news along the pike

MARCH 4, 2002

CENTER FOR DRUG EVALUATION AND RESEARCH

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Clinical reviewers use 2-day retreat to explore issues

Theme: Working together to build a community of excellence

BY THE RETREAT COORDINATING COMMITTEE

More than 20 years have passed since the clinical reviewer community got together to talk about what it means to be a physician within CDER. On Oct. 30 and 31, more than 120 clinical reviewers from throughout the Center met in Gaithersburg to network and discuss issues important to their community. The retreat was conceived by Center Director **Janet Woodcock, M.D.,** and **Sandra Kweder, M.D.,** then acting director of the former Office of Review Management and now director of the Office of Drug Evaluation II. **Kim Colangelo,** special assistant in the Office of New Drugs, made it a reality.

Before the retreat, clinical reviewers were invited to a brainstorming session to elicit discussion topics. They were also asked to volunteer to serve as topic leaders during the retreat, and several rose to the challenge. The brainstorming issues, which came directly from the clinical reviewer community, became topics for the break-out sessions (page 11). These were:

- Business management/best practices for team leaders and reviewers.
- Recruitment, retention and compensation.
- Communication with industry.
- Professional development.

(Continued on page 10)

Center offices reorganized, realigned, renamed

CDER began the new year with a revised structure aimed at aligning similar functions and creating smaller, more manageable work units. Organizational charts are at http://www.fda.gov/cder/cderorg.htm.

A new "super" office, the Office of Pharmacology and Statistical Science is headed by **Paul Seligman, M.D., MPH.** OPaSS includes the Office of Drug Safety (formally the Office of Post-marketing Drug Risk Assessment) and the Office of Biostatistics (moved from the former Office of Review Management).

In addition to the old OPDRA functions, the Office of Drug Safety now includes the MedWatch program (moved from the Office of Training and Communications) and the medication guides function (moved from the Office of Medical Policy). There are no changes within the Office of Biostatistics.

John Jenkins, M.D., will head the Office of New Drugs, which contains the Offices of Drug Evaluation I through V and the new Office of Pediatric Drug Development and Program Initiatives (September-October *Pike).*

The new Office of Executive Programs, headed by **Debbie Henderson**, includes the Executive Operations Staff, Review Standards Staff, Advisors and Consultants Staff (moved from ORM), the International Program and the Information Management Program.

The new Office of Regulatory Policy, headed by **Jane Axelrad,** includes the Divisions of Regulatory Policy I and II and the Division of Information Disclosure Policy.

OPaSS and the Controlled Substance Staff will report to the deputy center director.

See pages 6 and 7 for a story on ODS and interviews with Drs. Seligman and Jenkins.

Thompson names Crawford to be FDA deputy commissioner

HHS Secretary **Tommy G. Thompson** named **Lester M. Crawford Jr., DVM, Ph.D.,** to serve as FDA's deputy commissioner of the Food and Drug Administration beginning Feb. 25.

Dr. Crawford will be the senior official at FDA pending the installment of a permanent commissioner.

"Lester Crawford has devoted his career to promoting safer products for the public, and he brings to the FDA valuable experience and leadership skills," Thompson said. "With his help, FDA will continue to build on its suc-

(Continued on page 12)

JOE'S NOTEBOOK

The virtues of patience in busy times

My parents and teachers used to caution me that patience is a virtue. Well, the *Pike's* authors who have been patiently waiting for this issue to emerge from my PC are certainly a virtuous bunch. They may have imagined their submissions were dropped into the in-basket of some obscure astrophysics journal. You, readers, are also a virtuous group.

As you're well aware, the events from Sept. 11 on have altered priorities at the Center. If we haven't been working on counterterrorism, we've been picking up the slack for our colleagues who have. That is the short story for the long hiatus in *Pike* issues.

If you feel like you've fallen into a time warp when reading this issue, that's true. Our patient authors submitted some of this material last year, but it should still be news to you. Despite Jim Morrison's admonition to resist the urge to overpromise (page 3), I'll try to get your *Pike* out more frequently.

Happy New Year to *Pike's* authors. Last year's authors, including the patient post-Sept. 11 crew, certainly deserve our thanks and congratulations. They spent many hours over and above their normal duties to tell you about their contributions to our common mission. A big thank you goes to:

Funmilayo Ajayi, Ph.D., Tim Ames, Carrol Assouad, Mary-Jane Atwater, Jackie Barber, Margaret Bell, Greg Brolund, Mei-Ling Chen, Ph.D., Nichelle Cherry, MLS, Tony Chite, Patrick E. Clarke, LCDR Lindsay Cobbs, Jerry M. Collins, Ph.D., Dale Conner, Pharm.D., Page Cottingham-Streater, Terrie Crescenzi, R.Ph., Nancy Derr, Kathy Kruse, MLS, Don Duggan, Mary Fanning, Elaine Frost, Noreen Gomez, Mary Ann Holovac, Peter Honig, M.D., Rich Johnson, Deborah Kallgren, Carol Knoth, MLS, Lana Kostecka, Lawrence Lesko, Ph.D., Sherunda Lister, Tim Mahoney, Jim Marshall, E. Jane McCarthy, Ph.D., James Minter, Ed.D., Justina Molzon, M.S., Pharm.D., Jim Morrison, Dave Moss, Diane Murphy, M.D., Chris Nguyen, Carol Norwood, Thomas F. Oliver, Ph.D., John Quinn, R.Ph., M.S., Lisa Rarick, M.D., Rosemary Roberts, M.D., William Rodriguez, M.D., Sandip K. Roy, Ph.D., Deborah Selbert, Gloria Marquez Sundaresan, Vali Tschirgi, Victor Vail, Sandra Valencia, Fran Weiss, Janet Woodcock, M.D., Su Yang, R.N., MSN, Karen Zawalick, and **Scott Zeiss.**

From fan mail to downstyle. The eagle-eyed among you will notice a small change in headline style with this issue. In publication design circles, the headlines in this issue are called "downstyle." They are capitalized like regular sentences. This contrasts with the so-called "upstyle" used previously in the *Pike.*

Designers prefer downstyle headlines because they are supposed to be easier to read. They are also easier to write and automatically create a more open and inviting appearance. The three empirical studies that designers cite in support of this, however, compared headlines with upper and lower case letters to those written in all capitals. I'm not aware of any scientific study directly comparing downstyle and upstyle.

I was prompted to make the change by a number of e-mails from readers of the last issue. Because I don't get much fan mail, I pay close attention to it. Several readers commented on how much they liked having the e-mail notification contain the headlines with links to the articles.

I made the change in headline style to make both the e-mail and the HTML indexes easier to read. In this electronic age, that's apparently the way many of you use the Pike. I also think it gives the PDF version of the *Pike* a cleaner look. The stylized headings over the regular columns won't change.

news along the pike

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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

New Year's resolutions

BY JIM MORRISON

Admittedly, New Year's resolutions are not exactly innovative fodder for a column at this time of year. I have my personal list, which I'm not sharing; but this one is a list of resolutions for my work life. If you like them, feel free to borrow some or all of them.

I resolve in 2002 to:

- **Change the public's image of government.** Not by fiat, not by using PR, but by doing simple things better, faster and more thoroughly than the public expects. I want people who contact me to be startled by how fast I return their calls, answer their e-mails and give them useful assistance or information. It's also satisfying to hear the transition in people's attitudes as they go from expecting bureaucracy to finding help.
- **Take time to listen and to care.** I'm required by my job to care about others' problems. I aim to do that better this year. The world would be a lot better and my job would be easier if everyone took time to empathize.
- **Improve my environment.** I don't mean clean up my office; although, that would be a change. I mean noticing the little things that impede doing my job and changing them. It may be seeing a need for a particular type of data that isn't on the CDER Web site and doing something about it. Whatever the impediment, it's often surprising how simple it is to remove the small annoyances we put up with daily.
- **Resist the urge to overpromise**. This is a hard one for me. I tend to underestimate the time it will take me to do a given task. I'll try to compensate in advance by adding a fudge factor into any time frame I promise as a completion date. People are impressed and grateful for work done within the promised time. They get annoyed at delays. I can prevent those annoyances by making realistic promises.
- **Take responsibility.** When something goes wrong, my first instinct is to look for a logical cause that is outside of my control. I need to remember that people don't expect perfection from human systems. They'll trust me more in the long run if I own up to mistakes and problems, whether they are mine or belong to the Agency. People accept an admission that an error was committed. They get angry at anything that smacks of blame shifting or lame excuses.
- **Keep an open mind.** I generally pride myself on having an open mind. But those pesky biases creep back in if I don't work diligently at keeping them out.
- **Learn.** Continuing education sometimes gets forgotten in the press of daily work. But in this job, I either learn new skills and knowledge or I become obsolete. I want to devote some part of each day to learning—not gossip or rumors—but real stuff.
- **Value my colleagues.** I often have reason to be proud of the people who work for CDER. Although I get lots of complaints, when I look closer, I frequently find that my colleagues did all that could be expected of them and more. I'm proud to be associated with CDER, and I need to celebrate it more.
- **Enjoy my job.** None of us knows what will happen next. Sept. 11 certainly brought that message home. So in the precious time I have here and now, I need my work to be enjoyable. I'm fortunate to say that mine is enjoyable, satisfying and meaningful. If it becomes less than that, it's time to find something that is enjoyable.

May this year be your best ever.

Jim Morrison is CDER's ombudsman.

Drugs in the news: Treatments for rare disorders

FDA on Feb. 1 approved a new use for the cancer drug imatinib mesylate (Gleevec) for treatment of gastrointestinal stromal tumor, a relatively uncommon tumor, affecting about 5,000 people in the United States. It is a tumor that generally arises within the stomach or intestinal tract and metastasizes within the abdomen or the pelvis.

First approved in May 2001 *(Pike,* April-May 2001) for treatment of chronic myeloid leukemia, Gleevec works by blocking enzymes that play a role in cancer growth.

On Jan. 22, FDA approved a new drug, nitisinone capsules, to treat hereditary tyrosinemia type I, a rare pediatric disease causing progressive liver failure and liver cancer in young children. Fewer than 100 children in the United States are affected by the disease.

Because of liver failure or liver cancer, children with hereditary tyrosinemia type I rarely survive into their 20s without a liver transplant. However, for children treated early enough with nitisinone, liver failure and liver cancer occur at much-reduced rates.

FDA announced on Dec. 10 the approval of fondaparinux sodium (ARIXTRA™) injection for reducing the risk of blood clots after orthopedic surgery for hip fracture, hip replacement, and knee replacement. The drug is the first synthetic anticoagulant indicated for use in these types of surgeries.

Pike's Puzzler

BY TONY CHITE

Unscramble the medical words:

1. OTRAA
2. TTHEPOOECSS
3. MOUTR
4. OYZGET
5. TLAPAEL
6. NOTIIPPRRSCE
7. NIGDASSIO
8. ARTLONDUSU

Key: 1. aorta; 2. stethoscope; 3. tumor; 4. zygote; 5. patella; 6. prescription; 7. diagnosis; 8. ultrasound

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

INFORMATION TECHNOLOGY CORNER

IT changes in store for New Year; Inactive Ingredient Guide on tap

CDER has been running Windows 95/98 on desktop systems since 1995. User and application requirements have increased to a point where Windows 95/98 can no longer meet our needs.

Microsoft's Windows 2000 Professional will be our next desktop operating system as part of the FDA Information System Architecture initiative. Windows 2000 Professional will be FDA's standard desktop operating system. The Agency has formulated a cross-center matrix team, the NT Admin/Desktop Technical Working Group tasked with deploying Windows 2000 Server and Windows 2000 Professional in a cohesive and integrated enterprise configuration.

Some of the key benefits of Windows 2000 Professional are:

- Greater reliability and stability. The upgrade is more than 40 times more reliable than Windows 95/98 and two to three times more reliable than Windows NT 4.0.
- Improved safeguards to prevent legacy applications from corrupting shared system files.
- Enhanced security including directory- and file-level encryption.
- Full plug-and-play compliance.
- Multiple monitor support.
- Support for mobile systems.
- Positioning CDER for standardized desktop operating system and environment.

More information will be available closer to the release of this operating system in the Center. **Gini Khalsa** (KHALSA) is the project manager for the Windows 2000 upgrade and an IT specialist with OIT's Division of Infrastructure Management and Services.

Information management

Many significant enhancements are coming later this year in how we access and store our information. The following systems are the first step toward CDER's goal of seamless access to all incoming and outgoing documents and the data associated with them.

Corporate Database Redesign Project. The Centerwide ORACLE Management Information System, known as COMIS, is our corporate database. It is used to track the status and progress of applications for investigational new drugs, new drugs and generic drugs. It is also used to generate mandatory user fee reports and to enable tracking of milestones and workload statistics for improved management accountability. OIT has redesigned the corporate database structure to make it more modern, flexible and comprehensive. OIT is now in the process of developing the Web-based screens, reports and query modules for storing and retrieving the application, submission and document data along with associated assignments, products, goals and targets. Most CDER systems rely on data contained in the corporate database. In particular, this project is developing concurrently with the other systems described in this article.

Electronic Document Check-In System. EDCI is a Web-based enhancement of the Division Files System that will be used to centrally archive, search and retrieve CDER-generated documents related to INDs, NDAs and ANDAs. Eventually, the system will also include documents like MaPPs, SOPs and general reference material. The immediate impact of this project will be better searching capabilities, faster interaction and automated update of review assignments, goals and status. The system is expected to reduce document room costs and promote a streamlined, harmonized process.

IT Web portal. The purpose of this project is to create a single, centralized, easy-to-use Web portal through which the CDER community can access all IT services. Services accessible through the portal will include customer relations management, procurement and acquisition, change control requests, technical support, training, CDER IT project data, application specifications, news as well as searches across DFS, Retrievalware file rooms, the Electronic Document Room, the CDER intranet and the Internet. The portal will provide an organized, structured approach for information display, retrieval and manipulation of CDER information. In addition, the portal will provide access to designated existing Web-based systems as the first step in providing the CDER community with a single point of access for IT services.

CDER Standard Letters update. The next version of the CDER Standard Letters system will be a Web-based system. It will catalog, maintain the templates and parameters for and create all CDER-generated documents related to the review of INDs, NDAs and ANDAs. These include letters, reviews, forms, memoranda, meeting minutes, telecons and consults. The upgrade is intended to be a companion application for the E-Doc Check-In system. Responsibility for this project has now shifted to OIT. **Michael Folkendt** and **Bronwyn Collier** had been responsible for CDER Standard Letters. They and other staff helping with these projects are expected to continue to be involved in assessing and incorporating business rules.

What you can do

These projects are all slated for release near the end of 2002. We want to make sure that your input is received now, rather than toward the end of development when changes will have to wait until a future update. **Cathie Schumaker** (SCHUMAKER), **Mark Gray** (GRAYM) and **Randy Levin** (LEVINR) in the newly formed Information Management Program are assisting OIT. Please contact Cathie or Mark if you have questions or comments regarding these systems.

Inactive Ingredient Guide is coming

The IIG is a list of inactive ingredients that are present in approved drug products. It provides reviewers with information on inactive ingredients that have been approved by the Agency. Once an inactive ingredient appears in an approved product that has not been withdrawn for safety or efficacy for a particular route of administration, that inactive ingredient would not usually be considered new and may require a less extensive review. The IIG was last produced in 1996.

The new IIG will list the maximum approved potency for each inactive ingredient by route and dosage form. A CDERnet Web query version will be available soon. The IIG Query will be updated quarterly. A publicly releasable version of the IIG Query for the CDER Internet will

(Continued on page 5)

EEO CORNER

Black chemist overcomes prejudice, achieves distinguished career

BY PATRICK E. CLARKE

"I remember sneaking a drink of water out of the whites-only fountain to see if there was any difference," said CDER's **Richard Hogart.** "I found out that water was water was water."

Hogart, who retired in January after more than 41 years of federal service, most of it with FDA, was recalling an era when segregation was the norm. Over the years, Hogart, a chemist in the Office of Pharmaceutical Science, discovered that like water, people are people are people.

In 1962, when Hogart began working at the FDA, American society was in upheaval, and segregation was slowly being overcome. His first supervisor felt the need to warn him about the culture of animosity he might find in the workplace.

"When I joined the FDA, my section was all-white, except for a Puerto Rican lady," Hogart said. Fortunately, Hogart was in a section that was focused on the work.

"People were very nice to me. To be treated as an equal was one of the more comforting and satisfying experiences in my life. We just settled in and had a job to do."

And for the next 39 years, Hogart did his job at the Agency. "If I'm doing something and I enjoy it, then I keep with it," Hogart said. "I could have gone into private industry, but I was living comfortably and enjoyed it. Opulence and materialism have their place, but there are advantages that can transcend that."

Hogart was born in Franklin, Va., a sawmill town of about 800 people. "My father only finished the eighth grade and spent most of his life working at the sawmill," Hogart recalled. "But he lived to 91."

In his younger days, Hogart worked on a peanut farm. Something he shares with former President Jimmy Carter—although Hogart firmly professes Virginia peanuts to be better than Georgia peanuts.

Thanks to encouragement from his high school principal and a $100 scholarship—big money in those days—Hogart went to Virginia Union University in 1955. He earned a bachelor's degree in chemistry. He was the first one in his family to get a college degree.

"Grey fields against an overcast sky," is how Hogart recalled his first day at college. "But bricks and mortar do not an institution make—some of the best four years of my life were spent there—I was fortunate," Hogart said. "It's a primarily black college, and I looked at the teachers as intellectual emancipators in spite of societal opinion at that time."

Hogart has a simple philosophy that helped mold his life and his years at FDA: "People are people. I think it was Booker T. Washington who said, 'I don't want to get to a place where I can hate any man.' I don't think there's been a more profound statement in 150 years."

With Hogart's retirement, there are five black chemists working in CDER. Whenever there is an opportunity, he tries to recruit. "I do a lot of tutoring and talking to science classes. The world is getting more technical, and you have to be prepared," Hogart said. "I always extol the virtues of working for the FDA. Not as many African-Americans go into engineering and chemistry," Hogart said. "It's a trendy kind of thing."

At age 67, Hogart often reflects on all that he's overcome, and he sums things up proudly by noting: "It's not so much about what color you are, but whether you can perform."

Patrick Clarke is a public affairs specialist in OTCOM.

OIT plans upgrades for 2002

(Continued from page 4)

follow.

Robert Reinwald (REINWALDR), an analyst with OIT, can be contacted for more information.

IT security reminders

- Always keep an up-to-date copy of McAfee on your CDER PC at home. OIT is testing software that will automatically update McAfee at home. Until that point, you should create diskettes from the OIT Web page.
- Never, under any circumstances, provide any passwords to anyone. Change all your system passwords regularly. The system requires you to change your LAN password every 90 days, but you can change it more frequently.
- Do not open attachments on messages that you are not expecting. Just because the message comes from someone you know does not mean it is virus free.
- Do not send messages about viruses around to others in the Center. If you have questions about whether a message you've received is a hoax, contact **Dave Moss** (MOSSD), the Center's information systems security officer.

March OIT training

Monday	Tuesday	Wednesday	Thursday	Friday
4 NDA Electronic Submissions Training (C) (FULL) 9:00 – 12:00 NDA Electronic Data Analysis Training (C) 1:00 – 04:00	5 Introduction to JMP Session I (C) 1:00 – 4:00	6 Introduction to Excel (C) 9:00 – 12:00	7 Introduction to MS Word (P) 9:00 – 12:00 MS Word Formatting (P) 1:00 – 4:00	8 DFS (C) 1:00 – 4:00
11	12 Introduction to JMP Session II (C) 1:00 – 4:00	13	14	15
18	19	20	21 MS Outlook E-mail (C) 9:00 – 12:00 MS Outlook Calendar (C) 1:00 – 4:00	22

Key: Corporate Blvd (C), Park Building (P)
Go to http://OITWeb to access training registration and resources.

Office of Drug Safety highlights risk management missions

By Patrick E. Clarke

The Office of Drug Safety, formed from the former Office of Post-marketing Drug Risk Assessment, is located under a new super office, the Office of Pharmacoepidemiology and Statistical Science (OPaSS), headed by **Paul Seligman, M.D.** (page 1).

"I think some people didn't know what we did before the reorganization. Now we're actively working to get the word out about ODS," said **Kathleen Bongiovanni,** ODS associate director for regulatory affairs.

Dr. Seligman is the ODS acting director until a replacement is named for **Peter Honig, M.D.,** who left FDA. The ODS deputy director is **Martin Himmel. M.D., MPH.**

Under the reorganization, ODS gained the MedWatch program, formerly with the Office of Training and Communications, and patient labeling and risk communication functions formerly with the Division of Drug Marketing, Advertising and Communications in the Office of Medical Policy.

ODS has a new structure, with three divisions:

- The Division of Drug Risk Evaluation headed by **Julie Beitz, M.D.**
- The Division of Medication Errors and Technical Support headed by **CAPT Jerry Phillips, R.Ph.,** as acting director.
- The Division of Surveillance, Research and Communication Support, led by **Anne Trontell, M.D.**

Meanwhile, ODS has an ambitious set of priorities for the new year. Chief among them are implementing the reorganization by getting personnel in place, establishing internal procedures for existing and newly assigned responsibilities and maintaining close communication and synergistic relationships with the Office of New Drugs and the OND reviewing divisions.

ODS will be involved in many Center initiatives dealing with risk management. These will include the development of a Risk Management White Paper, the identification of a risk management and risk communication research agenda and the launch and utilization of the new Drug Safety and Risk Management Advisory Subcommittee to the Advisory Committee for Pharmaceutical Science.

The white paper will define the problem, describe a viable approach to resolving the problem and develop future initiatives. The new advisory subcommittee is comprised of nationally recognized experts in the areas of risk perception, risk management, pharmacoepidemiology, clinical pharmacology, clinical research and medication errors. They will advise FDA on both general and product-specific safety issues.

"Our mission is to add value to the review of risk management programs and the review of drug safety issues," Bongiovanni said.

Future editions of *News Along the Pike* will cover each division in ODS in greater detail.

Patrick Clarke is a public affairs specialist in OTCOM.

Seligman to emphasize patient safety, partnerships, risk management

Paul Seligman, M.D., MPH, a captain in the Commissioned Corps, is now heading the new Office of Pharmacoepidemiology and Statistical Science after briefly serving as special assistant to **Steven Galson, M.D.,** CDER's deputy director. Before coming to the Center, Dr. Seligman worked at the Department of Energy and the National Institute for Occupational Safety and Health.

"I've done a lot of work using surveillance data and epidemiology to address and prevent public health problems," Dr. Seligman said, "and I've worked closely with Dr. Galson in the past. I believe that there is a good match between my experience and the Center's priorities of enhancing the post-marketing surveillance program and more effectively managing the risks associated with drugs."

As part of the reorganization, Dr. Seligman will lead OPaSS in risk management initiatives and patient safety programs. For the current fiscal year, Congress appropriated an additional $3.6 million for initiatives and new hires related to patient safety.

The Office of Drug Safety (formerly the Office of Post-marketing Drug Risk Assessment) and the Office of Biostatistics will be part of OPaSS, as well as the MedWatch program (formerly part of the Office of Training and Communications) and the patient labeling/Medguide functions (formerly with the Division of Drug Marketing, Advertising and Communications).

Dr. Seligman believes that bringing MedWatch, an important vehicle for both receiving adverse event reports and reaching out to the medical community, into OPaSS is a "natural" fit.

"Given our focus on the prevention of adverse drug events through effective communication of risk, having staff with expertise in labeling and medication guides in OPaSS will greatly enhance our effectiveness," he said. "I believe that good safety decisions must be based on sound analyses of the best available evidence—so having the Office of Biostatistics as part of OPaSS ensures we will be using the latest and best techniques to identify safety signals."

The combination of offices under one super office will have a synergistic effect that will help all the offices in OPaSS function more effectively. "I believe that it's very important for us to understand the public health consequences of regulatory actions in order to improve the benefit-risk profile of using medicines," he said.

Dr. Seligman has five main goals initially for OPaSS:

- Focusing on the Centerwide risk management initiative.
- Improved utilization of existing data and recently acquired data sources.
- Conducting and supporting research.
- Improving our understanding of medication errors and the actions that prevent them.
- Broadening and strengthening partnerships in both the public and private sectors.

(Continued on page 7)

Jenkins hopes to build OND on previous successes of ORM

John Jenkins, M.D. the newly chosen permanent director of the Office of New Drugs, said he hopes to build on the successes of its predecessor, the Office of Review Management.

He said he sees delegation of responsibility and authority as key to making his new job a successful one.

Jenkins has served at every level in new drug review during his 10 years with CDER, most recently as the director of the Office of Drug Evaluation II since 1999.

"I've been a primary reviewer, a team leader, a division director and an office of drug evaluation director," Jenkins said. "That experience has provided me with a strong background for being OND director because I'm better able to understand the organization and to appreciate the viewpoint of every staff member."

Several challenges are on the horizon for the new office, Jenkins said.

These include:

- Implementation of the new pediatric exclusivity legislation recently passed by Congress.
- Negotiation and implementation of the reauthorization of the Prescription Drug User Fee Act.
- Finalization and implementation of good review practices and review templates.

"Another big challenge will be to find a way to manage the workload of the new job so that I have time to remain connected to the OND staff and the drug review process. I plan to do this by following my previous management practice of delegating responsibility and accountability to the lowest possible level while maintaining an appropriate level of involvement in the various tasks," he said.

OND is a streamlined and more focused organization than was ORM, which had been headed by **Murray Lumpkin, M.D.,** and then by acting directors Heidi Jolson, M.D., and **Sandra Kweder, M.D.**

"I hope to be able to build on the previous successes of ORM under the leadership of Drs. Lumpkin, Jolson and Kweder and to continue FDA's important role in promoting and protecting the public health of the United States," Jenkins said. "OND's greatest resource is its people and I know that I can count on the staff to join me in achieving this goal."

His immediate goal will be to get better acquainted with the staff across OND and get a more complete understanding of issues the office is dealing with. "I plan to do this through a series of 'site visits' to review divisions and ODEs that will allow me to meet formally and informally with division leadership and staff."

Jenkins is the recipient of numerous honors and awards from FDA and CDER in addition to the HHS Secretary's Award for Distinguished Service. That award extolled his "exemplary teamwork in developing a Department-wide strategic plan to counter the asthma epidemic through research, surveillance, public health practice, education and evaluation."

Jenkins entered federal service in 1990 as the staff physician for the pulmonary and critical care section at the McGuire Department of Veterans Affairs Medical Center, Richmond, VA.

He began his CDER career as the acting pulmonary supervisory medical officer, Division of Oncology and Pulmonary Drug Products.

Jenkins obtained his bachelor of science degree summa cum laude from East Tennessee State University in Johnson City and his medical degree with highest honors from the University of Tennessee in Memphis.

He is board certified in critical care medicine, pulmonary disease and internal medicine.

He served an internship and residency in internal medicine at the Medical College of Virginia in Richmond and served a fellowship in pulmonary medicine at the same institution. He is a fellow of the American College of Chest Physicians.

—Patrick E. Clark

Seligman expects synergistic effects in new office combinations

(Continued from page 6)

"Medication errors by definition are preventable," Dr. Seligman said. "To the degree we can accurately pinpoint the source of the errors and engage the clinical community in their prevention, we'll be able to reduce medication-associated morbidity and mortality."

Planned activities include the enhancement of the office's ability to track and analyze adverse events and the ongoing evaluation of the effectiveness of patient package inserts and other materials received with pharmaceutical products. Dr. Seligman wants to broaden collaborations with consumers, healthcare providers, academia and other federal agencies to reduce medication errors, improve the safe use of drugs and better define the impact of the Center's regulatory activities on improving public health.

Dr. Seligman has long been a champion of improving public heath. "I went to medical school after serving two years in the Peace Corps in Kenya, and I knew then that I wanted to work in the public health arena," he said.

Before joining CDER in July, Dr. Seligman served as the deputy assistant secretary for health studies at the Department of Energy from 1994 to 2001. Before that, he spent 10 years at the Centers for Disease Control and Prevention. In 1994, he was a congressional fellow for health policy working in the office of Sen. Paul Wellstone on health care reform legislation.

Dr. Seligman earned his bachelor of science degree in chemistry from Yale University in 1974, his medical degree from the University of California Davis in 1980 and a master's degree in public health from the University of Michigan in 1989. He is board certified in internal medicine, occupational medicine, and public health and general preventive medicine.

He is the author or co-author of numerous articles and book chapters focusing on work-related injuries and illnesses, including occupational lead exposures and lead poisoning, occupational skin disorders, carpal tunnel syndrome, public health surveillance, injuries resulting from violence in the workplace and radiation health studies.

—Patrick E. Clarke

OCPB SCIENCE DAY

Importance of gender, ethnic variability in PK/PD highlighted

BY KOFI KUMI, PH.D., HOUDA MAHAYNI, PH.D., SANDIP ROY, PH.D., VANITHA SEKAR, PH.D., AND LARRY LESKO, PH.D.

The Office of Clinical Pharmacology and Biopharmaceutics held its 10th Science Day Nov. 2. The scientific presentations attracted scientists from OCPB, the Office of Generic Drugs, the Center for Veterinary Medicine and the Center for Drug Development Science at Georgetown University.

In the Science Day's keynote address, Janice Schwartz, M.D., emphasized the importance of evaluating potential gender and ethnic differences in pharmacokinetic/pharmacodynamic analysis. Dr. Schwartz is professor of clinical medicine at the University of California at San Francisco and is a member of the core faculty in UCSF's clinical pharmacology training program.

Despite the underrepresentation of women and minorities in clinical studies, there is mounting evidence that the physiologic differences among these groups and differences in social habits can result in different responses to drugs, Dr. Schwartz said. She offered several examples:

- The bioavailability of verapamil is higher in women than men with chronic atrial fibrillation.
- Sex differences in drug clearance are clinically significant, especially for narrow therapeutic index drugs such as digoxin, cyclosporine and vancomycin.
- Midazolam clearance has been shown to be greater in women than men.
- Differences in renal tubular secretion were illustrated with quinine-amantidine interaction. This interaction is seen in men but not observed in women.
- The erythromycin breath test exhibits differences due to gender in response to the probe for CYP3A4/5. However, ethnic differences were not observed in response to this probe in men with hypertension.
- Population analysis of sustained-release nifedipine indicates differences in clearance due to gender and race. Women have higher clearance for sustained-release nifedipine than men, and whites have higher clearance than African-Americans.
- There are pharmacogenetic variants resulting in differing frequencies of each polymorphism among ethnic and racial groups. Ethnic differences in polymorphisms of CYP3A result in, for example, 30 percent slower hepatic midazolam clearances in CYP3A41B.
- Racial differences are exhibited in CYP3A5 expression.
- Ethnic differences in polymorphism of CYP2D6 and allelic variation in CYP2C9 exist.

In conclusion, Dr. Schwartz recommended that additional data be generated to provide information on the differences in gender and ethnic response to drug therapy. This will help practitioners to prescribe the right drugs and dosing regimen for women and people of different ethnic backgrounds.

Intramural presentations

B. Nhi Nguyen, Pharm.D., in her talk "Individual vs. population QT correction: Inferences from a pilot study," compared individual and population correction methods for drugs with different effects on heart rate and QT interval. Three models of QT correction were applied to dose, QT and heart rate for drug A and B. The general equation for the models is $QT = \alpha * RR^{\beta}$, where $\beta = 0.5$ for Bazett's model, 0.33 for Fridericia's model and is estimated for the Power model. Estimation was performed using the naive pooled and nonlinear mixed effects approaches. Dr. Nguyen noted that the Power model estimated by NONMEM provided the best fit of the data. She concluded that individual modeling of QT-heart rate data provides the best approach to correcting QT. Dr. Nguyen won first prize for podium presentations.

A presentation by **Gerald Fetterly, Ph.D.,** on "Pharmacokinetics of paclitaxel-containing liposomes" showed that liposomes alter the kinetics and tissue distribution of paclitaxel and largely explain the lower toxicity observed with liposomal paclitaxel. Dr. Fetterly won second prize for podium presentations.

Gabriel Robbie, Ph.D., presented results of sensitivity analysis of bioequivalence parameters of parent drug and metabolite. Dr. Robbie generated Monte Carlo simulations of parent drug and metabolite using a one-compartment model with first-order absorption. Each simulation scenario consisted of 1,000 studies with 24 subjects in each study. The results indicated that differential sensitivity of parent's and metabolite's maximum or peak drug concentrations, Cmax, and plasma concentration-time curves, AUC, to variability in different rate constants. In all the scenarios, he indicated, the results based on either parent or metabolite bioequivalence metrics reflected true bioinequivalence, but not necessarily true bioequivalence of the test product. Dr. Robbie concluded that differential sensitivity of parent and metabolite Cmax and AUC might have direct implications in powering bioequivalence studies. Dr. Robbie's presentation won third prize for podium presentations.

Sam Haidar, Ph.D., presented his research entitled "Evaluation of the QT interval in patients with ischemic heart disease using Holter monitoring." The goal of his study was to evaluate interday variability, circadian rhythm and heart rate correction of the QT interval in patients with ischemic heart disease. Electrocardiogram data were collected continuously over 66 to 72 hours by means of Holter monitoring in 45 ischemic heart patients. He noted that interday variability was highly subject dependent and ranged from a low of about 50 msec to greater than 100 msec. He concluded that variability in the QTc interval appears to be highly subject-dependent in this patient population. An apparent circadian pattern was observed in the QT interval even after correcting for heart rate.

Sandip Roy, Ph.D., presented a talk entitled "Genetic deficiency of Phase II enzymes can cause drug-mediated toxicity: An example." He presented results of a study that demonstrated reduced glucuronidation of SN-38 results in increased toxicity of irinotecan (CPT-11) and identified the specific isoform of UDP-

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OCPB Science Day examines ethnic, gender variability in PK/PD

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glucuronidation transferases, UGT, involved in SN-38 glucuronidation. The major dose-limiting toxicity of irinotecan therapy is diarrhea. Dr. Roy concluded that UGT1A1 is the isoform responsible for SN-38 glucuronidation. These findings indicate a genetic predisposition to the metabolism of irinocetan, suggesting that patients with low UGT1A1 activity, such as those with Gilbert's syndrome, may be at an increased risk for irinotecan toxicity.

Sandra Suarez, Ph.D., presented a talk titled "Pharmacokinetic/pharmacodynamic modeling as an aid to efficient drug delivery system selection: The effect of chaperon H-MAP on pulmonary delivery of insulin to rats." She concluded that PK/PD model can be utilized to predict and select appropriate doses of insulin and chaperone H-MAP to achieve maximum systemic exposure of insulin delivered by spray-instillation.

Poster presentations

This year saw a record number of 13 poster presentations. The poster prize award winners were: Dr. S.W.J. Lau, first prize; Drs. Elena Mishina and Vanitha Sekar, second prize winners. The posters included:

- "Exposure-response factors affecting long-term efficacy: A case study," **D.J. Chartterjee, Ph.D., A. Parekh, Ph.D., H. Malinowski, Ph.D., J. Hunt** and **H. Sun, Ph.D.**
- "PK/PD modeling of Drug C in cystinosis," **Sulliman I. Al-Fayoumi, Ph.D.**
- "Clinical consequences of *in vitro* estradiol (E2) binding to sex hormone binding globulin and albumin," **S.W.J. Lau, R.Ph., Ph.D.,** and **J. Venitz, M.D., Ph.D.**
- "The use of simulations to evaluate the effect of renal function on drug exposure and provide dosing recommendations," **Sam H. Haidar, Ph.D., Suresh Doddapaneni, Ph.D.,** and **David Udo, Ph.D.**
- "Example of PK/PD modeling utility in labeling recommendations," **Sulliman I. Al-Fayoumi, Ph.D.,** and **John Hunt.**
- "Assessment of the contribution of components in a combination drug product using population PK modeling," **Elena Mishina, Ph.D.,** and **Mehul Mehta, Ph.D.**
- "Bioequivalence testing of chiral drugs: A simulation study," **H.J. Kwon, C.G. Sahajwalla, M. Mehta, P.J. Marroum,** and **J.V.S. Gobburu.**
- "Population pharmacokinetic modeling to support pediatric use of fluvoxamine," **V. Sekar, Ph.D., J. Gobburu, Ph.D., Jim Chang, Ph.D.,** and **Troy ZumBrunnen, Pharm.D.**
- "Modeling and simulation supporting double IV bolus dose of eptifibatide in patients receiving percutaneous coronary intervention," **Gabriel J. Robbie, Ph.D., Emmanuel O. Fadiran, Ph.D.,** and **Mehul Mehta, Ph.D.**
- "Considerations in analyzing single-trough samples using mixed effect modeling" **Brian Booth, Ph.D.,** and **Joga Gobburu, Ph.D.**
- "The impact of imbalanced design of categorical covariates on model misspecification and parameter distinction between sub-groups in population analysis," **S. Lee, H. Sun, E.D. Bashaw, A. Selen,** and **J. Lazor**
- "Evaluation of the dermatopharmacokinetic approach for bioequivalence assessment of topical drug products," **Mamata S. Gokhale, Everitt H. Jefferson, Robert L. Hunt, Robbe C. Lyon,** and **Tapash K. Ghosh.**
- "Drug interactions involving St. John's wort data from the FDA Adverse Reaction Reporting System" **Min Chen, Shiew-Mei Huang, Julie Beitz,** and **Peter Honig.**

For the first time, this year's science day activities included OCPB Jeopardy. The three divisions in OCPB participated in this fun-filled, scientific game. The questions were selected from topics such as FDA regulations and history, PK/PD 101, Drug Metabolism 101, bioavailability, bioequivalence and analytical methodology.

The audience cheered loudly for the participants. We all learned more about the science, FDA regulations and trivia. The Division of Pharmaceutical Evaluations I answered the most questions, followed by DPE II and then DPE III. **Dr. Sandip Roy** hosted Jeopardy with assistance from **Dr. See-Yan Lam** of OTCOM and **Dr. Shiew-Mei Huang**, "The Judge."

A committee representing the three divisions and immediate office in OCPB and Office of Generic Drugs organizes the science day. The members are **Drs. V. Sekar (chairperson), G. Robbie, J. Duan, J. Gobburu, W. Qiu, R. Sandip, H. Mahayni, K. Kumi, J. Zongyi** along with **Susan Banks, Wes Metz** (deputy director, OCPB) and **Dr. Larry Lesko** (director, OCPB).

The authors are all members of the Office of Clinical Pharmacology and Biopharmaceutics, and Dr. Lesko is the director.

Five OTC manufacturers settle FTC charges of 'Made in USA' mislabeling

The five companies that account for nearly all of the private-brand manufacturing of pain relief products in the United States agreed in November to settle Federal Trade Commission charges that they falsely represented that certain of their over-the-counter analgesics were made in the United States.

According to the FTC, many of the "Made in USA"-labeled products contained imported active ingredients (bulk aspirin, acetaminophen or ibuprofen compounds) that constitute a substantial portion of the total cost of the finished products.

The FTC said that this labeling violates the Commission's standard that "Made in USA" claims be supported by evidence that the product is "all or virtually all" domestically made.

The proposed settlements in these cases would prohibit the companies from misrepresenting the extent to which any of their OTC drug products that contain analgesics are made in the United States.

"American consumers are more sensitive than ever to claims that a product is made in America," said Howard Beales, Director of the FTC's Bureau of Consumer Protection.

Clinical reviewers' retreat focused on 7 key themes

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- Review process and information technology issues.
- On-going interaction and communication/knowledge management.
- Tasks that could be done by others.

On the first day of the retreat, members of each break-out session identified a wide range of issues on each topic and grouped them into no more than 10 broad categories.

On the morning of the second day, all 120 participants met and used a new interactive survey tool to prioritize the issues identified in each break-out session. The Audience Response System, a survey tool available from OTCOM, allows individual participants at a meeting to answer questions anonymously using a wireless, hand-held keypad.

As each breakout group presented its list of 10 issues, each clinical reviewer identified which ones he or she felt were the first, second and third priorities on the list. The seven breakout sessions then reconvened to focus on potential solutions to their top three issues.

These results were presented on the second day (page 11). Joining the afternoon meeting to hear the presentations were office and division directors involved in new drug review and members of CDER's Senior Management Team.

Working groups, including volunteers and management champions, have been established to further develop the recommendations identified at the retreat.

During the retreat, facilitators and recorders from the Division of Drug Marketing, Advertising and Communications, and the Office of Training and Communications joined ORM to help the topic leaders keep their groups on track.

The retreat coordinating committee thanks these facilitators and recorders: **Thomas Abrams** (DDMAC); **Dorothy Ballmann, M.S.** (OTCOM); **Mandy Eisemann** (OTCOM); **Cynthia Fitzpatrick** (OTCOM); **John Friel** (OTCOM); **Noreen Gomez** (OTCOM); **Cheryl Kaiser** (OTCOM); **See Yan Lam, Ph.D.,** (OTCOM); **Jane McCarthy, R.N., Ph.D., FAAN,** (OTCOM); **James Minter, Ed.D.,** (OTCOM); **Janice Newcomb, M.S.** (OTCOM); **William Oswald** (ORM); **Nancy Smith, Ph.D.,** (OTCOM); **Leslie Wheelock, M.S., R.N.** (OTCOM); and **Dale Wilcox, M.S.** (OTCOM).

The keynote speech for the retreat was delivered by John F. Beary, III, M.D., FACP. Dr. Beary, the medical director for arthritis research at Procter & Gamble Pharmaceuticals, regarding "Leading for Change: Solving Complex Problems in a Government Environment."

A retired Navy captain, Dr. Beary also served as principal deputy assistant secretary of defense for health affairs from 1981 to 1983, where he was awarded the department's highest civilian award, the Distinguished Public Service Medal.

TRAINING AND DEVELOPMENT

Continuing education programs for physicians, pharmacists reaccredited

BY DALE WILCOX

The Accreditation Council for Continuing Medical Education recently granted four more years of certification to CDER's continuing medical education program for physicians. Also, the American Council for Continuing Pharmaceutical Education awarded us six more years of continuing pharmaceutical education accreditation.

Accreditation means that a specific educational activity such as Scientific Rounds, the Wednesday afternoon Scientific Seminar, courses and workshops can be designated for CME, CPE or both if certain educational and administrative criteria are met.

The ACCME and the ACPE each has its own accreditation standards and criteria for quality. However, both sets of criteria address three primary areas:

- Mission and purpose.
- Educational planning and evaluation.
- Administrative management.

The mission component pertains to the purpose or goal of the program, content areas, target audience, types of activities provided and the expected results of the program.

The educational planning and evaluation component relates to processes used to link educational need with a desired outcome and the use of needs assessment data to plan the activity, communicate its purpose or objective and evaluate the overall effectiveness of the continuing education activity in meeting identified educational needs.

Lastly, we must have an organizational and administrative framework with the resources to support our activities and have in place a system for presenting activities in compliance with policies for disclosure of commercial support.

As a condition of accreditation, we are periodically required to undertake an in-depth examination of our continuing education programs. The goal is to encourage us to reflect upon our continuing education program, conduct a self-study of our compliance with accreditation requirements, create a report of this self-study and, ultimately, move in the direction of better, more effective continuing education for our physicians and pharmacists.

There are three parts to the reaccreditation process: conducting a self-study, creating a self-study report and participating in a reaccreditation survey.

As required during 2001, the Division of Training and Development first conducted a self-study of the Center's continuing pharmaceutical education program. Next, DTD conducted a self-study assessment of the continuing medical education program.

After evaluation and analysis of this self-study report the ACCME recognized our continuing medical education program with its exemplary status for our use of an assortment of needs assessment methodologies. This best practice designation ranks CDER among the best nationally in the area.

Continuation of CDER's status as an approved provider of CME and CPE continues a mark of distinction that predates the formation of Center and was first conferred in the late 1980s to the former Bureau of Drugs.

Dale Wilcox is the DTD deputy director.

Clinical reviewers' retreat sets priorities to promote excellence

BY THE RETREAT TOPIC LEADERS

Here are summary reports from the clinical reviewers' retreat (pages 1, 10):

Business management/best practices for team leaders and reviewers

This session focused on processes and systems practices that optimize the timely completion of the review cycle. There was lively discussion of current methods for managing the review process and communicating within divisions, the Agency and with sponsors. The three prioritized issues for future attention are:

- Development of systems to facilitate consistency of regulatory policy.
- Exploration of methods to empower team leaders and clinical reviewers in order to facilitate the review process.
- Exploration of methods for achieving an optimal balance between written documentation and efficient decision making.

Topic leaders: **Susan J. Walker, M.D., John Kelsey, DDS, MBA,** and **Marcello Barreiro, M.D.**

Recruitment, retention and compensation

While numerous issues were raised, the attendees established the following priorities:

- Develop a streamlined, coordinated system to attract and retain new recruits.
- Improve clinical reviewer retention by, among other things, formulating career development plans and facilitating professional development opportunities.
- Evaluate current compensation and develop proposals to reflect today's marketplace.

Clinical reviewers clearly expressed their pride in serving the public and believe that addressing the issues will enhance CDER's ability to continue to attract and retain qualified staff.

Topic leaders: **Robert Harris, M.D., Ph.D., FACS, Sharon Hertz, M.D., Leonard Kapcala, M.D.,** and **Philip Sheridan, M.D.**

Communication with industry

Specific suggestions for improving the flow of information between industry and the Agency were developed. Foremost was the need for well-structured meetings with well-briefed participants.

Time should be set aside for summarizing issues and identifying areas of agreement and disagreement, whether the meeting is face-to-face or a teleconference. Key components in the communication process are flexibility, mutual respect and professional conduct.

Topic leaders: **William Boyd, M.D.,** and **Jennifer Harris, M.D.**

Professional development

The priority initiatives were:

- Establish a clinical reviewer course, similar to a hospital's grand rounds, which offers continuing education credits.
- Identify and promote opportunities to assist clinical reviewers in meeting their requirements for licensing, board credentialing and recertification.
- Establish a "detail swap/reviewer exchange" program.

Topic leaders: **Raymond E. Joseph, M.D., FACP, FACG, Scheldon Kress, M.D.,** and **Markham Luke, M.D., Ph.D., James Witter, M.D,, Ph.D.**

Review process/IT issues

Information technology issues affecting clinical reviewers raised a lively discussion. Some management perspective was added. **Randy Levin, M.D.,** the Center's associate director for electronic submissions, assisted with issues concerning the Electronic Document Room; and **Michael Ortwerth, Ph.D.,** a science policy analyst from the Review Standards Staff. assisted with the clinical review template. The three key issues were:

- Speed and searchability of the Division Files System.
- Laptop availability.
- Remote access speed and reliability.

Ralph Lillie, the director of the Office of Information Technology, responded with an outline of OIT's upcoming plans—"an E-doc check-in for every laptop"—and agreed to work closely with the clinical reviewer community.

Topic leaders: **Edward Cox, M.D., MPH, Peter Bross, M.D.,** and **Armando Oliva, M.D.**

Ongoing interactions and communications/ knowledge management

Participants discussed and identified issues of communication and information sharing within CDER, particularly as they relate to the work of clinical reviewers. Specific areas of concern included:

- Communication between divisions regarding drugs under review for multiple indications.
- Communication between primary review divisions and other disciplines, divisions and centers.
- Center- and Agency-level dissemination of information, such as new policies and guidances.

The participants identified a need for a user-friendly, searchable CDER intranet site for clinical reviewers. This site would contain tools, such as review templates, links, policies and guidances, as well as other relevant information.

Topic leaders: **Gerald J. Dal Pan, M.D., MHS, Deborah J. Leiderman, M.D., M.A., David Gan, M.D., Dr.PH** and **Eric Bastings, M.D.**

Tasks that could be done by others

Participants recognized that everyone works hard, but questioned whether particular tasks are best suited for those to whom they are currently assigned. The following key areas were identified:

- The assessment of several types of regulatory submissions.
- The preparation of final documents by clinical reviewers.
- The redundancy of having each discipline enter the same descriptive information into review documents.
- The concept of "essentializing" the review process.

The participants recommended further examination of the feasibility of two new positions, tentatively designated as regulatory associate and document specialist. These positions could provide professional growth opportunities for current Center employees while reducing the burden on clinical reviewers.

Topic leaders: **Mark S. Hirsch, M.D.,** and **Steven Hirschfeld, M.D., Ph.D.**

Crawford is top official at FDA; Schwetz to continue in science role

(Continued from page 1)

cesses in ensuring the safety of foods, drugs and medical products for all Americans."

In an e-mail to FDA employees, Dr. Crawford said he was delighted to be back among his colleagues.

"This Agency has always played a critically important role in the health and safety of American citizens," he said, "and that role has gained even more importance since September 11. As you continue to carry out your traditional tasks of ensuring the safety and effectiveness of medical products and ensuring that food is safe, you are also expanding your work on a variety of counterterrorism measures to protect the American public. I am proud to join you in these efforts.

"FDA's strength is FDA's people. I look forward to working with each and every member of FDA's dedicated staff in the days and weeks to come."

Dr. Crawford most recently served as head of the Center for Food and Nutrition Policy at Virginia Tech. He also served as administrator of the Department of Agriculture's Food Safety and Inspection Service from 1987 to 1991 and as director of FDA's Center for Veterinary Medicine from 1978 to 1980 and again from 1982 to 1985. He received a doctor of veterinary medicine from Auburn University in 1963 and a Ph.D. in pharmacology from the University of Georgia in 1969.

During his career, he has also served as executive director of the Association of American Veterinary Medical Colleges, executive vice president of the National Food Processors Association, as chairman of the University of Georgia's Department of Physiology-Pharmacology and as a practicing veterinarian.

Dr. Crawford takes over from **Bernard A. Schwetz, DVM, Ph.D.,** a career FDA executive who has served as acting principal deputy commissioner since Jan. 21 last year. Dr. Schwetz, senior advisor for science, will continue to work on public health and FDA issues within the Agency.

"Dr. Bern Schwetz has led the FDA during a challenging year, when the nation faced its first bioterrorism attack," Thompson said. "Forward-looking actions by FDA, like early and rapid approval of effective drugs against anthrax, played a crucial role in saving lives. I thank Bern for his service over the past year."

As he ended his role as acting principal deputy commissioner, Dr. Schwetz sent an all-hands e-mail to welcome Dr. Crawford and thank FDA employees for their help. "Unprecedented events have occurred in the past year, and it speaks well for FDA that we came through them so well," he said.

"Our success did not happen by chance or because of the efforts of one individual. FDA is an organization of experienced, talented and extremely dedicated public servants who rise to every challenge, be it cutting edge technology or public health crisis. This has long been true but was never been more evident than in the events of last fall. It has been a tremendous privilege and pleasure to work with you."

CDER Live! risk management broadcast to be available on-line for 90 days

By Elaine Frost

CDER and the Drug Information Association presented a *CDER Live!* satellite broadcast on March 1 and are continuing to make it available by webcast. The topic is, "Managing Medicines' Risks: Do We Have the Answers?"

Anyone, regardless of affiliation, who missed the broadcast may view it 24 hours later and for the next 90 days with no charge at http://www.lmpdg.com/docs/CDER.html.

Managing the risks of medicines is a shared responsibility of industry, CDER, the healthcare professional community and consumers. The program explores ways to improve understanding of the complex issues involved in managing these risks.

During the first part of the program, a group of outside experts gives an overview of the current societal environment concerning the risk management of medicines. In the second half of the program, CDER officials provide information about initiatives and the ongoing responsibility of managing medicines' risks within the Agency. In addition, the external group of guests poses a number of insightful questions to the Center panelists during the second part of the program.

Risk management goes to the core of what CDER does, said **Steven Galson, M.D., MPH,** deputy director of the Center. Galson kicked off the discussion of the risk management. He noted that premarket review cannot identify all the system issues that occur during a product's life cycle. The Center will continue to balance risk and benefit, he said, and not just focus on risk.

The panelists were:

- **Janet Woodcock, M.D.,** director, CDER.
- **Steven Galson, M.D., MPH,** deputy director, CDER.
- **David J. Horowitz,** acting director, Office of Compliance.
- **Ajaz Hussain, Ph.D.,** deputy director, Office of Pharmaceutical Science
- **Jerry Phillips, Pharm.D.,** associate director for medication error prevention, Office of Drug Safety.
- **Paul J. Seligman, M.D., MPH,** director, Office of Pharmacoepidemiology and Statistical Sciences.
- Laurie Flynn, senior research and policy associate, Columbia University.
- John A. Gans, Pharm.D., executive vice president and CEO, American Pharmaceutical Association.
- Arnold J. Gordon, M.S., Ph.D., former senior director of worldwide harmonization at Pfizer Inc. and now an independent consultant.
- Eric S. Holmboe, M.D., associate professor of medicine and director of faculty development and evaluation, Department of Medicine, Yale University School of Medicine.
- Malcolm Wheeler, director in the law firm of Wheeler Trigg & Kennedy.
- **Deborah Henderson,** director, Office of Executive Programs, who will moderate the discussion.

Elaine Frost, a public affairs specialist in OTCOM, is producer of CDER Live!