AAiPS

Newsletter

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AMERICAN ASSOCIATION
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,

The outbreak of COVID 19 has resulted in significant harm to our nation's health and economy, requiring that we adapt in ways we did not have to before the pandemic. At the same time, the pharmaceutical industry is uniquely positioned to find a way to beat this virus through a creative, innovative and collaborative process. As a result, it has never been more important to remain connected through groups like AAiPS, whose purpose is to foster networking and exchange of scientific ideas.

In light of this situation, we may have to adapt our approach to stay in touch. While no AAiPS events/regional meetings could be scheduled during the first half of 2020, we are hoping to commence with events for the second half of the year. The executive committee continues to stay connected through regular teleconferences to monitor the situation and during our next teleconference in early May, we will determine the path forward. We will be be sure to share an update with the broader group shortly thereafter.

Please stay tuned and in the interim do stay safe and healthy!

Sincerely,
Rupa Doshi, Ph.D.
President, AAiPS

QUOTE OF THE QUARTER

"What is Poison?
Anything which is more than our necessity is Poison. It may be power, wealth, hunger, ego, greed, laziness, love, ambition, hate or anything"

By: Rumi,
The great Turkish Poet

2020 AAiPS Sponsors:

- Associated Capsule Group (ACG)
- Ajni US LLC

AAiPS Executive team would like to thank their sponsors for their generous support.

AAiPS Students Awards Sponsors:

Thanks are due to our student awards sponsors:

- Dr Bharat Oza and Mr. Vijai Kumar: In recognition and memory of ***Dr Heddi Bhargava*** (for sponsoring for 4 years, 2019-2022)
- Dr Bharat Oza: To honor ***Dr. Krip Borah*** (for sponsoring for 4 years, 2019-2022)

Pharmaceutical News:

Wockhardt selling plant and piece of its business to Dr. Reddy's for $260M.

India's Wockhardt, which has had its financial fortunes dampened for several years by FDA-related manufacturing issues, has decided to improve its cash flow by selling a plant and portfolio of products to a competitor, a move that will raise more than $250 million.

The drug maker will sell the plant in Baddi, Himachal Pradesh, India, a portfolio of 62 products and transfer all of the employees and operations of them to Dr. Reddy's Laboratories for INR 1,850 crore ($260 million).

In a filing today, Wockhardt said the business being offloaded include some of its branded operations in India, as well as in Nepal, Bhutan, Sri Lanka and the Maldives. It said the business had sales of about INR 377 crore ($53 million) for the nine months that ended Dec. 31. That amounted to about 15% of its consolidated revenues for the three quarters.

https://www.fiercepharma.com/

USFDA clears four Indian manufacturing plants in 10 days

India's leading drug companies have had their manufacturing facilities cleared in the last 10 days by the US Food and Drug Administration (USFDA), a decision that comes at a time when supply-chain disruptions due to the Covid-19 pandemic are causing drug shortages across the world.

Lupin, the third largest generic drug supplier in the US by prescriptions, and Dr Reddy's Laboratories received establishment inspection reports (EIRs), indicating closure of investigation by the US drug regulator of their manufacturing plants. Lupin's manufacturing facility in the central Indian city of Nagpur was cleared based on a USFDA inspection conducted in January this year.

https://economictimes.indiatimes.com/

Mylan crowns ex-CEO Coury as exec chairman as Upjohn merger drags on

With the coronavirus pandemic pausing FTC reviews and complicating supply chains, Mylan is flying a holding pattern on its megamerger with Pfizer's Upjohn unit and scrambling to deal with worldwide drug demand at the same time. Looking for a steady hand in trying times, the generics giant is bringing back Robert J. Coury, its current chairman of the board and former CEO, to the role of executive chairman as the drug maker navigates its way through the final stages of a generics megamerger with Pfizer's Upjohn unit, the company said.

https://www.fiercepharma.com/

Novartis gives up on planned $1B generic drug sale to Aurobindo.

Swiss pharma Novartis said it's terminating a potential $1 billion agreement to sell its Sandoz U.S. generic oral solids and dermatology businesses to Aurobindo Pharma after failing to win Federal Trade Commission approval.

The deal, announced in September 2018, couldn't get the OK from the FTC "within anticipated timelines," Novartis said in an April 2 statement.

As recently as January, Novartis executives told investors they expected the transaction to close in the first quarter of this year. The decision to end the deal was mutual, Novartis said.

https://www.biopharmadive.com/news/

India, hoping to challenge Chinese dominance, plans API production push.

The novel coronavirus pandemic has caused a host of problems in the global pharmaceutical supply chain—particularly in China, a major producer of drug ingredients. Now, seeing an opportunity, India is reportedly working on a plan to supersize its own ingredient manufacturing to combat Chinese dominance in the market.

The Indian government is planning to escalate domestic production of pharmaceutical ingredients to counteract a perceived over-reliance on Chinese imports now hampered by COVID-19 shutdowns, Bloomberg reported.

India has identified and prioritized production of 53 raw materials and active pharmaceutical ingredients (APIs) as part of its "China-plus-one" policy to fill in supply gaps of affordable medicines, sources told the outlet. The plan includes investing $1.3 billion in domestic pharmaceutical producers and potentially reviving state-run companies to ramp up cheap generic production.

https://www.fiercepharma.com/

FDA halt of foreign inspections may delay some new product approvals.

The FDA has decided that the risk of inspectors crossing paths with COVID-19 is greater than the risk to consumers of drug makers failing to meet FDA standards and putting poor quality drugs on the market. The agency has decided to halt inspections of all foreign drug manufacturers after earlier putting inspections in China on hold.

The FDA Tuesday said it will consider “mission critical” inspections on a case-by-case basis but otherwise is postponing foreign inspections in April. Instead, it will rely on help from regulators in other countries, testing products at the border for safety and wielding authority to deny entry to drugs considered defective or unsafe.

https://www.fiercepharma.com/

Strides to acquire 18 ANDAs from Pharmaceutics International, Inc.

Strides Pharma Science announced that its step-down wholly-owned subsidiary, Strides Pharma Global, Singapore, has entered into a definitive asset transfer and licensing agreement with Pharmaceutics International, Inc.(Pii) to acquire 18 ANDAs for the US market.

With access to these products, Strides will significantly expand its niche offerings on its front end, which has grown multi-folds to attain a quarterly revenue size of $66 million.

Of the 18 products successfully developed by Pii with their Pharmaceutics Know How, 11 are currently approved by USFDA while the remaining seven (7) products are submitted and are under different stages of review with the Agency.

Out of the 11 approved ANDAs, Strides is currently commercializing two (2) ANDAs with product supply from Pii, while the remaining approved ANDAs will be transferred to Strides' global manufacturing facilities and commercialized over the next 18-24 months.

https://www.business-standard.com/article

FDA warns hyped COVID-19 drug hydroxychloroquine is too risky outside the hospital

In a new safety communication, FDA says it's heard reports of "serious heart rhythm problems" in COVID-19 patients treated with the drug or a similar compound, chloroquine, often in combo with the antibiotic azithromycin. Hydroxychloroquine and chloroquine are decades-old medicines used to treat arthritis, lupus and malaria, but they have known heart risks, the agency says.

The FDA has been following growing use of the drugs through outpatient prescriptions, and the agency said it "strongly" recommends close medical supervision because of their known side effects. The FDA reminded doctors that its emergency use authorization—issued despite limited evidence of efficacy—only covers hospitalized patients, and only when clinical trials are not available. And azithromycin isn't included under the emergency approval, FDA noted.

https://www.fiercepharma.com/

Merger of Mylan and Pfizer's Upjohn wins EU nod with product sell-off agreement

The proposed merger between Mylan and Pfizer's Upjohn, though facing a delay due to the COVID-19 pandemic, has won antitrust clearance from the European Commission—but not without conditions.

EU regulators said Wednesday they allowed the transaction after the pair agreed to sell some Mylan generic drugs across 20 countries in the European Economic Area and the U.K.

In a statement, Mylan said the required divestitures are "substantially in line with" the company's previously stated expectations.

https://www.fiercepharma.com/

AAiPS Research Awards: 2020

The **American Association of Indian Pharmaceutical Scientists (AAiPS)** is pleased to announce the availability of **SIX** awards for the graduate students in Pharmaceutical Sciences. Applicants in pharmaceutical sciences should submit their research findings. Applications for consideration to the regulatory and clinical science should be focused on the drug regulation and practice and science in the clinical setting. **FOUR** awards will be given to the students of Indian heritage and **TWO** are open to all graduate students. The awards will be presented at the AAiPS Annual Meeting.

Criteria for submission:

Interested graduate students should submit no more than an 800 words summary of their research findings and up to two (2) images. The format should include Title, Author/s, Affiliation, Purpose, Methods, Results and Conclusion. Title, author/s and affiliation would not be counted towards 800 words.

At the end of your abstract, please include contact details (primary author's name, email and phone followed by major advisor's name, email and phone)

All applicants must present their research findings at the 2020 Annual meeting of the American Association of Pharmaceutical Scientists (AAPS). Abstract should have been accepted by AAPS.

➢ Please include category on top of your abstract. You can apply to any one category from the five listed below. See the format below for writing your abstract.

Section:
Title:
Authors name:
Affiliation:
Purpose:
Methods:
Results:
Conclusion:
Contact details:

Categories to submit abstracts:

1. Drug Delivery/Pharmaceutical Technologies: All topics related to formulation, physical pharmacy, biotherapeutics, biotechnology, biosimilars, drug discovery and manufacturing/manufacturing Science and Engineering.

2. **Analysis and Pharmaceutical Quality:** All topics related to Dissolution Technologies, In Vivo-In Vitro Relationships/Correlations, Method Development and Validation, Electrophoresis, High-throughput Analysis, Hyphenated Methods—Small Molecule (e.g., GC-MC, LC-MS, etc.), PK Samples, Theoretical and Statistical Aspects of Method Validation.

3. **Pharmacokinetics, Pharmacodynamics, and Drug Metabolism:** All topics related to biopharmaceutics**,** bioavailability, First Pass Effects / Drug Absorption (Food Effects, Formulation Effects), Drug Interactions, PK and PK/PD Modeling, Tissue Distribution and Microdialysis, Toxicokinetic / Toxicology, Transporters.

4. **Clinical Pharmacology, Transitional Research and Biomarkers:** All topics related to clinical trials, pharmco economics, pharmacotherapy, and therapeutic drug monitoring and transitional research.

5**. Regulatory Affairs:** All topics related to regulatory affairs like cGMP, CMC, regulations/guidance, ICH guidelines etc.

Please send your submissions by Friday, September, 4th. 2020 to:

Prof. Hardeep Saluja; Chair

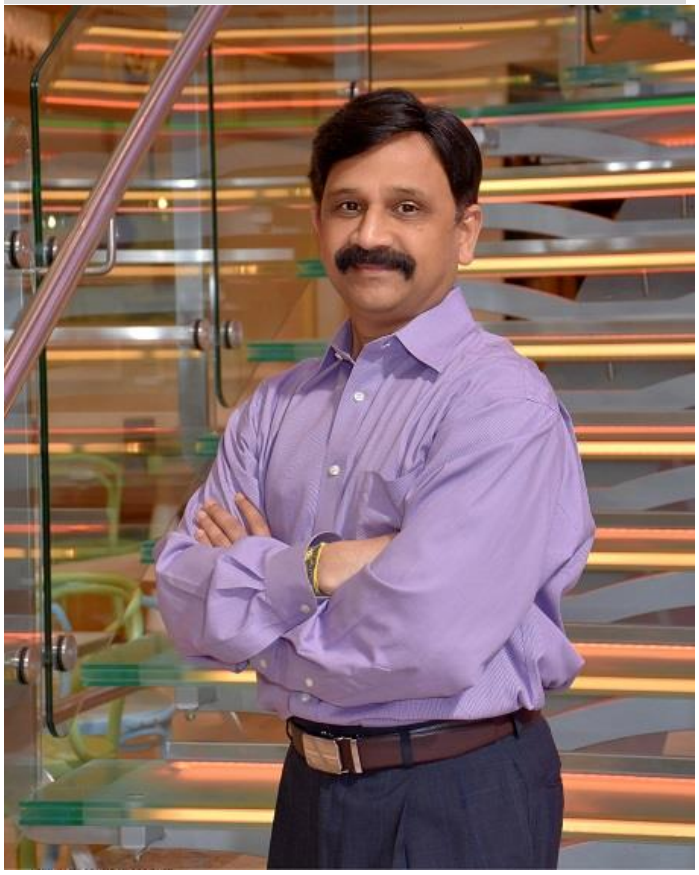
Chair, AAiPS Research Awards Committee

Southwestern Oklahoma State University

College of Pharmacy, Weatherford, OK 73096

Email: hardeep.saluja@swosu.edu, Office: (580) 774-3727

Obituary



We regret to inform you of the sad demise of Dr. Hanumantha Rao Marepalli, who passed away on Thursday, April 9, 2020. He was President & CEO, Sannova Analytical Inc., NJ.

He was very instrumental in supporting AAiPS with generous financial sponsorship at annual meetings.

PEOPLE ON THE MOVE

ADVERTISEMENT RATES

The rates of advertisement for the AAiPS newsletter are as follows:
One year (four issues): $1000 full page, $500 half a page, $250 quarter page
One time (one issue): $400 full page, $200 half a page, $100 quarter page.
Contact: Mukund Yelvigi, myelvigi@hotmail.com
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Vice President: *Shrikant Bhonsle.*

Secretary: *Kalyani Mediboyina*

Treasurer: *Suggy Chrai*

Immediate Past President: Vijai Kumar

Members-at-large: *Mukund (Mike) Yelvigi*, *Mohan kabadi*

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Sponsorship: *Ms. Sheetal Sharma*

Student Awards and Scholarship: *Dr. Hardeep Saluja*

Communication: *Kalyani Mediboyina*

Membership: *TBA*

Washington Chapter Chair*: Dilip Parikh*

Finance*: Ramesh Raikar*

TBA: To be announced