SUPREME COURT
OF THE UNITED STATES

IN THE SUPREME COURT OF THE UNITED STATES

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FOOD AND DRUG ADMINISTRATION,)

Petitioner,)

v.) No. 23-1038

WAGES AND WHITE LION INVESTMENTS,)

L.L.C., d/b/a TRITON DISTRIBUTION,)

ET AL.,)

Respondents.)

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Washington, D.C.

Monday, December 2, 2024

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

APPEARANCES:

CURTIS E. GANNON, Deputy Solicitor General, Department of Justice, Washington, D.C.; on behalf of the Petitioner.

ERIC N. HEYER, ESQUIRE, Washington, D.C.; on behalf of the Respondents.

C O N T E N T S

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

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

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

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

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

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

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

I welcome the Court's questions.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

They -- throughout, they said, you

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

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

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

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

literally fatal.

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

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

JUSTICE ALITO: Well, what --

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

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

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

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

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

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

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

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

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

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

MR. GANNON: It would have to --

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

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

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

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

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

Instead, they have inconclusive evidence about whether adults really need flavors to switch --

JUSTICE JACKSON: Can --

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

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

MR. GANNON: Sure.

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

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

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

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

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

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

MR. GANNON: I -- I --

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

MR. GANNON: I -- I --

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

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

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

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

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

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

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

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

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

MR. GANNON: Well --

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

MR. GANNON: -- that's --

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

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

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

existing business in the --

MR. GANNON: It's --

JUSTICE GORSUCH: -- in the restaurant hypothetical.

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

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

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

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

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

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

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

JUSTICE GORSUCH: Yes. Okay.

That's --

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

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

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

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

JUSTICE JACKSON: Isn't that --

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

MR. GANNON: Because --

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

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

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

JUSTICE GORSUCH: Okay.

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

JUSTICE JACKSON: On that standard, right --

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

JUSTICE JACKSON: Mm-hmm.

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

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

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

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

JUSTICE GORSUCH: No, I -- I --

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

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

MR. GANNON: That's correct.

JUSTICE GORSUCH: Okay.

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

JUSTICE GORSUCH: Thank you. Thank you.

Justice Jackson, I'm sorry.

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

I just wanted to ask about your

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

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

JUSTICE JACKSON: A particular showing.

MR. GANNON: -- FDA authorization.

JUSTICE JACKSON: So the showing --

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

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

MR. GANNON: That's correct.

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

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

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

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

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

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

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

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

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

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

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

JUSTICE JACKSON: But what was the remedy for that?

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

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

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

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

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

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

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

JUSTICE KAVANAUGH: So that --

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

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

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

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

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

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

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

MR. GANNON: Well --

JUSTICE KAVANAUGH: Or --

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

JUSTICE KAVANAUGH: Now they know.

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

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

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

sell the product.

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

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

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

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

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

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

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

JUSTICE KAVANAUGH: Because how could it be, right?

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

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

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

CHIEF JUSTICE ROBERTS: Counsel --

JUSTICE KAGAN: Can I --

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

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

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

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

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

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

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

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

JUSTICE KAGAN: And --

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

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

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

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

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

that? What?

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

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

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

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

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

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

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

JUSTICE KAGAN: But, if I understand

your position right, you're not defending that? You are --

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

JUSTICE KAGAN: -- conceding or --

MR. GANNON: We're not contesting --

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

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

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

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

CHIEF JUSTICE ROBERTS: Thank you, counsel.

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

CHIEF JUSTICE ROBERTS: Justice Thomas, anything further?

Justice Alito?

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

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

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

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

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

MR. GANNON: Right.

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

MR. GANNON: I -- I think --

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

MR. GANNON: I --

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

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

And -- and FDA said that it didn't

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

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

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

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

Do you agree with that?

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

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

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

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

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

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

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

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

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

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

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

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

JUSTICE ALITO: Okay. Thank --

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

JUSTICE ALITO: All right. Thank you.

CHIEF JUSTICE ROBERTS: Justice Sotomayor?

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

MR. GANNON: They contain nicotine.

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

MR. GANNON: That's correct.

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

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

JUSTICE SOTOMAYOR: Right.

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

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

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

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

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

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

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

MR. GANNON: We -- we --

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

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

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

JUSTICE SOTOMAYOR: Thank you, counsel.

CHIEF JUSTICE ROBERTS: Justice Kagan?

Justice Gorsuch?

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

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

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

it does and it doesn't.

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

MR. GANNON: Sure.

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

(Laughter.)

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

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

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

Do you follow me?

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

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

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

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

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

JUSTICE GORSUCH: Right.

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

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

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

risk that flavors pose. And so --

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

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

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

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

JUSTICE GORSUCH: Okay. So how -- how do you -- how do you deal with the Chenery problem then?

MR. GANNON: The -- the way I deal with the Chenery problem is the answer I gave to the Chief Justice, which ends your -- the way you phrased the first version of harmless error --

JUSTICE GORSUCH: Mm-hmm.

MR. GANNON: -- is the way the Court has said that -- that you apply harmless error as you do in civil litigation. And so you are asking yourself whether it makes any difference --

JUSTICE GORSUCH: I -- I know what that looks like. But the -- how does that --

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

MR. GANNON: That's right.

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

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

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

JUSTICE GORSUCH: Okay.

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

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

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

truth -- but --

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

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

JUSTICE GORSUCH: No, I --

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

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

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

(Laughter.)

JUSTICE GORSUCH: Thank you, Mr. Gannon.

CHIEF JUSTICE ROBERTS: Justice Kavanaugh?

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

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

Is it just the political process, public pressure --

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

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

JUSTICE KAVANAUGH: They could --

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

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

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

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

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

JUSTICE KAVANAUGH: And I --

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

JUSTICE KAVANAUGH: I guess another

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

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

JUSTICE KAVANAUGH: Right.

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

JUSTICE KAVANAUGH: Yeah.

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

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

CHIEF JUSTICE ROBERTS: Justice Barrett?

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

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

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

JUSTICE BARRETT: Right.

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

JUSTICE BARRETT: Just the marketing

question?

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

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

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

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

JUSTICE BARRETT: Thank you.

CHIEF JUSTICE ROBERTS: Justice Jackson?

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

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

are a strong driver for youth use.

And so those are all quotations from the 2020 guidance.

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

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

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

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

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

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

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

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

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

JUSTICE JACKSON: Thank you.

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

Mr. Heyer.

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

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

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

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

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

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

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

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

Before, FDA said that a marketing plan

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

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

I welcome the Court's questions.

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

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

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

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

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

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

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

acceptable.

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

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

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

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

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

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

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

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

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

year --

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

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

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

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

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

new comparative efficacy requirement.

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

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

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

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

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

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

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

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

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

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

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

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

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

JUSTICE KAGAN: Well, you know that --

MR. HEYER: The reality is --

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

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

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

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

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

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

MR. HEYER: Well --

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

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

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

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

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

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

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

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

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

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

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

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

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

Am I wrong about that?

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

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

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

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

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

But --

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

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

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

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

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

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

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

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

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

And any other evidence was --

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

MR. HEYER: Well, I respectfully disagree.

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

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

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

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

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

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

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

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

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

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

MR. HEYER: Yeah.

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

MR. HEYER: Yeah.

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

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

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

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

JUSTICE KAVANAUGH: Okay.

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

JUSTICE KAVANAUGH: Right.

MR. HEYER: I recognize that.

JUSTICE KAVANAUGH: Yeah.

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

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

MR. HEYER: One -- one could --

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

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

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

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

JUSTICE KAVANAUGH: Okay. That's helpful.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

After the fact, it must be -- it must

be a longitudinal comparative efficacy study. It can be a randomized control trial, a longitudinal cohort study, or some other evidence that tracks users over time during --

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

JUSTICE BARRETT: Counsel --

JUSTICE JACKSON: Oh, go ahead.

JUSTICE BARRETT: No, go ahead.

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

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

In other words, I see certain things in the statute --

MR. HEYER: Mm-hmm.

JUSTICE JACKSON: -- that appear to give people notice as to what the agency's going to look for, et cetera, et cetera. Let's -- hypothesize that the agency says something different than what the statute requires.

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

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

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

JUSTICE JACKSON: Thank you.

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

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

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

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

Can you walk me through how that can possibly be?

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

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

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

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

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

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

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

MR. HEYER: Correct, Your Honor.

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

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

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

JUSTICE GORSUCH: Counsel --

JUSTICE KAVANAUGH: When you say different --

JUSTICE GORSUCH: Sorry, please go ahead.

JUSTICE KAVANAUGH: Go ahead. Go ahead. Go ahead.

JUSTICE GORSUCH: All right.

(Laughter.)

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

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

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

Secondly --

JUSTICE GORSUCH: Putting aside the obvious --

MR. HEYER: Yeah. Yeah.

JUSTICE GORSUCH: -- as a legal matter --

MR. HEYER: Yeah.

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

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

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

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

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

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

JUSTICE GORSUCH: Yeah. All right.

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

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

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

JUSTICE KAVANAUGH: Well -- what --

MR. HEYER: Yeah.

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

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

JUSTICE KAVANAUGH: So that is a yes?

MR. HEYER: Yes.

JUSTICE KAVANAUGH: Okay. All right.

(Laughter.)

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

Am I reading you right?

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

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

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

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

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

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

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

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

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

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

JUSTICE KAGAN: Thank you.

CHIEF JUSTICE ROBERTS: Justice Thomas?

Justice Alito?

JUSTICE ALITO: I have one question.

CHIEF JUSTICE ROBERTS: Oh, I'm sorry.

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

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

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

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

JUSTICE ALITO: Okay. All right. Thank you.

CHIEF JUSTICE ROBERTS: Justice

Sotomayor?

Justice Kagan?

Justice Gorsuch?

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

I just want you to respond to that.

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

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

JUSTICE KAVANAUGH: Yeah, thank you.

CHIEF JUSTICE ROBERTS: Justice Barrett?

Justice Jackson?

Okay. Thank you, counsel.

MR. HEYER: Thank you, Your Honor.

CHIEF JUSTICE ROBERTS: Rebuttal, Mr. Gannon?

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

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

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

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

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

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

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

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

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

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

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

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

CHIEF JUSTICE ROBERTS: Thank you, counsel.

The case is submitted.

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