

SUPREME COURT OF THE UNITED STATES

IN THE SUPREME COURT OF THE UNITED STATES

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.)

Pages: 1 through 95
Place: Washington, D.C.
Date: December 2, 2024

HERITAGE REPORTING CORPORATION
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1220 L Street, N.W., Suite 206
Washington, D.C. 20005
(202) 628-4888
www.hrccourtreporters.com

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

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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:
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21 of Justice, Washington, D.C.; on behalf of the
22 Petitioner.
23 ERIC N. HEYER, ESQUIRE, Washington, D.C.; on behalf of
24 the Respondents.
25

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P R O C E E D I N G S

(10:03 a.m.)

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

Mr. Gannon.

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

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

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

Respondents' nicotine solutions for

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

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

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

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

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

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

9 I welcome the Court's questions.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 Throughout, they said, you need good

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

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

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

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

1 literally fatal.

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

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

19 JUSTICE ALITO: Well, what --

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

23 JUSTICE ALITO: Concretely, what would
24 fall into Box C? What would be an adequate
25 substitute for either a randomized control trial

1 or a longitudinal cohort study?

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

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

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

23 JUSTICE ALITO: Well, is this an
24 adequate -- an accurate summary of the -- of the
25 FDA's position? It seems to be what you just

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

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

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

11 MR. GANNON: It would have to --

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

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

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

1 order to say that we should be able to claim the
2 same benefits that are over there.

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

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

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

12 MR. GANNON: Sure.

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

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

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

1 review requires.

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

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

12 MR. GANNON: I -- I --

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

16 MR. GANNON: I -- I --

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

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

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

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

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

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

23 MR. GANNON: I -- I think, in -- in
24 those circumstances, maybe so, Justice Gorsuch.
25 But our point here is that this is a statute

1 that says that these products are unlawful
2 unless they have been authorized for marketing
3 by FDA. And -- and so, once -- once --

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

9 MR. GANNON: Well --

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

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

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

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

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

23 MR. GANNON: It's --

24 JUSTICE GORSUCH: -- in the restaurant
25 hypothetical.

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

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

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

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

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

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

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

20 JUSTICE GORSUCH: Yes. Okay.

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

24 JUSTICE GORSUCH: But, as a matter of
25 due process, they were entitled to that, is

1 my -- that's my -- my question. Are they
2 entitled to notice and a hearing?

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

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

10 JUSTICE JACKSON: Isn't that --

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

14 MR. GANNON: Because --

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

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

22 JUSTICE GORSUCH: Okay.

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

25 JUSTICE JACKSON: On that standard,

1 right --

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

4 JUSTICE JACKSON: Mm-hmm.

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

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

17 MR. GANNON: At -- at -- at that
18 point, for enforcement of the lack of
19 authorization, that would be true. With respect
20 to some of these product applications that
21 preexisted the -- the 2020 deadline that these
22 applications do, there -- there were -- they
23 were sort of grandfathered in. FDA had -- had
24 stayed enforcement action for a time because,
25 when it announced the deeming rule in 2016 --

1 JUSTICE GORSUCH: No, I --

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

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

9 MR. GANNON: That's correct.

10 JUSTICE GORSUCH: Okay.

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

14 JUSTICE GORSUCH: Thank you. Thank
15 you.

16 Justice Jackson, I'm sorry.

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

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

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

4 JUSTICE JACKSON: A particular
5 showing.

6 MR. GANNON: -- FDA authorization.

7 JUSTICE JACKSON: So the showing --

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

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

19 MR. GANNON: That's correct.

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

1 about what people have to do, and then there is
2 argument about whether or not they've changed
3 their mind.

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

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

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

24 MR. GANNON: No, that would not be
25 permitted by the statute. The statute says that

1 there need to be well-controlled investigations
2 or other scientific evidence, if FDA considers
3 that sufficient, to establish the relevance --
4 the relevant things that --

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

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

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

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

1 you don't have the evidence --

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

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

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

9 MR. GANNON: Well, I think there --

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

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

21 But I -- I take your point that in
22 that instance, if they really can't satisfy the
23 statutory standard at the end of the day, FDA
24 shouldn't approve them, even on remand.

25 JUSTICE KAVANAUGH: So that --

1 MR. GANNON: Of course, that's not
2 what we have here.

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

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

10 JUSTICE KAVANAUGH: And if they won
11 this case, they can reapply?

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

15 JUSTICE KAVANAUGH: That's --

16 MR. GANNON: So --

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

24 MR. GANNON: Well --

25 JUSTICE KAVANAUGH: Or --

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

5 JUSTICE KAVANAUGH: Now they know.

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

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

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

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

25 JUSTICE KAVANAUGH: All you get with

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

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

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

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

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

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

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

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

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

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

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

3 CHIEF JUSTICE ROBERTS: Counsel --

4 JUSTICE KAGAN: Can I --

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

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

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

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

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

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

15 And to the extent -- and so I think
16 when you look at the harmless error question in
17 this case -- and the Court has said that it
18 doesn't engage in idle and useless formalities.
19 This isn't supposed to be an endless game of
20 ping pong.

21 And so you're right if we didn't know
22 what the agency was going to do, then you should
23 remand.

24 JUSTICE KAGAN: And --

25 MR. GANNON: But in this instance we

1 do.

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

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

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

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

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

1 case-appropriate considerations. But I think
2 that the chief one that the Court recites there
3 is an estimation of the likelihood that the
4 result would have been different.

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

11 JUSTICE KAGAN: And -- and maybe just
12 out of curiosity, why didn't the agency just do,
13 with respect to each of these applications, you
14 know, this marketing plan is no different from
15 100 other youth marketing plans that we've seen
16 and none of them are sufficient for the
17 following probably boilerplate reasons?

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

25 The other side in the amicus briefs

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

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

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

22 MR. GANNON: We are not contesting --

23 JUSTICE KAGAN: -- conceding or --

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

25 JUSTICE KAGAN: Are you conceding it's

1 an error? You're not contesting?

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

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

21 CHIEF JUSTICE ROBERTS: Thank you,
22 counsel.

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

25 CHIEF JUSTICE ROBERTS: Justice

1 Thomas, anything further?

2 Justice Alito?

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

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

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

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

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

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

6 MR. GANNON: I think --

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

9 MR. GANNON: I --

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

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

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

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

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

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

18 Do you agree with that?

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

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

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

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

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

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

25 JUSTICE ALITO: Okay. One last

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

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

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

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

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

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

9 JUSTICE ALITO: Okay.

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

14 JUSTICE ALITO: All right. Thank you.

15 CHIEF JUSTICE ROBERTS: Justice
16 Sotomayor?

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

19 MR. GANNON: They contain nicotine.

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

22 MR. GANNON: That's correct.

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

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

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

4 JUSTICE SOTOMAYOR: Right.

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

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

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

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

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

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

10 JUSTICE SOTOMAYOR: No, this is more
11 curiosity, which is we know nicotine is
12 addictive. You put it in to addict people.
13 Presumably, you put it in to addict adults and
14 children.

15 MR. GANNON: We -- we --

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

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

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

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

3 JUSTICE SOTOMAYOR: Thank you,
4 counsel.

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

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

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

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

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

19 MR. GANNON: Sure.

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

22 (Laughter.)

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

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

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

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

12 Do you follow me?

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

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

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

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

1 demonstrate a public health benefit?

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

4 JUSTICE GORSUCH: Right.

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

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

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

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

19 MR. GANNON: Pardon? That they --

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

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

25 JUSTICE GORSUCH: Okay. So how do

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

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

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

17 MR. GANNON: That's right.

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

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

25 Here, we know what the reasoning was.

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

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

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

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

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

19 JUSTICE GORSUCH: No, I --

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

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

25 MR. GANNON: We will certainly comply

1 with what the law requires, Justice Gorsuch.

2 (Laughter.)

3 JUSTICE GORSUCH: Thank you,

4 Mr. Gannon.

5 CHIEF JUSTICE ROBERTS: Justice

6 Kavanaugh?

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

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

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

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

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

11 JUSTICE KAVANAUGH: They could --

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

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

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

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

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

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

7 JUSTICE KAVANAUGH: Yeah.

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

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

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

21 JUSTICE KAVANAUGH: Right.

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

25 JUSTICE KAVANAUGH: Yeah.

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

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

8 CHIEF JUSTICE ROBERTS: Justice
9 Barrett?

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

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

24 MR. GANNON: In this instance, we're
25 not saying it's -- it's a big burden in order to

1 reevaluate these particular applications as long
2 as the Court -- assuming that the Court is
3 reversing the Fifth Circuit on the other things
4 --

5 JUSTICE BARRETT: Right.

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

9 JUSTICE BARRETT: Just the marketing
10 question?

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

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

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

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

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

15 JUSTICE BARRETT: Thank you.

16 CHIEF JUSTICE ROBERTS: Justice
17 Jackson?

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

24 MR. GANNON: The chief risk that FDA
25 identified throughout here, and this was clear

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

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

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

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

1 their developing brains and may be, you know,
2 sentencing them to a long life of -- of -- of
3 needing to satisfy that addiction.

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

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

17 MR. GANNON: I wouldn't expect this
18 Court in the -- in the normal case in the first
19 instance to perform the harmless error analysis
20 itself. What we're saying is that we don't
21 think there needs to be a remand to the agency.

22 And -- and that's the point. So, if
23 you remand to the Fifth Circuit in order to
24 evaluate whether it is persuaded that the -- the
25 test that I was discussing with Justice Kagan is

1 satisfied here, that the estimation of the
2 likelihood of the result would not have been any
3 different here is sufficient --

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

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

18 JUSTICE JACKSON: Thank you.

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

21 Mr. Heyer.

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

24 MR. HEYER: Mr. Chief Justice, and may
25 it please the Court:

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

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

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

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

1 over time are robust and reliable.

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

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

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

25 I welcome the Court's questions.

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

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

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

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

23 A longitudinal cohort study has a lot
24 of different ways to possibly design it that
25 allow for selection of different flavors by the

1 users, but, again, it tracks them over time.

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

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

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

22 And I want to underscore what a
23 massive sea change this was, and I'll use a
24 hypothetical to explain it. If one had a
25 tobacco-flavored ENDS product that let's say

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

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

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

22 JUSTICE JACKSON: So when did the
23 applications go in? Because you -- you've set
24 up your whole argument as a before-and-after
25 kind of dynamic, and I'm trying to understand

1 when is the before and after.

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

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

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

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

22 So it seems like before your
23 applications were due, FDA was making
24 announcements about the significance of flavors.

25 MR. HEYER: Yes. And -- and -- and

1 Respondents satisfied that then. They -- they
2 provided extensive literature reviews of
3 studies, including consumer perception studies,
4 about the role of flavors.

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

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

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

23 MR. HEYER: Well, it -- it was -- it
24 was new. There -- there's no reference to
25 comparative efficacy studies. And there's no

1 evidence before the deadline, anything from FDA,
2 about the need to conduct any studies,
3 comparative efficacy or not, for flavored
4 products that differed from tobacco flavors.

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

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

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

21 And so, you know, the -- the
22 countervailing benefit might be if flavors were
23 also particularly good at getting adults to stop
24 smoking. And that's basically what FDA told
25 you, and it's basically what you tried to

1 convince FDA of.

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

8 So I guess I just don't see where the
9 gap is here.

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

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

17 JUSTICE KAGAN: Well, you know that --

18 MR. HEYER: The reality is --

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

1 vapes are very appealing to 16-year-olds, not to
2 40-year-olds.

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

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

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

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

22 MR. HEYER: Well --

23 JUSTICE KAGAN: You might disagree
24 with that because you think that, in fact, the
25 world of 40-year-olds really wants to do

1 blueberry vaping, but -- but you -- you can't
2 say that FDA hasn't told you all about what it's
3 thinking in this respect.

4 MR. HEYER: Well, going back to the
5 2020 enforcement guidance, which is a document
6 that my friend points to as providing notice on
7 this, the 2020 enforcement guidance doesn't
8 speak -- and I point -- respectfully point the
9 Court to Judge Jones' dissent from the initial
10 panel decision on this and also to the Bidi
11 decision out of the Eleventh Circuit.

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

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

22 That's the case for bottled e-liquids
23 generally. The devices with which they are used
24 don't have any sort of a track record of being
25 substantially attractive to youth, and -- nor

1 than do the e-liquids.

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

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

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

21 They say in the marketing denial
22 orders: We didn't look at anything except
23 whether there was longitudinal comparative
24 efficacy evidence. So I don't think they can
25 hang their hat on that point after the fact.

1 Had the applications been silent as to that, it
2 wouldn't have mattered.

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

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

13 Am I wrong about that?

14 MR. HEYER: Well, we certainly didn't
15 have notice that there was this requirement to
16 show this comparative efficacy in switching.
17 There was -- there was no notice on that. There
18 was -- there was --

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

1 cease use of more harmful products or dual use."

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

8 MR. HEYER: Because when it's speaking
9 to things like perception, which I think is what
10 -- and -- and intent, what it's speaking to is a
11 suggestions that single point in time surveys
12 and that can speak to that. It's not saying you
13 must do a longitudinal study comparing tobacco
14 flavored against flavored over time and track
15 the users.

16 That doesn't follow from page 88 from
17 what Your Honor just read. But --

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

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

4 MR. HEYER: The reason they say it's
5 not sufficient is because of the new standard
6 that they adopted after the fact.

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

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

1 MR. HEYER: And -- and in --
2 Respondents submitted the evidence that they
3 believed FDA -- they understood FDA was asking
4 for and FDA said it was asking for which is --

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

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

17 And any other evidence was --

18 JUSTICE SOTOMAYOR: But that is
19 because the statute makes it the litmus test.

20 MR. HEYER: I respectfully disagree.

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

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

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

1 the balance. And I understand that.

2 But I'm trying to figure out what the
3 legal error is there.

4 MR. HEYER: The challenge here is
5 procedural Your Honor Your Honor.

6 JUSTICE KAVANAUGH: All right.

7 MR. HEYER: It is procedural. It is
8 the change in position.

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

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

24 JUSTICE KAVANAUGH: And I know what
25 you're seeking here, I'm sorry to interrupt, but

1 what exactly would be, is the question I was
2 asking Mr. Gannon, the relief that you're
3 seeking in terms of what it would cause the
4 agency to do as a real-world practical matter?

5 MR. HEYER: So practically to have --
6 have the marketing denial orders vacated and
7 remanded as the 5th circuit did. And I'll point
8 out, we don't --

9 JUSTICE KAVANAUGH: That wouldn't
10 allow you to start selling the product.

11 MR. HEYER: Well because of the
12 deferred enforcement policy our clients are --
13 are still allowed to sell the products, but
14 that's because of FDA's --

15 JUSTICE KAVANAUGH: Right.

16 MR. HEYER: -- of FDA's policies, it's
17 a fairly unique circumstance here.

18 JUSTICE KAVANAUGH: Yeah.

19 MR. HEYER: And -- and frankly we
20 don't know how FDA is going to approach it on
21 remand. We have a new administration coming in,
22 the president elect is on record saying I'm
23 going to save flavored vapes. We don't know
24 exactly what that's going to look like. And
25 maybe that the approach the agency takes is much

1 more aligned with the statute and looks at all
2 the risks and benefits the --

3 JUSTICE KAVANAUGH: But you could
4 reapply -- all those things you talk about in
5 the political process, you could reapply and all
6 that could happen through that process, right?

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

8 JUSTICE KAVANAUGH: In other words I'm
9 trying to figure out what's different from
10 reapplying, just reapplying, and what's
11 different from reapplying after a vacatur?

12 MR. HEYER: The distinction here with
13 respect to Respondents specifically is they are
14 going to have to close their doors if they are
15 -- if they are -- this in effect is punitive for
16 them because reapplying, closing down, the
17 matter is even though the statute calls for
18 decisions in 180 days, FDA is taking three or
19 four years, at least, to make determinations on
20 these.

21 They can't afford to wait that out.
22 They -- if -- if -- if these MDOs are not
23 vacated and remanded back to the agency, they're
24 closing their doors and they're done. This was
25 their one shot. That's why it was so important

1 for FDA when it changed its position to
2 communicate that and give them an opportunity to
3 meet the new standard and that is what was
4 denied here.

5 JUSTICE KAVANAUGH: Okay. That's
6 helpful.

7 CHIEF JUSTICE ROBERTS: How -- how is
8 your position consistent with respect to how
9 much guidance has to be provided with the well
10 recognized authority of agencies to proceed on a
11 case-by-case basis?

12 MR. HEYER: In this case, Your Honor,
13 our -- our position is that FDA made this
14 determination that it was going to apply this
15 litmus test, this longitudinal comparative
16 efficacy requirement in the abstract without the
17 particular facts of any particular case. And
18 that's demonstrated through the internal August
19 17th memorandum which admittedly was rescinded
20 but then we see it copied word for word in each
21 of one of these lead reviews that underscore,
22 that underscore the denial orders for every
23 single applicant for, for flavored products.

24 And so here the -- the reality is that
25 this was a forward-looking determination

1 prospective determination, that in effect was --
2 was a rule. It was setting up a new standard.

3 CHIEF JUSTICE ROBERTS: So your
4 position is that the agency, again, at a fairly
5 general level of abstraction, your position is
6 that the agency has to give guidance on -- on
7 what's required to comply as opposed to simply
8 that the agency may not mislead an applicant on
9 what's required to comply?

10 MR. HEYER: Well they certainly misled
11 here. Once the agency has spoken, once the
12 agency spoken as it did here and when it changes
13 its position it certainly has an obligation to
14 communicate that change. We think that's the
15 lesson from this Court's precedents and from the
16 arbitrary and capricious standard that Congress
17 has set forth in the APA itself.

18 JUSTICE JACKSON: So you say there's a
19 change of position. The agency did not say
20 originally that you did not have to have this
21 information. I mean, I think I could appreciate
22 a change if on day one the agency said: Do not
23 submit this kind of information, you do not need
24 it. As opposed to what happened here. So can
25 you help -- can you say a little bit more about

1 the change?

2 MR. HEYER: Well, to Your Honor's
3 point, the agency did say you don't need to do a
4 randomized control trial. Afterwards that's one
5 of the options they are saying you do need to
6 do. Before they said you don't need to do a
7 six-month, you know, long-term study. And what
8 have we seen so far? We've seen the only
9 flavored product that FDA has, in fact, NJOY
10 menthol product was a six-month study.

11 JUSTICE JACKSON: I thought they said
12 these might not be necessary. There could be
13 other ways you could satisfy the standard.
14 That's different than saying this is irrelevant,
15 don't submit it. We're not going to look at it.
16 We don't care about it. That's the kinds of
17 it's not necessary that would create a conflict
18 in the way that you're trying to describe as
19 opposed to saying it's not necessary because you
20 can satisfy this in potentially other ways.
21 Right?

22 MR. HEYER: Your Honor, the -- in my
23 introduction I think I listed through five or
24 six ways we believe the agency absolutely
25 flip-flopped and misled applicants, it said one

1 thing and then ultimately required another.

2 When it says no specific studies are
3 required, which it said -- Slide 26 of the 2018
4 public meeting -- clearly, some specific study
5 is required.

6 It also said it in a letter to Bidi
7 Vapor, we've cited in a footnote, dated May 8th
8 of 2020, just four months before the application
9 deadline. Bidi wrote in and said: What
10 comparator products do we need to use? And FDA
11 said: We have no requirements for comparator
12 products.

13 After the fact, it must be -- it must
14 be a longitudinal comparative efficacy study.
15 It can be a randomized control trial, a
16 longitudinal cohort study, or some other
17 evidence that tracks users over time during the
18 --

19 JUSTICE JACKSON: Can I ask you this?
20 The statute --

21 JUSTICE BARRETT: Counsel --

22 JUSTICE JACKSON: Oh, go ahead.

23 JUSTICE BARRETT: No, go ahead.

24 JUSTICE JACKSON: The statute says you
25 have to have valid scientific evidence.

1 What if the agency had said you don't
2 have to present any evidence? Is it your
3 position that based on the agency's changing of
4 its position because, at the end of the day,
5 they asked for evidence, that you would be
6 entitled to authorization?

7 In other words, I see certain things
8 in the statute that appear to give people notice
9 as to what the agency's going to look for,
10 et cetera, et cetera. Let's hypothesize that
11 the agency says something different than what
12 the statute requires.

13 Is it your position that at the end of
14 the day, because of that change in position of
15 the agency, you would be entitled to
16 authorization?

17 MR. HEYER: If there were notice from
18 the statute, I don't know that that would be my
19 position, Your Honor. But, certainly, there's
20 no notice from the statute that comparative
21 efficacy studies are specifically required.

22 Again, the word "efficacy" or
23 "effectiveness" is not found in the statute,
24 much less that it must be flavored products
25 against tobacco-flavored products.

1 JUSTICE JACKSON: Thank you.

2 JUSTICE BARRETT: Counsel, can I ask
3 you a question about your good-faith reliance
4 argument?

5 So a lot of your argument turns on --
6 well, all of your argument turns on the switch
7 in position in the guidance.

8 Now let's say that I disagree with you
9 that this switch was so clear. How much are you
10 relying on, you know, listen, we interpreted it
11 that way, and we have good-faith reliance on
12 this interpretation? It's almost kind of like a
13 reverse Chevron deference except we're deferring
14 to the applicant rather than to the agency.

15 Can you walk me through how that can
16 possibly be?

17 MR. HEYER: Well, we're not saying
18 necessarily you must defer to the applicant,
19 Your Honor. We're saying this was, in fact, a
20 flip flop here. This was, in fact, a change on
21 the factual record. I understand it's a -- it's
22 a -- it's a factually driven analysis.

23 JUSTICE BARRETT: So you're not making
24 any kind of argument that you relied in good
25 faith because these guidelines could be

1 interpreted your way?

2 MR. HEYER: They were -- as a factual
3 matter, they were interpreted that way. So I
4 don't see the distinction of practicality given
5 the facts here, I guess is what I -- what I
6 would say.

7 JUSTICE BARRETT: So you're saying the
8 only way they could be interpreted is the way
9 that you interpreted them?

10 MR. HEYER: In terms of FDA saying
11 things like no specific studies are required,
12 yes, we interpret that to mean no specific
13 studies are required and certainly not --

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

17 MR. HEYER: Correct, Your Honor.

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

20 Do you agree or disagree that the FDA
21 didn't have to say anything? I mean, these were
22 sub-regulatory guidance that you're relying on,
23 but do you agree that the FDA didn't have to
24 provide that?

25 MR. HEYER: If FDA had never spoken

1 and said the deadline is September 9, 2020,
2 there is the statute, have at it, that would be
3 a different scenario. In how FDA ultimately
4 applied the statute, we may have different
5 arguments, but, here, FDA did speak, and that's
6 the -- and that's what then triggers the
7 obligation to communicate the change in
8 position.

9 JUSTICE GORSUCH: Counsel --

10 JUSTICE KAVANAUGH: When you say
11 different --

12 JUSTICE GORSUCH: Sorry, please go
13 ahead.

14 JUSTICE KAVANAUGH: Go ahead. Go
15 ahead. Go ahead.

16 JUSTICE GORSUCH: All right.

17 (Laughter.)

18 JUSTICE GORSUCH: The harmless error
19 argument, what do we do about that? Isn't it
20 pretty obvious what will happen on remand if we
21 bother -- require that formality with respect to
22 the marketing plans?

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

25 One, as I noted, there -- there's

1 going to be a change in administration, so we
2 don't know how this is -- the evidence is going
3 to be re-evaluated on -- on -- on remand -- or
4 evaluated for the first time, I should say, on
5 remand.

6 Secondly --

7 JUSTICE GORSUCH: Putting aside the
8 obvious --

9 MR. HEYER: Yeah. Yeah.

10 JUSTICE GORSUCH: -- as a legal
11 matter, all right, the statute does have a
12 harmless error rule in it. Now how to reconcile
13 that with Chenery is an interesting question,
14 but it's there and it has to mean something,
15 doesn't it?

16 MR. HEYER: Right. And, Your Honor,
17 here, the -- given that FDA -- going back to
18 Justice Alito's comment -- or questions earlier,
19 given that there is no evidence in the record of
20 what the contents were of the marketing plans
21 that FDA supposedly reviewed and said that these
22 aren't -- and then ignored these -- and, again,
23 it's a post hoc rationalization. FDA didn't
24 even say these aren't any different, so we're --
25 we're not looking at them for efficiency

1 purposes.

2 But given that that's -- that would
3 set up an unreasonable evidentiary burden on us
4 to prove that the outcome would have necessarily
5 been different on -- on remand, that's sort of
6 the -- the core -- the core of our argument.

7 And I think specifically here, going
8 back to Chenery, when you have an agency
9 determination that it's appropriate for the
10 protection of -- of the public health, the word
11 "appropriate" suggests that the agency has a lot
12 of power to determine -- to -- to establish
13 that. And this is particularly a technical and
14 scientifically driven determination. That --
15 that weighs strongly in favor of remand back to
16 the agency to look at the evidence.

17 Like Calcutt, this is a fact-intensive
18 inquiry, not one where the -- the Court
19 should -- either this Court or the Fifth Circuit
20 should step in and attempt to do the agency's
21 job for it.

22 JUSTICE GORSUCH: Yeah. All right.

23 JUSTICE KAVANAUGH: In response to
24 Justice Barrett's question about if the agency
25 had given no guidance and just said there's the

1 statute, have at it, I think your answer was
2 that would present a different scenario.

3 I just want to make sure. You agree
4 that the agency could do that?

5 MR. HEYER: Theoretically, they could.
6 There's nothing in the Tobacco Control Act that
7 required it.

8 JUSTICE KAVANAUGH: Well,
9 theoretically, is that a yes?

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

14 JUSTICE KAVANAUGH: So that is a yes?

15 MR. HEYER: Yes.

16 JUSTICE KAVANAUGH: Okay. All right.

17 (Laughter.)

18 JUSTICE KAGAN: Do I understand --
19 I've read your briefs as being a hundred percent
20 a change-of-position argument. I mean, there
21 are the -- these other little things, but I
22 guess what I'm saying, it's a change-of-position
23 argument and -- and not -- there's no
24 freestanding fair notice argument in your brief,
25 that -- that the fair notice idea comes into

1 play because you're saying there was a change of
2 position.

3 So you were following one set of
4 guidance when, in fact, they were applying
5 another set of guidance.

6 Am I reading you right?

7 MR. HEYER: That -- that's certainly
8 our primary argument, Your Honor. There is this
9 D.C. Circuit line of case law, and I would point
10 the Court specifically to the Salzer case, which
11 is referenced heavily in satellite broadcasting.

12 And Salzer is interesting and somewhat
13 analogous here because, in that case, Salzer v.
14 FCC, you had 51 applicants, and they were
15 applying for permission for radio towers or
16 something like that, and -- and there was a
17 specific form that FCC wanted, and 44 of those
18 applicants didn't include that form.

19 And the D.C. Circuit looked at that.
20 And that was only about benefits. That was
21 about getting a license to operate these radio
22 towers or what have you. And in that case, it
23 was only about benefits. And -- and the D.C.
24 Circuit said: If you're going to have very
25 specific and demanding criteria for acceptance

1 of the application, then you have to be more
2 specific in what you're setting out.

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

5 JUSTICE KAGAN: Yes. I guess what I
6 was suggesting was that I read your brief, and
7 whenever I read about notice in your brief, it
8 was always connected to the change in position.
9 And I took from your brief that that was your
10 argument, that it was this was unfair because
11 they changed position without telling us, not a
12 kind of freestanding notice argument that didn't
13 have anything to do with the change of position.

14 MR. HEYER: That's certainly our
15 primary argument, Your Honor, but I think -- I
16 think, if I can call it a secondary argument, I
17 think this line of case law is out there. It's
18 been long embedded in --

19 JUSTICE KAGAN: I mean, did -- did you
20 talk about that anywhere? Because I read your
21 brief, I didn't see that.

22 MR. HEYER: Yeah. Well, we -- we --
23 we cited that line of case law, I suppose, in
24 support. Given -- again, given the facts here,
25 the agency did speak, it did take a position, so

1 that's what we were addressing. But I think
2 that secondary one is there.

3 JUSTICE KAGAN: Thank you.

4 CHIEF JUSTICE ROBERTS: Justice
5 Thomas?

6 Justice Alito?

7 JUSTICE ALITO: I have a question.

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

9 JUSTICE ALITO: Did our decision in
10 Calcutt change harmless error analysis? Was
11 Calcutt a harmless error decision?

12 MR. HEYER: It -- it was -- it was a
13 harmless error decision, Your Honor, in
14 requiring -- inasmuch as it required remand.
15 Whether it moved the needle in terms of the
16 existing case law, I'm not sure that I would say
17 that it -- that it did.

18 JUSTICE ALITO: Well, do you have any
19 objection to the -- do you disagree with the
20 government's argument that the harmless error
21 rule applies and that the question is whether
22 the error had a substantial bearing on the
23 ultimate rights of the parties? Is that a
24 correct statement of the rule?

25 MR. HEYER: I don't think I would

1 disagree with -- I don't think I would disagree
2 with that, Your Honor. The point is, here, we
3 don't know what the comparison was. It's not of
4 record.

5 JUSTICE ALITO: Okay. All right.
6 Thank you.

7 CHIEF JUSTICE ROBERTS: Justice
8 Sotomayor?

9 Justice Kagan?

10 Justice Gorsuch?

11 JUSTICE KAVANAUGH: Just in its reply
12 brief on satellite broadcasting, the government
13 says that: Well, that case was one where the
14 D.C. Circuit required an agency to provide fair
15 notice before dismissing an application as a
16 sanction for violating a procedural rule and
17 that that's not the circumstance we have here.

18 I just want you to respond to that.

19 MR. HEYER: It -- it can be described
20 as the flip side of the coin. It can be
21 described as a sanction or it can be described
22 as denial of a benefit.

23 In Salzer -- the reason I go to
24 Salzer, which predates satellite broadcasting,
25 that was absolutely a denial of a benefit.

1 Here, it's even more -- as the Fifth Circuit
2 point out -- even more of a sanction, even more
3 punitive. This is closing the doors of
4 Respondents' businesses, Your Honor.

5 JUSTICE KAVANAUGH: Yeah, thank you.

6 CHIEF JUSTICE ROBERTS: Justice
7 Barrett?

8 Justice Jackson?

9 Thank you, counsel.

10 MR. HEYER: Thank you, Your Honor.

11 CHIEF JUSTICE ROBERTS: Rebuttal,
12 Mr. Gannon?

13 REBUTTAL ARGUMENT OF CURTIS E. GANNON
14 ON BEHALF OF THE PETITIONER

15 MR. GANNON: Thank you, Mr. Chief
16 Justice.

17 If I could just make three points.
18 First, following up on something that Justice
19 Gorsuch asked me before about the enforcement
20 actions that FDA has taken in this context, it
21 hasn't with respect to these applicants, but FDA
22 has brought civil money penalty proceedings
23 before ALJs, and when it asks for injunctions to
24 prevent marketing, those are -- those are suits
25 that it has to bring in district court.

1 Second, my friend said that there is
2 zero history of their products being used by
3 youth. That's a slight change from the position
4 that they articulated in their brief, which was
5 that, at the time FDA gave this denial in 2021,
6 that the number of people using open devices
7 that use the liquids like the ones that they
8 want to market were -- had -- had -- were only
9 being used by about six and a half percent of
10 youth at the time.

11 The statistics on that are -- are the
12 same. Seven percent of youth are still using
13 open tank systems or mod systems according to
14 survey results from earlier this year. That's
15 more than 114,000 middle and high school
16 students who are using devices that could use
17 liquids like the ones that Respondents want to
18 market.

19 And FDA has explained throughout that
20 its concern there was that, yes, it had limited
21 -- it had taken enforcement action against a
22 particular type of device in 2020. It -- it was
23 concerned most about cartridge devices that were
24 most -- most popular with youth at the time.
25 After that, by the time of the decision here,

1 youth had migrated to disposable devices. And
2 FDA is legitimately concerned that youth are
3 chasing the flavors that they want.

4 And they -- there's every reason to
5 think if they needed to use open systems -- open
6 devices, that use liquids like this in order to
7 get the flavors they want, that that number
8 would go up. FDA is legitimately concerned
9 about that. And so that's my third point.

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

17 And Respondents knew that they needed
18 to make this comparison. They tried to show
19 that flavors had an offsetting benefit with
20 adults in their applications. FDA reasonably
21 concluded that they didn't have sufficient
22 evidence to establish that proposition.

23 We urge the Court to reverse the
24 judgment of the court of appeals.

25 CHIEF JUSTICE ROBERTS: Thank you,

1 counsel.

2 The case is submitted.

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

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