

AAiPS

Newsletter



AMERICAN ASSOCIATION
OF INDIAN PHARMACEUTICAL SCIENTISTS

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Newsletter Editor: Rashmi Pai-Thakur

Editorial Committee: Krip Borah; Uday Doshi; Mike Yelvigi

PRESIDENT'S MESSAGE

Dear Members,

AAiPS had an exciting summer in 2010, as we held our second AAiPS regional meeting in June on Lifecycle Management: Regulatory and Clinical Strategies for 505 (b) (2) filings. Truly outstanding interactive presentations by Vijay Tammara, Ph.D., FAAPS, Director and Rajesh Krishna, Ph.D., FCP, FAAPS, Director Clinical PVE, Merck. Rajesh is our very own EC member-at-large. We want to thank Chrai Associates for sponsoring our regional meetings and Rupa Doshi, Chairperson Program Committee for overall coordination. The Washington DC Chapter, headed by Praveen Hiremath also held a meeting in July (sponsored by PII) with a follow up presentation on vaccines by Professor Anthony Hickey. Finally, a joint meeting was held with TiE on August 11 with a dynamic presentation by Dr. Prabha Fernandes, Founder and CEO of Cemptra Pharmaceuticals Inc. on "Entrepreneurship".

We are forging ahead and now looking forward to an exciting first ever combined meeting with NJPHAST and EPTM on September 16th to create an extraordinary event, as promised in the previous newsletter. Our Newsletters will continue to be published on the Web, which is being significantly enhanced for improved interaction and communications among our valued members. The "Vision" committee team is continuing to brainstorm several global ideas and will be selecting top 3 for

implementation. Laura Yelvigi, our secretary is developing programs for new students, and EC Extended team members will be visiting campuses in the future to discuss on how AAiPS can help them. She is also inviting AAiPS members to add AAiPS to their LinkedIn group.

This year's annual dinner meeting is to be held on Tuesday, November 16 at the AAPS meeting in New Orleans, LA (Hilton hotel) and is being coordinated locally by Burde Kamath with support from Sanjeev Gupta. We will be presenting the AAiPS awards at the meeting. More information follows in this newsletter from Rashmi Thakur and the aaps.org website. Vijay Naringrekar and his team are leading this important awards selection effort.

Sponsors are encouraged to contribute to the 1,200+ member organization by contacting Barry Fox, chairperson of the sponsorship committee. If also interested in presenting or offering speakers, please contact Rupa Doshi with details of abstracts or outline of content of presentations.

AAiPS is your organization and I encourage all members to continue to participate at the meetings, offer comments, suggestions and get involved in any way you can.

Best wishes.
Mohan Kabadi
President

FAMOUS QUOTES

"Use what talent you possess: the woods would be very silent, if no birds sang except those that sang best."
- Henry Van Dyke

"Ties between our two peoples have never been stronger. The over two million members of the Indian-American community are living examples of the bonds that bind our nations together and their accomplishments have become well-known and admired in both countries."

-Barack Obama on the occasion of India Independence Day Aug 15, 2010

UPCOMING EVENTS

Mark Your Calendars for September 16-17, 2010!

On September 16th, the first ever joint meeting of New Jersey Pharmaceutical Association for Science & Technology (NJPhAST) and the American Association of Indian Pharmaceutical Scientists (AAiPS) will be held at the Somerset Holiday Inn, Somerset, NJ featuring an FDA speaker. Following this on September 17th, the Eastern Pharmaceutical Technology Meeting 2010 conference will be held with a full day program.

The official meeting announcement, including the speakers, topics, registration from our website aaiips.org, reservation, and accommodation information will be issued soon in the near future.

And on November 16, 2010, we will be having the next major event of the year The AAiPS Annual Meeting. It will be held during the AAPS meeting in New Orleans.

Annual Meeting

***Tuesday, November 16
Hilton hotel,
New Orleans, LA.***



Over the years, the meeting has proven to be an excellent opportunity to network with friends and colleagues from the industry. The speaker session is usually preceded by a networking hour and will also involve a musical program this year.

Stay tuned to our website www.aaiips.org for more details soon to follow!

Do not miss the AAPS webinar from one of our members!

Conducted by Mehul U. Mehta, Ph.D., U.S. FDA
Thursday, September 9, 2010 from 12:30 pm to 2:00 pm EDT
Application of BCS in Regulatory Submissions
Organized by the AAPS Regulatory Sciences Section

For details and registration, visit

<http://mediaserver.aapspharmaceutica.com/meetings/webinars/rs-6/rs-6-info.pdf>.

AAPS News magazine

Our very own Mike Yelvigi co-authored an article: "A look at Pharmaceutical Manufacturing-Perspectives on the current State and a vision for the Future" in the Aug 2010 issue.

HIGHLIGHTS OF AAiPS REGIONAL MEETINGS, NEW JERSEY AND WASHINGTON D.C.

Review by: Rashmi Pai-Thakur

We had an interesting and well-attended regional meeting at the Crown of India Restaurant in Plainsboro, New Jersey. The audience was highly engaged and the speaker-audience debates and discussions were the highlights of the meeting.

The meeting started with introductions from Mohan Kabadi, President AAiPS, followed by a brief about the Aug 11th AAiPS-TIE entrepreneurship workshop. After the speaker introductions by Rupa Doshi, Vijay Tammara spoke about registration procedures, scenarios where 505 (b)(2) can be used and discussed these filings as compared with ANDA suitability petitions. Labeling of 505(b)(2) was also discussed.



Vijay Tammara on Lifecycle Management: Regulatory Strategies for 505(b) (2) filings

Rajesh Krishna followed by presenting case studies elaborating clinical strategies for support of these filings. Swanson et al's work on methylphenidate in ADHD with SKAMP rating scales was discussed in detail. A copy of his presentation is available at http://www.aaips.org/pdf/AAiPS_LCM_Clinical_Strategies_RK_Website.pdf.

The sessions were rendered all the more interesting due to the fact that recent approvals and current filings were also discussed. Examples discussed included Maxalt, Seligine patch, Tricor, Diclofenac patch on the regulatory aspects and Tobradex, Lipsovir, Embeda, Actoplus on the clinical front. This led to an exciting and highly informative session.



Rajesh Krishna on Lifecycle Management: Clinical Strategies for 505(b) (2) filings

The two-speaker format was implemented for the first time and this led to a meeting which provided comprehensive coverage of the topic and also catered to a larger audience from the clinical as well as regulatory fields. Additionally, the new venue contributed to the record attendance.

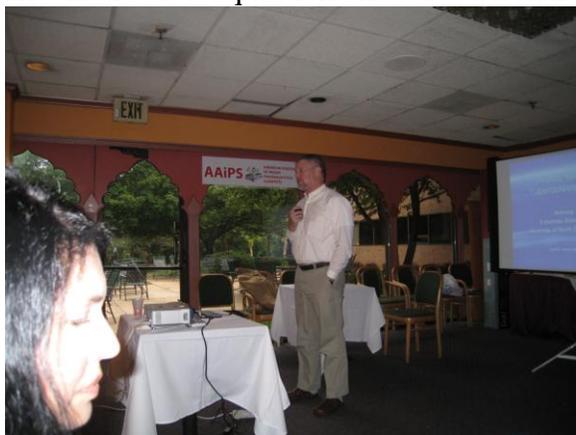


AAiPS meeting at Crown of India, Plainsboro



AAiPS team : L to R, Mohan Kabadi, Vijay Tammara, Rupa Doshi, Rajesh Krishna, Rashmi Pai-Thakur, Barry Fox, Uday Doshi, Ramesh Raikar at the New Jersey Regional Meeting

We also had a highly successful meeting with the Washington DC chapter. Anthony Hickey, Professor of Molecular Pharmaceutics at University of North Carolina, gave a talk on “Inhaled Vaccines for Tuberculosis Prevention”. There were about 30 people present at the meeting from NIH, FDA, PII, Sanaria, Capricorn and other pharma/biotech companies around Washington/Baltimore area (including our president, Mr. Mohan Kabadi). The talk was well received by the audience followed by the interactive question-answers session.



Professor Anthony Hickey at the Washington D.C. regional meeting



AAiPS team : L to R, Praveen Hiremath, Mohan Kabadi, Anthony Hickey, Vijai Kumar, Samit Deb

UNDERSTANDING THE DILEMMA OF THE MIND

Krip Borah – contributing editor

In 1906, a German physician out of curiosity performed an autopsy on a dead woman who had been acting very strangely and said crazy things. On opening her brain, he found certain parts of the brain had some gummy agglomerates. He then realized her unusual behavior was due to a diseased brain. The name of the physician was Alois Alzheimer and as he was the first to discover the disease, it was named after him as Alzheimer. Presently, there are about 5.3 million people in the USA who suffer from the disease and they are mostly above 70 years of age. Many of the baby boomers will be in that age in the not-so-distant future. It is estimated that in the next few decades the number will rise to 20 million. Nearly 100 billion US dollars are spent every year for Alzheimer and over the years that will rise to several trillion US dollars.

In the last two decades the major pharmaceutical companies, private and public research organizations and

researchers in the academia have been tirelessly working to find the cause for Alzheimer's and an appropriate remedy. The general consensus in the scientific community point out that the cognition part of the brain rests in the amyloid protein. An enzymatic cleavage of the protein resulting in a fragmented protein of 42 amino acids which forms agglomerates giving rise to Alzheimer's disease. But recent studies further show that in addition to the amyloid protein, its adjacent tau protein also plays a role. The proteins form fibrils and their fiber-like deformity causes loss of their communication skills adding to the problem.

Some of the leading authoritative researchers on Alzheimer's openly admit that they are nowhere close enough to know exactly how the real sequence of the disease occurs and accordingly find a remedy. Presently there are drugs in the market and many more in various stages of clinical trials but none of them help in the long run. Recently at an international conference on psychiatry and neuroscience in Hawaii, a group of physicians from California presented a guideline detailing how the gradual onset of very short episodes of dementia over the years may lead to Alzheimer. They contend that if such people are treated with medication at that early stage they would be able to control their Alzheimer's. The FDA has expressed reservations to such an idea unless there is definitive evidence which would indicate that such early medication improves the very short episodes of early dementia. Some of the leading pharmaceutical companies contend that it will take years to get results and they may not be able to wait that long. How the two views play out, only time will tell. But some of the leading physicians and researchers on psychiatry and neuroscience have cautioned on the above idea and expressed apprehension that insurance

companies and lawyers might get involved and the situation may lead to a veritable mess.

A few months ago at an international conference on psychiatry and neuroscience held in London, an interesting paper was presented. The paper was on a preclinical study in mice who were induced an Alzheimer-type brain condition, were treated with Curcumin- the polyphenol in the Indian spice Turmeric. In the study the authors demonstrated that Curcumin binds with the amyloid protein and prevents it from unfolding and subsequent deformation of the amyloid protein. Some investigators have also studied the effect of Curcumin on the Tau protein. Here again they showed that the polyphenol prevents it from forming fibrils and fiber-like deformation.

Some of the drugs which are presently marketed does prevent the formation of the amyloid protein and tau protein, thereby prevent their formation. But recent studies indicate that both amyloid and tau protein helps the immune system of the body. Certain autopsies conducted on people show that in some, the amyloid protein had entrapped bacteria within them and prevented them from activating. Hence those drugs that prevented the formation of the amyloid and tau proteins may not help in Alzheimer in the long run.

A survey was conducted around the world to find out the incidence in different countries. The survey resulted leading to data which suggest that about 17-18 percent in the USA and Western countries might get Alzheimer at a certain age group. In the Far East like Japan, nearly 6 percent may get it but in India only 2-3 percent may be afflicted with Alzheimer. Those who conducted the study were surprised at their finding why the number was so low. They claim due to the

fact that people there from their young age take the spice Turmeric. They think it is food and climate related. The most common beverage people take in India is tea. At times many people drink as much as 8-10 cups of tea per day. Tea contains the catechins. There are at least three catechins in tea. They are epicatechin, epigallocatechin and epigallocatechingallate. There are many references where animal studies have been conducted with the epicatechins. Their studies show they combine both with the amyloid as well as the tau protein and prevent them from deformation but they do not prevent their formation and hence would not interfere with their immune system functionality.

The next question is how the climate in India helps people. There are some scientific reports that Vitamin D3 helps to prevent people from getting Alzheimer. India being a tropical country, people get enough exposure to sunlight every day which is a rich source of Vitamin D3. Therefore food habits and climate may be playing a major role there which protects them from getting Alzheimer.

Recently there has been an US patent application which includes Curcumin, epigallocatechingallate and Vitamin D3 for mental alertness and mental health which may help people from not getting Alzheimer.

However all said and done most of the studies on curcumin, epigallocatechins and Vitamin D3 have been basically preclinical studies in animals. Hence the question arises how they shall perform in humans. In order to conduct studies in humans, funds will be necessary. Such funding has to come exclusively from research organizations both public and private and perhaps from non-profit organizations. Moreover there are

certain apprehensions that if any positive result comes out from such studies there might be attempts to somehow negate such outcome as it might impact negatively on other scientific investigations and research.

Presently, there are two studies underway one in UCLA in California and the other in Berlin, Germany- the former with curcumin and the latter with epigallocatechingallate. These studies have been planned on the basis of present day human clinical studies. The outcome of these studies is expected by the end of 2011 and 2012.

Tireless efforts are continuing with many pharmaceutical companies and it is hoped they will come out with some unique treatment.

It is also reported that turmeric and green tea also have beneficial effects in maintaining good memory. Many products are available in nutritional supplement stores

INDIAN PHARMA NEWS

Anil Gandhi

Cipla invests Rs 50 cr into Stempeutics Research for R&D and marketing of Stempeucel

Stempeutics Research Pvt. Ltd., a group company of Manipal Education & Medical Group has announced that it has completed the initial Phase I/II clinical trial of its product "Stempeucel-CLI". This multi centric, placebo controlled, double blind trial was approved by DCGI last year (2009). Stempeucel-CLI is a stem cell based product developed using mesenchymal stem cells derived from donated bone marrow, for Critical Limb Ischemia (CLI) patients. To market its product, Stempeutics has established strategic alliance with India's leading pharmaceutical company Cipla.

Under this alliance, Cipla is sponsoring up to Rs. 50 crores in Stempeutics in the initial phase for research and development of stem cell based products. The product is developed using mesenchymal stem cells derived from donated bone marrow. In India, CLI prevalence is 1,000 per one million population. Going by the high incidence of the condition known to affect young and productive population, SRPL was keen to find an alternative therapy using stem cells.

Ranbaxy, Lupin to benefit most from Japans' push for generics

Japan is world's second largest single drug market. India's top two drug makers, Ranbaxy Laboratories Ltd and Lupin Ltd, are expected to achieve the maximum benefits from a significantly large generic drug opportunity opening up in Japan. Ranbaxy and Lupin have direct connections in Japan pharmaceutical industry through cross-border equity deals. This establishment will help them to conquer a significant amount of market share in the emerging cheap drug segment in that country. Daichi Sankyo Co. Ltd, Japan's third biggest drug maker, acquired a 34.8% stake in Ranbaxy in 2008 in a \$4.6 billion (around Rs 20,750 crore today) deal. Lupin acquired 80% of Kyowa Pharmaceutical Industry Co. Ltd in 2007. Ahmedabad-based Cadila Healthcare and Dlsman Pharmaceuticals Ltd also have subsidiaries in Japan. Recently, Indian drug makers' revenues from the Japanese market are low compared with their sales in other regulated markets such as the US and Europe. Regulatory regime and lack of trust in foreign generic drugs among patients and doctors have been key obstacles for Indian

pharmaceutical firms in penetrating the Japanese market.

Glenmark signs licence agreement with Sanofi-aventis

Glenmark Pharmaceuticals S.A (GPSA) has signed licence agreement with Sanofi-aventis. GPSA is a wholly owned subsidiary of Glenmark Pharmaceuticals Ltd India and the out-licensing agreement is for development and commercialization of novel agents to treat chronic pain. Those novel agents are vanilloid receptor (TRPV3) antagonist molecules. Inhibitors of TRPV3 are predicted to be useful in the treatment of inflammation, various pain conditions, and other diseases and disorders. The goal of the partnership will be to advance GRC 15300 as well as potentially other promising drug candidates with the hope of providing patients better medicines for pain and other conditions. GRC 15300 is currently in Phase I clinical development as a potential next-generation treatment for various pain conditions, including diabetic neuropathic pain and osteoarthritic pain. Under this licensing agreement, Glenmark will receive an upfront payment of \$20 million, as well as development, regulatory and commercial milestone payments.

Alvogen to invest US\$ 5 million to start Norwich Clinical Services in India

Alvogen has made an investment of US\$ 5 million to commence its operations in India by setting up a clinical research organization under the name Norwich Clinical Services and an API sourcing office in Bangalore. The CRO will specialize in the management of clinical trials and offer a complete range of clinical research services including Phase I – IV trials, bio-analytical studies and pharmacovigilance monitoring to Alvogen

and third parties. The sourcing office will play a central role in further strengthening Alvogen's relationships with Indian suppliers for raw materials.

Opto Circuits has acquired stent manufacturer N S Remedies for US\$ 1.50 million

Opto Circuits (India) Ltd. is a healthcare equipment maker headquarter at Bangalore has acquired Kolkata-based N.S. Remedies Ltd. for \$1.50 million in an all-cash deal. Opto Circuits (India) Limited, India's leading developer and manufacturer of medical equipment and interventional products for world markets and this acquisition would help the company foray into manufacturing of cardiac stents. The acquisition is expected to cut costs by 23-25 percent currently incurred by Opto Circuits on outsourced manufacturing, a top official said. The alliance would enhance Opto manufacturing capacity and will significantly reduce the cost of manufacturing bare metal stents and also reduce dependency on external agencies.

Advanced Enzymes Technologies invests Rs 100-cr for expanding fermentation plant in Pithampur

Advanced Enzymes Technologies Ltd. (AETL), a biotechnology company headquartered in Mumbai, India, is expanding its fermentation plant at its 10-acre land in Pithampur, Indore at a total investment of Rs 100 crore. This expansion will occur in two stages of recovery and formulation, of which the first stage is complete. Besides the fermentation facility at Pithampur, AETL has another manufacturing plant located in Nasik, Maharashtra. They also have three other formulation plants at Nasik, Vasind and

Vapi. They have a research lab at Thane near Mumbai that focuses on front end research or application research. AETL informed that the company is looking towards expanding its reach to other countries as well through partnering for manufacturing operations and marketing purposes. Company expressed his interests in collaborating with companies in Europe, Africa, Australia, China and the SAARC region.

Allergan India to spur growth prospects in ophthalmic space and maximize market expansion with Botox

Allergan India will boost its growth prospects with its range of 35 products. It also intends to maximize its growth opportunities with Botox which is showing favorable response for several neurological disorders in both pediatrics and adult patients. The company's comprehensive ophthalmic portfolio of glaucoma, dry eyes, inflammation, infection control and post operative drugs have resulted in garnering healthy growth. "With a presence in India since February 1996, the company is now looking to consolidate its leadership status in the Rs 700 crore ophthalmic domestic markets" stated Allergan.

Cipla will be investing over Rs 300 cr to acquire two biotech companies in India and China

Cipla, the third largest pharma company in India has approved to invest in two biotech companies in India and China. The total investment for both the aforesaid biotech companies is estimated to be about USD 65 million about Rs 300 crore. The investment in the two biotech companies will facilitate Cipla to join the rank of Indian rivals

such as Wockhardt and Biocon in a bid to gain from the \$90 billion global biogenerics market. Indian biopharmaceutical firms have over time employed advanced capabilities in biogenerics market and are present in virtually all the biologics going off-parent. Indian pharmaceutical companies such as Reliance Life Sciences, Biocon, Wockhardt, Shantha Biotech, Panacea Biotech and Intas Pharmaceuticals are companies with strong capabilities.

Piramal Healthcare Limited to acquire assets of BioSyntech, a biotechnology company developing novel products in regenerative medicine

Piramal Healthcare said on Tuesday it will acquire Canadian firm BioSyntech's assets for C\$3.9 million (around Rs 18 crore). BioSyntech is a medical device Company specializing in the development, manufacturing and commercialization of advanced biotherapeutic thermogels for regenerative medicine (tissue repair) and therapeutic delivery. Thermogels has a market of roughly \$500 million (Rs 2,300 crore) in North America alone, and can be used to repair damaged tissue such as cartilage, bone and chronic wounds. Thermogels are used by patients to avoid invasive surgery. As per Piramals' statements, this product has completed phase I and II studies, and is in phase III of human trials. The Canadian company, however, has been unable to raise further capital to fund its ongoing operations and to repay maturing debt. Piramal Healthcare will, therefore, inject another Rs 35 crore to take the product through phase III and into the commercialization stage, which is expected in two years' time. The product will be part of Piramal Healthcare's critical care portfolio

RPG Life sets up 2 verticals, plans to launch 9 products

RPG Life Sciences has set up two new verticals and plans to launch nine new products. This approach is in line with their sharp focus to its formulation business. The two verticals are empathy (neuro-psychiatry) and neolife (oncology) and by end of third quarter of this year RPG is planning to launch nine products from these two divisions. The two new verticals, will give a sharp focus to RPG's formulations business, which has been growing tremendously over the last two-three-years. RPG has a strong formulations expertise and formulations business contributed Rs 100 crore of the company's turnover of Rs 163 crore in FY10, having grown to Rs 84 crore from Rs 66 crore in the previous years.

AAiPS AWARDS NOMINATION

AAiPS recognizes contributions of individuals and institutions in pharmaceutical field. AAiPS presents two recognition awards, one for a Distinguished Scientist Award and another for Outstanding Achievement Award and four student research awards. The guidelines for the nomination are given below. Applications for all awards must be received before **September 10, 2010.**

DISTINGUISHED SCIENTIST AWARD:

Recipient shall be individuals who have made significant and pioneering contributions particularly in the field of pharmaceutical sciences and technology and to the pharmaceutical and healthcare industry in general. Recipients may also be individuals who have made pioneering contributions through their academic and

professional excellence in the pharmaceutical and healthcare fields.

The nomination package should include:

- Letter of justification for nomination (maximum of 2 pages)
- Outline of significant achievement in pharmaceutical sciences

OUTSTANDING ACHIEVEMENT AWARD:

Individuals for this award should meet the requirements for Distinguished Scientist Award, listed above and in addition, this award is given to individuals who have shown outstanding contribution in both quality and consistency over an extended period (more than 10 years) in any of the health care areas. This award is given to only US based individuals of Indian origin.

Please visit our website to see the list of past award winners. Nominator must be a member of AAiPS. Nominee does not need to be a member. Information package for this nomination is similar to the one above, except **an additional recommendation letter is required.**

Please send nomination packages to Dr. Vijay Naringrekar, Awards Committee, AAiPS
P.O. Box 7244, Colonia, NJ 07067
E-mail: vijay.naringrekar@gmail.com

GRADUATE STUDENT RESEARCH AWARDS: FOUR Research Awards will be presented for the graduate students in Pharmaceutical Sciences. The applicants must present their research findings at 2010 Annual meeting of the American Association of Pharmaceutical Scientists (AAPS) in New Orleans, LA. Three awards will be given to the students of Indian

heritage and one is open to all graduate students.

Interested graduate students should submit a two page summary of their research findings. The format should include Title, Author, Affiliation, Objective, Methodologies and Results and Discussions. Please include your Telephone #, Fax #, and email address with your submission. Please send applications to

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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

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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