26-862

In the United States Court of Appeals
FOR THE SECOND CIRCUIT

KRISTA E. NOEL,
individually and on behalf of others similarly situated,
Plaintiff - Appellant,

v.

PEPSICO, INC., and PEPSICO ADMINISTRATION COMMITTEE,
Defendants - Appellees.

On Appeal from the United States District Court for the
Southern District of New York, No. 24-cv-07516, Hon. Cathy Seibel

BRIEF OF THE ERISA INDUSTRY COMMITTEE AS AMICUS CURIAE IN SUPPORT OF DEFENDANTS-APPELLEES

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases **Page(s)**

Statutes

Other Authorities

CORPORATE DISCLOSURE STATEMENT

In accordance with Federal Rule of Appellate Procedure 26.1, the ERISA Industry Committee states that it is not a publicly held corporation, does not have parent corporations, and no publicly held corporation owns 10% or more of its stock.

INTEREST OF AMICUS CURIAE[1]

The ERISA Industry Committee ("ERIC") is a national non-profit business trade association representing approximately 100 of the nation's largest employers in their capacity as sponsors of employee benefit plans for workers, retirees, and families. ERIC frequently participates as amicus curiae in cases that have the potential for far-reaching effects on employee benefit plan design or administration or affecting benefits plans.

ERIC's members sponsor benefit plans regulated by the Employee Retirement Income Security Act ("ERISA"). Many of those plans include wellness programs designed to encourage employees to adopt healthy practices, reduce the incidence of preventable disease and illness, and improve quality of life and longevity, including cessation of tobacco use. Wellness programs reduce healthcare costs for participants, plans, and employers. ERIC's members are often targeted in ERISA class actions like this one. It is important to ERIC that courts carefully enforce ERISA's statutory text, both in this case and more generally. ERIC submits this brief to provide the background and history of wellness programs, their importance in improving health and lowering healthcare costs, and the potential negative ramifications of the many tobacco surcharge class action cases pending nationwide. Not only

[1] All parties consent to the filing this brief. *See* Fed. R. App. P. 29(a)(2). No counsel for any party authored this brief in whole or part, and no entity or person, aside from amicus, their members, or their counsel, made any monetary contribution intended to fund or prepare submitting this brief.

do tobacco surcharge class actions wrongly attempt to turn wellness programs backwards, but they potentially expose plan sponsors to hundreds of millions of dollars in liability. This liability may be shouldered by participants through increased premiums, decreased benefits, or no wellness programs – all of which are detrimental to participants' health.

I. INTRODUCTION

The importance of this case transcends the interests of the parties, implicating the health of American workers and the cost and availability of health plan benefits. This case is one of at least 75 nationwide putative class actions challenging tobacco premium surcharges, a common feature of Congressionally sanctioned tobacco cessation "wellness programs." This appeal includes many important topics, but ERIC's focus is on one central issue in virtually all of these cases—namely, enforcement of ERISA's unequivocal mandate that *only* employees with certain qualifying medical conditions may skip or modify wellness program requirements when attempting to earn a reward. ERISA's statutory mandate has been trampled by the plaintiffs' bar, largely unaddressed by the courts, and amicus suggests that it bears careful consideration as part of this appeal.

Through clear and explicit amendments to ERISA over many decades, Congress repeatedly and consistently encouraged health plans to adopt wellness programs to improve employee health and drive health care costs down. Plaintiff wrongly tries to override ERISA's clear statutory text and Congress' intent by relying on a 2013 Department of Labor

("DOL") regulation that directly and impermissibly contradicts the statute by purportedly requiring plan sponsors to offer all participants (not just those with a qualifying medical condition) an alternative to earning wellness program rewards. Plaintiff here, like those in the many dozens of other tobacco surcharge cases, wrongly uses this regulation to allege that she should have been entitled to a wellness program reward despite not quitting tobacco, having any intent of quitting tobacco, and not having a qualifying medical condition showing why she could not quit tobacco. Not only is the regulation incapable of overriding clear statutory text, but it defeats the very aims of improving employee health, longevity, quality of life, and cost savings that Congress established wellness programs to enhance and protect.

ERISA allows plans to offer "premium discounts or rebates" in exchange for "adherence to" a wellness program. 29 U.S.C. § 1182. For wellness programs where a standard must be met to earn a reward, Congress carved out a small and individualized alternative option for those (and *only* those) participants for whom it is either "unreasonably difficult due to a medical condition to satisfy the otherwise applicable standard" or "medically inadvisable to attempt to satisfy the otherwise applicable standard." 42 U.S.C. § 300gg-4(j)(3)(D)(i). (This standard is referred to herein as the "Medical Condition Requirement.") The Medical Condition Requirement ensures that participants are not discriminated against based on a health status factor when participating in a wellness program and trying to better their health. But under ERISA's plain text, a reasonable

alternative standard need not be made universally available to everyone, but only those with medical conditions that make their participation "unreasonably difficult" or "medically inadvisable." This structure makes perfect sense considering Congress' goal of encouraging the establishment of and participation in wellness programs.

Plaintiff here, like those in dozens of other tobacco surcharge class actions, does not allege that she *could* have satisfied the Medical Condition Requirement (or even wanted to stop using tobacco at all). Contrary to ERISA's explicit statutory text, and based instead on DOL regulations incompatible with the statute, she wrongly alleges that a universal reasonable alternative standard is required for "any individual" who participated in a health plan with a wellness program, used tobacco, and paid a tobacco surcharge. These allegations fall far short of ERISA's statutory Medical Condition Requirement and fail to confer statutory standing. This deficiency is a common thread across the many dozens of tobacco surcharge cases, likely because application of the Medical Condition Requirement requires individualized inquiries into participants' medical conditions, undermining plaintiffs' attempts to certify these claims as class actions.

Ignoring ERISA's Medical Condition Requirement causes far-reaching harm, subjecting plans to unnecessary and unsupported class action litigation and jeopardizing Congressionally-authorized wellness programs, the long-term health of participants, and the

affordability of health plans relied upon by nearly half of the U.S. population.[2] To ensure protection of those interests, ERIC urges this Court to consider the Medical Condition Requirement and Plaintiff's failure to satisfy that requirement as an independent basis to affirm the District Court's judgment and to provide guidance to other courts addressing the same or virtually the same allegations.

II. STATUTORY AND REGULATORY BACKGROUND

ERIC recognizes that the parties and amicus curiae the U. S. Chamber of Commerce ("Chamber") have addressed the statutory and regulatory history of ERISA-sanctioned wellness programs in their briefing. While legislative history is typically not the stuff of cinematic excitement, it is critical to understanding how, in 2013, after decades of consistent statutory amendment and regulatory interpretation, things went off the rails when new regulations overwrote the Medical Condition Requirement. ERIC includes additional contextual background, with emphasis on the Medical Condition Requirement.

A. In 1996, Congress amended ERISA to encourage wellness programs.

In 1996, Congress amended ERISA through the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), Pub. L. No. 104-191, § 101, 110 Stat. 1936, 1946. As relevant here, the HIPAA amendments prohibit discrimination based on health status,

[2] *See* Tax Policy Center, *Who Has Health Insurance Coverage*, https://taxpolicycenter.org/briefing-book/who-has-health-insurance-coverage

preventing participants from "pay[ing] a premium or contribution which is greater than such premium or contribution for a similarly situated" individual or dependent "on the basis of any health status-related factor." 29 U.S.C. § 1182(b)(1).[3] As correctly explained in Pepsi's Brief, ERISA protects wellness programs by elaborating that "[n]othing in" the prohibition on discrimination "shall be construed … to prevent a group health plan … from establishing premium discounts or rebates … in return for adherence to programs of health promotion and disease prevention." *Id.* § 1182(b)(2)(B). When recommending passage of the amendment, the Senate Committee on Labor and Human Resources explained that "the legislation expressly allows employee health benefit plans … to modify premiums, copayments, and deductibles in return for adherence to programs of health promotion and disease prevention. For example, an employer could offer a reduced premium to non-smokers." S. Rep. No. 104-156, at 19-20 (1995).

B. The Medical Condition Requirement was a bedrock principle of the 2001 proposed regulations and the 2006 final regulations.

Congress instructed the agencies with authority over employer-sponsored health plans to "promulgate such regulations as may be necessary or appropriate to carry out the provisions of this part." 110 Stat. at 1951. The DOL, Treasury ("Treasury"), and Health and

[3] ERISA defines health status-related factors as: health status, medical condition, claims experience, receipt of health care, medical history, genetic information, evidence of insurability, and disability. 29 U.S.C. § 1182(a)(1).

Human Services ("HHS") began issuing a series proposed and interim rules addressing wellness program. As part of these rules, the agencies included provisions addressing situations where certain participants "might not be able to achieve a program standard due to a health factor." Notice of Proposed Rulemaking for Bona Fide Wellness Programs, 66 Fed. Reg. 1421, 1423 (January 8, 2001). From the start, the agencies proposed rules that reflected they wanted to "increase flexibility" for plans by allowing them "to make *individualized adjustments* to their wellness programs to address the health factors of the *particular individuals* for whom it is unreasonable difficult to qualify for the benefits under the program." *Id*. at 1423 (emphasis added). By way of example, the agencies stated that, where it was "unreasonably difficult" for an individual "to stop smoking cigarettes due to an addiction (a medical condition)," that particular employee could be accommodated by "participat[ing] in a smoking cessation program to avoid the surcharge" for as long as that employee was addicted to nicotine. *Id*. at 1432.

In 2006, the DOL promulgated final regulations. *See* Nondiscrimination and Wellness Programs in Health Coverage in the Group Market, 71 Fed. Reg. 75014 (Dec. 13, 2006) (the "2006 Regulations"). In keeping with the 2001 proposed rules, the 2006 Regulations required outcome-based wellness programs—*i.e.* those requiring "satisfaction of a standard related to a health factor," such as maintaining a certain BMI—to "provide a reasonable alternative standard for obtaining the reward for *certain* individuals." 71 Fed.

Reg. at 75019 (emphasis added); *see also* 75036. But again, the reasonable alternative standard was required *only* for participants for whom "it is unreasonably difficult due to a medical condition" or "medically inadvisable to attempt to satisfy" the otherwise applicable standard for obtaining an award. *Id*. at 75019 and 75036. As an example, the DOL explained that, if an employer adopted a wellness program providing rewards for "participants who have a body mass index between 19 and 26," but the goal was "unreasonably difficult due to a medical condition" or "medically inadvisable" for a particular participant, an alternative of "walk[ing] 20 minutes three days a week" could be offered to obtain the same reward. *Id.* at 75037.

Importantly, the 2006 Regulations stated that plans did "not need to establish" any "specific reasonable alternative standard before the program commence[d]." *Id*. at 75019. It was instead "sufficient to determine a reasonable alternative standard once a participant inform[ed] the plan" of a qualifying medical circumstance. *Id.* For example, with regard to smoking, if a plan "assessed a surcharge" on participants who self-reported tobacco use within the past year, and a participant informed the plan that it was "unreasonably difficult for [her] to stop smoking cigarettes," the plan could offer the option "to participate in a smoking cessation program to avoid the surcharge." *Id.* at 75037. That option would qualify as a reasonable alternative standard, and the plan would comply with the 2006 Regulations, including if the plan requested "a statement from a physician" or other "verification" of the

participant's medical needs before providing the alternative. *Id.* at 75019. Because alternative standards "need not be made available until they are sought by qualified plan participants," the DOL anticipated that "it might be possible for some plans to go for years without needing to make available an alternative standard." *Id*. at 75029.

C. In 2010, Congress amended ERISA to incorporate the 2006 Regulations nearly verbatim, including the Medical Condition Requirement.

In 2010, Congress amended ERISA through the Affordable Care Act ("ACA") and the Public Health Service Act ("PHSA"), incorporating the 2006 Regulations nearly word-for-word into the statute. 29 U.S.C. § 1185d(a)(1) (cross-referencing 42 U.S.C. § 300gg). Per the amendments, wellness programs may impose "conditions for obtaining" a "reward" as "related to a health status factor" if they meet certain requirements. *Id.* § 300gg(4)(j)(1)(C), (3). A wellness program satisfies the statutory provisions if it (1) is "reasonably designed to promote health or prevent disease," (2) provides "the opportunity to qualify for the reward under the program at least once each year," and (3) ensures the "full reward under the wellness program" is "available to all similarly situated individuals." *Id.* § 300gg-4(j)(3)(B)-(D). To satisfy requirement three, wellness programs may provide either a waiver or a "reasonable alternative standard" for those for whom it is "*it is unreasonably difficult due to a medical condition* to satisfy the otherwise applicable standard" or "*medically inadvisable* to attempt to satisfy the otherwise applicable standard." 42 U.S.C. § 300gg-4(j)(3)(D)(i) (emphasis added). The statute also allowed plans to "seek

verification, such as a statement from an individual's physician, that a health status factor makes it unreasonably difficult or medically inadvisable for the individual to satisfy or attempt to satisfy the otherwise applicable standard." *Id.* § 300gg-4(j)(3)(D)(ii). As explained in the Chamber's amicus brief, the ACA amendments were clear and comprehensive, leaving very few gaps to be filled by agency regulation. They were also nearly identical to the 2006 Regulations and consistent with more than a decade of agency interpretation.

D. In 2012, the DOL, HHS, and Treasury proposed additional regulations consistent with the statute and their longstanding interpretation of the Medical Condition Requirement.

In 2012, the DOL, HHS, and Treasury issued proposed rules for wellness programs. 77 Fed. Reg. at 70620. With regard to reasonable alternative standards, the agencies confirmed that the "proposed regulations would generally reiterate the requirements set forth in the 2006 regulations and codified in the PHS Act." *Id*. at 70624. As before, the Medical Condition Requirement remained, with alternatives (or waivers) required only for those for whom "it is either unreasonably difficult due to a medical condition" or "medically inadvisable" to attempt to satisfy the otherwise appliable standard. *Id*. Plans were not required to establish a particular reasonable alternative standard until "an individual's specific request for one." *Id*.; *see also* 70634. The proposed rules even included a full page

of examples showing how individuals satisfying the Medical Condition Requirement could potentially be accommodated with alternatives. *Id.* at 70635.

E. In 2013, the DOL, HHS, and Treasury inexplicably promulgated final regulations that jettisoned the statutory Medical Condition Requirement.

In 2013, the DOL, HHS, and Treasury promulgated regulations interpreting the ACA ("2013 Regulations"), and as the Chamber aptly summarizes, things "started to get squirrely." *See* 78 Fed. Reg. at 33158; *see also* Chamber Amicus Brief.[4] Untethered to any statutory or regulatory history or ERISA's clear statutory provisions, the 2013 Regulations abandoned the Medical Condition Requirement for outcome-based wellness programs (those programs that require "an individual to attain or maintain a specific health outcome," such as "not smoking" to obtain a reward). *See* 29 C.F.R. § 2590.702(f)(4)(iv)(A); *cf.* 42 U.S.C. § 300gg-4(j)(3)(D)(i)(I), (II). The 2013 Regulations abruptly pivoted, requiring a universal "reasonable alternative standard (or waiver of the otherwise applicable standard)" for "any individual," not just those for whom it is "unreasonably difficult due to a medical condition" or "medically inadvisable" to meet the initial outcome-based standard. *Id.,* §§ 2590.702(f)(1)(v) and 2590.702(f)(4)(iv). The agencies did not explain (or even acknowledge) the divergence between the 2013 Regulations and the Medical Condition Requirement.

[4] The Chamber's amicus brief has not been filed as of the time this pleading was finalized for submission to the Court. Therefore, a pinpoint citation is not yet available.

Based on the 2013 Regulations, the plaintiffs' bar began prolifically filing class action lawsuits challenging tobacco wellness programs. These lawsuits generally allege that a reasonable alternative standard must be universally available to "all individuals," not just the select few who satisfy the Medical Condition Requirement. This is wrong, directly at odds with ERISA, and incompatible with the very wellness programs that Congress intended. These meritless lawsuits persist, costing health plans millions in litigation expenses.

III. PARTICIPANTS FAILING THE STATUTORY MEDICAL CONDITION REQUIREMENT ARE NOT ENTITLED TO A REASONABLE ALTERNATIVE STANDARD.

Plaintiff's failure to allege that she could satisfy the Medical Condition Requirement provides an independent basis to affirm the District Court's decision. This case—and the many dozens of other pending tobacco surcharge cases—collapses without allegations that, "due to a medical condition," it was "unreasonably difficult" or "medically inadvisable" for Plaintiff to cease tobacco use and be eligible for a reasonable alternative standard. Because Plaintiff does not plausibly allege any facts triggering a need for a reasonable alternative standard, she lacks standing to pursue this matter.

As explained at length above, ERISA requires a reasonable alternative standard *only* for those for whom it "is unreasonably difficult" to satisfy "due to a medical condition" or "medically inadvisable to attempt to satisfy" the regular standard that otherwise applies. 42 U.S.C. § 300gg-4(j)(3)(D). The 2006 Regulations made this point particularly explicit,

stating that for "individuals addicted to nicotine" a reasonable alternative standard could be offered via a smoking cessation program. 71 Fed. Reg. at 75019. Therefore, as of 2006, the DOL understood that the "reasonable alternative" standard need only apply to a select subset of participants for whom it was "unreasonably difficult" or "medically inadvisable" to quit smoking. And again, Congress expressly incorporated the 2006 Regulation's Medical Condition Requirement into ERISA itself. Under ERISA's unambiguous text, the reasonable alternative standard need not be made available to everyone, just those satisfying the Medical Condition Requirement, which Plaintiff does not allege she can do.

This Court is not beholden to the 2013 Regulations as the controlling interpretation of statute, and instead "must exercise independent judgment in determining the meaning of statutory provisions." *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 394 (2024); *see also Anderson v. Diamondback Inv. Grp., LLC*, 117 F.4th 165, 187–88 (4th Cir. 2024) (citing *Loper* when rejecting the Drug Enforcement Administration's proffered interpretation of an unambiguous statute, acknowledging that "even if it were ambiguous, we needn't defer to the agency's interpretation."). In *Loper,* the Supreme Court instructed:

> [I]n an agency case as in any other, though, even if some judges might (or might not) consider the statute ambiguous, **there is a best reading all the same – "the reading the court would have reached" if no agency were involved.** *Chevron*, 467 U.S. at 843, n. 11, 104 S.Ct. 2778. It therefore makes no sense to speak of a "permissible" interpretation that is not the one the court, after applying all relevant interpretive tools, concludes is best.

603 U.S. at 400 (emphasis added). As explained in Pepsi's Brief, "a cardinal principle of statutory construction" requires courts to avoid surplusage and "give effect, if possible, to every clause and word of a statute." *Williams v. Taylor*, 529 U.S. 362, 404 (2000) (quotation marks omitted); *State St. Bank & Tr. Co. v. Salovaara*, 326 F.3d 130, 139 (2d Cir. 2003) (same). A regulation cannot contradict a statute by eliminating a requirement. *See e.g. Ragsdale v. Wolverine World Wide, Inc.,* 535 U.S. 81, 86 (1997) ("A regulation cannot stand if it is arbitrary, capricious, or manifestly contrary to the statute."); *Florez on Behalf of Wallace v. Callahan*, 156 F.3d 438, 445 (2d Cir. 1998) (same). The 2013 Regulation fails to provide Plaintiff with a cause of action because it strikes the Medical Condition Requirement from ERISA's statutory text, wrongly imposing a universally available reasonable alternative standard. 29 C.F.R. § 2590.702(f)(iv)(A). This is far from the "best reading" of the statute because it directly contradicts the unambiguous statutory language.

Plaintiff fails to plausibly allege that she could have satisfied the Medical Condition Requirement (such as by alleging addiction to nicotine) and lacks a statutory basis to challenge Pepsi's wellness program.

IV. TOBACCO-FOCUSED WELLNESS PROGRAMS ARE CENTRAL TO WORKER HEALTH AND HEALTH PLAN SUSTAINABILITY.

Tobacco use is the leading cause of preventable death in the United States, killing more than 480,000 people annually.[5] For every smoking-related death, at least 30 people live with a serious tobacco-related illness (including cancer, asthma, heart disease, stroke, diabetes, or lung disease).[6] Cigarette smoking is linked to about 80% of lung cancer deaths.[7] As of 2022, an estimated 11.6% of U.S. adults (28.8 million people) smoked cigarettes.[8] Sales of e-cigarettes increased from $75 million in 2017 to $469 million in 2022.[9] Smoking results in annual healthcare spending of more than $240 billion.[10] Tobacco users consume more healthcare resources, costing about 30% more to insure.[11] 16.4% of healthcare spending for adult inpatient care is attributable to cigarette smoking.[12] The dangers of

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[5] *See* CDC, *Tips from Former Smokers, Know the Facts*, https://www.cdc.gov/tobacco/campaign/tips/groups/general-public.html

[6] *Id.*

[7] *See* CDC, *Lung Cancer Risk Factors*, https://www.cdc.gov/lung-cancer/risk-factors/index.html

[8] *See* CDC, *Burden of Cigarette Use in the U.S.*, https://www.cdc.gov/tobacco/campaign/tips/resources/data/cigarette-smoking-in-united-states.html

[9] *Id.*

[10] *Id.*

[11] University of Wisconsin-Madison Center for Tobacco Research and Intervention, *Save on Health Insurance Premiums with Smoke-Free Policies*, https://ctri.wisc.edu/employers/business-case/premiums/

[12] Action on Smoking & Health, *Hidden Costs: The Economic Burden of Cigarette Smoking on U.S. Healthcare Spending*, https://ash.org/hidden-costs-healthcare/

tobacco are undeniable, with health warnings required on tobacco products for over 60 years.[13] Because unhealthy lifestyles—such as those involving tobacco use—cause illness, premature death, and medical expense, Congress encouraged wellness programs to promote healthy lifestyles, resulting in long-term health improvements and cost savings.[14] Tobacco users often need help to quit, and counseling and medication can more than double a tobacco user's chance of success.[15]

Tobacco surcharges are one type of wellness program that encourages healthy lifestyles by discouraging tobacco use. Requiring participants to cease tobacco use to obtain a waiver of the surcharge is a key component to the success of these programs. It makes perfect sense—and is consistent with the overall health and antidiscrimination goals of wellness programs—for ERISA to require plan sponsors to provide a reasonable alternative *only* for those individuals with a medical condition making it unhealthy or medically risky for them to stop using tobacco. On the other hand, it makes no sense for the regulation to impose a universal alternative standard requirement applicable to *all* tobacco users, even in the absence of a medical need for an alternative. This would enable them to avoid the very

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[13] American Lung Association, *Tobacco Control Milestones*, https://www.lung.org/research/sotc/tobacco-timeline

[14] Soeren Mattke et al., Rand Health, *Workplace Wellness Programs Study: Final Report* xiii, 1-2 and xvii (2013) (*RAND Report*).*; id.* at xix, xxvi, 53-65.

[15] World Health Organization, *Tobacco and Nicotine*, https://www.who.int/news-room/fact-sheets/detail/tobacco

purpose of the wellness program by availing themselves of an alternative (e.g., participation in a fee cessation program), but to continue using tobacco.

Plaintiff has not alleged any medical reason explaining why she (or any plan participant) is entitled to a reasonable alternative standard to avoid the tobacco surcharge. This failure is a common thread in the class actions filed over the past 2-3 years as plaintiffs instead rely on the 2013 Regulation's requirement for a universal reasonable alternative standard to avoid cessation of tobacco use. If that portion of the regulation is unenforceable – and it should be unenforceable because it conflicts with ERISA – the entire class action fabric falls apart because, at least so far, no plaintiff has even attempted, much less been able to plausibly allege that quitting tobacco is "unreasonably difficult due to a medical condition" or "medically inadvisable" for them.

ERISA class actions may incentivize employers to eliminate the very wellness programs Congress wanted to encourage. That result may jeopardize the health of American workers and increase healthcare costs for participants and plan sponsors. Plaintiff's Count I failed to state a claim, and the district court correctly dismissed it.

CONCLUSION

This Court should AFFIRM the judgment of the District Court.

Respectfully submitted: July 20, 2026.

s/ Mark E. Schmidtke

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CERTIFICATE OF COMPLIANCE

1. This document complies with the type-volume limitations of Federal Rule of Appellate Procedure 29(a)(5) and 32(a)(7)(B) and Local Rules FRAP 29(a) because it contains 3,914 words, excluding the parts of the petition exempted by Federal Rule of Appellate Procedure and 32(f).

2. This petition complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this petition has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Times New Roman font.

Dated: July 20, 2026.

s/ Mark E. Schmidtke
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