news along the pike

OCTOBER 1999

CENTER FOR DRUG EVALUATION AND RESEARCH

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INSIDE . . .

Theme for Year 2000: Review Assessment

Center Director Reviews Challenges, Current Status

BY JANET WOODCOCK, M.D.

The year 2000 will be devoted to assessment—improving the efficiency and ensuring the quality of our review work. Next year, we need to bring to closure a number of initiatives we started several years ago, including:

- Developing a review template for every discipline. Our reviews need to be organized and standardized so we can create them in as effective a manner as possible.
- Making sure our review documents communicate the issues and uncertainties about a drug clearly and concisely to health care practitioners and consumers.
- Implementing the quality assurance effort. We need to capture our knowledge and build on it so we aren't constantly starting from the ground.
- Completing the transition to the Divisional Files System. If we keep documenting and archiving on paper, we'll never be able to learn and share knowledge the way we need to. Imagine how helpful it will be for regulatory research if our review archives are available electronically.
- Implementing training to achieve these strategies. As an example, I will be inviting foreign regulators to present at Scientific Seminars. They are able to identify the problems and issues with a drug with one-tenth

(Continued on page 8)

Holston: ICH Integrates Well with FDA Initiatives

BY ROGER WILLIAMS, M.D., AND JUSTINA MOLZON, M.S.PHARM., J.D.

The International Conference on Harmonization deserves great credit for the acute awareness in the Agency, its centers, Congress and the Administration, "that FDA is not and cannot be a regulatory island—that our public health protection is tied in many ways to countries all over the world," said **Sharon Smith Holston,** Deputy Commissioner for International and Constituent Relations.

Holston presented her remarks on the integration of ICH with other FDA initiatives Oct. 8, following four days of meetings for the ICH steering committee and its expert working groups in Washington.

She called ICH "a pace-setter, a model and an inspiration with a powerful influence on FDA's plans and policies." The ICH emphasis on applying the most advanced scientific knowledge to harmonized guidances coincides with the policy of Commissioner **Jane Henney, M.D.,** to place top priority on using state-of-the-art science as the basis for FDA product reviews and other regulatory work, she said.

While the ICH documents enhance FDA's ability to conduct fast but rigorous premarket

(Continued on page 7)

Kobayashi Joins Malinowski as 2nd CDER Mansfield Fellow

Ken Kobayashi, M.D., a medical officer in the Division of Oncology Drug Products, began a two-year fellowship last month sponsored by The Mansfield Center for Pacific Affairs. One of six federal government employees selected as a Mike Mansfield Fellow this year, he is the second Center scientist picked for the program. **Henry Malinowski, Ph.D.,** began his fellowship last year and is currently in Japan (Sept. 1998 *Pike).*

Dr. Kobayashi began full-time Japanese language and area studies training in September and will spend the second year of the program in Japan working with drug regulators in the Japanese government. He would like to intends to explore the process of oncology drug development in Japan by studying how cancer clinical trials are designed, executed and analyzed, and how the results are applied in clinical and

(Continued on page 7)

JOE'S NOTEBOOK

Vital Statistics: Mine and Ours Improve

When I was taking health class in 1960 in an all-boys high school, our teacher asked how many of us thought we'd be alive at the turn of the century. We did the mental arithmetic, and most of us raised our hands—somewhat tentatively, of course. We were right to be cautious.

Our teacher told us that, based on the U.S. vital statistics of the time, one-third to one-half of us wouldn't be around to celebrate this coming Jan. 1. Well, thanks to advances in modern medicine, most of us are still here—and I'm here to bring you this month's *Pike*.

At the end of August, I joined the more than half million Americans who have bypass surgery each year. I was smugly trucking along doing everything right: not smoking, not drinking, exercising regularly and eating a low-fat, high-fiber diet (rabbit food). As my doctors, surgeons and nurses pointed out, I couldn't do much about my biggest risk factors, being a middle-age man with a family history of heart disease. After seven and a half hours of surgery, I'm sporting two impressive scars and four new coronary arteries. The good news is I avoided a heart attack, so I'm in good health, once again exercising and eating right.

For the first time since 1987, HIV infection has moved off the CDC's list of the top 15 leading causes of death, according the new preliminary vital statistics report, *Births and Deaths: Preliminary Data for 1998*, prepared by the National Center for Health Statistics.

CDER-approved highly active antiretroviral therapies have contributed to a precipitous 70 percent decline in HIV mortality since 1996—a 21 percent decline in AIDS deaths from 1997 to 1998 and a 48 percent decline for 1996 to 1997. The disease was the eighth leading cause of death in 1996 and dropped out of the top 10 last year. However, for the 25-44 year age group, the disease still ranks fifth among leading causes of death.

The 1998 age-adjusted death rate was a record low dropping 2 percent below the rate for 1997. Life expectancy in 1998 reached a record high of 76.7 years.

Reductions in mortality occurred in the top four leading causes of death. From 1997 to 1998, the death rate for heart disease declined by about 3 percent, while the death rate for cancer declined by 2 percent. Deaths from these two diseases combined accounted for more than 1.2 million deaths, which is more than one-half of the total deaths that occurred in 1998. While heart disease mortality has exhibited a downward trend since 1950, cancer mortality has declined only since 1990. The third and forth leading causes of death, stroke and chronic obstructive pulmonary disease experienced declines of 2.1 percent and 3.4 percent respectively.

The report on preliminary data, collected through the National Vital Statistics System from more than 85 percent of death and 99 percent of birth records, is available at the NCHS Web site at http://www.cdc.gov/nchswww.

As I was recovering from my personal encounter with health statistics, my boss, **Tony Sims,** edited the September *Pike*, available on the Internet at http://www.fda.gov/cder/pike/september99.pdf. Check it out to find:

- A report on the season's first Scientific Rounds.
- **Jim Morrison's** explanation of the ombudsman's impartial role in looking into complaints.
- OTCOM's recognition of videoconferencing focal points: **Sandy Shores** and **Donnie Wisner.**
- OIT's monthly update.
- **Robert Young's** outline of the NTEU/FDA contract's provisions on such items as performance appraisals, details, training and merit promotion.

news along the pike

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

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

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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

Annual Report

BY JIM MORRISON

It's time again for my end of fiscal year summary and analysis of trends and cases in the ombuds business. This past year was very similar to fiscal year '98, with about the same mix of complaints and an extension of the trends I reported on last year.

The number of cases were about equal, leveling off at below 100. The number of internal complaints dropped off further and now represent only 5 percent of my work. Those were equally divided between complaints about internal interactions and interactions with excessively aggressive outsiders. Because the number of internal complaints is so low, I eliminated them from my analysis.

E-mail contacts, which I usually don't count as cases, rose again this year, though not as dramatically as last year. Although I don't track them, I estimate that I received about 30 percent more than last year for a total of a few hundred e-mails. Again, the increase can be ascribed to a wider use of the Internet rather than heightened interest in CDER. Some of this correspondence resulted from the increasing volume of data on the CDER Web site and more difficulty in finding specific information. The redesign of the site, which should be available later this year, may help that situation.

The mix of issues in fiscal year '98 was very similar to those of fiscal year '97. It is worthy of note that complaints about timeliness of NDA and ANDA reviews have decreased to a very small number. Most complaints about timeliness relate to decisions outside the new drug review context, such as petition responses.

Of some concern is the consistency of the numbers of complaints regarding unfairness of decisions and policies. We all know that, as a result of decisions we make, there are likely to be perceived winners and losers. It is impossible to be popular with everyone. However, in my experience many problems are created by our failure to adequately explain the reasons for CDER decisions and policies. We can reduce the number of dissatisfied contacts, first, by understanding clearly the reasons behind our decisions and actions and, then, by adequately communicating those reasons to the regulated parties. It always impresses me that people will readily accept even adverse decisions if they understand the logic and fairness behind them.

External Complaints	%
Unfairness of a policy or decision	38
Problems with processes or inadequate information about them	36
Timeliness	15
Difficulty gaining access	5
Uncivil or unhelpful interactions	3
Miscellaneous	3

Although there were only a few complaints involving discourteous or unhelpful interactions with CDER staff, that is a complaint that we should aim to eliminate totally. We all get annoyed by problematic callers from time to time, but responding discourteously or in an agitated manner is just plain unprofessional.

Remember that even an isolated incident of such behavior damages CDER's reputation. Business people know that the effect of one dissatisfied customer gets multiplied enormously, because that person will tell everyone he or she knows about bad service. Stories of good service are not relayed with the same frequency.

When people complain to me, they are rarely angry nor do they show signs that they disrespect the Center. In fact, most people who contact me indicate that they view their problem as an exception rather than the norm. That was not true a decade ago.

We can all take pride in helping to make CDER respected for its efficiency, professionalism and scientific expertise.

As always, I'm grateful for your continued cooperation and support. If you have a complaint, problem or a suggestion about how to solve a problem, please give me a call (301 594-5443) or send me an e-mail (morrisonj@cder.fda.gov).

Jim Morrison is the Center's Ombudsman.

ADMINISTRATIVE MANAGEMENT CORNER

Survey Reveals 63% Satisfaction Level, Prompts 20% Improvement Goal

BY JOHN EMELIO

Results of last November's customer satisfaction survey sent to all CDER employees from the Administrative Management Team revealed a 63 percent overall satisfaction level with administrative management support in the Center.

The purpose of the survey was to provide feedback to the Center's administrative officers and managers on areas for improvement as well as to gauge progress in meeting the AMT's performance goal of increased customer satisfaction.

The team has established a target by the end of next year of reaching a customer satisfaction rate of 83 percent—a 20 percent increase. To accomplish this goal, the team is seeking to implement many of the ideas provided in the survey responses. Thanks to a generous response rate, there were many thoughtful comments to consider. Each subcommittee of the Administrative Management Coordinating Committee is working to accomplish these suggestions for improvement.

Early next year, a follow-up survey will be conducted to determine progress toward its 83 percent customer satisfaction goal and identify further areas for improvement. When you receive your survey, please take a moment to fill it out. Your completion of the last survey provided valuable insights for improvement, and your participation in future surveys will help us achieve our mission of providing the highest quality administrative management support.

John Emelio is Chief of the Management Analysis Branch in the Office of Management and serves as executive secretary for the AMCC.

INFORMATION TECHNOLOGY CORNER

OIT Releases Description of COMIS Update Project

The Office of Information Technology released a document that describes the data requirements and the associated functional requirements for the Center's Corporate Database Redesign Requirements project. The purpose of the document is to communicate to the CDER user community the OIT analysis team's understanding of the requirements. This document will be used as a baseline for the software design and development phase.

The document is the culmination of a requirements-gathering effort initiated by OIT and users of the current Centerwide Oracle Management Information System, known as COMIS. OIT has been working closely with the Office of Review Management and the Office of Pharmaceutical Science to gather the requirements. Each of the offices formed workgroups to address the needs of the redesign. The ORM point of contact is **Randy Levin, M.D.,** and OPS point of contact is **Jonathan Cook.**

Please e-mail the REDESIGN account if you would like a copy of the document. In addition, the document will be available on the OIT intranet (http://oitweb/oit/). If you have any comments on the document please contact either Randy Levin or Jonathan Cook.

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

QA Development Project Update

In September, OIT began peer review of guidance documents in the improvement target area of project planning. Information about this project is located on the CDER intranet (http://oitweb/oit/) under the OIT Activities button.

The OIT point of contact is **Jerry Yokoyama** (YOKOYAMAJ).

PM Coordination Update

OIT Senior Staff reviewed and approved the project baselines for the Corporate Database Redesign project and the Year 2000 project. The following projects were reviewed but have not yet been revised and signed-off by OIT senior staff:

- Web Development Environment.
- Division Files System version 2.0.
- Electronic Document Query.
- VMS/ORACLE Upgrade.
- St. Louis Migration.
- Secure e-mail.
- Dark Fiber.

As each project baseline is approved, the OIT project description will be screened for confidential and proprietary information and posted on the OIT intranet (http://oitweb/oit/) under PM Coordination. The schedule of reviews is posted on the CDER intranet.

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

November IT Training

Monday	Tuesday	Wednesday	Thursday	Friday
1	**2** **CDER's Standard Letters System** 9-12	**3** **Excel** 9-12 **Word Intro** 1-4	**4** **Word Formatting** 9-12 **Word Tables** 1-4	**5** **DFS** 9-12 **NEST** 1-4
8	**9** **DFS** 9-12	**10**	**11**	**12**
15	**16** **Creating PDF Documents** 9-12 **JMP Session 1** 1-4	**17**	**18** **CDER's Standard Letters System** 9-12	**19**
22	**23** **JMP Session 2** 1-4	**24**	**25**	**26**
29	**30** **JMP Session 3** 1-4			

The catalog, training materials, schedule and online registration are on OIT's intranet site.

DTD's Policy Education Team Assists in Designing Training Courses

BY JACK MORIN

The Policy Education Team in OTCOM's Division of Training and Development works with Center experts to design useful, informative and factual courses that introduce new policies and guidances.

The team provides experienced help in:

- Analyzing the intended students' learning styles.
- Making decisions on course content.
- Designing course agendas with appropriate sequencing of training materials.
- Developing visual aids and course handouts, including PowerPoint slides.
- Coaching instructors on their presentation skills.
- Implementing and evaluating pilot programs
- Coordinating training on the day it is delivered.
- Analyzing course evaluations and preparing summary report evaluations.

Some recent policy education programs that the team assisted with included training on human pregnancy outcome data, pediatric exclusivity, the pediatric rule implementation, the financial disclosure rule and two guidances for industry on container closure systems and on food effect bioavailability and bioequivalence studies.

Computer-based training modules on the pediatric rule implementation and human pregnancy outcome data are in development and will be available on CD-ROM in the spring.

Members of the Policy Education Team are **Dorrie Ballmann, Iris Khalif, Jack Morin** and **Leslie Wheelock.** Please Leslie Wheelock (WHEELOCKL, 7-3482) to schedule an appointment to discuss your policy education needs.

Jack Morin is a writer-editor in DTD.

Flowcharts of NDA Review Process Now Available on Internet

BY GRANT WILLIAMS, M.D.

Five flowcharts of the medical review process for new drug application in four divisions have been placed in the public domain on the CDER Internet site. Two draft flowcharts from two other review divisions are available for internal Center comment on the CDERnet.

The charts, the culmination of the Review Diagram Project, represent snapshots of individual review processes. They were created without a preconceived format and may address different parts of the review process or different approaches to review. These diagrams have been used as teaching aids to orient a variety of professionals to the review process.

The Internet address is http://www.fda.gov/cder/reviewer, and the intranet address is http://cdernet/revdiagram/revdiagram.htm. Copies obtained from the intranet should remain within the Agency. Please contribute comments or questions via the e-mail links on these sites.

The Reviewer Diagram Project was conceived in July 1996 under the auspices of Track II of FDA's Good Review Practices initiative, which aims at designing flexible, evolving and interactive processes of review that focus on development and improvement. The Reviewer Diagram Project sought to dissect individual review processes and create diagrams that would:

- Allow reviewers and supervisors to record and visualize the steps in their own review process.
- Communicate an understanding of the framework, content, process and issues involved in review activity.
- Create a final, customizable plan and diagram for each therapeutic area.

The two diagrams by **Stanka Kukich, M.D.,** Division of Anti-Infective Drug Products, and **Nasim Moledina**, **M.D.,** Division of Anti-Viral Drug Products, are broad outlines that provide an overview and are useful for organizing the medical review activities that must occur within the review timeline.

Gregory Dubitsky, M.D., Division of Neuropharmocological Drug Products, gives a detailed visualization of the safety review. His chart closely parallels the safety review processes described in the recent GRP safety review draft guidance document.

There are two diagrams from the Division of Oncology Drug Products. **Susan Honig, M.D.,** records numerous practical review tips that would be useful to any new reviewer. **Grant Williams, M.D.,** collects copies of useful pages from several other diagrams, presents advice on reviewing electronic data and illustrates detailed techniques for reviewing discipline-specific efficacy data.

Other reviewers provide valuable insights into review techniques specific to their divisions' therapeutic areas. **Eric Colman, M.D.,** charts the review process in the Division of Metabolic and Endocrine Drug Products.

Robert Yaes, M.D., and **Sally Loewke, M.D.,** teamed up to diagram the process in the Division of Medical Imaging and Radiopharmaceuticals.

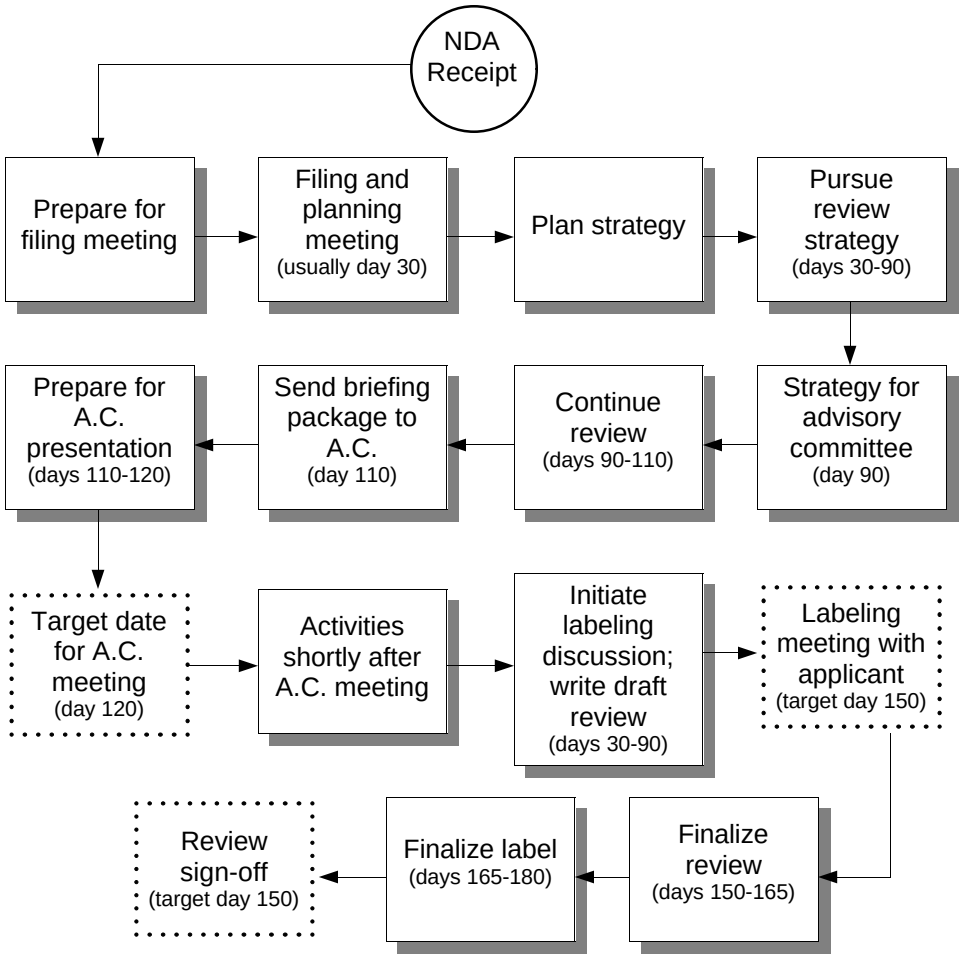
The diagrams are in PDF format and may be used interactively or printed. Clicking on the shadowed boxes will follow the diagram to a different level.

The diagrams were constructed by **Madeline VanHoose** from a written outline or interview with individual reviewers and edited by colleagues from the same division. They are not necessarily representative of CDER or division standards.

Members of the Review Diagram Project steering committee included **Julie Carlston, M.D.; Brad Leissa, M.D.; David Lepay, M.D., Ph.D.; Joy Mele, M.D.; Nancy Smith, Ph.D.; Madeline VanHoose,** project facilitator; **Grant Williams, M.D.,** project leader; and **Janet Woodcock, M.D.**

Grant Williams is a medical officer in the Division of Oncology Drug Products.

Sample Section of Review Diagram by Stanka Kukich, M.D.



UNION CORNER

Contract Interpretation Follows Four Well-Established Rules

BY ROBERT YOUNG

The NTEU-FDA contract went into effect on Oct. 1. There have been a few disagreements between the union and management on the exact meaning and interpretation of certain provisions, such as "official time" and "core hours."

The contract, however, has hundreds of provisions, which will be implemented. A recurring question will be: "What does a particular contract provision mean?" Each bargaining unit employee will have to make a first cut on whether there is a contract provision that even pertains to a particular situation.

The rules of interpretation are called "contract construction." These rules apply to any contract and have usefulness beyond the NTEU-FDA contract. Since these rules are also used to construe statutes, including the Food, Drug and Cosmetic Act and its associated regulations, you may already be familiar with them.

A contract is a set of promises, and the law provides a remedy when the promises are broken. The first and central question is: "What is the promise?" What did the parties to a contract intend to do or accomplish? What were their reasonable expectations?

Unfortunately, humans and contracts are not perfect and do not function perfectly. Contract deficiencies are frequently uncovered when an attempt is made to implement a contract provision. The very fact that the parties who actually drew up a contract may disagree over its meaning highlights the difficulty of these questions. In the case of the NTEU-FDA contract for 5,000 employees, only seven representatives were involved over five months in the entire negotiations.

Although disputed interpretations may be difficult to resolve, our system of law attempts to find contracts valid and enforceable as well as definite and operative. This approach is founded on a belief that individuals should control their own destiny in part by making their own bargains. When parties take the time to write out their promises in a contract, a court will first look within the "four corners" of the contract to discern the intentions of the parties.

The theory is that people communicate by means of language and what they say or write is an expression of what they actually were thinking. Practical experience tells us that this is not always true. There is a lot of non-verbal communication and unsaid things.

The analysis begins with the words and language used in the contract. This standard approach, developed over centuries of practical experience, gives the four basic rules of construction.

> "Two of the four basic rules focus specifically on language and the meaning of words. The other two attempt to discern the overall or general intent, which is given predominance over conflicting subordinate clauses."

- *Rule One.* Words are given their ordinary meaning. The assumption is that people engage in plain talk. Secret meanings of words thus have no status. On the other hand, technical terms and words are given their technical meaning when they are clearly used in a technical sense. For example, "official time" is used in its technical sense throughout the contract.
- *Rule Two.* A contract is interpreted according to business custom and use in the place where it was made or will be performed. This rule recognizes that in a particular business, certain words may have a different or trade meaning that all members of the group recognize and use. Our business is federal civilian service.
- *Rule Three.* Contracts are construed as a whole. A court will first attempt to find and then give effect to a contract's general or overall intent as expressed in the words of the contract. The court asks: What are the parties trying to do? What are they trying to achieve? What is the overall or dominant thrust?
- *Rule Four.* Specific clauses are subordinated to a contract's general intent. Even when a specific clause can literally be read to contradict the overall intent, it will be interpreted as implementing the contract's overall intent. Here the court is being practical. Over centuries of experience, it has seen all the infirmaries to which man is subject and goes for the big picture.

Two of the four basic rules focus specifically on language and the meaning of words. The other two attempt to discern the overall or general intent which is given predominance over conflicting subordinate clauses. If, after analysis, the intentions of the parties remain unclear, courts can go further and take testimony from the parties as an aid to accurate construction. A court might consider the parties' conduct, such as performance or the bargaining history. Each party explains what it understood and intended during the negotiations toward the presumed final understanding and agreement

A court may seek an explanation of the special meanings of words used in a technical sense.

Although not a rule of construction and not a formal part of contract interpretation, once a court is certain of the parties' intent to contract, it can and will infer reasonable terms consistent with the overall intent. Uncertainty as to some terms is not necessarily fatal to a contract.

Now that bargaining unit employees have individual copies of the contract and two hours to read it, their task is to find out their responsibilities and rights. Employees should be careful to note applicable standards and procedures. Employees do not have to go it alone. Help is available. The chapter has conducted and will sponsor lunch-and-learn sessions on various provisions of the contract.

Some provisions have been discussed in previous issues of News Along the Pike, the Chapter Newsletter or the chapter Web site at http://www.nteu282.org. Finally employees can contact union stewards.

Robert Young is president of the local chapter and a member on the D.C. and Maryland bars.

ICH Common Technical Document Reaches First Milestone

(Continued from page 1)

drug reviews, "we're not about to enter a worldwide regulatory nirvana—not yet," she said. For example, the expense of MedDRA terminology presents difficulties to small drug firms. The ICH's primary interest in new molecular entities means harmonized data to support OTC and generic applications has received less attention, Holston said.

In other developments, the steering committee reported scientific consensus had been reached on harmonized tables of contents for the quality, safety and efficacy sections of the Common Technical Document. These will now be released for initial public comment in all three regions—Japan, the European Union and the United States. In the United States, they will be published in the *Federal Register*.

Although significant work remains to be done, reaching this phase means the ICH is on target for unveiling the document at the Fifth International Conference on Harmonization planned for November 2000 in San Diego. The document will be an information package of technical data, in the same format and with the same content. A group working on the safety summaries and integrated executive summary for safety has also reached scientific consensus, and these will be made available for public comment.

The Expert Working Group on Electronic Standards for Transfer of Regulatory Information continued its work to identify and evaluate appropriate tools to be used with the electronic version of the Common Technical Document. The panel projects that its work will be completed six months after the Common Technical Document is approved in all three regions.

Another working group reached consensus on a guidance for the clinical investigation of medicinal products in pediatric populations (E-11). Scientific agreement on how these trials should be performed will facilitate the international availability of drug products for children. Maintenance activities on stability and impurity testing guidances are under way.

The steering committee signed off on the final version of *Specifications: Chemical Substances* (Q-6A) after receiving word from the U.S., European and Japanese pharmacopoeias that they had made substantial progress on harmonizing the 11 test methods closely linked to the guidance. The FDA and the other regional regulatory bodies will proceed to implement the guidance. The steering committee also signed off on the final version of the guidance outlining electronic standards for transfer of adverse drug reaction reports.

The steering committee agreed to begin maintenance activities on issues affecting the data elements for transmission of individual case safety reports. The proposed changes should promote a more efficient implementation of this standard.

An ICH Global Cooperation Group, a subcommittee of the steering committee, held its first meeting on Oct. 5. This group has developed an action plan to disseminate information more actively outside the ICH regions and identify needs for ICH products in close co-operation with the World Health Organization.

FDA's experience shows that globalization won't be halted or diminished, Holston said. "In the long run," she said, "the true challenge we face is far bigger than integrating ICH into FDA's initiatives. It is to develop and fully participate in a harmonized regulatory system that will bring superior public health protection to everyone in the global village."

More information on ICH can be found on the Internet at http://www.ifpma.org/ich1.html.

Roger Williams, Deputy Center Director (Pharmaceutical Science), is FDA's lead delegate to the ICH steering committee and is responsible for CDER's international activities. Justina Molzon, Associate Director for International Affairs, CDER, coordinates the Center's ICH activities.

Risk Management to Highlight FDA Science Forum 2000 Feb. 14, 15

The theme for FDA Science Forum 2000, to be held Feb. 14 and 15 at the Washington Convention Center, will be "The Science of Safety: New Perspectives."

Registration—free for FDA employees—and program information are available on the Internet at http://www.aaps.org/edumeet/fdas/index.html.

The forum will be devoted to the presentation and sharing of data, knowledge, and ideas among the disciplines of risk management. The forum will bring FDA scientists together with industry, academia, government agencies, consumer groups and the public to explore the scientific and practical issues related to the safety evaluation and risk management of FDA-regulated products.

Speakers and panelists will address emerging issues in the safety assessment of foods, drugs, biologics and medical devices. A poster session, sponsored by the FDA Chapter of Sigma Xi, the Scientific Research Society, will feature all areas of FDA science.

The forum is co-sponsored by the FDA Office of Science, the American Association of Pharmaceutical Scientists, the FDA Chapter of Sigma Xi - the Scientific Research Society, and the FDA Office of Women's Health.

For more information, contact **Donna Mentch** in FDA's Office of Science (7-3340) or AAPS (703-548-3000).

Kobayashi to Study Drug Development in Japan

(Continued from page 1)

regulatory decision making.

He hopes to develop a broad perspective by working both with researchers at clinical centers and with officials of the Japanese drug regulatory authority. Dr. Kobayashi is board certified in internal medicine, medical oncology and clinical pharmacology.

An intensive two-year program, the fellowships enable a select group of federal employees to develop an in-depth understanding of Japan and its government through hands-on practical work inside Japanese government ministries and agencies.

Improving Efficiency, Quality of Reviews Tops Agenda for 2000

(Continued from page 1)

to one-hundredth the staff we have.

This strategy for the coming year will increase our organizational efficiency, improve our communications with health professionals and the public, improve our focus on drug-related issues and provide us with a reliable method for incorporating and sharing knowledge throughout CDER.

Mission and Purpose

We have an obligation to focus on maximizing the health benefits of drugs and minimizing their risks. We have to deal with the whole purpose, not just what arrives in our inboxes each day. Protecting the public is the historical definition of our purpose, but that leaves out some important goals. Assuring availability of good drugs has become the more positive aspect of our purpose in recent years. Most recently, We have defined our purpose as promoting the public health and maximizing the health benefits of drugs.

To successfully fulfill our mission and purpose, we must strike a balance between doing our everyday work and investing time into activities that will help us improve the way we work. Over the last few years, we have invested our time and energy into such activities as information technology and ICH. These are bringing us a higher level of functioning.

We operate in a complex environment, and our challenge in investment is to organize and simplify. We have already been doing this. We have been organizing our research to join it to policy development and regulation. Our standard setting has been organized to a great extent by ICH. It was a painful investment for those who worked on it, because it was done on top of everyday work. But the payoff is that we have put what can be written down into codified language.

Risk Management

A drug is only as safe as the system that surrounds it. A complex, multicomponent system in this country has evolved to maximize benefits and minimize risk. CDER makes a premarket evaluation of risks and benefits for the studied population. After approval, the prescriber manages benefits and risks for the patient. In an ideal world, the patient should evaluate benefits and risks in terms of personal values.

The system tries to ensure everyone makes an informed decision and the right information is in the hands of practitioner and patient. Since we're not in charge of the system, we may think it's not our job to see that it operates correctly. But it's our mission to influence the system. That's why we have moved Center resources into communications. We need to make sure that what we know about risks and benefits penetrates the consciousness of prescribers and the public.

We must move forward on the recommendations in the risk management report and increase consumer information on the Center's Web site. We will be holding large public meetings with consumer and patient groups to focus on next steps in risk management. We will continue to fine tune the Office of Post-Marketing Drug Risk Assessment and the Adverse Event Reporting System.

Current Status

We are meeting our obligations to the pharmaceutical industry for the timeliness of reviews agreed to under PDUFA. We have also been able to turn to important public health issues in addition to turning around review times. Some accomplishments that we can be proud of include:

- Surveying the pharmaceutical industry on their prepahhredness for Y2K and launching a successful information campaign to allay public fears of drug shortages.
- Creating fliers for high school coaches and health clubs warning about the dangers of the party drug GBL.
- Moving forward on the Mutual Recognition Agreement with the European Union for reciprocal reliance on inspection systems. This is a paradigm shift for us since our thought has always been to do it ourselves.
- Implementing the OTC label rule.
- Partnering with the Product Quality Research Institute to collaborate on chemistry and formulation questions.
- Having a great series of Scientific Seminars and reinvigorating Scientific Rounds.
- Evaluating a huge number of requests for pediatric trials. The six-month exclusivity causes extra work for us but will be good news for children.

We have been tackling tremendously difficult problems, such as:

- Pharmacy compounding.
- Improving pregnancy labeling.
- Crafting the right line between structure and function claims for dietary supplements.

Editor's note: Dr. Woodcock's article is based on her Sept. 15 "State of the Center" presentation at Scientific Seminar. Videotapes of her Sept. 30 repeat presentation are available at the Medical Library and its branches. The slides for her presentation can be found on the intranet as "handouts" in the last column of the table at http://cdernet.cder.fda.gov/dtd/seminars.htm.

Proposed Plan for Clearer Reviews Unveiled

Our review documents provide the healthcare community as well as consumers with valuable information about what is known and what remains unknown about drugs at the time of approval. If we are to promote the public health, our review documents must exhibit seven qualities:

- Good organization.
- Inclusiveness and conciseness.
- Efficient and effective presentation of data.
- The use of clear English.
- Conclusions that are developed logically from the data.
- Independent thought.
- Independent judgment about the most pertinent and important information.

The Reviews Evaluation Steering Group, which drafted these qualities, has outlined a system for evaluating review documents and educating reviewers about improving review quality and clarity.

Their proposal—the Reviews Evaluation and Education Project—can be found on CDERnet at http://cdernet/reep/. I encourage you to visit the site and provide comments to any member of the steering committee or use the Forum button.

—Janet Woodcock, M.D.