

# 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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Pages: 1 through 96  
Place: Washington, D.C.  
Date: December 2, 2024

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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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1 P R O C E E D I N G S

2 (10:03 a.m.)

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

7 Mr. Gannon.

8 ORAL ARGUMENT OF CURTIS E. GANNON

9 ON BEHALF OF THE PETITIONER

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

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

25 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 -- 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 the -- we -- we -- we can't mislead  
15 them. 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  
6     quote -- "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 -- they had -- had said that they needed  
19    a 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            They -- throughout, they said, you

1     need good evidence. That's what the statute  
2     requires. Randomized controlled trials and  
3     longitudinal cohort studies would be good, but  
4     we're not -- we don't necessarily think you have  
5     to have 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, in 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  
12    the type of products that you describe.

13                It says, "In particular, the  
14    evidence" -- this is 243 of the Joint Appendix.  
15    "In 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  
10      with other evidence, but you didn't have  
11      sufficient 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 --

10 JUSTICE JACKSON: Can --

11 MR. GANNON: -- and that's where they  
12 failed on that part of the statutory calculus.

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

15 MR. GANNON: Sure.

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

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

23 MR. GANNON: Well, I -- I -- I think  
24 what we're saying is that the -- the Due Process  
25 doctrine that the other side is drawing upon we

1 think is inapplicable here. We think that there  
2 is fair notice that needs to be required in --  
3 in terms of what arbitrary-and-capriciousness  
4 review requires.

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

13 JUSTICE BARRETT: Are those D.C.  
14 Circuit cases right or wrong?

15 MR. GANNON: I -- I --

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

19 MR. GANNON: I -- I --

20 JUSTICE BARRETT: -- apart from  
21 arbitrary and capriciousness is what I meant?

22 MR. GANNON: I -- I'm not sure whether  
23 it's additional for -- for what the APA requires  
24 in arbitrary and capricious. I think that what  
25 I'm saying, in the D.C. Circuit case that

1     decided this case, this issue, said that the  
2     point is that they weren't misled about what  
3     they needed to show.

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

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

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

24            Wouldn't due process require an  
25    opportunity for notice and a hearing?

1                   MR. GANNON: I -- I -- I think, in --  
2     in those circumstances, maybe so, Justice  
3     Gorsuch. But our point here is that this is a  
4     statute that says that these products are  
5     unlawful unless they have been authorized for  
6     marketing by FDA. And -- and so, once --  
7     once --

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

13                  MR. GANNON: Well --

14                  JUSTICE GORSUCH: -- unless you can  
15    prove a net benefit.

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

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

21                  MR. GANNON: I -- our point is -- I  
22    understand that due process would apply to -- to  
23    when there is property at issue.

24                  JUSTICE GORSUCH: And, here, there are  
25    existing businesses, just like there was an

1 existing business in the --

2 MR. GANNON: It's --

3 JUSTICE GORSUCH: -- in the restaurant  
4 hypothetical.

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

9 JUSTICE GORSUCH: Sure. Of -- oh, of  
10 course.

11 MR. GANNON: -- these products are  
12 unlawful. And -- and so, if you --

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

17 MR. GANNON: You -- you -- they --  
18 they got a hearing, and -- and --

19 JUSTICE GORSUCH: I -- just -- I'm  
20 just asking on the legal point, Mr. Gannon,  
21 wouldn't they have a right to notice and a  
22 hearing?

23 MR. GANNON: They -- they have -- yes.  
24 They have --

25 JUSTICE GORSUCH: Yes. Okay.

1 That's --

2 MR. GANNON: -- they have notice from  
3 this statute, and they got a hearing from --  
4 from FDA about their application.

5 JUSTICE GORSUCH: But, as a matter of  
6 due process, they were entitled to that, is  
7 my -- that's my -- my question. Are they  
8 entitled to notice and a hearing?

9 MR. GANNON: And -- and what we are  
10 saying is that the fair notice question in this  
11 case, it really sounds in arbitrary and  
12 capriciousness, and it's not in Due Process  
13 doctrine. They had -- they had --

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

16 JUSTICE JACKSON: Isn't that --

17 JUSTICE GORSUCH: -- why -- why isn't  
18 there a due process right here if there -- if  
19 there -- if there is --

20 MR. GANNON: Because --

21 JUSTICE GORSUCH: -- you agree there  
22 is in the restaurant owner business?

23 MR. GANNON: That -- that that is a  
24 lawful business that is out there, and there  
25 is -- it is subject to regulation. In this

1 context, Congress has already made the baseline  
2 that these products are unlawful --

3 JUSTICE GORSUCH: Okay.

4 MR. GANNON: -- unless they actually  
5 get --

6 JUSTICE JACKSON: On that standard,  
7 right --

8 JUSTICE GORSUCH: If I might just --  
9 if I might just finish.

10 JUSTICE JACKSON: Mm-hmm.

11 JUSTICE GORSUCH: I -- I have a  
12 question to follow up on that, is how does the  
13 FDA enforce its denial orders?

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

23 MR. GANNON: At -- at -- at that  
24 point, for enforcement of the lack of  
25 authorization, that would be true. With respect

1 to some of these product applications that  
2 preexisted the -- the 2020 deadline that these  
3 applications do, there -- there were -- they  
4 were sort of grandfathered in. FDA had -- had  
5 stayed enforcement action for a time because,  
6 when it announced the deeming rule in 2016 --

7 JUSTICE GORSUCH: No, I -- I --

8 MR. GANNON: -- some of these products  
9 were already on the market.

10 JUSTICE GORSUCH: -- I do -- I do  
11 understand that. But -- but it -- it -- when it  
12 comes to an enforcement action, they wouldn't be  
13 able to collaterally attack the denial orders,  
14 would they?

15 MR. GANNON: That's correct.

16 JUSTICE GORSUCH: Okay.

17 MR. GANNON: They can attack the --  
18 the denial order in the judicial review, as they  
19 are doing in this particular proceeding.

20 JUSTICE GORSUCH: Thank you. Thank  
21 you.

22 Justice Jackson, I'm sorry.

23 JUSTICE JACKSON: Yes. No, no, I  
24 apologize for jumping in.

25 I just wanted to ask about your

1     hypothetical, Justice Gorsuch, which I  
2     understood -- and, Mr. Gannon, maybe is the  
3     distinction the fact that in the hypothetical  
4     that was just posed to you that counsel is  
5     creating the standard, and what you're saying is  
6     the statute creates the standard here?

7                 MR. GANNON:  -- in this instance, we  
8     are saying that the statute made these products  
9     unlawful, unless there was --

10                JUSTICE JACKSON:  A particular  
11    showing.

12                MR. GANNON:  -- FDA authorization.

13                JUSTICE JACKSON:  So the showing --

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

21                JUSTICE JACKSON:  Right.  But  
22    appropriate for the protection of the public  
23    health.  And the things that the FDA has to look  
24    at are in the statute?

25                MR. GANNON:  That's correct.

1 JUSTICE JACKSON: So this is not a  
2 discretionary call of the FDA. I mean, I  
3 understand the fair notice point in the context  
4 of a scheme in which the FDA has total  
5 discretion. The FDA comes up with the standards  
6 for approval, and the FDA makes representations  
7 about what people have to do, and then there is  
8 argument about whether or not they've changed  
9 their mind.

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

17 MR. GANNON: That is correct, that the  
18 statute sets the standard. FDA does, of course,  
19 have discretion in -- in when it is going to  
20 approve, but it is applying that statutory  
21 standard.

22 JUSTICE JACKSON: Correct. And so --  
23 so, if the FDA were to say suddenly, for  
24 example, that, you know, you don't have to  
25 supply any scientific evidence concerning

1     whether or not there is a benefit to your  
2     product, right -- let's say the FDA's guidance  
3     said such a thing. Would we -- could -- could  
4     it? I mean --

5                 MR. GANNON: No, that would not be  
6     permitted by the statute. The statute says that  
7     there need to be well-controlled investigations  
8     or other scientific evidence, if FDA considers  
9     that sufficient, to establish the relevance --  
10    the relevant things that --

11                JUSTICE JACKSON: So -- so, in that  
12    situation --

13                MR. GANNON: -- that the applicant is  
14    required to prove.

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

23                MR. GANNON: It is right that they  
24    wouldn't be able to say that they were entitled  
25    to approval under the statute. To the extent

1     that FDA had misled them, we are saying that  
2     that would be -- that would be something that  
3     would be vulnerable under arbitrary and  
4     capricious standards. If FDA said you just  
5     don't need any scientific evidence and then, at  
6     the -- at the time of the approval or denial,  
7     said sorry, you don't have the evidence --

8             JUSTICE JACKSON: But what was the  
9     remedy for that?

10            MR. GANNON: -- and that's not what  
11     happened here.

12            JUSTICE JACKSON: What -- I understand  
13     it's not what happened there, but I'm just --  
14     I'm -- I'm confused about your answer.

15            MR. GANNON: Well, I think, there,  
16     the --

17            JUSTICE JACKSON: I mean, a person --  
18     a person could claim that they would be entitled  
19     to approval on a lesser standard if the FDA had  
20     mistakenly told them something less than what  
21     the statute required?

22            MR. GANNON: I -- I mean, they would  
23     be able to say that FDA had -- had not acted --  
24     they had acted arbitrary and capriciously in  
25     making that particular decision. And FDA would

1     need to go back and -- and -- and do it  
2     correctly.

3                 But I -- I take your point that in  
4     that instance, if they really can't satisfy the  
5     stat -- statutory standard at the end of the  
6     day, FDA shouldn't approve them, even on remand.

7                 JUSTICE KAVANAUGH:   So that --

8                 MR. GANNON:   Of course, that's not  
9     what we have here.

10                JUSTICE KAVANAUGH:   As a practical  
11     matter then, I'm curious what relief looks like  
12     in this case, because the companies can always  
13     reapply, correct?

14                MR. GANNON:   That's correct.   They can  
15     reapply without a fee.   And some other  
16     applicants have reapplied.

17                JUSTICE KAVANAUGH:   And if they won  
18     this case, they can reapply?

19                MR. GANNON:   If they -- yes.   If they  
20     won this case or if they lose this case, they  
21     will be able to reapply.

22                JUSTICE KAVANAUGH:   That's -- that's  
23     my question about what the relief really  
24     accomplishes here that is being sought as a  
25     practical matter.   I understand the legal point,

1 the FDA acted arbitrary and capriciously, but  
2 either way, it's going to be that they can  
3 reapply and hope to succeed, right?

4 MR. GANNON: Well --

5 JUSTICE KAVANAUGH: Or --

6 MR. GANNON: -- yes, they would be  
7 able to reapply. And to the extent that they  
8 say, oh, we had no idea this is what we were  
9 supposed to be proving even they though were --

10 JUSTICE KAVANAUGH: Now they know.

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

15 I expect that they will say that,  
16 right now, they have a stay from the Fifth  
17 Circuit of enforcement of this denial order,  
18 and, therefore, they have some protection with  
19 respect to enforcement actions with -- with  
20 respect to this.

21 JUSTICE KAVANAUGH: That's why fair  
22 notice is a bit of an odd fit with this kind of  
23 scheme because, even if you didn't get fair  
24 notice, as Justice Jackson was saying, you don't  
25 get a court order that you are approved to now

1     sell the product.

2                 MR. GANNON:  -- that's correct.  And  
3     to the extent that FDA -- that the Fifth Circuit  
4     remanded to FDA, it -- it --

5                 JUSTICE KAVANAUGH:  All you get with  
6     lack of fair notice is that you can apply again,  
7     which you can do anyway.

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

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

1                   MR. GANNON: It is. I mean, I -- I --  
2 I understand the Fifth Circuit's remand to  
3 assume that they would actually have to apply  
4 different standards than the ones that they did.  
5 And, you know, we think that the Fifth Circuit's  
6 just flat wrong on that. That's different from  
7 the -- the question on which we're arguing  
8 harmless error.

9                   JUSTICE KAVANAUGH: I guess, just to  
10 tie this up, even if they'd given mistaken -- if  
11 you had given mistaken guidance before, FDA had  
12 given mistaken guidance before, they're not  
13 bound to adhere to the mistaken guidance when  
14 they now consider an application, correct?

15                  MR. GANNON: That -- I -- they  
16 shouldn't be. I think the Fifth Circuit  
17 decision here --

18                  JUSTICE KAVANAUGH: Because how could  
19 it be, right?

20                  MR. GANNON: -- I think -- I think is  
21 suggesting that they would have to apply the  
22 previous standards that the Fifth Circuit sees  
23 them as articulating in the guidance, which is  
24 you don't need this type of evidence and,  
25 therefore, you can't demand this type of

1 evidence now. We -- we think that that is  
2 wrong.

3 And to the extent that -- that --  
4 because we think that they didn't lack the  
5 notice that they -- that they deserved, I mean,  
6 in light of the statute and the things that FDA  
7 had said and that their application shows, that  
8 they knew they were supposed to be proving this.

9 CHIEF JUSTICE ROBERTS: Counsel --

10 JUSTICE KAGAN: Can I --

11 CHIEF JUSTICE ROBERTS: -- you -- you  
12 mentioned just a few moments ago your harmless  
13 error argument, and I wondered if you could tell  
14 me why you think that's consistent with -- with  
15 Chenery.

16 Here, you say that the agency made an  
17 error. Normally, under Chenery, we send it back  
18 so we can see what the agency would do in the  
19 absence of error rather than deciding it  
20 ourselves.

21 Does -- doesn't the harmless error  
22 argument violate that principle?

23 MR. GANNON: It -- it doesn't. And  
24 this is not a typical Chenery problem because  
25 the lawyers aren't coming up with an ad hoc

1     reason after the -- or a post hoc reason here.  
2     The agency has already revealed what it would  
3     have done in this context.

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

21            And to the extent -- and so I think,  
22    when you look at the harmless error question in  
23    this case -- and the Court has said that it  
24    doesn't engage in idle and useless formalities.  
25    This isn't supposed to be an endless game of

1 ping pong. And so you're right, if we didn't  
2 know what the agency was going to do, then you  
3 should remand.

4 JUSTICE KAGAN: And --

5 MR. GANNON: But, in this instance, we  
6 do.

7 JUSTICE KAGAN: And what are the  
8 materials that you look to to know whether you  
9 know that -- what the agency would do?

10 MR. GANNON: In this instance, the --  
11 the -- the chief thing is in the 2020 guidance,  
12 where the agency specifically said that age  
13 gating at -- at vape shops and online sales had  
14 not proved sufficient in order to keep  
15 e-cigarettes from getting into the hands of  
16 minors.

17 And so, to the extent that they are  
18 saying we want to limit sales only to adults,  
19 that's not going to prove sufficient. And FDA  
20 has already made it clear that that's not going  
21 to be sufficient.

22 JUSTICE KAGAN: And what is the  
23 standard that one uses in that inquiry? Do you  
24 have to be certain that the agency would do  
25 that, highly confident that the agency would do

1       that?  What?

2                   MR. GANNON:  Well, it -- I mean, the  
3       Court's discussion of this in *Shinseki* against  
4       *Sanders*, which we quote in our brief, says that  
5       there's no sort of all-purpose standard for  
6       evaluating harmless error.  There are  
7       case-appropriate considerations.  But I think  
8       that the chief one that the Court recites there  
9       is an estimation of the likelihood that the  
10      result would have been different.

11                   And I think that if it's a really low  
12      likelihood you can be confident that the agency  
13      wouldn't do something different, then it's just  
14      going to be the idle and useless formality  
15      that -- that the rule of prejudicial error keeps  
16      the courts from engaging in here.

17                   JUSTICE KAGAN:  And -- and maybe just  
18      out of curiosity, why didn't the agency just do,  
19      with respect to each of these applications, you  
20      know, this marketing plan is no different from a  
21      hundred other youth marketing plans that we've  
22      seen and none of them are sufficient for the  
23      following probably boilerplate reasons?

24                   MR. GANNON:  Yeah, you know, the  
25      record here doesn't actually, you know, get into

1     that.  It just has the footnote.  What the  
2     footnote says is that they're doing it for the  
3     sake of efficiency.  And we know that the FDA  
4     was considering a big backlog of applications  
5     that had piled up at that point.

6             The other side in the amicus briefs  
7     sort of say that it was a million -- a million  
8     plus products that FDA was evaluating at once.  
9     I think that's a little bit of an exaggeration  
10    of what the landscape was at the time because --  
11    because a single applicant could apply for tens  
12    of thousands of applications -- of -- of  
13    products at once such that that first tranche of  
14    decisions that were made in the weeks around  
15    when these decisions were included involved 1.2  
16    million products.  It was really 320 or so  
17    applications, but that is a significant backlog.

18            And what FDA said is that they're  
19    doing this for efficiency's sake.  They knew  
20    what the mine run of restrictions were that were  
21    out there in the world, and to the extent that  
22    anyone had something novel to propose, they had  
23    usually raised it with FDA on the side to say,  
24    hey, we're thinking about this.  And --

25            JUSTICE KAGAN:  But, if I understand

1 your position right, you're not defending that?

2 You are --

3 MR. GANNON: We -- we are not  
4 contesting --

5 JUSTICE KAGAN: -- conceding or --

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

7 JUSTICE KAGAN: Are you conceding it's  
8 an error? You're not contesting?

9 MR. GANNON: What -- what -- we didn't  
10 make that part of our -- our -- our cert  
11 petition. We're not contesting that here.  
12 We're saying, to the extent that it was an  
13 error, it was harmless because we know what FDA  
14 would do. It's like if you asked yourself -- if  
15 20 pages from this application were missing,  
16 when the key person did the review at the FDA,  
17 you would ask yourself, what difference does  
18 that make? You would want to know what's in  
19 those 20 pages. If those 20 pages were actually  
20 blank or they were filled with printer  
21 gibberish, wouldn't have made any difference.

22 If they had something new, we don't  
23 what FDA thought about it, then you should  
24 remand and let FDA figure whether those 20 pages  
25 made a difference. If they're 20 pages that FDA

1 has denied over and over, we don't think it  
2 matters that much that --

3 CHIEF JUSTICE ROBERTS: Thank you,  
4 counsel.

5 MR. GANNON: -- you didn't look at the  
6 20 pages.

7 CHIEF JUSTICE ROBERTS: Justice  
8 Thomas, anything further?

9 Justice Alito?

10 JUSTICE ALITO: On the harmless error  
11 point, does harmless error review -- is harmless  
12 error review confined to the administrative  
13 record in the case at hand?

14 MR. GANNON: I don't think in this  
15 instance -- I mean, I think you would need to  
16 evaluate on the basis of what you know about the  
17 agency. Here, I think you can take notice of  
18 all the public things that FDA has -- has  
19 already done.

20 And we're primarily pointing at things  
21 FDA had done before it engaged in these  
22 marketing denial orders, but we also note that  
23 subsequent marketing denial orders applied the  
24 same concern that these youth marketing  
25 restrictions weren't independently sufficient to

1     reduce the risk to youth posed by flavored  
2     e-cigarettes in order to say you don't need to  
3     have the extra benefit on the adult side of the  
4     equation in order to have a net population  
5     benefit.

6             JUSTICE ALITO: Well, a -- a big part  
7     of your harmless error argument -- more than a  
8     page, is based on the order that the FDA issued  
9     after the order in this case in the Logic  
10    Technology Development case.

11            MR. GANNON: Right.

12            JUSTICE ALITO: Is that -- is that  
13    proper, to look to --

14            MR. GANNON: I -- I think --

15            JUSTICE ALITO: -- an order that came  
16    after the order in this case --

17            MR. GANNON: I --

18            JUSTICE ALITO: -- to determine  
19    whether the error was harmless?

20            MR. GANNON: I think, in this  
21    instance, the reason why we're giving you that  
22    example is because it shows how what FDA said in  
23    the 2020 guidance predetermines the answer to  
24    that particular question.

25            And -- and FDA said that it didn't

1 think that these mine-run state-of-the-market  
2 restrictions that existed in 2020 and 2021, if  
3 you didn't have something novel, had not proved  
4 adequate to keep e-cigarettes out of the hands  
5 of youth. And, therefore, you can't just say  
6 we've solved the youth side of the equation, let  
7 us get whatever benefits happen on the adult  
8 side.

9 And so the Logic Technology  
10 application that we discussed there is an  
11 application saying, look, here's another place  
12 where FDA kept saying when it was reviewing that  
13 marketing plan that it wasn't good enough. And  
14 so the other side, I don't think, has said: Oh,  
15 we have something novel.

16 The one case that's gone the other way  
17 here, the Bidi Vapor case from the Eleventh  
18 Circuit, specifically cited novel proposals that  
19 those applicants had in their application. And  
20 the other side here isn't pointing to anything  
21 like that.

22 JUSTICE ALITO: Several amici in this  
23 case asked that if we rule in your favor, we  
24 should reserve on the issue of menthol-flavored  
25 e-cigarette products.

1 Do you agree with that?

2 MR. GANNON: I -- I -- I think that  
3 as -- as long as you say that FDA's standard  
4 here did not violate the statute or its previous  
5 guidance, I -- I think it's fine to say menthol  
6 may be a different point.

7 FDA has been applying the same  
8 standard to menthol. At first, it -- it -- the  
9 way it sequenced these applications is that it  
10 first looked at fruit, candy, and dessert  
11 flavors, like the ones that are at issue here,  
12 and that's where it -- that's where it -- it  
13 said that it -- it focused on this need to show  
14 the -- the -- the benefits for adults that  
15 counter -- that -- that -- that out-balance the  
16 harm to -- to kids.

17 It -- it was unsure at first whether  
18 menthol should be treated in the same way. It  
19 later concluded that the same test applied to  
20 menthol.

21 And earlier this year, in applying the  
22 same test to menthol, they authorized a handful  
23 of products because that applicant had survey  
24 research conducted in 2020 -- before these  
25 applications were even filed, the survey that

1 NJOY conducted specifically said they had  
2 substantial evidence to show that they had more  
3 impact on adult smokers ceasing to smoke  
4 cigarettes with their menthol flavors compared  
5 to tobacco flavors.

6 It's that type of evidence that was  
7 missing in these applications.

8 JUSTICE ALITO: Okay. One last  
9 question, and maybe this is just a matter of  
10 curiosity on my part. If there weren't a  
11 million application denials, there were  
12 certainly many hundreds of thousands, right?  
13 What would you say?

14 MR. GANNON: The -- the -- the  
15 number -- the prior -- the number of denials for  
16 products really was more than a million. What I  
17 was saying is that that tends to exaggerate  
18 maybe the sense of the other side saying that --  
19 that -- that this is cookie-cutter analysis by  
20 FDA because -- because that was really a few  
21 hundred applications that were being decided  
22 with -- with that many products that were  
23 underlying the application.

24 JUSTICE ALITO: Well, do -- do you  
25 maintain that these were really -- however many

1 hundreds of thousands there were, each one a  
2 bespoke consideration of the application and  
3 there was not some sort of checklist behind the  
4 scenes that was actually dictating the outcome  
5 in these cases?

6 MR. GANNON: What -- what -- my point  
7 is that an individual applicant, when it is --  
8 when it is applying for tens of thousands of  
9 products at once, is using the same application  
10 over and over. It has exactly the same evidence  
11 to say: We think that this product is going to  
12 be good on one side and not bad on the other  
13 side of the equation.

14 And so, to the extent that the  
15 applicant is saying the same thing over and over  
16 and over again, FDA is saying the same thing  
17 over and over again in denying it.

18 JUSTICE ALITO: Okay. Thank --

19 MR. GANNON: And in every instance,  
20 FDA is looking to see whether they have this  
21 evidence. And at the time, nobody had this  
22 evidence.

23 JUSTICE ALITO: All right. Thank you.

24 CHIEF JUSTICE ROBERTS: Justice  
25 Sotomayor?

1 JUSTICE SOTOMAYOR: All of these  
2 products contain tobacco, right?

3 MR. GANNON: They contain nicotine.

4 JUSTICE SOTOMAYOR: Nicotine. And  
5 it's nicotine that's addictive, correct?

6 MR. GANNON: That's correct.

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

9 MR. GANNON: I -- I mean, I -- some of  
10 these -- you can make an e-cigarette or a vaping  
11 product that doesn't have nicotine that can  
12 otherwise simulate other aspects of --

13 JUSTICE SOTOMAYOR: Right.

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

15 JUSTICE SOTOMAYOR: But those products  
16 are not at issue, meaning they don't need a  
17 license, correct?

18 MR. GANNON: If it doesn't have  
19 nicotine -- I mean, to the extent that it's  
20 intended to -- to play into smoking cessation,  
21 then -- then I -- I'm not sure. But all the  
22 products that are at issue here contain  
23 nicotine. And in 2022, Congress expanded the  
24 statute to include nicotine that doesn't even  
25 come from tobacco.

1                   So, in this instance, there's no doubt  
2                   that FDA is the agency that has the authority to  
3                   regulate whether products containing nicotine  
4                   are appropriate for the protection of the public  
5                   health.

6                   JUSTICE SOTOMAYOR: Other than  
7                   addiction, why would someone put nicotine into a  
8                   product and then try to hide the flavor of  
9                   tobacco? Meaning I -- I -- I'm a little bit at  
10                  a loss.

11                  MR. GANNON: I'm not going to deny  
12                  that there are -- there could be other reasons  
13                  why -- why users want flavors, why a -- a  
14                  manufacturer would want to say: Hey, if  
15                  somebody wants to see what -- what a cigarette  
16                  is like when it tastes like something that's not  
17                  a cigarette, what -- what's it like to smoke,  
18                  you know, Jimmy The Juice Man Peachy Strawberry,  
19                  which is one of the flavors here --

20                  JUSTICE SOTOMAYOR: Well, this is more  
21                  curiosity, which is we know nicotine is  
22                  addictive. You put it in to addict people.  
23                  Presumably, you put it in to addict adults and  
24                  children.

25                  MR. GANNON: We -- we --

1 JUSTICE SOTOMAYOR: And that's why  
2 you're acting to try and stop --

3 MR. GANNON: Congress was concerned  
4 about the fact that the -- that -- that most  
5 people who become addicted to nicotine start  
6 when they are underage, at a time when the  
7 adolescent brain is particularly vulnerable to  
8 the effects of nicotine.

9 And that was the main reason why it  
10 was concerned about trying to reduce youth  
11 smoking in the Family Smoking Prevention and  
12 Tobacco Control Act that it passed here.

13 JUSTICE SOTOMAYOR: Thank you,  
14 counsel.

15 CHIEF JUSTICE ROBERTS: Justice Kagan?  
16 Justice Gorsuch?

17 JUSTICE GORSUCH: I just wanted to  
18 follow up, Mr. Gannon, a little bit on -- on the  
19 harmless error question.

20 It seems to me there are two  
21 possibilities. One, we could say harmless error  
22 is treated here just like it is in civil  
23 litigation. But that kind of runs into the  
24 Chenery problem, right?

25 MR. GANNON: Well, it -- it -- it --

1 it does and it doesn't.

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

4 MR. GANNON: Sure.

5 JUSTICE GORSUCH: Because I'm trying  
6 to help you here, actually, I promise.

7 (Laughter.)

8 JUSTICE GORSUCH: Another -- another  
9 possibility would be to say that the harmless  
10 error rule applies in administrative contexts  
11 when we can be sure what the agency would have  
12 done, that the agency couldn't have reached a  
13 different conclusion.

14 And I'm wondering if that might be the  
15 case here and the nature of your argument given  
16 that the marketing plans go to the statute's  
17 second requirement.

18 There are two requirements. One, it  
19 helps smoking cessation, and, two, it doesn't  
20 create other problems. And two is kind of  
21 irrelevant if you fail under one.

22 Do you follow me?

23 MR. GANNON: I -- I follow you.

24 And -- and I think what the other side would say  
25 is the question is --

1 JUSTICE GORSUCH: I'm wondering what  
2 you would say.

3 MR. GANNON: I -- I -- I think the  
4 question is whether they really have some way of  
5 solving two, if they really had some knock-down  
6 argument about why they were going to prevent  
7 youth smoking in a way that nobody else has with  
8 respect to their particular product.

9 JUSTICE GORSUCH: But wouldn't they  
10 still fail under one, that they can't  
11 demonstrate a public health benefit?

12 MR. GANNON: They would still have to  
13 show a public health benefit.

14 JUSTICE GORSUCH: Right.

15 MR. GANNON: It wouldn't necessarily  
16 have to be the heightened benefit in order to  
17 counter the heightened risk that FDA had  
18 recognized exists with respect to youth.

19 JUSTICE GORSUCH: But I had thought  
20 your client took the position that there was no  
21 public health benefit here.

22 MR. GANNON: That -- that we -- we  
23 said that they haven't established that there is  
24 a higher public health benefit with respect to  
25 flavors in order to counterbalance the higher

1 risk that flavors pose. And so --

2 JUSTICE GORSUCH: So -- so they're

3 linked?

4 MR. GANNON: Pardon? They -- they --

5 JUSTICE GORSUCH: So you're -- you're

6 conceding they're linked?

7 MR. GANNON: -- they are absolutely

8 linked. And what I am saying is, to the extent

9 that it's a real --

10 JUSTICE GORSUCH: Okay. So how -- how

11 do you -- how do you deal with the Chenery

12 problem then?

13 MR. GANNON: The -- the way I deal

14 with the Chenery problem is the answer I gave to

15 the Chief Justice, which ends your -- the way

16 you phrased the first version of harmless

17 error --

18 JUSTICE GORSUCH: Mm-hmm.

19 MR. GANNON: -- is the way the Court

20 has said that -- that you apply harmless error

21 as you do in civil litigation. And so you are

22 asking yourself whether it makes any

23 difference --

24 JUSTICE GORSUCH: I -- I know what

25 that looks like. But the -- how does that --

1     how -- how do we -- how do we reconcile that  
2     with Chenery, which, you know, acknowledges that  
3     the agency may well have many good explanations,  
4     we can conjure them --

5             MR. GANNON:   That's right.

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

8             MR. GANNON:  I think that's right when  
9     it -- when it would be a completely different  
10    argument, when it would be a different standard  
11    where there may be some alternative form of  
12    reasoning.

13            Here, we know what the reasoning was.  
14    The question is just whether --

15            JUSTICE GORSUCH:  Okay.

16            MR. GANNON:  -- had the agency looked  
17    at the extra bit of information, it would have  
18    made a difference to its bottom line.  It's  
19    the -- it's the 20 blank -- missing pages hypo  
20    that I discussed earlier.

21            JUSTICE GORSUCH:  And let me just turn  
22    back real quickly to the enforcement action  
23    question.  Are those conducted before ALJs?

24            MR. GANNON:  The civil enforcement  
25    actions, I -- I'm not sure to tell you the

1 truth -- but --

2 JUSTICE GORSUCH: I'm just wondering,  
3 does a company ever have a chance to get before  
4 a -- a judge and a jury?

5 MR. GANNON: I -- I think the answer  
6 is yes, but I -- but I'm not sure about the  
7 details because we -- we haven't really been  
8 engaging in those --

9 JUSTICE GORSUCH: No, I --

10 MR. GANNON: -- with respect to the  
11 category -- the products that are at issue in  
12 these cases.

13 JUSTICE GORSUCH: I mean, after  
14 Jarkesy, perhaps the answer is yes?

15 MR. GANNON: We will certainly comply  
16 with what the law requires, Justice Gorsuch.

17 (Laughter.)

18 JUSTICE GORSUCH: Thank you,  
19 Mr. Gannon.

20 CHIEF JUSTICE ROBERTS: Justice  
21 Kavanaugh?

22 JUSTICE KAVANAUGH: I understand your  
23 main argument is that the guidance here was not  
24 misleading or mistaken and gave sufficient  
25 notice, but as the discussion earlier -- our

1 discussion earlier, I think, illustrated, when  
2 there is mistaken or misleading guidance in a  
3 situation where someone's trying to apply to  
4 obtain a benefit or license or something, that  
5 there's no real meaningful relief that the APA  
6 actually affords, and that raises a concern for  
7 me about what checks are there on mistaken or  
8 misleading guidance in situations where  
9 someone's applying for a benefit or applying for  
10 a license or something of that sort.

11 Is it just the political process,  
12 public pressure --

13 MR. GANNON: Well, I think, in that  
14 instance, the -- the answer would be that you --  
15 you -- you could send it back to the agency.  
16 The agency, because it was arbitrary or  
17 capricious for the agency to mislead and apply  
18 ultimately a different standard than the one  
19 that it told applicants it was going to apply,  
20 it would then have to -- it -- it -- it would --  
21 it would then have to give applicants a chance  
22 to apply under the correct standard and it would  
23 evaluate it.

24 And so the check would be that the  
25 agency wouldn't --

1 JUSTICE KAVANAUGH: They could --

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

6 JUSTICE KAVANAUGH: But you said you  
7 could do that anyway?

8 MR. GANNON: They -- yes, in this  
9 instance, they can do that.

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

13 MR. GANNON: I -- I -- I think, in  
14 that circumstance, it -- it -- it may not. To  
15 the extent that they have a stay that's tied to  
16 these particular denial orders, to the extent  
17 that this would be a remand and a -- and -- and  
18 the agency could just reconsider this  
19 application on -- with -- with respect to the  
20 information that -- that it includes in it,  
21 then -- then maybe -- maybe --

22 JUSTICE KAVANAUGH: And I --

23 MR. GANNON: -- it would be a quicker  
24 decision.

25 JUSTICE KAVANAUGH: I guess another

1 possibility -- you haven't said this -- is that  
2 the agency on remand could conclude that its  
3 current -- the earlier guidance was correct and  
4 they should back away from their current  
5 standard. I know that's not this case, but  
6 that's theoretically possible in the  
7 hypothetical I'm raising?

8 MR. GANNON: As long as it was then,  
9 you know, explaining its reversion to the  
10 previous position --

11 JUSTICE KAVANAUGH: Right.

12 MR. GANNON: -- yes, to the extent  
13 that the agency has leeway under the statute to  
14 go one way versus the other way --

15 JUSTICE KAVANAUGH: Yeah.

16 MR. GANNON: -- and it -- and it then  
17 explains that it is changing its position. Of  
18 course, our position here is that the agency  
19 didn't change its position at -- at any point in  
20 time here with respect to what the other side  
21 needed to prove.

22 JUSTICE KAVANAUGH: I understand that.  
23 I was just exploring the contours. Thank you.

24 CHIEF JUSTICE ROBERTS: Justice  
25 Barrett?

1 JUSTICE BARRETT: Mr. Gannon, I have  
2 what I hope is an easy practical question.  
3 Let's -- let's imagine that we are pretty  
4 confident, you know, let's say we have a high  
5 degree of confidence that the agency would  
6 decide the marketing question the same way on  
7 remand on the harmless error point, but we still  
8 think that Chenery requires us to send it back.

9 As a practical matter then, what  
10 happens? Because, if we're pretty confident the  
11 agency's going to reach the same decision, you  
12 know, is it going to take the agency a long time  
13 to reconsider these applications and do what we  
14 think they're going to do anyway?

15 MR. GANNON: I -- I -- in this  
16 instance, we're not saying it's -- it's a big  
17 burden in order to reevaluate these particular  
18 applications as long as the Court -- assuming  
19 that the Court is reversing the Fifth Circuit on  
20 the other things --

21 JUSTICE BARRETT: Right.

22 MR. GANNON: -- about -- about not  
23 having to -- about what studies it -- it can ask  
24 for, that it wants real scientific evidence.

25 JUSTICE BARRETT: Just the marketing

1 question?

2 MR. GANNON: It's just the marketing  
3 plans. We're not saying that -- that it's a big  
4 burden on the agency in order to have to decide  
5 the applications from -- from -- from these two  
6 applicants and look at the marketing plans and  
7 confirm that there's nothing in there that  
8 changes its mind about the bottom-line  
9 conclusion here.

10 JUSTICE BARRETT: So it's a pretty low  
11 stakes -- issue?

12 MR. GANNON: It -- it's low stakes  
13 with respect to that practical reality, assuming  
14 that we win on the other -- the other parts of  
15 the arbitrary-and-capricious analysis, but we do  
16 think that it vindicates the harmless error rule  
17 that Congress put in place here. And to the  
18 extent that you think that -- that we're --  
19 we're not supposed to play this endless game of  
20 ping pong where -- where -- where applicants get  
21 shuttled back and forth and the agency gets  
22 shuttled back and forth between its own decision  
23 and the courts, it's -- it's -- you'd say that  
24 that would be an idle formality. We don't need  
25 to engage in it.

1                   But -- but you're right, I'm not  
2                   saying it would be a huge burden to re-decide a  
3                   handful of applications with respect to what we  
4                   are saying. By definition, we think we already  
5                   know what the agency's going to say.

6                   JUSTICE BARRETT: Thank you.

7                   CHIEF JUSTICE ROBERTS: Justice  
8                   Jackson?

9                   JUSTICE JACKSON: So the statute  
10                  plainly requires the agency to evaluate benefits  
11                  and harms. So can you just speak for a moment  
12                  about why flavored e-cigarettes are more harmful  
13                  than unflavored from the government's  
14                  perspective?

15                 MR. GANNON: The chief risk that FDA  
16                  identified throughout here -- and this was clear  
17                  well before the marketing denial order here with  
18                  respect to flavors -- is -- is on -- in the 2020  
19                  guidance, where FDA said it is concerned about  
20                  the extraordinary popularity of flavored  
21                  e-cigarettes with youth. Research has long  
22                  shown that flavors increased youth appeal of  
23                  tobacco products. And evidence accumulates,  
24                  further confirming that youth are particularly  
25                  attracted to flavored ENDS products. Flavors

1 are a strong driver for youth use.

2 And so those are all quotations from  
3 the 2020 guidance.

4 JUSTICE JACKSON: So that was in the  
5 guidance, those?

6 MR. GANNON: That's in the 2020  
7 guidance before these applications were filed on  
8 pages 151 and 214 of the Joint Appendix. And  
9 the concern there is, as I said, that flavors  
10 are attracting youth into smoking when they are  
11 non-users. Congress said that we need to  
12 evaluate the likelihood that non-users are going  
13 to start using tobacco products. The concern  
14 would be that they're getting addicted to  
15 tobacco at a time when -- when tobacco -- to  
16 nicotine at a time when nicotine is dangerous to  
17 their developing brains and may be, you know,  
18 sentencing them to a -- a long life of -- of --  
19 of needing to satisfy that addiction.

20 JUSTICE JACKSON: All right. Let me  
21 ask you just one question about harmless error  
22 because I guess I'm -- I'm confused about the  
23 government's position. I took your reply brief  
24 in the sentence on page 18 where you say "This  
25 Court should reverse the Fifth Circuit's holding

1     that the harmless error rule simply does not  
2     apply and remand the case so that the Fifth  
3     Circuit can apply that rule" to be the  
4     government asking us to remand the case.

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

8             MR. GANNON: I -- I wouldn't expect  
9     this Court in the -- in the normal case in the  
10    first instance to perform the harmless error  
11    analysis itself. What we're saying is that we  
12    don't think there needs to be a remand to the  
13    agency and -- and that that's the point. So, if  
14    you remand to the Fifth Circuit in order to  
15    evaluate whether it is persuaded that the --  
16    the -- the test that I was discussing with  
17    Justice Kagan is satisfied here, that the  
18    estimation of the likelihood of the result would  
19    not have been any different here is  
20    sufficient --

21            JUSTICE JACKSON: So we don't have to  
22    make that harmless -- at a minimum, you're  
23    saying we can send it to the Fifth Circuit to  
24    have them make the decision?

25            MR. GANNON: If -- if -- if you want

1 to agree with us, I am certainly not going to  
2 prevent you from doing that. If you want to say  
3 that since you don't normally analyze that type  
4 of question in the first instance, you want to  
5 remand that to the Fifth Circuit, the point is  
6 to correct the Fifth Circuit's legal error in  
7 saying that harmlessness isn't applicable, a  
8 harmless error analysis isn't -- isn't  
9 applicable here.

10 JUSTICE JACKSON: Thank you.

11 CHIEF JUSTICE ROBERTS: Thank -- thank  
12 you, counsel.

13 Mr. Heyer.

14 ORAL ARGUMENT OF ERIC N. HEYER ON  
15 BEHALF OF THE RESPONDENTS

16 MR. HEYER: Mr. Chief Justice, and may  
17 it please the Court:

18 FDA's new longitudinal comparative  
19 efficacy requirement directly contradicts the  
20 guidance FDA provided before the submission  
21 deadline when FDA knew that roughly two-thirds  
22 of adult ENDS users use flavored products.

23 Before, FDA said, "No specific studies  
24 are required for an application." After, FDA  
25 denied applications for over one million

1 products and over 250 applicants because they  
2 lacked a randomized control trial, a  
3 longitudinal cohort study, or some "other  
4 evidence" comparing the flavored ENDS products  
5 at issue against tobacco-flavored ENDS products  
6 as to cigarette reduction over time. Not a  
7 single applicant included these studies in their  
8 initial application.

9 Before, FDA said applicants were free  
10 to select a comparator tobacco product and  
11 justify their selection. After, for flavored  
12 ENDS, only a tobacco-flavored ENDS product was  
13 an acceptable comparator.

14 Before, FDA recommended single-point-  
15 in-time studies on "consumer risk perception"  
16 and "intentions." After, FDA concluded only  
17 longitudinal studies that track user behavior  
18 over time are robust and reliable.

19 Before, FDA said it would make its  
20 determination based on the entire contents of  
21 the application. After, FDA admittedly did not  
22 assess anything in the applications beyond  
23 whether they contained longitudinal comparative  
24 efficacy evidence.

25 Before, FDA said that a marketing plan

1     was "critical, necessary," and "directly  
2     relevant to determining whether youth would be  
3     protected." After, FDA entirely ignored the  
4     marketing plans, determining that in its  
5     experience no marketing restrictions were  
6     adequate.

7             FDA's denial orders suffer from  
8     multiple flaws. FDA switched its position on  
9     what studies were required and, in so doing,  
10    failed to consider applicants' reliance  
11    interests in the original instructions and less  
12    drastic alternatives. It ignored the marketing  
13    plans, and it ignored the notice-and-comment  
14    process mandated by the -- the APA and the Food,  
15    Drug, and Cosmetic Act. The Court should,  
16    therefore, affirm the judgment below.

17            I welcome the Court's questions.

18            JUSTICE THOMAS: You make quite a bit  
19    in your argument that FDA required certain kinds  
20    of studies at one point and then changed its  
21    mind. And yet I'm confused as to what these  
22    studies are.

23            What's the difference between a  
24    long -- the long-term studies and the randomized  
25    controlled trials and the longitudinal cohort

1 studies? What's the difference, and why is that  
2 a change in FDA's requirements?

3 MR. HEYER: So, Your Honor, the -- a  
4 longitudinal study could be of any duration, and  
5 that's the core -- that -- that's our core claim  
6 here. FDA -- defined "long-term" as being six  
7 months or more. And longitudinal studies are  
8 any study that tracks users over time. The  
9 randomized control trial and longitudinal cohort  
10 studies are two types of longitudinal studies.

11 A randomized control trial will assign  
12 the users specific products: tobacco-flavored  
13 ENDS for one control group, whatever the subject  
14 flavored product is for another.

15 A longitudinal cohort study has a lot  
16 of different ways to possibly design it that  
17 allow for selection of different flavors by the  
18 users, but, again, it tracks them over time.

19 Now our point is what FDA said ahead  
20 of time in its guidance in the 2018 public  
21 meeting presentation is that single-point-in-  
22 time surveys asking users of these products  
23 about their experiences, whether they would  
24 intend to use these products if they're  
25 combustible cigarette smokers, et cetera, were

1 acceptable.

2           Afterwards -- and I point the Court to  
3 page 266 of the -- of the Joint Appendix -- FDA  
4 specifically said: Based on our experience over  
5 the last 10 months, after the deadline,  
6 reviewing these applications, we've decided it  
7 must now be a longitudinal study, that single-  
8 point-in-time studies are not sufficiently  
9 robust and reliable.

10           That -- that flies right in the face  
11 of what FDA said ahead of time and directly  
12 contradicts it. That misled applicants, going  
13 back to my friend's comments.

14           And I want to underscore what a  
15 massive sea change this was, and I'll use a  
16 hypothetical to explain it. If one had a  
17 tobacco-flavored ENDS product that let's say  
18 theoretically led to a 50 percent smoking  
19 cessation rate of users and a flavored ENDS  
20 product that -- that hypothetically led to a 25  
21 percent cessation rate, under the statutory  
22 standard and under the standard as FDA explained  
23 it beforehand, assuming that there was no youth  
24 usage of the flavored products -- of either of  
25 those products, the tobacco-flavored or the

1     flavored product, the flavored product would  
2     have to be approved because it would have a net  
3     benefit to public health.

4             Under the new standard that FDA  
5     adopted by assigning a set risk value to  
6     flavored products, after the application --  
7     again, 10 months after the applications went in,  
8     that flavored product must now have a 51 percent  
9     switch rate. It must be marginally more  
10    effective over the tobacco product.

11            It's a massive sea change not only in  
12    the plain language of the statute but in what  
13    FDA communicated after the --

14            JUSTICE JACKSON: So when did the  
15    applications go in? Because you -- you've set  
16    up your whole argument as a before-and-after  
17    kind of dynamic, and I'm trying to understand  
18    when is the before and after.

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

23            MR. HEYER: So the deadline that was  
24    set by FDA and -- by a district court was  
25    September 9, 2020, Your Honor. So we had a

1 year --

2 JUSTICE JACKSON: September 9, 2020.

3 All right. So I see various things in the  
4 record where the FDA is making comments about  
5 flavors, including the one that the SG pointed  
6 to in the -- the end of his presentation that  
7 happened before then.

8 I see, for example, on page 88 of the  
9 Joint Appendix a whole discussion by the FDA  
10 that says: It is important for PMTAs for  
11 flavored products to examine the impact of  
12 flavoring on consumer -- perception, especially  
13 given the attractiveness of flavors to youth and  
14 young adults.

15 So it seems like, before your  
16 applications were due, FDA was making  
17 announcements about the significance of flavors.

18 MR. HEYER: Yes. And -- and -- and  
19 Respondents satisfied that then. They -- they  
20 provided extensive literature reviews of  
21 studies, including consumer perception studies,  
22 about the role of flavors.

23 What FDA never said in any of the  
24 guidance over the multiple years up to  
25 September 9, 2020, is: We're going to have this

1 new comparative efficacy requirement.

2 The word "efficacy" is not in the  
3 statute. And -- and, again, this wasn't -- the  
4 case wasn't briefed or argued under Loper, but I  
5 think the -- the previous guidance is consistent  
6 with the language of the statute. And FDA  
7 has -- has massively changed that after the fact  
8 by -- by rigging the -- the weighing of the --

9 JUSTICE JACKSON: So we would have  
10 to -- we would have to agree with you that what  
11 the FDA has said here is actually something  
12 different or new than what it was saying about  
13 your need to provide scientific evidence --  
14 valid scientific evidence concerning the  
15 flavoring?

16 MR. HEYER: Well, it -- it was -- it  
17 was new. There -- there's no reference to  
18 comparative efficacy studies. And there's no  
19 evidence before the deadline, anything from FDA,  
20 about the need to conduct any studies,  
21 comparative efficacy or not, for flavored  
22 products that differed from tobacco flavors.

23 JUSTICE KAGAN: So -- yeah -- but can  
24 I -- I mean, FDA says: Look, you should think  
25 hard and you should give us materials about

1 flavors because that's one of the things that  
2 we're really going to be thinking about, is  
3 flavors.

4 And in your application, you talk  
5 about the role of flavors, right, that your  
6 application tries to show that if you have  
7 flavors, it's better at getting people to quit  
8 smoking, right? That's the -- one of the points  
9 of your application.

10 So I -- I guess I'm not really seeing  
11 what the surprise is here or what the change is  
12 here. Like, everybody basically knows that  
13 flavors are -- are particularly dangerous in  
14 terms of kids starting the use of smoking  
15 products.

16 And so, you know, the -- the  
17 countervailing benefit might be if flavors were  
18 also particularly good at getting adults to stop  
19 smoking. And that's basically what FDA told  
20 you, and it's basically what you tried to  
21 convince FDA of.

22 And then, at the end, FDA said: You  
23 haven't convinced us. You know, we think  
24 flavors are really bad in terms of youth  
25 smoking, and we don't think that you've shown us

1     that they provide any special benefits in terms  
2     of smoking cessation.

3                 So I -- I guess I just don't see where  
4     the gap is here.

5                 MR. HEYER: Your Honor, this certainly  
6     wasn't called out with any -- wasn't called out  
7     at all and certainly not with a level of  
8     specificity.

9                 And I would, you know, respectfully  
10    dispute the fact that everybody knows this and  
11    everybody knows that.

12                JUSTICE KAGAN: Well, you know that --

13                MR. HEYER: The reality is --

14                JUSTICE KAGAN: -- you know that FDA  
15    thinks that flavors -- I mean, FDA is -- has  
16    been completely upfront about this. And I think  
17    that the point, you -- you know, that flavors --  
18    you give people blueberry vapes, the -- the  
19    difficulty with that -- and FDA, I think, has --  
20    has tried to document this -- is that blueberry  
21    vapes are very appealing to 16-year-olds, not to  
22    40-year-olds.

23                MR. HEYER: I respectfully disagree,  
24    Your Honor. In fact, the literature review  
25    that -- that Respondents provided explained in

1 detail that often the cessation journey for  
2 combustible cigarette smokers begins after this.

3 JUSTICE KAGAN: No, I'm not saying  
4 that you don't have a point of view on that  
5 question. But you knew what FDA's point of view  
6 on that question was, was that blueberry vapes  
7 are really problematic in terms of youth  
8 smoking.

9 And you know -- that FDA was basically  
10 saying to you: So, given that -- that we think  
11 that, you know, you've got to show us otherwise,  
12 that your product, your flavored product, is  
13 going to be particularly good at getting people  
14 to stop.

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

17 MR. HEYER: Well --

18 JUSTICE KAGAN: You might disagree  
19 with that because you think that, in fact, the  
20 world of 40-year-olds really wants to do  
21 blueberry vaping, but -- but you -- you can't  
22 say that FDA hasn't told you all about what it's  
23 thinking in this respect.

24 MR. HEYER: Well, going back to the  
25 2020 enforcement guidance, which is a document

1     that my friend points to as providing notice on  
2     this, the 2020 enforcement guidance doesn't  
3     speak -- and I point -- respectfully point the  
4     Court to Judge Jones' dissent from the initial  
5     panel decision on this and -- and also to the  
6     Bidi decision out of the Eleventh Circuit.

7             What that -- what that enforcement  
8     guidance speaks to is cartridge-based flavored  
9     products, and it talks at length about the  
10    device characteristics that make those  
11    particularly attractive to youth.

12            Respondents' products have no history,  
13    zero history, of youth usage. And that's the  
14    case if we look at the National Youth Tobacco  
15    Survey data from CDC, et cetera, all this  
16    literature that was in the applications.

17            That's the case for bottled e-liquids  
18    generally. The devices with which they are used  
19    don't have any sort of a track record of being  
20    substantially attractive to youth, and -- nor  
21    than do the e-liquids.

22            JUSTICE KAGAN: I feel as though  
23    you're arguing the merits back to me, and -- and  
24    if I encouraged that, I apologize, because  
25    that's not what I was saying.

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

11           MR. HEYER: Well, Your Honor, FDA  
12 doesn't claim to have reviewed or -- after the  
13 fact, post hoc rationalization, FDA claims:  
14 This is -- this is what you set up to prove, and  
15 this is how you prove it.

16           They say in the marketing denial  
17 orders: We didn't look at anything except  
18 whether there was longitudinal comparative  
19 efficacy evidence. So I don't think they can  
20 hang their hat on that point after the fact.  
21 Had the applications been silent as to -- as to  
22 that, it wouldn't have mattered.

23           What FDA was looking for was this  
24 longitudinal comparative efficacy evidence.  
25 That's what the marketing denial orders show.

1 That's what the technical project lead reports  
2 or reviews show as well. And so --

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

8 Am I wrong about that?

9 MR. HEYER: What we certainly didn't  
10 have notice is that there was this requirement  
11 to show this long -- this comparative efficacy  
12 in -- in switching. There -- there was -- there  
13 was no notice on that. We -- there was -- there  
14 was --

15 JUSTICE JACKSON: Okay. So -- so you  
16 don't read the 2019 -- I'm looking again on page  
17 88. I'm just baffled by your argument in light  
18 of this sentence: "Additionally, to provide a  
19 better understanding of the appeal of flavors to  
20 adults, FDA recommends examining adult appeal of  
21 such flavors in their decisions to initiate use,  
22 cease use of more harmful products, or dual  
23 use."

24 So the FDA is telling you not just  
25 flavors to youth, but help us understand your

1 argument that there's a benefit to adults by the  
2 use of flavors. Why -- why is there a notice  
3 problem in light of the FDA saying things like  
4 this?

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

14 But --

15 JUSTICE SOTOMAYOR: I'm sorry. I'm so  
16 totally confused by your point because the FDA  
17 didn't say to you that a longitudinal study was  
18 necessary. It would be helpful. It -- it said  
19 that from the beginning repeatedly. It would be  
20 helpful if you had these, but you don't have to  
21 have it if what you're providing can give  
22 enough.

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

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

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

16                  So that's the statute speaking. Your  
17    evidence has to show that adults need these  
18    flavored products to stop using tobacco  
19    products, full tobacco products, and that youth  
20    won't start using these, and you have to weigh  
21    whether the one is going to outweigh the other.  
22    That's the statute speaking, not their guidance.

23                  MR. HEYER: And -- and in --  
24    Respondents submitted the evidence that they  
25    believed FDA -- they understood FDA was asking

1     for and that FDA said it was asking for, which  
2     was --

3             JUSTICE SOTOMAYOR: Well, no, no,  
4     they -- it -- it got the evidence. What they  
5     said is it just doesn't prove the point. You  
6     want us to say it does prove the point, but they  
7     never said to you what you're saying, which is  
8     it's just that this doesn't show it.

9             MR. HEYER: Respondents never  
10    understood because FDA never communicated that  
11    it was going to be an end-all-and-be-all litmus  
12    test as to whether there was this comparative  
13    efficacy evidence. And that's what ultimately  
14    happened here.

15            And any other evidence was --

16            JUSTICE SOTOMAYOR: But that is  
17    because the statute makes it the litmus test.

18            MR. HEYER: Well, I respectfully  
19    disagree.

20            JUSTICE SOTOMAYOR: You -- you --  
21    you're trying to change the statute, but the  
22    statute is very clear. Tell us that your  
23    product is going to help adults stop smoking  
24    cigarettes and show us that youth is not going  
25    to start.

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

15                  JUSTICE KAVANAUGH: But, if the agency  
16 says that doesn't outweigh the harm to youth,  
17 we've reviewed everything, we're aware of  
18 everything, of course, they're aware of  
19 everything that's out there, that's kind of the  
20 end of it, isn't it?

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

22                  JUSTICE KAVANAUGH: I mean, you  
23 disagree with the statute giving that much  
24 discretion to FDA and you disagree with FDA, to  
25 Justice Sotomayor's point, weighing of the two

1 parts of the balance, and I understand that.  
2 But I'm trying to figure out what the legal  
3 error is there.

4 MR. HEYER: The challenge here is  
5 procedural, Your Honor. It's procedural. It's  
6 the change in position. So --

7 JUSTICE KAVANAUGH: I understand that.  
8 I'm just making sure there's not -- you under --  
9 you agree that at the end of the day, the agency  
10 has to make a choice and it's going to be a  
11 choice with uncertainty?

12 MR. HEYER: It -- it has to make a  
13 choice, but when it changes like it did here  
14 what that test is going to be or its  
15 interpretation of the statute, it has an  
16 obligation to identify the fact that it -- to  
17 realize the fact that it's making a change and  
18 what it's communicated to consider less drastic  
19 alternatives, such as the option to give  
20 applicants an opportunity to go and conduct  
21 those studies, which is what we're seeking here.  
22 And --

23 JUSTICE KAVANAUGH: And on the what  
24 you're seeking here --

25 MR. HEYER: Yeah.

1 JUSTICE KAVANAUGH: -- I'm sorry to  
2 interrupt --

3 MR. HEYER: Yeah.

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

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

13 JUSTICE KAVANAUGH: That wouldn't  
14 allow you to start selling the product.

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

19 JUSTICE KAVANAUGH: Okay.

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

23 JUSTICE KAVANAUGH: Right.

24 MR. HEYER: I recognize that.

25 JUSTICE KAVANAUGH: Yeah.

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

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

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

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

20                  MR. HEYER: The -- the distinction  
21      here with respect to Respondents specifically is  
22      they're going to have to close their doors if  
23      they -- if they are -- you know, this, in  
24      effect, is punitive for them because reapplying,  
25      closing down, and -- the matter is, even though

1 the statute calls for decisions in 180 days, FDA  
2 is taking three or four years at least to make  
3 determinations on these.

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

13 JUSTICE KAVANAUGH: Okay. That's  
14 helpful.

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

20 MR. HEYER: In this case, Your Honor,  
21 our -- our position is that FDA made this  
22 determination that it was going to apply this  
23 litmus test, this longitudinal comparative  
24 efficacy requirement, in the abstract without  
25 the particular facts of any particular case.

1 And that's demonstrated through the internal  
2 August 17 memorandum, which admittedly was  
3 rescinded, but then we see it copied word for  
4 word in each and every one of these technical  
5 project lead reviews that underscore -- that  
6 underscore the -- the denial orders for every  
7 single applicant for -- for flavored products.

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

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

20 MR. HEYER: Well, they certainly  
21 misled here. But, once the agency has spoken,  
22 once the agency has spoken as it did here and  
23 then when it changes its position, then it  
24 certainly has an obligation to communicate that  
25 change. We think that's the lesson from this

1 Court's presidents -- precedents and from the  
2 arbitrary-and-capricious standard that Congress  
3 has set forth in the APA itself.

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

11 So can you help -- can you say a  
12 little bit more about the change?

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

23 JUSTICE JACKSON: I thought they said  
24 these might not be necessary. In other words,  
25 there could be other ways that you can satisfy

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

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

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

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

25 After the fact, it must be -- it must

1 be a longitudinal comparative efficacy study.  
 2 It can be a randomized control trial, a  
 3 longitudinal cohort study, or some other  
 4 evidence that tracks users over time during --  
 5 JUSTICE JACKSON: Can I ask you this?  
 6 The statute --  
 7 JUSTICE BARRETT: Counsel --  
 8 JUSTICE JACKSON: Oh, go ahead.  
 9 JUSTICE BARRETT: No, go ahead.  
 10 JUSTICE JACKSON: The statute says you  
 11 have to have valid scientific evidence.  
 12 What -- what if the agency had said  
 13 you don't have to present any evidence? Is it  
 14 your position that based on the agency's  
 15 changing of its position because, at the end of  
 16 the day, they asked for evidence, that you would  
 17 be entitled to authorization?  
 18 In other words, I see certain things  
 19 in the statute --  
 20 MR. HEYER: Mm-hmm.  
 21 JUSTICE JACKSON: -- that appear to  
 22 give people notice as to what the agency's going  
 23 to look for, et cetera, et cetera. Let's --  
 24 hypothesize that the agency says something  
 25 different than what the statute requires.

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

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

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

14                  JUSTICE JACKSON:  Thank you.

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

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

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

1 reverse Chevron deference except we're deferring  
2 to the applicant rather than to the agency.

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

5 MR. HEYER: Well, we're -- we're not  
6 saying necessarily you must defer to the  
7 applicant, Your Honor. We're saying this was,  
8 in fact, a flip-flop here. This was, in fact,  
9 a -- a change on the factual record. I  
10 understand it's a -- it's a -- it's a factually  
11 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  
17 factual matter, they were interpreted that way.  
18 So I don't see the distinction of practicality  
19 given the facts here, I guess is what I -- what  
20 I 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 -- what --

25 MR. HEYER: Yeah.

1 JUSTICE KAVANAUGH: -- theoretically,  
2 is that a yes?

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

7 JUSTICE KAVANAUGH: So that is a yes?

8 MR. HEYER: Yes.

9 JUSTICE KAVANAUGH: Okay. All right.  
10 (Laughter.)

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

23 Am I reading you right?

24 MR. HEYER: That -- that's certainly  
25 our primary argument, Your Honor. There is this

1 D.C. Circuit line of case law, and I would point  
2 the Court specifically to the Salzer case, which  
3 is referenced heavily in satellite broadcasting.

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

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

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

22 JUSTICE KAGAN: Yes. I guess what I  
23 was suggesting was that I read your brief, and  
24 whenever I read about notice in your brief, it  
25 was always connected to the change in position.

1 And I took from your brief that that was your  
2 argument, that it was this was unfair because  
3 they changed position without telling us, not a  
4 kind of freestanding notice argument that didn't  
5 have anything to do with the change of position.

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

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

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

21 JUSTICE KAGAN: Thank you.

22 CHIEF JUSTICE ROBERTS: Justice  
23 Thomas?

24 Justice Alito?

25 JUSTICE ALITO: I have one question.

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

2 JUSTICE ALITO: Did our decision in  
3 Calcutt change harmless error analysis? Was  
4 Calcutt a harmless error decision?

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

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

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

23 JUSTICE ALITO: Okay. All right.  
24 Thank you.

25 CHIEF JUSTICE ROBERTS: Justice

1 Sotomayor?

2 Justice Kagan?

3 Justice Gorsuch?

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

11 I just want you to respond to that.

12 MR. HEYER: It's a -- it can be  
13 described as the flip side of the coin. It can  
14 be described as a sanction or it can be  
15 described as denial of a benefit.

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

23 JUSTICE KAVANAUGH: Yeah, thank you.

24 CHIEF JUSTICE ROBERTS: Justice  
25 Barrett?

1 Justice Jackson?

2 Okay. Thank you, counsel.

3 MR. HEYER: Thank you, Your Honor.

4 CHIEF JUSTICE ROBERTS: Rebuttal,

5 Mr. Gannon?

6 REBUTTAL ARGUMENT OF CURTIS E. GANNON

7 ON BEHALF OF THE PETITIONER

8 MR. GANNON: Thank you, Mr. Chief

9 Justice. If I could just make three points.

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

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

1     want to market were -- had -- had -- were only  
2     being used by about six-and-a-half percent of  
3     youth at the time.

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

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

23            And they -- they -- there's every  
24    reason to think that if they needed to use open  
25    systems -- open devices that use liquids like

1     this in order to get the flavors they want, that  
2     that number would go up.  FDA is legitimately  
3     concerned about that.  And so that's my third  
4     point.

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

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

18                We urge the Court to reverse the  
19    judgment of the court of appeals.

20                CHIEF JUSTICE ROBERTS:  Thank you,  
21    counsel.

22                The case is submitted.

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

25

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