news along the pike

Center for Drug Evaluation and Research

Volume 2, Issue 11

Inside . . .

The Curtain Is About To Go Up . . . On Medical Library's Physical Transformation

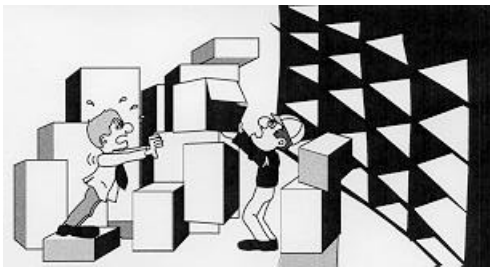
By Carol Assouad

A truly virtual library? It's not on our horizon, but a more up-to-date mix of physical and virtual is definitely just around the corner. You will soon begin to see a leaner, cleaner, more virtually oriented and customer-focused medical library and information center emerge from the construction dust in the main library. This renovation will reflect the major transformation that has occurred over the last 20 years in library science: a change from a passive, book-oriented, "inherently good" library to an exciting, proactive, resource-conscious information hub.

Except for minor surface changes, the Library has maintained the same early 1970's look and functionality in spite of the increasingly complex role we play in providing information services to CDER and the FDA. Our library staff functions and services have changed. More and more technology was introduced; more and more physical volumes came into the Library. We worked in areas that were scattered among stacks and not conducive to productivity. Users were inconvenienced by clutter, noise and lack of space. Safety and access became an increasing problem. This came to a crisis in the fall of 1995 when wooden stacks began collapsing because both sides and shelves were bowing. We temporarily shored these up and then began a year of making literally thousands of decisions.

On the Program: A Lean, Targeted Collection . . .

These decisions started with the drafting of an Information Resources Development (IRD) policy by IRD team leader, Karen Kapust. This policy takes a hard look at literally everything we have been amassing here and in a storage facility for 50 years and asks: "Does this further our mission of matching CDER and FDA information needs with our information resources?" The scope of the collection is



defined in this policy in terms of subject, format, years covered, services provided, archival need, uniqueness to our collection and the possibility of resource sharing with another regional library. Now we are examining and actually measuring individual titles to be discarded or sent to another library, to be moved to storage or to remain in the main collection. While modern-day libraries have never been the clean, quiet, leisurely paced environments popularly envisioned, some of the work we've been doing is triggering major allergies and some of the decisions we've had to make are truly causing heartache for quite a number of us. For example, bound volumes of *Index Medicus* from 1966 (the year the on-line version begins) through 1991 rolled out the door earlier this month after the medical librarians covered their eyes. We understood the need, but nevertheless . . .

Costuming and Makeup: Tears, Joy and One More Smudge . . .

The sadness though has been unexpectedly mixed with the excitement and delight of discovery. One of the things we've avoided doing for the last 15 years is cleaning out the Library's 600 square feet of storage in the Park Building or even touching the 150 linear feet of vertical files containing old materials here in the main library. We have discovered unreadable printouts on thermal paper, acid- and exhaust-rotted reprints (some of these materials were stored in the parking garage

(Continued on page 8)

Joe's Notebook

Sharing a Point of View

Art Shaw, from the Division of Gastro-Intestinal and Coagulation Drug Products, passed along a story that's making the rounds across the river at the Pentagon. It goes something like this:

What happens if you ask people in the military services to "secure a building"? Well, sailors will turn out the lights, lock the doors and go home. Soldiers will lock all the doors but one and make you show a photo ID and building pass and walk through a metal detector when you try to enter. People in the Air Force are likely to take out a three-year lease on the building with an option to buy. The Marines might assault the place, kick out the current occupants and prepare to defend the building against a counter attack.

We can all have a little chuckle at our friends in public safety, but when it comes to dealing with communications problems in large organizations, we might think that they have an advantage with only four services that have their own semi-autonomous status, history and traditions. Right here in CDER we have 65 semi-autonomous offices and divisions, many long histories and traditions of their own. Many serve constituencies in medicine that have roots as deep or deeper than a military or naval unit.

Each of us has our very own perspective on an organization. One way people in organizations learn to function smoothly as teams is to share each other's points of view and appreciate the other person's perspective on the collective work. In 1996, a remarkable group of CDER employees shared their own vision of the Center with you in a very personal way. Those are the writers whose work has appeared in the *Pike*. When you look through an entire year's worth of the *Pike*, an image of community in transformation emerges, and it emerges most powerfully in the words of each of the *Pike's* contributors.

So here's a holiday salute to all those who took the time to help you understand a bit more about CDER and to see the Center through another's eyes.

When you see them, thank them and wish them a heartfelt happy holidays from all the *Pike's* readers. Here they are:

Russ Abbott, Charles Anello, Sc.D., Marilyn Apfel, Ph.D., Carol Assouad, Paula Bourkland, Elaine Burch, Ruth Clements, Bronwyn Collier, Tom Conrad, Joseph F. Contrera, June Cory, Rose Cunningham, Susan Cusack, Robert DeLap, Thomas D. Doyle, Ph.D., Zan Fleming.

Lori A. Frederick, Katharine Freeman, Clare Gnecco, Ph.D., Stephen A. Goldman, M.D., Debbie Henderson, Rita Hoffman, Joanne Hough, David Isom, John Jenkins, David B. Katague, Ph.D., Lana Kostecka, Kathy Kruse, David Lester, Ph.D., Ron Lieberman, M.D., Ralph Lillie, Murray Lumpkin, M.D., Pam Mahoney, Raya McCree.

Edward Miracco, Nahid Mokhtari-Rejali, Ph.D., Melissa M. Moncavage, Jim Morrison, Dave Moss, Paul J. Motise, Norman Oliver, Sharon Olmstead, Barbara Palmisano, M.D., L. Miriam Pina, M.D., P. Scott Pine, Lisa G. Rider, M.D., Khyati Roberts, Kathie M. Robie-Suh, M.D., Ph.D., Nelson Rodriguez, Kevin L. Ropp, Nancy Sager, Rixie L. Scott.

Ted Sherwood, Diane M. Smith, Nancy Smith, Margaret Stavish, Lisa L. Stockbridge, Gloria Marquez Sundaresan, Ana Szarfman, M.D., Ph.D., Kathy Taylor, Marcia Trenter, Victor H. Vail, Jonathan Wilkin, Grant Williams, M.D., Roger Williams, M.D., Janet Woodcock, M.D., Jean A. Yager, Jeffrey Yorke.

news along the pike

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

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Ombudsman's Corner

A Holiday Story from CDER

By Jim Morrison

Lest you believe that the lot of an Ombudsman is an endless litany of complaints and woes, it is not. On occasion I am privileged to observe CDER at its best, and at this time of year it is especially appropriate that I share one such story with you. This story could be called "A Tale of Two Fathers."

In early November I was contacted by a man in the Midwest whose son was suffering from metastatic malignant melanoma, a particularly aggressive form of cancer. His son had been started on a chemotherapy mixture of three drugs two months earlier, but the hospital pharmacy was now unable to locate one of the drugs, dacarbazine. He had talked with the manufacturer but was told that a supplemental application was pending with FDA, and they couldn't promise delivery of the drug until the first quarter of 1997. His son needed to continue the chemotherapy soon, and he asked if there was anything I could do.

Once I determined from the company that supplies would be moving in a few days, I called the father of the boy with cancer. He expressed his and his family's gratitude for the support they received from CDER.

I checked with the Division of Oncology Drug Products, and **Leslie Vaccari,** a project manager, soon filled me in on the history of the supplement and the difficulties the firm had in finding a supplier. The division had worked long and hard in the face of diminishing supplies of the existing product to help the company find a new source of supply for the active ingredient. They had also received calls from patients and their families, and they had encouraged the firm to submit a supplement in a timely manner so that supplies of the newly manufactured product could be shipped quickly. In fact, Leslie told me, the supplement would be approved that very day. The night before the son of the reviewing chemist, **Steve Koepke,** had been in a serious car accident. Nonetheless, Steve came in after spending the night at the shock-trauma unit to make certain that the supplement would be approved.

Once I determined from the company that supplies would be moving in a few days, I called the father of the boy with cancer. He expressed his and his family's gratitude for the support they received from CDER. There are doubtless scores or hundreds of other families across the country who owe a similar debt to the folks in Oncology. Most of them will never know whom to thank.

So for them, I'll thank **Steve,** Steve's supervisor, **Eva Tolgyesi, Leslie** and all the dedicated people at the Division of Oncology Drug Products. I'm glad to report that Steve's son is doing well. Happy holidays to all.

Jim Morrison is the Center's Ombudsman.

Project Management Corner

Hazardous Duty Volunteers, Anyone?

By Susan Cusack

The FDA (well at least one CSO there) has determined that recording meeting minutes can be hazardous to your health. OK, maybe not, but sometimes it feels that way. I recently received an e-mail from an alert reader, stating that she was "swamped" by meetings and would really like to have a template to help organize minutes.

I was aware of at least one template. Attachment C of the Meeting MAPP (MAPP 4512.1) is an outline format that captures major discussion points, agreements, unresolved issues and action items. I didn't get an avalanche of e-mail (in fact, I didn't get any) offering other tools for minute taking. So I went to the top, the chief project manager herself, **Jean Yager.**

According to Jean, there is a template. "It is being placed on the network by DISD," she said. "It is basically the meetings minutes template used by Franklin Quest in their course (with some modifications)." It is being tested and some limitations have been identified. Jean wants to provide DISD with additional feedback from others in the Center who might like to view it and have input. "If we have several people who are interested," she said, "perhaps we can have DISD give a joint demo of the program and get everyone's feedback at once."

Is anyone interested? If so, please e-mail me at CUSACKS, and I will forward a list of guinea pigs . . . uh . . . er . . . volunteers to Jean.

One last note, the Franklin Quest course that Jean refers to was a pilot training session that was given on "Successful Meetings/Minutes Writing." The course has now been finalized and the Center hopes to offer it at the end of January. **Debbie Kallgren,** a consumer safety officer with the Division of Anti-viral Drug Products, will be working with Franklin Quest to orchestrate the next session. So if you, too, are feeling "swamped" by meetings, keep your eyes open for this course.

Susan Cusack is a consumer safety officer in the Division of Medical Imaging and Radiopharmaceutical Drug Products.

EEO Corner

Profile Prefigures Affirmative Employment Plan

By Gloria Marquez Sundaresan

During the Fall Planning Meeting, Margaret Bell, CDER's EEO manager, briefly presented some equal employment opportunity activities which included the Affirmative Employment Plan (AEP), CDER EEO Information Sharing and Training Satellites (CEISATS) and the EEO newsletter, the *Rainbow Connection.*

As part of the Affirmative Employment Plan, office and division directors were given a copy of their respective workforce profiles that show their representation of the different EEO groups of women, blacks, Hispanics, Asians and Native Americans. These profiles will serve as the baseline for the future profiles. Workforce profile reports are one of the major services that the EEO Staff provides to help office and division directors determine how well they have fared on equal opportunity and affirmative action issues. The EEO Staff will make appointments with each office director to discuss overall year-end workforce profiles. The next quarterly AEP report will be published shortly after the workforce data is updated in December.

Workforce profile reports are one of the major services that EEO Staff provides to help office and division directors . . .

The main goal of CEISATS is to conduct mini-EEO training sessions for as many employees as possible. Major obstacles to accomplishing this goal are the time and distance of the different FDA sites from the Parklawn Building where most training sessions are held. To overcome these two problems, CEISATS plans to conduct training at the different sites, if possible, during "brown bag sessions" at noon. This arrangement may help solve travel time for employees since the training will be conducted at their place of work. Another possibility is to use videoconferencing so that training in one site can be simultaneously shared by employees in other CDER satellites.

The original CEISATS group members continue to put their efforts together to improve this initiative. **Christina Chi** of ODE II has the honor of coining the word CEISATS. **Marta Locklear** of the Division of Information Systems Design has been the Hispanic EEO Representative for the past five years. **Guyann Toliver** of the Division of Neuropharmacological Drug Products is a new volunteer, serving as the representative of employees with disabilities. Guyann was also instrumental in the joint FDA/CDER observance of the Disability Awareness Month held on Oct. 30. So far, I have conducted the first CEISATS training on gender differences in the workplace with the help of the tape, "The Invisible Rules: Men, Women and Teams." This event was introduced during a training session on Diversity Day Celebration April 4. With the help of videoconferencing, more sessions on this particular topic will take place in the near future.

CEISATS will cover relevant topics and information from workshops that members of the EEO Staff and EEO representatives learn from attending training conferences. They will then share these experiences with other employees via CEISATS activities.

January will mark the debut of the quarterly EEO newsletter, the *Rainbow Connection (RC).* Topics in *RC* will include EEO issues, human interest stories, letters to the editor and articles on unsung heroes and heroines. A poem, "Open the Door" and a historical review of EEO activities in pictures will be included in the first issue. The EEO Staff wants to emphasize that the EEO newsletter is for everybody of all colors, hence the name, *Rainbow Connection.*

Gloria Marquez Sundaresan is a member of the Center's EEO Staff.

PHS Scholarship Fund-Raiser Set for Jan. 16 in Parklawn

By Diane M. Smith

In 1975, members of the Public Health Service agencies organized the Rev. Dr. Martin Luther King, Jr., Commemorative Committee to remember the civil rights leader's birth and his many contributions to this country. In addition, the Committee developed a scholarship fund for "marginal" students who are at risk and have had difficulty attaining their maximum academic potential. The scholarships are funded through donations received from our annual button drive.

This year we invite you to join us on Jan. 16, from noon to 2:30 p.m. in Conference Rooms D and E of the Parklawn Building, as we once again celebrate this event. The guest speaker will be the Rev. Charles T. Sembly, pastor of the Union Bethel A.M.E. Church of Randallstown, Md. The Duke Ellington School of the Arts Show Choir will provide a cultural presentation. The Center's EEO Manager, Margaret Bell, serves as co-chairperson of the Scholarship Committee, and I am the button chairperson. If you need more information regarding the program, scholarship or buttons, please contact us at 594-6645.

Diane M. Smith is a member of the Center's EEO Staff.

AMF Corner

Decision Support System Aims at Better Integration

By Kathy Taylor and Elaine Burch

For the past six months, the Division of Information Systems Design (DISD) has been developing a prototype for integrating frequently used databases from the Center Office Management Information System (COMIS) with the Decision Support System (DSS). As reported in the August *Pike*, the DSS is a Windows-based interface into the existing COMIS database. The DSS currently provides information that is available through the existing COMIS menu item, On-line Retrieval 18, but also includes enhanced search capabilities and a variety of new ways to view additional COMIS information.

The DSS integration effort resulted from user requests to link to other CDER databases without exiting the record they are viewing in DSS. These databases include major enterprise information resources, such as the Adverse Drug Reaction Information System, the Drug Product Reference File and resources under development such as the electronic Charge and History Card.

The DSS integration initiative envisions enabling users to do a query in the DSS, select the desired records they want to pass to other databases, then go directly to the other database application, for example, the Drug Product Reference File, while bringing the selected records with them. This eliminates the need to exit out of the DSS, select another application and then re-query the same data. Analysts and programmers have been hard at work compiling user requirements and developing the prototype. Many Center staff have been interviewed in the process. A prototype will soon be ready for piloting.

Current plans are to pilot the DSS integration capability along with the Charge and History Card project in the Division of Pulmonary Drug Products early next year. On-line help modules are also being designed to provide users with immediate access to documentation on the specific types of data stored in the various CDER applications. With validation from users, future plans can include incorporating the DSS integration capabilities into additional CDER graphical user interface applications as they become available.

Kathy Taylor and Elaine Burch are members of the DISD staff and authored this month's AMF Corner in cooperation with regular author David Isom.

Mentor's Corner

Insider Tips on Giving Feedback

By June Cory

CDER's mentors participated in a recent seminar led by **Jack Pevenstein** from the Division of Biometrics III. Participants discussed ways to give constructive feedback.

Some of the important issues about feedback covered in the seminar are also stressed in *The Team Handbook* by Peter Scholtes.

First it's important to know how to give feedback. Feedback should always be immediate and specific. Sholtes makes these useful points about the process of providing feedback:

- Use descriptive terms.
- Avoid using labels.
- Avoid exaggeration.
- Only speak for yourself.
- Try to phrase the issue as a statement, not as a question.
- Confine your feedback to matters you know for certain.
- Make sure people hear and accept your compliments when you have positive feedback to offer.

According to Scholte, you should avoid offering feedback when:

- You have spotty or incomplete knowledge about the circumstances of the behavior.
- The circumstances are clearly inappropriate, such as the presence of outsiders for negative feedback.

For more information on mentoring at CDER, or to borrow a copy of *The Team Handbook*, please e-mail me at CORYJ or telephone at 827-3489.

June Cory works in OTCOM's Division of Training and Development and coordinated the Mentoring Program for CDER.

Pediatric Corner

Center Gears Up for Labeling Supplements

By Kathy Robie-Suh, M.D., Ph.D.

As the Dec. 13 deadline for sponsors to comply with the 1994 pediatric labeling rule rapidly approached, increasing attention was focused on pediatric issues. In anticipation of an increase in the number of pediatric supplements we receive for review, now might be a good time for us in CDER to become familiar with the Center's Pediatric Subcommittee and its representatives from the review divisions. The subcommittee is well into its second year of work in spearheading the efforts of the Center to implement the Dec. 13, 1994, pediatric labeling rule.

In its first year of work, the Pediatric Subcommittee of the Medical Policy and Coordinating Committee (MPCC) has a number of accomplishments, including:

- Participation in industry and academic meetings and conferences to explain the requirements of the new rule and to discuss issues related to pediatric labeling.
- Writing of a guidance document for industry to describe information which should be included in pediatric supplements to approved NDAs.
- Working toward development of a tracking system for the Pediatric Page and Phase 4 pediatric commitments.
- Conducting training sessions on the new rule for CDER reviewers.

The Pediatric Subcommittee is composed of one representative from each of the reviewing divisions. Reorganization within the Center over the past year has led to the growth of the Pediatric Subcommittee from 10 division representatives (plus aiders and abettors) in mid-1995 to 14 division representatives (plus others). New members include **Drs. Jonca Bull, Steven Hirschfeld, Linda Hu, Denise Cook, Linda Golden, Roberta Kahn** and **Abraham Karkowsky.**

> In anticipation of an increase in the number of pediatric supplements we receive for review, now might be a good time for us in CDER to become familiar with the Center's Pediatric Subcommittee and its representatives from the review divisions.

The subcommittee enthusiastically welcomes these new members.

Kathy Robie-Suh, M.D., Ph.D. is a medical officer in the Division of Gastro-Intestinal and Coagulation Drug Products and a member of the Pediatric Subcommittee.

Pediatric Subcommittee Stands By To Help with Rule

The current membership of the Pediatric Subcommittee is:

- Division of Anesthetic, Critical Care and Addiction Drug Products (HFD-170), **Dr. Roberta Kahn.**
- Division of Anti-Infective Drug Products (HFD-520), **Dr. Rosemary Roberts** (chair).
- Division of Anti-Inflammatory, Analgesic and Opthalmologic Drug Products (HFD-550), **Dr. Jonca Bull.**
- Division of Anti-Viral Drug Products (HFD-530), **Dr. Sam Maldonado.**
- Division of Cardio-Renal Drug Products (HFD-110), **Dr. Abraham Karkowsky.**
- Division of Dermatologic and Dental Drug Products (HFD-540), **Dr. Denise Cook.**
- Division of Gastro-Intestinal and Coagulation Drug Products (HFD-180), **Dr. Kathy Robie-Suh.**
- Division of Medical Imaging and Radiopharmaceutical Drug Products (HFD-160, (vacant).
- Division of Metabolic and Endocrine Drug Products (HFD-510), **Dr. Gloria Troendle.**
- Division of Neuropharmacological Drug Products (HFD-120), **Dr. Cynthia McCormick.**
- Division of Oncology Drug Products (HFD-150), **Dr. Steven Hirschfeld.**
- Division of Over-the-Counter Drug Products (HFD-560), **Dr. Linda Hu.**
- Division of Pulmonary Drug Products (HFD-570), **Dr. Liza Pina.**
- Division of Reproductive and Urologic Drug Products (HFD-580), **Dr. Linda Golden.**

Dr. Victor Raczkowski (HFD-160) is the subcommittee's representative to the Pediatric Pharmacology Research Units (PPRU). **Dr. Elaine Esber** is the liaison between the subcommittee and CBER. **Dr. Paula Botstein,** Director, ODE III, serves as facilitator. **Ms. Sharon Olmstead** is the project manager, **Ms. Terry Martin** is the executive secretary for the group and **Ms. Tricia DeSantis** is an advisor from the Office of the Center Director.

These representatives are able to assist you in addressing issues related to the pediatric rule or direct you to someone who can help. Don't hesitate to let your representative know of any pediatric problems.

—Kathy Robie-Suh, M.D., Ph.D.

Pharm.D. Student Gets Inside Look at OTC Review

Demonstrating the processes that take place in the review and regulation of over-the-counter drugs to professional students has always been an auxiliary function of the Division of OTC Drug Products. Participants in the Commissioned Officer Student Training and Extern Program (COSTEPs) and clerkship students have continually proven themselves to be of enormous value to the division by introducing novel approaches to OTC drug issues. ***Pam Mahoney,*** *a doctoral degree candidate at the University of Kansas School of Pharmacy, performed her clerkship with the division during October and, before returning to the University, submitted the following reflections on her accomplishments.*

—Capt. Melvin Lessing

By Pam Mahoney

In the course of completing the clinical clerkship requirements for the Pharm. D. program at the University of Kansas, I had the privilege of spending a month in the FDA's Division of Over-the-Counter Drug Products and the opportunity to witness first-hand the work of the FDA and be involved in several small steps in the much larger process of OTC drug evaluation and review.

My initial task was to learn more about the process of OTC drug product review. Reading material furnished by **Capt. Melvin Lessing** provided an overview of the legislation that led to the creation of the OTC drug review and the steps involved in the review process.

Next, I worked on a feedback project. Feedback letters and minutes of meetings with industry, associations and the public concerned with OTC drug products were indexed according to date, recipient of the correspondence and drug ingredient, with a brief description of the contents of the letter or meeting.

This project gave me insight into several facets of the review process. Submission of data from appropriately designed studies helps to establish the safety and effectiveness of OTC drug product ingredients. The FDA examines these studies very thoroughly and provides assistance in study design and statistical analysis if requested by industry. Comments from industry, associations and the public regarding drug ingredients and contents of the monographs provide further data to support approval. As the feedback material covered several years, I was able to follow some of the issues through to completion. This overview of the process of monograph preparation and FDA requirements concerning appropriate data collection and analysis was very enlightening.

Following completion of the feedback project, I was assigned to conduct literature searches for information about OTC vaginal antifungal agents and spermicides. This project required the application of skills I developed in drug information class and in clinical rotation. Other pieces of the regulatory process fell into place as I searched for information on toxicology studies, pharmacokinetic properties, labeling comprehension studies, adverse drug reactions and safety data. All are essential elements of monograph preparation. Unfortunately, I also learned that the data are often lacking, especially for OTC drug products.

With that problem in mind, I was also able to participate in the development of a proposal for studying OTC vaginal antifungal products submitted to the Office of Women's Health. If approved, this study will provide data on the impact of the prescription-to-OTC switch of vaginal antifungal agents. From these data, the division hopes to ascertain the appropriateness of the labeling and educational efforts about these products and to make recommendations for changes if needed.

A major difference between traditional pharmacy practice in retail or hospital settings and the FDA is the time frame for task completion. The nature of the work that OTC drug personnel are doing is long term. It takes months, and often years, to complete the review process. I believe that the care taken by the FDA to protect consumers from unsafe products and those that are not effective is appropriate, even though the public and industry often express frustration with the time taken for review. It is better to establish that drugs are safe and effective prior to marketing rather than after release to the general public, when the potential for harm is much greater.

The switching of drugs from prescription to OTC is also facilitated by the FDA. I was able to attend an advisory committee meeting for the proposed switch of cromolyn sodium to OTC status for the treatment of allergic rhinitis. Presentations by Fisons Pharmaceuticals, the maker of the drug, and FDA representatives included data to support the safety and effectiveness of cromolyn sodium. The committee members addressed areas of concern about appropriate dosing and labeling, which were received favorably by the company. The process involved an exchange of ideas and concerns, with a common goal of providing the public with a new OTC drug to treat allergic rhinitis.

Another unique opportunity provided during my clerkship involved a tour of the state-of-the-art pharmacy at National Naval Medical Center in Bethesda, as well as the hospital itself. With a daily volume of around 3,000 prescriptions, the pharmacy must operate very efficiently. The innovations the pharmacy has implemented help both the pharmacy personnel and its military beneficiaries.

I was also fortunate to be able to attend "Overview of OTC Drugs and OTC Drug Review Procedures," a presentation by Gerald Rachanow, a regulatory affairs lawyer with the division. I was surprised to learn that a cereal that claims to have laxative effects is regulated as an OTC drug and has a warning on its label just like other OTC drugs.

I feel very fortunate to have been given the opportunity to be a very small part of the FDA regulatory process.

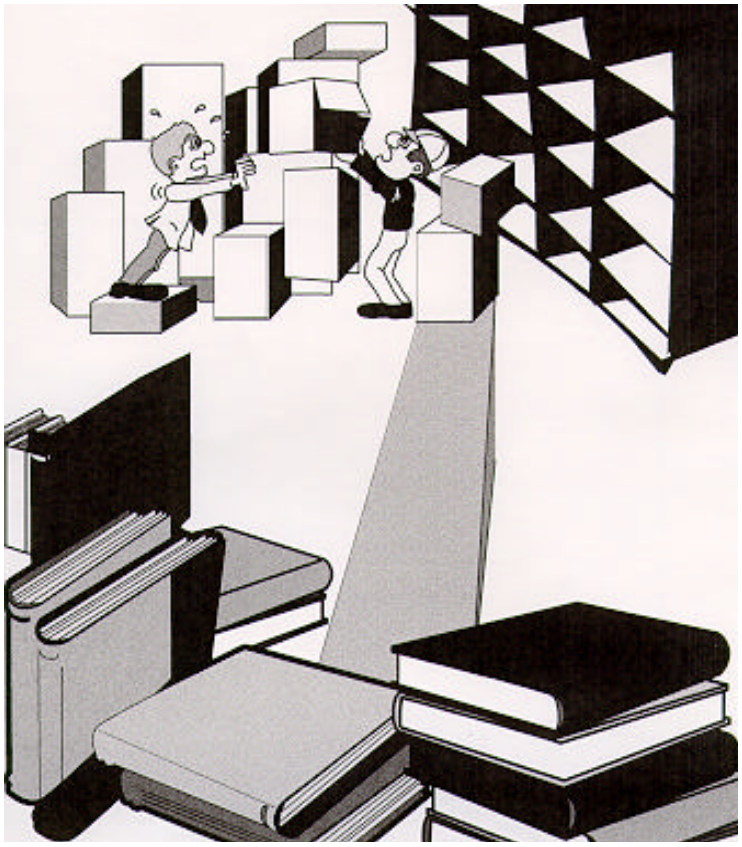
Pam Mahoney is a Pharm.D. candidate at the University of Kansas School of Pharmacy, and Melvin Lessing was her mentor for her clerkship with the Divison of OTC Drug Products.

Show Begins on Library's Transformation

(Continued from page 1)

until a flood forced their removal), dirt and what we think are assorted deceased vermin. There are indeed these, but there's so much more: material related to disapproved (we hope) drug applications accompanied by death certificates, an article on cabbage juice therapy and beautiful old anatomy cards. Everyday something new turns up. We haven't seen so much of the FDA historians in ages. That is good, since we can get a head start cataloging this historical material for the jointly managed FDA archives we envision for the consolidated facility.

The Directors Scoped Out the Stage Play . . .



While collection considerations were being made, we observed one of those interesting sociological phenomena that occur every now and then--a self-selecting, spontaneously forming team, this time of space designers. Librarian **David Graham,** who is both corporate library branch manager and collection management team leader, has likely found his true calling in library architecture. He and librarian/pharmacist **Carol Knoth,** reference and outreach services team leader, joined forces with technical information specialist **Enid Quincoses** to begin planning the physical renovation. Along the way, they enlisted the help of CDER facilities manager **Ruth Clements** and colleague, **Jim Cockran**, as well as **Bill Gazdik,** a project manager for CDER facilities; numerous vendors (notably **Stacey Narrow,** who merged all their ideas and turned them into the actual construction blueprints); FDA, PHS and Parklawn facilities staff and contractors; DISD computer guru, **Fred Goetze;** OTCOM's program specialists, **Katie O'Donnell** and **Bobbi Jones; Anne Beckmeyer** and **Mary Hawthorne** for telecommunications expertise; along with carpenters, electricians and movers; each and every library staff person; and curious bystanders. All in all, they put together quite a formidable, results-oriented tactical force.

And, By the Way, Had To Work Around a Few Production Constraints . . .

They were given just a few basic requirements: they couldn't have any more space; staff space needed to be entirely functional and sufficient for current government and contract staff; it needed to be separated from the collection and user areas; users needed to be provided with study space, an AV/computer training room, a reading area and a specified number of computers and microfilm reader/printers; stack areas (including approximately 14,000 square feet of replacement storage space at Wilkins Avenue) needed to be accessible, accommodate the current collection and allow sufficient space for growth for a few years. Oh, and also everything they selected needed to be reusable in a consolidated facility. They needed to get staff consensus on colors and materials, stay within budget and allow us to continue providing basic services during the actual renovations. Beyond that, they had authority, within reason, to do whatever they wanted.

But They Pulled It Together . . .

They planned and consulted, revised and planned some more. Designs were approved; funding, materials, furniture, and shelving were obtained; and construction money was obligated by late September. Weeding and collection cleanup started in late November. The new storage space was completed with new compact shelving installed Dec. 6. Actual renovations are scheduled to begin about Jan. 6 and are being done in six stages totaling about 10 weeks so that we can remain at least partly open and concentrate on doing final preparatory work one stage at a time. Whew!

And, Now, After a Few Program Notes, the Curtains Are Rising . . .

We hope you will bear with the mess and noise during construction and murmur something encouraging when you encounter us with a few tears in our eyes. We will certainly try very hard to maintain all services during this period, and we will provide periodic progress reports via e-mail and *News Along the Pike*. We're looking forward to showing off our new look at an open house during National Library Week in mid-April, and we hope you'll like our new home as much as we envision we will.

Carol Assouad is acting director of the Medical Library.

Please Follow Me on a Walk Through the Script . . .

Stage 1 (Jan. 20-Feb. 10) goes across the east end of the B Wing. Compact shelving will take up about two-thirds of this space and contain the FDA, legal/regulatory and historical pharmaceutical collections. This area will be book-ended at one end by a users' study area and microfilm storage units and book-ended at the other by my office and a secretary's office.

Stage 2 (Jan. 27-Feb. 15) will house a one- or two-user AV/computer training room with an entrance from the public area and a separate entrance to the staff area for the information resources development and collection management teams, the systems librarian, the cataloging staff, the mail room and the LERN equipment room.

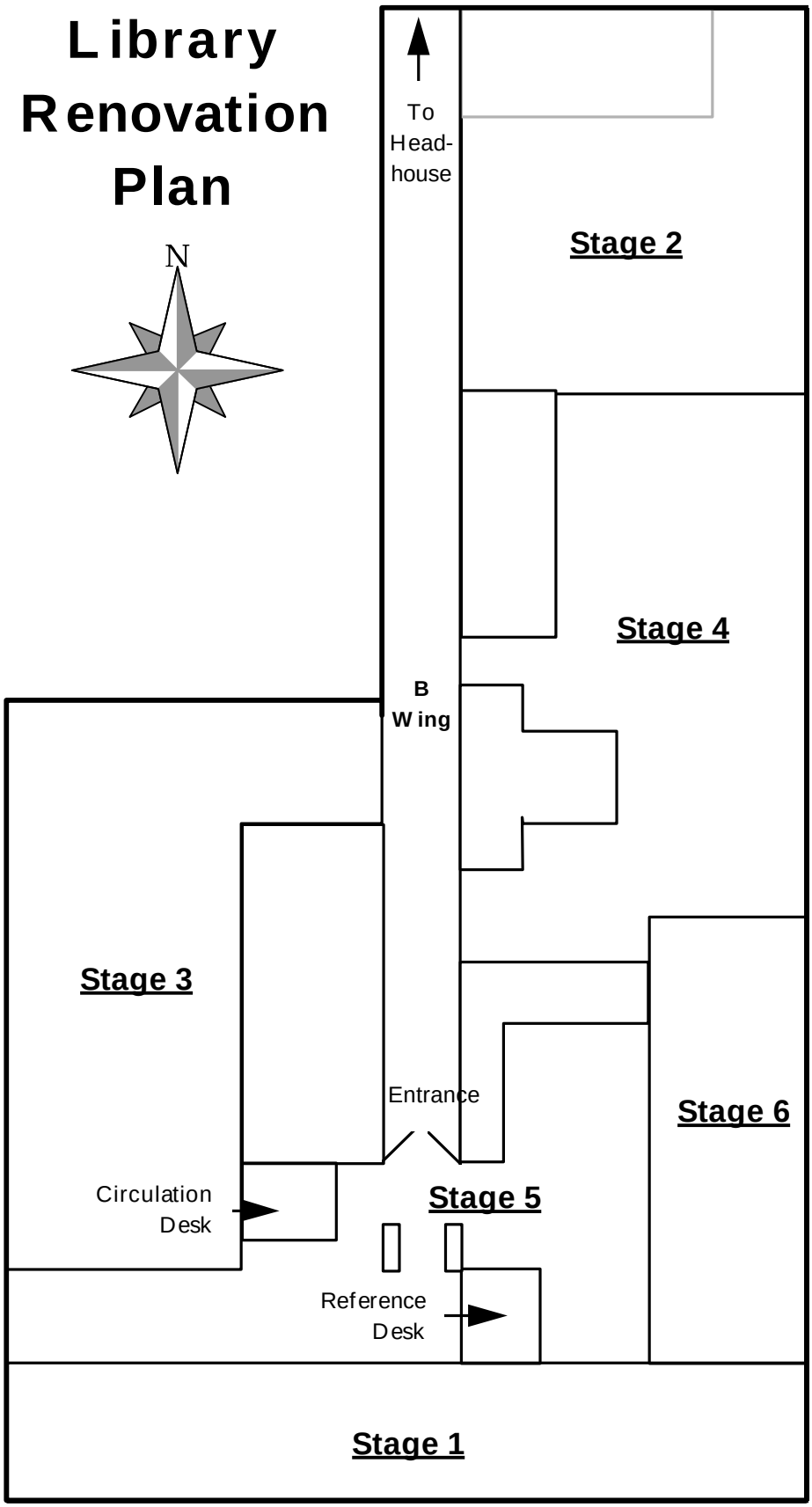
Stage 3 (Feb. 7-Mar. 1) is a second staff area containing the reference, user education, document delivery and web resources teams, along with an office for the deputy director, a staff photocopy room and a multipurpose staff area.

Stage 4 (Feb. 24-Mar. 15) is a stack area for journals A through approximately M.

Stage 5 (Mar. 10-21) will contain the reference and circulation desks, the main book collection, the reference collection and the user computers and microfilm reader/printers. The main doors will be relocated to face the corridor rather than the elevators (*deja vu* for those who were around before the freight elevator was installed). In case you were wondering why all the FDA commissioners' pictures disappeared, we've had them matted, framed and included a bronze name and tour-date plate. We expect to hang them in this area.

Stage 6 (Mar. 17-25) is the grand finale. It will contain the remainder of the journals, N-Z, an AV/conference room, a user reading area with newspapers, newsletters, current issues of major journals, the management and computer collections and two display cabinets which we've prevailed upon our friendly FDA historians to supply with periodically changing exhibits.

—Carol Assouad



—Artwork and floorplan by Belle Burkhart

World AIDS Day Observed with Parklawn Events

By Victor Vail

World AIDS Day was recognized at Parklawn Dec. 3 with two intra-Agency World AIDS Day activities: "World AIDS Day Observance" and "Ceremony of Remembrance: A Tribute to Those Who Have Died of AIDS." For the second year in a row, I participated by performing two songs I composed for this very special day. The subject of AIDS is emotional. To be before an audience, singing with this emotion, is difficult—very difficult—and, yet, as anyone who has lost someone to AIDS knows, when asked to participate in these gatherings, there is no choice. Forget that it's emotional, and you run the risk of breaking down in front of a few hundred people—it is your duty to take part. And so I sang.

We've all heard statistics on AIDS. The last I read, there are "40,000 individuals important to the lives of other folks who are not with us this year because of AIDS . . . AIDS is now the leading cause of death among Americans between the ages of 25 and 44 . . . An estimated 650,000 to 900,000 Americans are believed to be living with HIV . . . Since the AIDS epidemic began in 1981, more than 500,000 Americans have been diagnosed with AIDS and more than 300,000 men, women and children have lost their lives to this disease . . . "

In that 300,000 who have gone are **Michael, Gary, Art, Tony, Clark, Julio** . . .and **Dale.** All friends of mine—good people who were good friends, I think of them daily, not because I necessarily want to, but because these people are a part of me. They live in my brain, my heart, my soul. (I can't take a sip of coffee without hearing Dale laugh.) To have these people no longer with me, knowing they were all taken 30 years too soon, is a constant aching in my heart that I've learned to live with.

And so I sang for them:

"I see you in a photograph, smiling in the light
Gazing at the world around, taking in each sight.
Just a photograph—some proof that you were here . . .
Some need photographs to keep the mem'ry clear—
But I Remember You I Remember You . . ."

I also sang for those still with us, battling the virus on a daily basis. Three of my above-mentioned friends never told me they were sick, I learned only when told of their deaths. I can't help but wonder if they didn't tell me because they thought I couldn't handle the news, or were they afraid I would "shut them out"? I realize I'll never know this, but the questioning has raised my awareness of the fear some are forced to deal with in addition to the virus itself, and the need we all have for a "ready ear," someone to simply listen.

I'm proud to have taken part in the Parklawn intra-Agency World AIDS Day activities, and I thank the 1996 World AIDS Day Committee, in particular, **Kathy O'Neill** (HRSA) and **Richard Klein** (FDA), for the opportunity. I'm also proud to be a part of CDER, proud to be secretary to David Feigal, Director, ODE IV, where AIDS drugs are being reviewed and approved. I realized quite a while back that I'm not a medical officer who can review investigational new drugs, and I'm not a millionaire able to donate the big bucks to AIDS research. I am, however, a secretary who does a "mean" travel order. And if my travel orders help the cause, then in my own way, I'm contributing—I am an important part of the machine.

We do what we can.

Victor Vail is currently on detail to the Office of the Center Director.

People Along the Pike: CDER Scientists Take Share of Awards

Center scientists were honored earlier this month when the FDA announced its 1996 Center and Office of Regulatory Affairs (ORA) scientific achievement awards. CDER honorees are:

For excellence in laboratory science: **Adorjan Aszalos,** "For excellence in laboratory research exploring biophysical approaches to address and solve problems associated with the toxicities of multidrug resistance inhibitors in cancer chemotherapy."

For excellence in review science: **Ene I. Ette,** "For the performance of outstanding research leading to the development of scientific guidelines for the design and analysis of population pharmacokinetic/pharmacodynamic studies."

For excellence in science by a group: Drug Metabolism/Drug Interactions Review Group; **Peter K. Honig, John D. Balian, Atiqur Rahman,** and **Jerry M. Collins,** "For excellence in translation of state-of-the-art scientific principles into regulatory policy and high-quality reviews."

Whoops, Tripping Over the Ivy . . .

David B. Katague, Ph.D., notes that in his appreciation of his colleague **Dr. Vithal B Shetty** an an error in his academic background appeared.

Vithal obtained his B.S., M.S., and Ph.D. degrees in Medicinal Chemistry from the University of Pennsylvania, Philadelphia, PA. In addition he has a B.S. and M.S. degrees in Pharmacy from the Philadelphia College of Pharmacy and Science and is a pharmacologist by training.

"By the way," David writes, "I am no longer a primary reviewer. Two weeks ago, I was appointed Acting Chemistry Team Leader for ONDC III, collocated at HFD-520."

Congratulations and happy holidays, one and all

—Joe Oliver