news along the pike

JANUARY 2001

CENTER FOR DRUG EVALUATION AND RESEARCH

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INSIDE . . .

PIKE'S CORNERS

FDAMA's Pediatric Successes Noted in Report

58 Studies Completed, 25 Drugs Granted Exclusivity

BY DIANNE MURPHY, M.D., ROSEMARY ROBERTS, M.D., AND TERRIE CRESCENZI, R.PH.

The pediatric exclusivity provision of the 1997 FDA Modernization Act has done more to generate clinical studies and useful prescribing information for the pediatric population than any other regulatory or legislative process to date, according to an Agency report to Congress issued in January.

As a result of the law, FDA reported that, at the time the report was written, it had issued over 157 written requests asking for 332 studies. These would potentially involve more than 20,000 pediatric patients. The report said FDA had received more than 191 proposals from sponsors to conduct pediatric studies. In fewer than 3 years, more than 58 pediatric studies had already been conducted. Reports from these studies had been submitted, and exclusivity granted to 25 drugs.

Drugs that have or soon will have pediatric use information in their labeling are used to treat conditions such as:

- Asthma.
- Diabetes mellitus.
- Gastroesophageal reflux disease.
- Hypertension.
- Juvenile rheumatoid arthritis.
- Obsessive compulsive disorder.

(Continued on page 8)

CDER Launches Web Site for Continuing Education

BY ELAINE FROST

CDER launched a new Internet site for educational seminars on Jan. 16. The first seminar, "New Drug Development in the United States," was originally developed by pharmacists in the Office of Training and Communications as a live continuing education presentation for pharmacists and physicians.

In its first week on the Word Wide Web, more than 250 individuals from around the world have taken the seminar.

The seminar will familiarize health care professionals with the Center's mission of assuring that safe and effective drugs are available to the American people. It emphasizes the vital role health care professionals play in helping us achieve our mission.

If you take the seminar from a Center computer on the CDER network, you cannot view the video portion. You should press the Course Transcript button to download a PDF version of the script and read along with the slides.

Non-CDER computers will need the RealPlayer program to view the video. You should not load RealPlayer onto a CDER computer either at home or work.

You can access the seminar from CDER's

(Continued on page 8)

Drug-Induced Liver Injury Workshop Slated for Feb.

A two-day conference and workshop, "Drug-Induced Liver Injury: A National and Global Problem," will bring together experts from regulatory bodies, industry and academia. An extension of the internal CDER course presented in April and November 1999, the highly participatory workshop will be held Feb. 12 and 13 at the Westfields Conference Center in Chantilly, Va. It is cosponsored by CDER, the American Association for the Study of Liver Diseases and the Pharmaceutical Research and Manufacturers of America.

Drug-induced liver injury is the most common cause for removing approved drugs from the market, preventing marketing, limiting a drug to second-line use or requiring special monitoring or restricted use.

In a series of three "white papers," an FDA working group has identified issues in the preclinical, clinical and post-approval phases of drug development and marketing. These can be found on the PhRMA Web site at http://www.phrma.org/meetings/news//2001-02-12.4.phtml.

(Continued on page 8)

JOE'S NOTEBOOK

"Boomer-itis"

OTCOM was facing a typical Parklawn Building space crunch, so in mid-January I moved from the 12th floor to the 17th. The *Pike* now temporarily shares space with MedWatch in Room 17-65.

With New Year's resolutions on my mind and the Super Bowl stirring memories of faded athletic prowess, I was chatting with one of my new office mates, MedWatch's Medical Director **Norman Marks, M.D.,** about exercise plans and their associated aches and pains.

We're not alone. According to the Consumer Product Safety Commission, sports-related injuries to adults ages 35 to 54—today's baby boomers—increased by 33 percent from 1991 to 1998. (While I'm a couple of years older, I can certainly relate.)

The commission's report, "Baby Boomer Sports Injuries," notes that:

- There were just under 276,000 hospital emergency room-treated injuries to persons 35 to 54 in 1991 compared to slightly more than 365,000 sports injuries to persons of these ages in 1998.
- When all medically attended sports injuries are included, there were more than 1 million injuries to baby boomers in 1998, compared to 778,000 such injuries to persons 35 to 54 in 1991.
- Sports injuries to baby boomers cost the nation $18.7 billion in 1998.
- Bicycling and basketball caused the largest number of trips to hospital emergency rooms. More than 65,000 bikers and 45,000 basketball players were treated in hospital emergency rooms in 1998.
- Boomer bicyclists died from head injuries at nearly twice the rate as children on bikes—likely because 69 percent of children wear helmets while biking compared to only 43 percent of baby boomers.
- The largest increase in injuries by far is among boomers doing general exercise and running. In 1991, fewer than 10,000 exercise and running injuries were reported. By 1998, the number had more than tripled. Injuries also increased in soccer, golf, weightlifting, in-line skating and swimming.
- Baby boomers represented almost one-third of all Americans who participated in sports in 1998. These 79.1 million people comprised more than 29 percent of the total U.S. population. In 1998, there were 14 million more Americans in the 35 to 54 age group than in 1991.

You can find a copy of the commission's report at http://www.cpsc.gov/library/boomer.pdf.

To help boomers stay active while reducing the surge in their sports injuries, the commission, the American Academy of Orthopaedic Surgeons and the American Orthopaedic Society for Sports Medicine are cooperating on a public education program trademarked "Boomer-itis." You can locate the program on the Web at http://www.boomer-itis.org. The site describes age-related changes to the body and the most common boomer sports injuries—sprains and strains in the shoulder, knee and ankle. It provides advice on ways to exercise safely and avoid many of these injuries, including:

- Warming up before and after any athletic activity with stretching or flexibility exercises.
- Listening to your body. As we get older, we aren't as flexible as we once were.
- Wearing protective gear, such as helmets and knee pads.
- Using the 10 percent rule by increasing activity in small increments.

Correction: Am I embarrassed! **Jerry Yokoyama** and **Scott Zeiss** were left off last month's listing of Office of Information Technology contributors who made their monthly column possible in the year 2000. Scott, especially, has contributed many articles.

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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OMBUDSMAN'S CORNER

Tolerance and Openness

BY JIM MORRISON

Tolerance, by definition, is the absence of bigotry or a civil and fair attitude towards those whose viewpoints differ from our own. But being tolerant doesn't require that we must reevaluate our views in light of a newly received opinion. We simply must treat others' views with civility and, at least superficially, respect.

Contrast tolerance with openness. Openness implies not only tolerance, but also a willingness to reassess our own views when confronted with a differing viewpoint. True openness requires that the reassessment be genuine and not forestalled by a superficial analysis of the qualifications of the espouser of the new opinion. True openness is a rare commodity.

We become experts in our field of drug regulation. We form opinions and make findings of fact, sometimes based on much training and study. But they are also based on fundamental assumptions about the world and on our personal value systems and experiences.

Understandably, we become very comfortable with our opinions and beliefs. Faced with ideas that are inconsistent with those opinions and beliefs, we resist.

The people we serve, the public, are a diverse population, and they don't necessarily share our experiences, training or values. They may come to different conclusions, given the same set of facts. Are they wrong? Is there an absolute right or wrong?

As I have often said, drug regulation is one of the most complex endeavors one can tackle. Part of good regulation is based on science. Rightfully, we value highly our scientific knowledge and insights into the pharmaceutical and clinical sciences and the law. But that is only a part of the story. A significant part of drug regulation involves societal issues, values and judgments that, even within CDER, may differ.

Every day, we makes decisions about what is best for the public health. Of necessity, these decisions are often made with less information than we would like, because if we waited for all the desired data, bodies would start to pile up. In part, these decisions are also based on values and assumptions that have little relevance to science.

How much should we rely on physicians and patients to read labeling? If they misuse drugs because of failing to read or understand labeling, does responsibility for the consequences, which may include deaths, fall on them or on us? What should trigger removal of a drug from the market? How does one balance the benefit of improved quality of life for some against serious damage caused to others? Is a longer life in pain better than a shorter one free from pain?

These are difficult questions. Ask various people, inside FDA or outside, and you will get a broad spectrum of answers. There are no magic formulas that can be relied on to make these decisions. There are no absolute truths. We cannot expect to be right all the time, whatever "right" means.

Given the uncertainties, it is vital that we articulate clearly the basis for our decisions. And we should view the inevitable criticisms of our recommendations and decisions as an opportunity to reevaluate our positions, to challenge our assumptions and to learn.

However, learning does not occur if our mindset is one of mere tolerance for differing viewpoints. Learning comes with genuine openness.

Jim Morrison is the Center's ombudsman.

EQUAL OPPORTUNITY CORNER

CDER Employees Remember Martin Luther King with Scholarship Fund

BY GLORIA MARQUEZ SUNDARESAN

The Rev. Dr. Martin Luther King Jr. holiday was celebrated Jan. 15 with programs, parades, speeches, concerts, rallies and family get-togethers. The federal holiday to commemorate King was signed into law in 1983 and officially celebrated for the first time in 1986.

King, awarded the Nobel Peace Prize in 1964, was an advocate of the nonviolent methods of protest practiced by Indian nationalist leader Mohandas Gandhi (1869-1948). Today, King is a model for young Americans and leaders in the nonviolent pursuit of civil rights, equality and justice.

Every January, CDER joins with other agencies in the Parklawn complex to honor King by participating in raising funds for the Martin Luther King Scholarship Fund by encouraging donations for MLK buttons, teddy bears and cups.

The Martin Luther King Commemorative Scholarship Committee raised $3,000 to help three financially disadvantaged scholars in the fall of 2000. So far, donations to this committee have helped support the educational expenses of three financially disadvantaged students in the Washington metropolitan area. Anyone interested in making a donation for this scholarship fund may contact the EEO Staff at 4-6645.

Gloria Sundaresan is a member of the EEO Staff.

Hussain to Head Office of Testing and Research

Ajaz Hussain, Ph.D., has been appointed Director, Office of Testing and Research. Dr. Hussain has served as deputy director for the last year and acting director during the past few months.

He received his bachelor's degree in pharmacy from the University of Bombay and his doctorate in biopharmaceutics and pharmacokinetics from the University of Cincinnati. He joined the Center in 1995 and, in 1998, became the director of the Division of Product Quality Research.

His leadership has been instrumental in helping OTR achieve its goals including promoting scientific leveraging within the OTR and Center. He serves as technical director of the Product Quality Research Institute to oversee the scientific relevance of its projects.

Rollout of Outlook E-Mail Program Begins

The Office of Information Technology began the deployment of Microsoft Outlook in January. We anticipate completing the rollout to all divisions by the end of 2001. The first building slated for installation is Corporate. The transition will proceed in a series of steps.

The first step will be the installation of Outlook on your PC. As the rollout moves to your building, an OIT technician will install the Outlook client on your PC. The installation will take about one hour. You will not need to be present during the installation. At this point you will still use TeamLinks or ALL-IN-1 for e-mail.

The next step will be training. OIT will coordinate training registration. Follow the instructions provided at that time to register and attend Outlook training. In the training you will learn the basics of using Outlook.

Once you have completed Outlook training, your e-mail profile will be switched over to Outlook. Your new e-mail messages will go to Outlook.

At that point, you will have to use Outlook to read and compose e-mail messages. TeamLinks/ALL-IN-1 can still be used to view old e-mail messages.

Please note one key difference between Outlook and ALL-IN-1: Outlook is not a substitute for a file storage system.

Each user will have a quota of 70 megabytes in Outlook. While this is large enough to accommodate e-mail, it is not large enough to serve as a repository for documents, PowerPoint presentations and the other various attachments that arrive by e-mail.

Now is a good time to get in the habit of managing your e-mail. Helpful actions include deleting messages that you don't need, periodically checking and cleaning out mail folders, and breaking the habit of using e-mail for document storage. By including these small changes into your daily routine, you will help insure a smooth transition for yourself from TeamLinks/ALL-IN-1 to Outlook.

Please contact the Help Desk (HELP) with any e-mail questions or go to our Web page (http://oitweb) and follow the Outlook link from the Notices section.

February IT Training

Monday	Tuesday	Wednesday	Thursday	Friday
			1	2
5 **E-Doc/ RetrievalWare** 1:00-4:00 (C) **Word Intro** 9:00-12:00 (P) **Word Formatting** 1:00-4:00 (P)	6 **E-Doc/ RetrievalWare** 9:00-12:00 (P) **JMP Class 1** 1:00-4:00 (P)	7 **DFS** 9:00-12:00 (P) **Excel Intro** 1:00-4:00 (P)	8 **Word Tables** 9:00-12:00 (P)	9
12 **E-Doc/ RetrievalWare** 9:00-12:00 (P) **E-Doc/ RetrievalWare** 1:00-4:00 (P)	13 **JMP Class 2** 1:00-4:00 (P)	14 **PEDS** 9:00-12:00 (C) **Creating PDFs** 9:00-12:00 (P) **E-Doc/ RetrievalWare** 1:00-4:00 (C) **MS Project** 1:00-4:00 (P)	15 **Access 97 Intro** 9:00-12:00 (C) **DFS** 9:00-12:00 (P) **Access 97 Queries and Reports** 1:00-4:00 (C) **DFS** 1:00-4:00 (P)	16 **Access 97 Form Design** 9:00-12:00 **(C)** **Access 97 Report Design** 1:00-4:00 (C)
19	20	21	22	23
26 **E-Doc/ RetrievalWare** 9:00-12:00 (P) **E-Doc/ RetrievalWare** 1:00-4:00 (P)	27 **E-Doc/ RetrievalWare** 9:00-12:00 (P)	28 **DFS** 9:00-12:00 (P) **DataMart** 1:00-4:00 (P)		

Key: Corporate Boulevard (C), Park Building (P)

The catalog, training materials, schedule and on-line registration can be found under Training at http://oitweb/.

Help Desk FAQs

Q: Should I save files as read-only that I'm going to check-in to DFS?

A: No! Applying read-only or password protections to a document will cause errors in DFS and prevent your document from archiving as final form. Please do not save any files as read-only and do not password protect any documents that will eventually be stored in DFS. The DFS server is read-only and files archived on the system are protected by server-level security.

Q: Can I place PDF documents submitted by sponsors into DFS ?

A: Avoid checking in PDF files created outside of the Center as they may have PDF attributes that conflict with DFS. It is a better idea to insert those PDF files into your own, CDER-generated PDF files that are created using CDER standards. For example, you should not check in a document that is set to open a particular Adobe index when the document is opened. Attendance in a DFS or Creating PDF Review Documents class will help you better understand PDF files and how they relate to DFS.

Q: Whenever I type "(C)"in Word, it is replaced with the "©" symbol. Is there a way to turn off this feature?

A: Yes. The AutoCorrect feature of Word allows you to set up corrections that occur seamlessly as you type.

This question is an example of the "Replace text as you type" attribute of AutoCorrect.

To change your AutoCorrect options:

- On the menu bar, click Tools and select AutoCorrect.
- To turn off this feature for all replacements, remove the check before the box that says "Replace text as you type."
- To remove one instance, find the item from the list and click the delete button.

For more AutoCorrect options, see the Word Help feature or contact the Help Desk (HELP).

DRUGS IN THE NEWS

New Anti-Fungal OK'd; New Use for Breast Cancer Drug

FDA announced on Jan. 29 it had approved caspofungin acetate (Cancidas Intravenous Infusion), a new anti-fungal medication for patients who are unresponsive to or cannot tolerate standard therapies for the invasive form of aspergillosis.

Caspofungin is the first approved drug in a new class of anti-fungal agents called echinocandins, which are believed to work by disrupting the creation of fungal cell walls.

Invasive aspergillosis describes a group of fungal infections caused by the fungus *Aspergillus.*

Most healthy individuals are unaffected by this common fungus; however, exposed individuals with weakened or abnormal immune systems may become seriously ill. In this population, this type of infection is often fatal.

FDA based its approval decision on the results of a small, multicenter, open-label, non-comparative study that was designed to evaluate the safety, tolerability and efficacy of caspofungin, as well as an integration of the efficacy information submitted in the preclinical and supportive clinical studies.

Merck & Co. Inc., Whitehouse Station, N.J., is the sponsor.

FDA on Jan. 10 approved a new indication for the breast cancer drug letrozole (Femara) as a first-line treatment for postmenopausal women with hormone receptor positive or hormone receptor unknown, advanced or metastatic breast cancer. Letrozole, an aromatase inhibitor, was approved for treatment of advanced breast cancer in 1997 in women whose cancer had not responded to anti-estrogen drugs.

Letrozole was shown to be more effective than tamoxifen in a randomized, double-blinded, multinational trial of more than 900 postmenopausal women, with locally advanced or metastatic breast cancer not amenable to treatment with surgery or radiation. In the study, letrozole was found superior to tamoxifen in delaying time to progression of disease. Median time to disease progression with letrozole was 9.4 months compared to 6 months for tamoxifen.

The incidence of side effects in the study was similar for letrozole and tamoxifen with the most frequently reported side effects including bone pain, hot flushes, back pain, nausea, arthralgia (or joint pain) and dyspnea (or labored breathing).

The drug is manufactured by Novartis Pharmaceuticals Corp., East Hanover, New Jersey.

On Jan. 5, FDA and Bristol Myers Squibb warned health care professionals that pregnant women may be at increased risk of fatal lactic acidosis when prescribed the combination of the HIV drugs stavudine (Zerit) and didanosine (Videx or Videx EC) with other anti-retroviral agents.

Lactic acidosis occurs when cells of the body are unable to convert food into usable energy. As a result, excess acid accumulates in the body, and vital organs such as the liver or pancreas may be damaged. Severe lactic acidosis is an infrequent, but well-described complication of the class of HIV drugs known as nucleoside analogues. Pancreatitis is also a well-described complication of didanosine and stavudine.

This new warning follows three reported cases of fatal lactic acidosis, with or without pancreatitis, that occurred in pregnant women taking stavudine and didanosine in combination with other drugs used to treat HIV. For more information, see the MedWatch Safety Information Summaries at http://www.fda.gov/medwatch/safety/2001/safety01.htm.

PIKE'S PUZZLER

Science, Safety Quiz

BY TONY CHITE

1. This food may result in an overdose of certain drugs. Examples of affected drugs are the statins for lowering cholesterol and the calcium channel blockers for high blood pressure. The food causing the problem is:

a. spinach b. grapefruit c. corned beef d. diet cola e. licorice

2. This element, once called quicksilver, is so toxic that a few grams can contaminate a 40-acre lake for one year. The element is:

a. arsenic b. iodine c. silver d. mercury e. lead

3. A fire extinguisher labeled "A" may be used on

a. All types of fire
b. Fires involving flammable liquids like gasoline, oil, and some paints
c. Fires involving energized electrical equipment
d. Fires involving paper, wood and other ordinary combustibles

4. The area of a circle, A, is determined by:

a. πd (pi multiplied by diameter)
b. C/d (circumference divided by diameter)
c. πr^2 (pi multiplied by the radius squared)
d. ½bh (One-half of the base multiplied by the height)

5. The malleus, incus and stapes (small bones found inside the ear) are also referred to as the:

a. hammer, anvil and stirrup
b. club, pick and shovel
c. fa, so and la
d. drum, fife and bugle
e. mortar, pestle and caduceus

6. H.C. Traute is the person responsible for:

a. Inventing the cigarette filter
b. Coining the phrase "Close cover before striking" found on matchbooks
c. Discovering the addicting properties of nicotine
d. A detailed statistical analysis of smoking and lung cancer

Answer key: 1b, 2d, 3d, 4c, 5a, 6b

Tony Chite is a pharmacist and CSO on CDER's Freedom of Information Staff.

PROJECT MANAGEMENT PROFILE

Project Managers Help Illuminate Drug Review Process

BY PATRICK E. CLARKE

One definition of a black hole is "a great void, an abyss."

Imagine submitting a proposal that you've spent a significant amount of time on to an agency and then not getting any feedback for weeks at a time.

No doubt there would be a great deal of frustration and anxiety.

That's just how the pharmaceutical industry sometimes feels about CDER, according to **Craig Ostroff, Pharm.D.,** a project manager for the Division of Pulmonary and Allergy Drug Products. "A lot of times people in industry feel they are submitting into a black hole and hoping for the best," said Ostroff, who spent more than three years in private industry in drug development.

"I can help illuminate that black hole for a sponsor," Ostroff said. As a project manager, that's part of his job description. "Basically, project managers are CDER's liaison with industry, or anyone, in fact, who is an applicant. Our positions are called 'boundary positions,' where we are trying to take internal issues and, in an appropriate manner, explain them to industry and vice versa."

There are eight other project managers in his division. "We serve as a resource for questions on regulatory matters," he said.

Project managers are assigned to manage submissions that are at any stage of drug development and include investigational new drug applications and new drug applications to post-marketing submissions.

"At any one time we are managing multiple submissions regarding labeling, chemistry and new indications. Once a project manager has the assignment, for each submission we have to either form a new review team or notify the already active review team," Ostroff said.

The review teams are multidisciplinary. In addition to project managers, the teams include medical officers, pharmacologists, toxicologists, chemists and statisticians and, sometimes, microbiologists, clinical pharmacologists and biopharmaceutical scientists. Project managers coordinate with the team leaders of each discipline when forming a review team.

"As project managers, we're not anybody's boss," Ostroff said. "We are facilitators. Project managers have the responsibility to make sure the review is done on time and the appropriate procedures, regulations and laws have been followed. Yet, we don't have the supervisory or administrative power to make it happen."

Project managers accomplish their jobs by building relationships. "We have to develop friendly, professional relationships and build trust to get the reviews accomplished. I strive to come through for my team members when they need assistance, and I hope they come through for me in kind," he said.

Although Ostroff has only been with the Agency since August, he has already developed a strong sense of camaraderie within his 51-person division. That sense has grown so strong that he's planning to join the Commissioned Corps this year.

"Joining the Corps will be a way for me to feel more connected. I like it here. I like the people all the way from the division director to the people who co-locate from other offices," said Ostroff, who has an abiding fascination with medicine and pharmaceutical science.

"I've been interested since high school in medicine and the way medicines worked, and pharmacy seemed the best way to develop that interest," he said. After obtaining both bachelor's and doctoral degrees in pharmacy from Rutgers University, Ostroff served in the role of a regulatory affairs manager for a consulting firm in New Jersey.

"I was on the opposite end of the telephone. I would prepare INDs and provide regulatory advice on how to approach the FDA," Ostroff said.

At that time, Ostroff had the perception that CDER "was overwhelmed with work and maybe not as responsive as industry would demand."

Since joining the Center, Ostroff realized that the answer is more complicated. "The industry only finds out what we tell them. I've become aware that one submission, which may seem simple to industry, could trigger a multitude of internal meetings and discussions to figure out the right way to respond," he said.

In another industry position, Ostroff was a project manager for research and early development of an anti-epileptic drug. "We took it from chemistry and development through animal testing to early human trials to Phase II where we got to see that it actually worked in people," Ostroff said.

"A core group of about a dozen of us did it. Many others helped part-time. Each of us in our own discipline did most of the things that pharmaceutical companies need entire departments to do. The drug we were developing actually seemed to help some patients who were difficult to treat. It was one of my greatest joys to see this drug helping people."

The practical experience he gained has benefited him in his current position. "I know what it's like to be on the other end of the telephone line. I'm familiar with the politics, feelings and worries that can be involved. I can help sponsors possibly design better, more targeted submissions because I've been there," he said. "I can also try to help our side understand what industry might be doing."

Why did an up-and-coming industry whiz kid join CDER? "My boss in the private sector had worked for FDA in the late '70s," he said, "and I was very impressed with his knowledge of the FDA and drug development. Plus, I had such positive interactions with the Agency that it struck my curiosity enough to decide to become a member of the ranks of the 'overwhelmed.'"

Ostroff's positive interactions with FDA haven't stopped. "I love the communication in this division," he said. "We had a team-building seminar recently, and the facilitator asked us to go talk to someone we hadn't spoken to in a while. We told her that just wasn't an issue in our division."

Ostroff plans to continue illuminating black holes for people, whether they're within or without the Center.

Patrick Clarke is the Pike's associate editor. He and Craig Ostroff met while attending CDER's New Employee Orientation.

PROJECT MANAGEMENT CORNER

Highlights From Last Year; New Initiatives to Bloom in 2001

BY DEBORAH KALLGREN

January gives us the opportunity to look back while also looking forward. As project managers, we saw our share of changes in the review management process last year. We faced these changes by taking full advantage of training and learning opportunities.

We know that we don't just want to keep up—we want to stay ahead of the curve by improving our knowledge, our performance and our abilities to work together. We have benefited from a state-of-the-art educational and experiential program designed to enhance our unique and varied skills—the Center's Regulatory and Project Management Certification Program.

A one-of-a-kind undertaking, it has no equivalent in either private or public sector programs dealing with our subject matter. It seamlessly integrates the learning of specific knowledge that can be applied immediately and the development of more general team-building skills.

The other part of its unique character derives from the many courses designed and delivered by senior members of our own discipline. CDER project managers are both teaching their fellow project managers and, in more recent months, reviewers, too.

Here are a few courses to highlight:

- *The IND Regulatory Overview Course*, consisting of five comprehensive, four-hour modules, was offered in March and September. We still couldn't meet the demand. Because of the level of interest, the course has now been opened to reviewers as well.
- *Castles, Swords and Shields*, a regulatory training game, was piloted with high marks in November. It made learning new regulations fun while reinforcing current knowledge and encouraging team-building skills.
- *Meetings and Minutes Course*, offered in April and December, focuses on the details of meeting management and the "secret" behind writing great minutes and getting them out quickly.

Workshops and Go-Aways

- *The Project Management and Regulatory Forum* was held in February and October. These all-day training sessions focused on "need-to-know" regulatory topics, initiatives and updates on issues. Subjects discussed included financial disclosure, post-approval studies, drug shortages, Office of Post-Marketing Drug Risk Assessment, Division of Scientific Investigations, generic drug suitability petitions and off-label drug promotion. Presentations on guidances and MAPPs included electronic submissions, pediatric exclusivity and advisory committee procedural and voting changes.
- *A Joint FDA and Drug Information Association Project Management Training Workshop* took place in May. The learning experiences targeted building higher levels of communications, teamwork and effectiveness through interactive sessions among more than 250 CDER, CBER and industry regulatory and project management professionals. This was our best workshop yet. The next offering of the three-day workshop, currently under development, is scheduled for April 30 to May 2, 2002.

New Initiatives

- *The NDA Course Working Group* members got down to business building the framework for a comprehensive regulatory overview course tailored to the needs of project managers. The hard work paid off. The pilot for this seven-module course will be delivered in half-day sessions scheduled about twice a week between March 12 and April 2.
- *The Project Management Tours and Shadowing Program*, piloted in July opened up learning opportunities by touring a manufacturing facility and learning about their drug development activities. The interaction benefited both participants and hosts alike and was truly a positive "eye opening experience." Further tours and shadows are in planning.

Changes we have been anticipating are already on the horizon and this will certainly mean more challenges to be met as review management professionals. But in looking back at our pursuit of learning and the solid training foundation we have built to ensure our continued growth, we clearly have the future in mind.

Deborah Kallgren is a project manager in OTCOM's Project Management Staff.

OGD Holds Successful Open House for 60 Project Managers

BY TIM AMES

Project managers from the Office of Generic Drugs held a successful open house for their project manager colleagues from throughout the Center on Jan. 18.

Attended by about 60 project managers, the open house was one of the CDER Project Management Communications Subcommittee's initiatives to improve communications among project managers.

The open house provided an excellent opportunity to network and to open communication lines across the Center.

OGD project managers delivered several vignettes on the project management processes used in approving generic drug applications. The objective was to explain what OGD project managers do and to demonstrate OGD's project management tools and techniques.

Project managers not only learned about OGD's structure and function, they also gained insight into OGD's unique project management tools such as the master queue application tracking database, the post-approval commitment-tracking program and the OGD letters application.

The open house received good reviews from project managers, and the Project Management Communications Subcommittee is looking forward to having more open houses throughout the Center.

For photos, please view http://www.fda.gov/cder/pike/jan2001photo.pdf.

Tim Ames, an OGD project manager and a PM Communications Subcommittee member, coordinated the event.

Report on Pediatric Exclusivity Provision Cites Successes, Gaps

(Continued from page 1)

- Pain.

The law, which grants sponsors six months' marketing exclusivity in return for conducting pediatric studies, sunsets Jan. 1 next year and required FDA to report on its experiences with the provision. The full report is available on CDER's Internet site at http://www.fda.gov/cder/pediatric/reportcong01.pdf.

In addition to the effectiveness of the exclusivity provision, the report addresses its adequacy, its economic impact and makes recommendations for modifications.

The current exclusivity provision does not apply to older antibiotics and other drugs lacking market exclusivity or patent protection. The provision's incentive is inadequate to encourage studies in drugs with low sales because the value of the exclusivity fails to offset the costs of the studies.

Finally, the incentive is inadequate for certain younger age groups, especially the neonatal age group for whom an appropriate trial cannot be designed until studies of older pediatric age groups have been submitted and analyzed. Although a second period of exclusivity is available in the law, it is very limited in scope and so far no sponsor has used this option.

Some drugs of importance to children, but for which the incentive has little or no value, remain unstudied. For example, FDA in 1994 identified the 10 marketed drugs most frequently prescribed for children that lacked adequate labeling (*Pike*, January 1997). Of these, six have no remaining exclusivity or patent life, and their sponsors were unable to take advantage of incentives under the pediatric exclusivity program. The six drugs, therefore, remain inadequately studied in and labeled for the pediatric population.

The report estimates that the costs of pediatric exclusivity will add less than one-half of 1 percent to the nation's pharmaceutical bill. Pediatric exclusivity should reduce certain types of health care expenditures, but increase others.

Better drug treatment information is expected to permit quicker recoveries from childhood illnesses, with fewer attendant hospital stays, physician visits and parental workdays lost. On the other hand, extended exclusivity will delay the introduction of lower-priced generic drugs, which will temporarily raise the average price of prescription drugs.

The report recommends renewal of the pediatric exclusivity provision with modifications to increase the program's efficiency. It suggests alternative incentives may be needed to address gaps in the current law regarding specific groups of children and classes of drugs for which current exclusivity provisions are inadequate or don't apply.

We would like to thank those who helped with writing the report, especially: **Jane Axelrad, Larry Braslow, Therese Cevtkovich, Leanne Cusumano, Nancy Derr, Kim Dettelbach, Liz Dickinson, Larry Goldkind, Ed Hass, Ann Witt** and **Janet Woodcock, M.D.**

The authors are members the Center's Pediatric Team.

CDER Launches Web-Based Educational Seminars for CE Credit

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homepage or directly at http://www.cderlearn.com. A commercial vendor is maintaining the site. You will have to register to view the site.

The seminar, while aimed at health care professionals, is open to anyone. Students, patients and consumers should find it interesting and informative. Pharmacists and physicians can earn one hour of continuing education credit for taking the seminar and completing the exam.

The seminar features slides and video presentations from the course's developers, **Brenda Kiliany, Pharm.D.,** and **Mary Kremzner, Pharm.D.**

This seminar provides an overview of the Center's regulatory role in drug development, review and marketing, including:

- Investigational and new drug application review.
- Drug testing in the laboratory and clinical trials in patients.
- The Prescription Drug User Fee Act and the FDA Modernization Act.
- Generic and over-the-counter drug review processes.
- Post-approval surveillance.

Future seminars are in the planning stages, and OTCOM is pursuing CE credit for nurses.

Elaine Frost is a public affairs specialist in OTCOM.

Liver Workshop

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Attendees should read the white papers in advance and be prepared to make constructive suggestions.

The conference will not propose regulatory guidance, but will seek suggestions and consensus on principles, areas of research, possible solutions and further work. Openings are still available for FDA employees who have not yet registered and may wish to attend. Contact **Lana Pauls** (PAULSL, 4-5612) directly.

FDA Sets Up Child Care Tuition Assistance Pilot

FDA has set aside $200,000 for a nine-month tuition assistance pilot program to help cover child care costs for qualified FDA employees who have an annual family income of $45,000 or less.

The pilot was developed in partnership with the National Treasury Employees Union through the FDA and NTEU Agency Partnership Council.

Tuition assistance will be offered for child care provided from Jan. 1 through Sept. 30. The initial deadline for applying for tuition assistance under the nine-month pilot is Feb. 16. If your application is filed by then and approved, it will be retroactive to Jan. 1.

You can apply after the initial deadline; however, benefits will not be retroactive. Approved applications received after Feb. 16 will be effective the Monday following the week of receipt.

To find more information and apply, visit FDA's Quality of Work Life Web site at http://intranet.fda.gov/ohrms/qwl/qwl.htm.