



April 3, 2019

Mr. Ali Bahrami
Associate Administrator for Aviation Safety
Federal Aviation Administration
800 Independence Avenue., S.W.
Washington, DC 20591

**RE: FAA Toxicology Testing of Anonymous Urine Specimens from Pilot Medical Exams
NTSB Safety Recommendation A-14-95**

Dear Associate Administrator Bahrami,

On behalf of the Aircraft Owners and Pilots Association (AOPA), Allied Pilots Association (APA), Coalition of Airline Pilots Associations (CAPA), Experimental Aircraft Association (EAA), Helicopter Association International (HAI), National Air Transportation Association (NATA), National Business Aviation Association (NBAA), NetJets Association of Shared Aircraft Pilots (NJASAP), and Southwest Airlines Pilots Association (SWAPA) we write to object, in the strongest terms, to the FAA's proposal to proceed with the above-referenced urine testing study.

It is our recommendation that the study be immediately shelved and the FAA and the NTSB work with industry stakeholders on mitigations focused on prevention through outreach, communication, and education.

Furthermore, we will also call on the NTSB to rescind its impractical safety recommendation A-14-95, which this study is attempting to respond to and could result in misguided and ineffective mitigations.

Our organizations' members comprise the vast majority of pilots certificated by the FAA who regularly undergo medical examinations. They are the subjects whose urine will be taken and analyzed without their knowledge or informed consent, and whose FAA medical examinations will be directly impacted by this proposed study.

Collectively, we strongly contend that the study: (1) is fundamentally flawed and will not accomplish its stated goals; (2) does not comply with applicable legal requirements; (3) represents a waste of valuable time, money, and limited resources; and (4) will further erode trust between the pilot community and the Office of Aerospace Medicine.

BACKGROUND

On February 27, 2018, staff from the FAA Civil Aerospace Medical Institute (CAMI) presented an overview of the proposed study and detailed its purpose, regulatory authority, protocol, and research team members to AOPA. At the conclusion of that meeting, CAMI doctors indicated that their next steps were to collect additional input from other industry stakeholders in the following months. No others received such a detailed briefing.

Additionally, there was a request to have a final meeting with the FAA and all industry stakeholders, but was rejected, simply noting that "Dr. Berry has given me the 'go' for the project."

It is our collective recommendation that the study not proceed due to the following significant concerns and reasons.

STUDY IS FLAWED AND WILL NOT ACCOMPLISH ITS GOALS

First, it bears highlighting that the NTSB study did not require nor request urine testing of flying pilots. To the contrary, in its study design the NTSB explicitly rejected the use of urine specimens to identify drugs because the presence of drugs (or drug metabolites) in urine shows prior drug use – not present drug use, or current impairment or effect on the body. Thus, a positive urine test for a drug would merely mean that the pilot took a drug a day, several days, or even weeks before the urine collection – not at the time he or she intends to operate an aircraft. That determination is irrelevant to the assessment of whether a pilot is actively flying with a potentially impairing drug in his bloodstream or body.

For that reason, the NTSB used only toxicology results from pilots' blood and tissue specimens and specifically excluded drugs found only in urine. The FAA's flawed study methodology would fail to accurately report drugs present in flying pilots who are still living. Nor can it accurately identify "safety risks of using drugs while flying" as requested by the NTSB Recommendation.

Moreover, proposing to compare data from urine drug tests with data from blood and tissue specimen tests (with urine results excluded), will not yield scientifically meaningful results. The two categories of data are identifying drugs imbibed by two different pilot populations, at two different time frames in relation to pilot flying. Because the urine test results cannot definitively show drug use, or impairment while flying, such data would not be a valid basis of analysis with the NTSB toxicology data. To propose such, is a significant design flaw in the FAA proposed study.

Furthermore, with the stated purpose of the study to assess the prevalence of medications and drug use among flying pilots, it is important to note that a pilot who is being examined for his or her first, second, or third-class medical often has no intention of that day, or possibly that week of operating an aircraft. Most often they are simply renewing their medical when it fits best into their schedule and before their current certificate expires. Medical exams are usually scheduled on days pilots are not flying and thus may be taking cold (e.g. diphenhydramine), allergy or other medication they would not consume when flying an aircraft. Moreover, pilots undergo FAA medical examinations to maintain medical certificate currency but may refrain from flying during times of surgical recuperation, or short-term incapacitation. For example, consider a pilot currently taking a medication who "self-grounds" in accordance with 14 CFR 61.53, Prohibition on operations during medical deficiency. At the same time, the pilot may undergo a medical examination and appropriately disclose all medication currently being taken. Although this pilot does not intend to fly while taking the medication, if he or she is drug tested on the date of his medical exam, the results would erroneously be reported as that of an actively flying pilot, resulting in flawed and inaccurate conclusions.

By making the pilot aware of the study the FAA would allow pilots who are taking a medication, experiencing a short-term illness, and/or recovering from a surgery to simply opt-out and ultimately not incorrectly distort the results.

VIOLATES APPLICABLE LEGAL REQUIREMENTS

The collection of the pilot's identifying information risks violating federal regulations concerning research involving human subjects. Specifically, the identity of the sampled pilot could be linked, directly or indirectly, to a specific specimen. The FAA cited 45 CFR 46.101(b)(4) as the authority for this study, which stated:

(4) Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. 46 CFR 46.101(b)(4).

Under certain circumstances, it is possible that the identity of selected pilots could be determined from the identifying data provided with the airman's specimen. Even though the FAA removed the geographic

location from the initial urine cup label, the CAMI lab and personnel will be able to identify not only the region the cup came from but also the AME office – further eroding the privacy protections of the study.

That risk of loss of anonymity would remove the study from the parameters of Section 46.101(b)(4) and remove the authority for conducting the study in the manner presently proposed. Viewing this protocol in conjunction with the NTSB's study recommendation makes clear that collection of the identifying data is unnecessary and may be legally and ethically improper.

The study further contains an additional legal infirmity. The proposed study directs AMEs to collect specific information pertaining to pilot-subjects and provide that information on collection labels. The study fails to address whether this information collection has been evaluated to determine whether it constitutes a "collection of information" under 5 CFR 1320.3(c) that requires an Office of Management and Budget clearance.

When combined with the NTSB's recommendation to simply compare specimens from living versus deceased pilots, we maintain that collection of the identifying data is both unnecessary and improper.

MORE EFFECTIVE WAYS TO FOCUS LIMITED RESOURCES

In the NTSB safety study, in addition to recommendation A-14-95, recommendation A-14-92 called for the FAA to:

Develop, publicize, and periodically update information to educate pilots about the potentially impairing drugs identified in your toxicology test results of fatally injured pilots, and make pilots aware of less impairing alternative drugs if they are available.

We contend that the FAA should focus its limited time and resources on acting on this widely supported recommendation – one that would potentially prevent the same pilot community from taking any impairing medication in the first place – rather than spend considerable time and money on deceptively and unknowingly testing 7,500 pilot urine samples, only to then publish a report with potentially flawed and misleading results.

We all share the belief that pilots should be warned of the risks associated with impairing medications and drugs. Many of our educational material, media, videos and magazines highlight aeromedical issues and mitigations for our members – including lists of medications that we understand to be allowed/disallowed by the FAA.

Conversely, the Office of Aerospace Medicine has consistently resisted publicizing an official FAA list of medications – even though it is common knowledge that one exists that is regularly consulted and utilized by agency personnel. Since a pilot cannot consult the list beforehand, the FAA only reveals the acceptability of a medication after a pilot reports that the medication is currently being taken – leading to both confusion and distrust.

The FAA/Industry General Aviation Joint Steering Committee (GAJSC), through its data-driven accident analysis, implemented Safety Enhancement 30 (SE-30), which calls for the FAA to develop a comprehensive and robust list of medications and publish it online for the pilot community, but Aerospace Medicine has steadfastly resisted its implementation. Other than a short list of medications, located in its Guide for Aviation Medical Examiners, the FAA simply does not inform pilots of medications that are and are not safe to take. We recommend that, rather than wasting valuable time and resources, the FAA implement the GAJSC SE-30 to finally, and most effectively, inform pilots about medications that could risk their safety.

It should also be noted that the Federal Air Surgeon's own medical bulletin, a useful and widely circulated quarterly outreach to AMEs and others interested in aviation safety, has not been issued since 2016, under the previous Federal Air Surgeon's tenure. That communication, if renewed, could also serve as a valuable outreach and education on potentially impairing drugs and alternatives.

We believe there are more effective means to prevent a pilot, regardless of medical class or operation, from taking any substance that could jeopardize safety. We all stand ready and willing to partner with the FAA in that effort.

FURTHER ERODE THE TRUST BETWEEN PILOTS AND AEROSPACE MEDICINE

The FAA's involuntary taking of pilots' urine, without their knowledge or informed consent – even if later partially de-identified – risks serious erosion of trust between pilots and the FAA's Office of Aerospace Medicine and its designated AMEs. Pilots understand and submit to medical examinations for the purpose of evaluating their health – both physical and mental. Pilots have developed longstanding, trusting relationships with these doctors, and are expected to be candid and forthcoming to enable the AMEs to thoroughly and accurately assess pilots' medical fitness. Pilots submit to examinations, provide urine and other bodily fluids to have their health and medical fitness assessed. To introduce to this medical process, the compulsory taking and use of pilots' bodily fluids for other governmental purposes to which the pilot did not agree, will totally undermine the AME-pilot relationship. It will introduce pilot suspicion and plant and foster distrust. The cost of diminishing these relationships is great, and the negative implications significant. At a time when the FAA is seeking to foster pilot disclosure and trust, the approach proposed by this study undermines that goal.

Due to the foregoing concerns, we urge the FAA to abandon this urine study. As we have outlined above, we believe the study does not comply with legal requirements, represents a waste of government funds and resources, and will further erode any trust left between the pilot community and the Office of Aerospace Medicine.

Again, it is our strong belief that outreach, communication, and education are areas where the FAA should focus its resources.

We appreciate your consideration and positive response to our concerns and believe by working together on a path that focuses our collective resources, we can achieve improvements to aviation safety.

Sincerely,

Aircraft Owners and Pilots Association
Allied Pilots Association
Coalition of Airline Pilots Associations
Experimental Aircraft Association
Helicopter Association International

National Air Transportation Association
National Business Aviation Association
NetJets Association of Shared Aircraft Pilots
Southwest Airline Pilots Association

Cc: Honorable Robert L. Sumwalt
Michael A. Berry, M.D., M.S.
Philip Kemp, Ph.D., F-ABFT

