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CBI's Arrests of CDSCO regulators, a Biocon official & Intermediaries in an alleged bribery case exposed Corruption in Govt and Pharma sector

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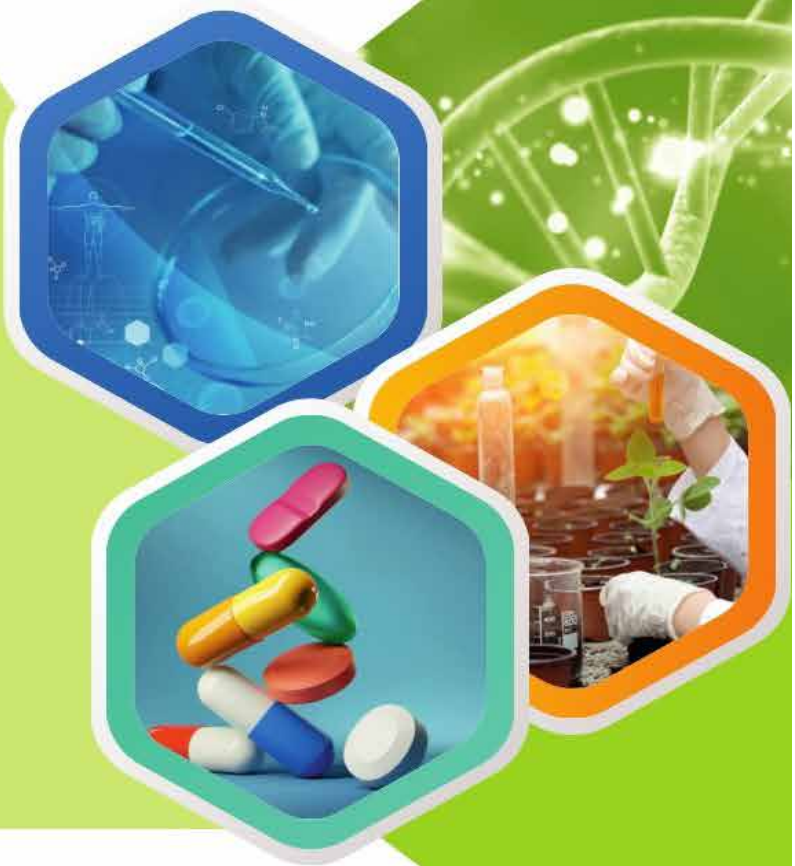

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Editorial

CBI Arrests of CDSCO officials, a Biocon official & Intermediaries in an alleged bribery case exposed Corruption in Govt and Pharma sector

Kamal Pratap Singh

Corruption and scams are not new in any business but is it ethically right to have corruption in industry like pharma where a drug which if approved incorrectly can impact thousands of lives. A new bribery case against CDSCO officials including Joint DCGI, intermediary agencies and a Biocon official has unsurfaced the wrongdoings in government regulatory offices and pharma industry and because it is related to biotech drug we are covering this story in this cover article. The intensity of wrongdoing by regulators and intermediaries can be felt by the fact that they were not caught red handed by any ordinary police but Central Bureau of Investigation (CBI).

Sudhir choudhary of Zee News had covered the story in his show DNA. This article has taken excerpts of Mr Sudhir as he covered this news very nicely with precise information. At the same time we had contacted Biocon spokesperson who denied the bribery alle-



Photo: (left to right) L. Praveen Kumar, Head-National Regulatory Affairs (NRA), Biocon, Joint Drug Controller S. Eswara Reddy, Dinesh Dua, director at Synergy Network India Private Limited

gations against the company and its officials as well as manywrong claims made in Zee news story.

Let us first see what has been reported by news agencies. The CBI had arrested, Easwar Reddy and Animesh Kumar who are officials of a Drug Authority of the Government of India i.e. Central Drugs Standard Control Organization (CDSCO) along with Dinesh Dua, Guljit Sethi, and associate vice president of Biocon Biologics L. Praveen Kumar on June 21 in a case of alleged bribery to the tune of Rs 9 lakh; Praveen Kumar, an official of Biocon Biologics was arrested later and brought to Delhi from Bangalore. Upon preliminary hearing, a special court had sent all the five accused, to judicial custody at Tihar Prison after they were arrested for alleged bribery of Rs 4 lakh to waive phase-3 clinical trial of 'Insulin Aspart' injection of Biocon Biologics to manage Type 1 and Type 2 diabetes. In bail plea lower court has denied application of all five on July 18, 2022. All of them are in Tihar prison.

According to Sudhir Choudhary, the name of the company with which this whole matter is related is Biocon Biologics, a subsidiary of Biocon Limited. This company manufactures medicines and at present its medicines are exported to 120 countries of the world.

CBI has arrested officials of CDSCO. The data related to the new medicines that are made in India is examined by CDSCO. These officers are alleged to get the drugs approved by taking bribe. Employees of the famous Biopharma Company Biocon have also been arrested in this scam. Seeing the advertisements of all the big pharma companies, you buy their medicines with great confidence. The most important thing is that this medicine was for diabetes.

In this case CBI has made total five arrests: Joint Drug Controller S. Eswara Reddy, Dinesh Dua, director at Synergy Network India Private Limited, Guljit Sethi alias Guljit Chaudhary Director, Bioinnovat Research Services Private Limited, Delhi; who used to look after regulatory work for Biocon Biologics, like many other pharma companies, Animesh Kumar, Assistant Drug Inspector (ADI), CDSCO, New Delhi and L. Praveen Kumar, Head-National Regulatory Affairs (NRA), Biocon.The CBI has alleged that the regulatory work of Biocon Biologics was looked after by Guljit Sethi of Bioinnovat Research Services Private Ltd. Bioinnovat and Synergy Network have business dealings hence Mr. Dua agreed to make the bribe payment.

So we have seen that CBI has arrested people in this case and it is not possible for them to make arrest without any concrete proofs. Although Sudhir chaoudhary has covered this public related matter with great details but Biotech spokesperson said that he has misinterpreted some things. A couple of points need to be noted. First is the drug is not substandard or adulterated because it has been already approved in Canada and Europe. Secondly, it is the middlemen that has been caught red handed and not Biocon employee.

Although Biocon has denied the allegations but it cannot be ignored that arrests have been made and government and intermediary officials were caught red handed, but as a responsible media we are presenting story of both sides and will wait for more truth which will come out subsequently. As of now we will see what other things have been interpreted from current case.

Biocon drug is awaiting approval by US FDA

The company says that it has done phase 1 and phase 3 trials in Germany and America respectively. And this is true, but it is equally true that the Drug Regulator Agency (FDA) of America has issued a CRL for this drug. The US FDA has issued a Complete Response Letter (CRL) for the Biologics License Application (BLA) for Insulin Aspart, however it did not identify any outstanding scientific issues with the product. The regulator had asked for some additional information. Biocon has responded to the CRL in April 2022 with the information asked, and its submission is awaiting review by the regulator. It is hoped it will accord approval to Biocon's BLA soon.

The Ethnicity factor

This company did the first, and third phase trials of this drug not in India but in Germany and America and so the studies related to ethnicity need to be evaluated in Indian population. It is written in the FIR that on the basis of approval in other countries, this company wanted that it should be exempted from the third phase trial in India and this drug should be granted marketing authorization so that this company can sell this medicine in the Indian market.

However, this is in keeping with international best practices. As per the ICH E5 guidance, for Insulin Aspart, there is no evidence through published literature and trial data that there are ethnic or population differences between Caucasians and Indian patients to suspect that the drug may have difference in safety or efficacy. The label and dosing/titration regimen of Aspart is identical in Europe, US, and India, Biocon spokesperson said.

Why a Diabetes drug is lucrative?

There are more than 70 million patients of diabetes in India. At present, after China, India has the highest number of 770 million patients of diabetes. That is, one out of every 6 patients of diabetes in the world is from India. And from this you can understand how serious and important this news is.

The approval procedure

Biocon Biologics said in its statement that "all our product approvals are backed by science and clinical data. Our biosimilar Insulin Aspart has undergone full Global Clinical Trials and is approved by global regulatory agencies like EMA and Health Canada".

"The rationale for seeking a waiver of Phase 3 clinical trials for Insulin Aspart in India, was based on the Indian regulatory guidance: Similar Biologics Guidelines 2016 & New Drugs and Clinical Trials 2019 (GSR 227 E). These guidelines provide a framework for waiver of Phase 3 clinical trials to be conducted in India based on a commitment to undertake a Phase 4 trial, the design of which should be approved by the Central Licencing Authority.

Similarly, in the document of the meeting, it is written in front of the fourth point that the Subject Expert Committee has decided that it exempts the Biocon company from the third phase trial of its drug in India and after this decision, this company will also sell this medicine in the Indian markets. Apart from this, it is also written in it that this company will have to tell how it will conduct the fourth phase

trial. For this, the word "Submit The Protocol" has been used. This is the reason why the word "protocol" replaced the word "data" as without the drug being launched in India, "data" from a Phase 4 trial in India cannot be presented.

This recommendation for approval by SEC without a phase 3 trial in India has been in line with the Indian drug regulations outlined in Similar Biologics Guidelines 2016 & New Drugs and Clinical Trials 2019 (GSR 227 E. Also, there are past instances of similar waiver of phase 3, trials given to other multinational pharma companies, who launched their product with a commitment to do a phase 4 marketing surveillance study.

Now, on the confusion between the use of word data and protocol, Biocon Spokesperson clarified that Phase 4 trials are conducted post marketing, hence it is impossible for any company to submit phase 4 data before the launch of the product. As such, Biocon Biologics needs to submit the protocol of Phase 4 trials before launching the product and later submit the Data generated post marketing study.

Biotech Express would like to clarify here that phase 4 clinical study is a post marketing study, many prior companies have used these provisions and agreed for phase 4 study, in lieu of doing phase 3 study in India.

Earlier Incidences of Pharma Corruptions

In July 2012, Parliamentary standing committee on health and family welfare said there was a "nexus between drug companies and regulatory officials" in clearing new drugs.

It said the Drug Controller General of India (DCGI) approved 31 new drugs between January 2008 and October 2010 despite mandatory clinical trials on patients in India not being conducted. The panel further alleged that medical opinions on the drugs were written by the "invisible hands of manufacturer ..and experts merely signed them" .

One of the examples outlined in its report was that of a drug called Clevudine, made by Pharmasset, a subsidiary of the $8.1 billion Gilead Sciences. The report points out how three experts in Delhi, Gulbarga and Kolkata wrote identical letters of recommendation to market the drug without clinical trials in India.

The legislators also looked at a random sample of 42 medicines from the list of new drugs uploaded by CDSCO on its website, accounting for just 2% of the 2,167 new drugs approved by the Drug Controller General of India (DCGI) during January 2001-November 2010. They found that, of these 42 products, 33 had been approved without clinical trials being conducted on Indian patients from January 2008 to October 2010.

Of the 42 drugs picked up randomly for scrutiny, the Health Ministry was unable to provide the Committee with any documents on three - the fluoroquinolone antibacterials pefloxacin, lomefloxacin and sparfloxacin - on the grounds that their files were non-traceable. All these drugs had been approved on different dates and different years, creating doubt if disappearance was accidental, said the report.

It adds: "strangely, all these cases also happened to be controversial drugs - one was never marketed in the US, Canada, Britain, Australia and other countries with well-developed regulatory systems, while the other two were discontinued later on

Of the 39 drugs on which information was available: - for 11, the mandatory Phase III clinical trials had not been conducted; - for two, clinical trials were conducted on 21 and 46 patients respectively, against the statutory requirement of at least 100 patients; - in one case, trials were conducted at two hospitals, against the legal requirement of three to four sites; and - in the case of four drugs, not only were the mandatory Phase II trials not conducted, but the opinion of experts was not sought - the decision to approve the drugs was taken solely by the non-medical staff of the CDSCO.

There is no scientific evidence to show that the 33 drugs approved without clinical trials are safe and effective in Indian patients, say the legislators, who had questioned the Health Ministry on the matter. Ministry officials had replied that the DCGI has the power to approve drugs without such trials if it is in the public interest. But, said the panel, no explanation was

available as to what constitutes public interest.

In August 2019, CBI, arrested Dr. Naresh Sharma, Dy. Drug Controller and another CDSCO official —Drug Inspector, CDSCO, Baddi, Solan— and four executives of an Amritsar or New Delhi-based pharma company in a Rs 1 lakh bribery case.It was alleged that the public servant demanded a bribe of Rs. 1 lakh in lieu of closure of file related to the said private firm and favourable action as the samples of dobutamine injection manufactured/ processed by the said firm were collected by CDSCO for testing and the said samples got failed during testing. The CBI said it "caught" the inspector accepting the bribe and that, later on, the firm's executives were also arrested.

Conclusion:

Where there's smoke there's fire. Since the accused have been caught red handed it will be interesting to see whether they will come out clean or not. Even after all if they succeed the public servant will never be able to come back in the organization as we have seen in the case of Dr Naresh Sharma and a bribe will destroy the life of Eswara Reddy as well.

Though the corruption in drug business is not endemic to India only but as a responsible citizen we need to look for more transparency and ethical practices while serving the most reputed sector which saves life of people. The bribery offered by Pharma companies can attract huge business for the company but may put in danger life of people if the drug poses adverse events.

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Interview

We are making best hygeine solutions through Biotech applications: Dr Rachna Dave, founder MicroGO

In the last issue Biotech Express has covered biotech startup expo which was held in June 2022 and inaugurated by PM Modi in Pragati Maidan, wherein hundreds of biotech startup showcased their products and services. Continuing the series, in this issue we are covering a startup that has gained special attention after pandemic due to their hygiene-based products. Here we discuss the journey of a founder and company with Dr. Rachna Dave who left her permanent job for starting an entrepreneur journey and now successfully fulfilling her endeavour.

"The pandemic has changed the way people and industry prioritise hygiene and infection control practices. MicroGO has developed disruptive smart solutions and has implemented digital hygiene practices. We are here to break the perception of hygiene practices being an expenditure and turn it into an investment".
Lead Investor of MicroGO

In this article we are presenting excerpts that came out after discussion with Rachna about her entrepreneur journey. Here they are…

So, Dr. Rachna, what's your story? what is your educational and professional background?

I have done PhD in Microbiology from Sardar Patel University, Gujarat and then had foreign education exposure from New York before I joined Bhabha Atomic Research Centre (BARC) at Kalpakkam, Chennai as DST fast track young scientist, where I was promoted as Scientist in short span.

During the end of 2015, I realized

that infectious diseases is a growing concern of public health. These are considered to be third among top ten factors for human mortality. There are several factors like increased global travel, lack of organized approach in sanitation management, lack of scientific approach to attain hygiene etc.

What was the idea and motive behind beginning an entrepreneur journey when you had job in hand?

Keeping many of the major factors in mind as discussed above, in May 2016, I left my permanent job and started MicroGO LLP which initially was a R&D based start-up that focuses on designing delivery systems to mitigate microbes with focus on Health and Hygiene. The idea behind was to create best hygiene solutions.

At that time, Govt. of India took great initiative of supporting ideas and entrepreneur and I realized that my idea has potential of becoming a reality while serving our country and people.
With the support of BIRAC BIG, MicroGO LLP first built a no power/ water requiring portable-light weight alternative to autoclave that can be used for sterilisation of surgical instruments.

Tell us how you went forward translating idea into a product and company

The company was started from a very small scale. We were housed in Golden Jubilee Biotech Park in Chennai where we began our journey of innovation in 2016. From the inception to 2019 we took huge R&D efforts and created effective products which focused on providing smart, assured, and sustainable hygiene solutions to curtail virus led infections.

The company piloted its technologies with anchor customers from 2020. In 2021 the company started process for product commercialization and now in 2022 we are looking forward for sales and marketing activities to reach more and more personnel.

After COVID we have got handsome support from DBT-BIRAC, DST, IKP-Hyd, TANSIM and international agencies such as the Bill and Melinda Gates Foundation among many others which led to our manufacturing department. Last year we also presented our startup to PM Shri Narender Modi in Startup Prarambh Summit on "Micro Swacchhta". In this summit we talked about the waste and dirt that is not visible with naked eye but is more harmful than ordinary waste that we can see.

Today, we have35+ team members who are working hard for the growth of company and putting efforts in providing solutions to our clients.

What are the products your company is making?

Our products range includes automated hand-hygiene compliance solutions, raw water treatment, wastewater treatment, surface cleaners and fruits and vegetables treatment. MicroGO assists industries to reduce hand hygiene expenses by 60%, saves water consumption by 50% and use smart solutions to maintain compliance and remotely monitor the hygiene ecosystem.

The company recently launched GOassure™ Lite, India's first smart hand hygiene station which assures good hand hygiene practices, compliance monitoring, and automates hand hygiene. MicroGO's products have been granted patents in as low as 90 days- one of the fastest patents granted in India.

About financial growth of the company

I am fortunate that I could get support from govt of India, without which it was not possible to build

a company like this. Though it was difficult to arrange funds initially, but now I can say that we have come out of break even, we have got excellent results where we made the investments.

In first three years we invested in R&D and came out with great products, then we invested in manufacturing and commercialization and now we have product ready for sales and now we are focusing on sales and marketing and I am confident we will achieve good results in near future.

MicroGO recently raised pre-Series A funding of INR 6 crore from angel investors. The funds will be utilized to strengthen sales and marketing activities and to expand their presence in Delhi & NCR, Gujarat, Mumbai and Maharashtra & Kolkata.

Who are the target customers of your company?

Our products are for prevention which is first line of defense against infectious diseases and is better than cure. We are targeting companies and outlets that need hygiene on bigger scale like hospitality industries and hospitals. For example in food industry, in case of any adverse event the whole lot can be rejected if even a small microorganism growth appears in starting material. Similarly, a hygienic environment in hospitals can prevent unnecessary and unwanted infections.

At present, MicroGO's hygiene-based solutions are used by leading businesses across industries like food & beverages, healthcare, pharma, commercial and residence complexes and hospitality industries. Some of our prestigious clients includes Airport Authority of India, Indian Army, IHCL (TAJ and Vivanta), IRCTC, Way Cool Foods, Bigbasket, Apollo Hospitals among many others.

Since many companies are working on hygiene products, what is the edge of your company?

Our company has smart products that work in automation, like in the absence of operator too, I don't think if anyone else can give you this advantage . In case of any problem the customer will be alarmed and then can access information through mobile and rectify in minimum time while sitting at other place, I think this is not possible with any other such product in the market.

If we atlk about our services we are pushing efforts to provide best services to our clientele. Since no product is 100% advanced, we work with our customers to make our products more effective and in this way we always look at every query of customer. Our service team works 24x7 and be always ready for any complaint.

What is the Cost of products your company offering and how much is it affordable by general public?

We have whole ecosystem of disinfection. For example, in kitchen one needs to clear feet and then clothes and then hand washing, so we have different solution to different problems. To give an idea, for 20-30 people in kitchen who prepare food for 5-600 people in three shifts the average cost is only 40-50 thousands per month for entire hygiene portfolio which is negligible if hotelier want their customers' prevention from diseases. Adding here that this whole package is completely digital i.e., the steps can be verified online on dashboard from remote places too.

How do you see future of your company?

I believe we are on the right path with right kindof products and services. Our products are required by all industrial sectors as well as residential complexes where hygiene is not only necessary for production but for the safety of people too. The confident of investors in our company reflect that we are on right path and our company will go enormously in near future.

Editorial

COVID-19 Vaccines: Pharma with Bumper Profits

by Kamal Pratap Singh

COVID-19 vaccines have lifted Pharma companies profit astronomically. The two pioneering vaccine manufacturers' in India viz. Serum Institute of India (SII) and Bharat Biotech International Ltd (BBI) has been in a lime light in context to their current financial balance sheets. Dr. Reddy's Laboratory (Sputnik V) and other contenders like Cadila Healthcare (ZyCoV-D), Biological E Ltd (Corbevax) have also left their mark in making exorbitant profits. Without a slightest doubt that monitory profits were involved, other perks were earned too. In USA, Pfizer and Moderna have also made huge profits after sale of COVID vaccines.

Ideally, according to Drug Controller General of India (DCGI) guidelines, Centre for Disease control and Prevention (CDC) & US FDA, any novel drug discovery or vaccines for licensing needs to undergo stringent process. For information, Exploratory stage, pre-clinical stage, clinical phase – I, clinical phase –II, clinical phase – III & IV. All these phases are mandatory to assess the safety which means that there is no sign of any adverse effect on the individual and efficacy which suffice the potency. Moreover, it takes on an average 12 years

and estimated cost is ~$1 billion for a novel drug discovery.

Unfortunately, within 10 months of COVID-19 inception, active pharmaceutical players with support from the government introduced their vaccine product, how! The overloaded cost required to be invested in R&D, marketing and distribution was deducted which leaves behind only manufacturing cost. Being in pharmaceutical sector for years, the manufacturing cost for any vaccine would be just peanuts!

It was reported that, India has vaccinated over 1.87 billion doses. The vaccination program covered administrating over 90 % with 1st dose and ~65% of second dose. With next to negligible low production cost, just imagine the profit incurred by selling doses to the Indian government!

Starting with, vaccine-maker SII earned the maximum net profit for every rupee of revenue. The net profit earned in FY 20 was Rs 5,926 cr had an expected trajectory elevation to approximately Rs. 15000 cr from the FY 21. In other words, tentatively 3 times the profit was generated with COVID-19 vaccine as compared to pre-COVID-19 phase. In one of the interview with *India Today TV*, heads of SII stated when the price went down to Rs. 150/-, "It is not the case where we're not making profits... but we are not making super profits, which is key to re-investing". Apart from that interview, in another one it was quoted that pharmaceuticals is optimistic to make a "reasonable profit" to increase production and earn returns similar to foreign companies.

Because, the government kept financial deal with Bharat Biotech International Ltd (BBI) secret, not much information related to profit margin was revealed. But from the information that nearly 700 million doses per year were manufactured, it can be estimated that Bharat Biotech's earning will be ~Rs. 22,725 cr. The aforementioned figure is suggestive from the fact that the cost of production with a marginal profit is Rs. 150/dose.

Dr. Reddy's Laboratory has been successful in case of technology transfer for vaccine, Sputnik from Russia. The company is currently under a clinical trial stage of universal booster for Sputnik Light. It means, anybody can take this vaccine irrespective of age group depending on trial results. Though current stage for Sputnik is under process to be marketed, but the pricing of Rs.995+tax wherein 1.2 million doses are produced, the profit ration will be unimaginable.

Cadila Healthcare, one of the India's largest pharmaceutical companies discovers, develops, produces and markets a broad spectrum of healthcare therapeutic modalities. It has produced COVID-19 treatment drugs like Remdesivir and indigenous vaccine like ZyCoV-D. The company's consolidated net profit was Rs.1, 176.1 Cr from drug Remdesivir and Rs. 3,687 Cr for FY22 from vaccine ZyCoV-D. It was reported that more than 1/3rd of its revenue was generated from exporting raw materials for vaccine production.

According to a news by *Business today* published on May 4, 2022, Hyderabad-based vaccine and pharmaceutical firm Biological E. Limited so far, have been administered around 43.9 Million doses of Corbevax to children across the country and it has supplied close to 100 Million doses to the government.

The expected profit to be earned by pharmaceuticals is liable to take over the market because of robust COVID-19 vaccine production. An analyst reports that, Serum Institute, Bharat Biotech, Dr Reddy's Laboratory and others would contribute 43%, 24%, 14% and 19% to the share market respectively.

Not only locally, but the COVID-19 vaccine approval has given international recognition to the Pharma companies. SII & BBI collaborated with US based leading vaccine manufacturing company Pfizer Inc and Ocugen Inc respectively. With enlisting of COVID-19 vaccines for emergency-use by WHO vaccines to as many as 170 countries were supplied.

The waiver on COVID-19 vaccines for Intellectual Property Right (IPR) at the time of rolling out of vaccines was an additional benefit for them. The patent filling, proving innovativeness and approval would have taken couple of years. With COVID -19 pandemic and without IPR filling, more royalty was earned by Pharmaceuticals as compared to scenario wherein IPR would have been required to be filled.

Considering the facts that earlier mortality rate was elevated, chaos for oxygen supply, disarray in arrangements for hospital beds, the necessity for COVID-19 vaccines existed. No doubt there was a need, but what about current jab for 3rd vaccination doses? Right now, neither novel mutated virulent variant strain, nor surge in cases related to COVID-19 prevails then why it still needs to be extended to 3rd and more precautionary dose. The questions about doses and mandates have discussed in article (http://www.biotechexpressmag.com/no-vaccine-mandates-after-supreme-court-order-next-compensation-to-aefi-survivors-from-covid-vaccine-makers-possible/) of Biotech Express

May 2022 issue.

In conclusion, with green signal for COVID-19 vaccine, the drug producer with nominal production cost has earned profit in leaps and bounds! Additionally, recognition at WHO & international market with supply of vaccines and raw material was gained with minimal efforts. Furthermore, waiving off DCGI guideline and IPR saved enormous money and time to license a new vaccine. Lastly, to utter surprise, new outburst for precautionary doses is still in the air!

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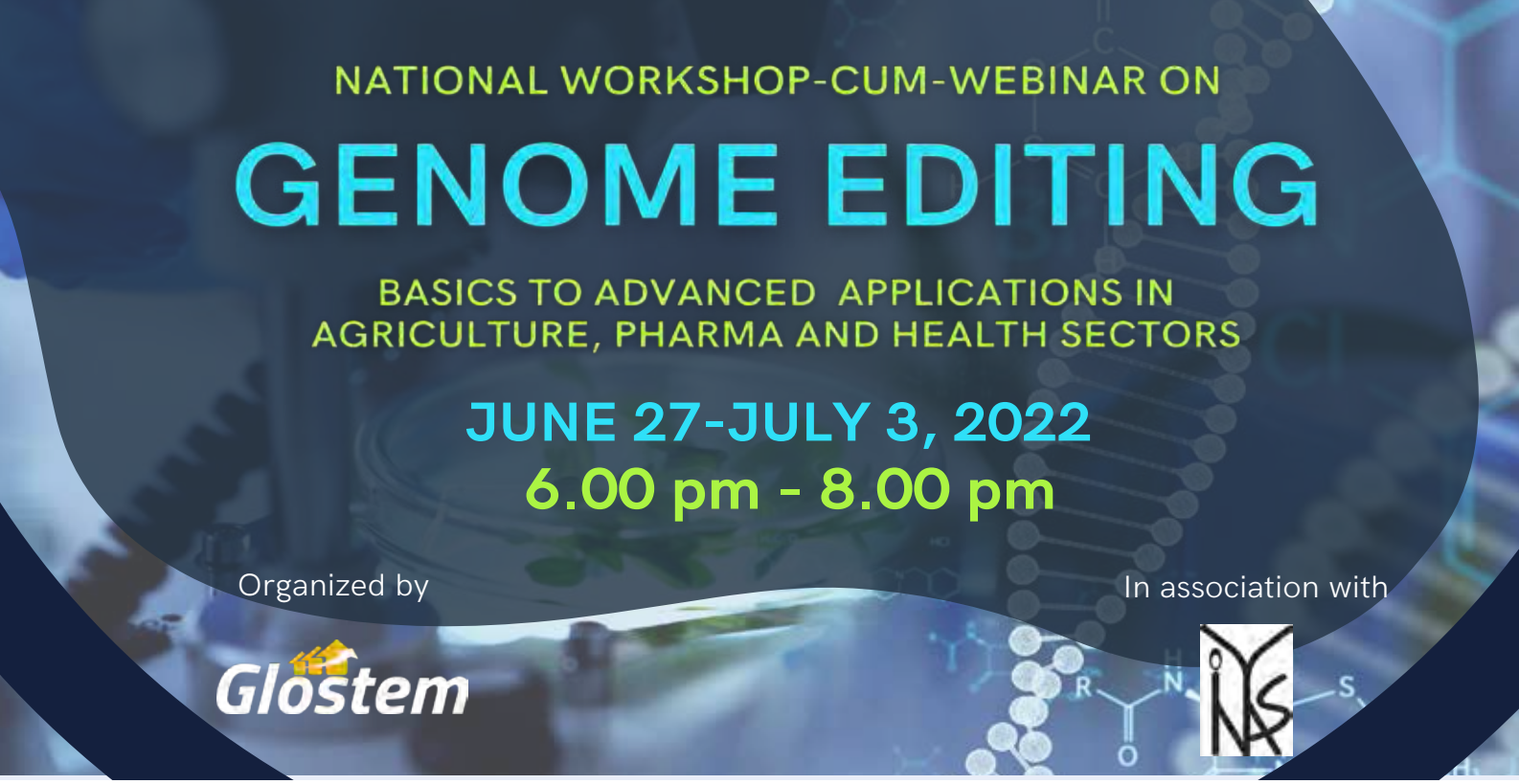

EVENT HIGHLIGHTS:

Genome editing as a novel technology for sustainable development

India on march for climate resilient, nutrition rich and sustainable agriculture with the use of Genome Editing": Prof KC Bansal

A "National Workshop-cum-Webinar on Genome Editing" was organized from June 27 to July 3, 2022 online with an objective of communicating the advances in science and technology to young students and researchers.

This workshop was organized under the Chairmanship of Prof KC Bansal, Secretary of the National Academy of Agricultural Sciences (NAAS), New Delhi, who is a former Director of the premier institution of ICAR, the National Bureau of Plant Genetic Resources (NBPGR). The workshop was Co-Chaired by a world-renowned scientist Prof Yiping Qi, Associate Professor, University of Maryland, USA.

The 7-day online workshop was attended by over 350 young researchers and faculty members belonging to various fields of biotechnology.

The speakers for the workshop were drawn from different national institutes like IISc, Bangalore; NCBS, Bangalore; CSIR-IGIB, New Delhi; CSIR-CCMB, Hyderabad; IIT, Kharagpur; DBT-NABI, Mohali; DBT-NIPGR, New Delhi; IISER, Mohali; ICAR-IARI, New Delhi and ICAR-NRRI, Cuttack. The resource speakers are the world class experts, highly experienced and renowned in their respective fields.

This was one of its kind workshop where Genome Editing was covered from the basics to advanced applications as in-

Photo: Prof KC Bansal

vestigated by researchers themselves in different organisms including model plant species, *Drosophila melanogaster, Caenorhabditis elegans*, yeast, mammalian and stem cells, for sustainable agriculture, better nutrition, health benefits and environmental sustainability.

In the inaugural talk on June 27, 2022, Prof KC Bansal highlighted the current state of Genome Editing and mentioned that "Since the discovery of the CRISPR-Cas9 based genome editing technology in 2012, the world is witnessing an unprecedented revolution in its use for various applications for genetic improvement and modification of various organisms." He also mentioned that since Government of India has recently issued guidelines easing the norms for bio-safety assessment for developing genome-edited crops, more opportunities have opened for research and development in this field, and therefore, this workshop is the need of the hour.

The Gene Editing technology enables the manipulation of targeted genes in a precise and efficient manner in many organisms and cell lines, and has become indispensable for all life science researchers globally, ranging from agriculture to pharma to health sectors. He also provided a brief of the future developments and directions of the emerging genome editing tools and technologies.

Prof Yiping Qi of Maryland University, USA delivered the Keynote address. He is involved in the development of new tools for simultaneously editing different traits for crop improvement. In his Keynote address, he presented his research on RNA-guided CRISPR activation (CRISPRa) systems and a versatile CRISPR-Combo platform, for simultaneous genome editing and gene activation in plants.

The other speakers who spoke at the event included Dr KA Molla, Scientist, NRRI, Cuttack, who was Convener of the workshop; Dr Siddharth Tiwari, Scientist, NABI, Mohali; Dr P Chandra Shekar, Principal Scientist, CSIR-CCMB, Hyderabad; Dr Debojyoti Chakraborty, Senior Scientist, CSIR-IGIB, New Delhi; Dr Viswanathan Chinnusamy, Principal Scientist, IARI, New Delhi, Dr Naveen Bisht, Staff Scientist V, NIPGR, New Delhi, Dr Kavita Babu, Principal Investigator, IISc, Bangalore; Dr Deepti Trivedi Vyas, Scientist, NCBS, Bangalore; Dr Amit Ghosh, Assistant Professor, IIT, Kharagpur; Dr Basudev Ghoshal, Research Scientist, Agriculture and Agri-Food Canada and Dr D T Singh, Founder & President, CloudSeq Pte Ltd, Singapore.

The valedictory function of the workshop was held on Sunday, July 3, 2022, with Dr Ashwani Pareek, Executive Director, National Agri-Food Biotechnology Institute, Mohali as the Chief Guest. Dr Ashwani Pareek, in his Valedictory Address stressed on the importance of the genome editing in agriculture and food sectors and called upon the young biotechnology scientists to be the "Technology Ambassadors". He asked them to take up and promote this technology in their respective fields.

The workshop was organized by the Chandigarh based Glostem Private Limited, an organization involved in organizing and managing scientific events for the last 10 years, in association with the Indian National Young Academy of Sciences.

Editorial

Climatic Effect on Marine Biodiversity and their impact on coral reefs

On the occasion of world biodiversity day May 22, 2021 and #SwachhSagarSurakshitSagar, World's longest coastal cleanup campaign which not only aims to clean 7500 km long coastline but will also give a major boost to the "Blue Economy" envisaged by PM Sh Narendra Modi.

by Seema Pavgi Upadhye

Despite the fact that our planet is mostly ocean and human activity is more intense than it has ever been, we know remarkably little about the state of the ocean's biodiversity -- the variety and balance of species that support healthy and productive ecosystems. And it's no surprise -- marine biodiversity is complex, human impacts are uneven, and species respond differently to different stressors.

Human impacts on marine biodiversity are increasing, dominated by fishing, direct human disturbance from land and ocean acidification. The extent to which at-risk species are facing these pressures from human activities, and the pace at which the pressures are expanding and intensifying, is worrisome. Corals are the most widely impacted marine organism on Earth. Coral species are facing impacts across essentially their entire ranges and those impacts are only getting more intense, particularly climate-related impacts, coral bleaching is also taking place. The species of the Coral

Triangle -- the tropical water connecting Indonesia, the Philippines, Papua New Guinea and the Solomon Islands -- are among the most affected by human impacts, as are species in the North Atlantic, North Sea and Baltic Sea.

Seabirds are a critically important distributor of nutrients for island and marine environments. They feed on fish often in the open ocean far from islands, and then return to islands to roost -- depositing nitrogen-rich nutrients on the island in the form of guano -- or poo. Some of the guano is then leached off the islands by rain and into the surrounding seas where the nitrogen fertilises corals and other marine species such as algae and sponges, boosting the food-chain.
The world's oceans – their temperature, chemistry, currents and life – drive global systems make the Earth habitable for humankind.

Our rainwater, drinking water, weather, climate, coastlines, much of our food, and even the oxygen in the air we breathe, are all ultimately provided and regulated by the sea. Over 3 billion people depend on marine and coastal biodiversity for their livelihood.

There will be disastrous effect of climate change and tourism on Marine ecosystem in coming years. Highlighting the contributions of large marine ecosystems to socio-economic development and to human well-being, UNESCO said those ecosystems alone contribute an estimated $28 trillion annually to the global economy through services and benefits provided by nature, including fish for food and trade, tourism and recreation, coastal protection from flooding and erosion, and the less tangible benefits from cultural, spiritual, and aesthetic connections to nature.

Maintaining the health and resource productivity of these transboundary water systems should help countries achieve global objectives to reduce poverty and hunger, and promote sustainable economic growth.

Open Ocean:

- 60 per cent of the world's coral reefs are currently threatened by local activities.
- 90 per cent of all coral reefs could be threatened in 2030 by the combined pressures of local activities and climate change.
- 100 international agreements currently "govern" the open ocean, signaling severe fragmentation.

Large Marine Ecosystems (LMEs):

- 64 of 66 LMEs have experienced ocean warming since 1957 ("Super-fast" warming in the Northwest / Northeast Atlantic and in Western Pacific).
- 28 per cent reduction in fish catch potential projected for high-risk LMEs in East Siberian Sea.
- 50 per cent of all fish stock in LMEs are overexploited.

Biodiversity and ecosystem is facing multiple pressures. Over the last decades to centuries, the intensive use of land, fresh water, and oceans with the extraction of marine and freshwater organisms, wood, and agricultural commodities has dominated the loss of biodiversity and the deterioration of ecosystems globally. Approximately 70–75% of the ice-free land area is affected by human use, nearly 50% intensively so. Since 1961, cropland production increased by about 3.5 times and production of animal products by 2.5 times, supported by a massive enhancement of fertilizer input (+800%) and freshwater withdrawal (+100%).

Demand for fish has increased by >3% per year thus increasing more fish capturing. In absence of strong conservation policies and changes in per capita consumption, agricultural expansion is projected to further hasten species extinctions , while the world fish production (capture and aquaculture) is projected to increase by 18% between 2016 and 2030. In addition to the pressure from direct exploitation, the detrimental impacts of multiple pollution sources all are also harmful to marine, freshwater, and terrestrial biodiversity. Continued human population growth and the concomitant increase in per capita consumption raise serious concerns about the acceleration of overexploitation and pollution of ecosystems.

The exponential rise of atmospheric greenhouse gas concentrations over the past 30 years has increased the average global temperature by 0.2°C per decade. Most of this extra heat is being absorbed by the world's oceans, particularly by their upper layers, with the mean global sea surface temperature (SST) increasing by approximately 0.4°C since the 1950s .The warming of the oceans drives greater stratification of the water column. It is reducing mixing in some parts of the ocean, which affects oxygen and nutrient availability and so primary production and the ecophysiology of water-breathing organisms.

The increase in water temperatures which is unevenly distributed also due to increased meltwater and discharged ice from terrestrial glaciers and ice sheets. It influences the behavior of ocean currents, which play critical roles in the dynamics, local climates, and biology of the ocean . with these environmental changes, industrial fisheries have resulted in the overexploitation and decimation of about 70% of world fish stocks, resulting in changes to fish communities and marine ecosystems. Both climatic and human pressures can lead to shifts in

the size, structure, spatial range, and seasonal abundance of populations, which, in turn, may alter trophic pathways from primary producers to upper-trophic levels, propagating changes throughout ecosystems in both bottom-up and top-down directions. Accordingly, climate and fishing impacts should not be treated in isolation from each other when it comes to conservation of marine biodiversity.

Therefore warming, combined with deoxygenation or food limitation, may cause reductions in the mean body size and abundance of fish and other marine ectotherms by the end of century. It will lead to negative interactions with fishing, which also reduces fish size and abundance significantly. In case of amphibians and strictly aquatic species, changes in precipitation patterns will play an additional crucial role. Where there are no barriers to movement, warmer temperatures may result in continued poleward and altitudinal shifts of species and entire biomes.

Rising levels of CO2 in the atmosphere, in addition to advancing climate change also lead to ocean and freshwater acidification, which is expected to reduce growth rates in calcifying phytoplankton and organisms like gastropods, crustaceans, shellfish, or corals, whereas some primary producers might benefit from increased CO2 . Direct effects of CO2 thus can have knock-on effects across all systems on food web structures and for the integrity of the habitats.

Industrial fisheries may pose another serious threat for the conservation of species inhabiting marine biodiversity hot spots when those areas overlap with areas of intense human fishing activity. However, fishery data are available in such poor spatial resolution that analyses of the overlap of fishing intensity with climate change effects are necessarily limited. FAO fisheries landings are available for the last 60 years, enabling us to at least evaluate trends in the exploitation of marine resources. Although fishing has been practiced for centuries, fishing pressure has intensified in recent decades as a consequence of technical developments in fishing techniques and the demands of a rapidly increasing human population, leading to overexploitation and even collapse of many fish stocks. The world's marine fisheries resources are under enormous pressure, with global fishing effort exceeding optimum and sustainable levels by an estimated factor of 3 to 4. Observed trends showing annual increases in fishing captures suggest that this harvest pressure will continue and further exacerbate pressure on fish stocks well into the future.

Fishing activities are particularly intense at Major Fishing Areas (MFAs, according to their FAO categorization) that overlap with marine biodiversity hot spots .This is particularly true for the tropical regions of the Indian Ocean and the western Pacific Ocean, where the highest increasing rates in fishing pressure have been recorded at both the regional and the local scale. Although biodiversity conservation is an issue of global concern, fishing policies are most commonly derived from decisions taken at a national level, particularly with regard to those occurring within EEZs where bordering sovereign states have special rights regarding the use of marine resources (United Nations Convention on the Law of the Sea, 1982).

Fishing pressure differs among countries. China and Peru contribute the most to global captures (ca. 20%) and are likely to continue to do so according to the observed trends in fishing captures. However, many other countries also contribute substantially to fishing captures within MFAs that overlap with marine hot spots. Around 30 different coastal countries that collectively account for 80.5% of fishing captures in the areas of high biodiversity.

All these environmental stressors likely interact in a number of ways, but little is known about the potential for synergetic or antagonistic interactions. Marine species may also respond differently to changes in environmental conditions. Some species may benefit from shifts toward environmental conditions outside the normal range of variability, but in most cases, these environmental changes will prove suboptimal, and this will be made apparent through changes to populations and communities. Ocean warming in temperate regions, such as the southwestern Pacific Ocean or the western Indian Ocean, can affect marine species through a reduction in primary productivity and also through trophic disruptions due to shifts in species distributions and changes in the timing of ecosystem-level processes.

Changes in ocean circulation, which largely control marine patterns of productivity and food availability, may also have important global consequences for biological communities. Thus, we should expect that consequences of changing climatic variables will be species-specific and even site-specific. Fine-scale, spatially explicit measurements on the distribution of environmental stressors are therefore crucial to effectively depict those local to regional areas of special concern for the conservation of marine biodiversity in the face of climate change.

The world's areas of highest marine biodiversity are threatened by the impacts from both global warming and human fishing pressure. Thus, it behooves the international community to find solutions that go beyond the interests and borders of various countries if we are to conserve the biodiversity in marine hot spots, in a similar way to which the world must tackle the associated causes of climate change itself.

About Coral Reef

World's coral reefs could bleach by the end of century, unless there are drastic reductions in greenhouse-gas emissions. This warning is given by United Nations Environment Programme(UNEP). The head of UNEP's Marine and Freshwater Branch Leticia Carvalho said that coral reefs will soon disappear.

Coral reefs are incredibly important and sustain a wide variety of marine life. They also protect coastlines from erosions from waves and storms, sink carbon and nitrogen and help recycle nutrients. Their loss would have devastating consequences not only for marine life, but also for over a billion people globally who benefit directly or indirectly from them. Coral reefs also called a s"rainforests of the sea," support approximately 25 percent of all known marine species. Reefs provide homes for more than 4,000 species of fish, 700 species of coral, and thousands of other plants and animals.

The architects of coral reefs are hard corals. Unlike soft corals, hard corals have stony skeletons made out of limestone that is produced by coral polyps. When polyps die, their skeletons are left behind and used as foundations for new polyps. An actual coral branch or mound is composed of layer upon layer of skeletons covered by a thin layer of living polyps. Due to hardened surfaces, corals are sometimes mistaken as being rocks. Corals are alive and unlike plants, corals do not make their own food. Corals are in fact animals.

"A coral" is actually made up of thousands of tiny animals called polyps. A coral polyp is an invertebrate that can be no bigger than a pinhead to up to a foot in diameter. Each polyp has a sac-like body and a mouth that is encircled by stinging tentacles. The polyp uses calcium carbonate (limestone) from seawater to build a hard, cup-shaped skeleton. This skeleton protects the soft, delicate body of the polyp.

Most reef-building corals have a unique partnership with tiny algae called zooxanthellae. The algae live within the coral polyps, using sunlight to make sugar for energy. This energy is transferred to the polyp, providing much needed nourishment. In turn, coral polyps provide the algae with carbon dioxide and a protective home. Corals also eat by catching tiny floating animals called zooplankton. At night, coral polyps come out of their skeletons to feed, stretching their long, stinging tentacles to capture critters that are floating by. Prey are pulled into the polyps' mouths and digested in their stomachs.

Corals reproduce asexually by budding or fragmentation. Through budding, new polyps "bud" off from parent polyps to form new colonies. In fragmentation, an entire colony (rather than just a polyp) branches off to form a new colony. This may happen, for example, if a larger colony is bro-

ken off from the main colony during a storm or boat grounding.

In terms of sexual reproduction, some coral species, such as Brain and Star coral, produce both sperm and eggs at the same time. For other corals, such as Elkhorn and Boulder corals, all of the polyps in a single colony produce only sperm and all of the polyps in another colony produce only eggs. Coral larvae are either fertilized within the body of a polyp or in the water, through a process called spawning. In some areas, mass coral spawning events occur one specific night per year and scientists can predict when this will happen.

Once in the water, larvae 'swim' to the ocean surface. If they are not eaten, they eventually settle to the ocean floor and attach to a hard surface. Once attached, they metamorphose into a coral polyp and begin to grow, dividing in half. As more and more polyps are added, a coral colony develops and eventually begins to reproduce.

When water temperatures rise, corals expel the vibrant microscopic algae living in their tissues. This phenomenon is called coral bleaching. Though bleached corals are still alive and can recover their algae, if conditions improve. However, the loss puts them under increased stressed, and if the bleaching persists, the corals die.

The last global bleaching event started in 2014 and extended well into 2017. It spread across the Pacific, Indian and Atlantic oceans, and was the longest, most pervasive and destructive coral bleaching incident ever recorded.

Under the fossil-fuel-heavy scenario, the report estimates that every one of the world's reefs will bleach by the end of the century, with annual severe bleaching occurring on average by 2034, nine years ahead of predictions published three years ago.

Corals are animals that create their own skeleton to help support them. These animals live in shallow warm waters around the world using sunlight to synthesize their sugar-based food. Reefs are not just "beautiful ecosystems" renowned for their biological diversity, according to Dr. Hagedorn, they are also crucial to life on Earth. "Almost 25 per cent of all marine life lives on a reef at some point and so without them many species of fish that we eat wouldn't exist. Corals provide a natural protection for our coastlines, for example against tsunamis. They also support people's livelihoods in the form of fishing and tourism and contribute 350 billion annually to the global economy. So, there are many reasons we should save them."

The underlying structures of the reefs -- which are home to a multitude of aquatic life -- could fracture as a result of increasing ocean acidity caused by rising levels of carbon dioxide.

Scientists observed that the skeletons of dead corals, which support and hold up living corals, had become porous due to ocean acidification and rapidly become too fragile to bear the weight of the reef above them.

Previous research has shown that ocean acidification can impact coral growth, but the new study demonstrates that porosity in corals -- known as coralporosis -- leads to weakening of their structure at critical locations. This causes early breakage and crumbling, experts say, that may cause whole coral ecosystems to shrink dramatically in the future, leaving them only able to support a small fraction of the marine life they are home to today. The findings complement recent evidence of porosity in tropical corals, but demonstrate that the threat posed by ocean acidification is far greater for deep-sea coral reefs. The research was led by University of Edinburgh scientists, under the EU-funded ATLAS and iAtlantic projects, with researchers from Heriot-Watt University and the National Oceanic and Atmospheric Administration (NOAA).

The team identified how reefs could become fractured by analysing corals from the longest-running laboratory studies to date, and by diving with submersibles off US Pacific shores to observe how coral habitat is lost as the water becomes more acidic.

Deep sea coral reefs and sponges

Corals and sponges are important foundations in ocean ecosystems providing structure and habitats that shelter a high number of species like fish, crabs and other creatures, particularly in the seamounts and canyons of the deep sea. Researchers at the University of New Hampshire have discovered that when it comes to climate change not all deep-sea corals and sponges are affected the same and some could be threatened if average ocean temperatures continue to increase in the deap sea.

These deep-sea corals and sponges are ecologically important because they are foundational species that contribute to the food web and losing them could eventually lower the biodiversity of the deep sea.

Although corals and sponges co-occur, climate-related variables tem-

perature, salinity and dissolved oxygen contributed to the distribution of sponges, whereas seafloor properties of slope and substrate contributed to the distribution of corals. Not all deep-sea corals and sponges were influenced by the same environmental variables and each has different levels of sensitivity. Changes in temperature and dissolved oxygen, that go beyond what the deep-sea corals and sponges are used to, could stress the species' physiology affecting growth, tissue loss and reproduction.

In general, deep-sea corals are found 200 to 10,000 feet below sea level where sunlight is nonexistent. Unlike shallow-water coral reefs, which are limited to warm tropical waters, deep-sea corals are found throughout the world's oceans, from tropical to polar regions, forming groves of tree or fan shapes that can reach feet to meters tall. Deep-sea sponge populations can filter water, collect bacteria and process carbon, nitrogen, and phosphorus. Deep-sea corals and sponges have been found on continental shelves, canyons and seamounts in deep seas around the world but their full extent is unknown because only 15 percent of the Earth's seafloor has been mapped with high-resolution imaging.

Deep-sea coral reefs face challenges as changes to ocean chemistry triggered by climate change may cause their foundations to become brittle and because of their special place in biodiversity we need to see the ways to protect them.

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3D printing of 'organic electronics'

June 27, 2022

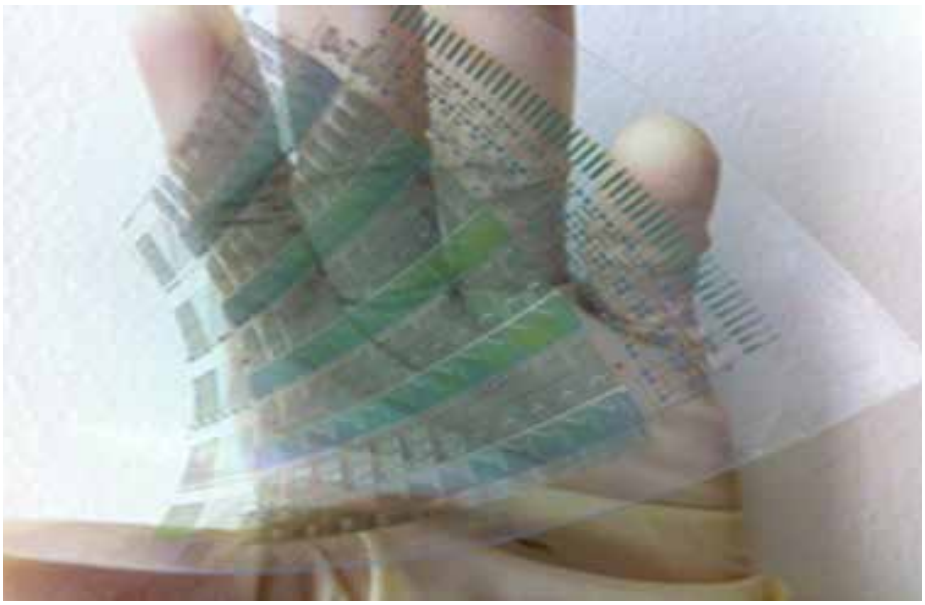
A research group has explored the potential production of micro-scale organic electronics for use in bioelectronics via multiphoton 3-D printers.

The newest paper from his research group examines the possibility of that technology. "Multiphoton Lithography of Organic Semiconductor Devices for 3D Printing of Flexible Electronic Circuits, Biosensors, and Bioelectronics" was published online in Advanced Materials.

"In this paper we introduced a new photosensitive resin doped with an organic semiconductor material (OS) to fabricate highly conductive 3D microstructures with high-quality structural features via MPL process," Abidian said.

They showed that the fabrication process could be performed on glass and flexible substrate poly(dimethylsilosane). They demonstrated that loading as low as 0.5 wt% OS into the resin remarkably increased electrical conductivity of printed organic semiconductor composite polymer over 10 orders of magnitude.

"The excellent electrical conductivity can be attributed to presence of OS in the cross-linked polymer chains, providing both ionic and electronic conduction pathways along the polymer chains," Abidian said.



To demonstrate the potential electronic applications based on the OS composite resin, his team fabricated various microelectronic devices, including micro-printed circuit board, which comprises various electrical elements, and an array of microcapacitors.

Three dimensional bioprinting of organic semiconductor microdevices based on MPL has potential in biomedical applications including tissue engineering, bioelectronics and biosensors. Abidian's team successfully incorporated bioactive molecules such as laminin and glucose oxidase into the OS composite microstructures (OSCMs). To confirm that the bioactivity of laminin was retained throughout the entire MPL process, primary mouse endothelial cells were cultured on OS composite microstructures. Cells seeded on laminin incorporated OSCMs displayed evidence of adherence to substrate, proliferation, and enhanced survival.

"We also assessed the biocompatibility of the OS composite structures by culturing lymphocytes, namely splenic T-cells and B-cells, on the fabricated surfaces and compared them with control surfaces. After seven days of culture, OS composite polymers did not induce cell mortality with approximately 94 percent cell viability compared to the control surfaces," Abidian

said. "In addition, the potential effect of OS composite polymers on cell activation was also studied. After seven days of culture, there was no significant difference in the expression of activation markers on the lymphocytes between OS composite structures and control surfaces."

Finally, Abidian proposed a maskless method based on MPL for fabrication of bioelectronics and biosensors. They fabricated a glucose biosensor similar to Michigan style neural electrodes. Glucose oxidase, an enzyme for the specific recognition of glucose, was encapsulated within the solidified OS composite microelectrodes via the MPL process. The biosensor offered a highly sensitive glucose sensing platform with nearly 10-fold higher sensitivity compared to previous glucose biosensors. In addition, this biosensor exhibited excellent specificity and high reproducibility.

Journal Reference: Multiphoton Lithography of Organic Semiconductor Devices for 3D Printing of Flexible Electronic Circuits, Biosensors, and Bioelectronics. Advanced Materials, 2022; 2200512 DOI: 10.1002/adma.202200512

Maternal mortality jumped during COVID-19 pandemic

June 28, 2022

A research letter published in JAMA Network Open by Marie Thoma in the UMD School of Public Health and Eugene Declercq in the BU School of Public Health compared maternal mortality data from 2018-March 2020, when the pandemic began, to April-December 2020. Overall, they found large increases in maternal death (33%) and late maternal deaths (41%) after March 2020 compared with before the pandemic, and conspicuous increases among Black and Hispanic mothers.

"The increase was really driven by deaths after the start of the pandemic, which are higher than what we see for overall excess mortality in 2020," said Dr. Thoma, assistant professor of family science in the UMD SPH. The study also showed that existing and new disparities emerged after the pandemic with a 40% jump among already high rates for non-Hispanic Black women and a 74% jump among formerly lower rates in Hispanic women.

Strikingly, said Dr. Declercq, professor of community health sciences at BUSPH, "for the first time in more than a decade, the maternal mortality rate for Hispanic women during the pandemic was higher than that for non-Hispanic white women, a shift that may be related to COVID and deserves greater attention moving forward."

COVID-19 was listed as a secondary cause of death in 14.9% of maternal deaths in the last nine months of 2020, with it being a contributing factor for 32% of Hispanic, 12.9% of Black and 7% of non-Hispanic white women giving birth.

In their analysis of causes of maternal death, they found the largest increases were due to conditions directly related to COVID-19 (respiratory or viral infection) and conditions made worse by COVID-19 infection, such as diabetes or cardiovascular disease. However, interruptions to the health care system could have led to delayed pre-

natal care that could have meant that risk factors for pregnancy complications went undetected.

Journal Reference: All-Cause Maternal Mortality in the US Before vs During the COVID-19 Pandemic. JAMA Network Open, 2022; 5 (6): e2219133 DOI: 10.1001/jamanetworkopen.2022.19133

Moderate drinking linked to brain changes and cognitive decline

July 14, 2022

Consumption of seven or more units of alcohol per week is associated with higher iron levels in the brain, according to a study of almost 21,000 people publishing July 14 in the open access journal PLOS Medicine.

There is growing evidence that even moderate alcohol consumption can adversely impact brain health. Anya Topiwala of the University of Oxford, United Kingdom, and colleagues explored relationships between alcohol consumption and brain iron levels. Their 20,965 participants from the UK Biobank reported their own alcohol consumption, and their brains were scanned using magnetic resonance imaging (MRI). Almost 7,000 also had their livers imaged using MRI to assess levels of systemic iron. All individuals completed a series of simple tests to assess cognitive and motor function.

Participants' mean age was 55 years old and 48.6% were female. Although 2.7% classed themselves as non-drinkers, average intake was around 18 units per week, which translates to about 7½ cans of beer or 6 large glasses of wine. The team found that alcohol consumption above seven units per week was associated with markers of higher iron in the basal ganglia, a group of brain regions associated with control of motor movements, procedural learning, eye movement, cognition, emotion and more. Iron accumulation in some brain regions was associated with worse cognitive function.

This is the largest study to date of moderate alcohol consumption and iron accumulation. Although drinking was self-reported and could be underestimated, this was considered the only feasible method to establish such a large cohort's intake. A limitation of the work is that MRI-derived measures are indirect representations of brain iron, and could conflate other brain changes observed with alcohol consumption with changes in iron levels.

Given the prevalence of moderate drinking, even small associations can have substantial impact across whole populations, and there could be benefits in interventions to reduce consumption in the general population.

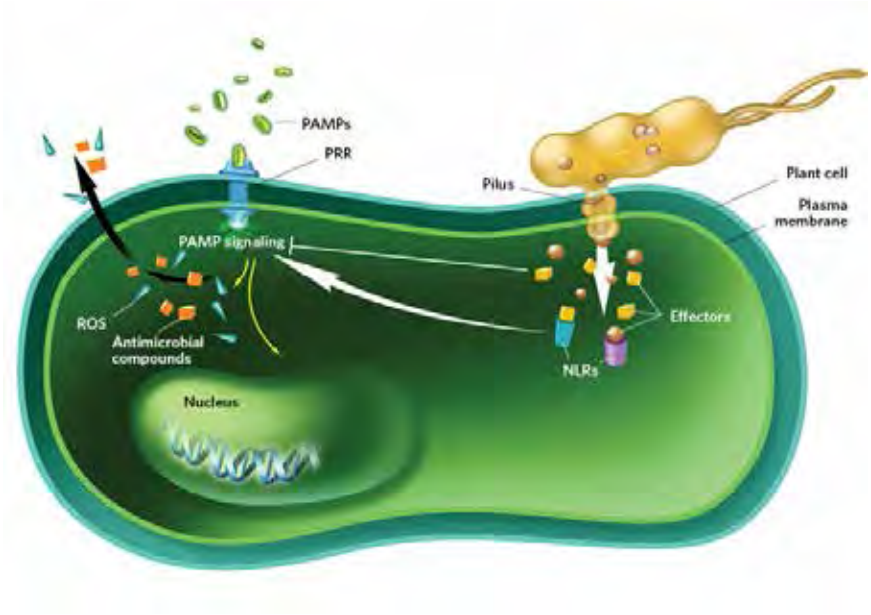
Topiwala adds, "In the largest study to date, we found drinking greater than 7 units of alcohol weekly associated with iron accumulation in the brain. Higher brain iron in turn linked to poorer cognitive performance. Iron accumulation could underlie alcohol-related cognitive decline."

Journal Reference: Associations between moderate alcohol consumption, brain iron, and cognition in UK Biobank participants: Observational and mendelian randomization analyses. PLOS Medicine, 2022; 19 (7): e1004039 DOI: 10.1371/journal.pmed.1004039

Molecules boosting plant immunity identified

July 7, 2022

Two studies published in the journal Science by researchers at the Max Planck Institute for Plant Breeding Research in Cologne, Germany in collaboration with colleagues in China have discovered natural cellular molecules that drive critical plant immune



responses.

Now, in two landmark studies, scientists led by Jijie Chai and Jane Parker from the Max Planck Institute for Plant Breeding Research in Cologne and the University of Cologne, Germany, collaborating with Junbiao Chang's group at Zhengzhou University in Zhengzhou and Zhifu Han and colleagues at Tsinghua University in Beijing, China, have identified two classes of molecules and determined their modes of action in mediating immune responses inside plant cells. Their findings pave the way for the design of bioactive small molecules that could allow researchers and plant growers to manipulate -- and thereby boost -- plant resistance against harmful microbes.

At a molecular level, a main immune strategy employed by plants involves proteins called nucleotide-binding leucine-rich repeat receptors, or NLRs for short. NLRs are activated by invading microorganisms and set in motion protective immune responses. These immune responses culminate in the so-called hypersensitive response, which involves restriction of pathogen growth and often strictly demarcated death of cells at the site of infection -- akin to amputating a toe to ensure survival of the body.

One class of NLR proteins, those with so-called toll/interleukin-1 receptor (TIR) domains, which are termed TIR-NLRs (or TNLs), have been shown to relay signals to the downstream immune protein Enhanced Disease Susceptibility 1 (EDS1). Smaller TIR-containing proteins also feed signals into EDS1 to potentiate disease resistance. EDS1 functions as a control hub which, depending on the types of other proteins it interacts with, pushes plant cells to restrict pathogen growth or commit to cell death. Earlier work showed that TNL receptors and TIR proteins are actually pathogen-induced enzymes. Evidence suggested that these TIR enzymes produce a small messenger or messenger(s) that signal to EDS1 inside cells. However, the identities of the precise molecules generated by TNLs or TIRs that stimulate the different immune responses have remained elusive.

Parker and colleagues established that the two functional EDS1 modules leading to immunity or cell death can be triggered by pathogen-activated TNL enzymes inside plant cells. To identify the small molecules produced by TNLs or TIRs and that act upon EDS1, the Chai group reconstituted key components of the signaling pathway in insect cells, a system that allows production and purification of high amounts of molecules which can then be isolated and characterized. Using this approach, the authors discovered two different classes of modified nucleotide molecules produced by TNLs and TIRs. These compounds preferentially bound to and activated differentEDS1 sub-complexes. Hence, the authors demonstrate that different EDS1 sub-complexes recognize particular TIR-produced molecules, which function as information-carrying chemicals, to promote immune responses.

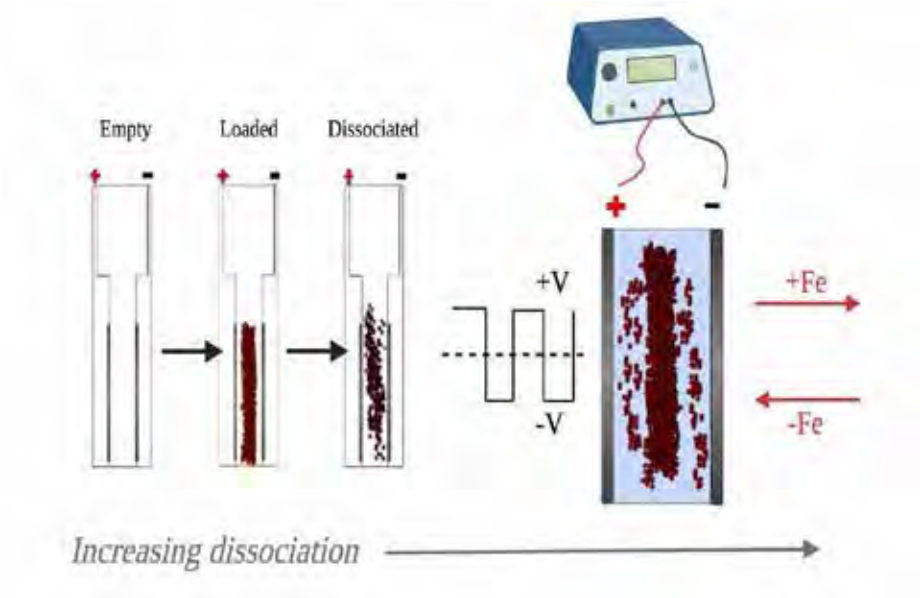
The TIR immune receptors and EDS1 hub proteins exist in many important crop species, such as rice and wheat, and Jijie Chai points out that "the identified TIR-catalyzed small molecules could be employed as general and natural immunostimulants to control crop diseases." Jane Parker further remarks that "knowing the biochemical modes of action of these small molecules opens a whole new chapter on plant immunity signaling and disease management."

Journal References:

1. TIR-catalyzed ADP-ribosylation reactions produce signaling molecules for plant immunity. Science, 2022; DOI: 10.1126/science.abq8180

2. Identification and receptor mechanism of TIR-catalyzed small molecules in plant immunity. Science, 2022; DOI: 10.1126/science.abq3297

Scientists develop new method and device to isolate single cells using electric fields



July 14, 2022

A team of researchers at Brown University has developed an advanced way to isolate single cells from complex tissues. In a study published in Scientific Reports, they show how the approach not only results in high-quality, intact single cells, but is also superior to standard isolation methods in terms of labor, cost and efficiency.

The challenge was to develop a technology to enable researchers to more quickly and easily isolate cells from biopsied cancer tissue to ready it for analysis, said Anubhav Tripathi, study author and director of biomedical engineering at Brown.

"From a technology standpoint, there's nothing like this available on the market right now," Tripathi said. "This technology will be useful for those looking for answers using genomics, proteomics, transcriptomics -- it will not only make those diagnostic and therapeutic investigations easier, but will also save researchers time and effort."

Tripathi added that beyond clinical applications, the technology will be useful in biomedical applications like tissue engineering and cell culture.

In the newly developed process, a tissue biopsy is placed in a liquid-filled receptacle between two parallel plate electrodes. Instead of enzymes, electric field fluctuations are applied to create opposing forces within the liquid. These forces cause the tissue cells to move in one direction and then in the opposite direction, which leads them to cleanly separate, or disassociate from one another.

This approach was invented by study author Cel Welch, a fourth-year Brown Ph.D. candidate in biomedical engineering in Tripathi's lab. The new process resulted in dissociation of biopsy tissue in as little as 5 minutes -- three times faster than leading enzymatic and mechanical techniques described by Tripathi and Welch in a previous study.

The approach also resulted in "good dissociation of tissues into single cells while preserving cell viability, morphology and cell cycle progression, suggesting utility for sample preparation of tissue specimens for direct single-cell analysis," the study concluded. According to the researchers, the new approach is, at minimum, 300% more effective than even the most optimized techniques using simultaneous chemical and mechanical dissociation.

Another advantage to the process, Welch said, is the compactness of the device they created: "In the traditional workflow, you need to use several different lab instruments, such as a centrifugation instrument, that cost several thousands of dollars each. This approach to single-cell sample preparation requires only a single device."

The samples used in the study were bovine liver tissues, triple negative breast cancer cells and human clinical glioblastoma tissues. The research team is now refining the technology and developing a device that will be able to quickly and effectively process multiple different kinds of small-scale tissue bi-

opsy samples at once, at a very low cost.

Journal Reference: Electric-field facilitated rapid and efficient dissociation of tissues Into viable single cells. Scientific Reports, 2022; 12 (1) DOI: 10.1038/s41598-022-13068-6

Why it is so hard for humans to have a baby?

July 5, 2022

New research by a scientist at the Milner Centre for Evolution at the University of Bath suggests that "selfish chromosomes" explain why most human embryos die very early on. The study, published in PLoS, Biology, explaining why fish embryos are fine but sadly humans' embryos often don't survive, has implications for the treatment of infertility.

There are number of clues that Hurst put together. Firstly, when the embryo has the wrong number of chromosomes it is usually due to mistakes that occur when the eggs are made in the mother, not when the sperm is made in the father. In fact, over 70% of eggs made have the wrong number of chromosomes.

Secondly, the mistakes happen in the first of two steps in the manufacture of eggs. This first step, it had been noticed before, is vulnerable to mutations that interfere with the process, such that the mutation can "selfishly" sneak into more than 50% of the eggs, forcing the partner chromosome to be destroyed, a process known as centromeric drive. This is well studied in mice, long suspected in humans and previously suggested to somehow relate to the problem of chromosome loss or gain.

What Hurst noticed was that, in mammals, a selfish mutation that tries to do this but fails, resulting in an egg with one too many or one too few chromosomes, can still be evolutionarily better off. In mammals, because the mother continuously feeds the developing fetus in the womb, it is evolutionarily beneficial for embryos developing from faulty eggs to be lost earlier rather than be carried to full term. This means that the surviving offspring do better than the average.

Hurst explained: "This first step of making eggs is odd. One chromosome of a pair will go to the egg the other will be destroyed. But if a chromosome 'knows' it is going to be destroyed it has nothing to lose, so to speak. Remarkable recent molecular evidence has found that when some chromosomes detect that they are about to be destroyed during this first step, they change what they do to prevent being destroyed, potentially causing chromosome loss or gain, and the death of the embryo.

"What is remarkable, is that if the death of the embryo benefits the other offspring of that mother, as the selfish chromosome will often be in the brothers and sisters that get the extra food, the mutation is better off because it kills embryos."

"Fish and amphibians don't have this problem," Hurst commented. "In over 2000 fish embryos not one was found with chromosomal errors from mum." Rates in birds are also very low, about 1/25th the rate in mammals.

Hurst's research also suggests that low levels of a protein called Bub1 could cause loss or gain of a chromosome in humans as well as mice.

Hurst said: "The levels of Bub1 go down as mothers get older and as the rate of embryonic chromosomal problems goes up. Identifying these suppressor proteins and increasing their level in older mothers could restore fertility.

"I would hope too that these insights will be one step to helping those women who experience difficulties getting pregnant, or suffer recurrent miscarriage."

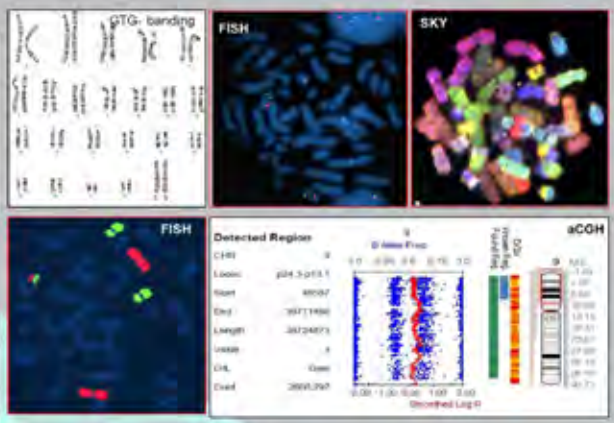
Journal Reference: Selfish centromeres and the wastefulness of human reproduction. PLOS Biology, 2022; 20 (7): e3001671 DOI: 10.1371/journal.pbio.3001671

Hands-on workshop
on
Clinical Applications of Cytogenetics and Molecular Cytogenetics

22 - 27th August 2022

Centre for DNA Fingerprinting and Diagnostics, Hyderabad

Cytogenetics is still a gold-standard technique to identify the numerical and structural chromosomal abnormalities in this era of next-generation sequencing. It provides a low resolution of the entire genome. The resolution has improved through the advent of molecular cytogenetic techniques. Molecular cytogenetics techniques like Fluorescence *in--situ* hybridization (FISH) and Microarray CGH have evolved as powerful diagnostics tools for identifying genomic rearrangements.



This workshop aims to introduce methods and hands-on experience for diagnosis of chromosomal disorders using cytogenetics, FISH and microarray techniques

HANDS-ON TRAINING IN

- Cytogenetics,
- FISH with single and dual-colour FISH probes (centromere, locus-specific, whole chromosome paint),
- Imaging and analysis
- Microarray data analyses
- Case-based discussions

WHO CAN APPLY?

Young Scientists, Medical professionals, and Students with minimum qualification of MSc/ MBBS

Last date for application:
20th July 2022

Registration fee Rs 10000/-
(Rs 8000/- for students)

Selection process: 25 participants would be selected based on screening of applications and writeup

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Featured News

ICAR celebrates its 94th Foundation Day and Awards Ceremony - 2022

16th July, 2022,

Union Agriculture Minister Shri Narendra Singh Tomar released a Compilation of Success Stories of 75,000 Farmers of Doubling of Farmers' Income

"The farmers' trust in the Krishi Vigyan Kendras is really a matter of pride for the Council", said Shri Narendra Singh Tomar, Union Minister of Agriculture & Farmers' Welfare while inaugurating the "94th Foundation Day of Indian Council of Agricultural Research & Awards Ceremony - 2022" held at the National Agricultural Science Centre Complex, New Delhi today.

In response to the clarion call of the Prime Minister Shri Narendra Modi for doubling Farmers' income, the income of millions of farmers has more than doubled with the consistent efforts of the Ministry of Agriculture & Farmers' Welfare / ICAR, State Governments and Farmers. As a part of the "Bharat Ka Amrut Mahotsav" to commemorate 75 Years of India's Independence, the Union Minister, Shri Tomar released E-Compilation of the Success Stories of 75,000 such successful Farmers who have more than doubled their income. He also released the State-wise summary of these successful farmers. Shri Tomar congratulated the ICAR and Krishi Vigyan Kendras for the Compilation. He exuded his confidence that this Compilation will motivate and inspire more and more farmers to raise their income leveraging the various Schemes and initiatives of the Central Government. The Union Minister also virtually interacted with the various successful farmers during the occasion.

Shri Tomar stressed that although the country has achieved self-reliance in the various crops' production; but the scientists should be ready to face the newer challenges that may occur in the due course of time.

The Union Minister congratulated the Council's Scientists for their dedication that has made the country to be self-reliant on the various fronts of the agricultural arena.

Shri Tomar urged ICAR to celebrate the ICAR Foundation Day as "Sankalp Diwas". Shri Tomar exhorted the Scientists of ICAR to set the various goals / targets for the benefits of the agricultural sector in general and farmers in particular and to take it as "Sankalp" to be fulfilled during the ensuing Year.

Shri Parshottam Rupala, Union Minister of Fisheries, Animal Husbandry & Dairying urged the Council to gear-up and work for compiling and documenting the Council's various unparalleled achievements made till date. The need for making the Drones available to the farmers through the Council's Custom Hiring Centres was accentuated by the Union Minister. Shri Rupala suggested the Council to disseminate the success stories of Doubling the Farmers' Income to the various farming communities to encourage them in achieving the same in their lives too.

The Guest of Honor, Shri Kailash Choudhary, Union Minister of State for Agriculture & Farmers' Welfare stated that the Farmers' Producers' Organizations are the milestones that enable the farmers to sell their products on a large scale at better prices. The Minister said that it is the hard work of the Council and its Scientists that a large number of farmers have doubled their income as has been envisioned by the Hon'ble Prime Minister, Shri Narendra Modi. He also stressed on the perfect utilization of the Drone Technology by the farmers that have helped the farming community on a large scale. Attracting the farming community to practice Natural Farming was emphasized in his address.

Prof. Ramesh Chand, Member, NITI Aayog also applauded the various landmarks achieved by the Council in the development of various technologies for the agricultural and farming communities.

Continuing its tradition to incentivize the individual Employees & Teams for the outstanding performances across the Organizations and make them more efficient, responsive & productive apart from improving their levels of job satisfaction, this Year, the Union Minister gave away 15 Awards in 4 major Categories. The Categories included National Award of Excellence for Agricultural Institutions, National Award for Excellence in Agricultural Research, National Award for Application of Agricultural Technologies and National Award for Innovations & Technology Development by the Farmers.

This Year, the ICAR selected 92 Awardees under 15 different Awards including 4 Institutions, 1 All India Coordinated Research Project, 4 Krishi Vigyan Kendras, 67 Scientists and 11 Farmers of whom 8 were Women Scientists and Farmers.

The Chief Guest and the dignitaries released the various ICAR Publications and Technologies on the occasion. Dr. Trilochan Mohapatra, Secretary (DARE) & Director General (ICAR) highlighted the Council's achievements made during the last Year.

The Ministers / Members of Parliament, Members of the ICAR Governing Body, Senior Officials of ICAR Head Quarters, Directors of ICAR Institutes, Scientists and Vice-Chancellors of State Agricultural Universities also virtually participated in the event.

ICAR-IIVR's Okra Variety - Kashi Chaman fetches bumper yield at farmer's field

July 12, 2022

Okra is one of the most important vegetables cultivated and consumed all over India. It is rich in many nutrients and particularly, high in Vitamins - C and K. Okra is enriched with the anti-oxidants which reduces the risk of serious diseases, prevents inflammation and contributes to the overall health. It contains polyphenols which is beneficial to heart and brain health. Okra contains a protein known as Lectin which is Anti-Cancerous.

The Okra Variety - Kashi Chaman developed at the ICAR-Indian Institute of Vegetable Research, Varanasi, Uttar Pradesh in the Year - 2019 can be cultivated in both summer and rainy seasons. The Variety is tolerant to Yellow Vain Mosaic Virus (YVMV) and Okra Enation Leaf Curl Virus (OELCV) Diseases which are the most dangerous diseases for the Okra Crops and a major problem in the Okra cultivation. The Variety's yield potential 21.66% more in its sector due to which the Variety is becoming popular in Uttar Pradesh, Bihar, Odisha and has already covered around 10,000 ha area at the farmer's field.

Shri Upendra Singh Patel from Bangalipur Village, Araziline Block, Varanasi had sowed the seeds of Okra Variety - Kashi Chaman on 10th July, 2021 in 10 Biswa (0.3 Acre) land and followed the scientific package of practices for its production. He also used the recommended fertilizers and chemicals as suggested by the Institute's Scientists.

The first flush of Okra fruit was harvested 46 days after sowing, that is, on 25th August, 2021. After that, he had taken regular harvest of 35 to 40 Kgs Okra in 3 to 4 days interval and had taken 19 harvests upto the last Week of October with a total yield of 668 Kgs in 90 days duration form 0.3 Acre of land with a net profit of Rs. 21,376/- after deducting the cost of cultivation and transportation cost to the market.

Bangladesh regulators approve introduction of 2 Bt cotton varieties

19 Jun '22

Bangladesh regulators recently agreed to introduce the transgenic Bt cotton in the country. With low yields, the country's homegrown cotton varieties produce only 3 tonnes of cotton per hectare. Two Bt varieties that the regulators have initially approved will would yield over 4 tonnes per hectare. Farmers will save costs on pesticides against bollworm too.

The Bangladesh National Technical Committee on Crop Biotechnology (BNTCCB), at a recent meeting, gave the go-ahead for two Bt cotton varieties, both sourced from the Hyderabad-based Indian company JK Agri Genetics.

Bangladesh has to pay up to $5 billion annually to import cotton, a key raw material for the apparel industry. The US Department of Agriculture recently projected that Bangladesh would have to import nearly 9 million bales of cotton in 2022-23 against a paltry domestic production of 155,000 bales.

Once introduced, Bt cotton will be Bangladesh's second genetically-engineered crop after Bt brinjal was introduced in 2013. The approval of another such product–vitamin A-enriched golden rice–has been pending with regulators for the past four years.

The Cotton Development Board's (CDB) field experiments found that farmers would earn over Tk 100,000 more from each hectare of Bt cotton compared to their earnings from the cultivation of traditional varieties, Bangla media reported.

Denmark Admits Vaccinating Children Was A Mistake

June 26, 2022

A top Danish health authority has stated that immunizations should not have been prescribed for all children aged 5 and up.

Søren Brostrøm, the director general of the Danish Health Authority, told TV 2 that depending on the information that has developed since late 2021, it was incorrect to generally immunize children.

"I want to look all parents of children who have vaccinated their child in the eye and say, 'You did the right thing and thank you for listening,'" Brostrøm said.

"But at the same time—and this is the important thing to maintain confidence—I will admit and say that we have become wiser and we would not do the same today. And we will not do that in the future either," he added.

Studies on the vaccinations' effects have revealed that they offer little protection from virus infection. Additionally, research has shown that vaccines do not provide adequate protection against severe disease in youngsters, who are generally at low risk for negative outcomes should they contract the virus.

In accordance with Denmark's new vaccine strategy, adults should get immunized, while children should receive different prescriptions.

FDA love to Pfizer's: Grants State-Licensed Pharmacists Authority to Prescribe Paxlovid

Jul 07, 2022

The U.S. Food and Drug Administration is authorizing state-licensed pharmacists to prescribe Pfizer's Paxlovid (nirmatrelvir and ritonavir) to treat COVID-19.

The granting of the emergency use authorization (EUA) comes with certain limitations, however, as the prescribing pharmacist must refer patients for clinical assessment with a physician, advanced practice registered nurse or licensed physician assistant.

They cannot prescribe Paxlovid if there is not enough information to evaluate renal and hepatic function or potential drug interaction, if modifications are needed because of possible drug interactions and if it is not deemed to be the right therapeutic option based on the fact sheet for healthcare providers or where monitoring will not be feasible.

Paxlovid has the FDA's authorization to treat mild-to-moderate COVID-19 in pediatric patients ages 12 years and up and weighing at least 40 kgs and adults who have tested positive for SARS-CoV-2 and are at high risk for progression to severe COVID-19.

Patients in the said populations who test positive using home rapid antigen diagnostic tests (PCR tests) are also eligible to receive the drug, with no need to conduct additional direct SARS-CoV-2 viral testing. Positive antibody tests are not classified as direct SARS-CoV-2 tests.

The FDA also noted that those who test positive for COVID-19 should first locate a Test-to-Treat site in their area or a regular healthcare provider. Only state-licensed pharmacists are allowed to prescribe the drug, and community pharmacists who are not part of a Test-to-Treat site should figure out how to provide the service outside of this location.

"The FDA recognizes the important role pharmacists have played and continue to play in combatting this pandemic," Patrizia Cavazzoni, M.D., director for the FDA's Center for Drug Evaluation and Research said.

"Since Paxlovid must be taken within five days after symptoms begin, authorizing state-licensed pharmacists to prescribe Paxlovid could expand access to timely treatment for some patients who are eligible to receive this drug for the treatment of COVID-19," Cavazzoni added.

To get Paxlovid through a state-licensed pharmacist, patients should bring electronic or printed health records not older than 12 months, including the latest blood work data, so that the pharmacist can evaluate for liver or kidney issues. Patients should also bring a list of all the medications they are currently taking to enable pharmacists to spot potential drug interactions.

The EUA is in effect for as long as the FDA deems it fit.

"This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act," the FDA wrote in its announcement.

HC orders IIT Delhi committee to conclude probe into plagiarism allegations

June 18, 2022

The petitioner alleged that his co-guide used his research proposals to obtain a fellowship worth Rs 10.80 lakh for herself

The Delhi High Court (HC) ordered a committee at the Indian Institute of Technology (IIT) Delhi to conclude its probe into the allegation of plagiarism made by a PhD scholar against two of professors and submit a report to it.

According to a report by PTI, Justice Sanjeev Narula was dealing

with the scholar's plea against the termination of his registration from the institute on account of unsatisfactory performance in two consecutive semesters. He stated that the facts of the case are "quite unsettling" and he requested a report from the Student Grievance Redressal Committee on the matter before making any interim decisions.

The petitioner alleged that his co-guide used two of his research proposals to obtain a Lok Sabha-sponsored fellowship that was worth Rs 10.80 lakh for herself. He said that the name of the chairperson of the Student Research Committee, who was also his research supervisor, was mentioned as the Co-Principal Investigator on research proposals for the fellowship.

The petitioner also claimed that after he confronted them about the issue of plagiarism, they adopted an adversarial attitude towards him, which led to his complaints to the Student Grievance Redressal Committee, the Institute Level Plagiarism Committee, and the Department of Administrative Reforms and Public Grievances.

The counsel for IIT Delhi agreed that the issue of plagiarism was very serious and the petitioner's allegation was viewed with seriousness by the institute. They informed that the Institute Level Plagiarism Committee would consider the complaint of the petitioner.

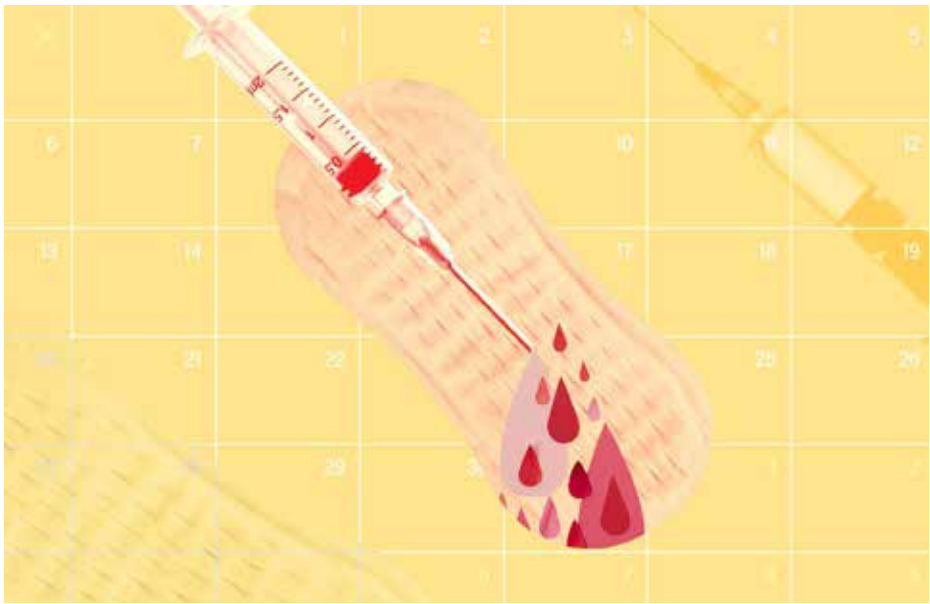
The lawyer said that any action that could be taken on the complaint would depend on the report of the committee. "In light of the foregoing, interim directions are deferred till the next date of hearing. In the meantime, the Institute Level Plagiarism Committee is directed to conclude the investigation and submit the report to the court. Further, the report prepared by the Student Grievance Redressal Committee be also filed with this court before the next date of hearing, with a copy to the Petitioner," said the court in its order passed earlier this month.

The court also issued a notice on the petition and granted time to the institute to file its response. The petitioner, who joined the Department of Management Studies as a full-time PhD scholar in 2018, also alleged that he virtually participated in several conferences at universities and institutes around the world but it was not appreciated by his co-guide and that she used to criticise him for the same on the grounds that he did not seek their approval prior to participating in such conferences. The court listed the matter for further hearing on July 19.

Thousands report unusual menstruation patterns after COVID-19 vaccination

July 15, 2022

According to a story published in Science, Kathryn Clancy got her first dose of a COVID-19 vaccine in early 2021 and 10 days later found herself sitting uncomfortably in a work Zoom meeting during one of the heaviest periods she'd experienced. "I had what's often called menstrual flooding," says Clancy, a biological anthropologist at the University of Illinois, Urba-



na-Champaign. Clancy wouldn't have thought to connect the experience to the Moderna dose she'd received were it not for her graduate student, Katharine Lee, now at Tulane University, who shared a similar tale. "I had the worst cramps of my life" after COVID-19 vaccination, Lee says. Intrigued, Clancy—who didn't experience similarly intense symptoms after her second dose—shared her story on Twitter. Hundreds responded with parallel stories, leading her to suspect a potential link to vaccination.

Those suspicions have grown with the completion of a more formal survey in which Clancy, Lee, and colleagues gathered thousands of stories of breakthrough bleeding and bleeding more heavily after a COVID-19 vaccine from people around the world. Between April and October 2021, the survey welcomed anyone 18 and older who gets or used to get a period. Because of that, Clancy cautions, the percentage affected is likely not representative of the general population—and indeed, a whopping 42% of about 16,000 people in the survey who had a regular menstrual cycle said they bled more heavily than usual after vaccination, a number far higher than others have reported. Still, the researchers captured a broad swath of people and their stories, including populations often neglected in menstrual research and breakthrough bleeding, which occurs when it is not expected, such as transgender and postmenopausal people.

Clarifying the issue is vital. "It's important to know about," says Victoria Male, a reproductive immunologist at Imperial College London. "Let's say you got the vaccine and the next day you felt really dreadful the way some people do." If you hadn't been informed of the chance of fever, muscle aches, and other effects that quickly dissipate, "you would be really worried," she said. Illuminating the chance of menstrual irregularities and confirming they aren't a health risk also helps combat widespread misinformation that COVID-19 vaccines impair fertility, Male and others say.

"We need these studies out there because it elevates the issue," says Alison Edelman, an obstetrician-gynecologist at Oregon Health & Science University who wasn't involved in this research but has examined menstrual irregularities after COVID-19 vaccination.

After Clancy's initial tweet drew such a response, she and Lee set out to learn more, initially aiming for a 500-person survey of menstrual experiences after COVID-19 vaccination. When 500 signed up in the first hour after the survey was posted online, Clancy realized the project would balloon well beyond what she'd anticipated.

More than 165,000 people around the world who were vaccinated with two doses participated. (Boosters weren't widely available during the survey period.) Today the team reports in Science Advances on a subset of 39,000 from its first round of analyses. (The paper was posted in February as a preprint.)

Given their anthropology background, Clancy and Lee focused their survey on obtaining narrative-style responses and on documenting symptoms, such as breakthrough bleeding, that are important but can be hard to measure quantitatively. Among postmenopausal people, unexplained vaginal bleeding is a symptom of uterine cancer, so it happening after a vaccine dose could cause needless worry. In the survey results published today, 66% of 673 postmenopausal people reported breakthrough bleeding, as did 39% of the 280 people on gender-affirming hormones. Because of these hormones the latter group take, many don't have a period and can find getting one distressing.

The survey results, even with the authors' caveats, could lead to concern that the chance of menstrual irregularities after vaccination is much higher than it actually is, worries Lill Trogstad, an obstetrician-gynecologist and epidemiologist at the Norwegian Institute of Public Health who wasn't involved with the study. In addition to likely attracting people who'd experienced these issues, the study didn't include surveys of a control group of unvaccinated people or compare prevaccine menstrual cycles with postvaccine cycles in respondents over time. "These two things sort of limit the study," Trogstad says. "You cannot estimate excess risk following vaccine" without a control group. Her own survey, done via smartphones and published as a preprint, found that just over 13%

of young women in Norway said their periods were heavier after COVID-19 vaccination; that compared with 7% of the same group who said their period prior to vaccination was heavier than normal.

Clinical trials of COVID-19 vaccines didn't look for effects on the menstrual cycle. Regardless of the prevalence of menstrual irregularities after COVID-19 vaccination, scientists note there are hypotheses that could explain it. Just like infections and fevers, which are known to affect periods, the immune system's response to vaccination may alter sex hormone patterns or the cells that build up and break down the uterine lining, both of which are interlinked with immunology. There's been limited research into other vaccines and periods, but one study from Japan found an association with the human papillomavirus vaccine and irregular menstruation.

The rash of anecdotes about menstrual irregularities after a COVID-19 vaccine, and resulting misinformation that the vaccines could disrupt fertility, spurred more studies on menstruation than the neglected topic usually receives. One March preprint by Male saw an effect on cycle length but not menstrual flow after vaccination in a small study of 79 people. A study this week on premenopausal women found a temporary half-day to 2-day increase, on average, in cycle length after a COVID-19 vaccine.

In her work, Edelman relied on anonymized data from a fertility awareness app. She found that, on average, vaccination altered cycle length by less than 1 day, but those who had both doses of vaccine in the same menstrual cycle experienced a 2-day difference, on average. About 10% of those individuals, who got both vaccine doses in the same cycle, saw a change of at least 8 days in their cycle length—but they appear to return to their baseline as soon as one cycle later. "We have this picture coming together that's very reassuring," Edelman says of these studies and others showing the vaccine doesn't affect fertility.

For her part, Clancy is keen to continue with this research. She wants to study menstrual flow pre– and post–COVID-19 vaccination by having volunteers track and report symptoms in real time—rather than rely on memory, as this survey did. But she hasn't been able to secure funding for such an effort. She's also interested in studying the phenomenon after influenza vaccination. In the meantime, her team is wrapping up a follow-up survey on how quickly menstrual patterns renormalized for respondents. "Our goal is to start from the position of believing the people talking to us," she says, and let that guide the studies to come.

Biotech Industry News

Twitter Sued For Suspending Physicians Who Posted Truthful Information About COVID

July 7, 2022

The physicians said that they were suing Twitter for permanently suspending them for posting truthful information about COVID and also failing to provide them with verified badges.

Drs. Robert Malone, Peter McCullough, and Bryan Tyson filed the lawsuit (pdf below) on Monday in San Francisco County Superior Court in California.

The complaint claims that by permanently suspending the plaintiffs' accounts, silencing their opinions, and failing to provide them "verified" badges, Twitter violated the terms of its contract.

Plaintiffs are seeking the judge to order Twitter to reactivate their accounts because they claim Twitter's actions were a major factor in harming them. Attorneys Bryan M. Garrie and Matthew P. Tyson are defending all three doctors (no relation to the plaintiff, Bryan Tyson).

On May 12, Matthew Tyson addressed a letter to Twitter's directors and managing agents requesting that the social media platform reinstate the accounts of five doctors, including the plaintiffs, and grant them "verified" badges. Twitter didn't respond.

Matthew Tyson acknowledged in the letter that Twitter is a "private company" with the right to "suspend user accounts for any or no reason." "However, Twitter also implemented specific community standards to limit COVID-19 misinformation on the platform, and Twitter was bound to follow those terms," he added.

The conditions of Twitter's content moderation, according to the complaint, included removal procedures for ineffective treatments and false diagnostic standards, as well as steps for "labeling" information as "misleading." "None of these physicians posted false or misleading information, nor did they receive five strikes before suspension," Matthew Tyson stated in his letter to Twitter.

"It's no accident that Twitter violated its own COVID-19 misinformation guidelines and suspended the accounts of Drs. Zelenko, Malone, Fareed, Tyson and McCullough," he wrote.

At least 50 Indian drug makers in queue for patent of oral anti-diabetes drug

July 07, 2022

According to market research firm AIOCD, at least 50 Indian drug makers are jumping into the fray with around 100 generic versions of the popular anti-diabetes drugs, leading to a likely price war. Analysts expect prices to drop by 60% with the entry of generics. They are also expecting that the competition will intensify.

Panacea Biotec launched single dose and combination medicines of anti-diabetes drug vildagliptin in 2019, the patent for which had expired a day earlier. This drug is used to treat uncontrolled type 2 diabetes mellitus. Annual sales of vildagliptin and its combination drugs was Rs 969 crore in 2019.

Vildagliptin is an oral antidiabetic drug that enhances the response of pancreatic islet cell to glucose, and in turn helps in controlling sugar levels.

Vildagliptin and Teneligliptin, two molecules of the same class that went off-patent in 2019 and 2015, respectively is again expected to enter the race to get a patent. Teneligliptin appeared to be more potent than voglibose or vildagliptin based on its glucose-lowering effects.

Januvia, which goes by the generic name Sitagliptin comes under the class of dipeptidyl peptidase (DPP4) inhibitors.

MSD also sells a fixed dose combination of sitagliptin and metformin under the brand name Janumet.

Sun Pharma also markets sitagliptin and a sitagliptin-metformin combination in India under licence from MSD.

The current market for sitagliptin and its combinations are around Rs 1,000 crore, which is 10% of India's oral anti-diabetes drug market.

Indian Immunologicals launches nationwide anti-rabies vaccine drive

July 06, 2022

Indian Immunologicals Limited (IIL) on Wednesday organised a nationwide free vaccination camp against zoonotic diseases on account of World Zoonosis Day 2022.

Diseases that transmit from animals to human beings are called zoonotic diseases and the day is observed annually on July 6 to commemorate the first immunisation against a zoonotic illness.

"Today, we administered 1 lakh doses of Raksharab and Starvac R (Anti-rabies vaccines of IIL) free of cost, to realize the vision of 'One health', a collaborative effort towards optimal health for humans and animals through innovative healthcare products," Dr. K. Anand Kumar, Managing Director, Indian Immunologicals Limited.

The drive was launched at Government Superspeciality Veterinary Hospital, Narayanguda.

In their fight against the spread of such zoonotic viruses, IIL's vaccination camp was escalated to 100 cities across the country through veterinary dispensaries, veterinary colleges and NGOs.

Zoonotic diseases such as rabies have imperilled human health since antiquity. Dogs are the source of most human rabies deaths, contributing up to 99% of all rabies transmissions to humans, and every year it causes 18,000 to 20,000 deaths.

"Through our 'Anti-Rabies vaccine drive', we aim to spread awareness on the disease and need to restrain it. Apart from Raksharab and Starvac-R, we have the largest range of zoonotic vaccines in the country such as CYSVAX, Bruvax, among others and we are constantly innovating novel vaccines to cater to the ever-emerging zoonotic risks," Dr. Kumar said.

DCGI gives nod to India's first mRNA vaccine, of Gennova Biopharma

July 15, 2022

The Drugs Controller General of India (DCGI) has given a green signal to the country's first indigenous mRNA vaccine against Covid by Gennova Biopharma for emergency use among adults in India.

With the nod, Pune-based Gennova Biopharmaceuticals aims to produce around 40-50 lakh doses per month. Beyond India, the company aims at providing sustainable access to the vaccine to low-income countries around the

world to blunt the spread of the coronavirus pandemic.

GEMCOVAC-19 is the very first mRNA vaccine developed in India and the third mRNA vaccine to be approved for Covid-19 in the world.

mRNA VACCINE

The two-dose vaccine is stable for storage at 2-8 degrees Celsius. These vaccines are highly efficacious because of their inherent capacity to be translated into the protein structure inside the cell cytoplasm.

mRNA vaccines are considered safe as mRNA is non-infectious, non-integrating in nature, and degraded by standard cellular mechanisms. Notably, this technology provides flexibility to quickly tweak the vaccine for any existing or emerging variants of the virus and this technology platform will empower India to be pandemic ready.

GEMCOVAC-19 has reached the primary endpoint of the Phase III clinical trial. The clinical data was evaluated by the Central Drugs Standard Control Organisation (CDSCO) and the vaccine was found to be safe, well-tolerated and immunogenic.

U.S. Public Health Agencies Aren't 'Following the Science,' Officials Say

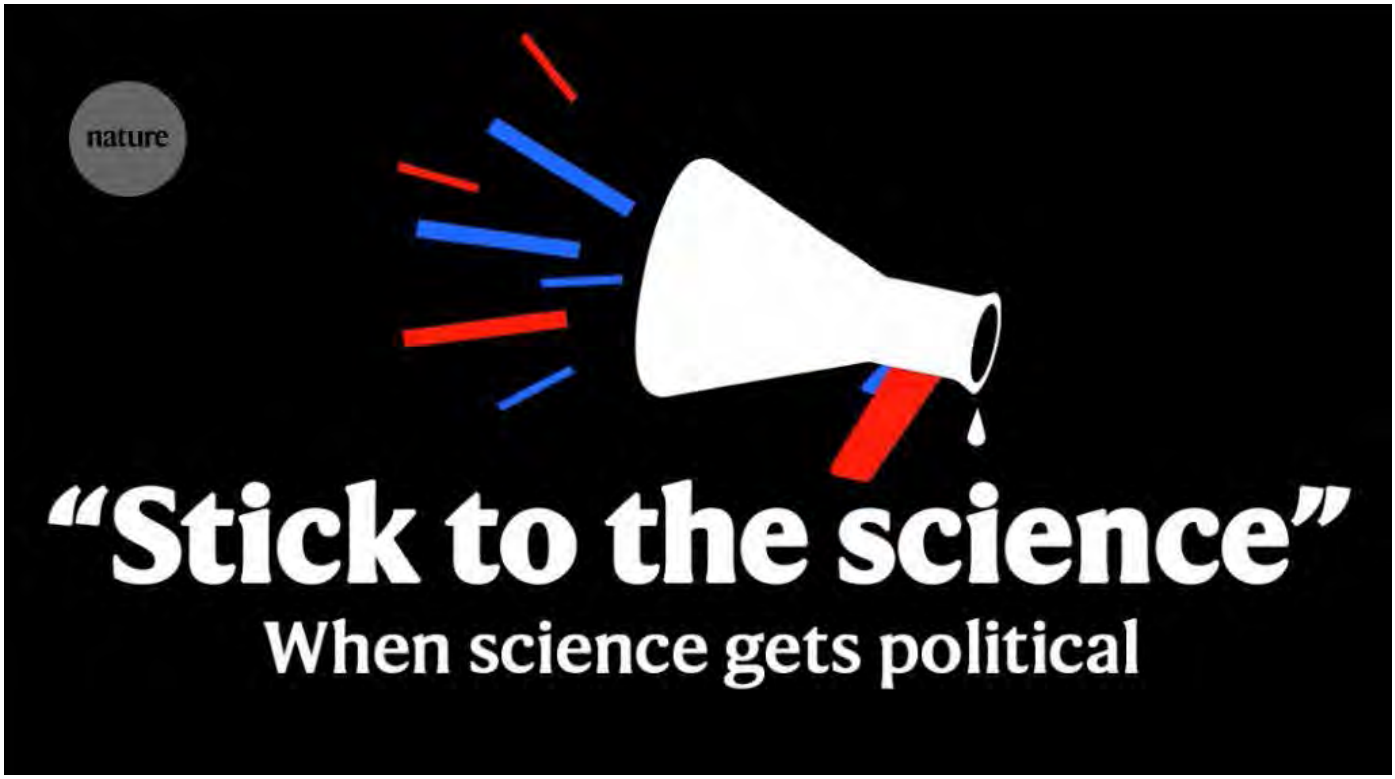
July 13, 2022

At the NIH, doctors and scientists complain to us about low morale and lower staffing: The NIH's Vaccine Research Center has had many of its senior scientists leave over the last year, including the director, deputy director and chief medical officer. "They have no leadership right now. Suddenly there's an enormous number of jobs opening up at the highest level positions," one NIH scientist told us. (The people who spoke to us would only agree to be quoted anonymously, citing fear of professional repercussions.)

The CDC has experienced a similar exodus. "There's been a large amount of turnover. Morale is low," one high level official at the CDC told us. "Things have become so political, so what are we there for?" Another CDC scientist told us: "I used to be proud to tell people I work at the CDC. Now I'm embarrassed."

An official at the FDA put it this way: "I can't tell you how many people at the FDA have told me, 'I don't like any of this, but I just need to make it to my retirement.'"
Right now, internal critics of these agencies are focused on one issue above all: Why did the FDA and the CDC issue strong blanket recommendations for Covid vaccines in children?

The trouble is that this sweeping recommendation was based on



extremely weak, inconclusive data provided by Pfizer and Moderna.

Start with Pfizer. Using a three-dose vaccine in 992 children between the ages of six months and five years, Pfizer found no statistically significant evidence of vaccine efficacy.

Referring to Pfizer's vaccine efficacy in healthy young children, one high-level CDC official—whose expertise is in the evaluation of clinical data—joked: "You can inject them with it or squirt it in their face, and you'll get the same benefit."

"It seems criminal that we put out the recommendation to give mRNA Covid vaccines to babies without good data. We really don't know what the risks are yet. So why push it so hard?" a CDC physician added. A high-level FDA official felt the same way: "The public has no idea how bad this data really is. It would not pass muster for any other authorization."

And yet, the FDA and the CDC pushed it through. That slap in the face of science may explain why only 2% of parents of children under age five have chosen to get the Covid vaccine, and 40% of parents in rural areas say their pediatricians did not recommend the Covid vaccine for their child.

The FDA's two top vaccine regulators—Dr. Marion Gruber, director of the FDA's vaccine office, and her deputy director, Dr. Philip Krause—quit the agency last year over political pressure to authorize vaccine boosters in young people. After their departure they wrote scathing commentaries explaining why the data did not support a broad booster authorization, arguing in the Washington Post that "the push for boosters for everyone could actually prolong the pandemic," citing concerns that boosting based on an outdated variant could be counterproductive.

"It felt like we were a political tool" a CDC scientist told us about the issue. That insider went on to explain that he got vaccinated early but chose not to get boosted based on the data.

As one NIH scientist told us: "There's a silence, an unwillingness for agency scientists to say anything. Even though they know that some of what's being said out of the agency is absurd."

That was a theme we heard over and over again—people felt like they couldn't speak freely, even internally within their agencies. "You get labeled based on what you say. If you talk about it you will suffer, I'm convinced," an FDA staffer told us. Another person at that agency added: "If you speak honestly, you get treated differently." And so they remain quiet, speaking to each other in private or in text groups on Signal.

Biogen Abandons Aduhelm Study Following Low Patient Enrollment after controversial results

Jun 24, 2022

Biogen indicated it has terminated an observational study of its approved Alzheimer's drug Aduhelm (aducanumab-avwa) following its post on ClinicalTrials.gov.

The company issued a statement about the trial that read, "As a result of the national policy for coverage, it is expected there will be limited aducanumab-avwa prescription and usage in routine clinical practice, making the study not feasible for enrollment."

The study was to be a prospective, single-arm, multicenter, non-interventional study of the drug as prescribed in the U.S. in a post-marketing setting. Patients would receive Aduhelm as well as standard-of-care and be followed for up to five years. Data would be collected at routine visits every six to 12 months. It was designed to enroll 6,000 patients, but after seven months of enrollment, only 29 patients had signed up.

In April, the U.S. Center for Medicare and Medicaid Services (CMS) implemented its guidance for Aduhelm, limiting its availability. The agency originally issued the draft guidance in January, allowing several months for public responses. The guidance restricts the drug to reimbursement only if used in a clinical trial.

This was a very unusual move for a drug approved by the U.S. Food and Drug Administration. CMS also applied the guidance to an entire class of beta-amyloid-clearing drugs that have yet to be submitted for approval.

Almost everything about this drug has been a debacle for Biogen. It was approved on June 7, 2021, becoming the first Alzheimer's drug approved in almost 20 years. Biogen and its collaboration partner Eisai had abandoned the drug program in March 2019 after a futility analysis found it would not hit its endpoints.
However, after a full analysis and discussions with the FDA, one of the trials, the Phase III EMERGE study, hit the primary endpoint at the highest dose. It demonstrated a significant decrease in clinical decline. Still, the data was very complex and not without its controversies.

The FDA's Peripheral and Central Nervous System Drugs Advisory Committee voted against recommending the drug in November 2020. The agency approved the drug anyway under an accelerated approval program that would require a post-marketing study to prove clinical efficacy. The approval was based on biomarker data showing the drug cleared beta-amyloid in the patients. The drug also has been connected to some potentially lethal side effects, especially amyloid-related imaging abnormalities (ARIA), which can lead to cerebral edema and death.

The drug was performing significantly below expectations even before the CMS decision, reporting only $300,000 in third-quarter 2021 sales, largely due to the reluctance of payers to reimburse for the drug, which was initially priced at $56,000 per patient per year. Fourth-quarter sales were only $1 million, well under early projections of $10.79 million, with peak projections of $9 billion. To improve uptake, Biogen had cut the price in half to about $28,000.

Bad Science

Bose institute scientists' paper earned expression of concern

July 17, 2022

An **Expression of concern was raised on** the paper "Mitogen-activated protein kinases regulate Mycobacterium avium-induced tumor necrosis factor-α release from macrophages" published in Pathogens and Disease (formerly FEMS Immunology and Medical Microbiology) ---Oxford Academic. The doi of article is https://doi.org/10.1111/j.1574-695X.2002.tb00605.x. The authors are from the famous, Department of Chemistry, Bose Institute, Kolkata, India. The concerned authrors are Asima Bhattacharyya, Shresh Pathak, Manikuntala Kundu and Joyoti Basu.

Photo: Joyoti Basu

The expression of concern was raised because of Concerns/Issues About Image and is further under Investigation by Journal/Publisher. According to Notice: With this notice, Pathogens and Disease states its awareness of concerns regarding irregularities in Figures 2 and 3 of the mentioned paper. These

concerns are under investigation. Readers will be updated at the conclusion of the investigation.

Bharathidasan University and IIT Madras researcher caught for manipulating images

July 19, 2022

A Paper "AEG-1/miR-221 Axis Cooperatively Regulates the Progression of Hepatocellular Carcinoma by Targeting PTEN/PI3K/AKT Signaling Pathway" published in International Journal of Molecular Sciences ---MDPI has been retracted. The authors are from Molecular Oncology Laboratory, Department of Biochemistry, School of Life Sciences, Bharathidasan University; Department of Biotechnology, Bhupat and Jyoti Mehta School of Biosciences, Indian Institute of Technology Madras, Chennai and Cancer Biology Laboratory, Department of Biomedical Science, School of Life Sciences, Bharathidasan University.

The article was retracted because of Duplication of Image, Manipulation of Images and Unreliable Results by the authors Maheshkumar Kannan, Sridharan Jayamohan, Rajesh Kannan Moorthy, Siva Chander Chabattula, Mathan Ganeshan, Antony Joseph Velanganni Arockiam.

According to notice:

The journal retracts the article, "AEG-1/miR-221 Axis Cooperatively Regulates the Progression of Hepatocellular Carcinoma by Targeting PTEN/PI3K/AKT Signaling Pathway, cited above. We have been made aware that a number of figures in the paper cited above contain manipulation. Several images from Figures 4 and 5 are unexpectedly similar. In accordance with our ethics procedures, an investigation was conducted.

The authors have not been able to provide a satisfactory explanation for these irregularities, which brings uncertainty regarding the scientific conclusions. Therefore, to ensure the addition of only high-quality scientific works to the field of scholarly publication, this paper has now been retracted and shall be marked accordingly. The authors agree to this retraction. We apologize to our readership that this went undetected until now.

Photo: Antony Joseph Velanganni Arockiam

Nirma Univ. scientist who is among 2% top scientists quoted for bad scientist

July 20, 2022

Paper from Snehal S Patel. "Insights from diversified anti-angiogenic models: role of β-interferon inducer DEAE-Dextran" which was Published by Pharmacological Reports ---Springer has been retracted. The authrors are from Department of Pharmacology, Institute of Pharmacy, Nirma University, Ahmedabad, Gujarat, India.

The article was retracted because there were anomalies like Concerns/Issues About Data, Concerns/Issues About Image, Duplication of Image, Original Data not Provided. The concerned authors

of paper are Anita K Bakrania, Bhavesh C Variya and Snehal S Patel.

The Editors have retracted this article. After publication, concerns were raised regarding potential issues in the figures. Specifically:

Fig. 2 panels I and J appear to contain the same image;

There are inconsistencies in the wound width and cell confluence among the 0 h samples in Fig. 2 (A, F and K);

There are inconsistencies in Figs. 4, 6 and 7 in terms of magnification and stretching;

Images in Fig. 7 panels G and K appear highly similar.

The authors have been unable to supply the raw data to address these issues. The Editors therefore no longer have confidence in the presented data.

Snehal S. Patel and Anita K. Bakrania do not agree to this retraction. Bhavesh C. Variya has not responded to any correspondence from the Editor about this retraction.

Sastra Scientists faked peer review, article retracted

July 15, 2022

According to a retraction notice of paper "Preclinical diagnosis of asthma with GMR sensor and RADWT algorithm" published in Journal of Ambient Intelligence and Humanized Computing ---Springer - Nature Publishing Group scientists from Department of Biomedical Engineering, Sri Jayaram Institute of Engineering and Technology, Chennai, Tamil Nadu, India; Department of Chemical and Biotechnology, SASTRA Deemed-To-Be University, Thanjavur, Tamil Nadu and Department of Biomedical Engineering, Rajalakshmi Engineering College, Chennai, Tamil Nadu, India earned a retraction. The reasons of retraction were Fake Peer Review and Rogue Editor. The authors of this faked paper are S Nithyaselvakumari, B A Gowri Shankar and M C Jobin Christ.

According to retraction notice: The Editor-in-Chief and the publisher have retracted this article. This article was submitted to be part of a guest-edited issue. An investigation concluded that the editorial process of this guest-edited issue was compromised by a third party and that the peer review process has been manipulated. Based on the investigation's findings the Editor-in-Chief therefore no longer has confidence in the results and conclusions of this article. Authors S. Nithyaselvakumari and M. C. Jobin Christ disagree with this retraction. Author B. A. Gowri Shankar has not responded to correspondence regarding this retraction.

Notifications

AcSIR

Academy of Scientific and Innovative Research (AcSIR)

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Website: https://acsir.res.in

ADVERTISEMENT FOR THE POSITION OF DIRECTOR

The Academy of Scientific and Innovative Research (AcSIR) invites applications/nominations for the position of **DIRECTOR**, which is equivalent to the post of Vice-Chancellor in the Central Universities. The primary location of the office of Director will be at the Headquarters of AcSIR in Ghaziabad, UP.

AcSIR was established as an "Institution of National Importance" by an Act of Indian Parliament, *"The Academy of Scientific and Innovative Research Act, 2011"*. AcSIR is mandated to undertake high quality teaching and advanced research in frontier areas of science and technology and has the authority to award degrees and diplomas. AcSIR has entered into a Memorandum of Understanding with the Council of Scientific and Industrial Research (CSIR), India, under which 38 CSIR institutes are affiliated with AcSIR as its Academic Centres. Additionally, 13 non-CSIR institutes are also affiliated with AcSIR as its Associate Academic Centres. Currently, about 5500 students are enrolled for PhD in AcSIR and thus far more than 3100 students have been awarded their PhD degree. Presently, AcSIR is ranked 2nd by "Scimago Institutions Ranking" (2022), 13th by "Nature index" (2020-21) and 22nd by "NIRF (2021) in the Research Category, among the academic institutions in India.

Eligibility: The candidate should be a citizen of India with a proven track record in cutting-edge research areas of science & technology with national and international recognition. The candidate should be of high academic standing with demonstrated administrative capabilities and possess leadership qualities, required for building/nurturing AcSIR to outstanding national and global visibility.

Tenure and Compensation: The tenure of the Director will initially be for a period of five years from the date of engagement on a contractual basis, which may be extended, up to the age of 70 years. The compensation package shall be recommended by the selection committee, currently in the range of Rs. 30.0 – 36.0 lakhs per annum with additional perquisites, subject to revision by the Board of Governors.

How to apply: The application, in the prescribed format, highlighting the academic and scientific contributions in details, along with list of publications/patents, may be sent through e-mail to the Associate Director, AcSIR on the e-mail ID: **hr-director2022@acsir.res.in** with a copy at **ad_admin.finance@acsir.res.in** (with subject: POSITION OF DIRECTOR in AcSIR - 2022). The last date of receipt of the application is **July 29, 2022**.

Govt. of Haryana

Azadi Ka Amrit Mahotsav

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For Eminent Scientists above 40 years of age

HARYANA YUVA VIGYAN RATNA AWARDS

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FOR THEIR OUTSTANDING CONTRIBUTION
IN THE FIELD OF SCIENCE & TECHNOLOGY

Last date for receiving nominations **July 31, 2022**

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