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## “CDER Jeopardy”

### What Was the Season's First Scientific Rounds?

The only thing missing was Alex Trebek, as CDER's new season of Scientific Rounds kick-started September 22 with a special Jeopardy® edition.

A standing-room-only crowd at Parklawn Conference Room D was on-hand to watch teams from Corporate, Woodmont and Parklawn square-off in two rounds of scientific facts, drug lore and, at times, incredible medical minutia.

With Peter Honig, OPDRA/ORM, tackling the Trebeck role and Judge

Judy, er...Nancy Smith, OTCOM, ensuring the correctness of all responses (and looking oh so very British in her white wig and black robe), the practice round went fast and furious. Topic categories included CDER ABOBs® (men named Bob in CDER), FDA trivia and potpourri.

In typical Jeopardy fashion, Honig provided the answers and the teams had to respond in question form (Answer A1,056"; Question AWhat is the number of parking spaces in A lot of the Park-

*(Continued on page 4)*

## OIT Testing, Coordinating, Processing for Y2K

Y2K efforts in OIT are proceeding as the millennium rapidly approaches. Three major efforts are underway: a testing and deployment plan has been implemented for Y2K replacement PCs; testing of the baseline configuration began in early September, and; actual deployment of the new PCs is estimated to begin in late September and end on December 1, 1999.

The CDER Business Continuity and Contingency Plan testing started in early September. The purpose of this test is to ensure that CDER's critical business processes can continue despite any failure in supporting mission critical systems caused by internal or external factors. Three areas--Pre-market Review and Approval, Postmarket Surveillance and Compliance Monitoring, and Financial Management--are participating in the testing.

Day One activities have progressed to the detail level of the planning stage. OIT scheduled a plan walk through in late September. OIT will participate in an actual dry run of the Day One Plan

with the Agency and other FDA Centers. A timeframe for this activity will be scheduled at the Agency level.

More detailed Y2K information can be obtained via the CDER Intranet (<http://oitweb/oit/>) under Y2K. OIT Point of Contact: Judy McIntyre (MCINTYREJU)

## Project Management (PM) Coordination Update

OIT Senior Staff reviewed and approved a project management lifecycle, a template for OIT project descriptions, a resource worksheet, criteria for prioritizing OIT projects, and criteria for selecting OIT project managers.

These documents are posted on the CDER Intranet (<http://oitweb/oit/>) under PM Coordination.

PM coordination requires formal review of the following OIT projects:

- Web Development Environment project

*(Continued on page 5)*

# SHOOTING FROM THE LIP

by Tony Sims

## Giveth and Taketh Away

**J**ust read where Feds will probably have a 4.8 percent pay increase kick in this January. But before we can even decide what flavor Super Big Gulp we're going to buy with our pay raise, government health insurance CEOs announce that they will bump up their costs 9.3 percent. Knowing that they have you by short hairs, they even have the nerve to try to sound sympathetic. One company president said, "There's little that one can do. This is just one of the unfortunate circumstance that occurs when you have cost issues vs. people's health."

Well, at least there is help for the truly needy. The Health Care Financing Administration recently opened its Free Medicine Program web-site at: [www.themedicineprogram.com](http://www.themedicineprogram.com). This volunteer program helps people with no insurance or Medicare/Medicaid to buy medicines. Just in case those in need don't have a computer, the phone number is (573) 778-1118.

## Pike Light

By now, you may have noticed the new design of the Pike. Well, it's not actually a redesign, it's just that some things are not in the same places they are usually. This is just a temporary thing until the Pike's rightful captain returns. (Actually, I tried to fool you into thinking this was a completely new publication, so you could read and enjoy it before realizing that this one was not produced by the talented hands of Joe Oliver!) Sort of consider this version "News Along the Pike" Lite—less filling, tastes great!

## Intelligence in the Air

Being relatively new (a little more than 2 years) here, I haven't had many opportunities to experience on a large-scale basis the knowledge base that is CDER. But I could only be impressed by the depths of drug, medicine and statistical knowledge shown during the recent Scientific Rounds Jeopardy competition. (See a full report of the event on page 1) I know it was only a game, and the material just touched the surface (and perhaps I was overly swayed because the Q&As were stuff I didn't know), but sitting there listening to the by-play was kinda=excitin=. I guess every once in a while we all need to open up a window and breath in the rarified air of intelligence.

I'm out. ;)

**news**  
along the  
**pike**



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## Ombudsman Neutrality

Periodically I am reminded that there is more confusion about the word 'ombudsman' than its spelling or pronunciation. Often, people erroneously assume that we ombuds are really advocates for those who come to us with complaints. There is a subtle but important distinction between ombudsmen and advocates. The distinction is so vital that it bears a fuller discussion.

Misunderstanding of what we do sometimes leads people to assume that if a complaint is lodged against them or their workgroup, answering an ombudsman's questions may get them in trouble.

### Impartial Role

An ombudsman is an impartial person whose role is to receive, to investigate and to seek resolution of complaints and disputes. The ombudsman may recommend changes to policies or processes based on his or her own observations or on complaints. The key characteristic of an ombudsman is impartiality.

Whereas an advocate, such as an attorney, is hired to espouse the interests of his or her client, an ombudsman evaluates all parties' interests and views before making any recommendations. It is often stated that an ombudsman is an advocate for fair process. Using the word 'advocate' in that context probably causes more confusion than clarification. Further, an ombudsman does not recommend actions that management should take against any individuals or

companies. An ombudsman recommends changes in processes and systems to make the organization work more effectively in accomplishing its mission.

### Must Listen Carefully

When I get a complaint, my first job is to listen carefully to the complainant and to understand the bases for the complaint. I then look into the subject of the complaint, which may be a person, organization or process, and I

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"...an ombudsman evaluates all parties' interests and views before making any recommendations"

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listen carefully to the other sides of the issues. When I feel confident that I understand the issues and the parties' positions, I negotiate with both sides to try to achieve a reasonable compromise. If appropriate, I also look at the processes that led to the complaint and recommend changes that might prevent future complaints.

Because the ombudsman operates confidentially, people in the ombudsman's organization tend to see only those cases that he or she decides has merit and need to be discussed within the organization. In my work, I get many complaints that result from

complainants' misunderstanding of the processes or the legal limitations imposed on CDER. When staff in CDER see me as an advocate for changing a policy or process, it means that I have evaluated a complaint and have seen the need for change. Put another way, when an advocate speaks for his or her client, one doesn't know whether the advocate really believes what is being said. After all, criminal defense attorneys spend most of their time advocating for people who they know or suspect are guilty. An ombudsman, on the other hand, speaks for a complainant only after he or she has evaluated the validity of the complaint.

### Advocate?

The distinction between ombudsmen and advocates is currently a topic of discussion and debate in the legal community. The American Bar Association's steering committee on ombudsmen is preparing a document that will define what an ombudsman is. There are a number of advocacy groups around the US that are called ombudsmen and believe they should be included in the definition, although they are not neutral or impartial by nature of their charter. Such groups are appointed by local and state governments or private organizations to act as advocates for various disadvantaged populations, such as abused children or nursing home patients.

*(Continued on page 5)*

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## Scientific Rounds Jeopardy Tasks CDER Teams

(Continued from page 1)

lawn Building.®

However, the ante was upped considerably when the real rounds began. Questions about CMCs (chemicals, manufacturings and controls), CFRs (Code of Federal Regulations), pharmacological toxicology, clinical pharmacy, statistics, drug disasters and the history of medicine jumped through the air.

AThis cellular organelle is most responsible for oxidative metabolism of drugs.®

*What is the endoplasmic reticulum*

Ats the SHE in SHE cell assay.®

*What is Syrian Hamster Embryo*

AThis was the first U.S. medical school to enroll women.®

*What is Johns Hopkins University*

ADeafness, syncope, prolonged QT interval.®

*What is Lange-Nielsen Syndrome*

A21 CFR 312.7.®

*What are the promotion/charging regulations for investigational drugs*

The answers came in spurts and were often correct; and often followed by the hoots and cheers of the audience.

At the end of the first round Corporate grabbed the lead with 2,900 points; Woodmont was riding shotgun with 1,200; and the home team Parklawn carried a load of -800.

During round two, Woodmont and Parklawn staged comebacks; galloping within 200 points during the middle stanza. By the end of the round, Woodmont had snatched the lead with 5,200 points; Corporate had 4,700 and, Parklawn, Apulling itself from the ashes,® according to Honig, stood with 3,200.

The Final Jeopardy answer: Athe first FDA commissioner,® separated the knowers from the unknowners...uh, sort of. Although all three teams got the question wrong (AWho is Walter G. Camp-

bell®), the betting patterns sealed the fates. When the points were tallied, Corporate emerged as the winner.

Based on fun-factor, knowledge gained and crowd interest, the first CDER Scientific Rounds Jeopardy was a rousing success. In addition, it earned its creator Honig lasting fame: as a result of the cajoling and favor-calling needed to pull this off, Amy e-mails are now treated as auto-delete,® said the smiling host.

### *Jeopardy Teams*

**Parklawn:** John Jenkins, ODEII (captain); Bob O'Neill, OEB; Steve Koepke, ONDC; Kati Johnson, ODEIII

**Woodmont:** Russ Katz, ODEI (captain); Richard Lostritto, ONDC; Rachel Behrman, OMP; Paul Andrews, ORM

**Corporate:** Bob DeLap, ODEV (captain); Bob Osterberg, ODEIV; Dennis Bashaw, OCPB; Norman Schmuff, ONDC

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## VC Focal Points Recognized for CDER Communications Contributions

By Pam Winbourne

For once, videoconference focal points were the focal point of a meeting.

Nancy Smith, Ph.D., Director, Office of Training and communications, presented gift certificates and awards to videoconferencing focal points.

Smith honored Sandy Shores, Division of Biometrics III, Jamie Metz, Office of the Center Director and Donnie Wisner, Office of Com-

pliance.

These volunteers are essential to the continuing success of many OTCOM-supported programs, such as Scientific Rounds, CDER Rounds and CDER staff meetings.

"We couldn't do our jobs without them," said Linda Emelio, Division of Training and Development. "Despite changes in personnel, OTCOM has managed to accommodate the videoconferencing needs of the Center through the

efforts of focal points."

"We are grateful for these volunteers and we are always ready to give an opportunity to those interested in becoming a focal point," said Smith.

Videoconference focal point training is available through the Division of Communications Management. Anyone interested in learning how to become a VC focal point should contact Pam Winbourne, 7-3788.

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## OIT Y2K Activities Involve Coordination and Processing

*(Continued from page 1)*

- Corporate Database Redesign project
- Year 2000 (Y2K) project
- Division Files System (DFS) Version 2.0 project
- Electronic Document Query project
- SMS Rollout project
- Adverse Events Reporting System (AERS) project
- VMS/ORACLE Upgrade project
- St. Louis Migration project
- Secure E-mail project
- Dark Fiber project
- FACTS/OASIS Rollout project
- FACTS-EES Coordination project
- EASE Rollout project
- ICH/M2 project
- Remote Access project
- Electronic Document Room (EDR) 2000 project
- Drug Registration and Listing System (DRLS)/Foreign Establishment Inspection (FEI) pro-

- ject
- Microsoft Exchange Rollout project
- Electronic Charge & History Card Rewrite project
- Enterprise Computing Architecture (ECA) project

OIT senior staff is scheduled to complete review of these 21 projects by October 26. The schedule of reviews is posted on the CDER Intranet.

The purpose of the review is to establish a documented and approved project baseline that will serve as the basis for monthly status meetings with the PM Coordinator.

Projects will be ranked in terms of their priority in order to facilitate IT management decisions.

OIT Point of Contact: Vali Tschirgi (TSCHIRGIV)

### Improvement Process Development Project Update

OIT concluded peer review meetings for guidance documents in the improvement target area of configuration management (CM).

Final changes will soon be incorporated for OIT senior staff sign-off. The five CM documents address:

- ◆ configuration identification
- ◆ configuration control
- ◆ configuration control boards
- ◆ configuration status accounting, and
- ◆ contractor CM monitoring.

In September, peer reviews began for documents in the target area of project planning.

Information about this project is located on the CDER Intranet (<http://oitweb/oit/>) under OIT Activities.

OIT Point of Contact: Jerry Yokoyama (YOKOYAMAJ).

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### OMBUDSMAN'S CORNER

## Ombudsmen vs. Advocates: The Jury is Still Not Sure of the Roles

*(Continued from page 3)*

While everyone recognizes the need for such groups, do they fit the definition of ombudsmen? The current subcommittee draft excludes these advocacy groups from the definition of ombudsman. I hope the ABA will articulate this important distinction when it finalizes the document.

Sometimes people confuse the ombudsman's investigative role with his or her mandates to resolve disputes and to improve the system. Because an ombudsman must contact the parties to a dispute to learn their position, the first

knowledge that a complaint has been made may come in the form of questions from the ombudsman about the case at hand or about the processes involved. It is important to realize that such questions do not mean that the ombudsman necessarily believes the complaint is valid. Further, it is important to understand that the purpose of the questions is not to pin blame on anyone. This notion may be fostered by the unfortunate use of the word 'investigate' in most listed duties of ombudsmen. I prefer to use the term 'look in to,' which better conveys the informal nature of an ombudsman's

inquiry. The ombudsman is separate from any management or disciplinary function. The information gathered by the ombudsman during his or her exploration of the issues is confidential and is not used by management or the complainant in any subsequent adverse action.

We in CDER are accustomed to dealing with attorneys and other advocates representing various stakeholders. Just remember that the ombudsman is a different species altogether.

*Jim Morrison is the Center's Ombudsman*

## Union/FDA Contract May Impact Many Personnel Activities

By Robert Young

This is the last of an introductory series on contract provisions that may have an immediate impact on employees.

### *Performance Appraisal System*

Each employee will receive a performance evaluation plan. It can have up to five critical elements that define what is important in the job. Performance measures for each element will define what is successful performance. The measures will be based on assigned duties and responsibilities and may be based on results where the final product defines success or manner of performance which describes the way an employee acts on the job to produce the results.

There will be three levels for rating performance on an element: exceeds, meets, or fails to meet. These are valued at three, two and one points respectively. Final ratings will have two levels: meets or fails to meet.

### *Position classification*

The phrase "other duties as assigned" in a position description includes tasks of an incidental or infrequent nature which are impractical to include in the narrative portion of a position description. Tasks so included cannot include work assignments or responsibilities of such importance that unacceptable performance would result in a determination that an employee's performance is unacceptable.

### *Assignment of work*

Work will be assigned in accordance with applicable laws, rules and regulations. In assigning work, workload, qualifications and experience, relationship of new assignments to existing work assignments, personnel ceilings, time limits, emergencies, and factors unique to the task will be consid-

ered. Assignment of work or denial of work assignments will not be made as a reward or penalty to an employee, but in accordance with agency needs and operational goals.

An employee with an unmanageable workload may request a workload adjustment. If work assignments cannot be accomplished within assigned criteria (i.e. quality, quantity, timeliness or cost), the manager will make an effort to adjust work assignments, prioritize work assignments or adjust time frames.

### *Details*

Selection for details will be made in a fair and equitable manner. Employees who are detailed will be relieved of work required in their previous position when the detail is in effect.

### *Training*

Opportunities for training will be provided in a fair and equitable manner. Employees will be selected for training based on the organization's need for new skills, employee's need to successfully perform on the job, and an employee's potential for completing the training and applying new skills on the job. Employees will be given training deemed necessary to assist them in performing their job. An employee will not be held responsible for failing at a task when the agency failed to provide the training deemed necessary to perform successfully.

Training (including professional meetings and conferences) that is not specifically related to immediate organizational or employee needs -- and where one or some, but not all similarly situated employees can participate -- will be assigned in descending order of seniority. Volunteers will first be sought. If there are more volunteers than training posi-

tions available, employees may exercise their seniority in descending order. An employee may hold seniority entitlement for up to two years or until each member of the group has had an opportunity to exercise his seniority.

Selection for training that is part of an authorized training agreement, part of a promotion program, required for promotion, or is part of a formal developmental program will be made through Merit Promotion.

### *Merit Promotion*

All promotions and other personnel actions will be made using systematic and equitable procedures on the basis of merit. Available positions will be publicized through vacancy announcements, which will be open for a minimum of ten workdays. Candidates will be evaluated against basic eligibility requirements, selective placement factors, and other appropriate criteria.

All applicants found to be minimally qualified will be rated and ranked by either a personnel representative or a qualifications review board. Candidates will be evaluated based on their knowledge, skills and abilities, which must be closely related to the principal duties of the position. During the first two years of this contract, only the first five applicants with the highest scores above the cut off score will be forwarded to the selecting official. If more than one position is to be filled, an additional applicant will be forwarded for each additional position to be filled as long there are applicants above the cut off score. In the last three years of the contract, only the first four applicants with the highest scores will be forwarded. If any of the forwarded applicants are interviewed, all must be interviewed.

*Robert Young is president of the local*