1   IN THE SUPREME COURT OF THE UNITED STATES

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3   MATRIXX INITIATIVES, INC., ET AL.,:

4   Petitioners   :

5   v.   :   No. 09-1156

6   JAMES SIRACUSANO, ET AL.   :

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8   Washington, D.C.

9   Monday, January 10, 2011

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11   The above-entitled matter came on for oral

12   argument before the Supreme Court of the United States

13   at 10:00 a.m.

14   APPEARANCES:

15   JONATHAN HACKER, ESQ., Washington, D.C.; on behalf of

16   Petitioners.

17   DAVID C. FREDERICK, ESQ., Washington, D.C.; on behalf of

18   Respondents.

19   PRATIK A. SHAH, ESQ., Assistant to the Solicitor

20   General, Department of Justice, Washington, D.C.; on

21   behalf of the United States, as amicus curiae,

22   supporting Respondents.

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1   C O N T E N T S

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

2   (10:00 a.m.)

3   CHIEF JUSTICE ROBERTS: We will hear

4   argument first this morning in Case 09-1156, Matrixx

5   Initiatives v. James Siracusano.

6   Mr. Hacker.

7   ORAL ARGUMENT OF JONATHAN HACKER

8   ON BEHALF OF THE PETITIONERS

9   MR. HACKER: Mr. Chief Justice, and may it

10   please the Court:

11   All drug companies receive on an almost

12   daily basis anecdotal hearsay reports about alleged

13   adverse health events following the use of their

14   products. Those incident reports do not themselves

15   establish any reliable facts about the drug's

16   performance or its safety, especially where, as here,

17   there are only a handful of reports out of millions of

18   products sold over a 4-year period, and --

19   JUSTICE GINSBURG: Mr. Hacker, do we know

20   that from this record? I mean, we know that the

21   plaintiffs were able to identify -- there's some dispute

22   whether it's 12 or 23, but do you represent that there

23   were no other complaints made? So that, let's say,

24   there has been discovery; now we're just at the pleading

25   stage. The company would have said: That's it, we

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1   didn't have any more?

2   MR. HACKER: All I can speak for is what's

3   alleged in the complaint, and the complaint, no matter

4   how read, doesn't allege any more than 23 adverse event

5   reports.

6   JUSTICE GINSBURG: But they might have been

7   able through discovery to find that there were many

8   more.

9   MR. HACKER: That's true, but there's no

10   allegation that what they -- what they know about or

11   what they could find would have been a statistically

12   significant difference between the rate of reported

13   events and the background of --

14   JUSTICE GINSBURG: But why shouldn't that

15   determination be deferred until there's discovery, and

16   then we can know how many reports there really were?

17   MR. HACKER: Because it's incumbent on a

18   plaintiff to come to court with a case, to plead the

19   facts necessary to establish all of the elements of a

20   claim. And a securities fraud claim, of course,

21   requires both materiality and scienter, and neither of

22   those is established unless the company has knowledge of

23   facts establishing a reliable basis for inferring that

24   the drug itself is the cause of the reported event.

25   Absent information like that, there is

1   neither materiality nor scienter under the securities

2   laws, because neither the company nor an investor --

3   until there's reliable evidence of a causal link between

4   the two products, neither a company -- excuse me, a link

5   between the product and the event -- neither the company

6   nor investor would have any reason to think that an

7   adverse event report is -- actually indicates a problem

8   with the product, as opposed to a coincidence.

9   JUSTICE ALITO: Can there be some situations

10   in which statistically significant evidence would not be

11   necessary?

12   For example, suppose some very distinguished

13   physicians concluded based on clinical trials that there

14   was a connection between a drug and a very serious side

15   effect. Could that establish materiality?

16   MR. HACKER: I think a distinguished

17   physician would not conclude that there's a connection

18   unless the clinical trials reveal a statistically

19   significant difference between what they've seen and

20   what they would expect to see were there no association.

21   So there's that point, Your Honor.

22   But the second point I would make is, we

23   acknowledge there are a very narrow, limited number of

24   circumstances under which a claim can be pled absent

25   statistically significant evidence, but that's -- that's

1   because doctors and researchers will conclude that there

2   may be causation under narrow circumstances. For

3   example, I think the most common set of criteria are the

4   Bradford-Hill criteria. But nothing like that is pled

5   here, Your Honor.

6   JUSTICE SCALIA: Mr. Hacker, the complaint

7   did not rely exclusively upon these adverse incidents

8   but also referred to a study, a report by researchers at

9   the American Rhinologic Society --

10   MR. HACKER: Yes.

11   JUSTICE SCALIA: -- which -- which asserted

12   that there was a connection. So the -- is the question

13   before us simply whether in isolation the adverse

14   incidents would be enough, or is not the question

15   whether those adverse incidents placed next to this

16   study would be enough?

17   MR. HACKER: Well, two points, Your Honor.

18   First, the plaintiffs have throughout this litigation

19   framed their case as one based on the failure to

20   disclose adverse event reports. It's the number of

21   adverse event reports that they say is the problem, and

22   they're not saying that there was a study out there and

23   that we failed to disclose the study. But they say it's

24   the fact of the adverse event reports.

25   JUSTICE SCALIA: Why didn't they say that?

1   MR. HACKER: Well, I think if you look at

2   the -- to be clear, the study is not attached to the

3   complaint, so there wasn't a basis in the complaint for

4   saying the company was aware of a reliable study and

5   here are the details of the study and they failed to

6   disclose it.

7   JUSTICE SCALIA: Well, I thought the --

8   you're saying the complaint did not refer to the study?

9   MR. HACKER: It did refer to it. That's

10   true. And if you look at the study, there's really

11   nothing there. It's based on, primarily on a case study

12   of one -- and again, this isn't in the complaint. It is

13   attached to the red brief, Your Honor.

14   There's one case study of one man who is 55

15   year old -- 55 years old, which is the population most

16   likely to experience anosmia. You're more likely to get

17   it when you're -- he's suffering from signs of lupus.

18   Which causes anosmia, and he is taking Flonase, which

19   also causes anosmia. And so the idea that you can infer

20   from that one incident out of millions over years of

21   product sales that -- that Zicam causes anosmia under

22   the --

23   CHIEF JUSTICE ROBERTS: You're talking about

24   -- you're talking about who is right or wrong about the

25   connection between Matrixx and anosmia. But that's not

1 the question. I'm an investor in Matrixx; I worry

2 whether my stock price is going to go down. You can

3 have some psychic come out and say "Zicam is going to

4 cause a disease" with no support whatsoever, but if it

5 causes the stock to go down 20 percent, it seems to me

6 that's material.

7   MR. HACKER: That's precisely the point,

8 Your Honor. If a psychic came out or a lunatic on the

9 street corner is barking, you know, through a megaphone

10 that there's a problem with the product, that's not the

11 kind of information to rely -- a real investor would

12 rely on.

13   JUSTICE SOTOMAYOR: But wait a minute.

14 These weren't psychics. These were 3 clinical doctors

15 in this area, one of them you knew poised to go to a

16 society meeting to make this allegation.

17   Doesn't it make a difference who the reports

18 are coming from and what the substance of those reports

19 may do to your product?

20   MR. HACKER: It may make a difference, Your

21 Honor, and I didn't mean to suggest that, you know,

22 these are psychics. The point simply is, following up

23 on the Chief Justice's question, that it does matter

24 what the basis of the allegation, and is the evidence,

25 the facts available to the company, reliable? Does it

8

1   create a reliable inference that a reasonable investor

2   would be concerned about?

3   JUSTICE KENNEDY: Well, suppose you

4   stipulate in response to the Chief Justice's question

5   that it is irrational, that it is probably baseless, but

6   that the market will react adversely. Is there a duty

7   then to address the claim?

8   MR. HACKER: Under the case law, it's not

9   clear that that's true. In this case, looking at this

10   case specifically, Your Honor, when the market reacted,

11   what the market was reacting to was a Good Morning

12   America report. It's very important to be clear about

13   what that report said.

14   On Good Morning America, a leading morning

15   news program, the allegation was made by Dr. Jafek that

16   Zicam causes anosmia. That's a very different

17   allegation that what the company was -- than what it was

18   the company was aware of, which was simply the adverse

19   event reports.

20   JUSTICE KENNEDY: But if there's a baseless

21   report and we stipulate that, although it's baseless,

22   it's going to affect the market, could that be the basis

23   for an allegation, assuming the requisite scienter, that

24   there's liability?

25   MR. HACKER: Two answers I would say, Your

 1   Honor. First of all, we have to be very careful about

 2   creating a rule through our interpretation of

 3   materiality that would require companies in advance to

 4   disclose the fact that a baseless, false allegation

 5   about the company is going to come out because it

 6   requires the company to ring the bell --

 7   JUSTICE KENNEDY: But it's not the

 8   allegation. It's the fact that the market may be

 9   affected.

10   MR. HACKER: Well, I understand, but the

11   problem is it's the underlying -- what the rule would

12   say is, because the company is aware the market may be

13   affected, the company in advance has to say: A false

14   report about us is about to come out. It requires the

15   company to first ring the bell and then un-ring it in

16   the same statement, and that's not a good rule for

17   companies.

18   Shareholders wouldn't want that rule, to

19   require companies to denigrate their product and then do

20   their best to explain why the allegation is untrue.

21   JUSTICE GINSBURG: Mr. Hacker -- Mr. Hacker,

22   you just said, if I understood you correctly, that when

23   the -- when the news came out on Good Morning America,

24   accurate or not, there was an obligation to do something

25   about it, but among the -- the charges, it's not simply

 1   that there was these reports, but it's the way the

 2   company responded to them: Two press releases that said

 3   allegations of any link of these drugs to anosmia are

 4   completely unfounded. That statement was made even

 5   after the -- what was it, Dr. Jafek?

 6   MR. HACKER: Right.

 7   JUSTICE GINSBURG: -- had this presentation,

 8   and he was going to put Zicam's name on it and the

 9   company said, you don't have any permission to do that.

10   So the company prevented Good Morning America from

11   happening earlier, and it made these affirmative

12   statements that there's no linkage.

13   MR. HACKER: Well, what they said was, and

14   this was true, that it was completely unfounded and

15   misleading. The very scientific panel that plaintiffs

16   themselves rely on, which convened and issued its report

17   2 weeks later, confirms that. There was no -- it's

18   absolutely unfounded at the time to --

19   JUSTICE GINSBURG: I thought that the

20   scientific report that came out later said, we can't say

21   one way or the other, as opposed to the company saying

22   that any suggestion of linkage is completely unfounded.

23   MR. HACKER: And that's correct, there

24   isn't. When -- when the scientific panel said you can't

25   make that claim, it's unfounded, there's no basis in the

 1   available science.

 2   JUSTICE GINSBURG: They didn't say

 3   "unfounded." They said the evidence is not -- we can't

 4   say yes and we can't say no. That's different from

 5   completely unfounded.

 6   MR. HACKER: Well, I'm -- with respect, Your

 7   Honor, I'm not entirely sure it is. When you're talking

 8   about science, you make a claim that's either supported

 9   in the science or it's without support, and the point

10   the scientific panel was making is there was no support

11   in the available science, and what Jafek was relying on

12   was unreliable. As I just described, the one --

13   JUSTICE KAGAN: Well, Mr. Hacker, you were

14   saying that the question of whether there is support is

15   reducible to the question of whether there are

16   statistically significant findings. Now, as I

17   understand it, the FDA takes action all the time as to

18   drugs -- they force the withdrawal of a drug from the

19   market, they force relabeling of a drug -- on the basis

20   of findings that are not statistically significant.

21   Now, clearly in those cases the market has a right to

22   know the very things that are going to make the FDA take

23   action against a product and that are going to severely

24   affect the product's value to the company. Not

25   statistical significance there.

1   MR. HACKER: That's true, but the problem

2   with that sort of standard -- well, first of all, to

3   emphasize, to look at the facts of this case, the FDA

4   didn't take any action until 5 years later, but -- which

5   shows --

6   JUSTICE KAGAN: Well, it could and

7   eventually it did.

8   MR. HACKER: But that's --

9   JUSTICE KAGAN: And you are suggesting a

10   test for what -- what counts as material, which is

11   statistically significant, a test that the FDA itself

12   doesn't use when it thinks about what it should what it

13   should regulate.

14   MR. HACKER: The problem is ex ante. You

15   have to -- you can't look at this through hindsight.

16   You have to look at it ex ante. When a company has a

17   handful of reports, it's absolutely true, nobody would

18   dispute, that some day in the future, with the

19   accumulation of more data, the FDA may take action based

20   on its own prophylactic public regulatory discretion.

21   But at the time, ex ante, no condition when it gets an

22   adverse event report can possibly know whether that's

23   enough information for the FDA to act. So the prospect

24   that the FDA may some day act on the basis of

25   additionally accumulated information would require

1 disclosure of all reports all the time, and that we

2 submit cannot be the standard.

3   JUSTICE SCALIA: Mr. Hacker, suppose Good

4 Morning America made the same claim, categorically

5 saying that this drug caused this condition, but did so

6 simply on the basis of these adverse incidents, and they

7 didn't have Dr. Jafek's, or whatever his name is,

8 reports, but nonetheless Good Morning America comes out

9 on the basis of those incidents saying Zicam causes

10 whatever the condition is. Would that have to be

11 reported? And if not, why not?

12   MR. HACKER: I think what you would have to

13 be hypothesizing is evidence that the company, say a

14 week in advance, knew that Good Morning America was

15 going to come out and say that. Because once Good

16 Morning America says it, it's said it and the effect is

17 what it is. But even in the hypothetical, you'd have to

18 sort of unpack what you said. If Good Morning America

19 came out and said just what Matrixx knew at the time,

20 there are a handful of adverse event reports, it's over

21 millions of product uses over a 4-year period, and no

22 indication that that's at all in any way different from

23 the incident rate in the general population, especially

24 among cold users, who of course are most likely to

25 experience anosmia, we don't know what would have

14

1   happened. But then you add the element that Good

2   Morning America then declares that Zicam causes anosmia

3   -- again, the hypothetical would have to be in advance

4   Matrixx is aware that the false claim is going to be

5   made.

6   JUSTICE SCALIA: Fine.

7   MR. HACKER: Right, and I would say, first

8   of all, we have to be very careful, as I said before,

9   about a rule that requires a company to disclose false

10   facts. I would say, second, that a reasonable investor

11   doesn't want false information; a reasonable investor

12   wants accurate information. And a reasonable investor

13   would actually --

14   JUSTICE SCALIA: These are unreasonable

15   investors who are relying on some talking head on Good

16   Morning America who says that this is true, even though

17   it isn't true.

18   MR. HACKER: That's the third point I would

19   make, Your Honor, is it's a different case, a

20   fundamentally different case, if you're talking about a

21   media --

22   JUSTICE SCALIA: You've neither answered yes

23   or no. There's no basis for its being said on Good

24   Morning America, but unreasonable investors by the

25   thousands rely upon it.

1   MR. HACKER: And I think the answer is no.

2   I think the reason it's no, a qualified no, is because

3   --

4   JUSTICE SCALIA: No --

5   MR. HACKER: -- the law doesn't respond to

6   irrational, unpredictable, or unreasonable investors.

7   It responds to a reasonable investor who wants

8   accurate -- a reasonable investor is going to hold the

9   stock.

10   CHIEF JUSTICE ROBERTS: A reasonable

11   investor is going to worry about the fact that thousands

12   of unreasonable investors are going to dump their

13   Matrixx stock.

14   MR. HACKER: I absolutely understand that.

15   CHIEF JUSTICE ROBERTS: I mean, there's

16   nothing unreasonable about that. If it looks -- if

17   you're looking at Good Morning America, you say, my

18   gosh, everybody else is going to sell this; I'm going to

19   sell, too. And if it turns out you knew about it you

20   should have told me about it before.

21   MR. HACKER: The point I would make is,

22   first of all, a company ex ante can't know when that's

23   going to happen. So all the hypotheticals are

24   suggesting some way of knowing the company --

25   CHIEF JUSTICE ROBERTS: It may not know, but

 1   it certainly can know. If you know this is a very false

 2   report, but we know that, I don't know, the surgeon

 3   general, somebody, is going to come out and announce it

 4   and that will cause an effect --

 5   MR. HACKER: That's why it's a meaningfully

 6   different case. If the plaintiffs had plead in their

 7   complaint that there's a memo inside the company, for

 8   example, so this false fact is going to come out, and we

 9   know it's going to cause a stock drop, that would be a

10   case involving the materiality of a media splash, a big

11   media event.

12   It can't be that there's a false claim out

13   there somewhere and the company becomes aware of the

14   false claim and then purely hypothetically it's possible

15   that somebody will make the false claim. It becomes

16   also possible that the media will pick up and not be

17   persuaded to ignore the false claim. That's the kind of

18   case we're talking about here.

19   JUSTICE KAGAN: In most cases we don't know

20   whether the claim is false or not. So let me give you a

21   hypothetical. There's a pharmaceutical company and it

22   comes out with its first and only product, it's 100

23   percent of the sales, and it's a new contact lens

24   solution. And it sells this product to many, many, many

25   hundreds of thousands of people. And most of them use

1   this product with no adverse effect whatsoever, but

2   there are ten cases where somebody uses this product and

3   they go blind. Three of those ten cases, the person had

4   to borrow a contact lens from a friend, only used it in

5   one eye, they go blind only in that one eye.

6   This is not statistically significant.

7   There is no way that anybody would tell that you these

8   ten cases are statistically significant. Would you stop

9   using that product and would a reasonable investor want

10   to know about those ten cases?

11   MR. HACKER: I would want to know more about

12   the number of uses and all that, but, no, there wouldn't

13   be a basis. A reasonable investor would want to know

14   all the facts and details that would establish a reason

15   to draw a --

16   JUSTICE KAGAN: There are a lot of contact

17   lens solutions in the world. So if I heard that, ten

18   people went blind, three used it in one eye, three went

19   blind in that eye, I'd stop using the product; and if I

20   were holding stock in that company, I would sell the

21   stock.

22   MR. HACKER: The problem is, there has to be

23   some reliable basis. You may be describing facts that

24   would satisfy the Bradford Hill criteria, for example,

25   where you can draw a reliable inference that the product

1   is the cause. That's the key here. There has to be a

2   reliable basis for inferring causation.

3   JUSTICE BREYER: This is the same kind of

4   question, but suppose I don't really know how drug

5   companies operate. I suspect, but I don't know, that

6   where you have a serious drug, people are hurt all the

7   time and they blame the drug. So probably drug

8   companies operate in an environment where they get all

9   kinds of complaints and some are valid, some are not;

10   who knows? People are frightened.

11   MR. HACKER: Very much so.

12   JUSTICE BREYER: Okay. Now, I don't know

13   that. But you say at the beginning your client says:

14   Look, we get complaints all the time; you know, just put

15   up with it if you buy our stock. Now, I don't know to

16   what extent that's true. I don't know how that fits in.

17   I don't know whether their complaint is unusual or not

18   unusual or general.

19   Who is supposed to decide that? The judge

20   at the complaint stage? Or the judge after you get some

21   evidence on it? Or the jury? And the same is true of

22   scienter, after all, because the scienter -- and you

23   have to plead that with particularity. Okay. What's

24   your answer? What's -- I mean, Justice Kagan had an

25   interesting view of this, and it could be that she's

 1   putting forward and others might have a different view.

 2   Who is to decide this?

 3   MR. HACKER: Well, ultimately it's a

 4   question -- it would go all the way to the jury if the

 5   plaintiffs were able to plead facts in the complaint

 6   that entitled them to --

 7   JUSTICE BREYER: Well, we don't know. You

 8   see, what they're saying is we have one respectable

 9   doctor, studier, at, you know, in Colorado. He, by the

10   way has an abstract, which isn't in the complaint, which

11   says that they do allege that it's zinc that's the

12   problem, a free zinc ion. And they say we also have 25

13   people who were hurt and some burning sensations in

14   people that didn't rise to that level.

15   You know, I don't know. I don't know if

16   that's within the range of expectation of drug companies

17   as part of the normal course of business which investors

18   should know about, and I suspect a district judge

19   doesn't know, either. So how does it work where we in

20   fact just don't know whether this does or not arise

21   above the background noise of a drug company?

22   MR. HACKER: We think the answer is

23   statistical significance, just like the Second Circuit

24   said in Carter-Wallace --

25   JUSTICE BREYER: Oh, no, it can't be. I'm

20

1   sorry, I don't mean to take a position yet. But, look,

2   Albert Einstein had the theory of relativity without any

3   empirical evidence, okay? So we could get the greatest

4   doctor in the world and he has dozens of theories, and

5   the theories are very sound and all that fits in here is

6   an allegation he now has learned that it's the free zinc

7   ion that counts. And that could be devastating to a

8   drug even though there isn't one person yet who has been

9   hurt. So I can't see how we can say this statistical

10   evidence always works or always doesn't work.

11   MR. HACKER: But, Your Honor, out of

12   millions of uses, if there was that problem, it wouldn't

13   be hard to plead a case that says there is a significant

14   problem --

15   JUSTICE BREYER: They did. They said --

16   they said the free zinc ion was -- that word on this was

17   told to your client by a person who knows a lot about

18   it, is apparently reputable, and was told to a person

19   who also knows a lot about it. I think they're saying

20   you ought to have been very nervous at that point. That

21   isn't just the usual background noise, okay? So I'm

22   back to my question, which is -- you can answer the

23   other one too if you like. But my question is: Who is

24   supposed to decide, how?

25   MR. HACKER: Well, I think a plaintiff -- I

21

1   mean, I may just be repeating myself, but a plaintiff

2   has to plead the facts that would entitle them to relief

3   at the end of the day. So, I'm not saying a judge --

4   JUSTICE BREYER: I know, and we are back to

5   my question --

6   MR. HACKER: And --

7   JUSTICE BREYER: The question is, the facts

8   that are pleaded is -- I think it's assumed that this is

9   above the normal background noise; they certainly argue

10   that at length -- that there was this free zinc ion

11   conversation, that there are 25 people who were hurt,

12   and there is a lot of burning sensation going on, even

13   though it doesn't rise to the level of people being

14   hurt, and that's supported by some of the zinc sulfate

15   studies in the fish --

16   MR. HACKER: I think you need to --

17   JUSTICE BREYER: -- okay? Now, they're

18   saying that's above the background noise and you say,

19   no, it isn't. Now, who decides and how do we decide?

20   Don't we have to go to a trial?

21   MR. HACKER: The answer is no, Your Honor,

22   because there is no basis on those pleaded facts for

23   inferring that there's actually a problem with the zinc

24   ion --

25   JUSTICE BREYER: I know. I know, but

22

1   over --

2   MR. HACKER: -- but look at the allegations

3   --

4   JUSTICE BREYER: We're not saying -- you're

5   saying if you are a scientist -- now we're back to

6   Justice Scalia's questions and the --

7   MR. HACKER: But it matters what a scientist

8   would think because it's only then that anybody ex ante,

9   again, remember --

10   JUSTICE BREYER: Well, then what --

11   MR. HACKER: -- has a basis for inferring

12   that there is a causal link which would be the problem,

13   and the zinc -- to be very clear, to be very clear about

14   the zinc studies, the claim made on the telephone wasn't

15   even a claim of causation. It said, are you aware of

16   the zinc sulfate studies, which of course is a

17   fundamentally different compound than --

18   JUSTICE BREYER: No, because the sulfate --

19   you see in the abstract, which they didn't put in the

20   complaint, that the problem that they saw arising out of

21   the zinc sulfate studies was the free zinc ion.

22   MR. HACKER: No, the zinc sulfate studies

23   were -- totally irrelevant. What they cited for the

24   free zinc ions were studies of catfish and turtles. And

25   nobody thinks, nobody thinks, that you can infer

23

1   anything from a study of catfish and turtles about their

2   smell sensation and human beings.

3   JUSTICE BREYER: The trouble is, you know,

4   the truth is I don't know, and so I'm back to my

5   question.

6   MR. HACKER: Well, in terms of scienter,

7   under the securities law there has to be a plausible

8   basis --

9   JUSTICE SOTOMAYOR: Counsel, you got cert

10   granted on a limited question, and the limited question

11   was whether in a complaint that alleges only adverse

12   reports can you prove materiality and scienter without

13   proving statistical importance. That's the question

14   presented.

15   Justice Kagan started with the point that

16   the FDA doesn't require that. It requires just

17   reasonable evidence of a connection, not statistical.

18   Many of the amici here have done a wonderful job of

19   explaining why statistical importance can't be a measure

20   because it depends on the nature of the study at issue.

21   So given all of that -- and even in your

22   brief, in a footnote, you answered the question by

23   saying, no, we can't establish that rule as an absolute,

24   because there are additional factors that could prove

25   materiality and scienter. So you've already answered

24

1   the question presented.

2   Are we down to what Justice Scalia asked

3   you, which is: We got a no to the question: Are the

4   facts in this case enough? I don't know why we would

5   have granted cert on that, but you presented a different

6   question presented. Given the question presented, is

7   the answer no? And if not, why not?

8   MR. HACKER: Let me -- let me start with the

9   premise of the question presented. It's presented on

10   the facts as the case has been litigated today, trying

11   to rely on adverse event reports, which is

12   understandable. The plaintiffs don't want to have to

13   prove all of the other -- you wouldn't think they would

14   want to prove all the other facts.

15   JUSTICE SOTOMAYOR: Can I just interrupt a

16   second?

17   MR. HACKER: Sure.

18   JUSTICE SOTOMAYOR: This wasn't an FDA-

19   approved drug.

20   MR. HACKER: Right.

21   JUSTICE SOTOMAYOR: So there weren't any

22   adverse reports in the legal sense of that word.

23   MR. HACKER: In the FDA sense, that's true.

24   JUSTICE SOTOMAYOR: In the FDA sense. So

25   we're using a misnomer here to start with.

1   MR. HACKER: Well --

2   JUSTICE SOTOMAYOR: Continue.

3   MR. HACKER: I would just say that adverse

4   event reports are not limited to what qualifies for the

5   FDA, certainly not by the way the case is --

6   JUSTICE SCALIA: Of course, if I may

7   interject --

8   MR. HACKER: -- litigated.

9   JUSTICE SCALIA: -- the FDA acts in the

10 public interest, doesn't it?

11   MR. HACKER: Yes.

12   JUSTICE SCALIA: And it doesn't make money

13 by withdrawing a drug from the market?

14   MR. HACKER: Yes.

15   JUSTICE SCALIA: As opposed to somebody who

16 sues, who makes money on the lawsuit?

17   MR. HACKER: That's true. But there's a

18 broader point about the FDA, which I think is underlying

19 your question and Justice Kagan's question, which is I

20 don't even think it's true that the FDA really requires

21 reasonable evidence. They have broad discretion and

22 should have broad discretion. Nobody is contesting

23 that. But the question is, again ex ante, before you

24 know what the FDA might do, before there's sufficient

25 evidence to justify the FDA to act. Remember, the FDA

1   didn't act for 5 years. The FDA didn't act on the basis

2   of what Matrixx was aware of at the time, and so, that

3   can't be the standard, the idea that the FDA may some

4   day act.

5   Statistical significance -- the question of

6   statistical significance is presented in this case to

7   the extent the courts below were arguing about and the

8   plaintiffs were arguing about whether or not the small

9   number of raw adverse event reports tell you anything

10   meaningful. The real standard -- the -- the case got

11   developed in the briefing here when the plaintiffs came

12   back and said, well, there's more to it and there can be

13   more to it, and that, of course, is true, but the

14   standard has to be reliability.

15   JUSTICE GINSBURG: You have said raw adverse

16   event reports. Am I not right that all of these reports

17   came from medical doctors, and in response to the very

18   first one, the company representative said, yeah, we've

19   been getting reports since 1999?

20   MR. HACKER: Well, there's a reference -- I

21   mean, there's a -- 1999 was the first call from

22   Dr. Hirsch, who reported one patient. There is a

23   discussion with Dr. Linschoten about one other patient.

24   And there were some reports -- nobody is disputing that

25   there were some reports out there.

27

1   JUSTICE GINSBURG: My question is, does it

2   make a difference if these reports come from medical

3   experts in this particular field?

4   MR. HACKER: No, because a doctor doesn't

5   have unique expertise in diagnosing causation. A

6   doctor -- if you have a sore knee, a doctor is qualified

7   to tell you -- to diagnose the fact that your sore knee

8   is the product of bone cancer. A doctor is not

9   qualified to tell you why you got bone cancer, and

10   that's the problem that we have here.

11   I would like to reserve the balance of my

12   time.

13   CHIEF JUSTICE ROBERTS: Thank you,

14   Mr. Hacker.

15   Mr. Frederick.

16   ORAL ARGUMENT OF DAVID C. FREDERICK

17   ON BEHALF OF THE RESPONDENTS

18   MR. FREDERICK: Thank you, Mr. Chief

19   Justice, and may it please the Court:

20   In TSC and Basic, this Court reaffirms the

21   longstanding rule that materiality is judged based on

22   the total mix of information available to investors.

23   Matrixx initially sought a major change to this Court's

24   contextual approach to materiality by offering a bright

25   line standard of statistical significance.

1   In its reply brief, Matrixx offer -- offers

2   a rule that would apply only in the hypothetical

3   scenario where investors rely solely on numbers of

4   adverse event reports in pleading securities fraud.

5   This Court should reject both arguments in

6   this case. The broad theory has numerous legal and

7   policy flaws. First, the longstanding totality of the

8   circumstances test best comports with the varied reasons

9   why investors make investment decisions.

10   JUSTICE ALITO: Suppose the allegations of

11   materiality are based solely on adverse event reports?

12   Suppose that it's alleged that ten million people

13   during -- during -- during 1 year have taken a

14   particular drug and five people shortly after taking the

15   drug have developed certain -- have had an adverse --

16   have had -- experienced an adverse event. Is that

17   sufficient to go to a jury?

18   MR. FREDERICK: Well, probably not

19   sufficient to go a jury absent a drop in the stock

20   price, absent evidence that there was a scientifically

21   plausible link, absent evidence that the product was

22   highly important to the company's long-term financial

23   prospects. All of these things go into the contextual

24   mix that investors would regard as important in making

25   an investment decision, and they all happen to be

1   present here. We --

2   JUSTICE SCALIA: If it was the only product,

3   they sold that might be enough, five adverse reports out

4   of ten million? If -- if that's the only product they

5   make, you say, totality of the circumstances, that may

6   be enough?

7   MR. FREDERICK: Under the Basic test, Your

8   Honor, that very well might if the probability and the

9   magnitude of the harm -- if those five incidents were

10   deaths from a product that was easily substitutable,

11   that might be a relevant decision and information that

12   investors might want to take into account.

13   CHIEF JUSTICE ROBERTS: In response to

14   Justice Alito, I heard you say something about a

15   scientifically plausible link?

16   MR. FREDERICK: Correct.

17   CHIEF JUSTICE ROBERTS: That seems to me to

18   be a rather significant concession. In other words,

19   you're saying it's not simply the fact that some psychic

20   would say something, that that is not sufficient, even

21   if that has an impact on the market price, that there

22   has to be some scientifically plausible link to the

23   report?

24   MR. FREDERICK: I think this goes back to

25   Justice Kennedy's question as well, Mr. Chief Justice,

1   because there could very well be materiality. The

2   information might be important for investors, but it

3   could very well be that the people making the

4   disclosures don't have the requisite scienter because

5   there is an absence of any plausible relationship.

6   The stock price might drop on news that

7   would not be regarded as news that the most highly

8   scientifically rational people would take into account.

9   JUSTICE KENNEDY: Well, I thought this might

10 come up. At some point do we look at scienter and then

11 go back from that to whether or not it's material, i.e.,

12 the argument would be the company knew that this would

13 affect the price, and that's why they didn't disclose it

14 and therefore that shows it's material? Or do we do

15 this with two isolated boxes: one, materiality, two,

16 scienter, and we don't mix the analyses.

17   MR. FREDERICK: They're both analytically

18 distinct and related, Justice Kennedy, and I don't have

19 a simple answer for you because many of the recorded

20 cases raise issues of both materiality and scienter.

21 What the Court has said in Basic is that the test is the

22 total mix of information and whether that -- under that

23 total mix the investor would find that information

24 important. In Tellabs the Court said that whether or

25 not the inferences of scienter could be deemed as

1   plausible as other inferences based on the mental state

2   of the people making the information.

3   So the Court has announced separate tests.

4   In a case like this there is a natural overlap, and in

5   fact the other side has litigated this case on the basis

6   that no one would have thought within the company, based

7   on the adverse event reports, that there was a basis for

8   thinking there was information.

9   We plead the other way by saying that when

10 you have three medical specialists in three distinct

11 periods where the last wants to bring findings to the

12 leading ear, nose and throat medical society suggesting

13 that, based on studies that go back as far back as the

14 1930s, there is a scientifically plausible link based on

15 the zinc ions, that's something that the company should

16 have taken seriously and disclosed to investors.

17   JUSTICE KAGAN: But Mr. Frederick, suppose

18 you are the CEO of a pharmaceutical company with a new

19 drug, you've just put it back on the market, and you get

20 a report back, this drug has caused a death, right?

21 This is your first adverse effect report. Do you have

22 to disclose it?

23   MR. FREDERICK: Well, I guess the first

24 thing I would say is if the drug has not been FDA

25 approved, that would be material information that

1   investors might want to know. If the drug had been FDA

2   approved and that report was then submitted to the FDA,

3   I think that there's a closer call depending on the, you

4   know, effect of the report that might be on the stock

5   price, because that's the only company product and the

6   other factors that we've mentioned in our brief.

7   I think the question of one event is

8   obviously much more difficult than where there are

9   multiple events submitted by doctors with a

10   scientifically plausible basis on a product that's 70

11   percent of the company's revenues.

12   JUSTICE ALITO: Now we're told that there

13   are hundreds of thousands of these; for a -- for a

14   typical drug there may be thousands of these adverse

15   event reports in -- in a year, and you're -- basically

16   you're saying all of those have to be disclosed?

17   MR. FREDERICK: Justice Alito, they already

18   are all disclosed.

19   JUSTICE ALITO: Well they -- already. So

20   then why does the company have to make additional

21   disclosure?

22   MR. FREDERICK: The --

23   JUSTICE ALITO: Analysts who follow the

24   stock price can easily look at the FDA web site and see

25   the adverse event reports that have been reported --

33

1   MR. FREDERICK: Right.

2   JUSTICE ALITO: -- and draw whatever

3 conclusions seem to be warranted based on that.

4   MR. FREDERICK: That's why I think this

5 presents the issue in a rather artificial way, because

6 the reports here were not the classic FDA-regulated

7 adverse event reports. This was a homeopathic drug that

8 was put on the market without FDA approval, and there

9 were no requirements of reports until 2006 which was

10 after the -- at issue here.

11   JUSTICE BREYER: How would you write --

12 look, I'm asking how do you write this, because what --

13 where I think where the other side has a point, is if --

14 with these -- this is a big class of these kinds of

15 things, you know, vitamins, all kinds of things like

16 that -- and if we say that they have to disclose too

17 much, what will happen is people won't pay attention to

18 it, you know.

19   And if -- if you have, you know, 4,000 pages

20 of small print saying everything that was ever reported,

21 what really happens in -- in such instances is the

22 public pays no attention, and they think -- and it will

23 hide things that are actually important.

24   So how would you write some words --

25 assuming that you're right, that their test is wrong --

1   but how would you write some words that will put a

2   disclosure obligation such that it's not going to be

3   overkill and it is going to get incidents that rise

4   above the background noise, and those are the incidents

5   that are -- that would be significant for a reasonable

6   investor?

7   MR. FREDERICK: I would start with the

8   language in Basic which says the total mix of

9   information is what has long standing been the test for

10   materiality under this Court's cases. I would say that

11   where there is credible medical professionals describing

12   the harms based on credible scientific theories to back

13   up the link, a very serious health effect risk for

14   products with many substitutes, and the effect is on a

15   predominant product line, then the company ought to

16   disclose that information. I will not --

17   JUSTICE BREYER: Okay, I'll go back and read

18   what you've just said, and -- I will, because it will be

19   in the transcript, and -- and the -- I -- this case, you

20   are very good, your clients, and the lawyers at writing

21   complaints.

22   MR. FREDERICK: Right.

23   JUSTICE BREYER: All right? So they've

24   alleged in this complaint everything they can show, and

25   I -- I suspect -- and during the class period. And what

1   it doesn't say is that very helpful chart that you put

2   in the brief, in the pocket. It doesn't say they ever

3   showed that to the company. All it says is there was a

4   phone call and this individual from -- from Colorado

5   said something, which it doesn't specify, about zinc and

6   the -- and the number of deaths.

7   MR. FREDERICK: Well, in 1999, though,

8   Justice Breyer, Dr. Hirsch, and this is outlined at

9   paragraph 25 of the complaint, also said that intranasal

10   application of zinc could be problematic, and he

11   specifically asked about how much zinc is put in Zicam

12   precisely because of his awareness of prior studies

13   going all the way back to the polio period in which zinc

14   had created a problem of persistent anosmia. But our

15   submission here is that --

16   JUSTICE SOTOMAYOR: How was your -- that

17   long litany of factors you mentioned a few moments ago

18   about how a company will go about determining whether an

19   adverse event report is material or not or should be

20   disclosed or not, are you saying that companies don't

21   have to respond to a rational securities holders? Are

22   you accepting your adversary's proposition that on some

23   level -- you said credible evidence -- that they don't

24   have to respond to things they judge are not credible?

25   MR. FREDERICK: It really depends, Justice

36

1   Sotomayor, and I don't mean to be evasive, but if there

2   is a product, say, that has some link to satanic

3   influences, and there is some reason to think that a

4   large body of followers in an irrational way might

5   regard there to be satanic influences on the basis of a

6   particular product, a cautious, reasonably prudent

7   investor might want to know that on the basis of that

8   information that most of us would regard as irrational,

9   might affect the stock price.

10   CHIEF JUSTICE ROBERTS: So what protection

11   is there at the summary judgment stage in response to

12   allegations? Because it doesn't have to be

13   scientifically valid; it can be completely irrational.

14   All you have to do is allege that, you know, if you had

15   told this the price would have gone down. If you had

16   disclosed this the price would have gone down, and the

17   response from the company is, well, but this is just

18   ridiculous. This is some guy in his garage who writes

19   this out on -- on a -- you know, a piece of paper in --

20   in handwriting; and the response is going to be, well

21   let's let the jury sort it out.

22   MR. FREDERICK: There are two answers, Mr.

23   Chief Justice. One is in Basic itself, the Court talked

24   about the actions of a reasonable investor, and this

25   Court and many courts have always looked at a reasonable

1   person's standard in making all sorts of these fine

2   judgments about the importance of particular

3   information. But the second answer is --

4   CHIEF JUSTICE ROBERTS: Well, you just told

5   me that it would be enough if somebody says that there's

6   a satanic, you know, impact on this, because a

7   reasonable investor would say there are enough crazy

8   people out there that this is going to affect the price.

9   MR. FREDERICK: What I said was if the

10   product was one that might be, you know, attractive in

11   some way to people who had that particular following. I

12   think you have to link up the product with the nature of

13   the complaint and the effect of the importance of the

14   information --

15   CHIEF JUSTICE ROBERTS: So it matters

16   whether -- I don't know what kind of product has

17   particular satanic susceptibility --

18   (Laughter.)

19   CHIEF JUSTICE ROBERTS: -- but I mean, are

20   you saying it matters if it's something that -- that

21   Satan's not going to be interested in? I don't

22   understand.

23   (Laughter.)

24   MR. FREDERICK: You're --

25   CHIEF JUSTICE ROBERTS: I don't mean to be

 1   facetious, but your way of distinguishing the satanic

 2   product is that it depends on whether people who follow

 3   satanic cults are going to be interested or not. I

 4   mean --

 5   MR. FREDERICK: Well, Your Honor, there are

 6   people who follow those things, and they spend money and

 7   they buy stocks, but my second point is that scienter --

 8   scienter is the other way around this problem. Because

 9   even though information --

10   JUSTICE SCALIA: I don't know if scienter is

11   -- it seems to me ridiculous to -- to hold companies to

12   -- to irrational standards; and we did -- and we did say

13   in -- in Basic that it's viewed -- whether it would be

14   viewed by the reasonable investor. And -- and you are

15   saying well, the reasonable investor takes account of

16   the irrationality. I don't think that's what we meant

17   in -- in Basic.

18   MR. FREDERICK: Well, Justice Scalia, you

19   can certainly write as a prophylactic here that that

20   isn't part of -- the test. We certainly have here all

21   of the indicia of credible medical professionals on a

22   credible scientific theory on a product that was

23   important to the company's finances, and a very serious

24   side effect for a drug that had ready --

25   CHIEF JUSTICE ROBERTS: So that -- I'm just

1   trying to get your response to that. You just talked

2   again about credible scientists and all that, and you're

3   putting those other things to one side.

4   So even if you have your satanic problem,

5   that is not enough. And you can sit there and allege it

6   would cause a drop of 30 percent in the stock price, and

7   you should have let this know. Your answer is no, they

8   don't have to let -- they don't have to disclose this

9   because there is no scientific credible basis for the

10   link that's alleged?

11   MR. FREDERICK: Now, I'm saying two things.

12   One is that there is a difference between scienter and

13   materiality. There is importance of information and an

14   intent to deceive, and the questions are analytically

15   distinct. In your hypothetical, Mr. Chief Justice, I

16   think you merged them, and I would like to keep them

17   separate because as we -- as this case comes to the

18   Court, the issue is what is the standard for materiality

19   and whether or not statistical significance is the only

20   way to --

21   JUSTICE ALITO: Can I give you -- because

22   I'm having a little difficulty understanding the

23   boundaries of the argument you're making.

24   Let me give 2 hypotheticals, and they both

25   involve companies that have one product, and this is

1   their one product. The first one was what I mentioned

2   before, and I wasn't -- I wasn't clear about your

3   answer. All that's alleged is that a very large number

4   of people took the drug and that three people, after

5   taking the drug, within a week developed a certain

6   syndrome. That's the first one. Is that enough for

7   materiality?

8   The second one is that a company receives a

9   telephone call: Hello, I'm a general practitioner from

10 wherever, and I treated a patient and the patient took

11 your medication and shortly after that developed this

12 syndrome, and I think there might be a connection. Is

13 that enough for materiality?

14   MR. FREDERICK: On the second one, I would

15 say probably not. And I would say on the first one,

16 there's not enough information about the side effect and

17 what the drug is intended to solve.

18   I mean, the probability magnitude test as

19 articulated by this Court goes to the probability of the

20 effect versus the magnitude that would be perceived by

21 investors, and those are important factors they go into.

22 So your hypothetical is very difficult to answer as you

23 have framed it.

24   JUSTICE ALITO: All right. This drug, let's

25 say it's a drug to relieve the common cold and the

41

1   effect is loss of the sense of smell. Five million

2   people take it. Three people, after taking it, lose

3   their sense of smell. Is that enough for materiality by

4   itself?

5   MR. FREDERICK: It -- by itself, that could

6   be enough, and the reason we know that could be enough,

7   Justice Alito, is that when, you know, some score

8   additional were released and this information was

9   disclosed, the stock price went down by 23.8 percent.

10   JUSTICE GINSBURG: Your time is running out,

11   and there is one thing you emphasize in your brief, and

12   I haven't heard you say one word about it here. And

13   that is: You're saying this is not a case of a company

14   that remains silent. The company, in response to this,

15   issued press releases in which it said any suggestion of

16   a linkage is completely unfounded. Now, that's

17   something different from, there are X number of reports.

18   To what extent are you relying on the affirmative

19   statements that the company made?

20   MR. FREDERICK: We're relying on those to

21   establish scienter, both at the beginning of the class

22   period when they forced Dr. Jafek, through their legal

23   threats, to take Zicam off his poster presentation, and

24   then later when they said that the reports of anosmia

25   were completely unfounded. And "misleading" was the

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1   word that they used. "And misleading." And they

2   repeated that after the Good Morning America program

3   came on, only to say three weeks later, after empaneling

4   a scientific expert panel, that the information was

5   insufficient to make that determination. Our submission

6   is that that is enough.

7   JUSTICE SCALIA: Mr. Frederick, I'm -- I'm

8   not clear on why you can draw a distinction between

9   materiality and scienter for purposes of the issue

10 before us here.

11   If, indeed, satanic effect is enough for

12 materiality, you say, well, it may not be enough for

13 scienter. Why? I mean, if the company knows that

14 satanic effect is material, then the company has --

15 knowingly withholds it because it thinks satanic effect

16 is irrational, why doesn't that company have scienter,

17 if it's material?

18   The scienter is withholding something that

19 is material that is known to be material, and once you

20 say that -- you know, that Satan is material, if the

21 company thinks Satan is involved here, it has to put it

22 in its report, no?

23   MR. FREDERICK: And it would depend on what

24 kind of stock effect occurred.

25   JUSTICE SCALIA: So there's no difference

43

1   between the materiality issue and the scienter issue.

2   MR. FREDERICK: Well --

3   JUSTICE SCALIA: You can't push this problem

4   off onto the scienter side of the equation.

5   MR. FREDERICK: It depends -- it depends on

6   this Court's application of its known precedent, which

7   my colleague here has not even referenced in his opening

8   argument, Basic, which says you look at the total mix of

9   the information. And all of these things go into play.

10   JUSTICE BREYER: Okay. I get that. Can I

11   just ask you one question in response to -- just picking

12   up on the last, what about the need for a, quote,

13   "strong inference of scienter," end quote, and does this

14   complaint show more than a borderline situation where it

15   doesn't strongly infer that the person intended to

16   mislead the defendant? What about that argument?

17   MR. FREDERICK: Well, we believe, and they

18   haven't argued that this complaint is not sufficient

19   under the PSLRA, which set the heightened pleading

20   standard for scienter that this Court articulated and

21   construed in the Tellabs decision, so we believe that

22   scienter is adequately pleaded here based on --

23   JUSTICE BREYER: Well, page 49 of their

24   brief -- they have two pages on it -- it does not give

25   rise to a strong inference of scienter.

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1   MR. FREDERICK: What I'm saying is that

2   there is already a heightened pleading standard, Justice

3   Breyer. I was not -- I misunderstood your question to

4   say, is there some other heightened pleading standard

5   other than the one --

6   JUSTICE BREYER: No, no, I mean -- I just

7   want to know why, if their inference on materiality is

8   enough to survive the background noise reply, is it

9   enough to show a strong inference that they did do this

10   intending to mislead, a strong inference of scienter?

11   MR. FREDERICK: The key aspects here are

12   their treatment of Jafek when Jafek was going to go

13   public with his scientifically linked claim of anosmia

14   from the Zicam, and then subsequently when they issued

15   press releases saying it would be completely unfounded

16   and misleading to assert any causal link. That is

17   sufficient to establish a strong inference of scienter.

18   CHIEF JUSTICE ROBERTS: Thank you, Mr.

19   Frederick.

20   Mr. Shah.

21   ORAL ARGUMENT OF PRATIK A. SHAH

22   ON BEHALF OF THE UNITED STATES, AS AMICUS CURIAE,

23   SUPPORTING THE RESPONDENTS

24   MR. SHAH: Mr. Chief Justice, and may it

25   please the Court:

45

1   For 35 years, this Court's precedents have

2   instructed that information is material for securities

3   fraud purposes if a reasonable investor would have

4   viewed it as having meaningfully altered the total mix

5   of information. Under the terms of their question

6   presented, petitioners propose to depart from that

7   contextual inquiry in favor of a categorical rule that

8   deems information about an adverse drug effect

9   immaterial absent statistical significance.

10   JUSTICE SCALIA: Mr. Shah, what do you think

11   about Satan?

12   MR. SHAH: Let me try to unpack the satanic

13   connection hypotheticals a little bit.

14   Now, to be sure, if someone just called a

15   company and said, hey, I think you guys are affiliated

16   with satanic practices, surely a company would not have

17   to go and disclose that to all the investors. But this

18   is going to depend on what the actual reality is and

19   what the company's statements have been.

20   Now, if the company has made a statement

21   that, look, consumer confidence in our products is at an

22   all-time high and we expect sales to double in the next

23   quarter, and yet they are aware that there -- a consumer

24   boycott is being planned by, let's say, 10 percent of

25   their consumer base premised on the irrational notion

1   that their company is tied to Satan, then certainly to

2   correct their affirmative representation that consumer

3   confidence is at an all-time high and that they expect

4   their sales to double, a reasonable investor would want

5   to know --

6   JUSTICE SCALIA: They haven't said that.

7   They haven't said that our sales are going to double.

8   They're just walking along at normal sales.

9   MR. SHAH: Right.

10   JUSTICE SCALIA: And they find out that

11   10 percent of nutty-nuttys out there are not going to

12   buy their stuff because of Satan. What about that?

13   MR. SHAH: Your Honor, in that hypothetical,

14   it depends on what affirmative statements the companies

15   have made. Under the securities law -- and this is an

16   important point that I don't think has come through yet.

17   Under the securities laws, there is no baseline duty to

18   disclose for a manufacturer or a company. A company

19   creates a duty to disclose once they have spoken. So

20   it's going to depend on what the company has said.

21   Now, in your scenario, if a company has made

22   statements projecting their company's success into the

23   next quarter, for example, and they have a concrete

24   basis to know that, as your hypothetical submits,

25   10 percent of their computer -- consumer base is going

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1   to leave the company's products, that is almost

2   certainly going to be material to an investor, and so

3   yes, they would have to disclose that we have reason to

4   believe, however ridiculous it is and untrue it is, that

5   10 percent of our consumer base has decided to boycott

6   our products. That's certainly reasonable.

7   CHIEF JUSTICE ROBERTS: You would have --

8   you just said they would have a duty to disclose?

9   MR. SHAH: Yes, sir.

10   CHIEF JUSTICE ROBERTS: I thought you

11   earlier just said there's no affirmative duty to

12   disclose; it only is based on what they say?

13   MR. SHAH: It's based on what they said.

14   So, for example, if the company had simply remained

15   silent and not said anything about its future sales, its

16   prospects, then under the securities laws there is no

17   duty to disclose. Basic and other cases have long made

18   clear that there has to be something to trigger a duty

19   to disclose. That is, under Rule 10b-5 it's only

20   statements that are rendered misleading by the omission

21   of a material fact that can trigger liability. If there

22   is no projection about the company's future success,

23   then it wouldn't have to disclose in that situation.

24   JUSTICE ALITO: What if the company makes

25   the kind of relatively common statements that were made

1   here, poised for growth in the upcoming season, very

2   strong momentum going into the season, extremely well

3   positioned for successful season?

4   MR. SHAH: Sure, Your Honor --

5   JUSTICE ALITO: That -- that triggers the

6   duty to disclose the satanic rumors?

7   MR. SHAH: In certain cases where there are

8   very generalized statements, for example, we think our

9   product will do well, that may close -- come close to

10   the line of puffery that is a non- actionable statement

11   that no reasonable investor would rely on. Petitioners

12   have never pressed that argument before this Court.

13   There is no dispute about whether the statements that

14   Matrixx made in this case are actionable, even though I

15   agree with you that some of them probably come close to

16   that puffery line.

17   Here, though, we don't just have those

18   statements about the company being well positioned for

19   future growth. There are additional statements, and

20   these were made to stock analysts that they expected a

21   50 percent increase in annual revenues, and, of course,

22   there are the much more affirmative statements that the

23   drug's safety had been well-established and that the

24   reports of anosmia were completely unfounded and

25   misleading. Those statements certainly crossed the

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1 line. And as I said before, there hasn't been an

2 argument in this case as to whether those less specific

3 and arguably puffery type statements --

4   JUSTICE SCALIA: So the government's

5 position is that reports of adverse effects that have no

6 scientific basis, so long as they would affect

7 irrationally consumers, have to be disclosed, assuming

8 the company has said we're doing well, right?

9   MR. SHAH: Well, Your Honor, yes, I think it

10 would depend, again, on the statements the company

11 makes. If -- if --

12   JUSTICE SCALIA: Well, I mean, if Satan

13 comes in, surely lousy science comes in as well, no?

14   MR. SHAH: Okay. So -- so, for example,

15 if -- if a company had been faced with potential adverse

16 effect and it had assembled its blue ribbon panel of

17 scientists, conclusively determined that there is no

18 causal connection between this purported adverse effect

19 and their drug, the question is, would they have to

20 disclose in that circumstance?

21   I think if the company had simply made

22 statements relating to the drug safety, we think our

23 drug is safe, there is no reason to believe that it

24 causes any adverse effects, then the answer is no,

25 because the reported adverse effect would not call into

1   question the accuracy of the company's statements

2   relating to the safety of the drug.

3   If, however, the company had made specific

4   statements relating to consumer demand for its products

5   and it knew, notwithstanding the fact that there was no

6   causal connection, it knew or had good reason to believe

7   that a significant portion of its consumer base would

8   avoid the product, then, yes, a reasonable investor

9   would want to know that information, and under Basic the

10   company would have a duty to disclose that, even though

11   unfounded, these reports may lead a significant

12   percentage of our consumer base to leave the product.

13   I think that falls squarely within the

14   definition of materiality, which is would a reasonable

15   investor want to have known that information?

16   JUSTICE KAGAN: Mr. Shah, what deference do

17   you think that the SEC's understanding of materiality

18   it's entitled to and why?

19   MR. SHAH: Well, Your Honor, this Court in

20   both TSC and Basic accorded what it called due deference

21   to the SEC's views on the application of the materiality

22   standard. I think it's certainly true -- and -- and

23   those, by the way, were both -- the -- the Court was

24   deferring to the views of the SEC as expressed in amicus

25   briefs to the Court just like in this case.

1   I think the SEC is due a significant

2   deference based on, one, its long-standing historical

3   practice in applying the materiality standard, which is

4   part of its own rule, Rule 10b-5, and its special

5   expertise in knowing what a reasonable investor would

6   want to know based upon its experience in this area.

7   So, I do think that to the extent there is

8   any ambiguity remaining in this case, the Court should

9   defer to the SEC's views. And back to Justice Breyer's

10 questions about what should the Court write simply

11 beyond reiterating the Basic standard, I think what the

12 Court did in Basic was it not only articulated the

13 general standard, but it laid out some factors. And in

14 laying out those factors, that's where the Court

15 deferred to the SEC's brief. And it laid out factors

16 that a reasonable investor might find relevant in that

17 case it was the merger context.

18   In here on page 28 of our brief, we lay out

19 several factors that we think bear on the materiality

20 question in this particular context; that is, involving

21 adverse drug information.

22   CHIEF JUSTICE ROBERTS: Is there any way

23 that consideration of those factors would support a -- a

24 summary judgment in favor of the pharmaceutical

25 manufacturer, other than the fact of having an extremely

1   poor lawyer drafting a complaint? Anytime you have a

2   variety of factors like that --

3   MR. SHAH: Sure.

4   CHIEF JUSTICE ROBERTS: -- I think it's very

5   difficult for the judge to say anything other than

6   that's for the jury.

7   MR. SHAH: If you mean at the motion to

8   dismiss phase, Chief Justice?

9   CHIEF JUSTICE ROBERTS: Yeah.

10   MR. SHAH: I think there would be some

11   cases. And in fact, we know there are dozens of

12   12(b)(6) motions granted in securities fraud cases, and

13   let me lay out a few scenarios for you.

14   One would be in the -- in the -- in the

15   scenario where the company has not made any actionable

16   statements. It has either -- statements predicated to

17   duty to disclose. It either has been made --

18   CHIEF JUSTICE ROBERTS: No, no, I'm talking

19   about the -- I'm talking about materiality. In other

20   words, based solely on -- in other words, you're saying

21   if they say anything related, it's going to be enough --

22   MR. SHAH: Sure.

23   CHIEF JUSTICE ROBERTS: -- whether it's a

24   scientific basis or not.

25   MR. SHAH: Sure. Two responses to that.

1   One, the PSLRA does have a safe harbor for companies

2   once they make forward-looking statements, that if they

3   add in meaningful cautionary language -- and this is in

4   the PSLRA itself, section 5(c)(1)(A), that if they add

5   in meaningful cautionary statements, then they cannot be

6   subject to liability. And I think there are a couple

7   other scenarios that would -- would trigger, for

8   example, if the product at issue is such a small

9   percentage of the company's income or expected growth

10   that no reasonable investor would care if it tanked,

11   then that might be a circumstance where a motion to

12   dismiss would be appropriate.

13   Thank you, Your Honor.

14   CHIEF JUSTICE ROBERTS: Thank you, counsel.

15   Mr. Hacker, you have three minutes

16   remaining.

17   REBUTTAL ARGUMENT BY JONATHAN HACKER

18   ON BEHALF OF THE PETITIONERS

19   MR. HACKER: Thank you, Mr. Chief Justice.

20   I would like to return to Justice Kennedy's

21   question about the role of scienter here, which I think

22   absolutely is critical as this Court emphasized recently

23   in the Merck v. Reynolds case.

24   Mr. Frederick correctly, I think, conceded

25   that there has to be a scientifically plausible basis.

1   And what you're talking about here is the company's

2   knowledge of a scientifically plausible basis. And he

3   has to make that concession in this case because of what

4   is alleged to be the material omission.

5   The material omission is not knowledge of

6   dubious scientific -- medical claims, it's not that we

7   get one phone call from a doctor. The real material

8   omission is that the adverse event reports told Matrixx

9   that Zicam causes anosmia. That's ultimately the fact

10   that -- that Matrixx supposedly did not disclose. So

11   there has to be a basis for believing that -- there has

12   to be allegation in the complaint that sufficient to

13   establish Matrixx actually knew that Zicam causes

14   anosmia and yet willfully refused to tell investors that

15   fact, and there's nothing in the complaint like that.

16   There's not -- you're not talking about a

17   case where there was a failure to disclose the doctor's

18   completely dubious untested claim. It's not a case --

19   it's not the Satan case where you're talking about a

20   media splash, a known fact that there is going to be a

21   major media splash and the company knows for a fact that

22   that splash is going to have the adverse effect on the

23   stock. There is not even a claim here --

24   JUSTICE SOTOMAYOR: Has that -- the

25   solicitor general's argument. He wasn't actually even

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1   talking about causation. He was talking about a

2   statement you made about the company poised to double

3   its growth. And I think he was saying that on the basis

4   of what you had heard up until that time, you had to

5   have known that that statement was misleading, as was

6   the statement that this drug, that there was absolutely

7   no proof or connection of causation, which was your

8   scientific panel said you couldn't make that extreme

9   statement.

10   MR. HACKER: Well, two points, Your Honor.

11   First, if the claim was about, you know, the consumer

12   sales, you would need an allegation in the case that

13   consumer product sales were actually affected. There's

14   no allegation like that, and the truth is they weren't.

15   And so you're not talking about falsifying any prior

16   claim. There's not even an allegation that that

17   happened, Your Honor.

18   Second, with respect to the -- the

19   statement, as I was discussing with Justice Ginsburg in

20   the beginning part of the argument, the statement was

21   what the scientific panel was addressing primarily was

22   Jafek's claim that Zicam causes anosmia, and the company

23   said accurately that that is completely unfounded and

24   misleading because there is no scientific support for

25   it. You can't go out and claim that Zicam causes

1   anosmia unless you have a scientific basis for that and

2   the scientific panel was saying that isn't true.

3   So the question is whether you can draw an

4   inference of scienter from the fact that -- from what's

5   alleged here, and there is simply no basis for an

6   allegation, supportable allegation that the company knew

7   it causes anosmia and nevertheless refused to tell

8   investors that. Thank you.

9   CHIEF JUSTICE ROBERTS: Thank you, counsel.

10   The case is submitted.

11   (Whereupon, at 10:59 a.m., the case in the

12   above-entitled matter was submitted.)

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