No. 26-862

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

KRISTA E. NOEL, on behalf of herself and all 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, Case No. 7:24-cv-07516-CS (Hon. Cathy Seibel)

BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS AMICUS CURIAE IN SUPPORT OF APPELLEE AND AFFIRMANCE

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CORPORATE DISCLOSURE STATEMENT

The Chamber of Commerce of the United States of America is a non-profit, tax-exempt organization incorporated in the District of Columbia. The Chamber has no parent corporation, and no company has 10% or greater ownership in the Chamber.

Dated: July 20, 2026

s/ Jaime A. Santos
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TABLE OF CONTENTS

Page

INTEREST OF AMICUS CURIAE 1

INTRODUCTION 2

ARGUMENT 5

I. The history of wellness programs is a classic case of congressional flexibility followed almost immediately by agency overreach. 5

II. The plaintiffs' bar ran with the agencies' overreaching regulation, suing dozens of employers that have tried to encourage healthy lifestyle choices and bring down healthcare costs through wellness programs 12

III. Plan participants who have no medical necessity for failing to comply with a wellness-program standard have no cause of action to complain about the adequacy of a "reasonable alternative" standard. 25

IV. These wellness-program lawsuits would eviscerate the flexibility Congress afforded to employers and undermine Congress's goal of encouraging healthy lifestyle choices. 29

CONCLUSION 31

TABLE OF AUTHORITIES

Page(s)

Cases

Am. Psychiatric Ass'n v. Anthem Health Plans, Inc.,
821 F.3d 352 (2d Cir. 2016) 25

Art & Antique Dealers League of Am., Inc. v. Seggos,
121 F.4th 423 (2d Cir. 2024) 28

Bailey v. Sedgwick Claims Mgmt. Servs. Inc.,
2025 WL 2779899 (W.D. Tenn. Sept. 26, 2025) 16

Chirinian v. Travelers Cos., Inc.,
2025 WL 2147271 (D. Minn. July 29, 2025) 15

Christensen v. Harris Cty.,
529 U.S. 576 (2000).....22

Collins v. Ne. Grocery, Inc.,
149 F.4th 163 (2d Cir. 2025) 25

Cunningham v. Cornell Univ.,
604 U.S. 693 (2025).....24

Gonzales v. Oregon,
546 U.S. 243 (2006).....21, 22

Gustavsen v. Alcon Lab'ys, Inc.,
903 F.3d 1 (1st Cir. 2018).....21

Hughes Aircraft Co. v. Jacobson,
525 U.S. 432 (1999).....17

Hughes v. Nw. Univ.,
595 U.S. 170 (2022).....1

Inv. Co. Inst. v. Camp,
401 U.S. 617 (1971).....23

Kisor v. Wilkie,
588 U.S. 558 (2019).....21

Lockheed Corp. v. Spink,
517 U.S. 882 (1996).....17

Long Island Care at Home, Ltd. v. Coke,
551 U.S. 158 (2007).....22

Loper Bright Enters. v. Raimondo,
603 U.S. 369 (2024).....20, 28

Nat'l Black Media Coal. v. FCC,
791 F.2d 1016 (2d Cir. 1986).....22

Rhodes-Bradford v. Keisler,
507 F.3d 77 (2d Cir. 2007).....23

Sec'y of Lab. v. Macy's, Inc.,
2021 WL 5359769 (S.D. Ohio Nov. 17, 2021).....12, 17, 20
2022 WL 407238 (S.D. Ohio Feb. 10, 2022).....17

Seife v. U.S. Dep't of Health & Hum. Servs.,
440 F. Supp. 3d 254 (S.D.N.Y. 2020).....21

Starbucks Corp. v. McKinney,
602 U.S. 339 (2024).....23

United States v. Kahn,
5 F.4th 167 (2d Cir. 2021).....22

Varity Corp. v. Howe,
516 U.S. 489 (1996).....30

Wyeth v. Levine,
555 U.S. 555 (2009).....21

Statutes

29 U.S.C. § 1104.....16

29 U.S.C. § 1106(a).....24

29 U.S.C. § 1180(c)(3)(A).....24

29 U.S.C. § 1182.....16, 23, 28

29 U.S.C. § 1182(a)(1).....6

29 U.S.C. § 1182(b)(1).....6

29 U.S.C. § 1182(b)(2).....6

29 U.S.C. § 1182(c) 24

29 U.S.C. § 1185d(a)(1).....8

42 U.S.C. § 300gg-4.....8, 16, 28

42 U.S.C. § 300gg-4(a)(9) 9

42 U.S.C. § 300gg-4(c)(3) 24

42 U.S.C. § 300gg-4(j).....21, 24

42 U.S.C. § 300gg-4(j)(1)(C).....9

42 U.S.C. § 300gg-4(j)(3) 9

42 U.S.C. § 300gg-4(j)(3)(A) 9

42 U.S.C. § 300gg-4(j)(3)(B).....15, 19, 29

42 U.S.C. § 300gg-4(j)(3)(B)-(D).....9

42 U.S.C. § 300gg-4(j)(3)(D) 9, 10, 21, 26, 27, 29

42 U.S.C. § 300gg-4(j)(3)(D)(ii).....26

Health Insurance Portability & Accountability Act (HIPAA), Pub. L. No. 104-191, § 101, 110 Stat. 1936 .....2, 5, 6

Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 2705, 124 Stat. 119 (2010).....2

Regulations

29 C.F.R. § 2590.702 .....5, 28

29 C.F.R. § 2590.702(f)(1)(v).....10

29 C.F.R. § 2590.702(f)(3)(iii) 15

29 C.F.R. § 2590.702(f)(4)(iii) 15, 29

29 C.F.R. § 2590.702(f)(4)(iv).....10, 22

29 C.F.R. § 2590.702(f)(4)(iv)(A).....28

Incentives for Nondiscriminatory Wellness Programs in Group Health Plans, 77 Fed. Reg. 70620 (Nov. 26, 2012).....13

Incentives for Nondiscriminatory Wellness Programs in Group Health Plans, 78 Fed. Reg. 33158 (June 3, 2013) 5, 11, 13, 14, 16, 24, 29

Nondiscrimination and Wellness Programs in Health Coverage in the Group Market, 71 Fed. Reg. 75014 (Dec. 13, 2006)..... 6, 7, 8, 10, 11, 21, 26

Other Authorities

Encore Fiduciary, *"Tobacco Surcharge" Litigation update* (Jan. 7, 2026), https://encorefiduciary.com/tobacco-surcharge-litigation-update/.....12

David Freeman Engstrom, *Agencies as Litigation Gatekeepers*, 123 Yale L.J. 616 (2013) 16

Groom Law Group, *Burning Questions: Employers Should Evaluate Wellness Programs as Tobacco Premium Surcharge Litigation Moves Forward* (Oct. 22, 2025), https://www.groom.com/resources/burning-questions-employers-should-evaluate-wellness-programs-as-tobacco-premium-surcharge-litigation-moves-forward/ 12

Katherine Baicker et al., *Workplace Wellness Programs Can Generate Savings,* 29 Health Aff. 304 (2010), http://publichealth.lacounty.gov/diabetes/docs/National_DPP_Research_Arti/_Workplace_Wellness_Programs_Can_Generate_Savings_2010.pdf.....3, 4

Soeren Mattke et al., Rand Health, *Workplace Wellness Programs Study: Final Report* (2013), https://www.rand.org/content/dam/rand/pubs/research_reports/RR200/RR254/RAND_RR254.pdf.....2, 3

U.S. DOL, HHS, Treasury, *FAQs* (Jan. 9, 2014), https://tinyurl.com/muhnpv45.....12, 15

INTEREST OF AMICUS CURIAE

The Chamber of Commerce of the United States of America (Chamber) is the world's largest business organization.[1] As the nation's leading advocate for business, the Chamber represents companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent its members' interests in matters before the courts, Congress, and the Executive Branch. The Chamber therefore regularly participates as amicus curiae in cases that raise issues of concern to the business community. *See, e.g.*, *Hughes v. Nw. Univ.*, 595 U.S. 170 (2022); *Vellali v. Yale Univ.*, No. 23-1082 (2d Cir. Mar. 14, 2024), ECF No. 104.

The Chamber has a strong interest in the outcome of this litigation because many of the Chamber's members sponsor benefit plans regulated by the Employee Retirement Income Security Act (ERISA), and many of those plans include wellness programs that help participants by encouraging healthy practices that reduce healthcare costs for plans as a whole. The Chamber files this brief to provide the Court with greater context regarding wellness programs and the flexibility that

[1] All parties have consented to the filing of this brief. *See* Fed. R. App. P. 29(a)(2). No counsel for a party authored this brief in whole or in part. No party, no counsel for a party, and no person other than amicus, its members, and its counsel made a monetary contribution to fund the preparation or submission of this brief.

ERISA affords plan sponsors in deciding whether to include wellness programs and how to structure those programs.

INTRODUCTION

Congress pursued an important goal in authorizing health plan sponsors to implement employee wellness programs in both the Health Insurance Portability and Accountability Act of 1996 (HIPAA)[2] and the Patient Protection and Affordable Care Act (ACA).[3] As a detailed report sponsored by the Department of Health and Human Services (HHS) and the Department of Labor (DOL) found, wellness programs encourage individuals to make healthy lifestyle choices and to take preventive measures that yield long-term health benefits and significant cost savings for employer-sponsored health plans—potentially lowering health costs system-wide. *See* Soeren Mattke et al., Rand Health, *Workplace Wellness Programs Study: Final Report* xiii, xix, xxvi, 1-2, 53-65 (2013) (*RAND Report*).[4]

This virtuous cycle is exactly what Congress wanted to enable and encourage when it enacted the ACA, which contains numerous provisions "intended to contain health care cost growth and expand health promotion and prevention activities." *RAND Report* 3. By contrast, unhealthy lifestyle choices (such as inactivity and poor

[2] Pub. L. No. 104-191, § 101, 110 Stat. 1936.
[3] Pub. L. No. 111-148, § 2705, 124 Stat. 119 (2010).
[4] https://www.rand.org/content/dam/rand/pubs/research_reports/RR200/RR254/RAND_RR254.pdf.

nutrition) increase the prevalence of chronic disease, such as diabetes, heart disease, and chronic pulmonary conditions—conditions that "lead to decreased quality of life, premature death and disability, and increased health care cost," along with loss of productivity and absenteeism, all of which Congress understandably wanted to avoid as much as possible. *Id.* at 3; *see id.* at xiii.

Congress chose to incentivize healthy lifestyle choices by allowing employers that sponsor health plans to incorporate wellness programs into those health plans and by affording plan sponsors wide flexibility to design those plans. Wellness programs can and do take many forms, including programs related to nutrition, weight loss, tobacco cessation, fitness, alcohol and drug abuse, and stress management. *RAND Report* xv. The incentives offered by these wellness programs are also highly varied, ranging from cash rewards to health premium surcharges or discounts, gift cards, novelty items (like t-shirts), or discounted gym memberships. *Id.* at xxi.

Wellness programs provide "statistically significant and clinically meaningful" health improvements in many cases. *RAND Report* xvii. For health plans in particular, the data show meaningfully positive results. A 2010 meta-analysis indicates that for every dollar spent, there was a $3 average return in reducing health care costs and absenteeism. Katherine Baicker et al., *Workplace*

Wellness Programs Can Generate Savings, 29 Health Aff. 304, 304-311 (2010).[5]

As health services and medications have gotten more expensive, healthy lifestyle choices have become an important way to contain healthcare costs. But there is no single tried-and-true method of encouraging people to make healthy choices. Accordingly, in expressly authorizing employers to adopt wellness programs as part of their employer-sponsored health plans, Congress gave employers the flexibility to implement different types and structures of wellness programs to encourage maximizing employees' adoption of healthy habits. Flexibility and innovation are crucial to achieving Congress's goals because there is still much that employers and healthcare providers can learn about what effectively incentivizes healthy lifestyles and outcomes.

That flexibility and innovation are at risk of being eviscerated. Through muddled and contradictory regulations and sub-regulatory guidance, combined with a recent flood of private-plaintiff lawsuits seeking an aggressive and overly restrictive interpretation of ERISA's wellness-program provisions, the flexible system Congress created has been distorted and weaponized in a way Congress could never have imagined. Wellness programs are intended to be laboratories of innovation, not litigation traps. This Court should reject Plaintiff's constrained view

[5] http://publichealth.lacounty.gov/diabetes/docs/National_DPP_Research_Articles/Baicker_Workplace_Wellness_Programs_Can_Generate_Savings_2010.pdf.

of ERISA's wellness provisions and embrace the flexible approach adopted by the district court—and, more importantly, by Congress.

ARGUMENT

I. The history of wellness programs is a classic case of congressional flexibility followed almost immediately by agency overreach.

For three decades, ERISA has expressly permitted employers to offer premium discounts to employees who engage in healthy lifestyle practices (or refrain from unhealthy practices) or participate in programs designed to promote health. As DOL has explained, numerous articles and studies have found a "statistically significant" positive impact on healthy lifestyle choices from workplace wellness programs, which results in "health care savings, reduced absenteeism, and [improved] employee satisfaction." Incentives for Nondiscriminatory Wellness Programs in Group Health Plans, 78 Fed. Reg. 33158, 33170 (June 3, 2013) (codified at 29 C.F.R. § 2590.702) (the "2013 Regulation").

A. Wellness programs were expressly authorized by Congress through HIPAA, 110 Stat. at 1945-1946. HIPAA amended ERISA to prohibit discrimination based on health status by forbidding any participant or beneficiary 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).[6] Congress made clear, however, that "programs of health promotion and disease prevention" (known as wellness programs) are not considered discrimination based on health status-related factors. 29 U.S.C. § 1182(b)(2). Specifically, HIPAA's amendments to ERISA state that the anti-discrimination provision shall not "be construed" to "prevent a group health plan" from "establishing premium discounts or rebates … in return for adherence to" a wellness program. *Id.*

While HIPAA amended ERISA to expressly authorize "programs of health promotion and disease prevention" and made clear that these types of programs are *not* considered a form of discrimination on the basis of a health status-related factor, the statute was light on the details of what "programs of health promotion and disease prevention" could or should look like. Instead, 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. Accordingly, HHS, DOL, and the Department of the Treasury filled in the statutory gaps. *See* Nondiscrimination and Wellness Programs in Health Coverage in the Group Market, 71 Fed. Reg. 75014 (Dec. 13, 2006) (the "2006 Regulation").

[6] ERISA defines the 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).

The 2006 Regulation imposed various requirements on wellness programs that conditioned rewards "on satisfaction of a standard related to a health factor." 71 Fed. Reg. at 75027. To start, the 2006 Regulation imposed limits on the monetary size of the reward, required wellness programs to be reasonably designed, and prescribed that individuals have the opportunity to qualify for the reward at least once per year. *Id*. at 75036. HHS, DOL, and Treasury made clear that these requirements were intended to afford employers maximum flexibility, and " to allow experimentation in diverse ways of promoting wellness." *Id.* at 75018.

Moreover, the 2006 Regulation was expressly intended to create "an easy standard to satisfy," as long as "a program has a reasonable chance of improving the health of participants and it is not overly burdensome, is not a subterfuge for discriminating based on a health factor, and is not highly suspect in the method chosen to promote health or prevent disease." *Id.* at 75018. Employers were not required to develop "a scientific record" establishing that the chosen wellness program *would clearly work*—employers were permitted, for example, to experiment with holistic wellness components, like "providing rewards to individuals who participated in a course of aromatherapy." *Id.* The 2006 Regulation described a number of other wellness programs that could qualify, as well including programs relating to participants' cholesterol levels, body mass index (BMI), exercise habits, and tobacco-cessation efforts. *Id.* at 75028, 75036, 75037.

The 2006 Regulation also required that if a wellness program required an employee to *satisfy* a particular standard (like having a BMI between 19 and 26), then the employer "must provide a reasonable alternative standard for obtaining the reward for certain individuals." 71 Fed. Reg. at 75019; *see id*. at 75036. But it required a reasonable alternative *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 75036. For example, an employer could permit an employee who could not satisfy a BMI requirement because of a medical condition to "walk[ ] 20 minutes three days a week" instead. *Id.* at 75037. And the duty to provide that alternative arises only after a participant informed the plan that meeting the standard was unreasonably difficult or medically inadvisable. *Id.* at 75019. As the agencies explained, "it might be possible for some plans to go for years without needing to make available an alternative standard." *Id.* at 75029.

B. In 2010, Congress ratified the 2006 Regulation by incorporating it into ERISA nearly verbatim. The ACA amended ERISA (and the Public Health Service Act (PHSA)) with respect to wellness programs. *See* 29 U.S.C. § 1185d(a)(1) (cross-referencing 42 U.S.C. § 300gg-4). Under the ACA's amendments, if a wellness program imposes any "conditions for obtaining" a "reward" that are

"related to a health status factor," then certain requirements apply. 42 U.S.C. § 300gg-4(j)(1)(C), (3). Wellness programs must, among other things:

- "be reasonably designed to promote health or prevent disease";
- "give individuals eligible for the program the opportunity to qualify for the reward under the program at least once each year"; and
- ensure that the "full reward under the wellness program shall be made available to all similarly situated individuals."

Id. § 300gg-4(j)(3)(B)-(D).

To satisfy the third requirement, the statute requires the wellness program to provide either a waiver or a "reasonable alternative standard" for those for whom it is "unreasonably difficult due to a medical condition" or "medically inadvisable to attempt to satisfy the otherwise applicable standard"—just like the 2006 Regulation. 42 U.S.C. § 300gg-4(j)(3)(D).

Unlike in 1996, Congress's amendment of ERISA through the ACA in 2010 included highly detailed requirements that left few gaps to be filled through regulation. And where Congress did leave gaps to fill, it noted those gaps expressly. *E.g.*, 42 U.S.C. § 300gg-4(a)(9) (empowering Secretary to determine other "appropriate" health status-related factors); *id.* § 300gg-4(j)(3)(A) (permitting rewards of "up to 50 percent … if the Secretaries determine that such an increase is appropriate").

But that did not deter HHS, DOL, and Treasury from going beyond those

parameters. In 2013, the agencies promulgated a lengthy new regulation governing employer-sponsored wellness plans. This is where things started to get squirrely. In promulgating that regulation, DOL did not limit itself to filling those specific gaps; instead, it *supplanted* Congress's view of what constitutes a "program of health promotion and disease prevention" through new or contradictory requirements.

For example, for outcome-based wellness programs—those that require "an individual to attain or maintain a specific health outcome (such as not smoking or attaining certain results on biometric screenings) in order to obtain a reward"—the 2013 Regulation requires a "reasonable alternative standard (or waiver of the otherwise applicable standard)" for *all* plan participants who request one, not just those for whom it is unreasonably difficult or medically inadvisable to meet the initial outcome-based standard. *See* 29 C.F.R. § 2590.702(f)(1)(v); *id.* § 2590.702(f)(4)(iv). That requirement lies in stark contrast with the statute—and with the 2006 Regulation that the statute incorporated nearly verbatim. *See* 42 U.S.C. § 300gg-4(j)(3)(D); 71 Fed. Reg. at 75036. The final rule did not even *acknowledge* the conflict with the statute, much less attempt to reconcile it.

The retroactivity requirement that Plaintiff contends is part of the wellness-program regulation is another prime example of post-ACA regulatory overreach. Nothing in the 2006 Regulation required employers to give a *full year's* worth of rewards for *part-year* compliance with a wellness program. To the contrary, the

2006 Regulation expressly enumerated as "permissible" a reasonable alternative tobacco-cessation program in which person "*F* can avoid the surcharge *for as long as F* participates in [a tobacco cessation] program, regardless of whether *F* stops smoking (as long as *F* continues to be addicted to nicotine)." 71 Fed. Reg. at 75037 (emphasis added). The clear implication: employers had no obligation to provide rewards to employees for the period of time before they satisfy a reasonable alternative wellness program.

Nothing in the ACA's text requires full-year rewards for part-year compliance. The agencies also did not propose a retroactivity requirement in the post-ACA proposed regulation, nor did they include one in the final 2013 rule. Instead, under the auspices of a "clarification," the agencies purported to craft a retroactivity requirement in the preamble to the 2013 Regulation: "[I]f a calendar year plan offers a health-contingent wellness program with a premium discount and an individual who qualifies for a reasonable alternative standard satisfies that alternative on April 1, the plan or issuer must provide the premium discounts for January, February, and March to that individual." 78 Fed. Reg. at 33163. But the agencies identified nothing in the statute that supported this purported "clarification." And following the promulgation of the 2013 Regulation, the agencies backtracked through subregulatory guidance stating that pro-rated rewards or discounts *are* permitted if employees have at least one chance to qualify for a

reward under a reasonable alternative standard at the beginning of a plan year. U.S. DOL, HHS, Treasury, *FAQs* 6 (Jan. 9, 2014) (Question 8) (*FAQs*), https://tinyurl.com/muhnpv45. Here too, the agencies did not even attempt to connect this interpretation to the statute's text.

II. The plaintiffs' bar ran with the agencies' overreaching regulation, suing dozens of employers that have tried to encourage healthy lifestyle choices and bring down healthcare costs through wellness programs.

ERISA's wellness-program provisions functioned fairly well for almost a decade. DOL brought one enforcement action against a plan sponsor that (among other things) required plan participants to successfully cease using certain products altogether to be eligible for a wellness program reward. *Sec'y of Lab. v. Macy's, Inc.*, 2021 WL 5359769, at *3 (S.D. Ohio Nov. 17, 2021). But plan sponsors were generally able to innovate by implementing a wide variety of wellness programs and structures. In the early 2020s, however, the ERISA plaintiffs' bar took the 2013 Regulation and ran with it, filing dozens of lawsuits in rapid succession (with most cases filed by the same firm that represents Plaintiff here).[7] Those lawsuits challenge many different wellness program structures, but they focus on a core theory: if an

[7] *See, e.g.*, Groom Law Group, *Burning Questions: Employers Should Evaluate Wellness Programs as Tobacco Premium Surcharge Litigation Moves Forward* (Oct. 22, 2025), https://www.groom.com/resources/burning-questions-employers-should-evaluate-wellness-programs-as-tobacco-premium-surcharge-litigation-moves-forward/; Encore Fiduciary, *"Tobacco Surcharge" Litigation update* (Jan. 7, 2026), https://encorefiduciary.com/tobacco-surcharge-litigation-update/.

employer offers a reasonable alternative standard for obtaining an award under an outcome-based program, then the employer *must* provide retroactive benefits going back to the beginning of the plan year no matter when an employee tries to qualify—indeed, even for employees who choose not to even enroll in an alternative program until the end of the plan year.

These lawsuits are striking in several ways. *First*, for all of the flaws contained in the 2013 Regulation, the agencies that promulgated it recognized (repeatedly) that ERISA's wellness-program provisions were not meant to be restrictive—instead, they "continue to provide plans and issuers flexibility and encourage innovation." 78 Fed. Reg. at 33162; 77 Fed. Reg. at 70625. For example, the agencies noted that "the final regulations do not prescribe a particular type of alternative standard that must be provided" but rather "permit plan sponsors flexibility to provide any reasonable alternative," and that employers could feel free to "select alternatives that entail the minimum net costs … that are possible to achieve offsetting benefits." 78 Fed. Reg. at 33172; *see also id.* at 33162 ("[P]lans and issuers have flexibility to determine apportionment of the reward among family members, as long as the method is reasonable."); *id.* at 33163 ("Plans and issuers have flexibility to determine whether to provide the same reasonable alternative standard for an entire class of individuals … or provide the reasonable alternative standard on an individual-by-individual basis …."); *id.* ("These final regulations

continue to permit plans and issuers flexibility in designing reasonable alternative standards."); *id.* at 33173 ("[T]he Departments believe that this final rule contains considerable regulatory flexibility for plans to design wellness programs that suit their needs.").

The slew of lawsuits filed by counsel for Plaintiff here attempt to gut that flexibility. These lawsuits challenge many different wellness program structures, but at bottom, the suits operate under the assumption that there is a single way to correctly structure a wellness program that includes some type of educational component in lieu of meeting an outcome-based standard. According to these suits, the reasonable alternative standard must be available to every single employee irrespective of their medical condition, it must allow employees to qualify for that reasonable alternative standard at any point during the year that they wish, and it also must provide retroactive benefits going back to the beginning of the plan year even for employees who choose not to attempt to qualify for the reasonable alternative standard until November or December. That is not how the 2013 Regulation is written, and it is certainly not how the *statute* is written. Instead, the statute imbues plan sponsors with flexibility and discretion to craft programs they think will resonate most with their employees and best encourage them to adopt healthy lifestyle practices, which will improve health outcomes and bring healthcare costs down for everyone. *See* 78 Fed. Reg. at 33172. To be sure, the statute and

Regulation are (correctly) focused on ensuring that a plan sponsor does not adopt a wellness program that is "overly burdensome" or is simply a thinly veiled "subterfuge for discriminating based on a health status factor," 42 U.S.C. § 300gg-4(j)(3)(B); 29 C.F.R. § 2590.702(f)(3)(iii), (f)(4)(iii). But no reasonable person could seriously contend that a wellness program that actively encourages participants to start complying with a reasonable alternative early to maximize the period of time during which they are obtaining the full reward is "overly burdensome" or mere "subterfuge" rather than a legitimate effort to encourage healthy lifestyle choices.

Second, while the 2013 Regulation clearly represents regulatory overreach, these private-party lawsuits take that overreach to an entirely new level. Even the agencies now at least adopt the view that pro-rated rewards are acceptable if employees have an opportunity to qualify for a full plan year worth of rewards (say, by satisfying the reasonable alternative standard before the plan year begins, as Pepsi's plan does, or at the very beginning of the plan year). *See FAQs* 6 (Question 8). But these lawsuits have incredibly taken the position that this subregulatory guidance is lawless and that ERISA itself requires year-round access to year-round refunds even for employees who choose not to enroll in an educational alternative to an outcome-based standard until the plan year is nearly over. JA157 n.12; *see also*, *e.g., Chirinian v. Travelers Cos., Inc.*, 2025 WL 2147271, at *7 (D. Minn. July

29, 2025); *Bailey v. Sedgwick Claims Mgmt. Servs. Inc.*, 2025 WL 2779899, at *10 (W.D. Tenn. Sept. 26, 2025). This approach perhaps best exemplifies the concern regarding "statutory drift and mission creep" when "private enforcers drive law enforcement efforts in new and democratically unaccountable directions" out of a profit-based pursuit. David Freeman Engstrom, *Agencies as Litigation Gatekeepers*, 123 Yale L.J. 616, 638 (2013).

Third, these lawsuits focus on ERISA's fiduciary obligations, framing their claims as being breaches of ERISA's fiduciary duties and violations of ERISA's fiduciary prohibited-transaction provisions.[8] But ERISA's non-discrimination provision and wellness-program requirements are not part of ERISA's fiduciary provisions, and the word "fiduciary" cannot be found in 29 U.S.C. § 1182 *or* 42 U.S.C. § 300gg-4. Nor did DOL cite 29 U.S.C. § 1104—ERISA's fiduciary-duty provision—in its long list of "statutory authority" for promulgating the regulation. 78 Fed. Reg. at 33175. Indeed, the only mention of "fiduciary" in the 2013 Regulation is a reassurance to plan sponsors that compliance has "no effect on other laws" and "is not determinative of compliance with any other provision of ERISA," including "ERISA's fiduciary provisions." 78 Fed. Reg. at 33168 (capitalization

[8] *E.g.,* JA026-030 (¶¶ 66-78); Compl. ¶¶ 63-70, *Plesha v. Ascension Health Alliance*, No. 24-cv-1459 (E.D. Mo. Oct. 30, 2024), Dkt. No. 1; Am. Compl. ¶¶ 68-79, *Williams v. Target Corp.*, No. 24-cv-3748 (D. Minn. Sept. 26, 2024), Dkt. No. 34; Compl. ¶¶ 115-135, *Brown v. Huntington Ingalls Indus., Inc.*, No. 26-cv-34 (E.D. Va. Mar. 12, 2026), Dkt. No. 1.

altered). Nothing about ERISA's non-discrimination provision or its wellness-program requirements relate to fiduciary acts—instead, they relate to the health plan structure chosen by a plan sponsor, which is decidedly *not* a fiduciary act. *See Lockheed Corp. v. Spink*, 517 U.S. 882, 890 (1996); *Hughes Aircraft Co. v. Jacobson*, 525 U.S. 432, 443-444 (1999).

Given the obvious lack of any fiduciary grounding for the wellness-program requirements—including in the 2013 Regulation—private plaintiffs likely would not have ever even contemplated pursuing *fiduciary-breach* claims against plan sponsors related to allegedly deficient wellness programs but for DOL's decision to do so. The agency doubled down on its regulatory overreach in 2017 by suing Macy's based on its implementation of a tobacco surcharge program that allegedly did not comply with the 2013 Regulation—and asserted a claim for breach of ERISA's fiduciary duties. *Macy's*, 2021 WL 5359769. The district court dismissed that claim, holding (twice) that "Macy's acted as a settlor rather than a fiduciary when it created the [program]," and that treating mere implementation of a plan design as a fiduciary act would eviscerate the foundational distinction "between [plan] creation (a settlor function) and implementation (a fiduciary function)." *Id.* at *18; *see also Sec'y of Lab. v. Macy's, Inc.*, 2022 WL 407238, at *3-10 (S.D. Ohio Feb. 10, 2022). The same reasoning applies with full force to the current wave of private wellness-program lawsuits.

Fourth, the interpretation of the statutory phrase "full reward" advanced by Plaintiff here and by her counsel in other lawsuits is largely divorced from ERISA's text. The most straightforward reading of "full reward" is that it ensures that participants who complete a reasonable alternative standard do not receive some fraction of the reward received by those who complete the original standard. In other words, if a wellness program provides a $100 gift card to a sporting-goods store, those who complete the reasonable alternative standard cannot be given a $50 gift card. If the reward is a monthly gym membership, those who complete the reasonable alternative standard also receive a monthly gym membership, rather than a 50% discount to the same gym. This straightforward interpretation of "full reward" gives full meaning to each word in the statute by preventing plan sponsors from providing some lesser percentage of a reward than that provided to those who complete the original standard.

Pepsi's Plan illustrates this straightforward reading of "full reward." Indeed, Pepsi goes above and beyond what the statute requires by allowing participants to avoid surcharges in two ways, both of which are equally (and independently) permissible under the statute. First, participants who complete the cessation program between May 1 and November 30 do not pay the surcharge for the entire *upcoming Plan year*, regardless of whether they continue to use tobacco. Second, participants who complete the program after November 30 through the end of the

following Plan year can have the surcharge removed *prospectively in that plan year*. JA131-132. Pepsi's arguments focus primarily on the specifics of its Plan—it asserts that the Plan satisfies the "full reward" requirement by allowing participants to avoid the surcharge for *the whole upcoming Plan year* if they complete the cessation program by November 30. That is undoubtedly correct, but the specific design of Pepsi's Plan is not the only way to structure a compliant wellness program.

Even if the Pepsi plan provided *only* for *prospective* avoidance of surcharges during the plan year in which a participant completes the cessation program, it would still be lawful. Returning to the gym membership hypothetical, nothing in the statutory phrase "full reward" mandates that the participant who completes the reasonable alternative standard late in the plan year also receive the hypothetical reward gym membership for months that have already transpired, or rebates of the same monetary value. Wellness programs that incentivize participants to complete the standard relevant to their circumstances early in the plan year are not unreasonable, overly burdensome, or mere subterfuge. *See* 42 U.S.C. § 300gg-4(j)(3)(B). Rather, such programs are reasonably designed—perhaps ideally designed—to improve the health of or prevent disease in the participating individual by encouraging participants to enroll in and complete the reasonable alternative standard as early as possible. *Id.* That Pepsi chose to go further by letting participants who complete tobacco cessation between May 1 and November 30

avoid surcharges for the entire upcoming plan year does not alter the analysis; other employers might reasonably determine that the most effective (and most cost-effectively administrable) approach is to incentivize completion of a cessation course as early as possible *each year*.

Plaintiff's contrary interpretation is heavily reliant on principles of agency deference—Plaintiff asks the Court to defer to the 2013 Regulation and to DOL's litigating position in *Secretary of Labor v. Macy's, Inc*., No. 1:17-cv-541 (S.D. Ohio). *See* Opening Br. 31-36; *Macy's*, 2021 WL 5359769, at *15. Neither is entitled to deference. To the contrary, DOL's attempts to leverage agency power to re-interpret and expand the plain text of the ACA should be given particular scrutiny. *See Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 400 (2024).

The 2013 Regulation differs from the ACA amendments in material ways, as described above—such as by changing the universe of participants who are entitled to a reasonable alternative standard and by trying to sneak in a new retroactivity requirement through the preamble. *See supra* pp. 10-15. Agency regulations that repeatedly depart from the plain statutory text are *far* from the "best reading" of that statute. *See Loper Bright*, 603 U.S. at 400. And "[i]n the business of statutory interpretation, if it is not the best, it is not permissible." *Id.*

Plaintiff's invocation of the preamble to impose a universal retroactivity requirement is particularly misguided. Even putting aside the well-settled principle

that agency preambles lack the force of law and do not reflect an agency's consideration in the same way that the regulatory text does,[9] the preamble's purported retroactivity requirement is untethered to ERISA's statutory text, which provides no indication that Congress ever contemplated a retroactivity requirement. *See* 42 U.S.C. § 300gg-4(j). The 2006 Regulation (the regulatory precursor to the ACA) did not include such a retroactivity requirement; to the contrary, one of the examples contained in the 2006 Regulation made clear that part-year awards were indeed viewed as "permissible," *see* 71 Fed. Reg. at 75037, and nothing in the statutory text or the legislative or regulatory history leading to the ACA suggests that Congress ever contemplated a retroactivity requirement.

Moreover, as the district court recognized, deference to HHS, DOL, and Treasury is particularly inappropriate because the "full reward" language the preamble purports to interpret is "parroted" directly from the statute. *See Gonzales v. Oregon*, 546 U.S. 243, 256-257 (2006); *see also Kisor v. Wilkie*, 588 U.S. 558, 578 n.5 (2019) ("[T]his Court has denied *Auer* deference when an agency interprets a rule that parrots the statutory text."); *compare* 42 U.S.C. § 300gg-4(j)(3)(D), *with*

[9] *Wyeth v. Levine*, 555 U.S. 555, 575-576 (2009); *see also Gustavsen v. Alcon Lab'ys, Inc.*, 903 F.3d 1, 13 (1st Cir. 2018) ("[I]t is well-established that a regulatory preamble is incapable of altering regulatory text's plain meaning."); *Seife v. U.S. Dep't of Health & Hum. Servs.*, 440 F. Supp. 3d 254, 275 (S.D.N.Y. 2020) (interpretation contained only in preamble was not promulgated pursuant to agency's authority to make rules carrying the force of law).

29 C.F.R. § 2590.702(f)(4)(iv). "An agency does not acquire special authority to interpret its own words when, instead of using its expertise and experience to formulate a regulation, it has elected merely to paraphrase the statutory language." *Gonzales*, 546 U.S. at 257; *see also United States v. Kahn*, 5 F.4th 167, 176-177 (2d Cir. 2021).

Indeed, deferring to DOL's preamble would "permit the agency, under the guise of interpreting a regulation, to create de facto a new regulation." *Christensen v. Harris Cty.*, 529 U.S. 576, 588 (2000). And there's a reason why DOL did not include the retroactivity requirement in the 2013 Regulation—it clearly would have violated the principle that a final rule must be a "logical outgrowth" from the proposed rule that was subject to notice and comment. *See Nat'l Black Media Coal. v. FCC*, 791 F.2d 1016, 1022 (2d Cir. 1986). This mandate is designed to provide "fair notice" to interested parties so they have the opportunity to comment on or criticize the proposal. *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 174 (2007); *see also Nat'l Black Media Coal.*, 791 F.2d at 1022. Regulated parties had *no* opportunity to comment on a proposed retroactivity requirement, which was not in the post-ACA proposed regulation and was in fact *contrary* to the 2006 Regulation that the ACA was modeled after. Deferring to an agency interpretation that was included in a preamble precisely because it could not (consistent with the APA) be

included in the final rule itself would turn principles of administrative law on their head.

As to Plaintiff's request that this Court defer to DOL's litigating position in *Macy's*: deference to an agency's litigating position is "entirely inappropriate." *Starbucks Corp. v. McKinney*, 602 U.S. 339, 351 (2024) (citation omitted); *see also Rhodes-Bradford v. Keisler*, 507 F.3d 77, 80 (2d Cir. 2007). That rule serves an important purpose: Substituting "counsel's discretion for that of the (agency) is incompatible with the orderly functioning of the process of judicial review." *Inv. Co. Inst. v. Camp*, 401 U.S. 617, 628 (1971) (alteration in original).

In sum, Plaintiff's argument that "full reward" requires full-year rebates covering portions of the year during which a participant did not complete an available original or reasonable alternative standard finds no purchase in the text or statutory history of the ACA, nor can Plaintiff fall back on DOL's preamble or litigating position.

Fifth, and finally, Plaintiff attempts to avoid *any* scrutiny of her claims at the motion-to-dismiss stage by claiming that ERISA's wellness-program provisions (incorporated through the PHSA) establish an "affirmative defense" that ERISA plaintiffs need not address in their pleadings at all. Opening Br. 38-40. But there is nothing in ERISA's text to support this argument. Moreover, the relevant portion of 29 U.S.C. § 1182 (introducing the permissibility of wellness-program provisions)

affirmatively characterizes this as a "[r]ule of construction" for how ERISA's anti-discrimination provision shall not "be construed," *id.* § 1180(c)(3)(A)—not as an "exception" or an "exemption" from the anti-discrimination provision, *contra* 29 U.S.C. § 1106(a); *Cunningham v. Cornell Univ.*, 604 U.S. 693 (2025). Nor does anything in the PHSA textually suggest that Congress was establishing an affirmative defense—it simply echoes § 1182(c) and then sets forth what a wellness-program must include. 42 U.S.C. § 300gg-4(c)(3) (same "[r]ule of construction"); *id.* § 300gg-4(j) (describing requirements for "[p]rograms of health promotion or disease prevention).

To be sure, DOL has characterized ERISA's wellness-program requirements as setting forth an "affirmative defense that can be used by plans." 78 Fed. Reg. at 33160. But that is just another example of the agency's regulatory overreach. ERISA's wellness-program requirements have existed since 1996, but DOL did not ever *hint* that these requirements were an affirmative defense until a throwaway sentence in the preamble to the 2013 Regulation, unaccompanied by reasoning, citation, or any explanation whatsoever. Whether Congress creates an affirmative defense in a statute is an issue of statutory interpretation, *see, e.g.*, *Cunningham*, 604 U.S. 693, not something that agencies decide—and certainly not something agencies are empowered to manufacture in a preamble to a final rule unaccompanied by any reasoning whatsoever.

III. Plan participants who have no medical necessity for failing to comply with a wellness-program standard have no cause of action to complain about the adequacy of a "reasonable alternative" standard.

Even beyond the issues discussed above, there is an additional reason that this Court can and should affirm the judgment below: Plaintiff lacks a statutory cause of action to complain about the adequacy of the Plan's "reasonable alternative" standard.

As this Court has explained in another ERISA case, "[p]laintiffs must establish for each claim that they have what [the court] previously called statutory standing," which asks whether a plaintiff has a "statutory cause of action to sue a defendant." *Collins v. Ne. Grocery, Inc.*, 149 F.4th 163, 170 (2d Cir. 2025) (internal quotations omitted). This analysis applies "traditional principles of statutory interpretation" to determine whether "the plaintiffs here fall within the class of plaintiffs whom Congress has authorized to sue." *Am. Psychiatric Ass'n v. Anthem Health Plans, Inc.*, 821 F.3d 352, 360 (2d Cir. 2016) (citation and quotation marks omitted). The wellness provision of ERISA (through the PHSA) does not provide Plaintiff with a cause of action here.

If an employer offers a wellness program that contains a standard that must be met in order to obtain a reward, the statute is clear that a reasonable alternative standard is required *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).[10] Indeed, the statute's plain text expressly allows plans to seek verification from a physician that a reasonable alternative standard is medically required for a particular participant. 42 U.S.C. § 300gg-4(j)(3)(D)(ii). In other words, the reasonable alternative standard need not be available to *all* participants—only for those for whom it is medically necessary. And those who have no statutory right to a reasonable alternative standard therefore plainly have no cause of action to challenge the *adequacy* of that reasonable alternative standard.

DOL's 2006 Regulation made this point particularly explicit: it said that for "individuals addicted to nicotine" a reasonable alternative standard could be offered via a smoking cessation program, and emphasized that even if such an individual might fail to actually succeed in quitting tobacco, the reasonable alternative standard must continue to be offered for "those individuals for whom it remains unreasonably difficult" to quit tobacco use "due to an addiction." 71 Fed. Reg. at 75019. There is no doubt, then, that as of 2006, DOL understood that the "reasonable alternative" standard need only apply to participants for whom it was unreasonably difficult or medically inadvisable to quit smoking—such as those who suffer from a nicotine addiction—and Congress expressly incorporated that standard (verbatim) into

[10] Because the district court decided the motion to dismiss on other grounds, it declined to decide whether this is the best reading of the statute. JA150 n.8.

ERISA. 42 U.S.C. § 300gg-4(j)(3)(D). Under that framework, merely alleging that one uses tobacco is insufficient to establish that it is "unreasonably difficult" or "medically inadvisable" to refrain from using tobacco. Not all tobacco users are addicted; some smoke only socially or occasionally—by enjoying a cigar while playing a monthly poker game, for example. Those individuals would not satisfy Pepsi's tobacco-free standard, but under the plain text of the statute, the reasonable alternative standard need not be made available to them.

The problem here is that Plaintiff does not allege any facts plausibly suggesting that ERISA entitles her to a reasonable alternative standard in the first place—and therefore she does not have a statutory cause of action to dispute whether the particulars of that standard comply with ERISA. Plaintiff provides *no facts* alleging that a nicotine addiction (or other medical condition) rendered her unable to comply with the tobacco-free requirement for obtaining lower premiums. To the contrary, all she alleges is that she "paid the tobacco surcharge"—an allegation that is not sufficient to establish that she has a statutory cause of action.

Plaintiffs in these wellness-program cases have typically argued that they need not allege a medical condition that made it "unreasonably difficult" or "medically inadvisable" for them to refrain from using tobacco because DOL's 2013 Regulation "clarified" that only some types of wellness programs have an "unreasonably difficult" or "medically inadvisable" trigger, and that for outcome-based programs

(like a tobacco-free program), a reasonable alternative is necessary for all plan participants. JA100-101 (citing HHS' analog to 29 C.F.R. § 2590.702(f)(4)(iv)(A)). But that regulatory language directly contradicts the statutory text and is therefore impermissible. *See Loper Bright*, 603 U.S. at 412; *Art & Antique Dealers League of Am., Inc. v. Seggos*, 121 F.4th 423, 435 (2d Cir. 2024) ("An administrative agency does not have authority to pass regulations that are inconsistent with the meaning of a statute."), *cert. denied*, 145 S. Ct. 2732 (2025).

This conflict is no small matter: every wellness-program case ultimately boils down to whether a plan participant was *discriminated against based on health status* in violation of 29 U.S.C. § 1182 ("Prohibiting discrimination against individual[s] … based on health status"). That is what the wellness-program requirements are all about,[11] and it is the express basis of all lawsuits challenging wellness programs, including Plaintiff's here, *see, e.g.*, Opening Br. 10, 12, 14-15, 21-23, 28. ERISA does not prohibit employers from imposing higher premiums for lifestyle factors like riding a motorcycle or cliff diving. Instead, it prohibits premiums that discriminate on the basis of "health status." 29 U.S.C. § 1182. Accordingly, it makes perfect sense that ERISA requires a plaintiff to demonstrate that she incurred higher premiums because "a health status factor makes it unreasonably difficult or

[11] *See* 42 U.S.C. § 300gg-4 ("Prohibiting discrimination … based on health status"); 29 C.F.R. § 2590.702 (similar).

medically inadvisable" to comply with a wellness program—*i.e.*, that she was *discriminated against on the basis of health status*. 42 U.S.C. § 300gg-4(j)(3)(D).

Plaintiff does not plausibly allege that she has a statutory cause of action to challenge Pepsi's wellness program. Accordingly, this Court can and should affirm the dismissal of Plaintiff's claims for that additional, independent reason.

IV. These wellness-program lawsuits would eviscerate the flexibility Congress afforded to employers and undermine Congress's goal of encouraging healthy lifestyle choices.

In context, it makes perfect sense that wellness-program rewards might only be available on a part-year basis for participants who choose to satisfy a reasonable alternative program partway through the plan year. That properly incentivizes participants to begin and complete the program in a timely manner and thus reap the health benefits for a greater portion of the plan year—even immediately after open enrollment, which typically occurs in the fall before the plan year even begins. In that way, the reward and the health benefit are in perfect sync. Moreover, the statutory and regulatory requirements are designed to ensure that wellness programs are not "subterfuge for discriminating based on a health status factor." 42 U.S.C. § 300gg-4(j)(3)(B); 29 C.F.R. § 2590.702(f)(4)(iii). At the same time, the requirements are designed to give plans a large measure of "flexibility" in designing programs that will be effective and encourage both "innovation" and the greatest degree of employee participation. 78 Fed. Reg. at 33162, 33163, 33172. But under

Plaintiff's theory, under which ERISA mandates that employers provide full-year benefits regardless of when a participant satisfies the reasonable alternative program, employers have *less* flexibility to innovate and craft programs that will best encourage employee participation. An employer that does not want to process retroactive refunds—a logistical nightmare for large plans, and one that provides weaker incentives for healthy behavior—would have to structure their plan to require satisfaction of the reasonable alternative standard *before* the start of the plan year and cut off any access to a reasonable alternative standard once the plan year begins. This illogical position harms employers, by limiting their flexibility to experiment with plan design, and participants, by reducing the benefits. Indeed, it would undermine Congress's twin desires in enacting ERISA: "to offer employees enhanced protection for their benefits" while not "creat[ing] a system that is so complex that administrative costs, or litigation expenses, unduly discourage employers from offering welfare benefit plans in the first place." *Varity Corp. v. Howe*, 516 U.S. 489, 497 (1996). The lower court was right to reject this "no-good-deed-goes-unpunished interpretation." JA156.

At bottom, Plaintiff's wellness-program challenge would replace the flexibility created by Congress and initially recognized by DOL and replace it with a rigid structure in which *only one* type of wellness program is compliant. That outcome has no basis in the statutory text and ultimately would benefit no one but

the lawyers who litigate these lawsuits. The Court should reject Plaintiff's theories and resist that outcome.

CONCLUSION

The district court's decision should be affirmed.

Dated: July 20, 2026

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that this document complies with the type-volume limitations of Federal Rules of Appellate Procedure 29(a)(5) and 32(a)(7)(B) and Local Rules 29.1(c) and 32.1(a)(4)(A) because it contains 6,997 words, excluding the parts of the document exempted by Rule 32(f).

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Dated: July 20, 2026

/s/Jaime A. Santos
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CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing brief with the Clerk of the United States Court of Appeals for the Second Circuit via the ACMS system on this 20th day of July 2026. I certify that all participants in this case are registered ACMS users and that service will be accomplished by the ACMS system.

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