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 OF WASHINGTON LEGAL FOUNDATION AS AMICUS CURIAE SUPPORTING RESPONDENTS

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QUESTION PRESENTED

Whether FDA's denial of premarket tobacco product applications because the applicant followed FDA's own directives and evidentiary standards was arbitrary and capricious.

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INTEREST OF AMICUS CURIAE*

Washington Legal Foundation is a nonprofit, public-interest law firm and policy center with supporters nationwide. WLF promotes free enterprise, individual rights, limited government, and the rule of law. Consistent with its free-market mission, WLF believes that the best way to limit smoking's adverse health effects is to provide smokers with less-harmful alternatives to combustible tobacco. So it often files briefs and regulatory comments about the Food and Drug Administration's regulation of modified-risk tobacco products. *See, e.g.*, WLF Comment, *In re Modified Risk Tobacco Product Application for iQOS System* (FDA-2017-D-3001); *In re Cigar Ass'n of Am.*, 812 F. App'x 128 (4th Cir. 2020) (per curiam).

If this Court reverses, millions of Americans would lack access to popular combustible tobacco alternatives. This would lead to more preventable diseases and deaths. As agencies cannot bar such lawful products from interstate commerce without providing due process and following the Administrative Procedure Act, this Court should affirm.

INTRODUCTION

The Court has long recognized the importance of fair notice under the Due Process Clause. Fundamental fairness requires that citizens "be informed as to what the State commands or forbids."

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* No party's counsel authored any part of this brief. No person or entity, other than Washington Legal Foundation and its counsel, paid for the brief's preparation or submission.

Lanzetta v. New Jersey, 306 U.S. 451, 453 (1939). In other words, the fair notice requirement is "the first essential of due process of law." *Connally v. Gen. Const. Co.*, 269 U.S. 385, 391 (1926) (citing *Int'l Harvester Co. of Am. v. Kentucky*, 234 U.S. 216, 221 (1914)).

The Court has often expounded on the right to fair notice when considering vague statutes. The Court has struck down statutes and regulations because parties cannot tell whether their conduct would violate a statute or regulation by reading its text. *See, e.g.*, *Johnson v. United States*, 576 U.S. 591, 595-605 (2015). Vagueness, however, is not the only basis for finding that an agency's action violates due process. Agencies can also violate due process by giving inadequate notice to regulated parties.

Agencies sometimes fail to give adequate notice by not complying with the APA's notice-and-comment rulemaking process. But they can also violate regulated parties' due-process rights by issuing a "new interpretation" "that creates 'unfair surprise' to regulated parties." *Kisor v. Wilkie*, 588 U.S. 558, 579 (2019) (quoting *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 170 (2007)).

That is what happened here. For years, FDA told electronic nicotine delivery system (ENDS) manufacturers that they need provide only certain data to obtain approval for their products. But when faced with a court-imposed deadline to act on applications, FDA denied nearly all of them for following its prior guidance. Rather than take FDA at its word, companies were told they should have assumed that FDA would change its mind and decide

that companies must present evidence that FDA had assured them was unnecessary.

Moving the goalposts is the antithesis of due process of law. When applications were due, regulated parties lacked notice of the information FDA later decided was crucial for approval. Companies spent eight figures for research studies to include with their applications. That money went down the drain when FDA did an about-face and rejected those studies as inadequate.

The APA protects parties' due-process rights by requiring courts to set aside agency actions like FDA's here. Allowing FDA to issue form denials to almost every company that complied with its prior guidance would invite other agencies to follow suit. The APA also cabins agencies' discretion by requiring courts to set aside arbitrary or capricious actions. FDA's actions here are quintessential examples of arbitrary decisions. Rather than rely on relevant science, FDA relied on unrelated findings to deny Respondents' applications. Because the Fifth Circuit correctly held that FDA pulled a bait-and-switch, this Court should affirm.

STATEMENT

The Family Smoking Prevention and Tobacco Control Act of 2009, Pub. L. No. 111-31, 123 Stat. 1776, grants FDA authority to regulate cigarettes and other tobacco products. Among the TCA's goals is to provide FDA with "new and flexible enforcement authority to ensure that there is effective oversight of the tobacco industry's efforts to develop, introduce, and promote less harmful tobacco products." 21

U.S.C. § 387 note § 4. To accomplish this goal, Congress gave FDA authority to address tobacco products' harms.

The TCA requires FDA to determine whether a product introduced to the market after 2007 would be "appropriate for the protection of the public health." 21 U.S.C. § 387j(c)(2)(A). If the answer is no, then the product may not be marketed. To ensure compliance with this provision, manufacturers must submit a premarket approval application before marketing a new tobacco product. *See id.* § 387j(a), (b).

For seven years, the TCA did not cover ENDS products. But then FDA deemed ENDS tobacco products to be covered under the TCA. *See* 21 C.F.R. § 1100.2. This meant that at least 25,000 ENDS products on the market at the time would become illegal overnight. *See Vapor Tech. Ass'n v. FDA*, 977 F.3d 496, 498 (6th Cir. 2020). It also would require ENDS manufacturers to seek premarket approval without direction about what evidence was needed to obtain premarket approval.

So at the same time FDA deemed ENDS products covered by the TCA, it promised not to start enforcement actions against ENDS manufacturers until it developed rules for the premarket applications—by 2018. *Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products*, 81 Fed. Reg. 28,974, 28,977-78 (May 10, 2016). FDA first extended its amnesty to 2022, but then changed the

deadline to 2021 for ENDS products with flavors other than tobacco, menthol, or mint.

In 2019, FDA reassured ENDS manufacturers seeking premarket approval that it "underst[ood] that limited data may exist from scientific studies and analyses." FDA, *Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems: Guidance for Industry*, 12 (June 2019). Thus, manufacturers need not "conduct long-term studies to support an application." *Id.* at 13. Later that year, FDA repeated that it did not think studies lasting six months or more were needed for applicants seeking premarket approval for ENDS products. *Premarket Tobacco Product Applications and Recordkeeping Requirements*, 84 Fed. Reg. 50,566, 50,619 (Sept. 25, 2019).

Activists eventually sued FDA for extending the application deadlines. Because it expected only 6,800 applications, FDA consented to a ten-month deadline for receiving applications and a one-year window for FDA to review the applications. The United States District Court for the District of Maryland ordered FDA to comply with those deadlines. *See Vapor Tech.*, 977 F.3d at 499-500. Because of COVID-19, the court later extended the application deadline by four months. *See id.*

FDA told ENDS manufacturers that their applications could include data "from a variety of sources" and that conducting new nonclinical or clinical studies was unnecessary. Joint Appendix at 34, *Avail Vapor, LLC v. FDA*, 55 F.4th 409 (4th Cir. 2022) (21-2077); *see* Iilun Murphy, *Premarket Tobacco Product Application Content Overview*, 26 (Oct. 23,

2018), https://perma.cc/2JF4-J3ZR. Many ENDS manufacturers relied on that guidance. They were later surprised to receive FDA's marketing denial orders faulting them for not conducting a randomized controlled trial or longitudinal cohort study to contrast flavored ENDS products with an appropriate comparator tobacco-flavored ENDS.

Respondents timely filed their applications for their ENDS products. Following FDA guidance, the applications included results from a focus group study and a cross-sectional perception and intent study. *See* Pet. App. 33a. They also included a marketing plan that had what FDA told Respondents were adequate measures to prevent youth vaping. *See* Pet. App. 17a. FDA denied Respondents' applications because the applications lacked a randomized controlled trial or longitudinal cohort study showing that non-tobacco flavored vaping products were more successful at helping smokers quit than tobacco-flavored vaping products. Pet. App. 166a-176a.

Respondents petitioned the Fifth Circuit for review of FDA's denial orders. The en banc Fifth Circuit granted the petition for review. This Court granted the FDA's certiorari petition to resolve a circuit split on the lawfulness of FDA's actions.

SUMMARY OF ARGUMENT

I. The Fifth Amendment guarantees due process of law. At the heart of this due-process guarantee is the right to know what conduct is prohibited. The Court has long applied this principle in many contexts and continues to do so today.

FDA denied Respondents and other ENDS manufacturers of fair notice of what it required for them to continue marketing and selling their products. In fact, FDA pulled a bait-and-switch. It told manufacturers what information must be included in applications. Then, after the deadline for submitting applications passed, FDA did an about-face and told manufacturers that its instructions were wrong. It then denied Respondents' applications because of these alleged shortcomings. This epitomizes a due-process violation.

II. FDA's denial orders will be used for decades in administrative law textbooks as the essence of arbitrary and capricious agency action. FDA ignored all the evidence Respondents presented because it didn't like the result of those studies, then faulted Respondents for failing to provide other evidence that FDA had said was unnecessary. This arbitrary and capricious process doesn't even consider FDA's about-face caused by congressional pressure. So even if the denials did not deprive Respondents of due process, they must be set aside under the APA.

III. The stakes here may seem low, but a closer look reveals what is at stake if this Court reverses. Every year, pharmaceutical companies spend billions of dollars relying on FDA guidance when developing drugs, vaccines, and medical devices. If that guidance is worthless, companies' research and development budgets will shrink. And reversing would make FDA guidance not worth the paper it's printed on. Affirming would reassure companies that, if they follow FDA's directions, the agency cannot arbitrarily do an about-face.

ARGUMENT

I. FDA'S DENIAL ORDERS DEPRIVED RESPONDENTS OF DUE PROCESS OF LAW BY NOT GIVING FAIR NOTICE OF THE APPLICATION REQUIREMENTS.

Fair notice of what the law requires is at the core of the Due Process Clause. *City of Chicago v. Morales*, 527 U.S. 41, 58 (1999) *(*citing *Lanzetta*, 306 U.S. at 453); *see* Pet. App. 27a (citations omitted). This is not a new development in the law. Almost 100 years ago, the Court described the fair notice requirement as "the first essential of due process of law." *Gen. Const. Co.*, 269 U.S. at 391 (citing *Int'l Harvester Co. of Am.*, 234 U.S. at 221).

The fair-notice requirement is not limited to statutes or formal regulations. Agencies may not "depart from a prior policy sub silentio or simply disregard rules that are still on the books." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *see Menkes v. Dep't of Homeland Sec.*, 486 F.3d 1307, 1310, 1314 (D.C. Cir. 2007). That is because due-process principles require agencies to "provide regulated parties fair warning" of what the agency "prohibits or requires" before taking adverse action. *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 156 (2012) (quotation omitted).

Fair notice bars agencies from announcing positions and then springing an "unfair surprise" by penalizing regulated parties for their "good-faith reliance" on the agency's representations. *Christopher*, 567 U.S. at 156-57 (quotation omitted); *see* Pet. App. 41a. This principle applies to both formal

and informal guidance. *See Morton v. Ruiz*, 415 U.S. 199, 235 (1974); *PHH Corp. v. CFPB*, 839 F.3d 1, 48 (D.C. Cir. 2016), *reinstated in relevant part*, 881 F.3d 75, 83 (D.C. Cir. 2018) (en banc).

FDA's denial orders flout this well-settled rule. They fault Respondents for not conducting a "randomized controlled trial[,] longitudinal cohort study," or similarly "reliabl[e] and robust[]" study "over time" comparing the effectiveness of "flavored" vs. "[t]obacco-flavored" products in promoting smoking cessation. Pet. App. 317a. And FDA now treats "cross-sectional surveys, consumer perception studies, and general scientific literature" as unreliable on this score. *Lotus Vaping Techs., LLC v. FDA*, 73 F.4th 657, 666 (9th Cir. 2023).

But any shortcomings in Respondents' applications flowed from FDA's own instructions to applicants. It continually reassured manufacturers that it "did not expect that applicants would need to conduct" longitudinal studies. *Liquid Labs LLC v. FDA*, 52 F.4th 533, 540 (3d Cir. 2022) (cleaned up). FDA also disavowed requiring longitudinal studies, including "randomized controlled clinical trials." *E.g.*, 84 Fed. Reg. at 50,619.

These statements alone are bad enough. Yet they only scratch the surface of FDA's bait-and-switch approach here. Its prior instructions also explicitly encouraged submission of the very evidence it later rejected. FDA "support[ed] the use of different types of studies, methods, instruments and analyses" from various sources. *See* Letter from Mary Kushman, Lead Toxicologist, FDA to Bidi Vapor LLC, USA (May 8, 2020). As to cessation, FDA offered "[e]xamples of

information that FDA recommend[ed]" as evidence of "likelihood of * * * cessation." FDA, *Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems* ("2016 guidance"), 36 (May 2016). This included studies that FDA now considers unreliable—"[p]ublished literature" and "observational studies (perception, actual use, or both) examining cessation behaviors." *Id.* at 37.

As to flavored products, FDA asked manufacturers to "describe consumer perceptions among current ENDS users and other tobacco users for appeal." 2016 guidance, *supra* at 40. It even told manufacturers to supply "published reports and data on consumer perceptions," including "data [they] collect[ed] on consumer perceptions" to gauge "intentions to use the product." *Id.* at 36. "Then FDA flip-flopped." Pet. App. 32a.

FDA's flip-flop creates obvious unfair surprises. FDA issued guidance to "assist persons submitting [applications] for [ENDS]" products, "to improve the efficiency of application submission and review." FDA, *Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems*, cover (Mar. 2023). FDA expressly sought to "enable ENDS manufacturers to consider and strengthen their applications based on the final PMTA for ENDS guidance." Decl. of Mitchell Zeller, Dir., Ctr. For Tobacco Prods., FDA, ¶ 13, *Am. Acad. of Pediatrics v. FDA*, 399 F. Supp. 3d 479 (D. Md. 2019) (No. 18-cv-883).

Respondents spent significant sums of money submitting studies that followed FDA's guidance. FDA cannot then penalize Respondents—by denying

their applications—for faithfully adhering to FDA's instructions. FDA's technical review acknowledges that FDA moved the evidentiary goalposts, based on what FDA had "learned" from "review[ing applications] for flavored ENDS so far." Pet. App. 181a n.vi. But if FDA wanted to change its evidentiary requirements based on its "deepened * * * understanding of the [appropriate for the protection of public health] evaluation," Pet. App. 201a, it should have acknowledged that shift before the application deadline and offered a "detailed justification." *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016) (quoting *Fox Television*, 556 U.S. at 515).

The APA forbids FDA from imposing new requirements on regulated parties after it is too late for them to comply. As the new requirements were "a substantive rule," *R.J. Reynolds Vapor Co. v. FDA*, 65 F.4th 182, 193 (5th Cir. 2023) (citation omitted), they violated Respondents' due-process rights. *See* Pet. App. 56a (FDA "did not give manufacturers fair notice of the rules"). And because the APA bars such due-process violations, the Fifth Circuit correctly granted Respondents' petition for review.

II. FDA'S DENIAL ORDERS WERE ARBITRARY AND CAPRICIOUS.

The Court requires agencies to "articulate a satisfactory explanation for [their] action[s]." *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 591 U.S. 657, 682 (2020) (quoting *Motor Vehicle Mfrs. Assn. of U.S., Inc. v. State Farm Mut. Auto. Ins.,* 463 U.S. 29, 43 (1983)). FDA claims that it weighed the risks of youth usage against the benefits of flavored ENDS products' reducing or

eliminating adult smoking. But it never actually weighed the costs and benefits because it disregarded key evidence.

FDA's conclusions about the risks of youth usage undergird its whole approach. FDA continues to view youth usage as a substantial threat, citing general studies about youths' using closed-system products—small, highly portable, and often disposable devices. It also purports to rely on scientific literature and consumer studies showing that flavors appeal more to youth than do tobacco-flavored or unflavored products. *See* Pet. App. 189a-191a.

WLF opposes youths' using ENDS products. Respondents similarly condemn youths' using ENDS. *See, e.g.*, Pet. App. 17a-18a. But FDA refused to consider evidence that its general risk assessment does not apply to Respondents' bottled e-liquid products used in tanks. *See* Pet. App. 16a. As former FDA commissioner Dr. Scott Gottlieb confirmed, "kids just don't like those big open-tank contraptions." Nicholas Florko, *Former FDA Commissioner Calls for a Full Ban on Pod-Based E-Cigarettes*, Stat (Nov. 12, 2019), https://perma.cc/ WRW6-ST8C.

FDA "did not * * * assess" the "aspects of the applications" that showed that youth are unlikely to use Respondents' products. Pet. App. 168a. Rather, it concluded that "across * * * different device types, the role of flavor is consistent." Pet. App. 116a (cleaned up). This was another abrupt change in course. In 2020, FDA found that youths "overwhelmingly prefer cartridge-based ENDS products" because of their concealability, high nicotine content, and ease of use.

Pet. App. 114a (cleaned up); *see also* Pet. App. 13a ("cartridge-based products [are] popular with young people" because of their "relatively small size that allows for easy concealability" (quotation omitted)). These characteristics are noticeably missing from Respondents' products. Yet FDA painted with a broad brush to conclude that flavor drove youth ENDS usage. Although that may be true within a given ENDS product type, FDA could not cite any evidence about the effect of flavor across all product types. The evidence shows that those who use Respondents' products are typically in their 40s. While this may sound youthful to octogenarians, it is not the vulnerable youth that FDA was worried about.

The Centers for Disease Control and Prevention's most recent data confirms that FDA missed the mark on youth ENDS use. It shows that youth use of tank-based ENDS compatible with Respondents' bottled e-liquids had decreased in recent years, *despite* the removal of flavored cartridge-based products from the market. *Compare* Teresa W. Wang et al., *E-cigarette Use Among Middle and High School Students – United States, 2020*, 69 Morbidity & Mortality Weekly Report 1310, 1310-12 (2020) (youths' use of ENDS dropped from 27.5% to 19.6%, of which only 14.8% used a tank system) *with* Eunice Park-Lee et al., *Notes from the Field: E-Cigarette Use Among Middle and High School Students – National Youth Tobacco Survey, United States, 2021*, 70 Morbidity & Mortality Weekly Report 1387, 1387-88 (2021) (youths' use of ENDS dropped from 19.6% to 11.3%, of which only 7.5% reported using a tank system).

This data shows that the percentage of youths who used a tank system after flavor-based cartridge ENDS were taken off shelves in 2020 decreased—not increased—by almost 50%. This would make no sense if FDA's assumption that flavor drives everything for youths was correct. Under FDA's reasoning, youths would have substituted tank-based systems for the cartridge systems once the cartridges exited the market. Because the exact opposite occurred, it further exposes FDA's conclusion that flavors drive youth initiation across ENDS device types as lacking a rational basis in the data and FDA's overall decision as arbitrary and capricious.

FDA also ignored evidence showing Respondents' successful efforts to prevent youth access. Respondents' applications detailed their thorough auditing and age-verification measures and marketing strategy that targeted only adults. *See, e.g.*, Pet. App. 17a-18a. But FDA acknowledged "not evaluat[ing] any" of this evidence. Pet. App. 201a n.xix. Instead, citing other applications, FDA claimed to be "[un]aware of access restrictions that, to date, have been successful in sufficiently decreasing the ability of youth to obtain and use ENDS." *Id.* Yet FDA had earlier confirmed that age-verification protections like Respondents' "would protect kids" by "preventing access to flavored" products. FDA, *Statement from Comm'r Scott Gottlieb, M.D., on proposed new Steps to protect youth by preventing access to flavored tobacco products and banning menthol in cigarettes* (Nov. 15, 2018), https://perma.cc/HQ8W-PFSN. Ignoring this contrary evidence was arbitrary and capricious. *See Roe v. Dep't of Def.*, 947 F.3d 207, 225 (4th Cir. 2020); *Clark County v. FAA*, 522 F.3d 437, 442-43 (D.C. Cir. 2008).

The Eleventh Circuit correctly analyzed this issue. There, as here, FDA "refused to consider the marketing and sales-access-restriction plans" showing that the applicant could limit youth use of the ENDS products. *Bidi Vapor LLC v. FDA*, 47 F.4th 1191, 1195 (11th Cir. 2022). Chief Judge Pryor, writing for the court, found this action to be "arbitrary and capricious." *Id.*

FDA also concluded that, to overcome the perceived high risk of youth usage, Respondents must produce especially rigorous evidence of countervailing benefits to adult smokers. *See Lotus*, 73 F.3d at 672; *Prohibition Juice Co. v. FDA*, 45 F.4th 8, 21 (D.C. Cir. 2022). Thus, if FDA miscalculated the risks of youth usage, it also mis-calibrated the evidentiary standard for judging benefits to adult smokers.

Even so, FDA's sky-high evidentiary mandate for showing benefits for smokers is arbitrary. FDA demands product-specific studies contrasting the appeal of flavored vs. tobacco-flavored products. Yet, as discussed above, FDA saw no need for such specifics in asserting risks to youth. In fact, it found that it need not consider more specific studies. The reason for this disparity was simple: the product-specific studies for youth usage did not support FDA's position but the broad studies did.

Similarly, to show that adult smokers reduce or stop smoking, FDA declared all "cross-sectional surveys, consumer perception studies, and general scientific literature" surveys inherently unreliable. *Lotus*, 73 F.4th at 666. Yet FDA had earlier called these very same studies "the best available evidence" of youth usage. Pet. App. 257a n.xxii. FDA thinks that

product-specific features drive adult cessation but not youth initiation. Pet. App. 256a n.xx. This "self-contradictory, wandering logic does not constitute an adequate explanation." *Del. Dep't of Nat. Res. & Env't Control v. EPA*, 785 F.3d 1, 16 (D.C. Cir. 2015) (quotation omitted).

FDA also failed to "adequately consider the impact of" its extraordinarily specific evidentiary standard. *See Ackerman v. U.S. Dep't of Agric.*, 995 F.3d 528, 533-34 (6th Cir. 2021). FDA ignored the consequences of employing a rationale that apparently rejects all flavored ENDS products for insufficient evidence using cookie-cutter reasoning. Those denials are forcing an exodus of products from the market—products that FDA acknowledges former smokers rely on to stop smoking. *See* FDA, *FDA Issues Decisions on Additional E-Cigarette Products*, PR Newswire (Mar. 24, 2022), https://perma.cc/TG5A-AHYH. FDA had cautioned that this "public health outcome" was to be "avoided if at all possible" because of the "serious" risk that former adult smokers would switch back to cigarettes. Zeller Decl., *supra* ¶¶ 12, 15. FDA likewise failed to consider that its denials could cause ENDS users to turn to the illicit market—another problem FDA previously recognized. *See* 81 Fed. Reg. at 29,007. Now FDA says nothing about what will happen to millions of former smokers. FDA's erratic regulatory approach was arbitrary and capricious.

III. REGULATED PARTIES WILL BE UNABLE TO RELY ON ANY AGENCY GUIDANCE UNLESS THIS COURT AFFIRMS.

This case is vital to the ENDS industry. At the start of the process, FDA expected to receive about 6,800 ENDS applications. Although that may seem like a lot, it is small in the scheme of our nation's economy. As usual, however, FDA missed the mark by light years. It received about 6.5 million ENDS applications, or over 900 times its projection. The astronomically high number of applications shows just how entrenched ENDS products are in our nation's marketplace. This alone confirms the reach of the FDA's abdication of its duty by issuing form denial letters to millions of ENDS applicants.

But the effects of this case will be felt far beyond the ENDS market. FDA, of course, must also approve prescription drugs for marketing in the United States. The process for obtaining that approval is long and arduous. Companies must go through multiple stages of clinical trials to show that the drug is safe and effective for human use. These studies normally take years but can sometimes last over a decade.

Drug manufacturers rely on FDA guidance when deciding how to structure their clinical trials so that drugs can be approved if the clinical trials are successful. Yet now drug companies undertaking costly research and development must assume the risk that FDA will do an about-face when ruling on their drug applications. Imagine a company that has spent hundreds of millions of dollars following FDA guidance while conducting clinical trials over a

decade. Then after the company submits its drug application, FDA changes its mind and wants a different type of clinical trial—one that will take years and millions of dollars to complete.

Under FDA's view of fair notice, the APA allows such flip-flopping. That is, FDA is not bound by its guidance and need not tell companies when it changes its mind or give them fair notice of the regulatory requirements. It can flip-flop any time its leadership faces tough questions at a congressional hearing.

Nor are drugs and tobacco products the whole of FDA's regulatory authority. Like drugs, vaccines (normally) go through years or decades of research and testing that cost millions of dollars. If this Court reverses, FDA could decide that all that testing was for nothing if a politician pressures FDA to change the requirements for clinical trials.

Medical devices must also undergo rigorous testing before sales can begin. But fewer companies will invest in researching and developing new devices if FDA gets to change the rules mid game. In short, any party following FDA regulations will have to factor in the chance of FDA's changing its requirements when deciding whether to invest in promising research.

The rule this Court announces, of course, will not be limited to FDA. The decision will control whether agencies may change their minds and deprive regulated parties of fair notice. If this Court reverses, nothing will stop the National Highway Traffic Safety Administration from changing its

guidance about automobile testing after production has started. This would mean that cars slated to hit the road soon could be blocked because of a NHTSA about-face. *Cf. United States v. Chrysler Corp.*, 158 F.3d 1350, 1356-57 (D.C. Cir. 1998) (agreeing with John G. Roberts, Jr. that NHTSA acted arbitrarily and capriciously by ordering a recall because it changed its guidance). Again, that would mean millions of dollars and years of innovation wasted because of an unelected bureaucrat's decision to alter requirements after the fact.

The same logic applies to any other product that needs federal regulatory approval. Be it something used on the ground, like herbicides regulated by the Environmental Protection Agency, or something that flies overhead, like airplanes regulated by the Federal Aviation Administration, development would slow if regulated companies must guess whether agencies will change their minds down the road.

It may be funny when Lucy yanks the football away from Charlie Brown at the last second in a Peanuts comic strip. It is not funny when a federal agency does it to millions of companies. The only way to stop this regulatory uncertainty is to affirm. Doing so will remind agencies that they must provide fair notice of what is required of regulated parties. Unannounced and poorly reasoned switcheroos will not survive judicial scrutiny.

CONCLUSION

This Court should affirm.

Respectfully submitted,

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