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Dr. Edith Hsiung Remembered



GUEH-DJEN (EDITH) HSIUNG, PHD 1918-2006

Gueh-Djen (Edith) Hsiung, Ph.D., died August 20, 2006 after a long illness. Dr. Hsiung was born on September 16, 1918 in Hupei, China and graduated with a degree in biology from Ginling College in Chengdu, China, in 1942. Her opportunity to attend medical school was lost, however, when Peking Union Medical College closed during World War II. Instead, she secured a job testing bacterial and viral vaccines for use in animals at the Epizootic Prevention Bureau of the Ministry of Public Health in Lanzhou, China. From this early experience Dr. Hsiung learned to be productive even in times of limited resources, a trait that served her well. When charged with the transport of a stock virus for rinderpest vaccine without the benefit of refrigeration or dry ice, Dr. Hsiung injected the vaccine virus into a goat and then traveled to her destination for 27 days by truck, with the goat at her side.

After the war, she came to the United States and obtained her Ph.D. in Microbiology from Michigan State University in 1951. At that time, she also underwent day-long surgery to fuse a congenitally

dislocated hip, spending nine months in a total body cast. In order to pay her medical expenses, she worked for the next two years at the Wene Poultry Laboratory in New Jersey, where she developed the first vaccine for infectious bronchitis virus in chickens.

Since her original interest was medicine, she applied for admission to Yale University School of Medicine, but was told she was too old. Instead she was offered a postdoctoral fellowship in 1953, working under Dr. Joseph Melnick on poliovirus and related enteroviruses. She joined the faculty the next year and, aside from a two-year sojourn at New York University, spent her entire professional career at Yale.

Her research spanned five decades, and produced more than 240 scientific publications. She was the first to describe the use of plaque morphology and a spectrum of cell cultures for recognition and characterization of polio, coxsackie, and echoviruses, and she recognized the importance of endogenous viruses in cell cultures derived from a variety of animal species. She discovered and characterized viral infections in guinea pigs that facilitated studies of disease pathogenesis and treatment in humans. For example, her demonstration of transplacental transmission of cytomegalovirus (CMV) in the guinea pig correlated with congenital CMV in humans and provided an important model for this infection. As an impassioned advocate for accurate viral diagnosis, she helped bridge the gap between basic research and clinical medicine. She became the first Director of the Diagnostic Virology Laboratory at Grace-New Haven Hospital in 1960, wrote the textbook "Diagnostic Virology" that became the standard in the field, and gave an intensive course entitled "Experimental and Diagnostic Methods of Virology" for decades in the U.S., China and Taiwan, thus training countless professionals in the field. In 1984, she established the National Virology Reference Laboratory at the Veterans Administration Medical Center in West Haven Conn., to serve VA hospitals nationwide, and became its first Director. From 1992 to 1998, Dr. Hsiung traveled annually to the National Cheng Kung University in Taiwan to help establish a model virology laboratory in the Department of Pathology. In September 2006, a new Virology Contract Laboratory named in honor of Dr. Hsiung will open at the National Health Research Institute in Tainan, Taiwan.

Dr. Hsiung received many awards and honors, including the Becton-Dickinson Award in Clinical Microbiology from the American Society for Microbiology, and the Wellcome Diagnostic Award from the Pan American Group for Rapid Viral Diagnosis (the previous name of the Pan American Society for Clinical Virology). In 1989, she received an Honorary Doctor of Science degree from Michigan State University.

Dr. Hsiung was well known for her persistence and determination, her infectious enthusiasm for every discovery no matter how small, and her skill in encouraging her many protégés. Her many friends, colleagues and trainees greatly appreciated her good cheer, boundless energy, social grace, and generosity. Although she was never known to take a vacation, her wonderful parties remain legendary.

(contributed by Marie Landry, M.D.)

Seeking Award Nominations

PASCV sponsors three annual awards in addition to the travel awards. They are the Diagnostic Virology, Clinical Virology, and Young Investigator Awards. Please go to our website at www.virology.org to view previous winners and criteria for eligibility. Nominations should be sent to Ella Swierkosz, Ph.D. (swierkem@slu.edu) at your earliest convenience.

2006 PASCV AWARDS

C.J. Peters, M.D.
Clinical Virology Award
Sponsored by Becton Dickinson



Dr. C.J. Peters is currently the John Sealy Distinguished University Professor of Tropical and Emerging Virology at the University of Texas Medical Branch in Galveston. He has an active research program in SARS, Rift Valley Fever, and other important human pathogens. He came to UTMB in 2000 after 9 years at the CDC where he was head of the Special Pathogens Branch. As examples of the work he did there, his group was called on to investigate a new disease in the southwestern US where they discovered the new virus that caused what is now known as hantavirus pulmonary syndrome; they described the disease manifestations and devised programs for surveillance and control.

He also led efforts in Africa (Ebola, Rift Valley fever), Asia (Nipah virus in Malaysia), and South America (Bolivian hemorrhagic fever, hantavirus pulmonary syndrome) to control diseases there.

Previous to working at the CDC he spent 13 years at the US Army Medical Research Institute of Infectious Diseases, the Department of Defense lead agency in biodefense and hazardous virus research.

Dr. Peters worked on several outbreaks overseas and led the team that controlled an Ebola virus introduction into a monkey facility in Virginia. In addition, Dr. Peters has published more than 300 papers on research and control of viral diseases and served on numerous committees dealing with disease problems worldwide. He has been called back as a consultant to the CDC and USAMRIID on influenza, vaccines, and other issues after his departure and he has consulted with the Taipei government on SARS control.

Robert S. Lanciotti, Ph.D.
2006 Diagnostic Virology Award
Sponsored by Bion Enterprises



Dr. Lanciotti received a BS in Chemistry from Loyola College in 1982. He was employed as a Laboratory Scientist in the Department of Microbiology at the University of Maryland School of Medicine, studying replication and protein expression of arthropod-borne viruses (arboviruses). During this time he began a Master of Sciences program at the University of Maryland.

In 1983, Dr. Lanciotti accepted a position as a Research Chemist in the Virology Division at the US Army Medical Research Institute for Infectious Diseases, researching the antigenic and molecular characterization of arboviruses with emphasis on novel approaches to vaccine development.

Dr. Lanciotti began working at Maryland Medical Laboratories in Baltimore (now Quest Diagnostics) as a Research Associate

in 1985. Between 1985 and 1989, he designed immunological and molecular based assays for HIV, hepatitis B virus, and human Papillomaviruses, and completed his MS in Biomedical Sciences at Hood College in Frederick, MD.

Accepting a position at the division of Vector-Borne Infectious Diseases of the CDC in Fort Collins, Colorado, in 1989, he researched the biology, evolution, and phylogeny of arboviruses with particular emphasis on the evolution of the four serotypes of dengue viruses. He also developed molecular amplification-based diagnostic assays for the rapid detection of a number of arboviruses for use in the CDC's Diagnostic Laboratory. In 1990, concurrent with his work at the CDC, he began a Ph.D. program in the Microbiology Department at Colorado State University, graduating in 1994.

In 1999, Dr. Lanciotti and his laboratory were responsible for the initial identification and characterization of West Nile virus in New York City. In 2000, he was appointed Chief of the Diagnostic and Reference Laboratory at the CDC, where he is currently employed. Since that time, he has been involved in the development, training, and distribution of West Nile and other arbovirus diagnostic assays to numerous public health laboratories.

Dr. Lanciotti is the author/coauthor of 55 scientific manuscripts and has authored three chapters on diagnostic technology of arboviruses.

He has been married for 21 years to Ruth and is the proud father of four children: Christopher (19), Elizabeth (16), Danny (12), and Maria (9).

James Dunn, Ph.D.
2006 Young Investigator Award
Sponsored by Remel, Inc.



Dr. James Dunn is Director of Infectious Disease Testing at Cook Children's Medical Center in Fort Worth, Texas. He received his doctoral degree from the University of Nebraska Medical Center and completed a postdoctoral fellowship in Clinical and Public Health Microbiology at the University of Utah and ARUP Laboratories. He is certified by the American Board of Medical Microbiology and an ASCP-certified medical technologist.

Dr. Dunn has taught in both graduate and medical programs in the fields of medical microbiology, clinical laboratory medicine, and molecular pathology. He has published in the disciplines of molecular virology, diagnostic virology, parasitology, mycology, and immunology and has presented his work at several national meetings. He holds patents in the areas of viral pathogenesis and molecular virology.

He introduced molecular diagnostic testing in the Cook Children's Medical Center Laboratory for diagnosis of pediatric and transplant infectious diseases. His research focuses on molecular diagnosis of bacterial and viral pathogens.

Travel Awards for Outstanding Abstract Submissions

The Edwin Lennette and G.D. "Edith" Hsiung Awards for The Most Outstanding Abstract Submissions are established and funded by Diagnostic Hybrids Inc. The Mario Escobar Award for The Most Outstanding Latin/South American Abstract Submission is funded by the Clinical Virology Symposium. Each recipient of these awards receives \$1000.

Seven additional travel awards in the amount of \$700 are funded by PASCV.

Award Recipients for 2006

Edwin Lennette Award – Daryl M. Lamson, New York State Health Department

G.D. "Edith" Hsiung Award – Zachary Wilkey, ARUP Laboratories, Salt Lake City, UT

Mario Escobar Award – Maria Prado, Pontificia Universidad Catholica de Chile

Additional awardees are:

Jennifer S. Goodrich, University of North Carolina, Chapel Hill, North Carolina

Claire Magauran, Cleveland Clinic, Cleveland, Ohio

Kimberly Martin, Provincial Laboratory for Public Health in Edmonton, Alberta Canada

Eederlyn Atienza, Fred Hutchinson Cancer Research Center in Seattle Washington

Regina M. Seaner, University of Virginia Health System in Charlottesville, VA

Vicki B. Richardson, University of Kentucky, Lexington, Kentucky

Sheilia Braun, Provincial Laboratory for Public Health, Calgary, Alberta, Canada

ASR or RUO?

Robyn McGuire, Ph.D.

Regional Quality Director, Southern California Region, American Red Cross

The FDA rule for Analyte Specific Reagents (ASRs) came into effect 8 years ago. Many laboratorians, however, are uncertain as to the differences between Research Use Only (RUO) reagents and ASRs when developing home-brew assays for clinical testing.

ASRs and RUOs have some similarities. They are usually antigens, antibodies, or nucleic acid sequences that are the active ingredients of in-house developed (home-brew) assays. It is the responsibility of the laboratory to determine the “recipes” and procedures for the assays as well as determining the performance characteristics of the assay. However, the similarities end there.

Rather than reiterate the regulations, it may be more helpful to compare some of the differences between these two types of reagents:

Comparison of ASRs and RUOs

Manufacturing Requirements	ASR	RUO
FDA Regulations	21 CFR part 809	None
Manufacturers	Must be FDA registered facilities	Not applicable
Manufacturing Requirements	Subject to Quality Systems Regulations and current Good Manufacturing Practices	None
Standard Operating Procedures for manufacturing process	Required	Not required
Quality Control Standards	Required	Not required
Lot-to-lot Variability	Minimal	May be highly variable
Sales	Restricted to in vitro diagnostic manufacturers, clinical laboratories qualified to perform high complexity testing as defined by CLIA, VA clinical laboratories regulated by the VHA Directive, and organizations that use the reagents to make tests for other than diagnostic purposes.	No restrictions, usually research laboratories
Intended Use	Active ingredient in home-brew assays for patient testing and diagnosis	Various, often for assays run a few times

Manufacturers of ASRs must be FDA-registered facilities and treat the manufacture of ASRs as they would any clinical test with standard procedures and established quality control standards. These requirements ensure lot-to-lot consistency, which is critical for the clinical laboratory. No such requirements exist for RUOs and lot-to-lot variability can be great. While many RUOs are made by FDA-registered companies, the companies may or may not follow the same processes as they do for production of ASRs.

The clinical laboratory also has some restrictions when developing home-brew assays from ASRs and RUOs:

Lab Requirements	ASR	RUO
Assay Development	Must have written recipes and procedures; these are reviewed by clinical regulatory bodies e.g. CAP, CLIA etc.	No oversight
Performance Characteristics	Must be determined by clinical laboratory based on CLSI and CAP requirements	None required
Clinical Utility	Depends on performance characteristics determined by facility	None
Labeling of Test Results	Must include: This test was developed and its performance characteristics determined by (Lab name). It has not been cleared or approved by the Food and Drug Administration.	Not applicable; tests are not reported beyond the research study
Reimbursement by Health Insurers	Eligible	Not eligible
Reporting Requirements	Manufacturers and healthcare facilities must report deaths and serious injuries to FDA	Not applicable

In summary, only ASRs can be used in clinical applications while research applications can employ both RUOs and ASRs.

On September 7, 2006, the FDA has issued a document entitled "Draft Guidance for Industry and FDA Staff - Commercially Distributed Analyte Specific Reagents (ASRs): Frequently Asked Questions". Comments concerning this important guideline can be submitted in writing to: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Alternatively, electronic comments may be submitted to <http://www.fda.gov/dockets/ecomments>. All comments should be identified with the docket number 2006D-0336. Comments will be accepted through December 2006.

Report on the 22nd Annual Clinical Virology Symposium and PASCV Annual Business Meeting

Attendance - The 23rd Annual Clinical Virology Symposium was held in Clearwater Beach Florida from April 30-May 3, 2006. There were 890 registrants 231 abstracts and 63 commercial exhibitors. The Molecular Virology Workshop, organized by PASCV, was held April 28-29 at the same venue. There were 336 participants.

Awards – Dr. C. J. Peters was the recipient of the 2006 Clinical Virology Award, sponsored by Becton Dickinson. Dr. Robert Lanciotti was the recipient of the 2006 Diagnostic Virology Award, sponsored by Bion Enterprises. Dr. James Dunn received the Young Investigator Award which was sponsored by Remel, Inc. Profiles of these distinguished scientists can be found on pages 3-5 of this Newsletter.

PASCV BUSINESS MEETING

The Annual Business Meeting of PASCV was held April 30th, 2006.

Travel Awards. Three travel awards were presented in the amount of \$1000; two were sponsored by Diagnostic Hybrids, Inc. in memory of Dr. Edwin Lennette, and in honor of Dr. Edith Hsiung. The third award of \$1000, sponsored by the CVS, was presented in memory of Dr. Mario Escobar to a recipient from Latin America. Seven additional travel awards for \$700, sponsored by PASCV, were also presented. Travel award recipients are listed on page 6 of this Newsletter.

Secretary-Treasurer's Report. Dr. Danny Wiedbrauk presented the Secretary-Treasurer's report. The PASCV balance as of December 31, 2005 was \$53,913. Most of the Society's income was generated from membership dues and the Molecular Virology Workshop. There are 433 members from 27 countries. Annual membership dues of \$25 are now due on January 1 of each year. PASCV membership entitles members to a \$50

discount on the MVW registration fee and a discounted subscription to the Journal of Clinical Virology.

Election of Officers. Dr. Jim Mahony, PASCV President, announced the election of new officers. President-Elect is Dr. Danny Wiedbrauk, and the new councilors are Dr. Marcela Echavarría, Dr. Kirsten St. George, and Dr. Alexandra Valsamakis.

Journal of Clinical Virology. PASCV members receive a discounted subscription to JCV for \$83. Members may subscribe to JCV by the following methods:

Online:

<http://intl.elsevierhealth.com/journals/jocv/subscribe.cfm>

By Email: usics@elsevier.com

By Phone: 800-654-2452

By Fax: 407-363-9661

By Post: Customer Services Department
6277 Sea Harbor Drive
Orlando, FL 32877-4800
USA

Website and Listserver. Dr. Dave Myerson gave an update on website activities. PASCV has employed MotherMedia to periodically update our website www.virology.org. A new feature on the website is a set of viral CPE images from a CDC slide set used with permission of the National Laboratory Training Network.

The PASCV listserver currently has 270 individuals on it. Any problems should be directed to dmyerson@fhcrc.org.

PASCV Officers and Council Members 2006-2008

President:

Ella Swierkosz, Ph.D. (08)
Department of Pathology
St. Louis University School of Medicine
1465 S Grand Boulevard
St. Louis, MO 63104
Phone: (314) 577-8383
Fax: (314) 268-5645
Email: swierkem@slu.edu

President Elect:

Danny L. Wiedbrauk, Ph.D. (08)
Warde Medical Laboratory
300 W. Textile Rd.
Ann Arbor, Michigan 48108
Phone (734) 214-0339
Fax: (734) 214-0399
Email: dwiedbrauk@wardelab.com

Past-President

James Mahony, Ph.D. (06)
Regional Virology and Chlamydiology Laboratory
St. Joseph's Hospital
50 Charlton Avenue East
Hamilton, Ontario Canada, L8N 4A6
Phone: (905) 521-6021
Fax: (905) 521-6083
Email: mahonyj@mcmaster.ca

Secretary/Treasurer:

Danny L. Wiedbrauk, Ph.D. (08)
Warde Medical Laboratory
300 W. Textile Rd.
Ann Arbor, Michigan 48108
Phone (734) 214-0339
Fax: (734) 214-0399
Email: dwiedbrauk@wardelab.com

Newsletter Editor:

Sheryl L. Johnston, M.S., RM(AAM) (10)
2856 Sleepy Hollow Dr.
Green Bay, WI 54311
Phone: (920) 465-0338
Email: PLANTSIT@aol.com

Latin American Correspondent:

Marcela Ferres, M.D., MPH (08)
Diagnostic Virology Laboratory
P. Universidad Catolica de Chile
Marcoleta 391, Santiago, Chile
Tel: 56 2 354 6824
Fax: 56 2 638 7457
Email: mferres@med.puc.cl

Councilors:

Max Q. Arens, Ph.D. (08)
Department of Pediatrics
Washington University School of Medicine
One Children's Place
St. Louis, MO 63110
Phone: (314) 454-8035
Fax: (314) 454-8020
Email: arens@wustl.edu

Marcela Echavarria, Ph.D. (10)

Clinical Virology Laboratory
CEMIC University Hospital
2258 Pena 6-19
Buenos Aires 1126, Argentina
Phone: 011-5411-4546-8228
Fax: 011-5411-4541-3790
Email: mechavarria@cemc.edu.ar

Christine C. Ginocchio, Ph.D. (08)

North Shore-LIJ Health System Labs
10 Nevada Drive
Lake Success, NY 11042
Phone: (516) 719-1079
Fax: (516) 719-1254
Email: cginocch@nshs.edu

Jeanne Jordan, Ph.D. (08)

Magee-Women's Research Institute
204 Craft Avenue
Pittsburgh, PA 15213
Phone : (412) 641-4104
Fax: (412) 641-6156 Fax
Email: rsijai@mwri.magee.edu

Kirsten St. George, Ph.D. (10)

Griffin Laboratory, Wadsworth Center
5668 State Farm Road (Route 155)
Slingerlands, NY 12159
Phone: (518) 869 4520
Fax: (518) 869 6487
Email: kxs16@health.state.ny.us

Alexandra Valsamakis, M.D., Ph.D. (10)

Department of Pathology
Johns Hopkins University School of Medicine
Meyer B1-193
600 N. Wolfe St.
Baltimore, MD 21287
Phone: (410) 955-5077
Fax: (410) 614-8087
Email: avalsam1@jhmi.edu

President, European Society for Clinical Virology (www.escv.org)

Professor Annika Linde, MD.
Swedish Institute for Infectious Disease Control
Department of Virology
SE-17182 Solna
Sweden
phone: +46-8-457 2652
fax: +46-8-337 272
e-mail: annika.linde@smi.ki.se

<p>Website and Listserv David Myerson, M.D., Ph.D. Fred Hutchinson Cancer Center 1100 Fairview Ave. N-D2-190 Seattle, WA 98109 Phone: (206) 667-4600 Fax: (206) 667-6519 E-mail: dmyerson@fhcrc.org</p>	<p>Clinical Virology Symposium Steven Specter, Ph.D. Univ. of South Florida College of Medicine BB Downs Blvd. Box 10 Tampa, FL 33612-4799 Phone: (813) 974-0897 Fax: (813) 974-4151 E-mail: sspecter@hsc.usf.edu</p>
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Future Virology Meetings

Clinical Virology

23rd Clinical Virology Symposium
April 29-May 2, 2007 in Clearwater Beach, FL.

Molecular Virology

2007 Molecular Virology Workshop
April 27 and 28, 2007 in Clearwater Beach, FL.

Other Virology Meetings:

European Society for Clinical Virology (ESCV) Meeting on Respiratory Viruses
May 24 and 25, 2007 in Lyon, France

Third European Congress of Virology
September 1-5, 2007 in Nurnberg, Germany
(The conference will also be the Annual Meeting of both the ESCV and the German/Swiss/Austrian Society for Virology.)

South American Clinical Virology Symposium
November 7 and 8, 2007 in Chile
Contact Dr. Marcela Ferres for further details (mferres@med.puc.cl)

11th Annual European Society for Clinical Virology (ESCV) Meeting
March 12-15, 2008 in Saariselka, Lapland, Finland



Pan American Society for Clinical Virology Membership Form

Please type or print all information

Member's Name _____ Degree: _____

Organization or Hospital Affiliation:

Mailing Address: _____

Telephone: _____ Fax: _____

E-mail: _____

PLEASE CHECK ONE

Renewal of Membership _____ \$25 New Member (\$25) _____

Members from U.S. and Canada:

Please make checks (U.S. dollars only) payable to PASCV.

Members outside of the U.S. and Canada:

PASCV can now accept VISA and MasterCard. Please include your card number, expiration date, and signature.

VISA/MasterCard number: _____ Expiration date: _____

Signature: _____

Return completed form with check or credit card information to:

Danny L. Wiedbrauk, Ph.D.
Secretary-Treasurer - PASCV
Warde Medical Laboratory
300 W. Textile Rd.
Ann Arbor, Michigan 48108

Phone (734) 214-0339
Fax: (734) 214-0399
Email: dwiedbrauk@wardelab.com

Scenes from the 2006
Clinical Virology
Symposium

