news along the pike

CENTER FOR DRUG EVALUATION AND RESEARCH

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PIKE'S CORNERS . . .

ICH: Common Technical Document Ready by 2000

Progress Reported on Worldwide Manufacturing Quality

BY ROGER WILLIAMS, M.D.

At a meeting in Tokyo last month, the steering committee of the International Conference on Harmonization:

- Heard progress reports on the Common Technical Document.
- Agreed to a U.S. West Coast site for the ICH 5 meeting.
- Moved closer to consensus on ways to ensure worldwide manufacturing quality of active ingredients.
- Agreed to begin work on a guidance for pediatric clinical trials.
- Launched a major revision of the stability testing guidance.
- Finalized the guidance on repeat-dose toxicity testing in animals.
- Neared consensus on a guidance for selecting control groups in clinical trials.
- Appointed a trustee for the new medical terminology, known as MedDRA.

The objective of the work on the *Common Technical Document* is to reach agreement on an information package of technical data, in the same format and with the same content, that would be submitted for registering new drugs in all three ICH regions—the United States, the European Union and Japan. Three expert working groups reported they have made significant progress on the *Common Technical Document*. The three groups are considering efficacy (human clinical trials), safety (animal pharmacology and toxicology) and quality

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Henney Confirmed by Senate as Commissioner

The Senate voted to confirm Jane Henney, M.D., as Commissioner of Food and Drugs on Oct. 21.

"Jane Henney is a seasoned professional who brings substantial management skills and a depth of experience to the agency," said HHS Secretary **Donna E. Shalala** immediately following the vote.

"The FDA safeguards food and drugs from the factory to the store shelf to every medicine cabinet and kitchen cupboard in America. Dr. Henney has the judgment to carry out that vital responsibility in a changing health marketplace, and I know she will forge new and productive relationships with consumers and industry.

"With her impressive medical and academic credentials, Dr. Henney will work to keep FDA agile and responsive, and her experience as a former deputy at FDA will help her lead this complex organization as it continues to reform and modernize."

Dr. Henney is a physician, a cancer specialist and a nationally recognized academic leader and public health administrator who has served in the Carter, Reagan, Bush and Clinton administrations. Dr. Henney will be the first

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Garry Picked in WJLA-TV's Working Women Tribute

BY THOMAS CONRAD, MPH, PH.D., RNC

Katrina Garry, a contract liaison officer in the Office of Post-Marketing Drug Risk Assessment, has been chosen the winner in the administrative category of News 7's fourth annual Tribute to Working Women.

Hosted by Kathleen Matthews of News 7, the awards are given each year to recognize the many ways that women influence the lives of others and make a difference at home, at work and in the community. Katrina will receive a number of gifts from the contest's commercial sponsors at an awards luncheon on Nov. 6.

Katrina began working for CDER in September 1996 as branch secretary for the Epidemiology Branch of the former Office of Epidemiology and Biostatistics. She was promoted to her current position in July.

Katrina's most significant contributions have been in using information technology to handle management issues. She has done this

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JOE'S NOTEBOOK

AIDS Falls from Top 10 Causes of Death

The first story about the AIDS epidemic that I worked on sticks in memory. It's not so much the fact that a bunch of G.I. writers more than a dozen years ago got the research and facts right, but that a test tube of my blood was used in the cover photo. To tell the truth, we were stumped when it came to thinking of an illustration for universal precautions and safe sex that could be used for a magazine that is taken home.

So one afternoon, I visited the public affairs folks at the National Institute of Allergy and Infectious Disease to check their photographs. One seemed to represent symbolically how the virus is transmitted and how transmission is thwarted—it showed a hand in a latex glove holding a vial of blood. The only problem was that the photo was in black and white. That's how my blood contributed to the color cover we needed. As you can imagine, I've been following the AIDS story with keen interest ever since.

So it was good news to learn that HHS Secretary **Donna E. Shalala** earlier this month reported an unprecedented decline in AIDS deaths when she released preliminary vital statistics for the nation in 1997.

Not only that, but Shalala said the decline in AIDS deaths is primarily due to the highly active antiretroviral therapies—approved by CDER—that help people with HIV live longer and healthier lives. At the same time, she emphasized that success in treating those with HIV does not mean we can relax our efforts to prevent HIV transmission. Unfortunately, there's an inverse link between the magnitude of a public health threat—represented by death rates—and the persuasiveness of public health messages that aimed at combating that threat.

"The report is very good news for the nation, and the tremendous decline in AIDS deaths is particularly striking," Shalala said. "These figures mean that new treatments have been very effective in extending the lives of people who already have HIV infection—but they do not mean that we have significantly reduced HIV transmission. We are working to see that people with AIDS get access to the dramatic new therapies that are available. Even more important, however, is our continuing task of preventing new cases of HIV. Our ultimate goal is to prevent the estimated 40,000 new HIV infections that occur each year."

According to Centers for Disease Control and Prevention, other available data suggest that, although death rates are decreasing dramatically, the annual number of new HIV infections in the United States has failed to decline in recent years, and the total number of people living with HIV is still on the rise.

Details from the report reveal that, from 1996 to 1997, age-adjusted death rates from HIV infection in the United States declined 47 percent and HIV infection fell from eighth to 14th among leading causes of death in the United States. For people 25 to 44 years old, HIV dropped from the leading cause of death in 1995 to third-leading in 1996 and fifth-leading in 1997. The age-adjusted HIV death rate of 5.9 deaths per 100,000 is the lowest rate since 1987, the first year mortality data were available for the disease. The 1997 rate is less than half the 1992 rate of 12.6 percent and almost one-third the 15.6 percent rate in 1995, the peak year.

The data come from a new report, *Births and Deaths: United States, 1997*, prepared by the National Center for Health Statistics, a part of the CDC. The report features preliminary data collected through the National Vital Statistics System from over 90 percent of all birth and death records. The information on causes of death is recorded on death certificates by physicians, medical examiners, and coroners, and reported to the states.

You can download a copy of the report from the NCHS Home Page on the Internet at http://www.cdc.gov/nchswww/.

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

Ombudsman's Annual Report

BY JIM MORRISON

Well, it's that time again. The leaves are falling, a new fiscal year has begun, and it's time for me to give you feedback on the past year's ombudsing. There are some trends emerging, now that I have three years of cumulative data.

First, the number of cases overall declined somewhat from last year. There were just under 100 this year, due in part to a significant drop in contacts by CDER employees. In my first year, internal cases represented about a third of the total. Last year, it had dropped to a quarter; although, the actual number of internal cases was greater than in the first year. This year internal cases fell to a tenth of my workload. There are a couple of factors that aided in that decline. First, some chronic problems related to internal management were solved, which helped greatly. Second, the advent of the union may have focused complaints away from the Ombudsman mechanism, at least for those in the bargaining unit.

Another trend which bears watching is a recent surge in e-mail traffic from outside FDA. I don't track e-mail contacts by subject the way I do cases, but I have been receiving a steadily rising number of e-mails, primarily from consumers, patients and health professionals. That number has increased markedly in the last few months to an annual rate of more than 300.

I believe that the increase reflects the rapidly expanding use of the Internet and underscores the need for a more systematic way of handling electronic correspondence. I am not alone in experiencing such an increase. The CDER Executive Operations Staff has been receiving an increasing number of e-mails as well, but their volume is more than 10-fold mine.

To give you an idea of the reasons for complaints, both external (excluding all but a few e-mails) and internal, general categories are in the table.

Although I have refined the method of categorization over time, it is clear that the percentage of issues related purely to the timeliness of reviews or actions has dropped each year. When complaints about access are included, however, the numbers are more constant. It is often difficult to separate timeliness issues from access issues such as difficulty setting up a meeting or failure to respond to phone calls. Both affect the length of the process in question.

External Complaints	*%*
Timeliness, access and process issues	37
Policies or decisions challenged	35
Poor advice or lack of information	25
Internal Complaints	
Personnel management	50
Management and administrative systems	50

The percentage of cases involving disputed policies or decision making has remained pretty constant over the past three years between 30 percent and 40 percent.

Both the number and the percentage of complaints about poor advice or a lack of information have bounced around, but may be on the rise. That is ironic, since with CDER's Web site, there has never been more information available. The numbers indicate, however, that we need to produce still more guidance documents, and we need to make sure that we are all knowledgeable about their contents.

With respect to internal complaints, the relative numbers of those associated with systems as compared to personnel practices has been rising. There are a number of reasons for the change, but I think that improvements in CDER operations generally have raised expectations of folks regarding all the systems. I notice that CDER's people are less likely to accept inefficiency as a way of life and are quicker to complain.

Not all the complaints were about CDER systems. There is a trend toward complaints about Agency and Department systems, such as personnel and payroll, that account for much of the increased percentage. We should not forget, however, that the overall number of internal complaints is moving in the right direction.

I stopped tracking the alerts I get from CDER staff regarding problematic external interactions. These alerts have been increasing, and such information has been very helpful and much appreciated. The earlier in a process that I become involved, the easier problems can be worked out.

I want to thank everyone in CDER for the excellent cooperation and help during the past fiscal year. For those of you who are new to the ombuds process, please remember that my role is not to assign blame but to resolve disagreements and, if possible, prevent them in the future by revising procedures or plugging holes in our processes and communications.

Jim Morrison is the Center Ombudsman.

Flu Shots Available at Parklawn, Woodmont II; Vaccination Goals Met

Free flu shots for CDER employees will be available in the Parklawn Building Health Unit until mid-December from 7:30 a.m. to 4:30 p.m. daily.

The Parklawn Wellness Center will be providing flu shots at Woodmont II, third floor Conference Room D, on Nov. 19 and Dec 17 from 8:30 a.m. to 11:30 a.m. Consent forms will be available. Because no privacy screens are available in Woodmont, please wear a short-sleeved shirt or blouse.

Meanwhile, HHS announced that the number of older Americans receiving flu shots in 45 states in 1997 has already surpassed the year 2000 goal set by the Public Health Service, and those receiving pneumonia shots are also the highest level ever reported. The Department noted that the flu remains a serious threat, particularly to older Americans, and urged seniors to begin getting their 1998 flu shots this month.

STRATEGIC PLANNING CORNER

CDER's FY 2000 Performance Plan Focuses on Public Health

BY CINDY MARX

The Government Performance and Results Act of 1993 aims to improve the management, effectiveness and efficiency of government programs. It establishes a system under which CDER set goals for performance and measure its results. The Results Act requires the Center to prepare multiyear strategic plans, annual performance plans and annual performance reports. The performance goals and measures are linked to program activities in the FDA's budget request.

Traditionally, CDER has focused on activity-based performance such as the number of drugs approved or the number of inspections conducted. However, the Results Act has forced us to change our way of thinking and focus on achieving goals that have a significant impact on the public health.

In early 1998, the Special Projects Staff in the Office of Management worked with various program contacts to develop a performance plan for fiscal year 2000 that includes creative, outcome-oriented performance goals that reach outside the Center to our customers and stakeholders. CDER's performance plan was submitted to the Agency in May.

CDER's Performance Plan consists of three strategic goals. Within those strategic goals are 42 performance goals. Baseline data, data sources, performance measures and milestones are outlined for each performance goal.

- Strategic Goal 1: *Reduce human suffering and enhance the quality of the public health by providing quicker access to important, lifesaving drugs, and assure to the American public the availability of safe and effective drugs.* Performance goals in this category include the premarket phase of drug review and development, such as drug review times, project management and electronic submissions.
- Strategic Goal 2: *Prevent unnecessary injury and death to the American public caused by adverse drug reactions, injuries, medication errors and product problems.* Performance goals related to adverse event reporting, communication, education and partnering are included in this section.
- Strategic Goal 3*: Protect consumers by assuring the ongoing availability of high quality drugs.* Testing, research, inspections, post-market safety and international harmonization are covered in this portion.

The Results Act requires us to prepare an annual progress report on program performance for the previous fiscal year. The Agency is to compare its performance with the goals established in its annual performance plan, summarize the findings of program evaluations and describe the actions necessary to address or revise any unmet goals.

A report for the FY 2000 plan is due to Congress by March 31, 2001. The Special Projects Staff will meet with program contacts periodically to update the progress of each performance goal. A list of CDER's performance goals for FY 2000 can be found on the Center's intranet site at http://cdernet/om/goals.pdf.

Cindy Marx is a program analyst in the Special Projects Staff, Office of Management.

EEO CORNER

Marta Locklear Completes Record 7 Years as Hispanic Representative

BY GLORIA MARQUEZ SUNDARESAN

After a stint of seven productive years, **Marta Locklear** is hanging up her hat as EEO Hispanic representative. Marta is a computer specialist in the Technology Support Services Staff. "It's time to step aside and for someone else to contribute their ideas," she said.

Marta holds the longest record of service as a CDER EEO representative. She took on the collateral duty when no one else would. During her seven years, she planned activities and programs and participated in big events such as the observance of the Hispanic Heritage months and Diversity Day celebrations. Marta's public relations skills were very helpful in the success of CDER's EEO programs. Her devotion and enthusiasm were highly contagious, inspiring other EEO representatives to work hard for the success of our Center's special emphasis activities.

Marta's collateral service to the Hispanic community in CDER was made possible by the great cooperation and support from her boss, **Dave Moss.**

Estela Gonzalez Barry will serve as our new CDER Hispanic EEO representative, as an additional duty to her principal occupation as a CDER pharmacologist and toxicologist. Estela brings experience as a founding member of the FDA Hispanic Employee Organization and as a former member of both the FDA Commissioner's Employee Advisory Council and the CDER EEO Advisory Council.

Estela's activities for the 1998 Hispanic Heritage Month, from Sept. 15 to Oct. 15, included e-mail dissemination of historical tidbits about Hispanic contributions to the common good. She also coordinated a small display of books and artifacts by and about Hispanics.

Christina H. Chi, Ph.D., a pharmacologist who is a regulatory health project coordinator in the Division of Special Pathogens and Immunologic Drug Products, has accepted collateral duty as an EEO representative for employees with disabilities. She will emcee the CDER program for Disability Employment Awareness Month, to be held Oct. 30 from 11 a.m. to 12:30 p.m. in Parklawn Room 13B-39 and videoconferenced to Metro Park North I, Room 259.

Betsey Pisciotta and her daughter Angela Skalkeas, a senior at J.F. Kennedy High School, will speak at the brown bag seminar on "Handicap Awareness: A Mother's Perspective." Angela was a student volunteer at CDER's EEO Staff this summer. Betsey will share her experience on the difficulties and joys of raising a daughter with cerebral palsy.

Special accommodation will be provided upon request. For more information, please call the EEO Staff (4-6645).

Gloria Marquez Sundaresan is an equal employment specialist on the EEO Staff.

RAC CORNER

Committee Works on Survey, Implementing Web Site, Team Model

BY MELISSA MAUST

The year 1998 is quickly coming to an end, and 1999 will bring new members and new officers to the Reviewer Affairs Committee. If you are interested in serving on the RAC or running for an office, please inform your representative or send an e-mail to MAUSTM, ABBOTTT or MARSIKF. Before the year is over, the RAC has plenty of business to finish. So in the next couple of months keep in close contact with your RAC representative for highlights.

Activities to look for include a "quick and easy" reviewer survey, a summary of the CDER Reviewer Career Path to be given by **Nancy Smith** at the November monthly RAC meeting, a networking event for all CDER reviewers, implementation of the RAC homepage, updates to the CDER Reviewer's Handbook, Team Model task force meeting with **Jean Yager,** one more quarterly meeting with the Senior Management Team and an end of the year finale with Center Director **Janet Woodcock, M.D.,** at the December monthly meeting.

In addition, the Quality of Worklife subcommittee has been very active this year by developing a purpose, goals and focus. The group hopes to develop a white paper and present it to the Senior Management Team. The Comparable Pay Subcommittee hopes to start researching pay issues for the various reviewing disciplines.

The RAC continues the fulfillment of its mission by communicating the needs and concerns of primary reviewers. Last month the RAC was invited to the Office of Pharmaceutical Sciences office directors' meeting to present an update of RAC activities. This month there will be a presentation about the RAC at the New Reviewers' Workshop; and, as always, there is the RAC Corner in the *News Along the Pike*. But the best place to go for up-to-the-minute information about RAC activities is your RAC representative. The 1998 roster can be located at X:\coor-comm\rac\roster\roster98.

Melissa Maust is a chemist in the Office of Generic Drugs.

Fall Honor Awards Ceremony to be Held Nov. 20 at Gaithersburg Marriott

BY JACKIE BARBER

The Center will hold its Fall Honor Awards Ceremony at 1:30 p.m., Friday, Nov. 20, at the Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Blvd.

Proud to recognize the noteworthy accomplishments of CDER employees, Center Director Janet Woodcock, M.D., and other senior managers will present the FDA's commendable service, outstanding achievement and group recognition awards to civilian employees. Public Health Service commissioned officers will receive commendation medals and unit commendations.

In addition to the FDA honor awards, CDER will present the center director's special citation and CDER special recognition awards. CDER peer honor awards will be presented for the following categories: team excellence, program administrative/management excellence, support staff excellence, excellence in communication, leadership excellence, information technology excellence and, for the first time, excellence in mentoring.

If you have any questions or need any special provisions are needed, please contact me by e-mail (BARBERJ) or phone (7-7376).

Jackie Barber is the CDER incentive awards officer.

Core Competencies for CDER's Administrators on Development Track

BY DEBBIE MCKEMEY

The management officers' core competency focus group has been assisting with the assessment phase of the Core Competency Program for management officers and program specialists. The goal of the Core Competency Program is to provide training that focuses clearly on the job needs to accomplish CDER's mission.

The focus group has been working to identify the skills and tasks needed by management officers and program specialists to do their jobs effectively. An example of a task would be the entry of information into the Division Financial Management System. The required skill is using a computer or a particular software program. DTD, the AMCC Advisory Committee, along with members of the management officer's focus group will determine what training is needed to develop the knowledge and skills. The final step will be to revise or develop courses to meet the core competencies.

Debbie McKemey is a training specialist in DTD.

Quality of Work Life Week Events Set for Nov. 12-20

BY SHELLEY JOHNSON AND LYNDA PAPIO

CDER will be observing its second annual Quality of Work Life Awareness Week by holding a Health, Wellness and Family Practices Open House. This fun and exciting event will be held during November at the following CDER locations:

- Nov. 12, Woodmont II.
- Nov. 17, Corporate Boulevard.
- Nov. 18, Metro Park North I.
- Nov. 19, MOD I.
- Nov. 19, St. Louis.

Activities will also be held in the Parklawn Building throughout the week.

The QWL Team is hosting this open house to promote good health and fitness, in addition to balancing family and work life. The open house will include wellness demonstrations, health screenings and informational handouts. CDER will conclude its QWL Week by recognizing its employees for noteworthy accomplishments at the Fall Honor Awards Ceremony on Nov. 20.

Mark your calendars and watch your e-mail for more details.

Shelley Johnson and Lynda Papio are CDER's QWL Team.

INFORMATION TECHNOLOGY CORNER

Secure Electronic Mail with Industry Focus of Center Development

BY GREG BROLUND

CDER is moving toward an all electronic regulatory submission and review environment, called ERSR for short. Current ERSR efforts, such as the NDA electronic archive guidance and the Adverse Event Reporting System, allow the pharmaceutical industry to submit regulatory documents electronically, either on physical media or directly on-line through the Internet.

Another effort under ERSR is the evaluation of secure electronic mail technology to allow rapid and secure two-way communication with regulated industry. This is especially important to protect the exchange of e-mail messages that contain trade secret or other privileged information.

Although e-mail is in widespread use within CDER and the pharmaceutical industry, CDER has not published a policy for the general use of e-mail with the regulated industry. Further, the relative immaturity of security and encryption products that can be efficiently used in large organizations has prevented CDER from putting a common Centerwide system in place. With the e-mail industry's offerings of encryption products and standards now maturing, CDER's Office of Information Technology is investigating secure e-mail products that will meet CDER's requirements and fit into the Center and Agency infrastructure.

CDER began defining requirements for secure e-mail use through experimentation with small-scale secure e-mail pilots ranging from a custom system provided by one NDA sponsor to the use of individual copies of the Pretty Good Privacy software product. These experiments and a more formal effort at requirements gathering will be the basis for designing and implementing a Centerwide secure e-mail system. The next steps are to establish a standard policy for using e-mail to communicate with the regulated industry and to pilot the capability of the commercial secure e-mail systems available on the market today.

A working group with representatives from CDER's Office of Review Management, Regulatory Policy Staff, the Office of Compliance and OIT has begun work on a standard e-mail policy. This policy describes who can send e-mail to a company and what can be sent in that message.

CDER has also established a Secure E-mail Team to plan a pilot and to work with the Pharmaceutical Research and Manufacturers Association and individual pharmaceutical companies to identify companies that are willing to participate in the pilot. The team will be contacting CDER review divisions for participants from CDER. As this project continues, more information will be published in *News Along the Pike* and on the OIT Web site. If you have comments or questions about this project, send me an e-mail (BROLUND).

Greg Brolund is a computer scientist in the Office of Information Technology.

Carl Peck Remembers Bill Abrams; Executive Helped Design Staff College

Editor's Note: William Abrams, M.D., executive director for scientific development at Merck & Co., Inc., died Sept. 15 after a long illness. The following is a portion the eulogy delivered by former Center Director Carl Peck.

BY CARL PECK, M.D.

It is a sad but uplifting honor to eulogize my friend and colleague, Bill Abrams.

While my remarks are very personal, reflecting more than 20 years of acquaintance and friendship, my sentiments reflect those of many, many colleagues in the American Society of Clinical Pharmacology and Therapeutics, FDA, academia and the pharmaceutical industry.

Cardiology, clinical pharmacology, development of therapeutic drugs, education and training, FDA and drug regulation, and geriatrics are formal labels of the fields to which Bill made many contributions, permanent evidence of which can be found in the scientific literature, texts of approved cardiovascular drug labels, and published books. But it was Bill's unique qualities as a wise and sensitive mentor and teacher, and as a caring friend and colleague, that I would like to recall.

My most intense personal engagement with Bill came while I directed FDA's Center for Drug Evaluation and Research from 1987 to 1993. Needing to establish a high quality educational resource within FDA to train and maintain staff expertise in drug evaluation sciences, Bill and his wife, Berenda, sacrificed convenience and much personal time to join the professional development staff at CDER.

There, Bill provided guidance and mentorship in the establishment of the CDER Staff College. Modeling the College after his extensive experience in the Merck internal training institute, Bill made a major and enduring contribution to the quality of FDA's scientific staff and, hence, their critical decisions concerning safety and effectiveness of the nation's therapeutic drugs. Bill uniquely accomplished what no one else could possibly do.

That Bill was able to work at FDA as a special government employee while an industry employee, reflects a larger impact of Bill's on his colleagues in FDA and academia. Ray Woosley chokingly expressed this sentiment to me when I asked him of Bill's influence on our field.

Ray said: "Bill was the pharmaceutical industry's finest role model. He represented the best of industry—critical scientist, admired physician, devoted to professional society service, articulate spokesman and champion for science, therapeutics, geriatrics, and clinical pharmacology." In this way, Bill affirmed that career scientists in industry practiced a respectable and admirable profession. Bill became the standard bearer for the best in the pharmaceutical industry—inspiring many to follow.

Speaking for thousands of colleagues in ASCPT, FDA, academia, and the pharmaceutical industry—we value so much Bill's manifold and selfless contributions as a fellow clinical pharmacologist, mentor, teacher, and best-of-industry role model.

WEB INSIGHTS

Government Performance Act Creates Results-Oriented Web Site

BY CAROL ASSOUAD

Since the Office of Training and Communications has just completed fiscal year 2000 planning for the Government Performance and Results Act (page 4), it's an opportune time to revisit the rationale behind the CDER Internet site. It's also appropriate to discuss how the site's objective has evolved and expanded from improving communication with consumers, industry and other stakeholders to helping consumers and health professionals make informed medication decisions and avoid medication errors.

For those of you unfamiliar with GPRA, this is the first time a management approach has been enacted into law. Implementing it has been both challenging and enlightening. As government managers and staff, we could dismiss zero-based budgeting, management by objectives and team quality management as mere fads.

Since GPRA was enacted into law in 1993, however, Federal government agencies have been required to manage their programs well, get results and be accountable for their operations. In other words, we now need to focus on program components that are aligned with our missions, determine what our results should be and really stretch to meet them.

While being responsible and accountable for achieving results might seem like a no-brainer, just defining program and agency results has been a transformational experience for many managers.

For centuries, managers have counted inputs, throughputs and outputs—for example, the raw materials for making widgets, the resources used in manufacturing the widgets and the number of widgets delivered and sold.

In CDER, we count the number and types of drugs reviewed, the number and types of adverse events reported, the number and types of material posted to the Internet site and the number of visitors to the site. We set and achieve performance goals based on measuring outputs, quality and productivity improvement, number of innovations or scientific breakthroughs.

We have seldom asked the important "So what?" or "So that?" questions and really looked at the results, outcomes or impacts of our programs.

Why are these question so important? You know that you have finally arrived at the program result when you can clearly answer the "So what?" and "So that?" questions.

We created, developed, converted and posted thousands of documents to the Internet site during fiscal year 1998. That's a measure of productivity when divided by the resources expended, but "So what?" We originally set out to improve communication with our stakeholders, remember. The number of annual users increased by 138 percent, from 628,000 in FY '97 to 1.7 million in FY '98; the number of hits or views increased by 139 percent, from 11 million to 28 million; and our feedback is almost always very complimentary.

You could deduce from this data that we are certainly strengthening our communication with users. But, again, "So what?" We now arrive at our Web program's desired result: Consumers and health professionals have the information they need to make informed medication decisions and serious medication errors decrease.

This objective is translated into performance goals, performance measurements, data sources and performance milestones.

It involves the whole of OTCOM, from Training's courses on improving the quality of technical writing and the development of reviews, to FOI's redaction of confidential information in reviews and other documents, to Communications staff's writing consumer-friendly drug information sheets, to the Library staff's organizing the information, creating Web documents and posting them. It involves the whole of CDER in producing the content for the site.

Moreover, our result has an external component over which we have little control because there are so many variables involved in making informed medication decisions, complying with medication regimens and in reducing serious medication errors. This lack of complete control over the result makes our Web site result a so-called "stretch result," a risky but very worthwhile challenge for us all.

The OTCOM goal, by the way, is a merger of the individual OTCOM division results; it in turn has been merged into CDER results by Office of Management staff (on CDERnet at http://cdernet/om/goals.pdf). The Center's results will be merged into FDA results and then HHS . You should be able to follow this process by reading the GPRA plans for FY 2000 as they are posted at each level of the Department.

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

Medical Library at Parklawn Changes Opening Time to 8:30 a.m.

The FDA Medical Library in the Parklawn Building is open for full service from 8:30 a.m. until 4:30 p.m. This changes its previous opening time of 7:30 a.m. There are no changes in staffing hours for the branches at Woodmont II and Corporate Boulevard.

The Library has closely reviewed all areas where it can increase productivity and efficiency and save either dollars or staff time. This began in anticipation of major cuts in both these resources due to budget restrictions, hiring pauses, several staff retirements and expected extended leave requirements. As much as possible, we have tried to target only those areas that would have the least impact on our users. The one-hour time slot that we are eliminating with the change in service hours had the lightest walk-in traffic of the day and will enable us to reallocate two staff hours daily (one each for the reference and circulation desks), for an annual savings of one-quarter of a full-time equivalent staff member.

We apologize for any inconvenience this may cause you and hope that you will bear with us as we face and deal with these new challenges and opportunities.

—Carol Assouad

Rule Change Cuts Red Tape Without Endangering Environment

By Nancy Sager

It was just over a year ago in August 1997 that FDA's rule amending its environmental regulations (21 CFR Part 25) became final. In the year before the regulation change, supervisory review was needed for more than 250 CDER environmental assessment actions. This required the efforts of three full-time employees and more than 100 part-time reviewers, including all chemistry reviewers in the Office of New Drug Chemistry and some pharmacology and toxicology reviewers in the Office of Clinical Pharmacology and Biopharmaceutics. In the year since the regulation change, the number of Center environmental assessment actions has been slashed to 20, with only one part-time reviewer needed, and without endangering the environment.

These regulatory changes were made in response to initiatives announced in the President's National Performance Reports, "Reinventing Drug and Medical Device Regulations" published in April 1995. The regulation change increased the efficiency of the agency's implementation of the National Environmental Policy Act by substantially reducing the number of environmental assessments required to be submitted by industry and reviewed by FDA. The change provides for categorical exclusion of additional classes of actions that do not individually or cumulatively have a significant environmental impact. The regulation change has allowed CDER to focus its resources in the environmental area on situations more likely to have an effect on the environment, for example, drugs derived from wild plants or animals and products used in large quantities.

The effort to reduce the regulatory burden associated with environmental assessments began in the Chemistry, Manufacturing and Controls Coordinating Committee and was accomplished in cooperation with the Regulatory Policy Staff, under the leadership of **Jane Axelrad.** The effort required countless hours of coordination among the FDA's centers and the Council on Environmental Quality, drafting guidances and Federal Register notices and responding to public comments.

An estimated paperwork reduction of more than 70 percent was included in the final rule, and one pharmaceutical trade organization predicted that the change would reduce by 90 percent the amount of environmental information submitted to the agency. Based on CDER's experience, these were underestimates.

Nancy Sager is the former environmental assessment team leader and currently acts as CDER's Environmental Officer in addition to her duties as Associate Director for Quality Implementation, Office of Pharmaceutical Science.

FDA Medical Library Celebrates 50 Years of Information Service

By Carol Knoth

On Oct. 2, the FDA Medical Library celebrated its golden anniversary with an open house attended by nearly 200 people.

Center Director **Janet Woodcock, M.D.,** opened the ceremony and commended the Library for having done an excellent job in preparing for the 21st century and cut the FDA cake catalog—a chocolate and marble cake shaped like the Library's old card catalog. Among attendees were retired FDAer, **Bob Bell,** former Library employees and renowned drug information expert, Winifred Sewell.

The Library's director, **Carol Assouad,** welcomed everyone to the festivities, spoke of many changes over 50 years and thanked the staff and those who made this possible. **Karen Kapust** recognized the work of library committees for the Library and its two branches and introduced those committee members who were present. **Kathie McConnell** and **Carol Knoth** awarded prizes for the Historical Treasure Hunt and Pharmacognosy 102 ("Weeds and Seeds") contests respectively.

In the Historical Treasure Hunt, first prize went to **Neal Bataller,** Center for Veterinary Medicine; second prize to **See-Yan Lam,** Division of Training and Development; and third prize to **Jonas Hylton,** a pharmacy student from Washington State University working as an intern in the Division of Pharmaceutical Evaluation II.

There were four perfect scores in the "Weeds and Seeds" contest. The winners were **Jonas Hylton; Heidi Burch,** Office of Training and Communications; **Joanne Kla,** CVM; and the CDER team of **Sharon Kelly** and **Mary Parks** from the Division of Metabolic and Endocrine Drug Products. The questions and answers to both contests along with the prize winners' names and photos of the party are on the Library's Web site at http://cdsml-web1/dml/.

To close the ceremony **Kathy Kruse** dedicated the Medical Library's historical pharmacy collection to **Elizabeth C. Kelly,** the Library's founder and director until 1995. A plaque honoring Kelly was unveiled.

Carol Knoth is a librarian in the Medical Library

OIT Sets Training Schedule for November, December

The Technology Support Services Staff in the Office of Information Technology offers monthly training on Microsoft Office 97 and other desktop applications, such as the new NDA Electronic Data Analysis Training, or NEDAT.

Class schedules for November and December are posted on OIT's intranet Web site (http://oitweb/oit).

Registration for any of these classes will be conducted by OIT until the technical difficulties with OTCOM's Classmate registration program are resolved. Therefore, you must send an e-mail to the person identified in the course announcement to register for the class. Since classes tend to fill quickly, you are encouraged to reserve as soon as you can.

To assist you in determining whether or not you need a class, a listing of the topics covered in the class is provided in the class announcement. From the Web site, you can access the manual or additional material created for the class.

Alcohol Warnings For Pain Relievers; Aspirin Professional Labeling

The FDA announced on Oct. 21 that all over-the-counter pain relievers and fever reducers must carry a warning label advising people who consume three or more alcoholic drinks every day to consult their doctors before using these drugs.

This announcement was based on a final rule requiring manufacturers to add the warning to the labeling within six months for OTC products and combination products intended for adult use that contain aspirin, other salicylates, acetaminophen, ibuprofen, naproxen sodium or ketoprofen.

FDA is issuing this final rule after considering public comments and data on the effect of combining chronic alcohol ingestion and the use of various OTC analgesics. The action also follows the recommendations of the Nonprescription Drugs Advisory Committee and the Arthritis Drugs Advisory Committee which concluded that chronic alcohol users should be warned that they may be at an increased risk of liver damage or stomach bleeding from use of these drugs.

The comprehensive action provides for an alcohol warning on all OTC pain relievers and fever reducers intended for adult use and may help prevent serious side effects in people who consume three or more alcoholic drinks every day.

The specific warnings concerning "liver damage" and "stomach bleeding" are being required because the Agency believes that consumers with a history of chronic alcohol use need to know the potential risk that use of OTC analgesic and antipyretic (fever reducing) drug products may pose to them.

"Consumers need to know that chronic use of alcohol while taking pain relievers or fever reducers can be hazardous to their health. FDA urges people with a history of alcohol use to seek a doctor's advice about their risk of side effects before taking these medications," said **Michael A. Friedman, M.D.,** Acting FDA Commissioner.

Also on Oct. 21, the Agency announced the final rule that substantially expands the recommended prescribed uses of aspirin for patients with cardiovascular and cerebrovascular problems. The rule also provides information for its use in treatment of rheumatologic conditions.

Under the rule, doctors and health care professionals will be provided with full prescribing information about the use of aspirin in both men and women who have had a heart attack, stroke and certain other cardiovascular conditions as well as rheumatological diseases. For stroke and cardiovascular conditions, lower doses are recommended than those previously prescribed by physicians in practice. Information on the use of aspirin for rheumatologic disease has also been expanded to include specific dosing information as well as information about side effects and toxicity.

The rule updates the professional labeling of OTC aspirin, buffered aspirin, and aspirin in combination with antacid that had been proposed by the Agency in 1988 and 1996. The new labeling is based on FDA's evaluation of multiple studies, both here and abroad, on the use of aspirin to treat cardiovascular, cerebrovascular, and rheumatologic conditions.

The rule, which provides labeling to help guide health care providers, does not recommend or suggest the use of aspirin by healthy individuals to lower their risk of heart attack. The final rule also concludes that there are insufficient data to recommend the use of aspirin in patients with peripheral vascular disease, such as those experiencing intense leg pain due to blockage of blood flow to that area of the body.

The following are highlights of the updated professional labeling:

The product is recommended for use in both men and women to treat transient ischemic attack, ischemic stroke, angina, acute myocardial infarction , recurrent MI, specific revascularization procedures and rheumatologic diseases.

To minimize adverse events, low dosages (50-325 mg) are recommended for cardiac and cerebral vascular uses. (75-325 mg are recommended for angina and previous heart attack.)

Aspirin manufacturers who wish to disseminate labeling on the professional uses of aspirin must use the labeling specified in the final rule. The new labeling, which goes into effect in a year, will be provided directly to practitioners licensed to prescribe drugs.

The Agency has determined that the advice and supervision of a health care provider is required for these professional uses. For more information, see "FDA Issues Professional Labeling for Aspirin" on the CDER's Website at http://www.fda.gov/cder/news/aspirin/aspirin_QA.htm.

Garry Wins Administrative Category in WJLA-TV's Tribute to Women

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through self-study, by developing and implementing MS Access databases and then teaching others to use them to increase the efficiency of their work.

In the first two years of her work for CDER, Katrina distinguished herself as a superior secretary. She maintained timekeeping, filing, scheduling, taking meeting minutes and other duties. During this time, she developed herself in the areas of program analysis, information technology and procurement through continuing education and training.

Katrina has developed databases that measure outputs and outcomes of the various components of our operational units. This helps us manage our scientific issues better without dampening the scientific inquisitiveness needed to keep reviewers keen in their fields. She has done this by promoting the management system as a means to highlight accomplishments instead of a new way of micromanaging. This has encouraged high quality work with direct relevance to public health.

Thomas Conrad is Director of the Extramural Program Staff in OPDRA.

ICH Predicts Common Technical Document Ready by 2000

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(manufacturing). They reported on the format and content of the emerging document.

Regulatory specialists reported that they are nearing consensus on the harmonization of the table of contents as well as the content of clinical and non-clinical summaries and tabulations. The steering committed agreed that the project is well on target with a finalized document expected by the year 2000.

Encouraged by this success, the steering committee agreed that work should commence on adapting the *Common Technical Document* for electronic submission. This would facilitate better and more economical management of documentation.

The steering committee also confirmed that a Fifth International Conference on Harmonization would take place in the United States in the last quarter of 2000. The main focus for ICH 5 will be agreements on completion of the *Common Technical Document.* A location on the West Coast is being sought.

Although the *Common Technical Document* is the primary project for ICH Phase II, the steering committee received reports on another important effort: good manufacturing practice requirements for active pharmaceutical ingredients. An extended expert working group moved closer to consensus on a consistent approach to ensuring the quality of active ingredients used in the manufacture of drugs worldwide. The group is aided by experts from outside the three ICH regions.

Recognizing initiatives in all three regions to promote the early availability of important new medicines for children, the steering committee formally adopted a new topic on clinical trials involving children. Other new topics considered for adoption in the near future include safety pharmacology and a pilot project to harmonize the approaches to clinical trials in specific therapeutic areas.

Another Phase II activity is maintaining and updating of previous ICH agreements. A major review of one of the earliest ICH Guidelines—Stability Testing (Q-1A)—was initiated. Several minor clarifications and updates of other guidelines will be undertaken including those on residual solvent impurities and on the format and content of individual adverse event reports.

At the same time, completion of Phase I activities drew a step closer. The Steering Committee confirmed the consensus, reached at the time of ICH 4 on repeat-dose toxicity testing requirements in animals. The publication of this finalized guidance will mark a further step toward eliminating redundancy in the testing process for new drugs.

Progress on a guidance for the choice of control groups in clinical trials (E-10) is nearing consensus and will complete the efficacy topics from Phase I.

The establishment of MedDRA as a new medical terminology to be used in a wide range of regulatory activities is moving toward completion. The Steering Committee is selecting a maintenance and support services organization to license, maintain and distribute the terminology under contract. The steering committee appointed the International Federation of Pharmaceutical Manufacturers Associations as trustee of the rights to the terminology in order to establish a contract.

Roger Williams, M.D., is the Deputy Center Director (Pharmaceutical Science) and is the FDA's lead delegate to the ICH steering committee. As Deputy Center Director, he is responsible for CDER's international activities.

V.P. for Health Sciences at University of N.M. Wins Senate Confirmation

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woman to serve as Commissioner of the Food and Drugs. During a distinguished career, she has championed modern management strategies and maintained the highest clinical and research standards at two federal public health agencies and has fashioned innovative health care strategies with a focus on individual patient care at two major university medical centers.

Since 1994, Dr. Henney has been the vice president for health sciences at the University of New Mexico where she presided over a major consolidation of the university's hospitals, schools of medicine, nursing and pharmacy, and specialized facilities for mental health, cancer and pediatrics.

From January 1992 to March 1994, Dr. Henney served as FDA's Deputy Commissioner for Operations where she managed the Agency's daily activities, revitalized FDA's six science centers and implemented key legislation, including the Prescription Drug User Fee Act of 1992.

From 1985 until joining FDA, Dr. Henney served as interim dean of the University of Kansas School of Medicine, as Vice Chancellor for Health Programs and Policy, and as acting director of the Mid America Cancer Center at the University of Kansas. Between 1976 and 1985, Dr. Henney served at the National Cancer Institute, rising to the position of deputy director, where she was instrumental in the development of two innovative programs which engaged community-based oncologists in research and provided physicians and patients with up-to-date information on state-of-the-art therapy and investigational research protocols.

Born in Woodburn, Indiana, she received a bachelor's degree in biology from Manchester College, North Manchester, Indiana, in 1969. At a time when relatively few women were admitted to medical school, Dr. Henney graduated from the Indiana University School of Medicine in 1973. She performed her internship at St. Vincent's Hospital in Indianapolis, her medical residency in Atlanta and held a fellowship in oncology at M.D. Anderson Hospital and Tumor Institute in Houston.

She is the author or co-author of some 40 academic articles and book chapters and has received numerous awards, including the Public Health Service Commendation Medal.

Shalala expressed her appreciation for **Michael Friedman, M.D.** and his "extraordinary service" as acting FDA commissioner. "His leadership and professionalism have served the nation well over the past 18 months" Shalala said.