AAiPS

Newsletter

Vol. 31 Issue 3 August 2020 – Dec 2020

AMERICANASSOCIATION
OF INDIAN PHARMACEUTICAL SCIENTISTS
P.O. Box 189 Mount Freedom, NJ 07970

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INSIDE THIS ISSUE

Newsletter Editor: Raghu Kasu
Editorial Board, Mike Yelvigi, Sampat Singhvi

PRESIDENT'S MESSAGE

Dear Members,

Wishing you all a very Happy Diwali and a safe Thanksgiving. This has been a challenging year with COVID restricting our daily lives both at work and at home. However, I am happy to say that AAiPS has stayed connected and conducted our first ever webinar late August on COVID 19 Vaccines – Pharma Challenges, Technology, Players and Status presented by our past President Mr. Vijai Kumar. This webinar was well received with good participation and follow-on discussion. Our second and final meeting is planned in early December and this will be a different type of meeting.

In a normal year our Annual Meeting would have coincided with the PharmSci 360 Meeting and we would typically invite speakers from the pharmaceutical industry and also recognize graduate students for outstanding research. This year, although the AAiPS annual meeting has been canceled, the Executive Committee has decided to move forward with the student awards so as to continue our tradition of encouraging students to pursue scientific research. On Dec 10th AAiPS will have a virtual Student Research Awards Showcase 2020 where the awardees will present their research projects in short 8-10 min presentations. All are invited to attend this event.

At this stage it is unclear if and when we will be able to go back to some face-to-face meetings in 2021. In this regard we have recently heard some positive news with two vaccines showing > 90% effectiveness in clinical studies. All of us are proud of these accomplishments by our fellow scientists and we hope for a return to some degree of normalcy in 2021.

In the interim stay well, stay safe!

Sincerely,

Rupa Doshi, Ph.D. President, AAiPS

QUOTE OF THE QUARTER

"Although I am a typical loner in my daily life, my awareness of belonging to the invisible community of those who strive for truth, beauty, and justice has prevented me from feelings of isolation." ― Albert Einstein

Student Research Awards & Virtual Meeting Update:

American Association of Indian Pharmaceutical Scientists (AAiPS)

List of Award Recipients for the Year 2020:

Manan Shah **University of Minnesota**	***Combination of STING and TLR 7/8 agonists as vaccine adjuvants for cancer immunotherapy***
Vineela Parvathaneni **St. John's University**	***Development and Evaluation of Transferrin Conjugated Amodiaquine Nanoparticles -Non-Small Cell Lung Cancer (NSCLC) Targeted Therapy***
Manali Patki **St. John's University**	***Overdose and Alcohol Sensitive Immediate Release Sleeping pills (OASIS) for deterring accidental overdose or abuse of sleeping pills***
Vrishali Salian **University of Minnesota**	***Molecular mechanisms of cerebrovascular inflammation in Alzheimer's disease.***
Navid Ayon **University of Missouri-Kansas City**	***Multidimensional Chemical Library Screening for Novel Antibacterial Activities***
YoungJun Yoo **University of California**	***Prolonged Antibiotic Exposure After Discontinuing Antibiotics in Premature Neonates Receiving Empiric Treatment for Early-Onset Sepsis***

You are Invited to the Student Research Awards Showcase 2020: Date: Dec 10, 2020 @ 6:30 PM Eastern Time

https://us02web.zoom.us/j/83939675524?pwd=ZmxzYlR6OXc3dzN4ZzJvQWF2MDVOdz09

Zoom Meeting Id: 839 3967 5524

Passcode: 354149

AAiPS members committee would like thank their Students Awards Chair (Dr. Hardeep Saluja) & other Graduate Awards Committee 2020 members for their efforts in making this happen during this Covid times .

The review committee comprised of the renowned academicians and scientists. Details as follows.

1. Dr.Hardeep S.Saluja, Chair, AAiPS Research Awards Committee. Bernhardt Professor of Pharmaceutical Sciences at Southwestern Oklahoma State University, Weatherford, OK.

2. Dr.S.Narasimha Murthy, Professor - Pharmaceutics and Drug Delivery, The University of Mississippi, MS.

3. Dr.Raj Suryanarayanan, Professor and William & Mildred Peters Endowed Chair, Department of Pharmaceutics, University of Minnesota, MN.

4. Dr.Martin J.D'Souza, Professor & Director of graduate programs, Endowed Chair of Pharmaceutics, Mercer University – Atlanta GA.

5. Dr.Ankur Sharma, Senior Pharmacometrician, Clinical pharmacology and pharmacometrics, CSL Behring Biotherapies for life, PA

6. Mr.Raghu Kasu, Director, Formulation Research & Development at Apicore, NJ.

7. Dr.Pharavee Jaiprasart, Senior Scientist, Clinical Pharmacology, Janssen Incl, PA

Pharmaceutical News:

Two vaccines might get emergency approval this month.

Vaccines often take years to roll out, but the U.S. Food and Drug Administration, which is tasked with vetting and approving new medical products, released guidelines this summer that included a provision to authorize their emergency use. Such authorization would circumvent the typical protocols and allow a new vaccine to be distributed if "the known and potential benefits of a product … outweigh the known and potential risks."

On Nov. 20, Pfizer and its partner BioNTech were the first to file for an emergency use authorization for their COVID-19 vaccine. Moderna submitted its candidate for similar authorization. Both requests are under review.

The Pfizer and Moderna vaccines are both RNA-based vaccines and require two doses. The Pfizer vaccine doses need to be administered three weeks apart; the Moderna doses, four weeks apart.

A green light from the FDA could set into motion a rapid sequence of bureaucratic procedures and logistical steps that would result in the initial delivery of 6.4 million doses of the Pfizer vaccine throughout the United States and eight territories no later than Dec. 14. The company says it expects to produce up to 50 million doses by the end of the year.

The Moderna vaccine, if authorized, would be ready for distribution a week later. The company expects to have approximately 20 million doses available in the U.S. by the end of 2020.

https://www.latimes.com/

Trump to issue 'Buy American' executive order for essential drugs: reports

Shortly after he issued four drug pricing executive orders—including one that generated significant pushback from the pharmaceutical industry—President Donald Trump is set to issue another centering on U.S. production for drugs and medical supplies, according to reports.

The new order will stipulate that the federal government buy essential medicines made only in the U.S., according to The Hill. The government would develop a list of those essential drugs, and then direct agencies such as the Department of Health and Human Services and Department of Veterans Affairs to purchase only from U.S. factories.

Trump's trade advisor Peter Navarro laid out the framework to reporters, according to reports. Navarro said the idea is to "establish a base level of demand" to encourage U.S. drug manufacturing, as quoted by The Hill.

Lupin, Mylan Launch Etanercept Biosimilar in Germany

Lupin announced the German launch of its etanercept biosimilar, Nepexto, for the treatment of rheumatoid arthritis, as well as all other approved indications of the reference product Enbrel®. Lupin, in association with Mylan will release its etanercept product as an injectable in an easy-to-use pre-filled pen and a pre-filled syringe. Lupin's announcement also noted that Nepexto is its "first biosimilar to receive regulatory approval in Europe." As we previously reported, the European Commission granted the marketing authorization for Nepexto

on June 4, 2020, after the biosimilar received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP**).**

https://www.bigmoleculewatch.com/

Mylan boosts Euro portfolio with $756M rights deal for Aspen's injectable thrombosis meds

Mylan's planned megamerger with Pfizer's Upjohn generics unit has had a rocky road to approval, with the novel coronavirus pandemic snagging regulatory review. Despite the delay, Mylan isn't twiddling its thumbs: The generics giant is now bolting on a major addition to its EU portfolio as it awaits its merger deadline.

Mylan will shell out $756 million for European rights to a suite of Aspen Pharmacare's sterile injectable anticoagulants that raked in nearly a quarter-billion dollars in the year ending June 30, the generics giant said.

Mylan will pay Aspen $310 million in cash up front with an additional cash payment of $446 million due by June 25, 2021. The deal is expected to close by Dec. 31, roughly in line with the closing date for Mylan's planned merger with Pfizer's Upjohn generics unit.

https://www.fiercepharma.com/

Pfizer, AZ, Moderna and more pledge not to rush COVID-19 vaccines

With President Donald Trump and others touting accelerated timelines for COVID vaccines—potentially ending in an emergency authorization before the U.S. election—public confidence in the process has taken a hit. But nine biopharma CEOs are seeking to turn that sentiment around with a joint safety and efficacy pledge.

The CEOs of AstraZeneca, BioNTech, GlaxoSmithKline, Johnson & Johnson, Merck, Moderna, Novavax, Pfizer and Sanofi vowed to not seek approvals or emergency use authorizations for their vaccine candidates without conclusive positive data.

The drug makers will "only submit for approval or emergency use authorization after demonstrating safety and efficacy through a phase 3 clinical study that is designed and conducted to meet requirements of expert regulatory authorities such as FDA," they said.

https://www.fiercepharma.com

Teva, on the heels of major reorg, plans to cut 350 more manufacturing jobs in Israel

After a multiyear effort to cut away roughly $3 billion in operational costs, Israeli drug maker Teva could be expected to take a short break to its slice-and-dice efforts. Instead, Teva is keeping its foot on the gas pedal, and hundreds of Israeli manufacturing jobs are now in the chopping block.

Teva will cut 350 positions at its active pharmaceuticals ingredient (API) plant in Neot-Havav, Israel, as part of a "global optimization plan" to streamline site operations through February 2022, the drug maker said.

Those cuts won't be immediate, Teva said; instead, the company has agreed to eliminate those positions at the 2022 cut-off date. Teva pledged in a statement to offer "fair separation benefits, beyond those required by the law or collective agreements" to its employees.

https://www.fiercepharma.com/

Newly passed House bill could close orphan drug loophole that evergreens exclusivity

The Orphan Drug Act of 1983 was intended to reward biopharma companies for developing drugs for rare diseases. But over the years, criticism has increased over unexpected misuse of the law. Now, a new bill has made the first step toward closing one loophole.

The U.S. House of Representatives unanimously passed a bill (PDF) that would require drug makers to prove that they don't expect to recoup R&D costs through U.S. sales in 12 years if they want to obtain the seven-year marketing exclusivity under one of two paths toward an orphan drug designation.

The bill closes a loophole drug maker have used to "piggyback" on the orphan status of an older drug, according to Democratic Rep. Madeleine Dean of Pennsylvania—a co-sponsor of the bill, known as the Fairness in Orphan Drug Exclusivity Act.

A companion bill bearing the same title was introduced in the Senate in February.

The FDA can grant seven years of market exclusivity to a drug if it's intended to treat a condition affecting fewer than 200,000 patients in the U.S., or, in a less common scenario, if the developer doesn't expect to recover the development costs from selling a drug**.** However, for the second pathway, the current law allows market exclusivity to be extended for a new version of the same drug without the drug developer having to show unprofitability again—and that's the loophole the bill aims to close.

https://www.fiercepharma.com/

Trump to unveil international pricing index, rebate crackdown rules: reports

Several years after saying the pharmaceutical industry was "getting away with murder," President Donald Trump appears poised to unveil new drug pricing rules that could shake up U.S. pricing dynamics in a big way. But it remains to be seen exactly how the implementation will play out or whether the incoming Biden administration will keep the rules.

Trump plans to unveil two major measures—an international pricing index and a rule to crack down on drug rebates, according to reports in The Wall Street Journal and Reuters. After campaigning on the issue of lowering drug prices and seeing limited policy success on the subject throughout most of his term, Trump reiterated his drug pricing ambitions this summer by unveiling a series of executive orders.

The international pricing index—also called the "most-favored-nations" clause—would tie U.S. prices in Medicare to lower prices abroad. The pharmaceutical industry has intensely resisted the proposal. Eli Lilly CEO David Ricks, for one,

characterized it as “horrible” policy, and Pfizer CEO Albert Bourla, Ph.D., said the president’s summer executive orders on drug pricing were “an enormous distraction” amid the COVID-19 fight and threatened American jobs.

https://www.investoradvisor.org/

India's Aurolife under water with the FDA after chronic ceiling leaks imperil generics produced on site.

In the antiseptic world of drug manufacturing, cleanliness is key and outside contamination is a drug maker’s worst enemy. That's why, generally speaking, chronic water leaks from the ceiling are a bad thing—a fact an Indian generics maker is having to learn the hard way.

Aurolife, a subsidiary of Aurobindo Pharma, failed to adequately address a raft of issues at its Dayton, New Jersey, plant, including a flood of water leaks and impurity concerns over active pharmaceutical ingredients (APIs) used in one of its generic antipsychotics, the FDA said in a **warning letter** posted online.

During an inspection between January and February, the FDA found numerous water leaks in the drug maker’s packaging and encapsulation rooms, a potential sign of contamination for a range of its generic medicines.

The FDA noted four instances in 2018 in which the ceiling in Aurolife’ s encapsulation room leaked, contaminating multiple batches of generic anticonvulsant gabapentin. There were at least five other leaks in Aurolife’ s packaging room, the FDA noted, including while workers were loading tablets into their packages.

Some of the leaks occurred directly over the packaging lines, posing a contamination risk to moisture sensitive" drugs including diabetes medicine pioglitazone hydrochloride, which Aurolife produces on site.

In its response, Aurolife pledged to recall unnamed drugs cited in the FDA's Form 483, but the agency found Aurolife’ s "executive management failed to fully recognize the risks from these leaks" and didn't outline an adequate plan to conduct repairs.

https://www.fiercepharma.com/

Obituary:

Dr Saran Kumar was renowned pharmaceutical scientist, worked at Hoffman la Roche at Nutley campus for a long time. He has contributed immensely to pharmaceutical field , especially New Drug Delivery. He later joined Novartis company in New Jersey and Section Leader in Pharmaceutical sciences. Saran was active member of AAiPS and AAPS..

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- Dr. Mahendra Dedhiya (LIU): (for sponsoring for 4 years, 2020-2023)

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