



# Alzheimer's disease biomarkers: another tool for FAA pilot screening?

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## ABSTRACT

Research advancements to improve the accuracy of diagnosing Alzheimer's disease (AD) have altered clinicians and researchers' understanding of the disease process. The discovery of amyloid and tau biomarkers as measures of disease pathology supports early identification of disease risk that precedes symptom onset. As a result, AD is now understood to be an underlying pathology that causes a spectrum of clinical syndromes, beginning with preclinical AD. Future clinical implementation of biomarkers will raise novel employment and professional licensure discrimination risks based on AD biomarker status. This article evaluates the potential consequences of biomarker status for commercial pilots within Federal Aviation Administration pilot licensing procedures. The article argues for a careful implementation of AD biomarker status in licensing procedures to emphasize public safety, integrate accurate scientific knowledge, and limit unjustified and adverse consequences for individual pilots.

**KEYWORDS:** Alzheimer's disease, aviation, biomarkers, neurology, pilots, licensure

## INTRODUCTION

Commercial pilots rely heavily on cognitive and visuospatial skills, including situational awareness, management of technical information, and decision-making capabilities.<sup>1</sup> The reliance on pilots' cognitive function establishes a direct relationship between pilots' neurological health and public safety. In the United States, the Federal Aviation

<sup>1</sup> *What Traits & Skills Must Pilots Have? What Makes A Good Pilot?*, Fly General Aviation <http://www.fly-ga.co.uk/traits-skills-good-professional-pilot/> (accessed Aug. 15, 2017).

Administration (FAA) is responsible for assuring public safety through the regulation of aerospace, including 'fitness to fly' medical certification necessary for pilot licensure. Standardized procedures for medical certification seek to identify active disease processes and disabilities that could impede fitness to fly, including neurological conditions.<sup>2</sup> However, the FAA has not yet identified standards for considering the role of Alzheimer's disease (AD) biomarkers, including measures of amyloid plaques and tau tangles, in licensing procedures for first-class commercial pilots.

'AD', the leading cause of dementia, is an insidious and progressive illness.<sup>3</sup> AD affects nearly 5.7 million individuals in the United States and approximately 200,000 of these individuals are younger than 65 years of age.<sup>4</sup> Symptoms associated with AD include impaired memory, executive function, and visuospatial skills.<sup>5</sup> For more than 30 years, AD was defined and diagnosed according to clinical criteria based on identifiable functional symptoms.<sup>6</sup> Now, AD is conceptualized as a disease that spans a spectrum, starting before symptoms are present.<sup>7</sup> Advancements in AD biomarker<sup>8</sup> diagnostics equip researchers to identify individuals who have an increased risk for future impairment due to AD.<sup>9</sup> These advancements raise novel questions regarding the appropriate use of biomarker status that indicates a risk for future impairment, which could be incorporated into the FAA licensing procedures for first-class commercial pilots.<sup>10</sup>

Prior research reported physicians' concerns about the potential impact of biomarker information for professions with public safety roles, including commercial pilots.<sup>11</sup> Similarly, human resource managers reported that their role in managing positive AD biomarkers in asymptomatic pilots would be different than managing the same information for other professions, including a corporate vice president and a car salesman.<sup>12</sup> Yet, there is a critical gap in understanding the legal and regulatory considerations for using AD biomarker information in professional licensing or certification procedures. This article evaluates the legal and regulatory framework for considering

<sup>2</sup> Federal Aviation Administration, *Guide for Aviation Medical Examiners* 135 (Jul. 25, 2018), available at [https://www.faa.gov/about/office.org/headquarters\\_offices/avs/offices/aam/ame/guide/media/guide.pdf](https://www.faa.gov/about/office.org/headquarters_offices/avs/offices/aam/ame/guide/media/guide.pdf).

<sup>3</sup> Alzheimer's Association Report, *2018 AD facts and figures*, 14(3) ALZHEIMERS DEMENT. 367 (2018).

<sup>4</sup> *Id.*

<sup>5</sup> *Id.*

<sup>6</sup> National Institute on Aging, *AD Diagnostic Guidelines*, <https://www.nia.nih.gov/health/alzheimers-disease-diagnostic-guidelines> (accessed Aug. 15, 2018).

<sup>7</sup> Clifford Jack, Jr., et al., *NIA-AA Research Framework: Toward a biological definition of AD*, 14(4) ALZHEIMERS DEMENT. 535 (2018).

<sup>8</sup> A biomarker is a 'defined characteristic that is measured as an indicator of normal biological processes, pathogenic processes, or responses to an exposure or intervention, including therapeutic interventions. Molecular, histologic, radiographic, or physiologic characteristics are types of biomarkers. A biomarker is not an assessment of how an individual feels, functions, or survives'. National Center for Biotechnological Information, *BEST (Biomarkers, EndpointS, and other Tools) Resource [Internet]*, <https://www.ncbi.nlm.nih.gov/books/NBK338448/> (updated May 2, 2018).

<sup>9</sup> *Id.*

<sup>10</sup> Biomarkers raise novel concerns more broadly in the employment context as well. See *infra* at note 12.

<sup>11</sup> Jalayne J. Arias, Rosa Gonzalez, and Jason Karlawish. *To Test Or Not To Test: Physician Perspectives On Biomarker Testing, Law, And Ethics*. 12(7) ALZHEIMERS DEMENT. 817 (2016).

<sup>12</sup> Jalayne J. Arias, et al., *Employment Discrimination Risks Based on Preclinical Alzheimer's Disease Biomarkers*, 14 ALZHEIMERS DEMENT. 888 (July 2018).

biomarker status as part of the FAA licensing procedures first-class commercial pilots. It is our aim to lay the groundwork for further study into the legal, ethical, and regulatory challenges of emerging technologies in AD and other neurological diagnostics. For example, it is unclear if the Americans with Disabilities Act ('ADA') could provide individual protection against employers who are not granted broad public safety mandates like the FAA. Our project here could inform the answer to such a question in the future.

Section I provides a background description on AD biomarkers and the FAA medical certification requirements as part of licensing procedures. Section II provides a historical perspective on the FAA's treatment of other conditions to inform medical certification decisions. Section III evaluates whether these FAA policies support using AD biomarkers to inform medical certification decisions. Section IV evaluates whether the FAA could justify creating broad policies for AD biomarkers, including whether the FAA could support a default denial based on AD biomarkers. In this final section, the manuscript proposes an approach that refrains from discriminating against pilots based on AD biomarkers, but balances their use to increase public safety through additional screening.

## I. BACKGROUND

The FAA implements distinct licensing procedures according to pilot classes, including first-, second-, and third-class medical certificates. Commercial pilots for common air carriers are formally called 'airline transit pilots' in FAA regulations and fall into the first class. The FAA subjects these pilots to the most scrutiny because they pose the greatest risk to public safety. For purposes of this analysis we evaluate the licensing and medical certification of first-class pilots due to the heightened scrutiny these pilots face.

### I. A. AD Biomarker Status in Asymptomatic Adults

Preclinical AD is the presence of disease pathology in the absence of clinical symptoms (i.e., memory loss).<sup>13</sup> AD pathology is characterized according to the presence of amyloid and tau, which are proteins associated with the hallmark plaques and tangles of AD. Research and clinical advancements to identify AD pathology using positron emission tomography (PET) imaging and measures of cerebrospinal fluid (CSF) to identify markers of increased amyloid (plaques) and tau (tangles.) While these markers can be used alongside clinical evaluation of symptomatic cognitive impairment (i.e., mild cognitive impairment or dementia), they are also identifiable up to 20 years before symptoms emerge.<sup>14</sup>

The presence of biomarkers in asymptomatic individuals indicates an increased, but not definitive risk, for clinical AD.<sup>15</sup> Approximately 24% of cognitively healthy adults between the ages of 50 and 90 years old are amyloid positive. The prevalence of amyloid positivity increases with age—less than 10% of cognitively healthy adults aged

<sup>13</sup> Clifford Jack, Jr., et al., *NIA-AA Research Framework: Toward a biological definition of AD*, 14(4) *ALZHEIMERS DEMENT.* 535 (2018).

<sup>14</sup> Ron Brookmeyer, et al., *Forecasting the prevalence of preclinical and clinical Alzheimer's disease in the United States*, 14(2) *ALZHEIMERS DEMENT.* 121 (Feb., 2018).

<sup>15</sup> *Id.*

50–60 versus 59% of cognitively healthy 90 year olds.<sup>16</sup> The rate of conversion for cognitively healthy-amyloid positive adults who develop symptomatic AD is unclear and currently under investigation, but not all adults who are amyloid positive will develop symptoms associated with AD.<sup>17</sup> Therefore, the presence of amyloid is only predictive, not definitive. Measures of tau (or a combination of amyloid and tau), may provide additional information regarding prognosis and deposit in brain regions associated with clinical symptoms.<sup>18</sup> However, further research is needed to validate tau as a predictive tool.

AD biomarker testing is not currently offered clinically to asymptomatic patients.<sup>19</sup> However, biomarkers are used in research as inclusion criteria in some clinical trials<sup>20</sup> and are central to research with the goal of identifying disease modifying treatment.<sup>21</sup> Major hypotheses for successful future treatment, as described in the National Alzheimer's Plan Act,<sup>22</sup> emphasize secondary prevention (i.e., treating AD before symptoms emerge). If secondary preventions are developed, biomarker screening in asymptomatic patients will become clinically necessary to identify individuals likely to benefit from treatment, but discrimination risks associated with disclosure are unsettled.<sup>23</sup>

### I. B. Licensing First-Class Commercial Pilots: The FAA Medical Certification Process

The FAA Administrator creates regulations to guide pilot licensures as part of the mandate 'promote safe flight of civil aircraft in air commerce'.<sup>24</sup> FAA licensing requirements vary between pilot classes, depending on the types of aircraft, cargo they are hauling, and purpose of their flights.<sup>25</sup> FAA licensing for first-class airline transit pilots requires applicants to be at least 21-years-old (usually 23), be proficient in English, complete training with an authorized instructor, pass knowledge and practical tests on the licensed aircrafts, complete the required number of flight hours, and hold relevant

<sup>16</sup> Rik Ossenkoppele, Willemijn Jansen, Gil Rabinovici, et al., *Prevalence of Amyloid PET Positivity in Dementia Syndromes: A Meta-analysis*, 313(19) JAMA 1939 (2015).

<sup>17</sup> Dubois, B., et al., *Cognitive and neuroimaging features and brain  $\beta$ -amyloidosis in individuals at risk of AD (INSIGHT-preAD): a longitudinal observational study*, 17 LANCET NEUROL. 4, 335 (Feb., 2018); Ron Brookmeyer & Nada Abdalla, *Estimation of lifetime risks of AD dementia using biomarkers for preclinical disease*, ALZHEIMERS DEMENT. (May, 2018).

<sup>18</sup> Renaud La Joie, et al., *Associations between [18F]AV1451 tau PET and CSF measures of tau pathology in a clinical sample* 90(4) NEUROLOGY e282, e290 (2017).

<sup>19</sup> Keith A. Johnson, et al., *Appropriate use criteria for amyloid PET: a report of the Amyloid Imaging Task Force, the Society of Nuclear Medicine and Molecular Imaging, and the Alzheimer's Association*, 9(1) ALZHEIMERS DEMENT., 1 (2013).

<sup>20</sup> Reisa Sperling, et al., *The A4 study: stopping AD before symptoms begin?*, 6 SCI TRANSL MED. 228 (2014).

<sup>21</sup> Leon Thal, et al., *The role of biomarkers in clinical trials for Alzheimer disease*, 20(1) ALZHEIMER DIS. ASSOC. DISORD. 6 (Mar. 2006).

<sup>22</sup> United States Department of Health and Human Services, *National Plan to Address Alzheimer's Disease: 2017 Update* (2017), available at <https://aspe.hhs.gov/system/files/pdf/257526/NatPlan2017.pdf>.

<sup>23</sup> Arno de Wilde, et al., *Disclosure of Amyloid Positron Emission Tomography Results to Individuals without Dementia*, 10(1) ALZHEIMERS RES THER. 72 (2018).

<sup>24</sup> See generally 49 U.S.C. § 44701-44703 (2018).

<sup>25</sup> *Id.* at §44703(b).

certificates or meet flight experience requirements.<sup>26</sup> In addition to the practical and training requirements, pilots must also complete the first-class medical certification to ensure fitness to fly.<sup>27</sup>

*I.B.i. Medical Certification: Procedures and Stakeholders*

Medical certification requirements also differ between pilot classes. First-class medical certificates are required for airline transport pilots, including first-class pilots employed by commercial airlines open to the public; second-class for private commercial pilots, flight engineers, flight navigators, and air traffic controllers; and third-class for private or recreational pilots.<sup>28</sup> Airline transport pilots fly for carriers who represent to the public a willingness to haul passengers or cargo for compensation, while private commercial carriers are not open for public business and do not require a first-class license.<sup>29</sup> We will be focused on pilots who require a first-class license and medical certification.

First-class medical certification requirements include routine certifications, either every 6 or 12 months depending on the age of the pilot.<sup>30</sup> Medical certification procedures rely on a certified medical examiner ('examiner') authorized by the FAA to determine the fitness of an applicant.<sup>31</sup> The examiner is responsible for providing a medical opinion regarding the pilot's fitness to fly. In this roll, the examiner conducts a medical exam and reviews the applicant's medical history. The examiner summarizes their findings in the Application for Airman Medical Certificates ('application'),<sup>32</sup> and submits the Application to the FAA with a recommendation to certify, deny, or a deferral to the FAA for review.<sup>33</sup> While the medical examiner's recommendation to approve or deny strongly influences certification decisions, the FAA ultimately has the authority to approve or deny an applicant's medical certificate.<sup>34</sup> If the examiner's recommendation is a deferral, the FAA automatically reviews the application and issues a decision.<sup>35</sup> Pilots may appeal FAA decisions through a chain of review: Administrative Law Judge, the full National Transportation Safety Board, Court of Appeals, and, ultimately, the Supreme Court.<sup>36</sup>

<sup>26</sup> 14 C.F.R. § 61.153 (2018).

<sup>27</sup> 14 C.F.R. § 61.3(c) (2018).

<sup>28</sup> *Id.*

<sup>29</sup> Federal Aviation Administration, Advisory Circular, *PRIVATE CARRIAGE VERSUS COMMON CARRIAGE OF PERSONS OR PROPERTY*, AC No: 120-12A § 4 (1986), available at [https://www.faa.gov/documentLibrary/media/Advisory\\_Circular/AC%20120-12A.pdf](https://www.faa.gov/documentLibrary/media/Advisory_Circular/AC%20120-12A.pdf) (last accessed July 3, 2019).

<sup>30</sup> 14 C.F.R. § 61.23(d) (2018).

<sup>31</sup> Guide, *supra* note 2, at 135.

<sup>32</sup> U.S. Department of Transportation, F-8500-8, *Application for Airman Medical Certificate* (2016), available at [https://www.faa.gov/about/office\\_org/headquarters\\_offices/avs/offices/aam/ame/guide/media/applicant%20history.pdf](https://www.faa.gov/about/office_org/headquarters_offices/avs/offices/aam/ame/guide/media/applicant%20history.pdf) (last accessed July 3, 2019). (Extensive guidance on how to use this form is also found in the Guide, and the guidance will be referenced throughout this article when referring to the form.)

<sup>33</sup> Guide, *supra* note 2, at 10.

<sup>34</sup> *Id.* at 13.

<sup>35</sup> Federal Aviation Administration, *Pilot Medical Certification Questions and Answers*, 'How does the appeal process work?' [https://www.faa.gov/licenses\\_certificates/medical\\_certification/faq/response14/](https://www.faa.gov/licenses_certificates/medical_certification/faq/response14/) (updated Apr. 16, 2013).

<sup>36</sup> *Id.*

*I.B.ii. Medical Certification: The Application for Airman Medical Certificates*

The application, completed by the pilot and examiner, reflects the FAA's current determination of conditions that are relevant to a pilot's fitness to fly.<sup>37</sup> The application is formatted much like a standard medical intake form and asks for a pilot's current and past certificate status, medications, corrective eyewear, afflictions, diseases, and medical history.<sup>38</sup> While the Guide for Aviation Medical Examiners ('guide') contains robust instructions on how to complete the medical examination, the application is the pilot's chance to reveal pertinent information.

Pilots have a duty to disclose all pertinent medical information on the application for medical certificate.<sup>39</sup> These disclosures are reviewed as part of the medical certificate exam and withholding information can result in negative consequences for a pilot, including a permanent denial even if the condition is otherwise not grounds for a denial.<sup>40</sup> For example, even though headaches unrelated to other conditions are not disqualifying,<sup>41</sup> the FAA has issued denials based on a failure to disclose headaches, and courts have upheld such denials.<sup>42</sup> Even perjury convictions are possible for failure to disclose.<sup>43</sup>

*I.B.iii. Medical Certification: The Guide for Aviation Medical Examiners*

The guide contains detailed instructions for examiner screening procedures, including conditions that result in a default denial (i.e., substance abuse, heart disease, and epilepsy).<sup>44</sup> The guide distinguishes between neurological conditions that justify a denial, require FAA decision (i.e., a default deferral), or require additional scrutiny.<sup>45</sup> For example, an 'established diagnosis of epilepsy, a transient loss of control of nervous system function(s), or a disturbance of consciousness is a basis for denial no matter how remote the history'.<sup>46</sup> While the application does not explicitly include AD or other causes of dementia, the guide does, making examiners attentive to those conditions.<sup>47</sup> Finally, the guide specifies a 'catchall' category<sup>48</sup> that provides discretion to deny an applicant for unlisted conditions that impede or might impede a pilot's fitness to fly or may be 'reasonably expected...to make the person unable to perform' during the time of the medical certification.<sup>49</sup>

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<sup>37</sup> F-8500, *supra* note 32.

<sup>38</sup> *Id.*

<sup>39</sup> F-8500, *supra* at 32.

<sup>40</sup> *US v Culliton* 328 F. 3d 1074 (9<sup>th</sup> Cir. 2003). (Upholding a conviction for not disclosing minor treatment for headaches and dizziness. The court held that F-8500 were not ambiguous even when the questions on the medical form are so broad that they can apply to everyone. Culliton argued that no person could deny a history of dizziness, headaches, etc. and therefore answering the question honestly provided no relevant information.)

<sup>41</sup> Guide, *supra* note 2, at 136.

<sup>42</sup> *Culliton*, *supra* note 40, at 1079.

<sup>43</sup> *Id.*

<sup>44</sup> Guide, *supra* note 2, at 9-10.

<sup>45</sup> *Id.* at 9-10 & 135-53.

<sup>46</sup> *Id.* at 34.

<sup>47</sup> *Id.* at 143.

<sup>48</sup> *Id.* at 64.

<sup>49</sup> *Id.* See also 14 C.F.R. § 67.109(b) (2018).

*I.B.iv. Medical Certification: The Examination*

The Guide articulates detailed examination procedures that examiners must adhere to.<sup>50</sup> If an examiner deviates, they may be liable for damages caused by an unidentified condition.<sup>51</sup> The instructions include specific guidance for neurological screening, including a comprehensive review of the pilot's medical history.<sup>52</sup> The examiner must administer a battery of functional neurological tests.<sup>53</sup>

*I.B.v. Medical Certification: Examiner and FAA Authority*

FAA policy, as articulated in the guide, and FAA authority to override examiners' recommendations limit a medical examiner's authority. The guide restricts the examiner's authority to approve, and an applicant may be denied by the examiner only if the pilot plainly fails to meet any of the criteria in the Guide.<sup>54</sup> An examiner must defer decisions to the FAA if a pilot's medical history or clinical examination raises concerns about his or her fitness that are not articulated in guiding policies. While the examiner's determinations account for a majority of medical certifications decisions, the FAA can override the medical examiner's decision and dozens of conditions require automatic FAA review and approval.<sup>55</sup> The FAA will typically only reverse a medical examiner's recommendation if a certificate is initially denied by the examiner and the pilot requests an Authorization for Special Issuance of a Medical Certificate ('the authorization').<sup>56</sup>

The authorization is designed for pilots with a history of disqualifying conditions who are now fit to fly or who have present conditions but who can demonstrate an ability to perform the duties required without heightened risk to public safety.<sup>57</sup> For example, if a pilot has a documented history of substance abuse, the examiner is obligated to note the history on the pilot's application and deny the certificate. However, the FAA may grant the pilot a medical certificate at the discretion of the Federal Air Surgeon if the pilot demonstrates that they have recovered.<sup>58</sup> Denials based upon default disqualifying conditions may only be reversed if the Federal Air Surgeon grants a Statement of Demonstrated Ability.<sup>59</sup> These may only be granted if the condition is 'static or non-progressive' and the pilot is able to perform their 'duties without endangering public safety.'<sup>60</sup>

<sup>50</sup> *Id.* at 38-161.

<sup>51</sup> *Id.* at 6. ('If the examination is cursory and the Examiner fails to find a disqualifying defect that should have been discovered in the course of a thorough and careful examination, a safety hazard may be created and the Examiner may bear the responsibility for the results of such action'.)

<sup>52</sup> *Id.* at 136.

<sup>53</sup> *Id.* (The basic neurological examination consists of an examination of the 12 cranial nerves, motor strength, superficial reflexes, deep tendon reflexes, sensation, coordination, mental status, and includes the Babinski reflex and Romberg sign. The examiner should be aware of any asymmetry in responses because this may be evidence of mild or early abnormalities. The examiner should evaluate the visual field by direct confrontation or, preferably, by one of the [perimeter visual] procedures, especially if there is a suggestion of neurological deficiency.)

<sup>54</sup> *Id.* at 10.

<sup>55</sup> *E.g., Id.* at 46-48, 50-51, 59-61, 138-48. (Past visual impairment, heart conditions, alcoholism, etc.).

<sup>56</sup> 14 C.F.R. § 67.401 (2018).

<sup>57</sup> Guide, *supra* note 2, at 22.

<sup>58</sup> 14 C.F.R. § 67.401(a).

<sup>59</sup> The Guide, *supra* note 2, at 21.

<sup>60</sup> *Id.* at 21-22.

*I.B.vi. Medical Certification: Protecting Sensitive Information Collected*

The FAA acts as gatekeeper to the sometimes sensitive information gathered in the certification process.<sup>61</sup> After an airline-employer hires a pilot, the pilot signs consent forms that allow the FAA, their former employer, and the National Driver Registry to release their records.<sup>62</sup> The employing airline then submits a request under the Freedom of Information Act<sup>63</sup> to gain access to the prospective pilot's medical certification status. If the request is granted, the FAA may disclose the status of the medical certificate (i.e., whether the pilot holds a valid medical certificate).<sup>64</sup> However, specific medical information collected during certification procedures is confidential and is not made available to the airlines unless the pilot personally discloses it to the employer.

Protections for sensitive information are a bulwark against employer discrimination, but it is unclear whether current federal laws and regulations would protect biomarker positive individuals from employers. The Genetic Information Non-discrimination Act ('GINA') only applies for conditions that have not yet manifested.<sup>65</sup> A reviewing court could determine that biomarkers are evidence of a manifested condition, and, therefore, GINA would not apply. Further, the ADA only provides protection for individuals who are suffering from a condition that has a substantial impact on one or more life activities or for those who are 'regarded as having such an impairment'.<sup>66</sup> Since biomarkers often appear in individuals with no symptoms, the ADA would likely not provide protection against employer discrimination based on biomarkers unless the individual could establish that they meet the 'regarded as' requirement. To meet this requirement, individuals must show that 'he or she has been subjected to an action...because of an actual or perceived physical or mental impairment, whether or not the impairment limits or is perceived to limit a major life activity'.<sup>67</sup> If an employer discriminated against someone who was biomarker positive as a matter of avoiding risk in the future, and not because the employer thought the individual was impaired at the time, the ADA would likely provide no protection for that individual. This presents a troubling gap in the regulatory structure that is ripe for further development and critique.

### I.C. FAA Discretion to Deny Individual Certification and Create Procedures for Issuing Policies

The FAA Administrator ('administrator') has broad discretion to implement licensing procedures<sup>68</sup> that promote air safety by reducing 'the possibility or recurrence of

<sup>61</sup> *Id.* at 13.

<sup>62</sup> Department of Transportation, Advisory Circular, *FAA: Pilot Records Improvement Act of 1996*, AC 120-68G § 2.1.1 (2016).

<sup>63</sup> 5 U.S.C. § 552.

<sup>64</sup> Pilot Records Act Advisory Circular, *supra* note 62 at § 5.5.2. (Commercial air carriers request medical certificate information 'under the authority of the Privacy Act or the Freedom of Information Act (FOIA) to determine the status of those certificates'.)

<sup>65</sup> Pub. L. 110-233 § 101(a)(3)(B).

<sup>66</sup> 42 U.S.C. § 12102 (Westlaw current through Pub. L. 116-5).

<sup>67</sup> *Id.*

<sup>68</sup> 49 U.S.C. § 44701 (Westlaw current through Pub. L. 114-190, approved Jul. 15, 2016).



accidents in air transportation'.<sup>69</sup> This discretion is limited only in circumstances of clear abuse of authority where the FAA fails to provide a reasoned explanation for creating and applying their rules.<sup>70</sup> To establish that an agency has abused its authority, challengers must show that the agency has provided no rational justification, not 'responded to relevant and significant public comments' (if required), or failed to consider possible alternatives to the policy.<sup>71</sup> This does not mean that the agency must integrate alternatives or public concerns into their policies but rather that they just have to have a reasoned explanation for why they did not. In general, courts defer to any choice that results from a rational connection between the facts and the decision made as long as statutorily or constitutionally mandated procedures were followed.<sup>72</sup> This means the FAA has discretion both to deny individual medical certificates and to establish policies that guide medical examiners' recommendations and exam procedures, even if those denials and policies are questionable.

#### *I.C.i. FAA Discretion: Individual Medical Certificates*

The FAA has unilateral discretion, regardless of the medical examiner's recommendation, to deny medical certificate applications based on a reasonable inference from the facts.<sup>73</sup> The reasonable inference may be based on a wide range of medical information or status, including evidence of asymptomatic conditions.<sup>74</sup> Courts have consistently held that evidence of heightened risk for manifestation of a disqualifying condition is sufficient for a denial when evaluating the breadth of the FAA's discretion.<sup>75</sup>

#### *I.C.ii. FAA Discretions: Policies to Inform Medical Certification*

The FAA has broad discretion to establish policies and guidelines that instruct decision-making, including policies that establish default decisions for conditions and populations. These policies remove, or greatly limit, the individualized case analysis when issuing medical certificates. For example, the FAA has articulated policies that direct broad sweeping medical certificate decision-making based on human immunodeficiency virus (HIV) and age. Additionally, the FAA's treatment of genetic information or status represents a gap in policies for establishing standard practices. An examination of these policies and approaches provides informative precedent for future FAA policies on asymptomatic conditions that confer risk for future disease or disability, including preclinical AD.

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<sup>69</sup> 49 U.S.C. § 44701(c).

<sup>70</sup> *Professional Pilots Federation v F.A.A.*, 118 F. 3d 758, 763 (D.C. Cir. 1997).

<sup>71</sup> *Id.* at 162.

<sup>72</sup> 'We examine the agency's decision to ensure that it was based on a consideration of the relevant factors and articulated a rational connection between the facts found and the choice made'. *Yetman v Garvey* 261 F. 3d 664, 669 (2001).

<sup>73</sup> *Reder v Administrator of the FAA*, 116 F. 3d 1261, 1263 (8th Cir. 1997). ('We will accept the findings of fact made by the agency, and the reasonable inferences drawn from those findings of fact, as long as the agency's findings are supported by substantial evidence in the record as a whole'.)

<sup>74</sup> *Id.*

<sup>75</sup> *Doe v Department of Transp., FAA*, 412 F. 2d 674, 677-78 (8th Cir. 1969). ('We detect no requirement that the disorder, to be disqualifying under the regulation, must be currently manifest at the time of the application or of the administrative hearing'.)

## II. HISTORICAL TREATMENT OF RELEVANT CONDITIONS

### II.A. Human Immunodeficiency Virus

The FAA subjects commercial pilots who are HIV positive to stricter medical certification scrutiny during licensure procedures.<sup>76</sup> The heightened scrutiny protocol requires pilots to comply with approved medication regimens, specific authorization by the FAA for approval of medical certificate applications, an initial two-year strict surveillance program, and ongoing surveillance after the two-year period.<sup>77</sup> The initial surveillance includes verification that viral load and CD4 cell count tests are within their acceptable ranges.<sup>78</sup> Cognitive function assessments are conducted every three months, and a report describing cardiovascular, cognitive, and other signs of HIV progression every six months.<sup>79</sup> After the initial two-year period, similar procedures are required every six months (cognitive testing) and 12 months (health report) respectively.<sup>80</sup>

Prior to 1998 the FAA enforced a default policy that disqualified all pilots with HIV as medically unfit.<sup>81</sup> The FAA cites the generally heightened risk of neurological and psychological disorders in those with HIV as justification of the current policy. HIV affects the immune system, which could lead to 'opportunistic' infections such as cryptococcal meningitis, fulminant bacterial meningitis, neurotuberculosis, toxoplasmosis, and neurosyphilis.<sup>82</sup> These are all examples of conditions that indicate neurocognitive functioning. Neurological disorders in HIV-positive people may be more prevalent than in the general public.<sup>83</sup> More than 50% of individuals with AIDS or advanced stage HIV experience neurological or mental disorder symptoms.<sup>84</sup> Additionally, preclinical neuropathology has been shown to be present in 75–90% of advanced stage HIV cases.<sup>85</sup> Yet, individuals in the early stages of HIV are unlikely to experience

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<sup>76</sup> Guide, *supra* note 2, at 262-65.

<sup>77</sup> *Id.*

<sup>78</sup> *Id.* at 261. ('At the time of initial application, viral load must not exceed 1,000 copies per milliliter of plasma, and cognitive testing must show no significant deficit(s) that would preclude the safe performance of airman duties.')

<sup>79</sup> *Id.* at 264. *See also Id.* at 261. ('Additional cognitive function tests may be required as indicated by results of the cognitive tests.')

<sup>80</sup> *Id.* at 265.

<sup>81</sup> *F.A.A v Cooper*, 132 S. Ct. 1441 (2012). (HIV positive pilot withheld his status after the threshold denial for HIV was changed in 1998. Cooper was denied certification and challenged the denial under the legal remedy in the form of damages for emotional pain and suffering after the court held that the FAA's reading of the statute was preferred under the doctrine of sovereign immunity.) *See* 'Man with HIV can train as airline pilot after ban is reversed', *The Guardian*, (Jan. 18, 2018). (The ban on HIV positive commercial pilots in the United Kingdom was not lifted by the FAA's parallel agency, the Civil Air Authority, until 2018.) <https://www.theguardian.com/world/2018/jan/18/man-with-hiv-can-train-as-airline-pilot-after-ban-is-reversed> (last accessed July 3, 2019).

<sup>82</sup> Dawn McGuire, HIV InSite Knowledge Base, *Neurologic Manifestations of HIV*, (June 2003), <http://hivinsite.ucsf.edu/InSite?page=kb-04-01-02> (last accessed July 3, 2019).

<sup>83</sup> *Id.*

<sup>84</sup> Joanna Hellmuth, et al., *Depression and Anxiety are Common in Acute HIV Infection and Associate with Plasma Immune Activation*, 21(11) AIDS BEHAV. 3238 (2017).

<sup>85</sup> Robert Levy, et al. *Neurological manifestation of the acquired immunodeficiency syndrome (AIDS)*, 62(4) J NEUROSURG. 475 (1985).

any neurologic symptoms<sup>86</sup> or experience mild symptoms that do not adversely affect function.<sup>87</sup> Neurological dysfunctions often have intervening factors that increase the risk for impairment and contribute to severity, including pre-existing mental health illness and/or history of substance abuse.<sup>88</sup> Despite evidence that HIV-positive pilots are at an increased risk of functional impairment, the FAA has faced opposition to policies increasing scrutiny for licensure.

In 1988, the World Health Organization issued a report challenging evidence that HIV affects function, stating 'HIV-1 infected individuals are no more likely to be functionally impaired from a neuropsychiatric viewpoint than uninfected persons'.<sup>89</sup> In 1993, a prominent group of doctors urged the Aerospace Medical Association to change its initial policy of disqualifying HIV positive commercial pilots.<sup>90</sup> The FAA has remained steadfast in its policies on increased scrutiny for pilots with HIV, and courts have consistently upheld the policies as reasonable, not an abuse of discretion.<sup>91</sup>

## II.B. Age

The FAA implements two restrictions on pilot licensure based on pilot age, default denial at age 65 and increased frequency of examination at age 40. First, the FAA prohibits licensure of first-class (commercial airline) pilots over the age of 65.<sup>92</sup> Unlike other potentially disqualifying factors (i.e., heart conditions and alcohol problems), the FAA does not reverse or exempt medical denials based on age for first-class pilots.<sup>93</sup> Originally enacted as the 'age-60' rule in 1959,<sup>94</sup> the FAA justifies the current 'age-65' rule based on evidence that age affects abilities to adjust to environmental and physical factors (e.g., fatigue, stamina).<sup>95</sup> In 1979, subsequent to a Congressional order the National Institutes of Health (NIH) concluded that there was 'no special medical significance to age sixty as a mandatory age for retirement of airline pilots'.<sup>96</sup> However, the NIH recommended that the rule remain in place, because there was no dependable way to 'single out those pilots who would pose the greatest hazard' due to deteriorating

<sup>86</sup> Shelli Farhadian, Payal Patel, and Serena Spudich, *Neurological Complications of HIV Infection*, 19(12) CURR INFECT DIS REP. 50 (2017).

<sup>87</sup> *Id.*

<sup>88</sup> *Id.*

<sup>89</sup> World Health Organization. *Report of the consultation on the neuropsychiatric aspects of HIV-1 infection* Geneva (1988).

<sup>90</sup> Ola Selnes & Eric Miller, *Asymptomatic HIV-1 Infection and Aviation Safety*, 64(2) AVIAT. SPACE ENVIRONM. MED. 172 (1993).

<sup>91</sup> *F.A.A v Cooper*, 132 S. Ct. 1441 (2012). (Plaintiff was denied certification and legal remedy in the form of damages after the FAA accessed his medical records in violation of federal privacy laws based on the doctrine of sovereign immunity.) *See also Doe*, *supra* note 75.

<sup>92</sup> 14 C.F.R. § 121.383(d-e) (2018). 'No certificate holder may use the services of any person as a pilot on an airplane engaged in operations under this part if that person has reached his or her 65th birthday...No pilot may serve as a pilot in operations under this part if that person has reached his or her 65th birthday'.

<sup>93</sup> Jeff Orkin, *Fair Treatment for Experienced Pilots Act-All Good Things Really Do Come to an End*, 73 J. AIR L. & COM. 579, 581 (2008).

<sup>94</sup> Geneve Dubois, *The Age 60 Rule: It is Time to Defeat It!*, 70 J. AIR L. & COM. 319, 325 (2005).

<sup>95</sup> F.R. Doc. 59-5410; Filed June 26, 1959.

<sup>96</sup> *Report of the National Institute on Aging, Panel on the Experienced Pilots Study 1* (Aug. 1981). *See also* 47 Fed. Reg. 29,782 (July 8, 1982). (Research of 62-year-old pilots was considered during flight operations. But the study never happened, because the FAA determined that 'no medical or performance appraisal system can be identified that would single out pilots who would pose a hazard to safety'.)

health associated with aging.<sup>97</sup> In 2009, the Fair Treatment for Experienced Pilots Act was enacted and revised the rule to make 65 the cutoff age.<sup>98</sup>

The age-65 rule only applies statutorily to common air carrier pilots who hold a first-class license.<sup>99</sup> However, the age-65 rule previously provided grounds for forced retirement of pilots with other classes of licenses by non-common carrier operators as well.<sup>100</sup> Non-public and small-scale operators who do not require a first-class carrier license (e.g., corporate-owned airplanes for transporting upper management and crop dusters) have discretion to employ pilots over 65. However, federal courts have supported employer policies that require pilot retirement on the basis of age without violating age anti-discrimination laws.<sup>101</sup> This reasoning finds support in other contexts where neurological disorders come to bear on public safety.<sup>102</sup> However, the precedent is mixed in this area, and further clarification is needed to understand how the statutory and regulatory structure would play out. The Supreme Court ruled that remedial factors can be used to determine whether or not an employee is disabled and thus afforded protections under the ADA.<sup>103</sup> In 2018, Congress expressly overturned the *Sutton* holding and affirmed that the protections afforded under the ADA are to be construed broadly to comply with the purpose of that legislation, which is to protect disabled persons from discrimination in a robust fashion.

Despite this, courts have recently continued to find it reasonable and legitimate for airline companies to discriminate on the basis of age, and Congress has acted in the area of pilot safety to implement the utmost care in screening pilots to protect public safety. Judicial review of the age-65 rule itself has found that it is a rational and justifiable discriminatory practice<sup>104</sup> not in violation of the Age Discrimination in Employment Act.<sup>105</sup> The rule remains applicable even in the context of pilots who do not exhibit any risk to public safety other than can be inferred from age.<sup>106</sup>

In late April of 2018, the United States House of Representatives passed the FAA Reauthorization Act with a provision that would force the retirements of private

<sup>97</sup> 49 Fed. Reg. 14,692, 14,695 (Apr. 12, 1984). ('The inability to detect or predict with precision an individual's risk of sudden or subtle incapacitation, in the face of known age-related risks, counsels against relaxation of the rule'.)

<sup>98</sup> 49 U.S.C. § 44729 (Westlaw current through Pub. L. 114-193, approved Jul. 7, 2016).

<sup>99</sup> 14 C.F.R. § 121.383(d-e) (2018).

<sup>100</sup> *E.E.O.C. v Exxon Mobil Corp.*, 560 Fed. Appx. 282, 289 (2014). ('Exxon has established that it was compelled to adopt the rule because there are no adequate means of individually testing each pilot'.)

<sup>101</sup> *Id.* at 288. ('The EEOC has not presented evidence explaining the FAA's rationale for declining to apply the rule to pilots regulated by Part 91 like Exxon's nor has the EEOC adequately explained why the FAA's safety rationale would be inapplicable to Exxon's pilots when the occupations are congruent'.)

<sup>102</sup> For example, the 7th Circuit ruled that a trucking company who refused to hire drivers with neurocardiogenic syncope did not violate the ADA. *EEOC v Schneider National, Inc.*, 481 F.3d 507 (7th Cir. 2007) (interstate *Sutton v United Air Lines, Inc.*, 527 U.S. 471 (1999)).

<sup>104</sup> Gregory Ripple & Miller Johnson, National Business Aviation Association, *Federal Court: Mandate Retirement Age for Pilots Is Not Age Discrimination*, <https://www.nbaa.org/admin/personnel/age-65/20140502-federal-court-mandatory-retirement-age-for-pilots-is-not-age-discrimination.php> (accessed Aug. 15, 2018).

<sup>105</sup> *Professional Pilots Federation v F.A.A.*, 118 F. 3d 758, 763 (1997). ('The general prohibition of the ADEA, addressed as it is to employers, should not be read by mere implication to override the specific grants of authority to the FAA in 49 U.S.C. § 44701'.)

<sup>106</sup> Ripple, *supra* note 104.

corporate pilots at age 70.<sup>107</sup> This legislation aimed to extend the logic behind the age-65 rule to those who fly private commercial planes for large corporations (i.e., Berkshire Hathaway and Chevron), but it was not included in the final version of the act. If passed, it would have affirmed the reasoning of the courts that have held that mandatory retirement ages are reasonable in cases that apply only to non-common carrier operations. That it got so close to passing indicates that the age limits for pilots and the reasoning supporting them are not going away any time soon.

The second FAA age-related policy requires increased frequency of medical certification for first-class commercial pilots over 40 years old. First-class commercial pilots under 40 must complete medical certification annually, while pilots over 40 must complete medical certification every six months.<sup>108</sup> The more frequent examinations maximize the ability of the FAA to screen for conditions correlated to aging.<sup>109</sup> Despite the increased monitoring of pilots older than 40-years old, the FAA maintains the age-65 rule as a preventative mechanism to reduce the risks of age associated deficits from manifesting in older pilots.<sup>110</sup>

### II.C. Genetics

Genetic testing and analysis can confirm a disease diagnosis or infer risk for a future illness.<sup>111</sup> As a result, genetic information can serve as evidence of disease etiology that causes or will cause clinical symptoms. However, genetic information by itself does not indicate a degree of functional impairment. For example, APOE4 confers an increased risk for AD but does not indicate whether the individual is actively experiencing symptoms associated with the disease.<sup>112</sup> Despite this, genetic information may still be useful in an FAA medical examination.

The FAA has not articulated clear policies on the use of genetic information during medical certification procedures. The 'GINA' protects against employment discrimination based on genetic information.<sup>113</sup> It is unclear whether GINA would bar the FAA from considering genetic information, because the law targets private employers with 15 or more employees, government employers, labor organizations, and employment agencies.<sup>114</sup> Therefore, it is unlikely that GINA would apply, since the FAA is an administrative screening agency and not an employer in the licensing process. However, Congress did not except public safety occupations from the mandates of GINA. In doing so, the implication is that the law requires strict protections against genetically based discrimination. It is unclear whether Congressional arguments in favor of broad protections in this area hold in the context of FAA pilot screening. While an interesting line

<sup>107</sup> FAA Reauthorization Act of 2018, HR 4, 115th Cong, § 582 (2018) available at <https://www.congress.gov/bill/115th-congress/house-bill/4/text> (last accessed July 3, 2019).

<sup>108</sup> 14 C.F.R. § 61.23(d) (2018).

<sup>109</sup> Diane Hyland, et al., Office of Aviation Medicine, *Age 60 Study, Part II: Airline Pilot Age and Performance – A Review of the Scientific Literature* (1994).

<sup>110</sup> Orkin, *supra* note 93. See also Experienced Pilots Study, *supra* note 96.

<sup>111</sup> National Human Genome Research Institute, *Genetic Disease Prevention and Treatment*, <https://www.genome.gov/19016938/faq-about-genetics-disease-prevention-and-treatment/> (last accessed July 3, 2019).

<sup>112</sup> Margaret O'Donoghue, et al., 'APOE genotype and cognition in healthy individuals at-risk of AD: a review', 104 *CORTEX* 103 (2018).

<sup>113</sup> 14 U.S.C. § 2000ff (Westlaw current through Pub. L. 115-185, approved Jun. 16, 2018).

<sup>114</sup> *Id.*

of inquiry, AD biomarker diagnostics measure proteins and not genetic markers, so we hold off on addressing the merits of the Congressional scheme in GINA for another day.

The term genetic does not appear in the statutes containing instructions on pilot screening.<sup>115</sup> Yet, there are several diseases listed under the 'Extrapyramidal, Hereditary, and Degenerative Diseases of the Nervous System' category in the guide (e.g. Huntington's disease, dystonia, AD, and Creutzfeldt-Jakob's disease).<sup>116</sup> The guide does not further clarify the use of genetic testing. The FAA's treatment of genetic information testing is notable given a failure to advise on how relevant genetic testing can bear on the pilot's application for medical certification. The FAA remains mostly silent on the issue even though it could be pertinent to the ongoing health of a pilot.

Despite the lack of FAA policies that explicitly address genetic risk for purposes of medical certification, the agency has issued some guidance as evidenced by reports on individual cases. In 2012, the Federal Air Surgeon released a report on a pilot with a second-class medical certificate who indicated on his application that he had the genetic mutation associated with Huntington's disease.<sup>117</sup> The pilot underwent further neuropsychiatric, imaging, and laboratory testing and showed no signs of cognitive impairment, and a Special Issuance Authorization was approved.<sup>118</sup> The report makes clear that, 'due to the unexpected nature and terminal prognosis of Huntington's disease', the airman's medical condition should be carefully monitored and changes in his condition would demand that he immediately stop piloting aircraft.<sup>119</sup> This case report provides another example of risk-based information leading to increased scrutiny and monitoring versus a default denial.

### III. APPLICATION OF FAA POLICIES TO AD BIOMARKERS

FAA policies and guidelines do not explicitly address AD biomarkers as a condition relevant to medical certification procedures. Whether a medical examiner or the FAA could base certification decisions on AD biomarker status relies on resolving two broader questions. First, would an examiner or the FAA have access to AD biomarker status during the evaluation? Second, if a medical examiner or the FAA has access to biomarker status, would current policies and guidelines support considering AD biomarkers during medical certification procedures? We conclude that if biomarker status was disclosed or made available to a medical examiner or the FAA, biomarkers could serve as grounds for a medical certification denial, increased scrutiny and monitoring, or deferral to the FAA for a determination.

#### III.A. Examiner/FAA Access to AD Biomarker Status

Medical examiners and the FAA base medical certifications on the information available or collectable under FAA regulations and guidelines. AD biomarker status, unique from other medical information, may not be available to examiners given current

<sup>115</sup> 49 U.S.C.A. Subt. VII, Pt. A, Subpt. III, Ch. 447 (2018).

<sup>116</sup> The Guide, *supra* note 2, at 143.

<sup>117</sup> Robert Craig-Gray, *Huntington's Disease: Case Report* 50(2) FEDERAL AIR SURGEON'S MEDICAL BULLETIN 16 (2012) available at [https://www.faa.gov/other\\_visit/aviation\\_industry/designees\\_delegations/designee\\_types/ame/fasmb/media/201202.pdf](https://www.faa.gov/other_visit/aviation_industry/designees_delegations/designee_types/ame/fasmb/media/201202.pdf) (last accessed July 3, 2019).

<sup>118</sup> *Id.* at 16-17

<sup>119</sup> *Id.* at 17

clinical standards that restrict the use of biomarker testing. Additionally, examiners may not have authority to request biomarker testing of pilots during medical certification procedures. However, biomarker status may become more readily available as clinical use of biomarker testing advances.

### III.A.i. Availability of AD Biomarker Information Under Current Clinical and Research Standards

Individual access to biomarker testing is limited to clinical use in symptomatic patients and research trials that include biomarker disclosure.<sup>120</sup> Clinically, appropriate use criteria for practitioners<sup>121</sup> and Centers for Medicare & Medicaid Services (CSM)<sup>122</sup> restrict biomarker testing to narrow circumstances. Among other restrictions, biomarker testing is not supported in asymptomatic patients or in patients with 'typical' onset of AD.<sup>123</sup> Center for Medicare & Medicaid Services (CMS) very narrowly supports reimbursement of amyloid imaging to rule out AD in 'difficult differential diagnoses', including distinguishing AD from frontotemporal lobar dementia.<sup>124</sup> The appropriate use criteria and restrictions on reimbursement make it improbable that an asymptomatic individual would learn their AD biomarker status through a clinical encounter. As a result, biomarker information will not be readily available to a medical examiner via a medical record review.

Disclosure of biomarker status to participants enrolled in observational or clinical research trials remains limited. Individual studies follow diverse protocols to disclosing biomarker status, making it difficult to characterize broad trends for disclosure. Anecdotal evidence indicates that some studies of symptomatic research participants may disclose biomarker status as part of larger reports of study findings. Among studies examining asymptomatic participants, the A4 trial is the most notable study known to disclose biomarker status to asymptomatic participants.<sup>125</sup> The study uses positive amyloid biomarker status as eligibility criteria to enroll participants for a treatment trial.<sup>126</sup> As a result, participants must agree to learn their biomarker status as part of the trial. In the context of the FAA medical certification procedures, there are limited circumstances that an asymptomatic pilot would learn his or her biomarker status through research (i.e., enrolled in a trial that discloses status).

Future clinical and research standards for disclosing AD biomarker information may change as advancements warrant testing asymptomatic populations. Leading hypotheses for identifying a disease modifying therapy for AD rely on an assumption that successful treatments will interfere with disease processes prior to symptom onset.<sup>127</sup> Disease modifying therapy that is effective prior to symptom onset, but after disease pathology has begun, are known as secondary preventions. Biomarkers may

<sup>120</sup> Johnson, *supra* note 19.

<sup>121</sup> *Id.*

<sup>122</sup> Centers for Medicare & Medicaid Services, *Decision Memo for Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease (CAG-00431N)*, <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=265> (last accessed July 3, 2019).

<sup>123</sup> Johnson, *supra* note 19.

<sup>124</sup> Decision Memo, *supra* note 122.

<sup>125</sup> Sperleng, *supra* note 20.

<sup>126</sup> *Id.*

<sup>127</sup> *Id.*

become the clinical standard of care in discrete populations, if researchers successfully develop secondary preventions to slow or halt the progression of AD. Disclosure of biomarker information to healthy individuals would accompany clinical implementation of biomarker testing and treatment. Under these circumstances biomarker status would be known to an applicant, available in his or her medical record, and need to be disclosed to an FAA medical examiner and the FAA.

### III.A.ii. *FAA Medical Examiner Access to Biomarker Information*

A medical examiner is allowed access to a pilot's full medical history to conduct a thorough review, as mandated by the FAA.<sup>128</sup> The FAA requires that pilots disclose all known medical information to the best of their knowledge.<sup>129</sup> As described above, pilots have a strict affirmative duty to disclose their medical history and can face a categorical denial if they fail to disclose pertinent information.<sup>130</sup> Disclosure requirements include mandated reporting of any visits to a health care professional in an application for medical certification.<sup>131</sup>

Courts have upheld the duty to disclose, supporting medical certification denials and possibly criminal prosecution. Broadly, judges have supported the duty to disclose and emphasized a pilot's knowledge of the condition as material to the outcome. In *US v Culliton*, the court upheld the conviction of a pilot who failed to disclose a head injury and associated treatment, even though the injury alone would have been unlikely to lead to a denial.<sup>132</sup> The court upheld the decision because the pilot knew that he was answering the question on the application untruthfully.<sup>133</sup> *Culliton* argued that since everyone has had dizziness, headaches, and vision problems at some point in their lives, the yes/no questions about them were 'unanswerable in any meaningful way' and that it is 'incomprehensible' to take them literally.<sup>134</sup> The court upheld his perjury conviction on the grounds that *Culliton* did not believe or attempt to assert that he answered truthfully or to the best of his knowledge.<sup>135</sup> In *Summers v Hinson*, a pilot's denial was upheld on the grounds that he did not list a visit to a psychologist on the application.<sup>136</sup> Conversely, in *Finazzo v Sturgess*, a pilot was denied by the FAA due to a failure to disclose a mental health condition, but the Ninth Circuit Court of Appeals overturned the denial because nothing in the record indicated that the pilot actually knew about the condition, although it existed.<sup>137</sup>

<sup>128</sup> Guide, *supra* note 2, at 6.

<sup>129</sup> F-8500, *supra* at 32.

<sup>130</sup> *Id.* at 31-32. See also *Culliton*, *supra* note 40.

<sup>131</sup> *Id.*

<sup>132</sup> *Culliton*, *supra* note 40, at 1078.

<sup>133</sup> *Id.* at 1078.

<sup>134</sup> *Id.* at 1078-79. (*Culliton*, who was also an attorney, was convicted of a felony for making false statements to the federal government and permanently denied a medical certificate for not disclosing the head injury. He claimed that the yes/no questions on the Application were vague and should not be taken literally.)

<sup>135</sup> *Id.* at 1080.

<sup>136</sup> 121 F. 3d 397 (1997). (The denial would have been overturned if the only basis was that *Summers* had falsely claimed to have never suffered from a mental disorder, because there was nothing in the record to support that he knew.)

<sup>137</sup> *Finazzo*, 407 Fed. Appx. 241, 243 (2011). (Although there was evidence in *Finazzo's* medical record that she suffered from a mental disability, her doctor only made a note of it and never personally shared that information with her. Since the record indicated that she had disclosed her history to the best of her knowledge, the Court of Appeals reinstated an ALJ decision that had granted her certificate.)



An applicant's knowledge of AD biomarker status, even if gained through research, raises novel questions about the duty of pilots to disclose relevant medical information during the screening process. It could be deemed a neurological condition, even post facto. Because AD biomarker testing is largely limited to research, it is unlikely that a pilot would learn his or her status clinically. FAA policies do not clarify whether information learned through research would justify a required disclosure. This gap in policies raise risks for pilots who choose not to disclose information learned through research and do not disclose. A pilot may face severe penalties if the FAA interprets biomarker status knowledge garnered through research to constitute information that must be disclosed.<sup>138</sup> Thus, this issue needs further clarification by the FAA.

Access to AD biomarker status may also be available if an examiner has authority to order testing. FAA policy, as articulated in the guide, provides grounds for tests a medical examiner requests as part of the medical certification evaluation. Biomarker testing, using either CSF or PET imaging measures, is not referenced in the guide. However, current FAA policies serve as precedent for requesting biomarker testing. The Guide instructs the medical examiner to review of neurological testing history, including magnetic resonance imaging, electrical activity scans, and lumbar punctures.<sup>139</sup> While a history of these tests alone might indicate neurological conditions,<sup>140</sup> the guide does not specify the criteria for ordering tests if they are not currently reported in the applicant's medical record or expressly required. If the FAA empowered examiners to order neurologic diagnostic tests or measures of risk, it is possible that examiners could gain authority to request AD biomarker testing. However, this practice is not currently within FAA policies and guidelines, and it would run counter to the clinical procedures described above.

### III.B. AD Biomarkers Under Current FAA Policies

This section will evaluate whether an individual assessment could incorporate AD biomarker status to inform a medical certificate decision. FAA guidelines and policies would likely support medical certificate decisions based on AD biomarkers status, if known. First, we find that the 'catchall' category may provide justification for denying an individual medical certificate application based solely on AD biomarker status. Next, we evaluate whether the FAA could issue new policies that would apply broadly, standardizing medical certificate decisions for individuals with positive AD biomarker status. The FAA's treatment of and precedent relevant to HIV and age provide evidence that active disease processes affecting function is not necessary to justify policies that create automatic denials or increase scrutiny, while, the FAA's gap in policy regarding the use of genetic information may also indicate that the FAA could remain silent on AD biomarkers.

#### III.B.i. Individual Assessment: Applying the Catchall Category

The guide's 'catchall' category enables a medical examiner to identify and examine neurological conditions that increase the likelihood of symptoms while flying, but that are

<sup>138</sup> *Id.*; Culliton, *supra* note 40; Cooper, *supra* note 81.

<sup>139</sup> *Guide*, *supra* note 31, at 135.

<sup>140</sup> *Id.*

not listed by name.<sup>141</sup> The catchall category would similarly enable clinicians to consider biomarker status, if known, during the examination and medical record review. The guide articulates the catchall category standard for denying an individual a medical certificate as a determination that the applicant is at risk of 'any neurological condition or disease that potentially may incapacitate an individual' prior to the next medical certificate evaluation.<sup>142</sup>

The catchall category might be categorically wrong for consideration of biomarkers, but it could be the basis for denial. While the catchall category is meant to describe existing functional symptoms that do not fit within listed conditions, in the context of AD biomarkers, risk for impairment is difficult to predict. This is particularly true if a medical examiner were to rely on amyloid biomarker status, which does not provide prognostic information. An individual who is asymptomatic and positive for amyloid or tau may remain asymptomatic for up to 20 years, well beyond the standard one year or six month medical certification period. Despite this, there is no mechanism to assure that a pilot will not begin experiencing symptoms that could impair judgment or capabilities to discharge his or her duties during the certification period. Therefore, a medical examiner could base a denial on a finding that AD biomarker status is sufficient to determine that the pilot is at risk of a neurological condition (AD) 'that *potentially* may incapacitate an individual.'

Alternatively, a medical examiner could defer the medical certificate to the FAA for a final determination. The FAA would likely have the discretion to justify initial denial or increased scrutiny of the application based upon the increased risk for neurological impairment. Since the FAA enjoys a deferential standard of review, their decision would hold as long as it was related to evidence found in the record. Since biomarkers do indicate an increased risk, they could serve as substantial evidence to uphold a denial.

### *III.B.ii. Broad Policies: HIV and Age as Precedent*

The FAA is only required to show that a condition shows some increased risk exists to justify denial, not that a condition indicates a substantial risk. The risks associated with AD biomarkers are likely sufficient to serve as grounds for policies that implement either a default denial or increased scrutiny. FAA policies based on age and HIV provide examples of conditions that lead to such policies, even in the absence of functional impairments.

The age-65 rule creates an automatic denial of a medical certificate. For almost all pilots, they are not at a significantly greater risk of experiencing a disabling condition on their 65th birthday than they were the day before. However, FAA policies have justified the potential increase of risk associated with age as sufficient to allow for an automatic denial of a pilot's licensure upon turning 65.<sup>143</sup> Similarly, a pilot who contracts HIV is not a more significant risk to display functional symptoms the day or even months or years after they would first test positive, but all pilots with HIV are subjected to heightened medical surveillance. The FAA could likely develop policies tailored to AD

<sup>141</sup> *Id.* at 137.

<sup>142</sup> *Id.*

<sup>143</sup> 14 C.F.R. § 121.383(d-e) (2018).

biomarkers that are modeled after either age or HIV, by creating either an automatic denial or increasing scrutiny.

### III.B.iii. *Lack of Policy: the 'Genetic Information' Approach*

The current guidance on genetic information in the FAA screening process is sparse. While there are some genetically-linked diseases listed in the guide, the FAA has no express guidance on how to deal with genetic information per se. For instance, Huntington's disease is listed in the guide,<sup>144</sup> but there is no guidance for genetic testing to confirm that a pilot who has the symptoms of Huntington's disease actually has the genetic trait necessary for that condition. However, as discussed, pilots who knowingly have and report the Huntington's disease gene mutation must go through increased neurological testing and can get a special issuance certificate after demonstrating that they are symptom free.<sup>145</sup>

Similarly, AD is listed as a disqualifying condition, but there is no guidance for confirming the presence of AD through biomarker or any other specific testing. If the FAA chooses the course of inaction, then nothing about the current process would change, though the possibility of examiners considering them on an individual case basis would remain. The example of Huntington's disease suggests that a known biomarker-positive status would indicate further neurological scrutiny, but it is unclear. Huntington's genetic markers indicate a much greater risk and the disease itself typically presents symptoms much earlier in life.<sup>146</sup> These are material factors that could impact FAA policies for AD biomarkers.

If appeals started being made after hypothetical examiner denials, the FAA would at least be forced to make individual determinations on the validity of biomarker status if not be spurred to issue guidance on the issue. However, as of the time of publication of this article, biomarker status has not been at issue in the adjudication of medical certificate applications. If the FAA is not receiving any complaints or issuing guidance, that could mean that biomarkers are not yet a live issue.

### III.B.iv. *Issues With Lack of Policy Guidance*

The FAA's lack of clear policy regarding genetic information could serve as an indicator that the FAA would similarly decide not to issue a direct policy on AD biomarkers. The fact that the FAA has published on Huntington's disease genetic markers without issuing any guidance on whether or not to test for them or incorporate them into codified policies further enforces this. Similar to AD biomarker status, genetic information may provide predictive or risk based information regarding future illness. Biomarkers, however, indicate the presence of active disease pathology, particularly if an individual is positive for both amyloid and tau. AD biomarker status is a discreet condition more analogous to HIV status. Biomarkers are also risk indicators for a disease that is already listed as a disqualifying condition. Therefore, the weight of the precedent errs on the side of the FAA integrating AD biomarker status in medical certification procedures, when and how remain less clear.

<sup>144</sup> Guide, *supra* note 2, at 143.

<sup>145</sup> Huntington, *supra* note 117.

<sup>146</sup> Richard Myers, *Huntington's Disease Genetics* 1(2) NEURORx 255 (2004).

The FAA and other agencies could refrain from establishing any policies until more is known about biomarkers. If at some point they can more accurately be used to identify people who will get AD, then the FAA could take that knowledge into consideration and promulgate rules at that time. However, a lack of policies that directly address AD biomarkers in asymptomatic individuals could lead to inconsistent approaches and outcomes. Without guidance, some examiners could start considering the status if it is known while others omit it from consideration. Some examiners have likely not even heard of AD biomarkers. A policy statement or mention in the guidelines about how to deal with biomarker status could reduce or eliminate the chance for inconsistency.

### *III.B.v. The 'Do Not Consider' Approach*

The FAA could actively issue a policy to restrict medical examiners and other decision-makers from evaluating biomarkers during the medical certification procedure. If this were to happen, nothing about the current medical certification process would change, and subsequent rulemaking would be required by the FAA to allow for future use of biomarker status consideration.

### *III.B.vi. Required Biomarker Testing?*

A final consideration is whether the FAA would require biomarker testing during the medical examination or only use information when it is available in a pilot's medical record. Mandatory biomarker testing would likely give rise to legal challenges, based on past pushback on HIV,<sup>147</sup> age,<sup>148</sup> and other denials relating to alcoholism, diabetes, and drug abuse. The challengers would have to argue that there is no rational relationship between the biomarker status and public safety and that testing itself would be an intrusive invasion of privacy not supported by the facts. However, there are few countervailing constitutional, statutory, or precedential impediments to keep the FAA from instituting such a mandatory, generally applicable policy.<sup>149</sup> Pilot licensure is a conditional privilege, which receives fewer protections than individual rights,<sup>150</sup> so it is likely that challenges would fail. The FAA's broad mandate to eliminate, not just reduce, the possibility of risk in the skies errs toward allowing biomarker testing for all pilots if the FAA decides that it is required.

## **IV. DISCUSSION AND RECOMMENDATIONS**

The FAA is uniquely positioned to conduct a careful analysis to inform policies that can be implemented alongside advancements that employ AD biomarker status. Because they are bound to supremely consider public safety, biomarker status bears on their responsibility to ensure safe skies. By being sensitive to the issues important to

<sup>147</sup> *Prilliman v United Airlines, Inc.*, 53 Cal. App. 4th 935 (1997).

<sup>148</sup> *Pilot's Association*, *supra* note 70.

<sup>149</sup> *But see* 49 U.S.C. § 106(f)(3)(B)(i) ("The Administrator may not issue a proposed regulation or final regulation that is likely to result in the expenditure by State, local, and tribal governments in the aggregate, or by the private sector, of \$250,000,000 or more (adjusted annually for inflation beginning with the year following the date of the enactment of the Wendell H. Ford Aviation Investment and Reform Act for the 21st Century) in any year, or any regulation which is significant, unless the Secretary of Transportation approves the issuance of the regulation in advance.")

<sup>150</sup> *Graham v National Transp. Safety Bd.*, 530 F. 2d. 317, 320 (1976). (Upholding a denial to a recovered alcoholic, the court stated that "[t]he requirements of due process are delineated in any given case by the consideration of both the governmental function involved and the private interests affected.")

pilots, the FAA can equitably incorporate what is known about biomarkers into their screening process without being reactive or suppressing a healthy pilot's right to fly. Future FAA policies regarding AD biomarkers will be informed by current policies and precedent policies that apply to other conditions, as has been analyzed above. We argue for a balanced approach that is modeled after FAA policies on HIV and tailored to AD biomarkers. It will be crucial for the FAA to reevaluate proposed policies regularly as science and clinical application of AD biomarker tests advance. The proposed policy recommendation reflects on the role of pilots as 'public safety' professionals, the current status of research describing AD biomarkers, and the potential consequences to individuals and the aviation system.

#### IV. A. Public Safety

First-class pilots, deemed a 'public safety' profession, are not uniquely required to complete medical certification procedures for licensure. The classification of a profession as one with public safety responsibilities heightens the importance of an individual's ability to complete critical job duties. Similarly, hospitals are increasingly requiring older physicians to complete competency screens to verify that their health status is consistent with safely and effectively completing job duties.<sup>151</sup> Police officers,<sup>152</sup> military members,<sup>153</sup> and truck drivers<sup>154</sup> all must pass medical evaluations unique to their profession. Further, public safety is commonly used as a justification for exceptions from other individual protections. For example mandatory vaccinations,<sup>155</sup> the right to not self-incriminate,<sup>156</sup> terrorism,<sup>157</sup> driver sobriety tests,<sup>158</sup> and gun laws<sup>159</sup> are all areas where public safety is invoked to promulgate protective policies.

<sup>151</sup> Lagnado L., *When are doctors too old to Practice?*, *Wall Street Journal*. June 24, 2017. <https://www.wsj.com/articles/when-are-doctors-too-old-to-practice-1498311380> (accessed Aug. 18, 2018).

<sup>152</sup> R. Leonard Goldberg, et al., *Medical Screening for California Law Enforcement*, California Commission on Peace Officer Standards and Training (1993).

<sup>153</sup> Elspeth Cameron Ritchie, *U.S. Military Enlisted Accession Mental Health Screening: History and Current Practice* 1(31) MILITARY MEDICINE 172 (2007).

<sup>154</sup> Department of Transportation, *DOT Medical Exam and Commercial Motor Vehicle Certification*, <https://www.fmcsa.dot.gov/medical/driver-medical-requirements/dot-medical-exam-and-commercial-motor-vehicle-certification> (updated Dec. 15, 2017).

<sup>155</sup> *Jacobson v Commonwealth of Massachusetts*, 197 U.S. 11 (1905). (Upholding the state mandatory vaccination law for school children.)

<sup>156</sup> *New York v Quarles*, 467 U.S. 649 (1984). (Holding that the evidentiary exclusionary rule does not apply when interests of public safety justify not reading Miranda rights. The court cites some examples of things that give rise to justifying a warrantless search where a gun might be present in the interests of 'public safety: an accomplice might make use of it, a customer or employee might later come upon it'. The court offers no definition of public safety. Concurring in judgment, Justice O'Connor expresses concern over the vagueness of this exception. 'A "public safety" exception unnecessarily blurs the edges of the clear line heretofore established and makes Miranda's requirements more difficult to understand'.)

<sup>157</sup> *Boumediene v Bush*, 553 U.S. 723 (2008). (Denying federal courts jurisdiction over Habeas Corpus actions involving 'enemy combatants' who pose a threat to national security.)

<sup>158</sup> *Birchfield v North Dakota*, 136 S. Ct. 2160 (2016). (Upholding implied consent laws that mandate drivers to submit to breathalyzers under the threat of criminal sanctions, while also striking down implied consent laws that impose criminal sanctions for refusing a blood draw.)

<sup>159</sup> *US v Miller*, 307 U.S. 174 (1939). (Upholding a ban of unlicensed sawed-off shotguns under the National Firearms Act, reasoning that possession of such weapons was and threat to public safety and not reasonably related to ensuring a well-regulated militia.)

#### IV. B. General Policy Considerations for AD Biomarker Use in Pilot Medical Certification

AD biomarkers provide a novel measure to identify an individual who is at risk of developing symptoms that would impede an applicant's ability to safely execute professional duties, including impaired memory and executive function. As science advances, biomarker accuracy will improve in asymptomatic individuals and support their use for predicting individuals' prognosis. Additionally, the prioritization of secondary prevention for drug development to treat AD increases the likelihood that clinical practices will inevitably lead to AD biomarker testing. Early preparation of policymakers to develop policies that incorporate AD biomarkers will mitigate negative consequences of reactionary policies.

Integrating AD biomarkers within the medical certification procedures is consistent with the FAA's statutorily mandated goal of ensuring safety by eliminating possible risks in the skies. Early identification paired with denials of a medical certificate would remove pilots who may be more likely to experience cognitive symptoms that would impede their ability to safely execute their professional duties. Because there are no reliable alternative methods to screen HIV positive pilots or pilots over age-65, policies to screen pilots categorically have continued to be recommended by outside agencies even after those agencies found that those classes of people presented no heightened risk.<sup>160</sup> Biomarker-based screening procedures would be consistent with these precedents.

Conversely, incorporating AD biomarkers for asymptomatic individuals in the pilot medical certification process may unnecessarily discriminate against biomarker positive pilots. After all, AD biomarkers are not clinically implemented for asymptomatic patients given limitations of their predictive value. Amyloid is a required biological measure for AD pathology, however it is not specific to those who develop clinical symptoms (i.e., not all who are amyloid positive will experience symptoms).<sup>161</sup> Additionally, those who are biomarker positive may not experience symptoms for up to 20 years. As a result, denying a medical certificate based on AD biomarkers alone could prematurely end a pilot's career who was unlikely to pose a risk to public safety in the next year.

Integrating AD biomarkers would also not greatly improve the process for reducing public safety risks associated with pilots who are suffering from AD. The age-65 rule will capture a majority of pilots who eventually develop AD. Only about 4% of individuals suffering from AD are under the age of 65.<sup>162</sup> As a result, it would be rare that a pilot who develops AD would begin experiencing symptoms before he or she was subject to the age-65 rule. Additionally, those who do develop early age of onset AD would likely be subject to additional regular screening of pilots over the age of 40 (occurring every six months under current policies). These screenings may already be a mechanism for identifying pilots with cognitive changes due to AD or other neurological condition.

Lastly, requiring biomarker testing of all pilots would violate individuals' right-not-to-know their own AD biomarker status. A significant concern associated with testing

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<sup>160</sup> Report, *supra* note 96.

<sup>161</sup> Clifford, *supra* note 7.

<sup>162</sup> Facts and figures, *supra* note 3.

and disclosing AD biomarkers are psychological risks, including worry.<sup>163</sup> Required biomarker testing would expose healthy pilot applicants to risks associated with disclosure, even in circumstances where the pilot would have otherwise chosen not to seek out testing.<sup>164</sup> However, this argument may be insufficient to counter policies that assure public safety. Particularly because pilots are already required to learn other potentially distressing medical information identified through a medical examination during certification procedures.

Denying medical certification based on biomarker status would have detrimental consequences for the aviation field. Notably, the pool of skilled and available pilots would shrink. The rate of amyloid positive healthy adults between the ages of 50–65 is approximately 10%.<sup>165</sup> Additionally, among the pilots removed from the field would be those pilots with the most experience. A similar argument was a major factor in revising the age from 60 to 65 in 2009.<sup>166</sup> However, this concern could be addressed by increasing scrutiny of AD biomarker positive applicants, without creating a default denial of the medical certificate.

A final and practical concern is the added cost of implementing biomarker testing. By implementing mandatory testing, the FAA could be initially placing further line item costs on the health care system writ large and on pilots themselves. However, insurance might cover pilot testing if the FAA implemented biomarker testing and it were to become the standard of care under pilot-specific insurance policies. Further, research shows that the cost-effectiveness of some biomarker testing increases with age as the likelihood of AD symptoms increase, so there is some trade off in early detection.<sup>167</sup> The FAA must consider the upfront costs, but it is unlikely that the aggregate costs of pilot biomarker screening would reach \$250 million, which would require Secretary of Transportation preapproval.<sup>168</sup> Nevertheless, unlike age which is known as a matter of course and HIV status which is discovered by a cheap and routine test<sup>169</sup> that a large percentage of people already get,<sup>170</sup> biomarker testing involves substantially more

<sup>163</sup> Gaël Chételat, et al., *Amyloid imaging in cognitively normal individuals, at-risk populations and preclinical AD*, 2 NEUROIMAGE CLIN. 356 (2013).

<sup>164</sup> Jalayne Arias & Jason Karlawish, *Confidentiality in preclinical Alzheimer disease studies: When research and medical records meet*, 82(8) NEUROLOGY 725 (2014).

<sup>165</sup> Willemijn Jansen, et al., *Prevalence of cerebral amyloid pathology in persons without dementia: a meta-analysis*, 313(19) JAMA 1924 (2015).

<sup>166</sup> Orkin, *supra* note 93.

<sup>167</sup> Spencer Lee, et al., *Cost-effectiveness of cerebrospinal biomarkers for the diagnosis of Alzheimer's disease*, 9(18) ALZHEIMER RES. THER. Open Access available at <https://alzres.biomedcentral.com/track/pdf/10.1186/s13195-017-0243-0> (last accessed July 3, 2019).

<sup>168</sup> 49 U.S.C. § 106(f)(3)(B)(i). *See* note 149. (There were 157,894 first-class pilots in 2016. Even assuming \$1500 per biomarker test, the aggregate cost would fall under the \$250,000 needed to prompt the requirement of Secretary approval.)

<sup>169</sup> Steven Pinkerton, et al., *Cost of Rapid HIV Testing at 45 U.S. Hospitals* 24(7) AIDS PATIENT CARE STDS 409 (2010).

<sup>170</sup> Kaiser Family Foundation, *Kaiser Family Foundation analysis of the Center for Disease Control and Prevention (CDC)'s Behavioral Risk Factor Surveillance System (BRFSS) 2013-2016 Survey Results 'Percentage of Persons Aged 18-64 Who Reported Ever Receiving an HIV Test'*, available at <https://www.kff.org/other/state-indicator/hiv-testing-rate-ever-tested/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D> (last accessed July 3, 2019).

expensive and invasive CSF testing and/or sophisticated imaging methods.<sup>171</sup> Biomarker status is not known as a matter of common practice and will remain relatively expensive to discovering age and HIV status for the foreseeable future.

#### IV. C. Specific Policy Implications of Implementation

##### *IV.C.i. Default Denial*

A default denial might be insensitive and overly burdensome on pilots due to the personal investment they make. Pilots would be at risk of becoming ineligible for flight decades before they are at risk of symptoms. This risks causing significant economic burden. Denied pilots would experience a loss of income and experience further financial and time losses that were committed to gain licensure (up to \$100,000 in out-of-pocket expenses and thousands of hours training).<sup>172</sup> This poses the issue of who would be responsible for compensating and supporting the disqualified pilots: the airlines, the Federal Government, or leaving them to their own devices. Perhaps more troubling is the infringement on a pilot's 'right not to know.' A default denial could give rise to the necessity that all pilots learn their status. Balancing the interest of the pilots and the need for safe skies is appropriate on these factors.

Additionally, an automatic denial could adversely affect the aviation field. Recent reports return mixed evidence regarding the availability of airline pilots to fulfill occupational demand.<sup>173</sup> Regional airlines have reported labor shortages, and the low pilot unemployment rate supports the idea that there is a pilot shortage.<sup>174</sup> On the other hand, indicators like wage stagnation and the amount of pilots who have left the field due indicate that many pilots might not be willing to work at lower pay rates point in the other direction, toward a surplus of pilots. Additionally, a default denial could also reduce the number of expertise and experienced pilots in the field. Further study seems to be needed to know how a default denial would impact the labor market for pilots.

A default denial approach would have the effect of eliminating the risk of AD in pilots staffing airline flights. The public's interest in safe airline transport is expressed through the FAA's congressional mandate, which calls for the elimination of risks, not just the reduction of them. This factor weighs the balance more in the favor of a default denial, but the safety mandate could be served in another way, at least potentially.

##### *IV.C.ii. Increased Scrutiny*

Increased scrutiny through functional neurological testing could ensure public safety and allow for less impact on pilots themselves, since far less pilots would ultimately be denied. This would lead to fewer pilots personally losing the time and money it took to become a pilot and the future pay they would earn working as pilots. Further, increased scrutiny would have the dual effect of ensuring that a pilot actually is functionally impaired while ensuring that pilots who are functionally impaired are not flying.

<sup>171</sup> Maria Biasutti, et al., *Cost-Effectiveness of Magnetic Resonance Imaging with a New Contrast Agent for the Early Diagnosis of Alzheimer's Disease*, 7(4) PLoS One e35559 (2012) available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3332046/pdf/pone.0035559.pdf> (last accessed July 3, 2019).

<sup>172</sup> United States Government Accountability Office, *Aviation Workforce: Current and Future Availability of Airline Pilots* 5 (Fed. 2014) available at <https://www.gao.gov/assets/670/661243.pdf> (last accessed July 3, 2019).

<sup>173</sup> *Id.* at Title, 'What GAO Found'.

<sup>174</sup> *Id.* at 11



By implementing an in-depth heightened scrutiny process, only the pilots who display functional symptoms would be denied certification, so there would be far less risk of an otherwise healthy pilot losing their right to fly.

#### IV. D. Recommendation

As described above, using biomarkers to disqualify pilots outright would be an arbitrary rule that would deny medical certification to many pilots who are able to safely discharge their professional duties. However, AD biomarkers could still provide value to the certification procedures. AD biomarkers would best serve the mission of purpose of the medical certification procedures by acting as a trigger for increasing scrutiny of pilots with a positive AD biomarker status. Under this proposed approach, if a pilot has positive AD biomarker test results, they would be required to undergo additional exams at an increased frequency.

Similar to the increased scrutiny implemented for pilots with HIV, the additional exams would be tailored to symptoms and disease progression markers in AD. Specifically, the FAA should require biomarker positive pilots to complete neuropsychological tests and neurocognitive exams tailored to identify functional impairments and structural imaging to identify atrophy that may indicate neurodegeneration. These exams would identify symptoms and disease progression associated with AD that would likely be undetected in the current FAA medical exam. Most importantly, neuropsychological batteries would be critical to reveal verbal, executive function, memory, and visuospatial deficiencies<sup>175</sup> in pilots that are key to ensuring the FAA's public safety mandate while ensuring the privacy, bodily, and economic integrity of the pilots.

There are several practical issues in implementing such a policy. Pilots could potentially face increased insurance costs and would have to spend time going through the initial and increased testing procedures. Given the specialized nature of AD biomarker testing, neuropsychological, and AD-specific cognitive-functional testing, the FAA would need to enlist new certifying examiners or mandate training for the existing examiners. The identification, training, and compensation of specialists could be quite a cumbersome and costly process.

Finally, further consideration should be given to implementing biomarker testing to incorporate AD biomarker status in the medical certification procedures. For pilots who learn their status through clinical encounters, increasing scrutiny through neurological exams and monitoring would accomplish the goals of the medical certification procedures. Currently, the status of science regarding AD biomarker status does not justify empowering medical examiners to order or triggering the FAA to require biomarker testing among pilots who do not already know their status. This question (whether to require testing) will require careful reconsideration as research advances regarding AD biomarker status. This is particularly true if future research supports capabilities to provide a prognosis for symptom onset and progression.

#### V. CONCLUSION

This article describes 'FAA' medical procedures and legal standards for screening pilots to protect public safety and analyzes how AD ('AD') biomarkers could be

<sup>175</sup> Robert Chapman, et al., *Diagnosis of Alzheimer's Disease Using Neuropsychological Testing Improved by Multivariate Analysis*, 32(8) J CLIN EXP NEUROPSYCHOL 793 (2010).

incorporated into the procedures and standards. We first conclude that AD biomarkers could be used by the FAA as a mandatory denial criterion, because the biomarkers indicate increased risk for neurological dysfunction. After studying HIV status, age, and genetics to provide a background on other conditions already treated by the FAA and weighing the interests of individual pilots against public safety concerns, we further conclude that when AD biomarker status is known, it should trigger heightened scrutiny of first-class airline transit pilots but that requiring testing for biomarkers is not justified at this time.

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