news along the pike

JUNE 2001

CENTER FOR DRUG EVALUATION AND RESEARCH

VOLUME 7, ISSUE 5

INSIDE . . .

PIKE'S CORNERS

Total of 61 Individuals, 39 Groups Recognized

Center, Agency, Department Hold Honor Awards Ceremonies

BY JACKIE BARBER

A total of 61 individuals and 39 groups from the Center received honors at ceremonies held by CDER, FDA and the Department in May and June. At the Center's Spring Honor Awards ceremony May 18 in Gaithersburg, 53 individual and 29 group awards were presented. At the FDA ceremony May 4 in Rockville (page 7), six Center employees and seven groups with CDER representatives were recognized. The HHS Secretary's Distinguished Service Award (page 7) was presented June 15 to two CDER employees and three groups with Center participants.

At CDER's ceremony, Center Director **Janet Woodcock, M.D.,** and Deputy Center Director **Steven Galson, M.D.,** along with senior management presented the awards. The Montgomery County Police Color Guard presented the colors, and Kevin Barber sang the national anthem. **Ruth Clements,** introduced each award and office directors provided an explanation of individual and team achievements. Those recognized at the ceremony were:

FDA Outstanding Service Award

A. Joel Aronson

Kevin M. Budich

Marc Cavaille-Coll, M.D.

Edward Cox, M.D., MPH

Maureen P. Dillon-Parker

Brenda L. Holmes

John P. Hunt

Claudia B. Karwoski, Pharm.D.

(Continued on page 5)

Center Lab Shares Patent for Anti-Tumor Drug

BY JERRY M. COLLINS, PH.D.

The Patent Office recently issued a patent for an anti-cancer drug based on work by **Neil Hartman, Ph.D., John Strong, Ph.D.,** and me in the Laboratory of Clinical Pharmacology, Office of Testing and Research. As part of a research program on metabolism-based drug-drug interactions, we evaluated several drugs in the development pipeline at the National Cancer Institute.

In particular, NCI had a highly neurotoxic drug, penclomedine, for which we found a prominent metabolite, demethylpenclomedine. NCI contractors tested the metabolite and found it has anti-tumor activity without the neurotoxicity of the parent molecule.

There's a strong parallel to the story of the antihistamine terfenadine and its metabolite, fexofenadine, in which the metabolite provides nearly all the beneficial effects of the parent without potentially fatal drug-drug interactions (Pike, January 1997).

Under Federal patent and licensing regula-

(Continued on page 10)

AERS Makes Finals in Information Technology Awards

BY PATRICK E. CLARKE

A weekly newspaper that covers the information technology industry picked the Adverse Event Reporting System as a finalist for its 2001 Computerworld Achievement Awards in the government and non-profit category.

Computerworld lauded AERS as one of the best examples of information technology being used to benefit society during a formal awards ceremony June 4 at the National Building Museum (see photo at http://www.fda.gov/cder/pike/june2001.htm#AERSphoto).

AERS is a state-of-the-art system that combines the voluntary adverse drug reaction reports from MedWatch and the required reports from manufacturers. AERS offers paper and electronic submission options, international compatibility and pharmacovigilance screening.

Melissa Chapman, deputy director for

(Continued on page 5)

JOE'S NOTEBOOK

It's Pronounced 'Pree-on,' Not 'Pry-on'

A tip of my hat goes to the Committee for Advanced Scientific Education and its executive secretary **Karen Zawalick.** They arranged for a special seminar by the 1997 winner of the Nobel Prize in physiology or medicine, Stanley Prusiner, M.D., from the Institute of Neurodegenerative Diseases at the University of California, San Francisco (page 9).

It required patient negotiations among Dr. Prusiner's office, the National Institutes of Health where he was attending a meeting, the Center for Biologics Evaluation and Research where he is a special government employee and various levels of CDER.

I've been fascinated by prion diseases ever since I discovered they were responsible for my first job in HHS at the National Institute for Neurological Disorders and Stroke, and now I know how to pronounce prion. At NINDS, part of my job was to talk to family members of people who had neurodegenerative conditions, some of which were related to prions, or "slow viruses" as we called them. It was encouraging to hear of research that may lead to ways to block the abnormal folding of proteins and that cells may be able to clear out the abnormal proteins.

So how did an ex-soldier journalist who couldn't even pronounce prion land a job writing and talking about neurology? In 1987, my editor at the Army's monthly magazine sent me off to the Armed Forces Institute of Pathology do write a story that was embarrassingly titled "A Pathological Lair." That institute traces its history to the Army Medical Museum, begun during the Civil War when soldiers would ship back their amputated limbs in whiskey casks to help train prospective battlefield surgeons.

While I was being shown the institute's Yakolev collection of about 2,000 human brains, I met another visitor, Barbara Potts, Ph.D., a research pathologist. At that time, she was working in the NINDS lab headed by D. Carlton Gajdusek, M.D., and Joe Gibbs, Ph.D. (1925-2001). Dr. Gajdusek shared the Nobel Prize in 1976 for research he conducted with Dr. Gibbs proving that kuru, a neurodegenerative disease among Fore tribe in New Guinea, was caused by an infectious agent rather than heredity.

Dr. Potts had found the proverbial needle in a haystack. I could tell from the gleam in her eye, the bounce in her step and the excitement in her voice that the jar she held in her hand contained something special. White tape sealed the lid. Inside, a thumb-sized roll of gauze floated in clear liquid. Barely visible through the alcohol and gauze were ivory-colored disks, each about the size of a quarter.

Those disks were wafer-thin slices from the brain of a mentally retarded infant who died shortly after birth in 1964. Dr. Potts was investigating a "virus related to scrapie in sheep" that might cause mental retardation in humans. To do this, she went to two large collections, both of which were more than 40 years old at the time of my story. One was the Yakolev collection and the other was a NINDS study of 55,000 abnormal births.

From the study of birth defects, she found a mother who had died of the requisite neurodegenerative disease. Fortuitously, the Yakolev collection had happened to have preserved the brain of her infant.

Potts described how the virus she was studying doesn't cause the classic signs of infection—fever, inflammation, changes in white blood cells or antibody response. Then she was handed a slide AFIP had made from the infant's brain. She had barely looked at the slide when her finger darted to a telltale node, smaller than normal. She didn't hang around to continue her discussion but hurried back to her lab to apply special stains to the samples.

As you may have guessed by now, Dr. Potts and the women who eventually hired me were close friends, and her story was part of my job application.

news along the pike

The Pike is published electronically on the X:drive in Cdernews and on the World Wide Web at:

http://www.fda.gov/cder/pike.htm

Photocopies are available in the Medical Library (Parklawn Room 11B-40) and its branches (Corporate Boulevard Room S-121 and Woodmont II Room 3001).

Views and opinions expressed are those of the authors and do not necessarily reflect official FDA or CDER policies. All material in the Pike is in the public domain and may be freely copied or printed.

Have ideas, news or comments to contribute?
Please contact a member of the Editorial Board or:

NEWS ALONG THE PIKE
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OMBUDSMAN'S CORNER

An Opportunity for the Taking

BY JIM MORRISON

Too often people regard training as something external that is done to them. Training and development, if they mean anything, come from within. Courses and programs facilitate the process, but learning and development occur within us.

Sometimes we feel so pressed by daily work that we let training and development opportunities go by. I'm not talking about training courses, necessarily, but also about opportunities to learn in our jobs by taking the extra time to research questions that arise. One of the benefits and joys of working at FDA is the opportunity to be exposed to a steady flow of new information and new experiences.

Some of us are contented with our current positions and some are searching for a new path to advancement or fulfillment. Either way, development must be a constant in our daily routine. We all need to grow, and growth comes from new challenges.

Sometimes we need a complete break to reassess the direction we want to grow in. If you find yourself in that situation, or even if you just like the idea of an intensive growth path within FDA, I highly recommend an Agency program, the Leadership Development Program. The opportunity to apply for the program comes only once every two years, and that time is now.

On June 1, an e-mail was sent to everyone announcing that applications will be accepted for the FDA Leadership Development Program through July 27. The LDP entails training and developmental assignments, generally consuming 12 months, to be completed within an 18-month span. While participants keep their current jobs, they spend only about a third of the time actually in their offices.

Participants' developmental plans are tailored to their individual needs and goals. They generally complete four developmental details of 30 to 90 days' duration each during the program. Most of these details are outside their home organization or center. A wide range of training courses is also available.

> "Applications will be accepted for the FDA Leadership Development Program through July 27"

All headquarters-based participants serve at least one detail in an FDA field office, and field participants come to headquarters for one assignment. However, those are minimum requirements, and it is not unusual for a participant to take a developmental assignment overseas.

The LDP is highly competitive, with only 15 slots available every two years from throughout the Agency. It is open to all permanent FDA employees in grades GS/GM 12, 13 or 14 and Commission Corps O-4 and O-5. It is paid for and coordinated by the FDA's training division and is guided by an Agencywide committee, soon to be chaired by **Dan Casciano** from the National Center for Toxicology Research. The committee has representatives from each center and Office of Regional Affairs, plus EEO and other Commissioner-level components. This committee interviews the candidates and makes the selections.

Graduates of the program are enthusiastic supporters and are glad to talk about their experiences. Before applying to any developmental program, it is wise to talk with some graduates to get a first-hand view of how it helped them, what they liked most and least about the experience and to find out if it is right for you. I have been the CDER representative on the committee for more than a decade, and I am always happy to advise CDER applicants on the process.

There was a joint CDER/CDRH forum on June 28. If you couldn't attend, just ask me for more information, and I'll be glad to talk with you about the program (MORRISONJ, 4-5443).

Applying to the program is in itself a valuable learning experience, because it makes you think about your career goals and how you plan to attain them. If you don't apply now, you'll have to wait until 2003.

Jim Morrison is the Center's ombudsman.

PIKE'S PUZZLER

Number, Please

BY TONY CHITE

1. An age range commonly used in medicine to define "infant" is:

a. 0-24 months
b. 0-30 days
c. 1-36 months
d. 1-24 months

2. The blood value (measured in mg/dL) for cholesterol that puts you at high risk is a reading that is greater than:

a. 24 b. 240 c. 160 d. 320

3. The normal range for carbon dioxide gas in arterial blood at sea level (P_{CO_2} measured in mmHg) is:

a. 10-20
b. 75-85
c. 35-45
d. 120-130

4. For converting Celsius temperatures to Fahrenheit temperatures, you should:

a. multiply Celsius by 9, divide by 5 and add 32.
b. subtract 32 from Celsius, multiply by 5 and divide by 9.
c. multiply Celsius by 5, divide by 9 and add 32.
d. add 32 to Celsius.

5. One-half grain in apothecary weight is most equivalent to which metric weight:

a. 120 mg
b. 60 mg
c. 30 mg
d. 15 mg

Answer key: 1d; 2b; 3c; 4a; 5c

Tony Chite is a pharmacist and CSO in Division of Information Disclosure Policy.

Audits to Address Center's Information Security Issues

Ensuring information security within the Center has always been a top priority due to the nature of our work. CDER handles non-public and proprietary information for which there is a potentially damaging impact resulting from its loss, misuse or unintentional disclosure.

We have always maintained a high level of security, sustainable because most of our work was paper-based. As we transition into the electronic world of documents, data and reviews, new and sometimes unanticipated security threats must be addressed.

A variety of oversight groups are weighing in on security. They are providing oversight, guidance, restrictions and new procedures to ensure integrity of our systems. Some of these include Presidential Decision Directive 63, Amended OMB Circular A-130 (Management of Federal Information Resources), the Security Act of 1987 and the Government Information Security Reform Act.

To meet these various requirements, the Agency has developed a series of staff manual guides (28 documents). These became effective June 1 and will be available soon via the OIT intranet site (http://oitweb) by clicking on Security and then Staff Manual Guides. The guides cover many areas of security but offer only general guidance. We will post a summary of important points from these guides for you.

Both the Center and the HHS Office of the Inspector General will audit our information technology systems to ensure adherence to these guides. This will include security "testing," including penetration testing conducted on our applications, networks and possibly our accounts. Potentially, these audits could happen to anyone at anytime without notice. The auditing process is necessary to ensure the security of our environment and is a major change in our security practices.

You should develop a good understanding of the security requirements necessitated by our move to electronic systems. If you have any questions, please contact **Dave Moss** (MOSS), the Center's information systems security officer.

July IT Training

Monday	Tuesday	Wednesday	Thursday	Friday
9	10 **MS Outlook (Reserved) (P)** 9:00-12:00 **MS Outlook (Reserved) (P)** 9:00-12:00	11 **MS Outlook (Reserved) (P)** 9:00-12:00 **MS Outlook (Reserved) (P)** 9:00-12:00	12 **MS Outlook (Reserved) (P)** 9:00-12:00 **MS Outlook (Reserved) (P)** 9:00-12:00	13 **MS Outlook (Reserved) (P)** 9:00-12:00 **MS Outlook (Reserved) (P)** 9:00-12:00
16 **MS Outlook (Reserved) (P)** 9:00-12:00 **MS Outlook (Reserved) (P)** 9:00-12:00	17 **New Employee Orientation—TL Day (C)** **9:00 – 4:00** **MS Outlook (Reserved) (P)** 9:00-12:00 **MS Outlook (Reserved) (P)** 9:00-12:00	18 **New Employee Orientation (C)** **9:00 – 4:00**	19 **DFS (C)** 9:00-12:00	20 **MS Outlook (Reserved) (P)** 9:00-12:00 **MS Outlook (Reserved) (P)** 9:00-12:00
23 **MS Outlook (Reserved) (P)** 9:00-12:00 **MS Outlook (Reserved) (P)** 9:00-12:00	24	25 **Word Intro (C)** 9:00-12:00	26 **Word Formatting (C)** 9:00-12:00	27
30 **PowerPoint Intro (C)** 9:00-12:00 **PowerPoint Charts (C)** 9:00-12:00	31 **NDA Electronic Submissions (P)** 9:00-12:00 **NDA Electronic Data (P)** 9:00-12:00	Key: Corporate Boulevard (C), Park Building (P) The catalog, training materials, schedule and on-line registration can be found at http://oitweb/.		

Draft Records Management Criteria

The Defense Department is circulating for public comment an updated draft of its design criteria standards for electronic records management software applications. This document, known as DOD 5015.2-STD, has been used by the department's Joint Interoperability Test Command to test and certify 25 commercial off-the-shelf records management applications as compliant for defense uses.

Many non-defense organizations use the certification list to review, test and select records management applications for their operations. A list of those products, the reports of the tests, along with the revised draft and comment forms, can be found at http://jitc.fhu.disa.mil/recmgt/.

To learn more about the draft criteria or CDER's records and information management policies, contact **Scott Zeiss** (ZEISSS)

Help Desk FAQ

Q: Why do I have to change my network password every 90 days?

A: OIT has implemented several security features designed to protect your network account from compromise. The most recent change involves changing your network password every 90 days.

This is important, because a hacker can access the FDA/CDER system with a username and password.

There are several possible scenarios for someone get your password:

- If you travel and use a laptop, someone could see you type in your password.
- Someone could call you and say her or she is with the Help Desk or are an auditor and needs your password.

The Help Desk will never ask for your password. Never give your password to anyone.

Here are some tips for creating passwords:

- Your password must be eight characters or more
- Don't use words such as a family member's name or a pet's name.
- Don't use the same password for all your access.

Information on how to change passwords you currently use to access corporate systems, please review Passwords in CDER at http://oitweb/Security/default.htm. Contact the Help Desk for more information.

AERS Makes Finals in Computerworld's Honors Program

(Continued from page 1)

program guidance of the Office of Information Technology, and the technical advisor for AERS, was chosen to represent OIT at the event. She had previously received a Commemorative Laureate Medallion at a ceremony held in San Francisco, when all the nominated programs were honored. The medallion is meant to symbolize the never-ending search for innovation, dedication, talent and achievement worthy of special recognition.

"It's great recognition for CDER's IT program for us to be chosen as one of the Computerworld laureates," Chapman said. "Much of the work we've done on AERS reflects OIT's move toward a best-practice approach in quality development. It's also great recognition for the progressive approach that the Office of Post-Marketing Risk Assessment is taking in doing post-marketing surveillance."

The AERS system, which supports both the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research, has been a work in progress since the mid-1990s.

It is the first system worldwide to implement international adverse reaction reporting standards created under the auspices of the International Conference on Harmonization. AERS was also the first system to utilize the Medical Dictionary for Regulatory Activities, the international medical terminology for medical event coding.

"It's a humbling, yet very validating experience to have one of our programs included in such a prestigious, innovative group," said OIT Director **Ralph Lillie**. He also noted other significant facts about AERS that helped the program to stand out.

AERS is the foundation the Agency will use to develop the standard for adverse event reporting for other types of products, such as nutritional supplements. The success of AERS has generated international interest, as countries from Canada to Singapore have used the AERS program as a benchmark for changing or refining their adverse event reporting systems.

"I'm really proud that we made the finals," said Center Director **Janet Woodcock, M.D.** "The ceremony was very inspiring. This honor is a landmark for CDER."

From it's small beginnings, AERS now has the capacity for the rapid capture and analysis of up to 350,000 reports of adverse drug reactions each year.

Booz, Allen & Hamilton Inc., a management and technology consulting firm, was the primary contractor for the program and nominated AERS for consideration in the competition.

"The Computerworld award, in particular, is about how information is changing technology and the world," said Heather Burns, a senior vice-president at the company, who helped make the decision to nominate the AERS program. "I believe the use of AERS has had a direct and immediate impact on public health and I'm very proud of the program."

Burns added that for her one of the best parts of the assignment was working with FDA. "The FDA staff really take their mission seriously, and it was terrific to be involved with such a worthwhile project and such great people," she said.

The firm's Susan Penfield, who managed the FDA contract said that most significant aspect of the program was the partnerships that developed. "It took FDA senior management, the safety evaluator user community, the data entry contractor and our software development domain knowledge to make the program a success," Penfield said.

Established in 1988, the Computerworld Honors Program is dedicated to identifying the men and women, organizations and institutions that are leading the IT revolution and to recording their impact on society.

Patrick Clarke is a public affairs specialist in OTCOM.

CDER Ceremony Recognizes 53 Individuals, 29 Groups

(Continued from page 1)

Ameeta Parekh, Ph.D.

Kellie Schoolar Reynolds, Pharm.D.

Barry A. Rosenzweig

Karol L. Thompson, Ph.D.

Douglas C. Throckmorton, M.D.

Case Management and Guidance Branch: **Shelia M. Banks, Frederick W. Blumenschein, Monica E. Caphart, Albinus M. D'Sa, Rick L. Friedman, Brian J. Hasselbalch, Paul W. Haynie, Luann M. Pallas, Barry Rothman, Duane S. Sylvia** and **Brenda W. Uratani.**

DMS Ceremony Assistants: **Jacquelyn A. Barber, James H. Cockran, William B. Gazdik, Patricia L. Gathers, Vance Gibson, Angela N. Harris, Jamey W. Henneberger, Shelley M. Johnson, Lynda M. Papio, Anna M. Rubino, Cassandra L. Shippey, Craig D. Thomas, Rita J. Thompson** and **Tessa C. Williams.**

Export Certificate Team: **Robin Carroll, James E. Hamilton, Brenda L. Holmes, Betty L. Jones, Jocelyn V. Lewis, Roxana L. Newquist, Mary L. Sejas , Vesna Stanoyevitch, Marlene Sue-Ling, Melvin F. Szymanski** and **Donald F. Wisner.**

FDA Group Recognition Award

Accutane Advisory Committee Group: **Julie Beitz, M.D., Allen Brinker, M.D., MPH, David Graham, M.D., Patrick F. Guinn, Claudia B. Karwoski, Pharm. D., Indira Kumar, Zili Li, M.D., MPH, Kathryn A. O'Connell, M.D., MPH, Lana L. Pauls, Marilyn Pitts, Pharm.D., Lynette Swartz, Erick Turner, M.D., Amarilys Vega, M.D., MPH, Maryjane Walling,** and **Diane Wysowski, Ph.D.** PHS Unit Commendation: **CDR Edward D. Bashaw, CAPT Mary Jean Kozma-Fornaro, CAPT Joslyn Swann** and **CDR Anne E. Trontell.**

BACPAC I—Intermediates in Drug Substances Synthesis Working Group: **Dennis Bensley, Ph.D., Eric P. Duffy, Ph.D., Robbe C. Lyon, Ph.D., Stephen Miller, Ph.D., Nashed E. Nashed, Ph.D., David Newkirk, Ph.D., Mary C. Norris, Hasmukh B. Patel, Ph.D., Edwin Riveria Martinez, John L. Smith, Ph.D., Kasturi Srinivasachar, Ph.D.**

FDA Medical Library Instructional Ser-

(Continued on page 6)

CDER Ceremony Recognizes 53 Individuals, 29 Groups

(Continued from page 5)

vices Team: **Nancy L. Muir, Maddy D. Carolan, Wendy W. Cheng, Nichelle Cherry, Lois G. Chester, Gail Chotoff, Karen M. Kapust, Kathy W. Kruse, Kathrin L. McConnell** and **Sally Winthrop.**

FDA Q-6A Internal Working Group: **Doris J. Bates, Raymond L. Brown, Peter H. Cooney, Ph.D., Albinus M. D'Sa, Ph.D., Eric P. Duffy, Ph.D., Rick L. Friedman, Devinder S. Gill, Ph.D., Ajaz S. Hussain, Ph.D., Henry J. Malinowski, Ph.D., Linda L. Ng, Ph.D., Larry A. Ouderkirk, Hasmukh B. Patel, Ph.D., Rashmikant M. Patel, Ph.D., Eric B. Sheinin, Ph.D., Andrew Shrake, Kasturi Srinivasachar, Ph.D.,** and **Neal J. Sweeney, Ph.D.**

Pediatric Inpatient Database Development Team: **Katrina S. Garry, Victoria Kao, Cynthia D. Kornegay, Carolyn A. McCloskey, M.D., Rosemary Roberts, M.D.,** and **Judy A. Staffa, Ph.D.** PHS Unit Commendation: **CDR Terrie L. Crescenzi.**

PK/PD Alternate Dosing Regimen Working Group: **Melisse S. Baylor, M.D., Therese A. Cvetkovich, M.D., Russell D. Fleischer, P.A., MPH, Heidi M. Jolson, M.D., MPH, Stanka Kukich, M.D., Linda L. Lewis, M.D., Jeffrey S. Murray, M.D., MPH,** and **Kellie Schoolar Reynolds, Pharm.D.** PHS Unit Commedation: **LCDR Kimberly C.,** and **Struble, CAPT Teresa C. Wu.**

Post-Marketing Drug Risk Assessment Competency Working Group: **Min Chen, M.S., R.Ph., David J. Graham, M.D., MPH, Lanh Green, R.Ph., MPH, Toni Piazza-Hepp, Pharm.D., Judy A. Staffa, Ph.D., RPh., Diane K. Wysowski, Ph.D.** PHS Unit Commendation: **CDR Anne E. Trontell.**

Sterile Manufacturing of Aqueous Inhalation Drug Products Team: **Peter H. Cooney, Ph.D., Carol E. Drew, John R. Lienesch, James L. McVey, Ph.D., Robert J. Meyer, M.D.,** and **Guiragos K. Poochikian, Ph.D.** PHS Unit Commendation: **CAPT David Hussong** and **CDR Sharon McCoy.**

FDA Quality Of Work Life Award

Patrick W. David

PHS Commendation Medals

CAPT Michael F. Johnston

CAPT Cathie L. Schumaker

CAPT George R. Scott

LCDR Kimberly A. Struble

PHS Unit Commendation

Pharmacy Professional Advisory Committee FDA Pharmacy Applicant Placement Workgroup: **LT Greg S. Davis, CDR Lillie D. Golson, LT Nasser Mahmud, CDR Denise P. Toyer** and **CAPT Valerie A. Vashio.**

CDER Special Recognition Award

Abimbola O. Adebowale, Ph.D.

Dhruba J. Chatterjee, Ph.D.

Barbara M. Davit, Ph.D.

Yung-Ao Hsieh, Ph.D.

Sung K. Kim, Ph.D.

Carol L. Krueger

Ijeoma N. Nnamani, Ph.D.

Juan Carlos Pelayo, M.D.

Rajeshwari Sridhara, Ph.D.

Maria Sunzel, Ph.D.

Kevin A. Swiss, Ph.D.

Clinical Microbiology Review Team: **Sousan S. Altaie, Ph.D., Frederick Marsik, Ph.D., Harold Silver, Albert T. Sheldon, Jr., Ph.D., Joel Unowsky, Ph.D.,** and **Holli Hamilton, M.D., MPH.**

Staff of the Division of Drug Information: **Mary F. Cooper, Barbara J. Daciek, Harold Davis, Donald Dobbs, Gelind H. Grable, Peter E. Khalaf, Brenda J. Kiliany, Mary E. Kremzner, Larry P. Lim, Joan K. Powers, Brenda J. Stodart** and **Diana Tyler.**

Center Director's Special Citation

Maryann Gordon, M.D.

John E. Koerner, Ph.D.

Division of Neuropharmacologic Drug Products: **Aisar H. Atrakchi, Ph.D., Eric P. Bastings, Doris J. Bates, Gerry A. Boehm, M.D., Ada L. Bowie, Karen L. Brugge, Lisa Champion, Barbara J. Durst, Edward J. Fisher, Ph.D., Linda H. Fossom, Lois M. Freed, Ph.D., Roberta L. Glass, M.D., Tarek Hammad, M.D., Ph.D., Robert D. Harris, M.D., David B. Hawver, Earl D. Hearst, M.D., Norman Hershkowitz, M.D., Anna Marie Homonnay, Leonard P. Kapcala, M.D., Russell G. Katz, M.D., Jim F. Knudsen, M.D., Thomas P. Laughren, M.D., Randy Levin, M.D., Ranjit B. Mani, M.D., Andy D. Mosholder, M.D., Andrea M. Powell, Ph.D., Jack S. Purvis, Judith Racoosin, M.D., Paul L. Roney, Barry N. Rosloff, Ph.D., Janeth Rouzer, M.D., Michael J. Sevka, M.D., Kathy J. Smith, Andrew Sostek, Ph.D., Gerald F. Tremblay, M.D.,** and **Erick H. Turner.** PHS Unit Commendation: **CDR Paul J. Andreason, CDR Lana Y. Chen, CAPT Gregory M. Dubitsky, CDR Melina N. Fanari, CAPT John J. Feeney III, CAPT Steve D. Hardemann, CAPT Mille J. Merril, CAPT Robin M. Nighswander, CDR Armando Oliva, LT Kevin A. Prohaska , CAPT Philip H. Sheridan, LT Melaine Shin, LCDR Jacqueline H. Ware** and **CDR Teresa Wheelous.**

Manufacturing Inspection Program Work Group: **Frederick W. Blumenschein, Nicholas Buhay, Joseph C. Famulare** and **Erik N. Henrikson.**

OPDRA Process Improvement Group: **Melissa L. Bates, Mary J. Dempsey, Patrick F. Guinn, Claudia B. Karwoski, Pharm.D., Lois A. LaGrenade** and **Mary E. Willy.** PHS Unit Commendation: **CDR Carol A. Holquist, CDR Denise P. Toyer** and **CDR Anne E. Trontell.**

CDER Administrative Program Management Excellence Award

Tammy S. Russell

Loretta J. Saey

Judith Gayle Schupp

CDER Excellence in Communication Award

Richard Pazdur, M.D.

Barbara Stryrt, M.D., MPH

CDER Faculty for the PERI Course: **Susan Flamm Honig, M.D., Alison Martin, M.D.,** and **Rajeshwari Sridhara, Ph.D.**

CDER's Videoconference Training and Communications Team: **Linda J. Emelio,**

(Continued on page 7)

8 Individuals, 10 Groups Honored at HHS, FDA Ceremonies

(Continued from page 6)

Pam Winbourne and **Amy B. Mason.**

OPDRA Communication Working Group: **Syed R. Ahmad, M.D., MPH, Janos T. Bacsanyi, M.D., Renan A. Bonnel, Pharm.D., MPH, Debbie E. Boxwell, Pharm.D., Min C. Chen, M.S., R.Ph., Mary J. Dempsey, Zili Li, M.D., MPH, Ann Mackey, R.Ph., MPH, Parivash Nourjah, Ph.D., Carol A. Pamer, R.Ph.,** and **Paul F. Reinstein.** PHS Unit Commendation: **CAPT Linda Brophy, CAPT Michael F. Johnston, CDR Denise P. Toyer** and **CDR Kathleen Uhl.**

CDER Information Technology Excellence Award

Ruth A. Warzala

Gary Gensinger

CDER Leadership Excellence Award

Karen A. Bernard, Ph.D.

Suresh Doddapaneni, Ph.D.

Kun Jin, Ph.D.

John M. Strong, Ph.D.

Margaret A. Tart

CDER Excellence in Mentoring Award

Shirley Jones

He Sun, Ph.D.

Grant Williams, M.D.

New Reviewer Course Team: **Raman K. Baweja, Ph.D., Brian P. Booth, Ph.D., Joga V. Gobburu, Ph.D., Mehul U. Mehta, Ph.D., Patrick J. Marroum, Ph.D., N.A.M. Atiqur Rahman, Ph.D., Gabriel J. Robbie, Ph.D.,** and **Chandrahas G. Sahajwalla, Ph.D.**

CDER Project Management Excellence Award

Glenna S. Caffrey

Grace N. Carmouze

Erik N. Henrikson

Internet Health Fraud Team: **Lois A. Duval** and **Roma Jeanne Egli**

CDER Support Staff Excellence Award

Linda L. Johnson

Melissa A. Lamb

Patricia J. Tuegel

Tisha L. Washington

CDER Team Excellence Award

OPS Booth Team: **Brian P. Booth, Jon E. Clark, Mei-Ling Chen, Ph.D., David Hussong, Ph.D., Mehul U. Mehta, Ph.D., William L. Myers, Shriniwas G. Nerurkar, Ph.D., Patrick E. Nwakama, Pharm.D., Hasmukh B. Patel, Ph.D., Rao Puttagunta, Ph.D., Nhan L. Tran, Ph.D.,** and **Pradeep M. Sathe, Ph.D.**

FDA Ceremony

FDA held its awards ceremony May 4 in Rockville. The following Center employees and groups were honored:

FDA Award of Merit

Heidi M. Jolson, M.D., MPH

Nancy L. Muir

Adaptive Clinical Trial Design/Analysis Development Team: **, Hsien-Ming James Hung, Ph.D., Lu Cui, Ph.D., Sue-Jane Wang, Ph.D.,** and **Yi Tsong, Ph.D.**

DDMAC Research and Review Branch: **Kathryn J. Aikin, Joan E. Hankin, Karen J. Lechter, Ph.D., Melissa M. Moncavage, Nancy M. Ostrove, Ph.D.,** and **Ellen R. Tabak.**

Therapy for HIV-Infected Treatment-Experienced Patients Working Group: **Thomas S. Hammerstrom, Ph.D., Heidi M. Jolson, M.D., MPH, Katie Laessig, M.D., Jeffrey S. Murray, M.D., MPH, Joseph Toerner, M.D.,** and **Richard Klein** (Office of the Commissioner). PHS Unit Commendation: **CAPT Harry Harvekos** and **LCDR Kimberly Struble.**

FDA Group Recognition

Clinical Pharmacology During Pregnancy Conference Planning Group: **Gail Y. Chotoff, Lesleyanne Furlong, M.D., Holli A. Hamilton, M.D., MPH, Margaret A. Miller, Ph.D., Arzu Selen, Ph.D., Wendy K. Stanfield** and **Marcia L. Trenter.** PHS Unit Commendation: **CAPT Dianne L. Kennedy, CAPT Sandra L. Kweder** and **CDR Kathleen Uhl.**

Development of Psychotropic Drugs in Young Children Working Group: **Roberta L. Glass, Kimberly Hoagwood, Ph.D.,** (National Institute of Mental Health), **Victoria Kao, Thomas P. Laughren, M.D., Andrew D. Mosholder, M.D., Dianne Murphy, M.D., Rosemary Roberts, M.D.,** and **Benedetto Vitiello, M.D.,** (National Institute of Mental Health). PHS Unit Commendation: **CDR Terrie Crescenzi.**

IND Reform-Formal Meeting Working Group: **Stephen K. Moore, Ph.D., Guiragos K. Poochikian, Ph.D., Patricia Troost Hughes, Ph.D.,** (CBER), and **William M. Ega2PT John A. Eltermann Jr.** (CBER).

Monoclonal Antibodies Working Group: **Javher V. Advani, Ph.D., Kurt A. Brorson, Ph.D.,** (CBER), **Martin T. Haber, Ph.D., Steven R. Koepke, Ph.D., James L. McVey,** (CVM), **Stephen K. Moore, Ph.D., Eugenia M. Nashed, Ph.D., Chien-hua, Niu, Ph.D., Eugene L. Schaefer, Ph.D., Brenda W. Urantani, Ph.D.,** and **Liang Zhou, Ph.D.**

St. John's Wort Public Advisory Team: **Heidi M. Jolson, M.D., MPH, Lori A. Love, M.D.,** (CFSAN), **Jeffrey S. Murray, M.D., MPH, Steve Piscitelli,** (NIH), and **Kellie Schoolar Reynolds, Pharm.D.** PHS Unit Commendation: **LCDR Kimberly Struble.**

Meritorious Service Medal

CAPT Eugene H. Herman

CAPT Frank D. Sistare

40 years' career service

Celia A. DeLawter

Frances O. Kelsey, Ph.D., M.D.

HHS Ceremony

These awards were presented to CDER employees at the HHS ceremony June 15 in Washington:

HHS Secretary's Award for Distinguished Service

Steven R. Gitterman, M.D.

Vivian Greenman (50 years of federal service)

Device Action Plan Team: **Joseph Famulare** and **Brian Nadel.**

Interagency Narcotic Treatment Policy Review Board: **, Elsworth Dory, Glen Drew, Betty Jones, Wayne Mitchell, Ron Wilson** and **Curtis Wright.**

DHHS QUIC Patient Safety Report Team: **Nancy E. Derr, Anne M. Henig, J.D., Chester G. Trybus** and **Janet Woodcock, M.D.**

Jackie Barber is CDER's incentive awards officer.

ICH Paves Way for Implementing Common Technical Document

By Justina Molzon, M.S., Pharm D.

CHIBA, Japan—The International Conference on Harmonization steering committee and its technical working groups met May 21 to 24 to focus on issues identified with implementing the Common Technical Document and released "for testing" the electronic version of the CTD.

The meeting clarified implementation dates. Beginning July 2003, submission in the CTD format will be expected in the United States and mandatory in the European Union and Japan. The various implementation working groups have also started work on explanations and clarifications that will be published on the ICH Web site (http://www.ifpma.org/ich1.html) in question-and-answer format.

The test e-CTD contains a specification document and the document type definition standard. This will allow the e-CTD to undergo "real case" testing by the industry and regulatory partners in the three ICH regions, Japan, the European Union and the United States. Definitive documents for comments on the e-CTD are expected to be released in October in Brussels. The test e-CTD and more information is on CDER's Web site at http://www.fda.gov/cder/m2/eCTD.htm.

The MedDRA management board also met here and agreed to the release of version 4.0 of the medical dictionary for regulatory activities on June 15. The large number of changes made in the terminology include new terms, modifications to existing terms and changes in linkages between the terms. The progress in making translations into E.U. languages was discussed. The first participation of a WHO observer to the MedDRA management board was welcomed.

The ICH process successfully pursued exploratory discussions in new areas, with a satellite meeting on biotechnology and gene therapy products and a brainstorming session on post-marketing activities.

Attendees at the meeting on biotechnological and gene therapy products agreed that the scientific principles for the regulation of gene therapy or gene therapy products are currently harmonized in the three regions. They also agreed on the need to continue to foster the exchange of information under the auspices of ICH in relation to emerging scientific information on such products.

Many areas of scientific importance were identified, and three topics were prioritized: dose definition and standardization; virus shedding; and germ-line integration. A spring 2002 workshop in Washington was recommended for reviewing technical issues related to dose definition and standardization.

A brainstorming meeting on post-marketing activities prioritized three issues for possible future activities: periodic safety update report information; rollout of new drug products; and case reports. The discussions will continue in Brussels in October.

Justina Molzon is the Center's associate director for international affairs.

Equal Opportunity Corner

HHS APAnet Honors CDER's Strides in High-Level Opportunities

By Gloria Sundaresan

The HHS Asian Pacific American Network presented its first Outstanding Award to Center Director **Janet Woodcock, M.D.**, at its second annual training conference and awards ceremony held at the Parklawn Building May 24. Dr. Woodcock was cited "for outstanding accomplishment in providing opportunities to Asian Pacific American employees to overcome the glass ceiling and successfully demonstrate their abilities" at the GS-15 level and above.

Under Dr. Woodcock's leadership, 17 of the Center's 197 Asian Pacific American employees, or 8.6 percent, serve at the highest levels of the Civil Service. This is the highest percentage in FDA and HHS. **Josephine Jee** from the Office of New Drug Chemistry in the Office of Pharmaceutical Science nominated Dr. Woodcock for the award.

Dr. Woodcock was appreciative and delighted that she was honored by APAnet. "Asian Pacific American employees are hard-working and dedicated, and I thank them for their great contribution to the Center," she said. "The support and commitment from Asian Pacific Americans have been tremendous, and they serve all Americans."

Based on the workforce profile as of December, the percentage of other groups in CDER serving at the top levels are as follows:

- Hispanics: 20 percent, highest in HHS.
- Native Americans: 12.5 percent, highest in FDA.
- Employees with disabilities: 21.9 percent, second to CVM's 30 percent.
- Non-minority men; 22.5 percent, second to Office of the Commissioner's 25.3 percent.
- Non-minority women: 10.7 percent, second to Office of the Commissioner's 12.2 percent.

Ruth Kirschstein, M.D., acting director of NIH, received the Outstanding Diversity Award

Special Awards were presented to individuals or groups that support the White House Initiative for Asian Americans and Pacific Islanders and supervisors/mentors who support APAnet members and APA activities. Recipients included:

- **Joseph Levitt,** CFSAN director.
- **Naomie Ritchfield-Fratz,** CFSAN.
- **Steven Falter,** CBER.
- **CAPT Susanne Caviness,** SAMHSA.
- **Dr. Donald Chi,** ORA, FDA.
- **Mohammed Huque, Ph.D.,** director, Division of Biometrics III, CDER.
- **Dr. Sudhir Srivasta,** NCI, NIH.
- **Dr. Aftab Ansari,** NIAMS, NIH.
- **Margaret Bell,** EEO manager, CDER
- The NIH Asian Pacific American Organization, (**Lucie Chen,** chair).
- **Frances Nguyen,** HRSA.
- The White House Initiative Office for Asian Americans and Pacific Islanders (Lisa Hasegawa, Charmaine Manansala, Parag Mehta and Angela Comeau).

The event was co-sponsored by: AHRQ, HRSA, IHS, NIH and the Federal Asian Pacific American Council

Gloria Sundaresan is a member of the EEO Staff.

Nobel Laureate Dr. Prusiner Lectures on Prions at CASE Seminar

BY FUNMILAYO AJAYI, PH.D., THOMAS F. OLIVER, PH.D., JOHN QUINN, R.PH., M.S., AND SANDIP K. ROY, PH.D.

Stanley Prusiner, M.D., the 1997 winner of the Nobel Prize in physiology or medicine, spoke to a standing-room-only crowd at a special CDER seminar held May 23 and arranged by the Committee for Advanced Scientific Education.

Dr. Prusiner, one of the world's foremost researchers in the new field of "prion" diseases, discussed the defective protein processing that causes such devastating neurodegenerative diseases as bovine spongiform encephalopathy in animals and Creutzfeldt-Jakob disease in humans.

This seminar drew participants from many FDA centers, the National Institutes of Health and the general public. Before the seminar, Dr. Prusiner met with FDA leaders to discuss the spread of BSE, also called mad cow disease, and FDA's role in mitigating and preventing this disease.

Murray Lumpkin, M.D., senior medical advisor in the commissioner's office, who is coordinating FDA's response to the BSE crisis, introduced Dr. Prusiner. Dr. Lumpkin noted how "three years at the NIH were critical in his scientific education and that he learned an immense amount about the research process: developing assays, purifying macromolecules, documenting a discovery by many approaches and writing clear manuscripts describing what is known and what remains to be investigated." Dr. Pruisner's autobiography is on the Nobel Foundation's Web site at http://nobelprizes.com/nobel/medicine/1997a.html.

For many years the diseases like BSE were thought to be caused by a slow-acting virus. In 1982, Dr. Prusiner proposed that the cause might not be viruses but instead a new type of infectious agent, which he called "prion" for "proteinaceous infectious particles." These infectious protein particles can cause a range of degenerative brain diseases by misfolding and causing other proteins to misfold in turn.

Among other prion-based diseases are scrapie in sheep and the human diseases of fatal familial insomnia, Gerstmann-Straussler-Scheinker disease and kuru. Research groups have started looking at other diseases where inappropriate conformational proteins seem to play a role. Examples include Alzheimer's, Parkinson's and Huntington's diseases. Other diseases, traditionally thought to be autoimmune mediated, such as multiple sclerosis, may be caused by an immune system response to a misfolded protein.

BSE appears to have spread from animal to animal through the practice of mixing slaughterhouse remains into the feed for live animals. Eating the meat of infected animals may have caused the infection to jump the species barrier and caused humans to develop a fatal neurodegenerative condition called new-variant Creutzfeldt-Jakob disease.

Approximately 100 persons, most in Great Britain, have died from nvCJD. There is no treatment and detection only occurs after symptoms develop. The incubation period in humans has not been well characterized but published estimates say it may be at least five and perhaps as long as 20 years.

Dr. Prusiner discussed other prion issues, including:

- Prions are resistant to our traditional disinfectant procedures and very high heat does not disable them. Coupled with the potentially long incubation period of prion diseases, there is concern about current hospital operating room sterilization procedures.
- The concept of prions can explain how a disease can be both inherited and infectious.
- There is an urgent need for a better test to screen for TSE-infected livestock. The current test only detects animals that are almost ready to develop clinical symptoms and long after they have become infective. He briefly discussed research that may lead to such a test.
- Research in cell cultures is pointing the way to potential drug-based interventions to prevent the abnormal processing of proteins and enhance their clearance.

A recent review article by Dr. Prusiner covering many of his lecture points can be found in the May 17 issue of the *New England Journal of Medicine.*

Dr. Prusiner's mentor at NIH took part in the discussion period following the seminar. Discussion also focused on the fact that there may be several more cases of TSE than what has been reported. There were also questions about the impact of age on the susceptibility to prion diseases.

The high interest in prion disease in our center and others brought an overflow crowd to our main Parklawn location. Attendance was also impressive at remote sites video links, which included Corporate Boulevard, Woodmont, Metro Park North and MOD I. In addition to our normal links, feeds to Beltsville and New York were set up.

BSE Scientific Rounds

The morning lecture set the stage for afternoon scientific rounds where BSE and CJD were the topics of discussion. The discussions focused on import policies from European countries, various surveillance programs, emergency response plans and prioritization of risk.

Dr. Lumpkin discussed briefly the involvement of the Commissioner's Office in coordinating initiatives among centers. Regulation development and harmonization of regulations among different countries was also discussed. The issue of smuggling of bovine raw materials also came up. Overall, scientific rounds was well attended and successful.

CASE provides timely continuing education for CDER reviewers. The committee works with the Office of Training and Communications, to provide seminars, scientific rounds, the visiting professor lecture series, workshops and short courses. These are geared to create an environment where reviewers are brought up-to-date with the latest scientific advances through direct interaction with the country's foremost scientists.

Contact **Tom Oliver, Ph.D.,** (OLIVERT, 4-2570) to submit ideas for future topics and speakers.

The authors are members of CASE, and Dr. Ajayi is 2000-2001 chair.

New CDER Deputy Director to Focus on Risk Management

By Patrick E. Clarke

Steven Galson, M.D., MPH, and a captain in the Commissioned Corps, joined the Center as its sole deputy director after serving in high-level medical positions at the Environmental Protection Agency and the Department of Energy.

"Risk management is coming of age in the drug safety world, not just in pre-marketing assessments for safety and efficacy but also in how safe the drug is after its release to the general public," Dr. Galson said. "I expect to play an important role over the next few years in developing policy in this area."

He considers his background very relevant to CDER, pointing out that assessing risks from drugs and environmental chemicals is a similar scientific process. He sees the need for the Center to enhance its way of gauging the response a drug can have after it has been released to the general public.

"Post-marketing decisions have always been a challenge for the Agency," Dr. Galson said. "We have to take a more comprehensive look at possible adverse effects and other variables such as medication errors that impact the use of drugs in order to reduce morbidity and mortality." Dr. Galson noted that he dealt with complex international issues at EPA. "Toxic chemical regulation as a whole is becoming harmonized internationally just as we are doing with drugs."

Dr. Galson's experiences working with refugee emergencies at the border between Thailand and Cambodia in 1982 crystallized his commitment to seek a career in public health. "Those experiences also reinforce my belief that public health problems are global and the solutions need to be global."

He sees several other areas where his previous experience will benefit him in his current position. "I have a lot of experience working with outside partners, interest groups and Congress—and trying to mediate conflict," he said. "I look forward to getting involved with some groups we haven't worked with as much in the past."

> "Risk management is coming of age in the drug safety world, not just in pre-marketing assessments for safety and efficacy but also in how safe the drug is after its release to the general public."
> —Steven Galson, M.D., MPH

At the EPA he was concerned with complex issues involving science, economics and public policy as well as balancing industry interests with public safety.

After less than two months at CDER, he said he was "very impressed with the dedication and scientific and management expertise here."

Dr. Galson's positions at EPA were director of the Office of Science Coordination and Policy in EPA's Office of Prevention, Pesticides and Toxic Substances and, before that, scientific director and advisor to the administrator of the Office of Children's Health. At the Department of Energy from 1994 to 1997, he was first chief medical officer in the Office of Environment, Safety and Health and then counselor on science and health in the Office of the Secretary.

He entered federal service in 1986 as an epidemic intelligence service officer for the Centers for Disease Control and Prevention. From 1988 to 1989, he was a medical epidemiologist in CDC's Preventive Medicine Residency Program, New York State Department of Health.

His service at CDC was with the National Institute for Occupational Safety and Health where he held positions of increasing responsibility ending as deputy director, Division of Standards Development and Technology Transfer.

Dr. Galson obtained his bachelor of science degree in biochemistry from the State University of New York at Stony Brook in 1978, his medical degree from Mount Sinai School of Medicine in New York in 1983 and a master's degree in public health from the Harvard School of Public Health in 1990.

He is board certified in general preventive medicine and public health and in occupational medicine. He is qualified in internal medicine. He also served a residency in internal medicine at the Hospitals of the Medical College of Pennsylvania in Philadelphia.

To view a photo of Dr. Galson, go to http://www.fda.gov/cder/pike/june2001.htm#galsonphoto.

Patrick Clarke is a public affairs specialist in OTCOM.

Laboratory of Clinical Pharmacology Shares Patent for Drug Discovery

(Continued from page 1)

tions, we first filed a PHS Employee Invention report. After a patentability assessment, a joint application was filed with the NCI contractors.

A patent by itself doesn't generate revenue, but NIH provides licensing services for FDA inventions via an interagency agreement. In this era of leveraging, legislation specifies that the lab and the inventors share in any revenue from licensing.

More importantly in this case, a potentially useful drug was about to be discarded, but now gets a second chance via its metabolite.

Realistically, the probability of success for any new drug is rather low, so any tools that can improve the chances should be applied.

Paula Bourkland and **Lowell Lima** in the Office of Management and **Joseph Hanig, Ph.D.,** in OTR's Division of Applied Pharmacology Research are our CDER contacts for leveraging and technology. For Agencywide activities and policy, **Beatrice Droke** is FDA's technology transfer officer. More information is available at: http://intranet.fda.gov/ofacs/techtran/1stpg.html.

An article on the Patent Office appeared in the March '99 *Pike* issue. Our patent, number 6,235,761, and all others are available on-line at the Patent Office's Web site: http://www.uspto.gov/patft/index.html.

Jerry Collins heads the Laboratory of Clinical Pharmacology in the Office of Testing and Research