AAiPS

Newsletter

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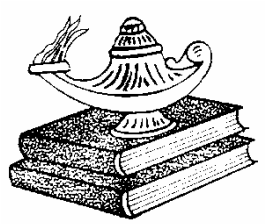

AMERICAN ASSOCIATION
OF INDIAN PHARMACEUTICAL SCIENTISTS
P.O. Box 7244
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AAiPS
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INSIDE THIS ISSUE

Newsletter Editor: *Uday Doshi*
Assisted by *Pankaj Paranjpe, Rashmi Thakur, Mike Yelvigi*

PRESIDENT'S MESSAGE

Dear Members,

I would like to express my profound gratitude to the entire AAiPS membership for giving me the opportunity to serve our organization. We have worked diligently and together as a formidable team under the leadership of Mike Yelvigi in the past and I am sure we will continue to work with the same enthusiasm this year. The regular meetings with the Executive Committee and the chairs of various committees, apart from being an excellent forum for exchange of ideas, have reflected this zeal and commitment.

AAiPS has also drawn up a road map for the next five years. The action plan includes recommendations of the three committee's - *Vision Strategy Committee, Awards Strategy Committee* and *Finance Strategy Committee formed by the Executive committee.*

On the collaborative side, NJPhAST has initiated dialogue with AAiPS Executive Committee for working together on issues of mutual interest especially with regards to a joint regional meeting in 2009.

I encourage all members to take an active role by attending our networking regional and annual meetings, recruiting new members, organizing local chapters. Please feel free to contact me with ideas on how to make AAiPS a stronger organization.

Regards
Vijai Kumar
President

QUOTE OF THE QUARTER

"The process of scientific discovery is, in effect, a continual flight from wonder."

- *Albert Einstein, German born American Physicist who developed the special and general theories of relativity. Nobel Prize for Physics in 1921. (1879-1955)*

REGIONAL MEETING UPDATES

***NEW JERSEY*- APRIL 10, 2008**
By: Dr. Krip Borah

The New Jersey chapter regional meeting was held on April 10, 2008 at the Cinnamon Indian Restaurant in Morris Plains, NJ. The dinner meeting in the cinnamon colored dinning hall presented an herbal hue to the atmosphere and thereby reminded pharmaceutical scientists the expanding horizon of natural products in which lies the basis of future drug discovery. The guest speaker was Ed Silverman, journalist and editor of Pharmalot, a popular pharmaceutical blog. The welcome address by Pankaj Paranjpe was followed by a review of the present state of affairs of AAiPS including the new executive committee and different awards and recognition projects by the new President Vijai Kumar. Thereafter Ed Silverman spoke about his career as a journalist with Star Ledger. In this connection, it is worth mentioning that Ed Silverman wrote interesting articles in the Star Ledger on herbal and neutraceutical products, their pros and cons. Also, noteworthy was his reporting on the counterfeit products of Pfizer's Lipitor. With the help of Tomer Laboratories, he exposed the fact that counterfeit Lipitor products were substandard.

AAIPS members with Ed Silverman (3 rd from Left) at the April 2008 meeting at Cinnamon India Restaurant in New Jersey.

He also explained the evolvement of Pharmalot, a website exclusively devoted to healthcare as an interactive media on pharmaceutical and biopharmaceutical areas. Overall his speech was interactive and encouraged the audience to be forthright even in their opinions about the negative impact of media on the pharmaceutical industry. At the end of his talk, Ramesh Raikar on behalf of the AAiPS presented Ed Silverman a plaque.

***AAiPS WASHINGTON D.C.* Chapter Meeting**
May 8, 2008

The DC Metro Chapter held its first meeting of the year at Rockville, Maryland with over fifty attendees. Prof. Graham Buckton of School of Pharmacy, University of London spoke about 'Developing an API into a drug product' and provided insights into topics such as physico-chemical information needed, importance of screening and control of polymorphism and related regulatory issues'.

Metro DC Chapter Chair Mehul Mehta with Professor Buckton, AAIPS president Vijai Kumar and Dr. Vinod Shah

UPCOMING SYMPOSIUM

June 13, 2008

Challenges in the Development of Poorly Water-Soluble Drugs: Formulation and Technological Approaches

Dr. Charles I. Jarowski Industrial Pharmacy Symposium organized by St. Johns University College of Pharmacy and Allied health Professions. For further information call (718) 990-2164.

MARK YOUR CALENDARS FOR NEXT REGIONAL MEETING ON JUNE 26, 2008
"Third Party Collaborations in Pharmaceutical Organizations"

Presented by Om Basavapathruni
Head of Acquisitions, Collaborations and Divestitures Worldwide Information Technology at Pfizer

Social/Networking Hour starts at 5:30 pm
Om's presentation at 6:30 PM, followed by Dinner at 7:30 pm.

Location: Cinnamon Indian Restaurant
2920 Rt 10 West, Powder Mill Plaza
Morris Plains, NJ 07950
Tel (973) 734-0040

Register Online at www.aaips.org, by mail or on-site For more information visit www.aaips.org or contact Punit Marathe (609) 252 5256 (punit_Marathe@yahoo.com)

AAiPS ANNOUNCES 2008 ANNUAL AWARDS!!

The AAiPS executive committee invites nominations for the;

- **AAiPS Distinguished Scientist Award**
- **Outstanding Achievement Award**
- **Graduate Student Scholarship Award**

These awards will be presented at the AAiPS Annual meeting in Atlanta, Georgia, Nov 16-20, 2008. The nominations with all the required details must be submitted to AAiPS office no later than September 1, 2008. Details for these awards and more please visit the AAiPS website www.aaips.org

AAiPS Distinguished Scientist Award:
Recipient shall be individuals who have made significant, pioneering and sustained contributions to pharmaceutical sciences. The areas of contribution include pharmaceutics, drug delivery, pharmaceutical technology, drug regulatory affairs, Biotechnology, analytical chemistry, Pharmacokinetics and drug metabolism and pharmaceutical and health care industry in general.
Information to be submitted by nominator;

- Letter of Justification – Max 2 pages
- Outline of significant achievement in Pharmaceutical sciences, publications, patents, abstracts, invited presentations, products developed that are marketed etc.
- CV
- One Letter of recommendation.

Outstanding Achievement Award:
Individual who has made outstanding, sustained contributions to the pharmaceutical and healthcare field in general, such as pharmaceutics, drug delivery, pharmaceutical technology, regulatory affairs, Bio-technology, analytical chemistry, Pharmacokinetics, drug metabolism, pharmaceutical education, pharmaceutical marketing, manufacturing operations, etc. In addition, individual should also be recognized nationally and internationally for his/her outstanding contributions in the pharmaceutical sciences and health care industry. Recipient shall also be an individual who has made sustained and pioneering contributions through academic and/or professional excellence in the pharmaceutical and healthcare filed. Moreover, individual should have provided services for sustained growth of AAiPS organization.
Information to be submitted by nominator;

- Letter of Justification – Max 2 pages
- Outline of outstanding achievements and pioneering contributions in Pharmaceutical sciences and healthcare industry. Details of recognition by National and/or International organizations, and service or support to AAiPS organization etc.
- CV
- Two letters of recommendations

Graduate Student Scholarships:
AAiPS is pleased to announce the availability of FOUR Research awards for graduate students in Pharmaceutical Sciences. The applicants must present their research findings at the 2008 Annual

meeting of the American Association of Pharmaceutical Scientists (AAPS) in Atlanta Georgia Nov. 16-20 2008. 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, Results and Discussion. Please include your Telephone number, Fax and email address with your submission. Send your submissions by September 1, 2008 to;

H.N. Bhargava Ph.D. Chair,
AAiPS Research Awards Committee
Prof. Emeritus, Massachusetts College of Pharmacy, Boston,
21 Sherwood Circle, Sharon, MA 02607
Email: hksv@aol.com
Tel: 781-784-6764

The awards will be presented at the AAiPS banquet on November 19, 2008 during the AAPS annual meeting in Atlanta, Georgia. Nov. 16-20 2008.

We also proudly announce that AAiPS will continue to offer the award initiated in 2007 to a **Pharmaceutical Faculty Member** from a recognized Indian Pharmacy education and research center. This award offers a grant of up to US $4000, covering participation at the Annual Convention of American Association of Pharmaceutical Scientists (AAPS), held in November every year in North America. This includes registration, travel expenses, reasonable lodging and boarding and possibly visits to an industrial setting and an academic institution.

AAiPS ANNOUNCES NEW "DR. VICTORIA HALE AWARD"!!

Another new award "Victoria Hale Award for Education" inspired by the speech by guest speaker, Dr. Victoria Hale at AAiPS annual meeting on November 2007, was established last year and will be initiated this year. Details to follow.

INDIAN PHARMACEUTICAL ASSOCIATION (IPA) UPDATES

Workshop on Quality - Good Manufacturing Practices for 21st Century,
Reported by: Tom Sam PhD MBM FFIP. Organon Inc Netherlands

This 2-day workshop was organized in Mumbai on February 20th & 21st, 2008, by Indian Pharmaceutical Association in collaboration with American Association of Pharmaceutical Scientists (AAPS) & International Pharmaceutical Federation (FIP). The theme of the workshop was Linking Process Understanding to Good Manufacturing Practices. The workshop was aimed at exposing the professionals from the Indian Pharma industry & academia to the concepts of 'Quality by Design' & Process Analytical Technology (PAT), the key initiatives of ICH Q8, Q9 & Q10 guidelines.

Mr. S.D. Joag the Honorary General Secretary of IPA, gave the participants an outline of the sessions planned during the workshop. Dr. Vinod Shah, Scientific Secretary of FIP, also welcomed the delegates. Dr. Shah also chaired the first session on 'Quality by Design'. Dr. Yelgivi and Mr Rajkondawar discussed Risk Prioritization matrix and provided examples and case studies.

Session 2, was chaired by Mr. Devinder Pal and was focused on PAT and Risk management.

Session 3 was focused on cGMPs and cGLPs and was chaired by Dr. Praful Sheth. The fourth session was chaired by Dr. Yelvigi and dealt with the regulatory perspective, Dr. Abdel Aziz Saleh, Special Advisor WHO/EMRO apprised the attendees of the WHO/GMP guidelines for pharmaceutical products and Dr. Milind Joshi presented on Global Regulatory Management.

Newly elected IPA office bearers for the term April 2008 – March 2010.

Dr. B. Suresh has been elected as President of the IPA. Dr. Suresh has a doctorate in Pharmacology and is the Principal of J.S.S. College of Pharmacy, Ooty.

The other elected Office Bearers are;

Mr. Raj Vaidya, Chairman - Community Pharmacy Division. Prof. T.V. Narayana, Chairman -

Education Division. Dr. R.N. Gupta, Chairman - Hospital Pharmacy Division). Mr. J.A.S. Giri, Chairman - Industrial Pharmacy Division). Mr. A. Krishna Dev, Chairman - Regulatory Affairs Division,. Mr. S.D. Joag - Hon. Gen. Secretary,
Mr. Ram Banarse – Hon. Treasurer, Mr. Kaushik Desai – Editor, Pharma Times and Dr. Rao V.S.V. Vadlamudi – Editor, Indian Journal of Pharmaceutical Sciences.
Mr. T.B. Nair will continue as the Executive Secretary of the Association.

The Indian Pharmaceutical Association has invited our own AAiPS EC committee members Dr Sam Singhvi and Mike Yelvigi to join the editorial board of their official monthly publication "Pharm Times".

PHARMA NEWS FROM INDIA

Compiled by Kinjal Gandhi and Anilkumar Gandhi (India)

New Drug Controller General of India Appointed

Dr Surinder Singh, Additional Director of Central Research Institute, Kasauli, Simla has been appointed new Drug Controller General of India (DCGI) who succeeds Dr M Venkateshwarlu. He was heading the Central Drugs Laboratory (CDL) of the CRI besides being in-charge of the Regional Drugs Testing Laboratory at Chandigarh.

Dr. Surinder Singh, promised an `interactive approach' with the industry and `team effort' to take Indian pharma sector to further heights. Dr. Singh said one of his main focus areas to begin with will be the study on spurious drugs. After settling down in the office, he is also planning to interact with the industry to garner their views on all the issues. ``We want to take their inputs in all matters to make India a global hub of pharma industry. I want teamwork along with the industry to improve the things. Also, one important area will be their perception about my office and its activities. We want a corporate work culture in CDSCO," explained Dr Singh, known for his humble nature and cordiality.

Budget 2008-09: Finance Minister brings cheers to pharma industry

In his budget for 2008-09 Finance Minister P Chidambaram announced a cut in excise duty on all pharmaceutical products from the present 16 per cent to eight present and extended a number of other sops including exemption in customs duty for life-saving drugs. "On certain specified life saving drugs and on the bulk drugs used for the manufacture of such drugs, I propose to reduce the customs duty from 10 per cent to 5 per cent as well as to totally exempt them from excise duty or countervailing duty," he said, bringing further cheers to the pharma industry. He also totally exempted anti-AIDS drug, Atazanavir from the excise duty.
The pharma companies in research and development also got some fillip, though no direct concession was offered in particular to them. ``In order to promote outsourcing of research, I propose to allow a weighted deduction of 125 per cent on any payment made to companies engaged in research and development," Chidambaram said. By not bringing in fresh burdens on the industry as whole, the Finance Minister also did not antagonize a section of the pharma industry in the excise-free zones that were apprehensive of some excise duty on contract manufacturing, against the backdrop of pending move to withdraw the tax exemption to them.

India to witness higher growth in pharma in next 5 years, says expert

Graham Lewis, vice president, Global Pharma Strategy, IMS Health mentioned that for the next five years, the pharmaceutical industry in 'pharmerging' countries including India, Brazil, Turkey, Mexico, China, Russia and South Korea are expected to grab more market space with focus in specialty segments, whereas the global pharmaceutical market is expected to remain in single digit growth.

In his special address in the inauguration of 'Pharmaceuticals: Market Prognosis - 2012', seminar organized by Federation of Indian Chambers of Commerce and Industry (FICCI), he said that the companies in these countries are already focusing on specialty products like

oncology, asthma and COPD, anti-ulcer, lipid regulators etc. Specialist driven market is currently counted as around two-third of the global pharma market and oncology is the number one in specialty market. The companies should further focus on specialty products and should have a wider idea than simply going for the overall generic market, he added.

Dr Kalam challenges the pharmaceutical industry in India to produce 40% of world generic drugs

Delivering the keynote address in the centenary celebrations of Alembic, Dr. Kalam expressed his vision of making India a hub for scientific research and pharmaceutical manufacturing. Former President of India Dr. APJ Abdul Kalam called upon the pharmaceutical industry in the country to accept the challenge of setting itself a target of producing 40 per cent of world's generic medicines. He also touched upon various opportunities to Indian Pharmaceutical Industry in the fields of collaborative research with national research laboratories for curing diseases like TB, Typhoid, Malaria, etc.

Avesthagen to launch novel herbal drug for diabetics

Avesthangen Ltd, India's leading life sciences firm has developed an herbal medicine based on methi or fenugreek as main ingredient, to manage blood sugar and prevent diabetes. The medicine, to be launched in the domestic market in the third week of May under Teestar brand, has been developed with World Bank funding and using the firm's two patented technologies and a comprehensive database. The product which underwent clinical trials at the Manipal AcuNova, a clinical research organization in Bangalore, has proved that it is particularly useful for people who are susceptible to type II diabetes. The medicine helps in maintaining blood glucose level by modulating the carbohydrate metabolism. It ensures that less quantity of glucose enters bloodstream by curbing absorption of carbohydrates in the body. The product will be available as a dietary supplement in the form of capsule or crackers produced by its subsidiary Good Earth. The other bio-actives in the pipeline are Aspand to control blood sugar, Bonapure to promote bone growth, Phytossea to assist inhibiting cartilage degradation, Cincata to maintain blood glucose, Smartchol to moderate cholesterol level and Xanomax as anti-oxidant property.

Neutropenia: A biosimilar product from India moves one step closer to Eurpoean market

A biosimilar protein that can be used to treat neutropenia (a side effect of cancer chemotherapy) is to be developed by Apotex Inc. of Canada in collaboration with Intas Biopharmaceuticals Limited (IBPL) of India. Neukine®, a recombinant granulocyte colony stimulating factor (G-CSF) is already manufactured and marketed in India and other countries by IBPL. Kwizda Pharma of Austria had been working with IBPL to develop G-CSF for the European market for some time. Effective immediately, Kwizda Pharma has transferred all of its rights in IBPL's G-CSF to Apotex. Apotex and IBPL have concurrently agreed to extend the collaboration to development of G-CSF for North America (US and Canada).

Data from a clinical phase I study showed that a biosimilar product for treating the negative effects that cancer chemotherapy can have on the white blood cells of patients is safe and exhibits an identical pharmacokinetic and pharmacodynamic profile compared to a reference product. Upon completion of an upcoming clinical phase III trial, both companies would lodge an application to get the product approved for the European market. The market launch is planned for early 2010.

IBPL operates an EMEA-certified manufacturing facility in India since March 2007 and is now due to launch its products on the European market. As part of its business strategy, IBPL is working with Kwizda Pharma, which is helping to secure EU approval and will provide support with marketing logistics. Kwizda Pharma (established 1853), which has a well-established clinical background and extensive experience with regulatory procedures, is now offering its expertise to companies that manufacture biosimilar products, particularly those based in India.

IIT Mumbai develops chip to detect myocardial infarction

Establishing its prowess in medical bio-sensing technology, IIT Mumbai's Centre for Research in Nanotechnology & Science has developed an affordable diagnostic chip to detect myocardial infarction (heart attack) well in advance so as to prevent critical emergencies. The chip, known as 'ISens', was developed under the Union government's National Program on Smart Structures with a funding of Rs 3.6 crore.

-Compiled from various sources

BIOTECH EXPANSIONS IN INDIA

Karnataka Biotech Park- Bangalore Helix

Bangalore Helix is a biotech cluster being planned by the Karnataka government. Bangalore Helix would support biotech units with common infrastructure. It would comprise eight biotech incubators, covering a total area of 10,000 square feet. Excluding the cost of land (around Rs 60 crore) that has already been acquired, the cluster will involve an investment of Rs 100 crore. The Karnataka Government has tied up with Alexandria Equities and Holdings, the biotech park developers in the United States, to set up a Rs. 6,000-crore state-of-the-art biotech park in the vicinity of Electronics City on the southern outskirts of Bangalore. The first phase, to accommodate two leading biotech-related research and development institutions on a six-acre plot — Institute of Bioinformatics and Applied Biotechnology and the Centre for Human Genetics — is ready for inauguration. The two institutions, which are now functioning at the Information Technology Park, Whitefield, will shift to the new park.

Shapoorji Pallonji Biotech Park

Shapoorji Pallonji Biotech Park is a joint venture between the Shapoorji Pallonji Group and the Andhra Pradesh government. The park will have an exclusive Lab Space of 15 lakh sq ft that will be reserved for research institutes, drug developers, finishing school for scientists and regulatory agencies, besides the institutions involved in intellectual property rights and patents issues. The project, which is coming up in the existing Biotech Park, is estimated to cost a little less than Rs 500 crore. Due to lower operational costs international pharmaceutical majors are evaluating options of starting their units while comparing the facilities with that of those in Singapore, Dubai, Ireland and parts of Europe.

Gujarat Biotech Park at Vadodara

Gujarat Biotech Park (GBTP)- a Rs 2000 cr venture- will be soon launched at Vadodara about 110 km from Ahmedabad as a joint venture company of Government of Gujarat in collaboration with the Mumbai based Akruti City Ltd and The Chatterjee Group (TCG) Ltd. It is said that the company has already completed development of basic infrastructure in an area of 90 acres, with most of the plots already sold out to major biotech companies in India and abroad. Designed to complete in three phases the project is currently undergoing second phase of the development with the 131 acres land handed over by the Gujarat Industries Development Corporation (GIDC).

PHARMA ECONOMY

Surviving the 'R' by *Rashmi Pai-Thakur, PhD*

The 'R' word has become very popular (or unpopular should I say?) since the April 2nd announcement from Fed chairman Ben Bernanke, close on the heels of the Bear Stearns rescue. 'R' has so far hit the banking industry, savings and loan (including mortgage), housing market, automobile, manufacturing, construction, energy (gas) and airline industry. '**R**ecession' is not uncommon to the American economy considering there have been four in the last 25 years each lasting about a year (April 1982- March 1983; Nov 1985-March 1987; April 2001-Dec 2001 and the current one). While the pharmaceutical sector was considered recession proof in the previous periods of economic slowdown along with healthcare, biotech, legal, and security firms, this time around it looks different.

The telltale signs began in 2006 with the first round of job-cuts and layoffs at Pfizer. Although that initially appeared to be more of a company-related

economic issue rather than an industry wide phenomenon, by first quarter of 2008 the whole industry seems deeply affected. Unofficial internet polls show that 60% respondents believe the industry is experiencing severe economic decline[1] while there are still a few who think otherwise. For example, according to a recent report, Massachusetts gained some 8,400 jobs in professional, scientific, and technical services in 2006, along with 2,100 jobs in scientific research and development and another 800 in the information sector. During the same period, it lost 2,600 jobs in manufacturing and 3,300 in construction. So is our industry truly in a recession? Perhaps a look at the industry figures and trends will help us determine this.

One of the warnings of an impending recession is the stacking of pink slips. This quarter the overall jobless rate (spanning all industries) rose three-tenths of a percentage point and for the third month in a row, the US employment rolls shrunk. Looking back at one full year of activity in the pharmaceutical job market, it is easy to see that our industry didn't exactly escape unscathed. A summary of this scenario is reflected in the following number of job cuts during this time period[2]: Pfizer (10,000), AstraZeneca (7,600), Bayer (6,100), Schering-Plough (5,500), Wyeth (5,000), Johnson & Johnson (5,000), Bristol-Myers Squibb (4,300), Novartis (3,750), Amgen (2,600), Glaxo (1,650). The annual report by PhRMA cites that the total US employment in R&D fell by 3.9 percent in 2006. Clearly cutting down R&D expenditure by bringing down the axe on jobs in these sectors is the first step in bailing the sinking economy.

Another sign of the slowdown is reduced expenditure in advertising and marketing. As companies face ever-increasing generic competition and a thinning pipeline leading to a decline in revenues, cost cutting measures such as a curb on spending in all aspects of business has gained momentum. Nielsen Monitor-Plus which tracks measured media advertising spending reports that there was a drop of 14.7% in Internet ad spending by pharma in Q1-Q3 2007 vs. 2006. While pharma spent $58.1 million in the first quarter of 2006, it spent only $49.5 million in the same period of 2007[1]. Clearly pharma marketers are becoming wary of where they put their dollars. On the brighter side however, *eMarketer* projected that annual growth in US pharmaceutical online ad spending is rising again after a dip last year (2007), and that the rate will hit 28.6% next year (2009)[3].

On the flip side there are several strategies that are being used by the pharma sector to fight back.
'Don't put all your eggs in one basket' couldn't have been truer at any other time. In other words, diversify to reduce dependence and avoid decline. But wait! Doesn't diversification contradict consolidation, the basic principle for survival in such an economic catastrophe? While a majority of businesses are using mergers as a strategy to fortify their core businesses, a few are venturing into newer businesses. An example is the recent move from Novartis AG to acquire stakes in Alcon's eye business, a step that will help take away burden from the declining prescription business, which is under the ever-increasing threat of patent expiration, to more OTC products. Novartis CEO Daniel Vasella says (Source excerpt form WSJ): From the point of view of portfolio management, we want to strengthen the businesses that give us growth opportunities and balance risks. (Eye care) is a specialty area with high growth and diversification from the point of view of risk'. Supporting this approach, Morgan Stanley believes drug makers need to invest more in areas like vaccines, molecular diagnostics and animal health to offset problems in conventional drug discovery, as new drug pipelines look increasingly sparse.

Diversification need not be just in businesses. Locations and markets also could play a vital role in salvaging a companies' financial downward spiral. Even with a slowdown, a business that is spread across many regions, especially in emerging markets, will be the one minimally affected. While diversifying into new markets can definitely reduce the threat to businesses, moving jobs from a slowing economy to an emerging economy to save money is another story. This seems to be a vicious cycle where cost cutting by outsourcing to save brings in a fresh wave of unemployment each time that could lead to a steeper decline.

Another smart move is moving away from research cost centers and buying creativity from others. As a case in point, Shire pharmaceuticals, which according to CEO Matt Emmens is foregoing expensive research and moving towards in-licensing compounds for development. The success of this unique business model is evident in the millions saved by the company by steering clear of the initial phases of drug discovery and in its revenue, which has doubled over the last five years.

Although all the above strategies will achieve the short-term goal of cost cutting, each company will have to evaluate carefully which approach will work for them the best in the short as well as long run. Dry pipelines and increasingly stringent requirements from the FDA only add to the challenges. While 'R' does stand for recession, retrenchment and reduction, it also stands for rebound and recuperation. Let us hope our transition to the better side is a smooth one.

*Views expressed here are personal opinions of the author backed by data from various reports and newsletters. (*Sources:

1. *http://www.pharmalot.com/2008/04/where-the-jobs-arent-the-latest-layoff-tally/*
2. *http://www.forums.pharma-mkting.com/showthread.php?t=2031*
3. *http://pharmamkting.blogspot.com/2008/03/pharma-recession-part-deux-online-ad.html*

PERSONALIZED MEDICINE: IS THIS REALLY THE FUTURE OF MEDICINE?

Diptee A. Kulkarni, MBBS, PhD, The Cancer Institute of New Jersey

There are quite a few unsolved puzzles in modern day medicine such as why some people develop cancer earlier than others or why a person who smokes cigarettes all his life never develops lung cancer while a non-smoker ends up with one or why some medicines prove efficacious in some people and adversely toxic to others. These interpersonal variations are increasingly being attributed to an individual's genetic makeup and gene-environment interactions.

The completion of the human genome project has established that humans are a young species and more than 99% human genome is identical between any two individuals. The vast majority of variations in the remaining ~1% human genomic DNA sequence are known as polymorphisms, the most common being single nucleotide polymorphisms or SNPs, which involve alteration in a single nucleotide. The DNA variation is called a SNP only when it is present in at least 1% of the population; variations with <1% frequency in population are known as mutations. SNPs occur every 100-300 bases along the 3 billion bases of the human genome and can be found in both protein-coding and non-coding regions of the genome.

Studies have shown that such single base variations in the human genome contribute toward outward differences among people. To name a few, it was shown that a SNP in one of the signaling receptors on the taste-bud cells determines how people perceive the taste of natural sugars versus artificial sweeteners such as saccharin. Similarly, recent work suggests that a single SNP in an evolutionarily conserved intronic region of a gene, *HERC2* can serve as a predominant predictor for blue versus brown color of eyes. In addition, a SNP in one of the cholinergic-nicotinic receptor genes of cigarette smokers has been implicated in nicotine dependence explaining why some people can quit smoking while others cannot.

The SNPs are also proving to be important markers for development and progression of complex disorders such as cancer or neurological diseases and modulation of drug response. The International HapMap Project, which is dedicated to find genes associated with health, disease and responses to drugs and environmental factors; the development of high-throughput and affordable genotyping assays, and the molecular epidemiology and pharmacogenetic studies initiated worldwide have significantly improved our understanding of the genetic basis of complex diseases and enabled development of improved therapies. For example, a SNP in the promoter region (SNP309) of Mdm2, a

well known oncogene and master regulator of the tumor suppressor protein, p53 has been shown to act independently as well as synergistically with p53 mutations to increase the incidence and earlier age of onset of various cancers. On the other hand, SNPs in one of the liver enzymes, cytochrome P450 2D6 (CYP2D6), have been linked to the metabolizing capacity of individuals. Individuals carrying the variant alleles have been classified as poor, intermediate, extensive, and ultrarapid metabolizers. Tamoxifen, one of the CYP2D6 targets, is metabolized to a more active form, endoxifen by CYP2D6. Poor metabolizers of tamoxifen have lower levels of endoxifen and poorer clinical outcomes as compared to extensive metabolizers. In fact, the poor metabolizer phenotype has been linked with increased risk of breast cancer recurrence. The FDA is considering a change in the label on tamoxifen advising CYP2D6 genotyping test before prescribing tamoxifen to breast cancer patients. Similarly, a SNP (UGT1A1*28) in the uridine 5'-diphospho-glucuronosyl-transferase gene (*UGT1A1*), a crucial drug-metabolizing enzyme for the anticancer drug irinotecan determines not only the efficacy of irinotecan, but also the susceptibility to irinotecan-related toxicity. The FDA has revised the label of irinotecan to warn of the association between UGTIA1*28 genotype and toxicity since even a single unadjusted dose may be life threatening.

Thus, the increasing need to improve drug efficacy and safety is going to change the concept of "one size fits all' therapy to "patient-tailored" therapy. With rapid advances in genomic and bioinformatic tools, clinicians should soon be able to create an individual genetic profile for a patient as well as develop an individualized treatment plan. However, the information obtained about an individual's genetic makeup also brings in a whole new set of ethical issues such as privacy protection, ownership of genetic information, implications for family members, and whether the genetic information that calculates an individual's risk for developing any disease in the lifetime or determines the response to drugs should be furnished to insurance companies. An ethical balance between genetic testing and proper use of that information should make Personalized Medicine a feasible rather than far fetched target.

PEOPLE ON THE MOVE

Prakash Kulkarni has moved to CorePharma, located in Middlesex, NJ, as V.P. R&D, Chief Scientific Officer.

Please send any "people on the move" announcements to Udaydoshi@aol.com for publication in the next newsletter.

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

No advertisements under a quarter page

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