

No. 19-1148

**UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT**

**In re: Mitchel Mitchell,
Petitioner.**

**RESPONDENT'S OPPOSITION TO
PETITION FOR WRIT OF MANDAMUS**

**JOSEPH H. HUNT
Assistant Attorney General**

**MICHAEL S. RAAB
ABBY C. WRIGHT
(202) 514-0664
Civil Division, Appellate Staff
U.S. Department of Justice
950 Pennsylvania Ave., N.W.,
Rm. 7252
Washington, D.C. 20530**

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES**A. Parties And Amici**

Petitioner is Mitchell Mitchell. Respondent is the Federal Aviation Administration. The American Diabetes Association is *amicus curiae*.

B. Ruling Under Review

Because petitioner seeks to compel agency action, there is no district court or administrative ruling under review.

C. Related Cases

This case was not previously before this Court or any court. Counsel is aware of no related cases currently pending in this Court or in any other court within the meaning of Cir. R. 28(a)(1).

s/ Abby C. Wright
Abby C. Wright
Counsel for Respondent

TABLE OF CONTENTS

	<u>Page</u>
GLOSSARY	
INTRODUCTION	1
BACKGROUND	2
ARGUMENT:	
PETITIONER HAS NOT DEMONSTRATED ENTITLEMENT TO THE EXTRAORDINARY WRIT OF MANDAMUS.....	9
CONCLUSION	18
CERTIFICATE OF COMPLIANCE	
CERTIFICATE OF SERVICE	
ADDENDUM	

TABLE OF AUTHORITIES

Cases:	<u>Page(s)</u>
<i>Aiken County, In re</i> , 645 F.3d 428 (D.C. Cir. 2011)	9
<i>American Hosp. Ass’n v. Price</i> , 867 F.3d 160 (D.C. Cir. 2017)	1
<i>American Rivers & Idaho Rivers United, In re</i> , 372 F.3d 413 (D.C. Cir. 2004)	13
<i>Friedman v. FAA</i> , 841 F.3d 537 (D.C. Cir. 2016)	14, 16
890 F.3d 1092 (D.C. Cir. 2018)	14-15
<i>Norton v. Southern Utah Wilderness All.</i> , 542 U.S. 55 (2004)	9
<i>Telecommunications Research & Action Ctr. v. FCC</i> , 750 F.2d 70 (D.C. Cir. 1984)	1, 9, 10, 13
Statutes:	
49 U.S.C. § 44701(a)(5)	2
49 U.S.C. § 44701(c)	5
49 U.S.C. § 44701(d)(1)	5
49 U.S.C. § 44703(a)	2, 14
Regulations:	
14 C.F.R. § 61.3(c) (2016)	3

14 C.F.R. § 61.23	3
14 C.F.R. § 61.23(a) (2016)	3
14 C.F.R. § 61.23(a)(1)	3
14 C.F.R. § 61.23(a)(2).....	3
14 C.F.R. § 61.23(a)(3).....	3
14 C.F.R. pt. 67.....	3
14 C.F.R. § 67.3.....	3
14 C.F.R. § 67.113(a)	1, 5
14 C.F.R. § 67.213(a).....	5
14 C.F.R. § 67.313(a).....	5
14 C.F.R. § 67.401.....	6
14 C.F.R. § 67.401(a)	4
14 C.F.R. § 67.401(d)	4
14 C.F.R. pt. 67, subpts. B, C, D (2016).....	3

Other Authorities:

24 Fed. Reg. 7309 (Sept. 11, 1959)	6
47 Fed. Reg. 16298 (Apr. 15, 1982)	4, 5
61 Fed. Reg. 59282 (Nov. 21, 1996).....	5, 6, 7

GLOSSARY

Federal Aviation Administration

FAA

*Telecommunications Research and Action
Center v. F.C.C.*, 750 F.2d 70 (D.C. Cir. 1984)

TRAC

INTRODUCTION

Petitioner Mitchell Mitchell, a pilot with insulin-treated diabetes, asks this Court to compel the Federal Aviation Administration (FAA) to act on his request for a special issuance first-class medical certificate. By regulation, an individual with an “established medical history or clinical diagnosis of diabetes mellitus that requires insulin or any other hypoglycemic drug for control” is not qualified for a first-class medical certificate. 14 C.F.R. § 67.113(a). Petitioner seeks an exemption from this requirement and the grant of a special issuance medical certificate.

The petition should be denied. Mandamus is “an extraordinary remedy, reserved only for the most transparent violations of a clear duty to act.” *American Hosp. Ass’n v. Price*, 867 F.3d 160, 165 (D.C. Cir. 2017).

Petitioner acknowledges that, under existing regulations, he is not qualified for a first-class medical certificate permitting him to fly for a commercial airline. And there is no statutory or regulatory requirement that FAA issue a decision on an exemption request in any particular timeframe.

FAA’s actions plainly satisfy the “rule of reason” this Court applies in considering petitions alleging unlawful agency delay. *Telecommunications Research & Action Ctr. v. FCC*, 750 F.2d 70, 79-80 (D.C. Cir. 1984). As

explained below, and in the accompanying declaration, FAA has completed and will soon publish a protocol that—consistent with the best medical data available and the agency’s air safety mission—provides for uniform treatment of pilots with insulin-treated diabetes who seek special issuance first-class medical certificates. FAA’s decision to await publication of that protocol before acting on petitioner’s request is reasonable and furthers the significant public interest in the safety of commercial air travelers.

If this Court nonetheless has concerns regarding the timeline of FAA’s issuance of the protocol and its actions with respect to petitioner’s request for a special issuance medical certificate, FAA does not object to this Court maintaining jurisdiction over this matter until FAA has published its protocol and acted on petitioner’s request.

BACKGROUND

A. FAA has broad authority to prescribe regulations and standards governing the “practices, methods, and procedures the Administrator finds necessary for safety in air commerce and national security.” 49 U.S.C. § 44701(a)(5). Consistent with this authority, FAA issues airman certificates to pilots who are “qualified for, and physically able to perform the duties related to [their] position.” *Id.* § 44703(a). In order to ensure that pilots are

physically able to safely perform their duties, FAA's regulations require a pilot (at least as to larger aircraft) to hold a medical certificate, in addition to a pilot certificate, in order to be authorized to fly. 14 C.F.R. § 61.3(c) (2016); *see also* 14 C.F.R. § 61.23(a) (2016).

The FAA issues three different classes of medical certificates; the class of medical certificate required depends on the type of pilot certificate the pilot holds and the privileges that the pilot wishes to exercise. *See* 14 C.F.R. § 61.23. *See generally* 14 C.F.R. part 67 subpts. B, C, D (2016). As relevant here, a pilot must hold a first-class medical certificate in order to fly for an airline. 14 C.F.R. § 61.23(a)(1). Second- and third-class medical certificates are needed for commercial and private pilot certificates, respectively. §§ 61.23(a)(2), (3).

FAA regulations found in 14 C.F.R. pt. 67 dictate the standards that an individual must meet in order to be medically qualified to perform pilot duties. *See* 14 C.F.R. § 67.3. When a pilot does not meet the part 67 medical standards for an unrestricted medical certificate, the Federal Air Surgeon may, in his discretion, grant a special issuance medical certificate if “the person shows to the satisfaction of the Federal Air Surgeon that the duties authorized by the class of medical certificate applied for can be performed

without endangering public safety during the period in which the Authorization would be in force.” 14 C.F.R. § 67.401(a).

In contrast to an unrestricted medical certificate, a special issuance medical certificate can contain conditions and limitations on its use. The FAA may limit the duration of the certificate; impose any operational limitation needed for safety; impose functional limitations on certain classes of certificates; or condition the granting of a new certificate on the results of subsequent medical tests, examinations, or evaluations. *Id.* § 67.401(d). The Federal Air Surgeon may also authorize a special medical flight test, practical test, or other medical evaluation for the purpose of establishing an individual’s eligibility for a special issuance. *Id.* § 67.401(a).

In deciding whether to grant a special issuance medical certificate, the Federal Air Surgeon must balance the needs of the individual applicant against the risks to public safety. Applicants for special issuance first-class medical certificates are reviewed with intense scrutiny, given the greater risk to the flying public. As the FAA has explained “a commercial or airline transport pilot, in virtually every circumstance, has the life or property of another individual in his or her care.” 47 Fed. Reg. 16298, 16301 (Apr. 15, 1982). “For this reason, if there is a reasonable risk that such a pilot may

experience an incapacitating medical event, even though that risk may be relatively small, the Federal Air Surgeon must consider the degree of protection to which the public is entitled in commercial operations.” *Id.* The heightened standard for issuance of a first-class medical certificate is consistent with FAA’s statutory responsibility to consider, among other things, “the duty of an air carrier to provide service with the highest possible degree of safety in the public interest.” 49 U.S.C. § 44701(d)(1); *see also* 49 U.S.C. § 44701(c) (mandating the FAA carry out its responsibilities “in a way that best tends to reduce or eliminate the possibility or recurrence of accidents in air transportation”).

B. Individuals with insulin-treated diabetes do not meet the FAA’s part 67 medical standards. *See* 14 C.F.R. §§ 67.113(a), 67.213(a), 67.313(a). The main rationale for disqualification is the risk of hypoglycemia; every person with diabetes is at some risk for hypoglycemia, which can produce impaired cognitive function, seizures, unconsciousness, and death. 61 Fed. Reg. 59282, 59282-83 (Nov. 21, 1996); 47 Fed. Reg. at 16302 (Apr. 15, 1982) (explaining the “significant risk of impairment of [a pilot’s] faculties from an undetected drop in the level of blood sugar”).

The part 67 regulations disqualifying airmen from unrestricted certification on the basis of insulin-treated diabetes have been in effect since 1959, when the FAA first explained that “the likelihood of occurrence of partially or totally incapacitating states directly attributable to [diabetes] is so great, and the ability to provide acceptable medical assurance of non-occurrence of such states in any given individual is so inadequate, that these conditions existing in airmen constitute a definite hazard to safety in flight.” 24 Fed. Reg. 7309, 7309 (Sept. 11, 1959).

In the intervening years since FAA adopted this regulation, there have been advances in the treatment and understanding of diabetes as a disease, and FAA’s practices for certifying pilots with diabetes have evolved accordingly. Although individuals with insulin-treated diabetes remain expressly disqualified from unrestricted medical certification, since 1996, pilots with insulin-treated diabetes have been eligible for an exemption from the third-class medical standards using the special issuance certification process in 14 C.F.R. § 67.401. *See* 61 Fed. Reg. 59282.

In order to grant special issuance third-class medical certificates to individuals with insulin-treated diabetes, FAA developed a protocol to govern when such certificates should be granted. This protocol, published as

a policy statement in the Federal Register, explains the criteria the Federal Air Surgeon uses to evaluate the eligibility of a given individual for a special issuance certificate. *See* 61 Fed. Reg. 59282. Among other things, the protocol includes minimum threshold requirements for recurrent hypoglycemic episodes and requires the submission of specific medical records. *Id.* at 59283. Once an individual satisfies the protocol's minimum eligibility criteria, he or she will then be subject to a case-specific, individualized assessment of his or her fitness for medical certification. *See id.* (explaining that an individual seeking a special issuance certificate must submit the specified medical records "in order to provide an adequate basis for an individual medical determination"). After being granted a special issuance certificate, the individual must also comply with any FAA-approved monitoring protocol and any other risk-mitigation measures required by the certificate. *Id.*

Based upon recent advances in continuous glucose monitoring technology, FAA has now completed a protocol governing the issuance of first- and second-class medical certificates to pilots with insulin-treated diabetes. *See* Declaration of Michael A. Berry, Federal Air Surgeon, at 4 (Addendum). The protocol was developed by FAA physicians in consultation

with board-certified endocrinologists outside the agency. *Id.* FAA intends to publish the protocol as a notice in the Federal Register once review has been completed. *Id.* at 4-5. “In the interest of fairness to all applicants,” FAA has chosen not to apply the protocol “until it has cleared departmental review and is published and effective.” *Id.* at 5.

C. Petitioner Mitchell Mitchell is a pilot with diabetes who has held a third-class medical certificate since 1993. In 2001, FAA became aware that petitioner has insulin-treated diabetes, and issued him a special issuance third-class medical certificate. In September 2015, petitioner requested that FAA also grant him a first-class medical certificate. Petitioner was thereafter in contact with FAA, and, at FAA’s request, submitted continuous glucose monitoring data. FAA has continued to issue petitioner special issuance third-class medical certificates on an annual basis, explaining that FAA is “presently not authorizing upgrades for first- or second-class certification for airmen with a history of diabetes mellitus requiring treatment with insulin. The Federal Air Surgeon is currently continuing to work on developing a potential protocol for certificating commercial airmen.” Add. 7.

ARGUMENT

PETITIONER HAS NOT DEMONSTRATED ENTITLEMENT TO THE EXTRAORDINARY WRIT OF MANDAMUS.

A.1. Petitioner has failed to meet the stringent requirements for the relief he seeks. Mandamus is “limited to enforcement of a specific, unequivocal command,” “the ordering of a precise, definite act . . . about which [an official] had no discretion whatever.” *Norton v. Southern Utah Wilderness All.*, 542 U.S. 55, 63 (2004) (quotation marks omitted; alterations in original). This Court has recognized that it cannot “interfere with the normal progression of agency proceedings” except as necessary “to correct *transparent violations of a clear duty to act.*” *In re Aiken County*, 645 F.3d 428, 436 (D.C. Cir. 2011). To determine whether it should exercise its power to grant the writ, this Court applies a six-factor standard drawn from *Telecommunications Research and Action Center v. F.C.C.*, 750 F.2d 70, 79-80 (D.C. Cir. 1984) (*TRAC*). These factors are:

- (1) the time agencies take to make decisions must be governed by a rule of reason;
- (2) where Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed in the enabling statute, that statutory scheme may supply content for this rule of reason;

(3) delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake;

(4) the court should consider the effect of expediting delayed action on agency activities of a higher or competing priority;

(5) the court should also take into account the nature and extent of the interests prejudiced by delay; and

(6) the court need not find any impropriety lurking behind agency lassitude in order to hold that agency action is unreasonably delayed.

TRAC, 750 F.2d at 79-80.

2. Consideration of the *TRAC* factors makes plain that petitioner is not entitled to mandamus. Petitioner has requested that the agency exempt him from a regulatory requirement and issue him a medical certificate that would allow him to become a pilot for a commercial airline and assume responsibility for the lives of hundreds of passengers. Because there are no statutory or regulatory requirements governing the timeline for responding to a request for a special issuance medical certificate, this case is governed by a “rule of reason.” *TRAC*, 750 F.2d at 79. And FAA’s decision to proceed as it has is entirely reasonable.

As explained, FAA has annually granted petitioner special issuance third-class medical certificates. In its decision letters, FAA has explained to

petitioner that until it has published a protocol for evaluating continuous glucose monitoring data it will not proceed with granting special issuance first-class medical certificates to pilots with insulin-treated diabetes.

It cannot reasonably be disputed that FAA may put in place a uniform, evidence-based protocol for evaluating requests for special issuance first-class medical certificates from pilots with insulin-treated diabetes before issuing those certificates. And, as the Federal Air Surgeon explains, “FAA has been proceeding with the development of the protocol cautiously, in order to ensure that we conduct an adequate risk assessment and consider the myriad factors facing pilots with [insulin-treated diabetes] in the cockpit.” Add. 2. The risks posed by inadequate diabetes management in the cockpit are real. As Dr. Berry describes, “a hypoglycemic event, which can result in impaired cognitive function, seizures, unconsciousness, and even death, that occurs in the cockpit of a commercial flight has the potential to place the safety of hundreds of individuals in jeopardy, [and] unrecognized hyperglycemic events can also insidiously impair performance and lead to subtle or sudden incapacitation.” Add. 3.

In the face of this significant risk to air passengers, FAA has quite reasonably proceeded in a deliberate manner, consulting medical experts

both inside and outside the agency, and studying the best available medical data. Developing the protocol has required the FAA “to develop *both* a method to identify low-risk pilots who have sufficient glycemic control *and* a method for ensuring those pilots can safely manage their diabetes while in the cockpit of a commercial flight.” Add. 3. As Dr. Berry explains, it is only with recent advances in treatment and monitoring that FAA has been able to consider what protocol might be appropriate “to meet the higher levels of safety demanded for applicants considered for airline transport or commercial pilot duties.” Add. 3. Decisions of this magnitude take time.

Because FAA has prioritized establishing a protocol, certain pilots, like petitioner, have not yet been granted special issuance first-class medical certificates even though they may have continuous glucose monitoring data available. That delay is no doubt frustrating to petitioner. As explained in Dr. Berry’s declaration, however, FAA has now completed the protocol, which will be published in the Federal Register and will take effect immediately upon publication. Add. 4. The Office of Information and Regulatory Affairs, within the Office of Management and Budget, reviewed the FAA designation and determined in late September that the protocol does not require further review. The protocol is now awaiting clearance by the Secretary of

Transportation. Add. 5. Although the timeline for final clearance is subject to some uncertainty, FAA anticipates that the protocol will be cleared for publication in the near future. *Id.*

B. Petitioner's arguments in support of his petition fail to demonstrate entitlement to the extraordinary remedy of mandamus.

Petitioner contends (Pet. 16) that he has a "clear and indisputable right to a timely decision," but he cites no statutory or regulatory requirement providing any such timeline. Instead, petitioner relies on general reasonableness standards found in the Administrative Procedure Act and this Court's precedent. Pet. 18. But, as explained above, the delay here is reasonable, and there has been no "breakdown of regulatory processes." *In re American Rivers & Idaho Rivers United*, 372 F.3d 413, 418 (D.C. Cir. 2004).

FAA is diligently engaged in the regulatory process that public safety requires. Rather than proceeding on an ad hoc case-by-case basis, FAA has properly developed a protocol to be published in the Federal Register that will govern all applicants in a fair, consistent, and evidence-backed way.

Petitioner also suggests that the length of time here is per se unreasonable. Pet. 23-24. But, as explained, this Court's cases employ a "rule of reason." *TRAC*, 750 F.2d at 79. The reasonableness of agency delay must

be considered in context, which here includes a request for a discretionary special issuance certificate and the need for FAA to develop an evidence-based medical protocol. Moreover, the agency has offered this Court a concrete timeline of its actions and only one step remains before publication of the protocol. Add. 5.

Petitioner's reliance on 49 U.S.C. § 44703(a) is similarly misplaced. Pet. 19-20. That provision states that FAA "shall issue an airman certificate to an individual when the Administrator finds, after an investigation, that an individual is qualified . . . and physically able." But petitioner acknowledges that he does not meet the regulatory requirements for a first-class airman medical certificate. Rather than deny his request outright, FAA has waited to respond because petitioner may be qualified for an exemption to those regulatory requirements under the new protocol, which is forthcoming. Add. 5.

Petitioner also contends that mandamus is warranted because "FAA represented to this Court nearly 18 months ago that it would not only act upon, but grant a first-class application from" an insulin-treated diabetic pilot who provided continuous glucose monitoring data. Pet. 17 (discussing *Friedman v. FAA*, 841 F.3d 537 (D.C. Cir. 2016); *Friedman v. FAA*, 890 F.3d

1092 (D.C. Cir. 2018)), Pet. 21. Petitioner's assertion that FAA agreed to grant a special issuance certificate to any pilot who obtained monitoring data does not withstand scrutiny. Any such data must obviously meet certain requirements (imagine data that revealed significant dips in glucose levels, for example), and it is the FAA protocol that will establish requirements for the monitoring data. If those data indicate that a pilot can operate safely, then, as FAA represented to this Court, a certificate will be granted.

Petitioner's argument that the regulatory scheme, which includes annual recertification, renders the delay in this case unreasonable similarly misses the mark. Pet. 24. A routine failure to grant or deny medical certificates within the appropriate period could undermine the short effective periods of medical certificates. But this is no routine case; petitioner indisputably does not qualify for a first-class medical certificate under current FAA regulations. He may qualify for a special issuance medical certificate, however, based on the development of the FAA protocol. Once that protocol is published, his continuous glucose monitoring data will be evaluated under that framework, and his request for a special issuance certificate denied or granted. Petitioner thus gets matters exactly backwards

when he urges that mandamus is warranted because the delay in this case is unusual. Pet. 25-26.

Nor does petitioner's suggestion that FAA is "manipulat[ing] its own processes . . . in an effort to thwart judicial review," Pet. 30 (quoting *Friedman*, 841 F.3d at 545), provide a basis for mandamus. FAA is not trying to "thwart judicial review" by not issuing petitioner a special issuance first-class medical certificate. As explained, FAA has declined to issue the certificate because it has not yet received approval to publish the protocol that will uniformly govern such requests. Indeed, petitioner may not ever need to seek judicial review once the protocol is published. The question in this case is whether petitioner can compel FAA to act on his special issuance certificate in the time it takes for internal review of the protocol to be completed. The answer is no.

Petitioner's concerns regarding the delay surrounding his special issuance medical certificate (Pet. 27-28) are understandable. But those concerns cannot override FAA's significant safety concerns, and, in any event, the delay should be nearing its end as FAA has completed its protocol. Nor is there any force to petitioner's contention that FAA is—for some unspecified reason—holding insulin-dependent pilots in "an indefinite

holding pattern.” Pet. 30. As explained, the “holding pattern” is not indefinite. *See* Add. 5. And, moreover, the reasons FAA has not granted the special issuance certificate petitioner seeks are clear.

C. The government has demonstrated that a writ of mandamus is not warranted given the agency’s reasonable decision to establish an evidence-based protocol to uniformly govern the grant of special issuance medical certificates to pilots with insulin-treated diabetes and given the government’s diligence in completing that protocol. If this Court has concerns about the timeline at issue in this case, however, the government has no objection to this Court retaining jurisdiction, as petitioner suggests at Pet. 31 n.7, and asking the parties to submit periodic status reports on the status of petitioner’s request.

CONCLUSION

For these reasons, the petition for a writ of mandamus should be denied.

Respectfully submitted,

JOSEPH H. HUNT
Assistant Attorney General

MICHAEL S. RAAB
/s/ Abby C. Wright
ABBY C. WRIGHT
(202) 514-0664
Civil Division, Appellate Staff
U.S. Department of Justice
950 Pennsylvania Ave., N.W.,
Rm. 7252
Washington, D.C. 20530

October 7, 2019

CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing complies with the type-volume limitation of Fed. R. App. P. 27(d)(2) because it contains 3,423 words, (under 7800) according to the count of Microsoft Word.

/s/ Abby C. Wright
Abby C. Wright
Counsel for respondent
Abby.Wright@usdoj.gov

CERTIFICATE OF SERVICE

I hereby certify that on October 7, 2019, I filed and served the foregoing with the Clerk of the Court by causing a copy to be electronically filed via the appellate CM/ECF system. I also hereby certify that the participants in the case are registered CM/ECF users and will be served via the CM/ECF system.

s/ Abby C. Wright

Abby C. Wright

Counsel for respondent

Abby.Wright@usdoj.gov

ADDENDUM

State University in 1977, during which I also received a Master's Degree in Preventive Medicine. Prior to my tenure at the FAA, I served as the Chief of the Flight Medicine Clinic at the NASA Johnson Space Center in Houston, Texas, where I was responsible for the screening and selection of new astronauts and participated in the certification and training of astronauts for space flight. I also previously worked in a private, aerospace medicine practice for 25 years serving as a Senior Aviation Medical Examiner.

2. In the course of my duties as the Federal Air Surgeon, I am responsible for, among other things, policy decisions concerning which airmen may be granted special issuance medical certificates under 14 C.F.R. § 67.401(a) in the interest of public safety. This includes airmen who have insulin-treated diabetes mellitus (ITDM), as these airmen are specifically disqualified from unrestricted medical certification by regulation. See 14 C.F.R. § 67.113(a). Although pilots with ITDM are presumptively unqualified for unrestricted certification, the FAA has incrementally amended its policies related to certifying pilots with diabetes using special issuance certificates as advances in medical science have allowed the agency to do so safely. In 1996, the FAA began allowing ITDM airmen to receive third-class medical certificates, which limit the airmen to exercising private pilot privileges. Using the protocol established for third-class airmen, the FAA has authorized over 500 ITDM pilots for third-class medical certification.

3. The FAA has been working diligently to develop a repeatable, evidence-based protocol that can be applied to first- and second-class applicants. The protocol is designed to enable consistent and standardized review of all ITDM airmen. The FAA has been proceeding with the development of the protocol cautiously, in order to ensure that we conduct an adequate risk assessment and consider the myriad factors facing pilots with ITDM in the cockpit. There is a significant difference between the privileges authorized by a third-class medical certificate (which

can be exercised under the existing protocol) and a first- or second-class medical certificate; pilots holding a first- and second-class medical certificate are permitted to fly aircraft commercially, carrying passengers and property for compensation or hire. There are reasonable risks to persons and property that are acceptable in the context of private pilots that are not acceptable in the exercise of commercial or airline transport pilot (ATP) privileges. A hypoglycemic event, which can result in impaired cognitive function, seizures, unconsciousness, and even death, that occurs in the cockpit of a commercial flight has the potential to place the safety of hundreds of individuals in jeopardy. Moreover, unrecognized hyperglycemic events can also insidiously impair performance and lead to subtle or sudden incapacitation.

Accordingly, more stringent standards are required for pilots operating commercial flights with paying passengers, who are owed the highest degree of safety. There are additional safety considerations to address with respect to the management of diabetes during a commercial flight. For example, the existing third-class special issuance protocol, in part, requires a process of finger-stick glucose testing during flight, while operating the aircraft. While this method has proven sufficient at the private pilot level, it does not ensure an adequate level of safety at the commercial level, as it would require pilots to actively manage their medical condition in the cockpit while simultaneously flying passengers. The mitigation strategies used in the third-class protocol require actions by the pilot that would shift focus away from a commercial pilot's primary duties and detract from that pilot's ability to safely fly the aircraft.

4. Accordingly, the development of a protocol that allows ITDM pilots to fly commercially has required the FAA to develop *both* a method to identify low-risk pilots who have sufficient glycemic control *and* a method for ensuring those pilots can safely manage their diabetes while in the cockpit of a commercial flight. Until recently, available medical science, treatment,

and monitoring were not sufficient to meet the higher levels of safety demanded for applicants considered for airline transport or commercial pilot duties. Absent adequate safeguards to prevent hypoglycemia in the cockpit, I therefore determined that the privileges permitted by first- and second-class certificates could not be performed without endangering public safety.

5. However, after extensive deliberation and careful consideration, the FAA has developed a new ITDM protocol with sufficient safety safeguards that will allow special issuance certificates for any class of medical certificate. Recent advances in technology and diabetes medical science have allowed the FAA to develop an evidence-based protocol that can both identify a subset of low-risk applicants whose glycemic stability is sufficiently controlled and also ensure these pilots can safely maintain diabetic control for the duration of a commercial flight.

Specifically, advancements in continuous glucose monitoring (CGM) now allow an individual to efficiently and accurately self-monitor blood sugar levels using a wearable CGM device. FAA believes CGM monitoring sufficiently increases the level of safety necessary to allow higher-level piloting by airmen with ITDM. The new protocol, by incorporating CGM, addresses the need to mitigate the additional occupational factors and safety challenges faced by commercial and ATP pilots, by providing continuous passive monitoring of the pilot's blood glucose during flight and allowing the pilot to take preventive actions with lower risk for potential distraction. The protocol was developed by FAA physicians and a doctor of clinical pharmacy on my staff, in conjunction with consultation with external physicians who are board certified in endocrinology and who have expertise in diabetes.

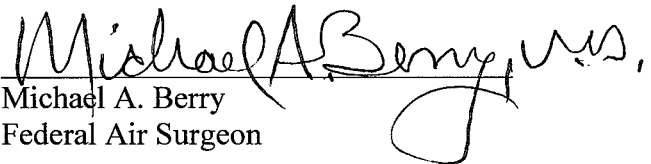
6. The FAA has chosen to publish the new first- and second-class ITDM protocol as a notice in the Federal Register before its implementation. While the FAA does not typically announce new medical protocols through publication, the FAA determined a notice was

appropriate here based on public interest because, for many years, affected pilots have been limited to consideration only at the private pilot level. We anticipate there will be significant interest from applicants, advocacy groups, and other stakeholders now that commercial and ATP pilots are eligible. The notice is also consistent with our historical practice of publishing in the Federal Register new protocols having potential high public interest. See Special Issuance of Third-Class Airman Medical Certificates to Insulin-Treated Diabetic Airman Applicants, 61 Fed. Reg. 59282 (Nov. 21, 1996). While the protocol will be immediately effective once published, the FAA is also using the notice to request comments and may revise the protocol based on comments received.

7. The protocol is completed and has been in coordination since June. It is currently undergoing the final stages of review. The Regulations Division of the FAA's Office of the Chief Counsel has coordinated review of the protocol with the Assistant General Counsel for Regulation of the Department of Transportation's (DOT) Office of General Counsel. The Office of Information and Regulatory Affairs (OIRA), within the Office of Management and Budget (OMB), has also reviewed FAA's designation request and determined the protocol to be non-significant. Accordingly, the protocol is currently pending final approval by the DOT General Counsel and the Secretary of Transportation. I anticipate the protocol will be published in the near future. In the interest of fairness to all applicants, we have chosen not to apply the content of the protocol until it has cleared departmental review and is published and effective. Once it is published, it will be applied to all pilots with ITDM who are seeking a first- or second-class medical certificate, including Mr. Mitchell.

8. I declare under penalty of perjury that the foregoing is true and correct to the best of my information, knowledge, and belief.

Executed on this 3rd day of October, 2019


Michael A. Berry
Federal Air Surgeon



U.S. Department
of Transportation
**Federal Aviation
Administration**

Federal Aviation Administration
Civil Aerospace Medical Institute (CAMI)
Aerospace Medical Certification Division

P.O. Box 25082
Oklahoma City, OK 73125 9867
(405) 954 4821

APRIL 30, 2018

MITCHELL MITCHELL

Ref: [REDACTED]

**AUTHORIZATION FOR SPECIAL ISSUANCE OF
A MEDICAL CERTIFICATE (AUTHORIZATION)
AAM-313**

Dear Mr. Mitchell:

We are still presently not authorizing upgrades for first- or second-class certification for airman with a history of diabetes mellitus requiring treatment with insulin. The Federal Air Surgeon is currently continuing to work on developing a potential protocol for certificating commercial airmen.

I have reviewed the information submitted by you in support of your request for an airman medical certificate. The medical evidence reveals a history of diabetes mellitus and the use of insulin. You are ineligible for medical certification under Title 14 of the Code of Federal Regulations (CFRs), revised part 67; specifically under paragraph(s) or section(s) 67.113(a), 67.213(a), and 67.313(a). I have determined, however, that you may be granted Authorization for special issuance third class airman medical certification under Title 14 of the CFRs, Section 67.401.

Since the medical certificate you now hold expires for third-class purposes on July 31, 2018, it will be necessary for you to undergo a current physical examination during that month. The Aviation Medical Examiner (AME) is authorized by this letter to issue you a third-class airman medical certificate bearing the limitation "Not valid for any class after July 31, 2019", provided you are found to be otherwise qualified.

This authorization expires: July 31, 2019 You must present this Authorization to your AME at the time of each FAA medical application.


Mitchell Mitchell

On or about May 01, 2019, you must furnish:

- A current Diabetes on Insulin worksheet (enclosed).
- A current eye specialist report.

See the enclosed specifications (Subsequent Medical Certification) for additional information/guidance. NOTE: You are required to visit your treating physician every 3 months for a check up and glycosylated hemoglobin (such as hemoglobin A1c) determination.

Submit your follow up information **to the FAA in one mailing to:**

Regular 1st Class Mail

Federal Aviation Administration
Aerospace Medical Certification Division
Medical Appeals Section
CAMI Bldg 13, Room 308 AAM-300
P.O. Box 25082
Oklahoma City, OK 73125

or

Special Delivery/Overnight Mail

Federal Aviation Administration
Aerospace Medical Certification Division
Medical Appeals Section
6500 S. Macarthur Blvd.
CAMI Bldg 13, Room 308 AAM-300
Oklahoma City, OK 73169

If there have been no adverse changes in your medical status, you have complied with the conditions of certification described in your Authorization, and the Federal Air Surgeon is satisfied that you can safely perform your authorization airman duties without endangering public safety, a new Authorization may be granted. You will still be required to have your regular third class medical examination at the frequency prescribed under the provisions of Title 14 of the CFRs, Section 61.23.

You must promptly report any adverse changes in your medical condition to the FAA Medical Appeals Section, AAM 313 at the above address.

You are cautioned to abide by Title 14 of the Code of Federal Regulations (CFRs), Section 61.53, relating to your physical deficiency, medication, or treatment. Because of your diabetes mellitus requiring insulin for control, operation of aircraft is prohibited at any time new symptoms or adverse changes occur or if you experience side effects, or require a change in medication.

You are required to monitor your blood sugar during all flights in accordance with the enclosed specifications.


Mitchell Mitchell

Use of the above reference numbers and your full name on any reports or correspondence will aid us in locating your file and expediting a reply to you.

Sincerely,

 for

David M. O'Brien, MD, MPH
Manager, Aerospace Medical Certification Division
Civil Aerospace Medical Institute

Enclosure: Diabetes on Insulin Worksheet

cc: ROBERT HABIG M.D.

krb