Vol. 42, No. 3 2004-3 For FAA Aviation Medical Examiners, Office of Aerospace Medicine Personnel,
Flight Standards Inspectors, and Other Aviation Professionals.

U.S. Department of Transportation

Federal Aviation Administration

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# Sport Pilot Rule Takes Off

Medical Qualification Provisions Described

By Judi Citrenbaum

THE SPORT PILOT Final Rule, officially called the "Certification of Aircraft and Airmen for the Operation of Light-Sport Aircraft Final Rule," became effective on September 1, 2004. In short, the rule addresses advances in sport and recreation aviation technology by providing new certification requirements for light-sport aircraft, pilots, and repairmen.

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### **QUICK FIX**

How to Eliminate the Most Common Errors on FAA Form 8500-8

By Richard 'Dick' Jones, MD

#### **PROBLEM**

The two most common errors found on FAA medical examinations are "DV CORRECTED VALUE EXCEEDS STANDARD OR BLANK" AND "NV CORRECTED VALUE EXCEEDS STANDARDS OR BLANK," in which "DV" and "NV" mean distant vision and near vision, respectively.

Continued on page 3

## **AASI Now Covers First- and Second-Class Aviators**

By Richard Carter, DO

Assisted Special Issuance (AASI¹), has been an outstanding success, thanks in great part to high-quality work by AMEs involved in the program. Federal Air Surgeon **Jon L. Jordan**, MD, has directed the Aeromedical Certification Division (AMCD) to expand AASI to include 1st- and 2nd-class airmen. All of the medical conditions approved for AASI, as listed in the *Guide for Aviation Medical Examiners*, can be applied to 1st- and 2nd-class airmen, effective September 7, 2004.

**Dr. Warren S. Silberman**, AMCD manager, says he anticipates that this

<sup>1</sup>For more information, see spring 2002 Bulletin, p 1 and Certification Update, winter 2003 Bulletin, p 3.

new initiative will improve customer service by further reducing the backlog of certification cases. The initiative we are implementing with this *Bulletin* will help further reduce certification delays and AMCD workload.

The key objective of the AASI program is high quality, expedited service for the airmen. The 19 medical conditions previously approved by the Federal Air Surgeon do not change. AMCD staff medical officers will make the initial certification decisions and grant the medical authorizations. The Authorization Letter is unique for the following reasons:

1. 6-year authorization is implemented

Continued on page 3

# Sorting Out 'Sport Pilot' Medical Provisions

There is no truth to rumors that the FAA is developing special, 'fourth-class' medical certification criteria for Sport Pilots.

Weeks have passed since the Experimental Aircraft Association's 2004 Air Venture fly-in at Oshkosh, and the excitement surrounding the long-awaited announcement of the publication of the Sport Pilot final rule still resounds. Reaction to the rule is mostly positive, with certain exceptions, chief among them the limitations added to the medical qualification provisions.

As of September 1, 2004, individuals found otherwise qualified to exercise Sport Pilot privileges may medically qualify using either a valid airman medical certificate or a current and valid U.S.

### Federal Air Surgeon's Medical Bulletin

Library of Congress ISSN 1545-1518

Secretary of Transportation Norman Y. Mineta

**FAA Administrator** Marion C. Blakey

Federal Air Surgeon Jon L. Jordan, MD, JD

### Editor

Michael E. Wayda

The Federal Air Surgeon's Medical Bulletin is published quarterly for aviation medical examiners and others interested in aviation safety and aviation medicine. The Bulletin is prepared by the FAA's Civil Aerospace Medical Institute, with policy guidance and support from the Office of Aerospace Medicine. An Internet on-line version of the Bulletin is available at: http://www.cami.jccbi.gov/AAM-400A/fasmb.html

Authors may submit articles and photos for publication in the Bulletin directly to:

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# The Federal Air Surgeon's Column By Jon L. Jordan, MD, JD

driver's license. However, an individual may use a current and valid U.S. driver's license to qualify only if:

- The individual was found eligible for the issuance of at least a third-class medical certificate at the time of his or her most recent application;
- The individual's most recently issued airman medical certificate has not been suspended or revoked; or
- The individual's most recent Authorization for a special issuance medical certificate has not been withdrawn.

While this limitation on the use of a current and valid U.S. driver's license may have been unanticipated, I believe most people will agree that the FAA cannot reasonably allow an individual to exercise pilot privileges if the individual's FAA records indicate that it would be unsafe to do so.

Critics may be quick to express the opinion that this limitation on the use of a driver's license is unfair because persons who applied for an FAA medical certificate and were not issued a certificate may be disadvantaged in comparison to persons who never applied. What must be recognized, however, is that it is a violation of FAA regulations for any person to act as a required flight crewmember if they know, or have reason to know, of a medical condition that would make them unable to operate a light-sport aircraft in a safe manner. This applies to individuals who exercise Sport Pilot privileges, whether using a driver's license or an FAA airman medical certificate to qualify.

Applicants may be denied airman medical certification for any number of reasons, including failure to provide sufficient information for the FAA to make a decision. Therefore, in the case of some individuals who have been denied medical certification, it may only be a matter of following up with the FAA and providing the necessary information. For others who were disqualified on the basis of available medical information, it becomes more complicated. These applicants will have to provide information that allows the FAA to make a favorable decision. For some, this may not be possible.

There is no truth to the rumors that the FAA is developing special medical certification criteria for Sport Pilots. Although we will always work with individuals to help them gain medical certification, tailoring a process to address special issuance procedures for Sport Pilots only would be inconsistent with the spirit of the medical provisions of the rule. In addition, it is unclear how we could structure what essentially would be "fourth-class" medical certification standards and certification criteria for Sport Pilots.

We have been asked whether an applicant for a medical certificate could avoid the limitation on the use of a valid U.S. driver's license by withdrawing an application for a medical certificate. The answer is *no*. Once we have adverse medical information in our files concerning an applicant, we must act on that information to ensure that a medically unqualified person does not pilot an airplane.

The intent in issuing the Sport Pilot rule was to bring safety oversight to a rapidly expanding segment of the aviation industry and to make way for increased public involvement in aviation activities. While this rule may not be fully satisfactory to everyone, I believe it will accomplish both objectives.

For more information on the new rule, see article on page 1 of this issue.

JLJ

### **QUICK FIX** from page 1

### RESULT

Several AMEs have called or written to complain that they have unfairly been assigned the above errors, usually both on the same examination and often on several examinations. They state they have checked their office work copies of the examinations and find that their notes show the individuals meet standards. (They then "suggest" various disposal methods for our computer system!) Nearly always, when we check our database for the results that were actually entered in the Document Imaging and Workflow System,

we find the AME is correct about the airman's meeting the standards in each eye, when tested separately, but that no values were recorded for both eyes tested together. The FAA requires that both eyes be tested together at all distances required for the specific examination type so, under these circumstances, it is appropriate to give an error to the AME. However, errors of this type are very frustrating to AMEs and cost us significant amounts of time to verify whether or not the error assessment was valid.

### **SOLUTION**

This problem should be corrected within months when the new and improved DIWS software is fielded. The new application will not permit transmission of examinations without you first correcting this kind of omission. Until then, it is hoped this article will improve the situation by reinforcing the requirement to you and staffmembers and by encouraging everyone to ensure these data fields are completed before submitting examinations to the Aerospace Medical Certification Division.



Dr. Jones manages CAMI's Aerospace Medical Education Division.

### AASI from page 1

- 2. AME reviews, approves medical follow-up reports without the need for verbal authorization from the AMCD or regional medical office
- 3. AMEs issue certificates (note, you will need blank certificates when medical exams are not required)
- 4. The letter advises the applicant that the AME may charge for the AME's AASI consult service
- 5. Accompanying the letter is a specification sheet to provide the AME a convenient reference to criteria (from the *AME Guide*) for deferral, should the condition change unfavorably
- 6. One condition— or even all 19— can be listed in the letter.

The 19 approved conditions for AASI are:

- Arthritis
- Asthma
- Atrial fibrillation
- Chronic lymphocytic leukemia
- Chronic obstructive pulmonary disease
- Colitis (ulcerative or crohn's disease)
- Colon cancer

- Diabetes on oral medication(s)
- Glaucoma
- Hepatitis C
- Hyperthyroidism
- Hypothyroidism
- Lymphoma and Hodgkin's disease
- Migraine headaches
- Mitral and aortic insufficiency
- Paroxysmal atrial tachycardia
- Prostate cancer
- Renal calculi
- Sleep apnea

Initial AASI certification can sometimes be a challenge to both the airman and the AME. How do you get started, for instance, when an airman reports to you with a newly diagnosed case of atrial fibrillation? The on-line *AME Guide* (hint, use the handy search engine, type in *atrial fibrillation*) has the answer:

Examiners may reissue an airman medical certificate, if the applicant provides the following:

• An Authorization granted by the FAA

- A summary of the applicant's medical condition since the last FAA medical examination, including a statement regarding any further episodes of atrial fibrillation
- The name and dosage of medication(s) used for treatment and/or prevention with comment regarding side effects
- A report of a current 24-hour Holter monitor performed within last 90 days.

Use the online AME Guide http://www.faa.gov/avr/aam/ Game/Version\_2/03amemanual/ home/home.htm

to review and keep updated on AASI medical conditions and changes to the program.



Dr. Carter is a medical review officer in CAMI's Aerospace Medical Certification



# **Certification Update**

Information About Current Problems

By Warren S. Silberman, DO, MPH

TRST, THERE ARE Some new issues to discuss. Recently, an aviation medical examiner phoned one of the regional medical offices and asked if he could wait beyond our required 14 days to transmit or send the Form 8500-8 (Application for Airman Medical Certificate or Airman Medical and Student Pilot Certificate) into the Aerospace Medical Certification Division (AMCD). The AME had an airman applicant with an AME-Assisted Authorization for Special Issuance (AASI) case, but the airman had not brought the required material in for review.

I don't want to sound harsh, but the answer is "no" to the AME and the airman. You are told at the Basic AME Seminars and in the *Guide for Aviation Medicine Examiners* that you have 14 days in which to provide the AMCD with the transmitted examination. We would also appreciate it if you would bundle up all the hard-copy 8500-8s and mail them in also— within the 14-day period.

The reason for the latter is that we must perform a 100-percent comparison of the transmitted and the hard-copy examination because some AMEs have omitted things and not correctly transcribed the data from their working copy onto the transmitted copy, and we have discovered significant discrepancies.

Recall, the airman is informed in our "Six-Year Authorization letter" (the AASI letter) that they are to bring the material for recertification to the AME's office when their medical certificate is about to expire. We also have made it "idiot proof," so to speak, as we have given both the airman and the AME a specification sheet that informs the airman and the treating physician what is

required by the AMCD for recertification and what will entail deferral.

We have had many problems with AMEs holding back transmitting and providing us with documentation to support granting issuance in a timely fashion. There have been numerous examples of AMEs holding back sending exams for 300 to 800 days! Obviously, this makes it appear as if we are not providing timely service to airmen, which is not the case.

#### Medications

We have reviewed several medications in the past several months. The following mentions them:

Xolair: Omalizumab is a medication that binds to immunoglobulin E (IgE). Omalizumab prevents IgE from binding to these cells, and therefore decreases allergic response. It is a new medication for the treatment of asthma. Xolair is treatment for more "moderate-to-severe" asthma patients. We are going to accept this medication after the airman has demonstrated a 30-day period of "observation." The treating physician will have to provide the airman with a statement explaining the reasons for prescribing this particular medication.

Humira: Adalimumab reduces the effects of a substance in the body called tumor necrosis factor alpha (TNF-alpha). TNF-alpha is involved in inflammatory processes in the body. Adalimumab is used in the treatment of rheumatoid arthritis. Humira is now approved for use by airmen.

Zoladex: Goserelin acetate implant, contains a potent, synthetic decapeptide analogue of luteinizing hormone-releasing hormone (LHRH), also known as a gonadotropin-releasing hormone (GnRH) agonist analogue. ZOLADEX acts as a potent inhibitor of pituitary gonadotropin secretion. Zoladex is used in palliative treatment of prostate cancer to suppress the secretion of testosterone. Zoladex is now permitted for use by airmen

Levitra: Vardenafil HCL is used for erectile dysfunction. Recall that we held off accepting the use of this medication because it reportedly increased the QT

interval, potentially causing arrhythmias. One of the USAF residents in aerospace medicine (see his article in this issue for an excellent presentation on these medications) performed a literature search and found that, in fact, this was shown not to be significant. There will be the same stipulation with Levitra as there is with our use of Viagra— a six-hour "bottle-to-throttle" use. This means that the airman cannot take the medication within six hours of flight.

### **Certification Quiz**

We have resurrected several cases from those previously presented in the *Bulletin*. I chose to repeat these cases as they demonstrate examples of ongoing problems with AMEs and their decisions on various medical certification issues. I still emphasize that we cannot perform this mission without you all, but I would really appreciate it if some of you paid more attention to detail.

Also note: An aviation medical examiner may not issue an authorization for special issuance without the verbal or written permission of the Federal Air Surgeon, Regional Flight Surgeon, or Aerospace Medical Certification Division.

1 Can a senior AME grant a medical certificate to an airman with a history of having had a coronary artery bypass graft procedure? (This is the applicant's first visit to your office.)

ANSWER: No AME shall issue a medical certificate to an airman of any class if the airman has had coronary artery disease that has been symptomatic or required treatment. This is true no matter how long ago the airman was treated. The airman will need to request medical certification under section 67.401, Special Issuance of Medical Certificates (refer to the Online Aviation Medical Examiner Guide).

Airman Jane is a famous aviator with 12,000 flight hours. She presents to you with an eight-month-old diagnosis of Type II diabetes mellitus. She has been taking Glyburide, and a recent hemoglobin A1C level was 6.4 (normal 4.4 to 6.4). Jane is also a known hypertensive, taking Metoprolol 50 mg. daily. She already has had a Special Issuance for her

Dr. Silberman manages the Civil Aerospace Medical Institute's Aerospace Medical Certification Division.

Continued >

hypertension, and the letter from her treating physician mentions that she has been quite stable over the past year with BPs averaging 120-130/70-80. As her AME, what should you do?

ANSWER: Diabetes mellitus on oral medications is one of the 15 specifically disqualifying illnesses, and thus you must defer the case to the AMCD. The other issue in this case is that Airman Jane is taking an oral hypoglycemic agent and a beta-blocker. Due to the effect that beta-blockers have of masking the symptoms of hypoglycemia, she will ultimately be denied by the AMCD. Her treating physician needs to change the antihypertensive medication before she reapplies for medical certification.

3 Å 15-year-old applicant (birth date Feb. 28, 1989) comes into your office on Jan. 29, 2004. He wants you to issue him a Medical/Student Pilot Certificate. His examination is unremarkable. What should you do?

ANSWER: An AME cannot issue a Medical/Student Pilot Certificate to an applicant who has not reached the 16th birthday. Recall that an AME may issue a medical certificate to an individual of any age. It is an internal AMCD policy that, if the prospective student pilot comes into your office within 30 days of the 16th birthday, you can issue both the medical and student pilot certificates with the restriction written on the combination Student Pilot/Medical Certificate, "NOT VALID UNTIL SIXTEENTH BIRTHDATE." In this case, that effective date is February 28, 2004.

Lucy Mcguilicudy was a 40-y/o wife of a well-known cabaret singer. She had always wanted to learn to fly. Several years prior, she had developed a viral upper respiratory illness. A short time later, she became quite ill. Her physicians thought she had developed a viral cardiomyopathy. Her resting ejection fraction was 30%. Despite treatment and time, she has maintained this level of cardiac function.

Her instructor pilot, being an AOPA member, went to the medical section of their Web site and discovered what she would need to have her medical condition assessed by an AME. She presented to her AME with the medical records of her illness and a current status report from her treating physician that included a list of current medications. She had also obtained a maximal Bruce stress test. On the test, she went 6 minutes for a maximal heart rate of 160. During peak exercise, she developed ventricular bigeminy and had numerous couplets and triplets. It took about 4 minutes of recovery time for her heart rate to drop to pre-exercise levels. A 2-D echocardiogram revealed biatrial enlargement and global hypokinesis with an ejection fraction of 30%. Her treating physician, Dr. Feelgood (the name has been changed to protect privacy), said that she was performing well and had great exercise tolerance. In his report to the AMCD, he said that Ms. Mcguilicudy was "good enough" to fly as a private pilot. (Dr. Feelgood's brother-inlaw is a pilot with a cargo-carrying operation.) The AME was impressed with the supporting documentation and issued a 3<sup>rd</sup>-class medical certificate. Was this the proper thing for him to do?

ANSWER: It sure wasn't! Ms. Mcguilicudy failed her exercise test. The FAA would like an applicant to reach at least 9 minutes on a stress test. She has either poor exercise capacity or cardiac reserve or both. The arrhythmias likely are associated with their increased incidence in cardiomyopathy, which is the major reason that we do not grant medical certification to applicants with this condition. Her treating physician should not have told her that she was healthy enough to fly, even in private operations, unless he was well versed in civil aviation medicine. I can understand his zeal to assist his patient, but it gives the AMCD folks a very difficult job to make the applicant understand our negative decision. The AME should never have granted medical certification but should have deferred the case to the Regional Medical Office or the AMCD in Oklahoma City.

Airman Stone Bonner comes to his AME for a 1<sup>st</sup>-class medical certificate. Three months ago, he had a bout of nephrolithiasis. He brings a report from the treating urologist that relates the presence of a 3 mm stone in the right upper collecting system without any evidence

of obstructive uropathy. There was no evidence of metabolic stone disease. He issues the medical certificate without consultation. Was he correct?

ANSWER: No, he was not! An AME may grant medical certification of any class when there is a history of passing a kidney stone, providing there is no metabolic stone disease and there is no evidence of retained stones. The AMCD has granted medical certification to airmen with retained stones, but usually the stone has been present for some time and it is lodged in the parenchyma or some area where it is not likely to pass. This does not appear to be one of those situations

6. An airman applying for a 1st-class medical certificate fails the conversational voice test and has the following results on her audiogram: right ear: 500Hz 10, 1000Hz 5, 2000Hz 30 and 3000Hz 35, left ear: 500Hz 25, 1000Hz 35Hz, 2000Hz 60 and 3000Hz 75. Did the airman pass? What should you do?

ANSWER: She failed both the conversational voice and audiogram tests. You should hold the exam and refer her to an audiologist for a speech discrimination test. If the applicant scores at least 70% in one ear at an intensity of 65db, you may issue the medical certificate.

An applicant for 3<sup>rd</sup>-class medical certification comes in for her medical examination. She reports to you that she had been diagnosed 6 months ago with a peripheral neuropathy and was given the medication Neurontin (gabapentin). Should you issue the certificate or...

Answer: No, you should not issue. While the *AME Guide* does allow medical certification for a peripheral neuropathy, anti-seizure medications are not acceptable—even (as in this case) if they are not being used for a seizure disorder. The side-effect profile of these medications is not compatible with aviation duties.

Six of the FAA's 15 Specifically Disqualifying Conditions are cardiacrelated. What are they?

ANSWER: Angina pectoris, coronary heart disease that has required treatment or, if untreated, that has been symptomatic; myocardial infarction;

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### **Depression and Use of SSRIs in Pilots**

Case Report, by Jeanine M. Czech MD, MPH, LtCol USAF, MC, FS

An estimated 17.5 million Americans suffer from depression; reported prevalence rates vary from as low as 2-4% to as high as 12-20%. Patients with depression are frequently evaluated and started on treatment with medications by primary care physicians. Since the 1980s, selective serotonin release inhibitors (SSRIs) have become the most popular initial treatment for depression, as well as many other mental health disorders and medical conditions. In the U.S., use of SSRIs for depression is currently disqualifying for all classes of airmen. This article presents a case report of a third-class pilot diagnosed and treated for depression, and includes a brief overview of depression, SSRI use, and aeromedical implications.

History. A 52 year-old male third-class pilot with 430 hours of flight time presented to his family physician because of persistent depressed mood. The patient had no specific physical complaints, just symptoms of a general lack of energy. The patient explained that he had been extremely worried lately about his job – the plant at which he worked was downsizing, and he was afraid he would be laid off. Because of these worries he was having a difficult time sleeping. Marital problems were also beginning to surface ("all my wife ever does is nag"). The patient denied any suicidal ideation but admitted that he didn't have enthusiasm for any activities - even flying.

After completing a physical exam and basic laboratory testing, the family physician diagnosed the patient with depression, and prescribed Sertraline 50 mg. each evening. The patient asked his physician about the wisdom of flying while taking medication; the (non-AME) physician reassured the patient that the medication dosage was low and would be well-tolerated, concluding with "I see no reason why you can't keep flying." The patient began taking the medication but checked with his AME before returning to flying. The AME informed him that flying with a diagnosis of depression and flying while taking SSRIs were both prohibited.

The AME contacted the Aerospace Medical Certification Division (AMCD) and reported the use of SSRIs by the patient.

Use of SSRIs. Since developed in the 1980s, selective serotonin reuptake inhibitors (SSRIs) have been successfully used to treat many psychiatric disorders and medical conditions. Working through blockade of 5HT reuptake pumps, SSRIs cause increased serotonin transmission in specific CNS pathways, mediating therapeutic effects on mood. Because SSRIs have been more effective and better tolerated than previous psychotropic medications, they soon became the most frequently prescribed medications for depression. Five of the top-40 medications prescribed in the U.S. are SSRIs (9). Primary care physicians frequently evaluate and treat patients with SSRIs for problems as diverse as depression, anxiety, social phobia, obsessive compulsive and panic disorders, premenstrual dysphoria, post-traumatic stress disorder, eating disorders, migraine headaches, fibromyalgia, and chronic fatigue syndrome.

SSRIs: Side effects and interactions. Although SSRIs have been more effective and better tolerated than medications used previously to treat depression, they too can produce substantial incapacitating side effects (5). Clinical evaluations of patients recently started on SSRIs show 29.1% with nausea, 22.4% with insomnia, and 13% with dizziness. Patients with underlying anxiety disorders or bipolar disease may have increasing symptoms of anxiety or mania. SSRI-treated patients have been reported with akathisia (restlessness,

Lt.Col. (Dr.) Jeanine Czech is a board-certified family physician and resident in the USAF Residency in Aerospace Medicine program. She is also a commercial-rated pilot and certified flight instructor. She wrote this case report while on a clinical rotation at the Civil Aerospace Medical Institute.

# Depression— Description and Etiology

Depression is an illness that involves the body, mood, and thoughts. It is manifested by a combination of symptoms, including persistent sad mood, feelings of hopelessness, decreased energy, and insomnia, all of which interfere with the ability to work, study, sleep, eat, and enjoy once pleasurable activities (8). Most significant for airmen, depression may also cause cognitive changes such as difficulty concentrating, remembering, and making decisions. A disabling episode of depression may occur only once but more commonly occurs several times in a lifetime.

The cause – or causes – of depression are still under investigation and debate. In recent years the mental health community has favored a biological model of depression causation. In this model, development of depression is mediated by an imbalance in central nervous system neurotransmitters; insufficient interneuronal serotonin seems to be the most specific biologic cause of depression.

pacing, purposeless leg movements). Sexual dysfunction affects 34% of patients, which may adversely affect marital relationships and, therefore, the patient's subjective mood.

SSRIs have been reported to cause symptomatic reactions with many substances and medications, primarily due to competition for isoenzymes of the cytochrome P450 system during metabolism. Use of SSRIs may lead to markedly increased caffeine levels, possible leading to caffeine intoxication, insomnia, and anxiety. Patients drinking alcohol while taking SSRIs may experience unintended and prolonged ethanol effects. Drinking

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pink grapefruit juice may raise SSRI levels significantly. Use of cough syrup while on these medications may lead to toxic levels of dextromethorphan, characterized by visual hallucinations, tremors, and confusion. Interactions similar to these have been reported with erythromycin, azithromycin, clarithromycin, isoniazid, narcotic analgesics, hypnotic medications, beta-blockers, St. John's wort, L-tryptophan, Gingko biloba, and even cigarette smoke.

Patients who stop taking SSRI medications may experience flu-like serotonindiscontinuance syndrome; symptoms may include dizziness, vertigo, headaches, confusion, memory difficulties, fatigue, and others. Symptoms may begin 12-72 hours after discontinuing short-acting SSRIs but up to 2-3 weeks after stopping fluoxetine; symptoms usually resolve spontaneously within 1-3 weeks.

Medical response to SSRIs and development of side effects and interactions are highly individualized, and difficult to predict from one patient to the next. Because of this, standards regarding the use of these medications for flight crews must be extremely conservative to err on the side of safety.

Aeromedical Issues. Current FAA regulations prohibit flying while taking psychotropic medications, including SSRIs. Banning SSRIs for flight crews, however, is not the total answer in helping aviators with depression while preventing unnecessary flight risk. As Colonel Robert Ireland, Chief of Aerospace Psychiatry Function at the USAF School of Aerospace Medicine writes, "Strict prohibition against the use of SRIs by fliers can lead to aviators flying with symptoms of depression (including impaired cognition), occult SRI use, and aggressive herbal/supplement regimens - all potential threats to aviation safety now." (5).

At the 2002 annual meeting of the Aerospace Medicine Association, a panel of experts discussed SSRI use in aircrew. The Canadian experience of allowing professional pilots to fly while using SSRIs was discussed; these pilots are highly selected and allowed to fly under restricted conditions (10). The experience of the Aviation Medical Advisory Service, the medical consulting service for the Air Line Pilots association was also reviewed; a five-year survey of case contacts confirms

that prevalence of depression among pilots is between 12 and 20%, consistent with prevalence rates for the general public (4). Postmortem toxicological evaluation of 4,128 pilots from civil aviation accidents between 1990 and 2001 showed that 61 (1.48%) pilots had been taking SSRIs (1). Recently, Federal Air Surgeon Dr. Jon L. Jordan appointed a special in-house committee to evaluate the FAA's position on the use of SSRIs while flying.

Role of the AME. What is the role of the AME when faced with a pilot undergoing depression? The AME should remind the pilot that under FAR 61.53, flying is prohibited while under medical deficiency – this includes experiencing symptoms of depression and taking medications for treatment of depression (3). The AME may (and should) contact the FAA Aerospace Medical Certification Division (AMCD) at the Civil Aerospace Medical Institute in Oklahoma City and report the medical deficiency of the airman. This may be done by letter or by calling the FAA hotline at (800) 255-1111.

The AME may request that the notification be confidential, in which case the pilot will not be informed of the AME's report. Alternately, the AME's report may become an official part of the airman's record, which the airman may obtain on request. When informed, the AMCD will send the airman a notification that re-examination is required. Under FAR 67.407, the Administrator has the authority to "Issue, renew, and deny medical certificates... to a person based upon meeting or failing to meet applicable medical standards." (3).

Although airmen may not fly while depressed, or while taking medication for depression, they may be reassured that their flying days are not necessarily over. Many cases of diagnosed depression fall more appropriately into the classification of adjustment disorder, mood disorders that develop in response to specific stressors, such as marital dysfunction or loss of a job. With appropriate psychotherapy and/or time-limited use of SSRIs, patients' symptoms of depressed mood may abate as the specific stressful conditions resolve (6,7). If an airman had used SSRIs for less than six months, has been off of SSRIs for at least three months, and has had no recurrence of symptoms of depression, he or she may be reconsidered

for medical certification (2).

Outcome. The patient took the Sertraline for a few weeks but stopped after concluding, "these things don't work anyway." He and his wife began marital counseling with their pastor, with very good results. The possibility of job loss resolved, at least for the present time. After six months—and more than three months off the medication—the patient regained his third-class medical certificate and happily resumed flying.

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#### FLAWED CERTIFICATES

Dear Editor:

[Dr. Jones'] article on "Flawed Airman Medical Certificates" in the last Medical Bulletin [QUICK FIX, by Dr. Richard F. Jones, Spring 2004, page 1] elicits the following comments.

Surely, the important thing is that the applicant's certificate should be error-free. Any typing error could be easily corrected by the typewriter and would show no sign of a correction. However, this would not be the case for the copy of this certificate on the "FAA original copy." A typewriter correction would aggravate the error on this copy and there is no way in which this error could then be flawlessly corrected.

Wouldn't a photocopy of the applicant's certificate, which could be attached to the FAA form be acceptable? It would obviate the need to have the whole form re-written by the airman and retyped by the AME.

Whatever the case I will in future pay particular attention when typing the medical certificate. Alas, a human error is always possible

**Dr. John Dax** Paris, France

### Dr. Jones' reply:

You are correct in pointing out how important it is that the applicant's certificate should appear to be flawless. It is permissible to correct any typing error if you have a correcting typewriter, but the finished certificate must show no sign of a correction. My article intentionally addressed only the medical certificate, not the shaded medical certificate portion of the "FAA ORIGINAL COPY" of the 8500-8. The instructions attached



to the student pilot certificate (8420-2) and the pilot medical certificate (8500-9) gives clear instructions on how to reassemble the form set and type the certificate. You are correct, however, that the instructions do not address errors and corrections on the shaded portion of the 8500-8. I assure you, no one insists the shaded area be perfect. If you made errors that were corrected using a correcting typewriter, the corrections would show in the shaded area; that is expected and acceptable.

There is another way to complete the certificates using a template and a printer. When this method is used, the shaded part of the form is not automatically typed. You may then type it separately, duplicating precisely the information on the certificate or, probably preferably, make a photocopy of the certificate to send to the AMCD with the "FAA ORIGINAL COPY" of the form, and also keep a copy of the certificate with your office work copy of the examination. You should never require the airman to fill out another application because of typographical errors you made in completing the medical certificate.

One additional note regarding replacement medical certificates: AMEs are only permitted to issue replacement certificates to applicants within two weeks of the examination to cover the common occurrence of an airman putting the certificate in a shirt pocket after the visit to you, then forgetting to remove it before the shirt is washed. Any requests for replacements after that period should be referred to the AMCD, to minimize opportunities for the rare scoundrel to give an original

certificate to someone else and get a replacement for personal use. Medical certificates are not to be copied by anyone, except as noted above, so pilots need to be advised of this.

Dr. Jones manages CAMI's Aerospace Medical Education Division.

Dear Editor:

The problem of flawed Medical Certificates could be alleviated somewhat if we were able to print them directly from the data put into the computer, as was possible under the Aerospace Medical Certification Subsystem. While it is theoretically possible to do this using the template supplied on the website, this is difficult to get lined up for various brands of printers. Upgrading it so it could be used for all of the popular printers would be very helpful.

Harry J. Wander, MD Yuba City, Calif.

Dear Dr. Wander:

Good idea! We have asked our DIWS contractor to find a solution that would work on many office printers. However, this might take a while to complete because of other pressing priorities.

Warren Silberman, DO, MPH

Manager, Aerospace Medical Certification Division



You are encouraged to take advantage of the forum to discuss important issues pertaining to airman medical certification.

Let us hear from you. Contact:

Editor, Federal Air Surgeon's Medical Bulletin FAA Civil Aerospace Medical Institute P.O. Box 25082, AAM-400 Oklahoma City, OK 73125 E-mail: Mike.Wayda@faa.gov

# Vardenafil as an Alternative to Sildenafil in the Treatment of Erectile Dysfunction

Case Report, by Peter Kovats, MD, MPH, LtCol USAF, MC, FS

#### **Abstract**

Erectile dysfunction (ED) affects 20 – 30 million men in the U.S. and more than 150 million men worldwide (2). ED is commonly associated with diseases such as hypertension, diabetes mellitus, ischemic heart disease, peripheral vascular disease, atherosclerosis, dyslipidemia, and prostatic hyperplasia (2,3). Sildenafil has been an FDA-approved oral treatment of ED since 1998 and has had a very safe profile. Currently, this medication is allowed for all classes of airmen—with the provision that dose-to-cockpit time be at least 6 hours. This is due to the potential for color vision effects with which sildenafil is commonly associated. Since March of 2003, vardenafil has been on the European market, has been FDA-approved in the U.S. since August 2003, and is currently used as an alternative to sildenafil for the treatment of ED. However, this newer, highly selective treatment is not currently approved for use by airmen for any certificate class.

### History

A 68 year-old airman with more than 1900 hours' flying time presents for renewal of a Special Issuance, Class III medical certificate. He has a history of hypertension, angina, dyslipidemia, homocystinemia, and erectile dysfunction. The airman's current medications, pieced together from various physician reports, include Avapro<sup>TM</sup>, HCTZ, Pravachol<sup>TM</sup>, Zetia<sup>TM</sup>, ASA, and folic acid. On a routine Bruce protocol exercise stress test, his cardiologist noted that the airman was also taking Levitra<sup>TM</sup> (vardenafil) for ED. The airman's cardiovascular work-up was normal and fulfilled all the requirements to successfully renew his Special Issuance for his cardiac history. However, because he was noted be on vardenafil (an unacceptable medication), a General Denial letter was issued. Notably, his primary care physician stated in a current status of health from July 2003 that the airman was reported to be taking Viagra<sup>TM</sup> (sildenafil). This demonstrated that at some time in the past year, the airman switched treatment modalities.

So why is vardenafil not acceptable for use by FAA standards? The concern was that the medication's 10-fold greater potency could cause QT prolongation, ultimately leading to Torsades. However, recent research may likely change this belief.

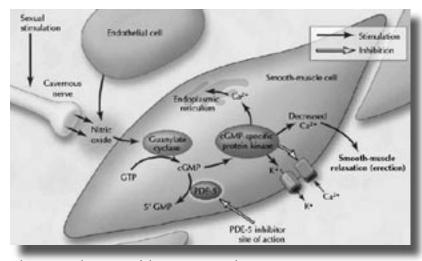
### Background

Oral phosphodiesterase type 5 (PDE-5) inhibitors are considered first-line treatment for ED. Phosphodiesterase enzymes have multiple roles in many tissues, but PDE-5 is predominately found in the corpus cavernosum of the penis. Figure 1 outlines the mechanism of action of the PDE-5 inhibitors. Nitric

oxide is released from nerve endings or from endothelial cells, which stimulate cGMP (cyclic guanosine monophosphate) production. This second-messenger molecule induces smooth-muscle relaxation by reducing the calcium ion concentration, thus producing an erection. The enzyme PDE-5 reverses this cascade of events by rapidly converting cGMP to GMP. All of the PDE-5 inhibitors (sildenafil, vardenafil, and tadalifil) work to inhibit this enzyme, thereby continuing smooth-muscle relaxation and prolonging an erection (4).

The pharmacokinetic parameters of both sildenafil and vardenafil are very similar and can be seen in Table 1(4). For a standard dose of vardenafil (20mg) and sildenafil (100mg), the half-life of both drugs is 4-5 hours for vardenafil and 3 – 5 hours for sildenafil. Additionally, the time to maximum concentration of both drugs is essentially the same at 0.8 hours. Vardenafil undergoes extensive first-pass metabolism by the cytochrome P450 enzyme system, primarily by CYP 3A4. It is here that vardenafil is N – desethylated to the major metabolite M1, which is also highly selective for the PDE-5 enzyme. Approximately 91% -95% of the drug is fecally eliminated, with the remainder of vardenafil excreted through the urine (3,4).

As mentioned previously, sildenafil has been used for ED treatment since 1998, but nearly 50% of patients discontinue use within 2 years because of lack of efficacy, slow onset of action (~ 1 hour), adverse side effects



**Figure 1**. Schematic of the erection pathway (4).

(most commonly headache, flushing, and rhinitis), and poor results for men with diabetes mellitus and severe ED secondary to radical prostatectomy (3). Clinically, vardenafil has been shown to have 10-fold *in-vitro* potency compared to sildenafil. This potent characteristic results in a lower amount of vardenafil required for onset of action and that the actual binding of the drug to PDE-5 occurs before any significant amount of drug appears in the blood plasma (3). It is postulated that this mechanism results in the rapid onset of action of vardenafil (3,4). Additionally, there is evidence that once vardenafil binds to PDE-5, it is very strong with very slow off-rates. Both of these effects can be seen in the maximum concentration and area under the erectile curve differences between sildenafil and vardenafil (Table 1; 4) This results in increased efficacy (penile hardness) and prolonged duration of action. Importantly, because lower amounts of vardenafil are needed to produce a clinical effect, the incidence of side effects may be less apparent (2,3,4).

In general, caution should be used when administering PDE-5 inhibitors to men with mild-to-moderate hepatic and renal impairment. Also, prudence should be used with other drugs that inhibit CYP 3A4. These include HIV

protease inhibitors, oral anti-fungal agents, and the macrolide antibiotic erythromycin. Similar precautions are in place as for sildenafil with nitroglycerin, alpha blockers, and grapefruit juice. Other commonly used medications can be given simultaneously without effect to bioavailability or metabolism. These drugs include H2 blockers, antacids, digoxin, warfarin, ASA, ACE inhibitors, -blockers, diuretics, and metformin (2,3).

Common side effects of both sildenafil and vardenafil include headaches, rhinitis, flushing, dyspepsia, and sinusitis. All of these adverse events become less apparent and less frequent with continued use of vardenafil (3). Interestingly, the color vision disturbances commonly associated with sildenafil have not been reported with vardenafil. Treatment-related visual disturbances have been observed in 3% of sildenafil patients and to only > 0.1% to < 1% of vardenafil patients. No cardiovascular adverse events have been reported with vardenafil (3).

Aeromedically, the most concerning effect of PDE-5 inhibitors is cardiac, with prolongation of the QT interval. Recent studies have demonstrated, however, that vardenafil has essentially the same cardiac profile as sildenafil, the currently FAA-acceptable medication (1, 5). These studies compared sildenafil and vardenafil with a known prolonger of the QT interval, moxifloxacin. The results demonstrated that therapeutic and supratherapeutic doses of vardenafil and sildenafil produced no increases of absolute QT and similar small increases in the corrected QT (QTc) interval. Essentially, the small increases in QTc for vardenafil and sildenafil were clinically insignificant (1,2,5).

Morganroth and associates employed a double-blind, randomized, single-dose, 6-way crossover, periodbalanced study of 54 healthy males, aged 45 – 60 years old and a BMI of < 35 kg/m<sup>2</sup> (1). Methodology involved obtaining 6 ECGs one minute apart, at 30 minutes, and 15 minutes immediately before drug administration. This was then followed by ECGs at 30 minutes, 1 hour, 1.5 hours, and 4 hours after dose to capture any effects from the M1 metabolite. ECGs were read manually using digital techniques by a central laboratory. Blood levels were also obtained before dosing and on completion of the ECG at each time point after the dose. The known QT effects of moxifloxacin, 400mg, were used as a positive control, which yielded an 8 ms QTc average.

Table 1. Pharmacokinetic characteristics of PDE-5 inhibitors (4)

Parameter	Sildenafil	Vardenafil	Tadalifil	
Oral dose, mg	100	20	20	
Median time to peak concentration, min	60	40-60	120	
Half-life, h	3-4	4-5	4-5 17.5	
Max concentration, μg/L	411	17	378	
Area under the erectile curve, µg h/L	1691	67	8066	
Volume of distribution, L	105	208	6.3	
Food interaction	Yes with high-fat foods; possible with low-fat foods	Minimal with low-fat foods; delay in time to peak concentration with high-fat foods	None	
Alcohol interaction	None	None	None	
Age >65 yr	Half-life ↑ Dose adjustment may be needed	Half-life ↑ Dose adjustment may not be needed	Half-life ↑ Dose adjust- ment may not be needed	

Table 2. QT change from baseline at 1 hour after dose

	Placebo	Moxifloxacin 400 mg	Sildenafil 50 mg	Vardenafil 10 mg
*QTcF	0 ms	8 ms	6 ms	8 ms
†QTci	2 ms	7 ms	4 ms	4 ms

<sup>\*</sup>QT interval corrected for heart rate using Fredericia's formula

Table 2 outlines the results of the QT intervals using different corrective techniques for measuring QT intervals. Not shown in Table 2 was the finding that increasing the dose of vardenafil over therapeutic and supratherapeutic (10 mg to 80 mg) doses produced only a small QTc average increase of 2 ms. Therefore, it was concluded that the relationship between the dose of vardenafil and QTc prolongation was nearly flat. As can be seen in Table 2,

the differences between sildenafil and vardenafil are clinically insignificant and are essentially the same.

Because of the similar clinical effects of both sildenafil and vardenafil, a proposal to the Federal Air Surgeon will be made to approve vardenafil as an alternative to sildenafil for the treatment of ED. This will almost certainly lead to an increase in sexual performance without compromising flight or public safety.

### **CERTIFICATION QUIZ** from page 5

cardiac valve replacement; permanent cardiac pacemaker; heart replacement. Richard Reid, a 35-y/o airman from Florida with a British accent, comes to you for a 1st-class medical certificate. His history is negative, with the exception of an appendectomy at age 10. You have not seen him before. He claims to have had a medical certificate from the Civil Aviation Authority in the United Kingdom for carrying cargo. You are one who keeps up with the information from the Federal Air Surgeon, so you ask him for some identification and he produces a current British passport. He claims to live at the Warren Short-Term Apartments on Bin Laden Blvd. You find him to be healthy, without any disqualifying defects, but in this current world situation (especially in America), you find his whole story does not "sit right" with you. What should you do?

ANSWER: In a case where you find nothing that disqualifies the airman you have evaluated, you should issue the medical certificate. After the airman leaves your office, call your Regional Flight Surgeon's office or the

AMCD to report your suspicions. We will then ask FAA Security to check the airman out.

 $O_{3^{rd}\text{-class}}^{Jose Cuervo goes to you for a}$ examination. On his history, he reports several "Driving While Intoxicated" offenses. You have never seen him before. He currently reports 20 hours of flight time. His initial DUI offense was in 1995 while going to bartender school. He informs you that he had been sampling his mixed drinks before he was stopped by police, and he blew 0.08% (the limit for his state was 0.08%). The next offense was in 1999 when he was stopped for erratic driving. His blood alcohol level at that time was 0.15%. He related that he was at a wine-tasting seminar and this was "job related." The most recent offense was in 2001 when he was stopped by the local police and tested. He claims that he was at a party and drinking. While waiting for his friend to drive him home, a police officer drove up and asked Jose why his car was parked in a no-parking zone in front of an apartment building on a

#### References

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- 4. Fazio L, Brock G. Erectile dysfunction: management update. *CMAJ* 2004; 170(9): 1429-37.
- 5. Ilson BE, et al. A definitive study of the effects of PDE-5 inhibitors on cardiac repolarization in middle-age males. *Clin Pharm Ther* 2004; 75:47.



busy street. He said he got into the car and was about to move it, but the police cited him for DUI. That time he blew a 0.25%. He says he has "not drank a drop since." So you issued a medical certificate. Was this a correct decision?

ANSWER: No, it was not. Even though the airman claims he has been sober for 3 years, do you believe him? How many times has he driven and not been stopped? What do you think about an alcohol level of 250 mg%? Might he be demonstrating tolerance? The AMCD has a rule that 3 DUI offenses in a lifetime require a denial. Remember, substance dependence and abuse are specifically disqualifying medical conditions. To be considered for a medical certificate for any class, this applicant will be required to provide current psychiatric and psychological evaluations. We have many cases when either the interviewing psychiatrist or the psychologist will not make a diagnosis of dependence while the other one does. This is the reason for the requirement for bot



<sup>&</sup>lt;sup>†</sup>QT intervals corrected to each subject's QT/RR relation

### **SPORT PILOT** from page 1

To exercise sport pilot privileges, individuals must meet the new sport pilot airman certification (training and qualification) requirements and operate light-sport aircraft that meets the definition of light-sport aircraft. A light-sport aircraft, basically, is a two-place aircraft (limited to a pilot and one passenger), having a maximum gross takeoff weight of 1, 320 pounds (1,430 pounds for water operations), and intended for day, visual flight rules operations.

The medical provisions of the rule are found under Title 14 of part 61 of the Code of Federal Regulations (CFR) under existing Subpart A (revised §§ 61.3, 61.23, and 61.53) and new Subpart J (new § 61.303). Individuals who exercise sport pilot privileges in a light-sport aircraft other than a glider or balloon must have either a current and valid U.S. driver's license or a valid FAA airman medical certificate. Using a current and valid U.S driver's license to exercise sport pilot privileges is not authorized, however, for individuals who were not issued an FAA airman medical certificate at the time of their most recent application, whose most recently issued airman medical certificate has been suspended or revoked, or whose most recent Authorization for a Special Issuance of a Medical Certificate has been withdrawn. Special issuance of an airman medical certificate is not considered a denial. Individuals must not exercise sport pilot privileges if they know or have reason to know of any medical condition that would make them unable to operate light-sport aircraft in a safe manner.

Exercising sport pilot privileges using a valid FAA airman medical certificate is optional, intended for those individuals who do not have or who, for whatever reason, do not want to qualify using a current and valid U.S. driver's license.

Because airman medical certification is optional for sport pilots, amendments to part 67 were not adopted. Instead, the rule maps sport pilot privileges (and limitations) to existing part 61 airman certification standards. The existing provisions of part 67 apply, in pertinent part, however, to individuals who choose to exercise privileges using a valid FAA airman medical certificate and, of course, to those in the process of pursuing airman medical certification.

Individuals who may have applied for or held an airman medical certificate needing clarification regarding their status for exercising sport pilot privileges using a current and valid U.S. driver's license should be advised to contact their Regional Flight Surgeon or the Aerospace Medical Certification Division (AMCD). This will enable them to determine what must be done in order to obtain a favorable decision with respect to at least third-class airman medical certification. It may be a matter of providing further information to the FAA, following through on an incomplete application, or requesting reconsideration — it all depends on their particular situation.

Aviation medical examiners (AMEs) should keep the following in mind regarding individuals seeking to exercise sport pilot privileges who may have applied for airman medical certification:

Applicants deferred by an AME awaiting a decision by AMCD may not request that their application be withdrawn-cases must be "worked" to completion.

Applicants requested to provide additional medical information or history who elect *not* to will be denied based on lack of sufficient medical merit as set forth under §67.413.

Applicants who submit incomplete, but signed applications (FAA Form 8500-8) should realize that it is long-standing FAA policy to consider such applications. The intent of the policy is to

prevent applicants from going to another AME and perhaps falsifying their record in an attempt to get certificated. Such cases may result in denial.

Individuals ultimately certified are not required to maintain airman medical certification to exercise sport pilot privileges provided they hold a current and valid U.S. driver's license and provided they otherwise qualify. Additionally, individuals who already hold a valid FAA airman medical certificate do not have to maintain it if they will only be exercising sport pilot privileges, provided they hold a current and valid U.S. driver's license and provided they otherwise qualify.

Judi Citrenbaum is a Washington Headquarters analyst who worked on the Sport Pilot rulemaking team.



### FAA's FY-2004 Safety Goals 'World-Class'

Fiscal Year 2004 ended September 30 with a three-year average of .021 fatal commercial aviation accidents per 100,000 departures, 340 fatal general aviation accidents (below the 349 not-to-exceed number), and 98 accidents in Alaska – way below the 125 not-to-exceed target. Also, there were eight injuries from turbulence – half the annual target.

In the words of **Nick Sabatini**, Associate Administrator for Regulation and Certification, "This is *world-class* safety performance."

From FAA Safety Highlights, a publication for FAA Regulation & Certification employees

### **SPORT PILOT FAQs**

The following 'Frequently Asked Questions' have been helpful to individuals seeking further clarity regarding the medical provisions of the rule.

QUESTION	ANSWER
What if my most recent application for FAA airman medical certification was denied (and I was not granted Special Issuance), my most recently held airman medical certificate was suspended or revoked, or my most recently held Special Issuance was withdrawn? I understand that I may not use my current and valid U.S. driver's license as medical qualification to exercise sport pilot privileges. What do I do?	You may ask the FAA for reconsideration of your eligibility to hold an airman medical certificate. While it is impossible to predict a favorable outcome, your medical condition may have improved, thereby permitting your certification. If you are not ultimately qualified by the FAA, you have the option of appealing the decision to the National Transportation Safety Board.
What if I hold a Special Issuance? Is that considered denial of an application for an airman medical certificate?	No. Special Issuance is not considered the denial of an FAA airman medical certificate.
What if I was previously denied a medical certificate, I resubmit my application and, ultimately, I am certified? Must I continue hereafter to renew my medical or may I use my current and valid U.S. driver's license as evidence of medical qualification?	If you are ultimately certified then you are no longer on record with the FAA as having had your most recent application denied or your most recently held FAA airman medical certificate suspended or revoked, etc. Therefore, it is not necessary to maintain airman medical certification thereafter to exercise sport pilot privileges provided you hold a current and valid U.S. driver's license and provided you otherwise qualify.
What if I already hold a pilot certificate and a valid airman medical certificate? Do I have to maintain my airman medical certificate if I will only be exercising sport pilot privileges or may I use my current and valid U.S. driver's license as medical qualification?	You may use your current and valid U.S. driver's license to exercise sport pilot privileges; however, you must hold the required, valid FAA airman medical certificate if you wish to exercise private pilot (or higher) privileges.
What if I know (or suspect) that I have a significant medical condition and I hold (and have been able to maintain) a current and valid U.S. driver's license? Am I authorized to exercise sport pilot privileges provided I otherwise qualify?	Long-standing FAA regulation, § 61.53, prohibits all pilotsthose who are required to hold airman medical certificates and those who are not-from exercising privileges during periods of medical deficiency. The FAA revised § 61.53 to include under this prohibition sport pilots who use a current and valid U.S. driver's license as medical qualification. The prohibition is also added under §§ 61.23 (c) (2) (iv) and 61.303 (b) (2) (4) for sport pilot operations. You should consult your private physician to determine whether you have a medical deficiency that would interfere with the safe performance of sport piloting duties. Certain medical information that may be helpful for pilots is posted on the FAA Web site at http://www.cami.jccbi.gov/aam-400A/400brochure.html.
What if I have a life-long, chronic medical condition (e.g., diabetes mellitus) and I have never applied for or held an FAA airman medical certificate and my medical condition has never precluded me from being able to renew my U.S. driver's license? Am I authorized to exercise sport pilot privileges provided I otherwise qualify?	You should consult your private physician to determine whether you have a medical deficiency that would interfere with the safe performance of sport piloting duties. You may exercise sport pilot privileges provided you are in good health, your medical condition is under control, you adhere to your physician's recommended treatment, and you feel satisfied that you are able to conduct safe flight operations.

# New Flight Surgeon Joins Southern Region

By David P. Millett, MD

The Southern Region is pleased to announce the arrival of **Michael B. Miller**, DO, OD, MPH, into the position of flight



surgeon in the regional office.

Dr. Miller assumed his duties in May of this year. He brings a wealth of knowledge and experience to the Federal Aviation Administration with board certification in family medicine and occupational and environmental medicine.

Dr. Miller graduated from Wake Forest University and attended U.S. Army Basic Officer Training. He attended the Illinois College of Optometry and earned his degree of Doctor of Optometry.

After two years of duty as an Army Optometrist, he furthered his education by entering the University of Health Sciences College of Osteopathic Medicine in Kansas City. He graduated with his Doctor of Osteopathic Medicine degree.

After his internship, he became an Army Flight Surgeon. His eight-year, active-duty tour as a flight surgeon included service in Southwest Asia during the Gulf War.

In 1993, he left the Army and completed a two-year residency in Occupational Medicine and a Masters Program in Public Health at Emory University. In 1995, he was designated as an aviation medical examiner after the rotation at the Civil Aerospace Medical Institute. He served as an AME for the Air Traffic Control Specialist Program and as an Occupational Medicine Physician in several Southeastern locations.

Prior to joining the FAA, Dr. Miller was with the University Occupational Health Center in Augusta,

Dr. Millett is the Southern Regional Flight Surgeon.



"Best of the Best." Dr. Silberman (rt.) receives RAM Instructor of the Year award from Lt.Col. Lawson.



Dr. Silberman Receives RAM's Instructor of Year Award By Lt.Col. Jeffrey Lawson

On 15 Sept 2004, the USAF Residency in Aerospace Medicine (RAM) Class 2005 presented Col. **Warren S. Silberman** with the "Instructor of the Year" award.

The RAM is a three-year program with approximately 50 residents in training. During the aerospace medicine year, the residents have the distinct honor of working with the best in aviation medicine worldwide. Each year, the RAMs select, by majority ballot, their choice of best instructor. The selection criteria include: excellence in teaching skills, dedication, value and quality of education, energy and enthusiasm, mentorship, and interpersonal skills.

Col. Silberman, a RAM himself, has been serving as the primary RAM preceptor since the inception of the Federal Aviation Administration's RAM rotation. He has consistently sacrificed personal time to provide the residents with the best possible educational experience in an environment that maximizes learning.

Out of the best in the world, the RAM Class 2005 has selected Col. Silberman as the aviation medicine instructor of the year. He is truly the "best of the best."

Dr. Silberman manages CAMI's Aerospace Medical Certification Division.

Ga. While in Augusta, he established the St. Vincent de Paul Eye Clinic for the underserved population.

We are indeed fortunate to have Dr. Miller on our team. He has already participated in our Health Awareness Program and has provided employee glaucoma screening, among other events.

### **AME Training**

### 2004 Was a Good Year

By Doug Burnett, MS

HE FY-2004 aviation medical examiner training program concluded with a total participation of 2,329 AMEs and staff members. Of the 2,329 participants, 855 attended theme seminars, 221 attended basic AME seminars in Oklahoma City, and 1,253 completed distance education training. Satisfaction with the on-site seminars was extremely high, with 96% of users rating the quality of the training "Good" or "Excellent."

AMEs enjoyed locations such as the new Gaylord Opryland Hotel in Dallas, Texas, the AsMA meeting in Anchorage, Alaska, and the Ritz Carlton Hotel in McLean, Va. Seminars were attended and supported by approximately 25 staff members from the regions, and regional staff attended every basic seminar.

International AMEs and other international physicians also took advantage of AME training and were represented in every AME theme seminar, basic seminar, and distance education course. Countries represented included: Australia, Austria, Belgium, Brazil, Canada, Colombia, Costa Rica, the Czech Republic, Egypt, Ethiopia, France, Germany, Greece, Guatemala, Hong Kong, Italy, Japan, Jordan, Korea, Malaysia, the Netherlands, Pakistan, Panama, the Republic of South Africa, Serbia, Singapore, Spain, Taiwan, Thailand, Trinidad and Tobago, Turkey, the United Arab Emirates, the United Kingdom, and Venezuela.

Approximately 80% of AME seminar attendees utilized registration by E-mail, which reduced administrative hassle for both AMEs and FAA staff members. Plans for 2005 include further expansion of services such as registration, confirmation of registration,

and information updates by E-mail, but we need your help. With only 80% of AMEs providing E-mail addresses (and many of these being inaccurate), it is difficult to reliably provide you with quick information updates, feedback regarding administration procedures, and much deserved "attaboys." Please provide or update your E-mail address by December 31, 2004. Establish or update your E-mail address with: Leah.Olson @faa.gov or Denese.Patt erson@faa.gov.

### Problems With FAA Form 8500-8

In June 2004, it was discovered that the new batch of 8500-8s was flawed. The "watermark writing" on each page of the form was not transparent, as it should have been, which blocked some of the printing on each page. Also, the paper was of different quality and difficult to write on. In some cases, the certificate number came through on the form, causing confusion among AMEs who were unsure if the certificate number belonged on the form.

The forms could still be read by flipping from page to page, but some AMEs were concerned that errors could be made due to someone misreading the text covered by the words, "FAA ORIGINAL," etc. The problem was brought to the attention of the printer, who agreed to replace the forms. However, it was late in September before we received the new forms, requiring that the flawed forms continue to be distributed until the new ones arrived.

The new forms, FF3614000 thru FF4363999, are now being distributed. The flawed forms will be destroyed. Those of you who received the flawed forms may use up your remaining stock, or may re-order and return the problem forms to us.

Mr. Burnett manages CAMI's Aviation Medical Examiner Program.

**+** 



Clearing Up Misunderstandings

By Bobby Ridge

Aviation Medical Examiners (IAMEs) to our mailing list for system-generated invitations to AME Theme Seminars. This gesture of goodwill to our IAMEs has resulted in confusion for some individuals. It was our intention to provide them the same courtesy as we do our U.S. AMEs, i.e., provide them with information concerning an upcoming FAA seminar. Unfortunately, a number of our IAMEs considered this seminar invitation as notification of delinquency in training and understood it to mean that it was mandatory that they attend this course. This was not our intent.

All AMEs should know when they are due for training, and they should not find it necessary to contact the FAA to inquire as to when they last trained. The last class- and self-training dates are indicated on the Individual AME Performance Summary Report. Therefore, upon receipt of an invitation to an FAA seminar, if you are unsure as to whether you are due training, you may refer to your personal report.

If the dates on the report do not seem accurate, then contacting the Region is warranted, preferably by an E-mail to Bobby.Ridge@faa.gov. If you know training is not required, the invitation should not be regarded as mandatory. However, all AMEs are welcome to attend any seminar, whether or not they are due training.

Part of the confusion may have resulted from our efforts to improve the excessive training delinquency for IAMEs reflected on our latest Consolidated AME Performance Summary Report. Because of the high number of delinquencies, on August 31, 2004, we advised all IAMEs of FAA training requirements and the necessary steps to correct their delinquencies. In our letter,

Continued ➤

### **INTERNATIONAL** from page 16

we explained that AME refresher training is required every three years by FAA Order 8520.2E, FAA Aviation Medical Examiner System. On-site (FAA or International) training is required at least every six years; distance learning (Multimedia AME Refresher Course (MAMERC) or Clinical Aerospace Physiology Review for AMEs (CAPAME)) may be substituted for on-site training in alternating three-year cycles.

Refresher training is required to ensure that you remain familiar with medical principles applicable to aeromedical certification, particularly as applied by the FAA. However, we recognize that the costs of traveling to the United States for our training can be prohibitive for some IAMEs, so we sometimes accept locally accomplished aviation medicine training, after a case-by-case review to ensure equivalency to FAA training. When you wish consideration of such training, it is necessary to provide a copy of the certificate of completion and the agenda to the International Region. This documentation must clearly define the content of the course and indicate the number of hours of training, so that the Regional Flight Surgeon, Dr. Richard Jones, can make a decision on whether or not it meets our training requirements.

We have been too liberal in the past, permitting International AMEs to complete back-to-back Distance Education courses to update their FAA training, instead of completing on-site training every six years as required by FAA Order 8520.2E; this practice actually became the norm rather than the exception. In the future, we will only permit back-toback Distance Education as a temporary measure, while an AME is waiting to attend on-site training that could not be accomplished earlier due to an unforeseen emergency. Permanent inability to travel will not normally be viewed as an adequate reason for not attending on-site training; this will require caseby-case analysis after the AME provides sufficient medical documentation.

Many IAMEs have inquired as to whether their records have been updated to reflect their attendance at International seminars that have been approved by Dr. Jones. We have updated our records accordingly, but due to the enormous amount of correspondence, we have been unable to provide timely written notice that records have been updated.

We apologize for any inconvenience our seminar invitation may have caused and hope that you now have a better understanding of its purpose. I assure you we appreciate the hard work you do for the FAA. It is wonderful to meet you all in person when you attend our seminars. Please take our invitations to train in the spirit in which they are intended—an opportunity to interface with FAA staff and other AMEs from around the world.

Ms. Ridge is the program analyst for the International/Military/Federal Region at CAMI's Aerospace Medical Education Division.



### Aviation Medical Examiner Seminar Schedule

### 2004

November 5-7Tampa, Fla	N/NP/N (2)
November 15-19Oklahoma City, Okla	Basic (1)

### 2005

<u> 2005</u>
January 21-23N/NP/P (2)
February 25-27Austin, TexasCardio (2)
March 14-18 Oklahoma City, Okla Basic (1)
May 9 - 12OOE (3)
June 13 - 17 Oklahoma City, Okla Basic (1)
July 15 - 17N/NP/P (2)
August 5 - 7Cardio (2)
September 12 - 16Oklahoma City, Okla Basic (1)
November 18 - 20Savannah, Ga AP/HF (2)
December 5 - 9 Oklahoma City, Okla Basic (1)

### **CODES**

AP/HF Aviation Physiology/Human Factors Theme

CAR Cardiology Theme

OOE Ophthalmology - Otolaryngology - Endocrinology Theme N/NP/P Neurology/Neuro-Psychology/Psychiatry Theme

- (1) A  $4\frac{1}{2}$ -day basic AME seminar focused on preparing physicians to be designated as aviation medical examiners. Call your regional flight surgeon.
- (2) A  $2\frac{1}{2}$ -day theme AME seminar consisting of 12 hours of aviation medical examiner-specific subjects plus 8 hours of subjects related to a designated theme. Registration must be made through the Oklahoma City AME Programs staff, (405) 954-4830, or -4258.
- (3) A 3½-day theme AME seminar held in conjunction with the Aerospace Medical Association (AsMA). Registration must be made through AsMA at (703) 739-2240. A registration fee will be charged by AsMA to cover their overhead costs (NONE OF THIS FEE GOES TO THE FAA). Registrants have full access to the AsMA meeting; however, it is mandatory of all attendees to attend the first FAA session for instruction on the requirements for seminar credits. CME credit for the FAA seminar is free.

The Civil Aerospace Medical Institute is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical education for physicians.