



American Chinese Pharmaceutical Association Newsletter

美洲華人藥學會通訊

Editor: James W. Shaw, Ph.D., Pharm.D., M.P.H.

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Message from the President Keith Chan, Ph.D.

To My Mentors Who Taught Me How to Be Stupid

I still vividly remember that, almost thirteen years ago, Bill Clinton was elected as the President of the United States, and Hillary Clinton was advocating health care reform. The pharmaceutical industry feared for its survival, and many pharmaceutical scientists were forced to retire or be laid off. We called that the period of downsizing, rightsizing, faster-time-to-market, first-to-market, and the start of the never-ending process called Merging and Acquisition (M&A). The pharmaceutical industry was in turmoil. In the midst of that crazy period, I was elected as the 1994 President of ACPA—an organization dedicated to the well-being of pharmacy practitioners and pharmaceutical scientists of Chinese heritage. During one of my many sleepless nights in those uncertain years, I wrote an article for the ACPA Newsletter entitled “Dedicated to My Mentors Who Taught Me How to Be Stupid.” The article was published in Volume 6, No. 2 of the newsletter in April 1994. Eleven years later, I am now in the same situation. No matter how much the world changes, something remains the same: I still feel stupid. Looking back, I am lucky to have survived so many changes with the help of many friends and colleagues. Without doing some stupid things, like serving ACPA, I would not have met many of these individuals. These persons have helped to make me what I am today. During yet another sleepless night, I would like to dedicate this article to those who are not sure about their future—who mistakenly think that they have to fight for their own survival and do not have time for their family members and others—your friends and colleagues in ACPA. My advice is to be stupid. What goes around will come around. Here it is:

Over the years, I have been known to do many stupid things that resulted in no apparent returns. With my full-time job, I still teach at universities and serve in organizations, such as ACPA. Many people advise me to “smarten up” and not to waste my time and energy in this lean and mean world.

I consider myself an accomplished scientist, but that’s not how it was many years ago. I was never an academic achiever. I was left back at the same grade level several times and graduated almost dead last in my high school (I attended high school in Hong Kong). No university in Hong Kong would accept a student like me. I decided to start studying to get into a university in Taiwan. Well, I was successfully accepted by the pharmacy program in Kaohsiung Medical College (KMC, a small and relatively unknown college at that time) in 1967. My grades at KMC were okay but not terribly impressive. I got a break when I met my first mentor, Dr. Lloyd Matheson, while pursuing my master’s degree at North Dakota State University. I was his first graduate student. I lived next to the school but had to go to the Veteran Affairs Hospital miles away for my research. It was impossible for me to walk to the VA Hospital especially during the winter. Lloyd picked me up every cold winter morning and gave me a ride to the hospital (he had to since I didn’t have a car at that time). One thing I will always remember is how he had his wife make me a sandwich for my lunch every day. He gently guided a lonely, frightened, graduate student with little proficiency in English for 2.5 years. Without him, I would certainly have quit and gone home.

My second and third mentors were Dr. Kenneth Miller and Dr. Ronald Sawchuk, respectively. I met them at the University of Minnesota, where I received my Ph.D. degree. They taught me how to get along even when both of them were working in the same field. There is plenty of research to be done, and you don’t have to kill one another. Ken gave me the freedom to explore and

learn by making my own mistakes (he was my advisor), and Ron never kicked me out of this office when I was in trouble with my research. Ron was not my advisor, contrary to what many believe, even though I published more with him than with Ken. Ken persuaded me to stay in graduate school when times were rough (especially after I got a couple of C's). Ron trusted me enough to let me teach (yes, teach, give lectures) in his undergraduate and graduate classes. That was the beginning of my teaching career. I taught part-time for the University of Minnesota for 12 years. Those two risked their reputations by letting me fool around in their laboratories and classrooms.

My biggest break of all came when I met Dr. Milo Gibaldi. He was a consultant to my company (Ciba-Geigy) at that time. Milo is a giant in my field (Pharmacokinetics), as you all know. I remember how we first met when I was an unknown fresh Ph.D. He asked about my work and my research interests. I asked him my first naïve industrial question, "Can we actually learn something about drug absorption by measuring plasma concentrations?" He told me to work on it, and we published four papers together. Many people still think I am one of his most prestigious students, which I hope I am. Milo has tons of papers, and he didn't need to publish with me. Over my career, I have met many great scientists, but none of them have ever come close to Milo as a person. He is the one who told me, "Don't thank me, pass it on. Help someone else who is less fortunate than you are. It will complete the circle and eventually come back to you."

These four wonderful persons all have one thing in common. They all have done some stupid things by helping others without asking for anything in return. I learned to listen to them. By being stupid, I have gained many friends who have helped me overcome many hurdles, while smart people who asked "what's in it for you?" My friends, it is time for you to stop smartening up and to get stupid. Let's tip our hats to the stupid among us: our mentors, teachers, and friends.

Report from the Treasurer Marina Chang, R.Ph.

During the past quarter, ACPA received a \$500 donation from GloboAsia (Keith Chan, CEO [also ACPA President]) and a \$2,000 donation from the Community of Asian Association at Johnson and Johnson (CAAJJ)

(Jonas Wang, founder [also Past-President of ACPA]) for the 2005 ACPA Regional Conference on Biopharmaceutical Comparability, which was held on October 1, 2005. In addition, Ms. Jane Chang provided a donation of \$1,000 for the 2005 ACPA Annual Dinner Meeting. ACPA wishes to thank all those who made contributions for their support.

Report from the Nominations Committee Yih-Chain Huang, Ph.D.

It is time to hold elections for the offices of President-Elect and Secretary. We currently have one candidate for each position. Ming Hu, Ph.D. has been nominated for the office of President-Elect, and James W. Shaw, Ph.D. has been nominated for the office of Secretary. With this issue of the newsletter, you have received an election ballot as well as a biosketch from each candidate. Please use the ballot to vote for one of the named candidates or write in the name of the individual for whom you wish to cast your vote. Marked ballots should be returned by e-mail to Yih-Chain Huang, Ph.D. at yihchain.huang@fda.hhs.gov. We strongly encourage all ACPA members to cast their vote and return their ballot by **December 30, 2005**. Members who do not return a ballot will be presumed to have cast their votes for Drs. Hu and Shaw.

Summary of ACPA Annual Dinner Meeting Jinn Wu, Ph.D.

The 2005 Annual Dinner Meeting took place from 6:30–10:00 PM on November 9, 2005 at the Gaylord Opryland Resort & Convention Center in Nashville, Tennessee. The meeting was held in conjunction with the 2005 Annual Conference and Exhibition of the American Association for Pharmaceutical Scientists. Eighty-one ACPA members attended the event.

The evening started with cocktails. This was followed by an American-style buffet and a brief message from ACPA's president, Keith Chan, Ph.D. The keynote speaker for the meeting was Duu-Gong Wu, Ph.D. The title of Dr. Wu's presentation was "A Regulatory Update on FDA's Pre-approval Inspection." The presentation provided a general introduction to the FDA's

organization, GMP regulations, and approaches related to pre-approval inspections for drugs as well as an update on the FDA's recent initiatives pertaining to risk-based GMP inspections.

Dr. Wu is the Executive Director of the Consulting Division of PharmaNet, Inc., which is located in Washington DC. PharmaNet is an international drug development company based in Princeton, New Jersey. The firm has over 800 employees as well as more than 20 offices in North America, Europe, and Asia. PharmaNet specializes in the Phase III and Phase IV clinical development of oncology, cardiovascular, neurology, and anti-infective drugs.

Before joining PharmaNet in 2004, Dr. Wu was employed by the U.S. Food and Drug Administration for over 12 years. During this time, he worked as a reviewer, Chemistry Team Leader, and as Deputy Division Director of the Division of New Drug Chemistry II, Office of New Drug Chemistry (ONDC), which supports CMC reviews for six clinical divisions in the Center for Drug Evaluation and Research (CDER). Dr. Wu was Chairman of the Protein Drug Products Technical Committee under the CDER Complex Drug Substance Coordinating Committee. Most recently, he represented CDER as a member of the ICH Expert Working Group for both Q5E and Common Technical Document Quality for biotech products. In addition to his aforementioned roles, Dr. Wu served as chairman of the Follow-on Growth hormone and Insulin Working group, was a member of the FDA Follow-on Biologics Working Group, and served as an Ad Hoc Reviewer for the USP Biotechnology Committee.

Dr. Wu received his Ph.D. degree in Biochemistry and Molecular Biology from the University of Maryland Medical School and did his postdoctoral research at the Johns Hopkins University Medical School.

Overall, it was a very informative and useful presentation. Everyone appeared to enjoy a good evening with old and new friends.

Summary of ACPA-CACS Joint Conference Jinn Wu, Ph.D.

ACPA held a joint regional conference with the Chinese American Chemical Society (CACS) on a highly practical and demanding topic: "Mass Spectrometry in Biomedical Research and Drug Discovery." The conference was held on September 30, 2005 at the Clarion Hotel & Towers in Edison, New Jersey. There were approximately 120 attendees from pharmaceutical industry. The presentations were well received, and the ensuing discussions were very enthusiastic. The presentation titles (speakers) were as follows: (1) Bioanalytical Challenges in the Use of Deuterium and Oxygen-18 Labeled Compounds in Drug Metabolism Studies (Bogdan Matuszewski, Merck); (2) Successful Strategies for Discovery ADME-PK Studies (Walter Korfmacher, Schering-Plough); (3) New Developments on the QSTAR XL LC/MS/MS System for Metabolomics and MALDI Imaging (Julie Wingate, Applied Biosystems); (4) Maximizing the Power of LC-Tandem Mass spectrometry: UPLC-Quattro Premier Applications in DMPK (Kate Yu, Waters); (5) LC-MS/MS in the Drug Discovery and Development Process (Timothy Olah, Bristol-Myers Squibb); (6) ADME Concerns Addressed with LC-MS (Cornelius E.C.A. Hop, Pfizer); (7) Simultaneous Quantitation of Parent Compounds and Screening of Metabolites in Biological Samples Using Qtrap (Wilson Shou, Covance); (8) New TSQ Quantum; Products and Developments (Rohan Thakur, Thermo Electron); and (9) Quantitation Aspects for LC-MS/MS on State-of-the-Art API Instruments (Yong-Xi Li, XenoBiotic Laboratories, Inc.). The symposium revealed one key puzzle: With the recent advances in modern instrumentation, why is the pharmaceutical industry not able to find and develop more effective and better new drugs?

Summary of 2005 ACPA Regional Conference on Biopharmaceutical Comparability Jennifer X. Han, Pharm.D.

The 2005 ACPA Regional Conference on Biopharmaceutical Comparability was held on October 1, 2005 at the University of Maryland Shady Grove Center in Rockville, Maryland. The event was sponsored by four organizations, including ACPA;

Centocor R&D, Inc.; CAAJJ; and GloboAsia. The conference started with opening remarks from the 2005 ACPA President, Dr. Keith Chan, and the conference program chair, Dr. Haishan Jang. Four speakers presented at the event. They represented major pharmaceutical associations, various international pharmaceutical companies, or consulting firms and were respected entrepreneurs in the biopharmaceutical industry. The topics, presentation titles, and presenters were as follows:

- *Regulatory*
Duu Gong Wu, Ph.D.
“Regulatory and Scientific Perspectives on Biopharmaceutical Comparability and Follow-on Biologics”
- *Pharmacokinetics/Pharmacodynamics*
Charles Pendley, Ph.D.
“Challenges of Demonstrating Biocomparability of Therapeutic Antibodies in Nonhuman Primates”
- *Pharmaceutical Development*
Fredric G. Bader, Ph.D.
“Demonstrating Comparability for Biotechnology Products, Issues and Challenges in a Global Environment”
- *Toxicology*
David J. Pepperl, Ph.D.
“Nonclinical Toxicity and Immunogenicity Testing: Key issues facing Developers of Biogeneric Products”

An excellent lunch was served at the conference, and participants were able to enjoy authentic Chinese cuisine while interacting with their peers. Positive feedback was obtained from the participants after the event. Colleagues enjoyed the open forum of communication that the conference had provided and found the sessions very enjoyable and informative. Dr. Haishan Jang stated, “I was very excited about our program this year, as it provided everyone an opportunity to discuss significant scientific issues impacting the biotechnology community, and I am pleased that everyone had found this memorable experience.”

Pictures from the event have been distributed with this issue of the newsletter. ACPA members may also access these (as well as the presentation slides) from the association’s website at www.acpa-rx.org.

Conference Announcement – 2005 SCBA Bio/Pharm Division Annual Meeting

The 2005 Annual Conference of the Society for Chinese Bioscientists in America Division of Bio/Pharmaceutical Sciences will be held from 9:00 AM to 6:00 PM on December 4, 2005 at the Busch Campus Center of Rutgers University in Piscataway, New Jersey. The purpose of this conference is to tackle issues related to pharmaceutical industry productivity. The meeting will provide the participants a forum to understand and discuss various approaches being used to increase productivity in the preclinical, clinical, and business development arenas. The program includes several keynote speeches to be presented by prominent leaders in the pharmaceutical field, including Dr. Ray Lipicky, former Director of the Cardioresenal Division at the FDA; Dr. Paul Chew, VP of Metabolism and Thrombosis at Sanofi-Aventis; Dr. Henry Pan, Chief Medical Officer at Neurocrine Biosciences; and Dr. Yung-Chi Cheng, Professor at Yale University.

There will be four parallel lecture tracks with over 40 speakers covering the following key areas of interest:

- Application of Genomics and Proteomics in the Pharmaceutical Industry
- Medicinal Chemistry & ADMET
- Animal Disease Models
- Biomarkers/Translational Medicine
- Clinical Research – Operational Aspects
- Clinical Trials and Statistical Considerations
- Today's Regulatory Environment
- Business Development

ACPA members who are interested in attending this event should refer to the meeting flyer that was received with this issue of the newsletter or contact SCBA at <http://biopharm.us> for more information.

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