

# SUPREME COURT OF THE UNITED STATES

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IN THE SUPREME COURT OF THE UNITED STATES

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FOOD AND DRUG ADMINISTRATION,            )  
  Petitioner,            )  
  v.                                    ) No. 23-1038  
WAGES AND WHITE LION INVESTMENTS,    )  
L.L.C., d/b/a TRITON DISTRIBUTION,    )  
ET AL.,    )  
  Respondents.            )  
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3   FOOD AND DRUG ADMINISTRATION,           )  
4                                    Petitioner,           )  
5                                    v.                                    ) No. 23-1038  
6   WAGES AND WHITE LION INVESTMENTS,    )  
7   L.L.C., d/b/a TRITON DISTRIBUTION,    )  
8   ET AL.,                                    )  
9                                    Respondents.           )  
10  - - - - -

11  
12                                    Washington, D.C.  
13                                    Monday, December 2, 2024

14  
15           The above-entitled matter came on for  
16   oral argument before the Supreme Court of the  
17   United States at 10:03 a.m.

18  
19   APPEARANCES:  
20   CURTIS E. GANNON, Deputy Solicitor General, Department  
21           of Justice, Washington, D.C.; on behalf of the  
22           Petitioner.  
23   ERIC N. HEYER, ESQUIRE, Washington, D.C.; on behalf of  
24           the Respondents.  
25

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P R O C E E D I N G S

(10:03 a.m.)

CHIEF JUSTICE ROBERTS: We will hear argument first this morning in Case 23-1038, Food and Drug Administration versus Wages and White Lion Investments.

Mr. Gannon.

ORAL ARGUMENT OF CURTIS E. GANNON  
ON BEHALF OF THE PETITIONER

MR. GANNON: Mr. Chief Justice, and may it please the Court:

Under the Family Smoking Prevention and Tobacco Control Act, a manufacturer may introduce a new tobacco product only with authorization from the Food and Drug Administration. An applicant must show that the marketing of its product would be appropriate for the protection of the public health, which requires FDA to take into account both the likelihood that existing users of tobacco products will stop using such products and the likelihood that those who do not use tobacco products will start using them if the product is marketed.

Respondents' nicotine solutions for

1 e-cigarettes are flavored to taste like fruit,  
2 candy, or various desserts. FDA denied their  
3 applications, concluding that Respondents failed  
4 to show that their products have sufficient  
5 benefits for existing smokers to offset the  
6 serious risk that the flavors pose to attracting  
7 youth to the use of tobacco.

8           Alone among the courts of appeals, the  
9 Fifth Circuit found FDA's reasoning to be  
10 arbitrary and capricious. But each of its five  
11 rationales was incorrect, and Respondents barely  
12 defend any of them, instead emphasizing other  
13 meritless objections that no court has  
14 countenanced.

15           Respondents were not unfairly  
16 surprised by FDA's denials. They now claim that  
17 they had no idea they needed to compare their  
18 flavored products with tobacco-flavored  
19 e-cigarettes. But their applications drew such  
20 a comparison. They just did not have sufficient  
21 scientific evidence to bear out their claim that  
22 non-tobacco flavors are "crucial to getting  
23 adult smokers to make the switch."

24           Nor did Respondents suffer any  
25 prejudice from FDA's failure to look at their

1 marketing plans. They've identified no features  
2 that FDA has not already found are insufficient  
3 to mitigate the heightened risk of youth uptake  
4 that flavored e-cigarettes pose, making the  
5 Fifth Circuit's remand to FDA a useless  
6 formality.

7 This Court should reverse the Fifth  
8 Circuit's outlier decision.

9 I welcome the Court's questions.

10 JUSTICE THOMAS: Well, in fairness to  
11 Respondents, I think their argument is that the  
12 guidance were actually a moving target, that  
13 either they weren't clear or you changed the --  
14 the guidance as time went on.

15 MR. GANNON: That is their argument,  
16 Justice Thomas, but I think that the key point  
17 is that they knew from the statute that they  
18 needed to be making this comparison about what  
19 the benefits were with respect to existing  
20 smokers and weighing that against the potential  
21 costs with respect to non-smokers and attracting  
22 youth.

23 They knew throughout that FDA was  
24 concerned about the fact that flavors are  
25 attractive to youth, and that's the second

1 column that was going to be problematic. They  
2 knew then, therefore, that if that was a  
3 heightened risk on that side, that they needed  
4 to show a heightened benefit on the other side.

5 And, as I said in my introduction,  
6 their applications acknowledged that they were  
7 trying to make this claim. This is clear. If  
8 you look at their application, they say when  
9 they're considering the question of evaluating  
10 the role of flavors with respect to population  
11 health incomes -- this is their application --  
12 "relevant questions include the impact of  
13 flavors on adult smokers who transition or not  
14 to e-cigarettes." That's at page 355 of the  
15 Joint Appendix for Triton's application. The  
16 same thing is on page 448 for Vapetasia's  
17 application.

18 So they were trying to make this  
19 argument, and they said that the research is in  
20 its infancy. But their own review of the  
21 scientific literature said that no conclusions  
22 can be drawn about the association of  
23 e-cigarette flavors and smoking cessation. And  
24 so the data just weren't there when they were  
25 filing their application in 2020.

1 CHIEF JUSTICE ROBERTS: Do you  
2 recognize an obligation to tell people what they  
3 have to do to comply with your regulation, or do  
4 you think it's simply an obligation not to  
5 mislead?

6 MR. GANNON: Well, we think that in  
7 this context, the statute gave them the -- the  
8 basic calculus that FDA was going to apply. FDA  
9 did give guidance saying that this is the way  
10 we're thinking about this right now. That was  
11 non-binding guidance.

12 We acknowledge that we can't mislead  
13 them about that. I don't think they were misled  
14 at all. And we -- we -- we can't mislead them.  
15 We can't change our approach without  
16 acknowledging that we're changing our approach  
17 and considering potential reliance interests  
18 that any applicants might have had in reliance  
19 on things that we previously said, but --

20 CHIEF JUSTICE ROBERTS: So you -- you  
21 do have to give them notice about how to comply?

22 MR. GANNON: No. We think that we  
23 could have -- we could have given no guidance  
24 and FDA would have been applying the statutory  
25 criteria here, which has both halves of the



1 calculus that I already said. It specifically  
2 says that they have the burden of proof, that  
3 they need to supply the evidence. It says that  
4 they have to supply evidence that the -- about  
5 whether their tobacco product -- this is a quote  
6 -- "presents less risk than other tobacco  
7 products." That's at subsection (b)(1)(A) on  
8 page 5a of our appendix.

9 They're supposed to be providing --  
10 providing scientific data. The statute requires  
11 that. It says there should be well-controlled  
12 studies, unless the FDA decides that other  
13 scientific evidence is actually sufficient in  
14 order to prove their case.

15 The FDA's guidance was consistent with  
16 all of that. And the only thing that the Fifth  
17 Circuit said is that they thought that FDA  
18 needed -- had -- had said that they needed a  
19 particular type of study. And we think that  
20 that's -- that's clearly not true. At the time  
21 FDA was making its decisions, it hadn't changed  
22 what types of studies needed to be used to prove  
23 up the things that the statute required them to  
24 prove.

25 Throughout, they said, you need good

1 evidence. That's what the statute requires.  
2 Randomized controlled trials and longitudinal  
3 cohort studies would be good, but we're not --  
4 we don't necessarily think you have to have  
5 those. But you still have to have good  
6 evidence. That was true throughout. That's  
7 true on this statute.

8 JUSTICE ALITO: Well, the July 9  
9 internal document -- and I recognize it's  
10 internal -- seems to go further on the question  
11 of comparing tobacco-flavored products and the  
12 type of products that you describe.

13 It says, "In particular, the evidence"  
14 -- this is 243 of the Joint Appendix. "In  
15 particular, the evidence necessary for this  
16 evaluation would be provided by either a  
17 randomized control trial or a longitudinal  
18 cohort study. The absence of these types of  
19 studies is considered a fatal flaw, meaning any  
20 application lacking this evidence will likely  
21 receive a marketing denial order."

22 MR. GANNON: Yes, that is something  
23 that the July memo said. I note that even  
24 though it says "fatal flaw," it says "likely  
25 receive" a denial order. So it wasn't even

1       literally fatal.

2                   But that memo was withdrawn a month  
3 later, and -- and so it did not govern the  
4 process. And the actual decision documents here  
5 make it clear that there could have been other  
6 evidence that was used to establish the thing  
7 that they knew they were trying to establish  
8 here. And that's what FDA said in its denial  
9 order. It said you could have shown this with  
10 other evidence, but you didn't have sufficient  
11 evidence.

12                   And they criticize FDA for using what  
13 they call a check-the-box format. I mean, it  
14 had -- there was Box A, do you have randomized  
15 control trial? No. Box B, do you have a  
16 longitudinal cohort study? No. But there was  
17 also Box C, which was other evidence. So there  
18 literally was a box for anything else that they  
19 had --

20                   JUSTICE ALITO: Well, what --

21                   MR. GANNON: -- that would satisfy the  
22 statutory criteria of being sufficient  
23 scientific evidence.

24                   JUSTICE ALITO: Concretely, what would  
25 fall into Box C? What would be an adequate

1 substitute for either a randomized control trial  
2 or a longitudinal cohort study?

3 MR. GANNON: Well, FDA in advance said  
4 it wasn't saying there is -- there's any  
5 particular thing you need. You need sufficient  
6 scientific evidence to persuade us that this is  
7 true.

8 And what they ended up providing was a  
9 review of the scientific literature that said  
10 there are no sufficiently reliable trials that  
11 establish a connection between flavors and adult  
12 cessation with respect to cigarette smoking.  
13 And -- and so it wouldn't have to be those  
14 particular trials. There could have been other  
15 surveys in the -- in the literature.

16 Had there been other studies in the  
17 literature that actually established this, there  
18 was this type of evidence about the -- about  
19 unflavored e-cigarettes that was out there.  
20 But, in -- in this instance, there -- there  
21 wasn't evidence that they needed in order to  
22 show their case, that flavors are crucial to  
23 getting adults to switch.

24 JUSTICE ALITO: Well, is this an  
25 adequate -- an accurate summary of the -- of the

1 FDA's position? It seems to be what you just  
2 said: You may be -- you may succeed if you have  
3 a randomized control trial or a longitudinal  
4 cohort study. It's possible that you could  
5 succeed if you had something else, but we're not  
6 going to tell you concretely what that something  
7 else might be?

8 MR. GANNON: What -- I mean, what --

9 JUSTICE ALITO: What -- what  
10 concretely would be an adequate substitute for  
11 either of those?

12 MR. GANNON: It would have to --

13 JUSTICE ALITO: What kind of a study  
14 would it be?

15 MR. GANNON: -- it would have to be  
16 valid scientific evidence that was sufficient to  
17 evaluate the product. That's what the statute  
18 says. That's in (c)(5)(B) on -- reprinted on  
19 page 9a of the government's brief.

20 And -- and so it needs to be  
21 scientific evidence. It could have been -- it  
22 didn't have to necessarily be about this  
23 particular product. It needed -- there could be  
24 sufficient evidence about other products and  
25 then an explanation about why your product is

1 sufficiently similar to the product at issue in  
2 order to say that we should be able to claim the  
3 same benefits that are over there.

4 The FDA talked about bridging studies,  
5 things like that, that could have been out  
6 there. They didn't have that sort of evidence.

7 Instead, they have inconclusive  
8 evidence about whether adults really need  
9 flavors to switch, and that's where they failed  
10 on that part of the statutory calculus.

11 JUSTICE BARRETT: Mr. Gannon, can I  
12 ask you a question about fair notice?

13 MR. GANNON: Sure.

14 JUSTICE BARRETT: So you say that it  
15 shouldn't apply here because this was the denial  
16 of an application, it was not a punishment.

17 So there's this line of D.C. Circuit  
18 cases about airwaves. Could you distinguish  
19 those for me? Would we need to worry about  
20 those?

21 MR. GANNON: Well, I -- I -- I think  
22 what we're saying is that the Due Process  
23 doctrine that the other side is drawing upon we  
24 think is inapplicable here. We think that there  
25 is fair notice that needs to be required in --

1 in terms of what arbitrary-and-capriciousness  
2 review requires.

3 FDA can't mislead people. It can't  
4 change its position without explaining that  
5 it's -- it's changing its position. But we're  
6 saying that in this context, they already knew  
7 enough from the way the statute is constructed  
8 that they didn't need any additional guidance  
9 from the agency in order to know what they  
10 should try to prove in order to --

11 JUSTICE BARRETT: Are those D.C.  
12 Circuit cases right or wrong?

13 MR. GANNON: I -- I --

14 JUSTICE BARRETT: Do you read them as  
15 applying some sort of additional fair notice  
16 standard --

17 MR. GANNON: I -- I --

18 JUSTICE BARRETT: -- apart from  
19 arbitrary and capriciousness is what I meant?

20 MR. GANNON: I -- I'm not sure whether  
21 it's additional for -- for what the APA requires  
22 in arbitrary and capricious. I think that what  
23 I'm saying, in the D.C. Circuit case that  
24 decided this case, this issue, said that the  
25 point is that they weren't misled about what

1 they needed to show.

2           And so we think that it is clear that  
3 they knew enough in order to make their  
4 application, and that's why they were barking up  
5 the right tree. They were trying to make  
6 exactly the comparison that -- that FDA, at the  
7 end of the process, said that they had failed to  
8 make. They just didn't have the particular --  
9 they didn't have sufficient scientific evidence  
10 on that score.

11           JUSTICE GORSUCH: Mr. Gannon, if I  
12 might just follow up on that for a moment.

13           Your brief says that the Due Process  
14 Clause doesn't apply here and that there's no  
15 constitutional right to fair notice. And that  
16 surprised me a little bit. Imagine I'm a  
17 restaurant owner and I've been operating for  
18 some time and the city health department tells  
19 me now they're going to shut -- shut down the  
20 business unless I can show that the food I serve  
21 provides a net benefit to public health.

22           Wouldn't due process require an  
23 opportunity for notice and a hearing?

24           MR. GANNON: I -- I think, in -- in  
25 those circumstances, maybe so, Justice Gorsuch.



1 But our point here is that this is a statute  
2 that says that these products are unlawful  
3 unless they have been authorized for marketing  
4 by FDA. And -- and so, once -- once --

5 JUSTICE GORSUCH: I understand that.  
6 Same -- same thing in the hypothetical, though.  
7 They're going to be -- your business is going  
8 to -- your existing business is going to be  
9 unlawful --

10 MR. GANNON: Well --

11 JUSTICE GORSUCH: -- unless you can  
12 prove a net benefit.

13 MR. GANNON: -- that's --

14 JUSTICE GORSUCH: And if you concede  
15 that there's -- I'm just -- just a legal point.  
16 Wouldn't due process apply here equally as  
17 there? If not, why not?

18 MR. GANNON: Our point is -- I  
19 understand that due process would apply to -- to  
20 when there is property at issue.

21 JUSTICE GORSUCH: And, here, there are  
22 existing businesses, just like there was an  
23 existing business in the --

24 MR. GANNON: It's --

25 JUSTICE GORSUCH: -- in the restaurant

1 hypothetical.

2 MR. GANNON: -- it's an existing  
3 business, but it was at risk. It was being  
4 conducted in the shadow of a statute that said  
5 that --

6 JUSTICE GORSUCH: Sure. Of -- oh, of  
7 course.

8 MR. GANNON: -- these products are  
9 unlawful. And -- and so, if you --

10 JUSTICE GORSUCH: No, I understand  
11 that. I'm not saying you have a right to  
12 continue it. I'm just asking: Would you have a  
13 right to notice and a hearing?

14 MR. GANNON: You -- you -- they --  
15 they got a hearing, and -- and --

16 JUSTICE GORSUCH: Just -- I'm just  
17 asking on the legal point, Mr. Gannon, wouldn't  
18 they have a right to notice and a hearing?

19 MR. GANNON: They -- they have -- yes.  
20 They have --

21 JUSTICE GORSUCH: Yes. Okay.

22 MR. GANNON: -- they have notice from  
23 this statute, and they got a hearing from --  
24 from FDA about their application.

25 JUSTICE GORSUCH: But, as a matter of

1 due process, they were entitled to that, is  
2 my -- that's my -- my question. Are they  
3 entitled to notice and a hearing?

4 MR. GANNON: And -- and what we are  
5 saying is that the fair notice question in this  
6 case, it really sounds in arbitrary and  
7 capriciousness, and it's not in Due Process  
8 doctrine. They had -- they had --

9 JUSTICE GORSUCH: Why -- why not?  
10 That's what I'm trying to explore. Why --

11 JUSTICE JACKSON: Isn't that --

12 JUSTICE GORSUCH: -- why -- why isn't  
13 there a due process right here if there -- if  
14 there -- if there is --

15 MR. GANNON: Because --

16 JUSTICE GORSUCH: -- you agree there  
17 is in the restaurant owner business?

18 MR. GANNON: That that is a lawful  
19 business that is out there, and there is -- it  
20 is subject to regulation. In this context,  
21 Congress has already made the baseline that  
22 these products are unlawful --

23 JUSTICE GORSUCH: Okay.

24 MR. GANNON: -- unless they actually  
25 get --

1 JUSTICE JACKSON: On that standard,  
2 right --

3 JUSTICE GORSUCH: If I might just --  
4 if I might just finish.

5 JUSTICE JACKSON: Mm-hmm.

6 JUSTICE GORSUCH: I have a question to  
7 follow up on that, is how does the FDA enforce  
8 its denial orders?

9 I -- I -- I suppose, as I understand  
10 it, they can go get an injunction against the  
11 business, like in my restaurant hypothetical.  
12 And in those enforcement actions, is a  
13 respondent able to contest the FDA denial  
14 orders? I -- I don't think they are. I think,  
15 if they -- if they don't have a license, they --  
16 they lose, and that's the only question at that  
17 hearing. Is that right?

18 MR. GANNON: At -- at -- at that  
19 point, for enforcement of the lack of  
20 authorization, that would be true. With respect  
21 to some of these product applications that  
22 preexisted the -- the 2020 deadline that these  
23 applications do, there -- there were -- they  
24 were sort of grandfathered in. FDA had -- had  
25 stayed enforcement action for a time because,

1 when it announced the deeming rule in 2016 --

2 JUSTICE GORSUCH: No, I --

3 MR. GANNON: -- some of these products  
4 were already on the market.

5 JUSTICE GORSUCH: -- I do -- I do  
6 understand that. But, when it comes to an  
7 enforcement action, they wouldn't be able to  
8 collaterally attack the denial orders, would  
9 they?

10 MR. GANNON: That's correct.

11 JUSTICE GORSUCH: Okay.

12 MR. GANNON: They can attack the --  
13 the denial order in the judicial review, as they  
14 are doing in this particular proceeding.

15 JUSTICE GORSUCH: Thank you. Thank  
16 you.

17 Justice Jackson, I'm sorry.

18 JUSTICE JACKSON: Yes. No, no, I  
19 apologize for jumping in.

20 I just wanted to ask about your  
21 hypothetical, Justice Gorsuch, which I  
22 understood -- and, Mr. Gannon, maybe is the  
23 distinction the fact that in the hypothetical  
24 that was just posed to you that counsel is  
25 creating the standard, and what you're saying is

1 the statute creates the standard here?

2 MR. GANNON: In this instance, we are  
3 saying that the statute made these products  
4 unlawful, unless there was --

5 JUSTICE JACKSON: A particular  
6 showing.

7 MR. GANNON: -- FDA authorization.

8 JUSTICE JACKSON: So the showing --

9 MR. GANNON: Unless there is FDA  
10 authorization for marketing of that product, the  
11 baseline is that these are unlawful. The  
12 assumption is that until an applicant persuades  
13 FDA with sufficient scientific evidence that  
14 these are appropriate for the protection of the  
15 public health, they should not be on the market.

16 JUSTICE JACKSON: Right. But  
17 appropriate for the protection of the public  
18 health. And the things that the FDA has to look  
19 at are in the statute?

20 MR. GANNON: That's correct.

21 JUSTICE JACKSON: So this is not a  
22 discretionary call of the FDA. I mean, I  
23 understand the fair notice point in the context  
24 of a scheme in which the FDA has total  
25 discretion. The FDA comes up with the standards

1 for approval, and the FDA makes representations  
2 about what people have to do, and then there is  
3 argument about whether or not they've changed  
4 their mind.

5 What I understood the government's  
6 point to be here is that the baseline standard  
7 appropriate for public health, taking into  
8 account certain things, is in the statute. So  
9 the FDA, no matter what it says, can't authorize  
10 an application on something less than that. Is  
11 that correct?

12 MR. GANNON: That is correct, that the  
13 statute sets the standard. FDA does, of course,  
14 have discretion in -- in when it is going to  
15 approve, but it is applying that statutory  
16 standard.

17 JUSTICE JACKSON: Correct. And so --  
18 so, if the FDA were to say suddenly, for  
19 example, that, you know, you don't have to  
20 supply any scientific evidence concerning  
21 whether or not there is a benefit to your  
22 product, right -- let's say the FDA's guidance  
23 said such a thing. Would we -- could it? I  
24 mean --

25 MR. GANNON: No, that would not be

1 permitted by the statute. The statute says that  
2 there need to be well-controlled investigations  
3 or other scientific evidence, if FDA considers  
4 that sufficient, to establish the relevance --  
5 the relevant things that --

6 JUSTICE JACKSON: So, in that  
7 situation --

8 MR. GANNON: -- that the applicant is  
9 required to prove.

10 JUSTICE JACKSON: Yes. In that  
11 situation, even though there might theoretically  
12 be a fair notice concern by an applicant who is  
13 following FDA's misguidance, right, that person  
14 couldn't say, we are entitled to approval of our  
15 application even though -- you know, on -- on  
16 the lesser standard that the FDA articulated,  
17 correct?

18 MR. GANNON: It is right that they  
19 wouldn't be able to say that they were entitled  
20 to approval under the statute. To the extent  
21 that FDA had misled them, we are saying that  
22 that would be -- that would be something that  
23 would be vulnerable under arbitrary and  
24 capricious standards. If FDA said you just  
25 don't need any scientific evidence and then, at



1 the -- at the time of the approval or denial,  
2 said sorry, you don't have the evidence --

3 JUSTICE JACKSON: But what was the  
4 remedy for that?

5 MR. GANNON: -- and that's not what  
6 happened here.

7 JUSTICE JACKSON: What -- I understand  
8 it's not what happened there, but I'm just --  
9 I'm -- I'm confused about your answer.

10 MR. GANNON: Well, I think, there, the  
11 --

12 JUSTICE JACKSON: I mean, a person --  
13 a person could claim that they would be entitled  
14 to approval on a lesser standard if the FDA had  
15 mistakenly told them something less than what  
16 the statute required?

17 MR. GANNON: I -- I mean, they would  
18 be able to say that FDA had -- had not acted --  
19 they had acted arbitrary and capriciously in  
20 making that particular decision. And FDA would  
21 need to go back and -- and -- and do it  
22 correctly.

23 But I -- I take your point that in  
24 that instance, if they really can't satisfy the  
25 statutory standard at the end of the day, FDA

1 shouldn't approve them, even on remand.

2 JUSTICE KAVANAUGH: So that --

3 MR. GANNON: Of course, that's not  
4 what we have here.

5 JUSTICE KAVANAUGH: As a practical  
6 matter then, I'm curious what relief looks like  
7 in this case, because the companies can always  
8 reapply, correct?

9 MR. GANNON: That's correct. They can  
10 reapply without a fee. And some other  
11 applicants have reapplied.

12 JUSTICE KAVANAUGH: And if they won  
13 this case, they can reapply?

14 MR. GANNON: If they -- yes. If they  
15 won this case or if they lose this case, they  
16 will be able to reapply.

17 JUSTICE KAVANAUGH: That's -- that's  
18 my question about what the relief really  
19 accomplishes here that is being sought as a  
20 practical matter. I understand the legal point,  
21 the FDA acted arbitrary and capriciously, but  
22 either way, it's going to be that they can  
23 reapply and hope to succeed, right?

24 MR. GANNON: Well --

25 JUSTICE KAVANAUGH: Or --

1           MR. GANNON: -- yes, they would be  
2     able to reapply. And to the extent that they  
3     say, oh, we had no idea this is what we were  
4     supposed to be proving even they though were --

5           JUSTICE KAVANAUGH: Now they know.

6           MR. GANNON: -- trying to prove that,  
7     they've had four years to try to assemble that  
8     evidence and persuade FDA. They could have  
9     applied in the meantime. They can reapply now.

10          I expect that they will say that,  
11     right now, they have a stay from the Fifth  
12     Circuit of enforcement of this denial order,  
13     and, therefore, they have some protection with  
14     respect to enforcement actions with -- with  
15     respect to this.

16          JUSTICE KAVANAUGH: That's why fair  
17     notice is a bit of an odd fit with this kind of  
18     scheme because, even if you didn't get fair  
19     notice, as Justice Jackson was saying, you don't  
20     get a court order that you are approved to now  
21     sell the product.

22          MR. GANNON: That's correct. And to  
23     the extent that FDA -- that the Fifth Circuit  
24     remanded to FDA, it --

25          JUSTICE KAVANAUGH: All you get with

1 lack of fair notice is that you can apply again,  
2 which you can do anyway.

3 MR. GANNON: That's right. And --  
4 but, you know, we do think that, not --  
5 notwithstanding that, you know, our -- our --  
6 our point with respect to the -- the -- the one  
7 aspect of the case where -- where we're -- we're  
8 arguing harmless error is something where we say  
9 that you -- you shouldn't -- the courts don't  
10 need to send this back to FDA because there's --  
11 there -- because FDA declined to look at  
12 particular parts of these applications with the  
13 details of the marketing order.

14 JUSTICE KAVANAUGH: And that's a  
15 different point. Again, picking up on Justice  
16 Jackson's point, that's an argument that we  
17 should have been approved under the law as it is  
18 and that they made a mistake in not approving  
19 our applications. That's a different kind of  
20 argument, I suppose. I mean --

21 MR. GANNON: It is. I mean, I -- I --  
22 I understand the Fifth Circuit's remand to  
23 assume that they would actually have to apply  
24 different standards than the ones that they did.  
25 And, you know, we think that the Fifth Circuit's

1 just flat wrong on that. That's different from  
2 the -- the question on which we're arguing  
3 harmless error.

4 JUSTICE KAVANAUGH: I guess, just to  
5 tie this up, even if they'd given mistaken -- if  
6 you had given mistaken guidance before, FDA had  
7 given mistaken guidance before, they're not  
8 bound to adhere to the mistaken guidance when  
9 they now consider an application, correct?

10 MR. GANNON: That -- they shouldn't  
11 be. I think the Fifth Circuit decision here --

12 JUSTICE KAVANAUGH: Because how could  
13 it be, right?

14 MR. GANNON: -- I think -- I think is  
15 suggesting that they would have to apply the  
16 previous standards that the Fifth Circuit sees  
17 them as articulating in the guidance, which is  
18 you don't need this type of evidence and,  
19 therefore, you can't demand this type of  
20 evidence now. We -- we think that that is  
21 wrong.

22 And to the extent that -- that --  
23 because we think that they didn't lack the  
24 notice that they -- that they deserved, I mean,  
25 in light of the statute and the things that FDA

1 had said and that their application shows, that  
2 they knew they were supposed to be proving this.

3 CHIEF JUSTICE ROBERTS: Counsel --

4 JUSTICE KAGAN: Can I --

5 CHIEF JUSTICE ROBERTS: -- you -- you  
6 mentioned just a few moments ago your harmless  
7 error argument, and I wondered if you could tell  
8 me why you think that's consistent with -- with  
9 Chenery.

10 Here, you say that the agency made an  
11 error. Normally, under Chenery, we send it back  
12 so we can see what the agency would do in the  
13 absence of error rather than deciding it  
14 ourselves.

15 Doesn't the harmless error argument  
16 violate that principle?

17 MR. GANNON: It -- it doesn't. And  
18 this is not a typical Chenery problem because  
19 the lawyers aren't coming up with an ad hoc  
20 reason after the -- or a post hoc reason here.  
21 The agency has already revealed what it would  
22 have done in this context.

23 And the APA, which is incorporated in  
24 the Tobacco Control Act, specifically applies  
25 the rule of prejudicial error to administrative

1 review. This Court has recognized that  
2 repeatedly. And that's what makes it different  
3 from the Chenery principle, is that here, we're  
4 not asking ourselves, well, gee, what would the  
5 agency do on remand, because the agency has  
6 already indicated that the marketing  
7 restrictions that -- that it -- it said that it  
8 didn't look at in these applications wouldn't  
9 have made any difference. The 2020 guidance  
10 said look at the landscape that's out there,  
11 things that include age gating in sales in vape  
12 shops or online. That has not proved sufficient  
13 in order to keep these products out of the hands  
14 of minors.

15           And to the extent -- and so I think,  
16 when you look at the harmless error question in  
17 this case -- and the Court has said that it  
18 doesn't engage in idle and useless formalities.  
19 This isn't supposed to be an endless game of  
20 ping pong. And so you're right, if we didn't  
21 know what the agency was going to do, then you  
22 should remand.

23           JUSTICE KAGAN: And --

24           MR. GANNON: But, in this instance, we  
25 do.

1 JUSTICE KAGAN: And what are the  
2 materials that you look to to know whether you  
3 know that -- what the agency would do?

4 MR. GANNON: In this instance, the --  
5 the chief thing is in the 2020 guidance, where  
6 the agency specifically said that age gating  
7 at -- at vape shops and online sales had not  
8 proved sufficient in order to keep e-cigarettes  
9 from getting into the hands of minors.

10 And so, to the extent that they are  
11 saying we want to limit sales only to adults,  
12 that's not going to prove sufficient. And FDA  
13 has already made it clear that that's not going  
14 to be sufficient.

15 JUSTICE KAGAN: And what is the  
16 standard that one uses in that inquiry? Do you  
17 have to be certain that the agency would do  
18 that, highly confident that the agency would do  
19 that? What?

20 MR. GANNON: Well, it -- I mean, the  
21 Court's discussion of this in *Shinseki* against  
22 *Sanders*, which we quote in our brief, says that  
23 there's no sort of all-purpose standard for  
24 evaluating harmless error. There are  
25 case-appropriate considerations. But I think



1 that the chief one that the Court recites there  
2 is an estimation of the likelihood that the  
3 result would have been different.

4 And I think that if it's a really low  
5 likelihood you can be confident that the agency  
6 wouldn't do something different, then it's just  
7 going to be the idle and useless formality that  
8 -- that the rule of prejudicial error keeps the  
9 courts from engaging in here.

10 JUSTICE KAGAN: And -- and maybe just  
11 out of curiosity, why didn't the agency just do,  
12 with respect to each of these applications, you  
13 know, this marketing plan is no different from a  
14 hundred other youth marketing plans that we've  
15 seen and none of them are sufficient for the  
16 following probably boilerplate reasons?

17 MR. GANNON: Yeah, you know, the  
18 record here doesn't actually, you know, get into  
19 that. It just has the footnote. What the  
20 footnote says is that they're doing it for the  
21 sake of efficiency. And we know that the FDA  
22 was considering a big backlog of applications  
23 that had piled up at that point.

24 The other side in the amicus briefs  
25 sort of say that it was a million -- a million

1 plus products that FDA was evaluating at once.  
2 I think that's a little bit of an exaggeration  
3 of what the landscape was at the time because --  
4 because a single applicant could apply for tens  
5 of thousands of applications -- of -- of  
6 products at once such that that first tranche of  
7 decisions that were made in the weeks around  
8 when these decisions were included involved 1.2  
9 million products. It was really 320 or so  
10 applications, but that is a significant backlog.

11 And what FDA said is that they're  
12 doing this for efficiency's sake. They knew  
13 what the mine run of restrictions were that were  
14 out there in the world, and to the extent that  
15 anyone had something novel to propose, they had  
16 usually raised it with FDA on the side to say,  
17 hey, we're thinking about this. And --

18 JUSTICE KAGAN: But, if I understand  
19 your position right, you're not defending that?  
20 You are --

21 MR. GANNON: We -- we are not  
22 contesting --

23 JUSTICE KAGAN: -- conceding or --

24 MR. GANNON: We're not contesting --

25 JUSTICE KAGAN: Are you conceding it's

1 an error? You're not contesting?

2 MR. GANNON: We -- we didn't make that  
3 part of our -- our -- our cert petition. We're  
4 not contesting that here. We're saying, to the  
5 extent that it was an error, it was harmless  
6 because we know what FDA would do. It's like if  
7 you asked yourself -- if 20 pages from this  
8 application were missing, when the key person  
9 did the review at the FDA, you would ask  
10 yourself, what difference does that make? You  
11 would want to know what's in those 20 pages. If  
12 those 20 pages were actually blank or they were  
13 filled with printer gibberish, wouldn't have  
14 made any difference.

15 If they had something new, we don't  
16 what FDA thought about it, then you should  
17 remand and let FDA figure whether those 20 pages  
18 made a difference. If they're 20 pages that FDA  
19 has denied over and over, we don't think it  
20 matters that much that --

21 CHIEF JUSTICE ROBERTS: Thank you,  
22 counsel.

23 MR. GANNON: -- you didn't look at the  
24 20 pages.

25 CHIEF JUSTICE ROBERTS: Justice

1 Thomas, anything further?

2 Justice Alito?

3 JUSTICE ALITO: On the harmless error  
4 point, does harmless error review -- is harmless  
5 error review confined to the administrative  
6 record in the case at hand?

7 MR. GANNON: I don't think in this  
8 instance -- I mean, I think you would need to  
9 evaluate on the basis of what you know about the  
10 agency. Here, I think you can take notice of  
11 all the public things that FDA has -- has  
12 already done.

13 And we're primarily pointing at things  
14 FDA had done before it engaged in these  
15 marketing denial orders, but we also note that  
16 subsequent marketing denial orders applied the  
17 same concern that these youth marketing  
18 restrictions weren't independently sufficient to  
19 reduce the risk to youth posed by flavored  
20 e-cigarettes in order to say you don't need to  
21 have the extra benefit on the adult side of the  
22 equation in order to have a net population  
23 benefit.

24 JUSTICE ALITO: Well, a -- a big part  
25 of your harmless error argument, more than a

1 page, is based on the order that the FDA issued  
2 after the order in this case in the Logic  
3 Technology Development case.

4 Is that -- is that proper, to look  
5 to --

6 MR. GANNON: I think --

7 JUSTICE ALITO: -- an order that came  
8 after the order in this case --

9 MR. GANNON: I --

10 JUSTICE ALITO: -- to determine  
11 whether the error was harmless?

12 MR. GANNON: I think, in this  
13 instance, the reason why we're giving you that  
14 example is because it shows how what FDA said in  
15 the 2020 guidance predetermines the answer to  
16 that particular question.

17 And -- and FDA said that it didn't  
18 think that these mine-run state-of-the-market  
19 restrictions that existed in 2020 and 2021, if  
20 you didn't have something novel, had not proved  
21 adequate to keep e-cigarettes out of the hands  
22 of youth. And, therefore, you can't just say  
23 we've solved the youth side of the equation, let  
24 us get whatever benefits happen on the adult  
25 side.

1                   And so the Logic Technology  
2                   application that we discussed there is an  
3                   application saying, look, here's another place  
4                   where FDA kept saying when it was reviewing that  
5                   marketing plan that it wasn't good enough. And  
6                   so the other side, I don't think, has said: Oh,  
7                   we have something novel.

8                   The one case that's gone the other way  
9                   here, the Bidi Vapor case from the Eleventh  
10                  Circuit, specifically cited novel proposals that  
11                  those applicants had in their application. And  
12                  the other side here isn't pointing to anything  
13                  like that.

14                 JUSTICE ALITO: Several amici in this  
15                 case asked that if we rule in your favor, we  
16                 should reserve on the issue of menthol-flavored  
17                 e-cigarette products.

18                 Do you agree with that?

19                 MR. GANNON: I -- I think that as --  
20                 as long as you say that FDA's standard here did  
21                 not violate the statute or its previous  
22                 guidance, I -- I think it's fine to say menthol  
23                 may be a different point.

24                 FDA has been applying the same  
25                 standard to menthol. At first, it -- the way it

1 sequenced these applications is that it first  
2 looked at fruit, candy, and dessert flavors,  
3 like the ones that are at issue here, and that's  
4 where it -- that's where it -- it said that  
5 it -- it focused on this need to show the --  
6 the -- the benefits for adults that counter --  
7 that -- that -- that out-balance the harm to --  
8 to kids.

9           It -- it was unsure at first whether  
10 menthol should be treated in the same way. It  
11 later concluded that the same test applied to  
12 menthol.

13           And earlier this year, in applying the  
14 same test to menthol, they authorized a handful  
15 of products because that applicant had survey  
16 research conducted in 2020 -- before these  
17 applications were even filed, the survey that  
18 NJOY conducted specifically said they had  
19 substantial evidence to show that they had more  
20 impact on adult smokers ceasing to smoke  
21 cigarettes with their menthol flavors compared  
22 to tobacco flavors.

23           It's that type of evidence that was  
24 missing in these applications.

25           JUSTICE ALITO: Okay. One last

1 question, and maybe this is just a matter of  
2 curiosity on my part. If there weren't a  
3 million application denials, there were  
4 certainly many hundreds of thousands, right?  
5 What would you say?

6 MR. GANNON: The number -- the prior  
7 -- the number of denials for products really was  
8 more than a million. What I was saying is that  
9 that tends to exaggerate maybe the sense of the  
10 other side saying that -- that this is  
11 cookie-cutter analysis by FDA because -- because  
12 that was really a few hundred applications that  
13 were being decided with -- with that many  
14 products that were underlying the application.

15 JUSTICE ALITO: Well, do -- do you  
16 maintain that these were really -- however many  
17 hundreds of thousands there were, each one a  
18 bespoke consideration of the application and  
19 there was not some sort of checklist behind the  
20 scenes that was actually dictating the outcome  
21 in these cases?

22 MR. GANNON: My point is that an  
23 individual applicant, when it is -- when it is  
24 applying for tens of thousands of products at  
25 once, is using the same application over and



1 over. It has exactly the same evidence to say:  
2 We think that this product is going to be good  
3 on one side and not bad on the other side of the  
4 equation.

5 And so, to the extent that the  
6 applicant is saying the same thing over and over  
7 and over again, FDA is saying the same thing  
8 over and over again in denying it.

9 JUSTICE ALITO: Okay. Thank --

10 MR. GANNON: And in every instance,  
11 FDA is looking to see whether they have this  
12 evidence. And at the time, nobody had this  
13 evidence.

14 JUSTICE ALITO: All right. Thank you.

15 CHIEF JUSTICE ROBERTS: Justice  
16 Sotomayor?

17 JUSTICE SOTOMAYOR: All of these  
18 products contain tobacco, right?

19 MR. GANNON: They contain nicotine.

20 JUSTICE SOTOMAYOR: Nicotine. And  
21 it's nicotine that's addictive, correct?

22 MR. GANNON: That's correct.

23 JUSTICE SOTOMAYOR: Could you make a  
24 smoking product that didn't have nicotine?

25 MR. GANNON: I mean, I -- some of

1 these -- you can make an e-cigarette or a vaping  
2 product that doesn't have nicotine that can  
3 otherwise simulate other aspects of --

4 JUSTICE SOTOMAYOR: Right.

5 MR. GANNON: -- of doing this, but --

6 JUSTICE SOTOMAYOR: But those products  
7 are not at issue, meaning they don't need a  
8 license, correct?

9 MR. GANNON: If it doesn't have  
10 nicotine -- I mean, to the extent that it's  
11 intended to -- to play into smoking cessation,  
12 then -- then I'm not sure. But all the products  
13 that are at issue here contain nicotine. And in  
14 2022, Congress expanded the statute to include  
15 nicotine that doesn't even come from tobacco.

16 So, in this instance, there's no doubt  
17 that FDA is the agency that has the authority to  
18 regulate whether products containing nicotine  
19 are appropriate for the protection of the public  
20 health.

21 JUSTICE SOTOMAYOR: Other than  
22 addiction, why would someone put nicotine into a  
23 product and then try to hide the flavor of  
24 tobacco? Meaning I -- I'm a little bit at a  
25 loss.

1 MR. GANNON: I'm not going to deny  
2 that there are -- there could be other reasons  
3 why -- why users want flavors, why a -- a  
4 manufacturer would want to say: Hey, if  
5 somebody wants to see what -- what a cigarette  
6 is like when it tastes like something that's not  
7 a cigarette, what -- what's it like to smoke,  
8 you know, Jimmy The Juice Man Peachy Strawberry,  
9 which is one of the flavors here --

10 JUSTICE SOTOMAYOR: Well, this is more  
11 curiosity, which is we know nicotine is  
12 addictive. You put it in to addict people.  
13 Presumably, you put it in to addict adults and  
14 children.

15 MR. GANNON: We -- we --

16 JUSTICE SOTOMAYOR: And that's why  
17 you're acting to address that.

18 MR. GANNON: Congress was concerned  
19 about the fact that the -- that -- that most  
20 people who become addicted to nicotine start  
21 when they are underage, at a time when the  
22 adolescent brain is particularly vulnerable to  
23 the effects of nicotine.

24 And that was the main reason why it  
25 was concerned about trying to reduce youth

1 smoking in the Family Smoking Prevention and  
2 Tobacco Control Act that it passed here.

3 JUSTICE SOTOMAYOR: Thank you,  
4 counsel.

5 CHIEF JUSTICE ROBERTS: Justice Kagan?  
6 Justice Gorsuch?

7 JUSTICE GORSUCH: I just wanted to  
8 follow up, Mr. Gannon, a little bit on -- on the  
9 harmless error question.

10 It seems to me there are two  
11 possibilities. One, we could say harmless error  
12 is treated here just like it is in civil  
13 litigation. But that kind of runs into the  
14 Chenery problem, right?

15 MR. GANNON: Well, it -- it -- it --  
16 it does and it doesn't.

17 JUSTICE GORSUCH: If -- if -- if I  
18 might -- if I might just finish.

19 MR. GANNON: Sure.

20 JUSTICE GORSUCH: I'm trying to help  
21 you here, actually, I promise.

22 (Laughter.)

23 JUSTICE GORSUCH: Another -- another  
24 possibility would be to say that the harmless  
25 error rule applies in administrative contexts

1 when we can be sure what the agency would have  
2 done, that the agency couldn't have reached a  
3 different conclusion.

4 And I'm wondering if that might be the  
5 case here and the nature of your argument given  
6 that the marketing plans go to the statute's  
7 second requirement.

8 There are two requirements. One, it  
9 helps smoking cessation, and, two, it doesn't  
10 create other problems. And two is kind of  
11 irrelevant if you fail under one.

12 Do you follow me?

13 MR. GANNON: I follow you. And -- and  
14 I think what the other side would say is the  
15 question is --

16 JUSTICE GORSUCH: I'm wondering what  
17 you would say.

18 MR. GANNON: I -- I think the question  
19 is whether they really have some way of solving  
20 two, if they really had some knock-down argument  
21 about why they were going to prevent youth  
22 smoking in a way that nobody else has with  
23 respect to their particular product.

24 JUSTICE GORSUCH: But wouldn't they  
25 still fail under one, that they can't

1 demonstrate a public health benefit?

2 MR. GANNON: They would still have to  
3 show a public health benefit.

4 JUSTICE GORSUCH: Right.

5 MR. GANNON: It wouldn't necessarily  
6 have to be the heightened benefit in order to  
7 counter the heightened risk that FDA had  
8 recognized existed with respect to two.

9 JUSTICE GORSUCH: But I had thought  
10 your client took the position that there was no  
11 public health benefit here.

12 MR. GANNON: That we -- we said that  
13 they haven't established that there is a higher  
14 public health benefit with respect to flavors in  
15 order to counterbalance the higher risk that  
16 flavors pose. And so --

17 JUSTICE GORSUCH: So -- so they're  
18 linked?

19 MR. GANNON: Pardon? That they --

20 JUSTICE GORSUCH: So you're -- you're  
21 conceding they're linked?

22 MR. GANNON: -- they are absolutely  
23 linked. And what I am saying is, to the extent  
24 that it's a real --

25 JUSTICE GORSUCH: Okay. So how -- how

1 do you -- how do you deal with the Chenery  
2 problem then?

3 MR. GANNON: The -- the way I deal  
4 with the Chenery problem is the answer I gave to  
5 the Chief Justice, which ends your -- the way  
6 you phrased the first version of harmless error  
7 is the way the Court has said that -- that you  
8 apply harmless error as you do in civil  
9 litigation. And so you are asking yourself  
10 whether it makes any difference --

11 JUSTICE GORSUCH: I -- I know what  
12 that looks like. But how does that -- how --  
13 how do we -- how do we reconcile that with  
14 Chenery, which, you know, acknowledges that the  
15 agency may well have many good explanations, we  
16 can conjure them --

17 MR. GANNON: That's right.

18 JUSTICE GORSUCH: -- but it didn't do  
19 the work, and so we're going to remand it?

20 MR. GANNON: I think that's right when  
21 it -- when it would be a completely different  
22 argument, when it would be a different standard  
23 where there may be some alternative form of  
24 reasoning.

25 Here, we know what the reasoning was.

1 The question is just whether, had the agency  
2 looked at the extra bit of information, it would  
3 have made a difference to its bottom line. It's  
4 the -- it's the 20 blank -- missing pages hypo  
5 that I discussed earlier.

6 JUSTICE GORSUCH: And let me just turn  
7 back real quickly to the enforcement action  
8 question. Are those conducted before ALJs?

9 MR. GANNON: The civil enforcement  
10 actions, I -- I'm not sure to tell you the  
11 truth. But --

12 JUSTICE GORSUCH: I'm just wondering,  
13 does a company ever have a chance to get before  
14 a -- a judge and a jury?

15 MR. GANNON: I think the answer is  
16 yes, but I -- but I'm not sure about the details  
17 because we -- we haven't really been engaging in  
18 those --

19 JUSTICE GORSUCH: No, I --

20 MR. GANNON: -- with respect to the  
21 category -- the products that are at issue in  
22 these cases.

23 JUSTICE GORSUCH: I mean, after  
24 Jarquesy, perhaps the answer is yes?

25 MR. GANNON: We will certainly comply



1 with what the law requires, Justice Gorsuch.

2 (Laughter.)

3 JUSTICE GORSUCH: Thank you,  
4 Mr. Gannon.

5 CHIEF JUSTICE ROBERTS: Justice  
6 Kavanaugh?

7 JUSTICE KAVANAUGH: I understand your  
8 main argument is that the guidance here was not  
9 misleading or mistaken and gave sufficient  
10 notice, but as the discussion earlier -- our  
11 discussion earlier, I think, illustrated, when  
12 there is mistaken or misleading guidance in a  
13 situation where someone's trying to apply to  
14 obtain a benefit or license or something, that  
15 there's no real meaningful relief that the APA  
16 actually affords, and that raises a concern for  
17 me about what checks are there on mistaken or  
18 misleading guidance in situations where  
19 someone's applying for a benefit or applying for  
20 a license or something of that sort.

21 Is it just the political process,  
22 public pressure?

23 MR. GANNON: Well, I think, in that  
24 instance, the -- the answer would be that you --  
25 you -- you could send it back to the agency.

1 The agency, because it was arbitrary or  
2 capricious for the agency to mislead and apply  
3 ultimately a different standard than the one  
4 that it told applicants it was going to apply,  
5 it would then have to -- it -- it would -- it  
6 would then have to give applicants a chance to  
7 apply under the correct standard and it would  
8 evaluate it.

9 And so the check would be that the  
10 agency wouldn't --

11 JUSTICE KAVANAUGH: They could --

12 MR. GANNON: -- just have to --  
13 would -- couldn't get the benefit of a bait-and-  
14 switch. The other side would, indeed, be able  
15 to respond to what the appropriate standard is.

16 JUSTICE KAVANAUGH: But you said you  
17 could do that anyway?

18 MR. GANNON: They -- yes, in this  
19 instance, they can do that.

20 JUSTICE KAVANAUGH: The APA is not  
21 adding any -- any value to what you could do  
22 anyway in that circumstance, I don't think.

23 MR. GANNON: I -- I -- I think, in  
24 that circumstance, it -- it -- it may not. To  
25 the extent that they have a stay that's tied to

1 these particular denial orders, to the extent  
2 that this would be a remand and a -- and -- and  
3 the agency could just reconsider this  
4 application on -- with -- with respect to the  
5 information that -- that it includes in it,  
6 then -- then maybe -- maybe --

7 JUSTICE KAVANAUGH: Yeah.

8 MR. GANNON: -- it would be a quicker  
9 decision.

10 JUSTICE KAVANAUGH: I guess another  
11 possibility -- you haven't said this -- is that  
12 the agency on remand could conclude that its  
13 current -- the earlier guidance was correct and  
14 they should back away from their current  
15 standard. I know that's not this case, but  
16 that's theoretically possible in the  
17 hypothetical I'm raising?

18 MR. GANNON: As long as it was then,  
19 you know, explaining its reversion to the  
20 previous position --

21 JUSTICE KAVANAUGH: Right.

22 MR. GANNON: -- yes, to the extent  
23 that the agency has leeway under the statute to  
24 go one way versus the other way --

25 JUSTICE KAVANAUGH: Yeah.

1           MR. GANNON: -- and it -- and it then  
2 explains that it is changing its position. Of  
3 course, our position here is that the agency  
4 didn't change its position at -- at any point in  
5 time here with respect to what the other side  
6 needed to prove.

7           JUSTICE KAVANAUGH: I understand that.  
8 I was just exploring the contours. Thank you.

9           CHIEF JUSTICE ROBERTS: Justice  
10 Barrett?

11           JUSTICE BARRETT: Mr. Gannon, I have  
12 what I hope is an easy practical question.  
13 Let's -- let's imagine that we are pretty  
14 confident, you know, let's say we have a high  
15 degree of confidence that the agency would  
16 decide the marketing question the same way on  
17 remand on the harmless error point, but we still  
18 think that Chenery requires us to send it back.

19           As a practical matter then, what  
20 happens? Because, if we're pretty confident the  
21 agency's going to reach the same decision, you  
22 know, is it going to take the agency a long time  
23 to reconsider these applications and do what we  
24 think they're going to do anyway?

25           MR. GANNON: In this instance, we're

1 not saying it's -- it's a big burden in order to  
2 reevaluate these particular applications as long  
3 as the Court -- assuming that the Court is  
4 reversing the Fifth Circuit on the other  
5 things --

6 JUSTICE BARRETT: Right.

7 MR. GANNON: -- about -- about not  
8 having to -- about what studies it -- it can ask  
9 for, that it wants real scientific evidence.

10 JUSTICE BARRETT: Just the marketing  
11 question?

12 MR. GANNON: It's just the marketing  
13 plans. We're not saying that -- that it's a big  
14 burden on the agency in order to have to decide  
15 the applications from -- from -- from these two  
16 applicants and look at the marketing plans and  
17 confirm that there's nothing in there that  
18 changes its mind about the bottom-line  
19 conclusion here.

20 JUSTICE BARRETT: So it's pretty low  
21 stakes?

22 MR. GANNON: It -- it's low stakes  
23 with respect to that practical reality, assuming  
24 that we win on the other -- the other parts of  
25 the arbitrary-and-capricious analysis, but we do

1 think that it vindicates the harmless error rule  
2 that Congress put in place here. And to the  
3 extent that you think that -- that we're not  
4 supposed to play this endless game of ping pong  
5 where -- where -- where applicants get shuttled  
6 back and forth and the agency gets shuttled back  
7 and forth between its own decision and the  
8 courts, it's -- it's -- you'd say that that  
9 would be an idle formality. We don't need to  
10 engage in it.

11 But -- but you're right, I'm not  
12 saying it would be a huge burden to re-decide a  
13 handful of applications with respect to what we  
14 are saying. By definition, we think we already  
15 know what the agency's going to say.

16 JUSTICE BARRETT: Thank you.

17 CHIEF JUSTICE ROBERTS: Justice  
18 Jackson?

19 JUSTICE JACKSON: So the statute  
20 plainly requires the agency to evaluate benefits  
21 and harms. So can you just speak for a moment  
22 about why flavored e-cigarettes are more harmful  
23 than unflavored from the government's  
24 perspective?

25 MR. GANNON: The chief risk that FDA

1 identified throughout here -- and this was clear  
2 well before the marketing denial order here with  
3 respect to flavors -- is -- is on -- in the 2020  
4 guidance, where FDA said it is concerned about  
5 the extraordinary popularity of flavored  
6 e-cigarettes with youth. Research has long  
7 shown that flavors increased youth appeal of  
8 tobacco products. And evidence accumulates,  
9 further confirming that youth are particularly  
10 attracted to flavored ENDS products. Flavors  
11 are a strong driver for youth use.

12 And so those are all quotations from  
13 the 2020 guidance.

14 JUSTICE JACKSON: So that was in the  
15 guidance, though?

16 MR. GANNON: That's in the 2020  
17 guidance before these applications were filed on  
18 pages 151 and 214 of the Joint Appendix. And  
19 the concern there is, as I said, that flavors  
20 are attracting youth into smoking when they are  
21 non-users. Congress said that we need to  
22 evaluate the likelihood that non-users are going  
23 to start using tobacco products. The concern  
24 would be that they're getting addicted to  
25 tobacco at a time when -- when tobacco -- to

1 nicotine at a time when nicotine is dangerous to  
2 their developing brains and may be, you know,  
3 sentencing them to a long life of -- of -- of  
4 needing to satisfy that addiction.

5 JUSTICE JACKSON: All right. Let me  
6 ask you just one question about harmless error  
7 because I guess I'm -- I'm confused about the  
8 government's position. I took your reply brief  
9 in the sentence on page 18 where you say "This  
10 Court should reverse the Fifth Circuit's holding  
11 that the harmless error rule simply does not  
12 apply and remand the case so that the Fifth  
13 Circuit can apply that rule" to be the  
14 government asking us to remand the case.

15 And from the podium here, you're  
16 saying no, we should apply the harmless error  
17 rule. So I don't know what you're asking for.

18 MR. GANNON: I wouldn't expect this  
19 Court in the -- in the normal case in the first  
20 instance to perform the harmless error analysis  
21 itself. What we're saying is that we don't  
22 think there needs to be a remand to the agency  
23 and -- and that that's the point. So, if you  
24 remand to the Fifth Circuit in order to evaluate  
25 whether it is persuaded that the -- the test



1 that I was discussing with Justice Kagan is  
2 satisfied here, that the estimation of the  
3 likelihood of the result would not have been any  
4 different here is sufficient --

5 JUSTICE JACKSON: So we don't have to  
6 make that harmless -- at a minimum, you're  
7 saying we can send it to the Fifth Circuit to  
8 have them make the decision?

9 MR. GANNON: If -- if -- if you want  
10 to agree with us, I am certainly not going to  
11 prevent you from doing that. If you want to say  
12 that since you don't normally analyze that type  
13 of question in the first instance, you want to  
14 remand that to the Fifth Circuit, the point is  
15 to correct the Fifth Circuit's legal error in  
16 saying that harmlessness isn't applicable, a  
17 harmless error analysis isn't -- isn't  
18 applicable here.

19 JUSTICE JACKSON: Thank you.

20 CHIEF JUSTICE ROBERTS: Thank -- thank  
21 you, counsel.

22 Mr. Heyer.

23 ORAL ARGUMENT OF ERIC N. HEYER ON  
24 BEHALF OF THE RESPONDENTS

25 MR. HEYER: Mr. Chief Justice, and may

1 it please the Court:

2 FDA's new longitudinal comparative  
3 efficacy requirement directly contradicts the  
4 guidance FDA provided before the submission  
5 deadline when FDA knew that roughly two-thirds  
6 of adult ENDS users use flavored products.

7 Before, FDA said, "No specific studies  
8 are required for an application." After, FDA  
9 denied applications for over one million  
10 products and over 250 applicants because they  
11 lacked a randomized control trial, a  
12 longitudinal cohort study, or some "other  
13 evidence" comparing the flavored ENDS products  
14 at issue against tobacco-flavored ENDS products  
15 as to cigarette reduction over time. Not a  
16 single applicant included these studies in their  
17 initial application.

18 Before, FDA said applicants were free  
19 to select a comparator tobacco product and  
20 justify their selection. After, for flavored  
21 ENDS, only a tobacco-flavored ENDS product was  
22 an acceptable comparator.

23 Before, FDA recommended single-point-  
24 in-time studies on "consumer risk perception"  
25 and "intentions." After, FDA concluded only

1 longitudinal studies that track user behavior  
2 over time are robust and reliable.

3           Before, FDA said it would make its  
4 determination based on the entire contents of  
5 the application. After, FDA admittedly did not  
6 assess anything in the applications beyond  
7 whether they contained longitudinal comparative  
8 efficacy evidence.

9           Before, FDA said that a marketing plan  
10 was "critical, necessary," and "directly  
11 relevant to determining whether youth would be  
12 protected." After, FDA entirely ignored the  
13 marketing plans, determining that in its  
14 experience no marketing restrictions were  
15 adequate.

16           FDA's denial orders suffer from  
17 multiple flaws. FDA switched its position on  
18 what studies were required and, in so doing,  
19 failed to consider applicants' reliance  
20 interests in the original instructions and less  
21 drastic alternatives. It ignored the marketing  
22 plans, and it ignored the notice-and-comment  
23 process mandated by the -- the APA and the Food,  
24 Drug, and Cosmetic Act. The Court should,  
25 therefore, affirm the judgment below.

1 I welcome the Court's questions.

2 JUSTICE THOMAS: You make quite a bit  
3 in your argument that FDA required certain kinds  
4 of studies at one point and then changed its  
5 mind. And yet I'm confused as to what these  
6 studies are.

7 What's the difference between a  
8 long -- the long-term studies and the randomized  
9 controlled trials and the longitudinal cohort  
10 studies? What's the difference, and why is that  
11 a change in FDA's requirements?

12 MR. HEYER: So, Your Honor, the -- a  
13 longitudinal study could be of any duration, and  
14 that's the core -- that -- that's our core claim  
15 here. FDA defined "long-term" as being six  
16 months or more. And longitudinal studies are  
17 any study that tracks users over time. The  
18 randomized control trial and longitudinal cohort  
19 studies are two types of longitudinal studies.

20 A randomized control trial will assign  
21 the users specific products: tobacco-flavored  
22 ENDS for one control group, whatever the subject  
23 flavored product is for another.

24 A longitudinal cohort study has a lot  
25 of different ways to possibly design it that

1 allow for selection of different flavors by the  
2 users, but, again, it tracks them over time.

3 Now our point is what FDA said ahead  
4 of time in its guidance in the 2018 public  
5 meeting presentation is that single-point-in-  
6 time surveys asking users of these products  
7 about their experiences, whether they would  
8 intend to use these products if they're  
9 combustible cigarette smokers, et cetera, were  
10 acceptable.

11 Afterwards -- and I point the Court to  
12 page 266 of the -- of the Joint Appendix -- FDA  
13 specifically said: Based on our experience over  
14 the last 10 months, after the deadline,  
15 reviewing these applications, we've decided it  
16 must now be a longitudinal study, that single-  
17 point-in-time studies are not sufficiently  
18 robust and reliable.

19 That -- that flies right in the face  
20 of what FDA said ahead of time and directly  
21 contradicts it. That misled applicants, going  
22 back to my friend's comments.

23 And I want to underscore what a  
24 massive sea change this was, and I'll use a  
25 hypothetical to explain it. If one had a

1 tobacco-flavored ENDS product that let's say  
2 theoretically led to a 50 percent smoking  
3 cessation rate of users and a flavored ENDS  
4 product that -- that hypothetically led to a 25  
5 percent cessation rate, under the statutory  
6 standard and under the standard as FDA explained  
7 it beforehand, assuming that there was no youth  
8 usage of the flavored products -- of either of  
9 those products, the tobacco-flavored or the  
10 flavored product, the flavored product would  
11 have to be approved because it would have a net  
12 benefit to public health.

13 Under the new standard that FDA  
14 adopted by assigning a set risk value to  
15 flavored products, after the application --  
16 again, 10 months after the applications went in,  
17 that flavored product must now have a 51 percent  
18 switch rate. It must be marginally more  
19 effective over the tobacco product.

20 It's a massive sea change not only in  
21 the plain language of the statute but in what  
22 FDA communicated after the --

23 JUSTICE JACKSON: So when did the  
24 applications go in? Because you -- you've set  
25 up your whole argument as a before-and-after

1 kind of dynamic, and I'm trying to understand  
2 when is the before and after.

3 You point to 2018 public meeting  
4 presentation as being before. And I guess  
5 there's some other -- what -- what is the point  
6 after, and when did your applications come in?

7 MR. HEYER: So the deadline that was  
8 set by FDA and by a district court was  
9 September 9, 2020, Your Honor. So we had a  
10 year --

11 JUSTICE JACKSON: September 9, 2020.  
12 All right. So I see various things in the  
13 record where the FDA is making comments about  
14 flavors, including the one that the SG pointed  
15 to in the end of his presentation that happened  
16 before then.

17 I see, for example, on page 88 of the  
18 Joint Appendix a whole discussion by the FDA  
19 that says: It is important for PMTAs for  
20 flavored products to examine the impact of  
21 flavoring on consumer perception, especially  
22 given the attractiveness of flavors to youth and  
23 young adults.

24 So it seems like, before your  
25 applications were due, FDA was making

1 announcements about the significance of flavors.

2 MR. HEYER: Yes. And -- and -- and  
3 Respondents satisfied that then. They -- they  
4 provided extensive literature reviews of  
5 studies, including consumer perception studies,  
6 about the role of flavors.

7 What FDA never said in any of the  
8 guidance over the multiple years up to  
9 September 9, 2020, is: We're going to have this  
10 new comparative efficacy requirement.

11 The word "efficacy" is not in the  
12 statute. And -- and, again, this wasn't -- the  
13 case wasn't briefed or argued under Loper, but I  
14 think the previous guidance is consistent with  
15 the language of the statute. And FDA has -- has  
16 massively changed that after the fact by -- by  
17 rigging the -- the weighing of the --

18 JUSTICE JACKSON: So we would have  
19 to -- we would have to agree with you that what  
20 the FDA has said here is actually something  
21 different or new than what it was saying about  
22 your need to provide scientific evidence --  
23 valid scientific evidence concerning the  
24 flavoring?

25 MR. HEYER: Well, it -- it was -- it



1 was new. There -- there's no reference to  
2 comparative efficacy studies. And there's no  
3 evidence before the deadline, anything from FDA,  
4 about the need to conduct any studies,  
5 comparative efficacy or not, for flavored  
6 products that differed from tobacco flavors.

7 JUSTICE KAGAN: So -- but can -- I  
8 mean, FDA says: Look, you should think hard and  
9 you should give us materials about flavors  
10 because that's one of the things that we're  
11 really going to be thinking about, is flavors.

12 And in your application, you talk  
13 about the role of flavors, right, that your  
14 application tries to show that if you have  
15 flavors, it's better at getting people to quit  
16 smoking, right? That's one of the points of  
17 your application.

18 So I guess I'm not really seeing what  
19 the surprise is here or what the change is here.  
20 Like, everybody basically knows that flavors are  
21 -- are particularly dangerous in terms of kids  
22 starting the use of smoking products.

23 And so, you know, the -- the  
24 countervailing benefit might be if flavors were  
25 also particularly good at getting adults to stop

1 smoking. And that's basically what FDA told  
2 you, and it's basically what you tried to  
3 convince FDA of.

4 And then, at the end, FDA said: You  
5 haven't convinced us. You know, we think  
6 flavors are really bad in terms of youth  
7 smoking, and we don't think that you've shown us  
8 that they provide any special benefits in terms  
9 of smoking cessation.

10 So I guess I just don't see where the  
11 gap is here.

12 MR. HEYER: Your Honor, this certainly  
13 wasn't called out with any -- wasn't called out  
14 at all and certainly not with a level of  
15 specificity.

16 And I would, you know, respectfully  
17 dispute the fact that everybody knows this and  
18 everybody knows that.

19 JUSTICE KAGAN: Well, you know that --

20 MR. HEYER: The reality is --

21 JUSTICE KAGAN: -- you know that FDA  
22 thinks that flavors -- I mean, FDA is -- has  
23 been completely upfront about this. And I think  
24 that the point, you know, that flavors -- you  
25 give people blueberry vapes, the -- the

1 difficulty with that -- and FDA, I think, has --  
2 has tried to document this -- is that blueberry  
3 vapes are very appealing to 16-year-olds, not to  
4 40-year-olds.

5 MR. HEYER: I respectfully disagree,  
6 Your Honor. In fact, the literature review  
7 that -- that Respondents provided explained in  
8 detail that often the cessation journey for  
9 combustible cigarette smokers begins after this.

10 JUSTICE KAGAN: No, I'm not saying  
11 that you don't have a point of view on that  
12 question. But you knew what FDA's point of view  
13 on that question was, was that blueberry vapes  
14 are really problematic in terms of youth  
15 smoking.

16 And you know that FDA was basically  
17 saying to you: So, given that -- that we think  
18 that, you know, you've got to show us otherwise,  
19 that your product, your flavored product, is  
20 going to be particularly good at getting people  
21 to stop.

22 I mean, there's just not a lot of  
23 mystery here about what FDA was doing.

24 MR. HEYER: Well --

25 JUSTICE KAGAN: You might disagree

1 with that because you think that, in fact, the  
2 world of 40-year-olds really wants to do  
3 blueberry vaping, but -- but you -- you can't  
4 say that FDA hasn't told you all about what it's  
5 thinking in this respect.

6 MR. HEYER: Well, going back to the  
7 2020 enforcement guidance, which is a document  
8 that my friend points to as providing notice on  
9 this, the 2020 enforcement guidance doesn't  
10 speak -- and I point -- respectfully point the  
11 Court to Judge Jones' dissent from the initial  
12 panel decision on this and also to the Bidi  
13 decision out of the Eleventh Circuit.

14 What that -- what that enforcement  
15 guidance speaks to is cartridge-based flavored  
16 products, and it talks at length about the  
17 device characteristics that make those  
18 particularly attractive to youth.

19 Respondents' products have no history,  
20 zero history, of youth usage. And that's the  
21 case if we look at the National Youth Tobacco  
22 Survey data from CDC, et cetera, all this  
23 literature that was in the applications.

24 That's the case for bottled e-liquids  
25 generally. The devices with which they are used

1 don't have any sort of a track record of being  
2 substantially attractive to youth, and -- nor  
3 than do the e-liquids.

4 JUSTICE KAGAN: I feel as though  
5 you're arguing the merits back to me, and -- and  
6 if I encouraged that, I apologize, because  
7 that's not what I was saying.

8 What I was saying is that FDA has been  
9 completely upfront about what it thinks about  
10 the role of flavors here, and you knew that  
11 because you can tell it from your own  
12 application, that your application was geared to  
13 trying to convince the FDA that notwithstanding  
14 what the FDA might think about how flavored  
15 products encourage youth smoking, there was a  
16 countervailing benefit in terms of  
17 encouraging -- enabling adults to quit.

18 MR. HEYER: Well, Your Honor, FDA  
19 doesn't claim to have reviewed or -- after the  
20 fact, post hoc rationalization, FDA claims:  
21 This is -- this is what you set up to prove, and  
22 this is how you prove it.

23 They say in the marketing denial  
24 orders: We didn't look at anything except  
25 whether there was longitudinal comparative

1 efficacy evidence. So I don't think they can  
2 hang their hat on that point after the fact.  
3 Had the applications been silent as to that, it  
4 wouldn't have mattered.

5 What FDA was looking for was this  
6 longitudinal comparative efficacy evidence.  
7 That's what the marketing denial orders show.  
8 That's what the technical project lead reports  
9 or reviews show as well. And so --

10 JUSTICE JACKSON: But isn't it your  
11 claim about notice -- I mean, just picking up  
12 what -- on -- on what Justice Kagan said, you're  
13 claiming: We didn't know we were supposed to be  
14 looking at certain things.

15 Am I wrong about that?

16 MR. HEYER: What we certainly didn't  
17 have notice is that there was this requirement  
18 to show this long -- this comparative efficacy  
19 in switching. There was -- there was no notice  
20 on that. There was -- there was --

21 JUSTICE JACKSON: Okay. So -- so you  
22 don't read the 2019 -- I'm looking again on page  
23 88. I'm just baffled by your argument in light  
24 of this sentence: "Additionally, to provide a  
25 better understanding of the appeal of flavors to

1 adults, FDA recommends examining adult appeal of  
2 such flavors in their decisions to initiate use,  
3 cease use of more harmful products, or dual  
4 use."

5 So the FDA is telling you not just  
6 flavors to youth, but help us understand your  
7 argument that there's a benefit to adults by the  
8 use of flavors. Why -- why is there a notice  
9 problem in light of the FDA saying things like  
10 this?

11 MR. HEYER: Because, when it's  
12 speaking to things like perception, which I  
13 think is what -- and -- and intent, what it's  
14 speaking to is suggestions that single-point-in-  
15 time surveys and that can speak to that. It's  
16 not saying you must do a longitudinal study  
17 comparing tobacco-flavored against flavored over  
18 time and track the users. That doesn't follow  
19 from page 88 from what Your Honor just read.

20 But --

21 JUSTICE SOTOMAYOR: I'm sorry. I'm so  
22 totally confused by your point because the FDA  
23 didn't say to you that a longitudinal study was  
24 necessary. It would be helpful. It -- it said  
25 that from the beginning repeatedly. It would be

1 helpful if you had these, but you don't have to  
2 have it if what you're providing can give  
3 enough.

4 And what it said is what you provided  
5 wasn't sufficient. So I -- I'm -- I'm still at  
6 a loss as to how that's a change in position.

7 MR. HEYER: Well, the reason they say  
8 it's not sufficient is because of the new  
9 standard that they adopted after the fact.

10 JUSTICE SOTOMAYOR: There is no new  
11 standard. The standard was always the statutory  
12 standard. The statutory standard says that --  
13 this is the statute speaking. This is not them.  
14 This is not a policy. This is not a guideline.  
15 This is the statute says, you have to show that  
16 the likelihood that existing users of tobacco  
17 products will stop using such products, that  
18 adults and hopefully children will stop using  
19 these products, and the likelihood that those  
20 that do not use the tobacco products will start  
21 using such products.

22 So that's the statute speaking. Your  
23 evidence has to show that adults need these  
24 flavored products to stop using tobacco  
25 products, full tobacco products, and that youth



1 won't start using these, and you have to weigh  
2 whether the one is going to outweigh the other.  
3 That's the statute speaking, not their guidance.

4 MR. HEYER: And -- and in --  
5 Respondents submitted the evidence that they  
6 believed FDA -- they understood FDA was asking  
7 for and that FDA said it was asking for, which  
8 was --

9 JUSTICE SOTOMAYOR: Well, no, no,  
10 it -- it got the evidence. What they said is it  
11 just doesn't prove the point. You want us to  
12 say it does prove the point, but they never said  
13 to you what you're saying, which is it's just  
14 that this doesn't show it.

15 MR. HEYER: Respondents never  
16 understood because FDA never communicated that  
17 it was going to be an end-all-and-be-all litmus  
18 test as to whether there was this comparative  
19 efficacy evidence. And that's what ultimately  
20 happened here.

21 And any other evidence was --

22 JUSTICE SOTOMAYOR: But that is  
23 because the statute makes it the litmus test.

24 MR. HEYER: Well, I respectfully  
25 disagree.

1 JUSTICE SOTOMAYOR: You -- you --  
2 you're trying to change the statute, but the  
3 statute is very clear. Tell us that your  
4 product is going to help adults stop smoking  
5 cigarettes and show us that youth is not going  
6 to start.

7 MR. HEYER: The statute, Your Honor,  
8 goes back to my hypothetical I gave previously,  
9 which is to show a net benefit of public health.  
10 And Respondents submitted literature reviews,  
11 they submitted ample information that a lot of  
12 adults use blueberry flavor and other  
13 non-tobacco flavors and -- and that often the  
14 quitting journey is to move away from tobacco or  
15 menthol flavors because they don't want to be  
16 reminded of the combustible cigarettes. They --  
17 they want to move to these other options to stay  
18 quit -- to be quit and to stay quit. And that's  
19 the type of literature they provided about these  
20 products.

21 JUSTICE KAVANAUGH: But, if the agency  
22 says that doesn't outweigh the harm to youth,  
23 we've reviewed everything, we're aware of  
24 everything, of course, they're aware of  
25 everything that's out there, that's kind of the

1 end of it, isn't it?

2 MR. HEYER: Well, Your Honor, what --

3 JUSTICE KAVANAUGH: I mean, you  
4 disagree with the statute giving that much  
5 discretion to FDA and you disagree with FDA, to  
6 Justice Sotomayor's point, weighing of the two  
7 parts of the balance, and I understand that.  
8 But I'm trying to figure out what the legal  
9 error is there.

10 MR. HEYER: The challenge here is  
11 procedural, Your Honor. It's procedural. It's  
12 the change in position. So --

13 JUSTICE KAVANAUGH: I understand that.  
14 I'm just making sure there's not -- you under --  
15 you agree that at the end of the day, the agency  
16 has to make a choice and it's going to be a  
17 choice with uncertainty?

18 MR. HEYER: It -- it has to make a  
19 choice, but when it changes like it did here  
20 what that test is going to be or its  
21 interpretation of the statute, it has an  
22 obligation to identify the fact that it -- to  
23 realize the fact that it's making a change and  
24 what it's communicated to consider less drastic  
25 alternatives, such as the option to give

1 applicants an opportunity to go and conduct  
2 those studies, which is what we're seeking here.  
3 And --

4 JUSTICE KAVANAUGH: And on the what  
5 you're seeking here, I'm sorry to interrupt, but  
6 what exactly would be -- this is the question  
7 that I was asking Mr. Gannon -- the relief that  
8 you're seeking in terms of what it would cause  
9 the agency to do as a real-world practical  
10 matter?

11 MR. HEYER: So, practically, to  
12 have -- have the marketing denial orders vacated  
13 and remanded, as the Fifth circuit did. And  
14 I'll point out we don't --

15 JUSTICE KAVANAUGH: That wouldn't  
16 allow you to start selling the product.

17 MR. HEYER: Well, because of the  
18 deferred enforcement policy, our clients are --  
19 are still allowed to sell the products, but  
20 that's because --

21 JUSTICE KAVANAUGH: Okay.

22 MR. HEYER: -- of FDA's -- of FDA's  
23 policies. It's a fairly unique circumstance  
24 here.

25 JUSTICE KAVANAUGH: Right.

1 MR. HEYER: I recognize that.

2 JUSTICE KAVANAUGH: Yeah.

3 MR. HEYER: And -- and -- and,  
4 frankly, we don't know what FDA is -- how FDA is  
5 going to approach it on remand. We have a new  
6 administration coming in, the president elect is  
7 on record saying, I'm going to save flavored  
8 vapes. We don't know exactly what that's going  
9 to look like. It may be that the approach the  
10 agency takes is much more aligned with the  
11 statute and looks at all the -- the risks and  
12 benefits than --

13 JUSTICE KAVANAUGH: But you could  
14 reapply -- all those things you talk about in  
15 the political process, you could reapply and all  
16 that could happen through that process, right?

17 MR. HEYER: One -- one could --

18 JUSTICE KAVANAUGH: In other words,  
19 I'm trying to figure out what's different from  
20 reapplying, just reapplying, and what's  
21 different from reapplying after a vacatur?

22 MR. HEYER: The -- the distinction  
23 here with respect to Respondents specifically is  
24 they're going to have to close their doors if  
25 they -- if they are -- you know, this, in

1 effect, is punitive for them because reapplying,  
2 closing down, the matter is, even though the  
3 statute calls for decisions in 180 days, FDA is  
4 taking three or four years at least to make  
5 determinations on these.

6           They can't afford to wait that out.  
7 They -- if -- if -- if -- if these MDOs are not  
8 vacated and remanded back to the agency, they're  
9 closing their doors and they're done. This was  
10 their one shot. That's why it was so important  
11 for FDA when it changed its position to  
12 communicate that and give them an opportunity to  
13 meet the new standard, and that's what was  
14 denied here.

15           JUSTICE KAVANAUGH: Okay. That's  
16 helpful.

17           CHIEF JUSTICE ROBERTS: How -- how is  
18 your position consistent with respect to how  
19 much guidance has to be provided with the  
20 well-recognized authority of agencies to proceed  
21 on a case-by-case basis?

22           MR. HEYER: In this case, Your Honor,  
23 our -- our position is that FDA made this  
24 determination that it was going to apply this  
25 litmus test, this longitudinal comparative

1 efficacy requirement, in the abstract without  
2 the particular facts of any particular case.  
3 And that's demonstrated through the internal  
4 August 17 memorandum, which admittedly was  
5 rescinded, but then we see it copied word for  
6 word in each and every one of these technical  
7 project lead reviews that underscore -- that  
8 underscore the -- the denial orders for every  
9 single applicant for -- for flavored products.

10           And so, here, the -- the reality is  
11 this was a forward-looking determination, a  
12 prospective determination that, in effect,  
13 was -- was a rule. It was setting up a new  
14 standard.

15           CHIEF JUSTICE ROBERTS: So your --  
16 your position is that the agency -- again, at a  
17 fairly general level of abstraction, your  
18 position is that the agency has to give guidance  
19 on -- on what's required to comply as opposed to  
20 simply that the agency may not mislead an  
21 applicant on what's required to comply?

22           MR. HEYER: Well, they certainly  
23 misled here. But, once the agency has spoken,  
24 once the agency has spoken as it did here and  
25 then when it changes its position, then it

1 certainly has an obligation to communicate that  
2 change. We think that's the lesson from this  
3 Court's precedents -- precedents and from the  
4 arbitrary-and-capricious standard that Congress  
5 has set forth in the APA itself.

6 JUSTICE JACKSON: So you say there's a  
7 change of position. The agency did not say  
8 originally that you did not have to have this  
9 information. I mean, I think I could appreciate  
10 a change if on day one the agency said do not  
11 submit this kind of information, you do not need  
12 it, as opposed to what happened here.

13 So can you help -- can you say a  
14 little bit more about the change?

15 MR. HEYER: Well, to Your Honor's  
16 point, the agency did say you don't need to do a  
17 randomized control trial. Afterwards, that's  
18 one of the options that they're saying you do  
19 need to do. Before, they said you don't need to  
20 do a six-month, you know, long-term study. And  
21 what have we seen so far? We've seen that the  
22 only flavored product that FDA has, in fact,  
23 authorized, the NJOY menthol product, was a  
24 six-month study.

25 JUSTICE JACKSON: I thought they said



1 these might not be necessary. In other words,  
2 there could be other ways that you can satisfy  
3 the standard. That's different than saying this  
4 is irrelevant, don't submit it. We're not going  
5 to look at it. We don't care about it. That's  
6 the kinds of it's not necessary that would  
7 create a conflict in the way that you're trying  
8 to describe as opposed to saying it's not  
9 necessary because you can satisfy this in  
10 potentially other ways. Right?

11 MR. HEYER: Your Honor, the -- in my  
12 introduction, I think I listed through five or  
13 six ways that we believe the agency absolutely  
14 flip-flopped and it misled applicants, it said  
15 one thing and then ultimately required another.

16 When it says no specific studies are  
17 required, which it said -- Slide 26 of the 2018  
18 public meeting -- clearly, some specific study  
19 is required.

20 It also said it in a letter to Bidi  
21 Vapor, we've cited in a footnote, dated May 8th  
22 of 2020, just four months before the application  
23 deadline. Bidi wrote in and said: What  
24 comparator products do we need to use? And FDA  
25 said: We have no requirements for comparator

1 products.

2           After the fact, it must be -- it must  
3 be a longitudinal comparative efficacy study.  
4 It can be a randomized control trial, a  
5 longitudinal cohort study, or some other  
6 evidence that tracks users over time during  
7 the --

8           JUSTICE JACKSON: Can I ask you this?  
9 The statute --

10           JUSTICE BARRETT: Counsel --

11           JUSTICE JACKSON: Oh, go ahead.

12           JUSTICE BARRETT: No, go ahead.

13           JUSTICE JACKSON: The statute says you  
14 have to have valid scientific evidence.

15           What if the agency had said you don't  
16 have to present any evidence? Is it your  
17 position that based on the agency's changing of  
18 its position because, at the end of the day,  
19 they asked for evidence, that you would be  
20 entitled to authorization?

21           In other words, I see certain things  
22 in the statute that appear to give people notice  
23 as to what the agency's going to look for,  
24 et cetera, et cetera. Let's hypothesize that  
25 the agency says something different than what

1 the statute requires.

2 Is it your position that at the end of  
3 the day, because of that change in position of  
4 the agency, you would be entitled to  
5 authorization?

6 MR. HEYER: If there were notice from  
7 the statute, I don't know that that would be my  
8 position, Your Honor. But, certainly, there's  
9 no notice from the statute that comparative  
10 efficacy studies are specifically required.

11 Again, the word "efficacy" or  
12 "effectiveness" is not found in the statute,  
13 much less that it must be flavored products  
14 against tobacco-flavored products.

15 JUSTICE JACKSON: Thank you.

16 JUSTICE BARRETT: Counsel, can I ask  
17 you a question about your good-faith reliance  
18 argument?

19 So a lot of your argument turns on --  
20 well, all of your argument turns on the switch  
21 in position in the guidance.

22 Now let's say that I disagree with you  
23 that this switch was so clear. How much are you  
24 relying on, you know, listen, we interpreted it  
25 that way, and we have good-faith reliance on

1 this interpretation? It's almost kind of like a  
2 reverse Chevron deference except we're deferring  
3 to the applicant rather than to the agency.

4 Can you walk me through how that can  
5 possibly be?

6 MR. HEYER: Well, we're not saying  
7 necessarily you must defer to the applicant,  
8 Your Honor. We're saying this was, in fact, a  
9 flip-flop here. This was, in fact, a change on  
10 the factual record. I understand it's a -- it's  
11 a -- it's a factually driven analysis.

12 JUSTICE BARRETT: So you're not making  
13 any kind of argument that you relied in good  
14 faith because these guidelines could be  
15 interpreted your way?

16 MR. HEYER: They were -- as a factual  
17 matter, they were interpreted that way. So I  
18 don't see the distinction of practicality given  
19 the facts here, I guess is what I -- what I  
20 would say.

21 JUSTICE BARRETT: So you're saying the  
22 only way they could be interpreted is the way  
23 that you interpreted them?

24 MR. HEYER: In terms of FDA saying  
25 things like no specific studies are required,

1 yes, we interpret that to mean no specific  
2 studies are required and certainly not --

3 JUSTICE BARRETT: Okay. So your  
4 position is that the switch is clear and that's  
5 all we have to decide for you to win?

6 MR. HEYER: Correct, Your Honor.

7 JUSTICE BARRETT: And just I want to  
8 return to a point the Chief was making.

9 Do you agree or disagree that the FDA  
10 didn't have to say anything? I mean, these were  
11 sub-regulatory guidance that you're relying on,  
12 but do you agree that the FDA didn't have to  
13 provide that?

14 MR. HEYER: If FDA had never spoken  
15 and said the deadline is September 9, 2020,  
16 there is the statute, have at it, that would be  
17 a different scenario. In how FDA ultimately  
18 applied the statute, we may have different  
19 arguments. But, here, FDA did speak, and that's  
20 the -- and that's what then triggers the  
21 obligation to communicate the change in  
22 position.

23 JUSTICE GORSUCH: Counsel --

24 JUSTICE KAVANAUGH: When you say  
25 different --

1 JUSTICE GORSUCH: Sorry, please go  
2 ahead.

3 JUSTICE KAVANAUGH: Go ahead. Go  
4 ahead. Go ahead.

5 JUSTICE GORSUCH: All right.

6 (Laughter.)

7 JUSTICE GORSUCH: The harmless error  
8 argument, what do we do about that? Isn't it  
9 pretty obvious what will happen on remand if we  
10 bother -- require that formality with respect to  
11 the marketing plans?

12 MR. HEYER: Well, it's not, Your  
13 Honor. First of all -- for -- for two reasons.

14 One, as I noted, there -- there's  
15 going to be a change in administration, so we  
16 don't know how this is -- the evidence is going  
17 to be reevaluated on -- on -- on remand -- or  
18 evaluated for the first time, I should say, on  
19 remand.

20 Secondly --

21 JUSTICE GORSUCH: Putting aside the  
22 obvious --

23 MR. HEYER: Yeah. Yeah.

24 JUSTICE GORSUCH: -- as a legal  
25 matter --

1 MR. HEYER: Yeah.

2 JUSTICE GORSUCH: -- all right, the  
3 statute does have a harmless error rule in it.  
4 Now how to reconcile that with Chenery is an  
5 interesting question, but it's there and it has  
6 to mean something, doesn't it?

7 MR. HEYER: Right. And, Your Honor,  
8 here, the -- given that FDA -- going back to  
9 Justice Alito's comment -- or questions earlier,  
10 given that there is no evidence in the record of  
11 what the contents were of the marketing plans  
12 that FDA supposedly reviewed and said that these  
13 aren't -- and then ignored these -- and, again,  
14 it's a post hoc rationalization. FDA didn't  
15 even say these aren't any different. It said  
16 we're -- we're not looking at them for  
17 efficiency purposes.

18 But, given that that's -- that would  
19 set up an unreasonable evidentiary burden on us  
20 to prove that the outcome would have necessarily  
21 been different on -- on remand, that's sort of  
22 the -- the core -- the core of our argument.

23 And I think specifically here, going  
24 back to Chenery, when you have an agency  
25 determination that it's appropriate for the

1 protection of -- of the public health, the word  
2 "appropriate" suggests that the agency has a lot  
3 of power to determine -- to -- to establish  
4 that. And this is particularly a technical and  
5 scientifically driven determination. That --  
6 that weighs strongly in favor of remand back to  
7 the agency to look at the evidence.

8 Like Calcutt, this is a fact-intensive  
9 inquiry, not one where the -- the Court  
10 should -- either this Court or the Fifth Circuit  
11 should step in and attempt to do the agency's  
12 job for it.

13 JUSTICE GORSUCH: Yeah. All right.

14 JUSTICE KAVANAUGH: In response to  
15 Justice Barrett's question about if the agency  
16 had given no guidance and just said there's the  
17 statute, have at it, I think your answer was  
18 that would present a different scenario.

19 I just want to make sure. You agree  
20 that the agency could do that?

21 MR. HEYER: Theoretically, they could.  
22 There's nothing in the Tobacco Control Act that  
23 required it.

24 JUSTICE KAVANAUGH: Well,  
25 theoretically, is that a yes?



1           MR. HEYER: Nothing -- yes, nothing in  
2 the Tobacco Control Act required them to put out  
3 guidance or a rule. Now this has sort of all  
4 occurred before the courts --

5           JUSTICE KAVANAUGH: So that is a yes?

6           MR. HEYER: Yes.

7           JUSTICE KAVANAUGH: Okay. All right.

8           (Laughter.)

9           JUSTICE KAGAN: Do I understand -- I  
10 read your briefs as being a hundred percent a  
11 change-of-position argument. I mean, there are  
12 the -- these other little things, but I guess  
13 what I'm saying, it's a change-of-position  
14 argument and -- and not -- there's no  
15 freestanding fair notice argument in your brief,  
16 that -- that the fair notice idea comes into  
17 play because you're saying there was a change of  
18 position. So you were following one set of  
19 guidance when, in fact, they were applying  
20 another set of guidance.

21           Am I reading you right?

22           MR. HEYER: That -- that's certainly  
23 our primary argument, Your Honor. There is this  
24 D.C. Circuit line of case law, and I would point  
25 the Court specifically to the Salzer case, which

1 is referenced heavily in satellite broadcasting.

2 And Salzer is interesting and somewhat  
3 analogous here because, in that case, Salzer v.  
4 FCC, you had 51 applicants, and they were  
5 applying for permission for radio towers or  
6 something like that, and -- and there was a  
7 specific form that FCC wanted, and 44 of those  
8 applicants didn't include that form.

9 And the D.C. Circuit looked at that.  
10 And that was only about benefits. That was  
11 about getting a license to operate these radio  
12 towers or what have you. And, in that case, it  
13 was only about benefits. And -- and the D.C.  
14 Circuit said: If you're going to have very  
15 specific and demanding criteria for acceptance  
16 of the application, then you have to be more  
17 specific in what you're setting out.

18 And that has been the law for -- at  
19 least in the D.C. Circuit for 60 years.

20 JUSTICE KAGAN: Yes. I guess what I  
21 was suggesting was that I read your brief, and  
22 whenever I read about notice in your brief, it  
23 was always connected to the change in position.  
24 And I took from your brief that that was your  
25 argument, that it was this was unfair because

1 they changed position without telling us, not a  
2 kind of freestanding notice argument that didn't  
3 have anything to do with the change of position.

4 MR. HEYER: That's certainly our  
5 primary argument, Your Honor, but I think -- I  
6 think, if I can call it a secondary argument, I  
7 think this line of case law is out there. It's  
8 been long embedded in --

9 JUSTICE KAGAN: I mean, did -- did you  
10 talk about that anywhere? Because I read your  
11 brief, I didn't see that.

12 MR. HEYER: Yeah. Well, we -- we --  
13 we cited that line of case law, I suppose, in --  
14 in support. Given -- again, given the facts  
15 here, the agency did speak, it did take a  
16 position, so that's what we were addressing.  
17 But I think that secondary argument is there,  
18 yeah.

19 JUSTICE KAGAN: Thank you.

20 CHIEF JUSTICE ROBERTS: Justice  
21 Thomas?

22 Justice Alito?

23 JUSTICE ALITO: I have a question.

24 CHIEF JUSTICE ROBERTS: Oh, I'm sorry.

25 JUSTICE ALITO: Did our decision in

1       Calcutt change harmless error analysis? Was  
2       Calcutt a harmless error decision?

3               MR. HEYER: It -- it was -- it was a  
4       harmless error decision, Your Honor, in  
5       requiring -- inasmuch as it required remand.  
6       Whether it moved the needle in terms of the  
7       existing case law, I'm not sure that I would say  
8       that it -- that it did.

9               JUSTICE ALITO: Well, do you have any  
10       objection to the -- do you disagree with the  
11       government's argument that the harmless error  
12       rule applies and that the question is whether  
13       the error had a substantial bearing on the  
14       ultimate rights of the parties? Is that a  
15       correct statement of the rule?

16              MR. HEYER: I don't think I would  
17       disagree with -- I don't think I would disagree  
18       with that, Your Honor. The point is, here, we  
19       don't know what the comparison was. It's not of  
20       record.

21              JUSTICE ALITO: Okay. All right.  
22       Thank you.

23              CHIEF JUSTICE ROBERTS: Justice  
24       Sotomayor?

25              Justice Kagan?

1 Justice Gorsuch?

2 JUSTICE KAVANAUGH: Just in its reply  
3 brief on satellite broadcasting, the government  
4 says that: Well, that case was one where the  
5 D.C. Circuit required an agency to provide fair  
6 notice before dismissing an application as a  
7 sanction for violating a procedural rule and  
8 that that's not the circumstance we have here.

9 I just want you to respond to that.

10 MR. HEYER: It -- it can be described  
11 as the flip side of the coin. It can be  
12 described as a sanction or it can be described  
13 as denial of a benefit.

14 In Salzer -- the reason I go to  
15 Salzer, which predates satellite broadcasting,  
16 that was absolutely a denial of a benefit.  
17 Here, it's even more -- as the Fifth Circuit  
18 point out -- even more of a sanction, even more  
19 punitive. This is closing the doors of  
20 Respondents' businesses, Your Honor.

21 JUSTICE KAVANAUGH: Yeah, thank you.

22 CHIEF JUSTICE ROBERTS: Justice  
23 Barrett?

24 Justice Jackson?

25 Okay. Thank you, counsel.

1 MR. HEYER: Thank you, Your Honor.

2 CHIEF JUSTICE ROBERTS: Rebuttal,  
3 Mr. Gannon?

4 REBUTTAL ARGUMENT OF CURTIS E. GANNON  
5 ON BEHALF OF THE PETITIONER

6 MR. GANNON: Thank you, Mr. Chief  
7 Justice. If I could just make three points.

8 First, following up on something that  
9 Justice Gorsuch asked me before about the  
10 enforcement actions that FDA has taken in this  
11 context, it hasn't with respect to these  
12 applicants, but FDA has brought civil money  
13 penalty proceedings before ALJs, and when it  
14 asks for injunctions to prevent marketing, those  
15 are -- those are suits that it has to bring in  
16 district court.

17 Second, my friend said that there is  
18 zero history of their products being used by  
19 youth. That's a slight change from the position  
20 that they articulated in their brief, which was  
21 that at the time FDA gave this denial in 2021,  
22 that the number of people using open devices  
23 that use the liquids like the ones that they  
24 want to market were -- had -- had -- were only  
25 being used by about six-and-a-half percent of

1 youth at the time.

2           The statistics on that are -- are the  
3 same. Seven percent of youth are still using  
4 open tank systems or mod systems according to  
5 survey results from earlier this year. That's  
6 more than 114,000 middle and high school  
7 students who are using devices that could use  
8 liquids like the ones that Respondents want to  
9 market.

10           And FDA has explained throughout that  
11 its concern there was that, yes, it had  
12 limited -- it had taken enforcement action  
13 against a particular type of device in 2020.  
14 It -- it -- it was concerned most about  
15 cartridge devices that were most -- most popular  
16 with youth at the time. After that, by the time  
17 of the decision here, youth had migrated to  
18 disposable devices. And FDA is legitimately  
19 concerned that youth are chasing the flavors  
20 that they want.

21           And they -- there's every reason to  
22 think that if they needed to use open systems --  
23 open devices that use liquids like this in order  
24 to get the flavors they want, that that number  
25 would go up. FDA is legitimately concerned

1 about that. And so that's my third point.

2           There's no mystery here, as Justice  
3 Kagan was explaining, that FDA thought that  
4 there is an increased risk to youth.  
5 Respondents were on notice of that. And,  
6 indeed, common sense tells us that a flavor like  
7 Mother's Milk and Cookies is going to be  
8 disproportionately attractive to children.

9           And Respondents knew that they needed  
10 to make this comparison. They tried to show  
11 that flavors had an offsetting benefit with  
12 adults in their applications. FDA reasonably  
13 concluded that they didn't have sufficient  
14 evidence to establish that proposition.

15           We urge the Court to reverse the  
16 judgment of the court of appeals.

17           CHIEF JUSTICE ROBERTS: Thank you,  
18 counsel.

19           The case is submitted.

20           (Whereupon, at 11:23 a.m., the case  
21 was submitted.)

22

23

24

25



## Official - Subject to Final Review

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## C

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