



## **New Regulation Gives U.S. Air Surgeon Broader Authority in Determining What Drugs And Treatments Are Cause for Medical Denial**

*Pilots also must be cautious in their use of more than 300,000 over-the-counter medicines, some of which can impair a pilot's ability to conduct flight operations safely.*

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The U.S. Federal Aviation Administration (FAA) has announced that a new regulation (Medical Standards) will authorize the federal air surgeon to specifically determine whether a given medication or treatment is cause for denial of medical certification.<sup>1</sup> Federal Aviation Regulations (FARs) Part 67 previously cited “hypoglycemic agent” as the only clear-cut prohibition among pharmaceuticals.<sup>2</sup> The new regulation, issued on Sept. 9, 1994, applies to all three medical certificate classes, and reads:

Section 67.13 First-class medical certificate.

(f) (3) No medication or other treatment that the Federal Air Surgeon finds —

(i) Makes the applicant unable to safely perform the duties or exercise the privileges of the airman certificate that the applicant holds or for which the applicant is applying; or

(ii) May reasonably be expected, within two years after the finding, to make the applicant unable to perform those duties or exercise those privileges;

and the findings are based on the case history and appropriate,

qualified, medical judgment relating to the medication or other treatment involved.

Section 67.15 Second-class medical certificate. Same as first class.

Section 67.17 Third-class medical certificate. Same as first class.

The addition of “or other treatment” to “no medication” in the new regulation gives a wider latitude to the federal air surgeon. Treatment involving electroconvulsive therapy, for example, could also be a cause for denial.

The rule change followed a decision by the U.S. Federal Court of Appeals. The court overruled the federal air surgeon in *Bullwinkle v. FAA*, the case of a pilot who was taking lithium.<sup>3</sup> [Lithium is a medicine used in psychiatric practice to treat manic-depressive illness. Possible (although rare) side effects of this medicine include drowsiness, muscle weakness, nausea or vomiting, slurred speech, dizziness, confusion, blurred vision or convulsions.] As a result, the FAA decided that it was necessary to give more authority to the federal air surgeon to prohibit various drugs in connection with medical certification.

Pilots and their physicians who have questions about a specific medication's possible adverse effect on air crew members previously have had little guidance; the most recent relevant publication is a book published in 1982.<sup>4</sup> Although the general principles with respect to drug categories still hold, some newer medications have been introduced (for example, Accutane, for acne).

The FAA has been reluctant to undertake an in-house publication because the task is quite onerous, and periodic supplements would be necessary. [A summary of the book cited above was published in Flight Safety Foundation's May/June 1983 *Human Factors Bulletin*.<sup>5</sup>]

In deciding whether a pilot can safely perform the duties authorized by an FAA certificate, the following considerations apply:

- Does the medication have adverse side effects, such as drowsiness, judgment impairment, excitability, decreased acceleration tolerance or other effects that would impair performance?
- Does the condition for which the medication is taken preclude medical certification under present FAA regulations and policies?

For example, flight duty while taking insulin for diabetes mellitus is prohibited by Part 67. Psychosis, epilepsy, myocardial infarction and unexplained loss of consciousness are also grounds for medical certificate denial under Part 67.

Physicians who have no background, experience or training in aviation may not be able to safely advise air crew members about medications with respect to flight duties. Should a question arise about flying with a specific medication or condition, the initial point of contact for a pilot usually should be the aviation medical examiner.

The pilot can also consult the FAA regional flight surgeon, or the aviation medical director or aviation medical consultant to the company, if the latter are available.

Another source of information is the Aeromedical Certification Division of the FAA Civil Aeromedical Institute, Oklahoma City, Oklahoma, U.S. The federal air surgeon's office in Washington, D.C., also can be consulted.

A wide variety of medicines and conditions can interact adversely to jeopardize safe flight. Thus, a conservative approach is recommended and when in doubt, flight should be avoided unless the safety of the medication has been demonstrated.

## Pilot Health Remains Primary Factor

Pilot health should be the prime consideration. Medications that are absolutely necessary for health should be taken until there is no longer a need for treatment. Prophylactic or preventive medications can be taken concurrently with flying duties if, as stated earlier, these do not impair safe flying performance. Flying duties can be suspended temporarily by a pilot while taking a medication on an acute basis if treatment would adversely affect flight safety.

Four words are used more or less interchangeably, depending upon the context, to refer to a substance other than a food or beverage that is taken to counter, or to prevent, an illness — medication, drug, medicine or pharmaceutical. Penicillin, antihistamines or any number of other substances, natural or man-made, for example, can be described by any of these terms.

Ethyl alcohol is a drug but it is in such common use that it is considered a beverage, contributing some calories when burned by the body's metabolism. Caffeine and nicotine are drugs, but the FAA in Part 67 specifically excludes these (nicotine as "tobacco") from the drug category. Tobacco's exclusion is based on history, in that this highly addicting slow killer (associated with heart disease, stroke, cancer and other conditions) and toxic substance (producing carbon monoxide and associated with retinal, nervous system and pulmonary damage) has been used so pervasively.

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## Illegal Drugs Can End a Flying Career

Illegal drugs should never be taken by a pilot. The FAA's drug testing program, which includes urine tests of those whose duties directly bear on air safety, specifically cites opiates, cocaine metabolites, marijuana derivatives and amphetamines. A pilot who uses illegal drugs faces severe penalties and loss of flying privileges. Such behavior demonstrates ignorance, illness or a reckless attitude.

The FAA has never associated birth control medications with air safety hazards, and they have never been prohibited.

The U.S. Food and Drug Administration (FDA) has approved more than 1,300 medicines as effective in accomplishing their intended purposes and, if used properly, relatively safe.<sup>5</sup> These medicines each have a generic name that is assigned by the American Medical Association and representatives of the pharmaceutical industry. A generic drug will have one or more proprietary names, also known as brand names or trade names. More than 7,000 of these named medicines have been

approved by the FDA. In addition, more than 300,000 over-the-counter medicines are available in the United States without prescription. Many of these are available because of decades, or even centuries, of use, whether or not the medicines have a real preventive or curative effect on illnesses. Some of them can impair a pilot's ability to conduct flight operations safely.

Medicines may be swallowed, injected, applied to the skin, taken by enema or inhaled. The varieties of medicine preparations include tablets, powders, syrups, tinctures, inhalants and other forms. In the body, the active ingredient in the medicine attaches to specific receptor sites within tissues, on cells or in the circulation fluids of the body. Chemical reactions may be modified, cell membrane characteristics may be changed, and other effects (including the death of certain cells) may take place to accomplish the medicine's objective.

When a medicine produces such side effects as drowsiness, impairment of judgment, excitability and manic behavior, decreased tolerance to acceleration, insomnia, hyperirritability, dizziness or nausea, the medicine may achieve its treatment objective but be a hazard to flight. This point must be stressed continually in pilot education programs.

When medicines are taken, they will, at a rate depending on how they are administered, produce an increased peak concentration in the blood with a progressive fall in the concentration. When half of the medicine has been eliminated from the body, that time period is referred to as the half-life of the substance in the body. Some drugs have a half-life of just a few minutes. Others have a half-life of three days or more. How often a medicine is given depends in part on its half-life, because a medicine with a short half-life is generally given more frequently than one with a long half-life.

### **Categories Define Terms Of Medicine Use and Flying Status**

Medicines can be placed in six categories in connection with flying activities. These are:

**Category 1** contains medicines that are safe in connection with flight duties. Some examples are acetaminophen (Tylenol), acetylsalicylic acid (aspirin) and undecylenic acid (Desenex).

**Category 2** contains medicines considered safe for a pilot to use during flight duties if a flight surgeon, an aviation

medical examiner or an FAA physician concurs. Examples are amoxicillin (Polymox), nystatin (Nilstat) and chloroquine (Aralen).

**Category 3** contains medicines that have been approved on an individual-pilot basis by the FAA following its review of related history and physical information. Examples are allopurinol (Zyloprim), griseofulvin (Fulvicin) and propranolol (Inderol).

**Category 4** describes medicines whose effects on a pilot are adverse to safe flight. At least three half-lives of these substances should pass before resuming flight duties after use of these medicines. The half-life time is available from the prescribing physician or relevant literature. Examples include allobarbitol (Dialog), codeine (various names) and flurazepam (Dalmane).

**Category 5** contains medicines that, because of the condition for which the medicines are prescribed, preclude safe flight. The FAA's new regulation giving the federal air surgeon authority to determine whether a given medication can be prohibited derives primarily from considerations in this category. Examples include lithium acenocoumarol (Sintrom), chlorpromazine (Thorazine) and deslanoside (Cedilanid).

**Category 6** involves a group of very potent medicines for which one should wait at least five times the half-life before engaging in flying duties, to be sure that the substance is cleared from the body. Examples include the amphetamine (Robese), diazepam (Valium) and indomelacin (Indocin).

Some medications that have been FDA-approved since the 1982 publication of the pilot's guide to medications are isotretinoin (Accutane, category 2); zidovudine (Retrovir-AZT, category 5); acyclovir (Zovirax, category 3); flutamide (Eulexin, category 3) and finasteride (Proscar, category 2).<sup>4</sup>

### **Standards Are Not Necessarily Universal**

Some countries have different opinions about the use of specific medications, particularly sleeping medications, in connection with flight duties. The preceding discussion was based on a U.S. viewpoint, and will not necessarily apply in other countries, although there is general agreement on the concepts.

As a general rule, a pilot should take no unnecessary medications, or only medications that deal with a specific health

circumstance requiring attention. He or she should fly only when neither the medication(s) nor the condition being treated preclude safe flight activities. Consultation with the aviation medical examiner, a flight surgeon or the FAA will provide guidance in combining flight duties with specific conditions and medications. ♦

## References

1. U.S. Federal Aviation Administration (FAA). Medical Standards and Certification. Final Rule — Medications, Part 67.13, .15, .17. *Federal Register*, Vol. 59:174, Sept. 9, 1994, 46706–46708.
2. FAA. 1994. Code of Federal Regulations, Title 14, Parts 67.13(f), 67.15(f), 67.17(f).
3. U.S. Court of Appeals, *Bullwinkle v. Federal Aviation Administration*, 7th Circuit, No. 93-1803, April 27, 1994.
4. Mohler, S.R. *Medication and Flying: A Pilot's Guide*.

Boston, Massachusetts, United States: Boston Publishing Co., 1982.

5. Mohler, S.R. "Medicines and the Pilot." *Human Factors Bulletin*. Volume 29 (May/June 1983): 1–6.

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