news along the pike

CENTER FOR DRUG EVALUATION AND RESEARCH

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FDA Releases Modernization Act Strategic Plan

Focus on Risk-Based Priority Setting, Science, Stakeholders

BY NORMAN J. OLIVER

Risk-based priority setting tops FDA's list of strategic directions outlined in an 81-page plan unveiled Nov. 23. The plan identifies "bold and innovative approaches to meet the increasingly complex public health challenges of the 21st century." The announcement meets the deadline in the 1997 FDA Modernization Act.

The plan is designed to bridge the gap between what FDA is required to do by law and what it is able to get done with current resources. It moves FDA closer to fulfilling its mission of consumer health protection and promotion.

The plan capitalizes on the opportunity the Modernization Act gives FDA to work with its stakeholders (see August and September *Pikes).* The plan identifies strategic directions for the Agency, addresses the objectives stipulated by Congress and outlines emerging challenges that are creating a gap between expectations and performance. The plan can be downloaded from FDA's Web site at http://www.fda.gov/oc/fdama/fdamapln/default.htm.

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Tamoxifen Approved for Breast Cancer Risk-Reduction

Breakthrough Cancer Pain Treatment OK'd; New Warnings

Recent drug news concerning the Center, announced in FDA press releases and talk papers, includes:

- The Oct. 29 approval of tamoxifen for reducing the incidence of breast cancer in women at high risk for developing the disease.
- Approval of a new dosage form of fentanyl that offers relief for breakthrough cancer pain.
- New pediatric labeling for inhaled, intranasal corticosteroids.
- New warnings of fatal liver injury linked to the anti-Parkinson's drug tolcapone.

Tamoxofin has been used as a breast cancer treatment for more than 20 years. The Center's approval of the new indication for cancer risk reduction resulted from a recent National Cancer Institute study of the drug in women judged to be at increased risk of breast cancer. The study showed that tamoxifen reduced the chance of getting breast cancer by 44 percent. The data also showed that tamoxifen treatment did not completely eliminate breast cancer risk, and that its longer term effects are not known.

In approving the drug for this new indication, FDA emphasized that tamoxifen should

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CDER Fall Honor Awards Highlight Individuals, Teams

BY JACKIE BARBER

The presentation of the first in a new category of CDER peer awards, Excellence in Mentoring, highlighted the Fall Honor Awards Ceremony held Nov. 20 at the Gaithersburg Marriott Washingtonian Center. The new award recognizes the importance mentors play in the development of our staff.

"The theme of this fall's presentations is communications, education and outreach," said Center Director **Janet Woodcock, M.D.** "Those receiving awards have shared their unique insights and perspectives with the country. Resources are shrinking but resourcefulness is increasing. Today's government is being asked to do more with less, and we must all continue to work together to work smarter. The awards prove that many of you are already doing just that."

The Montgomery County Police Color Guard presented the colors, and **Kevin Barber** sang the National Anthem. **Ruth Clements** introduced each award, and office directors provided an explanation of individual or team achievements. Those honored at the ceremony

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JOE'S NOTEBOOK

Rx: Plain Language ~~PRN~~ as Needed

Gorgias: Ah yes, if you knew all, Socrates, how it [rhetoric] comprises in itself practically all powers at once! And I will tell you a striking proof of this. Many and many a time have I gone with my brother or other doctors to visit one of their patients. We would find them unwilling either to take medicine or submit to the surgeon's knife or cautery. When the doctor failed to persuade them, I succeeded, by no other art than that of rhetoric.

—Plato (ca. 428-347 B.C.), *Gorgias*

The connections among good government, medicine, public health and communications are as old as Western civilization itself. It was exactly one-third of a century ago that I first came across this passage in one of our *Ur*-texts on government and public communications. But I've remembered it ever since. Plato has Socrates make the point that the rhetorical art—communications, if you will—doesn't create any true knowledge of its own. However, Socrates, who goes around poking holes in Athenian stuffed shirts, lets stand this particular example used by Gorgias.

How well did Gorgias translate and communicate the doctor's technical understanding of disease and its treatments? Was the public health of Athens improved? How often did the ancient Athenian physicians consult their public affairs folks? It appears from this passage that some of their patients were making their own choices about their health care and not surrendering their autonomy to the doctor. Communications in language they could understand persuaded them of the benefits of the treatments of the day.

Gorgias was a respected and influential member of the first group of professional educators—the sophists. It's too bad for Gorgias' reputation that we usually associate the sophists with the term "sophistry"—the use of seemingly plausible arguments to deceive someone else. Unfortunately, we have only Plato's dialogue and fragments of Gorgias' texts left, not enough to come to a well-rounded judgment of the man.

We do know that, as those early Greek experiments in democracy developed, there was parallel development in the systematic study of communications. The Greeks and their Roman inheritors have left a substantial body of theoretical and practical work on communications—or rhetoric. One of their categories was style, and they distinguished three types: a grand, a middle and a plain. Whenever, decisions on public issues have fallen into the hands of an elite, the style reverts to the grand or, even worse, the swollen.

CDER's ongoing transformation into an open, accountable agency and the increased autonomy of the patient in our day have created a ripe environment for the plain language initiative. Clear communications about medicine and its benefits has proven a popular portion of our Web site. Agency plain language honcho **Joanne Locke** reports that the President and Vice President's message on plain language has even received a positive reception among FDA and CDER lawyers. They have told her that it's plain language they would prefer to write.

That we are the only regulatory agency in HHS seems to stand in the way of plain language. The National Partnership for Reinvention prepared two regulatory documents as a test, one in traditional, formal language and one in plain language. They sent them to judges across the country. They report 85 percent of the judges preferred the plain language version.

Executive Operations Staff head **Debbie Henderson** will be spearheading the CDER effort. She'll be assisted by **Linda Brophy** in OTCOM, **Nancy Derr** in the Regulatory Policy Staff and **Lee Zwanziger,** also from Executive Operations. The Pike's Communications Corner (page 6) will be doing its part to bring you samples, tidbits and helpful hints on plain language.

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

What Is Customer Service?

BY JIM MORRISON

Customer service is a trendy concept. An Executive Order, No. 12862, mandates that we do it. But what is the "it," and who is our customer? The answers may vary greatly depending on the circumstances.

The FDA Customer Service Plan lists four types of customers: consumers, health professionals, other agencies and the regulated industry. During internal discussions about CDER's mission, vision and values, the term "customer" raised issues among staff who could readily see the consumer as a customer, but viewed the regulated industry as more of a stakeholder than a customer. Some used the term "compelled customer."

Our scientific education has conditioned us to believe that if you can name something and relate it to other named things, you know something about it. One might call it wisdom by taxonomy. What do we learn about customers or service by naming categories into which all people with whom we interact can be sorted? Not much. This categorization of customers may be useful for planning purposes, but it distracts us from an essential idea.

Let's take the consumer, whom we all agree is our ultimate customer. Which consumer is that? Is it the terminal cancer patient who wants access to highly risky experimental drugs and willingly accepts the risk that the therapy may be ineffective or harmful? Or is it the hypertensive patient who want assurances that the risks and benefits associated with the medicine he or she takes have been well-characterized by large clinical trials? Or is it the taxpayer who wants safe and effective drugs with a minimum of delay and expense?

It's all of the above and millions more. Each person is a consumer and each person has different needs and expectations at different times or in different circumstances.

Perhaps a better definition of a customer is the person with whom you are dealing right now. It may be an attorney representing a small manufacturer, a patient with a question about his or her medication, a representative in Congress who writes on behalf of a constituent, or it may be your co-worker in the next office who has a review she wants to discuss. Is there any reason to give one of these better service than another? I would guess that many in CDER would say that the representative would get better service, because, after all, Congress funds the Agency. It boils down to what you mean by "service."

Service does not imply immediate attention. When we are in a busy bank, we understand that not everyone can be accommodated immediately, so we wait and do not complain about the service unless the wait is excessive or unless our teller is rude or unhelpful. All of these breaches in customer service are difficult to define but easy to recognize when they happen to you.

Service allows for priorities, and it allows for queuing. "Service," like "customer," cannot be described taxonomically. It varies with each situation and with each customer. Inherent in the concept of excellent service are the notions of fulfilling needs and of meeting or exceeding customer expectations for quality, timeliness and courtesy. It also entails tailoring the response to the individual requirements of each customer and of each situation—flexibility. Excellent customer service requires that you mentally put yourself to be in the position of the customer—empathy.

In the example of competing priorities, the representative might wait while the co-worker's question concerning a review that is due that day gets answered. Or the attorney may wait for the patient because their calls arrived in that order. There are no hard and fast rules.

In addition to flexibility and empathy, excellent customer service requires tact, judgment and an understanding of the substantive issues at hand. When it occurs, the customer feels that someone in the organization genuinely cares that their needs are met and did all that was reasonably possible to meet them.

Feedback I get from people outside CDER is almost always positive about the professionalism and willingness of Center staff to be helpful. That is a great base upon which to build a first class customer service reputation. For further information about customer service, I recommend reading the FDA Customer Service Plan at http://www.fda.gov/oc/customerservice.

Jim Morrison is CDER's Ombudsman.

Child Health Care Advocate, ODE III Head Botstein to Leave Agency

Paula Botstein, M.D., acting Director, Office of Drug Evaluation III, will be leaving CDER Nov. 30 to pursue her interests in the private sector. Dr. Botstein came to the Agency 22 years ago from Children's Hospital Medical Center in Boston.

While at Children's, she became interested in drug safety issues and came to the Agency for "a few years" to learn more about adverse events. Those few years grew to a distinguished career of selfless public health service, and she has been a valued leader in many of the Center's more visible public health initiatives.

Dr. Botstein brought her scientific and managerial expertise to the Office of Review Management as deputy director in ODE I and then in setting up and serving as acting director of ODE III.

In the past, she led efforts to make CDER's regulation of over-the-counter consumer self-medication products more efficient and more responsive to the needs of the American people.

Because of her professional background as a pediatrician, her most lasting legacy will be her leadership efforts to make medications available to children and to foster the development of science-based dosing and other labeling information for using medicines in children.

Her passion for child health care culminated with her involvement in the 1994 pediatric labeling regulation change, the 1996 proposed pediatric rule and the sections of the FDA Modernization Act on exclusivity for specific pediatric studies in certain drug products.

How Courses Are Developed, Effect of Budget Crunch Outlined

BY JANICE NEWCOMB

During the next few weeks, the Division of Training and Development will be making final plans for the spring semester. As we complete these plans, I thought it would be a good idea to let you know what's going on in training and what to expect. This is the first in a series of articles we have planned to provide you with more information on the training and education activities available. Here, we have tried to answer some of the questions we get asked all of the time.

How do you decide what courses to offer?

Each semester, we try to balance the courses we offer by considering a number of different factors, including:

- How many new review staff have been hired within the Center.
- What specific knowledge and skills CDER staff need to do their jobs.
- What courses have been offered in the recent past.
- What managers tell us their staff need to learn more about.
- Who has indicated an interest—or who has the time—to teach a course.
- Available funding to hire external experts or pay for facilities and materials.
- The level of quality that can be expected from each possible course.

We work with the Committee for Advanced Scientific Education to ensure the quality of the advanced scientific courses under development and to prepare a schedule of Wednesday Scientific Seminars. We are also developing core competencies for each major discipline within CDER. We will use them to conduct a training needs assessment and develop an overall curriculum. In the future, core competency data will be used to develop guidelines for each discipline. New employees have information on which courses should be taken to learn specific skills and when it is best to take them.

Does my division or office have to pay for me to attend one of the courses?

There is no charge for attending any course organized by the Division of Training and Development. Most of our courses are developed and presented by CDER staff, with minimal costs for materials and facilities support (such as videoconferencing or conference room fees).

The Division of Training and Development pays for the materials and facilities centrally, so there is no cost to you or your division or office. The division works hard to minimize the cost of training and education programs for the Center.

How does the budget crunch affect CDER's training and education program?

Over the next few months, you will notice that we are taking extra measures to reduce the costs associated with training, due to the budget crunch. For example, we will no longer be giving every person who attends a course a textbook. Copies of the texts will be available through the Medical Library or Learning Resource Center.

We are scheduling as many activities as possible in our training room in the Parklawn Building or in your conference rooms to reduce the cost of facilities rental. In addition, to cut the copying costs associated with courses, handouts for each course will be posted to a page on CDERnet. You will then be responsible for downloading and printing the handouts, if you want copies.

By reducing the costs of each course, we hope to maintain the number of courses offered. We are not planning to offer any contractor-taught courses and are reducing the number of times a course may be offered.

What if my division or office has customized training or development needs?

The Division of Training and Development can help by customizing many programs for your specific needs. For example, we have helped a number of divisions and offices plan and conduct staff retreats. An experienced DTD facilitator will work with you to prepare an agenda, develop activities designed to achieve a specific objective and then carry out the plan on the day of the retreat.

In addition, we can prepare customized short courses for specific groups or help you develop a short course for your own division or office.

How can I get involved in teaching?

We are always looking for volunteers to help with courses. We use volunteers as instructors and presenters in most of our courses. CDER is extraordinarily lucky in the number of people who enjoy teaching and becoming involved in training and education programs.

Many senior managers in CDER, members of the Committee for Advanced Scientific Education and individuals from almost every office in CDER have become involved in helping to develop CDER staff. For example, the New Employee Orientation program takes 10 people who volunteer each time the program is given. The Division of Training and Development could not meet its mission without the assistance and expertise of these volunteers. If you are interested in volunteering, please contact me. Please be aware, however, that everyone who teaches or coordinates in a CDER course, does so in addition to their existing work assignments.

Where can I get more information about CDER training and education program?

For more information about the CDER training and education program or the Division of Training and Development, please e-mail me (NEWCOMBJ) or **Dale Wilcox** (WILCOX). You can visit our CDERnet homepage at http://cdernet/dtd/index.htm. We maintain a list of current activities in training under the What's Happening button on CDERnet. For more information on this, contact **Amy Mason** (MASONA).

Look in future issues of the *Pike* for additional articles on training.

Janice Newcomb is Director of the Division of Training and Development.

More Flexible, Efficient Corporate Database Tops List of OIT Plans

BY JUDY MCINTYRE

This is the first of a series of updates on the activities of the Office of Information Technology. Over the next few months, columns in the *Pike* will describe all of OIT's major activities, current and planned, in support of CDER's information technology initiatives. In the future, OIT will provide more detailed and updated information about each activity through the CDERnet OIT Web page. Comments or questions about any of these projects can be sent by e-mail to the OIT point of contact for each project.

Corporate Database Redesign: The central component of CDER's corporate database, known as COMIS, was designed in 1985 and became operational in 1986. Over the last 14 years, there have been many changes in what was the Bureau of Drugs, the Center for Drugs and Biologics and now the Center for Drug Evaluation and Research. The corporate database has been modified and extended dozens of times to support multiple reorganizations, user fees, the FDA Modernization Act, electronic submissions and many other policy and procedural changes in CDER.

The need for a more flexible and efficient database structure to meet CDER's rapidly evolving needs has prompted OIT to begin a major redesign. The Project Champion Team, chaired by Center Director **Janet Woodcock, M.D.,** held it's first meeting Sept. 25. Plans call for interviews and interactive workshops with key representatives of major functional areas over the next few months.

Although it is very early in this process, the plan is to have a core database design by May. The process of building new applications and converting the existing data will begin once the contents and design of the core database are approved.

The OIT point of contact is **Mark Gray** (GRAYM).

Year 2000 Renovations: Some computer programs and systems incorrectly process dates for the year 2000 and beyond. Simple functions that compute the number of days between two dates can return unexpected results when given the year "00." Virtually all of CDER's central computer applications use the ORACLE database and fully support dates in the next century. Where necessary, OIT staff have modified and tested changes to reports and data entry screens that use a two-digit year.

As part of an Agency program, all critical systems have been identified and are being tested under a formal independent validation and verification process. This is expected to be completed for all critical systems by March.

In addition, OIT is working to address the year 2000 impact on CDER's technical infrastructure, including PCs, servers and telecommunications systems. More information about year 2000 activities can be found by clicking the Year 2000 button on FDA's home page at http://www.fda.gov.

The OIT point of contact is **Judy McIntyre** (MCINTYREJU).

VMS/ORACLE Upgrade: OIT is currently planning the next major upgrade of the VMS operating system and the ORACLE relational database management system. In the three years since the last major upgrade, both VMS and ORACLE have undergone major enhancements to provide better performance and increased functionality.

VMS and ORACLE support the primary infrastructure of the Center. Major systems such as All-In-1 and TeamLinks, all the COMIS components, network printers and the local area network run on the VMS cluster.

This upgrade will move the CDER VMS cluster from a 32-bit to a 64-bit operating system and will enable the Center's systems to operate in a more reliable and higher performance environment. The upgrade is tentatively scheduled for spring.

Extensive planning and testing will be conducted before the actual upgrade, so the event will be as transparent to everyone as possible.

The OIT point of contact is **Greg Brolund** (BROLUND).

Web Development Environment: It has become very common to share information through the World Wide Web using a standard Web browser. The FDA Web site, CDERnet and the CDER WEBLERN system are examples that provide a wide variety of information in an easy-to-use format.

OIT is planning to make use of the Web environment to provide retrieval and, in some cases, update capability to the CDER corporate database. The OIT application development and infrastructure support divisions are collaborating in the evaluation of several Web development technologies. These include ORACLE and Documentum Web servers and tools, Citrix Winframe and the new Microsoft Windows Terminal software.

Product testing and evaluation will begin on a Windows NT server over the next few months.

The OIT point of contact is **Janet Gentry** (GENTRY).

Development Project for QA: OIT established a Quality Assurance Development Project in August to initiate continuous improvement and address OIT goals for innovation, excellence, reliability and cost-effectiveness.

The project is focusing on OIT software engineering. It uses the Software Engineering Institute's Capability Maturity Model for achieving efficient, high-quality practices and procedures. This means OIT software projects will have documented procedures to ensure good project planning, project tracking and oversight, quality assurance, configuration management, requirements management and contractor management.

Basic project management processes are established to track cost, schedule and functionality. More information about the QA development project can be found under OIT Activities on OIT's intranet homepage at http://oitweb/oit/.

The OIT point of contact is **Vali Tschirgi** (TSCHIRGIV).

Judy McIntyre is a supervisory computer specialist in OIT's Quality Assurance Staff.

STRATEGIC PLANNING CORNER

A Behind-the-Scenes Look at 18-Month Gestation for FDA Budget

BY CHARLENE CHERRY

Budget formulation in CDER has taken on new meaning with the advent of performance planning and the Results Act. The Results Act, or GPRA as it was formerly known, requires agencies to link annual budgets with performance planning—a process slowly taking shape in FDA. Future performance plans will be the driver for annual budget requests. This article will describe, in a very broad sense, how each fiscal year's budget comes to fruition.

The budget execution process, or the process of allocating and spending approved fiscal year money, is a visible one compared to budget formulation, or how future budget needs are determined. Under normal circumstances, budgets become official and agencies are authorized to spend on Oct. 1, the start of the new fiscal year. The process for developing the request implemented on Oct. 1, however, begins almost a year and a half earlier. The Results Act has added a new dimension to that process by incorporating annual performance goals.

The FDA budget cycle begins every March when the centers develop budget estimates for the fiscal year that will begin a year and a half later. Performance goals are also developed at this time. Future budget estimates will be based on goals identified in Center performance plans. This initial budget is referred to officially as the *Preliminary Budget and Performance Plan Submission to DHHS,* or *Preliminary DHHS Budget.* It is sent to the Secretary, Department of Health and Human Services, in June. This submission begins the process of negotiating and justifying budget increases. Once discussions with the Department are complete, usually in August, the *Preliminary DHHS Budget* is sent to the Office of Management and Budget. It now becomes the *Justification of Budget Estimates and Performance Plan Submission to OMB,* or simply, the *OMB Submission.*

The rubber meets the road at OMB. Over the next several months OMB gives FDA's submission a critical review. Major cuts in program funding can occur at this stage. Once OMB has reached a final decision on funding levels, the budget request is "passed back" to the agency. This is known as the *OMB Passback.* OMB gives the Agency the opportunity to appeal funding cuts at this time. Once the appeal process is navigated, usually December, the final OMB budget is presented to the Agency.

During each of these phases, the Commissioner, center directors and other FDA officials are given the opportunity to formally present and defend the budget request to department and OMB officials.

Even though the holidays are upon us, that doesn't mean anyone gets a break. Once the final passback is received from OMB, centers immediately begin preparing the budget submission for congressional review. This is known as the *Justification of Estimates for Appropriations Committees and Performance Plan,* or, simply, the *CJ.* Narrative justifications are reviewed. Prior year accomplishments are added. Issue papers and briefing materials are prepared to assist the Commissioner in defending the budget request.

The final package must be on the doorstep of Congress the first Monday of February when congressional hearings before the appropriations committees begin. In recent years, this phase hasn't ended until well into October and, at times, November or December. If this phase goes beyond Oct. 1, Congress must enact a continuing resolution to give departments and agencies the authority to spend.

I've simplified the process to give you a broad idea of the effort that goes in to developing Agency budgets. In reality, it's a complicated, arduous affair that can frustrate even the most seasoned civil servant. Visit the Office of Management CDERnet site to learn more about the CDER budget and budget process.

Charlene Cherry is Director, Strategic Planning Staff, Office of Management.

COMMUNICATIONS CORNER

Plain Language Mandated in New Documents This Year, Regs Next Year

BY JOE OLIVER

The ancient Roman poet Horace advised writers to set aside their projects for seven years before going back to revise them.

In this age, we don't have that luxury. Indeed, Acting Commissioner **Michael Friedman, M.D.,** has endorsed the deadlines in the plain language directive from President Clinton and Vice President Al Gore.

That directive spells out the types of documents that need to be in plain language and when:

- As of Oct. 1, you should have been using plain language in any new documents you write—other than a regulation—that explains how to obtain a benefit or service or how to comply with a requirement you administer or enforce.
- By Jan 1, 2002, any document that fit that description but was created before Oct. 1 has to be converted.
- By Jan. 1, 1999, you have to use plain language in all proposed and final rules published in the *Federal Register.*

According to the White House directive, plain language documents are logically organized and designed for easy reading. They use:

- Common, everyday words except for necessary technical terms.
- "You" and other pronouns in place of awkward third-person constructions.
- Verbs in the active voice.
- Short sentences.

I once had a boss in the military with a fondness for inflated language. I would suggest that we rewrite his messages to the field more simply before sending them. He said we didn't have time and then had to spend the next two days on the telephone explaining what he meant.

Reading plain language is easy. Writing it is another story. That takes time up front but saves time in the end. Some resources to get you started can be found at http://www.plainlanguage.gov/ and http://www.fcn.gov/resource/plain.htm.

300 from Agency, Industry Attend Joint FDA-DIA Workshop

BY JEAN YAGER

About 300 enthusiastic participants from FDA and industry attended the second Joint Project Management Workshop co-sponsored by FDA and the Drug Information Association in Bethesda Oct. 14 to 16. FDA participants included representatives from CDER and the Center for Biologics Evaluation and Research. Industry attendees included project managers and regulatory affairs professionals from large and small companies.

The focus and theme of this very successful workshop was building bridges between industry and FDA to facilitate the drug development and drug review process through effective communications and a better understanding of each other's processes.

Presentations and workshop activities were comprised of four major educational units:

- *The project managed team approach to drug development and drug review in industry and at FDA.* This was followed by table topic discussions of best practices. Some of the practices shared by participants included critical qualities for team players, maintaining high performance teams and conflict management
- *Video vignettes of the team drug development process in industry and the team review process in FDA.* The vignettes provided an opportunity for the analysis of logical interaction points between industry and FDA processes
- *Key factors critical to successful collaboration between industry and the FDA.* The critical key factors identified were: meaningful information exchange, communications, adherence to commitments and clarity of expectations
- *"Fireside chats."* These informal discussions provided participants an opportunity to hear speakers relate real-life case studies in which they had incorporated the key factors in their interactions to create a collaborative atmosphere that facilitated the drug development and review process.

The workshop was co-chaired by myself and Terry Baker, project management director at Wyeth-Ayerst. The support of executive management from both centers contributed greatly to the success of the workshop. Opening remarks were presented by Center Director **Janet Woodcock, M.D.,** and **David Feigal Jr., M.D.,** Deputy Center Director (Medicine), CBER. Closing remarks were provided by **Murray Lumpkin, M.D.,** Deputy Center Director (Review Management), CDER, and **Rebecca Devine, Ph.D.,** Associate Director for Policy, CBER.

> "The focus and theme of this very successful workshop was building bridges between industry and FDA . . ."

Much credit for the overwhelming success of the workshop goes to the program planning subcommittee leaders: **Joe Buccine, Bronwyn Collier** and **Deborah Kallgren** from CDER; **Julienne Vaillancourt** and **Bob Yetter** from CBER; and Susanne Hall from Glaxo-Wellcome, Irwin Martin from Park Davis, Donna Ohye from Janssen and Biff Owens from Syntex.

Thanks are owed to the dedicated members of the project management staff who contributed their time and talents to implement the workshop sessions by serving as speakers, panelists, moderators, case study presenters, table facilitators and reporters:

From CDER: **Mark Anderson, Patricia Beers-Block, Joseph Buccine, Maria De Carvalho, Michael Folkendt, Elaine Frost, Randy Hedin, Deborah Kallgren, Chin Koerner, Melodi McNeal, Corinne Moody, Lana Pauls, David Roeder, Cathie Schumaker, Kassandra Sherrod, Denise Toyer, Mary Jane Walling, Sakineh Walther, Robert West, Leslie Wheelock** and **Jean Yager.**

From CBER: **Allen Albright, Wendy Aaronson, Sheila Buck, Lydia Falk, Mark Heintzelman, Renita Johnson-Leva, Martha Monser, Mary Padgett, Kay Schneider, Suzanne Sensabaugh, Gail Sherman, Victoria Tyson-Medlock, Julienne Vaillancourt** and **Robert Yetter.** From CDRH: **Pauline Fogarty.**

From industry: Sultan Aziz (Merck-Medco), Eleanor Barbo (Whitehall-Robbins), Christian Bernhardt (Procter & Gamble), Joan Butler (Otsuka), Dennis Foley (Wyeth-Lederle), Dorothy Frank (TheraTech), Paul Gesellchen (Eli Lilly) , Susan Hall (Glaxo-Wellcome), Stuart Hamill (IBAH), Edwin Hemwall (J&J-Merck), Ira Katz (Janssen), Irwin Martin (Parke-Davis), Grove Matsuoka (Amgen), Donna Ohye (Janssen), George Ohye (Consultant), Biff Owens (Chiron), R. Richard Rhodes (formerly DuPont Merck), Lorraine Sachs (Taro), Stephen Sasson (Pfizer), Ronald Trust (Pfizer)

Bravos to the actors who took part in the key factors comical skits:

From CDER: **Joe Buccine, Michael Folkendt, Randy Hedin, Chin Koerner, Melodi McNeil, Corinne Moody, Jack Purvis, David Roeder, Matthew Tarosky** and **Mary Jane Walling.**

From CBER: **Wendy Aaronson, Gil Conley, Gail Sherman** and **Robert Yetter.** From CDRH: **Glen Simonelli.** From industry: Clare Kahn (SKB) and Dorothy Frank (TherTech).

The development and implementation of the workshop clearly demonstrated that mutually beneficial advances can be achieved through intercenter and Agency-industry collaboration.

The next FDA-DIA joint workshop is planned for the year 2000 and will move into a more advanced phase. Many FDA participants commented that primary, secondary and tertiary reviewers could benefit from participation. We are considering opening future workshops to the entire CDER and CBER community. Those individuals from CDER who think they may have an interest in participating in the next workshop should provide feedback to the Project Management Program Staff (4-6596).

Jean Yager is CDER's Project Management Director.

UNION CORNER

Right to Representation During Investigations, Discussions

BY ROBERT YOUNG

Since a contract between the union and FDA won't be in place until at least the summer, this article will explore the right to union representation in Agency investigations of employees and formal discussions between the Agency and its employees.

Representation during investigations. The law gives the union the opportunity to be represented at any agency examination of an employee in connection with an investigation if the employee reasonably believes that the examination may result in disciplinary action and requests representation. If you don't request representation, the union has no right to participate. Except for an annual reminder, the Agency has no additional obligation to tell employees of this right.

The right to representation during investigations is modeled on the same right private-sector employees have. It was provided to level the playing field and correct the imbalance in economic power between employer and employee. In practical terms, Congress recognized that a lone employee confronted by an employer trying to determine if certain employee conduct deserves discipline might be too inarticulate, fearful, frightened, confused or simply ignorant to make meaningful replies.

For many employees, agency investigatory interviews are inherently intimidating. The union is responsible for more than just representing an employee's interest. It also represents the interests of the entire bargaining unit by helping ensure that an agency doesn't initiate or continue a practice of imposing punishment unjustly.

Situations considered investigations include conversations, discussions, interviews, counseling sessions and meetings. The controlling factor is that an agency representative, not necessarily a manager or the employee's own supervisor, is asking an employee questions in order to elicit explanations and information from an employee. The employee must reasonably believe that his or her answers may result in disciplinary action.

Disciplinary situations include demotions, suspensions and admonishments as well as obvious investigations by supervisors or internal affairs units. In addition, courts have ruled that an examination or investigation within the meaning of the statute includes an employee's voluntary attendance at a credentials committee meeting to defend suggestions that his or her level of professional performance was substandard and if so found would be grounds for termination.

Finally, an employee must request representation. The request must be sufficient to put the agency representative on notice of the employee's desire for representation. Statements such as "Maybe I need to see a union rep" or "I would like to speak to a lawyer or somebody to advise me" are sufficient to put an agency on notice.

Once you have made the request in the appropriate setting, both the agency and union must act reasonably to accommodate you. This means that the interview is suspended until a representative is found. At the discussion, the representative is not simply a observer of or witness to or an assistant in presenting facts in the employee's defense. He or she may actively participate in asking questions, proposing resolutions and suggesting remedies.

Representation at formal discussions. Under the law, the union is given the opportunity to be represented at any formal discussion between an agency and employees concerning any grievance, personnel policy, practices or other general conditions of employment. This provision requires management to give the union adequate prior notice of and an opportunity to present at formal meetings.

The purpose of the provision is to allow the union an opportunity to safeguard the interests of bargaining unit employees as well as the union. A meeting need not include a discussion or discussion period to be a meeting. A meeting called only to make announcements could still be a formal discussion within the meaning of the statute. Meetings that begin informally may develop into a formal discussion. During the discussion the union representative has a right to participate.

Whether a discussion is formal or not is based on the totality of the facts and circumstances. Pertinent factors might include:

- The management level of the agency representative.
- Whether other management representatives attend.
- Where the meeting takes place
- How long the meeting lasts.
- How the meeting is called.
- Whether there is a formal agenda.
- The manner in which the meeting is conducted, minutes of the meeting identifying specific employees and comments.

An example of a formal discussion might be a meeting with an employee in which a third-level supervisor along with lower-level supervisors and representatives from other agency offices are present—especially if the meeting is called by and held in the third-level supervisor's office, the agenda specified in advance (even if it is unknown to the employee), and someone other than the employee takes notes.

On the other hand, a first-level supervisor's chance meeting with an employee in the restroom leading to a few minutes' chat might be found not to be a formal discussion.

Finally the subject matter of the discussion must be about a grievance, personnel policy or practice or other general condition of employment. Grievances are grievances. Personnel policies or practices or other general conditions of employment are matters which relate to the workplace or work environment.

Examples listed in the September issue of *News Along the Pike* were compensation such as overtime, time of work, place of work, performance appraisal, awards, discipline, details, promotions, assignment of work, assignment of offices, training, professional development, discrimination and occupational safety.

Robert Young, M.D., Ph.D., is interim president of Chapter 282, National Treasury Employees Union.

Reviewers Get Update on CDER Reviewer Career Path

BY MELISSA MAUST

Nancy Smith, Ph.D., Director, Office of Training and Communications, was guest speaker at the November RAC meeting and gave an update on the CDER Reviewer Career Path program. The program was developed as her CDER Fellows project and started as a pilot program in March. This promotion pathway is in addition to all other avenues for promotion. Through discipline-specific focus groups, the RAC played a key role in the development of the criteria for the promotional levels. FDA's Office of Human Resources and Management Systems was involved throughout the entire process to ensure Federal personnel regulations were incorporated.

Center Director **Janet Woodcock. M.D.,** has been very supportive of the program from the beginning and feels it is to the Center's and Agency's advantage to be able to promote and retain highly experienced staff. It is too early to tell if the program has helped retain reviewers, but this will be part of the evaluation.

Nancy stated that due to budgetary limitations, the Agency imposed a limitation of 5 percent of staff who could be promoted to Level IV in the first year. The Center hopes to have this limitation removed after the first year. It is expected that there will always be a limited number of promotions to this level because of the strict criteria. As of November, six Level III committees and one Level IV committee have been selected and trained.

Nancy explained the process:

- Your application is reviewed by your super office director.
- It is then sent to the committee chair who assigns it to a primary, in-depth reviewer.
- The in-depth reviewer is responsible for interviewing you, your supervisor and anyone else who could add valuable information. The in-depth reviewer also leads the committee's discussion.
- An OHRMS representative is always present at the committee meeting. The decision is usually reached by consensus rather than vote. OHRMS has the authority to make the final decision and sign off on the promotion.
- Within four weeks of the decision, a letter is sent through the supervisory chain notifying you of the committee's decision.

The most important part of the application is your statement. This should be well-written, free of spelling, typographical and grammatical errors, to the point and clearly state the impact you have had on the organization.

The second most important part consists of letters of recommendation. There must be two to three letters, including one from your supervisor or team leader and other internal colleagues who are very familiar with your work. Statements should show where your have made a difference. Your *curriculum vitae* is also part of the application. The bibliography should focus on work done at CDER.

There was a lot of discussion about the position description. Nancy indicated that personnel requires this. This position description doesn't have to be perfect at the time of application and can be rewritten with the help of OHRMS after promotion is approved. Sample position descriptions are included in the personnel plan on CDER's intranet at http://cdsmlweb1/vjext/CRCP/crcpindex.htm. The application also includes a transmittal memo and a checklist of documents.

Nancy discussed several issues and problems that have been identified with the process:

- *Training of supervisors.* This has been conducted at CDER staff meetings, and super office directors have been working with supervisors to help understand and use this process effectively.
- *Inadequate or oversized applications.* A well-prepared application should be no more than 40 pages and should be broken down by factors. Applications should be proofread by at least one other person. You should consider seeking the advice of colleagues who have been successfully promoted through the CRCP process.
- *Position description.* It isn't necessary to have a perfect position description at the time the package is submitted. OHRMS will help with the preparation. Generic position descriptions could be developed for Level III staff in the same discipline and division. The position description for Level IV will be unique for each applicant at that level.
- *Difficulty scheduling meetings.* For consistency, the same OHRMS person is attending all discipline-specific committee meetings. This makes meetings more difficult to schedule. However, this approach has the valuable benefit of consistency within the process and within the discipline review committees.

Nancy also explained that, in spite of the current budget situation, Dr. Woodcock is still very committed to the program. The current hiring freeze doesn't affect the program, because it doesn't include a freeze on promotions. Should a freeze on promotions be imposed in the future—and this isn't expected—the process will continue to the point of making the selections. The promotions would be effective after the freeze was lifted.

It isn't yet clear what, if any, union involvement there will be in the process.

The first committee meeting for interdisciplinary applications to Level III will be scheduled in the near future. The FDA Personnel Plan for Medical Officers, especially Title 38, has been written and the Medical Officer Committee has provided comments. It should be finalized soon. This plan, along with all others, will be available on the Intranet.

Nancy explained that a plan to evaluate the pilot phase needs to be developed and appropriate MAPPs will need to be revised and updated. Again, Nancy will look to the RAC for input. In anticipation of this type of feedback, the RAC has developed a task force to offer support during the evaluation. This task force will be open to any primary reviewer in the Center. If you would be interested, please inform your RAC representative.

For details, the meeting minutes can be located at: x:\coorcomm\rac\minutes.

Melissa Maust is a chemist in OGD.

Excellence in Mentoring Added to CDER Peer Honor Awards

(Continued from page 1)
were:

FDA Commendable Service Award

Kathryn Aikin, Ph.D.

Maureen Hess, MPH, R.D.

Karen M. Kapust

Aspirin Professional Labeling Team: **Charles Anello, D.Sc., Debra Bowen, M.D., Stephen Fredd, M.D., Katharine Freeman, Linda Katz, M.D., MPH, Debbie Lumpkins, Stephanie Mason, Anne Mustafa, Rosemarie Neuner, M.D., MPH, Linda Roberts, Robert Sherman, Robert Temple, M.D., Michael Weintraub, M.D.,** and **Ida Yoder.**

Coordinators of the New Reviewer's Workshop: **Carol Assouad, MLS., Heidi M. Jolson, M.D., MPH, Iris D. Khalaf, Kathryn W. Kruse, Kathrin L. McConnell, James C. Morrison, Lana L. Pauls, MPH, Lisa Rarick, M.D., Nancy D. Smith, Ph.D.,** and *(PHS Unit Commendation)* **CAPT Stephen E. Wilson.**

Pharmacist Education Outreach Program Learning and Exchange: **Brenda Kiliany, R.Ph., Mary Kremzner, Pharm.D.,** and **Larry Lim, R.Ph.**

FDA Outstanding Achievement Award

Bruce W. Hartman

Allen Kenyon, Ph.D.

Patrick J. Marroum, Ph.D.

Radhika Rajagopalan, Ph.D.

Edwin Ramos

Rae Yuan, Ph.D.

FDA Group Recognition Award

Electronic Orange Book Team: **Susan F. Daugherty, Gladys Lee-Holley, Janet L. Gentry, Robert L. Reinwald** and *(PHS Unit Commendation)* **CAPT Janet Anderson, CAPT James Cobb, CAPT Mary Forbes, CAPT Richard Lipov, CAPT George Scott.**

Bioequivalence Working Group: **Mei-Ling Chen, Ph.D., Sue-Chih Lee, Ph.D., Rose Cunningham, Moh-Jee Ng, Donald Schuirmann, M.S.,** and **Lawrence J. Lesko, Ph.D.**

Renal Studies Guidance Working Group and Training Planners: **Tien Mien Chen, Ph.D., Margaret Cunningham, Barbara M. Davit, Ph.D., Ahmed A. El Tahtawy, Ph.D., Peter Honig, M.D., Shiew-Mei Huang, Ph.D., Safaa S. Ibrahim, Ph.D., David J. Lee, Ph.D., Lawrence J. Lesko, Ph.D., Richard Lostritto, Henry J. Malinowski, Ph.D., Michael Olson, Ameeta Parekh, Ph.D., Toy Ping Tiara** and **Ruihua Yuan, Ph.D.**

New Employee Orientation Design Team: **Thomas W. Abrams, R.Ph., MBA, Susan H. Carey, Heather A. Chafin, Maria F. De Carvalho, Elaine C. Frost, Stephanie M. Hungerford, Bibi F. Jakrali, Debbie L. Kallgren, Iris D. Khalaf, Karen F. Koenick, Lana G. Kostecka, Kathryn W. Kruse, Michael C. Olson, Edward M. Sherwood, John E. Simmons, Ph.D., Wendy K. Stanfield**

PHS Commendation Medal

CDR Paul A. David

CAPT Lillian Gavrilovich

CDR Steven D. Hardeman

CDR David Hussong

PHS Unit Commendation

Office of Generic Drugs Mentoring Team: **LTJG Gregory S. Davis, LCDR Carol A. Holquist, CDR Charles V. Hoppes** and **LTJG Nasser Mahmud.**

CDER Fellowship Program Certificate

Tatiana A. Pavlova, M.D., Ph.D.

CDER Special Recognition Award

Carol Cronenberger, Ph.D.

Kuldeep R. Dhariwal, Ph.D.

Hoainhan Nguyen

Onset of Action Project Team: **Peter Honig, M.D.,** and **Janet Norden, R.N., MSN.**

Center Director's Special Citation

Review Science Research Group: **Chang H. Ahn, Ph.D., Charles Anello, D.Sc., Javier Avalos, John D. Balian, M.D., Julie G. Beitz, M.D., Vance Berger, Ph.D., Dan L. Boring, R.Ph., Ph.D., Paul Brown, Ph.D., George Y. Chi, Ph.D., Diana L. Clark, Lu Cui, Ph.D., Rose Cunningham, Denise Rahmoeller Dorsie, Michael R. Elashoff, Ph.D., David Feigal, Jr., M.D., Ji-Yang (Ted) Guo, Ph.D., William R. Fairweather, Ph.D., Mary Fanning, M.D., Ph.D., CDR Steven I. Hirschfeld, David Hoberman, Peter K. Honig, M.D., Chuanpu Hu, Ph.D., Hsien Ming James Hung, Abigail C. Jacobs, John K. Jenkins, M.D., Kun Jin, Lisa A. Kammerman, Ph.D., Michael Klein, Thomas P. Laughren, CAPT Ralph B. Lillie, Raymond Lipicky, M.D., Jack Longmire, Stella G. Machado, Ph.D., Toni M. McCannon, Mehul U. Mehta, Ph.D., Raymond Miller, S. Edward Nevius, Ph.D., Lillian Patrician, Nancy D. Smith, Ph.D., Ana Szarfman, Masahiro Takeuchi, Sc.D., Vijaya K. Tammara, Ph.D., Robert Temple, M.D., Su Tso, Yi Tsong, Ph.D.,** and **Sandi Van Buskirk.**

CDER Administrative/Program Management Excellence Award

Alice Gray

David C. Morley

CDER Excellence in Communication Award

Shirnette D. Ferguson

Nancy Haggard

Weston L. Metz

Daphne T. Lin, Ph.D.

Nancy Ostrove, Ph.D.

First Party Audit Group: **Joseph C. Famulare, Nancy Hallman, David Horowitz, Tom Kuchenburg, Paul Motise, Brian Nadel, Barry Rothman** and **Clyde R. Rutledge**

Report to the Nation Team: **Lori Frederick, Norman J. Oliver** and **Wendy K. Stanfield.**

CDER Information Technology Excellence Award

Linda Gail Stone

Electronic Pediatric Form Working Group: **CDR Steven I. Hirschfeld** and **Stacey L. Nichols.**

FDA Medical Library's Web Resources

(Continued on page 11)

Communications, Education, Outreach Form Central Theme

(Continued from page 10)

Team: **Carol S. Assouad, M.L.S., Gail Y. Chotoff, Wanda J. Clabaugh, Rhyonda M. Jackson, Eugene Jeffery, Jr., Karen M. Kapust, Stacey L. Nichols, Jack Pevenstein, Paul K. Stauffer** and **William B. Woodard, Jr.**

CDER Leadership Excellence Award

Hae-Young Ahn, Ph.D.

John Balian, M.D.

Joyce Bloomfield

Mary M. Fanning, M.D., Ph.D.

Maryla E. Guzewska, Ph.D.

John K. Jenkins, M.D.

Shriniwas G. Nerurkar, Ph.D.

N.A.M. Atiqur Rahman, Ph.D.

Lisa D. Rarick, M.D.

Rajagoplan Srinivasan, Ph.D.

CDER Excellence in Mentoring Award

Peter H. Cooney, Ph.D.

John P. Hunt

CDER Support Staff Excellence Award

Diane Ehrlich

Patricia Noyes

Donna Stewart

CDER Team Excellence Award

Adverse Drug Experience Team: **Nancy Haggard, Denis Mackey, Fred Richman, Doris Shepherd, Puri Subramaniam** and **Melvin Szymanski.**

Mutual Recognition Agreement Coordinating Team: **Brian J. Hasselbach** and **Paul J. Motise.**

Anesthetic, Critical Care, Addiction and Pulmonary Clinical Pharmacology and Biopharmaceutics Review Team: **Tien Mien Chen, Ph.D., Suresh Doddapaneni, Ph.D., LT Bradley K. Gillespie** and **Venata Ramana Uppoor, Ph.D.**

Metabolic and Endocrine Clinical Pharmacology and Biopharmaceutics Review Team: **Hae-Young Ahn, Ph.D., Michael Fossler, Ph.D., Pharm.D., Carolyn Jones, Ph.D., Robert Shore** and **Pharm.D.**

CDER Recruitment Team: **Keith Ariola** and **Joan Sitman**

Division of New Drug Chemistry III Chemists Team: **Daniel L. Boring, Ph.D., Chi-wan Chen, Albinus M. D'Sa, Ph.D., Rao V. Kambhampati, Ph.D., Mary Ann Jarski, Ph.D., Paul S. Liu, Ph.D., CAPT Ko-Yu Lo, George Lunn, Stephen P. Miller, Ph.D., Mark R. Seggel, Ph.D.,** and **Norman R. Schmuff, Ph.D.**

ONDC/Project Management Working Group: **Bonnie Dunn, Bronwyn Collier, David Roeder, Linda Carter, Dorothy Pease, Lana L. Pauls, MPH, Enid Galliers, John Simmons, Susan Lange, MPH, Steven Koepke, Guirag Poochikian, Ph.D.,** and **CAPT Cathie Schumaker.**

Viagra Drug Review Team: **J.V. Advani, Estela Gonzalez Barry, CAPT Gary Buehler, Albert DeFelice, Ph.D., Kooros Mahjoob, Ph.D., Patrick J. Marroum, Ph.D., Tom Papoian, Ph.D., James Short, Ph.D., Kasturi Srinivasachar, Ph.D.,** and **Norman Stockbridge, M.D., Ph.D.**

Institutional Animal Care and Use Committee: **Edward T. Greenstein, D.V.M., Joseph P. Hanig, Ph.D., Neil R. Hartman, Ph.D., Patricia E. Long-Bradley, Robbe C. Lyon, Ph.D., Donald Niebuhr, CAPT Carl J. Nielsen, CAPT Michael A. Ussery** and **Donna A. Volpe, Ph.D.**

OTR In Vitro Biopharmaceutics Methods Research Team: **Ebenezer Asafu-Adjaye, Ph.D., Charles Brownell, Christopher Ellison, Patrick J. Faustino, Ph.D., Ajaz S. Hussain, Ph.D., Gerald Shiu, Ph.D., Donna Volpe, Ph.D.**

OTR Skin Capp Analysis Group: **Harry D. Coffman, Moheb M. Nasr, Ph.D., John C. Reepmeyer, Ph.D.,** and **Larry K. Revelle, Ph.D.**

Caffeine Review Team: **Tien Mien Albert Chen, Ph.D., LT James L. Cobbs, Misoon Chun, Ph.D., Dale Conner, Ph.D., Peter Cooney, Ph.D., James Gebert, Ph.D., Martin Himmel, M.D., MPH, Miriam Pina, M.D., Guirag Poochikian, Ph.D., CAPT Cathie Schumaker, Vibhakar Shah, Ph.D., Hilary Sheevers, Ph.D., CAPT Stephen E. Wilson** and **Carol Vincent.**

CDER Orally Inhaled and Intranasal Corticosteroid Growth Working Group: **Tien Mien Albert Chen, Ph.D., Barbara Elashoff, Evelyn Farinas, R.Ph., M.G.A., David Graham, M.D., MPH, David Hilfiker, M.D., John K. Jenkins, M.D., Saul Malozowski, M.D., Ph.D., Anne Trontell, M.D., MPH,** and **Alexandra Worobec, M.D.**

Churg-Strauss Syndrome Joint Working Group:**Raymond Anthracite, M.D., Evelyn Farinas, R.Ph., M.G.A., David Graham, M.D., Peter Honig, M.D., Parinda Jani, Robert Meyer, M.D.,** and **Anne Trontell, M.D., MPH.**

Infasurf Team: **Girish Aras, LT Bradley Gillespie, Martin Himmel, M.D., Antonis Koutsoukos, Carole C. Kuzmik, John McCormick, Eugenia Nashed, Miriam Pina, M.D., Guirag Poochikian, Ph.D., CAPT Ching-Long Joseph Sun, Denise Toyer, Venata Ramana Uppoor, Ph.D.,** and **CAPT Stephen E. Wilson.**

Meeting Minutes Working Group:**Girish Aras, LT Bradley Gillespie, Barbara Elashoff, Miriam Pina, M.D., Brian Rogers, Vibhakar Shah, Denise Toyer, Anne Trontell, M.D., Gretchen Trout** and **Tracey Zoetis.**

Pediatric Subcommittee of CDER's Medical Policy Coordinating Committee: **John J. Alexander, M.D., CAPT Paula Botstein, Wiley Chambers, M.D., Denise Cook, M.D., Leanne Cusumano, Therese Cvetkovich, M.D., Patricia DeSantis, CAPT Elaine Esber, Roberta Glass, M.D., CDR Steven I. Hirschfeld, Linda Hu, M.D., Abraham Karkowsky, M.D., Elizabeth Ludwig, M.D., Sally Loewke, M.D., Sam Maldonado, M.D., Dianne Murphy, M.D., Tatiana Pavlova, M.D., Miriam Pina, M.D., Victor Raczkowski, M.D., Monica Roberts, M.D., Rosemary Roberts, M.D., Khyati Roberts, Kathy Robie-Suh, M.D., Rigoberto Roca, M.D., Jean Temeck, M.D.,** and **Karen Weiss, M.D.**

FDA Medical Librarians Team: **David E. Graham** and **Kathrin L. McConnell.**

Jackie Barber is the Center's Incentives Award Officer.

Risk-Based Priority Setting Tops List of FDA's Strategic Directions

(Continued from page 1)

The plan is divided into two parts. The first discusses a broad strategic framework and analyzes gaps between expectations and performance. Part two, a detailed blueprint for this fiscal year, provides performance commitments to narrow gaps.

The plan identifies six strategic directions that will help focus the Agency's energies:

- Establishing risk-based priories to target resources on health and safety risks that directly threaten the well-being of Americans.
- Strengthening the scientific and analytical basis for regulatory decisions.
- Collaborating more closely with external stakeholders to seek effective solutions to public health problems.
- Continuing to re-engineer FDA processes to achieve regulatory simplification and internal streamlining.
- Adopting a systems approach to regulation that looks for total problem solutions rather than piecemeal review and enforcement.
- Capitalizing on information technology to improve both internal efficiency and communications with stakeholders.

The plan addresses the Modernization Act objectives that FDA maximize the availability and clarity of information about the review process as well as information for consumers and patients concerning new products, implement inspection and post-marketing provisions of the law, ensure FDA's access to scientific and technical expertise, meet time periods for reviews by July 1 and eliminate backlogs a year from January.

The plan analyzes key challenges facing the Agency in the near future, including:

- Increased research and development place pressure on regulatory responsibilities. The pharmaceutical industry investment alone exceeds $20 billion a year, triple that of a decade ago.
- Product complexity continues to increase as technology advances.
- The growth in product complexity has seen a parallel growth in adverse events.
- New health and safety threats appear in a random and discontinuous pattern, including more virulent and antibiotic-resistant germs.
- A more knowledgeable and diverse consumer population escalates expectations for more information, as well as information tailored to specific groups.
- The international arena presents regulatory challenges with the larger drug firms now operating as multinationals.
- Imported products regulated by the FDA represent a significant component of U.S. consumption.
- Constraints on the Federal budget will continue.

Breakthrough Cancer Pain Treatment Approved; New Warnings Issued

(Continued from page 1)

be prescribed only for women at high risk for breast cancer following a medical evaluation of a woman's individual risk factors including age, personal health history and family history of breast cancer—factors outlined in the approved labeling.

The Agency noted that caution must be used in prescribing the drug because of its potentially serious side effects including endometrial cancer, deep vein thrombosis and pulmonary embolism.

Tamoxifen is manufactured under the brand name Nolvadex by Zeneca Pharmaceuticals, Wilmington, Del. The supplemental drug application for the new use of this product was reviewed and approved by FDA in six months. More information about tamoxifen is on CDER's Web site at http://www.fda.gov/cder/news/tamoxifen.

On Nov. 4, FDA approved a new dosage form of fentanyl developed specifically for cancer patients with severe pain that breaks through their regular narcotic therapy. Fentanyl is an opioid narcotic more powerful than morphine. The new dosage form is a flavored sugar lozenge that dissolves in the mouth while held by an attached handle.

While fentanyl is an effective treatment for breakthrough cancer pain, it is not without risk. Because the drug may be fatal to children as well as to adults not already taking opioid narcotics, FDA approved the medicine under special regulations that restrict distribution as defined in a comprehensive risk management plan. Anesta Corporation of Salt Lake City, Utah, will market the dosage form of fentanyl under the brand name Actiq with partner Abbott Laboratories.

FDA informed companies on Nov. 9 of new pediatric information that will be required on the labeling of all orally inhaled and intranasal corticosteroids. The new labeling language will alert health care providers that using these drugs in children may reduce their rate of growth. It will also recommend using the lowest effective dose of these drugs and routinely monitoring patients' growth rates.

Controlled clinical studies have shown that inhaled and intranasal corticosteroids may cause a reduction in growth velocity in pediatric patients.

In studies involving inhaled corticosteroids, the average reduction in growth velocity was approximately one-third of an inch a year.

FDA and the manufacturer of tolcapone are advising doctors about reports of a new finding of fatal liver injury associated with the Parkinson's disease drug and recommending significant changes in how it is used. FDA is closely monitoring this matter and may take further action if new reports show that the liver injury rate proves greater than it now appears.

Hoffmann-La Roche, the manufacturer of tolcapone under the brand name Tasmar, issued a "Dear Doctor" letter alerting physicians to the labeling changes and reports of three deaths from acute, severe liver failure.

Although a precise rate of these deaths is not known, about 60,000 patients have been given Tasmar worldwide, indicating a rate of approximately one reported death for every 20,000 patients using the drug. FDA and the manufacturer are asking health professionals to exercise additional caution in using the product. FDA requests that all cases of serious liver injury occurring in persons with Parkinson's disease be reported through MedWatch at http://www.fda.gov/medwatch/.