news along the pike

DECEMBER 6, 2001

CENTER FOR DRUG EVALUATION AND RESEARCH

VOLUME 7, ISSUE 8

INSIDE . . .

PIKES' CORNERS

CDER Celebrates Employee Achievements

Fall Honors Ceremony Held for 67 Individuals, 43 Groups

BY JACKIE BARBER

At the fall Honor Awards Ceremony in Gaithersburg, the Center presented awards to 67 individuals and 43 groups. Acting Center Director **Steven Galson, M.D.,** noted that he was delighted to help celebrate the many accomplishments of CDER employees.

"We have hard-working and highly motivated men and women in CDER who every day make contributions to the public health," Dr. Galson said.

The Montgomery County Police Color Guard presented the colors, and Kevin Barber sang the national anthem. **Rita Thompson,** the director of the Division of Management Services in the Office of Management, announced each award.

Office directors provided an explanation of the achievements, and Dr. Galson and the Center's senior managers presented the awards.

The awards and those recognized were:

FDA Outstanding Service Award

Funmilayo O. Ajayi, Ph.D.

Deborah L. Birenbaum, M.D.

Tawni M. Brice

Gregory V. Brolund

Jerry M. Collins, Ph.D.

Joseph P. Griffin

Coralee G. Lemley

Olivia A. Pritzlaff

(Continued on page 8)

Changes in Accutane Risk-Management Program OK'd

FDA advised consumers and health care providers Oct. 31 about significant changes to the risk management program for pregnancy prevention for users of isotretinoin (Accutane). The new program is called SMART (System to Manage Accutane Related Teratogenicity). The manufacturer, Roche Laboratories, developed SMART in consultation with FDA. The program is designed to enhance safe and appropriate use of isotretinoin by strengthening the drug's existing comprehensive patient education program.

Isotretinoin is approved to treat the most serious form of acne. This form of acne is painful, permanently disfiguring and does not respond to other acne treatments. Isotretinoin is very effective, but its use carries significant potential risks, including birth defects and even fetal death.

In recent years, as more women have been receiving prescriptions for isotretinoin, the risk that pregnant women may be inappropriately using the drug has increased. SMART involves

(Continued on page 12)

Library Outlines Resources for Risk Management

BY CAROL KNOTH, MLS, AND NICHELLE CHERRY, MSLS

A good starting point for gathering information on risk management is the FDA report, *Managing the Risks from Medical Product Use: Creating a Risk Management Framework*, available at http://www.fda.gov/oc/tfrm/riskmanagement.html. The report identifies the categories of risk from medical products, addresses FDA areas of current pre- and post-marketing involvement and presents recommendations for the future.

The five activities of risk management are good terms or phrases to use when searching for information in print or electronic resources. These terms are:

- Risk assessment.
- Risk confrontation.
- Risk intervention.
- Risk communication.
- Risk management evaluation.

(Continued on page 11)

JOE'S NOTEBOOK

Life Expectancy Reaches Record High

We trust that our day-to-day work is having a positive impact on public health, even if, at times, the link may seem remote. So you may be interested to know that your fellow Americans are living longer than ever before on average.

Life expectancy for Americans reached a record high of 76.9 years in 2000 as mortality declined for several leading causes of death, according to preliminary figures from a report by the Centers for Disease Control and Prevention.

Americans taking control of their own health with lifestyle changes has contributed to the falling death rates from leading killers like heart disease, cancer and stroke. Improved diets, exercise, avoiding substance abuse and smoking cessation are critical to the public's health.

However, many of us who have reached a certain age know that we still need medicine to lend a helping hand to our clean-living habits. We can take pride in the fact that our work has helped the improved estimates of the nation's health.

The new estimates for higher life expectancy and lower death rates are featured in the CDC report, *Deaths: Preliminary Data for 2000,* an analysis of over 85 percent of the death certificates recorded in the United States for 2000.

The report shows that age-adjusted death rates continued to fall for heart disease and cancer, the two leading causes of death that account for more than one-half of all deaths in the country each year. Mortality from heart disease has declined steadily since 1950, while cancer mortality has been on the decline since 1990.

Age-adjusted death rates also fell for other leading causes of death, including: stroke, diabetes, chronic lower respiratory diseases, chronic liver disease and cirrhosis, homicide, suicide and accidents or "unintentional injuries."

In addition, the preliminary infant mortality rate in the United States fell to its lowest level ever in 2000—6.9 infant deaths per 1,000 live births, down from a rate of 7.1 in 1999.

The report also shows that mortality decreased by 3.7 percent for HIV infection in 2000, the fifth straight year of decline. After increasing every year between 1987 and 1994 at an average of 16 percent annually, HIV mortality leveled off in 1995, dropped 29 percent in 1996, 48 percent in 1997, and 21 percent in 1998, before slowing to a 3.6 percent decline in 1999.

Meanwhile, mortality increased for certain leading causes of death, including Alzheimer's disease, influenza and pneumonia, kidney disease, hypertension, septicemia and pneumonitis due to solids and liquids, a condition that disproportionately affects the aging population and which emerged for the first time as one of the 15 leading causes of death.

The age-adjusted death rate has generally followed a decreasing trend from 1994 to 1998, but increased in 1999 relative to 1998. The 1999 increase was associated with two influenza outbreaks. The preliminary age-adjusted death rate for 2000 is 0.4 percent lower than the 1998 final rate despite a major influenza outbreak at the beginning of the year.

The general decrease in mortality between 1999 and 2000 resulted from decreases in the death rate for people 1 to 4 years old and for those 55 years old and older. A slight increase of less than 1 percent in the death rate occurred for age group 45–54 years. Other changes were not statistically significant.

The report can be found on-line at the CDC Web site at http://www.cdc.gov/nchs. If you're not a big fan of their preliminary reports, the same site has their final mortality data for 1999.

news along the pike

The Pike is published electronically approximately monthly on the World Wide Web at:

http://www.fda.gov/cder/pike.htm

Photocopies are available in the Medical Library (Parklawn Room 11B-40) and its branches (Corporate Boulevard Room S-121 and Woodmont II Room 3001).

Views and opinions expressed are those of the authors and do not necessarily reflect official FDA or CDER policies. All material in the Pike is in the public domain and may be freely copied or printed.

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

NEWS ALONG THE PIKE
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OMBUDSMAN'S CORNER

Annual Report: Process Problems, Unfairness Top Complaint List

BY JIM MORRISON

Recent history is counted as the time before Sept. 11 and the time since. This annual CDER Ombudsman's report is mostly from before that fateful day. It's too early to tell what effect, if any, the attacks will have on the rate or kinds of complaints in the future. Therefore, this report reflects business in the good old days.

The number of cases and complaints stayed within the ranges experienced in past years, except that e-mail traffic rose again an estimated 20 percent. In keeping with the trend over the past two years, internal complaints represented only about 1 percent of my work. I tabulated the external complaints using the same categories as previous years for better trend identification. As you can see, the percentages in each category were consistent with the preceding two years, but there are some apparent trends worth noting.

External Complaints	FY 1999	FY 2000	FY 2001
Process problems or inadequate information about them	36%	42%	41%
Unfairness of a policy or decision	38%	30%	37%
Untimeliness	15%	12%	11%
Difficulty gaining access	5%	6%	9%
Uncivil or unhelpful interactions	3%	6%	2%
Miscellaneous	3%	4%	1%

First, it was gratifying to see that the previous upward tick in uncivil or unhelpful interactions was reversed. I hope we are on our way to reducing it to zero. Complaints about timeliness continued to decrease, not only for user fee applications but also for generics.

On the negative side, the biggest increase in complaints this past year, both in percentage and importance, was the access issue. Most of these involved a failure to grant timely meetings or a failure to return phone calls within a reasonable time. Some of the process complaints also involved meetings. These included inadequate or late minutes, failure to resolve disagreements about what was said and other deviations from the meeting MaPP, which is available at http://www.fda.gov/cder/mapp/4512-1.pdf.

Complaints about meetings came from all segments of the drug industry, large and small firms alike. In talking with project managers, it is clear that meetings and minutes of meetings are a tremendous workload burden. The Center holds more than a thousand meetings a year with sponsors of new drug applications.

People in industry devote a lot of resources to preparing for and participating in these meetings, because they view them as absolutely vital to the drug development process. Whatever resources we spend on assuring that all parties walk away from the meetings with the same messages is well spent.

As I have said before in this column, well-written and timely minutes that reflect the understanding of the participants can save months of work for us and the applicants.

If you have a complaint or a solution to a problem, please send me an e-mail or give me a call (morrisonj@cder.fda.gov, 301-594-5443).

Jim Morrison is the Center's ombudsman.

FDA, VA Ink Agreement to Study Suspected Adverse Effect of HIV Drugs

FDA and the Veterans' Administration have agreed to work together to improve clinical knowledge about the adverse effects of drugs used to treat HIV infection. An interagency agreement was signed Nov. 20. Both agencies will jointly conduct an epidemiological study to determine whether the destruction of bone cells from avascular necrosis that affects people with AIDS is linked to the use of certain drugs to treat HIV or is a natural consequence of the viral infection.

The study will focus on cases of suspected AVN that are registered with the Veterans Health Administration's centralized HIV registry in Palo Alto, Calif. This is the world's largest clinical database on HIV and AIDS and contains data on approximately 50,000 patients, including 18,000 who are currently receiving VA's treatment.

The Center's Office of Post-Marketing Drug Risk Assessment will develop Web-based software that will help VA clinicians efficiently and confidentially augment the available information on suspected cases of AVN with the radiological data and other clinical detail necessary to confirm the diagnosis.

The resulting dataset, stripped of any information that could identify patients, will be used by FDA to conduct the epidemiological study. Depending on the study's outcome, FDA could take steps to change the labeling of certain antiviral drugs and inform prescribers.

"A team from OPDRA and the Division of Anti-Viral Drug products will be analyzing the data from the study," said **Judy Staffa, Ph.D.,** the principal investigator for FDA.

FDA Ranked in Top 7 Agencies as Good Places to Work

The October 2001 issue of *Washingtonian Magazine* ranked FDA fourth in the top seven Federal agencies that are "terrific places to be."

Our high retention rate was one of the reasons for the ranking The article added that willingness to implement FlexiPlace contributed to high retention. Also mentioned was the Agency's high level of monetary awards for employees.

INFORMATION TECHNOLOGY CORNER

Easier-to-Use, Web-Based Time Reporting System on Tap

New user-friendly software for time reporting will be available for the next time-reporting period in 2002. You will be able to access the new Time Reporting System for the Web, or TRS Web, from the current time-reporting home page at http://cdernet/timereport.

The software will feature the same data entry as the current application but with an enhanced Web interface that will make our time reporting easier and provide resources to increase accuracy.

One of the new features is proxy capability. You will be able to designate someone to enter time-reporting data for you and see a list of your designated proxies, guaranteeing privacy. You will also be able to see who has designated you as his or her proxy.

An additional improvement from the current application will be the capability to search on the time-reporting categories. You will be able to search on the category code, description, classification and the tasks in each of those categories.

Access to the new TRS Web user-friendly intranet interface will be available for home users connecting via the Remote Access System.

OIT is performing final testing to ensure you will find the TRS Web interface friendly and easy to use.

The OIT point of contact is **Sandra Valencia** (VALENCIAS).

Transfer of 1st NDA to Archives

The National Archives and Records Administration recently has accepted custody of new drug application No. 10976 as a permanent historical record. The NDA was the first approved for an oral contraceptive tablet, G.D. Searle & Co.'s norethynordrel/mestranol (Enovid).

NARA is the repository for those records considered historically significant and, therefore, worthy of permanent preservation for use by future researchers. This transfer marks the first time that a drug application has been accepted into the collection. After accessioning at NARA's Initial Processing Unit, the application will eventually be housed at the Archives II building in College Park.

Manufacture of Enovid ceased in 1992; however, it still remains an active application. NARA has agreed to protect those portions of the application covered by FDA's confidential, trade secret and privacy regulations.

Over the past two years, representatives from application's sponsor and the Agency have worked with NARA's appraisal archivists to ensure a smooth review and acceptance of the application.

At FDA, those involved in the transfer included the FDA History Office, the FDA records officer, CDER's Division of Reproductive and Urologic Drugs Products and OIT's Division of Data Management and Services. Once initial processing is done, a short ceremony will mark the occasion for the Agency, the company and the Archives.

To learn more about NARA and CDER's information and records management polices, contact **Scott Zeiss** (ZEISSS).

Help Desk FAQ

Q: I'm at another CDER computer and want to check my Outlook e-mail. How do I do that?

A: Through Outlook Web Access:

- Type CDMAIL in the Internet Explorer address field.
- Read the notices, then click on the OK-Goto-Exchange button.
- Select the Click Here link.
- In the Logon field, type your full, Internet e-mail address (e.g., user@cder.fda.gov).
- Enter your username and password.
- Click OK.

The Web interface is only available from PCs logged into the CDER network and provides similar functionality to Outlook, but is limited in that you can only view text attachments.

Contact the Help Desk (CDER HELP) for more information.

December OIT Training

Monday	Tuesday	Wednesday	Thursday
10	11 MS Outlook (P) 9:00—12:00 MS Outlook (P) 1:00—4:00	12 Word Tables (P) 9:00—12:00	13 MS Outlook (C) 9:00—12:00 MS Outlook (C) 1:00—4:00
17 MS Outlook for Admin Staff (C) 9:00—12:00	18 MS Outlook for Admin Staff (P) 1:00—4:00	19	20

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

Go to http://OITWeb to access training registration and resources.

PIKE'S PUZZLER

Know Your Bones

BY TONY CHITE

Match the bone in Column A with the region where it is found in Column B.

A	B
1. hamate	a. ankle
2. incus	b. hand
3. calcaneus	c. wrist
4. occipital	d. shoulder
5. ulna	e. lower jaw
6. talus	f. skull
7. mandible	g. neck
8. hyoid	h. ear
9. clavicle	i. foot
10. metacarpal	j. forearm

Answer key: 1c; 2h; 3i; 4f; 5j; 6a; 7e; 8g; 9d; 10b.

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

TRAINING AND DEVELOPMENT CORNER

CDER Visiting Professor Lecture Series Marks 1st Year

BY E. JANE MCCARTHY, PH.D.

To keep our reviewers and scientists current with changes in science, technology and the pharmaceutical industry, CDER seeks new and innovative ways to gain and exchange information. The Visiting Professor Lecture Series, which just completed its first successful year, is part of that effort. The program also aims at establishing positive relationships with academic experts.

The lecture series encourages informal dialogues with visiting university-based scientists. The discussions are held directly in the divisions and offices where our reviewers and scientists work rather than in a large lecture room. The topics are specific and targeted for a small number of reviewers. Ample opportunity for discussion and questions is provided.

This contrasts, for example, with the CDER Seminar series. These formal presentations are held centrally for a larger audience with only a little time allotted for specific questions and discussions.

The lecture series was developed with the assistance of reviewers from CDER offices and divisions. During the last year, more than 35 visiting scientists participated. Each month, two to five scientists have met with small groups of reviewers to provide focused scientific information exchange. Most divisions have held one or two discussions so far this year. Outstanding participants were the Division of Dermatological Drug Products with six speakers, the Office of Clinical Pharmacology and Biopharmaceutics with eight and the Office of New Drug Chemistry with five.

The Division of Training and Development in the Office of Training and Communications handles the travel orders, pays travel expenses and provides a small honorarium for the visiting scientist.

The Center plans to continue the program next year. For more information about the program, contact one of the division or office representatives or me (7-3492, MCCARTHYE).

The representatives working with the lecture series program are:

ODE I

- **Judith Racoosin, M.D.,** Division of Neuropharmacological Drug Products.
- **Richard Pazdur, M.D.,** Division of Drug Oncology Products .
- **Juan Pelayo, M.D.,** Division of Cardio-Renal Drug Products .

ODE II

- **Robin Huff, Ph.D.,** Division of Pulmonary and Allergy Drug Products.
- **Cynthia McCormick, M.D.,** Division of Anesthetic, Critical Care and Addiction Drug Products.
- **Mary Purucker, M.D.,** Division of Metabolic and Endorine Drug Products.

ODE III

- **Sandip Roy, Ph.D.,** Division of Gastrointestinal and Coagulation Products Drug.
- **Mark Hirsch, M.D.,** Division of Reproductive and Urologic Drug Products.
- **Nakissa Sadrieh, Ph.D.,** Division of Medical Imaging and Radiopharmaceutical Drug Products.

ODE IV

- **Narayana Battula, Ph.D.,** Division of Anti-Viral Drug Products.
- **Sousan Altaie, Ph.D.,** Division of Anti-Infective Drug Products.
- **Mark Goldberger, M.D.,** Division of Special Pathogens and Immunologic Drug Products.

ODE V

- **James Witter, M.D., Ph.D.,** Division of Anti-Inflammatory, Analgesic and Opthalmologic Drug Products.
- **William Timmer, Ph.D.,** Division of Dermatologic and Dental Drug Products.
- **Josie Yang, Ph.D.,** Division of Drug Products Over-the-Counter.

Other Offices

- **Kathleen Bongiovani,** Office of Post-Marketing Drug Risk Assessment.
- **Sonia Castillo, Ph.D.,** Office of Biostatistics.
- **Patrick Nwakama, Pharm.D.,** Office of Generic Drugs.
- **Shiew-Mei Huang, Ph.D.,** Office of Clinical Pharmacology and Biopharmaceutics.
- **Mona Zarifa, Ph.D.,** Office of New Drug Chemistry.
- **Moheb Nasr, Ph.D.,** Office of Testing and Research.

E. Jane McCarthy is director of the Visiting Professor Lecture Series in DTD.

2002 Science Forum to Focus on Multidisciplinary Support of Public Health

The 2002 FDA Science Forum will focus on how different scientific and regulatory disciplines support the Agency's public health programs. The event, "Building a Multidisciplinary Foundation," will be held Feb. 20 and 21 at the Washington Convention Center.

The first day will focus on research, policy development, and review in public policy decision-making. The second day will emphasize how the principles of public health surveillance, from both a domestic and a global prospective, can be applied to FDA's science issues.

An integral part of this year's science forum will be interactive break-out sessions that discuss in depth the importance of research, review, policy and regulation in the development of FDA's public health policies.

The break-out session topics will include bioengineered foods, botanicals, bioterrorism, antibiotic resistance, children's health issues, tissue engineering, genomics and bovine spongiform encephalopathy.

The break-out sessions on the first day will focus on the importance of sound research and review in responding to public health issues. Those on the second day will examine the impact of policy and regulation on public health programs.

The FDA Science Forum is open to all those interested in learning more about the Agency's multi-faceted scientific approach to many diverse public health issues. Information about the program and registration can be found at the FDA Web site at http://www.fda.gov or by contacting **Suzanne Fitzpatrick, Ph.D.** (7-4591, sfitzpat@oc.fda.gov). On-line registration is at http://www.aoac.org.

PROJECT MANAGEMENT CORNER

Pilot Trips Reveal Site Tours, Job Shadowing Better Together

BY DEBORAH KALLGREN

Because the impressive feedback from the pilot trip for Project Manager Site Tours and Job Shadowing training initiatives (September-October 2000 *Pike)*, the Project Management Coordinating Committee funded three more pilots. The objectives were to gather more data and to determine whether trips that focused only on the shadowing aspects of the program would be as useful a training experience.

In August, two teams of three to four senior project managers visited facilities of Pfizer Inc. in Groton, Conn., and Eli Lilly and Co. in Indianapolis. (A third trip planned for late September was canceled.)

Unlike the first pilot, which combined the site tour and shadowing experiences, these tours focused exclusively on job shadowing.

Most participants found the experience enhanced their understanding of how industry's regulatory affairs teams prepare themselves for the challenges faced in developing new pharmaceutical products and the importance of FDA and industry communication during the process.

"Shadowing industry's regulatory project managers shed significant light on how both industry and FDA conduct regulatory affairs," said **Sean Belouin** from the Dvision of Anti-Viral Drug Products. "It provided a greater sense of what each other does in our daily capacities as regulatory project managers and usefulness in improving the communication system between industry and FDA."

Alice Kacuba, from the Division of Gastrointestinal and Coagulation Drug Products, echoed Sean's viewpoint and emphasized that communication was key. "Neither we, nor industry should hesitate to ask questions of each other," she said. "There will always be two sides to any regulated business—the business and the regulators—but the perceived wall between us must come down."

Others gained insights through observing the discussions and planning involved in the drug development process. **Melodi McNeil,** also from DGCDP, especially enjoyed the chance "to sit in on a status meeting at Pfizer, which was analogous to our review team meetings."

All felt that in most cases the information and understanding that they gained from this experience could not have been obtained in any other educational forum. However, the participants from both groups agreed that they would have derived an even greater understanding of drug development had the site tours also been included in their trip agendas.

Even participants who had previously taken part in manufacturing tours as part of their pharmacy school educational curriculum expressed similar opinions.

Following review of the comments from all pilot group participants, blending site tours and job shadowing is optimal not only from a learning standpoint but also for time and budgetary reasons. As a result, we expect that future trips will be conducted as one program to maximize learning and that prospective agendas will need to reflect the new organization of the training program.

"While Industry certainly has an interest in financially rewarding drugs, it is obvious that we both share the goal of providing the highest quality pharmaceuticals to the public," **Rene Kimzey,** from the Division of Special Pathogens and Immunologic Drug Products. "It was great to feel that we are working together for the common good of the people."

Deborah Kallgren is a project manager on the Project Management Program Staff in OTCOM.

EQUAL OPPORTUNITY CORNER

Native American and Native Alaskan National Heritage Month Celebrated

BY GLORIA MARQUEZ SUNDARESAN

For about 25 years Native Americans have been recognized with presidential proclamations. In 1976, the president proclaimed a week in October as "Native American Awareness Week." This was followed with annual weeklong observances on different dates.

In 1994, based on a congressional resolution, the president proclaimed the month of November as "National American Heritage Month."

Of the 2.5 million estimated total U.S. Indian population today, there are about 558 federally recognized tribes in the United States. In addition, there are 225 Alaska Native tribal entities.

The first Americans contribute to the way of life, culture and progress of this country. They shared not only their appreciation of, respect for and love of nature but also their deep sense of commitment to family, spiritual values and pride in cultural heritage.

They have served well in times of war and peace. They served as soldiers in the battlefields. During World War II a group of native Americans volunteered to transmit confidential code messages in their native dialects. This group of volunteers, known as "code talkers" helped win the war and thus preserved freedom and the way of life in this country.

In times of peace, native Americans serve in Congress, hospitals, universities and scientific establishments. They work in the private and the public sectors, and they are into arts, sports and entertainment. They're everywhere quietly serving society with dedication and hard work.

In November, we in HHS honored our fellow native Americans with various activities:

- On Nov. 1, the traditional "Opening Ceremony" was held at the Humphrey Building.
- On Nov. 15, the Indian Health Service along with other agencies held a program at the Parklawn Building.
- CDER set up an educational display of native American posters, list of federally recognized tribes and other information in the lobby of Woodmont II.

Limited copies of the tribal list are available from the EEO Office at 4-6645.

Gloria Marquez Sundaresan is an equal employment specialist on CDER's EEO staff. Ann French, of the Indian Health, Service provided some materials for the article.

Cleanup of Postmarketing Commitments Shows 2,200 Ongoing

BY LCDR LINDSAY COBBS

During the past year, the Center evaluated all postmarketing commitments as part of our effort to fulfill the requirements for postmarketing reports in the 1997 FDA Modernization Act. About 900 applications were involved, some with commitments going back to the mid-1940s. There were about 3,000 postmarketing commitments with some involving one to several studies. Of these, about 2,200 have a pending status. Some of these studies have pending start dates, some are underway, and others are pending review in the Center.

For the remaining commitments, we took one of two actions. We sent fulfillment letters to applicants who had completed their studies and met the terms of the commitment. We judged other commitments to be no longer scientifically relevant and released sponsors from their obligations to conduct those studies.

The Modernization Act provides us with additional authority for monitoring the progress of postmarketing studies that applicants have agreed to conduct. The law also requires us to keep the public and the medical community abreast of postmarketing obligations and activities of applicants.

Specifically, we must develop and publish annually in the *Federal Register* a report on the status of postmarketing studies that applicants have agreed to conduct as part of the approval. This information will be displayed on a new FDA Web site for postmarketing commitments. The site should be available this winter. The law allows us to make public the information necessary to identify a study's sponsor, its status and the reasons for any failure to carry out the study.

To implement the law's provisions on postmarketing studies, FDA issued its proposed rule in December 1999 and its final rule in October last year. The rule made several changes to existing regulations for approved human drugs and licensed biological products.

Applicants who enter into an agreement with FDA to conduct a postmarketing study or who are required under regulations to conduct a postmarketing study must submit an annual status updated until the study is completed or terminated. These annual reports must address the progress of the study or the reasons for the failure to conduct the study. The Agency will review the reports within three months of their receipt date and before updating its Web site.

The regulations identify some postmarketing studies as proprietary and not releasable to the public. These include studies for chemistry, manufacturing and controls; stability studies; and all voluntary studies, such as those for new uses.

In April, FDA published a draft guidance that complements the rule by describing in greater detail the content, format and timing of postmarketing study reports. The guidance also describes our timeframes for reviewing the status reports, how we will make postmarketing study information available to the public and what that information will be.

Finally, the Modernization Act directed FDA to submit a special postmarketing study report to Congress. In this report, we must summarize the status reports that have been submitted; evaluate the sponsors' performance in fulfilling their commitments; evaluate our timeliness in reviewing the postmarketing study submissions received; and make any necessary legislative recommendations concerning postmarketing studies.

In helping complete the review of postmarketing commitments, I was privileged to work with CDER's review divisions in responding to this congressional mandate. I also worked with the Division of Training and Development to develop and conduct three policy-training courses in January and February.

In the last several months, we issued numerous fulfillment, release and dunner letters to assure that a centralized database had accurate and complete information for the special report to Congress.

The Division of Gastrointestinal and Coagulation Drug Products took the lead in verifying the status of their commitments and issued action letters under the leadership and coordination of **Karen Oliver,** a regulatory project manager. Karen then committed to a six-month part-time detail to assist other divisions in this concentrated effort.

To help with the postmarketing cleanup, Karen worked with **Doug Throckmorton, M.D.,** deputy director of the Division of Cardiorenal Drug Products; **Jeanine Best,** a regulatory project manager in the Division of Urologic and Reproductive Drug Products; **Sylvia Lynche,** a regulatory project manager in the Division of Antiviral Drug Products; **Mary J. Kozma-Fornaro,** the chief project manager in the Division of Dermatologic and Dental Drug Products; **Yoon Kong** and **Laurie Gorsky,** regulatory project managers in the Division of Anti-inflammatory, Analgesic and Opthamologic Drug Products; and **Daniel Keravich,** a regulatory project manager in the Division of Over-the-Counter Drug Products.

Cynthia McCormick, M.D., the director of the Division of Anesthetics, Critical Care and Addiction Drug Products and **CAPT Cathie Schumaker,** the division's chief project manager, took the lead in addressing their postmarketing commitments.

Coordinating efforts of regulatory project managers of their divisions to complete the cleanup were **Maureen Dillion-Parker,** a regulatory project manager in the Division of Anti-Infective Drug Products; **CAPT Robbin Nighswander,** a supervisory regulatory health manager in the Division of Neuropharmacological Drug Products; **Dottie Pease,** the chief project manager in the Division of Oncology Drug Products; **Kaye Cho,** the chief project manager in the Division of Medical Imaging and Radiopharmaceutical Drug Products; **Gretchen Trout,** a former regulatory project manager in the Division of Pulmonary and Allergy Drug Products; **Jamie Cross,** a regulatory project manager in the Division of Metabolic and Endocrine Drug Products; and **LCDR Ellen Frank,** the chief project manager in the Division of Special Pathogens and Immunologic Drug Products.

Congratulations to all for the successful effort in responsible implementation of Modernization Act's requirements for postmarketing reports.

J. Lindsay Cobbs is director of regulatory operations, postmarketing commitments, for the Review Standards Staff.

CDER Celebrates Employee Achievements at Ceremony

(Continued from page 1)

Ramana S. Uppoor, Ph.D.

Mary Jane Walling

David E. Wardrop Jr.

Karen R. Zawalick

Johns Hopkins University Graduate Training Program in Drug Development Team: **Jerry M. Collins, Ph.D., Mark J. Goldberger, M.D., Martin H. Himmel, M.D., Susan F. Honig, M.D., Ajaz S. Hussain, Ph.D., Russell G. Katz, M.D.,** and **Grant A. Williams, M.D.**

Medical Gas Task Force: **Frederick W. Blumenschein, Nancy E. Derr, Joseph C. Famulare, Paul W. Haynie, Howard P. Mueller Jr., Ph.D.,** and **Duane S. Sylvia.** PHS Unit Commendation: **CDR Paula A. Simenauer.**

Positron Emission Tomography Steering Committe: **Jane A. Axelrad, Esq., Laurie A. Baron, Frederick W. Blumenschein, Sonia C. Castillo, Ph.D., Kyong A. Cho, Kim M. Colangelo, Nancy L. Derr, James L. Dunnie Jr., Joseph C. Famulare, Raymond J. Farkas, John A. Friel, Esq., Tia M. Harper-Velazquez, Pharm.D., Brian J. Hasselbalch, David J. Horowitz, Esq., Florence Houn, M.D., Rubynell Jordan, Ravindra K. Kasliwal, Ph.D., Susan C. Lange, Adebayo A. Laniyonu, Ph.D., David J. Lee, Ph.D., Eldon E. Leutzinger, Ph.D., John Lienesch, Patricia Y. Love, M.D., William A. McConagha, Esq., Wayne H. Mitchell, Esq., Thuy M. Nguyen, Lana L. Ogram, Cecelia M. Parise, Brian L. Pendleton, Esq., Victor F. Raczkowski, M.D., Ramesh Raman, M.D., Fred Richman, William P. Rickman, Tracy Roberts, Warren F. Rumble, Nakissa Sadrieh, Ph.D., Alfredo R. Sancho, Ph.D., Vilayat A. Sayeed, Ph.D., Ellen Shapiro, Mahboob Sobhan, Ph.D., David George Udo, Ph.D., Brenda W. Uratani, Ph.D., Michael E.** and **Welch, Ph.D.** PHS Unit Commendation: **CDR Laurie B. Burke, CAPT David J. Hussong, CAPT Robert K. Leedham Jr.,** and **CAPT Yana R. Mille.**

Project Advisory Group: **Allen D. Brinker, M.D., Katrina S. Garry, David J. Graham, M.D., Leonard Grant, Arthur E. Hass Jr., Martin H. Himmel, M.D., Cynthia J. Kornegay, Ph.D., Lois A. La Grenade, M.D., Carolyn A. McCloskey, M.D., Parivash Nourjah, Ph.D., Martha L. O'Connor, Carol A. Pamer, R.Ph., Marilyn R. Pitts, Rosemary Roberts, M.D., Rosemary Springer, Judy A. Staffa, Ph.D.,** and **Yi Tsong, Ph.D.** PHS Unit Commendation: **CAPT George D. Armstrong, CDR Terrie L. Crescenzi, CAPT Dianne L. Kennedy,** and **CAPT Joslyn Swann.**

Reports and Data Management Team: **Michael S. Cu, Susan F. Daugherty, Brenda J. Harmon, Michael L. Lanthier, Deborah L. Lee, Nancy G. Maizel, Darlene V. Norris** and **Long P. Pham.** PHS Unit Commendation: **CAPT Elaine G.E. Abraham** and **CAPT Anna M. Myers.**

Street Drug Alternatives Litigation Team: **A. Joel Aronson, Lois C. Chester, Nancy E. Derr, Linda J. Eason, Stephen C. Eason, Robert A. Eshelman, Charles J. Ganley, M.D., Alan C. Gion, Barbara J. Holladay, Linda S. Hu, M.D., Eugene R. Leger, Gerald W. Miller, Nancy L. Muir** and **Sonal Vaid, Esq.**

FDA Quality of Work Life Award

S. Edward Nevius, Ph.D.

PHS Commendation Medals

CDR Robin E. Anderson

CDR Roy A. Blay

LCDR James L. Cobbs

CAPT Robert K. Leedham Jr.

CAPT Jane E. McCarthy

CDER Special Recognition Award

Craig M. Bertha, Ph.D.

Zili Li, M.D.

Margaret A. Miller, Ph.D.

David C. Morley

Chan H. Park, Ph.D.

Lana J. Ragazinsky

Vanitha J. Sekar, Ph.D.

Karen Templeton-Somers, Ph.D.

Liang Zhou, Ph.D.

OCPB Gleevec Review Team: **John Z. Duan, Ph.D.,** and **Jogarao V. Gobburu, Ph.D.**

OCPB Good Review Practices Working Group: **Abimbola O. Adebowale, Ph.D., Brian P. Booth, Ph.D., Dhruba J. Chatterjee, Ph.D., Young M. Choi, Ph.D., Philip M. Colangelo, Pharm.D., Ph.D., Suresh Doddapaneni, Ph.D., Jogarao V. Gobburu, Ph.D., Shiew-Mei Huang, Ph.D., Peter Lee, Ph.D., Lawrence J. Lesko, Ph.D., Patrick J. Marroum, Ph.D., Weston L. Metz, Ameeta Parekh, Ph.D., Atiqur Rahman, Ph.D., Kellie Schoolar Reynolds, Pharm.D., Vanitha J. Sekar, Ph.D., Robert M. Shore, Pharm.D., Veneeta Tandon, Ph.D., Gene M. Williams, Ph.D.,** and **Hong Zhao, Ph.D.**

Oncology Patient Advocacy and Education Team: **Patricia C. Delaney** and **Joann M. Minor.**

Pharm/Tox Good Review Practices Teach Tool Working Group: **Hamid R. Amouzadeh, Ph.D., Aisar H. Atrakchi, Ph.D., Cynthia A. Bigger, Ph.D., Karen L. Davis-Bruno, Ph.D., Robin A. Huff, Ph.D., John K. Leighton, Ph.D., Timothy J. McGovern, Ph.D., Thomas Papoian, Ph.D., Tim W. Robison, Ph.D.,** and **Barry N. Rosloff, Ph.D.**

Center Director's Special Citation

Katrina S. Garry

Karen Oliver

Gloria J. Overholser, Esq.

Bioterrorism Preparedness Team: **Frederic J. Marsik, Ph.D., Janice M. Soreth, M.D., Susan D. Thompson, M.D.** PHS Unit Commendation: **LTJG Destry M. Sillivan.**

Exposure-Response Working Group: **Tien Mien Chen, Ph.D., Philip M. Colangelo, Pharm.D., Ph.D., Peter K. Honig, M.D., Shiew-Mei Huang, Ph.D., Venkateswa R. Jarugula, Ph.D., Ken Kobayashi,**

(Continued on page 9)

Fall Honor Awards Presented to 67 Individuals, 43 Groups

(Continued from page 8)

M.D., Peter Lee, Ph.D., Sue-Chih Lee, Ph.D., Lawrence J. Lesko, Ph.D., Stella G. Machado, Ph.D., Elena V. Mishina, Ph.D., Robert T. O'Neill, Ph.D., Robert M. Shore, Ph.D., Gur J. P. Singh, Ph.D., and **Robert J. Temple, M.D.** PHS Unit Commendation: **CAPT Martin D. Green.**

Janssen Research Foundation's Limited Access Program for Cisapride: **Cynthia Chianese, Leonard Jokubaitis, M.D.,** and **Diane Tavin.**

Rx Studies Workgroup: **Mark D. Anderson, R.Ph., Michael T. Benson, R.Ph., Jeanine A. Best, Renan A. Bonnel, Pharm.D., Debra E. Boxwell, Pharm.D., Chandra S. Chaurasia, R.Ph., Ph.D., Anthony Chite, Ph.D., Beverly Conner, Pharm.D., Edward M. Cox, M.D., Edward J. Fromm, R.Ph., Bette A. Goldman, Donna J. Griebel, M.D., Tia M. Harper-Velazaquez, Pharm.D., Brenda J. Killiany, Pharm.D., Sung K. Kim, Ph.D., Lorene M. Kimzey, Crystal A. King, Pharm.D., Margaret M. Kober, R.Ph., Mary E. Kremzner, Pharm.D., Lois La Grenade, M.D., Charles E. Lee, M.D., Lauren Y. Lee, Pharm.D., Brad Leissa, M.D., David B. Lewis, Ph.D., Colleen L. LoCicero, R.Ph., Ann Corken Mackey, R.Ph., Ijeoma N. Nnamani R.Ph., Robert E. Osterberg, Ph.D., Carol A. Pamer, R.Ph., Chan H. Park, Ph.D., Maureen A. Pelosi, R.Ph., Kathleen M. Phelan, R.Ph., Ellyce F. Ratskoff, R.Ph., Barbara J. Sanchez, R.Ph., Sarah J. Singer, R.Ph., Brenda Stodart, R.Ph., Eugene J. Sullivan, M.D., Maria R. Thomas, Douglas C. Throckmorton, M.D., Melissa M. Truffa, R.Ph., Maria L. Villalba, M.D., Ronald T. Wassel, Pharm.D., Mary E. Willy, Ph.D.,** and **Christine H. Yu, R.Ph.** PHS Unit Commendation: **LT James T. Barlow, LCDR Sammie G. Beam, LT Sean K. Bradley, LCDR Carole C. Broadnax, LCDR Lana Y. Chen, LCDR James L. Cobbs, LT David T. Diwa, LT Jennifer E. Fan, LCDR Ellen C. Frank, LT Patricia N. Garvey, CDR Sharon K. Gershon, CAPT Lillie D. Golson, CAPT Rita R. Hassall, CAPT William A. Hess, CDR Richard G. Hills, CDR Carol A. Holquist, CDR Charles V. Hoppes, LCDR Lisa M. Hubbard, CAPT James R. Hunter, LCDR Valerie E. Jensen, CAPT Michael F. Johnston, LCDR Hye-Joo Kim, CDR William C. Koch Jr., LCDR Koung U. Lee, LT Alina R. Mahmud, CAPT Janet M. Morgan, CAPT Anna M. Myers, CDR Aida L. Sanchez, CAPT George R. Scott, LT Melaine M. Shin, LCDR Kimberly L. Struble, CAPT Joslyn R. Swann, CDR Matthew J. Tarosky, CAPT Theresa A. Toigo, CAPT Denise P. Toyer, CDR Kathleen Uhl, CDR Adolph E. Vezza,** and **CDR Teresa A. Wheelous.**

CDER Career Service Award

Ridgely C. Bennett Jr., M.D.

Vivian Greenman

Phill H. Price, M.D.

CDER Administrative/Program Management Excellence

Christina Benton

Barbara M. Jones

Sherunda R. Lister

Dana L. Walters

Rosa L. Williams

CDER Excellence in Communication Award

Martin H. Cohen, M.D.

Mandy T. Eisemann

Donna J. Griebel, M.D.

Merla R. Matheny

APPS Guidance Workshops Team: **Haeyoung Ahn, Ph.D., Upinder S. Atwal, Ph.D., Daniel L. Boring, Ph.D., Chiwan Chen, Ph.D., Mei-Ling Chen, Ph.D., Yuan-yuan Chiu, Ph.D., Peter H. Cooney, Ph.D., Eric P. Duffy, Ph.D., Bonnie B. Dunn, Ph.D., Florence S. Fang, Ph.D., Devinder S. Gill, Ph.D., Andrea S. High, Ph.D., Frank O. Holcombe, Ph.D., Ajaz S. Hussain, Ph.D., David Hussong, Ph.D., Marie Kowblansky, Ph.D., Kofi A. Kumi, Ph.D., Sze W. Lau, Ph.D., Patricia Alcock Lefler, George Lunn, Ph.D., Patrick J. Marroum, Ph.D., Mehul U. Mehta, Ph.D., Moheb M. Nasr, Ph.D., Ijeoma N. Nnamani, Ph.D., Hasmukh B. Patel, Ph.D., Rasmikant M. Patel, Ph.D., Atiqur Rahman, Ph.D., Edwin Ramos, Bryan S. Riley, Ph.D., Nancy B. Sager, Ph.D., Vilayat A. Sayeed, Ph.D., Paul Schwartz, Ph.D., Joseph Sieczkowski, Ph.D., John E. Simmons, Ph.D., Glen J. Smith, Ph.D., John L. Smith, Ph.D., Kasturi Srinivasachar, Ph.D., Rajendra Uppoor, Ph.D., Lawrence X. Yu, Ph.D.,** and **Liang Zhou, Ph.D.**

CDER's Gender Differences Team: **Julie G. Beitz, M.D.,** and **Jack E. Morin.**

Division of Oncology Drug Products: **Judy H. Chiao, M.D., Donna J. Griebel, M.D., Richard Pazdur, M.D., Wendelyn J. Schmidt, Ph.D.,** and **Grant A. Williams, M.D.**

Propylene Glycol Assessment Team: **Therese A. Cvetkovich, M.D., James G. Farrelly, Ph.D., Heidi M. Jolson, M.D., George Lunn, Ph.D., John R. Martin, M.D., Stephen Miller, Ph.D., Kellie Schoolar Reynolds, Pharm.D., Sandra Suarez-Sharp, Ph.D.,** and **Hao Zhang, Ph.D.**

CDER Information Technology Excellence

Leslie L. Saveland

Pamela G. Winbourne

IT Procurement Reengineering Team: **Janice L. Ausby** and **Rodney K. Smith.**

Biometrics II SAS/IntrNet Team: **Ted J. Guo, Ph.D.,** and **Feng Zhou, Ph.D.**

CDER Leadership Excellence Award

Thomas W. Abrams, R.Ph.

Mohamed A. Al-Osh, Ph.D.

George Y. Chi, Ph.D.

Charles J. Ganley, M.D.

Devota D. Herbert

Chih C. Lin, Ph.D.

Michael F. Ortwerth, Ph.D.

CDER Excellence in Mentoring

(Continued on page 10)

CDER Celebrates Employee Achievements at Ceremony

(Continued from page 9)

Donald N. Klein, Ph.D.

David L. Roeder

Norman L. Stockbridge, M.D., Ph.D.

Neuropharmacologic Chemistry Team: **Martha R. Heimann, Ph.D., Janusz Rzeszotarski, Ph.D.,** and **Mona R. Zarifa, Ph.D.**

Office of Compliance Mentoring Team: **Bruce W. Hartman,** and **Randall L. Woods.**

CDER Project Management Excellence Award

Mary J. Dempsey

Chris M. Nguyen

Dianne D. Spillman

Sandra Valencia

Jayne C. Ware

CDER Support Staff Excellence

Darlene T. Johnson

Donte D. Morris

Patricia M. O'Connor

Lillian Riley

Janice A. Shelton

Ellen L. White

Alicia M. Williams

Gladys M. Wood

ODE IV Support Staff: **Christine Moser, Dana C. Schuhly** and **Ann K. Sullivan.**

CDER Team Excellence Award

Biopharmaceutics Review Support Team: **James F. Allgire, Ph.D., Ebenezer B. Asafu-Adjaye, Ph.D., James F. Brower, Alan S. Carlin, Anthony B. Ciavarella, Christopher D. Ellison, Patrick J. Faustino, Ph.D., Christine Maupin, Ph.D., John C. Reepmeyer, Ph.D., Donna A. Volpe, Ph.D., Jin Tsai Wang, Ph.D., William N. Worsley** and **Lawrence X. Yu, Ph.D.**

CDER 101 Pilot Working Group: **Nicholas Buhay, Jean-Ah Choi, Pharm.D., John M. Dietrick, Antoine El-hage, Ph.D., John A. Friel, Esq., David J. Graham, M.D., Deborah J. Henderson, Charlotte M. Henning, Iris D. Khalaf, Norman S. Marks, M.D., Janice L. Newcomb, Toni Piazza-Hepp, Pharm.D., Barry W. Poole, R.Ph., Terri F. Rumble, Ellen Shapiro, Ted M. Sherwood, Nancy D. Smith, Ph.D., Kimberly L. Topper, Marcia L. Trenter, Sally Winthrop** and **Stan W. Woollen.** PHS Unit Commendation: **LCDR Carol A. Holquist, CAPT Justina A. Molzon, CAPT Andrea G. Neal** and **CDR Deborah F. Yaplee.**

CDER EASE Team: **Dong K. Kim** and **Jack B. Walsh.**

Chemistry Core Competency Working Group: **Karen A. Bernard, Ph.D., Yuan-yuan Chiu, Ph.D., Charles P. Hoiberg, Ph.D., Paul Schwartz, Ph.D., Ted M. Sherwood, James D. Vidra, Ph.D., Helen N. Winkle, Mona R. Zarifa, Ph.D.** PHS Unit Commendation: **CAPT Rita R. Hassall**.

Course Directors and/or Faculty for the PERI Course on Safety Surveillance: **Martin H. Himmel, M.D., Murray M. Lumpkin, M.D., Toni Piazza-Hepp, Pharm.D.,** and **Audrey A. Thomas.** PHS Unit Commendation: **CAPT Andrea G. Neal** and **CDR Deborah F. Yaplee.**

Division of Chemistry II, Team 7: **Brenda T. Arwine, J.D., Karen A. Bernard, Ph.D., Raymond L. Brown, Damaris C. Maldonado, Ijeomana N. Nnamani, Radhika Rajagopalan, Ph.D.,** and **Kassandra C. Sherrod.**

Division of New Drug Chemistry III Chemistry Team: **Vispi P. Bhavnagri, Ph.D., Bartholomew C. Ho, Ph.D., Sue-Ching Lin, R.Ph., Rao Puttagunta, Ph.D.,** and **Charlotte A. Yaciw, Ph.D.**

Dosimetry Calculations Team: **John M. Melograna, Ph.D.,** and **Robert J. Yaes, D.Sc., M.D.**

Gleevec NDA Review Team: **Shawnte L. Adams, Charles Ahn, Kimberly A. Benson, Ph.D., Regina T. Brown, Gang Chen, Ph.D., Martin H. Cohen, M.D., Janine M. D'Ambrogio, John M. Dietrick, John Z. Duan, Ph.D., Shirnette D. Ferguson, Melissa J. Garcia, Jogarao V. Gobburu, Ph.D., Bruce W. Hartman, Attila Kadar, M.D., Sung K. Kim, Ph.D., Douglas Kovac, Patricia Alcock Lefler, John K. Leighton, Ph.D., Richard Pazdur, M.D., Dorothy W. Pease, N.A.M. Atiqur Rahman, Ph.D., Irma Rivera, Michael C. Rogers, Mark D. Rothman, Ph.D., Ann M. Staten, William Tingley, Khin Maung U, M.D., Grant A. Williams, M.D.,** and **Rebecca H. Wood, Ph.D.**

Inhalation Drug Products Working Group of the Chemistry Manufacturing and Controls Coordinating Committee: **Craig M. Bertha, Ph.D., Timothy J. McGovern, Ph.D., Edwin D. Melendez, Robert J. Meyer, M.D., Guirag K. Poochikian, Ph.D.,** and **Michael Smela Jr., Ph.D.**

Laboratory Coordinating Team of the Division of Product Quality Research: **Anthony B. Ciavarella** and **Donna A. Volpe, Ph.D.**

NDA Course Team: **Bronwyn E. Collier, Julieann DuBeau, Michael M. Folkendt, Deborah L. Kallgren, Melodi McNeil, Robbin M. Nighswander** and **David L. Roeder.** PHS Unit Commendation: **LCDR Ellen C. Frank** and **CAPT Cathie L. Schumaker.**

ODE IV QT Working Group: **Philip M. Colangelo, Pharm.D., Ph.D., Amy L. Ellis, Ph.D., Sam H. Haidar, R.Ph., Ph.D., Stephen G. Hundley, Ph.D., John E. Koerner, Ph.D., Joyce A. Korvick, M.D., Frederic J. Marsik, Ph.D., Owen G. McMaster, Ph.D., Joette M. Meyer, Pharm.D., Terry S. Peters, DVM, George Rochester, Ph.D., Leonard V. Sacks, M.D., Douglas Shaffer, M.D., Sarah J. Singer, R.Ph., Janice M. Soreth, M.D., Susan D. Thompson, M.D., Douglas C. Throckmorton, M.D., Diana M. Willard** and **Jenny J. Zheng, Ph.D.** PHS Unit Commendation: **CDR Jose Cintron.**

Office of Generic Drugs Microbiology Team: **Patrica M. Beers-Block, Paul DeLeo, Ph.D., Lynne A. Ensor, Ph.D., Andrea S. High, Ph.D., Nrapendra**

(Continued on page 11)

Library Outlines Reference Resources for Risk Management

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In this month's article, we'll review some of the printed resources available in the FDA Medical Library in Parklawn 11B-05. You can request these from the library branches in Woodmont II and Corporate Boulevard.

To locate books and videos on risk management, use the FDA Libraries Catalog on the Medical Library's intranet site, http://medlib.cder.fda.gov. The catalog contains the holdings of all FDA libraries; however, books on risk management (and their library call numbers) available in the main Parklawn collection of the FDA Medical Library are:

- Evans, G., and U.S. Institute of Medicine. V*accine Safety Forum, Risk communication and vaccination: summary of a workshop.* National Academy Press, 1997. A pamphlet summarizing the conference on risk assessment of vaccine adverse effects. QR189.R55 1997.
- Fan, A.M., and Chang, L.W. *Toxicology and risk assessment: principles, methods, and applications.* Marcel Dekker, Inc., 1996. Discussion of principles, methods and applications of risk assessment. RA1211.T635 1996.
- Gillett, J.E. *Hazard study and risk assessment in the pharmaceutical industry*, Interpharm Press, 1997. Information on the pharmaceutical industry and risk management. RS92. G55 1997.
- Hunziker, J.R., and Jones, T.O. *Product liability and innovation: managing risk in an uncertain environment.* National Academy Press, 1994. Readings in risk management and product liability. Includes chapters on risk liability in chemical, medical device, automotive and aviation industries. T173.8. P7253 1994.
- Leviton, L.C., Needleman, C.E., and Shapiro, M.A. *Confronting Public Health Risks: A Decision Maker's Guide.* Sage Publications, 1998. Case studies on health risk communication. RA423.2.L48 1998.
- Lundgren, R.E., and McMakin, A. *Risk Communication: A Handbook for Communicating Environmental, Safety and Health Risks.* Battelle Press, 1998. Strategies for health, safety and environmental risk communication. T10.68.L86 1998.
- U.S. National Research Council, Committee on Risk Perception and Communication. *Improving Risk Communication.* National Academy Press, 1989. Discussion of risk communication. T10.68.I47 1989
- Powell, D.A., *Mad Cows and Mother's Milk: The Perils of Poor Risk Communication.* McGill-Queen's University, 1997. Risk management communication. T10.68.P69 1997.
- Sparrow, M.K. *The Regulatory Craft, Controlling Risks, Solving Problems and Managing Compliance.* Brookings Institute Press, 2000. Recommends finding important problems and fixing them. HD3616.U47S6 2000.
- Walters, K.A. *Dermal Absorption And Toxicity Assessment, Drugs And The Pharmaceutical Sciences (Volume. 91).* Marcel Dekker, 1998. Dermatotoxicology, environmental exposure, and skin absorption of cosmetics and pharmaceutical preparations. RM30. D7 v.91, 1998
- Willis, W.J., and Okunade, A.A. *Reporting on Risks: The Practice and Ethics of Health and Safety Communication.* Praeger, 1997. Ethics and health risk communication in the mass media. RA423.2.W55 1997

Videos available in the main collection of the FDA Medical Library include:

- FDA/CDER/OPS and Drug Information Association. *Risk Management System Perspectives.* Sept. 14, 1999. CDER LIVE #4 RISK MGMT (09-14-99)
- FDA and American Society for Healthcare. *Preventing Errors Using Medical Products.* June 22, 2000. CDER S.B. (06-22-00).
- CDER. *Risk management Workshop: Nov. 15 and 16, 1999.* VIDEO RISK MGMT.
- FDA and National Patient Safety Foundation. *Safe Medical Treatments: Everyone Has A Role, March 27-28, 2000.* VIDEO SAFE MEDICAL (03-27-28-00)

In addition, the Library subscribes to risk management journals including:

- *Journal of Risk and Uncertainty.* Kluwer Academic Publishers. Articles on risk and decision-making.
- *Risk Analysis: An Official Publication of the Society for Risk Analysis.* Plenum Press.

In the next issue of the *Pike*, we'll review books on risk management available on loan from the National Library of Medicine and Internet resources

Carol Knoth and Nichelle Cherry are librarians in the FDA Medical Library.

Fall Honor Awards Presented to 67 Individuals, 43 Groups

(Continued from page 10)

Nath, Ph.D., and **Marla Stevens-Riley, Ph.D.**

Office of Testing and Research Rapid Response Team: **James F. Brower, Ph.D., Joseph P. Hanig, Ph.D., David Lester, Ph.D., John M. Strong, Ph.D.,** and **Lawrence X. Yu, Ph.D.**

ONDC Retreat Committee: **Nallaperumal Chidambaram, Ph.D., Maria E. Guzewska, Ph.D., Charles P. Hoiberg, Ph.D., David Hussong, Ph.D., Susan C. Lange, Sue-Ching Lin, Ph.D., Stephen Miller, Ph.D., Thomas F. Oliver, Ph.D., Guirag K. Poochikian, Ph.D., Kevin A. Swiss, Ph.D.,** and **James D. Vidra, Ph.D.**

OPDRA Orientation Working Committee: **Patrick F. Guinn, Lauren Y. Lee, Susan Lu, Parivash Nourjah, Ph.D.,** and **Judy A. Staffa, Ph.D.** PHS Unit Commendation: **CDR Carol Holquist.**

OCPB Oncology Team: **Sophia S. Abraham, Ph.D., Brian P. Booth, Ph.D., John Z. Duan, Ph.D., Lydia V. Kieffer, Pharm.D., N.A.M. Atiqur Rahman, Ph.D.,** and **Gene M. Williams, Ph.D.**

XML Based CTOC Development Team: **Jon E. Clark** and **Naiqi Ya, Ph.D.**

Jackie Barber is CDER's incentive awards officer.

FDA OKs Changes to Risk Management Program for Isotretinoin

(Continued from page 1)

prescribers, patients and pharmacists in a partnership to prevent fetal exposure to isotretinoin.

The SMART program requires prescribers to study the manufacturer's "Guide to Best Practices" and then sign and return a letter of understanding to Roche. (The manufacturer has also developed a continuing medical education course for prescribers that includes specific, practical information about pregnancy prevention.)

Prescribers will then receive special self-adhesive Accutane Qualification Stickers. All prescriptions for isotretinoin should have the special yellow sticker attached to the prescriber's regular prescription form.

This sticker will indicate to the pharmacist that the patient is "qualified," which means that she has had negative pregnancy tests as well as education and counseling about pregnancy prevention.

All female patients must have two negative urine or serum pregnancy tests before the initial isotretinoin prescription is written, and for each month of therapy they must have a negative pregnancy test result before receiving their next prescription, regardless of whether they are sexually active.

Patients who are, or might become, sexually active with a male partner must also select and use two forms of effective contraception simultaneously for at least one month before starting isotretinoin therapy, during therapy and for one month following discontinuation of therapy.

They must sign a patient information and consent form about isotretinoin and birth defects, in addition to the consent form that all patients should receive about other potentially serious risks. Finally, female patients must be given the opportunity to enroll in a confidential survey that will collect data to help Roche and FDA decide if SMART is helping to prevent exposure of unborn babies to isotretinoin.

Pharmacists will dispense isotretinoin only upon presentation of a prescription with the special sticker. Pharmacists will dispense a maximum one-month supply of isotretinoin, fill prescriptions within seven days from the date of "qualification" and provide a Medication Guide for patients with each isotretinoin prescription. Requests for refills and phoned-in prescriptions will not be filled.

To measure the effectiveness of the SMART program, Roche will use several independent outcome assessments, including the survey and an independent audit of pharmacies to assess the use of the qualification stickers by prescribers.

Exposure of an unborn baby to isotretinoin is a serious adverse event and should be reported to Roche, or directly to the FDA MedWatch Program.

DRUGS IN THE NEWS:

FDA OKs 1st Pulmonary Hypertension Tablet, 1st Contraceptive Skin Patch

On Nov. 20, FDA announced approval of bosentan (Tracleer) tablets to improve the exercise ability of patients with pulmonary arterial hypertension, a rare but fatal lung disorder. PAH, or abnormally high blood pressure in the arteries between the heart and lungs, significantly reduces the ability of patients to exert themselves physically without becoming short of breath. PAH also significantly shortens life span because it leads to heart failure.

Bosentan blocks the action of endothelin, a substance that narrows blood vessels and elevates blood pressure. Although endothelin is present in healthy people, high concentrations of the hormone have been found in the plasma and lungs of patients with PAH, suggesting it is capable of causing the disease.

The drug will be available only through a direct distribution program from the manufacturer, Actelion Pharmaceuticals U.S. Inc. of South San Francisco.

Its use requires physician attention to two significant risks: liver toxicity and the drug's potential to damage a fetus. It will not be available in commercial pharmacies.

These safety issues are highlighted in the black box warning in the drug's labeling and explained in a brochure for patients. Specifically, liver enzyme levels must be measured before treatment and monthly thereafter. To date, the elevation of liver enzymes caused by bosentan has been resolved without causing permanent liver damage.

Because of the drug's potential to cause birth defects, female patients of childbearing potential must take measures to prevent pregnancy. Monthly pregnancy testing will be required.

Oral, injected and implanted contraceptives may not be reliably effective, because the drug may alter metabolism in a way that reduces the effectiveness of hormonal contraceptives. These hormonal methods must be supplemented by other methods or barrier methods.

Approval was based on two randomized, placebo-controlled clinical trials involving a total of 245 patients. A significant increase in the 6-minute walking distance compared to placebo was seen.

FDA announced on Nov. 20 the approval of the first transdermal patch approved for birth control. The weekly prescription skin patch releases norelgestromin, a progestin hormone, and ethinyl estradiol, an estrogen hormone, through the skin into the blood stream to prevent pregnancy.

Called Ortho Evra, the patch is applied to the lower abdomen, buttocks or upper body but not to the breasts.

Each patch is worn continuously for one week and then replaced with a new patch on the same day of the week for a total of three weeks of patch wear. The fourth week is patch-free, similar to the regimen for birth control pills.

Three clinical trials conducted worldwide involved 4,578 women of whom 3,319 used the patch. The other women in the trials used birth control pills.

The trials demonstrated that women using the contraceptive patch were able to adhere to the once a week dosing regimen as an alternative to a daily dose of birth control pills.

R.W. Johnson based in New Jersey will manufacture and market the patch.