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Randazzo and Civil Aviation Safety Authority [2014] AATA 581 (21 August 2014)

Last Updated: 21 August 2014

[2014] AATA 581

Division	**GENERAL ADMINISTRATIVE DIVISION**
File Number	**2013/5794**
Re	**Samuel Randazzo**
	APPLICANT
And	**Civil Aviation Safety Authority**
	RESPONDENT

DECISION

Tribunal	**Mr R Bartsch, Member and Dr W Isles, Member**
Date	**21 August 2014**
Place	**Sydney**

The decision under review is affirmed

.....**[sgd]**.....
Mr R Bartsch, Member and Dr W Isles, Member

CATCHWORDS

CIVIL AVIATION - Conditions placed upon pilots licence - Condition imposed requiring pilot to undertake all flights with safety pilot present - Applicant with medical conditions - Atrial fibrillation - Whether applicant likely to endanger the safety of air navigation - History of compliance with medications unsatisfactory - Conditions appropriately imposed - Decision under review affirmed

LEGISLATION

Civil Aviation Act 1988 (Cth), ss 9A, 20AB(1)

Civil Aviation Regulations 1988 (Cth), regs 5.04, 11.056

Civil Aviation Safety Regulations 1998 (Cth) (CASR), regs 67.150, 67.155, 67.180, 67.195

CASES

Civil Aviation Safety Authority v Ovens [2011] FCAFC 75

Randazzo and Civil Aviation Safety Authority [2011] AATA 375

Randazzo and Civil Aviation Safety Authority [2012] AATA 266

Re Hall and Civil Aviation Safety Authority [2004] AATA 21

Re Window and Civil Aviation Authority [1999] AATA 525

REASONS FOR DECISION

Mr R Bartsch, Member and Dr W Isles, Member

21 August 2014

INTRODUCTION

1. The applicant, Mr Samuel Randazzo, has applied to this Tribunal for review of a decision of the respondent, the Civil Aviation and Safety Authority (**CASA**), made on 16 October 2013 (the reviewable decision) which placed a number of conditions on his medical certificate, including a requirement to fly at all times with a safety pilot. Mr Randazzo's review application is directed towards the imposition of the safety pilot condition, He is not appealing any of the other conditions imposed on his medical certificate.
2. Mr Randazzo, who turned 77 years of age the day following the hearing, has held a private pilot licence since 1963. He has a number of medical conditions which are not in dispute. Mr Randazzo finds the conditions relating to the carriage of a safety pilot onerous, and does not believe that the condition is necessary to meet the interests of air safety. Mr Randazzo considers this to be the case given his good state of health and the fact that in

May 2013 he underwent a cardiac procedure, pulmonary vein isolation (PVI), which lowered his risk of developing atrial fibrillation.

PREVIOUS TRIBUNAL APPLICATIONS

3. Mr Randazzo has applied to this Tribunal previously for review of similar decisions made by **CASA** to impose conditions on his medical certificate. Mr Randazzo was successful when he first appealed the imposition of the safety pilot conditions by **CASA** in this Tribunal in June 2011.[1] He and his representative, Mr English, asked the Tribunal to only consider the two medical conditions which were of prime concern at that time, atrial fibrillation and Gastro Intestinal Stromal Tumour (GIST). They stated that the GIST was no longer of any concern, and that the risk of atrial fibrillation has been greatly reduced by the PVI procedure. The respondent agreed that those were the two conditions of concern in 2011 and also that the GIST was now no longer of concern thus leaving the atrial fibrillation as being the issue in dispute.
4. Shortly after the removal of the safety pilot conditions in 2011, Mr Randazzo was involved in an incident while flying solo, during which he was out of radio contact with air traffic control for a period of time. **CASA** cancelled his medical certificate at the time and ordered further medical investigations as they were concerned that he may have been incapacitated while in the cockpit. Mr Randazzo claimed that he was conscious at all times during this incident and that the incident was the result of a radio malfunction. In May 2012 Mr Randazzo appealed to this Tribunal once more, resulting in a decision which required **CASA** to reinstate the conditions imposed on his medical certificate in 2011, while also adding the safety pilot conditions.[2]
5. The applicant requested that in determining the present application the Tribunal refrain from considering the issues raised at the 2012 hearing. Although atrial fibrillation was considered in the 2012 decision, additional medical conditions were introduced and considered by the Tribunal in the present application. The respondent also refrained from raising the previous conditions at the hearing and agreed to focus consideration upon the issues surrounding Mr Randazzo's atrial fibrillation.

THE LEGISLATION

6. *Section 9A* of the *Civil Aviation Act 1988* (Cth) (the Act) requires **CASA** and the Tribunal in reviewing a decision made by **CASA** under the Act, to regard the safety of air navigation as the most important consideration.
7. Both s 20AB (1) of the Act and reg 5.04 of the *Civil Aviation Regulations 1988* (Cth) *(CAR)* require the holder of a pilots licence to hold a current medical certificate appropriate to that licence, in this case a class 2 certificate.
8. The issuing of medical certificates is governed by Part 67 of the *Civil Aviation Safety Regulations 1998* (Cth) *(CASR)*. Regulation 67.180 provides for the issuing of medical certificates, and prevents **CASA** from issuing a medical certificate unless the applicant meets the relevant medical standard or, if the applicant does not meet that medical standard, the extent to which the applicant does not meet that standard is not *likely to endanger the safety of air navigation*.
9. In addition, under reg 11.056 of the CAR, conditions may be imposed on a medical certificate which allow for **CASA** to be satisfied that the extent to which a person fails to meet the medical standard is not likely to endanger the safety of air navigation.
10. The meaning of the term "likely" should be construed consistently with earlier Tribunal decisions which have held that an event is "likely" if there is a real or substantial and not remote risk that it will occur.[3]
11. In order to meet medical standard 2, and thus qualify for the issue of a class 2 medical certificate, an applicant must satisfy the criteria in Table 67.155 of the CASR. The items from that table that are relevant to this matter include:

Abnormalities, disabilities and functional capacity

2.1 Has no safety-relevant condition of any of the following kinds that produces any degree of functional incapacity or a risk of incapacitation:

(a) an abnormality;
(b) a disability or disease (active or latent);
(c) an injury;
(d) a sequel of an accident or a surgical operation

2.2 Has no physical conditions or limitations that are safety-relevant

2.3 Is not using any over the counter or prescribed medication or drug (including medication or a drug used to treat a disease or medical disorder) that causes the person to experience any side effects likely to affect a person to the extent that is safety relevant.

2.9 Has no safety relevant heart abnormality

12. In accordance with CASR 67.150 a condition is "safety relevant" if it reduces, or is likely to reduce, the ability of a person to exercise the privileges conferred by a relevant licence.
13. CASR reg 67.195 allows **CASA** to issue a medical certificate to a person not meeting the relevant medical standard '*subject to any condition that is necessary in the interest of the safety of air navigation having regard to the medical condition of the person'*.
14. The suite of conditions which are in dispute in this hearing and are referred to as "Safety Pilot Conditions" are outlined in the letter from **CASA** to Mr Randazzo of 15 October 2013:[4]

Aircraft Requirements:

The aircraft flown must be configured with side by side seating in the cockpit;

The aircraft being flown must have a full set of dual flying controls.

Requirements of a pilot with a special medical certificate with conditions(s) 8 and/or 9:

To wear a shoulder restraint harness at all times when occupying a control seat;

To ensure the other pilot has read the requirements stipulated in this document.

Requirements of the other pilot flying with a pilot with a special medical certificate with condition(s) 8 and or 9:

To occupy a control seat, except for short absences (absences only in cruise with the auto pilot engaged);

To be endorsed and current on the aircraft type being flown;

To be appropriately rated for the in flight conditions;

To have a medical certificate not restricted to multi crew flight operations;

To be aware of the type of incapacity the pilot may suffer in flight;

To be prepared to take over the aircraft controls during the critical phases of flight;

To be competent and capable of concluding the flight safely from the control seat.

JURISDICTION

15. Mr English pointed out that Mr Randazzo's certificate expires on 30th July 2014. Accordingly, any decision made by this Tribunal would only apply to that certificate. The jurisdiction of the Tribunal in circumstances where a medical certificate has expired was considered by the Federal Court in *Civil Aviation Safety Authority v Ovens* [2011] FCAFC 75. In that case the Full Court questioned the utility of remitting the matter to the Tribunal given that the impugned certificate had expired and been replaced by a later certificate. On the basis that both parties advocated remittal, the Full Court decided to remit that matter, but varied the order by deleting the words which qualified the remittal so as to leave it open to the Tribunal to decide whether anything remained to be determined and whether there was any utility in the application proceeding.
16. Ms Swain, the representative for the Respondent, assured the Tribunal that **CASA** would take into consideration any decision of the Tribunal when issuing a new certificate for Mr Randazzo.

THE ISSUES FOR DETERMINATION BY THE TRIBUNAL

17. Mr Randazzo has a number of medical conditions which are not in dispute:
    - Obstructive sleep apnoea;
    - Type 2 diabetes mellitus;
    - Ischaemic heart disease;
    - Dilated aortic root;
    - Right renal calculus;
    - Cataract extraction and intra ocular lens replacement;
    - Admission to hospital with chest pain 2006;
    - Gastro Intestinal Stromal Tumour (GIST);
18. Other medical facts not in dispute are:
    - In May 2013 Mr Randazzo underwent a pulmonary vein isolation procedure (PVI);
    - There has been no recurrence of the GIST.
19. It is agreed that Mr Randazzo does not meet the medical standards outline in table 67.155 of the CASR. What is disputed is what conditions can be placed on his certificate that will allow **CASA** to be satisfied that the extent to which he does not meet the standards is not likely to endanger the safety of air navigation.
20. Both parties have agreed that the atrial fibrillation (AF) is the prime risk factor to be considered in this hearing. Before examining the extent to which

that may persist, we will consider what risks the AF poses for flight safety. **CASA**'s concerns are a risk of incapacitation of the pilot during a bout of AF, as well as the risk of stroke. Additionally there are risks associated with taking anti coagulant medication to prevent stroke. The need for medication also introduces issues of side effects and compliance.

MEDICAL EVIDENCE

21. Mr Randazzo and Associate Professor Pooshan Navathe, principal medical officer with **CASA**, gave oral testimony in person before the Tribunal, while Dr Eggleston, Mr Randazzo's treating cardiologist, gave his evidence by telephone.

Risk of incapacitation from atrial fibrillation

22. Mr Randazzo has suffered from paroxysmal atrial fibrillation (AF) for some 15 years. Prior to his PVI procedure, Dr Eggleston reported in 2010 that he was suffering bouts of AF approximately every 6 months. His symptoms during those bouts were described as mild with feelings of fatigue, palpitations and a reduction in exercise tolerance.[5] In evidence Mr Randazzo only admitted to some shortness of breath on exercise and pointed out that he could still play golf and drive a car. Associate Professor Navathe told the Tribunal that such symptoms could well be magnified if they were to occur at altitude while flying a plane and was concerned that they could be incapacitating.

The risk of stroke

23. There is no argument that AF carries a risk of stroke. It is also common ground that a stroke at any time, but particularly while flying, could be catastrophic and incapacitating. Associate Professor Navathe explained that when the heart is in AF it decreases the ability of the heart to pump blood and this can lead to some stagnation of blood in the atrium. That blood can then form clots which can travel to the brain causing stokes. The fact that most patients are treated with anticoagulants, which carry their own risks of complications, demonstrates that the medical experts believe the risk of stoke is significant.

Anticoagulation treatment

24. Associate Professor Navathe said that the risk of stroke in AF is 3 to 4%, but treatment with anti coagulants reduces this to 1%. Importantly, as the Associate Professor notes, the risk is not entirely eliminated.
25. We were told that there are two classes of anticoagulants. The first is warfarin which has been an established treatment for many years and is preferred by **CASA**. The other is a group of newer medications called NOAGs (novel oral anticoagulants). These are not approved by **CASA** for use by pilots for reasons discussed below.
26. There was some confusion about just what anticoagulants Mr Randazzo has been taking. Dr Eggleton in his latest report of February 2014 noted that Mr Randazzo was on rivaroxaban, one of the NOAGs, but noted that he thought he had previously been taking warfarin. When questioned on this issue, Mr Randazzo stated that he had never taken Warfarin and had been taking rivaroxaban for the past two years. This seems to be at odds with two reports from the Heart Rhythm Centre dated 19 July[6] and 22 November 2013.[7] The first reported that he was taking warfarin and the second "cartia" a low dose aspirin. Ms Swain also referred the Tribunal to an email from Mr Randazzo to **CASA** dated 2 July in which he says he has ceased Rivaroxaban and was taking cartia, and that he had asked for a prescription for warfarin which he would start taking if the AF were to reoccur.

27. Associate Professor Navathe explained that all coagulants carried a risk of haemorrhage, including haemorrhage into the brain which, again, could have serious implications for flight safety. Dr Eggleton agreed but said that the NOAGs had a lower risk of brain haemorrhage than warfarin. Associate Professor Navathe quoted the risk of bleeding was 3.4% over a period of 5 years, with it being much higher within the first 30 days of commencing treatment. He said they preferred warfarin because it had a longer half life in the body and thus could maintain levels reasonably well even if one or two doses were missed. The NOAGs did not have this feature, so poor compliance with medication could have a greater increase in the risk of stroke. Warfarin compliance was also much easier to monitor with the use of International Normalised Ratio (INR) tests. Similar testing for compliance with NOAGs was currently either not possible or not practicable in Australia.
28. The applicant believed that in the Tribunal hearing in 2011, Dr Fitzgerald for **CASA** had agreed that there were pilots flying with AF who had not been the subject of safety pilot conditions. Associate Professor Navathe said he was not aware of any individuals where that was the case, but noted that it may be possible in some instances where the individual presented as very low risk and where there were no additional risk factors.
29. Associate Professor Navathe was asked if pilots taking Warfarin for conditions other than AF were required to have safety pilot conditions on their certificates. He said there were very few such pilots and most had the conditions imposed due to the risks inherent in taking warfarin. He did say that some on low doses might not have the conditions imposed.
30. The Respondent stressed that compliance with taking medication had to be considered in any decision making process. They pointed to the fact that Mr Randazzo had misled some of his treating practitioners either deliberately or mistakenly about his taking warfarin. When Mr Randazzo was questioned about the matter he readily stated that he had avoided taking warfarin because he did not like it and had been told it was "rat poison". The respondent put it Mr Randazzo that he had been stopping and starting his medications, which put him at greater risk, but Mr Randazzo insisted that he had never taken warfarin and had remained on rivaroxaban for some time.
31. Associate Professor Navathe referred the Tribunal to some scientific papers which showed that in developed countries compliance with medication in general in patients with chronic diseases is poor, averaging only 50%.[8] The respondent further submitted that Mr Randazzo's history of not taking anticoagulants as prescribed or as reported by him, does not give **CASA** sufficient confidence that his compliance over the longer term would be likely to be strong. They would also prefer that he take warfarin, compliance with which is safer than rivaroxaban and can be monitored.

Risk of atrial fibrillation occurring following the pulmonary vein isolation procedure

32. In May 2013 Mr Randazzo underwent a PVI procedure to reduce the risk of AF occurring in the future. Mr Randazzo reports that he has had no symptoms since the procedure and asserts that this is proof that his AF has been successfully treated.
33. Associate Professor Navathe gave evidence that while the risk of AF is reduced following the PVI procedure, it is not eliminated. The risk of AF recurring is at its highest in the short to medium term, which he defined as being the first 5 years after the procedure.
34. Dr Eggleston supported this by saying that only 65% of patients have success after the first PVI procedure, whereas 80% of patients have no further AF after a second procedure.
35. Associate Professor Navathe also pointed out that being free of symptoms does not necessarily mean that AF is not occurring. He referred to a paper which showed that the ratio of asymptomatic to symptomatic AF increased significantly following the PVI procedure.[9] He said that asymptomatic AF had an increased risk of stroke. Dr Eggleston said that he too was aware of the findings about asymptomatic AF following PVI.
36. When asked why he continued to prescribe anti-coagulants after the PVI procedure, Dr Eggleston noted that he did so as a precaution. In his latest report of 18 June 2014, he said that treatment with rivaroxaban was appropriate with a history of AF and IHD (Ischaemic Heart Disease).

Other risk factors

37. Associate Professor Navathe pointed out that that the risk of stroke was higher in Mr Randazzo's case because of the presence of other risk factors. He referred to a paper which used a stroke risk score called CHAD-VASC. This score takes into account the other risk factors for conditions such as hypertension, age and diabetes.[10] He said Mr Randazzo's risk score was in the higher range which therefore further added to his risk.

CONSIDERATION

38. We accept that Mr Randazzo feels well and feels that he is in good health. It is clear that he enjoys flying, is a competent pilot and that a condition requiring a safety pilot on his flights is seen as an imposition by him.
39. We see that the risks of incapacitation in the cockpit from either the AF itself or from stroke are real and not insignificant. The risks of stroke are higher for Mr Randazzo because of the presence of other risk factors.
40. We are also satisfied that the PVI procedure, while decreasing the risk of AF, has not reduced the risk sufficiently to justify a removal of the conditions imposed by **CASA**. The most telling point is that Mr Randazzo's own treating cardiologist, in compliance with the current clinical guidelines, recommended that he should continue taking anticoagulants. We know that anticoagulants carry risks which are significant and would not be prescribed unless there was a real and substantial need.
41. Ironically, although the anticoagulants reduce the risk of stroke they also carry their own, albeit lower, risks of bleeding. Mr Randazzo's evasion and resistance to taking warfarin as advised by **CASA** does not instil this Tribunal with confidence when considering the likelihood of future compliance – a factor which we accept is very important.
42. Mr Randazzo wrote to the Tribunal after the hearing stating that he was prepared to take Warfarin if it meant he could hold a Class 2 licence without the safety pilot conditions. We note the risks inherent with both classes of anticoagulants. While we understand **CASA**'s preference for the use of warfarin, our final decision is not influenced by which type of anticoagulant Mr Randazzo is presently taking.
43. The applicant asserted that because he only flew approximately 50 hours per year, his risk of inflight incapacitation was thus lower and such a factor should be considered by the Tribunal. He offered to have a further condition added to his licence, which would restrict the number of hours he was permitted to fly within any year. Although the likelihood of such an inflight incapacitation would be reduced by virtue of the reduced flying time the potential consequences should such an event occur are such that the risk would still be of an unacceptable level if Mr Randazzo was the sole pilot onboard the aircraft.
44. We therefore do not accept the reasoning behind such a proposal, because having decided that there is a risk sufficient to warrant the imposition of the safety pilot conditions, it be incongruent for the Tribunal to then allow the applicant to exercise the privileges of his licence without those conditions no matter how many hours Mr Randazzo might spend in the cockpit.

DECISION

45. The Tribunal affirms the decision under review. The suite of conditions listed above at paragraph 14, and referred to as "Safety Pilot Conditions", should remain on Mr Randazzo's class 2 medical certificate.

I certify that the preceding 45 (forty
-five) paragraphs are a true copy of
the reasons for the decision herein of
Mr R Bartsch, Member and Dr W

Isles, Member

.....
Associate

Dated 21 August 2014

Date of hearing	**15 July 2014**
Solicitors for the Applicant	**Mr Dennis English, DCE Lawyers**
Solicitors for the Respondent	**Ms Carol Swain, Legal Services Group**

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[1] *Randazzo and Civil Aviation Safety Authority* [2011] AATA 375.

[2] *Randazzo and Civil Aviation Safety Authority* [2012] AATA 266.

[3] *See Re Window and Civil Aviation Authority [1999] AATA 525 at 60; and Re Hall and Civil Aviation Safety Authority [2004] AATA 21 at [35 - 36].*

[4] *T Documents page 632.*

[5] *T Documents report of Dr. Eggleston dated 3rd February 2010.*

[6] *Exhibit G.*

[7] *Exhibit H.*

[8] *Exhibits K,L,M.*

[9] *Exhibit E.*

[10] *Exhibit J.*

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