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NTSB Order No. EA-3776

UNITED STATES OF AMERICA
NATIONAL TRANSPORTATION SAFETY BOARD
WASHINGTON, D.C.

Adopted by the NATIONAL TRANSPORTATION SAFETY BOARD
at its office in Washington, D.C.
on the 25th day of January, 1993

Petition of)

MICHAEL L. MARTIN)

for review of the denial by)
the Administrator of the)
Federal Aviation Administration)
of the issuance of an airman)
medical certificate.)

Docket SM-3955

OPINION AND ORDER

The Administrator has appealed from the oral initial decision of Administrative Law Judge Jerrell R. Davis issued on June 30, 1992, at the conclusion of an evidentiary hearing.¹ By that decision the law judge concluded that petitioner had met his burden of proving that he was qualified to hold a first-class airman medical certificate by showing that "he does not pose a risk of incapacitation of unacceptable proportions either now or

¹The initial decision, an excerpt from the hearing transcript, is attached.

within two years." Initial Decision, TR at 237. We grant the appeal and reverse the law judge's decision.

By letter dated January 30, 1992, petitioner was issued a final denial of airman medical certification by the Federal Air Surgeon, who determined that petitioner did not meet the medical standards of paragraph (f)(2) of sections 67.13, 67.15, and 67.17 of the Federal Aviation Regulations (FAR), 14 CFR Part 67,² because of his history of hepatitis secondary to sclerosing cholangitis for which petitioner required a liver transplant in December, 1990. The Federal Air Surgeon further cited as reasons for his denial the fact that petitioner continues to be treated with immunosuppressive medications including the drug FK 506, which has not yet been approved by the Food and Drug Administration (FDA) and which he considers unacceptable for use by pilots. Finally, the Federal Air Surgeon cited petitioner's history of ulcerative colitis as a basis for his denial of certification.

² Paragraph (f)(2) of FAR §§ 67.13, 67.15, and 67.17 provides as follows:

"(f) General medical condition....

(2) No other organic, functional or structural disease, defect or limitation 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 he holds or for which he is applying; or

(ii) May reasonably be expected, within two years after the finding, to make him 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 condition involved."

Petitioner's medical records establish that he was diagnosed with liver disease in 1988. In October, 1990, his condition worsened, and on November 4, 1990, he experienced a massive gastrointestinal bleeding which required hospitalization. He was subsequently transferred to the Mayo Clinic in Rochester, Minnesota, and in December, 1990, he underwent a liver transplantation. Following his surgery, petitioner was placed on immunosuppressant medication, FK 506, and a steroid, Prednisone.³

He is required to undergo blood chemistries, including liver function tests, every six weeks to insure proper dosage of his medication and to evaluate whether he is experiencing rejection of the donor organ.⁴ Petitioner experienced post-surgery complications including ascites (build up of abdominal fluids), and he underwent post-transplant revision of his hepatic artery and three balloon dilations of the vena cava. He has in the past suffered tremors and renal dysfunction, both of which are known side-effects of FK 506, though he currently denies side-effects.

³Liver transplantations have apparently been performed successfully since the 1980's. Most liver transplant patients are treated with Cyclosporine to prevent rejection. FK 506 is a cyclosporine-type drug, still under investigation and not yet approved by the FDA. Its side effects are still being studied but are known to include nephro-toxicity, diabetes, tremors, hypertension, and headache.

⁴According to the FAA medical expert, Dr. Sorrell, chronic rejection is insidious, and is typically detected only by blood chemistries, as opposed to acute rejection, where a patient may experience symptoms such as fever, chills, and jaundice. The likelihood of petitioner becoming suddenly incapacitated because of acute rejection is apparently remote, provided he is compliant with his medication and monitoring. TR 89. Petitioner admits that on one occasion he forgot to take his medication.

In February, 1991, petitioner also suffered peritonitis, a bacterial infection.⁵ In April, 1991, routine blood chemistries indicated rejection. Petitioner's immunosuppressant dosages have been adjusted on several occasions. Petitioner's physicians testified that he is now in good health, and that he has no limitations which would affect his ability to operate an aircraft.

The Administrator asserts on appeal that the law judge's initial decision is erroneous and should be reversed because petitioner is not qualified to hold an unrestricted first-class airman medical certificate. The Administrator argues that petitioner must take immunosuppressant medication for the remainder of his life, and that he must be monitored to insure that this medication is effectively preventing his rejection of the donor organ. Petitioner urges the Board to affirm the law judge's initial decision.

The Board has carefully reviewed the medical evidence and we have considered the legal arguments of both parties. We find that petitioner's position is predicated on a fundamental misunderstanding of FAR Part 67, in that he argues that because the Federal Air Surgeon has issued restricted medical certificates to some airmen who have undergone liver transplantation and who are taking Cyclosporine, petitioner is entitled to an unrestricted certificate since he established that

⁵Infection is the most common cause of death in liver transplant patients.

the immunosuppressant drug he is taking, FK 506, is now favored by many renowned medical experts on liver transplantation. He asserts that based on this evidence, he has met his burden of proving his qualifications to hold an unrestricted first class airman medical certificate. We disagree.

Petitioner appears to believe that the testimony he elicited from an FAA witness, that restricted third-class certificates have been issued to other liver transplant patients, supports unrestricted medical certification in this proceeding.⁶ However, this testimony is irrelevant to the issue before us. Holders of restricted medical certificates are subject to the review of the Federal Air Surgeon, who, under FAR section 67.19, may place restrictions on the certificate which will ensure that any changes in an airman's medical condition are quickly detected, so that continued entitlement to a medical certificate can be evaluated.⁷ In this case, petitioner is asking for the issuance of a medical certificate with no restrictions. Thus, if his medical condition were to change within the next two years and the Administrator became aware of the change, the Administrator's only recourse would be to take administrative action to suspend or revoke the medical certificate.

⁶See testimony of Dr. Poole, TR 192-205.

⁷FAR § 67.19(d) provides that the Federal Air Surgeon may limit the duration of the certificate, condition the continued effect of the certificate on the results of subsequent medical tests, examinations, or evaluations, impose any operational limitation on the certificate needed for safety, or condition the continued effect of a second- or third- class medical certificate on compliance with a statement of functional limitations.

The law judge, having found convincing the testimony of petitioner's witnesses that FK 506 is a better immunosuppressive agent than Cyclosporine, and that its known⁸ side effects are not in their opinion disqualifying under the regulations, ruled that petitioner had met his burden of proof. We find this analysis lacking in that the law judge did not first determine whether petitioner's underlying condition, i.e., liver transplantation, and his ongoing treatment and the monitoring required because of that treatment,⁹ disqualify him. We do not intend to in any way disparage the petitioner's expert witnesses, who were persuasive in their testimony concerning the efficacy of FK 506. However, regardless of whether FK 506 is "better" than Cyclosporine, the fact remains that petitioner cannot survive without immunosuppressive agents, and this necessary medical treatment also requires monthly testing to ensure that petitioner has not begun to reject the donor organ.¹⁰

⁸One of petitioner's experts admitted that since FK 506 has been studied for a short period of time, all of its side effects are still not known. (Dr. Gores' deposition at 29).

⁹Petitioner's experts testified that petitioner must take immunosuppressant medication "indefinitely" (Dr. Gores' deposition at 32) and monthly monitoring is required (Dr. Gores' deposition at 32; Dr. Wiesner deposition at 17).

¹⁰Even petitioner's medical witness, Dr. Fung, when asked whether it could be anticipated in the next two years that something would happen to render petitioner ineligible to fly, he responded, "I don't know." (TR-130). When asked if petitioner's risk was higher than the general public's for something disqualifying to happen in the next two years, he told the judge, "you decide." (TR-131). In Dr. Fung's opinion, the petitioner is qualified "provided" he continues with his immunosuppressive therapy. (TR-132). According to Dr. Fung, "immunosuppression is an art, ...not really a science." (TR 35).

Thus, petitioner is disqualified because the medication he must take to prevent rejection is a limitation which may cause him to be unable to safely perform the duties or exercise the privileges of his airman certificate. E.g., Petition of Clark, 4 NTSB 13, 14 (1982). Petition of Bellenger, 4 NTSB 740 (1983), relied on by petitioner and cited by the law judge in his initial decision, is inapposite. In that case, we found that the medication and monthly monitoring of the effects of that medication were not disqualifying because the medication was prophylactic -- i.e., if Bellenger discontinued his medication, he would increase the risk of formation of thromboemboli, but his underlying disorder would not necessarily become more acute. Here, petitioner's own expert concedes that if petitioner were to discontinue his medication, rejection would be inevitable. See Testimony of Dr. Fung, TR at 56.¹¹ In sum, petitioner's survival is contingent on his adherence to a strict regimen of medication and medical monitoring. He is therefore not entitled to the issuance of a medical certificate without restrictions.

¹¹According to the FAA's expert witness, if a transplant patient were to take himself off of FK 506, he would be "horrified," presumably because that decision could ultimately prove fatal. (Testimony of Dr. Sorrell, TR-80).

ACCORDINGLY, IT IS ORDERED THAT:

1. The Administrator's appeal is granted;
2. The law judge's initial decision and order are reversed; and
3. The petition is denied.

VOGT, Chairman, COUGHLIN, Vice Chairman, LAUBER, HART and HAMMERSCHMIDT, Members of the Board, concurred in the above opinion and order.