news along the pike

Center for Drug Evaluation and Research

August 1998

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Inside . . .

Pike's Corners . . .

Center Holds Meeting to Help Set Priorities

Stakeholders Raise Communications, Drug Safety Issues

By Norman Oliver

Consumer safety, improved communications, direct-to-consumer advertising and limited FDA resources for obligations other than pre-market review emerged as major concerns for CDER's stakeholders during a meeting held Aug. 17 in Washington. Representatives from six patient and consumer groups, four professional societies and one trade association made formal presentations at the day-long event held to obtain public input into the Center's and FDA's priority setting for the coming year.

Input from the meetings, required under the Modernization Act, will contribute to an Agency priority plan that must be published in November.

Consumer and patient groups expressed fears that the resources dedicated to meeting deadlines for drug approvals were causing the Center and the FDA to sacrifice its traditional focus on consumer safety issues. Several said they regarded the Modernization Act as a rollback of FDA's standards and recommended the Agency receive adequate funding to preclude difficult choices over priorities.

Minimizing deaths and injuries needed to be built back into the priority plan they said. They expressed misgivings about how a fair balance of risk and benefit can be achieved in direct-to-consumer advertising. On the other hand, a group representing patients with the fatal neurodegerative disease amyotrophic

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Coordinating Committees Forge New Policy

By Jason Walther

To someone looking at an organizational chart of CDER, its management structure might appear hierarchical. In reality, though, the Center uses a matrix structure in which project managers coordinate reviewers from different divisions in the offices of Review Management and Pharmaceutical Science.

Likewise, many issues that come before CDER need input from several divisions or disciplines. Communication on these crosscutting issues is essential. This, along with requirements for international harmonization, spurred the formation of coordinating committees in the early 1990s.

The purpose of coordinating committees is to facilitate coordination among different offices, divisions and disciplines and develop uniform policies on specific issues. These are reflected in guidances and rules. The coordinating committees work with stakeholders on both current and up-and-coming drug issues—anything from new manufacturing processes to improving the application process. In 1997, coordinating committees helped the Center and FDA develop five proposed rules, 11 final rules and 40 guidances. Coordinating committees also help resolve conflicts and provide a development opportunity for junior staff members.

Coordinating committees work on many topics. The Chemistry Manufacturing Control CC, for example, has been working on post-approval changes for bulk active chemicals, which would allow drug manufacturers to make certain changes to their manufacturing processes without prior approval from the Center in order to reduce their manufacturing costs and the Center's workload.

As part of the Medical Policy CC, the Pediatric Subcommittee has helped develop the recently issued guidance on the six-month pediatric exclusivity provisions of the 1997 FDA Modernization Act. The Act grants companies six months of additional marketing exclusivity in exchange for performing pediatric studies.

The newly formed Complex Drug Substance CC is currently focusing on the major issue of

(Continued on page 8)

Guest Viewpoint

An Eye-Opening Summer

By Jason Walther

For all of the organizational charts and overheads that whizzed by me during my first day, I went home with two all-important facts: one, my first paycheck would come in three weeks, and two, there was *no* way I was going to tell my friends I was something as menial sounding as an Office Automation Clerk (now . . . "Executive Paradigm Manager" is another story).

I will leave knowing much more about CDER and what the Center does. A few things struck me as odd at first, though, like the term "stakeholders." I went to the Medical Library one day on my lunch break to conduct some research on the origin of the term. After the table of contents of the most recent issue of *FDA Consumer* revealed nothing, I gave up, resigned that my thirst for knowledge would forever be unquenched.

Luckily, when I told one of my co-workers about my failed quest, he knew the origin of the word. It turns out that "stakeholders" came from a time when the FDA was disliked and mobs of pharmaceutical executives would gather in the night, brandishing torches and yelling: "Kill the vampire!" He also said that's why everyone here wakes up before sunrise and why he called the garlic cookies I baked a few days ago "rancid balls of death."

As I said, I will leave knowing much more about CDER and what the Center does. For one, I now know that CDER exists. Previously, the FDA was a single unit in my mind. I knew that the FDA was an administration, which administered—and here things are a bit sketchy—food and/or drugs. My lack of knowledge would be understandable, except that I later found out that my mom works for CDER—and has been doing so for the past two years! (Yes, I am a bad son. But don't be so smug, parents. Your children think you work for the Federal Department of Agriculture. I know. We hang out together.)

Although the average American may know a little more than I used to know, you can't count on the news media to give them an accurate view of the inner workings of the FDA. My most recent FDA experience before starting here was the newspaper headline, "FEN-PHEN IS BAD-BAD."

If there is one problem I see, it is that the Center does not have a clear picture of what the public knows about the FDA and the drug approval process (or more importantly, doesn't know).

Now that I have a decent idea of how the drug approval process works, editorials arguing that the FDA has compromised public safety with the recent rash of drug withdrawals seem misinformed, even illogical in some of their assumptions. But if I had read those same editorials before I started working here, I probably would have agreed with them.

I think the Center and the FDA have to somehow educate the public on the basics of the drug approval process. The FDA needs to get the message out that although intuitively it seems so, there is little connection between how long the drug review takes and the drug's post-market safety experience. The Center has to refute this "common sense" notion and others, or risk facing a backlash.

Or we could sit back and wait for the villagers to come to us.

Jason Walther is a summer intern in the Office of Training and Communications.

Corrections: Thanks to last month's readers who detected two bad links in the July *Pike.* The links have been fixed, but here they are again:

- PDUFA 2 plan: http://www.fda.gov/oc/pdufa2/5yrplan.html.
- Cathie Schumaker's photos: http://www.fda.gov/cder/pike/july98sup.pdf.

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

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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

Feedback: A Valuable Commodity

By Jim Morrison

One of the best ways to improve any process is to get feedback. Sometimes feedback comes from an expert who watches a process and makes suggestions, such as a golf pro watching a student's swing. Other times feedback comes from customers who suggest ways to improve products and services. At CDER we get both kinds of feedback.

We get feedback from the press, from Congress, from consumer groups, from industry groups and, it sometimes seems, from anyone who has ever taken medicines or eaten food. A series of meetings (page 1) between FDA, the centers and our stakeholders is providing more feedback on important issues.

Feedback is effective when it is honest and accurate. On the other hand, it does little good to hear that we are doing a lousy job or a great job unless we know that the feedback is from a source who is able to evaluate our work fairly, accurately and without bias. The problem with much of the feedback we receive is that it can be distorted by false assumptions about what we do or false expectations about what we can do.

That is why I was impressed with a survey published last fall by Price Waterhouse, *Improving America's Health II: A Survey of the Working Relationship Between the Life Sciences Industry and the FDA.* This survey, a sequel to one published in 1995, was conducted by a group at the University of California at San Diego called Connect. While the survey was partially funded by a number of pharmaceutical and biotech companies and has some flaws, it is an honest attempt at identifying and tracking the key factors in FDA's product review processes.

The survey identified three areas in which the FDA review processes could be improved without jeopardizing patient safety: process guidelines, communications with applicants and submission quality. Questions in the survey dealt primarily with communications. Only 116 firms, including drug, device and biotech companies, responded. Thus, the answers to individual questions were often based on a small number of respondents and are useful mainly as qualitative indicators. Since this is the only such survey of which I am aware, qualitative data are better than none. Although comparisons are made in the report with the previous survey, the first one only queried West Coast firms while the second one included firms nationwide.

Most of the responses were generally favorable and could be predicted:

- Firms that had end-of-Phase II conferences generally found them helpful.
- Project managers and reviewers were seen as cooperative and knowledgeable.
- Accessibility to project managers was good, but a minority of respondents found it difficult to talk directly with reviewers.
- Overall communications with CDER were rated acceptable to excellent by all but a very few.

> "The survey identified three areas in which the FDA review processes could be improved without jeopardizing patient safety . . . "

However, responses to one of the questions is cause for some concern. Although the vast majority of respondents did not experience changes in policy during the review process, those who did were asked why they thought the change occurred. The most common single reason cited was a change in CDER personnel. I think we are doing better in this respect, but this survey serves to remind us that we have a legal mandate to honor advice and decisions made by our predecessors in the review process. Hopefully, if another survey is conducted next year, it would find that changes in reviewers no longer result in changes in policy.

I have asked Connect to send me copies of both surveys. As soon as I get them I will make them available to the CDER libraries. They are worth a read, and I hope these surveys are the forerunners of larger, more detailed ones in the future.

Jim Morrison is the Center's Ombudsman.

CDER Seminars, Scientific Rounds Start New Season Sept. 9

Center Director **Janet Woodcock, M.D.,** will kick off the 1998-'99 season of CDER Seminars and Scientific Rounds with a special session on the "The Future of Drug Regulation" to be held Sept. 9 from 3 p.m. to 4:30 p.m. at the University of Maryland Shady Grove Campus, following a reception at 2 p.m.

In a change from previous years, CDER Seminars will only be held on the first, third and fifth Wednesday afternoons of each month from 1:30 p.m. to 2:30 p.m. Scientific Rounds will occur on the second and fourth Wednesdays, 1:30 p.m to 3 p.m.

Starting Sept. 16, CDER Seminars will take place in Parklawn conference rooms and be videoconferenced to Woodmont II and Corporate Boulevard. Whenever possible, the CDER Seminar will continue to be presented at Corporate Boulevard at 10 a.m. on its Wednesday mornings.

Murray Lumpkin, M.D., will start Scientific Rounds Sept. 23 with a talk on thalidomide. The remaining 1998 Rounds will focus on Modernization Act issues, such as new programs, policies and guidances. Beginning in January, all offices and disciplines involved in the review and research programs at CDER will sponsor a Scientific Rounds topic of their choice.

The Committee for Advanced Scientific Education sponsors the CDER Seminar and Scientific Rounds series and always welcomes suggestions for topics. Chair for the 1998-'99 academic year is **Ken Kobayashi, M.D.,** a medical officer in the Division of Oncology Drug Products (KOBAYASHIK, 4-5715).

Karen Zawalick of the Division of Training and Development coordinates the series (ZAWALICKK, 7-1449).

Administrative Management Corner

AMT Sets Administrative Performance Goal

By John Emelio

Have you ever wondered why the administrative folks in CDER don't have a performance goal for which they are accountable? Well now they do. The Administrative Management Team, comprised of all the management officers and program specialists in the Center, has established the Agency's first administrative performance goal. The goal has been included as part of the CDER FY 2000 Performance Plan.

This effort began when **Charlene Cherry,** the Associate Director for Strategic Planning in the Office of Management, spoke at an Administrative Management Coordinating Committee (AMCC) meeting this past March. While discussing the Government Performance and Results Act (June 1997 *Pike)*, Charlene issued a challenge to the AMCC to develop a performance goal for the fiscal year FY 2000 Performance Plan (http://cdernet/om/goals.pdf). The AMCC embraced the challenge, and quickly set up a working group tasked with drafting a performance goal to present to the AMT. The aim of the goal was to foster advancement in the areas of administrative excellence and customer service among AMT members. The performance goal that was developed by the working group was:

"To improve CDER administrative management resulting in increased customer satisfaction within the CDER community. This will result in a 90 percent customer satisfaction level or a 20 percent increase over the current level, 80 percent of the AMT will meet the core competencies identified for administrative personnel, and at least 90 percent of the CDER community will be educated on the overall administrative management program."

To achieve the goal, the AMCC established five results teams, each with the task of accomplishing various components of the goal. The five teams and their leaders are the survey development team **(Bill Oswald),** the Staff Development Team **(Bobbi Jones),** the Process Improvement Team **(Rich Vengazo** and **John Emelio),** the Communication Team **(Tanya Abbott** and **Anna Rubino)** and the Assessment Team **(Ruth Clements** and **Anita Harrell).**

At the quarterly AMT meeting in June, **Bill Oswald** discussed with AMT members the development of the goal. This was followed by a panel discussion in which each results team leader described his or her team's purpose and recruited interested AMT members to join the team. By the end of the meeting, 55 AMT members had signed up to participate on the various results teams.

The first major task for the AMT is to develop a customer survey. The survey will be sent to all CDER employees sometime in the fall. The survey results will help to determine how satisfied the CDER community is with current administrative services. The survey results will also identify key areas for improvement. When you receive your survey, please take a moment to fill it out. Your participation will provide valuable insight concerning the specific administrative areas the AMT should focus on improving in the months and years to come.

John Emelio is chief of the Management Analysis Branch in the Office of Management and serves as executive secretary for the AMCC.

EEO Corner

Lessons in High School/High Tech Summer Program Go Both Ways

By Gloria Marquez Sundaresan

As part of the Center's outreach activities, CDER joined the High School/High Tech program this summer. The HS/HT program places students with disabilities in their third year of high school in volunteer positions with private and federal agencies. Students get an opportunity to learn computer skills, develop good working habits and learn other skills that will help them in future jobs. The program is sponsored by the United Cerebral Palsy Association.

Since this is the first time EEO has participated in the HS/HT program, few CDER employees knew of the program or were able to modify their schedules to mentor a student on such short notice. Three students were placed, though, in part due to the cooperation and support from executive secretaries **Tanya Abbott** and **Karen Weller.**

- **Erica Campbell,** from Blair High School, was placed in the credit union at Parklawn with the help of **Banks Johnson**, Office of Management, and credit union officials **Tyrone Carthwright** and **Sherry Neff**.
- **Brandi Pettaway,** from Kennedy High School, worked with CDER employees in several offices, such as **Tammy Mueller** Office of Research and Training, **Laurie Watson** Office of New Drug Chemistry and **Angela Davis,** Office of Epidemiology and Biostatistics.
- **Angela Skalkeas**, who also attends Kennedy, worked with us in the EEO Office.

Angela, who uses a battery-powered wheelchair, provided us with a better understanding of the accommodation needs for people with disabilities. In addition, Angela has some difficulty with her speech due to cerebral palsy. With patience, she was able to communicate with all of us in the office as we adjusted to her way of speaking.

Angela has had a productive summer at the EEO office. Her work assignments showcased her word processing, spreadsheet, computer presentation and Internet skills, and she made graphs and slides as well as worked on a newsletter. One of her projects was to create charts for race profiles for different pay grades.

Angela made her stay a successful one. She captured everybody with her quick smile, pleasant personality and great sense of humor. To find out more about the HS/HT program, contact UCP's Charles McNelly, Ph.D., at 301-262-4993.

Gloria Marquez Sundaresan is an EEO Specialist.

Web InSights

User-Friendly Web Pages Take Planning, Inspiration

By Carol Assouad

What goes into the planning, development, testing and evaluation of a Web page? If I make a recommendation for improving a test page, are my comments considered? Is this a long-drawn out affair? What are the resources available to me in this process?

With some experience behind us now, I'll try to answer in this month's column the first of these questions. We're increasingly asked about developing new pages for the CDER Internet site or CDERnet.

While putting together a page may seem merely a matter of some technical wizardry and a few good graphics, page design is actually a bit more complex. Along with technical expertise and quite a bit of creativity, each page needs to incorporate the sound principles of information management, publication design and information dissemination.

In addition, the page content and presentation should align with your mission and vision, as well as CDER's and the Agency's. Most of all, it needs to appeal to the intended audiences and be presented in a way that enables them to access and understand the information. The appearance, content and ease-of-use work together to send a message to users beyond the basic information content.

In essence, the jargon terms information management, publication design and information dissemination can be distilled to:

- Design a product based on user information needs, cognitive processing skills and ease-of-use.
- Design it so that the content fits into our Internet and CDERnet's overall organizational structure and, over time, builds into knowledge bases.

The Library's Web Resources Team provides just this sort of expertise to help you—the content provider or the individual page editor—develop pages that fulfill these criteria.

We like to start the planning process with a joint meeting of Web Team members and program staff. This meeting examines potential audience, content scope, expected size, update frequency, ongoing responsibility for maintenance. It also explores different types of access to the page including tables of content, keywords, date and multiple points of access.

From this initial meeting, we generally obtain enough information for the program staff to do their internal planning for structuring and developing the content, including accounting for any changes in work processes or flow.

For example, in developing the consumer drug information page (http://www.fda.gov/cder/consumerinfo/default.htm), the Division of Communications Management worked on structuring the drug information sheets so they would be easy to read and use, developed a style guide and page format to insure consistency across the sheets and set up a new review process for approving each information sheet that included the primary medical officer and Division of Drug Marketing and Advertising and Communications.

Simultaneously, the Web Team planned the structure and functionality of the page. Many questions had to be answered:

- How would users want to access information: by approval date, product name, drug class, indication, a combination of these?
- What format would provide this access and accommodate expected growth: a table of contents, frames (multipaned windows), multiple indexes, search capability confined to that page, an underlying database? How would updates be handled for labeling supplements (also a DCM decision)?
- What directional or navigational buttons would be needed: back to the CDER Homepage, back to a specific higher organizational level, to a comments page, to the What's New Page?
- What hyperlinks or bookmarks would be useful: to a glossary of terms or indications, to the full drug label, to other drug information?
- Would we need to develop content for the site or does other useful information already exist on the FDA site or elsewhere?
- What keywords should we develop for indexing this page?
- Is the information "chunked" in comprehensible, fast-to-access segments?
- What graphics would enhance use of this page?

> "The appearance, content and ease-of-use work together to send a message . . ."

Once these decisions were made, DCM and Web staff worked on their respective parts and put them together into a new page for iterative testing and incorporation of recommendations with a widening group of evaluators, until both groups were satisfied and the appropriate sign-offs have been obtained. Like newly marketed drugs, however, the evaluation and page development process doesn't stop once the page goes "live," but continues to incorporate recommendations and usage data from users and staff as well as technological developments. But more on that in the next column.

If all this tends to scare you off, take heart. The whole process can be shorter than the time it takes me to write this column—and I'm not telling you how long that is. If you wish to start a new page, please contact: **Gail Chotoff,** Manager, CDER Page Editors (CHOTOFFG, 7-5687); **Karen Kapust** Assistant Program Manager, CDER Web Sites (KAPUSTK, 7-5534); or myself (ASSOUAD, 7-5539).

This month's page that's under development is an adaptation for the FDA Kids' Homepage of the new drug development and review process from the CDER Handbook. If you'd like a sneak preview visit http://cdernet/kidsite/johnemilio/medfrom.htm. Let us know your comments. And many thanks to the Medical Library's **Wendy Cheng** for the new column name!

Carol Assouad is Division Director, Medical Library, and Program Manager, CDER Web Sites.

Union Corner

Legal History, Background of Federal Sector Unions

By Bob Young

President Kennedy authorized unions in the federal sector by executive order in 1962. Subsequently, Congress passed the Civil Service Reform Act of 1978. Federal unions are descendent from and similar to private sector unions. The laws and concepts which govern federal unions and agencies were forged in the private sector and then modified for use in the federal sector. This series of essays will explore some of the central concepts governing union-management relations in the Agency.

For FDA employees, the legal framework for union-management relations should be easily recognizable because it is analogous to the framework that is the basis for FDA activities:

- Where consumers are protected by the Food, Drug and Cosmetic Act, employees are protected by the Civil Service Reform Act of 1978.
- Both the FD&C Act and private sector labor laws were enacted when the economic strength of employers and producers was so great that it could not be fairly countered by consumers and employees, whose lack of organization and focus fatally crippled them as a viable economic force. Essentially, consumers and employees used their greater political strength at the ballot box to level the playing field.
- The FD&C Act establishes an agency, the FDA, to administer the statute. Similarly, the Civil Service Reform Act establishes an agency, the Federal Labor Relations Agency, to administer that law.
- Both agencies are empowered to issue and enforce rules and regulations to implement their respective statutory responsibilities.
- Actions of both agencies are subject to judicial review.
- It is the activities of manufacturers and sponsors that brings them under the FD&C Act. Certification of a union by the Federal Labor Relations Agency brings both the union and agency under the Civil Service Reform Act.
- Compliance with the rules and regulations of both the FDA and Federal Labor Relations Agency is not voluntary, but mandatory.
- The appropriate subjects of FD&C Act include food, drugs, cosmetics and biologics. The appropriate subject of Civil Service Reform Act are the conditions of employment.
- The end result of the FD&C Act is a market in which the consumers gets what they pay for. The end result of the Civil Service Reform Act is a workplace where employees are treated fairly and equitably.

The Civil Service Reform Act gives employees the right to establish unions and empowers unions to negotiate contracts with agencies that govern employee-management relations in the workplace. It is the provisions in the contract that specifically govern employee-management relations by spelling out the responsibilities and obligations of employees and management. As with any contract, the provisions are enforceable by law. Organization of a union and the conduct of contract negotiations are the responsibilities of the employees. Unions are employee self-help organizations. If employees do not do things for themselves, no one will do it for them. The term “union” should always be understood as “employees.” The Federal Labor Relations Agency only oversees the activities of unions and agencies. It does not act on behalf of either party.

When Congress passed the Civil Service Reform Act, it determined that labor organizations and collective bargaining in the civil service are in the public interest. Congress memorialized its factual findings in the statute: “Experience in both private and public sector employment indicates that the statutory protection of the right of employees to organize, bargain collectively and participate through labor organizations of their own choosing in decisions which affect them safeguards the public interest, contributes to the effective conduct of public business and facilitates and encourages the amicable settlements of disputes between employees and their employers involving conditions of employment.”

Some significant differences between the labor laws governing union-management relations in the private and federal sector include provisions that prohibit strikes by federal sector employees and exclude from bargaining those matters specifically provided for by federal law, such as rate of pay, leave and health insurance contribution. Since federal employees are prohibited from striking, disagreements between management and union that cannot be resolved by the parties are resolved by independent third parties whose decisions are binding on both the agency and employees. Unresolvable employee grievances are decided by arbitrators, and unresolvable negotiations are decided by the Federal Service Impasses Panel.

The National Treasury Employees Union was founded in 1938 as the National Association of Employees of Collectors of the Internal Revenue. This association received its charter as a federal union in 1967. In 1977, the union moved beyond Treasury Department employees to organize employees in other federal agencies.

During the 1997-’98 organizing campaign, a sufficient number of FDA employees, more than 30 percent, petitioned the Federal Labor Relations Agency to hold an election in the spring 1998. In April, a majority of FDA employees participating voted to have an FDA union, and the Federal Labor Relations Agency certified the National Treasury Employees Union. Contract negotiations will begin in September. Standard contracts cover such workplace activities as:

- The hours and place of work including related issues, such as overtime, compensatory time, office location and reorganizations.
- Performance appraisal and related issues such as tenure, promotion, discipline and awards; details; training; discrimination; grievances; contract violations; etc.

Before closing I wish to acknowledge the sad fact that many

(Continued on page 7)

Reviewer Affairs Corner

Subcommittee Targets Quality of Worklife Issues

By Karen Lechter

As part of the Reviewer Affairs Committee, the Quality of Worklife subcommittee aims to provide reviewers with a mechanism for participating in CDER's transformation. The group has decided to promote the creation of a CDER environment in which people are empowered and able to create extraordinary results. Our goal is to identify issues that affect the quality of daily worklife and to provide a more supportive and satisfying work environment.

The QWL subcommittee has been evolving for a period of about nine months. Since the group works by consensus, its initial efforts have been slow and deliberate. We have spent a considerable time laying down the philosophical foundation for the work before deciding on our direction and areas of emphasis.

The group has reached agreement on creating a set of norms, a mission, goals and other statements of objectives. To ensure full participation and direction for the work of the subcommittee, the duty of facilitating the meetings is rotated among members. For the first several months of functioning, the group's liaison to the RAC was **Lynnda Reid**. Currently, **Terri Rumble** serves in that capacity, with **Shahla Farr** as the alternate.

During the course of meetings there have been rich discussions about life in the organization, written statements of philosophy and explanations from each other about the differences in functions of divisions in various areas. This allowed the group to share ideas for improvements. Broad issues such as respect, responsibility, transparency, communication, empowerment and equality have been explored. We have also developed our guidance statement: "To create an environment that ensures partnership and respect for all members of the CDER community."

The subcommittee is now working on issues surrounding the need to maximize communication, accountability and respect within the CDER community. Once more details about these issues emerge, the group plans to develop a whitepaper to share with the RAC.

The group welcomes the input of all members of the CDER community interested in the goal of the Quality of Worklife Subcommittee. You can give comments to Terri (RUMBLET, 7-4260. If you are interested in joining the subcommittee or learning more about us, contact me (LECHTERK, 7-2828).

Karen Lechter is a social science analyst in the Division of Drug Marketing, Advertising and Communications.

Modernization Act Update for Industry to Be Broadcast Live

By Elaine Frost

CDER and the Drug Information Association are co-sponsoring a live satellite video conference, "Update on CDER's FDAMA Initiatives," on Sept. 16 from 1 p.m. to 3:30 p.m. The goal of the program is to inform, interact with and obtain feedback from industry on CDER's response to and progress on the FDA Modernization Act. CDER has solicited questions from industry in advance of the broadcast and will be accepting faxes and live call-in questions during the video conference.

The program will be shown in Parklawn Conference Room B; Woodmont II, Conference Room G; Corporate Boulevard, Room S-100; and the Metropark North II videoconference room. Seating is limited at all sites and available on a first-come basis. There is no advance registration.

The topics are fast track, data requirements, evidence document, NIH database, pediatrics, manufacturing changes and pharmacy compounding.

Panelists will be Associate Commissioner for Special Health Issues **Theresa A. Toigo,** Center Director **Janet Woodcock, M.D.,** Associate Director for Policy **Jane A. Axelrad,** chairperson of the Pediatrics Subcommittee **Rosemary Roberts, M.D.,** Office of New Drug Chemistry Director **Eric B. Sheinin, Ph.D.,** Division of Prescription Drug Compliance and Surveillance Director **Lana L. Ogram,** and CBER's Associate Director for Policy, **Rebecca A. Devine, Ph.D.**

Tapes will be available in the Medical Library soon after the broadcast.

Elaine Frost is a special assistant to the director of the Office of Training and Communications.

Union, FDA Contract Negotiations to Start in September

(Continued from page 6)

of the safeguards, rights, and liberties we enjoy today were obtained by the sacrifices of many patriotic individuals to whom we owe a debt of gratitude. This is true for those freedoms obtained in the Revolutionary War, enshrined in the Constitution and reaffirmed in the Civil War; the safeguards in the FD&C Act obtained by those who died and suffered in both the Elixir Sulfanilamide and thalidomide tragedies; and those employee rights now codified in the Civil Service Reform Act and obtained by those who suffered violence for such benefits as the eight-hour work day, a living wage, and a safe workplace.

Bob Young is serving as interim President (until the end of 1998) of Chapter 282, FDA headquarters, National Treasury Employees Union. He will be writing a short series of articles from his perspective on key labor-management concepts and how an FDA union conforms to FDA's consumer protection mandate.

Zan Fleming Leaves Improved CDER Seminars as Legacy

By John Senior, M.D.

G. Alexander "Zan" Fleming, M.D., familiar to many as host of the weekly CDER Seminars for the past two academic years, has announced his plans to leave federal service at the end of August and to seek opportunities in private sector pharmaceutical research and development. He intends to remain based in the Washington area.

Zan is a native of Nashville, Tenn., but grew up in Pensacola, Fla., the son of a busy practicing cardiologist who nevertheless found time to write and publish several books. He majored in biochemistry and molecular biology in college at Vanderbilt and the University of West Florida, followed by graduate work at Emory University before attending medical school there. He then trained in internal medicine and endocrinology, and subsequently was board-certified in both. It may be noted that he was elected president of both his college alumni and medical school classes.

Click here to view a photograph of Zan.

Zan was bitten by the research bug early in life and continued asking questions and seeking answers. As a medical staff fellow and senior staff fellow at the National Cancer Institute, he extended his early interests in the study of growth hormone effects on children to the investigation of amino acid derivatives as plasma signals for metabolic regulation.

Zan joined CDER as a medical officer in the Division of Metabolic and Endocrine Drug Products in 1986 and three years later became a medical team leader in the division while continuing to see patients on a part-time basis. He was a primary medical reviewer for three important new molecular entities: lovastatin to treat high cholesterol and metformin and troglitazone to treat diabetes.

For 18 months beginning in 1991, he was assigned to the World Health Organization in Geneva where he participated in writing the WHO good clinical practice document. Since its beginning in 1991, Zan has represented the FDA at International Conference on Harmonization meetings and is a member of the expert working groups on Good Clinical Practice (E-6) and on General Considerations for Clinical Trials (E-8).

He has worked in China on drug development projects and in Russia, Ukraine and Belarus on accrediting FDA approvals in those countries. Zan is frequently asked to meet with foreign officials and scientists visiting the FDA. Most recently, he organized and participated in symposia on drug development and evaluation in Boston, Vienna, Moscow, Kuoshiung in Taiwan, Beijing, Seoul and London.

In addition to becoming an excellent medical reviewer, Zan has continued to manifest outstanding vision, creativity and leadership. He has been an active contributor to the design and development of the CDER initiative on good review practices. Zan founded the Center's new *virtual Journal* and has served as its editor-in-chief. He wrote about initiating a career development path for medical reviewers, which came to fruition as the CDER Reviewer Career Path (February *Pike).* As 1996-'98 chair of the Committee for Advanced Scientific Education, he has fostered significant programmatic improvements in scientific excellence and a new atmosphere of collegiality at CDER Seminars.

Zan has a special interest in the concept of task and problem focus in facilitating the drug development process (see his editorial in the *vJ*). TPF is an issues-oriented means of communicating among drug developers and evaluators using an electronic, Web-like environment to capture organize, and store decisions and the data and other information on which they are based. TPF is being developed as a proof-of-concept project for the good review practices initiative.

Some comments from his friends about this quintessential Renaissance man:

- "Zan is the ultimate team builder . . . and can be your most trusted friend." **Yuan-Yuan Chiu.**
- "Zan leaves a legacy of a vibrant successful CDER Seminar program that we will have to strive mightily to match." **Ken Kobayashi.**
- "Zan is a communications wizard, a prolific writer and an accomplished speaker. He will be sorely missed." **Lori Frederick.**
- "Zan showed mastery of diplomacy in putting together a teaching collaboration between MIT, Harvard and FDA." Alan Moses of Harvard.
- "Zan has earned the admiration of industry counterparts by his creative ideas on improved drug development systems." Tim Franson of Eli Lilly.

John Senior is a medical officer in the Division of Gastro-Intestinal and Coagulation Drug Products.

Coordinating Committees Forge Center's New Policies

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botanicals, which when sold as dietary supplements are unregulated by FDA. The committee focuses on science and technical issues instead of regulatory ones, and is looking at how botanicals would be treated if any of them were submitted for approval as drugs.

Currently, there are 12 active coordinating committees. The majority of the work, however, is done by dozens of subcommittees, working groups and technical committees.

Membership for most coordinating committees is determined by a MAPP. Subcommittees are generally open to anyone who wishes to contribute. **A list of the coordinating committees with their chairpersons and executive secretaries is on the next page.** To find out more about a specific committee, you can look up their minutes in the appropriate subdirectory on X:\coorcomm\. A few of the coordinating committees have intranet sites which can be viewed at http:/cdernet/Committ.htm.

Jason Walther is a summer intern.

Coordinating Committees Tackle Crosscutting Policy Issues

- **Administrative Management (AMCC):** The AMCC recommends, develops and documents administrative policy. Among other responsibilities, it puts resource guides on CDERnet, test new types of training and recently gave out the first Administrative Management Team Quarterly Awards (July *Pike).* Some of its subcommittees are Human Resources, Training and Budget/Procurement. The committee recently established the first administrative performance goals for the Center (*page 4*). **Paula Bourkland** chairs the AMCC (BOURKLAND, 4-6741). Executive secretary is **John Emelio** (EMELIO, 7-0517).
- **Biopharmaceutics (BCC):** The BCC's main goal is to maintain consistent biopharmaceutics policy across the review divisions. They have recently been working on drafting a guidance for a biopharmaceuticals classification system. BCC's chair is Deputy Center Director for Pharmaceutical Science **Roger Williams, M.D.,** (WILLIAMSR, 4-2847). Executive secretary is **June Cory** (CORYJ 4-5631).
- **Compliance (CCC):** The CCC facilitates communication between the Office of Compliance and other CDER units. The committee recently developed a proposal for a First Party Audit Program (July *Pike).* Several of the committee's working groups are Active Pharmaceutical Ingredients, Plant Readiness and Evaluating Test Results. The chair is Office of Compliance Director **Stephanie Gray**. (GRAYS, 4-0054). Interim executive secretary is **Margaret Tart** (TARTM, 4-0054).
- **Complex Drug Substances (CDSCC):** Before the creation of the CDSCC, matters relating to complex substances were handled by the CMCC and the PTCC. Several months ago, the Center decided that complex drug substances warrants its own coordinating committee. The group has been discussing botanical-related issues, such as potency, purity control and classification. Co-chairs are **Roger Williams, M.D.,** and **Yuan-Yuan Chiu, Ph.D.** (CHIU, 7-5918). Executive secretary is **Rita Hassall** (HASSALLR, 7-5845).
- **Chemistry and Manufacturing Controls (CMCCC):** The CMCCC handles chemistry and microbiology policies and procedures. The committee has modified itself in response to a new need for less coordination between reviewers and more coordination between the Office of New Drug Chemistry and Office of Generic Drugs. The co-chairs are ONDC Director **Eric Sheinin, Ph.D.** (SHEININ, 7-5918) and OGD Director **Douglas Sporn** (SPORNB, 7-5845). Executive secretary is **June Cory.**
- **International Affairs (IACC):** The newest committee, the IACC deals with international activities such as overseeing CDER's foreign visitors program. The chair is **Roger Williams, M.D.** Executive secretary is **Jaime Henriquez**. (HENRIQUEZJ, 4-5633).
- **Information Technology (ITCC):** The ITCC handles centerwide information technology issues, such as establishing a standard computing architecture and archiving documents. The committee is currently working on electronic submissions to establish a completely electronic submission and review environment by 2002. The chair is Center Director **Janet Woodcock, M.D.** (WOODCOCKJ, 4-5400). Executive secretary is **Pat Sporn** (SPORNP, 7-6231).
- **Medical Policy (MPCC):** The MPCC is probably the most complex coordinating committee due to its extensive scope. The committee establishes medical and clinical policies and procedures. The various subgroups are too numerous to list, but projects with finite products are handled by working groups, such as the thalidomide working group. On-going issues are handled by subcommittees, such as the Pediatrics Subcommittee. Large intra-Center or inter-Center projects are handled by sections, such as Labeling. A few of their accomplishments are the proposed pediatric rule and the thalidomide patient information sheet. Co-chairs are Associate Director for Medical Policy **Roger Temple, M.D.**, (TEMPLE 4-6758) and **Roger Williams, M.D.** Executive secretary is **Janet Jones** (JONESJ, 4-5445).
- **Pharmacology and Toxicology (PTCC):** The PTCC is the primary decision-making body for scientific evaluation and policy involving pharm/tox issues. The committee solicits comments on proposals from industry groups and develops reviewer training sessions among other actions. One of their current projects is harmonizing toxicity testing in CDER. The chair is Assistant Director for Pharmacology and Toxicology **Joseph DeGeorge** (DEGEORGE, 4-6758). Executive secretary is **Adele Seifried** (SEIFRIED, 4-5447)
- **Project Management (PMCC):** The PMCC works with many parts of the Agency as well as industry. One of the larger coordinating committees, the PMCC has set up a regulatory project manager certification program, sponsored a joint training workshop with DIA and prepared a project manager resource manual. The co-chairs are **Jean Yager** (YAGERJ, 4-5480) and **Linda Carter** (CARTERL, 4-6758). Executive secretary is Debbie Kallgren (KALLGRENG, 4-5481).
- **Reviewer Affairs (RAC):** The RAC provides a forum for all CDER non-supervisory reviewers to present their concerns directly to the Center director. Last month the committee discussed how it is affected by the recent unionization of FDA. One of their notable accomplishments is the creation of the Reviewer's Handbook. The chair is Office of Generic Drug chemist **Melissa Maust** (MAUSTM, 7-5848). Executive secretary is **Tanya Abbott** (ABBOTTT, 4-6779).
- **Research (RCC):** About a year ago, the RCC was changed to better integrate the Center's priorities with its research program. The committee's focus is more on strategic planning than specific projects. Membership includes the chairs of policy-making coordinating committees and senior managers. Currently, the committee is evaluating major research programs by discipline and determining if these programs will help solve the problems the Center encounters. The chair is Office of Testing and Research Director **James MacGregor, Ph.D.,** (MACGREGOR, 7-5917). Executive secretary is **Helen Winkle** (WINKLEH, 7-5917).
- **Statistical Policy (SPCC):** Historically, there have been many ad-hoc statistical committees. The SPCC is being formed in response to a need for a single committee to handle statistical policies. Office of Epidemiology and Biostatistics Director **Robert O'Neill, Ph.D.,** will be the chair (ONEILL 7-3195). The committee has had no formal meetings.

Communications, Product Safety Concern Stakeholders

(Continued from page 1)
lateral sclerosis said the center should have no higher priority than rapid approval of new therapies for serious and life-threatening illnesses.

Professional societies offered suggestions on how they could assist in meeting the agency's objectives, especially in domestic inspections and information for health providers and patients. The trade association vigorously supported drug approval reforms, direct-to-consumer advertising, the provision of journal articles on unapproved uses to physicians and the industry's safety programs.

CDER's meeting was one of a series of opinion-gathering sessions held by each center designed to help the Agency get input on six objectives:

- Maximizing the availability and clarity of information about the review process.
- Maximizing the availability and clarity of information for consumers and patients about new products.
- Implementing inspection and postmarket monitoring provisions in the Modernization Act.
- Ensuring access to necessary scientific and technical expertise.
- Meeting application review time periods by July 1, 1999.
- Eliminating review backlogs by January 1, 2000.

Linda Suydam, Associate Commissioner for Strategic Management, said broad issues of concern to the Agency were adverse event and injury reporting; product safety assurance; product application reviews; food safety; outreach; scientific infrastructure and research; and tobacco. She said recent reports and studies on drug-related injuries mean that the FDA needs to focus on adverse event reporting and product safety. User fees have enabled the Agency to meet goals for product application reviews.

Food safety is a presidential initiative and will require increased focus from FDA, she said. Scientific infrastructure has been neglected while the Agency has focused on priority programs. FDA's tobacco initiative is uncertain in the light of the recent appellate court decision.

From 1993 to 1999, Suydam reported that the FDA's budget grew from $800 million to $1.26 billion. That looks impressive, she said, but inflation erosion and dollars mandated for priority programs have created a substantial underfunded workload. Priority programs include user-fee supported application reviews with a mandated level of appropriated fund support, the mammography quality screening program, tobacco and the food safety initiative.

As a consequence of directing funds into these mandated programs, support for the Agency's other program areas has fallen over the six-year period from $671 million to $586 million and created the imperative for seeking public input on priorities.

Center Director **Janet Woodcock, M.D.,** provided an overview of the current state of the U.S. drug regulatory system. The center faces a myriad of tasks and expectations, and its stakeholders are never in agreement.

She said it is important for stakeholders to see other priorities in the drug regulatory system. She provided details about the system's mission and the expectations of Americans for the system. She outlined the components of the system, its processes, its performance and its challenges. She said the system in the United States is very effective and performing well. There are, however, many expectations for improvement and competing priorities.

Making presentations at the meeting were the American Pharmaceutical Association, the Association of Food and Drug Officials, the Pharmaceutical Research and Manufacturers of America, the ALS Association, the Consumer Federation of America, the National Women's Health Network, the National Council on Patient Information Education, the American Society of Health-System Pharmacists, the Patients' Coalition, the Center for Medical Consumers and the American Society for Clinical Pharmacology and Therapeutics.

Among the many recommendations were that CDER and the FDA should:

- Take the lead to organize and support a sustained national Consumer Medicine Safety and Education Program, modeled after the Partnership for Food Safety Education.
- Develop more effective ways to communicate and disseminate information through the Internet, consumer publications, news media and professional health and trade journals.
- Have a Fax-on-Demand system for package inserts.
- Widely publish a telephone number for professional and consumer information.
- Keep its drug information on the Web current.
- Develop an Internet database for drug label information.
- Create an Office of Drug Safety with the resources and authority to fulfill surveillance and adverse event reporting responsibilities.
- Develop a stronger system to compel sponsors to conduct and complete post-marketing research.
- Encourage states to improve reporting of adverse drug events to FDA and for the FDA to improve communications back to the states.
- Develop a method for anonymous reporting of adverse events.
- Report updates on safety issues periodically.
- Open the MedWatch database to others so that additional analyses can be done.
- Create FDA fellowships for academics.
- Develop sabbatical programs for FDA scientists.
- Establish national search committees for important positions.
- Generate a professional judgment budget and submit it with the priority plan.

Dr. Woodcock's slides of her presentation can be found on CDER's Internet site at http://www.fda.gov/cder/present/406bjw/index.htm. A summary and transcript of the meeting will be available on FDA's Web site at http://www.fda.gov/oc/fdama/comm/default.htm.