news along the pike

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Jim Morrison
The Ombudsman's Corner
April 15, 1996, to January 7, 2003

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Introduction

This special edition of *News Along the Pike* contains all the essays written by Jim Morrison, the ombudsman for the Center for Drug Evaluation and Research from 1995 to 2003.

Jim began his career as a chemist with FDA in 1965 at the Los Angeles office. In 1972, he moved to the Office of Compliance in FDA's Bureau of Drugs, the forerunner to CDER. He became chief of the Over-the-Counter Compliance Branch in 1974 and special assistant to the bureau director in 1976.

In 1982, he was named director of the Regulatory Affairs Staff. A year later, he became deputy director for the Office of Drug Standards at the then National Center for Drugs and Biologics. In 1991, he became acting director of the Office of Drug Standards in CDER. He became deputy director for administration in the Office of Drug Evaluation I in 1994. He was named CDER ombudsman and senior advisor to the center director in 1995.

His thoughtful and provocative Ombudsman's Corner has served as a guiding light to the Center during an extraordinary period in the evolution of drug regulation in the United States. We are pleased to present this collection of essays as an educational service for all who work for or do business with the Center.

To See Ourselves as Others See Us

BY JIM MORRISON

Well, I've been on the Ombudsman job for over five months. I have talked with folks from the industry and from CDER about the way we interface, and, working with the Office of Training and Communications (OTCOM), I plan to do much more of that. It seems like a good time to share with you some of what I have learned, and I'll continue to do that periodically in this column.

Naturally, from my position as Ombudsman, I hear about and investigate only the cases where there have been serious miscommunications, delays and problems in our operations. If the cases and examples I get were reflective of CDER's normal functioning, we would not have been able to meet our user fee goals. Having said that, I believe we can learn much from our outlying cases, and if we can prevent future problems from happening, we can rob our critics of those prime examples they love to cite. We can also do our jobs better if we understand the problems faced by those with whom we interface.

I am always surprised to hear from knowledgeable people outside the agency that they are frequently mystified about how we operate, why we do many of the things we do or ask the questions we ask. The term "black box" is used by some of them to describe the drug review process. Clarity in communications, timely meetings and scientifically justified requests for additional data, when necessary, are high on the priority list of the people I have talked with. The new MaPP (Manual on Policy and Procedures), "Formal Meetings Between CDER and CDER's External Constituents (#4512)," issued on March 7, covers meetings with external customers and should be of great help in improving communications. (The MaPP will be placed on Internet.) Clearly, the regulated industry and applicants have an insatiable need for solid information about our policies and procedures. The Good Review Practice (GRP) guidelines are eagerly awaited outside the Center as a means of improved consistency in reviews and of a better understanding by the applicants about what we are looking for in submissions.

As science and policies evolve, as procedures change with new technologies and as personnel in reviewing divisions, in CDER management, and in the Commissioner's and the General Counsel's offices leave and are replaced, those who deal with the agency need up to the minute information about these changes. (I have found that need to be shared by our own staff.) In the new drug review area, firms find that, because the life-cycle of an NDA is long, experience gained with one application may no longer be valid when the next one is ready to be submitted. There is no way to avoid the inevitable shifts in the regulatory landscape.

However, we can be sensitive to the serious problems an applicant faces when

April 15, 1996

Timeliness, Policy Emerge as Top Complaints

BY JIM MORRISON

I have been "ombudsing" for a year now, and I'm asked frequently about the nature of the complaints I get. Naturally, the confidential nature of my contacts makes it difficult to get very specific, but now that I have a year's worth of data, I can give you a reasonably clear picture.

This analysis is based on 71 complaints or issues in 59 contacts. I included only those involving substantive complaints or issues. The ratio of contacts from outside the Center to those from within runs roughly 2:1. That is not too surprising, since the ratio of the population of the outside world to Center employees is even larger than that (about 3,000,000:1).

The complaints can be sorted into the following categories with corresponding frequencies:

External	
Timeliness	34%
Policy or decision challenged	29%
Priorities or inconsistencies	22%
Poor advice or lack of information	15%
Internal	
Personnel management	57%
External interactions	23%
Management/ administrative systems	20%

Timeliness is the most frequent complaint from outside. The 34% figure is really understated, because many of the complaints about priorities are aimed at speeding up our processes. This is expected. Even though we have made tremendous progress in shorten-

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ing review times, expectations have also been raised. Many complaints about timeliness relate to the new drug area, but others relate to activities throughout the Center. All of us can reduce the number of timeliness complaints by not promising anything we can't deliver. A careless estimate of a completion date by us can lead a company to use it in making costly business decisions.

Next to timeliness, I hear most about disagreements with policies, actions or decisions. About a third of the time, the problem stems from miscommunication and misunderstandings. When coupled with the third category, dealing with bad or lacking information, it is clear that we can prevent many complaints by getting more and better information out. I suspect that CDER's new Web site and the anxiously awaited internal CDERnet will significantly help improve understanding of our policies and procedures.

Another piece of advice I would give is to make sure you cite policies accurately, and if you think a policy doesn't make sense, don't pass it along until you understand it and find an interpretation of it that makes sense in the particular context you are working with.

It should be no surprise that over half of the internal complaints relate to poor personnel management practices. With the Federal work environment changing constantly, often not for the better, our supervisors and managers need to be aware of the impact on our people of bad press, dwindling opportunities for promotion to management positions, and the threat of downsizing. We can improve morale with honest positive and negative feedback, delegated responsibilities for meaningful work and expressions of appreciation for excellent performance.

One of the pleasant surprises of the Ombudsman's role for me has been the number of times I have been alerted by CDER staff to developing problems with external interactions. Please continue to let me know when you see a problematic interaction developing. This year I have been alerted to a systems problem in personal drug imports, multiple cases of deteriorating relations with companies and consultants, and problems with internal FDA investigations.

I also appreciate hearing about problems with administrative systems that are not serving our needs as they should. Don't assume that everyone knows about a problem you see and that no one cares. Send me an e-mail at MORRISONJ or call me at 594-5443. Together we can make CDER a better place to work.

October 18, 1996

CDER Transformation in Full Bloom

BY JIM MORRISON

So often we are too close to the trees that we miss seeing the forest. An excellent example of that cliché is CDER's transformation process. In my job as ombudsman, I see plenty of trees, in the form of calls, e-mail and letters, mostly complaining about what is wrong with our systems and people's behavior. I believe it is essential that I periodically take the time to step back from the trees and view the broader landscape.

One such opportunity came in the form of the Fall Planning Meeting. It was a marathon event lasting some 10 hours, but those of us who managed to sit through all the presentations were rewarded with a view of the Center that revealed some remarkable changes since the previous sessions. Incidentally, if you missed the live presentation, shortly there will be tapes of the sessions available through the library.

A lot has happened in the past six months to change CDER's outlook. It was only in March that CDER's senior managers first got together during a go-away to form the Change Team and drafted CDER's mission, vision and values statements. Since that time, the Change Team has begun to function cohesively, working together toward commonly set goals. If you compare the presentations at the fall planning sessions to those in the spring, you will see much more attention was paid to how the goals for each office align with those of the Center, and you will see many more references to cross-organizational activities.

Without much fanfare, CDER has moved from the initial phase of its transformation, that of establishing its vision, mission and values, to setting its goals and getting down to the nuts-and-bolts work of seeking results based on the broad goals. Currently, the Change Team, augmented by the Leadership Fellows, has identified six general results and specific projects and actions to accomplish those results. The results are:

- A highly satisfied, productive and efficient CDER staff.
- Improved efficiency of the drug regulatory system.
- Improved quality and timeliness of drug development and review.
- Expanded international harmonization.
- Improved communication of essential drug information to consumers, patients and health professionals.
- Increased internal and external awareness of CDER's work and the value it adds to society.

The working groups have met and will meet again Nov. 20. As the planning for these results efforts becomes firmer, additional people from throughout CDER will be recruited to help. If you want to be a part of this

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transformation process, and I certainly recommend that you do, keep watching your e-mail, the Pike and the new CDERnet for more information.

Speaking of the CDERnet, which was unveiled Nov. 5 (reachable by typing "www" in the address box for those of you with Microsoft Internet Explorer), that intranet site and CDER's Internet Web site are further evidence of the Center's transformation. I can personally attest to the power of the Internet in expanding communications. Since my Ombudsman page went online last month, calls, letters and e-mail to me from outside have tripled. Not only am I getting more industry complaints and suggestions, but I am also getting questions and requests for assistance from consumers, patients and health professionals. Progress has a price, but I am enjoying the challenge.

November 21, 1996

A Holiday Story from CDER

BY JIM MORRISON

Lest you believe that the lot of an Ombudsman is an endless litany of complaints and woes, it is not. On occasion I am privileged to observe CDER at its best, and at this time of year it is especially appropriate that I share one such story with you. This story could be called "A Tale of Two Fathers." In early November I was contacted by a man in the Midwest whose son was suffering from metastatic malignant melanoma, a particularly aggressive form of cancer. His son had been started on a chemotherapy mixture of three drugs two months earlier, but the hospital pharmacy was now unable to locate one of the drugs, dacarbazine. He had talked with the manufacturer but was told that a supplemental application was pending with FDA, and they couldn't promise delivery of the drug until the first quarter of 1997. His son needed to continue the chemotherapy soon, and he asked if there was anything I could do.

I checked with the Division of Oncology Drug Products, and **Leslie Vaccari,** a project manager, soon filled me in on the history of the supplement and the difficulties the firm had in finding a supplier. The division had worked long and hard in the face of diminishing supplies of the existing product to help the company find a new source of supply for the active ingredient. They had also received calls from patients and their families, and they had encouraged the firm to submit a supplement in a timely manner so that supplies of the newly manufactured product could be shipped quickly. In fact, Leslie told me, the supplement would be approved that very day. The night before the son of the reviewing chemist, **Steve Koepke,** had been in a serious car accident. Nonetheless, Steve came in after spending the night at the shock-trauma unit to make certain that the supplement would be approved.

Once I determined from the company that supplies would be moving in a few days, I called the father of the boy with cancer. He expressed his and his family's gratitude for the support they received from CDER. There are doubtless scores or hundreds of other families across the country who owe a similar debt to the folks in Oncology. Most of them will never know whom to thank.

So for them, I'll thank Steve, Steve's supervisor, **Eva Tolgyesi,** Leslie and all the dedicated people at the Division of Oncology Drug Products. I'm glad to report that Steve's son is doing well. Happy holidays to all.

December 23, 1996

When the 'R' Word Rears Its Ugly Head

BY JIM MORRISON

Most of us at some time in our lives have been in the uncomfortable position of being accused of doing something we didn't do. When that situation arises, it is often impossible to prove that we didn't do a particular thing or, if we did it, that didn't do it with the alleged motive. Such is the nature of defending ourselves or our organization against charges of retaliation. Unfortunately, CDER has had to do just that before Congress in recent years.

In the context of a regulatory agency, retaliation is usually defined as a regulator taking action, or not taking action, to the detriment of a regulated individual or company in reprisal for some previous action by that individual or company. Even an implied threat to retaliate is considered retaliation.

To use an example that might occur in CDER, Company A submits an NDA to CDER. There follows a scientific dispute about the review, which the company

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appeals to the office level, and the office director agrees with the company. A subsequent NDA that Company A submits to the same review division receives a not approvable letter citing numerous deficiencies requiring a lot of time and money to resolve. Company A charges that the division was overly picky on the second application in retaliation for the company's appealing the earlier dispute. The division maintains that its deficiency letter was entirely appropriate.

Obviously, there is no real defense that anyone in the division can offer to erase the perception of retaliation in the minds of the applicant and of those who want to believe that retaliation is part of the way we do business. The only way I know to reduce the likelihood that anyone will allege retaliation is to build trust by incorporating three simple customer service principles in all our contacts.

First, from my observation, the most important principle of good customer service is expeditious response. Nothing gets relationships off to a worse start than failing to return phone calls promptly or not answering letters. In addition, stating an approximate time in which a substantive answer can be expected, if one cannot be given right away, and meeting that time frame proves that our word is good and that we can be trusted.

CDER has already done much to establish a track record in timeliness. The entire Prescription Drug User Fee Act implementation has improved our relations with the public and with the regulated industry enormously. We need to extend that success to all aspects of our work.

Second, the response should be fair, reasonable and well thought out. If we give a quick response that is inappropriate, requires further explanation or seems inconsistent with other decisions, we convey a careless attitude and undermine our own credibility.

Third, the manner in which business is conducted should convey an understanding and caring attitude. This factor is more difficult to measure than the first two because it is subjective. It involves much more than a pleasant voice on the phone or a well-written letter. Customers look for evidence that the person they are dealing with understands their problem and cares about the outcome.

Everyone who comes to us has a problem, whether it is a company that needs our approval to market a product or a consumer who has had a bad experience with a drug product. If we respond to all our contacts promptly, take the effort to understand each person's problem and provide a fair, reasoned answer in a timely and appropriate manner, I guarantee you that charges of retaliation against CDER will be only bad memories.

For more information about retaliation, please refer to FDA Commissioner David A. Kessler's memo to all FDA employees dated June 29, 1995, available on the Internet at: http://www.fda.gov/cder/commis.htm.

January 17, 1996

Shakespeare's Advice on Career Development

BY JIM MORRISON

About a third of the issues brought to me concern internal CDER matters. Often the immediate cause of the complaint is not the real problem. Unfortunately, as in many scientific organizations, the press of technical work in CDER often becomes overriding, and we don't take enough time to attend to the human side of the enterprise. As a result, talented people sometimes find themselves underutilized or placed in positions for which they are not best suited or for which they have not been adequately prepared.

The problems that result from unwise management of human resources are tremendously destructive to the fabric of any organization. In CDER we are working through the transformation process to improve the way we manage all of our resources. But in the meantime, there are some things you can do to improve your lot in life if you find yourself in one of these career blind alleys.

To quote Shakespeare, "The fault is not in our stars, . . . but in ourselves that we are underlings." In Julius Caesar, Shakespeare described a support group run amok. Today, as in ancient Rome, assassination is never a viable remedy for problems with management. But there are other ways by which you can take charge of your own situation.

One method is to participate in a developmental program, such as the CDER Leadership Fellows Program or the FDA Leadership/Executive Development Programs. The CDER Leadership Fellows Program is in the midst of its maiden voyage, with 28 fellows working on projects that will make significant changes in CDER. A date has not been set for opening the next application process.

The FDA Leadership/Executive Development Programs are about ready to announce openings for the next two-year cycle. have a particular interest in the FDA programs, because I have been for many years the CDER representative to the FDA Management Devel-

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opment Committee, which oversees the programs and makes the selections. These programs are open to GS-13s to 15s and are highly competitive. They have evolved from the old FDA Mid-Level Program, and they offer a rich mix of course work and tailored developmental assignments to different parts of the FDA, including the field.

If you are interested in applying to the FDA Leadership or Executive Development Program, keep an eye out for the official announcement, coming probably in early spring. If you have questions about how to apply, please contact the OTCOM representative who will be identified in the upcoming announcement. For those who may want to talk about how they might fare in the competition or other aspects of the programs, I would be happy to serve as a resource. Please call me (4-5443) or e-mail me (MORRISONJ).

While these two developmental programs apply specifically to people in grades GS13-15, a wealth of other programs target different groups. One in particular is the Center's new Secretary Certification Program sponsored by OTCOM.

Developmental programs are only one aspect of personal and professional development. I always encourage applicants to the programs to develop their own plan and to consider acceptance to one of the programs a nice bonus but not essential to their career progression. In my next column, I will discuss other approaches people have used to get a career unstuck. I invite everyone to share techniques you have used or have seen others use successfully. Give me a call or send an e-mail, and I'll include the best ones in my column.

February 21, 1997

Building a Career . . . Part Deux

BY JIM MORRISON

Last month, we discussed how leadership and other developmental programs can sometimes cure the "my career has fallen and it can't get up" syndrome! But there are other ways you can jump start a stalled career.

For most people, career growth doesn't just happen; it is the result of considerable planning and self-analysis. The key is to take control of your future, do some real soul-searching about what you want out of life and from your career (there are plenty of self-help books to guide you), and then develop a strategy for attaining your career goals with realistic milestones. You should reassess your goals and plans annually.

In the old days, career growth and progressive promotions through the managerial ranks were synonymous. Today, we live in a different world. Management is one career track, and it is still a rewarding one for those who have appropriate talents and skills. But don't automatically assume that management is for everyone.

I believe that there has never been a time in CDER when there were more opportunities to demonstrate leadership and to develop your career. The matrix management structure and the transformation effort in CDER have resulted in a proliferation of subject-matter coordinating committees, subcommittees, transformation results teams, and subgroups that are producing significant procedural and policy changes.

When the FDA Management Development Committee interviews candidates for the Leadership Development Program, we ask about the person's ideal job in the agency. From the answers we get, it is clear that many people have the mistaken impression that there is a group somewhere in FDA that sits around all day and makes all the policy. It is true that some organizational units have the word "policy" in their names, but policy is made throughout the agency and throughout CDER. If you see a need for a policy or procedure in your work, chances are there is a group working on it that would welcome your help. If there isn't such a group already, why don't you start one? Just discuss it with your supervisor first and with your colleagues, and you may find it is easier than you thought.

While the financial and recognition rewards structure has not kept pace with the reality that management and leadership are not necessarily vested in the same people, things are changing. For example, as her CDER Leadership Fellows project, Nancy Smith, Director of the Division of Biometrics III, has been doing some outstanding work in developing a non-supervisory career pathway for reviewers from new hire through what is called the master reviewer level.

If you want to take a look at the draft, go to the CDERnet (just type "Bambi" at the Internet address prompt, then click on Master Reviewer Program). I believe that the same type of management and technical dual career pathways will come to pass in the regulatory and administrative areas as well. Perhaps you can make it happen.

CDER has made great strides in improving communications, and you will see even greater progress in the future. If you need information about any of the CDER committees or who is on them, you will soon be able to

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find the information quickly. The CDER internal Web site, CDERnet, will become the central place for all information needed by center staff. The site was created only a few months ago, but is growing rapidly so keep watching it for the information you need in your career planning.

You can also get information through networking and mentoring. By developing contacts with people who have progressed along the routes you see yourself going, you can profit from lessons they have learned. CDER is developing a mentoring program for new hires, and it is in effect in some review areas. But even if you have been around CDER for a while, you can find opportunities to be mentored by more senior staff. Remember the rule for career building: Your career is your own; take responsibility for its growth and development.

March 26, 1997

Learning from Our Successes

BY JIM MORRISON

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

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

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

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

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

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

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

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

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

April 29, 1997

CDER Transformation—Thoughts on Virtuosity

BY JIM MORRISON

The CDER transformation is gaining momentum. Changes, both large and small, are now occurring with such rapidity that it is often difficult to keep up with them. One of the larger changes to be unveiled recently is the *CDER Virtual Journal (vJ).* The internal forum in which CDER scientific and regulatory staff can communicate freely about the issues that confront us daily has been needed for a long time. In case you haven't yet seen it, you can do so by accessing the CDERnet (type CDERnet at the address prompt in Internet Explorer).

I might quibble about the name. The word "virtual" connotes something almost as good as the real thing. For example, the movie *Virtuosity,* with Denzel Washington, features a virtual reality that flirts with but ultimately is separate from reality itself. However, the first issue shows the *vJ* to be a real journal in the best sense of the word. It is filled with relevant, important and timely articles on issues that affect us all. The *vJ's* premiere issue not only demonstrates the medium, but it sets a high standard for content.

Janet Woodcock's lead article on science, law and public policy reminds us how infrequently we have taken the time to discuss the philosophy of drug regulation and how important it is to understand the basis for what we do. It is a "must read." **Bob Temple's** scholarly review of the history of drug regulation can make you an instant expert on the subject. Other articles include such wide ranging subjects as carcinogenicity testing, meta analysis, drug advertising, bioequivalence, clinical trial design, the review of an NDA, and much more. They demonstrate that, if we all participate, a forum like the *vJ* allows us to learn about and to discuss openly and frankly the unique scientific issues that we face. Such a forum can not only inform but can also build more consistency and rationality into our work as well.

To be able to conduct such a discussion within the security of CDER's firewalls is a welcome change from the goldfish bowl in which we usually work. But the *vJ* is too valuable to hide it from public view. The many people who produced the *vJ* are also working on a companion version for the CDER Word Wide Web site. A forum that provides for an ongoing dialogue with patients, health care providers, the regulated industry, other regulatory bodies around the world and our many other stakeholders would be of inestimable value.

Not only is the *vJ* itself impressive, but the way it came into being epitomizes the CDER transformation. It originated in the Good Review Practices' (GRP) Track 2 Committee organized by **Julie Carlston** and **Debbie Henderson**. With the proactive nurturing of **Nancy Smith** and **Zan Fleming** plus the support and talents of **Steve Wilson, Grant Williams, Jack Pevenstein** and a host of people from all over CDER, it has become a reality—not a virtual reality. It was not budgeted or allocated FTEs, but it grew from the grass roots of CDER. The *vJ* is truly a model of how the transformation is changing the environment and culture of CDER. It brings to mind the original meaning of virtuosity.

May 27, 1997

CDER and FDA Leadership Development Programs

BY JIM MORRISON

In my February column, I advocated taking charge of your career development and cited two structured ways to do that: the CDER Leadership Fellows and the FDA Leadership Development (LDP) programs. Since the Fellows program has announced about 20 openings for its second class beginning in the fall, and with the FDA LDP announcement due out this month, I thought it would be useful to discuss them further. They both have "leadership" in their titles, a natural source of confusion, and they both are aimed at identifying and developing future leaders. However, they are quite different.

The Fellows program is newer and is run out of the Office of Training and Communications' (OTCOM) Division of Training and Development under a contract with the Council for Excellence in Government, which facilitated the initial phase of CDER's transformation. The CDER Fellows remain in their current jobs more or less full time, but they meet periodically for facilitated training experiences and discussions. In addition, they each select a project to develop and complete, preferably in collaboration with other CDER or agency staff. A wisely chosen project can lead to considerable visibility in CDER and to a sense of accomplishment at a level usually reserved for senior managers.

Both the CDER Fellows and the FDA LDP are geared to the modern concepts of leadership in a matrix management system. Leadership no longer equates to supervisory or management titles. In fact, the FDA program changed its name a few years ago, substituting "Leadership" for "Management." The LDP grew out of what was known as the "Mid-Level Program." Com-

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pared with the Fellows, the FDA LDP is more time-intensive and requires some geographical flexibility. The LDP entails training and developmental assignments, generally consuming 12 months, to be completed within the program's 18-month span. While participants keep their current jobs, they spend only about a third to half of the time actually in their offices. They generally complete four developmental details of 30 to 90 days duration each during the program. Most of these details are outside their home organization (e.g., Center). It is a requirement that all headquarters-based participants serve at least one detail in an FDA field office and field participants must come to headquarters for one assignment. However, these are the minimum requirements, and in the group that just graduated, assignments carried some as far away as Europe and Latin America.

The LDP is more highly competitive, with only about 15 slots available every two years from throughout the agency. It is run out of the FDA's training division but is guided by an agencywide committee, chaired by Sharon Smith Holston. The committee has representatives from each Center, the Office of Regulatory Affairs, EEO, and other Commissioner-level components. This committee interviews the candidates and makes the selections.

Graduates of both programs are enthusiastic supporters and are glad to talk about their experiences. Before applying to any developmental program, it is wise to talk with some graduates to get a firsthand view of how it helped them, what they liked most and least about the experience, and to find out if it is right for you.

Although the last day for applications to the Fellows program for FY '98 was June 16, career development is an ongoing pursuit. It is not too early to think about next year if you are interested. As of this writing, the application period for the LDP has not been announced, although it should be opened in June. Be sure to watch for the announcement, if interested. The LDP comes around only every two years, so if you miss this opportunity, you'll have to wait until 1999. Selections for the Fellows program will not likely be known before the applications for the LDP are closed, but there is no bar to applying to both programs, although it would be impractical to participate in both simultaneously.

For more information about the CDER Fellows program, contact OTCOM's Janice Sheehy or former CDER Fellow Mary Lambert. For LDP application, contact Sarah Thomas in CDER's Training Division. As CDER's representative to the FDA Leadership Development Committee, I encourage CDER employees who are considering applying to the LDP to contact me directly for more details about the program.

June 1997

There's No Substitute For A Caring Manager

BY JIM MORRISON

In my annual feedback column last October, I commented that over half of all internal complaints related to poor personnel management practices. Now, we all know about the decades of oppressive and sometimes dumb personnel rules and regulations that left government managers chafing and new hires perplexed. But that is not what I was referring to when I wrote about poor personnel management practices. I meant practices that individual managers in CDER chose to use to manage their people and their work.

Has anything changed in the eight months since that column? Well, with a new office structure for information systems management, a new review division created, departure of some managers and reshuffling of others, there has certainly been a change in the landscape. In addition, managers at all levels have been given a new tool for self-evaluation: the 360-degree assessments that we all completed recently. In that process, CDER managers and supervisors received feedback from their subordinates, peers and supervisor on a wide range of management performance factors. Information was also provided about where each of us stood with respect to norms established by thousands of other managers. In general, we fared well in most areas compared with a government norm. However, just being better than average is not where we should want to be.

I wish I could report that internal complaints have dropped off and that a new era in management brilliance has swept CDER to new heights of productivity and élan. Alas, I cannot. If anything, I am hearing reports that there are areas in CDER with significant morale problems. And while we continue to improve our Prescription Drug User Fee Act (PDUFA) performance, there are signs of increased stress.

As we gear up to implement whatever changes will come with the PDUFA reauthorization and its companion FDA reform legislation, it is essential that we make sure that we are most effectively using the resources we have. Our most valuable resource is people. We have been fortunate that the PDUFA increase in CDER staffing coincided with a weak job market that allowed us to recruit some really talented

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individuals. As demands on us increase, we cannot afford to squander the time and talents of our people. But that is exactly what we do when we fail to ensure that we have matched the right jobs to the right people. It is also what we do when we distract staff from their work by employing ill-conceived management practices.

We in CDER care almost universally about our public health mission, about consumer protection, and about our work. This caring attitude is one factor that binds us together and makes CDER a great place to work. However, we sometimes get so busy with the technical aspects of our work that we forget to care enough about our customers closest to home—the people with whom we work daily. In supervisors, this neglect often takes the form of the "thank you" not said or the constructive feedback not given, but we can improve this situation.

The 360-degree assessments provide valuable feedback to supervisors and managers. It's been a few months since we formally reviewed those assessments. We need to take them out again and look at how we were perceived in areas such as giving information, feedback, and appreciation to our staffs. In addition, we need to ask ourselves how effectively we communicate both positive and negative aspects of our staffs' performance. However much feedback our staffs think we give, if it is not honestly or effectively given, it misses the mark. We need to set specific managerial goals for ourselves, such as giving each person we supervise feedback every week or taking time to improve our own management skills. Above all, if we as managers do not create an environment of respect for all staff members, problems will surely occur.

If you sense that the climate in your work environment is strained, you may want to discuss it with someone you trust. There are many solutions to personnel problems, but the earlier they are identified and addressed, the more likely a successful outcome. If you want to discuss personnel issues, my door is always open, not only to employees with complaints, but also to managers seeking solutions.

July 29, 1997

Mediation—Ready for Prime Time

BY JIM MORRISON

All of us at CDER have, at one time or another, experienced problematic interactions, either inside the Center or with our outside contacts. These interpersonal disputes can be among the most time-consuming issues we deal with. Despite the Center's extensive efforts at improving management and supervisory practices, difficult interactions continue to surface.

I have my own theories about why we run into such problems. In this politically correct world, we have become accustomed to interacting with our coworkers, supervisors and subordinates as well as with our outside contacts through stylized relationships that are based on certain assumptions. In our communications we tend to assume that we know what other people expect and need, but we dare not ask them directly, lest we violate some ill-defined borderline between appropriate and inappropriate interactions. Instead we seek to wrap every sentence in mumble-speak so that no one knows what we are really thinking, and everyone plays the game of inferring what each of us really means. After a while, we lose sight of even our own needs and expectations.

In addition, most of us are so busy with the technical side of our work that we don't take enough time to really listen. Even when our well intentioned communications suddenly provoke unexpected responses, we too often choose to ignore them rather than engaging in a meaningful dialogue to find out what prompted the response.

Whatever the cause of a problem interaction, if you are a party to one of them, you need to know how to deal effectively with it. There are a million ways to prevent problematic interactions from occurring, but if you get into a situation in which failed communication escalates into a real problem, is there a viable solution?

Not only is there a solution, but it is becoming more available to us. The mechanism is mediation. Mediation is simply a structured, confidential conversation between two people, facilitated by a trained mediator, with the aim of coming to a mutually accepted agreement. It is widely used in communities for everything from family disputes to reducing gang violence. It is also being used increasingly as an alternative to litigation. It is highly successful, with agreements achieved in more than 90 percent of the cases.

If this seems somehow familiar, I have written about mediation before, and I have offered to mediate disputes within CDER and between our staff and outside contacts. I have not been overwhelmed with requests. However, things are changing.

The FDA EEO Office has just given a one week training course in mediation to more than 20 people

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from all parts of the agency. The plan is to use mediation routinely as part of the EEO process for resolving complaints. I'm hoping that as mediation becomes a part of the EEO process it will spill over into other areas and become recognized as a valuable tool in resolving all types of disputes. As people use mediation, they will find it to be a safe environment in which they can turn negative or hostile feelings about their working situation into positive and productive relationships. I won't kid you; it is not always painless, and it does take some real thought and work by the parties involved. But the rewards are great, and it can be a turning point in a career stalled by misunderstandings.

If you want to find out more about EEO mediation in CDER, talk with Margaret Bell (4-6645). And, as always, I'll be glad to answer your questions about mediation in general (4-5443).

August 27, 1997

Innovations Award—Nothing Succeeds Like Success

BY JIM MORRISON

With the many posters floating around the various CDER sites and the kudos coming our way, we in CDER have reason to be proud that we are the primary factor in FDA's being recognized as one of the finalists in the 1997 Innovations in American Government Award, sponsored by the Ford Foundation and Harvard's John F. Kennedy School of Government. Whether we wind up as winners or just finalists, we have won. In addition to the $20,000 prize already gained, we have achieved recognition as being in the vanguard of a new era in government.

When the CDER transformation was rolled out last year, many of you may remember that one of the exercises was to write a headline for the Washington Post of whatever date it was in the year 2000. There were quite a few people who suggested something like, "CDER Wins Malcolm Baldridge Award." Although the criteria are different for the Innovations in American Government Award, who among us would have predicted we would be finalists for such a prestigious award just one year later?

It is just as important to analyze one's successes as well as one's failures (and it's a lot more enjoyable). The Innovations Award is based largely on our success with new drug reviews and in exceeding user fee goals. It is easy to say that the Prescription Drug User Fee Act (PDUFA), which authorized a hefty increase in resources to CDER and CBER, is the reason we performed in such an outstanding manner. But such an analysis would be superficial and only half right. If you look at the statistics, you will see that the time to first action on NDAs started to fall before we accrued benefits of any increase in resources.

Our review times fell initially because we set goals to which we were committed. Other aspects of the award, such as accelerated approvals, came about independently of either additional resources or PDUFA. In fact, one can find many examples of projects that are infused with additional resources but fail because they are poorly managed. So my analysis of our success leads me to conclude that progress comes from measuring critical processes of an organization (or better yet, measuring outcomes), setting strategic goals, finding better ways of doing the job and then implementing them. Incidentally, this is not my original idea. You will find exactly this prescription in every reengineering or management book and in the application for the Malcolm Baldridge Award. There is a lot of verbiage around these principles, but the message is basically the same.

What is the payoff in all this for those of us who are toiling in fields not fertilized by PDUFA funds? The answer is that this system that led to the Innovations Award can be scaled down to any working unit, even down to the individual working alone. If you don't have extra funds coming in to cover the expense of measuring what you do, that's OK; this system comes with a built-in resource benefit.

As you identify ways to do things better and faster, you gain more time. With extra time, you can measure other processes and save even more. As you become more efficient, you can actually do some of those things you always wanted to but couldn't because you didn't have the time. You will enjoy your work more. You will be noticed for your better work or faster service. You will start to get awards for your performance. You will be innovating. People and organizations will come to you for advice and use you as a benchmark of excellence.

Think about it. Are there things you do that could be done more efficiently and more effectively? After all, we work for an award winning, innovative organization. We have an image of excellence to uphold.

September 29, 1997.

Another Year of Ombudsing

BY JIM MORRISON

It doesn't seem like a year has passed since I prepared my first annual report (see October 1996 *Pike*), so that must mean that I'm having fun. This year has been busier than last, which I credit to the Ombudsman's page going up on CDER's Web site.

It's always difficult to decide what constitutes an ombudsman's "case," because one issue or problem may generate many contacts from the client, and one client or contact may bring several issues or problems. To give you a feel for the increase in my workload, however, I can say that last year I reported 71 complaints from 59 clients. This year I was contacted by an estimated 135 clients involving many more than 200 contacts.

The mix of issues changed to some extent, however. Because of the Web site, I received many e-mails in addition to the usual phone calls and letters. Some of these e-mails presented general problems or complex issues rather than complaints about CDER's action or inaction. I hear more now from consumers and health professionals than I did last year. As you might expect from the increased business, the ratio of external to internal cases rose from FY 96's 2-to-1 to more than 3-to-1 during the fiscal year just ended.

I decided to array the analysis somewhat differently this time, following the natural grouping of cases involving complaints about CDER actions:

External	
Policy or decision challenged	41 percent
Timeliness or priorities	29 percent
Failure to respond or bad advice	30 percent
Internal	
Personnel management	59 percent
Management/ administrative systems	35 percent
External interactions	6 percent

Last time I included a category of priorities or inconsistencies, which accounted for 22 percent of the complaints in the external category. However, it is often difficult to separate challenges to policies or decisions into those where inconsistency among divisions is involved and those where it is not, so I folded that category into either policy/decision challenges or timeliness/priorities, depending on the gist of each complaint.

I heard fewer complaints about timeliness in PDUFA review areas as the old application backlog was eliminated and as applicants have come to believe that goal dates will be met. I also believe that we are getting better in eliminating inconsistencies among reviewing divisions. Some non-PDUFA areas have dealt effectively with backlogs. The Office of Compliance has eliminated the backlog in issuing Certificates of Free Sale. These are now a source of user fee funds, thanks to a new law and a lot of dedicated effort. However, timeliness remains a consistent concern in other Center activities. It will continue to be of concern, requiring us to learn to work smarter and more efficiently, often with fewer resources.

Policy, decisions and priorities continue to be a major area of concern. We reduce such complaints by documenting our policies and practices better, getting more MaPPs published, including more policy documents on our Web site, making sure that we articulate our policies and decisions clearly and that we follow those policies that have been published.

Internally, management issues continue to be the primary concern, with an increased effort needed to ensure that supervisors and managers spend the time and effort necessary to improve personal interactions and the working climate. That means, among other things, providing effective positive and negative feedback to employees and foreseeing and heading off potential personnel problems. It also means improving our methods of recruitment and orientation as well as analyzing the information we are already getting from the 360-degree evaluations and satisfaction surveys.

It seems that CDER folks are complaining more about management and administrative systems that are based outside CDER. That may signify that CDER administrative systems are improving faster than FDA and HHS systems. Clearly, though, such systems in general are improving.

Finally, I received fewer alerts from CDER divisions about problematic interactions with outside contacts. Please remember that such alerts are very helpful in smoothing out problems before they become critical. And, as always, I appreciate getting feedback from inside or outside CDER about systems, problems and suggestions for making things work better. Just e-mail me (MORRISONJ) or call 4-5443.

October 31, 1997

What You Say—Part I

BY JIM MORRISON

How many times have you been certain of what you meant to say, but the party to whom you were speaking didn't take it in the way you expected? It may happen more frequently than you think. I hear about problems of miscommunication all the time, but I get only those cases where someone received a message that provoked them enough to contact me.

In recent sessions of the New Reviewers' Workshop, I have given examples of communications with regulated industry that miss their mark. In this and subsequent columns, I'll share some of these examples and others that pertain to how well we communicate in CDER.

First, there is this one—which I still hear sometimes—that all we can say to an applicant is that the application is "under review." For many years, we were instructed that such information was all we could impart. If there is a single type of communication, or lack thereof, that causes more problems than any other for CDER, it is the failure to keep applicants or other stakeholders apprised of what is happening with the paperwork they have submitted.

I firmly believe that we would receive fewer calls and questions and more good will if we let people know where their application is and when each segment of the review is expected to be completed by the members of the team and their supervisors. So long as you give reasonable estimates and really make a good faith effort to meet them, you will gain credibility and significantly improve CDER's reputation for fairness and efficiency.

Second, the meetings MAPP (4512.1) has helped, but it has not eliminated the problems with scheduling meetings. It seems that it still takes too long to get meetings scheduled in the views of those we regulate who have a lot riding on our decisions. Some of the scheduling problems lie with the overcrowded calendars we all have and the demands created by PDUFA due dates and other pressing work. However, we can get out of this box if we simply stop assuming that all problems are solved by meetings. From my experience, very few are.

Perhaps the issue that is presented by the applicant or by the internal indecision can be resolved by telephone or e-mail. Some issues can be settled by the skillful use of a short consensus paper that is used as the basis for reaching mutual agreement. Many alternatives to meetings are more efficient and effective. Try them, you'll like the way they can free up time on your calendar.

In communicating with one another, it is always important to keep in mind that the relative positions of the people communicating greatly affect how the communication is received.

Just as a supervisor talking with a subordinate should be careful in choosing words that will be listened to for any nuance of threat, disapproval or praise, those of us who work in a regulatory agency must be cognizant of the effect our words have on those we regulate.

Dr. Woodcock likes to use the example of how you would react to an IRS auditor and perceive his or her words. The analogy is a good one to keep in mind. I'll continue this discussion of communications in the next issue of the *Pike.*

November 28, 1997

What You Say—Part II

BY JIM MORRISON

In my last column, I discussed two significant hindrances to communication with the regulated industry: not keeping applicants informed of the progress of their applications, and slowness or unwillingness to set up meetings. This month, I'll give you more examples of problems in communication I've seen in CDER.

Many new reviewers do not appreciate the havoc that ensues from a casual request for more information in an application. In the New Reviewers Workshop session on industry interactions, we bring in a representative of the pharmaceutical industry to address and dialogue with the participants. Most of them have stories to recount about CDER requests that caused some real headaches.

In general, companies treat each request seriously. If it is easy to provide, there is never any hesitation about answering your questions. However, if it entails additional work to answer, the company has to decide whether the requested data are reasonable, how much it will cost to provide the information, and how long it will delay the process. Unless it is onerous and time-consuming and clearly unwarranted by the review requirements, most firms won't balk. I have heard of questions that took several hundred thousand dollars and several months to answer, but the applicant

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complied, even when the basis for the request was not clear or when the information was not viewed as useful in evaluating the safety or effectiveness of the product. My advice is always to be careful about what you ask for, how you describe it and to clear even minor requests through supervisors.

Nothing enrages applicants more or destroys our credibility faster than a request that is viewed as arbitrary and motivated by personal interest rather than as necessary for establishing the safety and effectiveness of the product. Even legitimate questions or requests for additional data, if the reasons for them are not clearly stated, can appear arbitrary and capricious. Please remember that the Administrative Procedures Act prohibits government actions that are arbitrary and capricious.

The best way to avoid the appearance of asking for information out of personal interest or intellectual curiosity is to publish a guidance that informs everyone of our requirements and the bases for them. But slavish adherence to a guidance that does not make sense in a particular case will absolutely drive applicants crazy. There is a fine line between following guidances for the sake of consistency and blindly insisting that the methods suggested in guidances be followed, even when the applicant prefers to use an equally valid alternative method. Guidances are recommendations, not requirements. Of course, alternatives suggested by the applicant should be reasonable, valid and appropriate.

Old habits are hard to break. Before PDUFA, it was fairly common for CDER staff to explain delays to applicants in terms of a lack of resources. Such explanations seemed reasonable when meetings were held in small conference rooms with distressed tables and an eclectic array of ugly chairs. But times have changed. Particularly when dealing with applicants covered under PDUFA, explaining that a lack of resources is delaying an application, even if true, is not well received. No one believes the government doesn't have enough money, especially representatives of a company that just forked over $200,000 in user fees. So keep your credibility and swallow those excuses about a lack of resources before you utter them.

I'll give you the last three of my top eight problems with communications in an upcoming column. In the meantime, have a great holiday season.

December 15, 1997

What You Say—Part III

BY JIM MORRISON

In the first two columns of this series, I discussed five of my top eight hindrances to communication between CDER and the world outside. They were a lack of accurate and timely information to applicants on the progress of their application; problems with setting up meetings; requests for information that seem unnecessary or personally motivated; rigidity in applying guidelines; and poor-mouthing to explain delays.

Working in the confidential world of trade secrets and proprietary information, we sometimes underestimate how much companies know about their competitors' products and research. We are surprised when an applicant challenges a guideline or a request for a new analysis or data by telling us their competitor's product got approved without such an analysis or data. To some applicants, the regulatory scheme should be simple: develop standards for proving the safety and effectiveness of a drug class, and apply the same standards to all other members of the class forever. The problem with that philosophy, of course, is that science constantly changes as we learn more about new drugs. Requirements that were not contemplated before become essential for a new application, and what seemed essential for the first member of a class may seem unimportant when the fifth one comes up for review.

Recognizing how such changes in the ground rules may be perceived by applicants is the key to communicating new requirements effectively. Care must be taken that new requirements are explained in light of new information, lest applicants come to believe that we are really favoring competitors already in the market by throwing added road blocks in the path of newcomers.

Closely related to the problems stemming from evolving science are those caused by changes resulting from divisional reorganizations or reassignments of reviewers. Needless to say, such an abrupt change may leave an applicant bewildered and angry when the result is conflicting advice or a different review outcome.

We are making strides in developing better consistency across divisions in the application of policies and practices. But continuity is equally important. We must honor advice and commitments made by previous reviewers of an application, unless to do so would lead to an unsafe or ineffective product on the market. Such commitments should not be made lightly, they should be documented, and they should be altered only for significant reasons, with the

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concurrence of the division director. In fact, the new legislation recognizes that we shouldn't deviate without appropriate justification and supervisory concurrence. It requires that we adhere to our guidances and that we seek public comment as part of the process for general guidance documents.

Finally, I want to make a plea for rationality in regulation. I have heard people say: "I know it doesn't make much sense, but the regulations require that . . ." The law and the regulations were written to make sense. If your interpretation of them does not make sense in dealing with a particular case, you should reassess the interpretation you're using. Discuss it with your colleagues and supervisor and get an opinion from the Chief Counsel's office. Even if you sometimes feel that you are just passing along guidance or recommendations to the regulated firm, please take responsibility for what you tell the firm. If the logic of what you are saying is not clear in your mind, it won't be clear in theirs. That is the essence of communication.

So that completes my list of communication mishaps. If you have some you would like to contribute to my list, please give me a call (4-5443) or e-mail me at MORRISONJ.

January 15, 1998

Plugging in the V-Chip at Work

By Jim Morrison

In a sleepy, up-scale bedroom community outside Los Angeles, a junior high school vice principal calls a faculty meeting. When about half of the teachers have arrived, he pulls out a .45 automatic and opens fire. He then goes around the school looking for teachers who weren't at the meeting. When the shooting ends, five teachers are dead and one is crippled for life.

That was my introduction to violence in the workplace. It occurred at the school I attended, but I wasn't there when the killings happened. I was there 15 years later, when he came up for his first parole hearing. The teachers for whom he searched unsuccessfully were very nervous. They recounted the story with the immediacy of yesterday's news.

Was this another case of a nice, mild-mannered guy who snapped and became a lethal maniac? That stereotype is a myth, perpetuated by news media interviews with neighbors and acquaintances after the fact, according to violence expert Dennis Davis. In his book, *Threats Pending, Fuses Burning: Managing Workplace Violence,* Davis says:

"Human behavior is not organized in such a way that a 'perfectly normal,' hardworking family man wakes up one day and suddenly decides to act out his rage in a manner that leads to the injury or death of others. There are always warning signs."

He explains that after the fact, coworkers and acquaintances are reluctant to say publicly that they knew the guy was weird and suspected that he might act violently. Such statements would beg the question: "Then why didn't you do something?"

It's easy to ignore the threat of violence if one believes that, like tornadoes, it occurs randomly and with little or no warning. There is a natural reluctance to talk about violence in the workplace. We think it won't happen here. After all, there are only about 1,000 workplace homicides a year out of a 100 million workers. And, let's face it, there is the fear factor. The Postal Service now has a rule that bringing a gun to work will mean the worker will be fired on the spot. But should the supervisor fire the worker before or after he is disarmed?

According to Davis, there are plenty of warning signs. They are known and easily recognized. Many of the warning signs are the types of lesser violence that are reported over a 100,000 times a year. There are many more that are not reported. When one includes that number, we are dealing with at least one incident per year per 1,000 workers. Based on averages, that would mean about nine reported incidents per year for FDA. We experienced a tragic episode a few years ago, when an FDA employee killed three people, but not at work.

So what are the warning signs, and what should organizations do to prevent violence in the workplace? Fortunately for us, Davis teaches a course on violence in the workplace for the Parklawn Training Center (PTC). The CDER EEO Staff, PTC and I are arranging for him to give a one-hour presentation as part of a regular CDER staff meeting in March. It will cover such subjects as spotting the warning signs and identifying preventative measures. As usual, it will be held in Parklawn and videoconferenced to WOC II and Corporate sites. I encourage everyone who has not already taken the PTC course to attend, especially supervisors and managers.

If we educate ourselves about the nature of violence, we stand a better chance of filtering it out of the workplace, just as the V-chip will one day filter out violent programming on TV sets in the home.

February 13, 1998

Expert's Update on Workplace Violence: Know Warning Signs

BY JIM MORRISON

As a follow-up to last month's column, I thought I would pass along some lessons learned from Dennis Davis, Ph.D. He is the expert on workplace violence who gave an excellent and provocative presentation at the March CDER staff meeting.

Dr. Davis described the three levels or stages of violence. Each level tracks a progression of behavioral changes. Since the nice guy who suddenly snaps and kills people is a myth, it is important to recognize changes in behavior and deal with the warning signs early. These warning signs point to a person who no longer cares about himself (90 percent of workplace violence is committed by men). "If an employee does not care about himself and the consequences of his actions," Dr. Davis said, "you should be concerned for yourself and for others around him."

The first stage may consist of a variety of hostile expressions, including dehumanizing others by name-calling or derogatory comments; challenging authority; being frequently argumentative; alienating others; swearing excessively; using sexually explicit language; and otherwise verbally abusing others. We don't ordinarily think of these as violence, but they can signal future trouble and should be taken seriously

Most such warning signs never escalate into more serious behavior, but supervisors should deal with them promptly and appropriately. Failing to discuss the inappropriate behavior with an employee, however, implicitly condones that behavior and encourages an escalation to more violent behavior. Documenting such behavior is important, Dr. Davis said, not for the individual's personnel file, but for the supervisor's reference should further action be necessary. If the acts are sufficiently serious, the supervisor should bring in experts and inform the second-line manager.

Second-stage behavior typically includes: arguing frequently and intensely; blatantly disregarding organizational policies and procedures; inventing gossip about co-workers or sabotaging their work; committing petty vandalism or theft of the organization's property; making verbal threats or unwanted advances and, more importantly, putting them in writing or e-mail; and blaming others for any problems the individual has at work.

If such behavior is observed by or reliably reported to supervisors, immediate action is essential. Experts should be brought in, and the person should be counseled. The Employee Assistance Program has experts who can advise supervisors on dealing with such situations. They are only a phone call away (3-HELP) and have a trained staff of psychologists who are glad to help and to offer suggestions about how to get troubled employees into counseling. The supervisor and the Employee Assistance Program should not be the only ones informed, however. Confidentiality restrictions prohibit the program's staff from disclosing the problem. Therefore, it's wise to notify others in the supervisory chain and Employee Relations.

The third level of workplace violence is one that no one wants to witness. It consists of displaying weapons, actual acts of physical violence and may include arson, rape, homicide or suicide. In the event of a third-stage incident, Dr. Davis advises that witnesses have three responsibilities: first, get out of harm's way; second, warn others to stay away; and, third, call the authorities.

It is good to have emergency response procedures, but the most effective approach is to practice prevention. That means not hiring people with a history of violent behavior (effectively done reference checks can prevent many different problems), keeping alert to possible warning signs of potential violence, addressing problems early and seeking professional help before a crisis occurs.

Dr. Davis acknowledged that it is often difficult for a supervisor to approach an employee who is behaving oddly on the job or who is becoming aggressive to others. However, the alternative is to ignore the situation and wait for an escalation in violence. A supervisor should avoid confronting the employee in a hostile way. A caring but firm tone in a private conversation will usually be effective in first-stage cases. Resistance to taking advice or orders can be overcome by a supervisor using examples from his or her experience rather than dictating behavior to the employee. If the employee reacts negatively to the supervisor's attempt to address the problem, further action is indicated.

March 25, 1998

When a Drug Isn't a Drug

BY JIM MORRISON

Responsibility for determining where FDA-regulated products belong rests with the Agency's Ombudsman, **Amanda Norton.** My job as the Center's Ombudsman includes being CDER's point person for intercenter jurisdiction. Before becoming involved with intercenter jurisdiction, I had little idea about the number and variety of products that fall into the gray areas between centers. Besides the 30 to 40 formal requests for designation filed with Amanda Norton's office each year, there are many informal questions from prospective applicants about which center should review their product.

Three intercenter agreements, developed and signed in 1991 by the three centers that review medical products, describe the rules for deciding product jurisdiction. Those documents, each one involving two centers, are helpful, but cannot describe every possible product. Anyone who does this work quickly develops sympathy for the regulatory affairs people in the industry who must decide which center has jurisdiction over their proposed product. Those of us inside the Agency have significant difficulty deciding where some products belong, and we have access to prior decisions about investigational products that cannot be disclosed to those outside the Agency.

We occasionally find products reviewed in CDER that belong elsewhere or are very similar to other products in another center. Correcting the misdesignation is very difficult when the product has already been approved or is far along in the review process. This article is my plea to staff in CDER for help in identifying products that really belong in another center.

Although product sponsors have the first opportunity to make the decision on jurisdiction, they may not be unbiased in their choice. If a product might arguably be a device or a drug, many sponsors prefer device status to avoid user fees and to be subject to what are perceived as less stringent requirements. Thus, sponsors often submit the product for review as a device and look to the Agency to tell them if they are wrong. Conversely, some drug companies would prefer that their products be regulated as drugs to benefit from exclusivity or because they are more comfortable with the CDER review process.

The consequences to the Agency and to sponsors of misdirected applications can be substantial, but they are less severe when the problem is identified early in the product's regulatory life. Whether misdesignation occurs by inconsistent Agency decisions over time or by a failure to recognize an error, the courts look unfavorably on the Agency when virtually identical products are regulated by different centers. A recent court opinion involving the assignment of some ultrasound imaging agents to Center for Devices and Radiological Health and others to CDER stated that assigning similar products to different regulatory jurisdictions is by definition arbitrary and capricious.

Later this year, I hope to distribute to the new drug project managers an algorithm that will help them decide when a product belongs in CDER.

In the meantime, if you see an IND for a product that seems to belong in CDRH or the Center for Biologics Evaluation and Research, or if the product appears to be a combination drug/device or partly composed of a substance that may be CBER's, please discuss it with your supervisor and let me know. Likewise, if you get a consult from another center for a product that you think really belongs in CDER, question it. Your instincts may well be right. Even if you are wrong, you will learn something about product jurisdiction, and you will earn our gratitude for being alert to possible problems.

April 21, 1998

Alternative or Appropriate Dispute Resolution Gathers Steam

BY JIM MORRISON

I was privileged to participate in the HHS ADR Forum held April 30 at NIH's Natcher Auditorium. The growing interest in ADR, which stands for alternative dispute resolution or appropriate dispute resolution, depending on who you talk to, is evidenced by the turnout for this conference.

Planners originally anticipated that perhaps 200 people would attend this forum for employees of the Department. Registration quickly grew to 500, the capacity of the auditorium, and more than 250 others had to be turned away. This is truly remarkable, considering that most people were unaware of what ADR stood for just a couple of years ago.

The program began with a plenary session. Among the speakers was Kevin Thurm, deputy secretary of HHS and the Department's chief operating officer, who observed that litigation, with its adversarial nature, frequently destroys relationships. In contrast, the purpose of ADR—whether it is conciliation, mediation or negotiation—is to seek a consensus that repairs and

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strengthens relationships.

John Settle (what an appropriate name!), who recently left government after 18 years at the helm of the Departmental Appeals Board, noted that ADR represents a new paradigm in how disputes are handled. He urged managers everywhere to adopt new approaches to avoid becoming obsolete. He used the analogy of the Swiss watch industry, which, when given the opportunity to adopt the quartz technology that was developed in Switzerland, chose to rest on its laurels as the world's best clock makers. Instead the technology was snapped up by Texas Instruments and Seiko.

The forum then broke up into a series of concurrent sessions, including:

- ADR 101, a discussion of the basics of dispute resolution.
- Negotiated Rulemaking, a briefing on how the Health Care Financing Administration used this relatively new process.
- ADR in the Workplace, a look at how ADR is being used at FDA and Government Accounting Office (with FDA's **Kathy Vengazo** discussing how the Division of Employee Relations uses ADR instead of formal disciplinary actions).
- Mediate Instead of Litigate, a demonstration of how ADR can be used as an alternative to litigation by the Federal Government (with **Kay Cook** from FDA's Office of Chief Counsel presenting).
- Role of Ombuds in Federal Agencies, with yours truly and **Suzanne O'Shea** talking about ombuds in FDA, along with ombuds from U.S. Information Agency and NIH in a highly interactive session.
- Real Life Experiences, ADR in the Medicare, Medicaid and Head Start Programs.
- New Directions in Federal ADR Initiatives, a discussion of the ADR and Negotiated Rulemaking Acts of 1996.
- Partnering: Exploring the Use of ADR in the Labor-Management Arena, a session that should be useful to FDA management in the coming months.

Finally, the forum concluded with a general question-and-answer session with the speakers.

I left the forum with a renewed sense of optimism that as the word spreads that conflicts in all arenas can be solved through ADR, we will see a more harmonious and productive atmosphere emerge. When we are willing to see that other people in whatever capacity they operate are not enemies but are just other people with different interests that have an equal right to be heard and respected, we will adopt the principles of ADR in all facets of our work and private lives. As John Settle said in his remarks: "I urge you all to bring ADR from the workplace into your homes and into your communities. You won't hear that said about GPRA or TQM."

If you are involved in a dispute with internal or external customers, consider ADR. Contact me by phone (4-5443) or e-mail (MORRISONJ), and I'll help or find the expert who can.

May 18, 1998

Avoiding Conflicts of Intellectual Interest

BY JIM MORRISON

Anyone who has been in the Center for more than a few days has been made aware of rules and regulations regarding standards of conduct and conflict of interest. Over the years, the FDA has placed great emphasis on financial conflicts, ethics and bribery awareness. To be sure, such an emphasis is warranted. Nothing is quite so damaging to the Agency as having one or more employees convicted of exchanging regulatory decisions for monetary or other favors.

However, in our zeal to protect our good name against financial misfeasance, we should not neglect potential conflicts of interest where financial gain is not involved. For example, if a reviewer of a drug belongs to an organization that publicly espouses a point of view for or against that particular drug or its therapeutic class, most people would question the reviewer's ability to perform an unbiased evaluation of that drug.

CDER MAPP 4641.3 covers outside activities and addresses active participation in an organization as evidenced by holding an office or otherwise prominently representing that organization. But is it reasonable to draw a distinction between the levels of participation in an organization? Or what about a reviewer with strongly held views that pose a conflict who does not belong to any outside organization? While the issue may be raised in the context of an outside activity, the problem really stems from an appearance of an intellectual conflict of interest.

In Title 45 of the Code of Federal Regulations, a section is devoted to standards of conduct specifically for the FDA. Section 735-101(a) states in part:

"Because of FDA's special regulatory responsibilities to the consumer and industry, its employees must be especially alert to avoid any real or appearance of conflict of their private interests with their public duties. Their actions must be unquestionable and free from suspicion of partiality, favoritism, or any

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hint of conflicting interests."

Conflicts arise when we, as private citizens, exercise our right to espouse causes that we believe but which also impact our work. In our public lives, we are commissioned by the American people through Congress to be unbiased evaluators of the safety and effectiveness of drugs.

The real or apparent intellectual conflicts cannot be dismissed by an assertion that scientific principles outweigh reviewers' subjective opinions or that the data speak for themselves. The plain fact is that the data do not speak for themselves. If they did, we would not need statisticians. No matter how much objectivity is built into the review process, the judgment of primary reviewers still weighs heavily.

When an advisory committee member has an apparent intellectual or financial conflict of interest, for example, when the member has pioneered the drug being discussed, we ask him to recuse himself or herself from the deliberations on the drug. We should demand no less intellectual honesty from ourselves.

There are many issues in our society that evoke strong feelings on both sides. Some of those issues involve drugs that we are asked to evaluate and to monitor. Abortion and contraception come immediately to mind. There are also many controversial issues related to treatment of drug and alcohol abuse, AIDS and animal testing. If we believe strongly in one or another side of an issue that may bias us with respect to a particular drug, class of drugs or methodology, we have an obligation to discuss the matter with our supervisor and to refrain from participating in any regulatory activity in which we might seem to have a conflict. Supervisors also have an obligation to assure that the work products coming from their areas of responsibility are free from bias or the appearance of bias.

Ultimately we are the only ones who can say for certain whether we hold views that, if known, may appear to bias us in performing our work on a project. There is a natural reluctance to raise such issues with our supervisor for fear that we might be viewed as less valuable to the Agency. But raising such issues strengthens the ethics of the Agency and actually makes those who come forward more valuable. An intellectually honest scientist is the most valuable asset the Agency can have.

June 29, 1998

The Internet: Problems vs. Opportunities

BY JIM MORRISON

Now that almost all of us have adapted to the emergence of electronic communication, it is a good time to reflect on its significance to our work. We are comfortable with e-mail, but working with the Internet plus localized variations like intranets and extranets takes electronic communication to another level. We are only beginning to see and experience the potential of this medium.

The Internet, originally created for scientists to communicate with each other, has long since been appropriated by the rest of the world. No one speculates anymore about when it will contain a critical mass of information and thus become useful to the average person. It reached that point some time ago. It is growing at an astounding rate—both in numbers of users and in the quality and amount of information, services, commerce and societal impact.

I can attest personally to the power of the Internet. After putting my Ombudsman page on CDER's site a year and a half ago, the volume of contacts I receive has more than doubled overnight. I get e-mails and calls from distant parts of the globe. Thankfully, I still remain undetected by most Web crawlers, so the people who contact me are generally limited to those who started in the FDA site. That keeps incoming e-mail to a manageable level and minimizes intrusions.

On the output end of things, the Internet has revolutionized the Agency's transparency. Now, instead of sending out material in response to individual Freedom of Information requests, we can make source documents and other information available to the world instantaneously.

As with all revolutionary advances in technology, the Internet has brought both promise and problems. To cite an oft-repeated litany, it seems that we are drowning in data, not all of which are accurate. In addition, it seems the total of letters, phone calls and e-mails to CDER is now larger than the volume of letters and calls we received in the past, meaning that e-mail is not just replacing conventional media but has opened communications with people who haven't contacted us before. That means a bigger workload, but it also means more opportunities to get our information out to where it will do the most good. It also means that we can save some costs in the way we operate.

We can distribute vital information worldwide, immediately and at minimal cost. If we can anticipate questions and put answers on our site quickly, we can

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possibly cut the number of letters, e-mails and phone calls we receive.

Each of us should take some time to think about what information we have and use daily that could benefit our constituencies, such as health care professionals, patients, the public, industry and other government agencies. Before I strike terror into **Carol Assouad,** who does an excellent job overseeing the CDER sites as part of the Medical Library, let me hasten to add that there are resource limitations on how much data can be added usefully to our servers and how quickly. Nevertheless, we should all contribute to planning what information appears on our sites.

I plan to follow this advice and post some guidance on intercenter jurisdiction for reviewers on CDER's intranet. If you have ideas for other information that you would like to see on our Web sites, I encourage you to tell the people who have access to the information, or tell me, and I will see what I can do to get it posted. Incidentally, that invitation goes for anyone reading this, whether you are in FDA or outside. Just send me

Feedback: A Valuable Commodity

BY JIM MORRISON

One of the best ways to improve any process is to get feedback. Sometimes feedback comes from an expert who watches a process and makes suggestions, such as a golf pro watching a student's swing. Other times feedback comes from customers who suggest ways to improve products and services. At CDER we get both kinds of feedback.

We get feedback from the press, from Congress, from consumer groups, from industry groups and, it sometimes seems, from anyone who has ever taken medicines or eaten food. A series of meetings between FDA, the centers and our stakeholders is providing more feedback on important issues.

Feedback is effective when it is honest and accurate. On the other hand, it does little good to hear that we are doing a lousy job or a great job unless we know that the feedback is from a source who is able to evaluate our work fairly, accurately and without bias. The problem with much of the feedback we receive is that it can be distorted by false assumptions about what we do or false expectations about what we can do.

That is why I was impressed with a survey published last fall by Price Waterhouse, *Improving America's Health II: A Survey of the Working Relationship Between the Life Sciences Industry and the FDA*. This survey, a sequel to one published in 1995, was conducted by a group at the University of California at San Diego called Connect. While the survey was partially funded by a number of pharmaceutical and biotech companies and has some flaws, it is an honest attempt at identifying and tracking the key factors in FDA's product review processes.

The survey identified three areas in which the FDA review processes could be improved without jeopardizing patient safety: process guidelines, communications with applicants and submission quality. Questions in the survey dealt primarily with communications. Only 116 firms, including drug, device and biotech companies, responded. Thus, the answers to individual questions were often based on a small number of respondents and are useful mainly as qualitative indicators. Since this is the only such survey of which I am aware, qualitative data are better than none. Although comparisons are made in the report with the previous survey, the first one only queried West Coast firms while the second one included firms nationwide.

Most of the responses were generally favorable and could be predicted:

- Firms that had end-of-Phase II conferences generally found them helpful.
- Project managers and reviewers were seen as cooperative and knowledgeable.
- Accessibility to project managers was good, but a minority of respondents found it difficult to talk directly with reviewers.
- Overall communications with CDER were rated acceptable to excellent by all but a very few.

However, responses to one of the questions is cause for some concern. Although the vast majority of respondents did not experience changes in policy during the review process, those who did were asked why they thought the change occurred. The most common single reason cited was a change in CDER personnel. I think we are doing better in this respect, but this survey serves to remind us that we have a legal mandate to honor advice and decisions made by our predecessors in the review process. Hopefully, if another survey is conducted next year, it would find that changes in reviewers no longer result in changes in policy.

I have asked Connect to send me copies of both surveys. As soon as I get them I will make them available to the CDER libraries. They are worth a read, and I hope these surveys are the forerunners of larger, more detailed ones in the future.

August 28, 1998

Better Internal Meeting Management—Just a MAPP Away

BY JIM MORRISON

Whenever industry representatives talk about how CDER has improved over the past few years, meetings are usually mentioned. We are perceived as scheduling meetings in a more timely manner and running the meetings more effectively. Those of us who regularly attend internal CDER and FDA meetings would probably not find the same improvement in that arena.

Whether we work in the new drug review or other areas of CDER, we are under constant pressure to work more efficiently and effectively. While we have streamlined many of our processes, we will need to reduce the expenditure of resources even more. Where is the fat now? There is a fair chunk of it in internal meetings.

Wasting time in meetings is not a CDER invention. It seems to be universal. In a recent private sector survey, 80 percent of managers estimated that half their time spent in meetings was wasted. I would guess that a survey of CDER managers would yield about the same results. The biggest gripe I hear about internal meetings is that we often have the same meeting over and over again, because the first meeting failed to arrive at a clear decision or consensus.

The question, then, is: "Why can't we improve the effectiveness of internal meetings the same way we improved external meetings?" The answer is: "We can!" Why don't we then, and since everyone has the same problem, why hasn't it been successfully addressed in so many organizations?

I put the question to **Bob Potter,** an expert in meeting management who teaches a course on effective meeting management for the Parklawn Training Center. He believes that most managers do not think of meeting time as a resource to be managed. However, most supervisors and managers average about 35 percent of their time in meetings. If half that time is wasted, it represents more than a sixth of the salaries of CDER management. That is a substantial amount of money, not to mention the lost opportunity for doing other work while half the meeting time was being wasted.

Effective meeting management is not rocket science. That's unfortunate, since if it were, perhaps we would devote more time and attention to it. The basics for effective meetings are contained in the external meetings MAPP (4512.1) and other sources:

- Having clearly stated objectives for the meeting.
- Having the right people present and adequately prepared to discuss the issue.
- Keeping to a written agenda with realistic time allotment.
- Taking good minutes that record decisions made and that are circulated promptly to everyone in attendance.
- Assigning action items with due dates that are tracked and followed up.

For those who are new to running meetings or others who feel a little rusty on the subject, there are courses available from CDER's Division of Training and Development (contact **Janice Newcomb**, 7-1262, NEWCOMBJ) and from the Parklawn Training Center (3-6790). In addition, **Beverly Compton** of PTC highly recommends a book, *How to Make Meetings Work: The Interaction Method,* which is available at the PTC office in Parklawn, Room 16A-55. For managers who would like their staffs to get training *en masse,* both training offices are glad to bring training on site.

September 29, 1998

Ombudsman's Annual Report

BY JIM MORRISON

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

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

Another trend which bears watching is a recent surge in e-mail traffic from outside FDA. I don't track e-mail contacts by subject the way I do cases, but I have been receiving a steadily rising number of e-mails, primarily from consumers, patients and health

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professionals. That number has increased markedly in the last few months to an annual rate of more than 300.

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

To give you an idea of the reas
both external (excluding all but a
internal, general categories are in the

Although I have refined
categorization over time, it is clear
of issues related purely to the time
actions has dropped each year. Wh
access are included, however, the
constant. It is often difficult to separ
from access issues such as diffi
meeting or failure to respond to pho
the length of the process in question.

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

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

With respect to internal complaints, the relative numbers of those associated with systems as compared to personnel practices has been rising. There are a number of reasons for the change, but I think that improvements in CDER operations generally have raised expectations of folks regarding all the systems. I

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

s people are less likely to accept way of life and are quicker to

plaints were about CDER systems. ward complaints about Agency and , such as personnel and payroll, that of the increased percentage. We owever, that the overall number of s moving in the right direction.

ng the alerts I get from CDER staff ic external interactions. These alerts ng, and such information has been much appreciated. The earlier in a e involved, the easier problems can

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

October 27, 1998

What Is Customer Service?

BY JIM MORRISON

Customer service is a trendy concept. An Executive Order, No. 12862, mandates that we do it. But what is the "it," and who is our customer? The answers may vary greatly depending on the circumstances.

The FDA Customer Service Plan lists four types of customers: consumers, health professionals, other agencies and the regulated industry. During internal discussions about CDER's mission, vision and values, the term "customer" raised issues among staff who could readily see the consumer as a customer, but viewed the regulated industry as more of a stakeholder than a customer. Some used the term "compelled customer."

Our scientific education has conditioned us to believe that if you can name something and relate it to other named things, you know something about it. One might call it wisdom by taxonomy. What do we learn about customers or service by naming categories into which all people with whom we interact can be sorted? Not much. This categorization of customers may be useful for planning purposes, but it distracts us from an essential idea.

Let's take the consumer, whom we all agree is our ultimate customer. Which consumer is that? Is it the terminal cancer patient who wants access to highly risky experimental drugs and willingly accepts the risk that the therapy may be ineffective or harmful? Or is it the hypertensive patient who want assurances that the risks and benefits associated with the medicine he or she takes have been well-characterized by large clinical trials? Or is it the taxpayer who wants safe and effective drugs with a minimum of delay and expense?

It's all of the above and millions more. Each person

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is a consumer and each person has different needs and expectations at different times or in different circumstances.

Perhaps a better definition of a customer is the person with whom you are dealing right now. It may be an attorney representing a small manufacturer, a patient with a question about his or her medication, a representative in Congress who writes on behalf of a constituent, or it may be your co-worker in the next office who has a review she wants to discuss. Is there any reason to give one of these better service than another? I would guess that many in CDER would say that the representative would get better service, because, after all, Congress funds the Agency. It boils down to what you mean by "service."

Service does not imply immediate attention. When we are in a busy bank, we understand that not everyone can be accommodated immediately, so we wait and do not complain about the service unless the wait is excessive or unless our teller is rude or unhelpful. All of these breaches in customer service are difficult to define but easy to recognize when they happen to you.

Service allows for priorities, and it allows for queuing. "Service," like "customer," cannot be described taxonomically. It varies with each situation and with each customer. Inherent in the concept of excellent service are the notions of fulfilling needs and of meeting or exceeding customer expectations for quality, timeliness and courtesy. It also entails tailoring the response to the individual requirements of each customer and of each situation—flexibility. Excellent customer service requires that you mentally put yourself to be in the position of the customer—empathy.

In the example of competing priorities, the representative might wait while the co-worker's question concerning a review that is due that day gets answered. Or the attorney may wait for the patient because their calls arrived in that order. There are no hard and fast rules.

In addition to flexibility and empathy, excellent customer service requires tact, judgment and an understanding of the substantive issues at hand. When it occurs, the customer feels that someone in the organization genuinely cares that their needs are met and did all that was reasonably possible to meet them.

Feedback I get from people outside CDER is almost always positive about the professionalism and willingness of Center staff to be helpful. That is a great base upon which to build a first class customer service reputation. For further information about customer service, I recommend reading the FDA Customer Service Plan at http://www.fda.gov/oc/customerservice.

November 25, 1998

Holidays Throw Spotlight on Patient Access Questions

BY JIM MORRISON

One of the toughest jobs any of us face is telling a dying patient or his family member why he can't have access to a drug he believes is his last, best chance for survival. Maybe the holiday season makes them more memorable, but lately it seems that I've received more patient-access questions.

Thankfully, my job usually puts me in the positive position of trying to find a way to get needed drugs to patients rather than withholding them. When we are successful, the feeling of making a difference is terrific.

But often the problem is not simply one of access. Sometimes I know that a product is being promoted or used in a questionable manner, and an IND has been filed to lend an air of legitimacy. An IND also cloaks the product in secrecy, limiting what we can say about it.

One way out of this legal bind is used effectively by some project managers in CDER. They guide the inquirers by suggesting questions to ask of those who are promoting the fraudulent product:

- Where were the studies showing effectiveness of the product published?
- What are the credentials of those treating patients?
- Who is currently conducting studies of the drug?

Besides fraudulent products, there are other difficult issues relating to patient access. For example, a study may be on clinical hold—a procedure that prevents a sponsor from beginning a study because of unresolved issues related to patient safety or a lack of information. Such issues can't be discussed outside the Agency unless the sponsor chooses to make them public.

Sometimes the drug is approved in another country but not here. Since there are ways to import the product for one's own use if one has the resources or contacts with foreign physicians and pharmacists, difficult issues of equal access to such drugs arise.

Many of us in CDER deal with patient-access issues. Reviewing divisions, especially Oncology and Anti-Virals, and those who handle consumer questions and requests all face the issue often. Most people working in CDER will at some time be faced with questions about patient access. From my experience, CDER staff generally respond to such questions admirably, and patients and their families greatly appreciate a caring

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attitude from CDER staff.

At times, however, it is all too easy to merge into the gray fog of the organization, diluting responsibility for actions or policies. "After all," you may tell folks, "it is not I who took the action (or did not take an action), but the Center is bound by law and regulations to follow this path. If it were up to me, I would gladly do things differently."

For anyone tempted to use that old bureaucratic ploy, please remember CDER's mission to protect and enhance public health. We are all embarked on that mission, and we must all take ownership of it. If the mission statement is to be more than a facile sound bite, it must be translated into day-to-day, person-to-person interactions. It's very rare that laws or regulations mandate that we do things that, were we in our customer's shoes, would seem heartless and cruel. Laws and regulations generally have flexibility built into them.

Taking ownership does not mean shouldering the burden alone. Fortunately, there are excellent resources to help with patient access problems:

The FDA's Office of Special Health Issues is a source of information and help to patients with AIDS, cancer, Alzheimer's disease, chronic fatigue syndrome and other serious and life-threatening diseases and to their families. The staff does a terrific job, and they are advocates for patients, which is something we in CDER often don't have the time or mandate to do.

The OSHI staff can explain what it means to be in a clinical trial and can put patients in touch with NIH and other government and private sources of help. The Office of Special Health Issues can be reached at (301) 827-4460.

Within CDER, you can refer telephone inquiries to the Drug Information Branch and written or e-mail requests to the Executive Operations Staff. Both staffs can provide information on emergency INDs, personal importation and other issues related to experimental therapies, especially for disorders that OSHI doesn't handle.

December 30, 1998

Assisting Patients, Families with Trials, Investigational New Drugs

BY JIM MORRISON

Imagine yourself in a doctor's office. You have just learned that your cancer, which was diagnosed two months ago, is not responding to aggressive radiation and chemotherapy. Your doctor is telling you to get your affairs in order because there is nothing more to be done for you. But you aren't willing to lay down and die without having pursued every possible treatment, no matter how tenuous it is. But where do you go from here?

Unless you are at a teaching hospital, your physician may not know of clinical trials being conducted within commuting distance. Even well-informed, educated patients report that finding out about ongoing trials is a singularly frustrating task.

Many patients or their families look to the FDA for assistance. The disease may vary. It may be Alzheimer's, AIDS or the fatal neurodegenerative disease ALS rather than cancer. Because FDA, and more specifically CDER, regulates drugs and drug trials, they expect us to know what is happening and to guide them to the right study.

On the other side of the coin, if you are in CDER and are asked to aid such a patient, you are faced with the constraints imposed by the Freedom of Information Act. This law prohibits us from even acknowledging the existence of an investigational drug unless it has been made public by the sponsor. Often it's difficult to determine whether information about the study has been made public.

That limitation might lead you to think that there is little we can do to aid those who want information about clinical trials of drugs for specific diseases. However, things are changing rapidly.

The FDA Modernization Act of 1997 mandated that the FDA and the NIH work cooperatively to establish and maintain a comprehensive data bank of information on clinical trials for drugs for serious or life-threatening diseases. That data bank has been started. Even without this requirement, there has been a growing trend toward more disclosure of ongoing clinical trials.

The Internet provides a wealth of information about clinical trials that are open to enrollment:

- In the oncology field, the National Cancer Institute lists about 1,600 trials in its PDQ site (http://cancernet.nci.nih.gov/pdq.htm).
- Trials for other diseases are listed in NIH's Web site (http://www.nih.gov/health/trials).
- For more information, NIH lists telephone numbers for a wide variety of organizations that can help patients find needed resources (http://www.nih.gov/news/infoline.htm).
- There is also a for-profit organization that maintains a site with information about trials and protocols (http://www.centerwatch.com).

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The second most frequently asked question we get is from patients who are ineligible for a trial but who want to get access to the investigational drug for treatment purposes. Sometimes even patients who have been in a study become no longer eligible to continue because of protocol criteria or because the trial is ending. Yet, if they feel the drug has helped them, they want to continue on it. These patients look to FDA to intervene with the sponsor to allow them to continue to receive the drug.

When we are contacted by a patient, it is only natural to want to assist in any way we can. Certainly, many in CDER do just that very effectively. However, there are limits to the time we can devote to such assistance and to our mandate when interceding on a patient's behalf with a regulated company.

As I mentioned in my last column (December *Pike)*, there is a group in FDA whose primary function is to assist patients with serious and life-threatening illnesses. That group is the Office of Special Health Issues. I strongly encourage you to refer patients with cancer, Alzheimer's, AIDS and other such serious diseases and their advocates to OSHI. Unlike CDER staff, they are in a position to contact drug companies on behalf of patients from an advocacy as opposed to a regulatory standpoint. They can be reached at (301) 827-4460.

January 27, 1999

Two Sides to Every Issue

BY JIM MORRISON

One thing every ombudsman learns quickly is that there are at least two sides to every issue. I can't remember one complaint in the past three years that turned out to be exactly as the complainant described it initially. This explains why so many ombuds are attorneys. The first thing you learn in law school is to see diverse sides to any issue and to espouse the one with which you disagree.

I know that "there are two sides to every issue" is not exactly the most brilliant or original observation of the century. But I never cease to be amazed at how often we forget this simple truth.

Maybe we have become so accustomed to learning about what is happening in the world through 30-second sound bites that we have lost sight of the fact that the truth usually isn't so simple that it can be revealed in 30 seconds. All that can be conveyed in so short a time is a biased impression.

It's easy to fall into the trap. In that first instant when I hear a complainant relate a scenario that portrays the other party as a total imbecile or a card-carrying member of the Evil Empire, my reaction is to wonder how anyone could be that wrong.

My next reaction is to realize that I am hearing one side of the story. But the important message is that someone actually believed that the other party was that dumb or that nefarious.

When communications break down, especially when we don't like the outcome, we humans tend to ascribe to the other party all sorts of sinister motives or incredible ignorance. We then behave as if those assumptions were true. We get self-righteous and infuriated, further widening the breach.

Real damage to communications is done when one or both parties hang a label on the other. As soon as we perceive the other person as evil or idiotic, our brain uses that perception as a filter through which is passed everything said by that person. If an applicant is viewed as dishonest or incompetent by a reviewer, then everything in the application will be seen as flawed.

Armed with its filters, our brain will automatically "correct" any data that does not conform to our perceptions and easily ascribe motives that are not evident from what is spoken or written.

I'm not advocating that we accept everything without evaluation. Critical thinking is essential to active listening and other skills that enable us to communicate effectively. However, I am saying that communication is a deceptively complex process.

For communication to succeed, both parties must recognize the traps set by differences in perceptions and work hard to overcome biases, clarify meaning and focus on the facts, using a mutually understood vocabulary.

Because we have communicated all our lives, we take our communication skills for granted. If you haven't read extensively or taken a course recently in listening and communication skills, you might want to look at what OTCOM's Division of Training and Development has to offer. They have courses, books, audio- and videotapes, and interactive computer-based training.

If you think that you have really come across an idiotic policy or decision, please talk it over with your mentor, supervisor, or division director; and, if all else fails, you can always give me a call.

February 25, 1999

Understanding the Big Picture Improves Learning

BY JIM MORRISON

If we think back to when we learned a complex new task, such as driving a car, we can remember that at first we were preoccupied with the mechanics of the operation. When we first got behind the wheel, we were sometimes so engrossed in all the knobs, buttons and pedals that our instructor had to remind us that it was equally important to watch the traffic. After a while, the mechanical operations became second nature, so we could concentrate on watching the road and anticipating problems.

The same pattern holds for any complex task, and the more complex it is the more time we spend on the mechanics of the operation. There are few tasks in life as complicated as regulating drugs. Not only is the science complex and constantly evolving, but also laws, regulations and constituents' expectations are always in flux.

It's little wonder, then, that even the best and brightest who come to CDER become preoccupied with the mechanics and the technical aspects of the regulatory process. With heavy workloads and training focused primarily on technical subjects, scientists new to CDER and even experienced reviewers seldom have time to delve into the philosophy of drug regulation.

In addition to complexity and the constraints on available time, many people concentrate on the mechanics of their jobs for another reason. They labor under the impression that strategic planning, societal concerns and other "big picture" issues are the sole provinces of senior management.

This paradigm results naturally from hierarchical and mechanistic management theories that have only recently been challenged. Organizations managed mechanistically revere specialization and the division of labor. But while such principles have worked well on the factory assembly line, they don't work well in the more challenging workplaces of the Information Age.

A new order of organizational theory is emerging—the natural or organic model. Rather than viewing an organization as a machine and workers as cogs, the organic model of organization views the enterprise as a living system and staff as integral to the whole. This change in organizational thinking is important and fascinating. I'll have more to say about it in a later column.

CDER is evolving from a mechanistic organization structured to optimize strict division of labor into an organic one heavily influenced by self-directed teams, such as CDER's coordinating committees (August *Pike).* If those teams don't have a vision of where the enterprise should be headed, if they don't have the big picture, then the enterprise is in trouble. Such organizations come to the same end as a neophyte driver fiddling with the radio instead of watching the road.

That is why it is so important that each of us take time to understand CDER's role in society, to know how each of us contributes to CDER's mission and to be aware of FDA's current priorities. In the end, time spent on reading, thinking and talking about these topics will save time and effort that would otherwise be wasted on projects that are inconsistent with the direction in which the Agency is heading.

There are many sources that deal with the larger issues of drug regulation. Just a few include:

- Preambles to key regulations.
- The FDA's and CDER's Internet and intranet sites
- CDER seminars and scientific rounds.

Why should an ombudsman care about your understanding the big picture? If everyone in CDER understood more about the context of their work, I might get fewer complaints about inconsistencies among divisions and about the uneven application of regulations and policies.

March 31, 1999

Self-Empowerment is the Only Empowerment that Counts

BY JIM MORRISON

I must be getting old, because I'm starting to sound like Andy Rooney. Don't you hate it when someone lets on they're giving you a great gift when it was yours anyway? For example, income tax refunds. It was my money in the first place; I just lent it to the government for eight or nine months interest free!

Another case in point is one of the more inane buzzwords among the recent crop of management-fads-of-the-year: empowerment. Whenever I hear that word, I get the mental image of an elf going around the workplace sprinkling magic dust on everyone, saying, "You're empowered!" Well excuse me, but I am a human being, and I was therefore born empowered. I even have an authoritative book at home that says so. I don't need someone to tell me that management has empowered me to do the job they hired me to do in the first place.

As I understand it, empowerment is supposed to make it OK for me to ask my supervisor why I have been assigned the task of moving paper clips from pile A into pile B. If I question why that task needs to be done and my supervisor tells me to shut up and just do it, I'll assume that he or she just slept through the supervisory training course. I have always felt it was not only my right but also my duty to know why I am doing whatever I do. Not only that, but it is also my duty to suggest a better way to do it if I see one. In addition, I have always believed that it was a supervisor's duty to mentor me (note the clever use of a noun as a verb) so that I understand not just my job but the reasons for doing it in a specified way, how it relates to my colleagues' jobs and how it fits into the overall mission of the organization. I have had supervisors during my career who didn't see that as part of their jobs. However, I didn't let that stop me from learning what I needed to know.

At its best, empowerment also means that everyone takes a proprietary interest in the organization and its mission. In that way, it becomes my duty to see that the organization's customers or constituents get what they legitimately need without having to be referred through an endless chain of unhelpful people.

Now, empowerment taken to the extreme is chaos. While chaos theory is the latest in management fads, it doesn't mean that people actually want chaos in the workplace. However, if everyone feels so empowered that they just go off and do whatever job they think needs doing in the way they want to do it, everything gets very complicated really fast.

With empowerment (that is, being a human) comes responsibility. Just as it is my duty to learn the purpose of my job and to apply my knowledge, skills and creativity to doing my job in the best way I can, it is also my responsibility to inform all those who need to know about my activities. I should also give them time to evaluate what I do and my methods before I do it. In that way, they can save me from doing something really stupid because I failed to factor in an important element or two.

After all this, if you still need someone to empower you, just think of me as a really large elf and that white stuff on the paper (or monitor) as magic dust. Poof—you're empowered! What you do now is up to you.

Leadership Development Programs

Speaking of self-empowerment, whether you see your future in supervision and management or just want to kick your career up a notch, watch for announcements and Forums regarding the FDA Leadership Development Program, which will be opening for applications soon. There was a Forum in Parklawn April 8, another is planned for Corporate May 24. **Janice Newcomb** and I plan to discuss the CDER Leadership and the FDA Leadership Development Programs at the CDER Forum on May 11. CDER participants in these programs will be there to give their insights and to answer questions.

May 3, 1999

Judgment in Rockville

BY JIM MORRISON

In the Ombudsman's job, I'm frequently reminded of the complexity of drug regulation. I'm not talking about drug regulations, those volumes of colorful prose that take up more than a foot of shelf space. I'm referring to the entire process of assuring that drugs are safe and effective, both when they are marketed and throughout their commercial lives. Science, consumer expectations and, therefore, the Agency's regulatory and scientific policies are in a state of constant change. This flux adds to the already complex decision-making in CDER.

At the core of the Center's decision-making is risk assessment. The new drug review process involves many risk-benefit decisions. The benefit side of the equation is most often reflected in the drug's efficacy studies. Effectiveness compared to a placebo can be analyzed statistically and is relatively easy to define. Risks, on the other hand, are usually represented by the

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adverse effects of a drug or the unknowns associated with its initial introduction into humans. These are not quantifiable.

Weighing the potential benefits of a drug against its risks, whether it is new or already marketed, is an inexact and value-laden science. What may seem a reasonable risk to one person may appear unreasonable to another. Often the patient is willing to assume more risk than the caregiver.

FDA Commissioner **Jane Henney, M.D.,** has made the agency's risk assessment processes among her highest priorities (see page 1). Such attention is well-placed, since risk assessment requires the application of very sound scientific judgment.

In the context of a regulatory agency, the exercise of judgment presents a paradox. Without the application of sound judgment to scientific issues, the result is mindless bureaucracy. The exercise of sound judgment produces flexibility in regulation, which is good. But judgment is based on individual values, which differ greatly among people, especially in a multicultural society such as ours.

So, the exercise of judgment without guidance leads to inconsistency, which is bad. Inconsistency sometimes leads courts to brand actions of a regulatory agency as arbitrary and capricious and then to issue sharply worded opinions chastising the agency while finding for the other side.

To reduce inconsistencies in decision-making, agencies develop regulatory and scientific guidances and policies through a consensus-building process. Once these policies are developed and published, all of us in a regulatory agency are obligated to follow them—even if they occasionally don't coincide with our own judgment.

It is essential that everyone who makes decisions or recommends actions understand the rationale for policies. If we understand the reason for a policy but simply do not agree with it, we have an obligation to discuss it with our supervisors and to seek to change it through established processes.

The one thing we must not do is go off on our own and impose different policies in our regulatory work.

The next time you are tempted to substitute your own judgment for established agency policy, please ponder this quote from Aesop: "Good judgment comes from experience, and experience—well, that comes from poor judgment."

May 27, 1999

Arrogance

BY JIM MORRISON

There was a time, not so long ago, that, if you asked those who had contact with the Agency to give one word that best described the FDA, many would have answered "arrogance." The arrogance they saw came from people who believed it was appropriate for a regulator to tell those in the regulated industry how to do every aspect of their jobs, to educate the public and others about what they really need and to explain to them why it was unrealistic to expect the FDA to provide it anytime soon.

Thankfully, those days have passed. Whether the reputation was entirely deserved is moot. Perception is reality. Some of the factors that led to perceived arrogance by CDER employees still exist, and we need to be aware of them. The first and foremost is power. Those who control the supply of any commodity people need have a lot of power. It may be a computer operating system, a license to drive a car or permission to market a new drug. Often the needed commodity is information. Possession of such information gives anyone a sense of power. But the true test of character is how one uses that power.

There is a story that illustrates the point. In the early days of television, there were no network news programs. After the first transcontinental live TV news broadcast, some of the newscasters were celebrating the feat in a local establishment. Howard K. Smith was waxing eloquent about how they could shape the thinking of the American public and have a tremendous impact on society. Edward R. Murrow, the dean of TV newsmen, put things in perspective. He said: "Remember, Howard, because your voice travels to the end of the continent doesn't make you any smarter or wiser than when it traveled only to the end of the bar."

So it is with regulatory agencies. People join CDER from academia, health care institutions and companies. They bring with them their own expertise. But the day after they arrive, people suddenly turn to them for information and advice about drug regulation.

All of us at times feel pressure to fulfill the role of an expert, even when we don't know much more about the subject than the person asking for advice. At those times it's important to remember that it's OK to say: "I don't know." Hopefully, you'll add "but I'll find out and get back to you." In addition, regulators hold the fate of the regulated in their hands. Some people relish the power of that position.

However, the ability to make grown men tremble is a false and fleeting power. For as soon as they are able, those who tremble will attack and bring down the

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powerful. On the other hand, power exercised with humility creates trust and respect. And trust and respect make a regulatory agency first rate.

Although CDER has come a long way in the past few years, I still hear complaints that result from perceived arrogance on the part of some CDER staff. Arrogance is likely to be perceived when a regulator comes to the table with a fixed position or a presumption that the person with whom they are meeting is of inferior competence or out to skirt or break the law. These attitudes prevent the regulator from listening openly and impartially to what the person is saying.

If you want to get a sense of what a regulated person might be feeling, imagine yourself as the subject of an IRS audit. Would it make a difference to you that the auditor has already concluded that you are cheating on your taxes and that his or her job is to document that for the prosecutors? You are already nervous, but the feeling that you are presumed guilty and that you must prove your innocence is enough to send your blood pressure into orbit.

Suppose, instead, that the auditor approached you by saying that he or she was not clear about some items in your return and needed your help to better understand them. Would you leave the audit with a different view of the IRS? Both approaches get the same information for the IRS. The first one makes an angry taxpayer, while the second gains respect for the agency.

To avoid giving the appearance of arrogance, before each meeting or phone call, it's helpful to tell yourself that you are there to listen as well as to advise and that you don't know everything about the subject matter. But remember that feigned humility is easy to spot. To be successful, you must actually believe what you're telling yourself.

June 30 1999

Objectivity

BY JIM MORRISON

Objectivity is one of the most important words in drug regulation. CDER's primary role in society is as an objective scientific arbiter of whether a new drug should be introduced onto the market or whether a marketed drug should stay there.

Yet as important a principle as objectivity is, it is also a very elusive quality. We all have biases that affect our thinking and judgment. No matter how extensive our scientific training, we all have within us a system of values and our own a view of the world which were not scientifically derived. Added to these factors, each new endeavor contributes opportunities for additional biases.

In the drug development process, we know that certain biases exist, depending on one's role. Biases come from investment. It may be a monetary investment, such as a pharmaceutical company that has spent millions of dollars on a new product. Or it may be an emotional investment, such as a scientist who stakes his or her credibility on being right about a particular outcome.

Each stakeholder in the drug development and regulatory processes has a bias. Patients with serious diseases want to believe that a new drug will save them from agony, and they vent their frustration at anyone who seems to be standing between them and the drug. Investigators studying a new drug have a bias, since if the drug is successful, they will attain stature, publications and more funding. The news media has a bias toward whichever side of an issue will make better headlines. And consumer groups have a bias toward whatever stance will show that they are protecting the public.

Into this maelstrom of biases are thrown the data and CDER. The data are supposed to be neutral, but they certainly do not, as is so often said, speak for themselves. If data were that talkative, we would not need statisticians. Is CDER as objective and neutral as the public expects? Alas, even regulatory agencies have biases.

It is vitally important for those of us in CDER to recognize potential sources of bias. For example, there is a danger that reviewers who work closely with sponsors from the early IND stage may start to take a proprietary interest in the drug. This is especially true if the reviewer has suggested an approach to the design of the study. The reviewer then has an intellectual investment in the success of the study. It is a rare individual who can contribute to the creation of something and then step back and take an objective view of the product.

On the other hand, if a sponsor spurns a reviewer's advice and conducts the study using an alternative design, the reviewer could have a bias against the data. This is why applicants sometimes follow CDER's advice even when they don't think it is optimal. Even identifying too closely with patients of the disease being treated by the drug may lead to a reviewer's adopting some of the patients' biases.

Post-marketing evaluation can also be subject to biases. For example, if a petition to remove a drug from the market is couched in language critical of the

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Agency, it is natural to respond defensively. Natural, but not objective. The public deserves better.

How can you tell if you are losing objectivity? Here are some examples I've witnessed:

- If you get emotional about a drug, either in favor of or opposed to its marketing, ask yourself: "Why am I invested in the fate of this product?"
- If you feel your blood pressure rise when you think about a drug or company, you have lost your objectivity. Even prosecuting criminal behavior should be done dispassionately.
- If you believe that all drug companies are evil and are always trying to slip one by the FDA, or if you believe that all drug companies are motivated only by humanitarianism, you have lost your objectivity. In fact, if you find yourself applying a predetermined stereotype to anyone or any group, you are biased.
- If you find yourself reanalyzing a firm's data in ways the applicant would never be permitted to do in order to prove your point, you have lost your objectivity.
- If you believe your job is to protect the consumer from any possible harm, you have lost the objectivity required to make sound risk-benefit decisions.

Trying to recognize and eliminate your biases is hard work. But we must all keep in mind that our value to CDER and to the public is directly related to our objectivity.

July 30 1999

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.

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

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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?"

August 25 1999

Ombudsman Neutrality

BY JIM MORRISON

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 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,

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such as abused children or nursing home patients.

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.

September 29, 1999

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.

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

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

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fairness behind them.

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).

October 29, 1999

Say What You Mean

BY JIM MORRISON

Surprisingly, I get quite a number of complaints about how tactful people in CDER are. I don't mean courteous, which we should always be. The kind of tact I'm referring to is what my parents would have called "mealy mouthed" or "beating around the bush."

The complaints involve applicants being told in subtle, coded language that they have a problem with their application, compliance or other matters in dealing with the agency. Examples of phrases that convey a tentativeness—suggesting the speaker or writer is not sure of the validity of what he or she is saying—include:

- "Please review carefully your study size."
- "You may want to consider whether the Ames test alone is sufficient."
- "We cannot conclude that your product is exempt from the new drug provisions of the Act."

Let's face it, it's tough to come right out and say that if you conduct a study this way the Agency won't find the methodology wanting years down the road. So instead, we tend not to say anything that can come back to haunt us. The problem is, if we give advice in such a way that people in the future won't be able to pin down what we said, the people we are communicating with today won't understand it either.

Tact and circumspect language are absolutely essential if you are trying to tell someone you think they look older than their years. However, applicants and others whose livelihoods depend on how the Agency views their products want the straight, unvarnished truth. One can be direct without being discourteous, disrespectful or arrogant. If you know from experience that the proposed study is underpowered, tell the applicant that they need to design a larger study. Of course, you should always back up your statements with sound reasoning and data.

On the other hand, if you really feel reluctant to commit yourself to a piece of advice, you should reconsider giving it at all. No one expects you to be a universal expert. CDER is in a unique position to give advice on study design when we have seen similar studies conducted on the same class of drugs.

We also have expertise in what the law, regulations and guidances say. However, in less familiar territory, sometimes people who have a good background in designing studies, for example, know more than we do. In such cases, we can be most helpful by giving advice only in those areas we know best. If we are not sure of our statements, we should come right out and say so. No one will think less of you if you admit you are unsure. Although directness is appreciated, extraneous opinions and intemperate language are not. FDA regulation [10.70(c)(4)] directs Agency staff not to use "defamatory language, intemperate remarks, undocumented charges, or irrelevant matters (e.g., personnel complaints)" in Agency documents. The same caution should be used in meetings.

I would go further and add that even vague innuendoes of violative acts, such as references to filing false statements or doctoring data, should either be stated forthrightly in Agency regulatory actions or remain unuttered and deleted from documents. Besides causing everyone problems, such statements are just plain unprofessional. Purple prose and double entendres are best saved for moonlighting activities as a gothic romance novelist.

November 30, 1999

CDER's Pet Peeves—Part 1

As part of our transformation to a more transparent organization, we have provided many opportunities for the industry to air complaints about CDER. During a recent meeting with industry folks, the suggestion was made that I let them know what most bugs the Center's staff about the industry. I conducted an informal, Centerwide e-mail poll, and I'm using this column and the next to report the results.

I received a wide spectrum of responses. Some expressed appreciation for the opportunity and then unloaded lists of grievances. At the other end of the spectrum were comments that the industry pretty much has its act together. I have grouped the complaints into four main categories: interactions, operational and submission quality, expectations and gaming the system.

Overly Aggressive Interactions

By far the most common complaints involved what are perceived as overly aggressive contacts by industry representatives. This type of behavior includes:

- Calling very frequently regarding the status of a document or review.
- Repeatedly asking the same question looking for the desired answer (either asking the same person the question in different forms or shopping around in different offices for the desired answer).
- Leaving a message for someone and then calling his or her supervisor shortly thereafter complaining that calls are not being returned.
- Failing to control anger, using inappropriate and demeaning statements to staff (almost always when a manager is absent).
- Insisting on an estimate of completion dates of reviews before anyone has looked at the submission.
- Asking for early warning of possible problems and then demanding a meeting with the division to discuss the problems before they have had supervisory review.
- Bypassing several levels in the supervisory chain to bring problems to senior management that could be solved at a lower level.

In general, I believe most CDER staff understand the time pressures industry people face and are sympathetic to their sense of urgency about products. These complaints stem from behavior that goes beyond normal angst.

I always recommend to applicants that they determine with the CDER project manager for their application what is reasonable in the way of status checks. In anyone's book, the several status calls a day that some complaints cited are excessive.

Most of the complaints are self-explanatory. However, the difference between early warning about bad news and premature alarm deserves more discussion.

Clearly, industry scientists want to learn of potential problems as soon as possible. But do applicants really want to know what concerns reviewers at every step? Besides generating ulcers, what is an applicant going to do with such information?

Unless everyone at CDER who needs to evaluate the potential problem has done so, the applicant runs the risk of getting an incomplete picture of the problem or perhaps doing unnecessary work. On the other hand, if concerns can be allayed by pointing out information in the submission, early, informal contact may save substantial time.

My recommendation is that applicants wait for at least a supervisory review before pushing for insights on potential problems and that such issues be broached by reviewers in the form of neutral questions to minimize alarm.

Other complaints about interactions focused on administrative or protocol problems, such as:

- Contacting a reviewer directly without going through the project manager.
- Bringing legal representatives and arguing legal issues at scientific meetings.
- Amending the agenda for a scheduled meeting at the last minute and sending in more data.

Operational, Submission Quality

Complaints about the quality of submissions and science ranked just behind aggressive interactions. They include:

- Submitting poorly organized or sloppy documents, for example: too much redundancy; poor pagination; unnecessary data—such as printouts from lab equipment; inconsistent data; and repeated mistakes.
- Ignoring advice on protocols and other input from previous meetings and correspondence.
- Not stating in a cover letter what is in the attached submission.
- Mixing important data in with routine submissions.
- Not identifying when data have been previously submitted.
- Submitting MedWatch forms with missing data and no assessment or explanation.

The quality of submissions and data sent to CDER varies widely. Overall, the quality of submissions has been improving steadily. Attention to detail, especially in aspects that make submissions more understandable, is well worth the time entailed.

Also, I would recommend that if an applicant does not want to follow the Center's advice on a protocol or

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suggestions provided in letters conveying deficiencies, it is wise to state that up front and to explain the reasons or, better yet, discuss plans with CDER. There may have been miscommunication about what is expected and the reasons for the advice or suggestions.

Early in the new millennium, I'll give you the rest of my survey results. Until then, have a great holiday season.

December 30, 1999

CDER's Pet Peeves—Part II

BY JIM MORRISON

This month's column concludes my report of an informal, Centerwide poll seeking feedback on what behaviors by the regulated industry bug our staff the most. Remember, industry folks suggested this topic, so I hope it proves useful in improving our interactions.

In my last column, I covered complaints regarding overly aggressive communications and quality problems with submissions. This month we'll look at unrealistic expectations and what may appear to Center staff to be industry attempts at "gaming the system."

Unrealistic Expectations

Several complaints involved firms' requests for exceptions from stated policies and procedures or for special treatment, such as expedited review or moving up in the queue. Naturally, each such request is justified by appeals to the staff member's sense of fairness and equity. Appeals usually cite hardships, sometimes, but not always, created by CDER's past actions. It's just not realistic to expect Center staff to bend or break established rules of procedure or change priorities to accommodate everyone's specific circumstances.

Were CDER to honor these requests, charges of favoritism and misfeasance would soon follow. If you really feel you've suffered a grave injustice that needs to be addressed, I would recommend that you talk with the director of the appropriate division or contact me.

Another common complaint was that newcomers to the pharmaceutical industry sometimes expect CDER to function as a consulting service. Many of us in the Center have been approached by someone who claims to have discovered a great treatment for a disease and wants us to tell him or her how to get the product on the market. I always recommend that neophytes seek the services of a consultant.

The Center makes a lot of information about the drug review process available through the Internet and elsewhere, and it offers guidance to the industry in meetings. However, it is unrealistic to expect that the limited time CDER staff members have would be sufficient to guide a company through the entire drug product development process. One shouldn't expect extensive training in drug development from CDER anymore than one would expect training on how to build a space station from NASA.

Other examples of unrealistic expectations include:

- Asking for a determination when there is clearly insufficient information on which to base a decision.
- Seeking immediate answers to complex regulatory issues at meetings or on the phone.

Gaming the System

The term "gaming the system" implies an intentional effort to subvert or misuse procedures and systems. I know that not all examples of the behaviors discussed below are intentional gaming strategies; however, they are often perceived by Center staff as such.

From my experience, the vast majority of people who work in the regulated industry are honest and try to do the right thing. When their motives are questioned, they are understandably affronted. Industry representatives do try to further their company's position but do not see themselves as gaming the system.

However, CDER staff must occasionally deal with those who seek to test legal and ethical limits. When they see behavior that can be construed as devious, they may well assume the worst—that the person is gaming the system. Avoiding the following behaviors can materially increase trust and improve interactions:

- Deviating from an agreed-upon protocol design to achieve a more favorable result. Examples include changing inclusion and exclusion criteria or using different statistical methods.
- Burying protocol changes or other key information in general correspondence and not discussing them with the reviewing division.
- Exaggerating the consequences of failing to get whatever is being sought. Staff hear so frequently that the company will fold if the requested accommodation is not made, that they routinely ignore such claims.

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- Aiming to come as close to the regulatory line as possible or to do the absolute minimum work needed to fulfill regulatory requirements.
- Complaining about a competitor's behavior and then asking to do the same thing if immediate regulatory action is not forthcoming.
- Being less than forthright about safety issues with investigational or marketed drugs.
- Asking CDER to delay an action to avoid adverse publicity or postpone bad news until after a shareholders' meeting or a critical financing decision. The last two are particularly troubling to Center staff. Nothing destroys working relationships and trust so much as appearing to be willing to trade public safety or corporate reputation for financial advantage. In the long run, strategies that attempt to hide information, even for a short time, cause much more damage than they can ever avoid.

One of the messages I took away from this survey of pet peeves is the wide range of behaviors and ethics to which CDER staff are exposed. It is well for industry people to keep in mind that Center staff are exposed to enough examples of untrustworthy behavior that it may color other interactions. That thought may help those interacting with the Center to forgive staff members who have become generally suspicious.

The most difficult aspects of any type of law enforcement or regulatory work are how to recognize who is trustworthy and who is not—and to deal with each accordingly. It is a credit both to the regulated industry and to CDER staff that the vast majority of interactions between the Center and the regulated industry are positive, straightforward and mutually respectful.

Whether you are a member of the regulated industry or a Center employee, you should be able to expect high standards of professionalism, courtesy and respect in your interactions. I appreciate hearing about interactions that fail to meet those standards. You can contact me by phone or e-mail (301-594-5298, morrisonj @cder.fda.gov).

January 31, 2000

Happy Anniversary to the *Pike*

BY JIM MORRISON

At times, it seems my memory of FDA predates recorded history. My tenure here really began with the Bureau of Drugs in the early 1970s. From that perspective, the changes have been spectacular. But since this is the fifth anniversary of the *Pike,* in this column my reflections go back only as far as 1995, which is also the year the CDER Ombudsman position was created. The major focus of activity in CDER then was the 1992 Prescription Drug User Fee Act. The Center was getting into the tough part of the goal dates for NDAs.

Judging by complaints from the industry, it was still too early to tell if PDUFA was going to be a success or if it would be another failed attempt to revolutionize new drug reviews. There was a dwindling backlog of pre-PDUFA applications, but some review divisions were struggling to get their work done on time. Inside CDER, however, there was a clear mandate to make PDUFA work, and there was a sense of urgency that meant reviewers were working harder, smarter and longer hours. However, just doing more of the same was not the long-term solution.

In February of 1996, Center Director **Janet Woodcock, M.D.,** led about 30 senior managers in a go-away. CDER had management go-aways before, and some in attendance were skeptical that anything more would come from this one. But instead of focusing on planning or budgets, this one focused on taking a step back, on breaking down the barriers to communication among CDER's diverse offices and on figuring out what CDER was about and what it needed to do to adapt to a changing world. The participants in that go-away became the CDER Change Team.

The result was a palpable change in the climate in CDER. There was a growing cohesiveness, collegiality and a renewed sense of direction. To illustrate the extent of the change in CDER, I'll cite one example. In the fall of 1996, during one of many sessions to acquaint first- and second-line supervisors with the change process and to get their input, we had an exercise to write a headline for the Washington *Post* for a date in the year 2000. Several of the working groups produced a headline that read something like: "CDER Wins Prestigious Award for Outstanding Achievement." Although that mock headline was viewed as an improbable stretch at the time, just two years later, CDER and the Agency won the Ford Foundation's prestigious Innovations in Government award.

Awards are fine, but are there more lasting indicators that CDER has changed in five years? From my perspective, while the number of complaints has stayed fairly constant, the attitude of complainants has

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changed. Five years ago, complainants from the industry and members of the public were angrier and were very willing to buy into the image of CDER as a group of hide-bound bureaucrats who delighted in putting roadblocks in the path of progress.

While there is still a small minority of people out there who cling to that image, those who contact me and who know CDER have a greater respect for us and an expectation that whatever problem they have encountered is an aberration that can be fixed. The edge in people's voices is generally gone, as is most of the anti-FDA sentiment. No award or public relations campaign can bring about that change in attitude. People believe their own experiences over PR. The surest way to win people over is one person at a time, and CDER has been doing just that.

No five-year retrospective would be complete without some mention of where we are headed in the next five years. The Internet is changing the way people think about information. It is also raising expectations about how much information should be instantly at everyone's fingertips. One of CDER's most important challenges over the next five years will be to fill the demand for better information about health care and medicines.

This demand is coming, not only from the public, but also from health care professionals and other stakeholders. With the number of Internet sites numbering in the tens of millions and increasing daily, there will be more misinformation about drugs and dietary supplements out there spreading confusion. As people realize the need to get information from reliable sources, they will grow to depend on sites such as FDA's.

CDER needs to be there with accurate information, displayed in an easy to use format that is updated constantly. To do that, we will need to completely rethink the way we handle information within CDER.

CDER has come a long way in the past five years in transparency and openness. The *Pike* has been part of that progress. It has become a popular and trusted source of information about CDER, not only for staff here but perhaps more so for people outside the organization. That underscores the need for even more openness and transparency by CDER. The challenges in the next five years will be tough, but if the past five years are any indication, CDER will successfully meet those challenges.

February 28, 2000

What's What

BY JIM MORRISON

It's been about two years since I made an appeal for CDER staff to be alert to whether the product they were reviewing was really a drug *(Pike,* April 1998).

I haven't been flooded with questions, so I assume that either everything coming into the Center belongs here, which is mostly true, or that folks don't spend a lot of time worrying about intercenter jurisdiction, which is also mostly true.

Since I am an exception to the latter assumption—it's part of my job to worry about intercenter jurisdiction—I have been thinking about ways to simplify how we distinguish between drugs, devices and biologics.

The boundaries between the different product classes, each of which has its own regulatory system, are interesting. Some fascinating products straddle normal boundaries.

Liquids and powders can be devices—for example, liquid bandage preparations and bone cements. Monoclonal antibodies coupled with oncologic agents are drugs. Cultured skin is a device; although, tissue implants are biologics.

In this counterintuitive world, where products may not be what they seem, it helps to have a general, simplified algorithm to follow. I have devised one, but I stress that it is *only intended for internal use by CDER staff.* It is oversimplified, informal and cannot replace, annotate or amplify the formal intercenter agreements. Any inconsistency with the intercenter agreements is unintended.

The algorithm is designed to be an easy way to decide if it is appropriate to ask the CDER intercenter jurisdiction contact—that would be me—to take a closer look. Ultimately, the determination of intercenter product jurisdiction rests with the FDA Ombudsman's office.

This algorithm may generate more questions for me, but the extra effort is worthwhile if we can avoid learning at a pre-NDA meeting that a product is in the wrong center and regulatory system. This happened recently.

Even if a product doesn't fit anywhere in the algorithm, the prudent rule is: when in doubt, ask!

If you want to take a look at the intercenter agreements, they can be found on the FDA Web site at http://www.fda.gov/oc/ombudsman/pj.htm.

April 3, 2000

Informal Product Jurisdiction Guide

Drugs

In general, a product is virtually always a drug if it is:

- Synthetically produced.
- Similar to other products that are drugs and easily characterized.
- An antibiotic to treat humans.

Biologics

However, the product may be a biologic—and you should consult the intercenter jurisdiction officer—if it or any of its parts is:

- A vaccine.
- An *in vivo* diagnostic.
- An allergen for therapeutic or diagnostic use.
- Derived from human blood.
- Used in blood transfusion or blood banking.
- A blood-cell substitute.
- An immunoglobulin.
- Composed in any part of intact cells or microorganisms.
- A protein, peptide or carbohydrate produced by recombinant cells or transgenic animals, except for antibiotics, hormones and products very similar to approved drugs.
- An animal venom.

Devices

Finally, the product may be a device—and you should consult the intercenter jurisdiction officer—if it or any of its parts uses:

- An implanted drug delivery system.
- Computer software or hardware, for example, programs or devices that calculate dosage or activate the drug.
- Device components, such as: inhalers, catheters, probes or bandages.

A product is also likely to be a device if it:

- Is used to irrigate, moisten, lubricate or flush skin or indwelling devices.
- Protects the body from injury, irritation or infection by physically shielding it.
- Does not achieve its primary function by chemical or metabolic action on or in the body.

'FDA Made Me Do It'

BY JIM MORRISON

In December and January, I focused on pet peeves about the industry from CDER reviewers. This time, I'd like to add one of my own. It seems that some people in drug company customer service departments and some pharmaceutical sales representatives have developed a new strategy. Whenever they get a complaint about their product, they just say that FDA made them do it. Over the years, I have received occasional questions from people who were told that FDA made a company do whatever was the subject of the complaint, but lately it has become a much more frequent occurrence.

For example, just recently I received several complaints alleging that drug company representatives said they couldn't change the size of the packaging, because FDA made them put the drug in that container size. Alternatively, one person was told that the company would have to redo all of its studies in order for FDA to allow a change in packaging. The implication was that they would have to retest the drug for safety and effectiveness, not just stability.

Another person was allegedly told that the same product was given two different names because FDA required it. Now, in rare instances FDA has asked companies to give a different name to a drug with a new indication, but only when safety issues were involved, such as special warnings, dosages and routes of administration. The complaint I'm concerned about involved a drug product that is sold under two different names purely for marketing reasons, a practice that FDA usually tries to discourage.

This shifting of blame doesn't involve just one or two companies. It is such a common element in complaints about drugs made by different companies, that it appears to be a growing industry practice. I don't think it's a conspiracy. It's more likely the result of misinformed employees.

My appeal is to the folks at pharmaceutical companies who have opted to take this easy approach to dealing with complaints from consumers and health professionals. Every organization makes mistakes and unwise decisions. FDA certainly makes them, and when we do, it is difficult to explain to the public why they occurred. I certainly can empathize with customer service personnel, since a significant part of my job is handling complaints. But passing the buck eventually hurts the credibility of those who try to shift responsibility.

I am grateful to people who seek me out to confirm that FDA really did require that companies do these things. It gives me a chance to set the record straight. But I know that for every one of these questions I get,

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there are perhaps hundreds of people who don't bother to ask or who are all too willing to believe in the inherent stupidity of government agencies.

I also ask CDER staff to please let me know when they get a complaint from someone who was told by a drug company: "FDA made me do it." It will help me track this trend and try to find ways to address it.

May 31, 2000

Now, If Only We Could Float an IPO

BY JIM MORRISON

An ancient Chinese blessing says: "May you live in interesting times." Well, we are blessed. We are privileged to witness the beginning of a new age, the Information Age, which is fast replacing the Industrial Age.

The Information Revolution is being fueled by computer, Internet and wireless technologies, just as the Industrial Revolution was fueled by steam and electric power, the assembly line, the telegraph, the telephone and better transportation technology.

When the telegraph was invented, people said: "It will change our world, and it will transform the way we live." In my view, the Internet has a greater potential to change our world than the telegraph ever had. Who can say if the new economy can sustain the multibillion-dollar capitalization of IPOs (initial public offerings) that have made a lot of people rich? But the hype has provided an unprecedented bankroll for venture capitalists to play with and to feed progress.

When venture capitalists decide to fund infotech startups, they ask several questions:

- Does the company have unique information that businesses or the public want or need?
- Does the company have a catchy dot-com name or can it develop name recognition?
- Can the startup sustain a buzz that will keep its name in the public consciousness?
- Can the firm manage and sustain growth?
- Does it have the technological savvy to stay at the cutting edge?

Since all organizations, not just startups, need to assess how they will meet the challenges of the Information Revolution, lets look at how CDER would fare in a venture capitalist driven world. First, we certainly have unique information that people want and need. Secondly, we have an Internet identity that attracts Web traffic, and FDA is a household name that is kept in public view daily by news media reports of our activities. Our growth is limited by the budget, but we have shown we can manage growth to improve performance dramatically. Do we have cutting edge information technology? Well, four out of five isn't bad. In fact, if we were a private enterprise, venture capitalists would be beating down our door. Now, if only we could float an IPO . . .

About now, you are probably asking yourself: "Any moron knows CDER can't sell stock, so what is his point?"

Good question. My point is that regulatory agencies, like the rest of society, are greatly affected by paradigm shifts. The FDA was created in the Industrial Age, when the focus of enterprise was on producing goods. The FDA was created to act like a funnel with a filter. All drugs would pass through the funnel before reaching the consumer. In the Information Age, when people in Peoria are hard-wired to Paris, Potsdam and Beijing, the funnel is developing leaks.

Rather than being dismayed that we cannot create a funnel large enough to encompass the whole world, we should recognize that we are in an excellent position to thrive in the new Information Age. Although we don't have cutting edge information technology, that's OK. The Information Revolution is propelled by technology, but it is really about content, about developing relationships among far-flung strangers with common interests and about communicating information instantaneously and globally.

Hardly a day passes that I don't get e-mail from consumers and health professionals complaining about being spammed or about seeing Internet sites for fraudulent products or for prescription drugs obtainable without actually seeing a physician. With over a million Web sites being created annually and a 150,000 new Internet users added daily, the world is drowning in information about diseases and treatments, much of which is of dubious veracity.

When people are bewildered by the glut of contradictory information about drugs and health, they

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look to the Websites of organizations they trust. That is why venture capitalists put so much value on name recognition and ongoing publicity about startups. The FDA has that already, and we can do a lot of good if we understand how to communicate what we know about drugs.

That isn't to say we should abandon our traditional role of filtering and regulating. There will always be pharmaceutical development and production, just as agriculture is still an important enterprise long after society stopped being predominately agrarian. All of us need to keep doing what we are doing now while devoting thought and resources to adapting CDER to the Information Age. We have vital information to communicate. We need to do it more effectively.

June 30 2000

St. Sebastian Kept a Stiff Upper Lip

BY JIM MORRISON

Well, it seems like slings-and-arrows season again. The Center has certainly received more than its share of bad press in the past few months, and it takes its toll in staff morale. From the mail I've been getting, mainly from consumers, it is apparent that there is a lot of misinformation and false perceptions about the benefits and risks of drugs and how CDER decides to approve a drug or ask its sponsor to withdraw it from the market.

It's painful to get flaming e-mails, but it's equally painful to hear colleagues express a stoic acceptance of these barbs as the fate of regulatory agencies. The Agency's traditional approach has been to quietly accept the public's wrath, born of misperceptions and incomplete information, while waiting for the complete, scientific truth to emerge some time in the future and prove the wisdom of Agency actions. But information delayed is an educational opportunity lost—or worse—a tacit endorsement of the misinformation.

The situation reminds me of paintings by Giovanni Bellini (1426-1516) and others depicting the martyrdom of St. Sebastian. He is usually shown with his body pierced by arrows and a woeful expression on his face. But Sebastian kept a stiff upper lip. Sporting numerous arrows protruding from your body may look good if you are applying for sainthood, but it is less becoming to a regulatory agency. One of our important obligations to society is to educate the public about drugs, how to use them safely and about what the Agency is doing to assure that only appropriate drugs are on the market.

To quietly endure the slings and arrows of a misinformed press and public is not noble—it is a failure to communicate. The public needs to have a basic understanding of drugs and how to decide whether to take a drug in a particular circumstance.

The public does not learn from reading transcripts of advisory committee meetings or scientific articles. The public needs to get this information in short, comprehensible messages that are not unlike the sound bites they get from the media.

We have no one but ourselves to blame for the public's lack of understanding that "safe drug" is an oxymoron and that benefits must be weighed against risks, with different people usually getting the benefits and suffering the risks.

Thanks to the science fiction genre, the public has a better comprehension of Einstein's special theory of relativity ($E=mc^2$) than it does of drug regulation and benefit-risk evaluation. It's doubtful that the average person will ever need to use Einstein's equation, but ignorance of the risks of drugs can be fatal.

If the public is being educated by the media in sound bites, we need to educate the public and to explain our actions in a collection of sound bites that add up to a cohesive picture. If these bites are repeated in interviews, posted on the CDER Web site and disseminated to the public at every opportunity, the messages will sink in. Stating the reasons for actions is always preferable to remaining silent in the face of criticism.

We simply can't afford to allow misinformation to prevail. Educating the public and the media is an important function of government. In the Information Age, it is becoming even more important. Fortunately, this vital function is becoming easier to fulfill. With the Web, the Agency has the opportunity to interact with the public individually in numbers never before possible.

Each of us can contribute to the process. We can begin by trying our communication skills on our family and friends. If we can't explain to our spouses and kids about benefit-risk in drugs, it's not likely we can get the message across to people who call and write letters. We also need to carry on a dialogue among ourselves and to share consensus views with the public.

July 31, 2000

Pride and Prejudice

BY JIM MORRISON

Political comedian Mort Sahl said of President Eisenhower that once he had made his mind up, he was thoroughly confused. Historians have made similar comments about George Washington's alleged indecisiveness. These were meant as criticisms, but I sometimes wonder. Are the pundits and historians identifying true indecision or are they mistaking a willingness to revisit decisions for weakness or indecision? Being always willing to review a decision and to change it in light of new information is a rare virtue. Sadly, it is rare because of the tendency in most of us to exhibit pride and prejudice.

We take pride in making the right decision. Pride in itself is fine. All of us should take pride in our work and in our lives. But pride sends us astray when it prejudices us so that we are reluctant to revisit a decision in the light of new information or a reanalysis of old information.

Almost every significant decision in life must be made with less data than one would like. This is certainly true of governmental decisions, whether made by the president or by regulatory staff at the FDA. We should recognize that such decisions are inherently susceptible to challenge later. However, having pride coupled with prejudice about a decision leads to a reluctance to reexamine it when new data become available. And that unwillingness may lead to flawed decisions subsequently. Such reluctance can also create a delay in acting on new information.

Specifically, if the new information were adverse to a newly approved drug, the consequences to the public of a delay in action caused by a reluctance to reexamine the decision could be grave. On the other hand, this pride and prejudice can lead to an unwillingness to accept supervisors' and managers' reviewing a decision and overruling it. It can also bias a reviewer whose negative recommendation regarding a drug's effectiveness was overruled, causing him or her to unnecessarily restrict labeling or to suggest new studies in a supplemental application that would not otherwise be needed.

Fortunately, decisions made in CDER are generally institutional rather than individual, so it is unlikely that one person's pride and prejudice will have a major effect. The true danger of such bias is when a group of individuals adopts a bias about a collective decision.

The institutional nature of our decisions should be a basis for curbing our pride and prejudices. None of us is fully responsible for Agency decisions, whether we think they are good or bad. That should allow us to distance ourselves from our decisions and to be willing to revisit them when new data or analyses come to light.

August 31, 2000.

Ignorance Is Not Bliss

BY JIM MORRISON

The composer Gian Carlo Menotti once wrote: "A man only becomes wise when he begins to calculate the approximate depth of his ignorance." One benefit from working in CDER is a never-ending depth gauge for ignorance. It isn't that we are dumb, it is just that the science, policies and issues are so extensive and change so frequently that it is not possible for us to ever feel that we have mastered them. Whenever we think we are on top of them, it's time to wake up.

There are both internal and external opportunities for displaying our ignorance. But knowing that we don't know everything is a safety net most of us acquire sometime after adolescence. It is always possible to learn by asking someone or to defer to someone who does know. When we don't know what we don't know, as Yogi Berra might say, we get into trouble.

Each of us has areas of expertise, and collectively CDER has a wealth of knowledge about drug development and regulation. But there are blind spots. For example, too many of us tend to make assumptions about marketing and economic factors that motivate drug companies. And, yes, it does work the other way. Sometimes companies make assumptions about what motivates the FDA rather than asking the Agency.

Just recently I saw such a case of mutual ignorance. Reviewing staff were encouraging a company to pursue studies that might have led to an expansion of the labeling and use of a drug. The company viewed the encouragement as an unwanted requirement. The reviewers could not understand why the company was resisting such sound scientific advice. The situation developed into something of an impasse.

Had the reviewers asked the company about its plans for the drug, they would have learned that the firm viewed the product as very marginal and were unwilling to spend additional resources to develop it further.

Had the company asked the reviewers about their

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proposals, it would have learned that the reviewers thought they were being helpful and that the suggestions were not intended as requirements. Five minutes of discussion would have prevented weeks of perplexed correspondence.

Even CDER staff who have worked in the pharmaceutical industry are unlikely to know the particular reasons behind the actions or inaction of applicants. Motivations may not be knowable by even the most astute observers. Confidential business deals or commercial strategies may be involved that even the company's regulatory affairs contacts are not aware of. Just know that we can't know enough to predict regularly what people or companies will do, so don't try.

Too often regulated companies assume that FDA is making a request or acting out of bureaucratic ignorance. From my observations, most often FDA staff have legitimate motives and intelligent reasoning behind their requests and actions.

It is never inappropriate for companies to discuss with the Agency the reasons behind their actions. Likewise, it is appropriate for CDER staff to engage applicants in a discussion of their aims and plans for a proposed product. Of course, it is not legitimate for CDER staff to press companies for financial information.

Not only is it difficult for companies to discern what motivates the Agency, but CDER staff should not assume they always know what other parts of the Center or the Agency are doing. In our ignorance we sometimes unknowingly create a Catch 22. But believe me, regulated companies are very good at knowing when they are presented with a Catch 22.

I don't know how the notion that "ignorance is bliss" ever got started (perhaps a misquote from a poem), but from where I sit, ignorance is anything but blissful.

October 16, 2000

Annual Report: Complaints About Processes Move to Top

BY JIM MORRISON

Two things you can count on at the end of a fiscal year are continuing resolutions to keep the Agency funded and my Ombudsman's annual report. The continuing resolutions are over, and here is my report. Complaints to the CDER Ombudsman are on a plateau, but there are a few worrisome trends that point to problems that need addressing.

As with last year, the number of cases stayed a little below 100, virtually all externally generated. I tabulated the complaints into the same classes that I did last year to make trends easy to spot. While unfairness of policies or decisions led the list last year, it dropped to second place, behind problems with processes or inadequate information about them. Specifically, there was a 20 percent decrease in unfairness complaints and a similar percentage rise in process problems.

External Complaints	FY '99	FY '00
Process problems or inadequate information about them	36%	42%
Unfairness of a policy or decision	38%	30%
Untimeliness	15%	12%
Difficulty gaining access	5%	6%
Uncivil or unhelpful interactions	3%	6%
Miscellaneous	3%	4%

The Center has spent a considerable effort to reduce inconsistencies among reviewing divisions, and I believe those efforts account for at least some of the drop in the unfairness complaints. I don't know why reported process problems rose, except that if one category drops others must rise, because reporting is on a percentage basis. However, many of the process-related complaints could have been avoided with additional clarity in our communications.

Untimeliness complaints continued to drop, a constant trend throughout the five years I have been ombudsman. The predictability of actions through user fee goals has made grumbling about new drug reviews virtually disappear.

Two trends are troubling, in that complaints about both difficulty in gaining access (mostly a lack of returned phone calls) and rude or unhelpful interactions rose, with the latter doubling from last year. It is difficult to pinpoint why this should be, but I would encourage CDER staff to reread my column in the June 1999 *News Along the Pike* (http://www.fda.gov/cder/pike/june99.pdf).

In December and January I devoted two columns to the results of a survey I did among CDER staff about their pet peeves regarding industry behavior. Those articles gained a lot of attention, demonstrating the wide readership of *News Along the Pike* outside the Agency. They resulted in a chapter in a Food and Drug Law Institute book about working with the FDA, and I heard from several companies that they were required reading in their regulatory affairs departments. The interest in the articles also shows that people are hungry for insights into the

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workings of the Center.

As I have said many times, most of the problems I see relate to miscommunications, a lack of communications and inappropriate communications. Despite the numerous guidances and procedures published by the Center, there is still a lot of mystery surrounding how CDER works and why we do what we do. The publication of standards and criteria is a good thing. But publishing *why* the Center is setting those particular standards and criteria is important as well.

People outside CDER will never fully understand what makes the Center tick unless they understand *why* we take the actions we do. Adding a few sentences in not approvable and clinical hold letters, for example, to explain why the actions are being taken, not just what needs to be done, will aid those receiving the letters immensely. We too often assume that the reasons for our actions are self-evident. But that assumption doesn't hold if you are addressing the letter to the person who put the application together and thought everything was fine.

Overall, the actions CDER takes are well-reasoned and valid. We can reduce the complaints about processes if we take the time to explain the actions we take to those we regulate and to those we serve.

If you have a complaint or suggested solution to a problem, please give me a call (301-594-5443) or send me an e-mail (morrisonj@cder.fda.gov).

November 30, 2000

A Map to the Road Ahead

BY JIM MORRISON

An important event has been lost in all the finger-pointing at FDA in the press lately. It is a quality assurance report on the processes involved with troglitazone (Rezulin). The report is available on CDER's Web site at http://www.fda.gov/cder/about/qualityassurance/default.htm.

There are two remarkable things about this report. The first is that it was done at all, because, until recently, there was no organizational process in the Center by which lessons could be learned from outcomes that didn't meet either the public's or our expectations. And the second is that it was published for all to see.

From comments in the press, it seems, sadly, that the prevailing concept of quality assurance is still to find someone to blame, execute him or her and then get on with business as usual. The problem with that approach is that we execute the one person who probably knew most about how the problem occurred and how to prevent it from happening again. Beyond that, it instills in people within an organization a fear of being wrong or of making a mistake. Put another way, it encourages people to do nothing.

As all quality assurance experts and ombudsmen know, the way to solve problems in any organization is to recognize that all humans make mistakes, to analyze the system as a whole, to identify what went wrong and to publish consensus recommendations. Then people, freed from the need to defend their actions, can learn from their own and others' mistakes.

Those of us who have been in FDA for a long time are conditioned to working in a fish bowl. It is the price we pay for doing work that is important to people. In the private sector, quality assurance reports are virtually never made public. That CDER's reports are and will continue to be posted on our Web site shows a strong commitment to our stated values, one of which is transparency.

However, publishing quality assurance reports and recommendations is but one step in a journey. The report highlights important issues. There are procedural and organizational recommendations that may be easier to implement than the scientific ones. The most difficult by far to implement will be developing a prospective plan for assessing new safety information about marketed drugs and taking action. But, as recent events have shown, such a plan is critically needed, and it can be invaluable to us in explaining to the public the reasoning behind CDER's actions.

There is not much doubt that the trend toward FDA operating in full public view will continue. The public's demand for a carefully thought out and generally understandable explanation for every action CDER takes will also intensify. I see it in the content and volume of the e-mail I get. We are rapidly moving into the information age, and there is no turning back. The road will have many curves and we will need to learn new ways of thinking and new approaches to old problems. CDER will flourish in that new age, so long as we all keep in mind the saying, "A bend in the road is not the end of the road . . . unless you fail to make the turn."

December 29, 2000

Tolerance and Openness

BY JIM MORRISON

Tolerance, by definition, is the absence of bigotry or a civil and fair attitude towards those whose viewpoints differ from our own. But being tolerant doesn't require that we must reevaluate our views in light of a newly received opinion. We simply must treat others' views with civility and, at least superficially, respect.

Contrast tolerance with openness. Openness implies not only tolerance, but also a willingness to reassess our own views when confronted with a differing viewpoint. True openness requires that the reassessment be genuine and not forestalled by a superficial analysis of the qualifications of the espouser of the new opinion. True openness is a rare commodity.

We become experts in our field of drug regulation. We form opinions and make findings of fact, sometimes based on much training and study. But they are also based on fundamental assumptions about the world and on our personal value systems and experiences.

Understandably, we become very comfortable with our opinions and beliefs. Faced with ideas that are inconsistent with those opinions and beliefs, we resist.

The people we serve, the public, are a diverse population, and they don't necessarily share our experiences, training or values. They may come to different conclusions, given the same set of facts. Are they wrong? Is there an absolute right or wrong?

As I have often said, drug regulation is one of the most complex endeavors one can tackle. Part of good regulation is based on science. Rightfully, we value highly our scientific knowledge and insights into the pharmaceutical and clinical sciences and the law. But that is only a part of the story. A significant part of drug regulation involves societal issues, values and judgments that, even within CDER, may differ.

Every day, we makes decisions about what is best for the public health. Of necessity, these decisions are often made with less information than we would like, because if we waited for all the desired data, bodies would start to pile up. In part, these decisions are also based on values and assumptions that have little relevance to science.

How much should we rely on physicians and patients to read labeling? If they misuse drugs because of failing to read or understand labeling, does responsibility for the consequences, which may include deaths, fall on them or on us? What should trigger removal of a drug from the market? How does one balance the benefit of improved quality of life for some against serious damage caused to others? Is a longer life in pain better than a shorter one free from pain?

These are difficult questions. Ask various people, inside FDA or outside, and you will get a broad spectrum of answers. There are no magic formulas that can be relied on to make these decisions. There are no absolute truths. We cannot expect to be right all the time, whatever "right" means.

Given the uncertainties, it is vital that we articulate clearly the basis for our decisions. And we should view the inevitable criticisms of our recommendations and decisions as an opportunity to reevaluate our positions, to challenge our assumptions and to learn.

However, learning does not occur if our mindset is one of mere tolerance for differing viewpoints. Learning comes with genuine openness.

January 31, 2001

The Art of Reading Tea Leaves

BY JIM MORRISON

As I've noted many times, those outside CDER often view our new drug review process as a giant black box. In the absence of complete transparency, applicants sometimes look for occult signs and surrogate markers to tell them how their new drug applications are progressing.

Applicants who are not seasoned veterans at maneuvering NDAs through the review process sometimes interpret the statements from Center staff and Agency actions in a manner that is just about as accurate as reading tea leaves.

Lately it seems that I've been seeing more unsuccessful tea-leaf reading than usual. I thought it would be useful to those on both sides of the regulatory fence to share some examples I've encountered.

These examples all relate to firms that have come to me in a state of shock after they received not approvable letters. I've divided them into erroneous interpretations of statements made by CDER staff and false inferences based on activities by the Agency during the review process.

Statements

In meetings or telephone conversations with CDER reviewers and project managers, applicants may ask: "Do you need any more information?"

The reviewers may say: "No, we have all the data

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we need," or, "No, there are no outstanding issues." They mean that the application is complete—not necessarily approvable—and that no more amendments to the NDA are needed for them to reach a decision.

Unfortunately, some applicants think this means that there are no problems with the drug, the data or the application.

As a word of advice to reviewers and project managers, it would be good to emphasize to applicants that we won't know whether the application is approvable until all the data have been reviewed.

Another occasionally misunderstood statement is, "There are no issues that need to go to the advisory committee."

Some applicants take this to mean that the data are so good that the drug is clearly safe and effective. But it could also mean that the data are so negative that the drug is clearly unsafe or ineffective, so there is no reason to waste the advisory committee's time. Most often it means that the drug is not novel, and there are no real areas of uncertainty.

Sometimes applicants interpret the absence of contacts or questions to mean everything is fine with the application. "No news is good news" may apply when your teen-ager borrows the car, but it is useless in predicting the outcome of an NDA review.

Activities

I have heard applicants say, "But DSI [the Division of Scientific Investigations, which inspects clinical investigators] did their inspection, and everything seemed fine. They wouldn't have done the inspection if the application was not approvable." Wrong.

I've also heard the same thing said about field investigators inspecting the manufacturing facility for current good manufacturing practices.

Those assumptions may have had some validity years ago. However, with the short user-fee review timeframes in place today, inspections are ordered very early in the review process, before any conclusions can be made about whether the application is approvable.

Even if the reviewing division believes that an application will not be approvable, the inspections are done so all deficiencies can be identified and conveyed to the applicant.

The Center gets many applications from startup companies run by entrepreneurs who have invested years of sweat and a lot of their own money in the development of a single product that will make or break them. It is only natural that they are extremely anxious about the progress of their application. They seek any clue they can find about how their drug is faring.

With that in mind, it is important for us to be very careful to avoid inadvertently misleading applicants by being less than crystal clear about what our statements and activities mean with respect to the outcome of their applications.

February 28, 2001

Minutes Save Months

BY JIM MORRISON

I've often said that 90 percent of my work consists of picking up the pieces after breakdowns in communication. Ninety percent may well be too low an estimate. The most common scenario of miscommunication occurs when we are not crystal clear in what we say and the listener doesn't want to hear our message. Imagine you are the NDA applicant in the following example.

You work for a privately owned startup pharmaceutical company. It has purchased the rights to develop a new drug for the U.S. market from a company that went belly-up. The defunct company had completed Phase II studies, and the drug appeared promising.

You were hired to oversee the Phase III testing and to assure that the drug receives FDA approval. You have been working on the project for three years. You followed the guidance FDA gave you in the end of Phase II meeting, and your statisticians believe the data from Phase III trials demonstrate the drug is safe and effective.

You arrive with other members of your team in Rockville to attend the pre-NDA meeting. The CDER staff members at the meeting agree that the drug has great potential and that things look promising. However, they state:

"It would be advisable for your company to do an additional study to address questions raised by somewhat elevated liver enzymes in a small percent of the subjects in the studies."

When you ask if the study is a requirement for approval, the CDER participants say only: "It would be very helpful."

When you caucus with your team after the meeting, there is some uncertainty as to exactly what CDER said. Most of your team agrees that the Center meant that it would be OK to submit the NDA, and that the additional study could be done in Phase IV after approval. Your team estimates that it will take three years additional work to complete the suggested study. You think that there is a small chance that FDA would not approve

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the NDA without the additional study.

When you get back to your room in the hotel, there is a message from the CEO of your company asking how the meeting went. You see three possible scenarios of what to say in returning the CEO's call:

A. "Well, boss, we didn't do very well. We'll need to do another study, which will take another three years before we can submit the NDA. But there is a bright side. We can save the $50,000 you would have paid for my bonus. For that matter, you can save my salary for the next three years, too. And the bankruptcy judge will look favorably on any company that sacrifices itself to prevent even the possibility of its product doing harm. By the way, I'll be staying around here for a few days to look for a new job."

B. "Well, boss, we had the meeting, but we can't figure out what FDA said. I think we can file the NDA, but maybe we should first do this three-year study they suggested. What do you think?"

C. "Well, boss, the meeting went fine. We are on track to submit the NDA next month. They suggested an additional study, which I'm confident we can do in Phase IV."

Which of the above scenarios would you choose?

The point is, when so much is at stake, people will naturally interpret our statements to suit their expectations best. Therefore, it is essential that we be clear and precise in verbal statements and, most importantly, in the minutes of meetings.

Equally important is the timeliness with which minutes are conveyed to the company. CDER MaPP 4512.1 specifies that minutes of formal meetings be transmitted to industry participants within four weeks. Clearly stated minutes do little good if they are sent six months later, after the applicant has submitted an NDA or has begun studies according to misunderstood verbal guidance.

Not only must the firm receive the minutes in a timely manner (or check with the project manager if they have not been received in four weeks), but the firm should send their minutes to CDER, and we should read them.

I've heard some in CDER say: "Our minutes are the official ones, so we don't need to read the firm's version." That is technically true, but costly if the firm's minutes show a misunderstanding about a planned study, and no one catches it until the study has been completed and an application is submitted.

If there is a misperception, it is better corrected sooner than later. The added time it takes to review the firm's minutes is well worthwhile, even if only occasionally significant differences are detected.

Anyone who has sat through long meetings following appeals can attest that clear and timely minutes can save months of work on both sides of the regulatory fence.

April 5, 2001

To Err Is Human, To Admit It Sublime

BY JIM MORRISON

People who do not admit they made a mistake, particularly when the mistake is obvious to all around them, are sometimes likened to an ostrich burying its head in the sand.

Although ostriches lack some social graces, that characterization does them a disservice. When an ostrich appears to bury its head in the sand, it is actually putting its ear to the ground to better hear the approach of predators. That leaves humans who refuse to admit mistakes pretty much in a class by themselves.

It's bad enough when individuals do it, but when organizations refuse to admit mistakes, it infuriates those who are affected by the error. Remember the tobacco company executives with their right hands in the air, swearing before Congress that cigarettes don't cause health problems? Unfortunately, it is an exceptional organization that does not commit the *faux pas*.

So what should those of us who work in CDER do if we realize we have made a mistake? First, we shouldn't panic. Everyone makes mistakes. It's what distinguishes humans from inanimate objects. Next, assuming it is a mistake that has some significance, we should tell someone about it, preferably our supervisor. In that way, we save our supervisor from getting blind-sided about the error later.

Whatever we do, we should not deny the mistake was made. And we must never, never try to cover it up. Occasional errors may or may not get noticed. However, covering up errors often gains headlines. Richard Nixon was not impeached for the Watergate break-in; he was impeached for trying to cover it up.

That brings me to the reason for my column this month. Many of the cases that come to my desk have a history of one or more errors that could have been avoided by CDER staff. Once in a while, those errors form the basis of an appeal, or, at least, lend credibility to a company's complaint.

Yet, rarely do I hear anyone admit in a meeting with the distressed party that any mistakes were made. Sometimes they are glossed over, and other times they are explained in a manner that absolves an individual but still leaves the Agency in a bad light.

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Invariably, the company representatives are incensed, making an amicable resolution of the issues more difficult. You won't see company representatives turn red and pound the table, given the realities of the regulator-regulated relationship. However, they become more entrenched in their positions and less amenable to meeting the Agency half way. I wonder, if those meetings had opened with an admission that mistakes were made and regretted, how much time, resources and ill will could have been saved.

We say that individually we want reputations for honesty, credibility and trustworthiness. The CDER operating principles also seek to establish such a reputation for our organization. Admitting our mistakes, both individually and organizationally, is the key to attaining that reputation.

May 25, 2001

An Opportunity for the Taking

BY JIM MORRISON

Too often people regard training as something external that is done to them. Training and development, if they mean anything, come from within. Courses and programs facilitate the process, but learning and development occur within us.

Sometimes we feel so pressed by daily work that we let training and development opportunities go by. I'm not talking about training courses, necessarily, but also about opportunities to learn in our jobs by taking the extra time to research questions that arise. One of the benefits and joys of working at FDA is the opportunity to be exposed to a steady flow of new information and new experiences.

Some of us are contented with our current positions and some are searching for a new path to advancement or fulfillment. Either way, development must be a constant in our daily routine. We all need to grow, and growth comes from new challenges.

Sometimes we need a complete break to reassess the direction we want to grow in. If you find yourself in that situation, or even if you just like the idea of an intensive growth path within FDA, I highly recommend an Agency program, the Leadership Development Program. The opportunity to apply for the program comes only once every two years, and that time is now.

On June 1, an e-mail was sent to everyone announcing that applications will be accepted for the FDA Leadership Development Program through July 27. The LDP entails training and developmental assignments, generally consuming 12 months, to be completed within an 18-month span. While participants keep their current jobs, they spend only about a third of the time actually in their offices.

Participants' developmental plans are tailored to their individual needs and goals. They generally complete four developmental details of 30 to 90 days' duration each during the program. Most of these details are outside their home organization or center. A wide range of training courses is also available.

All headquarters-based participants serve at least one detail in an FDA field office, and field participants come to headquarters for one assignment. However, those are minimum requirements, and it is not unusual for a participant to take a developmental assignment overseas.

The LDP is highly competitive, with only 15 slots available every two years from throughout the Agency. It is open to all permanent FDA employees in grades GS/GM 12, 13 or 14 and Commission Corps O-4 and O-5. It is paid for and coordinated by the FDA's training division and is guided by an Agencywide committee, soon to be chaired by **Dan Casciano** from the National Center for Toxicology Research. The committee has representatives from each center and Office of Regional Affairs, plus EEO and other Commissioner-level components. This committee interviews the candidates and makes the selections.

Graduates of the program are enthusiastic supporters and are glad to talk about their experiences. Before applying to any developmental program, it is wise to talk with some graduates to get a first-hand view of how it helped them, what they liked most and least about the experience and to find out if it is right for you. I have been the CDER representative on the committee for more than a decade, and I am always happy to advise CDER applicants on the process.

There was a joint CDER/CDRH forum on June 28. If you couldn't attend, just ask me for more information, and I'll be glad to talk with you about the program (MORRISONJ, 4-5443).

Applying to the program is in itself a valuable learning experience, because it makes you think about your career goals and how you plan to attain them. If you don't apply now, you'll have to wait until 2003.

July 6, 2001

Reserve Disdain for Supermarket Checkout

BY JIM MORRISON

About the only enjoyment I get from shopping at the supermarket anymore is reading the headlines of the tabloids while waiting at the checkout counter. It's the only way I can catch up on the latest Elvis sightings and the mating habits of extraterrestrials. It's amusing, because the stories are so over the top that they don't threaten my smug comfort in my own knowledge base.

Reading serious scientific publications, on the other hand, can be an unsettling experience. Every new issue of *Scientific American* pokes a few more holes in my intellectual armor, which by now has more patches than the Mir space station before it burned up in the atmosphere.

We like to think that we are enlightened and open to new ideas. After all, that is the essence of science. We in CDER frequently express our openness to and nurturing of new concepts in drug development. But on an individual level, when new ideas clash with our personal concepts of reality, problems can arise.

It's easy to understand why we are loath to abandon old ideas for new ones. A lot of our inner tranquility and peace of mind comes from a confidence that we know certain things about how the world works. Then someone comes along and pulls a loose thread in the fabric of our knowledge. We see our protective clothing start to unravel, and we react defensively. This phenomenon is universal. Consider, for example, how long the Australian researcher, Barry Marshall, had to struggle to get the international medical community to accept his proof that *H. pylori* causes most ulcers.

When we come upon a new therapeutic entity, it's only natural to try to fit it into the fabric of our previous experience. It's unrealistic to expect that we can deduce the mechanism of action of such a new entity, but we all try. We try despite knowing that many drugs make it all the way through development to approval and marketing, and we still don't have a clue about their mechanisms of action.

Clearly, an investigational new drug should not be put on clinical hold simply because the reviewing division finds the drug's postulated mechanism of action implausible. However, it wouldn't be totally irrational to argue that if a proposed remedy cannot possibly work, and if it carries any risk, then it is unreasonable to allow patients to be exposed to it. But if the assessment that it cannot work is erroneous, then it is unreasonable not to allow patient exposure to it for clinical studies.

Thus, the difference between a drug regulator being a heroic public protector or a dangerous obstruction to the public health can be the quality of his or her knowledge. Unfortunately, it is one of life's persistent truths that we all know substantially less than we think we know.

There is a lot of room for judgment in drawing regulatory lines and in weighing benefits and risks. In using our judgment, we inevitably involve our own values and biases. We can't eliminate them, but we can be aware of them and keep them from exerting an inappropriate influence on our decision making.

We must be careful that our own views and biases about a new drug don't color risk-benefit decisions, not only in initial Phase I trials, but throughout the drug review and regulatory processes as well.

September 4, 2001

Tolerance

BY JIM MORRISON

We in CDER are truly blessed to be a part of a multicultural, multiethnic and multidisciplinary staff working together toward a common mission. In this troubling time, as we try to comprehend the enormity of what has happened and what we as a nation should do, we all must keep in mind the vision of America as a land of opportunity and a sanctuary for peoples from around the world.

At critical times in America's history, we have lost sight of that vision. In searching for someone to punish for unprovoked attacks, whether it be Pearl Harbor, the hostages in Tehran or the World Trade Center and the Pentagon, some have lashed out at those whose only connection with the perpetrators was a religion, a skin color or an ethnic ancestry.

We can be assured that our leaders are taking actions that will bring the real perpetrators and their abettors to account. These actions, as the president has made clear, will take time.

In the meantime, we may see acts or hear expressions of religious or ethnic intolerance. Such intolerance stems from ignorance and from a lack of close contact with people in whatever group is being disparaged.

Thinking back to the Oklahoma City bombing a few years ago, when the perpetrators were identified, we did not hear of incidents of intolerance against white males. I believe that was because everyone knew many white men who were good, so that the evilness of the act was

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associated only with the individuals involved and the fringe organizations that condoned the bombing.

Because we in CDER have daily contact with people of all races and religions and witness their enormous contributions to American society, we tend to forget that many of our fellow citizens do not. Each of us, especially those of us who are not of the Islamic faith or of Middle Eastern ancestry, should accept as a moral imperative to speak out against any intolerance. When we do, we will be paying homage to the victims of the attacks, who are of all races, religions and ethnicities.

I have not heard of any incidents of ethnic or religious intolerance in CDER following the recent attacks, nor would I expect such incidents here. But if anyone has ideas about how CDER can help in combating such intolerance in the larger community, please e-mail me (MORRISONJ).

November 1, 2001

Annual Report: Process Problems, Unfairness Top Complaint List

BY JIM MORRISON

Recent history is counted as the time before Sept. 11 and the time since. This annual CDER Ombudsman's report is mostly from before that fateful day. It's too early to tell what effect, if any, the attacks will have on the rate or kinds of complaints in the future. Therefore, this report reflects business in the good old days.

The number of cases and complaints stayed within the ranges experienced in past years, except that e-mail traffic rose again an estimated 20 percent. In keeping with the trend over the past two years, internal complaints represented only about 1 percent of my work. I tabulated the external complaints using the same categories as previous years for better trend identification. As you can see, the percentages in each category were consistent with the preceding two years, but there are some apparent trends worth noting.

External Complaints	FY 1999	FY 2000	FY 2001
Process problems or inadequate information about them	36%	42%	41%
Unfairness of a policy or decision	38%	30%	37%
Untimeliness	15%	12%	11%
Difficulty gaining access	5%	6%	9%
Uncivil or unhelpful interactions	3%	6%	2%
Miscellaneous	3%	4%	1%

First, it was gratifying to see that the previous upward tick in uncivil or unhelpful interactions was reversed. I hope we are on our way to reducing it to zero. Complaints about timeliness continued to decrease, not only for user fee applications but also for generics.

On the negative side, the biggest increase in complaints this past year, both in percentage and importance, was the access issue. Most of these involved a failure to grant timely meetings or a failure to return phone calls within a reasonable time. Some of the process complaints also involved meetings. These included inadequate or late minutes, failure to resolve disagreements about what was said and other deviations from the meeting MaPP, which is available at http://www.fda.gov/cder/mapp/4512-1.pdf.

Complaints about meetings came from all segments of the drug industry, large and small firms alike. In talking with project managers, it is clear that meetings and minutes of meetings are a tremendous workload burden. The Center holds more than a thousand meetings a year with sponsors of new drug applications.

People in industry devote a lot of resources to preparing for and participating in these meetings, because they view them as absolutely vital to the drug development process. Whatever resources we spend on assuring that all parties walk away from the meetings with the same messages is well spent.

As I have said before in this column, well-written and timely minutes that reflect the understanding of the participants can save months of work for us and the applicants.

If you have a complaint or a solution to a problem, please send me an e-mail or give me a call (morrisonj@cder.fda.gov, 301-594-5443).

December 6, 2001

New Year's resolutions

BY JIM MORRISON

Admittedly, New Year's resolutions are not exactly innovative fodder for a column at this time of year. I have my personal list, which I'm not sharing; but this one is a list of resolutions for my work life. If you like them, feel free to borrow some or all of them.

I resolve in 2002 to:

- **Change the public's image of government.** Not by fiat, not by using PR, but by doing simple things better, faster and more thoroughly than the public expects. I want people who contact me to be startled by how fast I return their calls, answer their e-mails and give them useful assistance or information. It's also satisfying to hear the transition in people's attitudes as they go from expecting bureaucracy to finding help.
- **Take time to listen and to care.** I'm required by my job to care about others' problems. I aim to do that better this year. The world would be a lot better and my job would be easier if everyone took time to empathize.
- **Improve my environment.** I don't mean clean up my office; although, that would be a change. I mean noticing the little things that impede doing my job and changing them. It may be seeing a need for a particular type of data that isn't on the CDER Web site and doing something about it. Whatever the impediment, it's often surprising how simple it is to remove the small annoyances we put up with daily.
- **Resist the urge to overpromise**. This is a hard one for me. I tend to underestimate the time it will take me to do a given task. I'll try to compensate in advance by adding a fudge factor into any time frame I promise as a completion date. People are impressed and grateful for work done within the promised time. They get annoyed at delays. I can prevent those annoyances by making realistic promises.
- **Take responsibility.** When something goes wrong, my first instinct is to look for a logical cause that is outside of my control. I need to remember that people don't expect perfection from human systems. They'll trust me more in the long run if I own up to mistakes and problems, whether they are mine or belong to the Agency. People accept an admission that an error was committed. They get angry at anything that smacks of blame shifting or lame excuses.
- **Keep an open mind.** I generally pride myself on having an open mind. But those pesky biases creep back in if I don't work diligently at keeping them out.
- **Learn.** Continuing education sometimes gets forgotten in the press of daily work. But in this job, I either learn new skills and knowledge or I become obsolete. I want to devote some part of each day to learning—not gossip or rumors—but real stuff.
- **Value my colleagues.** I often have reason to be proud of the people who work for CDER. Although I get lots of complaints, when I look closer, I frequently find that my colleagues did all that could be expected of them and more. I'm proud to be associated with CDER, and I need to celebrate it more.
- **Enjoy my job.** None of us knows what will happen next. Sept. 11 certainly brought that message home. So in the precious time I have here and now, I need my work to be enjoyable. I'm fortunate to say that mine is enjoyable, satisfying and meaningful. If it becomes less than that, it's time to find something that is enjoyable.

May this year be your best ever.

March 4, 2002

If you don't know the rules, who does?

BY JIM MORRISON

Every time I go through the annual agony of doing my taxes, I marvel at the arcane minds of CPAs and of the programmers who devise tax software. I frequently wish there were a software program called *FDA Rules for Dummies.* Let's face it, keeping up with the changes in the laws, regulations, guidances, MAPPs and policies we work with every day is a Herculean task. It is made somewhat easier by the information contained on FDA's Web site and other Internet resources.

Unfortunately, with the increasing exodus of staff with institutional memory, those of us who are left have fewer people we can go to for easy answers. That leads, inevitably, to an increasing number of problems caused by either ignorance of the rules or a lack of experience in interpreting them. That, in turn, leads inevitably to an increased business for the ombudsman.

There are some critical rules that can make a big difference to consumers and to those we regulate if they are ignored or improperly interpreted by CDER staff. Some examples include the rules for:

- Fast track or accelerated approval.
- Pediatric testing and exclusivity.
- Orphan product exclusivity.

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- Importation of drugs for personal use.
- Drug manufacturing and quality standards.
- Patent certification for generic drugs.

There are numerous others as well.

No matter what we do or how we do it, there are more people looking over our shoulders than ever before. The news media daily make the public and us aware of our impact on the public health, drug costs and the financial markets. While that has always been the case to some extent, in recent years the public awareness of our activities has increased. The anthrax attacks last fall have also heightened the public's awareness of and expectations for our role in drug regulation.

Whether we are dealing directly with the regulated industry and the public or whether we are scientific reviewers or researchers tucked safely away in labs and offices, none of us can afford to be ignorant of the rules under which CDER operates.

These rules create public expectations that affect our organizational priorities and how we accomplish our mission. Ultimately, they affect how each of us does our work.

Realistically, we cannot individually know every law, regulation, guidance and policy that guides the Center. However, we must have a general knowledge of what rules exist, where they are written and who to ask for advice about their application.

It is also helpful for us to know our larger environment and a little about the forces that impact the Agency. Above all, I urge everyone to be honest about the extent of his or her knowledge. It is no sin to say you don't know. However, winging it can land you in deep trouble.

Fortunately, we have some good resources to help us keep abreast of the rules, policies and environment. The FDA Web site has been improved by replacing its original search engine with Google. Just remember that you sometimes have to search the FDA and CDER sites separately, since you may get some different hits with each.

You can search the Food Drug and Cosmetic Act, other laws enforced by FDA and FDA regulations by going to the Reference Room heading on FDA's Internet home page at http://www.fda.gov/.

The FDA intranet, available to FDA employees only, has a way to keep abreast of the latest news via the Clips, put out daily by the FDA's Office of Public Affairs at http://intranet.fda.gov/clips.

Of course, CDER's Web site has all the guidance documents, MAPPs and policies you need to refer to. The CDER weekly report, circulated by e-mail and posted on the CDERnet lists updates in regulations and other new documents.

Unless we make these resources part of an ongoing learning effort, however, they are of little avail. And, as always, I strongly recommend that if you don't feel fully up to speed on an issue, regulation, guidance or whatever, please ask someone who is.

July 24, 2002

Conspiracy theory

BY JIM MORRISON

On the heels of every rash of overblown promises by companies or individuals touting panaceas for the world's ills, comes the day of reckoning. In the day of reckoning for promising drugs comes the epiphany that FDA thinks they don't work—or at least haven't been shown to work. The day of reckoning is soon followed by the day of deflection and the conspiracy theory.

Now, I'm not thinking of any specific case, because there are more than enough examples in the media. It has become commonplace for the beleaguered company, whose stock price rocketed on whispered results of testing for a new drug that would cure cancer, stroke or hangnails, to blame FDA when it all falls apart.

The Web chat rooms are then soon filled with speculation about how big competitors and FDA conspired to block the drug. When the conspiracy theorists get really going, they may include the AMA in the cabal, since if all diseases were cured, doctors would be out of business. Sometimes the conspiracy is given credence by the news media, usually through less than thorough fact gathering.

Face it—we all believe what we want to or are conditioned to believe. We need our heroes and we need our villains. Heroes should be individuals acting in the face of insurmountable odds. Villains should be powerful people or organizations over which the public has virtually no control. That is where FDA comes in. If you are sick, it is more comforting to think that a cure for your illness is out there. It is just FDA that stands in the way of your survival. That leaves the door open for individuals to fight FDA and its co-conspirators, to get the drug released and the patient cured. That allows the helpless to take hope and to take action. It is not comforting to find that the company or people pushing the drug company stock lied, that there isn't any cure and that the patient will die (or that the investors were scammed out of their money).

FDA gets blamed either way. If we approve a drug that is later found to have unexpected side effects, we

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are criticized as being too fast and sloppy, in the hip pocket of industry or worse. If we fail to approve a drug, we are accused of being overly bureaucratic, stupid and causing the financial markets to collapse.

We in FDA should accept as inevitable that our organization and we as individuals will occasionally be painted as villains. It's the price we pay for taking action in the arena of public health. But it is necessary for all of us to be careful about what we say and to whom.

Further, if we see a drug that is yet to be approved but is being promoted by the sponsoring company far beyond its therapeutic value, we should convey that information to CDER's liaison with the Securities and Exchange Commission—**Debbie Henderson,** director of the Office of Executive Programs. The SEC has the authority to take action if the promotion is coming from the company and if the company has not truthfully informed stockholders. We should also alert DDMAC, because, if the promotion is coming from the company, it may be illegal.

Patients, patients' families, investors, stock analysts and reporters should do their homework and not believe pie-in-the-sky promises of a breakthrough drug that is just around the corner if only FDA would get out of the way. True breakthroughs do happen. Unfortunately, they happen far less often than people hope for. When they do occur, FDA is usually willing and able to speed them through the review process. Everyone should recognize that FDA cannot legally disclose information about pending applications.

What are purported by rumor mills to be leaks from FDA almost always come from within the company, the researchers or elsewhere. If anyone has substantial evidence of an FDA employee leaking information, report it to the FDA's Office of Internal Affairs (7-0243). It is a crime, punishable by dismissal and perhaps prison for FDA staff to leak such information. Conspiracy to break the law is a crime, and, fortunately, is also one rarely committed by FDA employees.

August 30, 2002

Risk management is our job

BY JIM MORRISON

One truth has been etched in my brain since I became an ombudsman seven years ago: You cannot please everyone.

Often the mistrust of governmental risk-benefit decision-making and risk management stems from a natural dichotomy between societal risk/benefit and individual risk/benefit.

For example, a mentally competent citizen may want to be able to make informed decisions about a full range of risks that he or she may assume. That position suggests that even risks that appear unreasonable for society at large should be available to individuals, but with sufficient information for them and health care professionals to make intelligent decisions.

Government generally sees its role as protecting the health and welfare of society as a whole. However, a substantial segment of the public expects to be protected from what they personally would consider unreasonable risks. Moreover, there is such a wide variation in the risks individuals are willing to accept that whatever decision the government makes regarding acceptable risk is doomed to attract criticism.

By eliminating risks that are unreasonable for the majority of its citizens, a government appears paternalistic to that subset of the population who want to make their own decisions and for whom the benefits may outweigh the risks in particular instances.

When the government makes decisions for its citizens, it automatically imposes value judgments that do not reflect the views of everyone. For example, when faced with evaluating a new drug that shortens life but improves the quality of life, conventional wisdom usually favors prolonged life over quality improvements. However, some terminally ill patients may not agree.

These reasons and more underscore the importance of CDER's risk management initiative. Without some clearly stated operating principles in risk-benefit decision making, CDER policy makers will be second-guessed by the press, the public and health care professionals. The worst scenario, as we have observed, is a risk-benefit decision altered *post facto* in the wake of media pressure. It is imperative that CDER clearly state the bases for its risk-benefit and risk management decisions and to make its decision-making transparent.

In theory, it is wise to allow the public to determine the amount of risk that is acceptable to them. However, which public should determine acceptable risk? Is it the public that won't tolerate the miniscule risk posed by saccharin? Or is it the public that downs a myriad of prescription drugs they buy online without consulting a physician?

Increasing the responsibility for risk-benefit decisions of individuals and their health care professionals, if the Center takes that course, requires more useful information about drugs than is currently available in labeling. It also means a willing acceptance of that responsibility by the public and health care professions. So far, there does not appear to be a public consensus to

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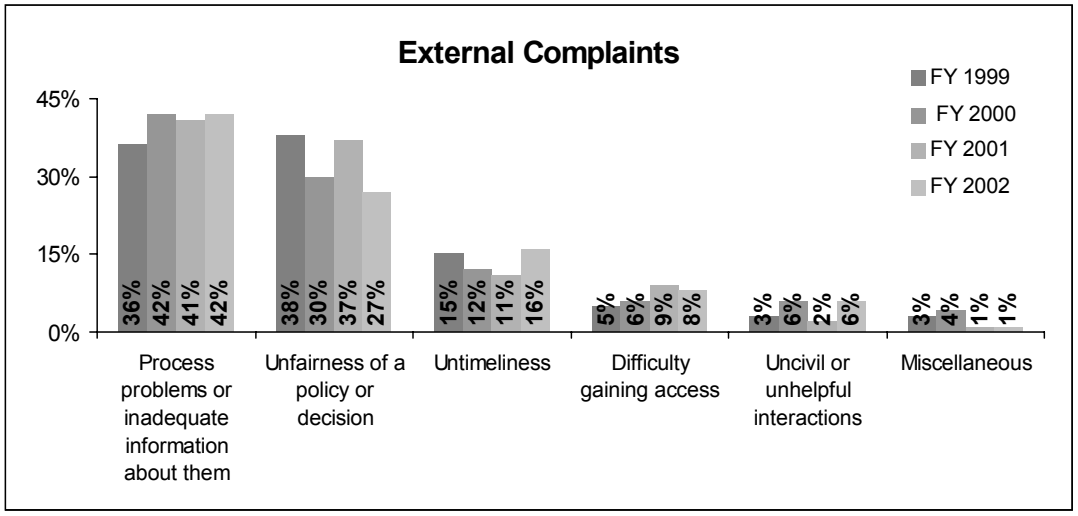
accept such increased responsibility.

Clearly, CDER's increased emphasis on risk management is most welcome. Part of our job will be educating the public and health professionals about the true risks and benefits associated with drugs. It also means that we need to come to a consensus within CDER about how we define acceptable risks for society. To that end, it is incumbent on each of us in CDER to understand the principles of risk management and to engage in learning opportunities and discussions within CDER and in other forums.

October 31, 2002



Annual report: Process issues remain on top of complaint list

BY JIM MORRISON

In my last annual report before leaving for pastures, greener or otherwise, I was hoping I could report that we had made significant progress in eliminating some of the more troublesome problems of the past.

Alas, that was not to be.

The number of cases and complaints rose moderately this past year, as did e-mail traffic. Of some concern was a significant rise in internal complaints, which, while still low, may reflect the cumulative effect of turnover in CDER's middle management, coupled with stress brought on by the increasingly tight timeframes of PDUFA II. Many reviewers and managers in CDER have felt pushed to their limits of capacity for workload and look forward to the added resources and realistic goals contained in PDUFA III.

As has been my custom, I tabulated external complaints according to six categories by percentage of total complaints. I compared the figures with three previous years to show trends better.

There are some trends worth noting. Unfairness became less of an issue, and timeliness bounced up, as did unhelpful interactions. I think these changes are further evidence of the workload stress that accompanied the last year of PDUFA II. I'm happy to report that complaints about uncivil interactions have dropped, and that the category was composed of the less offensive "unhelpful" variety of interactions.

Difficulty gaining access to CDER staff, in the form of meetings denied, phone calls not answered and late responses to correspondence (as well as delayed meeting minutes), has continued at an undesirable rate. At times this past year I have been snowed under, and I can sympathize with staff who just can't find the time to respond. But we really need to devote an extra effort to being more responsive. The people who try to contact us deserve better.

I plan to write one more column before I leave, but I would be remiss if I did not take this opportunity to thank the many people in CDER who have made my seven years as Ombudsman a truly rewarding experience. **Janet Woodcock** is at the top of my list, because she has strongly supported and appreciated the ombudsman function. The Center has made great strides under her leadership and will continue to do so in the future. I have received universal cooperation and help from CDER management and staff, for which I have been most grateful. Even the vast majority of those who have found themselves the subject of complaints have been forthcoming and cooperative, and, I hope, they have found it helpful that the role of the ombudsman is to

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listen to all sides of an issue and to get it resolved without recrimination or assigning blame.

All this thankfulness naturally leads to the question: "Why am I leaving?" Because it's time. In my 37 years with the FDA, I have never spent more than seven years in any one position. So it feels right for me to exit at this time. I don't know exactly what I'll be doing next year, but I have more goals and interests than I have time. Even after I depart, the people in CDER and their mission will always have a special place in my mind and heart.

We will be working to make the transition to a new ombudsman as smooth as possible, so stay tuned for more information.

December 31, 2002

Some last thoughts from the old ombudsman, in with the new

BY JIM MORRISON

In this, my final column and the first *Pike* issue of the new year, I'll give you some parting thoughts and introduce my replacement. I could write a book about the changes I have seen in drug regulation since I joined the agency in 1965. Trying to leave you with some meaningful thoughts in a 700-word column is challenging, but here goes.

In 1965, medicine was very paternalistic. It wasn't uncommon for physicians to tell terminal cancer patients that, "there is always hope." And patients believed them, because they wanted to. The FDA had just been revamped to include effectiveness as well as safety in the evaluation of new drugs, and clinical studies were regulated in the wake of the thalidomide tragedy. Fundamentally, the system was designed with the FDA acting as a funnel with a filter through which all products must pass before reaching the market. But later that model started to fall apart.

The public became more educated, and the news media began routinely reporting preliminary results of pharmaceutical research. People demanded more candor from their physicians. As they became aware of potential treatments for life-threatening diseases, they realized that they did not have time to wait until the normal drug development process had been completed. When the AIDS epidemic reached a critical point, its victims became the militant vanguard of patients demanding treatment with drugs based on only preliminary signs of effectiveness and safety. While the FDA adjusted its rules accordingly, the demand for new, inadequately tested treatments increased. Patients learned how to research the medical literature themselves. Soon, patients with no alternatives demanded treatments that had been shown to work only in animals.

The end of the twentieth century saw the rapid adoption of the Internet, a new technology with the potential to change society as dramatically as did the printing press and movable type more than five hundred years earlier. In a few short years, the Internet went from a means for scientists to communicate to a common forum for international communication. It has changed the rules. Anyone, from Bangkok to Bimini with a hundred dollars can set up a Web site and accept credit card payments. And as yet, no government has been able to regulate the transcontinental flow of information and products moving with speed and relative anonymity.

The FDA's legal model of a filter preventing dangerous or ineffective drugs from reaching the consumer has been breached. While the legitimate drug industry needs the regulatory framework as much as the FDA needs companies to adhere to it, we cannot ignore the challenges posed by drugs marketed through the Internet.

The key to drug regulation now and in the future is information. Whoever has the most useful and informative Web site will be in the best position to influence the public's health care decisions. CDER has a good Web site now, which is a tribute to the staff who keep it up. However, we need to do much more to make it user friendly and to upgrade its content and timeliness.

The CDER site needs to go beyond the information contained in drug labeling. It needs to include a compendium on drugs and drug usage, perhaps through links to other sites as well, and it needs to explain the risks and benefits of drugs in language that the lay public can understand. That will require multiples of the current resources being put into the site. If CDER does not expend that additional effort, however, other organizations or commercial entities will become the premier sources for information about drugs. And that would be unfortunate indeed.

So much for the old Ombudsman. It has been a pleasure to serve CDER in that capacity and in other ways during my career here. **Warren Rumble** has agreed to take over the ombuds duties, at least until the position is advertised and filled permanently. His background as a NIH researcher and nuclear pharmacist, a program manager in CDER and a senior reviewer in the Division of Drug Marketing and Advertising gives him a good foundation for success. Most importantly, he has a warm and calm personality, an invaluable asset to an ombudsman. I know you will give Warren the same generous cooperation you have given me, and I wish him and CDER all the best in the future.

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