported from July to December 2021. The application was filed by RTI activist Chetan Kothari.

Nearly 23.8 per cent (17,880) of the total 75,165 deaths recorded till June last year in Mumbai were attributed to heart attacks. This information was revealed through an RTI filed by an activist Chetan Kothari.

As per city-based doctors, they too have seen an increase in the number of heart ailment cases since last year.

The figures have raised several questions about the sudden, unprecedented surge in deaths related to heart attacks. Medical officials have attributed several factors behind the staggering spike – post-Covid development of thrombosis, delay in diagnosis in heart-related ailment amid the second wave, better recording of heart-attack cases, major lifestyle changes and additional distress noticed in the second wave.

"Globally, it has been witnessed that heart attack related deaths increased in the pandemic, so it is not a new phenomenon that has only been observed in Mumbai. Secondly, since the start of the pandemic, the medical practitioners are more conscious in segregation and bifurcation of types of deaths, so it has possibly helped to maintain better data related to heart attacks," said Dr Supe.

Other than the critical risk factors, the prolonged lifestyle changes in the pandemic added to the risk of developing heart attacks.

"Life has become more sedentary with less options of socialisation and physical activities. The sugar and cholesterol levels are going haywire along with weight gain. Along with that, during the second wave, a lot of people were under stress – all these can also be contributing to the rise in heart attacks," said Dr Supe.

Doctors have witnessed an increase in the prevalence of diabetes, hypertension, smoking, alcohol use and an unhealthy lifestyle in the last two years.

HIGHEST MORTALITY

DISEASE	2018	2019	2020	2021*
Heart attack	8,601	5,849	5,633	17,880
Cancer	10,073	9,958	8,576	6,861
Kidney failure	1,396	1,516	1,634	1,182
Covid-19	0	0	11,105	10,289
Tuberculosis	4,940	4,899	3,719	2,921
Head injury	1,021	1,000	760	545

Source: RTI response from BMC **(Jan-June)*

Biotech Industry News

Dr. Radha Rangarajan takes charge as CSIR-CDRI director; Becomes second woman to occupy post

September 7, 2022

Dr. Radha Rangarajan on Monday took charge as the new director of CSIR-Central Drug Research Institute (CDRI), Lucknow in Uttar Pradesh. Dr. Rangarajan has become the second woman to occupy the post since the institute came into existence. Dr. Madhu Dixit who took charge of the position from 2015 to 2017 was the first female director of the institute.

Dr. Rangarajan, an eminent scientist, has contributed a lot to the public health arena for the last two decades with her involvement in translational research and product development. Moreover, she worked in the drug discovery division of Reddy's Laboratories in Hyderabad between 2003 and 2009.

Over the years, she has served in multiple roles in therapeutic areas such as anti-infectives, diabetes and cardiovascular disease. She was selected for the "Champions of Change" initiative of Prime Minister Narendra Modi recognising India's emerging entrepreneurs in 2017.

Rangarajan obtained her Bachelor of Science in Biology from Stanford University, Master of Science from the University of Michigan, Ann Arbor, and Ph.D. from Rockefeller University. She was a postdoctoral fellow at the Harvard School of Public Health.

Reportedly, the director of CSIR-Indian Institute of Integrative Medicine, Jammu Prof D. Srinivasa Reddy who was managing the position till now, remarked that Dr. Rangarajan will be an asset to the institute, which works for affordable healthcare for all.

Dr. Rangarajan has also co-founded Vitas Pharma, a drug discovery and development company focused on novel therapies to treat an infection. She is also associated with several committees and councils.

CSIR- Central Drug Research Institute (CSIR-CDRI) is a drug research institute in India. It was established on 17 February 1951 by the then Prime Minister of India Jawaharlal Nehru.

Bharat Biotech wins BusinessLine's Changemaker of the Year award

September 09, 2022

FM Nirmala Sitharaman gave away awards at the fourth edition of the event that honours human catalysts

In a glittering ceremony with emotion-packed moments and a soul-stirring musical performance, Finance Minister Nirmala Sitha-

raman presented BusinessLine's Changemaker of the Year award to Bharat Biotech for its stirring work during the pandemic in producing a homegrown vaccine in super quick time. The prodigiously talented Mithali Raj, who single-handedly put women's cricket centre stage, was crowned the iconic changemaker of the year. Receiving the award, the cricketer said, "My lesson to young girls would be not to dream to be like Mithali Raj but be bigger than Mithali Raj."

Talking about their 27-year journey, Suchitra Ella, JMD Bharat Biotech stressed that they wanted to get away from copycat products and generics, "We have believed India needs to innovate and develop indigenous technologies and also manufacture them here," she stressed.

The fourth edition of the event saw awards being given in six categories – digital transformation, social transformation, financial transformation, young changemaker, iconic changemaker, and changemaker of the year. DeHaat (a one-stop shop for agricultural services), Ramesh Raliya (the inventor of nano urea), Zerodha (a pioneer in discount brokerage), Prachi Shevagaonkar (a climate action warrior) and Akash Singh (who upskills prisoners and also addresses river pollution) were among the winners.

The 2022 awards function is presented by Life Insurance Corporation of India and powered by State Bank of India and Sastra University. Other partners are Manipal Hospitals (Healthcare partner); Karnataka Bank (Banking partner); Punjab & Sind Bank (Associate partner); PepsiCo (Sustainability partner); City Union Bank (Co-Partner) Zee Business (Telecast Partner) and Anand Prakash (Gift partner).

Bharat Biotech's intranasal Covid vaccine gets DCGI nod for restricted emergency use

September 7, 2022

THE NATIONAL drug regulator has given the green signal to the country's first intra-nasal Covid vaccine for emergency use in adults, the Government said on Tuesday.

Called iNCOVACC and manufactured by Bharat Biotech, the company behind Covaxin, the new vaccine has been approved for primary immunisation — it can be administered only to the unimmunised.

Officials said those who have already received the first and second doses of other vaccines will not be eligible to get iNCOVACC as the "precaution" third dose.

Yet, Tuesday's approval by the Central Drugs Standard Control Organisation (CDSCO) is significant: iNCOVACC will be delivered through the nasal route, which would potentially trigger an immune response in the mucosal membrane. It has been designed to not only protect against infection but also reduce transmission of the virus.

Taking to Twitter, Union Health Minister Mansukh Mandaviya posted: "Big Boost to India's Fight Against COVID-19! Bharat Biotech's ChAd36-SARS-CoV-S COVID-19 (Chimpanzee Adenovirus Vectored) recombinant nasal vaccine approved by @CDSCO_INDIA_INF for primary immunization against COVID-19 in 18+ age group for restricted use in emergency situation."

The vaccine uses a modified chimpanzee adenovirus, which cannot replicate in the body, to carry the Covid spike protein to induce immunity.

Bharat Biotech developed the new vaccine in partnership with Washington University-St Louis. While the US university developed the vector that carries the spike protein and evaluated it in pre-clinical studies, Bharat Biotech is handling product development and manufacturing. The development of the vaccine was partly funded by the Department of Biotechnology's Covid Suraksha programme.

"iNCOVACC has the double benefit of enabling faster development of variant specific vaccines and easy nasal delivery that enables mass immunization to protect from emerging variants of concern," Bharat Biotech said in a statement. "Being an intranasal vaccine, BBV154 (iNCOVACC) may produce local antibodies in the upper respiratory tract, which may provide the potential to reduce infection and transmission."

According to Bharat Biotech, the vaccine was found to be "safe, well-tolerated, and immunogenic" when compared to its own Covaxin in a phase III trial of nearly 3,100 participants across 14 sites in India. The company also conducted a trial with 875 participants to see whether the vaccine may be used as a booster in those who received Covaxin or Covishield as their primary vaccine.

Dr Krishna Ella, chairman and managing director of Bharat Biotech, said, "We are proud to announce the approval of iNCOVACC, a global game changer in intra nasal vaccines technology. Despite the lack of demand for COVID-19 vaccines, we continued product development in intra nasal vaccines to ensure that we are well prepared with platform technologies for future infectious diseases."

California Biotech Executive Is Guilty in $77 Million Blood-Testing Scheme

Sept. 2, 2022

A biotech executive in California was convicted of orchestrating a $77 million scheme involving false and fraudulent claims for Covid-19 and allergy testing, federal prosecutors said.

The executive, Mark Schena, 59, served as the president of Arrayit Corporation, a biomedical company that

claimed to have invented technology to test for any disease using only a finger-prick drop of blood. According to the Arrayit website, its "microarray" technology could test for ovarian cancer, Parkinson's disease, colon cancer and male fertility, among other diseases and conditions.

Mr. Schena was convicted of a total of nine federal charges, including conspiracy to commit wire and health care fraud and three counts of securities fraud. He faces up to 20 years in prison for conspiracy to commit health care fraud and conspiracy to commit wire fraud, as well as 20 years for each count of securities fraud.

Starting in 2018, Mr. Schena paid kickbacks and bribes to recruiters and doctors to run allergy testing for 120 different allergens, including hornet stings, shrimp, peanuts, dairy and Bermuda grass, regardless of medical necessity, federal prosecutors said.

The U.S. Justice Department said he then developed "a deceptive marketing plan" that falsely promoted the test's accuracy "when it was not, in fact, a diagnostic test."

According to the department, Mr. Schena submitted fraudulent claims to Medicare and private insurance for unnecessary allergy testing. The company billed more per patient to Medicare for blood-based allergy testing than any other laboratory in the United States, the Justice Department said. Some commercial insurers were billed more than $10,000 per test.

As Arrayit's allergy-testing business foundered during the coronavirus pandemic, the company turned to Covid-19 testing and claimed to have developed a blood-based test using its purported technology.

As Arrayit falsely claimed that its Covid test was more accurate than a PCR test, the U.S. Food and Drug Administration had informed Mr. Schena that the Arrayit test was not accurate enough to receive an emergency use authorization. Mr. Schena concealed that rejection from investors.

Mr. Schena described himself to investors as "the father of microarray technology" and falsely stated that he was on the shortlist for the Nobel Prize, the Justice Department said.
A phone number listed for the company has been disconnected. A lawyer for Mr. Schena, Todd A. Pickles, declined to comment on Friday.

Arrayit compared itself to Theranos, the failed blood-testing start-up, at least once in its Facebook page, writing that its technology can use drops of blood "which are 250,000 times smaller than the volume of the Theranos nanotainer," according to the Justice Department's initial complaint in 2020.

Elizabeth Holmes, the founder of Theranos who once promised to revolutionize health care through a simple blood test, and Ramesh Balwani, a former top executive at the company, were accused of exaggerating the abilities of its blood-testing machines in order to appeal to investors and customers. In January, Ms. Holmes was convicted of four counts of fraud, and in July, Mr. Balwani was found guilty of 12 counts of fraud.

FDA Lifts Hold on Sarepta's DMD Trial Following Protocol Adjustments

Sep 06, 2022

The FDA removed the clinical hold on Sarepta Therapeutics' investigational Duchenne muscular dystrophy (DMD) therapy Tuesday after the company agreed to adjust its clinical trial protocols to include expanded monitoring of urine biomarkers.

The FDA ordered a halt in June to the United States arm of the Phase II trial assessing the safety and efficacy of SRP-5051 (vesleteplirsen) after a seri-

ous safety signal was detected. A trial participant developed a dangerously low level of serum magnesium, a condition known as hypomagnesemia.

The FDA lifted the hold after Cambridge, Mass.-based Sarepta agreed to adjust the trial's protocols to expand the monitoring of urine biomarkers.

"We will implement the changes in the protocol to resume dosing in the U.S. as quickly as possible," said Louise Rodino-Klapac, the company's executive vice president and chief scientific officer, in a press release. "Our monitoring plan is designed to mitigate the risks of hypomagnesemia."

Sarepta spokesperson Tracy Sorrentino told BioSpace the trial's adjusted protocols will also require spot urine assessments of patients prior to visits. Sorrentino said the new requirement should "help minimize intra-patient variability of the urine biomarkers."

The trial, dubbed MOMENTUM, continued to enroll patients in Canada and the European Union not covered by the FDA's hold. Sarepta said it expects to complete enrollment in part B of the 60-patient study by the end of the year.

Part A of the trial, completed last year, showed that 12 weeks of monthly SRP-5051 infusions led to an eight-fold increase in dystrophin in the skeletal muscle compared to eteplirsen. Cases of reversible hypomagnesemia were also detected in part A.

Part B's protocols include the lab tests that detected the serious hypomagnesia case. The patient also reported mild-to-moderate tingling of the extremities and muscle cramps and was found to have low serum potassium levels. Protocol-prescribed supplementation resolved the patient's symptoms within three days, including the return to normal magnesium levels.

DMD patients have very limited treatment options.

SRP-5051 is a next-generation peptide-conjugated phosphorodiamidate morpholino oligomer. The treatment is being developed for patients with DMD who are amenable to exon 51 skipping.

Moderna sues rival COVID-19 vaccine makers Pfizer and BioNTech

Moderna previously pledged not to enforce COVID-19-related patents but changed its stance as the pandemic shifted gears.

Moderna has said it is suing rival vaccine maker Pfizer and its German partner BioNTech, citing infringement on its patents in developing the first COVID-19 vaccine approved in the United States, alleging they copied technology that Moderna developed years before the pandemic.

The lawsuits set up a high-stakes showdown between the leading manufacturers of COVID-19 shots that are a key tool in the fight against the disease.

"Moderna believes that Pfizer and BioNTech's Covid-19 vaccine Comirnaty infringes patents Moderna filed between 2010 and 2016 covering Moderna's foundational mRNA technology," the US-based biotech firm said in a statement.

"Pfizer and BioNTech copied this technology, without Moderna's permission, to make Comirnaty," Moderna said. Pfizer and BioNTech said they have not fully reviewed the complaint, but expressed surprise over the litigation.

US FDA issues 11 observations each for two sites in Bengaluru: Biocon

September 1, 2022

US health regulator has issued Form 483s with 11 observations each for two sites in Bengaluru and six observations for a plant in Malaysia, following inspection of seven manufacturing facilities of its arm Biocon Biologics.

As per US Food and Drug Administration (USFDA), Form 483 is issued to a firm's management at the conclusion of an inspection when the investigator has observed any conditions that may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts.

The USFDA conducted three on-site inspections of Biocon Biologics' seven manufacturing facilities spanning two sites in Bengaluru, India and one at Johor, Malaysia, Biocon said in a regulatory filing.

The inspections started with the Bengaluru site on August 11, 2022 and concluded with the Malaysia site on August 30, 2022, it added.

The observations primarily relate to the need for improving strategies for microbial control, enhancing quality oversight, augmenting the use of software applications and computerised tools to aid risk assessment and investigations and other procedural and facility upgrades, it added.

Biocon said the inspections were on account of three pre-approval inspections for biosimilar Bevacizumab, rh-Insulin and Insulin Aspart and a capacity expansion inspection for biosimilar Trastuzumab. "These included multiple drug substance and drug product facilities and other support infrastructure at these sites," it added. The company said it will submit Corrective And Preventive Action plans (CAPA), to the USFDA in the stipulated time frame.

Takeda's Qdenga dengue vaccine approved in Indonesia

August 28, 2022

Japanese pharma major Takeda announced the company's dengue vaccine, Qdenga (dengue tetravalent vaccine [live, attenuated]; formerly known as TAK-003), was approved by the Indonesia National Agency for Drug and Food Control, Badan Pengawas Obat dan Makanan (BPOM), for the prevention of dengue disease caused by any serotype in individuals six years to 45 years of age. This is the first approval for the vaccine anywhere in the world.

The approval of Qdenga is based on results through three years after vaccination from the ongoing Phase III Tetravalent Immunization against Dengue Efficacy Study (TIDES) trial that enrolled over 20,000 healthy children and adolescents ages four to 16 years living in dengue-endemic areas in Asia and Latin America. Qdenga demonstrated continued overall protection against dengue illness and hospitalization three years after vaccination, regardless of an individual's previous dengue exposure. Qdenga has been generally well tolerated, with no important safety risks identified in the TIDES trial, to date.

French drug major Sanofi (Euronext: SAN) previously laid claim to the world's first dengue vaccine in 2016. However, the rollout of its Dengvaxia vaccine imploded amid a public health scandal about its safety in late 2017, after the Philippines suspended it public immunization program having already purchased $70 million worth of Dengvaxia.

Bad Science

Nobel Prize winner Gregg Semenza retracts four papers

A Johns Hopkins researcher who shared the 2019 Nobel Prize in Medicine or Physiology has retracted four papers from the Proceedings of the National Academy of Sciences (PNAS) for concerns about images in the articles.

A Johns Hopkins researcher who shared the 2019 Nobel Prize in Medicine or Physiology has retracted four papers from the Proceedings of the National Academy of Sciences (PNAS) for concerns about images in the articles.

Gregg Semenza is "one of today's preeminent researchers on the molecular mechanisms of oxygen regulation," the work for which he shared the 2019 Nobel, according to Hopkins. But even before that, the pseudonymous Claire Francis began pointing out potential image duplications and other manipulations in Semenza's work on PubPeer, as described in October 2020 by Leonid Schneider.

The four papers retracted are:

1. Hypoxia-inducible factors mediate coordinated RhoA-ROCK1 expression and signaling in breast ancer cells

2. Mutual antagonism between hypoxia-inducible factors 1α and 2α regulates oxygen sensing and cardio-respiratory homeostasis

3. Anthracycline chemotherapy inhibits HIF-1 transcriptional activity and tumor-induced mobilization of circulating angiogenic cells

4. Hypoxia-inducible factors are required for chemotherapy resistance of breast cancer stem cells

Together, the papers have been cited more than 750 times, according to Clarivate's Web of Science. From 1998 until 2013, Semenza was principal investigator on NIH grants totaling more than $9 million.

One of Semenza's co-authors on one of the papers is Denis Wirtz, the vice provost for research at Hopkins. Semenza, who did not immediately respond to a request for comment, is hardly the only Nobel Prize winner to later retract papers. Retraction watch had describe four such cases in a 2019 column for STAT, and Frances Arnold did the same in 2020. Daniel Kahneman walked back some claims, although he did not retract a paper per se.

Brain tumor researchers retract paper from Science journal

A brain tumor researcher at the University of California, San Francisco, has retracted a paper from Science Translational Medicine, and is a co-author on an article that another journal is examining.

The problems in both papers, and several others with shared authors, came to light via comments on PubPeer by Elisabeth Bik and a pseudonymous commenter.

The Science Translational Medicine paper, "A subset of PARP inhibitors induces lethal telomere fusion in ALT-dependent tumor cells," was published last May by a group led by Russell O. Pieper, director of basic science in the UCSF Brain Tumor Center and vice-chairman of the UCSF department of neurological surgery. The paper has been cited six times, according to Clarivate's Web of Science.

Bik posted concerns about some of the images in the paper on PubPeer last month. According to the retraction notice, Pieper requested the retraction after learning of concerns with the same figures Bik mentioned on PubPeer

Several of Pieper's other papers, most with Mukherjee, have comments on PubPeer pointing out potential image duplication. One pseudonymous commenter, "Rumex rupestris," identified an image that appeared to have been used in three separate papers to depict different types of cells.

Pieper and Mukherjee are also listed as middle authors on a Nature Communications paper that "Rumex rupestris" earlier this month noted had an image with "unexpectedly similar" elements. The article, "Non-invasive assessment of telomere maintenance mechanisms in brain tumors," was published last January, and has been cited 11 times.

First author Pavithra Viswanath, another cancer researcher at UCSF, responded to the PubPeer comment that the figure in question "was generated by a co-author and we are working with the journal to address the highlighted issues." She also wrote that problems with the figure "do not impact our publication."

'Papermill alarm' software flags potentially fake papers

A software tool that analyses the titles and abstracts of scientific papers and detects text similar to that found in bogus articles is gaining interest from publishers.

The tool, called the Papermill Alarm, was developed by Adam Day, who is director of scholarly data-services company Clear Skies in London. Day says he ran all the titles listed in citation database PubMed through the system, and found that 1% of currently listed papers contain text very similar to that of articles produced by paper mills — companies or individuals that fabricate scientific manuscripts to order. The Papermill Alarm does not say definitively whether an article is fabricated, but flags those that are worthy of further investigation.

The tool uses a deep-learning algorithm to compare the language used in the titles and abstracts of manuscripts with that used in articles known to have come from paper mills. The comparison is based on lists of paper-mill articles compiled by research-integrity sleuths including Elisabeth Bik and David Bimler (also known by the pseudonym Smut Clyde). The tool uses a traffic-light system, assigning red flags to papers with many similarities to known paper-mill articles, orange flags to those with some similarities and green flags to those with none.

Bik says that the real number of paper-mill papers listed in PubMed might be even higher, but points out that their impact on science overall is probably low, because most of these articles are not highly cited or influential. "But it damages the reputation of science and the trust that we put into research papers," she says.

International Virtual Meet on

Non-Coding RNAs In Health And Disease

Jointly Organized by

All India Institute of Medical Sciences (AIIMS), Bhopal, India
Flow cytometry Solutions (P) Ltd, India
Septroum Life Sciences, India

12th to 14th OCT. 2022 | 2:00 to 6:00 PM (IST)

THEME OF THE VIRTUAL MEET

Day 1 Non-coding RNAs in cardiovascular and metabolic diseases

Day 2 Non-coding RNAs in diagnosis and management of Cancer

Day 3 Non-coding RNAs and infectious diseases

PROGRAM AT A GLANCE

The virtual meet will uncover the regulatory role of non-coding RNAs such as microRNA, long non-coding RNAs etc in various diseases such as cancer, metabolic diseases and microbial infections. Diagnostic, prognostic and therapeutic application of non-coding RNAs in aforementioned diseases will also be discussed.

SPEAKERS

- Prof. Shyam S. Mohapatra, University of South Florida, USA
- Prof. Himanshu Kumar, IISER Bhopal
- Prof. Yashwant V Pathak, University of South Florida, USA
- Dr. Debina Sarkar, Otago University, New Zealand
- Prof. Debasis Biswas, AIIMS Bhopal
- Dr. Subhra Mohapatra, University of South Florida, USA
- Dr. Smita Kulkarni, Texas Biomedical Research Institute, San Antonio, USA
- Dr. Bhupendra Verma, AIIMS Delhi
- Dr. Rakesh Naduvile Veedu, Murdoc University, Perth, Australia
- Prof. Rajesh Singh, Banaras Hindu University, India
- Prof. Swasti Tiwari, SGPGIMS, Lucknow
- Prof. S S Kanwar, HP University, Shimla, India
- Prof. Chun Hei Antonio Cheung, National Cheng Kung University, Tainan, Taiwan
- Prof. Sasidharan Sreenivasan, Institute for Research in Molecular Medicine, Malaysia
- Dr. Rakesh Tekade, NIPER Ahemdabad
- Dr. Aklank Jain, Central Univ. of Punjab

Oral presentations

Abstracts are invited from registered participants for oral presentation. Only 6 participants will be selected for oral presentation on above mentioned subject area. **Last date for submission of abstract - 08 Oct 2022.**

Registration Fee

From India :

Students/Technicians/JRF/SRF/Trainee/MBBS Students - **INR 500**

Postdocs/Residents/Faculty/Technical or Research Officers/Consultants/Research Associates/Scientist - **INR 750**

Diagnostic Labs/Companies/Any Non-Academia-Clinical or Research - **INR 1200**

Outside India : USD 15

Organising Team

Organizing Chairperson:
Prof. Jagat R Kanwar, AIIMS Bhopal, India

Organizing Secretary:
Dr. Ashok Kumar, Associate Professor, AIIMS Bhopal

Organizing Joint Secretary:
Dr. Neha Arya, Assistant Professor, AIIMS Bhopal

Collaborative Partner,
Dr. Hemant Agrawal, Director, Flow Cytometry Solutions (P) Ltd, India
Mr. Sujit Chakraborty, CEO, Septroum Life Sciences

E-certificate will be given to all participants

Last Date Of Registration
10th Oct. 2022

Scan & Register

Registration link: https://forms.gle/TubSH1XZqYmSfJiD7

For more information, write to us at ashok.biochemistry@aiimsbhopal.edu.in
neha.tmc@aiimsbhopal.edu.in, training@flowsols.com, +91-7665130114, +91-9818320214

Biometra Thermal Cycler Family

Analytik Jena's Biometra thermal cycler family provides outstanding PCR technology.

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Users looking for a premium system will find their desired device in the **Biometra TAdvanced.** Its features include the combination of ultra-fast heating and cooling rates, the wide range of exchangeable block modules and the professional user management system.

The **Biometra TRIO** thermal cycler includes three independent blocks in one instrument. Both multiuser environments as well as users with lower sample numbers but different samples will enjoy this model. The three-block design and the specific Temperature Optimization Step function support the fast optimization of ideal annealing temperatures.

Biometra TRIO

Biometra TAdvanced Twin

Unique features of the Biometra thermal cycler family:

- **Fast Ramping, Best Accuracy, Block Control (RAC):** What you set is what you get
- **High-performance Smart Lid (HPSL):** Defined pressure control for highly reproducible results
- **Whisper Quiet:** Low noise emission of max. 45 dB
- **Linear Gradient Tool:** For easy gradient programming to identify the ideal annealing temperature