news along the pike

AUGUST 1999

CENTER FOR DRUG EVALUATION AND RESEARCH

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INSIDE . . .

PIKE'S CORNERS . . .

FDA Outlines Action Plan on Internet Rx Sales

Enforcement, Partnerships, Public Outreach Emphasized

At a congressional hearing on July 30, FDA outlined new efforts to help curb illegal marketing of prescription drugs on the Internet. A major component of the Agency's action plan will be new cooperative partnerships with federal and state law enforcement agencies and regulatory bodies.

Under federal and state law, generally a patient must be physically examined by a licensed health care practitioner before receiving a prescription drug for the first time. The patient then has the prescription filled by a registered pharmacist working in a licensed pharmacy that meets state practice standards.

While reputable online pharmacies can be of great assistance to consumers—many even allow patients to consult with pharmacists from home—Web sites can be easily created to look like legitimate pharmacies when in fact both the sellers and the products are illegitimate.

The FDA action plan was triggered by the increasing number of Web sites—both in the United States and abroad—that sell potent drugs without valid prescriptions or without meaningful interaction with a physician or other health care professional. Often sales are based only on the buyer's answers to a questionnaire.

The risks run by patients who accept these illicit offers include adverse side effects from inappropriately prescribed medications, dangerous drug interactions and harm from contami-

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'State of Center' Seminar Planned for Sept. 15

Scientific Rounds to Open with 'Jeopardy' Game on Sept. 22

BY ROBIN HUFF

The Committee for Advanced Scientific Education announces the kickoff of the '99-'00 CDER academic year on Sept. 15 from 2 p.m. to 3:30 p.m. at the University of Maryland Shady Grove campus. Light refreshments will be served starting at 1 p.m. Following a brief introduction of educational initiatives, Center Director **Janet Woodcock, M.D.,** will deliver her "State of the Center" address as the first seminar of the season.

With the FDA Modernization Act and PDUFA II in place and mandates initiated, some in CDER might feel that the era of big change is behind us, at least for a few years.

Not so, according to **Dr. Woodcock** who is preparing the Center to undergo a further series of changes.

Dr. Woodcock will address a variety of issues including CDER's roles in risk management and quality assurance.

On Sept. 22, the first Scientific Rounds of the year will be held from 1:30 p.m. to 3 p.m. in

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4th 'CDER Live!' to Focus on Risk Management Sept. 14

BY ELAINE FROST

Societal issues pertaining to the increasing use of medical products, with special emphasis on risk management, will be the focus of a "CDER Live!" satellite broadcast for the pharmaceutical industry on Sept. 14 from 1 p.m. to 4 p.m. Eastern time.

Center Director **Janet Woodcock, M.D.,** will lead the conversation that will take a close look at the report to Commissioner **Jane Henney, M.D.,** *Managing the Risks from Medical Product Use.*

The program will be shown at CDER's regular videoconference sites—Woodmont II, Conference Room G; Parklawn 13B-39; Metropark North, Room S-259; and Corporate Boulevard S-100. CBER will also be offering the program to its employees.

The "CDER Live!" series of broadcasts for the pharmaceutical industry is the result of a co-sponsorship agreement between CDER and the Drug Information Association. As in previous broadcasts, the industry audience is invited

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JOE'S NOTEBOOK

Hypertension Canary

Sometimes I feel like the canary that warned old-time coal miners of toxic fumes. In my last job at NIH, I talked nearly everyday with friends and relatives of people who had suffered strokes.

The most potent risk factor for this devastating disease is high blood pressure. Invariably the callers wouldn't appreciate the importance of treating high blood pressure. Many thought readings above 140/90 were OK. That's high blood pressure, a cause for concern and a reason to get to the doctor.

If you search the electronic PDR on CDER's intranet under the WebLern button, you'll find more than 100 drugs that FDA has approved for the hypertension indication. Even allowing for multiple dosage forms and combinations, that should be enough—as my doctor and I discovered—to find one or more that will control your high blood pressure with a minimum of side effects.

I'm fortunate that my job gave me an appreciation of the importance of blood pressure control. Unfortunately, the rates of awareness and control of high blood pressure among Americans appear to be falling after rising for more than a decade. According to a report that will be coming out in the September issue of the American Heart Association's journal *Hypertension* both the general public and the nation's physicians need a wake-up call to reverse this potentially dangerous trend.

"We are seeing a definite leveling-off, even a deterioration, in our level of awareness, treatment and control of hypertension, possibly because we aren't paying enough attention to it," says Irene Meissner, M.D., a neurologist who is leading a study at the Mayo Clinic's department of neurology to examine risk factors for stroke and heart disease in the community.

When Meissner and other researchers interviewed 636 adults from the Olmstead, Minnesota, community and measured their blood pressure they found that 53 percent had high blood pressure. Of great concern, two out of five—or 39 percent—of these subjects were unaware of their condition. Fewer than one out of five—or 17 percent—were receiving treatment to control it.

From the mid-1970s to the early 1990s, there was progressive improvement in the rates of awareness, treatment and control of high blood pressure, according to the CDC's National Health and Nutrition Examination Survey. During this period, the percentage of patients who were aware of their high blood pressure rose from 31 percent to 55 percent. The percentage with controlled hypertension increased from 10 percent to 29 percent. However, the trends changed in the early 1990s and showed small, but significant, declines in these percentages, to 53.6 percent and 27.4 percent respectively.

"Instead of making progress in combating the health threat posed by high blood pressure, we may actually be backsliding," Meissner says.

"People aren't as aware as they should be and control rates are quite low. This is happening despite solid clinical evidence that proper detection and treatment can dramatically reduce the number of deaths and disabilities caused by uncontrolled high blood pressure. Our results from the Olmstead County study show a low rate of high blood pressure awareness and control that is disturbing, particularly because the study participants lived in an economically prosperous area with easy access to health care."

Medal Mix-up: CDR Paul Judd Andreason, CDR Gregory Dubitsky and **LCDR James S. Williams, III,** were awarded PHS Commendation Medals during the Center's Spring Honor Awards ceremony.

Each received the individual award for a personal achievement and not the group award as erroneously reported on Page 6 of last month's *Pike.*

news along the pike

The Pike is published electronically on the X:drive in Cdernews and on the World Wide Web at:

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

Back to Basics : Examining the Words We Use Everyday

BY JIM MORRISON

Winston Churchill once described Britain and America as two countries separated by a common language. We find the comment amusing because beneath the glibness lies a profound truth. In different cultures, even those having the same language, identical words have different meanings. And nothing hinders communication more. America is blessed with many different cultures and diverse viewpoints. Yet, we often forget that the simplest words may convey different meanings to different people.

CDER's mission statement expresses a noble concept: "CDER assures that safe and effective drugs are available to the American people." But to accomplish such a mission, it is essential that everyone in the organization have a common understanding of what the mission statement means. It would be desirable if the public we serve also understood that meaning.

. That lack of common definitions is not surprising. After almost a century of legislation, regulation, court cases and public discussion, the meaning of the word "drug" is still in flux.

Those of us who frequently interact with the public know that the words "safe" and "effective" are relative concepts that mean different things to different people. Some expect a safe product to lack even a minute potential for harm. Some think that effective drug products generate dramatic therapeutic results in everyone who takes them. Disabusing people of these false notions is a constant challenge for CDER, and we need to do a better job of it. However, if we are to educate the public effectively, we in CDER need to speak and understand a common language. We should not take comfort that we can rattle off a dictionary definition of the words we use. Words are meaningfully defined only in the context of their use.

CDER recruits people from a variety of backgrounds. Some come from teaching hospitals, some from research labs and others from industry. How can we expect that each new employee will inherently understand safety and effectiveness or risk-benefit in the same way? Making risk-benefit judgments for an individual patient is quite different from making such judgments for a population.

> "Daily I see evidence that the words in the mission statement . . . are not commonly understood"

Within our organization, cultural differences evolve among individual scientists, scientific disciplines and divisions. Weighing risks vs. benefits in the context of drug regulation is not a mathematically definable process. Strong elements of judgment and preference are involved. I hear phrases like, "I'm not comfortable with the safety of this product." But what is comfortable to one person is intolerable to another, depending on life experiences and expectations.

So how can we assure the safety and efficacy of drugs unless we have commonly understood, operational definitions and a common value system for weighing each side of the equation? Fortunately, many products do not pose difficult issues, because they are clearly on one side or the other of the line by any reasonable standard. But what about the many others that fall into that gray area close to the line?

Establishing working definitions of words like risk-benefit, safe, and effective and then creating an algorithm for applying the definitions to make consistent and appropriate regulatory decisions require much careful thought and discussion. While efforts like the Good Review Practices document, guidances and the coordinating committees are helpful, I'm writing this as a plea for discussions at a more basic level that involve everyone. I see too frequently the results of a lack of such discussions.

I encourage everyone in CDER to spend some time in thinking about the fundamentals of each of our jobs and in discussing with colleagues what each of the words we commonly use means and how critical recommendations and decisions are or should be made. We should also expand our efforts to include CDER's stakeholders in the discussion, because their collective needs and expectations ultimately define our work.

We have all the tools we need to accomplish the task. The tools can be as sophisticated as the Internet or as simple as just talking. The key to success is in the mindset we bring to our work. Sometimes it's helpful to adopt the persona of a 3-year-old and to greet everything with the word, "Why?"

Jim Morrison is the Center's Ombudsman.

Registration Opens for 2000 FDA Science Forum Feb. 14, 15

The 2000 FDA Science Forum, will focus on the topic: "FDA and the Science of Safety: New Perspectives."

The annual meeting brings FDA scientists together with industry, academia, government agencies, consumer groups and the public.

Co-sponsored by FDA, Sigma Xi and the American Association of Pharmaceutical Scientists, the meeting will take place Feb. 14 and 15 at the Washington Convention Center.

Today more than ever scientists must stay current with new technologies, methods and discoveries.

The 2000 FDA Science Forum offers an opportunity to explore scientific and practical issues related to the safety evaluation and risk management of FDA-regulated products.

Top scientists from FDA and around the world will address emerging issues in the safety assessment of foods, drugs, biologics and medical devices.

Jane Henney, M.D., Commissioner of Food and Drugs, will present her views on "Science and the FDA. "

For additional information and a registration form for the 2000 FDA Science Forum please visit FIRSt at http://first.fda.gov or call the FDA Office of the Senior Advisor for Science (7-3340).

Latest Release of Adobe Acrobat Has Enhanced Tools for CDER

The Portable Document Format, or PDF, is a vital component of the Electronic Regulatory Submission and Review. The Center uses PDF documents in the electronic review process, document repositories and various Web platforms. Recently, Adobe Systems Inc. released version 4.0 of Adobe Acrobat, which allows users to create, view, navigate, annotate and search PDF files.

Since the software's release, OIT, with input from CDER reviewers, has been testing Acrobat's capability with in-house systems and core Center software. Testing is complete, and you can download the software to your PC from the OIT intranet homepage (http://oitweb/oit) under Notices.

In order to download Adobe Acrobat 4.0 correctly, closely follow the instructions on the CDER intranet.

If you need to install a less powerful version of Acrobat to save disk space, Acrobat Reader 4.0 is also available from the CDER intranet. Reader provides the basic tools to open and view PDF files.

Please contact the OIT Help Desk (phone: 7-0911; e-mail: HELP) if you encounter any problems during either installation.

The Center's customized installation of Adobe Acrobat contains:

- Enhanced document comparison features.
- Annotation and graphic markup utilities.
- Formatted text and table copying tools.
- Specialized graph copy plug-ins.
- Enhanced PDF creation tools.

In order to explain the benefits of Adobe Acrobat 4.0 fully, OIT has updated the NDA Electronic Submissions Training and NDA Electronic Data Analysis Training courses to reflect the new software.

OIT is also adding a third course, Creating Documents in the FDA Archiving Standard.

This new class will walk participants through the process of formatting a Word document and then converting the document to PDF using the new Acrobat 4.0 features.

Please visit the training section of the OIT intranet (http://oitweb/oit) to review class schedules, register for classes and obtain manuals.

If you have already taken the NEST or NEDAT courses, you can find updated documentation in the training section. The OIT point of contact is **Debbie Lorentz** (LORENTZD).

September IT Training

Monday	Tuesday	Wednesday	Thursday	Friday
		1	**2**	**3**
6	**7** **JMP Intro. (Session 1)** 1-4	**8**	**9**	**10**
13 **Team-Links Intro.** 9-12 **Team-Links Attachments** 1-4	**14** **RCM** 9-12 **JMP Intro. (Session 2)** 1-4	**15** **Creating Documents that meet FDA Archiving Standards** 9-12 **NEDAT** 1-4	**16** **Access & Tables** 9-12 **Access Queries & Reports** 1-4	**17** **Access Form Design** 9-12 **Access Report Design** 1-4
20	**21**	**22**	**23**	**24**
27 **NEST** 9-12 **DFS** 1-4	**28** **Creating Documents that meet FDA Archiving Standards** 9-12 **JMP Intro. (Session 3)** 1-4	**29** **CDER's Network & IT Web Services** 9-12 **File Management & Desktop Tools** 1-4	**30** **Word Intro** 9-12 **Word Formatting** 1-4	**Oct. 1** **Word Tables** 9-12

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

Year 2000 Activities

CDER's Y2K activities remain a top OIT priority. The primary areas for the upcoming month are desktop compliance and Day One planning.

As reported last month, the OIT Desktop Team is working to ensure that all desktop computers and software in CDER are Y2K compliant. OIT has completed work on existing PCs that could be upgraded to be Y2K compliant.

Those PCs that cannot be upgraded will be replaced. The deployment of the new PCs is scheduled to begin in September following OIT testing.

In order to address any desktop Y2K concerns of CDER staff, a special e-mail account has been established. Please e-mail any questions or comments you have to the account Y2K. Throughout this process we will strive to keep interruptions to your computing services to a minimum.

Day One planning is progressing. Detailed planning includes development of schedules, test scenarios and checklists and overall coordination of activities for the millennium crossover.

More detailed Y2K information can be obtained via the OIT intranet (http://oitweb/oit/) under Y2K. The OIT point of contact is **Judy McIntyre** (MCINTYREJU).

QA Development Project

In July, OIT commenced peer review of guidance documents in the area of configuration management. Final changes and senior staff sign-off are imminent for the initial document: configuration identification. Given the reviewer effort that was required to tailor this document for OIT use, peer reviews for other documents are being rescheduled to allow more time for revisions. Finalized guidance documents will be posted on the OIT intranet (http://oitweb/oit/) under the OIT Activities button. The OIT point of contact is **Jerry Yokoyama** (YOKOYAMAJ).

PM Coordination

In OIT, the term project management refers to the management of individual projects and is performed by designated project managers. The term project management coordination refers to higher-level oversight across projects and is performed by the project management coordinator.

Each OIT project manager meets at least monthly with the coordinator to dis-

(Continued on page 5)

REVIEWERS CORNER

Center's Mission Linked to Nation's Founding Principles

BY STEVEN HIRSCHFELD, M.D., PH.D.

When we think about our mission—assuring that safe and effective drugs are available to Americans—we don't usually think about the founding principles of this country. It's a useful and enlightening exercise to do so.

The preamble to the U.S. Constitution outlines the general functions of government as:

- Forming a more perfect union.
- Establishing justice.
- Insuring domestic tranquillity.
- Providing for the common defense.
- Promoting the general welfare.
- Securing the blessings of liberty to ourselves and our posterity.

Implicit in the concepts of justice, common defense and general welfare is compassion. Compassion is a quality that is universal in the ethical systems and spiritual beliefs of most cultures. It is formally defined as "sympathetic consciousness of others' distress together with a desire to alleviate it." A further implication is that the distress that is found in others is due to, related to or caused by a vulnerable or weakened state.

In contrast to the concept of might makes right, the Declaration of Independence of the United States affirms a number of truths to be self-evident and specifies that:

- All men are created equal.
- They are endowed by their Creator with certain unalienable rights.
- Among these are life, liberty and the pursuit of happiness.

The common aims of the documents that form the basis of our system of government are to promote the general welfare, provide for common defense and affirm the legal equality of each individual. Among the mechanisms to provide these aims are legal and procedural safeguards and institutions to implement these procedures.

The maintenance of a common defense has many fronts. Broadly speaking, there are threats from nature and threats from other people. A large portion of the resources of the U.S. government are devoted to defending against threats from other people. Examples include organizations such as the Departments of State, Defense, Commerce, Justice and agencies such as the FBI, CIA and Federal Trade Commission.

A few are devoted to defending against threats from nature, among which are diseases. There are some organizations devoted almost exclusively to this arena such as the National Institutes of Health, the Veteran's Administration Hospital System, Federal Emergency Management Agency and National Oceanic and Atmospheric Administration.

The FDA occupies a unique niche. The expertise to evaluate and monitor products that protect, alleviate or improve the life of people is necessary. In addition, the tools to discover and enforce the threats from people who make claims or use products to exploit or manipulate other people is also critical. Lastly, an awareness of the principles of protection of patients in the process of product development is intrinsic to the overall mission.

The basis of our mission can be found in the most fundamental principles of the country, and the validity of our mission should never be in doubt.

Steven Hirschfeld is a medical officer in the Division of Oncology Drug Products.

FDA Issues Final Rule On OTC Drug Products Containing Colloidal Silver

The FDA has issued a final rule on Aug. 16 declaring that all over-the-counter drug products containing colloidal silver or silver salts are not recognized as safe and effective and are misbranded. The rule becomes effective Sept. 16. Colloidal silver is a suspension of silver particles in a gelatinous base.

In recent years, colloidal silver preparations of unknown formulation have been appearing in stores. These products are labeled to treat adults and children for diseases including HIV, AIDS, cancer, tuberculosis, malaria, lupus, syphilis, scarlet fever, shingles, herpes, pneumonia, typhoid, tetanus and many others.

A colloidal silver product for any drug use will first have to be approved under an NDA. Colloidal silver products are misbranded because adequate directions cannot be written so that the general public can use these drugs safely for their intended purposes. They are also misbranded when their labeling falsely suggests that there is substantial scientific evidence to establish that the drugs are safe and effective for their intended uses.

Colloidal silver ingredients and silver salts include silver proteins, mild silver protein, strong silver protein, silver chloride and silver iodide.

The indiscriminate use of colloidal silver solutions has resulted in cases of argyria, a permanent blue-gray discoloration of the skin and deep tissues. The dosage form of these colloidal silver products is usually oral, but product labeling also contains directions for topical and, occasionally, intravenous use.

Y2K Upgrades for PCs Completed, Replacement Desktop Machines to be Deployed

(Continued from page 4)

cuss the status of projects and any issues requiring senior management assistance. Project management coordination is intended to improve senior management insight into projects, increase project accountability, facilitate project progress and ensure projects remain aligned with Center and OIT priorities.

OIT's senior staff reviewed new procedures for improving project coordination. These included a defined project management lifecycle, a template for project descriptions, a resource worksheet, criteria for prioritizing projects and criteria for selecting project managers.

Comments were incorporated and the final documents are being posted on the intranet (http://oitweb/oit/) under OIT Activities.

The next step in the plan is to prepare for an OIT senior staff review of existing projects. The OIT point of contact is **Vali Tschirgi** (TSCHIRGIV).

UNION CORNER

NTEU Holds Convention, Local Chapter Ratifies FDA Contract

BY ROBERT YOUNG

NTEU held its 47th national convention during the first week of August. Our Chapter 282 newsletter won the best start-up newsletter award.

The convention delegates elected Colleen Kelley national president and Frank Ferris executive vice president. Both will serve four-year terms. Colleen was formerly national executive vice president, and Frank was director of negotiations. Frank was chief negotiator in the recent FDA contract bargaining session. Bob Tobias, immediate past president of the national, retired after a 31 years with NTEU.

Chapter 282 has ratified the contract. The signing ceremony is scheduled for Sept. 1 and the contract's effective date will be Oct. 1. This article is a continuation of last month's on contract provisions that may have an immediate impact on employees.

Investigatory Interviews

Before an investigatory interview begins, affected employees will be told the purpose and nature of the interview in detail sufficient to allow them to determine whether they want a union representative to be present to assist. Employees must reasonably believe that the examination may result in disciplinary action to invoke the right to a representative.

The representative may clarify questions, clarify answers, assist an employee in providing favorable or extenuating facts, identify other employees who have knowledge of relevant facts, request a caucus and advise an employee during the examination. The contract restricts the investigative interview solely to matters of official interest and private matters outside the scope of the investigation are excluded.

Office Searches

There will be no intrusive searches unless there is a legitimate, work-related basis for them. The employer will notify employees in advance of searches of non-electronic equipment and work spaces and will give employees time to arrange to have a union representative or other employee witness the search if they so wish.

Contacting a Union Representative

A supervisor cannot require an employee to explain the specific circumstances surrounding the need to contact a union representative.

In obtaining permission to leave the work site, an employee need only explain the general nature of the visit. The amount of time granted must be reasonable. The meeting will be scheduled for a time such that the employee's absence will not create a "severe workload problem." Examples of a severe workload problem include the inability to complete a specific or previously assigned work project, which must be completed during the period of time in question, or a lack of office coverage in the employee's absence. This is a standard used repeatedly in many other situations, such as a decision to disapprove annual leave. Only in the most unusual circumstances will the delay exceed one workday.

Annual Leave

Requests for annual leave are to be approved unless they create a severe workload problem. Requests are to be approved "expeditiously" after receipt, that is, within days. The only variation is for leave of a week or more or leave around a holiday. These requests should be made in advance. Requests submitted by Jan. 1 for leave falling in May through November will be considered and acted upon within five days of Jan. 1. The similar deadline for leave falling in December through April is July 1.

Requests made after Jan. 1 or July 1 will be approved if they do not create a severe workload problem. The next deadline will be Jan. 1 for the time period May through November 2000.

If there is a conflict that results in the denial of an employee's request, the employee may use seniority to obtain approval once during the year or until each employee has exercised his or her seniority rights in that year.

Overtime

Overtime will be distributed fairly and equitably. A determination as to who is qualified to perform overtime work will be based on the nature of the work; employee knowledge, skills and abilities; and the cost effectiveness of using particular employees. Volunteers from the qualified group will first be solicited. If there are more or fewer volunteers than work requires, the employees will attempt to allocate the work among themselves. Failing that, work assignments will be made in order of descending seniority when there is an excess of volunteers. If there are no or fewer than a sufficient number of volunteers, work assignments will be made in order of ascending seniority. Assigned employees will be excused if they can find a qualified replacement.

Honor Awards

Awards will be made in a fair and equitable manner. Honor award committees will include union representatives.

Cash Awards

Each year, a bargaining unit employee awards pool will be created based on a percentage of bargaining unit salaries. Any employee may nominate any employee for an award recognizing achievements. Joint labor-management awards committees will be created to determine the use of informal recognition items and to review nominations for awards and approve awards. Committees will meet quarterly to make recommendations. Recommendations will be reached by consensus and favorable decisions will be forwarded to the official with approval authority. If that person modifies or rejects a recommendation, her or she will inform the committee in writing of the action. When no consensus is reached, a nomination will be forwarded to the approving official for final decision.

Reassignments

FDA has the right to reassign employees solely to accomplish the Agency's mission. Consequently reassignments will be based on a good faith determination based on legitimate management considerations. When a decision is made to fill a position through reassignment, FDA will make the opportunity known to qualified employees at least three days in advance through the e-mail system. Employees in identical positions with the same title, series, grade and qualifying experience may swap positions so long as FDA does not have just cause to bar the swap. Circumstances permitting, FDA will give at least two week's notice to an employee who is going to be reassigned.

Robert Young is president of the local.

RISK MANAGEMENT CORNER

Proposed Model Introduces Concept of 'Risk Confrontation'

Once the FDA Risk Management Task Force had identified the different types of risks (June Pike), it looked at how the Agency relates to other groups involved in managing the risks. Given the complexity of today's healthcare system, the task force concluded that an understanding of risk management must evolve from an emphasis on the functions and responsibilities of freestanding components, such as FDA and hospitals, to an understanding of drug safety as a systems issue.

To see how a systems approach might look, the task force adapted a model proposed in 1997 by the Presidential/Congressional Commission on Risk Assessment.

The activities included in the model are:

- *Risk assessment:* estimating and evaluating risk.
- *Risk confrontation:* determining an acceptable level of risk in a larger context.
- *Risk intervention:* taking risk control action.
- *Risk communication:* interactively exchanging risk information.
- *Risk management evaluation:* measuring and ensuring the effectiveness of risk management efforts.

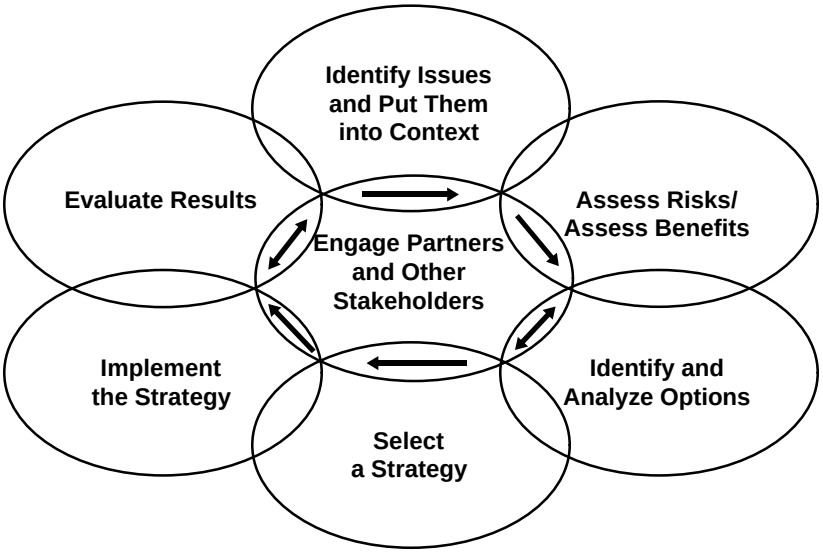
Risk confrontation may be a new concept to many who are familiar with FDA's premarket approval and postmarket surveillance risk-benefit decision-making processes.

Risk confrontation is community-based problem solving that actively involves relevant stakeholders in the decision-making process. This definition implies that social and community values are at least as important as the technical judgments of professionals and should be included in the determination of acceptable risk.

Science provides a statistical assessment of risk but cannot determine its acceptability. Affected communities may differ from regulators in how they value risks or benefits and may make different judgements about the amount of uncertainty that is tolerable.

Adapted from: *Managing the Risks from Medical Product Use.*

Proposed Risk Management Model



TRAINING AND DEVELOPMENT

Plain Language Tip: Stick to the Active Voice

BY JACK MORIN

The Division of Training and Development emphasizes plain language in its technical writing courses. As DTD's plain language coordinator, I will be using this column from time to time to pass along some helpful suggestions to improve your writing.

Taking a hard look at how you use verbs is a good place to start. The active voice reduces confusion by forcing you to name the actor in a sentence. The passive voice makes a sentence less direct, often longer and obscures responsibility. Passive verbs have a form of the verb "to be" plus the past participle of a main verb. Examples of passive verbs are:

- Was received.
- Is being considered.
- Has been selected.

The passive voice reverses the natural, active order of English sentences. In the following example the receiver of the action comes before the actor.

- *Passive:* The regulation [receiver] was written [verb] by the FDA [actor].
- *Active:* The FDA [actor] wrote [verb] the regulation.

Passive sentences can be confusing when used in regulations. An active sentence must have an actor, but a passive sentence is complete without one. Placing the actor before the verb forces you to be clear about responsibility. For example:

- The messenger will deliver the notebook.
- The contractor will decide the start date.
- The administrator must approve the budget.

The passive voice is appropriate when the actor is unknown, unimportant or obvious. This doesn't usually apply in regulatory text. Examples are:

- Small items are often misplaced.
- The applications have been stolen.

Let me know if you have a plain language example from your office to share with others (MORINJ, 7-1672).

Joanne Locke, FDA's senior plain language coordinator, is looking for volunteers to try out a software package that edits and polishes your writing into clear and concise English. If you are interested call or e-mail Joanne (7-4441). You will be asked to complete an evaluation survey after two or three weeks of using the program on your PC.

Jack Morin is a writer/editor in DTD.

FDA Issues Final Guidance for Direct-To-Consumer Rx Drug Ads

FDA on Aug. 6 issued final guidance concerning direct-to-consumer broadcast advertisements for prescription drugs. The final guidance differs little from the August 8, 1997, draft guidance, which described an approach that fulfills the requirements for prescription drug advertisements broadcast on television and radio.

The final guidance will continue the four-pronged approach to disseminating product labeling in connection with broadcast advertisements:

- A toll-free telephone number.
- Referral to a print advertisement in a concurrently running print publication, or provision of enough product brochures in various convenient outlets.
- Referral to a healthcare provider, such as a physician, pharmacist, veterinarian or other healthcare provider.
- An Internet Web page address.

By providing these avenues for obtaining more information about prescription drugs, broadcast ads satisfy the "adequate provision" requirement of the prescription drug advertising rules. This helps ensure that a diverse audience with different information-seeking styles will be able to receive comprehensive product information. This diverse audience includes people who are particularly sensitive to privacy issues in seeking out additional information.

As required in the prescription drug advertising regulations, advertisements broadcast over radio, TV or through telephone communications systems must include a thorough "major statement" prominently disclosing all of the major risks associated with the drug.

This guidance encourages sponsors to consider the benefits of providing nonpromotional, consumer-friendly product information in addition to the required product labeling. The guidance and frequently asked questions are available on CDER's Website at http://www.fda.gov/cder/guidance/1804fnl.htm and http://www.fda.gov/cder/guidance/1804q&a.htm.

Enforcement, Partnerships, Outreach Emphasized for Internet Drug Sales

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nated, counterfeit or outdated drugs.

FDA's action plan includes:

- *Customized and expanded enforcement efforts.* FDA will begin upgrading and expanding its monitoring of Internet violative sites to make Internet drug sales more of an enforcement priority, including initiating criminal or civil enforcement actions when appropriate. The Agency will initially target its enforcement efforts on three areas: unapproved new drugs, health fraud and prescription drugs sold without a valid prescription. Efforts will focus on areas where there is a significant public health risk.
- *Partnering with federal and state bodies and other organizations.* Several federal agencies, as well as the states, have the authority to regulate and enforce laws related to online drug sales. Also, FDA has signed a "principles of understanding" with the National Association of Boards of Pharmacy and the Federation of State Medical Boards, with the backing of the American Medical Association and the American Pharmaceutical Association. These commit the signatories to cooperate in enforcing federal and state laws against unlawful sellers and prescribers in the United States.
- *Engaging in public outreach.* FDA will implement other strategies to counter the illicit Web practices including outreach to alert consumers to public health risks of illegal online offerings.

A copy of FDA's testimony to Congress, presented by Center Director **Janet Woodcock, M.D.,** can be found at http://www.fda.gov/ola/drugsonline.html.

Sept. 15 CDER Seminar to Feature Dr. Woodcock's 'State of the Center' Address

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Parklawn Conference Room D. The event will be in the format of a "Jeopardy" game with three teams led by office directors representing the Parklawn, Woodmont and Corporate Boulevard office buildings.

Questions will be based on regulatory decisions and guidelines, peppered with a few CDER factoids.

Due to the interactive nature of the program and room availability restrictions, this event will not be videoconferenced.

A complete listing of this fall's CDER Seminars and Scientific Rounds will soon be available under What's Happening on the Center's intranet site, http://cdernet.

Robin Huff, Ph.D., is the CASE chair.

4th 'CDER Live!' Broadcast to Focus on Risk Management, Communication Issues

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to fax or phone in questions to the panelists during designated parts of the program.

The first panel, focusing on global issues in risk management, will include:

- Laurie Flynn, Executive Director, National Alliance for the Mentally Ill.
- Linda F. Golodner, President, National Consumers League.
- Eleanor M. Vogt, R.Ph., Ph.D., Senior Fellow, National Patient Safety Foundation.

The second panel, which will discuss risk management and risk communication issues specific to CBER, CDRH and CDER, will include:

- **Kathryn C. Zoon, Ph.D.,** Director, CBER.
- **Susan Alpert, Ph.D., M.D.,** Director, Office of Device Evaluation, CDRH.
- **Nancy Smith, Ph.D.,** Director, Office of Training and Communication, CDER.

Deborah Henderson, Director, CDER Executive Operations Staff, will moderate the program.

Details on establishing a downlink to the broadcast can be found on DIA's Website at http://www.diahome.org/meetings/programs/99144fly.htm.

Elaine Frost is a public affairs specialist in OTCOM.