

BY SUSAN PARSON



From FDA *to* FAA

How the FAA Evaluates Drugs for Aeromedical Use

In preparation for the private pilot flight training that I started in August 1991, earlier that summer I made my very first visit to an FAA Aviation Medical Examiner (AME) to acquire the necessary third-class medical and student pilot certificate ... a yellow-beige document that I still keep among the treasured souvenirs and mementos of my status as a certificated pilot. I upgraded the third-class medical to a second-class medical when I trained a few years later for my commercial pilot certificate. And, for the first 16 years of my aviation career, I was fortunate enough to breeze through both the many check-boxes on the FAA Airman Medical Application (FAA Form 8500-8, now exclusively online via MedXPress) and the exam itself.

That all changed in 2007, when I was diagnosed with a medical condition — multiple sclerosis — that made things a little more complicated. As is the case for any passionate pilot, one of my biggest and most immediate concerns was for the impact this annoying and most unwelcome development would have on my ability to hold an FAA medical certificate. Since I had always been able to take my health, and thus my eligibility for FAA medical certification mostly for granted, I had never had cause to investigate this issue. But now I was motivated!

I was immensely relieved to learn several things. First, the FAA's special issuance process — which the FAA medical staff has worked very hard to improve in the last few years — provides the means to certificate an astonishing range of medical conditions and limitations. My particular brand of MS (relapsing-remitting) is happily among the many certifiable conditions under the special issuance process, and so I threw myself into becoming an expert on what the FAA requires for special issuance.

That process also made me aware of the fact that, while there is a long list of potentially certifiable medical conditions and limitations, the list of allowable medications is somewhat more limited. Even more confounding was the fact that the FAA itself does not publish a list of such meds. Like many pilots, though, I was able to get the information I needed from one of the many aviation advocacy organizations that research this information with the FAA and maintain an "FAA-approved" pharmaceutical database for their members.

Why the Mystery on Meds?

So why does the FAA decline to make this all-important information directly available, and how does the FAA go about approving drugs in the first place? For answers, I went to Dr. Michael Berry, Manager of the Medical Specialties Division in the FAA's Office of Aerospace Medicine. This Division is responsible for a wide range of issues, including Aerospace Medicine policy and procedures regarding pilot medical certification, and medical clearances for air traffic control specialists, the evaluation and management of complex psychiatric cases and

issues, and oversight of the agency employee drug and alcohol testing program.

"The first thing to understand is that the FAA does not 'approve' drugs," stresses Berry. "Our colleagues in the FDA [Food and Drug Administration] have that function." Rather, Berry and his staff evaluate medications to determine whether they can safely be used in the aviation environment. Another important point, says Berry, is that the FAA does not look at drugs alone. "Our primary concern is not just about the drug and its side effects, but also about the underlying medical condition it is intended to treat," he notes. A drug that successfully and effectively treats a particular condition on the ground may not be safe or suitable for use in the flying environment. "The airman's overall fitness and aviation safety are the guiding principles," says Berry, "and because we can sometimes approve medications for some conditions, but not for others, it's almost impossible to have a single policy that applies to all possible uses of a given drug. Again, it's about the drug's impact on the underlying medical condition as well as the effect on the individual, so we have to take almost a case-by-case approach."

That's partly why there is no "official" list of allowable medications, but Berry also points to other factors. "The number of possible medications and combinations is enormous, and there are new medications coming on the market frequently" he observes. The agency would need a much larger staff simply to develop such a document. Keeping it up to date would also be prohibitively resource-intensive. "There are so many different products out there, with so many different uses. New information emerges almost every day, and we are constantly re-evaluating our policies on the basis of that information." This ongoing evaluation creates changes in both directions. "Sometimes," says Berry, "we get adverse information about a drug's effects after we have accepted it for use in aviation, and we have occasionally had to withdraw our acceptance of that drug. At other times, new information acquired over several years of use persuades us that we can accept one we initially declined to allow."

The Regulations

The regulations are very clear about the FAA's expectations with respect to an airman's medical condition:

14 CFR 61.53 prohibits a person from acting as pilot in command or as a required pilot flight crew member while that person (1) "knows or has reason to know of any medical condition that would make the person unable to meet the requirements for the medical certificate

necessary for the pilot operation"; or, (2) "Is taking medication or receiving other treatment for a medical condition that results in the person being unable to meet the requirements for the medical certificate necessary for the pilot operation."

14 CFR 91.17 states (a) No person may act or attempt to act as a pilot crewmember of a civil aircraft...(3) While using any drug that affects the person's faculties in any way contrary to safety.



How Long, and Which Ones?

The need for careful evaluation of a drug's effects is the reason for the FAA's general policy of waiting at least a year after a drug receives FDA approval before it will be considered for use by airmen. "The FDA obviously does extensive testing," observes Berry, but testing inherently involves only a small segment of a drug's target population. "We wait at least a year to let the FDA establish a more complete profile of benefits and side effects before we commit the resources required for aviation evaluation," he states.

And it is indeed a resource-intensive process. A small team of FAA physicians in Berry's Division make up the Pharmacy and Therapeutics Committee headed by Dr. Arleen Saenger, which looks at everything it can find, starting with the FDA label (i.e., officially approved uses), the FDA's research and reviews (including post-market safety reviews), academic research, and publications such as PubMed. Also of interest is the work and experience that foreign pharmaceutical and aeronautical authorities have had with a given combination of medical conditions and drugs. Once the Committee reaches consensus on the possible aeronautical use of a drug, Saenger makes a recommendation to Berry. The Federal Air Surgeon, Dr. Fred Tilton, has the final say.

Another important point on FAA resources: "There is simply no way we could evaluate every new drug that appears," notes Berry. Instead, the FAA chooses to evaluate a drug primarily when there

appears to be an appropriate cost-benefit ratio. "If there are a number of airmen with a given condition who request acceptance of a new drug to treat that condition, there is obviously a benefit in committing the resources to review it."

How Do I Decide?

Berry stresses that the FAA's primary concern is whether the underlying medical condition being treated is compatible with safe flying, and then the safety of the medication being used. He also reiterates the wisdom of advice that some aviation advocacy groups offer their members: Even if the FAA allows a given medication for your condition, anyone taking a drug for the first time should conduct a "ground run" self-evaluation period for at least 48 hours before attempting to fly. The idea is to ensure that there are no unexpected adverse reactions. "There are wide variations in individual physiology," says Berry, which is one of the reasons that drug evaluation is a process that defies a simple or cookie-cutter approach.

Another important point: No matter how much you want to fly, your health has to come first. "The fact that the FAA allows some medications and not others will obviously be of interest to airmen, but never let that drive the decision," he counsels. "You and your doctor have to make whatever decision is best for your overall long-term health. And remember that things do change—new drugs are developed all the time, and new information may allow us to reconsider accepting drugs that we initially declined to permit for use in aviation." ✈️

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CAMI Pilot Safety Brochure "Medications and Flying"
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Aeronautical Information Manual, Chp 8 Medical Facts for Pilots (medication section)
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