news along the pike

JULY 2000

CENTER FOR DRUG EVALUATION AND RESEARCH

VOLUME 6, ISSUE 7

INSIDE . . .

PIKE'S CORNERS

Center Opens Reexamination of OTC Drugs

50 Industry, Scientific, Consumer Groups Make Presentations

BY SHERUNDA LISTER

More than 300 people—FDA officials, drug and health care industry representatives, consumer advocates and physicians—heard more than 50 presentations on FDA's role in over-the-counter drug regulation at a two-day public hearing held last month. CDER had received a number of inquiries about OTC drug marketing from the pharmaceutical industry, consumer groups, health care organizations and scientific societies. This prompted the Center to seek input from all its stakeholders at the public meeting, which took place June 28 and 29 in Gaithersburg.

"Health care in the United States is changing with more products being marketed directly to consumers," said **Robert DeLap, M.D.,** Director of the Office of Drug Evaluation V, who served as chairperson of the hearing. He said FDA expects the trend to continue. "We are open to the possibility of having more and different kinds of medicines available to consumers," he said.

The first day was dedicated to process issues. These included procedures for determining which drugs should be available over the counter, who should initiate Rx-to-OTC switches and safety concerns about OTC availability of medicines for chronic conditions without symptoms like high blood pressure or high cholesterol.

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CDER, FDA, HHS Honor 56 Individuals, 58 Groups

BY JACKIE BARBER

The Center presented 48 individual and 50 group awards at its Honor Awards Ceremony in Gaithersburg on June 16. The ceremony was also used as the occasion to present the HHS Employee of the Month Award for April to Ted Sherwood from Office of Pharmaceutical Science (page 9). Another seven individual and eight group awards were presented to CDER employees a week earlier at the FDA ceremony in Rockville (page 9).

Center Director **Janet Woodcock, M.D.,** noted that the Agency has made leveraging resources and partnering with outside groups an important goal. "Many of you are already doing this as evidenced by some of the awards," she said.

The award recipients represented a wide array of backgrounds and disciplines. "They are secretaries, administrators and scientists with one thing in common," Dr. Woodcock said, "a

(Continued on page 6)

Visiting Professor Lecture Series Successfully Piloted

BY E. JANE MCCARTHY, CRNA, PH.D.

A program to bring distinguished academicians to CDER for cutting-edge scientific presentations to specific groups of reviewers was successfully launched with a pilot lecture on June 22 in the Division of Anti-Infective Drug Products.

Charles Cooney, Ph.D., from the Massachusetts Institute of Technology spoke on "Fermentation Manufacturing Procedures and Scale-up," which targeted the division's chemistry team and the Antibiotic Working Group. About 35 reviewers attended the lecture, which was followed by an animated discussion.

The CDER Visiting Professor Lecture Series, developed by the Office of Training and Communication, will sponsor about 40 lectures from September to June. By bringing in nationally recognized experts, the series will help the Center's reviewers stay abreast of the latest scientific and technological information related to their reviews.

CDER reviewers will identify both scientific topics and experts. University experts in these areas will then be invited to provide an informal lecture and hold a discussion targeted at physicians and scientists working in the specific area. Although the lectures will be open to all, they will be held in the target divisions or

(Continued on page 12)

JOE'S NOTEBOOK

Taking Care of Family

You have to be impressed by the accomplishments of your colleagues. Their sense of dedication, commitment, collaboration and cooperation is only hinted at in the six pages of this issue outlining their awards, the courses they taught and their willingness to step forward and help with a new program. These deeds wouldn't have been possible without the cooperation, understanding, patience and, in many cases, forbearance of family members.

So it seems only right that the federal government stepped up to the plate last month and published final regulations that expanded the sick leave policy for federal employees. Until recently, you were permitted to use a total of up to 13 days of sick leave each year for family care and bereavement purposes. The expanded regulations permit you to use a total of up to 12 weeks of sick leave each year to care for a family member with a serious health condition.

This benefit broadens the options available for you to meet your family responsibilities. There are some definitions you should be aware of.

A "family member" is :

- Your spouse and spouse's parents.
- Your children, including adopted children, and their spouses
- Your parents.
- Your brothers and sisters and their spouses.
- Any individual related to you by blood or affinity whose close association is the equivalent of a family relationship.

"Serious health condition" includes such conditions as cancer, heart attacks, strokes, severe injuries, Alzheimer's disease, pregnancy and childbirth. A serious health condition doesn't include short-term conditions for which treatment and recovery are very brief. The common cold, the flu, earaches, upset stomaches, headaches (other than migraines) and routine dental or orthodontia problems are not serious health conditions unless complications arise.

Previously, you could use 13 workdays of sick leave each leave year to:

- Provide care for a family member who is incapacitated as a result of physical or mental illness, injury, pregnancy or childbirth.
- Provide care for a family member as a result of medical, dental, or optical examination or treatment.
- Make arrangements necessitated by the death of a family member or attend the funeral of a family member.

The same limitations apply to the use of sick leave to care for a family member with a serious health condition as apply to the use of sick leave for general family care or bereavement purposes. The circumstances under which you may use more than 13 days of sick leave are more limited. For example, you must maintain a sick leave balance of 80 hours to use the full 12 weeks of sick leave to care for a family member with a serious health condition. Regardless of your sick leave balance, you may use an initial 40 hours of sick leave for family care purposes. To use more than 40 hours, however, you must maintain a sick leave balance of 80 hours.

If you have any questions, you should contact your personnel generalist or the FDA Pay and Leave staff (7-4150).

Correction: On page 10 of the April-May issue of the *Pike,* should have we should have included **Joyce Korvick, M.D.,** co-principle investigator along with **Ana Szarfman, M.D.,** on their project, "Improvement of the analytical processes involved in review safety data of an NDA: Application of preprogrammed interactive graphical tools." The project was funded by the Center's Regulatory Science and Review Enhancement Program.

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
CDER Office of Training
and Communications (HFD-200)
Parklawn Building, Room 12B-45

Editor: Norman "Joe" Oliver (OLIVERN)
Phone: (301) 827-1670
Fax: (301) 827-3055

OMBUDSMAN'S CORNER

St. Sebastian Kept a Stiff Upper Lip

BY JIM MORRISON

Well, it seems like slings-and-arrows season again. The Center has certainly received more than its share of bad press in the past few months, and it takes its toll in staff morale. From the mail I've been getting, mainly from consumers, it is apparent that there is a lot of misinformation and false perceptions about the benefits and risks of drugs and how CDER decides to approve a drug or ask its sponsor to withdraw it from the market.

It's painful to get flaming e-mails, but it's equally painful to hear colleagues express a stoic acceptance of these barbs as the fate of regulatory agencies. The Agency's traditional approach has been to quietly accept the public's wrath, born of misperceptions and incomplete information, while waiting for the complete, scientific truth to emerge some time in the future and prove the wisdom of Agency actions. But information delayed is an educational opportunity lost—or worse—a tacit endorsement of the misinformation.

The situation reminds me of paintings by Giovanni Bellini (1426-1516) and others depicting the martyrdom of St. Sebastian. He is usually shown with his body pierced by arrows and a woeful expression on his face. But Sebastian kept a stiff upper lip. Sporting numerous arrows protruding from your body may look good if you are applying for sainthood, but it is less becoming to a regulatory agency. One of our important obligations to society is to educate the public about drugs, how to use them safely and about what the Agency is doing to assure that only appropriate drugs are on the market.

To quietly endure the slings and arrows of a misinformed press and public is not noble—it is a failure to communicate. The public needs to have a basic understanding of drugs and how to decide whether to take a drug in a particular circumstance.

The public does not learn from reading transcripts of advisory committee meetings or scientific articles. The public needs to get this information in short, comprehensible messages that are not unlike the sound bites they get from the media.

We have no one but ourselves to blame for the public's lack of understanding that "safe drug" is an oxymoron and that benefits must be weighed against risks, with different people usually getting the benefits and suffering the risks.

Thanks to the science fiction genre, the public has a better comprehension of Einstein's special theory of relativity ($E=mc^2$) than it does of drug regulation and benefit-risk evaluation. It's doubtful that the average person will ever need to use Einstein's equation, but ignorance of the risks of drugs can be fatal.

If the public is being educated by the media in sound bites, we need to educate the public and to explain our actions in a collection of sound bites that add up to a cohesive picture. If these bites are repeated in interviews, posted on the CDER Web site and disseminated to the public at every opportunity, the messages will sink in. Stating the reasons for actions is always preferable to remaining silent in the face of criticism.

We simply can't afford to allow misinformation to prevail. Educating the public and the media is an important function of government. In the Information Age, it is becoming even more important. Fortunately, this vital function is becoming easier to fulfill. With the Web, the Agency has the opportunity to interact with the public individually in numbers never before possible.

Each of us can contribute to the process. We can begin by trying our communication skills on our family and friends. If we can't explain to our spouses and kids about benefit-risk in drugs, it's not likely we can get the message across to people who call and write letters. We also need to carry on a dialogue among ourselves and to share consensus views with the public.

Jim Morrison is the Center's ombudsman.

PIKE'S PUZZLER

Regulation or recreation?

BY TONY CHITE

1. "Tinker to Evers to Chance" refers to:

a. The serendipitous discovery of a new drug.
b. Three physicians who discovered a drug for cocaine addiction.
c. Baseball Hall of Fame infielders noted for their double play combination.
d. A medical officer, chemist, and pharmacologist who have won the Nobel Prize.

2. Our National Anthem, "The Star Spangled Banner," was composed during a battle of:

a. The Revolutionary War.
b. The War of 1812.
c. The Spanish American War.
d. The Civil War.

3. A horse that places first in the Kentucky Derby, Preakness and the Belmont horseraces has won the:

a. Triple Crown.
b. World Series.
c. Stanley Cup.
d. U.S. Open.

4. "All I Need Is a Miracle" is:

a. A play based on Helen Keller's life.
b. A movie taking place at Christmas.
c. An essay about the FDA review process by a regulatory project manager.
d. A song by Mike and the Mechanics.

5. Upton Sinclair's most famous book, which outraged the public, launched a government investigation of meatpacking plants of Chicago and changed the food laws of America, is entitled:

a. *Blackboard Jungle*.
b. *It Happens Every Spring*.
c. *Silent Spring*.
d. *The Jungle.*

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

Tony Chite is a CSO in the Center's Freedom of Information Division.

EEO CORNER

High School-High Tech Program Marks 3rd Year in CDER

BY GLORIA MARQUEZ SUNDARESAN

For the third consecutive year, we are partnering with United Cerebral Palsy Inc. from July 5 to Aug. 4 to have high school juniors with disabilities gain work experience. The summer program, established eight years ago, enjoys from both public and private sponsorship.

"It's a very comprehensive plan involving career exploration and work experience in which almost any youngster could benefit," said Charles McNelly, Ph.D., executive Director of UCP for Prince Georges and Montgomery counties. "Our program has a very good reputation because it offers students with disabilities a quality experience." This year CDER has placed three students in these components:

- **Casey Reeder,** from Watkin's Mill High School, Gaithersburg, in the Executive Operations Staff. His mentors are **Tanya Abbott** and **Jody Moore.**
- **Clement Jalloh,** from Montgomery Blair High School, Silver Spring, in the Division of Training and Development. **Iris Khalaf** is his mentor.
- **Alexander Roy**, from John F. Kennedy High School, Silver Spring, in the Office of Testing and Research. **Tammy Mueller** is his mentor.

EOS and DTD are first-time participants in the program this year, and OTR has provided support for three summers in a row.

Special thanks go to the mentors for their time and effort and to **Debbie Henderson, Janice Newcomb,** and **James MacGregor, Ph.D.,** directors of EOS, DTD and OTR respectively, for setting aside funds to support the program. In return, we have extra help, a chance to show what we do and partner with United Cerebral Palsy in serving the community.

Working with students with disabilities can provide a learning experience for us as well, especially in raising our awareness that, although employees may have some disabilities, we can focus on their abilities that make them valuable members of the workforce.

For now, only CDER has sustained participation in the program for the last three years. However, **Evelyn M. White,** HHS deputy assistant secretary for human resources, recently learned about the program and expressed her desire to encourage other HHS agencies to take part. White champions the cause of employees with disabilities in the federal government.

At UCP, Mary Panella, Ph.D., directs the summer program, and Alison MacKenzie is the employment instructor assigned to assist the students in CDER.

More information about the program can be obtained by calling UCP at 301-262- 4982 or the EEO Staff at 4-6645.

Gloria Marquez Sundaresan is team leader for special emphasis and diversity management in the Center's EEO Staff.

CDER Lab Partnership with German Lab Benefits Students, Center

BY CHRISTINE KAIBNI

July roughly marks the halfway point of the collaboration between the Division of Product Quality Research in the Office of Testing and Research and a small German laboratory known as the Zentrallaboratorium Deutscher Apotheker, or ZL. Running from late January to early December, this informal alliance arose when the German lab offered to send two graduate students to work in DPQR. The Center is providing laboratory space and equipment.

Research chemist **Donna Volpe, Ph.D.,** is the students' supervisor in the cell culture laboratory at the Nicholson Lane Research Center. According to Volpe, this was an ideal opportunity for a lab with more ideas than either hands or time. She said the students' work on cell culture models of drug permeability represented "two projects that we wanted to do anyway and we wouldn't have been able to do without their extra hands."

As much as the CDER division has to gain, for **Stefanie Schulte-Loebbert,** one of the two graduate students, the collaboration offers even more. Schulte-Loebbert, a student at J.W. Goethe University in Frankfurt, said it gives her a chance to work exclusively on her dissertation. She is studying the permeability of hyperforin, a component of St. John's Wort, through the human gut wall using a traditional cell assay. "At the university," she said, "I would have to help students and teach classes. There is a lot of work besides your own studies. Here it is just me, myself and hyperforin."

Working at CDER provided Schulte-Loebbert with a much-desired opportunity to spend time away from her studies in Germany and to visit the United States. Before receiving the ZL's offer she had planned to work at a hospital in Milwaukee, though it would not have been a chance to work on her dissertation.

She has visited much of the Washington area and experienced both the museums and clubs. She most enjoyed downtown on the Fourth of July. Already she has plans to go Christmas shopping in New York City, so far her favorite city in the country.

If there is one aspect of her stay in the United States that Schulte-Loebbert finds a little disappointing, it is that she has not met more people her own age. Partly she attributes this to her experience that Americans are not as friendly as they first seem. However, Schulte-Loebbert gets along well with her co-workers and hopes to return to the United States after she completes the remaining two years at her university.

The collaboration offers many of the same benefits for **Britta Klaembt,** the other ZL graduate student. A year in DPQR's cell culture laboratory allows her to work toward her doctorate evaluating a a novel epithelial cell model of drug permeability to optimize an alternative assay.

Klaembt, from the University of Heidelberg, recently rejoined the CDER laboratory after a six-week return to Germany in which she took her exam to become a pharmacist. With a laugh, she says the only thing left to do with her remaining time in the United States is to finish her dissertation. Though Klaembt describes the collaboration as a "great experience" and something that she "wouldn't miss," she traveled much of the United States with her

(Continued on page 5)

New E-mail System Is Coming to a Division Near You

OIT will begin rolling out Microsoft Exchange version 5.5 and Outlook 2000 to CDER divisions beginning this fall. Microsoft Exchange is the e-mail server software and Microsoft Outlook is the e-mail client software that resides on your PC.

As the project progresses, OIT will distribute regular updates in future *Pike* articles, e-mails and on the OIT intranet (http://oitweb).OIT will arrange training to ensure a smooth transition.

Microsoft Outlook 2000 will be taking the place of All-In-1/TeamLinks. Outlook is a messaging and personal information management program that centralizes many of the everyday tools you use and activities you perform to keep your work life in order.

Inside Outlook, you'll find:

- *E-mail.* Correspond with others, send file attachments, send and respond to task requests, filter out junk e-mail messages and use the Rules Wizard to automatically move, delete, forward, or flag incoming and outgoing messages.
- *Calendar.* Schedule appointments, meetings and all-day events. Track important dates. The Russell Calendar Manager will remain the official calendar system until all Center employees have migrated to Outlook/Exchange. There will be more information about this transition in the Centerwide training.
- *Contact list.* Store names, addresses and phone numbers.
- *Task list.* Create and maintain a to-do list, categorize and prioritize your tasks, set reminders for deadlines and track your progress. You can also assign tasks to others, monitor their progress and receive status reports.
- *Notes.* Set up critical reminders.
- *Files and folders.* Store and manage information using files, folders and nested folders, similar to Windows Explorer.

OIT looks forward to a smooth transition and is excited about the benefits for the Center.

Please contact the Help Desk (HELP) if you have any specific e-mail or calendar questions.

August IT Training

Monday	Tuesday	Wednesday	Thursday	Friday
	1	2	3	4
7	8	9	10	11
14 **Intro. Word 97** 9:00-12:00 **Word 97 Formatting** 1:00-4:00	15	16 **Word 97 Tables** 9:00-12:00 **NEDAT** 1:00-4:00	17 **Intro. Access** 9:00-12:00 **Access Queries** 1:00-4:00	18 **Access Form Design** 9:00-12:00 **Access Report Design** 1:00-4:00
21	22	23 **DFS** 9:00-12:00 **Creating PDF Documents** 1:00-4:00	24 **Excel** 9:00-12:00	25
28	29	30	31	

The catalog, training materials, schedule and online registration can be found at http://oitweb/.

Draft IT Records Control Schedule

Members from each of OIT's units reviewed a draft General Records Schedule covering electronic records. The National Archives and Records Administration had circulated the draft for comment. That agency will review our comments and make any necessary revisions before publishing the schedule in the *Federal Register* for public comment. Once all public comments are received and analyzed, the schedule will be formally issued for use throughout the federal government.

This review marks the culmination of a process begun last July in which OIT commented on a previous draft *(Pike*, July 1999). For more information about this and other records schedule issues, you can also visit the General Records section of the OIT Activities page on the OIT intranet (http://oitweb), or you can contact **Scott Zeiss** (ZEISSS) to learn about CDER's records and information management policies.

Help Desk FAQ

Q: When I paste text into a Microsoft Word document, I always have to reformat the text to look like the rest of my document. Is there a way around this?

A: Yes. Instead of using Word's regular paste feature, try using the "paste special" feature. Paste special allows you to paste the contents of the clipboard as formatted or unformatted text.

For example, if you copy blue, Arial text from a Website, but your Word document text is black and Times New Roman, using paste special and unformatted text should paste the text as black, Times New Roman.

To use paste special:

- Copy your desired text.
- On the menu bar, go to Edit, Paste Special.
- In the As: field, choose Unformatted Text (or read the descriptions for the other formats available).
- Click OK.

Paste special also works for tables, graphs and pictures. Consult the Help Desk (HELP) for more information.

German Students Help CDER Cell Culture Laboratory

(Continued from page 4)

parents on previous trips and feels as though she knows the country well.

Klaembt estimates she will need another two years after returning to Germany to complete her work and earn her degree. Just as Schulte-Loebbert, she is considering a return to the United States.

Although, there are no current plans for future collaborations, this alliance promises a productive year for both the cell culture laboratory and the students.

Christine Kaibni, a summer intern in OTCOM, attends the College of William and Mary where she is a film and finance double major.

Leveraging with Outside Groups Emphasized in Several Awards

(Continued from page 1)

true spirit of innovation and inventiveness combined with a strong commitment to teamwork."

A highlight of the ceremony was the peer awards, given to and by those who work side-by-side carrying out the important work of the Center. "The large number of nominations submitted for each ceremony demonstrates the genuine respect and admiration you have for one another," Dr. Woodcock said. "This support and encouragement is a vital element in a successful organization."

The Montgomery County Police Color Guard presented colors, and Kevin Barber sang the National Anthem. Ruth Clements introduced each award, and the office directors provided an explanation of individual or team achievements.

Dr. Woodcock thanked those who manage the awards program and produce the ceremonies: **Jackie Barber, Tessa Williams, Ruth Clements** and the members of the Division of Management Services as well as those who serve on the CDER Peer Honor Awards Review Committee. She also thanked the family members for their continued support of their CDER loved ones, which made their accomplishments possible.

FDA Commendable Service

Joyce A. Korvick, M.D.

Karen J. Lechter, Ph.D., J. D.

Toni M. McCannon

Moheb M. Nasr, Ph.D.

Norman J. Oliver

Sally Winthrop

Albuterol Team: **Patricia L. Alcock, Sandra L. Barnes, Craig M. Bertha, Frederick W. Blumenschein, Yuan Yuan Chiu, Ph.D., Joseph Famulare, John J. Gibbs, Daniel J. Grabicki, Martin H. Himmel, M.D., Parinda Jani, John K. Jenkins, M.D., Chong-Ho Kim, Steve R. Koepke, Douglas C. Kovacs, Robert J. Meyer, Brian Nadel, Guiragos K. Poochikian, Ph.D., Brian D. Rogers, Nancy L. Rolli, Kevin Swiss, Richard T. Trainor** and **Michael J. Verdi;** PHS Unit Commendation: **CDR Harvey A. Greenberg, CAPT Alan C. Schroeder** and **CDR Matthew A. Spataro.**

Sirolimus Review Team: **Funmilayo O. Ajayi, Ph.D., Matthew A. Bacho, Shukal Bala, Ph.D., Marc W. Cavaillé-Coll, M.D., Ph.D., Cheryl A. Dixon, Ph.D., Kofi A. Kumi, Ph.D., Steven C. Kunder, Ph.D., Mark R. Seggel, Ph.D., Nancy L.P. Silliman, Ph.D.,** and **Rosemary Tiernan, M.D.**

Thiazolidinediones Working Group: **Hae-Young Ahn, Ph.D., David J. Graham, M.D., Lanh Green, Joy D. Mele, Robert I. Misbin, Stephen K. Moore, Lee Ping Pian, Herman M. Rhee, Jon T. Sahlroot, John R. Senior, M.D., Robert M. Shore, Ronald W. Steigerwalt, Ph.D., Jena M. Weber, Xiao-Xiong Wei, Xavier J. Ysern** and **Feng Zhou.**

FDA Outstanding Achievement

Girish A. Aras, Ph.D.

Melissa J. Egas

Allan H. Fenselau, Ph.D.

Jogarao V. Gobburu, Ph.D.

John F. Grace, R.Ph.

Joette M. Meyer, Pharm.D.

David C. Morley

Shelley R. Slaughter, M.D., Ph.D.

Lenore K. Tavenner

Marcia L. Trenter

Vali M. Tschirgi

FDA Group Recognition Award

MedDRA Coding Working Group: **Toni D. Piazza-Hepp, Pharm.D., Sally J. Singer, R.Ph.,** and **Maria R. Thomas, M.D.;** PHS Unit Commendation: **CAPT Evelyne R. Edwards, CAPT Roger A. Goetsch** and **CAPT Andrea G. Neal.**

Metrics Working Group: **Mei-Ling Chen, Ph.D., Barbara M. Davit, Ph.D., Laszlo Endrenyi, Ph.D., Michael J. Fossler, Pharm.D., Ph.D., Mamata S. Gokhale, Ph.D., Chaunpu Hu, Ph.D., Yih-Chain Huang, Ph.D., Ajaz S. Hussain, Ph.D., Thomas N. Tozer, Ph.D.,** and **Zakaria Z. Wahba, Ph.D.**

OTC Tracking Initiative Team: **Marina Y. Chang, Maria Rosanna Cook, Helen Cothran, Charles J. Ganley, M.D., William E. Gilbertson, Pharm.D., Daniel P. Keravich, John D. Lipnicki, Debbie L. Lumpkins, Babette A. Merritt, Valerie J. Miguele, John P. O'Malley, Sally C. Prescott, Linda W. Roberts, Albert Rothschild, Kerry G. Rothschild, J.D., Mary Jane Walling;** PHS Unit Commendation: **LT Elizabeth F. Yuan.**

Risk Management Workshop Coordinating Group: **Tracy L. Acker, Pharm.D., Sonya R. Armstrong, Elaine C. Frost, Deborah J. Henderson, Peter K. Honig, M.D., Robert J. Hopkins, M.D., Chin C. Koerner, Thomas P. Laughren, M.D., Randy Levin, M.D., Amy B. Mason, Iris P. Masucci, Pharm.D., Cynthia G. McCormick, M.D., Janice L. Newcomb, Chris M. Nguyen, Nancy M. Ostrove, Ph.D., Leah M. Palmer, Pharm.D., Delores A. Rhodes, Nancy D. Smith, Ph.D.,** and **Robert J. Temple, M.D.;** PHS Unit Commendation: **CDR Linda S. Brophy, CDR Laurie B. Burke, CDR John J. Feeney, CAPT Dianne L. Kennedy, CAPT Sandra L. Kweder, CDR Evelyn M. Rodriguez** and **CAPT Stephen E. Wilson.**

Working Group for the HIV-1 Anti-Viral Drug Resistance Testing: **Girish A. Aras, Ph.D., Narayana Battula, Ph.D., Andrew I. Dayton, M.D., Ph.D., Indira Hewlett, Ph.D., Heidi M. Jolson, M.D., Katherine A. Laessig, M.D., Johnathan Ma, Ph.D., Lalji Mishra, Ph.D., Jeffrey S. Murray, M.D.,** and **Joanne L. Rhoads, M.D.;** PHS Unit Commendation: **CAPT Lauren C. Iacono-Connors** and **LCDR Kimberly A. Struble.**

PHS Unit Commendation

New Data Initiative Working Unit: **CAPT Andrea G. Neal, CDR Evelyn M. Rodriquez, CAPT Joslyn R. Swann** and **CDR Anne E. Trontell**

PHS Commendation Medal

LCDR Jeffrey R. Fritsch

CDR Harvey Greenberg

LCDR Valerie E. Jensen

LCDR Juliaette Johnson

(Continued on page 7)

Family Members Thanked for Support of CDER Employees

(Continued from page 6)

LCDR David Konigstein

CAPT Ching-Long J. Sun

CDR Anne E. Trontell

Center Director's Special Citation

S. Edward Nevius, Ph.D.

Larry Versteegh, Ph.D., (Procter and Gamble Pharmaceuticals)

OCPB Quality Assurance/Quality Control Initiative Working Groups: **Funmilayo O. Ajayi, Ph.D., Suliman I. Al-Fayoumi, Ph.D., Ramen K. Baweja, Ph.D., Brian P. Booth, Ph.D., Min Chu Chen, R.Ph., Philip M. Colangelo, Pharm.D., Ph.D., Suresh Doddapaneni, Ph.D., Emmanuel O. Fadiran, Ph.D., Shiew-Mei Huang, Ph.D., Kofi A. Kumi, Ph.D., Lawrence J. Lesko, Ph.D., Iftekhar Mahmood, Ph.D., Theresa M. Martin, Weston L. Metz, Ameeta Parekh, Ph.D., Chandrahas G. Sahajwalla, Ph.D., Vanitha Jagannathan Sekar, Ph.D., He Sun, Ph.D., Vijaya Tammara, Ph.D.,** and **Venkata Ramana S. Uppoor, Ph.D.;** PHS Unit Commendation: **CAPT Paul L. Hepp** and **LCDR Kathleen Uhl.**

Co-Chairs of the Complex Drug Substances Coordinating Committee: **Yuan-Yuan Chiu, Ph.D.,** and **Roger L. Williams, M.D.,** (U.S. Pharmacopeia).

OPDRA Ephedra-Dietary Supplement Working Group: **Min Chu Chen, R.Ph., Marion L. Gideon, Claudia B. Karwoski, Lynette Swartz** and **Maria R. Thomas.**

CDER Special Recognition

Hae-Young Ahn, Ph.D.

Virginia Beakes

Thomas S. Hammerstrom, Ph.D.

Ferrin D. Harrison, Ph.D.

Patricia E. Long-Bradley

Donald N. Klein, Ph.D.

Ranjit B. Mani, M.D.

Joy D. Mele

Thomas F. Oliver, Ph.D.

Chan H. Park, Ph.D.

Brian Rogers, Ph.D.

Mona R. Zarifa, Ph.D.

Ad Hoc CDER Clinical Pharmacology Research Grant Management Group: **Tina M. Hamilton, Peter K. Honig, M.D., Olia Hopkins, Shiew-Mei Huang, Ph.D., Lawrence J. Lesko, Ph.D., Weston L. Metz, Robert Robins, Rosemary Springer, Helen R. White, Joslyn A. Williams** and **Roger L. Williams, M.D.**

Hismanal Team: **Laura Bradbard, James R. Gebert, Ph.D., Ravi S. Harapanhalli, Ph.D., Peter K. Honig, M.D., John K. Jenkins, M.D., Andrea C. Masciale, Esq., Nancy M. Ostrove, Ph.D., Guiragos K. Poochikian, Ph.D., David T. Read, CAPT Ching-Long Joseph Sun, Gretchen S. Trout, Venkata R. S. Uppoor, Ph.D., and CAPT Stephen E. Wilson.**

Paclitaxel Chemistry Review Team: **Li-Shan Hsieh, Ph.D., Patricia F. Hughes, Ph.D., Josephine M. Jee** and **Rebecca H. Wood, Ph.D.**

CDER Administrative/Program Management Excellence

Michelle L. Mathias

OB Management Team: **Pamela S. Granta** and **Kathy A. Rios.**

CDER Excellence in Communication

Erica H. Brittain, Ph.D.

William Peter Rickman

Sue-Jane Wang, Ph.D.

CDER Clinical Pharmacology Guidance Implementation Team: **Emmanual O. Fadiran, Ph.D., Jogarao V. Gobburu, Ph.D., Peter K. Honig, M.D., Chuanpu Hu, Ph.D., Shiew-Mei Huang, Ph.D., Iris D. Khalaf, See Yan Lam, Ph.D., Peter Lee, Ph.D., Lawrence J. Lesko, Ph.D., Weston L. Metz, Mary D. Murphy, M.D., Robert T. O'Neill, Ph.D., William Peter Rickman, Arzu Selen, Ph.D., Vinod P. Shah, Ph.D., He Sun, Ph.D., Robert J. Temple, M.D., Joslyn A. Williams** and **Roger L. Williams, M.D.**

DPADP/PhRMA Dialogue Session Work Group: **Robin A. Huff, Ph.D., Daniel J. O'Hearn, M.D., Brian D. Rogers, Ph.D., Gretchen S. Trout, Venkata R. S. Uppoor, Ph.D.,** and **CAPT Stephen E. Wilson.**

Y2K Consumer Working Group: **Carol S. Assouad, Larry P. Lim, R.Ph., Sherunda R. Lister, Barry W. Poole, Khyati N. Roberts, Ellen Shapiro, Anthony E. Sims, Wendy K. Stanfield** and **Paul K. Stauffer:** PHS Unit Commendation: **CDR Linda S. Brophy.**

CDER Information Technology Excellence

Adverse Event Reporting System Change Control Board: **Melissa R. Chapman, Min Chu Chen, R.Ph., Charlene M. Flowers, R.Ph., Peter K. Honig, M.D., Ralph B. Lillie, R.Ph., Carolyn A. McCloskey, M.D., Sarah J. Singer, R.Ph.,** and **Ronald T. Wassel, Ph.D.**

AERS Programming Support Team: **Lynette Swartz** and **Feng Zhou.**

Division of Pharmaceutical Analysis Computer Installation Team: **James S. Black, Prince E. Bosley** and **James W. Marshall.**

OPDRA Document Tracking Team: **Min Chu Chen, R.Ph., Katrina S. Garry, Tina M. Hamilton, Peter K. Honig, M.D., Ralph B. Lillie, R.Ph., Maureen D. Majors, Toni D. Piazza-Hepp, Pharm.D.;** PHS Unit Commendation: **CAPT George D. Armstrong Jr., CAPT Thomas G. Phillips, CDR Evelyn M. Rodrigueza** and **CAPT Joslyn R. Swann.**

OTCOM Data and Storage Retrieval Team: **Mary F. Cooper** and **Charles A. Rigsby.**

CDER Leadership Excellence

Maryla E. Guzewska, Ph.D.

OCPB Mentoring Team: **Brian P. Booth, Ph.D.,** and **Gabriel J. Robbie, Ph.D.**

OTCOM Mentoring Team: **Brenda J. Kiliany, Pharm.D., Mary E. Kremzner, Pharm.D.,** and **Larry P. Lim, R.Ph.**

CDER Project Management Excellence

Matthew A. Bacho

Philip N. Orticke Jr.

OPDRA Project Management Group:

(Continued on page 8)

CDER Ceremony Honors 48 Individuals, 50 Groups

(Continued from page 7)

CDR Sammie G. Beam, Mary J. Dempsey and **Patrick F. Guinn.**

CDER Support Staff Excellence

Peter E. Khalaf

Judith G. Schupp

Mildred R. Williams

Special FOI Team for DDMAC: **Marsha T. Casey** and **Cynthia A. Durant.**

CDER Team Excellence

CDER FACTS Team: **Shirnette D. Ferguson, CAPT David Holovac, Lana G. Kostecka** and **Kathy P. Miracco.**

Chemistry Dermatologic and Dental Drug Products Review Team: **Wilson H. DeCamp, Ph.D., Joel S. Hathaway, Ph.D., Janet G. Higgins, Ernest G. Pappas, William G. Timmer, Ph.D.,** and **James D. Vidra, Ph.D.**

Chemistry Vitravene Review Team: **Rao V. Kambhamnpati, Ph.D., Stephen Miller, Ph.D., Hasmukh B. Patel, Ph.D.,** and **Su C. Tso, Ph.D.**

Division of Pharmaceutical Analysis Dissolution Team: **Don C. Cox** AND **Terry W. Moore.**

Division of Pharmaceutical Analysis Laurel Methods Validation Program Team: **Arthur R. Bryant, Valerie A. Flournoy, Richard M. Hogart, Almetia L. Hoskins, Susan Jenney, James Marsh** and **Sylvester West.**

Division of Special Pathogen and Immunologic Drug Products Project Management Team: **CDR Robin E. Anderson, Brenda J. Atkins, Christina H. Chi, Ph.D., Mary J. Dempsey, LCDR Ellen C. Frank, Lorene M. Kimzey** and **Karin M. Klunk.**

Drug Information Branch E-Mail Group: **Barbara J. Daciek, Brenda J. Kiliany, Pharm.D., Mary E. Kremzner, Pharm.D., Larry P. Lim, R.Ph.,** and **Brenda L. Stodart.**

JMP Training Team: **Zei-Pao Huang, CDR Armanda Oliva, Timothy M. Mahoney** and **Judith A. Racoosin.**

LDPE Overwrap Work Group: **Badrul A. Chowdhury, M.D., Linda L. Ng, Ph.D., Richard A. Nicklas, M.D., Luqi Pei, Ph.D., Miriam L. Pina, M.D., Vibhakar J. Shah, Ph.D.,** and **Tracey S. Zoetis;** PHS Unit Commendation: **LCDR James L. Cobbs.**

Levofloxacin Team: **Funmilayo O. Ajayi, Ph.D., Renata Albrecht, M.D., CDR Robin E. Anderson, Philip M. Colangelo, Pharm.D., Ph.D., Edward M. Cox, M.D., Peter A. Dionne, Cheryl A. Dixon, Ph.D., Michael R. Elashoff, Ph.D., LCDR Ellen C. Frank, LCDR Jeffrey R. Fritsch, Mark J. Goldberger, M.D., CAPT Thomas H. Hassall, Robert Hopkins, M.D., CAPT Sandra L. Kweder, Leonard V. Sacks, M.D., Nancy L.P. Silliman, Ph.D.,** and **Sheryl L. Whiteford, Ph.D.**

Malarone Team: **Funmilayo O. Ajayi, Ph.D., Renata Albrecht, M.D., Shukal Bala, Ph.D., Mary J. Dempsey, LCDR Ellen C. Frank, Mark J. Goldberger, M.D., CAPT Thomas H. Hassall, Kenneth L. Hastings, Ph.D., Robert Hopkins, M.D., LCDR Valerie E. Jensen, Qihao Jiang, Ph.D., Steven C. Kunder, Ph.D., CAPT Sandra L. Kweder, LCDR Houda Mahayni, Andrea N. Meyerhoff, M.D., Leonard V. Sacks, M.D., Norman R. Schmuff, Ph.D., Nancy L.P. Silliman, Ph.D., John L. Smith, Ph.D.,** and **Sheryl L. Lard Whiteford, Ph.D.**

Moxifloxacin Team: **Thomas Abrams, R.Ph., Tracy Acker, Pharm.D., Funmilayo O. Ajayi, Ph.D., Renata Albrecht, M.D., Eileen E. Almario, M.D., Allen D. Brinker, M.D., Shaw T. Chen, M.D., Ph.D., Philip M. Colangelo, Pharm.D., Ph.D., Mary J. Dempsey, Peter A. Dionne, Michael R. Elashoff, Ph.D., Amy L. Ellis, Ph.D., Mark J. Goldberger, M.D., Maryanne Gordon, M.D., Kenneth L. Hasting, Ph.D., Robert Hopkins, M.D., John E. Koerner, Ph.D., Brad G. Leissa, M.D., Dorota M. Matecka, Ph.D., Joette M. Meyer, Pharm.D., Andrea N. Meyerhoff, M.D., Robert E. Osterberg, Ph.D., John H. Powers, M.D., Leonard V. Sacks, M.D., Norman R. Schmuff, Ph.D., Liji Shen, Ph.D., Nancy Paul Silliman, Ph.D.,** and **Sheryl L. Lard Whiteford, Ph.D.;** PHS Unit Commendation: **LCDR Valerie E. Jensen, CAPT Sandra L. Kweder, CDR Eric A. Mann, CDR Evelyn M. Rodriguez** and **CDR Jo Ann Spearmon.**

Near Infrared Team: **Everett H. Jefferson, Thomas P. Layloff, Ph.D.,** and **John A. Spencer, Ph.D.**

National Testing Laboratory Taskforce: **Lawrence W. Farina, Gary J. Lehr, Melissa J. Maust, Luann M. Pallas, Tej N. Poonai, Kim A. Rice** and **Vilayat A. Sayed, Ph.D.**

OCPB Reproductive and Urologic Review Team: **Dhruba J. Chatterjee, Ph.D., Sam H. Haidar, Ph.D., Venkateswar Jarugula, Ph.D., Sze W. Lau, Soraya Madani, Ph.D.,** and **Ameeta Parekh, Ph.D.**

OGD Chemistry Reviewers Team: **David J. Cummings** and **James M. Fan.**

OIT Web Internet Team: **Kathleen A. Bright, Gregory V. Brolund, Wilberforce E. Brooks Jr., Donovan F. Duggan II, Kenneth Edmunds Jr., Janet L. Gentry, Lana G. Kostecka, Mark A. Magee, Timothy D. Mahoney, Judith M. McIntyre, David M. Moss, Stacey L. Nichols, Raye P. Parker, Heather W. Pierce, Rodney K. Smith, Vali M. Tschirgi, Jennifer A. Wagner, Carolyn A. Yancey** and **Jerry Yokoyama.**

ONDC Microbiology Team: **Peter H. Cooney, Vivian Greenman, Patricia Hughes, CAPT David Hussong, Bryan S. Riley, Ph.D., Paul S. Stinavage, Neal J. Sweeney** and **Carol K. Vincent.**

ORM Redesign Group: **Suzanne M. Childs, Bronwyn E. Collier, Maria R. Cook, Michael M. Folkendt, Gaynell Fritz, Enid M. Galliers, Gary M. Gensinger, Mark A. Gray, Michael L. Lanthier, Natalia A. Morgenstern, Darlene V. Norris, John P. O'Malley, Leah W. Ripper, Linda G. Stone, Carolyn A. Yancey;** PHS Unit Commendation: **CAPT Elaine G.E. Abraham, CAPT Anthony W. DeCicco, LCDR Ellen C. Frank, CDR Michael D. Jones, CAPT Anna M. Myers, CAPT Robbin M. Nighswander** and **CAPT Cathie L. Schumaker.**

PEDEX Team: **Suresh Doddapaneni,**

(Continued on page 9)

HHS EMPLOYEE OF THE MONTH

Sherwood Cited for Exceptional Performance in OGD, OPS

Ted Sherwood in the Office of Pharmaceutical Science received the April HHS Employee of the Month Award. Center Director **Janet Woodcock, M.D.,** and **Helen Winkle,** Acting Director of the Office of Pharmaceutical Science, presented the award at the CDER Spring Honor Awards Ceremony on June 16.

Sherwood serves as an invaluable and outstanding advisor and management facilitator for the Office of Pharmaceutical Science in a variety of capacities. Over the last few years, he served as a special assistant to the director and deputy director of the Office of Generic Drugs and subsequently to the OPS director, deputy directors and, currently, the acting director.

He has supported and assisted with the development and implementation of a variety of significant initiatives for OPS and OGD and has performed all assignments in an outstanding manner.

Sherwood's performance consistently exemplifies the highest standards of excellence and dedication to OPS and CDER.

Sherwood is the consummate professional employee. He is very dedicated and conscientious in the performance of his duties. He demonstrates exceptional initiative in the performance of all of his duties and does what is needed without having to be asked.

He willingly works many extra hours without compensation to ensure that the job is done well and that the needs and interests of OPS and CDER are effectively met.

The HHS employee of the month award recognizes those whose talents and daily activities show the dedication and exemplary acts and services that have made the FDA and the department a success. The award rotates through each major organization in HHS on a 14-month cycle, and April was CDER's month.

Nominees for this award must have provided overall excellent services to a center or office in FDA enabling its efficient operation as well as demonstrating initiative, persistence and adaptability in performing their duties or demonstrating the ability to work as a team member.

—Jackie Barber

7 Individual, 8 Group Awards Presented at FDA Ceremony

(Continued from page 8)

Ph.D., Patrick J. Marroum, Ph.D., Prabhu Rajagopalan, Ph.D., Arzu Selen, Ph.D., Eva Maria Sunzel, Ph.D., and **Venkata R. S. Uppoor, Ph.D.**

Pediatric Tracking Team: **Renata Albrecht, M.D., Gail Y. Chotoff, Steven R. Gitterman, CDR Steven I. Hirschfeld, Victoria Kao, John D. Mahoney, Stacey Nichols** and **Rigoberto A. Roca.**

Unapproved, New Drug and Prescription Drug Labeling Team: **Herb Gerstenzang Ada Irizarry John P. Loh Betty McRoy Margaret M. O'Rourke James R. Rowell Melvin F. Szymanski** and **Sakineh H. Walther;** PHS Unit Commendation: **CAPT Joan C. Ginetis.**

FDA Ceremony

The following awards were presented at FDA's ceremony held June 23:

Award of Merit

Maureen P. Dillon-Parker

Ralph Lillie, R.Ph.

Mary D. Murphy, M.D.

Nancy B. Sager

Helen N. Winkle

Educational Campaign Design Team: **Ellen Shapiro, Wendy K. Stanfield** and **Marcia L. Trenter.**

Y2K Readiness Initiative Team: **Mark J. Goldberger, M.D.,** and **Khyati N. Roberts.**

FDA Commendable Service

FDA Libraries Consortium: **Harriet B. Albersheim, Deborah H. Brooks** and **Karen M. Kapust, Susan Laney-Sheehan, Anna T. McGowan** and **Patricia K. Michalowskij.**

Post-Approval Changes Working Group: **Dennis M. Bensley Jr., Ph.D., Nicholas Buhay, Chi-wan Chen, Ph.D., Yuan Yuan Chiu, Ph.D., Margaret E. Cunningham, Rebecca A. Devine, Ph.D., Eric P. Duffy, Ph.D., Bonnie B. Dunn, Ph.D., Florence S. Fang, John J. Gibbs, Ph.D., Carol J. Haley, Ph.D., Charles P. Hoiberg, Ph.D., Frank O. Holcombe Jr., Ph.D., Mai X. Huynh, Steven R. Koepke, Ph.D., William G. Marnane, Melissa J. Maust, G. Bert Mitchell, DVM, Howard P. Muller Jr., Susan H. O'Malley, Hasmukh B. Patel, Ph.D., Rashmikant M. Patel, Ph.D., Glenn A. Peterson, Ph.D., Denver Presley Jr., Allen Rudman, Ph.D., Nancy B. Sager, Vilaya Sayeed, Ph.D., Eric B. Sheinin, Ph.D., John E. Simmons, Ph.D., Michael D. Smedley, Kasturi Srinivasachar, Ph.D.,** and **Robert A. Yetter, Ph.D.**

FDA Group Recognition

Dioxin Working Group: **Jane A. Axelrad, Esq., Norman W. Baylor, Ph.D., Frederick W. Blumenschein, Yuan Yuan Chiu, Ph.D., Nancy E. Derr, Eric P. Duffy, Ph.D., Joseph Famulare, Ali Al Hakim, Ph.D., Christopher C. Joneckis, David B. Lewis, Ph.D., John C. Matheson III, Robert E. Osterberg, Ph.D., Brenda W. Urantai, Ph.D.,** and **Robert A. Yetter, Ph.D.**

Joint ADE CDER-ORA-OCC Compliance Team: **Christine M. Cerenzio, Min Chu Chen, R.Ph., Nancy Haggard, Diana M. Hernandez, Claudia B. Karwoski, Carol L. Krueger, Kathryn A. O'Connel, Robert M. Spiller Jr., Amarilys Vega** and **Kevin D. White;** PHS Unit Commendation: **LT Lisa B. Hall.**

Mercury FDAMA Section 413(a)—List and Analysis Work Group: **Norman W. Baylor, Ph.D., Marina Y. Chang, Linda M. Katz, M.D., Erica L. Keys, J.D., Babette A. Merritt, Valerie J. Miguele, Gloria J. Overholster, J.D., Gerald M. Rachanow, J.D., Linda W. Roberts** and **Tracey S. Zoetis;** PHS Unit Commendation: **CDR Leslie K. Ball** and **CAPT William C. Keller**

PHS Meritorious Service Medal

CAPT Sandra L. Kweder

PHS Outstanding Service Medal

CDR Edward D. Bashaw

Jackie Barber is the Center's Incentive Awards Officer.

Center Honors Volunteer Instructors for '99-'00 Academic Year

By Chris Nguyen

The Division of Training and Development, Office of Training and Communications, held an Instructors' Awards Ceremony on June 23 in Gaithersburg to honor those who volunteered their time and expertise to teach courses during the 1999-2000 academic year.

In opening remarks that kicked off the ceremony, OTCOM Director **Nancy Smith, Ph.D.,** expressed her appreciation and thanks to all the instructors for their effort and involvement. DTD Director **Janice Newcomb** followed by welcoming the group and conveying thanks from the DTD project managers who presented the awards.

The courses and instructors were:

Risk Management Workshop: **Tracy Acker, Linda Brophy, Laurie Burke, John Feeney, Elaine Frost, Deborah Henderson, Peter Honig, M.D., Robert Hopkins, Dianne L. Kennedy, R.Ph., MPH, Chin Koerner, Sandra L.Kweder, M.D., Thomas Laughren, M.D., Randy Levin, M.D., Iris Masucci, Pharm.D., Cynthia McCormick, M.D., Nancy Ostrove, Ph.D., Leah Palmer, Pharm.D., Evelyn Rodriguez, M.D., Nancy D. Smith, Ph.D., Robert J. Temple, M.D.,** and **Steve Wilson, Ph.D.**

The Biopharmaceutic Classification System Guidance Training: Mei-Ling **Chen, Ph.D., Dale P. Conner, Pharm.D., Ajaz Hussain, Ph.D., Carol Kim, Larry Lesko, Ph.D., Robbe C. Lyon, Ph.D., Mehul Mehta, Ph.D., Vanitha Sekar, Ph.D., Vinod P. Shah, Ph.D., Donna A. Volpe, Ph.D.,** and **Lawrence Yu, Ph.D.**

DIA/FDA Workshop—Overview of the Pharmaceutical Industry for the Regulatory Agency Manager and Reviewer: The Drug Development Process, the Drug Life Cycle and the People Who Manage Them: **Susan Allen, M.D., MPH, Lisa Rarick, M.D.,** and **Nancy D. Smith, Ph.D.**

Human Pregnancy Outcome Data: **Sandra L. Kweder, M.D.,** and **David E. Morse, Ph.D.**

FDA/Industry Container Closure Packaging Guidance Training: **Mike Adams, Frank Holcombe, Donald Klein, Ph.D., Melissa Maust, Ph.D., John Smith** and **James D. Vidra, Ph.D.**

Financial Disclosure Rule Guidance Training: **Linda Carter** and **Robert J. Temple, M.D.**

Applied Pharmacoepidemiology: **David Graham, M.D., Murray M. Lumpkin, M.D., Evelyn Rodriguez, M.D.,** and **Judy A. Staffa, Ph.D., R.Ph.**

Regulatory Science: **Dennis Bashaw, Pharm.D., Yuan-Yuan Chiu, Ph.D., Bronwyn Collier, Claudia Karwoski, Thomas Laughren, M.D., Robert Osterberg, Ph.D., Nancy Ostrove, Ph.D., Grant Williams, Ph.D.,** and **Steve Wilson, Ph.D.**

Pharmacokinetics and Pharmacodynamics for Reviewers: **Dennis Bashaw, Pharm.D., Mei-Ling Chen, Ph.D., Suresh Doddapaneni, Ph.D., Angelica Dorantes, Ph.D., Joga Gobburu, Ph.D., Shiew-Mei Huang, Ph.D., Venkat Jarugula, Ph.D., Ron Kavanagh, Ph.D., David Lee, Ph.D., Sue-Chih Lee, Ph.D., Peter Lee, Ph.D., Larry Lesko, Ph.D., Stella G. Machado, Ph.D., Joette Meyer, Ph.D., Young Moon Choi, Ph.D., Ameeta Parekh, Ph.D., Gabriel Robbie, Ph.D., Chandra Sahajwalla, Ph.D., Arzu Selen, Ph.D., Robert Shore, Pharm.D., Maria Sunzel, Ph.D., Dan Wang, Ph.D., Gene Williams, Ph.D.,** and **Jenny Zheng, Ph.D.**

New Employee Orientation: **Thomas W. Abrams, Robert Berger, Laura Bradbard, Jason Brodsky, Susan Carey, Magdalene D. Carolan, Heather Chafin, Lois Chester, Gail Chotoff, Leanne Cusumano, Elaine Frost, Michael Jones, Deborah Kallgren, Karen Kapust, Karen Koenick, Lana Kostecka, Kathy Kruse, William Ledford, Andrea Masiale, Nancy Muir, J. Sanford Williams, Ellen Shapiro, Ted Sherwood, John Simmons, Sally Winthrop, Crystal Wyand** and **Robert Young.**

Introduction to Design, Conduct and Review—Clinical Trials in Drug Development: **Aloka Chakravarty, Ph.D., Victor F.C. Raczkowski, M.D., M.Sc., Kathy Robie-Suh, M.D., Ph.D., Grant Williams, M.D.,** and **Steve Wilson, Ph.D.**

CDER Support Staff Knowledge Exchange: **Deborah Henderson** and **Barry Poole.**

New Reviewers Workshop: **Funmilayo Ajayi, Ph.D., Susan Allen, M.D., MPH, Carol Assouad, Celeste Bové, Paul Brown, Ph.D., Magdalene D. Carolan, Igor Cerny, Pharm.D., Kim Colangelo, Jonathan Cook, Susan Cruzan , Gregory Davis, Tricia DeSantis, Bonnie B. Dunn, Ph.D., Antonine El-Hage, Amy Ellis, Patrick Faustino, Mark Goldberger, M.D., Deborah Henderson, Dena Hixon, Brenda Holmes, Abby Jacobs, Heidi Jolson, Linda Katz, M.D., MPH, Lydia Kieffer, Pharm.D., Kathy Kruse, Kofi Kumi, David Lester, Ph.D., Randy Levin, M.D., Ralph Lillie, Sheldon Markofsky, Norman Marks, M.D., Frederick J. Marsik, Ph.D., Iris Masucci, Pharm.D., Kathie McConnell, Kate Meaker, M.S., Joy Mele, Jim Morrison, Nichelle Cherry, Lana L. Pauls, MPH, Lisa Rarick, M.D., Monica Revelle, Evelyn Rodriguez, M.D., Terri Rumble, Nancy D. Smith, Ph.D., Lisa Stockbridge, Kimberly Topper, Rajendra Uppoor, Ph.D., Michael Verdi, Andrea Weir, Ph.D., Steve Wilson, Ph.D., Sally Winthrop** and **Janet Woodcock, M.D.**

Basic Topics in Applied Statistics—Survival Data Analysis: **Kate Meaker.**

Topics in Applied Statistics—Evaluating the Accuracy of a Diagnostic Test: **Victor F.C. Raczkowski, M.D., M.Sc.,** and **Michael Welch, Ph.D.**

Drug-Induced Hepatotoxicity: **Jerry M. Collins, Ph.D., David Graham, M.D., MPH, Thomas Laughren, M.D., John Senior, M.D.,** and **Robert J. Temple, M.D.**

Successful Meetings and Minutes: **Jean Yager, Julieann Dubeau, Maureen Pelosi, Deborah Kallgren, Patrick Guinn, Chin Koerner** and **Alvis Dunson.**

Basic Concepts of the CDER Review Process for Non-Reviewers: **Tanya Abbott, Thomas W. Abrams, Margaret Bell, Linda Brophy, Ruth Clements, Beverly Friedman, Deborah Henderson, Bobbi**

(Continued on page 11)

Malaria Treatment OK'd; Generic Recalled; New Use for Fluoxetine

On July 14, FDA approved Malarone, a new combination drug for the prevention and treatment of acute, uncomplicated *P. falciparum* malaria. Malarone is a combination of atovaquone and proguanil HCL. Atovaquone is currently marketed in the United States under the trade name Mepron for *pneumocystis carinii pneumonia.* Proguanil was approved in the United States in 1948 for use in malaria. Because it was not widely used in this country, it ceased to be marketed here in the 1970s.

Malarone has been shown to be effective in regions where resistance to other anti-malarial drugs has developed. Malarone was evaluated for the treatment of malaria in adults, children, partially immune, and non-immune individuals. Eight active-controlled clinical trials were conducted in countries in Africa, Asia, South America, and Europe. Overall efficacy in 521 evaluable patients was 98.7 percent.

Malarone is manufactured by Glaxo Wellcome Inc. of Research Triangle Park, N.C.

FDA announced on July 10 the nationwide recall of SangCya oral solution, a generic version of the anti-rejection drug cyclosporine (Neoral oral solution), because of clinical evidence that the generic drug's availability is reduced relative to Neoral oral solution if the drug is administered with apple juice. Patients taking cyclosporine capsules are not affected by this recall.

SangStat Medical Corporation of Fremont, California, the makers of SangCya, recently informed the FDA about a study that was completed before the approval of the application. The data from this clinical study showed that taking SangCya oral solution with apple juice diminishes its absorption relative to Neoral oral solution. Because the drug's labeling suggests that it be taken with apple or orange juice, the Agency asked the sponsor to recall the product.

Since it is recognized that some patients may be adversely affected by abruptly changing from SangCya oral solution to another cyclosporine product, FDA will allow the product to remain in pharmacies and hospitals. This continued availability should allow a smooth transition of patients from the SangCya product to another cyclosporine product.

FDA is reviewing all data related to this product and will take any appropriate further steps needed to assure the safety of patients. In the meantime, patients taking cyclosporine oral solution should consult with their health care provider about their treatment.

FDA said on July 6 it had approved fluoxetine (Sarafem) as the first drug treatment for premenstrual dysphoric disorder, a condition that causes mood changes and physical symptoms such as bloating and breast tenderness. Fluoxetine, approved as Prozac in December l987 for treating depression, has also been approved for treating obsessive compulsive disorder and bulimia.

According to the American Psychiatric Association, a diagnosis of PMDD requires that patients experience at least five of the symptoms that characterize the condition. The disorder has both affective (mood) and physical symptoms, including depressed mood, anxiety, tension, affective lability (a tendency to alternate between cheerful and somber moods) and persistent anger or irritability.

Sarafem will be marketed by Eli Lilly, of Indianapolis, Ind., with a patient information brochure and physician labeling specific for the drug's use. The drug was not studied in women who were taking oral contraceptives. Common side effects were similar to those experienced by other fluoxetine users and included nausea, tiredness, nervousness, dizziness and difficulty concentrating.

DTD Instructor Awards

(Continued from page 10)

Jones, Michael Jones, Lana Kostecka, Mary Kremzner, Larry Lim, Andrea Masciale, Jim Morrison, Bill Myers, Bill Oswald, Evelyn Rodriguez, M.D., Ellen Shapiro, John Simmons, Nancy D. Smith, Ph.D., and **Karen Weller.**

Videoconferencing Skills: **Charles Rigsby** and **Pam Winbourne.**

Videoconferencing Focal Points: **Sousan Sayahtaheri Altaie, Ph.D., Meyer Katzper, Merla Matheny, Jamie Metz, Charles Rigsby, Chris Shipe, Doris Teresinski, William C. Timmer, Ph.D., Pam Winbourne, Donnie Wisner, Josie Yang, Ph.D.,** and **Elizabeth Yuan.**

Topics in Clinical Trials: **Susan Ellenberg. M.D., Thomas Laughren, M.D.,** and **Robert J. Temple, M.D.**

Fundamentals of Genetic Toxicology: **Aisar H. Atrakchi, Ph.D., R. Daniel Benz, Ph.D., Anita Bigger, Ph.D., Joseph DeGeorge, Ph.D., Rosalie Elespuru, Ph.D., James MacGregor, Ph.D.,** and **Michael J. Prival, Ph.D.**

Basic Statistical Methods: **Ruthanna Davi, Barbara Elashoff, Karen Higgins, Ph.D.,** and **Kate Meaker.**

Preclinical Pharmacokinetics and Toxicokinetics: **Aisar H. Atrakchi, Jerry M. Collins, Ph.D., Barbara Davit, Joseph DeGeorge, Ph.D., James Farrelly, Ph.D., Martin Dave Green, M.D., Peter Honig, M.D., Stephen Hundley, Gur Jai Pal Singh, John Koerner, Sandip Roy, Ph.D., Nakissa Sadrieh, Ph.D.,** and **Mark Vogel.**

Topics in Applied Imaging: **David Lester, Ph.D.,** and **Scott Pine.**

Committee for Advanced Scientific Education: chairperson, **Robin Huff, Ph.D.,** vice chairperson, **Sousan Sayahtaheri Altaie, Ph.D., Funmilayo Ajayi, Ph.D., Sonia Castillo, Marc Cavaillé-Coll, CAPT William A. Hess, Peter Honig, Shiew-Mei Huang, Ph.D., Meyer Katzper, Ph.D., Ken Kobayashi, Joyce Korvick, M.D., MPH, David Lester, Ph.D., Rik Lostritto, Pramoda Maturu, Ph.D., Juan Pelayo, Mary Purucker, Judith A. Racoosin, M.D., MPH, Evelyn Rodriguez, Sandip Roy, Ph.D., Nakissa Sadrieh, Ph.D., William C. Timmer, Ph.D., Kathleen Uhl, M.D., Andrea Weir, Ph.D., Josie Yang, DVM, Ph.D.,** and **Mona Zarifa, Ph.D.**

Chris Nguyen is a training specialist in DTD.

Center Opens Reexamination of OTC Drugs in 2-Day Public Meeting

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Currently, there are two ways in which a drug may be marketed over the counter. In the most common, FDA publishes monographs that establish acceptable ingredients, doses, formulations and consumer labeling. Products conforming to a final monograph may be marketed without further FDA clearance. Otherwise, drugs may be marketed under the terms of an approved new drug application. Such drugs have almost always been marketed first as prescription drugs.

Several presenters argued that FDA should avoid publishing a list of drugs or classes of drugs that would never be considered for OTC status. They proposed instead that FDA evaluate each request for OTC marketing on a case-by-case basis with its supporting scientific data.

A number of presenters called for greater efficiencies in finalizing monographs, noting that some have languished at FDA for two decades without action. Trade associations representing both prescription and OTC drug manufacturers argued in favor of the current system of manufacturer-initiated switches. Others argued that manufacturers of prescription drugs with a better safety and efficacy profile than current OTC drugs should be forced to market them over the counter.

In discussing which drugs should or should not be available over the counter, speakers on both days raised questions of consumer ability to self-diagnose, the circumvention of the doctor-patient relationship, increased risk of adverse reactions due to multiple medications, increased consumer out-of-pocket costs and societal issues relating to the availability of OTC oral contraceptives.

In an open exchange, panel members and speakers discussed the issues surrounding a third drug class that would be available without a prescription but only from a pharmacist. This class already exists in Canada and several other countries.

The second day was devoted to discussing issues related to these specific drug classes:

- *Oral contraceptives.* Although one speaker spoke of the safety posed to women by the use of prescription or OTC oral contraceptives, most of the speakers raised societal issues about OTC availability, specifically their use by minors and single women. They expressed concern that making oral contraceptives available without a prescription would lead to increased sexual activity among teens and a loss of parental guidance related to sexual activity.
- *Emergency contraceptives.* Most speakers favored the OTC availability of emergency contraceptives. The speakers cited statistics showing emergency contraceptives are more effective when taken as early as possible. OTC availability would avoid time lost in finding a physician and filling the prescription.
- *Cardiovascular drugs.* Patient self-diagnosis and follow-up monitoring were primary concerns. The need for prescription refills provides physicians an opportunity to monitor blood pressures or cholesterol levels.
- *Anti-microbials and antibiotics.* An increase in resistant strains was the main concern with increased access to anti-microbials and antibiotics. Consumer ability to self-diagnose and recognize that antibiotics are an ineffective treatment for a cold were also raised.
- *Allergy and asthma drugs.* Again, concerns focused on consumer self-diagnosis and treatment. Some current prescription allergy medications are less sedating and, in certain situations safer, than several current OTC drugs. Discussions focused on whether FDA should initiate Rx-to-OTC switches for these drugs. Speakers also discussed whether prescription-strength asthma medications could be safely used without a health-care provider's oversight.

FDA will be accepting written comments on OTC issues until Aug. 25. In addition to Dr. DeLap, other members of the panel included: **Russell Campbell,** Office of Consumer Affairs; **David Fox, J.D.,** Office of Chief Council; **Louis Cantilena, M.D., Ph.D.,** member of the Nonprescription Drugs Advisory Committee and **Sandra Titus, Ph.D.,** executive secretary of the committee; and, from CDER, **Gary Chikami, M.D.,Charles Ganley, M.D., Ph.D, Florence Houn, M.D., John Jenkins, M.D., Dianne Murphy, M.D., Robert Temple, M.D.,** and **Janet Woodcock, M.D.,** .

Sherunda Lister is a public affairs specialist in the Office of Training and Communications.

Visiting Professor Lecture Series Successfully Piloted

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offices. The informal format was chosen for maximum discussion and feedback.

The Office of Training and Communication will fund the program. General questions can be sent to Jane McCarthy (MCCARTHYE, 7-3492). Suggestions for content and subject matter experts should be sent to the scientific contact listed below.

Contacts for medical review divisions in the Office of Review Management are:

- **Susan Altaie, Ph.D.,** (DAIDP).
- **Narayana Battula, Ph.D.,** (DAVDP).
- **Mark Hirsch, M.D.,** (DRUDP).
- **Robin Huff, Ph.D.,** (DPDP).
- **Joyce Korvick, M.D.,** (DSPIDP).
- **Jane McCarthy, Ph.D.,** (DACCADP).
- **Richard Pazdur, M.D.,** (DODP).
- **Juan Pelayo, M.D.,** (DCRDP).
- **Mary Purucker, M.D.,** (DMEDP).
- **Judith Racoosin, M.D.,** (DNDP).
- **Sandip Roy, Ph.D.,** (DGICDP).
- **Nakissa Sadrieh, Ph.D.,** (DMIRDP).
- **Bill Timmer, Ph.D.,** (DDDDP).
- **James Witter, M.D.,** (DAIAODP).
- **Josie Yang, Ph.D.,** (DOTCDP).

Other ORM contacts are **Evelyn Rodriguez, M.D.,** (Office of Post Marketing Drug Risk Assessment) and **Sonia Castillo, Ph.D.,** (Office of Biostatistics).

Contacts in the Office of Pharmaceutical Science are **Gary Beuhler** (Office of Generic Drugs); **Shiew-Mei Huang, Ph.D.,** (Office of Clinical Pharmacology and Biopharmaceutics); **Mona Zarifa, Ph.D.,** (Office of New Drug Chemistry); and **David Lester, Ph.D.,** (Office of Testing and Research).

Bill Hess is the Office of Information Technology contact.

E. Jane McCarthy is administering the Visiting Professor Lecture Series for the Division of Training and Development.