news along the pike

April 1997

Center for Drug Evaluation and Research

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Pike's Corners . . .

Development Initiative Launched

Secretaries, Support Staff Get Own Program

By Sarah Thomas

A new professional training opportunity for CDER secretarial and support staff kicked off at the end of February when the Division of Training and Development, Office of Training and Communicationss (OTCOM), announced the CDER Secretarial and Support Staff Career Development Certificate Program.

The program is open to CDER's career and career-conditional full-time permanent secretaries and support staff in grades GS-1 through 9. The career development program requires an individual development plan and completion of eight courses over a three-year period. A certificate of accomplishment will be issued to those who successfully complete the program. The courses cover four core areas:

- Communications (one course each in interpersonal communication and writing).
- Skill building, such as time keeping and travel (three courses).
- Career transition (one course).
- Computer skills (two courses).

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OEB: Adverse Event Overhaul on Fast Track

By Norman Oliver

At a public meeting held in Rockville last month, Center and Agency officials presented informaiton to about 250 representatives from the drug industry about plans to build a world-class safety surveillance system for drugs. Based upon a revitalized program, new regulations, and international harmonization agreements, the new Adverse Event Reporting System (AERS) will be designed to provide improved safety reports, more efficient processing, and analysis of reports of drugs once they have been on the market.

According to the Agency, the final regulations governing the new system should be written by the beginning of 1998.

The March 17 meeting was held to update industry on the Agency's progress and to solicit comments from manufacturers on what is likely to be a major change in how drug companies do business.

The goal is to move from "a torturous paper process" to a real-time, on-line system that allows both drug companies and the FDA to get a better picture of what's happening with a

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OTCOM Open House Slated for May 7

By David Kausal

With the newly renovated Medical Library and the new Learning Resource Center ready to open in the Parklawn Building, the Office of Training and Communications (OTCOM) is inviting all CDER employees to an Open House on May 7. Our theme is "Celebrate Learning, We're Here to Serve You." You are invited to visit from 12:30 p.m. to 4:00 p.m. and see many of the technological applications that are available in communication and training for everyone in the Center.

One starting point for your visit is the reception area of 12B-45, where you can pick up a map of the divisions, or you can become part of a guided tour leaving every half hour. Open for tours will be the 13th floor Training and Videoconference rooms, the Medical Library, the Learning Resource Center, and CDER's Freedom of Information central office.

We will share the following to underscore

(Continued on page 8)

Joe's Notebook

High Fat, Low Fat—You Choose

The manager of my local supermarket tells me that low fat food products are the hot new items in his line of work. That's good for my health. But he still has to please all customers, so his isn't a low fat only store. I think of the *Pike* as a little bit like his store, something for everyone. Unlike the grocery store, however, you, the *Pike's* customers, have to bring in the products we offer up each month.

So come to OTCOM's open house May 7 and let me show you how I put the *Pike* together and just how easy it is to get your story into the *Pike.* Better yet, if you stop by I can offer you a choice of a high fat treat of homemade creme de menthe brownies or a fat free pretzel. Your choice. I'll even give you the recipe for the brownies if you promise never to eat more than one a week. My conscience is clean on this matter, since I just used HHS' healthfinder (see page 7) to go to the American Heart Association's Web site and discover that they now say that you can calculate your fat intake for the week, not just the day.

Whoops! I knew when I set out to get all the CDER players accounted for in *Pike* stories, I would eventually miss a key team member. Well, it happened in last month's story on the CDER team that was instrumental in getting out the proposal on phasing out ozone-depleting propellants in drug products. Somehow, through one of those editorial gremlins that invades copy late at night, **Wayne Mitchell,** a regulatory counsel with Regulatory Policy Staff in CDER was left off the working group list. "He was *the* key person in authoring and championing the process," says **Bob Meyer** from Pulmonary Drug Products. A neat thing about the Pike, however, is that it's published electronically, so you'll find a corrected version on the X:drive and on the Internet. So throw out that photocopy you picked up in the Library and print out a nice fresh copy for your files.

Can you help us decide if we are about to have an FDA first? Even **John Swann** of the FDA's History Office is taking a pass on this one. John, by the way, has volunteered to help us all know where our roots are as we march into the technologically exciting 21st century. You'll find his first column on page 5. Anyway, **David Katague,** who rejoins us this month as guest author of the Mentor's Corner believes we may have an FDA first. You may recall his profile of **Vithal Shetty** in November's *Pike.* Vithal, while a full-time review chemist with CDER, has discovered a new class of antiviral and antimicrobial compounds. He made his discovery as part of his professional development arrangement with the NIH. The patent he earned is assigned to the U.S. Government. This new class of compounds is about to enter Phase 1 of human testing for use as an oral antimicrobial for the treatment of gingival inflammation and bleeding or as a skin antiseptic and antimicrobial agent. A private company has obtained licensing rights from NIH, and this private company is submitting all the pre-IND information for FDA oversight.

We know that many *Pike* readers in CDER have invented compounds when they worked in academia or industry, and those compounds have made it through the drug review process while they are reviewers here. But, as far as David and I know, this could be the first time in either CDER or FDA history, that a full-time FDA employee has invented a new class of compounds while on duty with the Agency and will see them enter into the human drug development and into FDA oversight. If you know of a similar case, stop by OTCOM's open house on May 7 or e-mail me (OLIVERN).

news along the pike

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http://www.fda.gov/cder/pike.htm

Photocopies are available in the Medical Library (Parklawn 11B-40) and its branches (Corporate Boulevard S-121, Woodmont I 200-S, and Woodmont II 3001).

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

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Ombudsman's Corner

Learning from Our Successes

By Jim Morrison

It is just as important to learn from our successes as to learn from our mistakes. Since my aim is to make the job of Ombudsman obsolete because there is nothing left for anyone to complain about, it is worthwhile to study those areas in CDER where we don't get complaints; for example, the PDUFA (Prescription Drug User Fee Act) area of the new drug review.

One of the biggest sources of complaints from the outside is the timeliness of CDER processes. And yet, I get very, very few complaints about the time taken to review an NDA that was in the PDUFA system. Oh, I get complaints about other aspects of the new drug development process; whether they should be subject to user fees for some supplements, whether requiring a more costly study is justified, why it takes so long to schedule a meeting, and the like. But once a drug is in the NDA review process under PDUFA, I just hear the sweet sound of my phone not ringing.

Is that because applications get reviewed so fast that it boggles the minds of applicants? Not really. Even though we have cut review times in half over the past few years, it still took about 15 months last year from submission to approval.

I believe that the most important reason for the lack of complaints about PDUFA reviews is their predictability. User fee goal dates are set, and everyone knows what the goal date is for a given application. Not only that, everyone knows that CDER will meet or beat that date with the same certainty that we require for clinical studies (95% confidence or better).

Therein lies the key to our success. In the non-PDUFA world, where I still get many complaints about timeliness, I would guess that about half would not arrive at my door if there were a way for the complainant to know exactly when to expect a response. The more forthcoming we are about the exact status of a review, the fewer the causes for complaint.

I know it's easier said than done. With declining resources and shifting priorities, it can be a nightmare to predict a date when a review will be completed. But on the positive side, I would point to the success we have had with PDUFA and say that not all of that success was due to an increased staffing level. Review times had begun to drop before the new employees came on board.

A critical element in achieving a reputation for delivering results in a timely manner is having a mind set that places a high priority on setting and meeting realistic timeframes. Once adopted, this behavior applies to all interactions within CDER and with outside contacts. I try to use it in my work, and for each caller I give a time by which I expect to deliver an answer. I then try to get the answer by the date promised. If I can't, I call anyway to tell what has happened up to that time. People will forgive a reasonable number of missed due dates if they feel you are honestly trying your best to get the work completed.

The cardinal rule of customer service is not to overpromise. Nothing destroys credibility so much as giving an estimate and not meeting it, then giving another estimate and not meeting that. After a while, excuses, no matter how valid they sound, will not be accepted. If you find yourself giving overly optimistic estimates, try adding a fudge factor. I tend to be too hopeful, so I often double my first assessment before I predict a due date.

Not only will you build credibility by giving estimated dates and meeting them, you will gain skill at making time estimates. You will even derive a sense of satisfaction from your newly developed expertise.

Jim Morrison is the Center's ombudsman.

CDER Set to Kick Off Savings Bond Drive

By Paul Brown

As the CDER coordinator for the 1997 U.S. Savings Bond Campaign, I want to encourage everyone to consider investing in U.S. Savings Bonds through the payroll savings plan. During the month of May, every CDER employee will be contacted by a Savings Bond Canvasser and offered the opportunity to invest. Take some time and consider how you might benefit from investing in Savings bonds.

Why should you invest in U.S. Savings Bonds?

- Bonds are a safe investment.
- You can do what you want with the money you have in Bonds.
- Payroll allotment is an easy and painless way to save.
- Savings Bonds have distinct tax advantages including special provisions if they are used for educational expenses.

Even if you invest elsewhere, don't underestimate the value of investing in U.S. Savings Bonds. More information on U.S. Savings Bonds can be obtained through Videotex on SmartTerm or through the Department of the Treasury World Wide Web page on Savings Bonds:

http://www.publicdebt.treas.gov/sav/sav.htm.

Remember the campaign motto: "A Great Way To Save."

Paul Brown is coordinating this year's campaign for CDER.

Quality of Work Life Week, May 12-16

FDA will sponsor events May 12-16 to explain the DHHS strategy to improve the quality of work life initiatives and to unveil the Agency's strategic plan to continuously improve the quality of work life for all FDAers. The overall goal of the Quality of Work Life Strategy is to improve employee satisfaction, strengthen workplace learning, and empower and involve employees. The strategic plan focuses on improving employee communications, work and family programs, becoming a learning organization, and appreciating diversity.

Administrative Management Corner

Payroll Subcommittee Gets Off to Great Start

By Rich Vengazo

Had a pay problem lately? How about a leave problem? What, both? Have error notices been prepared, and you're uncertain about their status? How about not being paid on time, or worse yet—not at all? Read on . . .

These are just a few of the issues that are being addressed by the payroll subcommittee of the Center's Administrative Management Coordinating Committee (AMCC). This subcommittee is attempting to implement for payroll the goal of the AMCC, which is to improve, enhance and streamline administrative processes in the Center.

In last month's corner, **Charlene Cherry** described the plans and initiatives of this very active and enthusiastic coordinating committee. Fortunately, for the payroll subcommittee, there is representation from each of the Center's six super offices; and our next member, hopefully, will be from the Payroll Office itself. Our members had a very casual meeting for the first time in March. We got to know each other, addressed some common challenges and had time to develop some plans and initiatives. Another meeting is scheduled for April, when someone from Payroll will address our group. The subcommittee chair and a representative from the Center for Biologics Evaluation and Research attended a presentation on a database system being developed by Accounting that, once implemented, will make it easier for individual timekeepers and timekeeper contacts to obtain the up-to-date status of all submitted error notices.

Other plans for this subcommittee include: having an error-free pay system for special government employees, gaining more accessibility with Payroll personnel, requesting more timekeeper training and having ongoing training, ensuring timely data input by both Personnel and Payroll for cash awards, and resolving all leave and pay errors more quickly. Other issues will probably surface as the AMCC matures. If you have a general payroll issue for us to look at, please e-mail it directly to me (VENGAZOR), and I will do my best to have it resolved. All subcommittees, including payroll, are still accepting membership; if you are interested in joining, please see last month's *Pike* for contacts for the various administrative areas.

Rich Vengazo is a management officer in the Office of Pharmaceutical Science.

Mentor's Corner

Chemistry Team Puts Mentoring Program into Full Swing

By David B. Katague, Ph.D.

Seven years ago, when I first joined the FDA, there was no Mentoring Program—not even a formal orientation program. Although I had 20 years of industrial experience in chemistry, my first three weeks as a reviewer were filled with trauma, confusion and frustration because I had nobody to whom I could take my "trivial" questions. I promised that I would not allow this to happen to new reviewers if I become a team leader. This occurred, and, thanks to OTCOM's Mentoring Program, I have already accomplished one of my goals as team leader. The Mentoring Program is already paying high dividends in our division after only three months.

Two new reviewers, **Dorota Matecka, Ph.D.,** and **Milton Sloan, Ph.D.,** are currently participating in the program with **Jim Timper,** a review chemist in the division, as their mentor. In addition to mentoring these two new reviewers, Mr. Timper has been very active on a formal basis with the Mentoring Program and serves on its advisory committee.

June Cory, who coordinates the program, reports that his dedication to mentoring has been very helpful in getting the entire program launched and off to its successful start.
Dr. Matecka started in January and Dr. Sloan joined our group in February. Because of Jim Timper's mentoring activities, the standard orientation time for both reviewers has been shortened.

"I was assigned a mentor from the very first day and I think this was a great idea," Dr. Matecka reports. "I have had a new IND and NDA almost from the very beginning, and I have been working on them together with Jim. We are discussing all kinds of scientific and regulatory problems, and Jim is sharing with me his great experience in the review process."

Matecka came from the NIH where she was doing research in medicinal chemistry and did not have much experience in the regulatory science. "I found that having somebody I can ask any question about work, without being afraid that perhaps it is a trivial one, makes this process more comfortable," she said. "Attending meetings with my mentor is very helpful in learning about the products that come to the division and about the review process in general. It also helps to get to know other reviewers from other disciplines. My other colleagues are also very helpful."

Based on our group's experience with the current program, we have decided to try a group mentoring approach based on specialties for our next round of mentoring. This will be fairer to the mentor, require less time and provide a mentoring experience that covers more areas of expertise. By doing group mentoring, we hope to impart different areas of specialization. I will let you know the rewards and advantages of this modification, group vs. individual mentoring, in a future article.

My congratulations to OTCOM for coordinating the Mentoring Program and especially to the mentors and their respective team leaders. If you have any questions on how to become a mentor, how to get a mentor, who is eligible, who are the points of contact, please call or e-mail June Cory of the Division of Training and Development (7-4580 or CORYJ).

David B. Katague, Ph.D., is a chemistry team leader in the Division of New Drug Chemistry III.

History Corner

FDA's Encounter with Goof Balls, Bennies Before DEA

By John Swann, Ph.D.

From the late 1930s until the mid-1960s, the greatest drug enforcement problem FDA faced was the illegal sale of dangerous drugs. Amphetamines and barbiturates—and later, hallucinogens—occupied more of the agency's time in that era than all other pharmaceutical concerns combined. Under the mandate of the 1938 Act that drugs be labeled with adequate directions for safe use, the FDA was soon issuing numerous warnings to be labeled on a variety of drugs or drug groups. However, certain products simply could not be labeled for safe use because of potential complications in their therapeutic application or abuse potential. Two months after the 1938 Act was passed, FDA promulgated the policy that such medicines be labeled with a version of what we now know as the prescription drug legend that prohibits dispensing without a prescription. By 1940, amphetamines and barbiturates joined that group.

These products had been introduced for legitimate medical reasons. Barbital (Veronal), the first of the barbiturates, arrived in 1903 as a useful hypnotic and was employed successfully in epilepsy and other therapeutic venues. In 1932, Smith Kline & French introduced an amphetamine (Benzedrine) as a nasal decongestant, which soon found other medical applications, such as in narcolepsy. However, the abuse potential of both drugs quickly emerged.

The early locus of illegal distribution was the retail pharmacy, although FDA pursued this source slowly until 1948, when the Supreme Court ruled that the agency could move against violative drugs at the retail pharmacy level as long as they had traveled in interstate commerce. Thereafter, scores of prosecutions were pressed against pharmacies each year, often for unauthorized refilling of prescriptions for barbiturates. Robert Fischelis, Secretary of the American Pharmaceutical Association and a prominent spokesman for the field at this time, complained that FDA did not understand the physician-pharmacist-patient relationship and that professional pharmacists were being unfairly singled out.

Conversely, FDA reported some high profile results of illegal drug refills, such as a Waco, Texas, pharmacy that dispensed more than 18,000 barbiturates in an 18-month period without a single prescription, or the Kansas City woman who slowly died an addict after securing over 40 refills—mostly mail order—from two original prescriptions for barbiturates at a Los Angeles pharmacy. Some pharmacists were to blame for the problem, as were some physicians who exhibited remarkably sloppy prescribing and dispensing practices.

FDA continued to focus on the community pharmacy as the primary source for illegal sales of dangerous drugs, even after the Durham-Humphrey Amendment of 1951 clarified the meaning of prescription drugs and mandated prescriber authorization for refills. But different sources of barbiturates and amphetamines began to emerge in the 1950s, such as weight reduction salons, bars and cafes, street corner peddlers and, especially, truck stops—the trucking industry having come under intense public scrutiny following many highly publicized highway accidents resulting from these drugs.

A special part of the agency called the Bureau of Drug Abuse Control was created in 1965 to help deal with the growing problem of non-narcotic drug abuse. Interdiction efforts, aided by undercover techniques that had been used by agency personnel for a decade, were improved when the Bureau was authorized to utilize an array of criminal investigative methods. In 1968, jurisdiction over the illegal use of amphetamines, barbiturates and many other drugs prone to abuse was transferred to the predecessor of the Drug Enforcement Administration, but the agency retained authority over therapeutic uses of these substances. Amphetamines and barbiturates, the focus of enormous agency resources for three decades, now were the Department of Justice's headache, but their departure by no means meant the agency no longer would have to deal with mass abuse of prescription or over-the-counter medications. Our experience with "goof balls," "bennies" and other misappropriated therapeutic agents would be an important history to draw from in the future.

John Swann works in the FDA History Office.

Industry Reacts Positively to BACPAC Proposal to Reduce Regulatory Burden

CDER Chemists met last month with 490 representatives from academia and the pharmaceutical industry to discuss the scientific issues surrounding bulk drug substance manufacturing changes. The workshop was sponsored by FDA and the American Association of Pharmaceutical Scientists.

Currently, when certain changes in manufacturing or synthesizing a drug's active ingredient take place, each product with that ingredient may need a supplement. BACPAC, or Bulk Active Chemicals Post Approval Changes, proposes to find scientifically sound ways to ease the burden that a cascade of supplemental applications has on both industry and FDA reviewers and possibly shorten the industry's implementation time. Changes are frequently made to enhance efficiency, protect the environment, improve the product, reduce impurities, or lower costs to the consumer. Last year, CDER approved 4,152 manufacturing supplements.

Industry is excited about the prospect of a BACPAC guidance. Center chemists are excited, too, because BACPAC holds the potential of enhancing innovation in manufacturing and also reducing the load of repetitive reviews. Chemists would gain more time to focus on NDA reviews and interact with industry. The next step is for the Office of Pharmaceutical Science to draft a BACPAC guidance. For additional information, contact **Kasturi Srinivasachar** or **Eric Duffy**.

Center Sets May 9 for Spring Honor Awards Ceremony

By Jackie Barber

CDER will hold its Spring Honor Awards ceremony on Friday, May 9, at 10 a.m. at the Doubletree Hotel's Regency Room, 1750 Rockville Pike.

CDER will present the following awards to recognize the accomplishments of its employees: Commendable Service, Outstanding Achievement, Equal Opportunity Achievement, and Group Recognition Awards. Commissioned Officers will receive PHS Commendation Medals and PHS Unit Commendations.

In addition to FDA honor awards, we are proud to announce that we will be presenting three new CDER Peer Honor Awards. These awards were established as a result of the Reviewer Affairs Committee recommendation for changes in the awards process. A CDER Peer Honor Awards Committee was established to review and approve the following awards:

- CDER Team Excellence Award, recognizing a team for extraordinary contributions to CDER's mission.
- CDER Support Staff Excellence Award, recognizing clerical, technical, assistant and general support individual(s) or teams whose activities demonstrate excellence in achieving CDER's mission.
- CDER Administrative/Program Excellence Award, recognizing individual(s) or a team who effectively carry out the program's mission, ensuring excellence, as well as striving to make significant contributions to CDER program goals.

In addition to the Peer Honor Awards, CDER will also present the CDER Special Recognition Award and CDER Fellowship Program Certificates.

This year will mark the first time that the Center will have two awards ceremonies. The Reviewer Affairs Committee recommended that we host spring and fall ceremonies so that the Center can recognize and reward the CDER community's many accomplishments throughout the year.

The Fall ceremony is scheduled to be held on Nov. 21 at the Gaithersburg Hilton. For more information, please call me at 4-0584.

Jackie Barber is the CDER incentive awards officer.

Leadership Fellows' Corner

Taking Another Look at CDER's Awards Program

By Mary Lambert

Most of us in the CDER community are familiar with at least some aspect of the Center's awards program. Whether you are intimately acquainted with the program or whether you are mystified by it, you will probably be interested to know that CDER is evaluating the program. This "second look" begins the process of aligning what we as a community value—our operating principles—with what we recognize through our awards system.

As a part of my experience in the CDER Leadership Fellows program, I have been involved with a project to reengineer some aspects of the awards program. The purpose of this project is to provide a greater variety of awards that recognize both employee programmatic contributions, as well as service to all CDER staff, to the FDA, to the pharmaceutical industry and to the public at large, as well as to streamline and improve the nomination process. The work of this project was to develop the criteria for each new award. I am in partnership with **Jackie Barber** of the Program Management Services Branch (also **Rhonda Alderman, Ellen Johnsey** and **Ruth Clements**) to accomplish this work.

Based on a Reviewers Affairs Committee recommendation to senior management, new peer honor awards have been established for CDER. Criteria for these awards were developed to reflect CDER's operating principles. Three of these awards will be presented at CDER's Spring Awards Ceremony on May 9 (see Jackie Barber's story above).

A call for volunteers recruited CDER individuals to serve on the peer honor awards committee, which makes the selection recommendations from among the nominations for the new peer honor awards. A complete description of the criteria for each award was included in the call for nominations sent by e-mail on Dec. 13.

Criteria for additional peer honor awards are currently under development to recognize excellence in other areas such as information technology, science and service. These new peer honor awards will be added for presentation at the fall CDER awards ceremony.

Mary Lambert is a special assistant in the Office of Training & Communications.

FDA to Provide Inspection Reports

Starting in April 1997, FDA will automatically provide firms that have been inspected with a copy of the Agency's final report—establishment inspection report (EIR)—of the firm's facility. The EIR will be provided as soon as the Agency has determined that the inspected firm's facility is in compliance with FDA rules and guidelines.

This new FDA policy eliminates the need for the inspected facility to request these reports through formal Freedom of Information Act procedures and should provide them with quicker, easier access to useful information about the inspection. The Agency undertook this action in direct response to comments from industry trade associations that their members could benefit from more timely access to these reports. This action is part of the Agency's overall effort to enhance its regulatory efficiency and to reduce unnecessary burdens on industry.

Reviewer Affairs Corner

RAC's Semi Hi-Tech Suggestion Box Calls for Your Input

By Karen Oliver

The purpose of the Reviewer Affairs Committee (RAC) is to provide a forum representing all CDER primary reviewers and to improve communications among reviewers and between reviewers and CDER management. In an effort to identify your needs, concerns and address issues of concern, the RAC has established an on-line suggestion box. The suggestion box is up and running, although there is always the possibility of a few glitches, so please be patient. The suggestion box is located on the X:drive in Coorcom\RAC\Suggest.

The RAC suggestion "box" is less like a box and more like a folder in which you can place a file with your comments and index you comments in the index:

- Navigate to the X:drive using WordPerfect, the Windows 3.1 File Manager or Windows 95 Explorer.
- Open the file $content.wpd in WordPerfect.
- Read the directions. In the next open row of the table, type in a file name sequential to the previous one. You will use this file name to save your suggestion. In the next column type in the title of your suggestion. If your suggestion is related to a previous suggestion, be sure to say so.
- Type your suggestion in a separate document and save it in the folder with the file name you used the index.

We know that this isn't exactly the state of the art, but your suggestions are important to the committee. If you can help us automate a suggestion box on the CDERnet, we'd really appreciate it.

Please be as clear, concise and specific as you can. This is not a "gripe" box, rather a mechanism for identifying appropriate and pertinent reviewer issues. Please use the suggestion box in a wise, kind, gentle and friendly manner.

If you have any questions regarding the use of the suggestion box, please e-mail RAC chairperson **Janet Higgins** (HIGGINSJ).

Karen Oliver is a regulatory health project manager in the Division of Gastrointestinal & Coagulation Drug Products.

HHS Eyes Reliable Information on 'Healthfinder' Web Site

The HHS Office of Disease Prevention and Health Promotion (ODPHP) in collaboration with many other agencies has launched healthfinder, a new Federal gateway site on the Internet that makes it easier to find trustworthy health information on the World Wide Web. The Internet address for healthfinder is: http://www.healthfinder.gov.

Healthfinder brings together under one umbrella the broad range of consumer health information resources produced by the Federal government and its many partners. Its current resources include:

- Hyperlinks to more than 550 Web sites, including more than 200 Federal sites and 350 state, local, not-for-profit, university and other consumer health resources.
- Links to nearly 500 selected on-line documents.
- Links to FAQs (frequently asked questions) on top health issues of concern to the American public.
- Links to databases and web search engines by topic and agency.
- Graphical and text versions to accommodate all users.

Healthfinder combats "information overload" and endless searches by organizing these resources in a subject index, which allows consumers to quickly locate the health information they want. Future plans for the site include a full-text index, health risk appraisals, and expanded publication ordering. Collaborations with public and private sector organizations, such as public and medical libraries, will expand healthfinder's reach to those who do not have personal Internet access. Healthfinder was developed by ODPHP in collaboration with other agencies.

Atlas Maps Changing Mortality Patterns for U.S. Localities

The first atlas to map the leading causes of death by race and sex for small geographic areas throughout the United States has identified high risk areas for heart disease, cancer, stroke and violence deaths in America. The *Atlas of United States Mortality*, developed by the Centers for Disease Control and Prevention's National Center for Health Statistics, reveals shifts from previously documented mortality patterns and points to new areas now at greater risk.

The atlas maps death rates for 1988-92 for the 805 Health Service Areas, which are clusters of counties defined on the basis of where county residents obtain hospital care. This approach provides much more local detail than maps of states and allows a more reliable analysis than could be performed at the county level, especially in sparsely populated areas.

Key findings show important geographic patterns or shifts in the three top causes of death—heart disease, cancer and stroke.

The atlas can be used to determine the approximate rate of an individual area; discern clusters of areas with similar rates; visualize broad geographic patterns; and compare regional differences by age, race and sex for each cause of death.

The causes included in this atlas account for more than 80 percent of all deaths in the United States. The atlas is available from the National Center for Health Statistics, 6525 Belcrest Road, Hyattsville, Md. 20782. The news release and excerpts from the atlas can be downloaded from the NCHS Home Page: http://www.cdc.gov/nchswww/nchshome.htm.

Bringing the Forest into Focus

Center Envisions Clinically Relevant Adverse Event Reporting

(Continued from page 1)

particular drug product, said **Robert Nelson,** associate director of CDER's Office of Epidemiology and Biostatistics (OEB).

Currently, drug makers, health care professionals and even individual consumers submit adverse event reports singly or in batches to the Agency. The current system cannot easily evaluate signals in a population-based manner.

The current paper-based system focuses on the trees, said **Vincent Guinee,** director of the OEB's Division of Pharmacovigilance and Epidemiology, and the new system is designed to bring the forest into better focus. Adverse event reporting now captures rare, isolated events.

Not only that, Guinee said that his office is flooded with 180,000 paper adverse event reports each year. The proposed AERS is designed to provide a variety of clinically relevant reports and analyses on a drug's safety profile and aid in determining a drug's risks and benefits in special populations such as children and the elderly.

State-of-the-art information technology will be the backbone of the system. An overview of AERS can be found on CDER's World Wide Web site by clicking on the What's Happening button or going to:

http://www.fda.gov/cder/aers/index.htm.

AERS will mean changes for the way industry does its business as well. For instance, manufacturers will have to define "serious" reactions more closely, provide follow-up on cases, and make linkages where possible. The FDA will be able to call up reports on particular products more easily. Also, the Agency will have the capability to monitor submitted adverse event reports from manufacturers on a real-time basis, thus getting a quicker handle on potentially serious problems.

Other CDER officials presenting at the meeting were Deputy Center Director for Review Management, **Murray Lumpkin, M.D.,** and OEB Director **Robert O'Neill, Ph.D.**

Secretaries, Support Staff Get Own Development Program

(Continued from page 1)

Most of the courses are about a day long. All participants are assigned mentors who work with them and their supervisors to set goals that will ensure successful completion of the course work. This program was developed by a four-member committee: **Sarah Thomas** (chair), **Delores Rhodes, Iris Khalaf,** and **Charlotte Henning.** The committee members all work in DTD and also serve as mentors for the program.

Your supervisor can nominate you, or you can nominate yourself. The program may be started anytime during 1997. The courses that qualify have to begin in March of this year or later. Even if you have already taken many courses, we can find new ones for you that can be applied to the program.

Enthusiasm for this program is high and continues to rise, with approximately 30 percent of CDER's secretarial staff now participating. We are encouraged that so many of our hard-working secretaries and support staff are taking advantage of this opportunity and are happy that we can expand CDER's long tradition of excellent training and education to include this program. There is no cost for participation in the program; however, your office has to pay for any courses given by other government agencies or private vendors. For additional information or to submit an application, call any of the committee members at 7-4580.

Sarah Thomas works in the Division of Training and Development.

OTCOM Open House to Feature High-Tech Support to CDER

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how OTCOM serves CDER's community:

- **Medical Library** (11B-45). CDERnet demonstrations and information, self-guided tours of the library, and a give-away of withdrawn books.
- **Division of Training and Development** (12B-10). The Learning Resource Center, training facilities for Distance Learning, and information on training, development and scientific courses and programs.
- **Division of Communications** (12B-45). Demonstrations of videoconferencing equipment in 13B-37, a desktop videoconferencing unit in 12B-02, a digital electronic camera, Fax on Demand room and displays of resource materials such as informational packets on NDAs, INDs, ANDAs and GCP.
- **Freedom of Information** (12B-05). Processing facilities for FOI requests and a copy of the latest *CDER's Guide to the Freedom of Information Act and the Privacy Act.*

Refreshments will be served at locations throughout the office. You can join a "treasure hunt" by collecting tokens at each location for fun and prizes.

Come by and get to know the staff of OTCOM—we're ready to serve your communications, training and research needs.

David Kausal works in the Division of Training and Development.