news along the pike

JUNE 1999

CENTER FOR DRUG EVALUATION AND RESEARCH

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INSIDE . . .

PIKE'S CORNERS

Center's Commissioned Corps in Action at Fort Dix

Volunteers Provide Medical Care for Kosovar Refugees

BY NORMAN OLIVER

At least six Public Health Service Commissioned Corps officers and one Civil Service employee assigned to the Center helped with the medical screening and treatment of more than 4,000 refugees flown to Fort Dix, N.J., from the conflict in Kosovo. They provided health and medical services in support of Operation Provide Refuge, including reception, acute care clinical support and medical processing for resettlement.

Among those answering the call to help were:

- **CDR Linda Brophy,** a nurse, from the Office of Training and Communications.
- **CAPT Eugene Herman,** who provided laboratory and logistics support, from the Office of Testing and Research.
- **ENS Kathryn A. Herbert,** a pharmacy student from Duquesne University, who is working for the Center this summer under the Commissioned Officer Student Training and Extern Program.
- **CAPT William Hess,** a pharmacist, from the Office of Information Technology.
- **Joyce Korvick, M.D.,** a physician, from the Office of Drug Evaluation IV.
- **LCDR Eric Mann, M.D.,** a physician, also from ODE IV.
- **LCDR Matthew Tarosky,** a pharmacist, from the Office of Medical Policy.

(Continued on page 12)

CDER Employees Earn 250 FDA-Level Awards

BY JACKIE BARBER

About 250 CDER employees received awards during the FDA ceremony held June 11 at the DoubleTree Hotel in Rockville. Commissioner **Jane Henney, M.D.,** and Agency senior managers presented the awards during the 1999 annual ceremony. The awards and employees receiving them are:

Award of Merit

James G. Farrelly, Ph.D.

Rheumatology Working Group: **Lauren Black, M.D., Wiley Chambers, M.D., Rose E. Cunningham, Sahar Dawisha, M.D., Kent R. Johnson, M.D., Linda Katz; M.D., Peter Lachenbruch, Ph.D., Asoka Mukherjee, Ph.D., Teresa M. Neeman, Ph.D., Rosemarie Nuener, M.D., Kathleen Reedy, Patricia J. Rohan, M.D., William Schwieterman, M.D., Jeffrey N. Siegel, M.D., James Witter, M.D., Ph.D.,** and **Janet Woodcock, M.D.** *PHS Outstanding Unit Citation:* **CDR Dennis D. Bashaw, CAPT Dennis M. Klinman, CAPT Frederick W. Miller** and **CDR Lisa G. Rider.**

Ritonavir Shortage Team: **Charles Ahn, Debra Birnkrant, M.D., Chi-wan Chen, Ph.D., Norman A. Drezin, R.Ph., J.D., Mark J. Goldberger, M.D., M.P.H., Bruce Hartman, Janice Jenkins, Ph.D., Christine M. Kelley, R.N., M.S., M.B.A., Rochelle K. Kimmel, Sam Maldonado, M.D., Steven P. Miller, Ph.D., Jeffrey Murray, M.D., M.P.H., Kellie Schoolar Reynolds, Pharm.D., Arzu Selen, Ph.D., Sherrie Shade, R.Ph., J.D.,** and **Michael J. Verdi.** *PHS Outstanding Unit Citation:* **LT Debra A. Gump, CDR Sandra Kweder, CAPT Ko-Yu Lo** and **LT Kimberly A. Struble.**

FDA Commendable Service

Pharmacy Compounding Steering Committee: **Kathleen R. Anderson, R.Ph., Jane A. Axelard, J.D., Igor Cerny, R.Ph., Rita R. Hoffman, David J. Horowitz, Esq., Kim Keller-Reid, Lee Korb, John R. Lienesch, Wayne H. Mitchell, Lana L. Ogram, Luann Pallas, R.Ph., Brian Pendleton, Frederic J. Richman, M.S., Richard Schwartzbard, Vaiyapur Subramaniam, M.S.,** and **Kimberly Top-**

(Continued on page 8)

JOE'S NOTEBOOK

Americans Make Health Progress

Most of us don't have the chance to make a close and personal impact on other people's health the way Center employees who helped at Fort Dix did (page 1). But the work of everyone in the Center impacts the public health. According to data released in June from the National Center for Health Statistics, Americans have reached or are on track to meeting half of the objectives of the Healthy People 2000 initiative. The best rating in two decades of assembling its annual progress review can be found in the report, *Healthy People 2000 Review: 1998-'99.*

The report shows that 15 percent of the objectives of the Healthy People initiative have met their targets, including reduction of outbreaks of water-borne diseases and foodborne infections, and oral and breast cancer deaths. In addition, 44 percent of the objectives are progressing on schedule toward their target, including childhood immunizations, breastfeeding, regular dental visits, mammography screening and consumption of five fruits and vegetables a day. Other objectives, such as reduction in infant mortality, are only a fraction away from their targets.

However, the results of the review were not all positive. One-fifth of the Healthy People objectives moved away from their targets, including an increase in the number of overweight individuals. For example, the incidence, prevalence, complications and mortality of diabetes are all on the rise. The report also shows that 6 percent of the objectives demonstrated mixed results, 3 percent had no change from the baseline figure, and 11 percent of the objectives lacked sufficient data to evaluate progress.

The report groups objectives into four age-related categories: infants and children; adolescents and young adults; adults; and older adults. Among infants and children, the death rate for children 1-14 years of age decreased 26 percent during the decade, which surpassed the objective. On the other hand, hospitalization due to asthma in this age group has risen throughout the decade and is a major cause of morbidity.

Among individuals in the 15-24 age group, death rates have declined substantially and have met the year 2000 goal of 85 deaths per 100,000 people. Alcohol-related motor vehicle crash deaths, suicides, fighting and weapon carrying have all declined. However, heavy alcohol drinking among high school seniors and college students has increased. Among adults in the 25-64 age group, the death rate is near the year 2000 target and has dropped 31 percent since 1979. Cancer death rates are near the year 2000 target.

Among the elderly, life expectancy rates have risen, and mortality rates have declined 6 percent since 1979. There has been a decrease in deaths due to heart disease and stroke, and a decrease in suicide rates among elderly white males. However, deaths resulting from falls and motor vehicle crashes increased during the past decade.

The Healthy People initiative began in 1979 and provides an annual review of Americans' progress in health. The news release at http://www.cdc.gov/nchswww/releases/99news/99news/99hp2000.htm has a button to download the PDF file of the report, which is 2.9 megabytes in size.

Reviewer diagrams now on the Web. Ever since the Pike ran **Grant Williams'** first article on his reviewer diagram project in the November 1997 issue, I have had many requests for copies from outside the Center. The diagrams help visualize the review process. The Center has placed five diagrams on the World Wide Web. Diagram authors are **Greg Dubitsky, Susan Honig, Stanka Kukich, Nasim Moledina** and Williams. The diagrams, constructed by **Madeline VanHoose** and edited by the reviewers, can be found at http://www.fda.gov/cder/reviewer/default.htm.

news along the pike

The Pike is published electronically on the X:drive in Cdernews and 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).

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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

Arrogance

BY JIM MORRISON

There was a time, not so long ago, that, if you asked those who had contact with the Agency to give one word that best described the FDA, many would have answered "arrogance." The arrogance they saw came from people who believed it was appropriate for a regulator to tell those in the regulated industry how to do every aspect of their jobs, to educate the public and others about what they really need and to explain to them why it was unrealistic to expect the FDA to provide it anytime soon.

Thankfully, those days have passed. Whether the reputation was entirely deserved is moot. Perception is reality. Some of the factors that led to perceived arrogance by CDER employees still exist, and we need to be aware of them. The first and foremost is power. Those who control the supply of any commodity people need have a lot of power. It may be a computer operating system, a license to drive a car or permission to market a new drug. Often the needed commodity is information. Possession of such information gives anyone a sense of power. But the true test of character is how one uses that power.

There is a story that illustrates the point. In the early days of television, there were no network news programs. After the first transcontinental live TV news broadcast, some of the newscasters were celebrating the feat in a local establishment. Howard K. Smith was waxing eloquent about how they could shape the thinking of the American public and have a tremendous impact on society. Edward R. Murrow, the dean of TV newsmen, put things in perspective. He said: "Remember, Howard, because your voice travels to the end of the continent doesn't make you any smarter or wiser than when it traveled only to the end of the bar."

So it is with regulatory agencies. People join CDER from academia, health care institutions and companies. They bring with them their own expertise. But the day after they arrive, people suddenly turn to them for information and advice about drug regulation.

All of us at times feel pressure to fulfill the role of an expert, even when we don't know much more about the subject than the person asking for advice. At those times it's important to remember that it's OK to say: "I don't know." Hopefully, you'll add "but I'll find out and get back to you." In addition, regulators hold the fate of the regulated in their hands. Some people relish the power of that position.

However, the ability to make grown men tremble is a false and fleeting power. For as soon as they are able, those who tremble will attack and bring down the powerful. On the other hand, power exercised with humility creates trust and respect. And trust and respect make a regulatory agency first rate.

Although CDER has come a long way in the past few years, I still hear complaints that result from perceived arrogance on the part of some CDER staff. Arrogance is likely to be perceived when a regulator comes to the table with a fixed position or a presumption that the person with whom they are meeting is of inferior competence or out to skirt or break the law. These attitudes prevent the regulator from listening openly and impartially to what the person is saying.

If you want to get a sense of what a regulated person might be feeling, imagine yourself as the subject of an IRS audit. Would it make a difference to you that the auditor has already concluded that you are cheating on your taxes and that his or her job is to document that for the prosecutors? You are already nervous, but the feeling that you are presumed guilty and that you must prove your innocence is enough to send your blood pressure into orbit.

Suppose, instead, that the auditor approached you by saying that he or she was not clear about some items in your return and needed your help to better understand them. Would you leave the audit with a different view of the IRS? Both approaches get the same information for the IRS. The first one makes an angry taxpayer, while the second gains respect for the agency.

To avoid giving the appearance of arrogance, before each meeting or phone call, it's helpful to tell yourself that you are there to listen as well as to advise and that you don't know everything about the subject matter. But remember that feigned humility is easy to spot. To be successful, you must actually believe what you're telling yourself.

Jim Morrison is the Center's Ombudsman.

Printed Copies of Report to the Nation

OTCOM has ordered a small supply of printed copies of the the *CDER 1998 Report to the Nation: Improving Public Health Through Human Drugs.* You can find the electronic version of the report and PowerPoint slides of the charts on CDER's Web site at: http://www.fda.gov/cder/reports/rptntn98.pdf The printed copies of the book are primarily intended for visitors and guests. If you're having a meeting with industry and would like copies, please contact **Joan Powers** by phone (7-3473) or e-mail (POWERSJ). We don't have enough copies to provide everyone in CDER with a copy. If you need one for reference, contact Joan or look for extra copies in the Medical Library and its branches.

OTR Mourns Loss of James Vick

Col. James Vick, a pharmacologist with the Office of Testing and Research, died following a diving accident, which occurred while he was on vacation. Many will remember Jim's colorful lectures on his field and laboratory research with the Army on poisonous snakes and the development of antivenoms. He was proud of his Minnesota origins; proud of his dedicated service to his country as evidenced by his accomplished career with the Army (including service in the Korean War), his participation with the PHS Disaster Medical Assistance Team, and his research in FDA laboratories over the past 18 years. He was very proud of his four surviving children and his grandchildren.

UNION CORNER

FDA, Union Negotiators Agree on Contract

BY ROBERT YOUNG

After a one-year gestation, the contract has been delivered—almost. The first two Union Corner articles last year (August and September *Pikes)* discussed the importance of collective bargaining agreements as principal, practical, everyday embodiments of employees' rights in the workplace. The February Union Corner described the actual negotiation process, which ended under the watchful eye of the arbitrator at 4 a.m. on Saturday May 22. No issues were submitted to arbitration. All terms were worked out between and agreed to by the union and the Agency.

To go into effect, the proposed contract must be agreed to by the Commissioner and ratified by the membership. Each bargaining unit employee will be given a copy of the final contract and two hours of official time to read it. The contract contains some 60 articles and will run about 150 pages.

Neither party got everything it wanted, nor will every term in the contract please everyone. We hope the contract creates an employee friendly environment and makes FDA the best place in the world to work.

There are three kinds of articles in the contract: those that go to the administration of the contract, those that relate to the union and those that pertain to the employee work environment. The better each employee understands the plan, the more likely we will realize the goal of the better FDA workplace.

The contract, however, is not self-executing. The most important things to be aware of are employee rights; procedures to be followed, including deadlines; duties and responsibilities; and standards for making decisions. When an employee lapses, he or she must take corrective action. When the employer lapses, it should be called to account. The ordinary ways to point out lapses are informal discussions and, when those fail, grievances.

Grievances flag lapses and get things on track. They are the union's preferred approach to lapses because they are cheap and fast. The union, however, is not going to be poking into everyone's affairs to see that things are done according to the book.

Administrative. The contract's term is five years. At 30 months, the union may, at its option, reopen for negotiations and bargaining three of the 60 contract articles. Employees who work under the contract must identify what doesn't work or needs to be fixed or could be improved. If no one speaks up, any shortcomings and defects in the contract will not be addressed.

Union. For representational activities, official time (time on the clock) will be available on a reasonable-time basis (December *Pike).* FDA has promised not to penalize any employee for his or her use of official time. Union representatives may elect to have a collateral duty statement added to their position descriptions. The statement will describe the kinds of representational activities that an employee representative will engage in, such as processing of grievances, participation in negotiations and attendance at examinations of other employees.

Representatives are responsible for keeping track of and reporting all official time they use. When performance appraisals are made, the total amount of official time used will be divided by the usual number of hours for a full-time employee (2,080 hours a year) to determine the proportion to be appraised in accord with the employee's assigned duties. In other words the representative will be appraised as a part-time employee. FDA managers will make no appraisal of an employee's representational activities.

Employee work environment. This constitutes the bulk of the contract. One example—alternative work schedules—illustrates the three keys to making the contract work for you: procedures, duties and responsibilities, and standards. Standard FDA business hours are 8 a.m. to 4:30 p.m. Monday through Friday. Any other tour of duty is an alternative work schedule. A joint labor-management committee will be created to handle alternative work schedule questions and controversies. This committee has the authority to make such rules as it believes will make the approval of alternative work schedules more efficient and less troublesome.

It is each employee's duty and responsibility to determine whether he or she would like to have an alternative work schedule and what that schedule will be. An employee who would like to have an alternative work schedule must follow the procedure of informing his or her supervisor of the proposed schedule and obtaining approval. After receiving the proposed schedule, the supervisor's duty and responsibility are to review the proposed schedule in light of the business needs of the office and determine if approving the proposed schedule would result in an adverse Agency impact (standard for denial). An adverse impact is defined in the contract as a reduction in productivity, diminished level of service to the public or an increase in operating cost.

If the supervisor finds an adverse Agency impact and denies the request, he or she must then inform the employee by memorandum within 30 days of the reasons, supported by evidence as appropriate, why there will be an adverse impact. The employee may then adjust the proposed alternative work schedule to negate the identified adverse impact. This can be done in conjunction with other employees, if appropriate. Procedures then require the employee to resubmit the proposed alternative work schedule for supervisory approval.

An employee who has failed to obtain approval of a proposed alternative work schedule may take the proposal to the Joint Labor-Management Committee. The employee explains his or her position to the committee and provides all relevant documents. The committee works to resolve disputes. Those disputes not resolved after 180 days will be referred to a neutral third party for assistance and resolution, which will be binding.

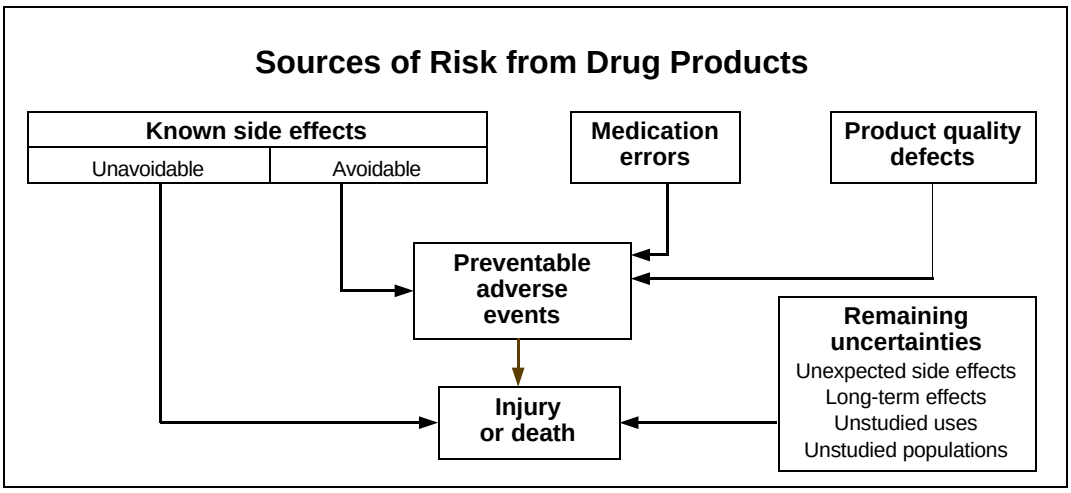
For those who need help in understanding the contract and putting it into effect, there will be a series of lunch-and-learn sessions over the next few months to be held at the various FDA locations in the Washington area.

Robert Young, M.D., Ph.D., is president of the local NTEU chapter.

RISK MANAGEMENT CORNER

Systems Approach Requires Understanding of Risk Types

One of the first questions the FDA Task Force on Risk Management (May *Pike)* had to ask was: "What are the different types of risks?" Understanding the different types of risks and their sources is the first step to managing medical product risk and identifying mechanisms to improve the system. The task force called for more data to be collected about the causes, incidences, preventability and relative contribution of the various risks.



The task force identified four general categories of risks:

- Known side effects.
- Medication errors.
- Product quality defects.
- Remaining uncertainties.

These risks lead to both preventable and unavoidable adverse events. Most injuries and deaths associated with the use of drugs result from their known side effects. Some side effects are unavoidable, but the task force estimated that more than one-half can be prevented or minimized by careful product choice and use.

Sources or other preventable adverse events are medication errors and product defects. Medication errors occur when the drug is administered incorrectly or the wrong dose or drug is administered. Injury from product defects is unusual in the United States because of the great attention paid to product quality control and quality assurance during manufacturing.

The final category of potential risk involves the remaining uncertainties, which the task force identified as:

- *Unexpected side effects.* The contribution of serious adverse events resulting from unexpected side effects to the overall rate of serious adverse events is relatively small. However, some very rare, serious or life-threatening side effects may be recognized only after marketing.
- *Long-term effects.* Because long-term studies to assess these risks are not required prior to product approval or for continued marketing, considerable uncertainty exists about them, particularly in treating chronic diseases.
- *Effects of off-label uses.* Marketed products are frequently used to treat conditions that were not studied during clinical development.
- *Effects in populations not studied.* Some groups such as children and pregnant women may not have been studied before marketing.

Adapted from the task force report available at http://www.fda.gov/oc/tfrm/risk-management.html.

EEO CORNER

CDER Participates in High School/High Tech Program for 2nd Year

BY GLORIA MARQUEZ SUNDARESAN

FDA was mentioned on the front page of the June 10, Montgomery County Weekly Section of the Washington *Post* ("Disabled Teenagers See the Possibilities") as a result of CDER's participation in the High School/ High Tech Program.

One of the Center's EEO initiatives is the summer program for high school juniors with disabilities run in partnership with the United Cerebral Palsy Inc. We were able to place three students in the program last summer, our first year participating in the program. Comments from individuals who worked with the students were all positive, and this encouraged EEO to participate again this year.

This summer, Charles McNelly, Ph.D., executive director of United Cerebral Palsy, asked the Center to help place four students. So far, we have placed three: one in the EEO Staff and two in the Office of Pharmaceutical Science. The two students in OPS are assigned to work in OPS immediate office and the Division of Applied Pharmacology Research.

The program has been operating for the last seven years, and it was formed in partnership with the schools, families, federal, county and private organizations. Besides doing regular work, the students with disabilities are introduced to career opportunities in science, engineering, information technology and other high tech fields.

The students are expected to learn the discipline and responsibility of being a part of a work environment where they contribute their skills and abilities and are paid for their work. In addition, the students will gain experience, additional skills, self esteem and most importantly the work ethic needed for them to compete in their search for jobs and become independent, contributing taxpayers in the future, For more information please call the EEO Office on 594-6645.

Gloria Marquez Sundaresan is a CDER EEO specialist.

INFORMATION TECHNOLOGY CORNER

Y2K Testing Advances; New TeamLinks to Support Long Filenames

These updates from the Office of Information Technology describe major activities, currently underway or planned. More detailed and updated information about many of them is available on the CDERnet OIT page at http://oitweb/oit/. Comments or questions about any of these projects can be sent through e-mail to the OIT point of contact listed for each project.

Year 2000 Activities

Year 2000 work continues to advance in CDER with several internal readiness projects in progress. These include Y2K compliance of desktop PCs, local application testing, Business Contingency and Continuity Plan testing and Day One planning. CDER has begun buying 464 PCs using Agency funds. Deploying these PCs and upgrading current non-compliant PCs is scheduled to begin in early July and should be completed by September. Y2K desktop questions may be addressed to the e-mail account entitled Y2K.

Testing of the Business Contingency and Continuity Plan was scheduled to begin in June. Participants include the Agency contractor and various CDER components, such as the document rooms, OIT's Division of Data Management Services, the Office of Management and the review divisions. Completion is scheduled for September.

OIT testing for non-mission critical applications was completed in May and local application testing is in progress. Three CDER organizations have scheduled time on the Y2K server to test their systems. Please contact **Judy McIntyre** (MCINTYREJU) for more information on how to request testing time.

Day One planning is progressing. Day One is a term used to describe activities the federal government will undertake on the weekend of Jan. 1 to demonstrate to itself and the public that its technical operation capabilities are functional. OIT is drafting an operating plan for CDER's Day One activities. More information on this project will be provided in future updates.

The CDER Y2K Task Force leads the external outreach efforts. Responses to the CDER survey are being entered into a database as they are received. The task force continues to meet with other agencies and government organizations regarding Y2K issues.

More information about CDER and FDA's Year 2000 activities can be found on the FDA web site (www.fda.gov/cder/y2k). The OIT point of contact is Judy McIntyre (MCINTYREJU).

New TeamLinks Coming Soon

An upgrade to the current TeamLinks software is being scheduled. The new TeamLinks software (version 4.0) is a 32-bit application, which takes advantage of the speed and reliability of Windows 95 and Windows NT. There is no learning curve since TeamLinks 4.0 preserves the functionality and "look and feel" of the familiar 16-bit TeamLinks. The OIT desktop team will be installing TeamLinks 4.0 on approximately 800 new systems. These new systems will replace older systems that are not Y2K compliant. All other systems will be upgraded at a later date. More information about upgrading your system to TeamLinks 4.0 will be made available soon.
Some of the new features are:

- Long filenames. Attach documents with long filenames to TeamLinks messages. In the current TeamLinks, filenames cannot be longer than 8 characters with a 3-character extension, for example, "thisfile.doc."
- Quick send. Quickly send files as mail messages directly from the Windows Explorer.
- Drag and drop. Drag and drop files from the Windows Explorer into TeamLinks messages.
- Office 97 support. Send, receive and view documents created with Microsoft Office 97 without launching the applications.
- Active Web addresses. Active links inside a message can now take you to the Web page by double clicking on the address.
- New employee directory. A new HHS Employee Directory on the Web has replaced the FDA Phone Directory. The new directory is an easy way to search for employees who work for DHHS. For example, you can search for all Directors within a specific Agency and Center (FDA/CDER). Once the query is completed, you can click on the name and get detailed information about the employee.

The OIT point of contact is **Liz Gomez** (GOMEZL).

Intranets Available Agencywide

CDER is sharing a wealth of data on the CDERnet with the rest of the Agency. OIT has recently made many changes to the CDER firewall. These changes allow all FDA employees to view CDERnet and all of CDER's staff to access any of the other center's sites.

CDERnet has been available to CDER for more than two years, but other centers could not access this data without special permission. Access had to be granted to non-CDER individuals on a case-by-case basis. That access list had grown to several hundred people throughout FDA. In addition to creating an administrative nightmare, it was apparent from all of the requests for access that the information contained on the CDERnet was valuable to everyone in FDA.

With the implementation of the FDA firewall last fall and recent changes to the CDER firewall, OIT revisited the issue of access to CDERnet within the FDA network and came up with a simpler solution. Individual access permission is no longer necessary. In addition, OIT worked with the CDER Medical Library staff to remove any CDER-proprietary material so that it could not be viewed in the other centers. That proprietary information has been moved to other sites. OIT also worked with the Network Control Center to set up the naming of the CDERnet site so that non-CDER personnel could type in the name instead of a network address of numbers, which was necessary before.

When you submit information for inclusion on the CDERnet, you should remember that all Agency personnel can now view that data.

Other FDA centers' Web sites are also available for CDER employees without

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CDER, Other Center Intranets Now Available to All FDA Employees

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requesting special permission. You can find them in the alphabetical listing on the Office of Science's intranet site at http://first.fda.gov/ under the Internet Resources button. To take advantage of these Web sites, you must make sure that you have disabled proxy server usage on your browser. Everyone has one of the following two browsers which can be identified when the browser is started. Please follow the directions for the browser version you are using.

For Internet Explorer 3 users:

- Open IE 3.
- Click View.
- Click Options.
- Click the Connection tab.
- Remove the check mark in the box beside "Connect Through a Proxy Server" by clicking the box.
- Click apply.

For Internet Explorer 4 users:

- Open IE 4.
- Click View.
- Click Internet Options.
- Click the Connection tab.
- Remove the check mark in the box beside "Access the Internet Using a Proxy Server" by clicking the box.
- Click Apply.

As a bonus, you will speed up your browser's access times to the World Wide Web. If you encounter problems, please contact the Help Desk (7-0911) to guide you through the process. The OIT point of contact is **Fred Goetze** (GOETZE).

July IT Training

Monday	Tuesday	Wednesday	Thursday	Friday
			1 **PowerPoint Intro** 9-12 **PowerPoint Charts** 1-4	**2**
5	**6**	**7**	**8**	**9**
12 **Word Intro** 1-4	**13** **Word Formatting** 9-12 **Word Tables** 1-4	**14** **NEST** 9-12 **NEDAT** 1-4	**15** **Access & Tables** 9-12 **Access Queries & Reports** 1-4	**16** **Access Form Design** 9-12 **Access Report Design** 1-4
19	**20**	**21** **TeamLinks Intro** 9-12 **TeamLinks Attachments** 1-4	**22** **Calendar Manager** 9-12	**23** **CDER Network & Web** 9-12 **DFS** 1-4
26	**27**	**28**	**29**	**30**

The catalog, training materials, schedule and online registration are on OIT's intranet site.

PM Coordinator

The trial period for the new project management coordinator position began May 18. The new position is a result of OIT's process improvement effort.

The PM Coordinator's job is to review the progress of OIT projects and report summary status information to the OIT Director; facilitate project success by obtaining senior management issue resolution, as needed; and ensure management quality goals are met. (The PM coordinator is roughly analogous to the supervisory project manager in CDER's review divisions).

The first activity is to plan the trial period. This includes defining the goals of the trial period, measures of success, scope, activities, and schedule. A high-level summary of this information was approved by the OIT Director and is available on the CDER Intranet under PM Coordination. OIT Senior Staff will review the detailed trial period plan in June. The OIT point of contact is **Vali Tschirgi** (TSCHIRGIV).

QA Development Project

The writing phase of OIT's Improvement Project is well under way. On June 1, OIT senior staff peer-reviewed the policy for each of the improvement target areas: project management coordination; project planning; project tracking and oversight; configuration management; and quality assurance.

The writing of 17 documents to support these areas is progressing, and implementation is scheduled for September. The OIT point of contact is **Jerry Yokoyama** (YOKOYAMAJ).

Reviewer Affairs Corner

RAC Briefs SMT on Comparable Pay, Communications Initiatives

By Robert Shore

At the Reviewers Affairs Committee quarterly meeting with the Center's Senior Management Team in May, the subcommittee chairs presented updates on their work.

Milton Sloan, chair of the Comparable Pay Subcommittee, briefly summarized the group's activities (May *Pike).* The SMT mentioned that the subcommittee's objectives were timely, since retention problems have been noted recently. Since the clinical pharmacology and biopharmaceutics data are the most complete, the subcommittee was urged to place its primary efforts on reclassification of the clinical biopharmaceuticists and pharmacokineticists. These efforts may serve as a model for other review disciplines. Each review discipline will still need to gather its own statistics have paperwork in place should funds become available.

Jacqueline White, chair of the Communications and Training Subcommittee, reported that a proposed RAC intranet site would contain many of the documents now available in the X:\coorcomm\rac directories.

Just a reminder. Primary reviewers can submit comments, questions and concerns to the RAC through their representative listed at X:\coorcomm\rac\roster\roster99.doc) or by e-mail to RAC. Meetings of the RAC, its subcommittees and task forces can be found on the RAC account of the Russell Calendar Manager—just "proxy schedule" RAC.

Robert Shore, Ph.D., a pharmacologist in DPE III, is RAC vice chair.

CDER Employees Earn 250 FDA-Level Awards

(Continued from page 1)

per. *PHS Unit Commendation:* **CDR Ronald E. Brown, CAPT Elizabeth E. Hiner, CDR Michael Jones, CAPT Yana R. Mille** and **CAPT Robert J. Tonelli.**

Selane NOOH Working Group: **Elizabeth Dickinson, Esq., Donald Hare, Martin Himmel, M.D., John Jenkins, M.D., Andrea Masciale, Esq., David Read, Esq., Gretchen Trout** and **Alexandra Worobec, M.D.** *PHS Unit Commendation:* **CAPT Gordan Johnston** and **CAPT Thomas G. Phillps.**

Viagra Working Group: **Larry Bachorik, Wiley Chambers, M.D., Susan Cruzan, Kim Colangelo, Evelyn Farinas, M.G.A., R.Ph., Mark Hirsch, M.D., Florence Houn, M.D., Murray M. Lumpkin, M.D., Marianne Mann, M.D., Lorrie McHugh-Wytkind, Toni Piazza-Hepp, Pharm.D., Lana L. Pauls, M.P.H., Lisa Rarick, M.D., Linda Ruckle, Terri Rumble, Daniel Shames, M.D.,** and **Diane Wysowski, Ph.D.** *PHS Unit Commendation:* **LCDR Mark Askine** and **CDR Evelyn M. Rodriguez.**

FDA Group Recognition

FDA Topical Microbicide Working Group: **Debra Birnkrant, M.D., Gloria Chang, R.Ph., Ling Chin, M.D., Susan Cobb, Daniel Davis, M.D., Michael Elashoff, Ph.D., James G. Farrelly, Ph.D., Paul Flyer, Ph.D., Holli Hamilton, M.D., M.P.H., Elias D. Harvey, D.V.M., Ph.D., Ajaz Hussain, Ph.D., Sheryl Lard-Whiteford, Ph.D., Dorota Matecka, Ph.D., Kellie Schoolar Reynolds, Pharm.D., Shelley Slaughter, M.D., Ph.D.,** and **Ita Yuen, Ph.D.** *PHS Unit Commendation:* **LCDR Julienne Valliancourt.**

Inter-Divisional Working Groups on Antibiotic Resistance: **Tracy Acker, Pharm.D., John Alexander, M.D., Gary Chikami, M.D., Mary Dempsey, Peter Dionne, Beth Duvall-Miller, M.S., Mark Goldberger, M.D., M.P.H., Robert Hopkins, M.D., M.P.H., Joyce Korvick, M.D., M.P.H., Sheryl Lard-Whiteford, Ph.D., Brad Leissa, M.D., Daphne Lin, Ph.D., Mamodikoe, Makhene, M.D., Frederick Marsik, Ph.D., Andrea Meyerhoff, M.D., Nasim Molendina, M.D., Diane Murphy, M.D., Jeffrey Murrary, M.D., M.P.H., Nancy Ostrove, Ph.D., Frank Pelsor, Alexander Rakowsky, M.D., Rosemary Roberts, M.D., David Ross, M.D., Leonard Sacks, Al Sheldon, Ph.D.,** and **Janice Soreth, M.D.** *PHS Unit Commendation:* **CDR Carmen L. DeBellas, CAPT Lillian Gavrilovich, CDR Lauren Iaconno-Connors** and **CDR Sandra L. Kweder.**

Medication Errors Committee: **Charles J. Ganley, M.D., Anna Marie Hommonay-Weikel, R.Ph., Khyati N. Roberts, R.Ph.,** and **Vaiyapuri Subramaniam, R.Ph., M.S.** *PHS Unit Commendation:* **CAPT Gary J. Buehler, CAPT Roger A. Goetsch** and **CAPT Evelyn T. Phillps.**

Pediatrics Team: **John Alexander, M.D., Jane A. Axelrad, J.D., Jonca Bull,M.D., Wiley Chambers, M.D., Denise Cook, M.D., Leanne Cusumano, Esq., Therese Cvetkovich, M.D., Patricia DeSantis, Elizabeth H. Dickinson, Esq., Roberta Glass, M.D., Lind Hu, M.D., Abraham Karkowsky, M.D., Sally Loewke, M.D., Elizabeth Ludwig, M.D., Murrary M. Lumpkin, M.D., Samuel Maldonado, M.D., Dianne Murphy, M.D., Tatiana Pavlova, M.D., Miriam Pina, M.D., Victor Raczkowski, M.D., Khyati Roberts, R.Ph., Monica Roberts, M.D., Rosemary Roberts, M.D., Kathie Robie-Suh, M.D., Rigoberto Roca, M.D., William B. Schultz, Jean Temeck, M.D., Karen Weiss, M.D.,** and **Ann Witt, Esq.** *PHS Unit Commendation:* **CAPT Paula Botstein, CAPT Elaine C. Esber, CAPT Thomas H. Hassall, CDR Steven I. Hirschfeld** and **CAPT Thomas G. Phillips.**

Project Management Workshop Planning Group: **Wendy Aaronson, Pat Beers Block, Shelia Buck, Bronwyn Collier, R.N., Gil Conley, Maria DeCarvalho, M.S.N., Lydia Falk, Ph.D., Pauline Fogarty, Michael Folkendt, Jody Ford, Elaine Frost, Mark Heintzelman, Ph.D., Renita Johnson-Leva, Debbie Kalgren, Chin Koener, M.S., Melodi McNeil, Corrine Moody, Martha Monser, Mary Padgett, Lana Pauls, M.P.H., Jack Purvis, David Roeder, Mary "Kay" Schneider, Glen M. Scimonelli, Suzanne Sensabaugh, Gail Sherman, Victoria Tyson-Medlocke, Mary Jane Walling, Saineh Walther, R.N., Leslie Wheelock, M.S.N., Jean Yager** and **Robert Yetter, Ph.D.** *PHS Unit Commendation:* **LCDR Allen G. Albright, CAPT Mark D. Anderson, CDR Joe M. Buccine, CDR Durand M. Hedin, CAPT Cathie L. Schumaker, CDR Kassandra C. Sherrod, CDR Matthew J. Tarosky, CDR Denise P. Toyer, LCDR Julienne M. Valliencourt** and **CAPT Robert L. West.**

Rebetron Combination Therapy Review Team: **Nara Battula, Ph.D., James G. Farrely, Ph.D., Russ Fleischer, PA-C, M.P.H., Paul Flyer, Ph.D., Rao V.B. Kambhampati, Ph.D., Stanka Kukich, M.D., Stephen Miller, Ph.D., Dave Morse, Ph.D., Nancy M. Ostrove, Ph.D., Prabhu Rajagopalan, Ph.D., Kellie Schoolar Reynolds, Pharm.D., William D. Schwieterman, M.D., John R. Senior, M.D.,** and **Greg Soon, Ph.D.** *PHS Unit Commendation:* **CDR Laurie B. Burke, LCDR Terri L. Crescenzi** and **CDR Tan T. Nguyen.**

Meritorious Service Medal

CDR Michael D. Jones

Outstanding Service Medal

CDR Laurie Burke
CAPT Ralph B. Lillie
CAPT George R. Scott

Outstanding Unit Citation

User Fee Team: **CAPT Thomas H. Hassall** and **CDR Joslyn P. Swann**

40-Year Career Service Recognition

Sylvia H. Colson

FDA Alumni Award

Carl Peck, M.D.

Jackie Barber is CDER's incentive awards officer.

Nominations for FDA Scientific Achievement Awards Due Aug. 18

The FDA Scientific Achievement Awards recognize FDA scientists who have made outstanding contributions to the Agency. The deadline for nominations is Aug. 18.

There are four award categories for 2000. Nominations, both individual and group, will be considered for the following:

- Excellence in Analytical Science.
- Excellence in Laboratory Science.
- Excellence in Review Science.
- Outstanding Intercenter Scientific Collaboration.

All FDA scientists who have demonstrated exemplary performance in their assigned scientific duties are eligible.

For the first three awards, the process will be two-tiered. In the first tier, selection committees in the centers and Office of Regulatory Affairs will pick winners for their respective centers and ORA. For the second tier, these winners will be forwarded to the Office of Science as nominees for the FDA Scientific Achievement Awards. The FDA Scientific Achievement Awards Selection Committee and the FDA Science Board will name the recipients of the FDA-level awards. Recipients of the FDA-level awards in the first three categories will receive a $2,000 cash award, a plaque and a letter and framed certificate signed by the Commissioner.

Review of nominations for the Outstanding Intercenter Scientific Collaboration Award will be single-tiered, with review by the FDA Scientific Achievement Award Selection Committee and the FDA Science Board. The recipients of this award will share a $5,000 cash award, plaques and letters and certificates signed by the commissioner. Nominations for the Outstanding Intercenter Scientific Collaboration Award should be sent directly to **Susan Homire, Ph.D.,** FDA Office of Science, HF-33. Parklawn Room 1735

Award nominations may be made by any employee, including the nominee or the nominee's immediate supervisor.

Nomination packages for the CDER Scientific Achievement Awards should be sent to **Robert O'Neill, Ph.D.,** (e-mail: ONEILL; phone 7-3195) in Parklawn Room 15B-45, HFD-700.

To obtain a nomination package, please visit FIRSt, FDA's Information Retrieval System, on the FDA intranet, at http://first.fda.gov or call the Office of Science (7-3340). The nomination package may be downloaded in MS Word format.

Presidential Panel Issues Guidance for Consumers on Y2K Conversion

The President's Council on Year 2000 Conversion announced guidelines June 14 for consumer and other users of prescription drugs to follow in refilling medications as the country approaches the date change for the next century.

"Prescription drugs are an important part of everyday life for millions of Americans," said John A. Koskinen, assistant to the president and chair of the Y2K council. "For a vast number of patients, regular medication is critical to overall health and well being. In recent months, attention has increasingly been focused on how the Y2K computer problem could affect the consistent supply of prescription drugs."

The council convened a meeting of industry representatives to examine the Y2K readiness of the pharmaceutical supply system. The group reviewed how the pharmaceutical supply system operates and the efforts by all system participants to ensure that it is equipped to handle the Y2K transition. Also participating were the Department of Veterans' Affairs, the Department of Health and Human Services, the Department of Defense and FDA.

A working group then developed the guidance announced June 14. The council agreed that consumers and other participants can be assured a continued supply of medications for the date change by refilling prescriptions when they have a five- to seven-day supply of medication remaining. Consumers should know it is clear that companies within the system are taking very seriously their responsibility to patients by testing critical computer systems and refining contingency plans. In addition, the pharmaceutical supply system typically operates with a 90-day inventory and, as a matter of course, maintains readiness for emergency situations that may occur.

The council found that government agencies and organizations within the pharmaceutical industry supply system have been working closely together to prepare for the date change. Substantial progress has been made and government and industry are confident that the pharmaceutical supply system should continue to function normally through Jan. 1. The council's recommendations and findings were that:

- Local pharmacists will be within easy access of a substantial supply of pharmaceuticals. The industry typically operates with an 90-day supply in the distribution system among manufacturers, distributors and pharmacies.
- Consumers should get a normal refill of medication when they have a five- to seven-day supply of medication remaining. This is good practice not only for Jan. 1, 2000, but for any other time. The supply system is resilient and can correct any issue that might arise within five to seven days.
- The pharmaceutical industry has emergency response plans in place and extensive past experience using these plans in handling disruptions caused by severe weather, transportation or other unforeseen occurrences.
- Government and organizations within the supply system that manufacture, purchase, distribute and provide prescription and over-the-counter medicines and medical supplies are continuing to work together to further enhance contingency planning for Y2K-specific issues throughout the supply system.
- Consumers who use prescription medications and have any questions about their supply, should speak with their local pharmacists or doctors.

The council's Web site can be found at http://www.y2k.gov/.

Volunteer Instructors Honored for '98-'99 Academic Year

By Chris Nguyen

The Division of Training and Development, Office of Training and Communications, held an Instructors' Awards Ceremony on June 4 to honor those in CDER who volunteered their time and expertise to teach courses during the 1998-1999 academic year.

In opening remarks that kicked off the ceremony, Center Director **Janet Woodcock, M.D.,** expressed her appreciation and thanks to all the instructors for their effort and involvement. OTCOM Director **Nancy Smith, Ph.D.,** followed by welcoming the group and conveying thanks from the DTD coordinators who presented the awards. DTD Director **Janice Newcomb, M.S.,** gave the closing remarks.

The courses and instructors were:

Guidance for Industry: Food-Effect Bioavailability and Bioequivalence Studies Training: **Sayed Al-Habet, Dennis Bashaw, Suresh Doddapaneni, Yih-Chain Huang, Ajaz Hussain, Larry Lesko, Ameeta Parekh, Kellie Reynolds** and **Roger Williams.**

Power Presentations: **Laura Bradbard, Elaine Frost** and **Florine Purdie.**

Successful Meetings and Minutes: **Chin Koerner.**

Regulatory Review of Investigational New Drug Applications: **Bronwyn Collier, Leanne Cusumano, Michael Folkendt, Debbie Kallgren, Andrea Masciale, Melodi McNeil, Corinne Moody, Robbin Nighswander, Dave Roeder, Cathie Schumaker** and **Matthew Tarosky.**

Drugs and the Liver: What They Do To Each Other: **Ray Anthracite, David Feigal, Bob Fenichel, David Graham, Peter Honig, John Hyde, Tom Laughren, Randy Levin, Mac Lumpkin, Judy Racoosin, John Senior, Sol Sobel, Bob Temple** and **Andrea Weir.**

Basic Topics in Statistics: ANOVA and Regression: **Michael Elashoff.**

Regulatory Science: **Dennis Bashaw, Debra Boxwell, Bronwyn Collier, Tony El-Hage, Charlene Flowers, Tom Laughren, Robert Osterberg, Nancy Ostrove, Eric Sheinin, Grant Williams, Steve Wilson** and **Alexandra Worobec.**

FDA Guidance for Industry: Population Pharmacokinetics Workshop: **Emanual Fadiran, Chuanpu Hu, Larry Lesko, Raymond Miller, Arzu Selen, He Sun, Bob Temple** and **Roger Williams.**

Secretary Week Recognition and Training: **Margaret Bell, Sandi Coffin, Noreen Gomez, Carol Hall, Devota Herbert, Susan O'Malley, Lisa Rarick, Eric Sheinin, Nancy Smith, Victor Vail** and **Janet Woodcock.**

New Employee Orientation: **Tom Abrams, Bob Berger, Laura Bradbard, Stephanie Cafarelli, Susan Carey, Maddy Carolan, Heather Chafin, Leanne Cusumano, Ruthanna Davi, Elaine Frost, Erik Henrikson, Mike Jones, Debbie Kallgren, Karen Koenick, Lana Kostecka, Kathy Kruse, Buck Ledford, Andrea Masiale, Kathy McConnell, Zelda McDonald, Ellen Shapiro, Ted Sherwood, John Simmons, Brad Stone, Neeru Takiar, Margaret Tart** and **Santford Williams.**

New Reviewers Workshop: **Tracy Acker, Funmilayo Ajayi, Pat Alcock, Susan Allen, Carol Assouad, Celeste Bove, Maddy Carolan, Igor Cerny, Kim Colangelo, Joseph Contrera, Jonathan Cook, Tricia DeSantis, Norm Drezin, Bonnie Dunn, Tony El-Hage, Amy Ellis, Pat Faustino, Rick Friedman, Steve Goldman, Debbie Henderson, Peter Honig, Patricia Hughes, Abby Jacobs, Heidi Jolson, Lydia Kieffer, Carol Knoth, Kathy Kruse, Dave LePay, David Lester, Randy Levin, Frederic Marsik, Iris Masucci, Melissa Maust, Joy Mele, Jim Morrison, Bob Osterberg, Lana Pauls, Lisa Rarick, Kathy Robie-Suh, Evelyn Rodriguez, Nancy Smith, Kimberly Topper, Raji Uppoor, Michael Verdi, Andrea Weir, Steve Wilson** and **Janet Woodcock.**

Basic Concepts of the CDER Review Process for Non-Reviewers: **Tanya Abbott, Tom Abrams, Margaret Bell, Ruth Clements, Beverly Friedman, Debbie Henderson, Bobbi Jones, Lana Kostecka, Mary Kremzner, Andrea Masciale, Jim Morrison, Bill Myers, Bill Oswald, Evelyn Rodriguez, Ellen Shapiro, John Simmons, Nancy Smith, Margaret Tart** and **Karen Weller.**

Topics in Clinical Trials: **Tom Laughren** and **Bob Temple.**

Human Pregnancy Outcome Data: **Sandy Kweder.**

Pediatric Rule Implementation: **Dianne Murphy, Khayti Roberts** and **Rosemary Roberts.**

Pediatric Exclusivity: **Jonca Bull, Mac Lumpkin** and **Thomas Hassall.**

Container Closure Systems for Packaging Guidance: **Mike Adams, Donald Klein, Robbe Lyon, Sheldon Markofsky, Melissa Maust, Radhika Rajagopalan, Barry Rothman** and **John Smith.**

Safety Pharmacology: **Aisar Atrakchi, Anthony Proakis** and **Lawrence Sancilio.**

Introduction to Research Data Management, Clinical Trial Information Processing and Biostatistics for Medical Reviewers: **Kaye Fendt.**

Clinical Pathology for Pharm/Tox Reviewers: **Lois Freed.**

Topics in Applied Statistics for FDA Reviewers: Introduction to Quantitative Overviews, Meta-Analysis and Research Synthesis: **Charles Anello.**

Basic Statistical Methods: **Ruthanna Davi, Barbara Elashoff, Karen Higgins, Kate Meaker, Nancy L.P. Silliman** and **Nancy Smith.**

Immunotoxicology: **Ken Hastings, James Weaver** and **Susan Wilson.**

Awards were presented to the Committee for Advanced Scientific Education: chairperson, **Ken Kobayashi;** vice chair,

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CASE Selects New Members; Huff Tapped as 1999-2000 Chair

By Ken Kobyashi, M.D.

The Committee for Advanced Scientific Education is pleased to announce that 13 new members were elected from a large slate of highly qualified nominees. The Committee is pleased to welcome the following new members:

- **Funmilayo Ajayi, Ph.D.,** Office of Clinical Pharmacology and Biopharmaceutics.
- **Clare Gnecco, Ph.D.,** Division of Biometrics I.
- **Alexandra Kapatou,** Division of Biometrics I.
- **David Lester, Ph.D.,** Division of Research and Testing.
- **Juan Pelayo, M.D.,** Division of Cardiorenal Drug Products.
- **Mary Purucker, M.D.,** Division of Pulmonary Drug Products.
- **Judith A. Racoosin, M.D.,** Division of Neuropharmacologic Drug Products.
- **Evelyn Rodriquez, M.D., MPH,** Division of Risk Evaluation II.
- **Sandip Roy, Ph.D.,** Division of Oncology Drug Products.
- **Kimberly Struble, Pharm.D.,** Division of Antiviral Drug Products.
- **Kathleen Uhl, M.D.,** Office of Clinical Pharmacology and Biopharmaceutics.
- **Josie Yang, DVM, Ph.D.,** Division of Anti-inflammatory, Analgesic and Ophthalmologic Drug Products.
- **Mona R. Zarifa, Ph.D.,** Division of New Drug Chemistry I.

The Committee also wishes to thank **Nilambar Biswal, Aloka Chakravarty, Mohammed Huque, Ravi Kasliwal, John Senior, Frank Sistare, Sidney Stolzenberg** and **Alexandra Worobec** for their many contributions during their tenure on CASE.

The new committee officers for 1999-2000 are **Robin Huff, Ph.D.,** a pharmacologist and toxicologist with the Division of Neuropharmacologic Drug Products, who will be the chair, and **Sousan Altaie, Ph.D.,** a microbiologist with the Division of Special Pathogens, who will serve as vice chair.

CASE Mission

As a CDER standing committee, CASE serves as the Center's principal advisory body for advanced scientific educational activities. Its mission is promote excellence in advanced scientific education and assist CDER's scientific personnel in maintaining currency and a high level of competency in the advanced regulatory and scientific knowledge of drug evaluation, in order to meet the complex challenges of evolving and innovative drug development in a global environment.

The Committee consists of 27 members of CDER's scientific staff, nominated at large by their peers and elected by the current CASE membership. The new members are appointed by the center director for a three-year term. About one-third of the committee turns over each year. The committee meets once a month, with subcommittees meetings in addition to the full committee meeting.

CASE Activities

The most visible CASE activity is the highly successful CDER Seminar series, which has attracted nationally and internationally known speakers. Among the more notable CDER Seminars of this year were a presentation by FDA Commissioner Jane Henney, M.D., and a panel discussion on the ethics of placebo-controlled clinical trials.

This year, Scientific Rounds was revitalized into a vibrant, popular discussion of timely and important regulatory dilemmas. The committee also accomplished the difficult task of successfully integrating Scientific Rounds and the CDER Seminar into a single ongoing program. the committee also sponsored or co-sponsored several special seminars. These seminars, generally more technical and aimed at more targeted audiences than the regular Wednesday series, have proved to be quite popular and well attended.

The committee also completed the process of writing and ratifying a set of bylaws governing its structure and activities. Two important longer-term accomplishments were the establishment of the William Abrams Memorial Lectureship, in recognition of Dr. Abrams' services to the Center, and the creation of the Outstanding Science Teaching Award, which will be inaugurated during the 1999-2000 academic year.

The CDER Seminar program has begun to receive attention from outside organizations. The panel discussion on placebo-controlled clinical trials was covered by the *Pink Sheet* and mentioned in the *Boston Globe*. The Abrams Lectureship was publicized by the American Society of Clinical Pharmacology and Therapeutics in their journal *Clinical Pharmacology and Therapeutics* and on their Website.

CASE members were also instrumental in developing and sponsoring important education events such as the Drugs and the Liver Course and the Workshop on PK/PD of Antimicrobial Drugs.

Other activities that Committee members have participated in include the reaccredidation site visit by the American Council on Continuing Medical Education and efforts by the Division of Training and Development to develop important new initiatives aimed at providing incentives to potential course instructors.

CASE also reviews proposals for courses in advanced scientific topics, assists in the development of such courses and evaluates the success of the advanced scientific education programs.

Ken Kobayashi, a medical officer in the Division of Oncology Drug Products, is current CASE chair.

DTD Instructor Awards

(Continued from page 10)

Robin Huff; subcommittee chairpersons, **John Senior, Alexandra Worobec** and **Andrea Weir;** and committee members: **Sousan Altaie, Nilambar Biswal, Sonia Castillo, Marc Cavaille-Coll, Aloka Chakravarty, Bill Hess, Peter Honig, Shiew Mei Huang, Mohammad Huque, Ravi Kasliwal, Meyer Katzper, Joyce Korvick, Rik Lostritto, Pramoda Maturu, Nakissa Sadrieh, Frank Sistare, Sid Stolzenberg** and **Bill Timmer.**

Chris Nguyen is an educational training technician in DTD.

CDER Commissioned Corps Officers Help with Refugee Screenings

(Continued from page 1)

The operation, which peaked during May and is expected to end July 8, was an interagency task force directed by HHS Office of Refugee Resettlement, a part of the Agency for Children and Families.

Other organizations supporting the operation included:

- The Joint Volunteers Agency, a private, non-profit group responsible for the resettlement of the Kosovar guests.
- The Department of Defense, responsible for logistics.
- The PHS Office of Emergency Preparedness, a part of the HHS Office of Public Health and Science, tasked with the medical component of the operation.

The Office of Emergency Preparedness activated the National Disaster Medical System and the Commissioned Corps Readiness Force to obtain personnel for the medical mission. Once activated, the system called for health care providers from disaster medical assistance teams, including the PHS-1 DMAT, which can include civilians. The Commissioned Corps Readiness Force provided commissioned officers for the operation.

The Corps operated the health clinic in a hastily converted Army mess hall. Babies were delivered and other care provided at local hospitals. "The medical mission had two components, medical screening and acute health care," said **CDR Kevin Yeskey,** chief medical officer in the Office of Emergency Preparedness and commander of the medical mission.

"In addition to providing medical screenings for each refugee, there were more than 4,600 treatments delivered," said OEP's **CDR Kathleen Downs**, medical readiness coordinator and education specialist for the Commissioned Corps Readiness Force. Downs, reported that at least 53 of the refugees were pregnant and seven babies were delivered.

Other statistics included: nearly 11,000 immunizations, more 2,800 X-rays taken, almost the same number of blood samples drawn, nearly 1,000 dental procedures and more than 7,000 prescriptions filled.

Commissioned Corps specialties represented on the operation included physicians, nurses, pharmacists, laboratory and preventive medicine specialists, social workers, physical therapists and medical records technicians.

"Pharmacists comprised a sizeable portion of those sent from the Center," Hess said. **CDR Sheila O'Keefe,** a pharmacist from the HHS Program Support Center, learned enough Albanian to communicate prescription directions to the refugees in their own language. "Her effort made a huge, positive impression on the refugees, many of whom stood in front of the pharmacy in amazement that someone cared about them enough to take the time and trouble to learn their language," Hess said.

All labels and medication directions had to be typed in Albanian. A chart with common phrases, such as "Take 1 tablet," and their Albanian equivalents was posted over the typewriter. Preprinted auxiliary labels, such as "Take with food," couldn't be used. Any additional directions also had to be translated and typed.

"When directions were complicated, pharmacists had to mix and match words from several phrases," Hess said. "Since the pharmacy had an Albanian interpreter, most complicated directions could be checked by the interpreter for accuracy."

To view photographs of the Corps activities at Fort Dix, click here.

To find out more about the Commissioned Corps Readiness Force and the PHS-1 Disaster Medical Assistance Team, including volunteering, visit their Web site at http://oep.osophs.dhhs.gov.

The challenge posed by the language barrier, the trauma that the refugees had experienced and the limited supplies stimulated pharmacists to find ways to overcome them, said Herbert, who is working with Hess this summer. Hess, Herbert and Korvick all noted that the work of the interpreters was invaluable in delivering care.

"Instead of filling from a script alone, we filled prescriptions directly from the patients medical records," said Herbert. "This was a new experience for me, and it was interesting to see the whole scope of their therapy. We had a limited formulary and, in several cases, had to recommend therapeutic substitutions."

The pharmacists lacked equipment for compounding. "To deliver tuberculosis medication to a child," Herbert said, "one of the pharmacists developed a recipe for a TB cocktail that included using a hammer to break tablets into powder to be suspended in a mixture of suspending vehicle donated from a local pharmacy and peach juice from canned peaches. This proved to be not only effective in helping patient compliance but also quite inventive and resourceful."

The medical records specialty also proved particularly relevant said Brophy. "Initially, the records were organized according to the individual's family name," she said. "With the inevitable misspellings, it became very difficult to verify that each individual had all the required medical screenings." The files were reorganized according to each family's immigration number.

"It was one of the most profound and meaningful experiences I've had in the Public Health Service," Brophy said. "The camaraderie among the Corps was exceptional, and the medical care and personal caring made a huge difference in the outlook and attitudes of the refugees."

"What I was really impressed with was how people responded to the crisis," said Korvick, a medical officer. "It's good to see human nature working well, reaching out, helping others. I must say that this was a very intense, personal experience which brought together all of the lessons I learned in the CDER leadership fellows program. I saw leadership, I really felt what teamwork was all about, and I know why mission is critical."

After she was there for a few days, Korvick picked up a local newspaper and saw a picture of a New Jersey Army Reservist about to leave for Kosovo carrying his 3-year-old son on his shoulders.

"Well that did it for me," Korvick said, "I was touched. The world has so much pain, it is nice that we have the opportunity to blow a few bubbles and make a child smile."