No. 23-1038

IN THE

Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION,

Petitioner,

v.

WAGES AND WHITE LION INVESTMENTS, L.L.C., DBA TRITON DISTRIBUTION, *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

BRIEF *AMICUS CURIAE* OF GOLDWATER INSTITUTE IN SUPPORT OF RESPONDENTS

TIMOTHY SANDEFUR
Counsel of Record
JOHN THORPE
SCHARF-NORTON CENTER FOR CONSTITUTIONAL LITIGATION AT THE GOLDWATER INSTITUTE
500 E. Coronado Road
Phoenix, AZ 85004
(602) 462-5000
litigation@goldwaterinstitute.org

Counsel for Amicus Curiae Goldwater Institute

117035

COUNSEL PRESS
(800) 274-3321 • (800) 359-6859

QUESTION PRESENTED

Whether the United States Food and Drug Administration's ("FDA") denial of Respondents' marketing applications was arbitrary and capricious where FDA changed its position on the authorization requirements without fair notice to Respondents and without considering Respondents' reliance interests, and where the FDA ignored other aspects of the applications the agency previously described as "critical."

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IDENTITY AND INTEREST OF AMICUS CURIAE[1]

The Goldwater Institute was established in 1988 as a nonpartisan public policy and research foundation devoted to advancing the principles of limited government, individual freedom, and constitutional protections through litigation, research, policy briefings, and advocacy. Through its Scharf-Norton Center for Constitutional Litigation, the Institute litigates cases and files amicus briefs when its objectives or those of its clients are implicated.

The Institute is committed to ensuring accountability and limited government in the administrative state, particularly in areas where government regulation affects health and healthcare. To this end, the Institute wrote and helped pass the pathbreaking "Right to Try" law, Pub. Law 115–176, 132 Stat. 1372 (2018), and has advocated for additional reforms to the FDA's approval system to protect patients' rights to access safe and effective new treatments. *See, e.g.*, Goldwater Institute, *Right To Try For Individualized Treatments* (last visited Oct. 10, 2024).[2] The Institute also advocates for principled, sensible approaches to regulating e-cigarettes and other products that can help people quit smoking. *See, e.g.*, *Bates v. Oregon Health Auth.*, No. A180270 (Or. Ct. App. filed Dec. 20, 2022) (constitutional challenge to Oregon's restrictions

1. Pursuant to Rule 37, amicus affirms that no counsel for any party authored the brief in whole or part and that no person other than amicus, its members, or its counsel, contributed money to fund the brief's preparation or submission.

2. https://www.goldwaterinstitute.org/right-to-try-for-individualized-treatments-right-to-try-2-0/.

on advertising for e-cigarette and vape products). The Institute believes its litigation experience and public policy expertise will aid this Court in resolving this case.

SUMMARY OF ARGUMENT

In evaluating Respondents' applications, the FDA had to evaluate whether "permitting such tobacco product to be marketed would be appropriate for the protection of the public health." 21 U.S.C. § 387j(c)(2)(A). The FDA must make this "determin[ation] with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product." *Id.* § 387j(c)(4).

The FDA acted arbitrarily and capriciously in its determination that the proposed products would not "provide a benefit to adult users that would be adequate to outweigh the risks to youth," and in its requirement that Respondents present "evidence" in the form of "a randomized controlled trial and/or longitudinal cohort study" or other "reliabl[e] and robust[]" evidence that demonstrated the benefit of [Respondents' products]." Pet. App. 167a–168a.

In fact, electronic nicotine delivery devices ("ENDS") like Respondents' products provide well-documented benefits to smokers seeking to quit or to transition to safer and healthier alternatives. First, flavored ENDS products reduce harm by offering a vastly less dangerous substitute to conventional tobacco for users seeking to quit or to reduce their conventional tobacco use. Second, ENDS are *more* effective at helping smokers quit or reduce their conventional tobacco use than existing FDA-approved therapies. Third, denying Respondents' applications and

banning flavored ENDS products disproportionately harms vulnerable populations.

ARGUMENT

The Family Smoking Prevention and Tobacco Control Act of 2009—the basis for the FDA's regulatory authority over Respondents' applications for bottled e-liquids in this case—requires the FDA to determine whether "permitting such tobacco product to be marketed would be appropriate for the protection of the public health." 21 U.S.C. § 387j(c)(2)(A). The FDA must make this "determin[ation] with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product." *Id.* § 387j(c)(4).

The FDA's determination regarding the million-plus applications for e-cigarettes and e-liquids was arbitrary and capricious for several reasons. This brief focuses on the FDA's baseless conclusion that the proposed products would not "provide a benefit to adult users that would be adequate to outweigh the risks to youth," Pet. App. 167a, and the FDA's unwarranted requirement that Respondents present "evidence" in the form of "a randomized controlled trial and/or longitudinal cohort study," or other "reliabl[e] and robust[]" proof to demonstrate the benefit of their products. *Id.* 167a–168a. Contrary to the FDA's determinations, flavored ENDS products like Respondents' reduce harm by offering a vastly less dangerous substitute product to conventional tobacco users. Indeed, they are the most effective means of smoking cessation currently available. By denying Respondents' applications, the FDA denied unique public health benefits to vulnerable communities that are disproportionately harmed by tobacco use.

I. Flavored ENDS reduce harm by offering a vastly less dangerous substitute product to conventional tobacco users.

The goal of public health regulation is not *perfection*, which is unattainable and utopian, but rather *improvement*. In other words, the goal is harm reduction, not harm elimination. And that means avoiding, as the aphorism goes, "making the perfect the enemy of the good." The question is not, therefore, whether ENDS products are harmless, but whether they are less harmful than the likely alternative: cigarettes.

Conventional cigarettes are some of the most toxic products available on the U.S. market. Upon combustion, they release more than 6,000 chemicals, including arsenic, ammonia, and radioactive elements. *See* Am. Cancer Soc'y, *Harmful Chemicals in Tobacco Products* (last visited Oct. 10, 2024).[3] Many of these chemicals cause cancer, heart and lung disease, and other serious health problems, making tobacco use the leading preventable cause of death in the United States, and accounting for approximately one in every five American deaths. *See* Am. Cancer Soc'y, *Health Risks of Smoking* (last visited Oct. 10, 2024).[4]

Because ENDS products vaporize liquid instead of burning tobacco, and thus release no carbon monoxide or other combustion products, they are significantly safer than conventional tobacco products like cigarettes.

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3. https://www.cancer.org/cancer/risk-prevention/tobacco/carcinogens-found-in-tobacco-products.html.

4. https://www.cancer.org/cancer/risk-prevention/tobacco/health-risks-of-tobacco/health-risks-of-smoking-tobacco.html.

A substantial body of scientific literature confirms this. For example, a review of more than 800 studies by The National Academies of Sciences, Engineering, and Medicine concluded that e-cigarettes significantly reduced a user's and non-user's exposure to toxicants and carcinogens. *See Public Health Consequences of E-Cigarettes* (Stratton, et al. eds. 2018).[5]

Accordingly, in 2014, when a panel of international experts convened by the International Scientific Committee on Drugs ranked twelve common nicotine-containing products, the panel found that ENDS were among the least harmful products, just behind nasal sprays, oral products, and patches. *See* Nutt et al., *Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach*, 20 European Addiction Research 218 (2014)[6] (rating cigarettes with an overall harm score of 99.6, while ENDS, nasal sprays, oral products, and patches, which each scored less than 5).

While ENDS products are not risk-free, the dramatically reduced risks relative to conventional tobacco products make them an excellent tool for mitigating the harms of smoking. A 2018 study of more than 5,000 participants revealed that smokers who transition to ENDS products for one year have lower levels of carcinogens in their urine, approaching the levels of individuals who have never used tobacco products. Goniewicz et al., *Comparison of Nicotine and Toxicant Exposure in Users of Electronic Cigarettes and Combustible Cigarettes*, 1 JAMA Network

5. https://nap.nationalacademies.org/read/24952/chapter/1.

6. https://karger.com/ear/article/20/5/218/119463/Estimating-the-Harms-of-Nicotine-Containing.

Open e185937 (2018).[7] In fact, if every American smoker switched to ENDS products over the next ten years, this would prevent more than 6 million premature deaths from tobacco use. Levy et al., *Potential Deaths Averted in USA by Replacing Cigarettes with E-Cigarettes*, 27 Tobacco Control 18 (2017).[8]

The harm-reduction benefits of ENDS products are particularly significant among pregnant mothers and newborns. In 2018, the National Center for Health Statistics found that one in fourteen expectant mothers smoked during pregnancy, and in some states like West Virginia, nearly 25% of women reported smoking at least once during pregnancy. Drake et al., *Cigarette Smoking During Pregnancy: United States, 2016*, NCHS Data Brief No. 305 (Feb. 2018).[9] Research has shown that women are more likely to quit smoking during pregnancy if they transition to ENDS products. For example, a 2022 study by the *American Journal of Obstetrics and Gynecology* found that the rate of U.S. smoking cessation during pregnancy was significantly higher among ENDS users (80.7%) than among conventional smokers (54.4%). Shittu et al., *Changes in E-Cigarette and Cigarette Use During Pregnancy and Their Association with Small-for-Gestational-Age Birth*, 226 Am. J. Obstetrics & Gynecology 5 (2022).[10]

Smoking cessation during pregnancy is critical, due to a variety of detrimental birth outcomes associated

7. https://pubmed.ncbi.nlm.nih.gov/30646298/.

8. https://tobaccocontrol.bmj.com/content/27/1/18.

9. https://www.cdc.gov/nchs/products/databriefs/db305.htm.

10. https://pubmed.ncbi.nlm.nih.gov/34864040/.

with smoking, including intrauterine growth restriction, low birth weight, preterm delivery, and reduced head circumference. While some of these adverse effects may be due to fetal nicotine exposure, the principal culprit is probably carbon monoxide, which affects the oxygen-carrying capabilities within fetal blood. *See, e.g.*, Froggatt et al., *The Effects of Prenatal Cigarette and E-Cigarette Exposure on Infant Neurobehavior: A Comparison to a Control Group*, EClinicalMedicine (Oct. 15, 2020).[11] Because ENDS products do not release combustion products like carbon monoxide, ENDS use during pregnancy—while still riskier than complete cessation—is *far* less harmful than conventional tobacco use.

Multiple studies have concluded that ENDS-exposed infants have similar birthweight, head circumference, and gestation length to as infants who were not exposed to tobacco products in utero. For example, a United Kingdom study found that non-smokers and ENDS users had babies who were significantly heavier (3,461 grams and 3,470 grams, respectively) than those who exclusively smoked combustible cigarettes (3,166 grams). McDonnell et al., *Electronic Cigarettes and Obstetric Outcomes: A Prospective Observational Study*, 127 British J. Obstetrics & Gynecology 750 (2020).[12] Despite some documentation of decreased motor maturity among ENDS users, almost all studies on the topic conclude that ENDS use during pregnancy is significantly safer than smoking cigarettes.

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11. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7700948/.

12. https://obgyn.onlinelibrary.wiley.com/doi/10.1111/1471-0528.16110.

These and other benefits of ENDS use relative to conventional tobacco products far outweigh any "gateway" effect whereby non-smokers begin using ENDS products and then progress to conventional tobacco products. *See, e.g.*, *E-Cigarettes Are Not a Gateway into Smoking*, Queen Mary Univ. of London (Sept. 21, 2023)[13] (summarizing "[t]he most comprehensive study to date," which found "no sign that e-cigarettes and other alternative nicotine delivery products promote smoking").

Many studies claiming that ENDS are a "gateway" to conventional cigarettes do not actually present sufficient evidence to support this claim. In fact, even a cursory review of this literature reveals multiple confounding factors that likely account for most or all of the alleged correlation between ENDS use and youth smoking. For example, one such study found that youth who vape are also significantly more likely to engage in other risky behaviors. Chen et al., *E-Cigarettes May Serve as a Gateway to Conventional Cigarettes and Other Addictive Drugs*, 3 Adv. Drug & Alcohol Res. 11345 (June 29, 2023).[14] This study also found that different forms of illicit drug use often co-occur in adolescents (i.e., cigarette use and alcohol consumption) and are associated with other risky behaviors such as unprotected sex, violent and criminal behavior, and antisocial activity. Based on these findings, inferring that ENDS use may lead to conventional cigarette use is tenuous—and certainly far less significant than the substantial benefits illustrated by the literature on harm reduction.

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13. https://www.qmul.ac.uk/media/news/2023/smd/e-cigarettes-are-not-a-gateway-into-smoking.html.

14. https://www.frontierspartnerships.org/journals/advances-in-drug-and-alcohol-research/articles/10.3389/adar.2023.11345/full.

II. ENDS are more effective than FDA-approved therapies at helping smokers quit.

For every 100 smokers who try to quit "cold turkey" (i.e., without any counseling or medication), only three to five will manage to avoid smoking for longer than six months. Office of the Surgeon General, *Smoking Cessation by the Numbers* (last visited Oct. 10, 2024).[15] Thus, for the great majority of smokers wishing to quit, some kind of intervention is critical.

ENDS products are the most successful cessation aid on the market, surpassing FDA-approved treatments like nicotine patches and chewing gum. *See* Hartmann-Boyce et al., *Electronic Cigarettes for Smoking Cessation*, 11 Cochrane Database of Systematic Reviews CD010216 (2022).[16] An article published by Harvard Medical School found ENDS were nearly twice as effective as other approaches to quitting smoking. *See* Shmerling, *Can Vaping Help You Quit Smoking?*, Harv. H. Pub. (Oct. 28, 2021)[17] (citing meta-analysis estimating "that out of every 100 people who tried to quit smoking by vaping, nine to fourteen might be successful," while with "other methods, such as nicotine patches or behavioral counselling, only four to seven smokers out of 100 might quit").

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15. https://www.hhs.gov/surgeongeneral/reports-and-publications/tobacco/2020-cessation-sgr-infographic-by-the-numbers/index.html.

16. https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010216.pub7/full.

17. https://www.health.harvard.edu/blog/can-vaping-help-you-quit-smoking-2019022716086.

One of the largest studies of ENDS products, published in 2024 by researchers at the Hollings Cancer Center at the Medical University of South Carolina, found that across eleven American cities, e-cigarette use increased one's likelihood of quitting even among the most stubborn smokers who reported no intention of quitting. Users of e-cigarettes were more likely to completely abstain, or to reduce their daily number of cigarettes and their number of quit attempts from conventional cigarettes. Carpenter et al., *Effect of Unguided E-Cigarette Provision on Uptake, Use, and Smoking Cessation Among Adults Who Smoke in the USA*, 63 eClinicalMedicine 102142 (Sept. 2023).[18]

III. Banning flavored ENDS disproportionately harms vulnerable populations.

Smoking is far more prevalent—and the harms more salient—among populations who have other poor determinants of health, such as poverty, mental illness, and disabilities. As a result, ENDS products disproportionately benefit these vulnerable groups.

Despite the "good news" that "overall smoking rates in the U.S. have decreased in the past decade and are near historically low levels," "not all people across America are benefitting equally from this decline." American Lung Ass'n, *Top 10 Communities Disproportionately Affected by Cigarette Smoking and Tobacco Use* (last visited Oct. 10, 2024).[19] The public health effects of

18. https://www.sciencedirect.com/science/article/pii/S258953702300319X.

19. https://www.lung.org/research/sotc/by-the-numbers/top-10-populations-affected.

smoking are disproportionately borne by vulnerable populations: smoking rates are higher than average among poor, rural communities, veterans, individuals identifying as "LGBTQ+," adults without a high school degree, lower income earners, indigenous communities, and people suffering from depression or disabilities. *Id.* For example, "[p]eople living in poverty smoke cigarettes more heavily and smoke for nearly twice as many years as people with a family income three times higher." *Id.* Likewise, Native Americans have a higher prevalence of cigarette use than any other racial or ethnic group in the United States. Hodge & Nandy, *Factors Associated with American Indian Cigarette Smoking in Rural Settings*, 8 Int'l J. Env't'l Res. & Pub. H. 944 (2011).[20]

Mental illness also correlates strongly with tobacco use, in part because individuals suffering from mental illness often use nicotine to self-medicate. *See, e.g.*, Duffy et al., *Risk of Smoking and Receipt of Cessation Services Among Veterans Affairs Patients with Mental Disorders*, 63 Psych. Serv. 325, PMC3323716 (2013) [21] (finding among U.S. Department of Veterans Affairs patients the odds of being a current smoker were highest among those with a substance use disorder, schizophrenia, and bipolar disorder). It is also much harder for these individuals to quit smoking: over 70% of smokers with mental illness want to quit, and want to do so for the same reasons mentioned by others (e.g. health and family). But they are significantly more vulnerable to relapse, due to stress, poor medication adherence, and negative feelings associated with their underlying condition.

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20. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3118872.

21. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3323716/.

What's more, the risk factors tend to compound, meaning that the more vulnerable an individual, the more disproportionately he or she suffers the harms of smoking: for example, a 2013 study indicates that 26% of Native American women smoked during the last three months of pregnancy—the highest proportion compared to all other racial and ethnic groups. Tong et al., *Trends in Smoking Before, During, and After Pregnancy—Pregnancy Risk Assessment Monitoring System, United States, 40 Sites, 2000–2010*, 62 Surveillance Summaries (Nov. 8, 2013).[22] Further illustrating this compounding effect, one study on a tribal nation with particularly high smoking rates found that some of the strongest predictors for cigarette usage during pregnancy were depression, unemployment, and low levels of education. Jorda et al., *Protective Factors Against Tobacco and Alcohol Use Among Pregnant Women from a Tribal Nation in the Central United States*, 16 PLoS One, PMC7877617 (Feb. 11, 2021).[23]

ENDS products offer a unique means for members of these vulnerable populations to suffer less harm from tobacco products by quitting or reducing their conventional tobacco use. Like conventional tobacco use, ENDS use correlates with factors like poverty, lower education, and mental illness. *See, e.g.*, Ctr. for Disease Control, *E-Cigarette Use Among Adults*.[24] Many studies have specifically identified ENDS products as a viable way to help with smoking cessation or reduction among

22. https://www.cdc.gov/mmwr/preview/mmwrhtml/ss6206a1.htm.

23. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7877617.

24. https://www.cdc.gov/tobacco/e-cigarettes/adults.html.

vulnerable groups. *See, e.g.*, Gentry et al., *Are Electronic Cigarettes an Effective Aid to Smoking Cessation or Reduction Among Vulnerable Groups? A Systematic Review of Quantitative and Qualitative Evidence*, 21 Nicotine & Tobacco Res. 602 (2019).[25]

Because ENDS products are much less harmful than conventional tobacco use and are effective at helping smokers quit, the FDA's decision not to approve Respondents' flavored ENDS products only adds to the already disproportionate burden on vulnerable populations by denying them one of the few existing opportunities to help reduce or eliminate tobacco-related harms from their lives.

* * *

The FDA had extensive evidence showing flavored ENDS' public health benefits would outweigh any harms, and it ignored this evidence. In doing so, it violated its own policies and procedures in evaluating Respondents' applications, it declined to even review Respondents' proposed marketing and sales access restriction plans "for the sake of efficiency," and it essentially copied from its own prior, limited findings rather than taking into account the extensive body of scientific literature on ENDS. *See* Pet. App. 22a–23a. *See, e.g.*, *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221–22 (2016) (noting that agencies must "provide a reasoned explanation for [a] change" to "their existing policies").

25. https://pubmed.ncbi.nlm.nih.gov/29608714/.

If the FDA had properly reviewed the relevant literature and examined the issue consistent with the law and its own policies, it would have found that flavored ENDS products offer substantial public health benefits in the form of risk reduction for adult tobacco users, far outweighing any detrimental effects on minors or non-smokers. It would have also found that flavored ENDS products are more effective than other treatments the FDA has approved, and that by denying Respondents' applications, it would harm vulnerable communities by denying individuals in those communities one of the few viable means of mitigating the already-disproportionate harms they suffer from tobacco use.

CONCLUSION

The Court should affirm the judgment below.

Respectfully submitted,

Timothy Sandefur
Counsel of Record
John Thorpe
Scharf-Norton Center for
Constitutional Litigation
at the Goldwater Institute
500 E. Coronado Road
Phoenix, AZ 85004
(602) 462-5000
litigation@goldwaterinstitute.org

Counsel for Amicus Curiae Goldwater Institute