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FLIGHT PHYSICIAN

A Publication of the Civil Aviation Medical Association

Volume 6, Number 3

June 2003



Tamisiea Award. Dr. Manuel Rico Jaime (center), receives the 2003 Tamisiea plaque from CAMA President Dr. Robin E. Dodge (right) and ASMA President Dr. Claude Thibeault.

This year's recipient of CAMA's top award, the Tamisiea Memorial Award, went to Brig. Gen. Victor Manuel Rico Jaime, M.D., "for his contribution in the application of the art and science of aviation medicine and to general and commercial aviation over the past 22 years..." Dr. Rico Jaime designed and implemented a primary course in aviation medicine for military and civilian AMEs in Mexico. He serves as an AME for both Mexico and the US Federal Aviation Administration. *FP*

The Aerospace Medical Elective

First aerospace medical elective in Arizona given birth by physician

BY DAVID BRYMAN, D.O.

AT THE DECEMBER 2002 CAMA Board meeting in Dallas, Dr. Dodge proposed that the board members consider contacting their local medical schools to discuss the possibility of offering medical students some lectures in Aerospace Medicine. The idea of introducing students to this subject was to broaden their educational experience and pique their interest in choosing Aerospace Medicine as a career.

Designing and implementing an aerospace curriculum intrigued me. I contacted Dr. McWilliams, Associate Dean of Midwestern University at the Arizona College of Osteopathic Medicine and presented him with a formal proposal and course outline. The curriculum committee met shortly thereafter and unanimously approved the

Continued on page 5

How Not to Perform a Flight Physical

Most pilots go to great lengths to comply with FAA medical reporting requirements. But, there are a few who will go to equally great lengths to conceal a serious problem. (Plus other potential pitfalls confronting each "new generation" of AMEs.)

BY STACY VEREEN, M.D.

The FAA flight physical: If it were a person rather than a concept, it would truly have my sympathy! It was doomed to unpopularity from the beginning.

Think about it! It's mandatory. It costs money. And the government regulates it. If that weren't enough, the findings from this

physical could swiftly bring an end to anyone's flying career or avocation. As AMEs or flight surgeons, we are called upon to perform this physical exam and use our findings to ultimately decide on three possible courses of action: deny, defer, or issue.

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Rebuilding a Premier Aerospace Medical Association

FOR SEVERAL REASONS, I feel that the effort expended to rebuild CAMA and its infrastructure over the last decade is showing signs of success.

1— CAMA is better known now so that when it is mentioned in a conversation, it does not evoke a blank stare.

2— The number and type of contacts or requests received at the Home Office. A number of these are from sources that have not previously been in the habit of dealing with CAMA.

3— The CAMA Sunday session held in conjunction with the annual Aerospace Medical Association scientific meeting.

The second annual CAMA Sunday was recently held in San Antonio. The quality of the speakers who agreed to give presentations and their general positive response to the event afterwards speaks well for CAMA.

This also indicates the planning orchestrated by Dr. Jack Hastings, was a professional effort.

We would like to see the audience grow a little faster, and are working on an improved advance notification system for next year when the CAMA Sunday will be in Anchorage, Alaska.

THE PRESIDENT'S THOUGHTS



BY ROBIN E. DODGE, MD

The current CAMA governance team does not condone the *status quo* as an acceptable attitude. Improving, updating, and developing new approaches—while ensuring that current solid practices are maintained—are the essential elements in moving an organization forward.

To this end, at the Board of Trustees meeting in San Antonio, an updated draft of CAMA's constitution and by-laws was reviewed. Also, an ad hoc committee was created and tasked to look into productive ways to engage fellow medical associations in meaningful dialogue about the role of front-line, primary-care physicians in dealing with the ill and injured flying public.

The Age 60 Rule continues to simmer along, coming to a boil periodically. Just prior to the recent Board meeting, CAMA was asked to comment on its current

“It is an exciting time to be a leader or member of a premier aeromedical association whose membership is on the front lines.”

position on the issue. The Board confirmed that the press release, as posted on our Web site, reflects our position and that it is not a medical issue.

The recent SARS outbreak combined with the depressed economic circumstances of the airlines, has created conditions ripe for major stress. This is particularly important for the Aviation Medical Examiner when dealing with his airline pilot clientele. The AME must be leery of the effect(s) that these stressors might have on the pilot's health.

All in all, it is a busy time to be involved with the aeromedical aspects of flight safety. However, it is also an exciting time to be a leader or member of a premier aeromedical association whose membership is on the front lines.

So, if you are not yet a member of the Civil Aviation Medical Association, visit our Web site's application page—

<http://civilavmed.com/ap.htm> and become an active CAMA team member.

Have a good, healthy, and safe summer.

FP

FLIGHTPHYSICIAN

A Publication of the
Civil Aviation Medical
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Report From the CAMA President-Elect

BY JIM ALMAND, MD

It is a pleasure to report the health of our organization. We continue to flourish. Our membership status continues to increase and the financial stability of the organization remains quite healthy. All CAMA-supported and directed educational programs and activities are on-line and excellently managed.

Your management team needs some input, particularly in the Secretary-Treasurer position, due to the illness of the current owner of that chair. However, your President is making steps in that direction.

Next, of particular recognition, is the success of CAMA Sunday scientific session, coordinated yearly with the annual Aerospace Medical Association meeting. Should it be possible, CAMA should further investigate mutual support in the meetings and programs sponsored by the Airline Medical Directors Association.

In conclusion, it's been quite satisfactory to watch the progress of CAMA's dedicated management team over the last year. The future of the association continues to look bright and secure.

Newsletter Progress

This year, the Civil Aviation Medical Association's *Flight Physician* has been the source of challenges, interest, perseverance, and a few hard knocks! Meeting deadlines of issues for the newsletter every two months has been a rewarding experience and has resulted in a very active voice for your membership, as well as outside aviation authorities.

I have recommended that the editorship of the CAMA *Flight Physician* be jointly served by both the appointed editor and the president-elect, with both terms to last concurrently and terminate at the end of the president-elect's two-year term. In such a format,

a greater appreciation of the mechanics of publishing the newsletter will be shared through the editor to the president-elect.

The president-elect will support the newsletter by actively contributing articles. Such rotation of duties of dual editorship of the newsletter on a two-year basis should result in "hopefully" a fresher turnover of ideas, editorials, aviation articles, and membership stimulus. A strong emphasis will consistently be needed in the securing of advertisements for the newsletter.

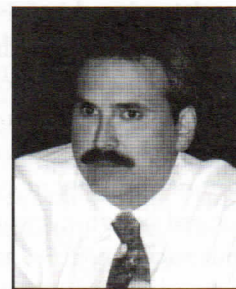
Most importantly, our biggest "editor-in-the-sky" — Executive Vice-President Jim Harris — is to be recognized as the greatest contributor to your *Flight Physician's* success!

Dr. Bryman New Co-Editor

A positive change is anticipated because Dr. David Bryman is now your *Flight Physician* co-editor. David is a prolific writer and has now begun lecturing an aerospace medicine course (which he developed) as an elective program at Midwestern University in Phoenix, as well as teaching in the graduate and undergraduate programs at Embry-Riddle Aeronautical University [see *Aerospace Medical Elective*, page 1].

Dr. Bryman is one of CAMA's active younger members with plenty of writing capability. Please help him along with your written article contributions.

FP



Dr. Bryman

PHYSICAL from page 1

Over my short years of AME work, I have, from time to time, made a few pilots very unhappy with my choice of action in all three categories. Lest you think it impossible to upset a pilot with the issuance of a valid medical certificate, I recount the following tale: Captain Heavy (whose name is fictitious, but which suggest nicely the type of equipment he flew, not to mention his habitus) came to me with mild asthma. Oh, this was no new problem. He'd had mild symptoms for years, but his asthma had been well controlled with an acceptable medication. This time however, things were different.

"Doc," he said, "I think I want to hang it up. I think I'll use my asthma to get an early retirement." After pulmonary function studies revealed that his asthma had definitely not worsened and, in fact, was better than ever, he was very unhappy.

"What if I quit taking my medicine? Would that do it?" he asked. I explained to him that there were, theoretically, many things one could do to achieve medical disqualification. Self-inflicted injury or the intentional mismanagement of a condition or disease or even the fabrication of symptoms would be possible, but such course of action would be unwise on two counts.

First, it could compromise his health, and second it would be relatively easy to detect. It would also be dishonest and would necessitate falsifying at least two documents: the FAA form 8500-8, and the disability forms from his airline.

Captain Heavy was somewhat less than exuberant over my interpretation of Western ethics, but he conceded, "The risks would be too great..." (This was, of course, his

interpretation of Western ethics and perhaps a more popular one at that.)

The lessons here are simple. When disability is involved, keep a modicum of suspicion and quantify all that you can. When there is a question as to the validity of a complaint, you don't have to confront or preach. Do what I should have done. Just say those magic words, "Well, we'll send all this in to the boys in Oklahoma City and see what they say."

One of the most tempting traps to fall into is what I call "certification on the come." That is when you issue a certificate on good faith expecting a hard copy confirmation of something or other. An example (regrettably from my own files) follows:

Sid Stone (not his real name, but if I tell you Sid was short for *residual*, it will begin to make sense later) called the office late one afternoon desperately needing a second-class flight physical. We agreed to "work him in," and so he was the last thing for me between a hard day and a hot dinner.

When I reviewed his history on the front of the Form 8500-8, I noticed 18J was checked and "kidney stone 2 years ago" was written in the comments field below it. Sid explained, "I had a pain in the right side of my back, so I went to my family doctor, and he did an X-ray. Later that night, the stone passed. I went back to the doctor the next day and he sent me over to the hospital to get one of those fancy X-rays with dye in your veins. Anyway, the X-ray showed that the stone had passed, and I have had no problems since then. Gosh Doc, I've got a job interview in the morning, and I have to have a current second-class medical to even get in the door! This isn't going to delay things is it?"

I explained that normally I would have to see a copy of the X-ray report to verify all this, but in this case, I would let him have a certificate that day if he would promise to have that report in my hands the next day. He promised that as soon as the job interview was over, he would comply forthwith. He was a man of his word.

The next day, he came to the clinic, smiling from ear to ear. He had gotten the job and he also had the records from his previous bout with renalithiasis. The radiologist's report of the IVP showed conclusively that he had passed the stone.

I would like to think I had been compassionate and that I did the right thing. I would like to think that, but I can't. The IVP showed two additional stones in the left renal pelvis. I was extremely lucky that everything turned out all right. He wasn't due to begin his new job for several weeks, so he opted to have lithotripsy in the interim, and we managed to get him recertified shortly thereafter.

What if he had taken to the skies and had an attack of acute renal colic? The point is ...verify THEN certify. The reverse is sometimes tempting, but it can lead to a real scare (or worse!).

Another variation of trying to put you on the spot is the "out of the blue" phone call. "Doc, I have a friend who just had a bypass. Does he have to report that to the FAA?" asked the caller.

"Well, of course," I replied. So far so good. But then the caller said. "Well, this friend also asked me what would happen if he didn't report it on his next flight physical. What can you tell me about that?"

I went into the standard diatribe about fraudulently filling out a government document, and then it sud-

Continued →

denly dawned on me to mention that the scar would prompt some pretty tough questions at the physical exam.

"Well, Doc, he's got a year and eight months left on his third-class physical (funny how he knew to the month the duration of this friend's physical) so he's OK 'til then, right?" was the next question.

"No, not right," I replied, "Read Part 61.53..."

"OK Doc, thanks a lot," concluded the conversation.

One year and eight months later, a 54-year-old private pilot, who had been getting his flight physicals with me for years, attempted to obtain third-class certification with a fellow AME. He reported no health problems, but did have a curious mid-sternal chest scar that he had cleverly attempted to conceal with an elaborate chest tattoo.

The lesson, of course: People will do anything for certification. *No one loves flying half so much as the grounded pilot.* The majority of pilots will go to great lengths to comply with FAA medical reporting requirements. But, there are a few who will go to equally great lengths to conceal a serious problem. Watch for these few! Very often these types will call an AME "out of the blue and ask if this or that condition or medication is approved." Armed with the latest scoop, they will visit another AME and fill out their paperwork accordingly.

Another easy goof-up is the pilot suffering from Historipenia, the poor historian. Consider the pilot with gingival hyperplasia. He presented with a "clean" history. That is, there were no "yes" answers on items 17, 18, or 19. He took no medicines and had no medical encounters. Since he was 66 years old, I asked him about his history. He said that everything was fine: i.e., no hospitalizations, no

serious illnesses, etc. I asked him about his gingival hyperplasia. "No medicines," he said.

I was about ready to chalk this one up to some sort of gum anomaly and go ahead and certify. But something prompted me to ask if he'd ever seen a dentist about his gums. He replied, "Nope, this gum problem has been with me since I was in my twenties. They say it's from my Dilantin."

But you said no medicines," was my immediate response.

"Well, Doc, I guess technically Dilantin is a medication but I've been taking it for 40 years."

"Oh," is all I could muster at this point.

I won't bore you with the rest of the details. The gentleman is happy. He flies with his son who is a commercial pilot, and who, of course, assumes pilot-in-command duties. As hard as it may be to believe, I think the omission was honest.

I have run into this same scenario several times with insulin, anti-hypertensives, and antidepressants. Many people who have been taking a specific medication for a long time (usually for some chronic condition) will fail to report it. This is not because of any attempt to deceive, but because they simply don't think of it.

Well, these are the ones I've detected. How many have I missed? I hope not many. The potential tragedy of even one medically-related accident is horrible, of course. The dividing line between flight safety and freedom to fly is not an easy one to draw, nor can it always be drawn with precision. Many pitfalls await us, so we must be ever vigilant. FP

Author's note: This piece appeared in the Fall of 1966. I resubmit it herewith because I believe that each "new generation" of AMEs goes through these pitfalls— and many more.

ELECTIVE from page 1

course as a ten-week elective. The students could be in any year of their training, as the course had no prerequisite requirements. Thus, the first aerospace medical elective in Arizona was born.

For course materials, I utilized a variety of videos, Power Point presentations, and handouts. I had accumulated most of these items while teaching at Embry-Riddle Aeronautical University and lecturing as a safety counselor for the FAA. I added useful information on flight physiology and aviation safety from the Aerospace Medical Association's Web site, as well as articles from the "Blue Journal." Pertinent, interactive case studies reinforced the new knowledge and maintained the student's attention.

We began the program by providing some background information on aviation and aerospace medicine history. We reviewed available residency programs and current requirements to obtain board certification. Case studies helped the students integrate textbook information with real-life situations, especially when we covered the physiological and psychological effects that space travel can have on the human body. We discussed how the musculoskeletal, vestibular, and cardiovascular systems are affected by the zero-gravity environment. They left with an in-depth understanding of conditions that can elicit hypoxia, hypoglycemia, hyperventilation, decompression sickness, and many others, and how the symptoms may present in the flight environment.

Continued on page 7

CAMA Members Recognized for Achievements at 2003 Aerospace Medical Association Meeting

WON CHUEL KAY AWARD

Sponsored by
The Korean Aerospace
Medical Association

The Won Chuel Kay Award is presented annually to a member who has made outstanding contributions to international aerospace medicine.

The recipient was SILVIO FINKELSTEIN, M.D. (Past President of CAMA).



AsMA President Dr. Claude Thibeault (left) presents the Won Chuel Kay Award to Dr. Finkelstein.

THEODORE C. LYSTER AWARD

Sponsored by
Lockheed Martin Space
Operations

The Theodore C. Lyster Award is given for outstanding achievement in the general field of aerospace medicine.



New AsMA Fellows.

Above: Dr. Hansrote and Dr. Claude Thibeault
Left: Dr. Wolbrink and Dr. Claude Thibeault

The recipient was CLAUD CURDT-CHRISTIENSEN, M.D. (Honorary CAMA Member).

FELLOW, AEROSPACE MEDICAL ASSOCIATION

Two CAMA members were elected Fellow in the Aerospace Medical Association. They were RONALD W. HANSROTE, M.D., and ALEX M. WOLBRINK, M.D.

**Theodore C. Lyster
Award Recipient.**
Dr. Claus Curdt-Christianszen and Dr. Claude Thibeault



ELECTIVE from page 5

One class was dedicated to the anatomy and physiology of vision and hearing, and how it could be affected in flight by hypoxia, fatigue, and alcohol. We covered visual illusions—including the black-hole effect, white-out effect, and landing illusions. Another class was dedicated to studying cockpit resource management, in-flight medical emergencies, and what medical equipment one might expect to find on board a commercial airliner. We discussed the possible costs of a medical diversion.

I presented accident scenarios and actual cases from the NTSB files on airplane crashes involving disorientation and situational awareness. The students (and the instructor) were amazed at the fre-

quency of accidents that involved CFIT (controlled flight into terrain) due to lost situational awareness. This helped them understand the limitations of human anatomy and physiology in the flight environment.

I stressed the complex interaction between our visual, vestibular, and proprioceptive systems and their importance as it relates to orientation. We explored the possible consequences to a pilot who is impaired by hypoxia, fatigue, dehydration, or over-the-counter medications. I showed the students a short video on pilots who met their fate due to the graveyard spiral, and other somatogravic illusions.

Throughout the classes, I tried to relate basic anatomy and physiology to the flight environment. For example, after discussing nor-

mal sleep cycles, we then discussed circadian dysrhythmia and how insomnia and fatigue might affect performance in flight.

The remaining classes covered aviation medical topics. We reviewed medical risks associated with air travel including: cabin air quality, communicable diseases, cosmic radiation, air rage, venous thromboembolism, and bioterrorism.

The last class discussed the general health of pilots and the medical certification process. We reviewed an 8500-8 form and listed conditions that could disqualify airmen from becoming FAA-certified. The students ended the course with a 100-question, written, take-home test.

The students have given tremendously positive feedback. Two students have already requested clinical rotations in aerospace medicine this summer. I am currently looking for facilities that will be able to provide them with practical experience.

I would like to share this curriculum with any CAMA members who are interested in teaching this course. As this is an original outline and my first attempt at teaching this topic, suggestions for improvement are welcome.

I've enjoyed this new teaching experience and look forward to my next class. It has been exciting to see so many young physicians share my interest in this field. I agree with Dr. Dodge— It is good for our organization and our profession as a whole to educate our medical students to ensure that the aerospace medical community will continue to grow.

FP

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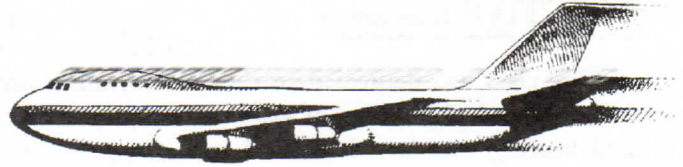
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By the
Board of Trustees
Civil Aviation Medical Association



FROM THE FLIGHT LINE

Fatigue Issues for Flight Crews

BY MARK BURMAN, PILOT- AMERICA WEST AIRLINES



How do flight crews and airlines prevent fatigue-related risks? A commercial pilot gives the low-down.

FATIGUE ISSUES for flight crews have existed almost since the dawn of time. Over the years, both aviators and the medical professionals that certify them as being fit to fly have become more and more aware of the negative consequences that can occur while pilots operate aircraft in a fatigued state.

In recent years, as the science of fatigue has advanced, terms like MSOT (missed sleep opportunity) and WOCL (window of circadian low) have surfaced to describe periods where fatigue might be prevalent. In the airline business, we use other terms to describe potentially fatiguing flights. Terms are used like Flip-Flop, Redeye, and the newest one, Black Flag (which is used to describe a set of flights conducive to fatigue). Whatever you call them, the risk factors increase for pilots operating these flights.

So how do flight crews and airlines prevent fatigue-related risks? At the airline where I fly, there is a big difference of opinion between the pilot group and management on this issue. While management has a written policy on fatigue and safety, in practice it appears that their commitment only goes as far as the pen. Let me give some examples of what I mean.

The written policy is that when pilots feel fatigued enough that they are not safe to fly, they are required to immediately call Scheduling and

get themselves replaced. Here is where problems start at my airline. Under our current contract, if a pilot "calls in fatigued," they will be removed from the flight or flights, but will not be pay protected. Yes, if you call in fatigued, you lose pay.

For many, this is a very strong incentive NOT to make the call. In truth, most pilots will call in sick (as there is pay protection in doing this) rather than call in fatigued, or they will just fly the pairing fatigued. The company continues to make the argument that the trips (or pairings as we refer to them) are not fatiguing, as evidenced by the very low number of fatigue calls.

Despite all of the data on sick calls and a study showing that over 90% of our pilot group has flown fatigued, the company stands behind its belief that a fatigue problem does not exist. They continue to cite the policy on calling in fatigued. The study of pilots also showed that about the same percentage, 90%, have fallen asleep while acting as a crew member while airborne.

Additionally, an equally large percentage indicated that they coordinate naps with other crew members on flights where fatigue is an issue. The company's response to this data was, for the most part, to question its validity.

The subject of fatigue is not germane to operations at my airline.

Every major airline deals with this problem. Some attempt to mitigate the effects of fatigue in late-night flyers by scheduling only one leg.

For instance, on a late-night flight from Los Angeles to Boston, the crew would have no other flights that day. At my airline, it is common to start your day at around 7:00 p.m. and fly three legs. The first from City A to B, next from B to C, finally from C to D. The flight from C to D is a late-night flight from the Western US to the East Coast.

This is the type of pairing called a *black flag pairing*. To alleviate the fatigue factor, our pilot representatives have consistently asked that the first two flights are flown by one crew and the late-night flight done by another.

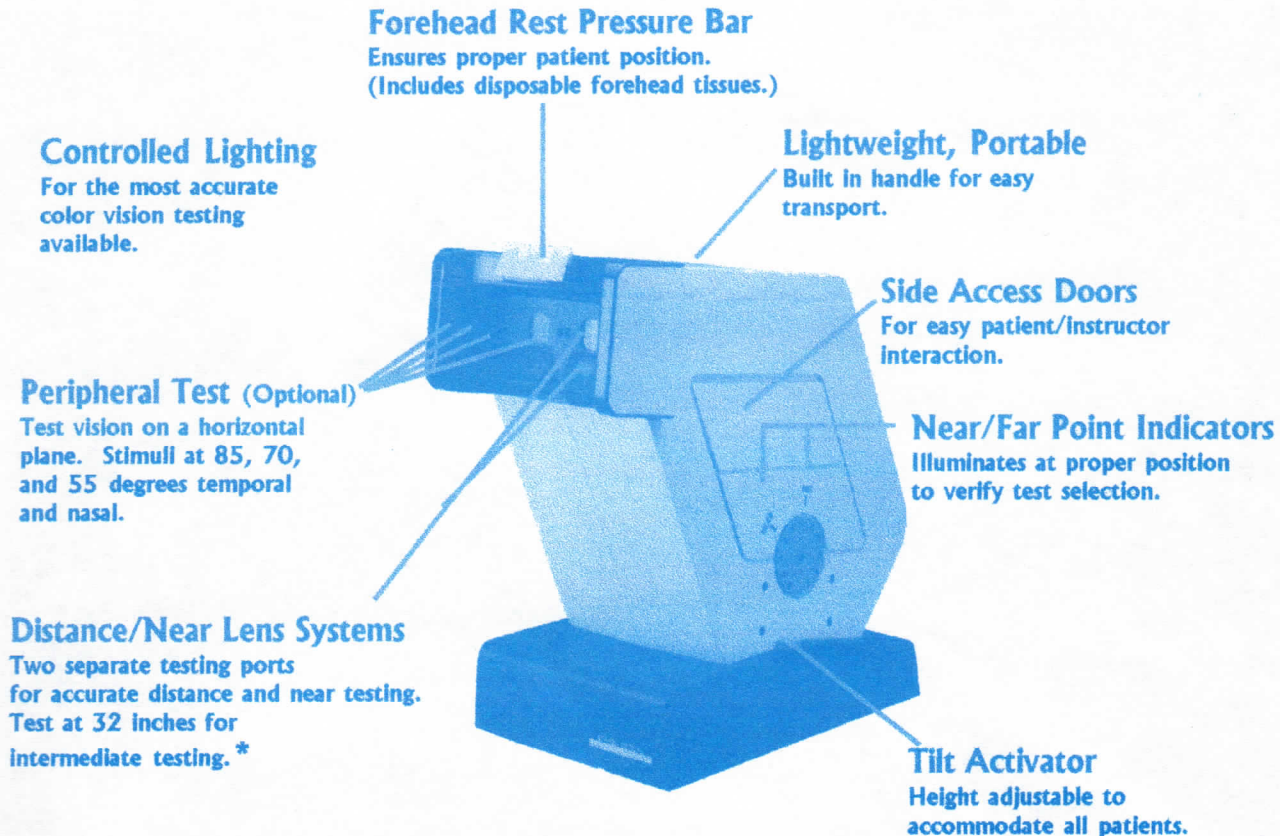
The company has maintained for some time that if the flight or flights comply with FAA regulations, then it is OK. From time to time, we see improvements; however, economics seem to dominate, and the black flag pairings continue.

Here is some more data to reflect on. At my airline, 27% of the trips assigned fly through a WOCL. Additionally, 50% of the trips assigned are identified as pairings, including MSOT. These numbers are derived using established criteria from NASA studies, as well as leading industry standards for fatigue criteria.

FP

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* This is a requirement for all airmen over the age of 50.

** These tests are required for F.A.A. vision exam.

For the relief of the nasal and non-nasal symptoms of seasonal allergic rhinitis (SAR) and perennial allergic rhinitis (PAR) in patients 12 years of age and older, as well as for the symptomatic relief of pruritus, reduction in the number of hives, and size of hives, in patients with chronic idiopathic urticaria (CIU) 12 years of age and older

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In allergic rhinitis, the most commonly reported adverse events included pharyngitis (4.1%, placebo 2.0%), dry mouth (3.0%, placebo 1.9%), and fatigue (2.1%, placebo 1.2%).

In chronic idiopathic urticaria, the most commonly reported adverse events included headache (14%, placebo 13%), nausea (5%, placebo 2%), and fatigue (5%, placebo 1%).

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TABLETS

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INDICATIONS AND USAGE: Allergic Rhinitis: CLARINEX Tablets 5 mg are indicated for the relief of the nasal and non-nasal symptoms of allergic rhinitis (seasonal and perennial) in patients 12 years of age and older.

Chronic Idiopathic Urticaria: CLARINEX Tablets are indicated for the symptomatic relief of pruritus, reduction in the number of hives, and size of hives, in patients with chronic idiopathic urticaria 12 years of age and older.

CONTRAINDICATIONS: CLARINEX Tablets 5 mg are contraindicated in patients who are hypersensitive to this medication or to any of its ingredients, or to loratadine.

PRECAUTIONS: Carcinogenesis, Mutagenesis, Impairment of Fertility: The carcinogenic potential of desloratadine was assessed using loratadine studies. In an 18-month study in mice and a 2-year study in rats, loratadine was administered in the diet at doses up to 40 mg/kg/day in mice (estimated desloratadine and desloratadine metabolite exposures were approximately 3 times the AUC in humans at the recommended daily oral dose) and 25 mg/kg/day in rats (estimated desloratadine and desloratadine metabolite exposures were approximately 30 times the AUC in humans at the recommended daily oral dose). Male mice given 40 mg/kg/day loratadine had a significantly higher incidence of hepatocellular tumors (combined adenomas and carcinomas) than concurrent controls. In rats, a significantly higher incidence of hepatocellular tumors (combined adenomas and carcinomas) was observed in males given 10 mg/kg/day and in males and females given 25 mg/kg/day. The estimated desloratadine and desloratadine metabolite exposures of rats given 10 mg/kg of loratadine were approximately 7 times the AUC in humans at the recommended daily oral dose. The clinical significance of these findings during long-term use of desloratadine is not known.

In genotoxicity studies with desloratadine, there was no evidence of genotoxic potential in a reverse mutation assay (*Salmonella/E. coli* mammalian microsome bacterial mutagenicity assay) or in two assays for chromosomal aberrations (human peripheral blood lymphocyte clastogenicity assay and mouse bone marrow micronucleus assay).

There was no effect on female fertility in rats at desloratadine doses up to 24 mg/kg/day (estimated desloratadine and desloratadine metabolite exposures were approximately 130 times the AUC in humans at the recommended daily oral dose). A male specific decrease in fertility, demonstrated by reduced female conception rates, decreased sperm numbers and motility, and histopathologic testicular changes, occurred at an oral desloratadine dose of 12 mg/kg in rats (estimated desloratadine exposures were approximately 45 times the AUC in humans at the recommended daily oral dose). Desloratadine had no effect on fertility in rats at an oral dose of 3 mg/kg/day (estimated desloratadine and desloratadine metabolite exposures were approximately 8 times the AUC in humans at the recommended daily oral dose).

Pregnancy Category C: Desloratadine was not teratogenic in rats at doses up to 48 mg/kg/day (estimated desloratadine and desloratadine metabolite exposures were approximately 210 times the AUC in humans at the recommended daily oral dose) or in rabbits at doses up to 60 mg/kg/day (estimated desloratadine exposures were approximately 230 times the AUC in humans at the recommended daily oral dose). In a separate study, an increase in pre-implantation loss and a decreased number of implantations and fetuses were noted in female rats at 24 mg/kg (estimated desloratadine and desloratadine metabolite exposures were approximately 120 times the AUC in humans at the recommended daily oral dose). Reduced body weight and slow righting reflex were reported in pups at doses of 9 mg/kg/day or greater (estimated desloratadine and desloratadine metabolite exposures were approximately 50 times or greater than the AUC in humans at the recommended daily oral dose). Desloratadine had no effect on pup development at an oral dose of 3 mg/kg/day (estimated desloratadine and desloratadine metabolite exposures were approximately 7 times the AUC in humans at the recommended daily oral dose). There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, desloratadine should be used during pregnancy only if clearly needed.

Nursing Mothers: Desloratadine passes into breast milk, therefore a decision should be made whether to discontinue nursing or to discontinue desloratadine, taking into account the importance of the drug to the mother.

Pediatric Use: The safety and effectiveness of CLARINEX Tablets in pediatric patients under 12 years of age have not been established.

Geriatric Use: Clinical studies of desloratadine did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. (see **CLINICAL PHARMACOLOGY – Special Populations**).

Information for Patients: Patients should be instructed to use CLARINEX Tablets as directed. As there are no food effects on bioavailability, patients can be instructed that CLARINEX Tablets may be taken without regard to meals. Patients should be advised not to increase the dose or dosing frequency as studies have not demonstrated increased effectiveness at higher doses and somnolence may occur.

ADVERSE REACTIONS: Allergic Rhinitis: In multiple-dose placebo-controlled trials, 2,834 patients received CLARINEX Tablets at doses of 2.5 mg to 20 mg daily, of whom 1,655 patients received the recommended daily dose of 5 mg. In patients receiving 5 mg daily, the rate of adverse events was similar between CLARINEX and placebo-treated patients. The percent of patients who withdrew prematurely due to adverse events was 2.4% in the CLARINEX group and 2.6% in the placebo group. There were no serious adverse events in these trials in patients receiving desloratadine. All adverse events that were reported by greater than or equal to 2% of patients who received the recommended daily dose of CLARINEX Tablets (5.0 mg once-daily), and that were more common with CLARINEX Tablet than placebo, are listed in Table 5.

Table 5
Incidence of Adverse Events Reported by $\geq 2\%$ of Allergic Rhinitis Patients in Placebo-Controlled, Multiple-Dose Clinical Trials

Adverse Experience	CLARINEX Tablets 5 mg (n=1,655)	Placebo (n=1,652)
Pharyngitis	4.1%	2.0%
Dry Mouth	3.0%	1.9%
Myalgia	2.1%	1.8%
Fatigue	2.1%	1.2%
Somnolence	2.1%	1.8%
Dysmenorrhea	2.1%	1.6%

The frequency and magnitude of laboratory and electrocardiographic abnormalities were similar in CLARINEX and placebo-treated patients.

There were no differences in adverse events for subgroups of patients as defined by gender, age, or race.

Chronic Idiopathic Urticaria: In multiple-dose, placebo-controlled trials of chronic idiopathic urticaria, 211 patients received CLARINEX Tablets and 205 received placebo. Adverse events that were reported by greater than or equal to 2% of patients who received CLARINEX Tablets and that were more common with CLARINEX than placebo were (rates for CLARINEX and placebo, respectively): headache (14%, 13%), nausea (5%, 2%), fatigue (5%, 1%), dizziness (4%, 3%), pharyngitis (3%, 2%), dyspepsia (3%, 1%), and myalgia (3%, 1%).

The following spontaneous adverse events have been reported during the marketing of desloratadine: tachycardia, and rarely hypersensitivity reactions (such as rash, pruritus, urticaria, edema, dyspnea, and anaphylaxis), and elevated liver enzymes including bilirubin.

DRUG ABUSE AND DEPENDENCE: There is no information to indicate that abuse or dependency occurs with CLARINEX Tablets.

OVERDOSAGE: Information regarding acute overdosage is limited to experience from clinical trials conducted during the development of the CLARINEX product. In a dose ranging trial, at doses of 10 mg and 20 mg/day somnolence was reported.

Single daily doses of 45 mg were given to normal male and female volunteers for 10 days. All ECGs obtained in this study were manually read in a blinded fashion by a cardiologist. In CLARINEX-treated subjects, there was an increase in mean heart rate of 9.2 bpm relative to placebo. The QT interval was corrected for heart rate (QT_c) by both the Bazett and Fridericia methods. Using the QT_c (Bazett) there was a mean increase of 8.1 msec in CLARINEX-treated subjects relative to placebo. Using QT_c (Fridericia) there was a mean increase of 0.4 msec in CLARINEX-treated subjects relative to placebo. No clinically relevant adverse events were reported.

In the event of overdose, consider standard measures to remove any unabsorbed drug. Symptomatic and supportive treatment is recommended. Desloratadine and 3-hydroxydesloratadine are not eliminated by hemodialysis.

Lethality occurred in rats at oral doses of 250 mg/kg or greater (estimated desloratadine and desloratadine metabolite exposures were approximately 120 times the AUC in humans at the recommended daily oral dose). The oral median lethal dose in mice was 353 mg/kg (estimated desloratadine exposures were approximately 290 times the human daily oral dose on a mg/m² basis). No deaths occurred at oral doses up to 250 mg/kg in monkeys (estimated desloratadine exposures were approximately 810 times the human daily oral dose on a mg/m² basis).

Schering

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Kenilworth, NJ 07033 USA

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U.S. Patent Nos. 4,659,716; 4,863,931; 4,804,666; 5,595,997; and 6,100,274.

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Chronotherapeutics in Aviation Medicine

Circadian Variance and the Aviator

BY JAMES R. ALMAND, M.D.

One hour of sleep before midnight is worth two after.

—Ancient Proverb

SLEEP LOSS— sleep deprivation, or “sleep debt” —can affect one’s reaction time, attention, cognition, physiology, memory, and alert status. This change can be acute in the sleep-deprived individual or it can be insidious.

All individuals react differently to sleep times (e.g., from Dr. Alfred Sweitzer, who averaged four hours nightly to today’s studies of eight hours’ recommended sleep). Some individuals suffer neurobehavioral changes from sleep loss differently from others. Lost sleep has a cumulative effect and accumulates as sleep debt.

Insomnia includes complaints of difficulty initiating sleep, maintaining sleep, resuming sleep, or unrefreshing sleep. Impairment in functioning, fatigue, or somatic symptoms can follow. Insomnia is categorized as transient (a few days), short term (longer – from significant stressors), and long term (months or years – from medical or psychiatric cause). Untreated sleep disorders can also be associated with medical problems, such as heart disease, hypertension, and strokes.

Insomnia therapies in use today include older hypnotics (benzodiazepines), which can cause abuse potential, hangover, impairment, dizziness, and memory impairment. More recent changes in hypnotics evolved in the non-benzodiazepine varieties, which offer greater safety and fewer side effects, with far fewer

residual effects than benzodiazepines – zolpidem (Ambien) and zaleplon (Sonata) are in this class and produce sedation through a neurochemical effect on the brain’s GABA-a receptor. Better prescribed normal sleep patterns are an advantage of these newer medications, with minimal side effects, tolerance rebound, and psychomotor performance.

Other non-prescribed sleep aids include antihistamines (Unisom, Benadryl, Nytol, Sleep Eze, Somnex) and also herbs (valerian and melatonin). Many studies to date suggest that antihistamines and herbs are associated with long-term hangover and metabolic/hepatic side effects.

Medical theories in the past taught the concept that bodily function was constantly in equilibrium throughout the 24-hour day. Experience developed in the careful study of circadian variance, both in travel (“jet lag”) or in one’s own biological clock, now has revised that theory.

The human brain has an indwelling “pacemaker” for circadian clock dependent alerting, which resides in the suprachiasmatic nucleus of the hypothalamus. This endogenous biologic clock coordinates the body’s sleep and wakening cycle. Lack of synchronism of the human biologic clock (or desynchronization) develops when the brain’s circadian rhythm is out of phase with the environment – and termed “jet lag.” Individuals adjust

to desynchronization at differing levels, with variable tolerance to circadian changes.

In the human body, cyclical biologic functions are also tied to the timing of drug administration for achieving maximum physiologic benefit. Timing of medication dosage in clinical aviation – civilian or military – is vital to the aviator’s biologic cyclical circadian rhythm. Examples of timing of drug dosages to circadian bodily clocks are noted in many aspects – e.g., diseases and drugs such as anticoagulants, cholesterol lowering medications, asthma therapies, arthritics, antihypertensives, and anginal medications.

Circadian early-morning awakening is closely tied to bodily physiological surges in blood pressure, pulse, cortisol and catecholamine levels, increased platelet aggregation, increased myocardial oxygen demand, testosterone elevation, and even blood viscosity.

Human diseases also exhibit circadian variances and historically relate exacerbation of primary occurrences to the time of day or night – e.g., epilepsy, myocardial infarction, cardiac arrest, strokes, migraine, early morning contrasted with nighttime asthma, apnea, and congestive heart failure, or daytime hemorrhagic gastric ulceration, or hypertensive emergencies.

The aviator faces circadian changes in all flights that interrupt

Continued →

the individual's regular biologic clock—early departures, overnight flights, or short layovers before the next starting “show.” Add to this the “phase advance” of travel circadian factors is more notable in flights to an eastern direction, causing increase in jet lag in traveling east related to the brain's light-dark melatonin cycle. This form of jet lag results in increased sleepiness, insomnia, fatigue, and gastrointestinal problems, and it is more notable than in western travel.

On layovers, the flyer must learn to accommodate his body to a strange hotel, an early time to sleep based on the next day's flight show, daytime sleep, night-time or departure from a region distant by miles and multiple time zone changes from his domicile, and many other personal or schedule-determined factors – all of which pose a challenge to gain a satisfactory eight hour required sleep or a satisfactory flight performance the following day.

In aviation medicine, flight crews have repeatedly discussed the value of circadian bodily demands in the flyer. Many flight crews, in recognition of this factor commonly employ sleep assistance drugs or herbs (Nytol, Stilnox, Benadryl, chamomile, Kava Kava, etc.), which are frequently secured from overseas drug sources or prescribed by their private physicians. In many instances, this usage of “sleep aids” is unknown or overlooked (or accepted) by the flyer's

flight surgeon and this not entered on the FAA's 8500 form. The safety of this practice in aviators has drawn the attention of the FAA and the flight surgeon community, and it can be an unacceptable practice.

Couple the above self-medication for sleep to the use the following day for stimulants (caffeine, etc.) – there is a “triple-armed” concern in aviation medicine interest regarding “circadio-aviation” in all flyers' therapeutic use of medications.

Consider the stimulant use (“go pill”) in the varied militaries (Faulkland campaign, Afghanistan war, etc.) as a defined positive factor in troop or aircrew performance – this controlled medication regimen has strong historical evidence of positive performance outcomes. But certainly, such a practice of controlled stimulants use in commercial aviation is highly disapproved – plus would ring a lot of bells in a random drug screen.

What is the human's limit to biologic variance in time zone changes, sleep deprivation, alteration in the circadian homeostasis of human physiology (or psyche), the use of stimulants or stressors, or even use of prolonged drug delivery systems that function with plasma drug levels over 24 hours?

Many questions still are unresolved regarding the human physiology of bodily sleep cycle demands – or alterations of the same. With longer-duration intercontinental flights in larger “super jumbo”

aircraft occurring and documented adverse passenger health developments reported (vascular, pulmonary, cardiac, etc), few studies of flight crew immediate, delayed, or future health consequences are ongoing – radiation effects of prolonged high-altitude exposure is but one long-term concern that demands ongoing research.

Should not a similar concern be present regarding chronic circadian physiologic changes affecting flight crews?

Today's challenge to the commercial aviation community – and their flight surgeons – is to better educate the flyer concerning aspects of long flight legs, insomnia or circadian-induced issues, symptoms of sleep deprivation, commonly available “sleep aids,” hazards of hypnotics for sleep, FAA guidelines on the subject, and (by all means) actively participate in preventive medicine for all pilots. Only in this way can flight medicine accomplish its true mission – keeping the flyer healthy.

Currently, transient insomnia in the aviator requires no treatment, with usually only sleep hygiene training being effective, but the pilot population requires special consideration in choosing any agent for sleep improvement, due to their requirement for a high degree of alertness on awakening. *FP*

'CAMA SUNDAY' SPECIAL EDITION

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Complexity and Safety

BY CHARLES E. BILLINGS, MD, THE OHIO STATE UNIVERSITY, COLUMBUS, OHIO

Aviation is a very complex, highly distributed, highly dynamic domain similar to medicine. Both domains are comprised of many diverse groups and individuals with agendas often in competition. Both domains involve very real dangers for consumers.

I HAVE BEEN ASKED to discuss complexity and safety in relation to health care. For over 40 years, I have worked to improve aviation safety, both as a physician and as a human factors specialist. In 1997, I became involved in attempts to improve patient safety. Your hosts have asked me to discuss our work in adverse event reporting and how it might be applied in the medical domain.

Aviation is a very complex, highly distributed, highly dynamic domain. It is rather similar to medicine, which also is complex, highly distributed and highly dynamic. Both domains are comprised of many diverse groups and individuals with agendas that are often in competition. Both domains involve very real dangers for consumers. The products produced by both domains are essential and in both, there has been continually increasing demand for services.

Interestingly, each system has only one major product. In aviation, that product is the transport of people and goods from one place to another. In medicine, the product is the delivery of services to enhance, maintain, or restore health. All of the resources and people in each system are devoted more or less directly to delivering that one product, and doing so economically, for both systems operate in demand-based markets.

These two systems have been dramatically affected by the introduction of a great deal of high technology. As a result of organizational, managerial, and technical advances, both domains have become increasingly opaque, even to the experts within them. This has been an almost inevitable concomitant of increasing

complexity in many industries and, I should say, in government as well.

Perrow, in 1984, pointed out that accidents are *normal* under these conditions. He wrote,

Our ability to organize (and manage) does not match the inherent hazards of some of our organized activities. Better organization will always help any endeavor. But the best is not good enough for some activities we have decided to pursue. (p. 10)

In other words, increasing complexity and system opacity are threats to system safety. Your problem, as system managers, is to accomplish four major tasks to:

- understand the system (or systems) for which you are responsible;
- understand how that system is supposed to behave under all conditions;
- understand how that system can misbehave; and
- learn how to avoid or ameliorate unwanted system behavior.

This is a tall order. You are ultimately responsible for the safe, efficient delivery of your product—even though you may not have the knowledge and skills to provide medical care, just as most airline CEOs cannot either pilot or maintain their aircraft and other tools.

You are hindered in these tasks by what Sydney Yoshida called “The Iceberg of Ignorance.” His work suggests that the following percentages of an organization’s operational problems are known to:

- Top managers: About 4%
- Middle managers: About 9%
- Supervisors: About 74%
- Front-line employees: Nearly 100%

In the 1999 revision of his book,

Normal Accidents, Perrow asks a question that gets to the heart of learning about safety problems in very complex organizations:

How can we create the atmosphere, the *culture*, that will allow underlings to speak up, or copilots to warn chief officers; get operators to see the whole system rather than just their part of it; keep the watcher of the autopilot alert ... ? (p. 378)

Dr. Perrow, an organizational sociologist, has neatly captured the reason for establishing the NASA Aviation Safety Reporting System.

What is the prevailing culture now with respect to adverse events and outcomes? Most people, I think, still feel that punishment for serious errors is an appropriate way to enforce our society’s attempts to maintain a safe and healthful environment for its citizens.

David North expressed this viewpoint in an editorial last year in *Aviation Week and Space Technology*, called “Let (the) Judicial System Run Its Course in Crash Cases.” He said in Part, “NTSB Chairman James Hall has visited the U. S. Attorney General’s Office in Washington many times to discourage prosecutors from attempting to find criminal fault while the board, industry and pilot organizations are still trying to determine the cause of an accident. Hall and others contend that if blame or threat of litigation is allowed to move to the fore, people will be afraid to talk to accident investigators. And that will hinder the fact-finding that is aimed at preventing similar crashes. Hall is worried that the lawyers are getting out of hand...”

Continued →

However, I believe that the failure of SabreTech employees to put caps on oxygen generators constituted willful negligence ... Prosecutors were right to bring charges. There has to be some fear that not doing one's job correctly could lead to prosecution. Aviation is not and should not be exempt from legal due process...

One would hope that attorneys representing the survivors of an accident would not get in the way of a safety investigation ... At some point, the legal world may start to interfere with the overarching goal of improving safety ... For now, though, the safety board should not overreact to the ValuJet criminal prosecutions and upset the balance of safety and blame. This would be unfortunate because the NTSB and judicial system have all of the necessary tools to help aviation safety, if they use them with wisdom. (Unfortunately, they do not.)

Human Error Issues

The concept of human error as causation implies that human error is blameworthy, as expressed by Mr. North in the aviation context, and by the Institute of Medicine when it said in its Executive Summary, "the external environment should create sufficient pressure *to make errors costly* to health care organizations and providers, so they are *compelled* to take action to improve safety."

I contend that this concept is counterproductive because it can inhibit our efforts to understand the real causes of unwanted occurrences. But what should replace it? The IOM spoke to the issue of understanding immediately after the assertion cited above: "At the same time, there is a need to enhance knowledge and tools to improve safety and break down legal and cultural barriers that impede safety improvement." Let me suggest that it is very likely that this need will *not* be satisfied if the previously expressed need (making errors costly to compel action to improve safety) is our primary goal. Why do I think this is true?

It has been my experience that the greatest "legal and cultural barrier" to efforts to improve our understanding of unwanted events is the culture of blame, punishment and retribution that pervades our society and which is now becoming even more manifest in the criminalization of professional (e.g., pilot, physician, nurse) behavior when it is associated with adverse events. It is noteworthy that the pilot of an airline aircraft that crashed while carrying out an instrument approach in New Zealand in 1995 has just been tried (and fortunately acquitted) on four manslaughter charges. The police secured the cockpit voice recorder tapes through the courts for its investigation, the first time that this has happened. Can you believe that this misuse of safety-critical data will improve the climate for aircraft accident investigation in that nation?

I have come to believe that you can't have it both ways. You can mandate the reporting of adverse events, then count and categorize them, eliminate either the people or the behaviors associated with them, then observe whatever improvement you can find in your "error" counts, as the IOM has recommended. Alternatively, you can take the imperfect world as you find it, solicit *voluntary* reports of incidents, use them as opportunities to *learn* about their processes and causes, and focus your remediation efforts on the *system* in which errors occur.

This approach led us to develop a voluntary, confidential, non-punitive incident reporting system that for 25 years has brought to light undesired behaviors and unwanted occurrences in aviation, in order to learn what latent and manifest factors were involved in those incidents.

Incident Reporting as a Source of Information and Learning

I do not advocate an "enlightened, blame-free, humane approach to collecting data about unwanted events" for any philosophical reason. I

advocate confidential, voluntary reporting of adverse events simply because I know it works when the collection and analysis system is designed properly and implemented sensitively. Because it works, it can lead knowledgeable people like yourselves to the information, insights, and knowledge that you must have to effect the improvements that politicians and society are demanding in health care, largely as a result of the IOM report. I should point out that a similar hue and cry was raised by the Congress and the public after the crash of TWA flight 514 in 1974, and that f uror led to our NASA team being tasked to develop our Aviation Safety Reporting System.

Figure 1 [see model, next page] shows a model of the incident reporting system that we developed and are still using to collect incident data in civil aviation in the United States. I believe strongly that incident reporting, analysis and interpretation must follow some sort of closed loop model like this in order to keep the industry and its practitioners motivated to use it to share the information they have.

Some important "first principles" are embodied in this concept as realized in the NASA Aviation Safety Reporting System. I describe them briefly because I think each is essential to the success of a voluntary adverse event reporting system. They include:

- **The aviation community are the stakeholders in an Incident Reporting System.**

The aviation community has been deeply involved in the design, implementation and use of our incident reporting system since its inception in 1975. Community representatives act as a "board of overseers" and provide criticism, expertise and advocacy for the system. They and we consider themselves as the primary stakeholders in the venture, along

Continued →

with the Federal Government which supports our system and makes heavy use of its data.

- **The community are the providers of information.**

Nearly 100% of reporters are from the pilot, dispatcher, flight attendant, air traffic controller and aircraft maintenance engineering communities. These are the occupational groups represented on our advisory committee, whose members encourage their groups to report to the system.

- **The reporting system must be credible: Its objectivity must be paramount.**

The choice of NASA, a research agency without regulatory or enforcement powers, as the parent organization for ASRS helped the new reporting system to establish a reputation for credibility and objectivity. Widespread use of its publications has helped to maintain that reputation during its 25 years of service to the community.

- **The reporting system must be safe and non-punitive.**

NASA's unique role as a research agency helped to foster the impression that data provided to it would not be misused, but the reporting system went to considerable lengths to ensure that this impression was correct. To our knowledge, there has not been a security breach in 25 years; none of the over 500,000 persons who have submitted reports has incurred personal harm as a result.

- **The reporting system must be independent.**

It was obvious in 1975 that a voluntary aviation incident reporting system, to be successful, would have to be independent of the many political and other pressures that might arise from its data and conclusions. This assumption was proven correct when ASRS released the results of a study whose conclusions ran counter to the strongly-held beliefs of its sponsor, which tried to shut it down by removing immunity from its operations. I believe now, as I did then, that to be useful, a reporting system must be able

Fig. 1.
First Principles of
Voluntary Incident
Reporting

to report its results as it sees them; it must be independent of the many competing interest groups in its community.

- **Subject-matter experts classify, analyze & interpret data.**

Since its beginning, our reporting system has utilized highly experienced, usually recently-retired, pilots, controllers and other subject-matter experts as its analysts, to ensure that incoming reports are screened by knowledgeable people who understand the context of the reports. These persons perform all of the primary analyses of incoming data, and some secondary analyses as well when their insights suggest new avenues of inquiry. Other analyses are done by academic and other experts who utilize special studies to collect data on topics in which they are interested.

- **The community receives ongoing feedback from ASRS**

No one particularly enjoys filling out reports. It is vital that prospective reporters see tangible evidence that their reports are being used constructively to improve safety. ASRS utilizes many avenues of feedback to practitioners and the aviation industry. Among its most important feedback mechanisms are the following.

- **ASRS has issued over 1000 Alert Bulletins**
- **Callback reaches 85,000 subscribers each month**
- **The system has performed over 500 special studies of data**
- **The system routinely performs quick-response studies for the NTSB, FAA, the Congress, and many other requesters**
- **DirectLine, a technical publication, goes to 1800 organizations**



- **The community has been given incentives to continue reporting to ASRS**

In addition to disseminating the results of its studies of incoming reports, other incentives are built into the system. These are specific to ASRS; other incentives may be needed in other contexts.

- **Philanthropy:** reporters identify with the ASRS safety mission
- **Confidentiality:** reporters are protected from identification
- **Prophylactic effect:** reporters receive limited immunity from punitive action
- **Therapeutic effect:** reporters learn from their errors and share their insights

Discussion

I believe that these principles are paramount in the establishment and maintenance of a voluntary reporting system within a community which finds a need for data concerning operational problems and sensitive human factors issues. Such factors are involved in 70-80% of the incidents reported to ASRS, and in a roughly equal percentage of accidents in aviation and other complex domains.

Note that since this is a voluntary, confidential system, we believe that our first obligation is to protect all reporter identities. Does this matter? Our stakeholders clearly believe it does. When the FAA established

Continued →

voluntary incident reporting as an in-house activity in 1975, it received perhaps 200 reports in a year. When the NASA safety reporting program replaced it a year later, we received 100 reports a week; this number now averages 600 reports a week. The FAA promised the same level of confidentiality that we did—but it is the enforcement agency for civil aviation and it was not trusted by the community.

We completely deidentify our reports during intake processing, and some have criticized this step. All processed data from the ASRS are public data; at least one large national newspaper demands, and receives, the data on a monthly basis. If the public's interest is in what is really going on in the aviation system, they can find out without much difficulty. All that they cannot learn from processed data is who reported what, who was directly involved, and the exact date and time of an occurrence. If one's primary interest is in assigning blame or liability for specific occurrences, these data are useless. But if that is *not* one's interest, what has been lost by this approach? The data,

and our conclusions, are freely available to all who care to inquire.

Because our system is voluntary, we cannot evaluate the incidence or prevalence of such occurrences. More important, however, *the presence* of specific problems in the national aviation system can be reliably inferred if reports of such problems are received. We can reasonably assume that the number of reports of a given type of occurrence represents a lower bound for the frequency with which such problems occur. Is this not what we need to know to aim our analytic resources toward the most important problems? Do we really need precise estimates of their incidence to decide whether they are worth bothering with? We have assumed (we think correctly) that busy people do not bother to report non-events, and that our reporters are generally truthful in their narratives.

Our analysts can contact reporters to ASRS before deidentifying their reports, and they have done so on thousands of occasions to obtain further details of the occurrences reported. These "callbacks" have made it possible for us to do detailed

studies of problems that represent a high potential for serious harm. We often discuss deidentified incidents with experts who can assess that potential or who can suggest possible solutions for the problems presented. We publicize serious reports extensively so that the community knows of emerging threats and can watch for them in their operations.

Finally, our analysts represent several hundred years of aviation experience. They share what they are seeing with each other on a daily basis (and with FAA during frequent teleconferences). These interactions make the analysts more sensitive to what they see in incoming reports, and help to provide insights into possible causes or remedial actions. This isn't tidy science, but it has been quite remarkable in its effectiveness. And effectiveness is what we are after, not science. *FP*
This concludes Part I of this article. It will be concluded in the next issue of the FlightPhysician. Prepared for the Premier CEO Leadership Forum, Aspen, Colorado, September 11, 1991.
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CAMA CONSULTANTS

To our new members and as a reminder to all: This is a list of more experienced AMEs that have volunteered to help with troublesome certification cases. For involved questions, E-mail or fax is preferred. This list is NOT for use by airmen, but solely for AMEs within the CAMA membership.

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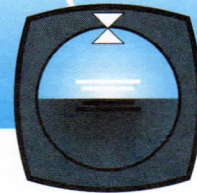
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On The Horizon



FAA Aviation Medical Examiner Seminar Schedule

2003

- July 18 - 20 ___ Chicago, Ill. (Aviation Physiology/HF)
August 15 - 17 ___ Washington, D.C./McLean, Va. (Cardio)
September 15-19 ___ Oklahoma City, Okla. (Basic)
October 3 - 5 ___ Salt Lake City, Utah (Ophth/Otolaryn/
Endocrin)
November 3 - 7 ___ Oklahoma City, Okla. (Basic)

2004 Basic Seminars

- March 15-19 ___ Oklahoma City, Okla.
June 21-25 ___ Oklahoma City, Okla.
September 13-17 ___ Oklahoma City, Okla.
November 15-19 ___ Oklahoma City, Okla.

For information, call your regional flight surgeon. To schedule a seminar, call the FAA Civil Aerospace Medical Institute AME Programs Office (405) 954-4830

CAMA Headquarters

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October 8 - 11, 2003
We are meeting in
Seattle, Washington
Make plans to attend

Aerospace Medical Association's Annual Meeting Schedule

- May 2 - 6, 2004 ___ Anchorage, Alaska
May 8 - 12, 2005 ___ Kansas City, Missouri

Civil Aviation Medical Association's Annual Meeting Schedule

- October 8 - 12, 2003 ___ Seattle, Washington,
Marriott Sea Tac Hotel
October 6 - 10, 2004 ___ Omaha, Nebraska,
Marriott Omaha Hotel
October 5 - 9, 2005 ___ Charleston, South
Carolina, TBA
October 4 - 8, 2006 ___ Ottawa, Canada,
Ottawa Marriott Hotel

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