The Committee Secretary 11 October 2019
Senate Standing Committee on Rural and Regional Affairs
And Transport Legislation Committee
By email

Dear Secretary

Inquiry into the operation of the Australian Transport Safety Bureau, and in particular its report on the June 2017 crash of a flight conducted on behalf of Angel Flight, Australia
Comment on Senate Report October 2019

1. I refer to the above Inquiry to which my committee made a submission, and note the subsequent report dated October, released on the 4th of October (Figure 1), which was drawn to my attention by the media.

The Senate

Rural and Regional Affairs and
Transport Legislation Committee

Performance of the Australian Transport Safety Bureau, and in particular its report on the June 2017 crash of a flight conducted on behalf of Angel Flight Australia

Figure 1 Part First Page Senate Report re Angel Flight & ATSB Performance

2. My Committee has reviewed the Report of the Senate (The Report). We note the rapid turnaround time.
3. We note that the Inquiry was "into the operation of the Australian Transport Safety Bureau [ATSB}, AND (emphasis mine) in particular its report on the June 2017 crash of a flight conducted on behalf of Angel Flight".
4. With regard to the operation of the ATSB we note the following comment in The Report:

> 1.57 Nothing in this report is a criticism of ATSB's investigations into any particularly incident. The work of the ATSB in accident investigation is, by and large, considered by the committee to be world class. The committee further appreciates that both the ATSB and CASA's actions are aimed at improving safety and reducing risk. However, the committee welcomed the opportunity to question both the ATSB and CASA further, about their findings in relation to elevated levels of risk for CSFs.

   a. It is not clear how The Report reached the decision that its (the ATSB) work "is, by and large, considered by the committee to be world class". Respectfully, the Senate did not review the work of the ATSB against any international standard or comparison that would permit it to draw such a conclusion. The conclusion goes well beyond the evidence available to it in this inquiry. This is a decision based on opinion, not evidence. It is not clear how the committee reached this decision.
   b. The very fact that The Report draws attention to the problem that the ATSB did not interview any Angel Flight pilots (section 1.25), and that there are potential problems with the statistical analysis of the data by ATSB which still seem to not be fully understood by ATSB should raise, in our view, significant questions about the "world class" conclusion.
   c. It is not clear how the conclusion was reached that "Nothing in this report is a criticism of ATSB's investigation into any particular incident" when in fact the inquiry was

'particularly' into the 2017 Angel Flight accident. Respectfully, The Report is replete with identified problems with the ATSB investigation which, in our view, remain unresolved.

5. We are perplexed by the view of Dr Aleck set out in Section 1.42 of The Report (Figure 2)

1.42 Dr Jonathan Aleck, Executive Manager of Legal and Regulatory Affairs at CASA, laid out the objective of CASA's approach to this issue:

> Our objective here is not to specifically address what caused those two accidents; it's to address what kinds of things can cause incidents and accidents of this kind. We're being prospective. If we were to wait for sufficiently robust data to support an evidence based decision for every individual decision we took in this space, we would have to wait for a dozen or more accidents to occur.[41]

Figure 2 Quote from Senate Report

What does this statement mean? How can you "address what kinds of things cause incidents and accidents of the kind" set out in the ATSB report with regard to Angel Flight without looking at the data? The statement just doesn't make sense. Is stuff made up out of thin air? In our view some clarity needs to be brought to what is being said here. By all means employ the Precautionary Principle which appears to be being invoked here, but the Principle needs to be based on some **pertinent** evidence which will only come from examination of the detail. Care needs to be taken however in going beyond the data.

6. In our submission we raised the possibility that the 2017 Angel flight incident might have been caused by a catastrophic vascular accident of some kind rather than the disorientation hypothesis put by the ATSB to explain the crash. Our hypothesis was not canvassed or examined at all in The Report yet given the age of the pilot and lack of information about the autopsy or the pilot's medical condition we still have the view that this matter must be considered.
We draw the committee's attention to recent findings in Occupational Cardiology which we believe supports our view that this matter should be considered further :

Occupational Coronary Artery Disease Assessment: Moving Beyond the Stenosis Paradigm
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DISCLOSURES
Eur Heart J. 2019;40(34):2844-2846.
As already outlined in this series of papers on occupational cardiology, it is necessary to mitigate the risk of distraction and/or incapacitation in individuals undertaking high-hazard occupations, to ensure safety of the individual worker, co-workers, and often the general public. As a result, many organizations that employ individuals in these roles (the emergency services; the military; the transport and logistic industry, including aviation, railway, and haulage companies; and those operating in remote or physically demanding environments) screen for cardiovascular disease and make a determination of (acceptable) risk based on these findings.
Coronary artery disease (CAD) is a significant cause of incapacitation in both the general public and those undertaking high-hazard occupations. In those of working age, the first clinical presentation is often not preceded by symptoms, and acute coronary syndromes may occur due to plaque rupture or erosion, in contrast to those that present following progressive luminal stenosis and anginal symptoms. This presents a particular challenge to

the cardiologist assessing CAD in an individual planning to, or actually undertaking hazardous employment. This applies both to screening and to making a risk assessment for returning to work following a coronary event.

It is traditional in many high-hazard occupations to screen individuals with risk calculators, usually in addition to a resting 12-lead ECG, and then to perform additional investigations in cases where there is increased likelihood of CAD. These investigations have often focused around functional assessment with an exercise stress ECG (or exercise tolerance test) and/or coronary artery calcification scoring (CACS). Invasive coronary angiography may be required to determine stenosis severity in those with equivocal or abnormal enhanced screening tests. The decision regarding whether an employee is fit to return to high-hazard employment following a coronary event is typically based on either the exclusion of a functional deficit (i.e. ischaemia) or exclusion of a stenosis severity above an acceptable threshold (often a lesion causing >50% luminal narrowing).

As an example of current recommendations, in professional aviation, operating within Europe [regulated by the European Aviation Safety Agency (EASA)], in asymptomatic workers, the identification of CAD in a single vessel lesion >50%, (or >30% in the left main stem), or more than 2, 30% lesions in main epicardial vessels renders personnel unfit to fly commercially. The acceptable risk threshold varies between employers but in professional aviation this is usually based on a 1% per annum risk of incapacitation.[1] The use of such arbitrary stenosis cut-offs for this threshold of risk do not stand up to scrutiny when the evidence is reviewed and has led to calls for a more up-to-date approach to CAD risk assessment.[2]

Our understanding of CAD has also changed rapidly in the last decade and a more refined approach to CAD risk assessment is now possible.

New evidence about coronary anatomy and inflammation allows a more nuanced approach to risk determination; one that allows us to move beyond a maximum stenosis paradigm and arbitrary confirmation or exclusion of ischaemia. This change in understanding has been driven, in large part, by data from CT coronary angiography (CTCA), a diagnostic modality that permits assessment of luminal narrowing; overall plaque burden and plaque composition. This investigation allows the identification of high-risk plaque characteristics such as positive (Glagov) remodelling, low attenuation (non-calcified) plaque disease, spotty calcification, and the so-called napkin ring sign (Figure 1).

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Vulnerable plaque features as seen on CTCA and correlated with ICA in a patient presenting with acute coronary syndrome (from reference 11).

It is already well known that most lesions that lead to acute coronary syndromes and myocardial infarction are not those that exceed 70% and cause anginal symptoms. Recently, CTCA data from the PARADIGM study[3] have demonstrated that the strongest predictors of events related to CAD are based on the presence of disease within the left mainstream and overall burden of atherosclerosis. This is unsurprising given that an increased volume of plaque disease not only increases the likelihood of a significant (ischaemia provoking) lesion being present; but also, an increased likelihood of non-calcified, non-obstructive plaques that cause lesser luminal stenosis, but which are prone to rupture and erosion. This is why, in occupational risk assessment it is recommended that a more global assessment of CAD should be used to derive risk (using an aggregate stenosis approach), in addition to assessing the maximal stenosis.[4]

Using a non-invasive test such as CTCA (that allows determination of overall plaque burden, type, and vulnerability) adds significantly to our ability to quantify this overall risk. It is for

this reason that CTCA has gained prominence in recent occupational risk assessment standards documents.[1] An aggregate stenosis of >120% has been suggested as a more appropriate cut-off for grounding by a recent NATO cardiology working group due to an annual event rate of >3% in the US Air Force. However, this is not without ethical and cultural challenges. Individuals in this group would often not be considered for revascularization on clinical grounds. They would usually have neither significant fractional flow reserve (FFR) nor detectable ischaemia on functional imaging. Such individuals have crossed the threshold for disqualification from high-hazard employment but not the threshold for clinical intervention.[2]

Despite the rise of CTCA as the non-invasive test of choice for CAD, we must be careful not to overlook the diagnostic and prognostic value of more traditional tests such as the ExECG and CACS. In this series, the paper on risk assessment[5] has alluded to the importance of exercise stress testing. While the ExECG is an insensitive and non-specific test for significant CAD, the demonstration of high exercise capacity in the absence of signs of ischaemia is a powerful marker of good prognosis, regardless of the coronary anatomy. ExECG remains useful for confirming symptom severity, aerobic fitness, blood pressure response to exercise, and arrhythmia screening. For these reasons, a recent NATO aviation cardiology consensus paper suggested that while ExECG as the sole test for the confirmation or exclusion of significant CAD was not recommended, its use as part of a wider risk assessment of CAD is valuable.[6] Furthermore, CACS is a strong and robust marker of CAD and a score of zero, in those over the age of 50, is associated with a very low event rate. However, its use in younger patients, who are at increased risk of significant non-calcified plaque disease, is less clear, and used in isolation CACS may miss significant, occupationally relevant disease.[7]

The assessment of CAD post-myocardial infarction or revascularization also warrants discussion. As a minimum, an assessment of residual ischaemia, infarction size, scar burden, and ventricular function is necessary as part of risk quantification post-event or intervention. Following a previous myocardial infarction, professional drivers who hold a Group 2 (Heavy Good Vehicle) license in the UK are required to demonstrate a LVEF >40% and no signs/symptoms of ischaemia while completing a functional fitness assessment of 9 min of the Bruce protocol. Commercial aircrew typically needs a LVEF >50% to retain a (usually limited) license.

Additionally, some regulatory agencies (such as EASA) require complete revascularization (of any occupationally relevant lesion) prior to consideration of recertification. This can put the occupational requirements for return to work at odds with usual clinical practice. This variance is particularly acute where bystander lesions of 50–70% stenosis are concerned. The desire for complete revascularization is driven solely by an occupational mandate and may result in low/no-flow and possible limitations to the siting of bypass conduits in the future.[8] This provides another challenge to the cardiologist/cardiothoracic surgeon responsible for a high-hazard employee, who may be unable to resume work despite optimal clinical revascularization.

With advances in coronary imaging increasingly translating into clinical practice, it is likely that novel technologies will refine the assessment of coronary disease. Refinements include quantification of FFR from CT datasets (CT-FFR), other computational flow dynamic parameters, such as axial or wall shear stress, or assessment of coronary inflammation, and peri-coronary lipolysis via the use of fat attenuation screening (CT-FAI) (Figure 2).[9] There is also research into the assessment of coronary inflammation with cardiac MRI.[

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A positive case of CT-FAI in a patient with normal coronary arteries who was identified as high risk (white asterisk highlighting the area of peri-coronary lipolysis, secondary to vascular inflammation) who had a subsequent myocardial infarction (courtesy of Prof. Charis Antoniades).
These techniques have the potential to drive accurate quantification of CAD risk further, informing appropriate primary and secondary prevention and allowing a more personalized and evidence-based approach to occupational CAD assessment.

Our comment As indicated in our submission the risk of vascular accident increases dramatically with age. We have the view that in light of the paper reproduced here that if risk is to be managed properly for aviation generally and Community Service flights in particular then proper consideration must be given this important risk factor particularly for older pilots. Certainly having a responsible co-pilot aboard a Community Flight for pilots over a specified age would certainly have an impact on potential risk. We now ask that this matter be raised again with advice from an appropriate independent body with expertise in this particular field. We note The Reports request for clarity with regard to the matter of crew. Thank you.

My Committee is prepared to address any of the issues raised here in the interest of public safety.

Yours sincerely

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