

January 24, 2023

VIA EMAIL AND FEDERAL EXPRESS

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*Re: Change in ECG PR Interval in FAA 2022 Guide for Aviation Medical Examiners
Violates Code of Federal Regulations*

Dear Mr. Nolen, Mr. Fields, and Mr. Boutler:

We write on behalf of Informed Consent Action Network (“ICAN”) regarding the recent change in the Federal Aviation Administration’s (“FAA”) Guide for Aviation Medical Examiners which substantially broadened the electrocardiogram (“ECG”) requirements to encompass much higher PR intervals. This higher PR interval, which was previously deemed noncompliant by the FAA, increases the risk of a pilot having a medical emergency during flight. If no adequate reasoning is provided for this change, we have been instructed to bring suit under the Administrative Procedures Act (“APA”).

Pursuant to FAA regulations, “A person applying for first-class medical certification must demonstrate an absence of myocardial infarction and other clinically significant abnormality on electrocardiographic examination.” 14 CFR § 67.111(b). Until recently, the FAA’s Guide for Aviation Medical Examiners interpreted this as requiring “normal” ECG parameters with PR interval less than 0.21 seconds in airmen under 51 years of age.¹ This ECG standard was in place

¹ Normal Variants, FAA (Nov. 30, 2016), https://web.archive.org/web/20220309003311/http://www.faa.gov/about/office_org/headquarters_offices/avs/offices/aam/ame/guide/media/Normal_Variants.pdf.

since at least 2014,² until the FAA quietly updated the definition of normal to include PR intervals less than 0.3 seconds.³ Why was this change made?

The ramifications of this change cannot be understated. In short, the PR interval concerns electrical transmission in the heart. A PR interval greater than 0.2 seconds has generally been established to indicate “first degree heart block,” which means there is a delay in the electrical transmission in the heart.⁴ There are significant clinical impacts associated with higher PR intervals. For example, a 2022 large Brazilian study of over 1.5 million participants showed that people with a PR interval of more than 0.2 seconds had a 24% lower survival rate than the control group.⁵ Crucially, once the PR interval increases above 0.2 seconds, silent heart irregularities are much more likely to eventually manifest clinically.

The FAA’s May 2022 Guide for Aviation Medical Examiners acknowledges the grave public safety risk when medical examinations are not done properly:

The consequences of a negligent or wrongful certification, which would permit an unqualified person to take the controls of an aircraft, **can be serious for the public, for the Government, and for the AME.** If the examination is cursory and the AME 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 AME may bear the responsibility for the results of such action.⁶

The FAA’s sudden change in long-standing standards for ECGs does just that: it poses a safety hazard to the general public. The FAA has provided no justification for its unilateral decision to medically certify pilots with PR intervals that were previously universally accepted as abnormal and indicative of a first degree heart blockage. The public deserves an explanation from an agency that claims to be responsible for “providing the **safest**, most efficient aerospace system in the world.”⁷

In the absence of adequate explanation from the FAA, we have been instructed to pursue legal action against you pursuant to the APA, 5 USC §706(2)(E), on account of this arbitrary and

² James R. Fraser, MD, MPH, *From the Federal Air Surgeon’s Perspective: Anchors Aweigh*, 52 Fed. Air Surgeon’s Med. Bulletin 2, at 4 (2014), https://www.faa.gov/other_visit/aviation_industry/designees_delegations/designee_types/ame/fasmb/media/201402.pdf.

³ Normal Variants, FAA (Oct. 26, 2022), https://web.archive.org/web/20221031131522/http://www.faa.gov/about/office_org/headquarters_offices/avs/offices/aam/ame/guide/media/Normal_Variants.pdf.

⁴ Mike Cadogan, MA, MBChB, FACEM, FFSEM, *PR Interval*, Life in the Fastlane (Feb. 4, 2021), <https://litfl.com/pr-interval-ecg-library/>.

⁵ Gabriela Miana de Mattos Paixão, *et al.*, *Association between Atrioventricular Block and Mortality in Primary Care Patients: The CODE Study*, ABC Cardiol (2022), <https://abccardiol.org/article/associacao-entre-bloqueio-atrivoentricular-e-mortalidade-em-pacientes-de-atencao-primaria-o-estudo-code/>.

⁶ Guide For Aviation Medical Examiners (May 25, 2022), https://www.faa.gov/about/office_org/headquarters_offices/avs/offices/aam/ame/guide/media/guide.pdf (emphasis added).

⁷ FAA, <https://www.faa.gov/> (last visited Jan. 24, 2023) (emphasis added).

capricious action. Based on the regulations, a person must demonstrate an absence of “clinically significant abnormality on electrocardiographic examination,” but the FAA’s latest update violates that provision by allowing pilots with clinically relevant cardiac issues to be medically cleared.

All rights are reserved. Govern yourself accordingly.

Very truly yours,

A handwritten signature in blue ink, appearing to be 'AS', is written over the typed names.

Aaron Siri, Esq.

Elizabeth A. Brehm, Esq.

Thomas Stavola, Esq.