news along the pike

MARCH 2001

CENTER FOR DRUG EVALUATION AND RESEARCH

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INSIDE . . .

CDER'S CORNERS

Comment Period Extended for Rx Labeling Proposal

April 26 'CDER Live' Talk Show to Feature Proposed Rule

BY ELAINE FROST

Another edition of "CDER Live!" will air on April 26 from 1 p.m. to 3:30 p.m. EDT and will present a discussion about FDA's proposed rule for revising prescription drug labeling.

On March 30, FDA announced in the *Federal Register* that it is reopening to June 22 the proposal's comment period. The Agency extended the comment period in response to a request from PhRMA.

The proposal would, among other things, require that the labeling of new and recently approved prescription drug products include a section containing highlights of prescribing information and a section containing an index to prescribing information.

"CDER Live!" is a talk show aimed primarily at the pharmaceutical industry co-sponsored by the Center and the Drug Information Association. The programs are broadcast live by satellite or by webcast. They have been ongoing since 1997.

Guests on "CDER Live!" will explore the proposed revisions to prescription labeling regulations that are designed to make information easier to find, read and use.

Panelists for the program are:

- **Janet Woodcock, M.D.,** Center Director.
- **Nancy Ostrove, Ph.D.,** Chief, Research and Review Branch, Division of Drug Marketing, Advertising and Communications.
- Robert Califf, M.D., Associate Vice Chancellor for Clinical Research, Duke University.

(Continued on page 8)

Clinical Pharmacologists Honor Dr. Temple in Florida

BY PETER HONIG, M.D.

ORLANDO, Fla.—The American Society for Clinical Pharmacology and Therapeutics held their 101st annual meeting here from March 6 to 10, and many from CDER attended and participated in the proceedings.

One of the highlights of the meeting was the presentation of the prestigious Rawls-Palmer Progress in Medicine award to **Robert Temple, M.D.,** (click here for photo). Dr. Temple is the director of the Office of Medical Policy and the Office of Drug Development I.

Richard Crout, M.D., a former FDAer, who recruited Dr. Temple from the National Institutes of Health introduced Dr. Temple's award lecture: "The Interaction of FDA and Clinical Pharmacology." In the lecture, Dr. Temple highlighted the contributions of clinical pharmacology to drug development and clinical study design methodologies.

Shiew-Mei Huang, M.D., Deputy Director, Office of Clinical Pharmacology and Biophar-

(Continued on page 8)

CDER's Support Staff Workshop Scheduled for April 27

BY VICTOR VAIL

In conjunction with this year's Administrative Staff Recognition Week, formerly called Secretaries' Week, CDER's Support Staff Coordinating Committee and the Office of Training and Communications will sponsor a one-day workshop entitled "Getting Results" on April 27 from 9:30 a.m. to 3:30 p.m. at the Gaithersburg Hilton Hotel.

This program will be conducted by the American Management Association. The association is committed to assisting government agencies in their institutional transformation efforts, helping provide solutions to meet the challenges government faces in today's world and increasing the effectiveness of employees' performance.

Don't miss out on the workshop. Online registration is required and must be completed by close of business April 20. To register, go to the CDERnet at http://cdernet.cder.fda.gov/dtd/index.htm.

The workshop will focus on three topics

(Continued on page 8)

JOE'S NOTEBOOK

Diabetes Stamp Encourages Awareness

I have been saddened and deeply affected by one of our neighbor's struggles with diabetes. It has taken a terrible toll on the quality of his life, impaired his ability to walk and left him with low vision.

Diabetes is a devastating illness that kills one American every three minutes. Since 1990, diabetes rates have skyrocketed by 40 percent. Today, more than 16 million Americans have diabetes, with about 800,000 new cases diagnosed each year.

This year, the United States Postal Service will help support and encourage diabetes education with the issuance of the Diabetes Awareness commemorative postage stamp. The stamp has been available at post offices nationwide since its first day of issuance on March 16 in Boston.

The Postal Service is launching a year-long diabetes awareness campaign along with the National Institutes of Health, the Centers for Disease Control and Prevention and several voluntary health organizations.

Diabetes is a chronic, debilitating disease affecting every organ system. Insulin is not a cure, merely life support. There are two major types of diabetes: Type I (juvenile) and Type 2 (adult onset). Anyone at any age can get diabetes, including children. Many people die or suffer life-threatening health problems because the warning signs are very often missed or mistaken for something else. There is no cure, but there is hope through research.

Diabetes is a leading cause of blindness, amputation, heart attack, stroke and kidney failure. It accounts for more than $105 billion of annual U.S. health care costs. One of every four Medicare dollars goes to pay for health care of people with diabetes.

Since the mid-1950s, the Postal Service has issued stamps that highlight social awareness issues. Recent social awareness stamps include Breast Cancer Awareness, Organ and Tissue Donation, Prostate Cancer Awareness, Hospice Care and Adoption.

Illustrated by artist James Steinberg, and designed by Richard Sheaff, the Diabetes stamp includes two elements associated with diabetes testing and research: a microscope and a test tube containing blood. Featuring the phrase, "Know More about Diabetes," the design conveys the importance of diabetes awareness and early detection of the disease. Click here to view an image of the stamp. The Postal Service Web site is http://www.usps.com.

Science awards. The 2001 FDA Scientific Achievement Awards were announced in February at the FDA Science Forum held in the Washington Convention Center.

The Outstanding Intercenter Scientific Collaboration Award was presented to **Emanuel Petricoin, Ph.D.,** from the Center for Biologics Evaluation and Research and CDER's **Frank Sistare, Ph.D.** Their research was for the development of a rapid proteomic-based platform for toxicity screening using heuristic cluster analysis of SELDI protein biomarkers.

Also competing for the same award was the DES Analytical Methodology Team. The team members, **Pak-Sin Chu, Ph.D., CVM, John M. Strong, Ph. D., CDER,** and **Robert J. Parker, Ph.D., CDER,** were nominated for their research on the evaluation and improvement of an ultra-trace method of analysis of the synthetic hormone, diethylstilbestrol in meat.

Corrections: In last month's *Pike* some job titles were incorrect. **Dale Connor, Pharm.D.,** is Director, Division of Bioequivalence, Office of Generic Drugs. **Randy Levin, M.D.,** is the Center's Associate Director for Electronic Review. Also, in the story on the Controlled Substances Staff on page 7, NIDA is National Institute on Drug Abuse and butorphanol is an analgesic.

news along the pike

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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).

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

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

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

OMBUDSMAN'S CORNER

Minutes Save Months

BY JIM MORRISON

I've often said that 90 percent of my work consists of picking up the pieces after breakdowns in communication. Ninety percent may well be too low an estimate. The most common scenario of miscommunication occurs when we are not crystal clear in what we say and the listener doesn't want to hear our message. Imagine you are the NDA applicant in the following example.

You work for a privately owned startup pharmaceutical company. It has purchased the rights to develop a new drug for the U.S. market from a company that went belly-up. The defunct company had completed Phase II studies, and the drug appeared promising.

You were hired to oversee the Phase III testing and to assure that the drug receives FDA approval. You have been working on the project for three years. You followed the guidance FDA gave you in the end of Phase II meeting, and your statisticians believe the data from Phase III trials demonstrate the drug is safe and effective.

You arrive with other members of your team in Rockville to attend the pre-NDA meeting. The CDER staff members at the meeting agree that the drug has great potential and that things look promising. However, they state:

"It would be advisable for your company to do an additional study to address questions raised by somewhat elevated liver enzymes in a small percent of the subjects in the studies."

When you ask if the study is a requirement for approval, the CDER participants say only: "It would be very helpful."

When you caucus with your team after the meeting, there is some uncertainty as to exactly what CDER said. Most of your team agrees that the Center meant that it would be OK to submit the NDA, and that the additional study could be done in Phase IV after approval. Your team estimates that it will take three years additional work to complete the suggested study. You think that there is a small chance that FDA would not approve the NDA without the additional study.

When you get back to your room in the hotel, there is a message from the CEO of your company asking how the meeting went. You see three possible scenarios of what to say in returning the CEO's call:

A. "Well, boss, we didn't do very well. We'll need to do another study, which will take another three years before we can submit the NDA. But there is a bright side. We can save the $50,000 you would have paid for my bonus. For that matter, you can save my salary for the next three years, too. And the bankruptcy judge will look favorably on any company that sacrifices itself to prevent even the possibility of its product doing harm. By the way, I'll be staying around here for a few days to look for a new job."

B. "Well, boss, we had the meeting, but we can't figure out what FDA said. I think we can file the NDA, but maybe we should first do this three-year study they suggested. What do you think?"

C. "Well, boss, the meeting went fine. We are on track to submit the NDA next month. They suggested an additional study, which I'm confident we can do in Phase IV."

Which of the above scenarios would you choose?

The point is, when so much is at stake, people will naturally interpret our statements to suit their expectations best. Therefore, it is essential that we be clear and precise in verbal statements and, most importantly, in the minutes of meetings.

Equally important is the timeliness with which minutes are conveyed to the company. CDER MaPP 4512.1 specifies that minutes of formal meetings be transmitted to industry participants within four weeks. Clearly stated minutes do little good if they are sent six months later, after the applicant has submitted an NDA or has begun studies according to misunderstood verbal guidance.

Not only must the firm receive the minutes in a timely manner (or check with the project manager if they have not been received in four weeks), but the firm should send their minutes to CDER, and we should read them.

I've heard some in CDER say: "Our minutes are the official ones, so we don't need to read the firm's version." That is technically true, but costly if the firm's minutes show a misunderstanding about a planned study, and no one catches it until the study has been completed and an application is submitted.

If there is a misperception, it is better corrected sooner than later. The added time it takes to review the firm's minutes is well worthwhile, even if only occasionally significant differences are detected.

Anyone who has sat through long meetings following appeals can attest that clear and timely minutes can save months of work on both sides of the regulatory fence.

Jim Morrison is the Center's ombudsman.

Parklawn Classic 5-Mile Run, 2.5-Mile Walk Set for April 27

The 2001 Parklawn Classic, open to current and former employees of the Department of Health and Human Services, will take place April 27 rain or shine. The Classic features a 5-mile run and a 2.5 mile health walk.

Walkers and runners may register through the day of the event by completing a registration form.

The Classic hotline (3-5350) has up-to-date information about the event. The Classic Web site at http://classic.dhhs.gov/ has course details and registration forms.

The 2.5-mile health walk is free.

The 5-mile run costs $10 by April 25 and $20 on April 26. There will be no run or race registration during the day of the event.

All runners will receive a T-shirt at the finish line. All volunteers will receive a free "Classic" Award T-shirt the morning of the event. Walker T-shirts are for sale at the Parklawn R&W Store in Room 5-01) for $9. They will also be for sale the day of the event from 8:30 a.m. to 10:30 a.m. in the Parklawn Building, B-wing lobby, on the 5th floor.

INFORMATION TECHNOLOGY CORNER

PCs at Work, Home Upgraded; National Drug Code Directory

OIT is in the process of updating every personal computer in the Center so that everyone has at least a 333-megahertz machine. We have recently purchased and deployed 427 new PCs, and 200 more are expected to arrive soon. About one-third of Center staff will receive a new PC every year, which should result in each person getting a new PC once every three years.

When you receive a new office PC, you will have the option of taking your existing office machine home for work on CDER efforts.

To do this, you will need to submit and gain approval of an off-site computing request. OIT will then install the approved software. This action will make getting a PC for home use easier and faster for those approved to work at home.

If you are not approved or elect not to take your PC home, OIT will transfer it to a needed area in the Center. Users or divisions will not be able to "stockpile" old PCs, as they may be needed to meet critical computing needs in another area of the Center.

OIT is working to meet the computing needs of the Center, and this new policy will result in more frequent upgrades of equipment for all staff. Please refer to the OIT Web at http://oitweb for off-site computing forms and contact the Help Desk (HELP, CDER HELP for Outlook) for PC support.

Important Changes in Remote Access

The recent CDER implementation of MS Outlook and the increased use of PCs at home by CDER users has put some stress on the Center's Remote Access Server utility. OIT has initiated several short- and long-term solutions to enhance remote access.

Recently, all modems in the Center have been upgraded to 56K speed, which may result in some increase in speed; although, we are still limited to the capacity of the existing phone lines.

Over the next six months, OIT will implement a redesign of CDER's remote access capabilities for dial-in users.

We are moving from a system that uses 48 individual phone lines to one with high capacity "trunk" lines. These trunk lines provide the ability for us to receive 24 incoming calls on the single trunk.

Once the project is complete, we will have the capacity to support 196 dial-in users at one time, more than four times what we can support now.

The redesign will also involve the removal of the physical modems that we are currently using. This will alleviate any potential problems caused by the modems.

To help identify remote issues and quickly resolve problems, it is important that anyone experiencing RAS problems contact the Help Desk (HELP, CDER HELP for Outlook, 301-827-0911) as soon after the problem as possible. The Help Desk will help resolve the problem and report any unresolved issues to system staff.

April IT Training

Monday	Tuesday	Wednesday	Thursday	Friday
2 NEST (C) 9:00-12:00 NEDAT (C) 1:00-4:00	3 JMP Session I (C) 1:00-4:00PM	4 Word Intro (C) 9:00-12:00 Word Formatting (C) 1:00-4:00	5 JMP Session II (C) 1:00-4:00PM	6 Excel Intro (C) 9:00-12:00PM DFS (C) 1:00-4:00
9	10 E-Doc/ RetrievalWare (P) 9:00-12:00	11 E-Doc/ RetrievalWare (P) 1:00-4:00	12	13
16	17	18	19	20 DFS (P) 9:00-12:00 AERS Datamart (P) 1:00-4:00
23	24 Access 97 Intro (P) 9:00-12:00 Access 97 Queries & Reports (P) 1:00-4:00	25 Creating PDFs (C) 9:00-12:00 Access 97 Forms (P) 9:00-12:00 Access 97 Reports (P) 1:00-4:00	26 PEDS (P) 9:00-12:00 E-Doc/ RetrievalWare (C) 1:00-4:00 MS Project 98 for PMs (P) 1:00-4:00	27
30 E-Doc/ RetrievalWare (C) 9:00-12:00 DFS (C) 1:00-4:00				

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

National Drug Code Directory Query Available Soon

The National Drug Code System serves as a universal product identifier for human drugs. The information in this system is used in the enforcement of the Federal Food, Drug and Cosmetic Act and for third party payments of prescription drugs.

Each listed drug product is assigned a unique 10-digit, three-segment number. This number, known as the National Drug Code or NDC, identifies the labeler or vendor, the product and the package size of a given drug product.

With the release of OIT's Electronic NDC Directory, it will be possible for you to do an on-line query for NDC-related information. Previously, the data were only available in an outdated, two-volume hard-copy directory and non-searchable data files.

The Electronic National Drug Code Directory has over 38,000 prescription and selected OTC drug product records searchable by proprietary name, active ingredient, NDC number or firm name with links to related detailed information.

The Electronic NDC Directory was developed in a fashion similar to the Electronic Orange Book, which was released in 1997 and has been in the top 10 most-requested pages on the CDER Internet site for the past two years.

You will be able to access

(Continued on page 5)

WEB INSIGHTS

CDER Internet Site Grows to 30,000 Pages, 600,000 Users a Month

BY CAROL ASSOUAD

After a long hiatus, it's good to be back to a first love of mine, journalism. Of course, doing a column is just a good excuse to grab a cup of coffee, pull up a chair and have a chat with you.

We've been busy here, so I'd like to catch you up on what's going on with our CDER Web activities, though it will take several columns to do this.

Web site development and usage is growing phenomenally around the world, and the majority of the users are interested in health information at least some of the time. Our own Internet site averages 600,000 users a month, accessing our pages more than 9 million times.

CDERnet usage is way up, too: nearly 70,000 visits from 4,000 unique visitors from all over the Agency and 850,000 hits. This growth is paralleled by an increase in number and complexity of our pages, documents and databases—more than 30,000 items on our Internet site alone.

In future columns, I'll revisit the issues of user demographics and site usage and what it means for us as a Center, but I want to let you know that our users really appreciate all that information you produce and that we publish on the web site.

Today, though, I really can't resist telling you about some of the exciting projects and pages that we've been working on and have just launched.

The first two projects will be available on the Internet. The second two will be on CDERnet, and only available to FDA employees.

National Drug Code Directory

An updated, Internet version of the National Drug Code Directory will launch shortly (page 4). This is an OIT Division of Data Management and Services Web project, led by **Mary Ann Holovac.** The database will have a link in from the CDER front page at http://www.fda.gov/cder.

Proposed Proprietary Drug Names

In an ongoing effort to minimize medication errors resulting from confusing drug names, we are developing a Proposed Proprietary Drug Name database that will be added to the Medication Error Page at http://www.fda.gov/cder/drug/MedErrors/default.htm.

The database will include the proposed proprietary drug name, the applicant name and the date of OPDRA's tentative approval. It will provide a mechanism for industry and others to screen these names for potential confusion.

Drug Safety Signal Detection

The Drug Safety Signal Detection Database, at http://cdernet.cder.fda.gov/dataminingsignals/default.htm, is a data-mining research tool used for identifying adverse events. This new surveillance approach was conceptualized by **Ana Szarfman, M.D., Ph.D.,** from the Office of Post-Marketing Drug Risk Assessment. It was programmed by William DuMouchel of AT&T Labs.

The database screens for higher-than-expected signal scores in paired drug adverse-event combinations, biologic adverse-event combinations and simple drug interaction effects. The database consists of approximately 2,000 graphical summaries of these analyses based on over 12 million counts of drug-event combinations collected over 32 years.

You will be able to search by record title, drug, adverse event or text words to examine the graphical safety profiles of marketed drugs. With this new tool, you will be able to identify many serious rare adverse drug reactions that were not identified during randomized clinical trials.

Hot Topic InfoWebs

Hot Topic InfoWebs is a new FDA Medical Library service found at http://medlib.cder.fda.gov. Designed by our Reference and Research Team, it provides you with basic background information on Agency initiatives and subjects of high interest.

The first InfoWeb is devoted to oxycodone. The InfoWeb summarizes the issues surrounding this drug and links to relevant FDA pages. Adverse events, chemical information, news and marketing information are covered. The resources included range from commercial databases, such as Micromedex, to relevant Internet sites, such as the Drug Enforcement Agency's Drugs of Abuse text.

This InfoWeb will be updated frequently, as new information becomes available. Future topics may include bovine spongiform encephalopathy, risk management and antimicrobial resistance. Initially, it will only be on CDERnet.

If you have suggestions about additional Web content or ways to improve existing content, please let us know.

Carol Assouad is Director, Division of Library and Information Services and Program Manager, CDER Web Sites

National Records and Information Management Week Celebrated

(Continued from page 4)

the Electronic NDC Directory from the CDER homepage at http://www.fda/gov/cder. Contact **Mary Ann Holovac, R.Ph.**, (HOLOVACM) for more information.

National Records and Information Management Week

April 1 to 7 in not only National Library Week (page 8), it is also National Records and Information Management Week.

Originally known as National Records Management Day, it was first held on April 6, 1995, the day Congress passed the 1995 Paperwork Reduction Act.

This year's celebrations bear special significance as the Paperwork Reduction Act is currently up for renewal.

As part of the festivities, the D.C. chapter of the Association of Records Managers and Administrators will host a seminar on "Electronic Imaging from A to Z" on April 2. Also, on April 5, the Gaithersburg chapter will be holding a forum at the National Archives and Records Administration in College Park, entitled "NARA II: Records Management for a New Millennium."

Have a Happy National Records and Information Management Week!

For more information, contact **Scott Zeiss** (ZEISSS).

Technical Writing Courses Aim at Improving Center Documents

The Division of Training and Development in OTCOM offers three courses to improve your writing skills.

Managing Written Communications for Team Leaders. This one-day seminar will be offered on May 9, in Parklawn Conference Room J from 9 a.m. to 4 p.m. Participants will improve the efficiency of their teams, ensure the quality of their written products and guide collaborative writing projects. Participants are also provided instruction on how to manage their time; and check their team members' documents for quality, focus, organization, coherence and clarity. The audience for this seminar is team leaders who successfully complete the three-day seminar, Technical Writing Skills for Reviewers.

Technical Writing Skills for Non-Reviewers. This two-day seminar will be offered on May 16 to 17 in Parklawn Conference Room J from 9 a.m. to 4 p.m. Participants will learn proven techniques to produce better documents in less time. Participants will also improve their ability to analyze a document's purpose and organize documents according to readers' needs. The audience is CDER's non-reviewer professionals in grades 9 to 15.

Technical Writing Skills for Reviewers. This three-day seminar will be offered on June 12 to 14 in Parklawn Room 13B-39 from 9 a.m. to 4 p.m. Participants will learn a proven system of techniques to help them produce better documents in less time. Participants will also improve their abilities to analyze a document's purpose; organize information according to readers' needs; and edit documents for coherence, clarity and economy. The audience is reviewers in grades 9 to 15.

You can register for these courses on DTD's Intranet site at http://cdernet.cder.fda.gov/dtd/index.htm.

Drugs in the News: Rapacuronium Withdrawn; 2 Eye Drugs Approved

The injectable anesthesia drug rapacuronium bromide (Raplon) is being voluntarily withdrawn from the market after its manufacturer received reports indicating that the drug may be associated with bronchospasm—a mild to severe inability to breathe normally that can lead to permanent injury or death. Five deaths, reported to the manufacturer, occurred during the administration of Raplon. Beginning March 27, the drug's sponsor, Organon Inc., of West Orange, N.J., contacted FDA and sent a letter to all anesthesiologists, hospital pharmacists and other consignees of the drug notifying them of the voluntary withdrawal.

FDA announced approval on March 16 of two new drugs to treat elevated intraocular pressure, which is often associated with glaucoma. The drugs are bimatoprost ophthalmic solution (Lumigan 0.03 percent) and travoprost ophthalmic solution (Travatan 0.004 percent).

The drugs will provide additional alternatives for the reduction of intraocular pressure in patients who are intolerant of other intraoular lowering medications or in patients who have had insufficient responses to other intraocular pressure lowering medications. Many of these patients might otherwise need surgery for management of their glaucoma.

FDA is advising women who take the prescription blood-thinner warfarin to consult their doctor or pharmacist for advice before using an OTC vaginal miconazole product.

FDA has also advised manufacturers of vaginal creams and suppositories containing miconazole to add a new warning to the Drugs Facts box on product labels. The warning states: "Ask a doctor or pharmacist before use if you are taking the prescription blood thinning medicine warfarin, because bleeding or bruising may occur."

Pike's Puzzler: First Aid

BY TONY CHITE

1. When a front tooth is completely knocked out, you should see a dentist or emergency room physician immediately. In the meantime, to save the tooth, it should be:

a. Rinsed gently and placed in the space where it was.
b. Discarded, then pack the wound with gauze.
c. Scrubbed with alcohol then stored in 70 percent ethanol.
d. Soaked in milk, not water if unable to restore in mouth.
e. Both a and d are correct.

2. True or False: When walking with crutches, your weight should be on your hands, not on your armpits, so your elbows should be slightly bent.

3. In the event of a nosebleed, you should:

a. Sit down and tilt your head slightly backward.
b. Sit down and tilt your head slightly forward.
c. Place a cold, wet cloth on your nose to constrict blood flow.
d. Pinch nostrils together for 10 minutes if both nostrils are bleeding.
e. b, c and d are correct.
f. a, c and d are correct.

4. If a dislocation (for example, an elbow, finger or thumb) is suspected, the person giving first aid should:

a. Apply a splint to the joint to keep it from moving.
b. Try to keep the joint elevated to slow blood flow to the area.
c. Immediately pop the joint back into place.
d. Consult a physician soon to have the bone set back into its socket.
e. a, b and d are correct.

5. Heart attack victims may complain of which of the following:

a. Chest pressure and shortness of breath.
b. Sweating.
c. Heartburn and/or indigestion.
d. Upper back pain or jaw pain.
e. All of these .

Key: 1. e; 2. true; 3. e; 4. e; 5. e.

Tony Chite is a pharmacist and CSO in CDER's DFOI.

REVIEWER'S CORNER

Full Moon over Barcelona: A PharmacE.U.tical Odyssey

BY LISA RARICK, M.D.

Several of your colleagues attended and participated in the Annual EuroMeeting of the Drug Information Association held March 6 to 9 in Barcelona, Spain. Fortunately, FDA is able to accept "in-kind" financing for such meetings. Thus, this participation was not paid for by our own organizations.

Although the most productive and entertaining portions of the week may have been outside of the formal meeting hours (more on this later), I'll start with highlights from the official agenda.

George Chi, Ph.D., Division Director, Biostatistics I, and **Robert O'Neill, Ph.D.,** Director, Office of Biostatistics, were very active in the regulatory biostatistics sessions. They gave presentations and participated in discussion on topics such as "Quantitative Assessments of Safety and Communication Risks," "Interim Analysis and Data Monitoring" and "Evaluating the Magnitude of Treatment Effect for Non-Inferiority Comparison."

Dr. O'Neill also provided instruction at a formal tutorial session on the choice of controls in clinical trials. This session was organized in large part by the chief European regulatory statisticians from the United Kingdom and Germany.

At the same time, **Joseph DeGeorge, Ph.D.,** CDER's Associate Director for Pharmacology and Toxicology, joined in sessions on preclinical development and integration with clinical development and provided the U.S. perspective in areas such as safety pharmacology, metabolites in safety testing and new approaches to carcinogenicity testing.

Randy Levin, M.D., CDER's Associate Director for Electronic Review, sought every opportunity for discussion with the vendors in the exhibit hall. He also presented at two sessions. One session focused on the development of data and metadata standards to support the acquisition, regulatory submission and archive of electronic clinical trial data. In his second session, Dr. Levin presented an overview of electronic submissions in CDER and participated in a discussion of globalization of data standards.

Dr. Levin made very efficient use of his time and also met with representatives of the Product Information Management team to improve the publishing of labeling by using XML technology. The PIM is a cooperative effort between the European Agency for the Evaluation of Medicinal Products and the European professional trade association similar to PhRMA.

Bronwyn Collier, ODE III Associate Director for Regulatory Affairs, represented CDER in a tutorial session and provided the U.S. perspective in various other discussions. The tutorial a forum for project managers and regulatory associates to identify key opportunities and processes for interaction with regulatory authorities to optimize clinical development. There was a great deal of interest in FDA's "free and easy" meeting management process as compared to the stricter requirements of the CPMP and member states of the European Union.

There is much interest in understanding the "FDA way."

I had the privilege of chairing and presenting in several sessions for **Murray Lumpkin, M.D.,** FDA's Senior Medical Advisor, who was unable to attend. Thus, I had the opportunity to present my planned talk on good review practices as well as sharpen my knowledge and present on topics such as fast track designation and early access to medicines. I also discussed some recent safety issues of common concern to European regulators as well as FDA.

Peter Bross, M.D., a medical officer with the Division of Oncology Drug Products, had hoped to learn something about the European approach to drug development. As Peter continues to ask: "Why do different oncology drugs get approved in Europe compared with the United States; what are the issues with surrogate endpoints; and what do you mean, in some members states, there are no INDs?"

For those of you who have attended the U.S. annual DIA meetings, you are aware that much of the interest and productive work is generated outside the formal agenda. The half-hour exhibit hall coffee breaks, receptions each evening and gala dinner provided further opportunities for discussion and reflection. As is customary for these events, a live band and (reasonably) live dancing followed the dinner.

It seems that the U.S. delegation benefited from the time change and was able to slip easily into the Barcelona late-night eating pattern. We were also the main contingent still awake for the 11 p.m. dancing opportunity.

Fortunately Dr. O'Neill can really dance. He and his wife, Patty, were the envy of the crowd. We were definitely impressed with the O'Neill smiles and Barcelona swing and salsa moves!

Several reflections deserve further mention. For one, these folks actually stay for the entire meeting. Those of us involved with the last sessions on the last day universally commented that the meeting rooms remained full and the audience engaged.

Some other behavior differences—there were even more cell phones ringing and one-sided phone conversations in the audience than you'd expect at an telephone company convention, including one call taken by a speaker during his presentation. Also, we are extremely fortunate that in the United States we have a lot more no-smoking sections and other second-hand smoke prevention schemes.

An actual meeting-related comment is worth sharing. There is much interest in understanding the "FDA way." Rather than finding ourselves on the hot seat or in a defensive posture, this audience seemed to believe that many of our processes and practices are advances in regulatory systems.

It was clear to all that the European Union and United States have similar concerns when it comes to drug development, postmarketing activities and regulatory science. We hope that our participation in this type of international meeting can benefit regulators, industry and all our citizens.

Lisa Rarick is director of the Center's Review Standards Staff.

Medical Library Sets National Library Week Open Houses, Training

By Kathy Kruse

National Library Week 2001 takes place April 1 to 7. We invite you to join staff members of the FDA Medical Library, along with vendor representatives for WebLERN information products, in celebrating this special occasion. WebLERN is the Library Electronic Reference Network on the CDER intranet. WebLERN gives all Agency employees desktop access to a variety of bibliographic and full-text information products (http://weblern.cder.fda.gov).

Come to our three open houses to enjoy light refreshments and informative demonstrations and conversations with representatives from EMBASE.com, ISI-Current Contents Connect and Micromedex. You'll be able to collect instructional handouts on numerous WebLERN products, as well as Library and vendor-supplied National Library Week souvenirs. Winners of our pharmacognosy contest will be announced.

During this week, you'll also have an opportunity to interact with our WebLERN vendors at a series of training sessions we've scheduled. Learn about products you have never tried before or bring your questions, problems or suggestions for those you have already used.

For more about our National Library Week activities, consult the Library's CDERnet site at http://medlib.cder.fda.gov.

You can also direct any questions to our Reference Desk staff at 7-5703 or to our MEDLIB e-mail account

Kathy Kruse is a supervisory librarian in the Medical Library.

Open Houses

- Parklawn, 11B-40, April 5, 2 p.m. to 4 p.m.
- Corporate Boulevard, S-121, April 6 9:30 a.m. to 11 a.m.
- Woodmont II, 3001, April 6, 1:30 a. m. p.m. to 3 p.m. (EMBASE.com and Micromedex only).

Training Sessions

- Parklawn, 12B-02, April 3, Food and Drug Library, 10 a.m. to 11:30 a.m.
- Corporate, S-111, April 3, Lexis-Nexis hands-on, 9 a.m. to noon.
- Corporate, S-400, April 3, Food and Drug Library, 1:30 p.m. to 3 p.m.
- Woodmont II, 3001, April 4, Micromedex, 10 a.m. to 11:30 a.m.
- Parklawn, April 5, 13B-39, EMBASE.com, 9 a.m. to 10 a.m. and 10:30 a.m. to 11:30 a.m.

FDA Extends Comment Period for Prescription Drug Labeling Proposal to June 22

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- Alan Goldhammer, Ph.D., Director, Technical Affairs, PhRMA.

Moderator for the program will be **Debbie Henderson,** Director, Executive Operations Staff.

CDER and DIA jointly choose topics for this series. DIA handles the administration, including registration for industry.

"CDER Live!" may be viewed free at satellite downlink sites throughout the Agency. There is no advance registration.

The following rooms have been designated for viewing the program: Parklawn 13B-39; Corporate II S-100; Woodmont II Conference Room G; Metro Park North I Conference Room 259; and Metro Park North II Conference Room B. Videotape copies of the program will be available later in the FDA Medical Library.

One more note: CDER staff are requested not to receive the webcast because this would put a strain on our server.

Elaine Frost is a public affairs specialist in OTCOM.

Dr. Temple Honored at American Society for Clinical Pharmacology & Therapeutics

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maceutics, chaired a workshop on "Drug Interactions with Herbal Products." The session featured original research performed under a cooperative agreement grant from CDER by Indiana University on the mechanisms of drug interactions with St John's Wort.

At the session, **Peter Honig, M.D., MPH,** Director, Office of Post-Marketing Drug Risk Assessment, spoke on "Drug Labeling as a Risk Management Strategy: Recent FDA Experience with Drug Interactions." Also, in the same session, **Lori Love M.D., Ph.D.,** from the Center for Food Safety and Nutrition, spoke on "Dietary supplements: Safety and Regulatory Considerations."

Dianne Kennedy, R.Ph., MPH, project manager for the Pregnancy Labeling Task Force, spoke about the FDA pregnancy labeling initiative in a symposium on "Clinical Pharmacology and Pregnancy: Addressing Clinical Needs with Science." **Lawrence Lesko, Ph.D.,** OCPB Director, chaired the session.

The public policy forum on "Clinical Pharmacology: the Scientific Basis for Improved Medication Use" was co-chaired by Dr. Honig and included presentations by **Carolyn Clancy, M.D.,** from the Agency for Healthcare Research and Quality; David Bates, M.D., from Harvard Medical School; and Alaistair Wood, M.D., from Vanderbilt University.

In addition to these sessions, the Center was well-represented with poster presentations. These included a survey of undergraduate and graduate medical program directors on their teaching of clinical pharmacology and adverse drug reaction recognition and reporting by **Curt Rosebraugh, M.D,** from the Division of Pulmonary and Allergy Drug Products.

Peter Honig is OPDRA director.

'Getting Results' Support Staff Workshop on April 27

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important to CDER's support staff:

- Partnering with your boss.
- Getting results without authority.
- Managing chaos.

The speaker and instructor will be Gay Gooen, a senior instructor for the American Management Association and a management consultant. Gooen specializes in the development of human potential in the business world.

Victor Vail is secretary for OTCOM's immediate office.