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FEDERAL AIR SURGEON, FRED TILTON, M.D., PUBLISHES THE FAA'S NEW OBSTRUCTIVE SLEEP APNEA POLICY

I.

The Tilton Memorandum

The Federal Air Surgeon periodically publishes a Medical Bulletin distributed to Aviation Medical Examiners (AMEs). In Volume 51, Number 4 of that Bulletin, Federal Air Surgeon Fred Tilton, M.D. published his article entitled "New Sleep Apnea Policy." As part of this policy announced in the Bulletin, AMEs will now be required to calculate the body mass index (BMI) of pilots and controllers. Pilots and controllers with a BMI of 40 or above will not meet the requirements of 14 CFR Part 67 and will have to qualify under a "special issuance" — a process involving more paperwork. The FAA is already backlogged with 55,000 special issuance applications. Accordingly, this new "policy" will only exacerbate the FAA's workload. Additionally, in order to qualify for a special issuance, the airman/controller will have to undergo testing for obstructive sleep apnea (OSA). In announcing this new policy, Dr. Tilton did not follow the notice and public comment requirements of the Administrative Procedures Act (APA). This may put the FAA's new policy on OSA in peril of being challenged in court for failure to comply with the APA requirements.

In the Bulletin, Dr. Tilton wrote:

OSA (Obstructive Sleep Apnea) inhibits restorative sleep, and has significant safety implications, because it can cause excessive daytime sleepiness, cognitive impairment, cardiac dysrhythmias, sudden cardiac death, personality disturbances, and hypertension, to cite just a few.

However, Dr. Tilton did not cite one aircraft accident where obstructive sleep apnea was the cause.

FAA Spokesperson Laura Brown said in a statement:

The updated sleep apnea guidelines that we plan to implement are designed to help airmen and aviation safety by improving the diagnosis of unrecognized and untreated obstructive sleep apnea.

The FAA's new policy has certainly caught the interest of the news media which has carried stories of this new directive on ABC News, CNN, and Fox News, to name a few. The FAA's new policy, if implemented, would require sleep apnea testing for 124,973 airmen identified as obese by the FAA in 2011, and could cost airmen as much as \$374,000,000.00. It is strange irony that one government agency (the FAA) would be mandating the performance of medical tests and procedures to be paid for by airmen/controllers at a time when another government agency (Health and Human Services) has promulgated Affordable Care Act regulations in the Federal Register which have had the effect of terminating health insurance coverage for over five million self-insured Americans. Moreover, by the fall of 2014, another 50,000,000 to 100,000,000 Americans will forfeit their existing health insurance coverage thanks to the Affordable Care Act and regulations published by HHS in the Federal Register. As a result of this new FAA policy, airmen/controllers may find themselves in the position of having to pay for costly medical procedures not covered by

health insurance, because the government has intentionally coerced airmen/controllers into uninsured status where affordable health insurance coverage may not be available to pay for these FAA-mandated medical tests and procedures. Presumably, airmen/controllers who cannot absorb these medical expenses will simply lose their certificates, their jobs, or both. To declare the FAA's political timing is awkward is a gross understatement.

Pushback by the Aviation Community

In a joint letter by Jack Pelton, Chairman of the Experimental Aviation Association (EAA) and Dr. Stephen Leonard, Chairman of the EAA Air Medical Advisory Council, dated November 20, 2013, they noted:

The FAA charge is to protect the flying public, not to practice preventive medicine or to further public health policy. While severe sleep apnea is clearly associated with an increased risk of sudden cardiac death, that increased risk primarily results from fatal arrhythmias during sleep. It is not during waking hours where the individual might be at the controls of an aircraft. There have undoubtedly been incidents of pilots, with or without sleep apnea, falling asleep at the controls; however, we are unaware of any studies where sleep apnea was identified as a primary cause of an aircraft accident. Sleep deprivation, prolonged duty times, and diurnal cycle disruption are likelier culprits in these instances — far more than sleep apnea.

This new sleep apnea policy also represents a sharp break with the FAA's historic approach to evaluating airmen health. Invasive and expensive testing has only been required if personal medical history, physical or laboratory evidence suggest a condition that might lead to in-flight incapacitation. Accident history has shown that coronary artery disease and diabetes are certainly at least as dangerous as sleep apnea. However, not every smoker with elevated cholesterol is required to have a nuclear stress test, and not every overweight airman with a sweet tooth is sent for a six hour IV glucose tolerance test. This new policy would subject every airman who might be at risk of having sleep apnea, even in the complete absence of clinical evidence, to a minimum of \$3,500.00 worth of testing and evaluation.

This is simply wrong. Using this logic, there is any number of expensive, invasive tests that could be ordered from a purely preventive medicine standpoint, ranging from prosthetic ultrasounds, colonoscopy and pap smears, to mammograms, CBCs, chemistry panels, stress ECGs or even nuclear tests. It is not the government's role to mandate them, at an airman's expense to possibly detect something an airman might have.

In a letter of the same date, Aircraft Owners and Pilots Association (AOPA) President, Mark Baker, insisted that the FAA withdraw its new sleep apnea policy and go through the traditional rulemaking process of the Administrative Procedures Act (APA), Baker noting:

We believe this policy inappropriately bypasses the rulemaking process; overlooks potentially more effective and efficient solutions; provides not clear safety benefits; and imposes unjustified costs on the user community.

III.

What Is Likely to Happen?

In October of this year, the Department of Transportation attempted to require sleep apnea testing for commercial truck drivers. In response, Congress enacted legislation requiring the Federal Motor Carrier's Safety Administration to go through the formal rulemaking process before requiring such testing. If the action of Congress dealing with overweight truck drivers is any indication of what is to be expected in relation to the FAA's new sleep apnea policy, one can anticipate a similar outcome.

The FAA is charged with ensuring air safety. However, it is not charged with venturing into the realm of predictive medicine in the absence of threats to safety or medical symptoms that endanger air safety. If enough pilots contact their congressmen, Dr. Tilton and the FAA will likely be forced to pursue rulemaking in the Federal Register in accordance with the Administrative Procedures Act and make out their case in the arena of public opinion where those affected by such expansive initiatives can voice their concerns and opposition to this new "safety" policy.

Conclusion

As we ponder the wisdom of the FAA's new sleep apnea policy, the following concerns should be the subject of public debate:

1. Sleep Apnea does not present a direct threat to air safety. Accordingly, there is arguably no rational basis for informally rewriting Part 67 of the Federal Aviation Regulations in the form of some of uncodified policy published in the Federal Air Surgeon's Medical Bulletin. A legal challenge could be mounted to this new sleep apnea policy arguing it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 USC §706(2)(A).

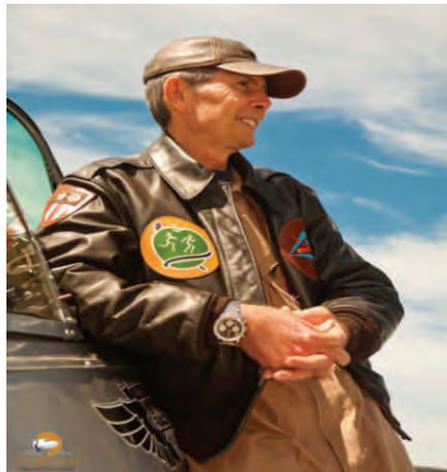
2. Assuming *arguendo* the new sleep apnea policy has a rational basis, it is still subject to challenge on the theory it is "contrary to constitutional right, power, privilege or immunity" under 5 USC §706(2)(B), because the FAA did not promulgate the new policy in the Federal Register as an amendment to Part 67 of the Federal Aviation Regulations and give affected stakeholders an opportunity to comment on the wisdom of this new safety initiative.

3. The FAA currently being backlogged with 55,000 existing special issuance cases, this new uncodified policy will exacerbate the FAA's inability to timely process these new special issuance (sleep apnea) applications.

4. The FAA's new sleep apnea policy is announced at a terrible time politically with the Affordable Care Act stripping five million Americans of existing health care insurance coverage to date and with between 50,000,000 and 100,000,000 Americans scheduled to lose their existing healthcare insurance coverage by the fall of 2014.

It has been said that legislators and technocrats in Washington, DC live in a bubble separated from the realities ordinary men and women experience. The promulgation of this new sleep apnea policy at this time and in these circumstances underscores the reality of that statement.

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