news along the pike

September 2006

Center for Drug Evaluation and Research

Volume 12, Issue 1

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News Along the Pike

September 15, 2006

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Have ideas, news or comments to contribute? Please e-mail a member of the editorial team:
Editor: **Norman "Joe" Oliver**
Associate Editors: **Patrick Clarke, Sherunda Lister**

Joe's Notebook

Welcome to the new look; name the new *Pike* contest

By Norman "Joe" Oliver

It's been increasingly apparent that the print-oriented version of the *News Along the Pike* was taking too much time to edit and format. Consequently, when other projects came up that couldn't be put off, editing the Pike took second place. A major project, like the *CDER Report to the Nation,* put the Pike on a six-month or longer hiatus.

Well, that's all going to change. There's a new print layout that makes it easier to accommodate your stories with a minimum of formatting and editing.

We are returning to a monthly publication cycle. Deadline for you to submit your articles is the 15th of each month. That gives us a few days to edit and a few days for the center director's office to clear the newsletter for publication.

As you can see from the new layout, we will cut and paste your articles into the layout program as we get them. The new format also provides an easier to read document for those who prefer the print version to the online version. If you read the online version, you'll notice the similarity. It will speed up the conversion process for us.

Name the new *Pike* contest

With most of you at White Oak, the name of the newsletter is overdue for a change. So think of a name and e-mail it to me. Dr. Galson and friends will pick the winner. We have an assortment of prizes for the winner and runners-up. Win or lose, the first 10 entrants will get their very own *News Along the Pike* coffee cup.

What we look for in *Pike* articles

We like to see articles from you that explain your programs, problems and solutions. How does what you do help your colleagues in the Center do their work better? What is the public health problem you are addressing? How does your program help solve that problem?

The *Pike* and the *Report to the Nation* are mutually supporting. Most entries in the *Report* began at some point as *Pike* articles.

Who is the audience?

We assume that our readers are well-educated and interested in the Center's work. We don't assume, however, that they share the same technical, regulatory, medical or scientific background that our authors have. When editing, we try to make sure that folks with different backgrounds can understand the article, without resorting to a medical dictionary or the *Code of Federal Regulations.*

How to write for the Pike

It's always best to write the way you would if you were writing a letter to a friend or relative explaining what you do. The editors will take care of polishing it up for either *News Along the Pike* or the *Report to the Nation.*

Some of the things we will do when we get your story are:

- Find the main point and make sure it's stated up front.
- Edit for style and grammar using the Associated Press *Stylebook.*
- Make use of Plain Language techniques such as bulleting lists and clumping related information together.
- Ensure that technical, medical and scientific terms are adequately explained.
- Eliminate the use of most abbreviations and acronyms. We are OK with FDA and CDER. Beyond that, we think you need to justify using them. We think many of our readers are not familiar with our organizational structure and the abbreviations of our structural units. You should mention your division or office once and then use common nouns such as "division" or "office."

When to write for the Pike

Right now! We are no longer going to pad the *Pike* out with rehashed news releases and talk papers. We think you have adequate access to those in this electronic age. We want to know what YOU are doing.

CDER ceremony honors 70 individuals, 31 groups

Dr. Galson cites resourcefulness, innovation, teamwork

By Jackie Barber Washington

During CDER's Fall Honor Awards Ceremony, the Center's top managers presented 70 individual awards and 31 group or team awards. The ceremony was opened by the PHS Honor Corps, and Tracy O'Neill sang the National Anthem.

Opening remarks presented by Center Director **Steven K. Galson, M.D., MPH,** encompassed CDER's move to the new White Oak Campus and the deployment of many employees to assist with the hurricane and disaster relief effort and the implementation of organizational changes and new initiatives. He said that these additional responsibilities and challenges have been met with resourcefulness, innovation and teamwork by the CDER community Dr. Galson and Deputy Center Director **Douglas Throckmorton, M.D.,** presented the awards along with CDER's senior staff. The awards presented at the ceremony were:

FDA Outstanding Service Award

Frederick Blumenschein
Gerald Dal Pan, M.D.
Barbara Jones
Myong-Jin Kim, Pharm.D.
Cindy Kortepeter, Pharm.D.
Joyce Korvick, M.D., MPH
Kooros Mahjoob, Ph.D.
Eileen Navarro, M.D.
Kelly Phelan
Meiyu Shen, Ph.D.
Yi Tsong, Ph.D.

NSAID Scientific Review Team: **Renan Bonnel, Pharm.D., MPH, Jonca Bull, M.D., Gerald Dal Pan, M.D., Jane Dean, Barbara Gould, Laura Governale, Pharm.D., David Graham, M.D., MPH, Brian Harvey, M.D., Ph.D., Sharon Hertz, M.D., John Jenkins, M.D., Lauren Lee, Pharm.D., Coralee Lemley, Qian, Li, Sc.D., Aaron Mendelsohn, Ph.D., MPH, Robert Meyer M.D., Robert O'Neill, Ph.D., Joel Schiffenbauer, M.D., Judy Staffa, Ph.D., Robert Temple, M.D., Yi Tsong, Ph.D., Maria Villalba, M.D., James Witter, M.D., Joann Zhang, Ph.D.** PHS officers nominated for companion award: **CAPT Sandra Kweder, CAPT Paul Seligman, CAPT Anne Trontell.**

Ortho-Evra Team: **Evelyn Farinas, R.Ph.,** and **Rita Ouellet-Hellstrom, Ph.D., MPH**

FDA Leveraging/Collaboration Award

Mandy Eisemann
Florence Houn, M.D., MPH

Pediatric Multi-Disciplinary Review Group: **Paul Andreason, M.D., ShaAvhree Buckman, M.D., Ph.D., Kate Gelperin, M.D., Laura Governale, Pharm.D., Solomon Iyasu, M.D., MPH, Ronald Kavanagh, Ph.D., Cindy Kortepeter, Pharm.D., David Jacobson-Kram, Ph.D., Susan McCune, M.D.,** and **Kathleen Phelan, R.Ph.**

PHS Commendation Medals

CAPT Paul Andreason
LCDR Renu Chhabra
CDR Ruthann Giusti
LT Elaine Hu
CDR Joseph Johnson
CDR Jean Makie
CAPT Justina Molzon
LCDR Narayan Nair
CDR Armando Oliva
LT Stephan Ortiz
LCDR Tejashri Purohit-Sheth
LT Melissa Robb
LCDR Jouhayana Saliba
LT Rebecca Saville
LT Yon Yu

Center Director's Special Citation

Ann Corken Mackey, R.Ph., MPH
Mary Singer, M.D., Ph.D.

BIMS to DMF Data Migration Team: **Wendy Aaronson, Sharon Brownewell, Roger Eastep, Arthur Shaw, M.D., Linda Sigg, Lonnie Smith** and **CAPT Cathie Schumaker.**

BIMS to DMF Data Support Team: **Eric Gonitzke, Jonathan Lenko, Bethany Lenko, Lisa Wilder, Charlene Do** and **CDR Kellie Clelland.**

CDER Situation Room Team: **Rosemary Addy,**

ShaAhvree Buckman, M.D., Larry Cress, M.D., Joan Flaherty, Joanne Holmes, MPH, Brad Leissa, M.D., Susan McCune, M.D., Shirley Murphy, M.D., Frank Pelsor, Ph.D., Denise Pica-Branco, Rosemary Roberts, M.D., Hari Sachs, M.D., Lewis Schrager, M.D., Alan Shapiro, M.D., Alla Shapiro, M.D., Cheryl Turner, Dorothy Wawrose, M.D., and **Su Yang.** PHS officers nominated for companion award: **LCDR Michael Bourg, LTJG Thomas Christl, CDR Narayan Nair, LCDR Tracy MacGill, CDR Lisa Mathi** and **CDR Mitchell Mathis Jr.**

Isotretinoin Small Working Group: **Jeanine Best, Kalyani Bhatt, Allen Brinker, M.D., Jill Lindstrom, M.D., Claudia Karwoski, Pharm.D., Cynthia Kornegay, Ph.D., Lauren Lee, Pharm.D., Gerard Nahum, M.D., Parivash Nourjah, Ph.D., Toni Piazza-Hepp, Pharm.D., Marilyn Pitts, Pharm.D.,** and **Janice Steinschnieder.** PHS officers nominated for companion award: **CAPT Rita Hassall** and **CAPT Dianne Kennedy**

CDER Special Recognition

Paul Brown, Ph.D.
Charles Cooper, M.D.
Cheryl Dixon, Ph.D.
Kathleen Fritsch, Ph.D.
Stephen Hundley, Ph.D.
Frederick Hyman, DDS, MPH
M. Lisa Jones, M.D., MPH
Qian Li, Sc.D.
Jill Merrill, Ph.D.
Srikanth Nallani, Ph.D.
Bindi Nikhar, M.D.
Carol Pamer, R.Ph.
Kurt Stromberg, Ph.D.
Thamban Valappil, Ph.D.
Jyoti Zalkikar, Ph.D.
Derek Zhang, Ph.D.

Oncology Team: **Sophia Abraham, Ph.D., Brian Booth, Ph.D., Angela Men, Ph.D., Roshni Ramchandani, Ph.D.,** and **Gene Williams, Ph.D.**

CDER Dr. Frances O. Kelsey Drug Safety Excellence Award

Alice Hughes, M.D.

CDER Administrative/Program Management Excellence Award

Candee Chadwick
Pamela Hampton
Sandra Hill
Anne Wilcox
Ellen White
Gladys Wood

CDER Excellence in Community Service/Citizenship Award

Tammie Massie, Ph.D.

USPHS Pharmacists Professional Advisory Committee Workgroup: **Gururaj Bykadi, Ph.D.,** and **Kimberly Compton.** PHS officers nominated for companion award: **LT Kristina Arwine, LCDR Michelle Dillahunt, LCDR Tia Harper-Velazquez, CDR Carol Holquist, LCDR Jinhee Jahng, LCDR Brenda Marques, LCDR Nina Mezu-Nwaba, LT Paras Patel, LCDR Laura Pincock, CDR John Quinn, LCDR Nora Roselle, LCDR Melanie Shin, LCDR Tara Turner, LCDR Hawyee Yan** and **LT Zeo Zadecky.**

CDER Excellence in Communication Award

Kathleen Frost
Cecelia Parise
Lillian Patrician

CDER Oncology Small Business Working Group: **Robert Kane, M.D., Anne Pilaro, Ph.D., Haleh Saber-Mahloogi, Ph.D.,** and **William Timmer, Ph.D.**

CDER Packaging Technical Committee: **Albert Mueller, Ph.D., Hullahalli Prasanna, Ph.D., Joseph Prograr, Lorenzo Rocca, Mujahid Shaikh, James Vidra, Ph.D., Geoffrey Wong, Ph.D., Maria Ysern, Ph.D.,** and **Susan Zuk.**

Pediatric Research Information Team: **Rosemary Addy** and **Grace Carmouze.**

CDER Leadership Excellence Award

Dale Conner, Pharm.D.
Sharon Hertz, M.D.
Norman Stockbridge, M.D., Ph.D.

CDER Excellence In Mentoring Award

David Frucht, M.D.
Adebayo Laniyonu, Ph.D.
Antoinette Mason
Duckhee Toler

The Mentoring Machine: **Tanya Clayton, Julieann DuBeau, Ruyi He, M.D., Alice Kacuba, Lolita Lopez, M.D., Kathie Robie-Suh, M.D., Ph.D., George**

Shashaty, M.D., and **Ann Marie Trentacosti, M.D.**

CDER Project Management Excellence Award

Joan Flaherty

CDER Regulatory Science Excellence Award

Barbara Rellahan, Ph.D.

CDER Support Staff Excellence Award

Joan Broadwater
Patricia Downs
Pilar Martinez
Kelly Townsend

CDER Team Excellence Award

AtoZ Team: **Jennifer Coakley, Rebecca Jacob** and **Gary Masters.**

CDER Perrigo Infant Drops Recall Team: **Susan Allen, M.D., Kevin Budich, Walter Ellenberg, Ph.D., Robert Heller, Andrea Leonard-Segal, M.D., Curtis Rosebraugh, M.D., Daiva Shetty, M.D., Steven Silverman** and **Michael Verdi.**

CDER Visiting Professor Lecture Series Representatives: **Sonya Armstrong, Vikram Arya, Ph.D., Charles Bonapace, Pharm.D., Chandra Chaurasia, Ph.D., R.Ph., Ling Chen, Ph.D., Joan Flaherty, Ph.D., Federico Goodsaid, Ph.D., Mary Gross, Ruyi He, M.D., Shiew-Mei Huang, Ph.D., Leonard Kapacala, M.D., Mansoor Khan, Ph.D., Bing Li, Ph.,D., Jill Lindstrom, M.D., Markham Luke, M.D., Ph.D., Ann Corken Mackey, R.Ph., MPH, Patrick Nwakama, Pharm.D., Chris Nguyen, Jody Payne, Edwin Rock, M.D., Ph.D., Donald Stanski, M.D., Dianne Spillman, Orhan Suleiman, Ph.D., Sue Jane Wang, Ph.D., Huiquan Wu, Ph.D., Sally Yasuda, Pharm.D.** PHS officers nominated for companion award: **CAPT E. Jane McCarthy, CDR Virginia Giroux, CAPT John Kelsey, LCDR Tracy MacGill** and **LCDR Devvrat Patel.**

Center-Wide Scanning Project Team: **Rosanna Alston, Anthony Baldwin, Jared Barnhardt, Joshua Barnhardt, Lori Benner, Joy Bennett, Kyle Boyd, Martha Carter, Betty Clark, Tamika Conerly, Mary Cook, Nicole Cooper, Allison Dietz, Velma Cunningham, Eric Gonitzke, Patrick Gunn, Rita Hecker, Rhonda Hill, Mina Hohlen, Zei-Pao Huang, Norma Jiggetts, Heather Jones, Bethany Lenko, Jonathan Lenko, Monica Lewis, Linda Livingston, Jamie Metz, Diane Moore, Sheila Moore, Dolores Pinkney, Kim Robertson, Carol Rochester, Alexander Schaub, Lonnie Smith, Fayleen Susinno, Tisha Washington, Ellen White** and **Adam Zetts.**

Cilansetron Review Team: **Suliman Al-Fayoumi, Ph.D., Mark Avigan, M.D., Julie Beitz, M.D., Allen Brinker, M.D., Jeanine Best, Sushanta Chakder, Ph.D., Howard Chazin, M.D., Jasti Choudary, B.V.Sc., Ph.D., Bronwyn Collier, Ann Corken-Mackey, Gerald Dal Pan, M.D., Susan Daugherty, Gary Della'Zanna, Suresh Doddapaneni, Ph.D., Julieann DuBeau, Eric Duffy, Ph.D., Milton Fan, Ph.D., Ray Frankewich, Ph.D., Hugo Gallo-Torres, M.D., Ph.D., Laura Governale, Lahn Green, Pharm.D., MPH, Stella Grosser, Ph.D., Florence Houn, M.D., MPH, Russell Katz, M.D., Joyce Korvick, M.D., Claudia Korwoski, Thomas Marciniak, M.D., Khairy Malek, M.D., Ph.D., Parvish Nourjah, Ph.D., Kathy Robie-Suh, M.D., Ph.D., George Shashaty, M.D., Linda Wisniewski, Feng Zhou, Liang Zhou, Ph.D.** PHS officers nominated for companion award: **LCDR Shannon Benedetto, CDR Carol Holquist, CDR Quynh Nguyen, CAPT Anne Trontell** and **LT Kendra Worthy.**

Cluster ANDA Bioequivalence Review Team: **James Chaney, Kuldeep Dhariwal, Ph.D., Xiaojiang Jiang, Ph.D., Jenny Lee, Shirley Lu, Ph.D., Moheb Makary, Ph.D., Shriniwas Nerurkar, Ph.D., Hoainhon Nguyen, Sikta Pradhan, Ph.D., Surendra Shrivastava, Ph.D., Gur Singh, Ph.D., Ethan Stier, Ph.D.** PHS officers nominated for companion award: **CDR Beth Fabian-Fritsch, LT Sheryl Gunther, LCDR Connie Jung, CDR Steven Mazzella, LCDR James Osterhout, LCDR Devvrat Patel, LT Paul Seo** and **LCDR Aaron Sigler.**

Division of Bioequivalence Review Seminar Organizing Committee: **Barbara Davit, Ph.D.,** and **Ethan Stier, Ph.D.** PHS officers nominated for companion award: **CDR Beth Fabian-Fritsch, LT Sheryl Gunther, LCDR Connie Jung** and **LCDR James Osterhout.**

Healthcare Antiseptic Review Team: **Tia Frazier, Michelle Jackson, Ph.D., Debbie Lumpkins, Steven Osborne, M.D., Colleen Rogers, Ph.D., Thamban Valappil, Ph.D.,** and **Eric Zhou, Ph.D.**

Hematology Review Team: **Ryan Barraco, Andrew Dmytrijuk, M.D., Ali Hakim, Ruyi He, M.D., Ron Honchel, David Joseph, Alice Kacuba, Min Lu, M.D.,**

Diane Moore, Kathy Robie-Suh, M.D., Ph.D., George Shashaty, M.D. and **Liang Zhou.**

Late Radiation Toxicity Team: **Siham Biade, Ph.D., Tushar Kokate, Ph.D., Adebayo Laniyonu, Ph.D., Sally Loewke, M.D., George Mills, M.D., Yanli Ouyang, Ph.D., Renee Tyson** and **Robert Yaes, M.D., Ph.D.**

MedDRA Terminology Team: **Linda Kim-Jung, Pharm.D.,** and **Maria Thomas, M.D.**

OPS Level III Detail Coordination Group: **Ali Afnan, Ph.D., Ralph Bernstein, Ph.D., Eileen Cole, David Cummings, Mark Darj, Ph.D., Lynne Ensor, Ph.D., Yung Hsieh, Ph.D., Mansoor Khan, Ph.D., Joseph Kutza III, Ph.D., Stephen Langille, Ph.D., Larry Ouderkirk, Sarah Pope, Ph.D., Mark Seggel, Ph.D., David Skanchy, Ph.D., Rajendra Uppoor, David Watts, Ph.D., Benjamin Westenberger, Ph.D., Kathy Woodland-Outlaw** and **Huiquan Wu, Ph.D.**

Palladone Working Group: **Lucinda Bushe, Ph.D., Mei-Ling Chen, Ph.D., Andrew Fussner, Zongming Gao, Ph.D., Abhay Guypta, Ph.D., Ajaz Hussain, Ph.D., Ravindra Kasliwal, Ph.D., Mansoor Khan, Ph.D., Vincent Lee, Ph.D., Mehul Mehata, Ph.D., Robert Meyer, Ph.D., Terry Moore, Moheb Nasr, Ph.D., Hullahalli Prassana, Ph.D., Nakissa Sadrieh, Ph.D., Vilayat Sayeed, Ph.D., Rakhi Shah, Ph.D., Edward Sherwood, John Simmons, Ph.D., Anjanette Smith, Solomon Sobel, M.D., Mobin Tawakkul, Ramana Uppoor, Ph.D., Benjamin Westenberger, Ph.D.,** and **Lawrence Yu, Ph.D.**

Pharmakon Litigation Team: **Deborah Autor, Marc Caden, Robert Eshelman, Brian Hasselbalch, Linda Hu, M.D., Rosa Motta, Steven Silverman, Janice Steinschneider** and **Sakinah Walther.**

Process/Transition Focus Group: **Mamta Gautam-Basak, Ph.D., Michael Folkendt, Rao Kambhampatai, Rapti Madurawe, Amit Mitra, James Vidra, Ph.D., Yvonne Yang.** PHS officer nominated for companion award: **CAPT Alan Schroeder.**

Subcommittee of the Reviewer Education Committee: **Ruthanna Davi, Cheryl Kaiser, Joette Meyer, Terri Rumble, Edward Sherwood** and **Jennifer Snellings.**

Today Sponge Review Team: **Julie Beitz, M.D., Jonca Bull, M.D., Helen Cothran, Jinhui Dou, Ph.D., Karen Feibus, M.D., Tia Fraizer, Charles Ganley, M.D., David Hilfiker, Linda Hu, M.D., Claudia Karwoski, Ph.D., Moheb Nasr, Ph.D., Rao Puttagunta, Ph.D., Andrea Leonard-Segal, M.D., John Smith, Ph.D.,** and **Arlene Solbeck.**

Tygacil Review Team: **John Alexander, M.D., Charles Cooper, M.D., Edward Cox, M.D., Maureen Dillion Parker, Mark Goldberger, M.D., MPH, Jarugual Venkat, Ph.D., Frances LeSane, Daphne Lin, Ph.D., Frederick Marsik, Robert Osterberg, Ph.D., Shrikant Pagay, Ph.D., David Roeder, Wendelyn Schmidt, Janice Soreth, M.D., Ana Szarfman, M.D., Mathew Thomas, M.D., Thamban Valappil, Ph.D., James Vidra, Ph.D.,** and **Yaning Wang, Ph.D.** PHS officers nominated for companion award: **CAPT Lillian Gavrilovich** and **LCDR Jeffery Tworzyanski.**

Jackie Barber-Washington is CDER's incentive awards officer.

Dr. Temple reflects on 30 years of improvements

Editor's note: Dr. Temple's article is adapted from his acceptance remarks for the 2005 Drug Information Association Distinguished Career Award.

By Robert J. Temple, M.D.

Career awards are scary. I watched Lewis B. Sheiner, M.D., receive a similar award—the 2004 Oscar B. Hunter Memorial Award in Therapeutics from the American Society for Clinical Pharmacology and Therapeutics.

One of the things he did at the award was show a survival curve of the award winners. A week after that, he died while traveling in Europe. So, none of that's going to happen—I have a better dose of statin than he did.

The DIA award offered a nice opportunity to reflect on what I've been doing for 30-plus years, and the thing you notice most, if you try to think back, is how different everything is. I doubt very many people will remember this, but in 1972 when I came, we at FDA and most people in industry were substantially clueless about how to do a proper randomized trial.

Some people knew—there were people at NIH who were

getting it—but mostly nobody knew much. We at FDA didn't help much. In fact, there was a viewpoint that if we helped someone design a trial, we were co-opted and couldn't properly review it. So people actually told me then that even when they saw a trial wasn't going to be any good and couldn't be used, they would let it go on because it would be wrong to do anything about it. That's ethically doubtful, and now in fact we can put a study like that on hold.

Meetings that we had then with industry were not very constructive and often fairly hostile. But things began to change a lot, which I think started with the arrival in 1973 of **J. Richard Crout, M.D.,** as director of the Bureau of Drugs, as the Center was known then. Dr. Crout, who served until 1982, was an academic and used to civilized discourse. He and **Marion Finkel, M.D.,** who directed what would now be called the Office of New Drugs, started massive changes: guidance documents were developed, we had advisory committees and things began to change.

For me, a major experience was participating in the Drug Efficacy Study Implementation. That was the program we conducted because we were obliged to review all the drugs we'd approved between 1938 and 1962 on the basis of safety only, to see if they worked.

We put out hundreds of reviews and Federal Register notices describing in enormous detail what was wrong with all the studies that had been submitted. It was a variety of incompetency experience—you learned all ways you could screw up a study. It was just fascinating. I was the final sign-off on most of those, so I got to see all of them. Nobody else can have that experience anymore, so that's too bad.

In 1972, we had maybe six or seven biostatisticians. Except for **Chuck Anello, Ph.D.,** and **Bob O'Neill, Ph.D.,** who is still here, most of them would be unrecognizable as statisticians. They were passionate about ethics and things like that, but they didn't know much about numbers.

Here are a few examples just to illustrate what we did. When cimetidine, the first H-2 antagonist came along—a very important drug—they did four studies of ulcer healing: two 2-week studies, a 4-week study and a 6-week study. As each patient completed the two weeks, four weeks or six weeks, they added up the score and calculated the P. As soon as the P value was less than 0.05, they stopped.

A novel, interesting approach—we didn't know. We wouldn't have even known that was not right. Nobody had ever thought about that before. The 2-week studies worked out for them, but the 4- and 6-week studies turned out a couple more cases came in after they crossed the 0.05 and it took them above. So their initial labeling never mentioned the 4- and 6-week studies. Obviously, nobody behaves that way now.

Around the same time, we got to review the Anturane Reinfarction Trial, a claim for sulfinpyrazone to prevent sudden death and reinfarction. We discovered at the end of the study six people who died on the active drug had been removed from the study because they really weren't qualified to be in the study. Of course, they did finish the study, in a sense.

Another major claim out of that study involved cause-specific mortality: sudden death versus heart attack death versus other death—and it was an entirely bogus procedure. So we had no idea about any of those things: that cause-specific mortality is treacherous, that you have to account for every patient, all of those things. Well, we've been learning them ever since.

We know about multiplicity, we're thinking about group sequential approaches and adapted designs and dose-response and non-inferiority studies—a very big deal, which actually I first raised at a DIA meeting in 1980. First time we actually thought about it much. Anyway, we didn't know any of those things when I first got there.

Safety reviews now (we all do an integrated summary of safety)—that concept was invisible prior to about 1980. I don't quite know what we did; I mean how else could you look at safety except to accumulate the data. But it was never discussed.

Actually, in a DIA paper for a meeting, I reviewed the history of that. Nobody thought about that before. We didn't focus on deaths and drop-outs, we didn't know that was important, all of those things.

So watching it change has been extraordinary. And probably the single thing about working in FDA that I notice most is the constant diverse input: you're doing legal thinking one day (not acting as a lawyer of course, that would be wrong), you're thinking about study design, you're negotiating. The infinite number of challenges; it's like a board game where people keep coming at you.

As anyone who reads the papers will notice, this is a tough time for FDA. People, including some internal people, are saying bad things about us, none of which I believe are true. It's interesting that when I arrived in 1972, the same thing was going on. There were stories in the newspapers about how devoted, loyal reviewers were being overruled by their cynical, sold-out managers. Really, the same thing; there were very, very unpleasant hearings before the Kennedy committee, they were very difficult. A review of the experience on the whole said that most of the charges were wrong.

But when I came, I had no idea what the reality was going to be. I had my own views of government agencies and they weren't entirely flattering. So I had no idea.

What I found, and what I believe is still true, is that the place was and is devoted to getting the right answer, it's perfectly comfortable with internal disagreement—celebrates it, in fact. It's been a wonderful place to work, and I've loved it all.

Dr. Temple is acting director of the Office of Drug Evaluation I and acting director of the Office of Medical Policy.

Office of Surveillance and Epidemiology

Contracts expand rapid evaluation of newly marketed drugs

By Judy A. Staffa, Ph.D., R.Ph.

In the Office of Surveillance and Epidemiology, we have strengthened our ability evaluate the safety of newly marketed drugs faster and more effectively. In September, we awarded four contracts at $1.6 million a year that give us access to databases that include more than 20 million patients in different geographic areas and include special populations. These contracts provide for up to five years of access to data resources that can be used to:

- Conduct safety analyses to benefit the public health.
- Respond in a timely manner to urgent public safety concerns.
- Provide a mechanism for collaborative pharmacoepidemiological research designed to test hypotheses, particularly those arising from suspected adverse reactions reported to us.
- Enable our rapid access to U.S. population-based data sources to ensure public safety when necessary.

In the past, our collaboration with researchers who have pharmacoepidemiologic databases was through a cooperative agreement or grant mechanism. This same type of research collaboration to conduct pharmacoepidemiologic studies will now occur through a contract mechanism. This will give us more flexibility and access to a wider range of data resources. The contractors and their unique resources are:

- *Kaiser Foundation Research Institute* has large, fully integrated databases, some dating back to 1981, representing all 6.1 million current Kaiser Permanente members in northern and southern California. The Kaiser databases are linked annually to state vital statistics and cancer registry files. . Electronic records will be fully implemented in 2006.
- *I3 Drug Safety* has access to claims data on a very large, geographically diverse, insured population having a total membership of 12 million (United Health Care). This contract also allows us to use i3 Drug Safety's new Web-based tool that allows us to quickly assess the feasibility of many drug safety studies relating to new molecular entities. Some laboratory data are also available.
- *Harvard Pilgrim Healthcare* represents a large experienced HMO research network of eight health plans geographically diversified within the states of Massachusetts, Maine, Minnesota, Washington, Colorado, Georgia and New Mexico having a total membership of 3.2 million. Electronic medical records are available for six of the eight sites.
- *Vanderbilt University* represents small but

ethnically diversified, state Medicaid populations who are medically at high risk, such as those with HIV infection, the poor, psychiatric patients and nursing home residents. These data represent 2.2 million recipients in Tennessee and Washington. This site includes data as far back as 1974 in Tennessee and also has linked maternal-child, cancer registry and other encounter files.

Judy Staffa is project officer for the contracts and a lead epidemiologist in the OSE Division of Surveillance, Research and Communications Support.

Pharm/Tox Corner

Fall Retreat focuses on nanotechnology, tissue cross-reactivity studies, guidances on National Formulary reference terminology, statistical consults for carcinogenicity studies, Pharm/Tox Web Page, Education Subcommittee updates

BY GARY P. BOND, PH.D., DABT

The pharm/tox semi-annual scientific retreat held in September gathered reviewers within CDER. The retreat started by opening remarks from chair **Haleh Saber-Mahloogi, Ph.D.,** and **John Leighton Ph.D., DABT. David Jacobson-Kram, Ph.D., DABT,** the associate director for pharm/tox in the Office of New Drugs, welcomed all to the meeting.

The fall retreat focused on:

- Nanotechnology.
- Tissue cross-reactivity studies.
- Guidances on national formulary reference terminology.
- Statistical consults for carcinogenicity studies.
- The Pharm/Tox intranet site.

Nanotechnology

FDA's activities dealing with the potential of nanotechnology on the products it regulates were discussed by **Nakissa Sadrieh, Ph.D.,** associate director for research policy and implementation in the Office of Pharmaceutical Science and **Steve Stern, Ph.D.,** from the National Cancer Institute's Nanotechnology Characterization Lab.

[Nanotechnology creates small materials at the scale of molecules by manipulating single atoms. A molecule's size is measured in nanometers or billionths of a meter.] FDA is engaged both on the scientific level and on the regulatory and policy level to address the possible challenges that products utilizing nanotechnology present:

- Scientifically, FDA is involved in a number of nanotechnology research projects.
- On the regulatory and policy level, FDA participates in various committees to coordinate the activities and policies of the government regulatory agencies.

At FDA, a NanoTechnology Interest Group, or NTIG, includes representatives from all FDA centers and all FDA offices that report directly to the Office of the Commissioner. Also, the center have established multidisciplinary working groups.

While the impact of nanotechnology and its applications is expected to be in the future, FDA has already approved many products with particle dimensions in the nanometer range. Specifically, there are imaging agents that have been on the market for a number of years with particles that are smaller than 100 nanometers. There are also reformulated products that contain nanoparticles of previously approved products, in order to improve product performance. Similarly, there are sunscreens and cosmetics where the particle size of titanium dioxide and zinc oxide are reported to be smaller than 100 nanometers.

Some novel platforms being developed, such as the multifunctional dendrimers, may require a multifaceted approach towards their review and evaluation.

Previously approved products with particles in the nanometer range were not considered to be nanotechnology products. They were, therefore subject to the same testing requirements as all other products. However, we expect some of these novel products utilizing nanotechnology will be combination products (i.e., drug-device, drug-biologic, or device-biologic).

While sponsors of nanotechnology products will be subject to the same testing requirements as non-nanotechnology products, there may be challenges before commercialization. Specifically, there will need to be an understanding of the physical and chemical parameters that are crucial to product performance. Additionally, appropriate test methods and specifications to control the product or the manufacturing processes will need to be developed.

Guidance/MaPP Updates

National Drug Formulary Reference Terminology MaPP and Guidance. **John Leighton, Ph.D. DABT,** a supervisory pharmacologist from the Division of Drug Oncology Products, discussed the draft guidance and MaPPs on the initiative for pharmacologic classification for the highlights section of labels. The guidance provides industry and our reviewers direction to access the National Drug File Reference Terminology, which was designed by the Veterans Administration to provide consistency in drug terminology use in healthcare.

MaPPs associated with the proposed guidance are intended to guide pharmacology and toxicology reviewers through the process of requesting new terminology if the appropriate terminology for pharmacologic classification for new molecular entities is not available. Terminology can be accessed publicly through the National Cancer Institute's Terminology Browser at http://nciterms.nci.nih.gov/NCIBrowser/Startup.do, and several examples were provided to retreat attendees.

Statistical Consults for CARC Studies. **Abby Jacobs, Ph.D.,** Assoc. Dir. Pharm/Tox ONDIO, talked about statistical consults for carcinogenicity studies. She emphasized the importance of good communication between the pharmacology/toxicology reviewer and the reviewing statistician. The talk covered the preliminary review by the pharmacology/toxicology reviewer, what to convey to the statistical reviewer, what to look for in the statistician's review and the importance of feedback to the statistician.

Tissue Cross-Reactivity

Tissue cross-reactivity studies for potential therapeutic antibodies that are included as part of the Pharmacology/Toxicology Sections of INDs were discussed by **Joan Wicks, DVM, Ph.D., DACVP; Shari Price-Schiavi, DVM, Ph.D., DACVP;** and **Jennifer Rojko, DVM, Ph.D., DACVP** of Charles River Laboratories, Pathology Associates, Molecular and Immunopathology Division.

The objectives of these studies are to identify expected and unexpected tissue binding (or cross-reactivity) of antibodies (test articles) in human and animal tissues and to evaluate the relevance of a given species for use in toxicity studies with that antibody.

Most potential therapeutic antibodies are chimeric, humanized or human. For these test articles, the most common staining methods include avidin-biotin complex (ABC) for a biotinylated test article, tertiary antibody detection for a FITC (or otherwise) labeled test article, or precomplexing with a labeled anti-human IgG for an unlabeled test article.

For all test articles, a species, isotype and, where appropriate, similarly labeled negative control antibody must be included to aid in evaluation of specificity of any staining observed with the test article. An assay control should also be included to define any background staining from the detection reagents themselves.

An appropriate positive control material may include one of the following: a tissue element or cell line known to express the target antigen, sepharose or agarose beads coated with the target antigen, or the target antigen spotted and cross-linked onto UV-resin slides. An appropriate negative control material may include a tissue element or cell line that does not express the target antigen, beads coated with an irrelevant antigen, or an irrelevant antigen spotted and cross-linked to UV-resin slides.

Specific reactions of the test article with the positive control material and the lack of specific reactivity with the negative control material, as well as lack of reactivity of the negative control antibody demonstrate the sensitivity, specificity and reproducibility of the assay. In a typical cross-reactivity study, a staining method most

appropriate for the test article is developed. In a typical 36 or 37 tissue cross-reactivity study, cryosections of normal human (3 unrelated donors) and/or animal (2 or 3 unrelated donors) tissues are stained.

The slides are evaluated first to see if the tissue is adequate and normal. Any staining observed is judged specific (CDR mediated) or nonspecific (non-CDR mediated) by comparison to the corresponding control slides and by the nature of the staining. Any specific staining is judged to be either an expected or unexpected reactivity based upon known expression of the target antigen in question. Any staining judged specific is scored for intensity, frequency, and staining affinity (where appropriate). A report containing a summary, introduction, materials and methods, results, and discussion is prepared and submitted to the Sponsor.

Regulatory Stance on Mutagenesis and Carcinogenesis. **Ed Matthews. Ph.D. and Joe Contrera, Ph.D.,** made a presentation entitled "A Retrospective Analysis of Genetic Toxicity, Reproductive Toxicity, and Carcinogenicity Data: Identification of Carcinogens Using Biomarkers and In Silico Methods." Both are from Office of Pharmaceutical Science. Dr. Matthews is from Science and Research Staff, and Dr. Contrera heads Informatics and Computational Safety Analysis Staff.

The subject matter was based on two reports that have been accepted for publication in *Regulatory Toxicology and Pharmacology* in 2006 titled "An Analysis of Genetic Toxicity, Reproductive and Developmental Toxicity" and "Carcinogenicity Data: I. Identification of Carcinogens Using Surrogate Endpoints" and "II. Identification of Genotoxicants, Reprotoxicants, and Carcinogens Using *In Silico* Methods."

The first article is a retrospective analysis of standard genetic toxicity (genetox) tests, reproductive and developmental toxicity (reprotox) studies and rodent carcinogenicity bioassays (rcbioassay). The study was performed to identify the genetox and reprotox endpoints whose results best correlate with rcbioassay observations. A database of 7,205 chemicals with genetox (n=4961), reprotox (n=2173) and rcbioassay (n=1442) toxicity data was constructed; 1,112 of the chemicals have both genetox and rcbioassay data and 721 chemicals have both reprotox and rcbioassay data.

This study differed from previous studies by using conservative weight of evidence criteria to classify chemical carcinogens, data from 63 genetox and reprotox toxicological endpoints and a new statistical parameter of correlation indicator (CI, the average of specificity and positive predictivity) to identify good surrogate endpoints for predicting carcinogenicity. Among 63 endpoints, results revealed that carcinogenicity was well-correlated with certain tests for gene mutation (n=8), in vivo clastogenicity (n=2), unscheduled DNA synthesis assay (n=1) and reprotox (n=3).

The current FDA regulatory battery of four genetox tests used to predict carcinogenicity includes two tests with good correlation (gene mutation in Salmonella and *in vivo* micronucleus) and two tests with poor correlation (mouse lymphoma gene mutation and *in vitro* chromosome aberrations) by our criteria.

The second article II examines a novel method to identify carcinogens that employed expanded data sets composed of in silico data pooled with actual experimental genetic toxicity (genetox) and reproductive and developmental toxicity (reprotox) data. We constructed 21 modules using the MC4PC program including 13 of 14 (11 genetox and 3 reprotox) tests that we found correlated with results of rodent carcinogenicity bioassays (rcbioassays) [Matthews et al., 2005b]. Each of the 21 modules was evaluated by cross-validation experiments and those with high specificity (SP) and positive predictivity (PPV) were used to predict activities of the 1442 chemicals tested for carcinogenicity for which actual genetox or reprotox data were missing. The expanded data sets had ~70% in silico data pooled with ~30% experimental data. Based upon SP and PPV, the expanded data sets showed good correlation with carcinogenicity testing results and had correlation indicator (CI, the average of SP and PPV) values of 75.5 - 88.7%. Conversely, expanded data sets for 9 non-correlated test endpoints were shown not to correlate with carcinogenicity results (CI values <75%). Results also showed that when Salmonella mutagenic carcinogens were removed from the 12 correlated, expanded data sets, only 7 endpoints showed added value by detecting significantly more additional carcinogens than non-carcinogens.

Updates

Pharm/Tox Web Update. **Tom Papoian, Ph.D., DABT,** from the Division of Cardiovascular and

Renal Products, presented a brief overview of the Pharmacology and Toxicology Home Page, a CDER intranet site that serves as an in-house resource of information related to the pharmacology and toxicology of therapeutics. The site averages about 40,000 visits a month and contains an extensive collection of documents, guidances, tools, and links that are commonly used by pharm/tox reviewers.

Role and Objectives of the Education Subcommittee of PTCC. **Aisar Atrakchi, Ph.D.,** from the Division of Psychiatry Products and Co-Chair of the Educational Subcommittee of the Pharmacology and Toxicology Coordinating Committee, said that objectives of the subcommittee are to identify and prioritize the specific scientific needs of the Pharm/Tox reviewers and to enhance their scientific competency.

This is accomplished through organizing formal courses, lecture series, seminars or workshops on a specific topic and, coordinating with the PTCC Retreat Subcommittee. This subcommittee is also responsible for the scientific training of new reviewers as well as satisfying the continuing educational needs of senior reviewers.

The subcommittee is made up of a chair and a co-chair, voting members who are pharmacologists/toxicologists from CDER and when possible an executive secretary. Non-voting members include a representative from the Office of Training and Communication and scientists from other centers to encourage cross-center and inter-Agency interactions.

Case Study

Tissue Cross-Reactivity. **Melanie Hartsough, Ph.D.,** from the Division of Biologic Oncology Products, presented tissue cross-reactivity data from a pre-IND and subsequent IND submission that had problems with the development of the immunohistochemistry (IHC) assay and the interpretation of the results, with regard to relevant species.

She emphasized that in some instances flexibility in the IHC design is needed in order to obtain informative data and explained that the division had agreed with the sponsor's proposal to utilize an alternative test-article, provided sufficient comparability to the material intended for the clinic was established. Finally, she described the thought process behind determining that there was no relevant species to perform a toxicology study and the impact of this decision on the initiation of the clinical trial.

Q and A on Promotion Tracks. **Dave Morse, Ph.D.,** a supervisory pharmacologist in the Division of Drug Oncology Products, **Bob Osterberg, Ph.D.,** Supervisory Pharmacologist in Division of Anti-Infective and Ophthalmic Drugs, and Abby Jacobs, Ph.D., Assoc. Dir. Pharm/Tox ONDIO conducted a 15 minute question and answer period to discuss the promotion track programs available to Pharm/Tox staff within the CDER.

The discussion period for this topic was led by **David Morse** (Chair, CDER Reviewer Career Path Committee - CRCP), **Abby Jacobs** and **Bob Osterberg** (committee members of the Expert program). Reviewers were encouraged to work with their immediate supervisors in the evaluation of performance issues and identification of regulatory and scientific issues that might contribute to their promotion as well as on the preparation of promotion related documents. Reviewers were directed to the CRCP and the Expert track program intranet sites for detailed information on the preparation of application materials for the various committees.

Retreat team

The retreat was organized by pharm/tox reviewers and staff from various divisions at CDER including: **Jinhui Dou, Linda Fossom, Luan Lee, John Leighton, Haleh Saber-Mahloogi** (chair), **Bob Osterberg, Yanli Ouyang, Tom Papoian, Lilliam Rosario, Adele Seifried** and myself.

Gary Bond is a pharmacologist in the Division of Pulmonary and Allergy Products and would like to acknowledge the assistance of speakers and retreat committee members in the preparation of this article.

OCPB Science Day 2005

Clinical pharmacologists explore future of pharmaceuticals

By Ray Baweja, Ph.D., Sophia Abraham, Ph.D., Sandra Saurez, Ph.D., Abimbola Adebowale, Ph.D., Charles Bonapace, Pharm.D., Srikanth Nallani, Ph.D., Patrick Nwakama, Pharm.D, Venkat Jarugula, Ph.D., Chandra Sahajwalla, Ph.D., Shiew Mei Huang, Ph.D., and Larry Lesko, Ph.D.

The 14th Science Day sponsored by the Office of Clinical Pharmacology and Biopharmaceutics enthusiastically celebrated the theme of "Molecules to Bits: The Future of Pharmaceuticals" in October.

The keynote address was presented by **Juan Enriquez,** a business leader, author and academic who is recognized as an authority on issues related to the economic and political impacts of life sciences. His lecture focused on the theme of how we generate "wealth and better living" for citizens of this planet and which countries end up being wealthy versus those that stay poor.

During the Renaissance from the 14th to the 17th centuries in Europe, arts and banking flourished. This was followed by the Industrial Revolution. The mid-20th century saw the independence of 61 countries over a span of 13 years, and later in the century it was technologically the era of computers. Currently, we are in the "digital" and "genomic" revolutions.

In each instance, he noted, that whichever country adopted the latest technology, stayed on top. Still, over the course of time, neither any one "country" nor any given "technology" can be taken for granted. Consistently no one country or continent has stayed on top. It is always an evolutionary and turning process on this planet.

The current era is that of genomics. He compared the current infancy of the genomics revolution to that of European navigators who even with "perfect" maps of their time, knew that they had "landed somewhere" but did not know exactly where.

Similarly, with the human genome project, science is setting out to "map" each one of us, and this mapping will eventually change everything. He congratulated the Agency for taking the lead in this area mentioning that it has a "front row seat" and was complimentary of its national initiative toward developing a guidance.

The podium presentations covered:

- Imaging biomarkers for drug discovery in Parkinson's disease.
- Applications of exposure-response to optimize benefit-risk ratio for combination therapy.
- Concentration QTc relationship derived endpoint for decision-making.
- Genomics in drug development.
- Semi-mechanistic PD modeling.
- Clinical pharmacology issues for oral inhaled insulin.
- Updates on drug interactions and pharmacogenomics guidances.

Similarly, the posters covered a range of topics, such as:

- Pharmacogenomics information for drug labels.
- Repository of drugs used in pregnancy and lactation.
- Applications of population pharmacokinetics in drug labeling.
- Improving drug development efficiency of drugs for osteoporosis.
- Current opinions on drug-drug interactions studies.
- The President's Emergency Plan for Aids Relief.

The Commissioned Corps team had a visual presentation in which they highlighted their assistance in the Katrina relief effort both in the state of Louisiana and through their coordination efforts from the Washington area. The finale of the day was the Talent Hour, and features included Middle Eastern dancing, a demonstration of radio broadcasting and folk and country melodies.

Science Day began in 1996 and, over the years, has seen participation of clinical pharmacologists from the Uniformed Services University of Health Sciences, Walter Reed Army Institute of Research, Office of Generic Drugs, CBER, Center for Drug Development Science at Georgetown University, the National Institutes of Health, University of Maryland and the Medical College of Virginia.

To date there have been about 250 scientific presentations, including the seven podium and 26 posters for 2005. Distinguished guest speakers have shared the latest findings in the field of medicine, clinical pharmacology, optimization of the drug development process, and have included **Drs. Curtis Wright, Carl Bjornsson, David Greenblatt, William Jusko, Bill Evans, Robert Powell, Janice Schwartz, Jay Cohen, Stephen Naylor** and **Kenneth Kaitin.** The main theme of Science Day has been to share and exchange scientific information and ideas among clinical pharmacologists.

The authors are members of OCPB, and Larry Lesko is the office director.

Shelf Life Extension Program means big savings for U.S. military

By Patrick E. Clarke

When the U.S. military stockpiles items, they do it in a big way. If stockpiled drugs are past their expiration date and have to be destroyed, it can cost the Department of Defense and the taxpayers millions of dollars.

Enter the Shelf Life Extension Program, begun in 1985, at the request of the Air Force. All military branches now participate in the testing program that determines a new expiration date for stockpiled drugs.

Donna Porter, who is the shelf life project manager in the Office of Regulatory Affairs, estimated that about 35 different drugs are currently tested through the program. "When the military requests a drug product for testing, I research it—look at the packaging and get long-term stability and accelerated stability data," said **Jeb Taylor,** a chemist in the Division of Product Quality Research. Taylor then develops a testing protocol for one of the FDA field labs to use.

The principle upon which the program is based is annual real-time testing to provide data to extrapolate how long that lot can be stored, and then a new expiration date is determined. "In some cases we use the process of artificial aging to assist with the initial prediction of extended life," Taylor said. The three main labs doing the testing are the ORA district laboratories in Detroit, Philadelphia and San Juan, Puerto Rico.

Porter emphasized that consumers should abide by the expiration date set by the manufacturer. "You cannot compare shelf-life testing, which is done with product lots that have not been opened and are stored under labeled storage conditions, to consumer-purchased prescription products, which are often not in ideal storage conditions," she said.

Taylor noted that the main drugs tested are military-specific "such as atropine sulfate and pralidoxime chloride, which are antidotes used in case of a nerve gas attack."

Biological drugs and blood products are not tested, and any drugs known to be unstable are not tested. "Sometimes it's not cost-effective to test if the military doesn't have sufficient quantities of a drug," Porter said.

One example of a drug where the expiration date was extended, at great savings, is the antibiotic ciprofloxacin.

Drugs that pass testing are initially extended one or two years. "Then one year later a retest is given," Porter said. "If the retest data are OK—the drug can be extended another year. We will re-test until we've hit the limit on extensions or else the military no longer has the product available for testing."

Commissioned Corps White Oak Working Group

Group seeks a smooth transition to White Oak

LCDR Stephan Ortiz

The Commissioned Corp White Oak Working Group was established to identify and address the needs of Commissioned Corps officers as the FDA continues its transition to the White Oak campus. **Betsy Bretz,** chair of the LABQUEST group, is credited with proposing the creation of this group. Soon thereafter, upon receiving the blessing from **RADM Steven Galson,** Center Director, the working group was created. The working group is chaired by me, and its members, from several FDA centers, include both Public Health Service commissioned officers and civilians. The working group has identified and addressed many needs in its first few months.

Much of our initial efforts have been aimed at increasing the visibility of the Commissioned Corps on the White Oak campus. We have helped create the format of a temporary sign for the White Oak campus that will include the Public Health Service logo, along with the HHS and FDA logos. Indoor U.S. and PHS flags have been purchased and will soon be displayed in the lobbies of buildings 21, 22 and the Life Sciences Building, as well as conference room 2205 in building 22. We are currently working to get the outdoor nautical flagpole refurbished and furnished with U.S., Maryland, PHS and FDA flags in time for the dual FDA Centennial celebration and Central Shared Use Building dedication in mid-September. Additionally, we have worked to ensure the presence of the PHS Ensemble and/or Color Guard for participation in all FDA Centennial-related events scheduled through the end of year.

Other topics the group has worked on include creation of a three-quarter mile path with one-quarter mile mark offs, to accommodate the physical fitness training requirements of all corps officers. We hope to coordinate frequent group-facilitated annual physical fitness tests on the White Oak campus in the near future. Additionally, an information e-mail distribution list that includes all commissioned officers at White Oak or scheduled to move to White Oak.

We meet once monthly to provide updates on progress made and to offer new topics for discussion. If you are interested in becoming a working member of this group or have ideas for consideration, you can contact me by e-mail or phone at (301) 796-1584.

Stephan Ortiz is a regulatory review officer in the Office of Translational Sciences.

Educational materials accentuate your presentations

By Cindi Fitzpatrick

Accentuate and augment your presentations at meetings and conferences with CDER's educational materials. These pamphlets, flyers and posters are created for physicians, pharmacists, nurses, consumers and clinical research professionals.

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Cindi Fitzpatrick is a consumer safety officer in OTCOM's Division of Public Affairs.