news along the pike

MAY 1999

CENTER FOR DRUG EVALUATION AND RESEARCH

VOLUME 5, ISSUE 5

INSIDE . . .

CDER'S CORNERS . . .

Risk Management Task Force Issues Report

Calls for Systems Approach, Makes Recommendations

Declaring that "the time is right to apply a systems framework to medical product risk management," the FDA Task Force on Risk Management issued its report May 10. The task force applied a risk-management model used in other Federal sectors. Noting that the FDA "plays only a part in the complex system of risk management," the task force said that a systems framework would enable better integration of the efforts of all parties.

The task force was spearheaded by the center directors for medical products, CDER's **Janet Woodcock, M.D.,** CBER's **Kathryn Zoon, Ph.D.,** and former CDRH director **Bruce Burlington, M.D.** The full, 164-page report, *Managing the Risks from Medical Product Use: Creating a Risk Management Framework,* can be found on the FDA's Internet site in PDF at http://www.fda.gov/oc/tfrm/riskmanagement.pdf and in HTML at http://www.fda.gov/oc/tfrm/riskmanagement.html. The executive summary is at http://www.fda.gov/oc/tfrm/executivesummary.pdf.

The task force found some ways in which the FDA can improve its risk management activities within the confines of the existing system. It also identified a number of options that would need full public policy analysis and review, including meetings with stakeholders,

(Continued on page 10)

CDER, FDA Lead HHS in Quality of Worklife

BY LYNDA PAPIO AND SHELLEY JOHNSON

For the past two years, the Department of Health and Human Services has surveyed FDA employees about their perceptions of the quality of work life. Results of the Secretary's 1999 Quality of Work Life Survey on Organizational Climate show that overall FDA still leads in the quality of work life in the Department; however, the results remain mostly unchanged from the 1998 survey.

For CDER, the survey results show that the Center's strengths are in family and work programs. Eighty percent of CDER respondents said they "almost always or usually could balance their work and family lives through the use of scheduling and leave options." In addition, managers and co-workers were reported supportive of employees using flexible scheduling and leave options to balance work and family lives.

A majority of our employees feel people are treated fairly with regard to training opportunities, length of lunch periods and leave. The survey also revealed that communications was an area of strength. An increased number of our employees responded positively to the question: "Is information about what is happening in the organization communicated to your work group in a timely fashion."

Although CDER maintains a positive working environment that allows employees to balance work and home life, we still seek to improve our quality of work life. To accomplish this, we will focus on areas of less strength as shown in the survey results.

Of the three areas that the Agency plans to review and work to improve, CDER results show that the majority of the Center's respondents felt that their energies and abilities are utilized in an effective manner. The Center also received a positive and favorable response to the question about management delegating the authority to employees that they need to do their jobs. Although the response to the question about encouraging employees to try new approaches for getting the work done was also positive, there was a decrease in positive responses from the 1998 survey.

If you are interested in reviewing the Agency's results from the 1998 and 1999 surveys, you can find them on the QWL Web site at http://intranet.fda.gov/ohrms/qwl/qwl.htm.

Lynda Papio and Shelley Johnson are management analysts in the Office of Management and coordinate the Center's Quality of Worklife program.

JOE'S NOTEBOOK

Introducing Pike's Puzzler

Paul Motise has broken the ice for a new feature, Pike's Puzzlers (see page 6). Paul is a consumer safety officer in the Office of Compliance's Division of Manufacturing and Product Quality.

"Some of us here are big crossword fans," Paul writes. "At lunch we pool our efforts at solving crosswords from a variety of sources. It's educational, entertaining and builds teamwork. We've learned the standard tricks of the trade, like discerning literal from figurative meanings." Paul gave an example: the clue "back of the kitchen" has a literal answer—a suffix to "kitchen," namely "-ette."

His passion has led him to enter the ranks of novice crossword puzzle constructors. "I have gained great respect for the pros," he said. "At this point, I've only prepared a few puzzles, including two CGMP-related ones for *Human Drug CGMP Notes."* He promises more from time to time, but claims his skill level keeps him from making many.

His points about team building and keeping your mind sharp are well taken. If you have a brain-tease with a CDER connection and want to share it with the *Pike's* readers, e-mail it to me (OLIVERN) for consideration.

When I was an editor at the Defense Department's daily newspaper published for folks stationed in the Far East, we could buy standard features such as crossword puzzles, bridge columns, comics and horoscopes. We depended on the less than efficient interface between the U.S. Postal Service and the military's own postal system. When features were delayed in the mail, we had to use a "field expedient."

Usually, that meant going back a few years and pulling an old crossword or horoscope out of the morgue and printing it. It became clear to me that solving crossword puzzles sharpens the mind, because crossword fans would always catch on and let us know they didn't appreciate solving puzzles twice.

We didn't have the skill to write our own crossword puzzles. But when the horoscopes, or "horriblescopes" as we called them, were late, it was an excuse to unleash our creative juices. If you read them—and we did to check for typos—you'll discover they have less to do with the stars and more to do with the cycle of everyday life. Horoscopes on paydays deal with financial matters and on weekends with romance. Naturally, being closer to the cycles of military life, we were able to do much better and not get caught.

Tales of our youthful misadventures are entertaining, in part, because we've survived to tell them. In a NIH-funded research finding that will surprise few parents, a University of California San Francisco scientist has shown that what adults say about the probability of harm from a risky behavior can have different—even opposite—meanings to teenagers.

"If you give the same risk message to two people of different ages, they may walk away with different interpretations and may make different decisions," said UCSF adolescent medicine expert Bonnie Halpern-Felsher, Ph.D. She was presenting pilot data from an ongoing study at the annual meeting of Pediatric Academic Societies in San Francisco earlier in May.

We typically use probability terms like "likely" and "rarely" to communicate risk because we don't know the precise percentage chance that a risky action will lead to trouble. But the UCSF data show that children, adolescents and even adults neither understand nor interpret these terms as we would expect. To make sure that messages about probability are getting across, Halpern-Felsher said that a numeric scale may be more effective than vague terms like "probably" or "possibly." She is conducting her studies among 5th graders, 7th graders, 9th graders and adults in their 20s.

news along the pike

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

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OMBUDSMAN'S CORNER

Judgment in Rockville

BY JIM MORRISON

In the Ombudsman's job, I'm frequently reminded of the complexity of drug regulation. I'm not talking about drug regulations, those volumes of colorful prose that take up more than a foot of shelf space. I'm referring to the entire process of assuring that drugs are safe and effective, both when they are marketed and throughout their commercial lives. Science, consumer expectations and, therefore, the Agency's regulatory and scientific policies are in a state of constant change. This flux adds to the already complex decision-making in CDER.

At the core of the Center's decision-making is risk assessment. The new drug review process involves many risk-benefit decisions. The benefit side of the equation is most often reflected in the drug's efficacy studies. Effectiveness compared to a placebo can be analyzed statistically and is relatively easy to define. Risks, on the other hand, are usually represented by the adverse effects of a drug or the unknowns associated with its initial introduction into humans. These are not quantifiable.

Weighing the potential benefits of a drug against its risks, whether it is new or already marketed, is an inexact and value-laden science. What may seem a reasonable risk to one person may appear unreasonable to another. Often the patient is willing to assume more risk than the caregiver.

FDA Commissioner **Jane Henney, M.D.,** has made the agency's risk assessment processes among her highest priorities (see page 1). Such attention is well-placed, since risk assessment requires the application of very sound scientific judgment.

In the context of a regulatory agency, the exercise of judgment presents a paradox. Without the application of sound judgment to scientific issues, the result is mindless bureaucracy. The exercise of sound judgment produces flexibility in regulation, which is good. But judgment is based on individual values, which differ greatly among people, especially in a multicultural society such as ours.

So, the exercise of judgment without guidance leads to inconsistency, which is bad. Inconsistency sometimes leads courts to brand actions of a regulatory agency as arbitrary and capricious and then to issue sharply worded opinions chastising the agency while finding for the other side.

To reduce inconsistencies in decision-making, agencies develop regulatory and scientific guidances and policies through a consensus-building process. Once these policies are developed and published, all of us in a regulatory agency are obligated to follow them—even if they occasionally don't coincide with our own judgment.

It is essential that everyone who makes decisions or recommends actions understand the rationale for policies. If we understand the reason for a policy but simply do not agree with it, we have an obligation to discuss it with our supervisors and to seek to change it through established processes.

The one thing we must not do is go off on our own and impose different policies in our regulatory work.

The next time you are tempted to substitute your own judgment for established agency policy, please ponder this quote from Aesop: "Good judgment comes from experience, and experience—well, that comes from poor judgment."

Jim Morrison is the Center's Ombudsman.

FDA Issues 'Final Monograph' for OTC Sunscreen Products

FDA published its final rule for over-the-counter sunscreen drug products in the *Federal Register* May 21. The rule, referred to as a "final monograph," lists the sunscreen active ingredients that can be used in these products as well as labeling and testing requirements. The rule provides for uniform, streamlined labeling for all OTC products intended for use as sunscreens to assist consumers in making decisions on sun protection.

Highlights of the new rule include:

- Similar labeling requirements to provide good, useful information to consumers for all OTC products intended for use as sunscreens, including sunscreen-cosmetic combinations such as makeup products carrying sun protection claims.
- Uniform, streamlined labeling for all sunscreens. Accommodations in labeling will be made for sunscreens that are labeled for use only on specific small areas of the face, such as the lips, nose, ears and around the eyes.
- A list of 16 allowed sunscreen active ingredients, with zinc oxide and avobenzone being the two most recent additions.
- Required and optional label claims, warnings and directions.
- Requirements for sun protection factor testing. The higher the SPF, the more sunburn protection.
- A new SPF category of "30 plus" or "30+" for SPF values above 30.
- Simplification of the previously proposed five sun protection categories to "minimum," "moderate" or "high," plus optional claims to help consumers with selection of sunscreen products.
- A "Sun Alert" statement that reflects the important role sunscreens play in a total program to reduce the harmful effects of the sun ("Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer and other harmful effects of the sun.")
- Cessation of unsupported, absolute and misleading and confusing terms such as "sunblock," "waterproof," "all-day protection" and "visible and/or infrared light protection".

Also, new cosmetic regulations require tanning preparations without a sunscreen ingredient to display a warning that the product does not contain a sunscreen and does not protect against sunburn. Claims concerning ultraviolet A, or UVA, protection will continue as previously proposed.

REVIEWER AFFAIRS CORNER

Subcommittee Tackles Clinical Pharmacologist Classification

BY MILTON SLOAN AND LYDIA V. KIEFFER

The Comparable Pay Subcommittee at its May 6 meeting outlined several objectives it hopes will ameliorate reviewer retention, including a new series classification for clinical pharmacologists and biopharmaceuticists and updating and initiating special pay categories for reviewers.

The subcommittee invited the Pay Policy Group from FDA's Office of Human Resource Management Services to present information and details needed for new series classification and completion of the Office of Personnel Management's Form 1397, a detailed worksheet for special salary rate requests. Classification specialist George Calvert presented an overview of position classification.

"Title 5 of the U.S. Code is the legal basis for position classification," he said, "and it codifies the 15 general schedule grade levels, GS-1 through GS-15, with statutory definitions." Just as Title 5 regulates permanent positions, Title 42 does the same for fellowship positions. OPM is required to prepare classification standards for placing positions into the proper series and grade levels in accordance with these statutory definitions.

The requirements placed on FDA are that the general schedule and wage positions must be classified in accordance with applicable standards published by OPM. A new series implies a competitive service that can be transferred across government agencies.

The pay group answered fundamental questions about how position classifications are developed. There are two major parts to the position classification process—management and human resources.

The management responsibility is to assign work to employees in accordance with the requirements of law, executive orders or other delegations. Federal managers and supervisors have the responsibility to organize work to accomplish an agency's mission in the most efficient and economical manner.

A personnel management specialist or a position classification specialist reviews and evaluates the duties and responsibilities assigned to a position. That person must then classify the position in accordance with OPM standards.

When implementing a new series, an agency must show a problem with the "three R's," recruitment, retention, and relocation. Also, the agency must identify what makes the new classification special. The pay group explained the differences between special rates and retention allowances and mentioned that both might be used effectively.

Special pay is part of base pay and can range from 1 percent to 30 percent of the step 10 pay for a specific grade. A retention allowance comes from the Center's budget and may be renewed each year and is given based on impact of departure. The Federal Employees Pay Comparability Act paved the way for special pay and retention allowances, but they cannot be implemented if the funds are not in the budget.

The subcommittee presented statistics that compared the clinical pharmacologist position in industry and the Agency. Differences exist in title, pay and other benefits. A survey of 12 people who left FDA for industry reported a 48 percent increase in salary and benefits upon transferring to industry.

A new series classification would possibly be called "clinical pharmacologist" and would require a new position description. A new series classification is more difficult to justify than a "parenthetical." A parenthetical would force fit clinical pharmacologist and pharmacokineticist into one classification. The subcommittee decided it will need more discussion before picking a timeframe to complete this objective.

In other developments, J**ohn Senior, M.D.,** a medical reviewer from the Division of Gastro-Intestinal and Coagulation Drug Products, briefed the RAC on progress being made by the Reviews Evaluation and Education Project, which he has chaired since its inception in early 1997. As a subproject of the good review practices initiative, the project members are addressing the issue of how to make review in all disciplines more readable and logical.

The Center's reviews are the primary basis for regulatory decisions and CDER's principal work product. Since they are now published on the Internet in redacted form, they are "publications" in the full sense of the word. However, members of the project's steering group and a consulting firm discovered that completed reviews are highly variable in clarity, length and quality.

Because there are many and divergent opinions on the purpose of the review, quality standards are lacking.

Developing guidance for the content and format of a review is under consideration by the good review practices Track 8 committee. However, there needs to be a consensus on the purpose of reviews and their audience.

The Review Evaluation and Education Project has a vision that good reviews will be well organized, inclusive and yet concise.

Data will be presented efficiently and effectively. They will be written in clear English with conclusions logically derived from the data. Reviews should reflect the reviewer's independent thought.

Milton Sloan, Ph.D., is a review chemist in DNDC III, and Lydia V. Kieffer, Ph.D., is a clinical pharmacology and biopharmaceutics reviewer in OCPB DPE I.

FDA Approves 2nd Cox-2 Inhibitor for Osteoarthritis

FDA on May 21 approved rofecoxib, a new drug for treatment of osteoarthritis, menstrual pain and the management of acute pain in adults. Rofecoxib is the second NSAID approved in a class of drugs known as Cox-2 inhibitors. Celecoxib, the first, was approved in December (See January *Pike).*

In clinical trials, rofecoxib was found to be an effective treatment for the signs and symptoms of osteoarthritis, the management of acute pain in adults and pain related to the menstrual cycle.

Rofecoxib will be marketed under the trade name Vioxx by Merck & Co. Inc. of West Point, Pa.

LEADERSHIP FELLOWS CORNER

Vision, Mission Communication, Measurable Results Emphasized

"Leaders must balance sensitively the needs of people and of the institution"

Max DePree
Leadership Jazz, 1992

BY DONNA VOLPE

For the fourth year, CDER is sending some of its employees to the Council for Excellence in Government's Leadership Fellows Program. This year-long development program has as its goal to recast mid-level federal managers into leaders who produce results.

The council is a national, non-profit organization whose mission is to improve the performance of the American government. The Council is made up of approximately 700 members, called principals, who are former senior public officials currently in leadership positions in corporate and private-sector institutions. The council carries out programs to strengthen results-oriented management and build public confidence and participation in government. The Council looks to the private sector for concepts and methods to achieve the goals of their programs.

The Leadership Fellows Program is a year-long series of events designed to explore the demands and commitments required of successful leaders. Fellows come from all departments of the executive branch of the federal government. Through a series of interactive learning activities, the fellows explore ways to:

- Create a shared sense of vision.
- Communicate a clear and powerful mission.
- Take actions that lead to measurable results.

During the year, the fellows meet with Council Principals, government executives and other private and public sector leaders to discuss their successful leadership paths. The program includes:

- Day-long coaching sessions to examine core leadership concepts.
- Leadership benchmarking by visits to corporations and government agencies to see how these organizations achieve results
- Workshops to explore the qualities that define effective and successful leaders.
- Peer coaching groups to investigate concepts from the formal sessions and to work on individual and team results projects.

"The first responsibility of a leader is to define reality. The last is to say thank you. In between, the leader is a servant."

Max DePree
Leadership is an Art,1989

The program challenges participants to build fast-moving, customer-focused, results-oriented organizations. It encourages fellows to question old ways of doing business and to look at new and innovative ways to get results. Each Fellow has an individual project specific to the mission of his or her agency or the federal government.

Throughout the program year, fellows formulate strategies to achieve their desired results. At the end of the year, the fellows "graduate" and join a long list of senior fellows. For more information see the council's Web site at http://www.excelgov.org.

CDER fellows in the program also meet periodically as a group to discuss their experiences within their different coaching groups. They share lessons and ideas from their benchmarking visits and guest speakers.

One way is to write articles such as this about our experiences in the program to share with the entire CDER community. Future articles may deal with benchmarking site visits, workshops and book reviews. The current group of fellows is also proposing that an informal group of past and present fellows meet on a periodic basis for guest seminars, discussions and presentations. They also want to communicate the importance and value of leadership programs to senior CDER management.

For many of us, the program is a journey, one that will teach us what is needed to change in ourselves to become effective leaders. It has been an exciting and educational year so far, one that we hope continues for the benefit of CDER and our stakeholders.

Donna A. Volpe, Ph.D., is a research chemist in the Division of Product Quality Research, Office of Testing and Research.

'Y2K Bug' Infects OIT's Loebach at Parklawn Classic

BY BRONWYN COLLIER

OIT staff member **Paul Loebach** appeared to have acquired the Y2K infection when he showed up at the Parklawn Classic with the bug firmly attached to his head and neck. This is the first recorded incidence of a computer bug jumping to another species. The close proximity of 270 other Classic runners did not, however, result in spreading the infection.

Despite Y2K, competing priorities and tough PDUFA deadlines, CDER boasted a good showing in the 5-mile run including medal winners **Susan Rosencrance, Ray Frankewich, Russ Abbott, Richard Adams, Linda Carter** and **Jim Bilstad.** CDER participants also figured significantly in the 2.5-mile health walk led by FDA Commissioner **Jane Henney.** Overall, there were 1,200 walkers.

This was the 24th annual Parklawn Classic, an HHS activity to promote exercise and healthy habits. **Laura West,** management officer in the Office of Drug Evaluation III, coordinated the event. Evidence that the office was race headquarters quickly mounted up as box after box of T-shirts, prizes and logistical supplies appeared. New ODE III director, **Florence Houn,** graciously took it in stride and worked around the boxes piled up in her office.

Race day dawned sunny and breezy with moderate temperatures. About 275 volunteers dressed in snappy blue Classic T-shirts worked hard to ensure that the event ran smoothly and safely. It was a perfect day for all. Join us next year for the silver anniversary of the Classic!

Browyn Collier is a special assistant in ODE III.

INFORMATION TECHNOLOGY CORNER

Y2K Activities Accelerate; Industry Survey Gets Under Way

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

Year 2000 Activities

As we approach the middle of 1999, CDER's Year 2000 activities are accelerating. These encompass both internal readiness and external outreach. The internal readiness is now focusing on ensuring CDER's desktop PCs are Y2K compliant.

The Agency obtained funding to replace non-compliant PCs, and OIT developed a PC inventory. A project team led by **Margaret Cates** was established and a plan developed to upgrade or replace non-compliant PCs. OIT is developing a Web page to inform CDER employees of Y2K desktop issues and remedies. OIT created an e-mail account for Y2K desktop questions. All questions should be addressed to the account "Y2K."

In other areas, work continues on testing non-mission critical application systems. This effort is scheduled for completion by the end of May.

The Y2K server will then be made available to local developers to test their own ORACLE applications residing on the CDER VMS Cluster or to test a download process from CDER corporate databases. A testing schedule is being developed for all those who requested time on the Y2K server. Please contact **Judy McIntyre** for more information.

The CDER Y2K Task Force chaired by **Mark Goldberger, M.D.,** leads the external outreach efforts. The goal of the task force is to provide assurance to the American public that pharmaceutical firms have addressed the Y2K problem and that they are committed to helping ensure an adequate supply of safe and effective drug products.

A letter and survey to assess industry Y2K readiness was sent to innovator and generic companies as well as distributors and bulk manufacturers on April 21.

The responses to this survey will be compiled and aggregate data will be posted on the Web regarding industry readiness. The Center is also considering posting the names and Web addresses of firms that have indicated they have taken all necessary steps to ensure Y2K compliance.

Planning has begun on the second phase of this effort in which FDA will select a sample of companies and check the accuracy of their survey responses. This sample will be based on various criteria including:

- Sole-source product manufacturers.
- Manufacturers and distributors of the top 200 drugs prescribed.
- Manufacturers of orphan drug products.
- Manufacturers making inconsistent responses to the surveys.

In addition, the task force is meeting with pharmaceutical associations to establish a dialogue between CDER and industry regarding Y2K issues. The task force is also meeting with other agencies and government organizations.

More information about CDER and FDA year 2000 activities can be found on the FDA Web site at http://www.fda.gov/cder/y2k. The OIT point of contact is Judy McIntyre (MCINTYREJU).

(Continued on page 7)

PIKE'S PUZZLER

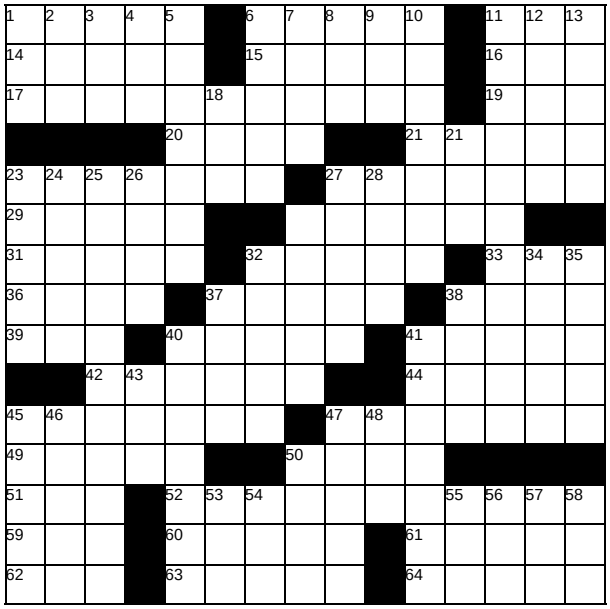
Solution on page 9

Location, Location!

BY PAUL J. MOTISE

Across
1 Hindu text
6 Put out
11 Mil. auxiliary of 1948
14 Relating to carbamides
15 Extinguish, in South Atlantic
16 Ladies' room
17 Mix
19 Matured acorn
20 Propellers
21 TV manicurist
23 Rues
27 Decorated
29 Phantom's venue
30 Loyal
31 When
32 Water conveyances
33 Marketing license, briefly
36 Parent in Paris
37 They come in pieces
38 At the zenith
39 ____ Paulo
40 Measured
41 Heard at 29 across
42 Cleric
44 Keen
45 Spud state resident
47 Contemporary principle
49 Fluid
50 Word before out or of
51 Orca's mating ground
52 Playground mower?
59 100 square meters
60 Shut up, musically
61 Terminal
62 Edge of Marseilles
63 George and Artie
64 Gas generator

Down
1 Chinese Dynasty, 589-618 AD
2 Final container?
3 Gumshoe
4 "Blame it on ___"
5 Of a crab's pre-oral anatomy
6 They may be open or shut
7 It belongs to us
8 Lizard
9 Place
10 Opponents
11 Forest diversity?
12 Saw
13 Deceived
18 Way to stand
22 Quant.
23 Incomplete masks
24 Breathtaking condition
25 Bus valet, perhaps
26 Border lake
27 Put to the test
28 Hose lines
30 Received
32 Georgia town
34 White cliffs locale
35 Nautical direction
37 Madrid residence
38 Part of UAR
40 PC requests
41 It has inner and outer loops
43 Polynesian platform
45 Moslem world
46 Peerless runner?
47 Fools
48 Financial instrument
50 Distort
53 Ooh's partner
54 "His master's voice" corp.
55 Dir. from Atlanta to Boston
56 Stole
57 Tube dimensions, briefly
58 Moreover



Paul J. Motise is a consumer safety officer in the Division of Manufacturing and Product Quality

Project Coordinator Named; CDER Menu Roll-Out Delayed

(Continued from page 6)

QA Development Project Update

On April 21, OIT senior managers signed off on the Improvement Project Plan. The plan is posted on the CDER Intranet on the Quality Assurance Development page under OIT Activities.

Improvement will occur in two phases: a writing phase and an implementation phase. The writing phase addresses assessment findings by providing OIT with policy and guidance in each of the following areas:

- Project planning.
- Project tracking and oversight.
- Configuration management.
- Quality assurance.
- OIT-level project coordination.

The implementation phase consists of training OIT staff in the new policies and guidance and working with OIT project managers to implement the improvements.

As discussed in the April *Pike*, the improvement effort includes the trial of a new position, the project management coordinator, who will address assessment findings regarding the need for greater senior management oversight of projects.

The project management coordinator will regularly review the progress of OIT projects, report summary status information to the OIT director, facilitate project success by obtaining senior management issue resolution as needed and ensure management quality goals are met.

Vali Tschirgi will perform this function for six months, when OIT senior managers will determine the position's merit. During this time, **Jerry Yokoyama** and **Sheila Andrew** will manage the Improvement Project.

Information on the QA Development Project is available on the CDER Intranet under OIT Activities. The OIT point of contact is Jerry Yokoyama (YOKOYAMAJ).

CDER Menu

The CDER Menu will be rolled out at a future date to be determined instead of in May, as previously announced. The delay accommodates upgrades to the PCs, which place a load on the servers. This will ensure that retrieval of data and data entry in client-server applications is as quick as possible for all users.

The CDER Menu will provide improved client-server access to important CDER information systems.

A single menu will allow employees to access the following corporate information systems: Decision Support System, MIS Comments, Establishment Evaluation System, Geriatric Labeling System, Industry Meeting Tracking System, Pediatric Labeling System, Special Products Online Tracking System and Pediatric Exclusivity. The OIT point of contact is **Sally Newman** (NEWMANS).

June Information Technology Training

Monday	Tuesday	Wednesday	Thursday	Friday
	1 **Intro JMP (Part I)** 1-4	**2** **Windows 95** 9-12 **Word Intro** 1-4	**3** **NEST** 9-12 **DFS** 1-4	**4** **Word Formatting** 9-12 **Word Tables** 1-4
7	**8** **Excel Intro** 9-12 **Intro JMP (Part II)** 1-4	**9** **PowerPoint Intro** 9-12 **PowerPoint Charts** 1-4	**10**	**11** **Access & Tables** 9-12 **Access Queries & Reports** 1-4
14 **Access Form Design** 9-12 **Access Report Design** 1-4	**15**	**16** **Excalibur Intro** 8:30-12 **Drug Master Files** 1:30-4:30	**17** **Intro JMP (Part III)** 1-4	**18** **Project 98** 1-4
21	**22**	**23**	**24**	**25**
28 **NEST** 9-12 **NEDAT** 1-4	**29** **LAN** 9-12 **NEDAT** 1-4	**30**		

The catalog, training materials, schedule and on-line registration are on OIT's intranet site at http://oitweb/oit/.

June 4 Awards Ceremony to Honor Center's Volunteer Instructors

By Janice Newcomb

On June 4, the Division of Training and Development will hold its third annual Instructor Awards Ceremony. Awards will be given to a record 167 CDER employees who served during the academic year as instructors for our internal courses or as members of the Committee for Advanced Science Education. Many taught more than one course. Each will receive a small token of appreciation, which remains a surprise until the ceremony. Last year's honorees received a green canvas attaché with the CDER logo.

Instructors and CASE members provide support for the CDER curriculum in addition to performing their regular work as reviewers, managers, administrators or support staff.

Their dedication of time and expertise is above and beyond that normally expected of a CDER employee, but the value to our training and education programs is immeasurable.

In addition, the body of expertise represented by this faculty is immense and world class. Our courses cover topics ranging from orientation to CDER and the drug review process, to basic science and advanced science seminars and workshops. CDER staff have volunteered to develop and deliver courses in all of these areas, as well as communications, leadership, management and discipline specific topics.

The ceremony begins at 2 p.m. on Friday, June 4, in Conference Room D of the Parklawn Conference Center. Center Director **Janet Woodcock, M.D.,** and **Nancy Smith, Ph.D.,** Director OTCOM, will be the featured speakers. The Division of Training and Development staff will be handing out the awards. There will be a reception following the ceremony.

Janice Newcomb is Director, DTD.

UNION CORNER

Unfair Labor Practices—Part II

BY ROBERT YOUNG

Last month, I discussed unfair labor practices that resulted from actions which agencies took against employees. This month, we'll look at unfair labor practices by labor organizations, how a complainant files an unfair labor practice charge and how the Federal Labor Relations Authority processes them.

Union Unfair Practices

The Federal Service Labor-Management Relations Law imposes duties and responsibilities not only on agencies but also on labor organizations. The law says, for example, that it is unfair for a labor organization to:

- Interfere with, restrain or coerce employees in the exercise of their rights under the law.
- Refuse to consult or negotiate in good faith with an agency.
- Call or participate in a strike.
- Conduct internal union business on duty time.
- Fail to represent employees fairly in a bargaining unit in matters which are within the union's scope of responsibility as the exclusive representative and over which the employee may not seek representation from another source, such as a private attorney.
- Fail to represent an employee properly.
- Otherwise fail or refuse to comply with any provision of the law.

This short list suggests that unions generally are unlikely to run afoul of the law. Most unions spend a great deal of time and energy attempting to get employees to exercise their rights, defending those who did exercise their rights and engaging agencies in negotiations and bargaining. Very few federal unions call or participate in strikes or need to conduct internal union business, such as the election of officers, on duty time.

Although any person can file a charge of an unfair labor practice, historically 95 percent of charges have been filed by unions against an agency and fewer than 5 percent have been filed by employees against an agency or a union and by management against a union.

The two typical situations in which a ULP charge is brought by an employee against a union are:

- An non-union member feels he or she is being treated differently from union members in the administration of a collective bargaining agreement or other condition of employment.
- An individual employee has a dispute with the agency that adversely affects him or her and feels the union has failed to provide effective representation in that dispute.

The union may not treat a non-union employee differently from its dues-paying members in matters where the non-member has no other choice than the union for representation and over which the union has exclusive control. This is called the duty of fair representation. For example, the union cannot negotiate a liberal alternative work schedule plan for union members and, as a trade-off, allow management to impose a restrictive alternative work schedule plan on non-union employees. A union cannot vigorously enforce the provisions for granting an alternative work schedule for union members, but ignore the requests by non-union employees to obtain the same work schedule.

In ineffective representation cases, the union to be held liable must have engaged in conduct that amounts to more than mere negligence or ineptitude. The union's conduct must be outside the range of reasonableness and must have constituted a deliberate and unjustified treatment of the complaining employee different from other bargaining unit employees.

The union's mistakes must rise to the level of being deliberately and unjustifiably arbitrary and constitute bad faith conduct. This standard may remind some readers of the old adage: "You only get what you pay for." At FDA, the core problem is not so much money, in the form of dues, but the generous contribution of time, talent and effort in the mutual aid and protection of fellow employees.

Procedures

Any person may file an unfair labor practice charge. It is not necessary that the person filing a charge be the aggrieved party. An agency manager, for example, can file a charge against his or her own agency. To initiate a charge the following information must be submitted on a prescribed form in writing and signed:

- Name, address and telephone number of the person making the charge.
- Name, address and other information about the organization against whom the charge is made.
- A clear and concise statement of facts constituting the alleged unfair practice, the provisions of the law alleged to have been violated and the date and place of occurrence of the acts.
- A statement of other procedures invoked involving the charge.
- Supporting evidence and documents.

The charge must be filed within six months of the precipitating conduct or events with the appropriate regional director of the Federal Labor Relations Authority. The charge should inform the organization of the general nature of the alleged violation.

After investigation by the Federal Labor Relations Authority and if the charge is found to have merit, the regional director attempts to reach a voluntary settlement to remedy the situation. In the past decade, 89 percent of all charges filed were either withdrawn, dismissed or settled at this stage.

If the settlement attempt fails, a complaint is issued. Failure to answer the complaint or respond to any allegation constitutes an admission, absent a showing of good cause to the contrary. If the facts of the case are in dispute, it is heard by an administrative law judge who issues a decision that may be reviewed by the authority. An average of 88 percent of all cases for which the Authority issued a complaint ended in settlement without a hearing.

Remedies

By statute the FLRA can order an agency or labor organization engaged in or engaging in an unfair labor practice to:

- Cease and desist from any such unfair

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Dr. Henney Outlines Priorities for FDA at CDER Seminar

By Laura Alvey

FDA Commissioner **Jane Henney, M.D.,** was the featured speaker at the CDER Seminar on May 5. Dr. Henney addressed a close-to-capacity crowd on her vision of the priorities and emerging issues facing the Agency.

Dr. Henney outlined what she sees as the five major priorities facing the Agency:

- Implementing the FDA Modernization Act.
- Enhancing the Agency's science base.
- Ensuring food safety.
- Enhancing blood safety.
- Restricting minors' access to tobacco.

After addressing the specific components of the Modernization Act, Dr. Henney summarized what she characterized as FDA's outstanding implementation record since enactment:

- 19 final rules.
- 10 proposed rules.
- 12 notices.
- 38 guidance documents.
- Two reports.

She expressed her gratitude to the many employees who have contributed to this, especially considering it has only been 18 months since the Act became law.

The one area that Dr. Henney said she was most passionate about was enhancing the Agency's science base. "This is the only way at the end of the day that we can say with certainty and conviction that our decisions are based soundly on science," she said. "Our Agency basically sits in judgement of other scientific organizations, and if we don't have scientists that are of the same caliber as the organizations we regulate than we can't in good faith support our decisions.

Greater training opportunities, the possibility of sabbaticals and further education were some areas she outlined that might help make sure that opportunities are in place to retain FDA scientists and keep them at "the top of their game."

Dr. Henney emphasized that the issue of food safety is at the core of the Agency's mission and that the public looks primarily to FDA, not the Agriculture Department, to protect the nation's food supply. She cited several factors that have contributed to the nation's food safety problems in the past decade, including:

- What people eat has changed. Americans are no longer just a meat-and-potatoes culture. They like lots of fresh fruits and vegetables
- Where people eat has changed. Over 50 percent of meals are eaten in a restaurant or prepared by someone else.
- Who's eating is changing. There are more elderly and more people with compromised immune systems.
- The emergence of new foodborne pathogens.

Dr. Henney said that "remarkable progress" had been made in improving blood safety in the last 15 years. The risk of acquiring an infection from a blood transfusion is lower than ever before. The industry and FDA have had to undergo vast transformations in the past decade and both must remain vigorous in maintaining what has been achieved.

The tobacco initiative was begun for a good reason, she said. More than 400,000 Americans die each year from tobacco-related illnesses. Access to tobacco by minors has been restricted with a minimum age for purchase and requirements for a photo I.D. Currently, the Agency is contracting with 41 states, the District of Columbia and the Virgin Islands on enforcement of these provisions.

Dr. Henney also highlighted budget requests for fiscal year 2000. FDA is seeking large increases in funds for inspections and injury reporting programs.

She ended with an outline of emerging issues, including:

- Dietary supplements and alternative medicine.
- Y2K preparedness.
- Genetic testing.
- Internet promotion and sale of regulated products.

The questions and comments from the audience focused on:

- Improving intercenter communication.
- Facilitating more interchange with other science-based organizations such as the National Institutes of Health.
- Enhancing communications with the public and Congress.

In response to a question about botanicals and supplements, Dr. Henney said that it is a challenge to draw the boundaries among drugs, foods and dietary supplements.

Laura Alvey, a consumer affairs specialist in FDA's Office of Consumer Affairs, was on detail to OTCOM.

Unfair Labor Practices—Part II

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labor practice.

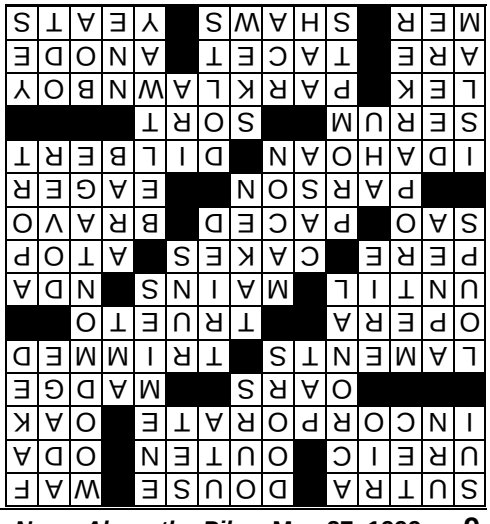
- Renegotiate a collective bargaining agreement and require that the agreement be given retroactive effect.
- Reinstate an employee with back pay, allowances and differentials.
- Take such action as will carry out the purposes of the statute.

Examples of actions that the authority has ordered as remedies include:

- Retroactive promotions and awards.
- Reimbursement for losses not covered by back pay, such as travel expenses or late charges for delayed car and mortgage payments.
- Recision of disciplinary actions.
- Posting of notices explaining violations.
- Reinstatement of previous practices.
- Payment of attorney's fees.

Enforcement of the authority's orders is obtained through the U.S. circuit courts of appeals.

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



Risk Management Task Force Report Calls for Systems Approach

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before they could be implemented.

The task force noted that many of its specific recommendations for Agency improvements in existing systems are already underway.

These recommendations generally include:

- Establishing separate quality assurance units in each center.
- Ensuring and documenting ongoing professional education and core competency training for all reviewers.
- Completing the good review practice documents and keeping them up-to-date.
- Rapidly completing the Adverse Event Reporting System.
- Integrating existing postmarking surveillance systems so that analytical tools, data entry and editing can be uniformly applied and all information made readily available to each reviewer.
- Enhancing and intensifying surveillance of newly marketed drugs.
- Developing new methodological tools for making inferences from existing datasets.

Options that might improve the entire system but would require engaging other stakeholders include:

- Examining and evaluating mechanisms to address the inherent limits of premarket development, such as, wider use of large, community-based simple trials or restricting exposure during the early postmarket period.
- Designing and implementing additional mechanisms to obtain postmarket information, such as sentinel sites, prospective product use registries and enhanced links to external databases.
- Enhancing FDA's research in epidemiological methods.
- Enhancing FDA's role and responsibilities in risk communication.
- Increasing the number of postmarketing risk interventions for products with special risks, such as restricted distribution or mandatory education for health professionals and patients.

Other CDER members of the task force were **Deborah Henderson,** Executive Operations Staff; **Ralph Lillie, R.Ph., MPH,** OPDRA; **Leah Palmer, Pharm.D.,** DDMAC; and **Nancy Smith, Ph.D.,** OTCOM.

Top FDA Officials Address Drug Safety in May 12 *JAMA*

In a seven-page special communication in the May 12 issue of the *Journal of the American Medical Association,* top FDA officials examined the cluster of five drugs withdrawn in a recent 12-month period.

"When the removed drugs were analyzed by date of approval, no increase in the number of drugs taken off the market was seen," the authors wrote, "demonstrating that reduced review processing time was not the reason for the cluster of removals. We conclude that the Agency's drug review procedures and postmarketing surveillance system after a drug has been marketed are currently adequate but must continually adjust to future challenges."

The authors were **Michael A. Friedman, M.D., Janet Woodcock, M.D., Murray M. Lumpkin, M.D., Jeffrey E. Shuren, M.D., J.D., Arthur E. Hass** and **Larry J. Thompson, M.S.**

'CDER Live!' TV to Profile Office of Pharmaceutical Science on June 8

By Elaine Frost

'A Conversation with the CDER Office of Pharmaceutical Science" will form the basis for the third edition of "CDER Live!," a satellite broadcast to regulated industry co-sponsored by CDER and the Drug Information Association. The program will air June 8 from 1 p.m. to 4 p.m. EDT to downlink sites throughout the United States and parts of Canada.

CDER sites will include Parklawn, Conference Rooms G and H; Woodmont II, Conference Room G; Metropark North, Room S-259; and Corporate S-100.

The first part of the program will feature information about the assignments and responsibilities that form the core activities of the four OPS offices:

- Office of Generic Drugs.
- Office of Clinical Pharmacology and Biopharmaceutics.
- Office of New Drug Chemistry.
- Office of Testing and Research.

The first panel will include **Roger L. Williams, M.D.,** Deputy Center Director (Pharmaceutical Science); **Lawrence J. Lesko, Ph.D.,** Director, OCPB; **James T. MacGregor, Ph.D.,** Director, OTR; **Eric B. Sheinin, Ph.D.,** Director, ONDC; and **Douglas L. Sporn, MBA,** Director, OGD.

Discussions for the second panel will center on three "hot topics" in OPS:

- A botanicals guidance with **Yuan-Yuan Chiu, Ph.D.,** Deputy Director, ONDC.
- Implementation of Section 116 of the FDA Modernization Act on manufacturing changes with **Nancy B. Sager, MBA,** Associate Director for Quality Implementation, OPS.
- A drug interactions guidance with **Shiew-Mei Huang, Ph.D.,** Associate Director for Science and Regulatory Policy, OCPB.

The program will also feature several pre-recorded interviews, including a follow-up discussion on PDUFA II with Center Director **Janet Woodcock, M.D.,** and Searle Executive Vice President for Medical Research **John Alexander, M.D., MPH.**

Deborah Henderson, Director, Executive Operations Staff, will again moderate the program which will be broadcast from a Washington, television studio.

Through a co-sponsorship agreement with CDER, the Drug Information Association, a non-profit, underwrites these programs by selling access information to its members, with the goal of breaking even on out-of-pocket costs.

There are no production costs to the government and no fees for its access to the broadcasts. The goal is to build a communications bridge with regulated industry. Evaluations of the programs have been positive and there is strong support for more programming in the future.

Elaine Frost is a public affairs specialist in OTCOM.