

# AAiPS

## Newsletter



AMERICAN ASSOCIATION  
OF INDIAN PHARMACEUTICAL SCIENTISTS

P.O. Box 7244  
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## PRESIDENT'S MESSAGE

Dear Members,

On behalf of AAiPS let me wish you a Happy and Prosperous New year! I want to thank our outgoing President, Mohan Kabadi and his team for the great job they have done. Our Annual Meeting in Washington DC was a great success where we unveiled the new AAiPS website, shared the recommendations of the Vision Committee and announced the new Executive Committee (EC). The EC team is as follows, Rashmi Pai-Thakur – Secretary; Ramesh Raikar- Vice-President; Rupa Doshi- Chair Program Committee; Mike Yelvig- Chair, Membership Committee; Barry Fox Chairman - Sponsorship committee and Vijai Naringrekar Chair- Awards committee. The EC team will build on the successes of the previous years and work towards implementing the recommendations of the Vision committee.

Our goal is to grow our membership base, expand the scope of our meetings, increase our student membership and add student

chapters at various universities and pharmacy schools across the country. Our regional and annual meetings will have a broader scientific scope and will include diverse and innovative programming. We have a new website which is fully functioning and we would ask that you take the opportunity to visit, stay connected and be informed about AAiPS activities. The site is also your place to renew your membership and register for all of our regional and annual meetings.

AAiPS is your organization and I encourage each of you to participate in its activities and get involved in any way you can. We will also be hosting our first regional meeting in New Jersey on March 15<sup>th</sup> with a discussion on Probiotics. Details will be posted on the website shortly.

Best wishes.

Uday Doshi

President

## QUOTES

“We will open the book. Its pages are blank. We are going to put words on them ourselves. The book is called Opportunity and its first chapter is New Year’s Day”- Edith Lovejoy Pierce

“We must not cease from exploration. And the end of all our exploring will be to arrive where we began and to know the place for the first time” —T.S. Elliot

**HIGHLIGHTS OF AAiPS ANNUAL MEETING 2011, WASHINGTON DC**

- By Uday Doshi

The 2011 AAiPS Annual Meeting was held on October 26, at the Renaissance Washington DC Downtown Hotel. It was attended by more than 150 scientists from Industry & Academia and included students, entrepreneurs, sponsors and business leaders. The participants were in a great spirits, greeting their old friends, making new friends and exchanging personal and professional news. The excitement was palpable and the good food certainly helped!

Oct 26 being Diwali day, the meeting commenced with the ceremonial lighting of the lamp. Dr. Rupa Doshi, Program Committee chair welcomed all the attendees and Dr. Mohan Kabadi President of AAiPS reviewed the progress AAiPS has made over the last couple of years detailing the creation of a Vision Committee and its recommendations to expand the scope of AAiPS and the launch of a new and improved [aaips.org](http://aaips.org) website. The invited Chief Guest was Yatindra M. Joshi, Ph.D., Vice President and Head of US and Latin America Generics R&D at Teva Pharmaceuticals and the Guest of Honor from India was Dr. C. Gopalakrishna Murty, President, Indian Pharmaceutical Association. The meeting was also attended by Dr. Phil Mayer, President of AAPS and Dr. Vinod Shah, past President of AAPS.

Dr. Joshi spoke about the Journey of the Pharmaceutical Industry, highlighting the various industry leaders and the challenges faced by them. Applying his Wharton MBA lens and gazing into the future, Yatindra told us that the low hanging fruit has been picked, costs of developing new molecules and products is soaring and he touched upon

our role as leaders is to help identify and develop new talent.

Dr. Gopalakrishna Murty informed us that the Indian Pharmaceutical Association was established in 1939 and today has close to 13,000 members representing various facets of the pharmaceutical profession including industry, regulatory, community and hospital pharmacy and education. The IPA will be having its 2012 annual meeting from March 17-18 in Manipal, and Dr. Murty has invited AAiPS members to attend the same if they were visiting India.

Following the speakers was the AAiPS awards ceremony. Awards were presented in four categories:

*AAiPS Distinguished Scientist Award:* Given to individuals making exemplary contribution to the Pharmaceutical Sciences. This year the award was given to three well known scientists: Dr. Gurvinder Singh Rekhi, Elan Drug Inc. Gainesville GA; Dr. Mansoor Khan, Center for Drug Evaluation and Research (CDER) at the US FDA; Dr. Gordon Amidon, University of Michigan, Ann Arbor Michigan.

*AAiPS Outstanding Achievement Award:* Given to an individual who has made significant contributions to Pharmaceutical Sciences and Technology both at the academic and industrial level. This was awarded to Dr. Avinash Thombre from Pfizer.

*AAiPS Distinguished Education & Research Award:* This award offers a grant of up to \$4000 to a faculty member from a recognized University from India and covers the cost of attending the AAPS annual meeting. This was awarded to Dr. Padma

Devrajan, a distinguished educator and researcher in the field of Pharmaceutical Sciences and Drug Delivery, and Head of Department of Pharmaceutical Sciences and Technology at the Institute of Chemical Technology, Mumbai.

Four Graduate Students, were also awarded a scholarship of \$500 each, for their Novel Research. The students were Sunny Bhardwaj, University of Minnesota, Minneapolis MN, Namita Dowadkar, Northeastern University, Boston MA, Arupa Patel, Florida A&M University, Tallahassee FL, Pissal Dipak, State University of New York, Buffalo NY.

Dr. Mike Yelvigi Past President of AAiPS recognized the dedication and significant contributions of Dr. Mohan Kabadi and presented him with a plaque for his leaderships as President of AAiPS 2010-2011.

Dr Uday Doshi gave the vote of thanks and acknowledged the continued support AAiPS has received from the sponsors. Without their help and support such a wonderful evening would not have been possible. He also thanked the chief guests, speakers and various attendees and the volunteers that helped make the event a success. Please see pictures of the grand event in the following pages.





*Dr Vinod Shah and Manju Shah*



*Dr Phil Mayer, President AAPS*



*Dr Rupa Doshi, Program Committee Chair  
welcoming attendees*



*Dr Yatindra M. Joshi, Vice President and  
Head of US and Latin America Generics  
R&D at Teva Pharmaceuticals*



*Guest of Honor from India was Dr. C.  
Gopalakrishna Murty, President, Indian  
Pharmaceutical Association.*



*Dr Vijai Kumar, Past President AAiPS with  
Dr Yatindra Joshi*



*Dr Mohan Kabadi with Sunny Bhardwaj,  
University of Minnesota, Minneapolis MN,  
Namita Dowadkar, Northeastern University,  
Boston MA, Arupa Patel, Florida A&M  
University, Tallahassee FL, Pissal Dipak,  
State University of New York, Buffalo NY.*



*Dr Mohan Kabadi with Dr. Gordon Amidon,  
University of Michigan, Ann Arbor  
Michigan, .Dr. Gurvinder Singh Rekhi, Elan  
Drug Inc. Gainesville GA; Dr. Avinash  
Thombre from Pfizer, Dr. Mansoor Khan,  
Center for Drug Evaluation and Research  
(CDER) at the US FDA*



*Dr Padma Devarajan, recipient of AAiPS  
Distinguished Education & Research Award  
Head of Department of Pharmaceutical  
Sciences and Technology at the Institute of  
Chemical Technology, Mumbai.*



*Dr Mukund Yelvigi, past president AAiPS with Dr Mohan Kabadi, president AAiPS*



*Dr Mohan Kabadi, president AAiPS with Dr Ramesh Raikar, treasurer AAiPS*

## PHARMA NEWS FROM INDIA

*-Anil Kumar Gandhi*

### **Indian pharma remains top in US generics**

Indian pharmaceutical companies led by Glenmark, Aurobindo and Sun Pharma maintained their number one position in the US generics market, by bagging 33.17 per cent or 139 of 419 original Abbreviated New Drug Application (ANDA) approvals from the US Food and Drug Administration (FDA) in 2010. Glenmark and its US subsidiary, Glenmark Generics, received the highest approvals (18 approvals) from FDA in the past year, beating its previous year's performance of 11 approvals. Aurobindo Pharma, which led in 2009 with 18

approvals, came close behind with 17 approvals last year. The Indian companies had a similar 33.17 percent share or 142 of 428 ANDA approvals in 2009. Lupin is already among the top five generic drug companies operating in the US market in terms of number of prescriptions, a first among Indian generic companies selling drugs in the US. Ranbaxy, facing FDA regulatory issues for its two facilities in India for the past few years, had only seven approvals in 2009 and just three in 2010. Both Dr Reddy's and Ranbaxy used to top the chart in previous years, with several approvals every year. Similarly, Wockhardt, which had 14 approvals in 2009, got only four in 2010. Other leading Indian companies in the US market include Zydus Cadila, Alembic, Orchid, Strides Arcolab, Torrent, Hetero Drugs, Alkem Labs, Emcure and Unichem, with one to six approvals each in the past two years.

### **India to launch 'Brand Pharma India' at CPhI-Japan in March 2012**

As part of its global exploration for tapping pharmaceutical markets, India is now planning to promote the "Pharma Brand India" in the forthcoming CPhI-Japan which is to be held in Tokyo from 21 to 22 March, 2012. As India has seen intense global competition in the recent past, the Union commerce ministry has decided to promote the Indian Pharmaceutical Brand and sustain the growth by enhancing its global image. India realize that it is high time for it to maintain its quality standards and live up to the challenges of increasing market share in existing and new markets and to counter the negative publicity in some countries by vested interests. Today Japan is regarded as the second largest pharmaceutical market in the world. It is predicted to be worth US\$ 87 billion by the end of year 2014. The government of Japan is encouraging

generics to account for a 30 per cent market share by 2012. Lately Dr Reddy's lab has entered into a business deal with Fuji Company, a Japanese film making firm, but not many Indian companies have ventured in to the Japanese markets. Recent Comprehensive Economic Partnership Agreement (CEPA) between India and Japan is also likely to provide an excellent opportunity for Indian pharmaceutical manufacturers and exporters to explore opportunities in Japanese market as it would catalyse bilateral trade between India and Japan to touch \$25 billion by 2014.

### **Takeda Expresses Eagerness to Expand Its Business in India**

Japan's largest drug maker, Takeda Pharmaceutical Co is looking forward to talk with Indian generic drug makers, Cipla and Lupin. Takeda has expressed enthusiasm to expand its business in India, which is believed to be one of the rapidly growing markets in the world. Consequently, the Company had preliminary conversation with Cipla whereas talks with Lupin are believed to progress beyond the initial stage. Cipla has the status for selling low-cost generic versions of anti-retroviral drugs to fight HIV/AIDS whereas the Lupin has a name among the major producers of generic drugs.

### **Bayer targeting \$1 billion revenue in India**

German chemicals and pharmaceuticals company, Bayer Group has said that it is aiming to double its revenues in India to \$1 billion in the next four years. The company has seen good business in businesses of crop protection and hybrid seeds and expects to generate more revenues in the segment. Bayer India focuses on crop science (pesticides and seeds), healthcare and material science sectors in the country at present. The crop science sector accounts for

about 60% of revenues, Healthcare about 30% and material science about 20%.

### **India to be among top 10 pharma markets by 2015**

Emerging markets India and China will figure in the top 10 pharma markets of the world by 2015, an Ernst & Young report has said. The report has identified India as the preferred choice for outsourcing in the area of late stage drug discovery, shared services and complex manufacturing while China has been the preferred market for building blocks and intermediates. The other major emerging markets are likely to be Brazil, Russia, Venezuela, Turkey and Korea, according to OPPI & Ernst & Young's latest report on "India emerging: Pharma's evolving business models". Associated Chambers of Commerce and Industry has said it expects the Indian pharmaceutical industry to reach \$20 billion by 2015, making it one of the world's top 10 pharmaceuticals markets. India has seen some significant acquisitions in terms of valuations e.g, Abbott's acquisition of Piramal, Reckitt's acquisition of Paras and Daiichi's acquisition of Ranbaxy.

### **DRDO's Rs.7 cr tulsi project finds anti radiation properties of tulsi extracts in animal trials**

There are more revelations coming to light about the home grown tulsi plant's medicinal values. In a recent research conducted by scientists at DRDO's (Defence Research Development Organization) Institute of Nuclear Medicines and Allied Sciences and Department of Radiobiology, Kasturba Medical College, Manipal, the scientists have successfully tested tulsi extracts on mice for its anti-radiation and anti-cancer properties. The DRDO is spending Rs.7 crore on the tulsi project. Earlier, the research students had revealed that Tulsi extracts had useful medicinal



ingredients which can treat diabetics and cancerous ailments in humans. Now as the scientists have discovered one more medicinal value in tulsi extract which can be used as an anti-radiation agent, it is evidently proved that the ancient Indian tradition of growing tulsi (*Ocimum Santum*) in the backyard is not without scientific backing. With this new revelation, it can be said that tulsi plant is embedded with multiple medicinal values, as it can be used not only to treat diabetics, but also can be used for treating cancer and now as an anti-radiant substance. In fact, the research on the anti-radiation effect of tulsi in animals has been going on in India since the past 40 years and it is only in the recent years that scientist have been coming out with concrete evidence of tulsi's mythic medicinal values.

#### **Zydus Cadila to Acquire Neshor Pharmaceuticals Inc**

The Zydus Group unit, Cadila Healthcare Ltd, has entered into agreement to acquire the assets of Neshor Pharmaceuticals Inc. The procurement consists of Abbreviated New Drug Application pipeline, some manufacturing amenities and a research and development laboratory. Neshor is an US-based pharmaceutical company which deals in niche therapies used in managing the obstacles of production and growth by DEA-controlled substances and controlled release medications. Now Zydus will be able to produce and sell generic controlled substances that previously could not be traded in. The overall cost of the controlled substances medications in U. S is around \$7 billion. The niche unit prevails with \$ 2.1 billion share in the U. S market. This purchase will assist in the future growth of the Cadila.

#### **India emerging as key centre for clinical trials for pediatric cancer drugs**

India is fast emerging as a center for pediatric oncology drug trials. Currently, major hospitals like All India Institute of Medical Science (AIIMS), Rajiv Gandhi Cancer Institute and Research Centre, New Delhi, Gujarat Cancer and Research Institute, Ahmedabad are carrying out studies on pediatric cancer cases. Childhood cancers are malignant diseases that affect children under the age of 18 years. Two-thirds of children with cancer are cured. Despite enormous progress in the treatment of childhood cancer, it is the second-most common fatality in children older than one year.

#### **Maharashtra FDA launches online licensing for pharmacy outlets**

The Maharashtra Food and Drug Administration (FDA) has started the online facility for granting licenses or license application to the pharmacists across Maharashtra on the lines of Gujarat FDCA. The new facility will be restricted to pharmacists looking to apply for new licenses or renew their old licenses though the FDA revealed that other services will also be made available in the near future. Maharashtra FDA has adopted the similar features of Gujarat FDCA and has already started the facility. This helps the officers to get the information about the samples withdrawn from the market, communication facility is also possible related to the data which also enforces us to inform the applicants about the expiry date of licenses in the next month or in next 12 months.

## CONGRATULATIONS

Our lifetime member, Dr Navnit Shah, was awarded the NJ Inventor of the year award for his multiple inventions and innovations enhancing the science of drug delivery.

*Here is an excerpt from the ceremony:* Dr Shah, a Distinguished scientist and Head of oral formulation group in the Pharmaceutical R&D Department at Hoffmann-La Roche Inc. Nutley, received Inventor of The Year Award on October 27 2011 by New Jersey Inventor Hall of Fame (NJIHoF) of New Jersey at the ceremony in W. hotel in Hoboken. Dr Shah's original work in Drug delivery research encompassing over 70 papers and 120 abstracts as well as 19 issued patents and 14 patent applications in drug delivery area covering improving bioavailability of poorly water soluble molecules, Lipid based delivery and controlled release medication has resulted in to this prestigious award. He also has received numerous awards for his original research in drug delivery area. He was elected as fellow of American association of pharmaceutical sciences (AAPS fellow) in 1998. He received Thomas Alva Edison Patent Award in 2005, distinguished Alumni award in 2008 and Research Leadership award from NJ association of biomedical research (NJABR) in 2010. His greatest achievement is the development of novel MBP technology for improving the bioavailability of poorly soluble compounds. The MBP technology was successfully utilized in the development of recently approved Roche Melanoma drug Xelboraf. Without the MBP technology, the efficacy of the active compound in Xelboraf product could not have been realized. Dr Shah lives in Clifton, NJ with his family. He acknowledges his success to the support from his management at Roche and sacrifice of many years from his wife Gita

and children Neha, Mona and Nikhil. We are very proud of Dr Shah's achievements.



## OBITUARY

It is with a heavy heart that we inform you that Dr Malati Baichwal, a former principal of UDCT, Mumbai passed away on December 20, 2011.

Dr Mrs. Malati R Baichwal (nee Manik Vangikar) was born on January 9, 1923, in Pune. Her love for learning from early childhood prompted her to pursue higher education, which brought her to Mumbai. She was amongst the first women to join the University Department of Chemical Technology (UDCT) in 1943. She obtained post-graduate degrees in pharmaceutical technology and pharmacy from Universities of Bombay and Toronto, Canada, where she went as recipient of the Columbo Fellowship. She received her Ph.D. degree working in Prof. M.L. Khorana's laboratory at UDCT, where she also met her future husband Dr. R.S. Baichwal. After returning from Canada, she taught at UDCT for more than three decades. Later she was principal and subsequently was appointed director of Research at C U Shah College of Pharmacy, SNDT Women's University, Mumbai. She has guided more than 50 students in research for M Pharm, MSc Tech and Ph D degrees.

She was recipient of many awards, including the Acharya P C Ray, Prof. M L Khorana Memorial, Shri Amrut Mody Research, and best teacher-PAMDAL. Recently, the American Association of Indian Pharmaceutical Scientists (AAiPS) also awarded its Fellowship to her in San Francisco, USA. She was an active member of the Indian Women's Scientists' Association (IWSA) and served as its President from 1981-1983. She will be best remembered as one who rendered dedicated service to the cause of pharmaceutical education and industry in India. She is survived by her three children currently residing in the US.

Mike Yelvigi

### JOB OPENINGS

If you are looking for a job or want to advertise a job, send the editor an email at [thakurrashmi@gmail.com](mailto:thakurrashmi@gmail.com) and we will post your requirements/credentials in the career section we intend to create on our website.

### PEOPLE ON THE MOVE

Mike Yelvigi retires at Pfizer end of Jan 2012. He worked at various companies for last 36 years, which include Parke Davis, G.D Searle, Roche, Wyeth Ranbaxy, India. His email address is [MYELVIGI@hotmail.Com](mailto:MYELVIGI@hotmail.Com), Tel :[908 625 9512](tel:908-625-9512)

Narayan Kanikkannan recently joined Xcelience LLC as Manager, Preformulation and Formulation Development. Xcelience, LLC, 5415 W. Laurel St. Tampa, FL 33607  
Tel: 813-637-6049, Email: [narayan.kanikkannan@xcelience.com](mailto:narayan.kanikkannan@xcelience.com)

This forum is a great platform for informing every one of recent changes in your professional life. If you have moved to a new job or need to update contact information, email us and we will post it.

### 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: Ramesh Raikar  
[rraikar5@yahoo.com](mailto:rraikar5@yahoo.com)

*No advertisements under a quarter page*

*Opinions expressed in this newsletter belong solely to the authors, and do not represent the views of AAiPS or its members.*

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