news along the pike

June 1997

Center for Drug Evaluation and Research

Volume 3, Issue 6

*Inside . . .*



*Pike's Corners . . .*



# CDER Transformation, GPRA Go Hand-in-Hand

**By Betty L. Jones**

In 1993, President Clinton and a bipartisan Congress passed the Government Performance and Results Act (also known as the "Results Act" or RA) as part of the "reinventing government" initiative. The purpose of the Results Act is to hold Federal agencies accountable for achieving program results; to improve the confidence of the American people in the capability of the Federal Government; to improve program effectiveness and public accountability by promoting a new focus on results, service, quality and customer satisfaction; and to improve internal management of the Federal Government.

Under the Results Act, each Federal agency must answer basic questions: What is our mission? What are our goals and how will we achieve them? How can we measure our performance? How will we use that information to make improvements? RA forces a shift in the focus of Federal agencies away from traditional concerns such as staffing and activity levels toward the single overriding issue of results. The Act requires agencies to develop a 5-year strategic plan, set goals, measure performance, and report on their accomplishments.

The most important element of results management is strategic planning. This is the starting point and foundation for defining what we seek to accomplish, identifying the strategies that will be used to achieve the desired results, and determining our success in achieving results-oriented goals and objectives. The development of a strategic plan helps to clarify organizational priorities and unify the community in the pursuit of shared goals.

FDA's first performance plan has a June 15, 1997, deadline for submission to the Department and covers Fiscal Year (FY) 1999. In April, Dr. Woodcock initiated the

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***1996 Leadership Fellows***

# Contributions to CDER Are Many

**By Mary Lambert**

CDER's first class of Leadership Fellows got under way last August. The program featured activities designed to heighten awareness of changes facing the Center. CDER's Fellows were also provided with leadership tools to foster the Center's continuous improvement efforts, information on "best-in-class" business practices, and opportunities to apply this knowledge to existing problems.

The Fellows developed projects to further the Center's strategic priorities. For example, a previous issue of *News Along the Pike* (Feb. '97) featured an article by **Karen Lechter**, a social science analyst and attorney in the Division of Drug Marketing, Advertising and Communications (DDMAC). Karen's project entailed an analysis of CDER's organizational assessment (Spring 1996). The objectives of this project were to assess the usefulness of the survey and to identify additional helpful analyses and opportunities for future assessments.

My project, featured in the April 1997 *Pike*, involved the development of new peer honor awards for CDER. **Nancy Smith's** development of the Master Reviewer Track program provided a professionally and scientifically

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***Joe's Notebook***

# CDER Transformation, GPRA Mean Nothing Without the People—You

First order of business, I am temporarily filling in as editor of *News Along the Pike* for Norman "Joe" Oliver. He has been on sick leave for the past few weeks. We are looking forward to his return.

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Now, on to the business of the *Pike*. We've all heard our senior managers talk about CDER's transformation goals. We've heard how important they are and what they will do for the Center. Now we're starting to see the big picture and getting a better understanding about how these transformation goals tie in to the Government Performance and Results Act. In a few words, both of these efforts will lead to responsible, less costly, more efficient government. CDER has proven that government can work smarter—our success under the Prescription Drug User Fee Act is ample evidence of this fact. But what do each of these initiatives mean to us, as employees? Neither of these efforts will work without each one of us doing our bit, after all we're the ones who are performing; we're the ones who are "converting to a community," "working collaboratively," "improving management and processes," and "developing and implementing plans to improve information management and technology."

And we're not just working to make the American drug regulatory system better, we're working to make the system better in other countries around the globe as well. We're partnering—"working collaboratively"—with Russia, Saudi Arabia and many other countries. These countries see that we are taking a good, hard look at how we do business and see that we are striving to make it work better. They see what's going on and they want our help. For example, Saudi Arabia is planning to implement a number of post-marketing surveillance programs modeled after CDER's.

What is it, though, that makes this system work? It's not CDER's transformation goals or the Government Performance and Results Act. It's people like **Bob Tonelli** and **Yuan-Yuan Chiu, Joel Aronson** and **Brad Williams, Paul Loebach** and **Roger Gregorio,** all of our 1996 CDER Fellows. In other words, it's you and me, working day-in and day-out to make our system the best in the world.

Lest we forget, however, our people are not just doctors, pharmacists, scientists, secretaries and clerks—they are humans, with human interests. In this issue of the *Pike* we learn about Bob Tonelli, a PHS pharmacist in the Office of Compliance. Bob doesn't just *enjoy* bowling, he's good at it, too. For those of you who know anything about bowling, rolling a perfect 300 game is a significant accomplishment. And what about CDER's own daredevil pilot, Russ Rutledge? Russ also works in CDER's Office of Compliance, but, alas, we learn that he's not perfect. Not one to let a little plane crash ground him, Russ was back in the air within a week of his little "accident"—cast and all.

The point I'm trying to make is this—laws and regulations define our responsibilities, but it's the dedicated, hardworking, fun-loving people who make this organization one that's respected the world over.

**—Kevin Ropp**


**news along the pike**

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

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

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

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***Ombudsman's Corner***

# 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." Compared 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 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.

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.

*Jim Morrison is the Center's Ombudsman.*

## 7,000-Year-Old Skeleton Bears Evidence Of Successful Trepanning

WESTPORT, Conn., May 22 (Reuters) - While it is known that trepanation has been practiced for centuries, archeologists have found what they believe to be "the earliest unequivocal evidence" of the successful use of the procedure in the skeleton of a 50-year-old man from more than 7,000 years ago.

In the May 22nd issue of *Nature*, an international team led by Dr. Kurt W. Alt of Freiburg University in Freiburg, Germany, describes the circumstances of the discovery that was made in 1996 at a stone-age burial site at Ensisheim in Alsace, France.

According to Dr. Alt, the skeleton's skull has two large trepanations, both of which show clear evidence of healing. "The case we describe is exceptional for several reasons," Dr. Alt writes. "[I]t appears to be the oldest healed neurosurgical operation known worldwide, its technical realization testifies to the high craftsmanship and well-founded anatomical knowledge of the surgeon, and the success of the unusual trepanations is established by the long survival of the patient."

***Administrative Management Corner:***

# AMCC Facilities Subcommittee—Making the Move Easy

**By Ruth Clements and Charlene Cherry**

Everyone knows how painful moving can be. In fact, some of us move as often as once per year. Although most moves cannot be avoided, they can at least be made less painful.

The Administrative Management Coordinating Committee (AMCC) Facilities Subcommittee is working to make this process more pleasant. A MAPP that explains the move process is being developed. When finalized, the MAPP will cover everything from who is responsible for each phase of the move (whether moving an employee, an office, or an entire division) to when you can expect the boxes and labels to arrive. Understanding how the process works, and who is responsible for what, may help alleviate some of the pain that accompanies moving.

The Subcommittee is also tackling voice mail. We have all had to deal with the irritations associated with this indispensable tool. The Subcommittee hopes to soon publish a document to inform CDER staff about how to request new voice mail service, change a voice mailbox, and other available options.

Finally, the Subcommittee plans to develop a "cheat sheet" for facility related issues. The cheat sheet will provide information on who to call for special cleaning, lights out, and other building-related facility issues that can disrupt daily work activities. Although these initiatives do not provide a permanent "fix," they do offer a step in the right direction.

The work of the Facilities Subcommittee demonstrates AMCC's commitment to improving how CDER does business. Other subcommittees include: Human Resources, Information Technology for Administration, Budget and Procurement, Payroll, Training, and Travel. AMCC welcomes your membership on any of these subcommittees.

Next month, look for a recap of the Administrative Retreat (June 11 - 12). We expect many good ideas to emerge from this first-ever gathering of CDER Management Officers, Management Specialists, and Program Specialists.

*Ruth Clements is the Director, Division of Management Services, and Charlene Cherry is Executive Secretary to the AMCC and the Chief, Management Analysis Branch, DPERM.*

***CDER's Bob Tonelli***

# Pharmacist by Day, Outstanding Bowler in 'Spare' Time!

**By Edward Miracco**

How many of you know someone who can lay claim to bowling a 300 game? That's 300 as in no-pins-left-standing-after-the-dust-settled perfection. There is one in our midst, and many of you probably know him. He's Bob Tonelli, disguised as a CDER PHS pharmacist currently in the Office of Compliance, Division of Prescription Drug Compliance and Surveillance.

Bob bowls and he bowls a lot. He bowls for fun. He bowls for profit. He bowls in tournaments. He bowls recreationally. He teaches kids to bowl on weekends. He loves the sport. It's easy to see this by his enthusiastic reaction when the topic turns to balls, pins and alleys.

Bob's passion for bowling began at the tender age of 5 in Boston where his dad started him in the Saturday morning candlepins kids league. For those of you unfamiliar with bowling nomenclature, candlepins is a type of bowling that uses tall, thin pins and a ball about the size of a grapefruit. It is a very difficult game, more difficult than duckpins, which uses shorter but heavier pins and a heavier ball, or tenpin bowling, the name given to the type of traditional bowling most of us are familiar with (which uses the more robust pins and ball). In candlepins the bowler gets three balls per frame and the dead wood (bowling vernacular for pins that have been knocked down) isn't removed until the end of the frame. A high average score is in the low 100's. Indeed, Bob says that hitting the #1 pin straight on in candlepins often results in only one or two downed pins. What he calls loads of fun, most of *us* would define as frustration.

In his teen years, Bob stopped bowling. He had other priorities and interests. But the fire came roaring back in his college years when he began his tenpin bowling in the Boston PHS hospital league. This was his "bowling-for-fun" period. The "get-serious" era arrived at about age 25. Although he never took a lesson, this is when Bob's game improved significantly and when he began participating in local amateur tourneys. He has never looked back.

Many of you probably know Bob. In the approximately 10 years that he's worked in CDER, he's had four different assignments—Division of Metabolism and Endocrine Drugs, Division of Drug Information Resources, Office of Generic Drugs, and now the Office of Compliance. Indeed, being a Public Health Service Officer for 28 years has resulted in numerous other moves including assignments in Savanna, Ga., his first duty station, Milwaukee, Indianapolis, Iowa City, Iowa, Baltimore, Staten Island, N.Y., and Hardin, Mont., where he worked for the Indian Health Service. But no matter where his peregrinations took him, the one constant, in addition to his family of course, was bowling. By his own estimates, he has visited several hundred different alleys and bowled tens of thousands of games.

Having been to so many places and bowled so many games, Bob, as one would expect, has experienced the thrill of victory and the agony of defeat. One of his most exciting moments was his first tournament victory. He was the fifth qualifier in a field that started with several hundred bowlers. This position required

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# FDA Prohibits Mammalian Protein in Sheep, Cattle Feed

The FDA announced the June 5 publication of a final regulation that prohibits the use of mammalian protein, with certain exceptions, in the manufacture of animal feeds given to ruminant animals such as cows, sheep and goats. The rule will take effect 60 days after publication.

This prohibition is a preventive measure designed to protect animals from fatal, transmissible degenerative diseases of the central nervous system such as bovine spongiform encephalopathy (BSE) and to minimize any potential risk to humans. No case of BSE has ever been documented in cattle in the United States. But if a case of BSE were ever found here, these measures would prevent the spread of BSE through feeds by precluding amplification of BSE in U.S. cattle. BSE is one of several transmissible spongiform encephalopathies (TSEs) that include Creutzfeldt-Jakob disease (CJD) in humans. In March 1996, the United Kingdom reported evidence of a new variant of CJD that might be due to eating meat from cows infected with BSE. So far, there have been at least 16 cases of the new CJD variant reported in Europe.

The current state of knowledge concerning TSEs is far from complete. The Agency is continuing its close collaboration with the scientific community and with pubic health officials, at home and abroad, on other measures to reduce the potential risk of these diseases. **Yuan-Yuan Chiu,** Deputy Director of CDER's Office of New Drug Chemistry, is chairperson of the Agency's BSE Working Group. Other Center staff on the working group are **Joel Aronson, Paula Botstein, William Berlin, Donald Carrington, George Chen, Florence Fang, Jack Longmire, Stephen Moore, Karen Oliver, Carol Vincent, Duu Gong Wu, Diane Wysowski,** and **Maria Ysern.**

In January, the Agency proposed a regulation that would have prohibited the feeding of ruminant protein to other ruminant animals. In a draft rule published April 17, the Agency expanded that prohibition to include nearly all mammalian protein. Like the proposal, however, the final rule allows the use of products believed to pose a minimal risk of BSE transmission. These products include blood, blood products, gelatin, milk, milk products, protein derived solely from swine and equine sources, and inspected meat products which have been offered for human food and further heat processed for food, such as plate waste from restaurants and other institutions.

By prohibiting nearly all mammalian protein from being used in ruminant feed, the FDA believes it has made the final regulation more practical and effective. Pure pork and pure equine protein are excluded because these animals are not known to have TSEs, and because the protein is processed so that it is not contaminated by potentially infective proteins.

In addition to prohibiting tissues with the potential to spread TSEs such as BSE, the final regulation also requires process and control systems to ensure that feed for ruminants does not contain the prohibited mammalian tissue.

The first case of BSE was reported in the United Kingdom in 1986. Epidemiological evidence suggested an association between the outbreak there and the feeding to cattle of protein derived from sheep infected with scrapie, another TSE.

***Pike Interview:***

# Brad Williams on the Road to Russia

**By Joe Oliver**

*Bradford Williams is Director of the Division of Labeling and Nonprescription Drug Compliance in the Office of Compliance.*

**The Pike has learned that you've been helping the Russians with their drug program. Is this true?**

Yes. Russia and the United States signed a Memorandum of Understanding in 1995. Under the agreement, the Russians will accept drug development work done here. When a drug company goes to register its product in Russia, they can supply the FDA approval letter. The Russians then don't have to review all the clinical data that we did in CDER.

**Is Russia the only former Soviet Union member we have an agreement with?**

No. We also have one with Belarus and are negotiating one with Ukraine.

**Why did this happen?**

When the old Soviet Union collapsed, the centralized drug manufacturing system they used collapsed as well. Under the old centralized system, a factory specialized in what it did best. Say, for example, a factory in Russia was good at making bulk pharmaceuticals. Well, that's all that factory would do. Another factory in Belarus might be good at making the finished product, and a third factory in the Ukraine would be good at packaging. So the product would start in Russia in bulk, be shipped to Belarus where it would be made into pills and then to a factory in Ukraine for finishing. When this centralized system fell apart, the individual countries ended up importing a lot of drugs. Public health officials in these countries have a great deal of confidence in drugs made in the United States.

**What is your personal connection with the agreement?**

I am the official U.S. correspondent for the agreement.

**These recent trips aren't your first experience in Russia are they?**

Actually, I first visited Russia in the summer of 1968.

**Are there a lot of changes?**

The basic landmarks are still there. When I first went, Russia was the "workers' paradise." The change is most noticeable at night. There used to be street lights for pedestrians, and hotels and restaurants would have one small, lighted sign to help you find them. Now the main street into Moscow looks like Times Square. The people are a lot freer and happier under the democratic system. Their public health officials are as concerned and committed as ever.

# Agency Staff Visit Saudi Arabia, Promote Post-Marketing Surveillance Programs

**By Roger Gregorio**

Agency staff members **Mary Doug Tyson**, associate director, Africa and Middle East, Office of International Affairs; **Paul Loebach**, computer specialist, Division of Data Management, CDER; **Ray Aldefer, M.D.**, Division of Pharmacovigilance and Epidemiology, CDER; and **Roger Gregorio**, consumer safety officer, Division of Prescription Drug Compliance and Surveillance, CDER, visited the Kingdom of Saudi Arabia May 22-27, 1997.

At the request of the Ministry of Health of Saudi Arabia, FDA planned and conducted a seminar on Post-Market Surveillance (PMS). The PMS seminar was the most recent FDA contribution to the U.S./Saudi Arabia Joint Commission on Economic Cooperation (JEC) in which FDA has participated since 1985. The Commission was established in 1974 and has been extended four times with the current extension continuing the JEC through the year 2000. Since its inception, the two governments have signed 36 project agreements—22 are current and 14 have been completed.

The seminar was designed to assist Saudi Arabian government officials in the development of adverse drug experience (ADE) and post-marketing drug quality surveillance programs. Dr. Artist Parker of Bristol Myers Squibb and Dr. Martin Ten Ham of the World Health Organization also participated in the seminar.

CDER staff presented an overview of the agency's MedWatch program and included details on the receipt, evaluation and follow-up of ADE and drug quality reports. Saudi Arabian health and industry representatives are enthusiastic about our programs and plan to implement a post-marketing surveillance program for reporting ADEs. After the ADE reporting segment becomes operational, they plan to expand the program to include the surveillance of drug quality problems. A Saudi health official will visit the United States in the near future for an on-site demonstration of the agency's ADE and post-marketing drug quality surveillance programs.

The FDA staff adjusted to the culture in a short period and a couple members "appear" to have enjoyed the tasty cuisine of a local kabob shop. FDA's Tyson made a definite fashion statement when adorned in an abaya—the local dress.

*Roger Gregorio is a consumer safety officer in the Division of Prescription Drug Compliance and Surveillance.*

# CDER's Tonelli Is Tops in the Alley

*(Continued from page 4)*

that he defeat all four higher qualifiers in succession. He defeated qualifiers four, three and two without much drama. But against qualifier number one, the contest wasn't decided until the final frame where Bob rolled three strikes for the win. In his luckiest moment, again in the finals of a tournament, his sole remaining opponent needed only to score a 17 in the last frame, that is, a spare and 7, to win. Hardly an impossible task for a quality bowler. He hit the spare and then inexplicably took down only three pins on his final roll. Bob stood victorious with a score of around 240.

However, for each favorable moment there are equivalent moments of disappointment. For example, Bob says that there have been a number of instances where, at a crucial time, he has left a pin standing after believing he had rolled a perfect ball. These kinds of mishaps have cost him several tournament victories. There are also occasions where Bob can look back and laugh. In one of these moments, a bowler a few lanes over had the ball slip from his hand and go crashing over, not one, but two adjoining lanes Wouldn't you know it, at the end of its trip to the wrong lane, the ball felled all 10 pins. Alas, neither the guy from whom the errant ball had originated, nor the person playing the lane where the ball came to rest, was credited with a strike!

So where does all this take us? Now, Bob enjoys bowling in National Amateur Bowling Incorporated (NABI) tournaments. These are what he calls amateur/professional tournaments, that is, tournaments in which the participants are not members of the Professional Bowlers Association, but which nevertheless pay cash awards to the winners. He finds these tournaments to be loads of fun and often financially rewarding. Most of the events in which he participates are in the Washington metropolitan area. Once a year, however, he travels to Las Vegas for the NABI national championship where the winner is awarded 40 thousand dollars. Bob was automatically entered into this year's competition and had his $200 entrance fee waived because he is the Tournament of Champions winner for the local NABI competitive area. Last year, he placed fourth in the Las Vegas NABI nationals out of thousands of highly capable entrants. This year, he hopes to do even better.

So there you have it, someone who strives for perfection, and has touched it. In a world full of mediocrity, perfection is both elusive yet at the same time fascinating and refreshing. To attain it in any endeavor is something to be cherished. So if you haven't been able to reach the pinnacle in some of your other activities, try bowling. It's never easy to be the best, but for the rare individual, like Bob, it may be within reach, and in any case the challenge will be plain and simple fun.

*Ed Miracco is a non-bowling consumer safety officer in CDER's Office of Compliance.*

# CDER Transformation, GPRA Go Hand-in-Hand

*(Continued from page 1)*
development of CDER's performance-based and outcome-oriented plan with the establishment of a GPRA Taskforce comprised of Betty L. Jones, Banks Johnson and Pamela Slatt Fagelson. Over the past two months, the GPRA Taskforce has worked with CDER's senior management to identify and articulate performance goals that align CDER's strategic vision with the Agency's strategic goals and links our program performance to the budget.

CDER's program performance goals reflect the strategic thinking of FDA and CDER management, the new strategies being used by programs to support the Agency's mission, and are consistent with CDER's four transformation goals. The performance goals are aligned with an Agency strategy that supports four strategic goal areas: Pre-Market Review, Post-Market Assurance, Internal Capacity, and External Leverage.

The Pre-Market Review goals focus on making timely and cost-effective pre-market review decisions while assuring product safety and efficacy. This cluster includes Prescription Drug User Fee Act (PDUFA) goals projected to FY '99 and supports the strategies of streamlining reviews, informing and assisting product sponsors, and focusing on high-priority reviews.

The Post-Market Review goals focus on strengthened assurance that products on or about to enter the market are safe. The cluster addresses the strategies of informing and assisting firms to achieve compliance, targeting high priority domestic and import risks, improving surveillance and follow-up on adverse events, maintaining inspectional visibility, and developing science-based product and process standards.

Internal Capacity goals focus on our capacity for effective pre- and post-market regulatory decisions. This cluster relates to implementing decision-supportive information systems, cultivating a highly qualified and motivated workforce, and achieving greater economies in facilities.

External Leveraging goals focus on augmenting the ability of external stakeholders to manage FDA-regulated risk. This cluster covers a particularly broad spectrum of activities which include partnerships that support the exchange of information and cooperative agreements with international and domestic governments related to surveillance and inspections, trade-related regulations and standards, harmonization of drug review standards and Good Manufacturing Practices. This cluster addresses the strategies of fostering industry quality assurance programs, supporting United States interests in setting global standards, empowering consumer choice through product labeling, and collaboration with Federal and state regulators to reduce health risks.

CDER's FY '99 Performance Plan has been developed and submitted to FDA. Twenty-four of CDER's goals have been included in FDA's FY '99 Performance Plan. FDA's responsiveness to implementation of GPRA has already been recognized in the Government Accounting Office - GPRA Report of June 1997 and on June 3, 1997, the *Washington Post* cited FDA as one of a few agencies that have adopted a disciplined approach to setting goals and measuring performance.

*Betty Jones is the deputy director of CDER's Office of Compliance.*

# Fellows Make Significant Contributions

*(Continued from page 1)*
meaningful career path for superior CDER reviewers. **Marianne Mann's** project assembled a group of experts in the field of wasting research. A workshop on the design of wasting trials (with participants from the United States and Europe) took place last month. Work continues on drafting FDA guidance documents for wasting trials.

**Clare Gnecco's** project involved cancer patients as observers of the CDER drug review process. The project established mechanisms for cancer patients to observe the development/ approval process. **Tim Ames** developed a Home Page on the World Wide Web for the Office of Generic Drugs. This project debuts this month at the National Association of Pharmaceutical Manufacturers Mid-Year Meeting and Educational Conference in Washington, D.C.

**Michael Kline** developed three MAPPS to ensure consistency in standards and procedures in reviewing new drugs with abuse/dependency potential. The first MAPP concerns drugs being reviewed under INDs, the second MAPP deals with drugs reviewed under NDAs, and the third MAPP involves responses to petition and international treaty compliance. A draft guidance for industry is also underway. **Ubrani Venkataran's** project involves electronic submission of Chemistry, Manufacturing and Controls Annual Reports (post-approval) using the World Wide Web.

These are only a few examples of the project activities for the 1996 CDER Leadership Fellows. Other projects have included computer skill competencies, medical/statistical review improvement, CDER transparency, and labeling issues.

Fellows are very appreciative for the support and assistance of the CDER community and others, without whom project activities would not have been possible. The CDER Fellows have expressed pride in having had the opportunity to contribute to the Center.

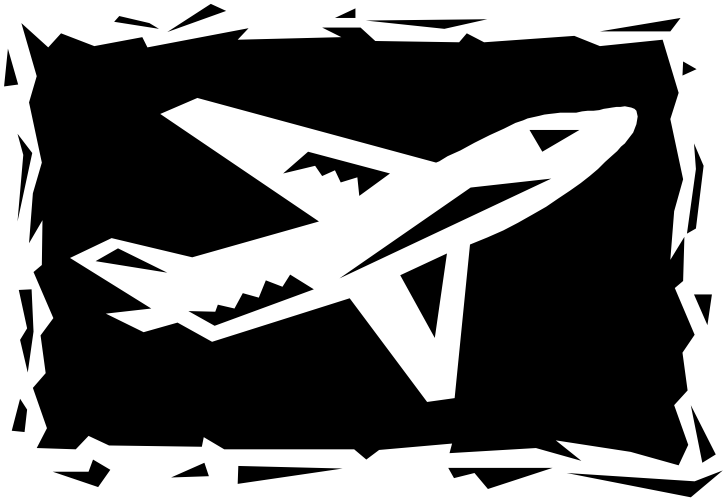
*Mary Lambert is a special assistant in CDER's Office of Training and Communications.*

# CDER's Red Baron Crashes And, Undeterred, Flies Again

**By C. D. (Russ) Rutledge**

Chief among my outside interests are scuba diving, flying and building airplanes from scratch. My current project has an efficient space-age design that features pusher prop, small wing in front (canard), and swept-back main wings with winglets. It can carry three people and cruise at 180 mph while sipping just 5 gallons of av-gas per hour. It has a proven design that is stall and spin resistant; the perfect "pocket rocket."

I recently helped a friend move a plane to Colorado. His plane has the same design as my dream machine so this was the opportunity of a lifetime. We planned to fly to Laramie, Wyo., on the first day, then with an early-morning start, thread the Rockies into Grand Junction. We left Martinsburg, W.Va., climbed to 8,500 feet to be above the clouds, then after clearing the Adirondacks, descended to take advantage of milder headwinds over the plains. Four hours later we landed at Logansport, Ind., and refueled. The new line boy had never seen a canard aircraft before and was tripping over his feet to get a closer look!



During the next leg, we had a minor incident when my friend accidentally hit the release lever and the canopy popped open about an inch. Fortunately, the safety catch held and we were able to close and lock it while still flying with few ensuing problems. Believe me, this will wake you up faster than any pot of coffee!

We reached Shenandoah, Iowa, circled the field, and set up to land on the longer runway. I was holding onto the thermos in one hand, maps and airport directories in the other, and my feet were tucked under the rudder pedals. While in the landing pattern, my friend let the airspeed get a little slow and the plane responded by getting sluggish while turning. I told him the altitude and airspeed and to speed up, but he kept saying that there was something wrong. I called out the airspeed and to speed up at three distinct points in the pattern. On the final approach, he did speed up a little, so I was not particularly concerned. We crossed a power line, but we were high and a little right of the runway. At this point he should have gone around, but my friend ignored me when I again told him the airspeed and to add power.

At about 150 feet altitude, the pilot reduced our power to idle, kicked the left rudder to line up with the runway, and the main wing lost lift. He pulled back on the stick, and I was yelling to add power when we pancaked onto the grass just short of the runway. We bounced over the runway lights, slid on the grass about 125 yards, and stopped just short of a ditch. It felt like a roller coaster ride. I remember hitting and feeling a sharp pain in both ankles but don't recall bouncing or sliding. I felt dizzy and wondered if we were upright or upside down and was relieved to see blue sky above. My next thought was about fire. I noticed that the switches were still on so I quickly shut them off. My friend had opened the canopy and was out by the time I finished. There was no fire, only deafening silence. I wasn't scared or angry, but I was incredulous that my friend had not added power for a go-around. The seriousness of the situation did not make an impression until several hours later, and I didn't sleep much that night.

Some very kindly retired folks stopped to watch us land when they saw us flying over the airport. They said that we had bounced about 15 to 20 feet. They drove us to the emergency room in a new Cadillac, and I tried hard to keep from bleeding on the new leather seats. These folks could not have been nicer or more helpful in going out of their way to help us. I had one broken ankle, one sprained ankle, a severely bitten tongue, mild whiplash, and various abrasions and bruises. My friend suffered mild whiplash and a bruised ego. I had to wear a plastic walking cast that made me look like a Star-Wars Stormtrooper (well, half of one). Because of my tongue, I could not eat, so I just sipped water for three days. We later found that we had made the highlights of the local evening news.

In retrospect, I credit the aircraft's design for saving our lives. The canard kept the nose high, which allowed the main gear and engine to absorb most of the impact. Likewise, the nose gear cushioned the blow when the plane slammed forward. Fortunately, the plane remained upright and did not cartwheel, so it can be repaired despite heavy damage. I am glad to have the chance to share my experience with you since few people survive a stall-spin entry.

Even though I got off lucky this time, it hasn't scared me away from airplanes. The next weekend I flew with another friend (an FDAer) in a rented Cessna. He has a pronounced limp, and with me still in the walking cast, we were a sight hobbling around the airport together. I hope we did not scare off any prospective student pilots. That flight was thoroughly enjoyable, but the plane seemed real slow after being used to a high-performance pocket rocket. I am looking forward to healing so I can finish building and keep flying!

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