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IN THE SUPREME COURT OF THE UNITED STATES

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MATRIX INITIATIVES, INC., ET AL., :

Petitioners :

v. : No. 09-1156

JAMES SIRACUSANO, ET AL. :

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Washington, D.C.

Monday, January 10, 2011

The above-entitled matter came on for oral argument before the Supreme Court of the United States at 10:00 a.m.

APPEARANCES:

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

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

PRATIK A. SHAH, ESQ., Assistant to the Solicitor General, Department of Justice, Washington, D.C.; on behalf of the United States, as amicus curiae, supporting Respondents.

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P R O C E E D I N G S

(10:00 a.m.)

CHIEF JUSTICE ROBERTS: We'll hear argument first this morning in Case 09-1156, Matrixx Initiatives v. James Siracusano.

Mr. Hacker.

ORAL ARGUMENT OF JONATHAN HACKER

ON BEHALF OF THE PETITIONERS

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

All drug companies receive, on an almost daily basis, anecdotal hearsay reports about alleged adverse health events following the use of their products. Those incident reports do not themselves establish any reliable facts about the drug's performance or its safety, especially where, as here, there are only a handful of reports out of millions of products sold over a 4-year period, and --

JUSTICE GINSBURG: Mr. Hacker, do we know that from this record? I mean, we know that the plaintiffs were able to identify -- there's some dispute whether it's 12 or 23, but do you represent that there were no other complaints made? So that, let's say, there has been discovery; now we're just at the pleading stage. The company would have said: That's it; we

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, requires
21 both materiality and scienter. And neither of those is
22 established unless the company has knowledge of facts
23 establishing a reliable basis for inferring that the
24 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 an investor would have any reason to think that an
7 adverse event report is -- actually indicates a problem
8 with the product --

9 JUSTICE ALITO: Can there be --

10 MR. HACKER: -- as opposed to a coincidence.

11 JUSTICE ALITO: Can there be some situations
12 in which statistically significant evidence would not be
13 necessary?

14 For example, suppose some very distinguished
15 physicians concluded, based on clinical trials, that
16 there was a connection between a drug and a very serious
17 side effect. Could that establish materiality?

18 MR. HACKER: Well, I think a distinguished
19 physician would not conclude that there's a connection
20 unless the clinical trials reveal a statistically
21 significant difference between what they've seen and
22 what they would expect to see were there no association.
23 So there's that point, Your Honor.

24 But the second point I would make is we
25 acknowledge there are a very narrow, limited number of

1 circumstances under which a claim can be pled absent
2 statistically significant evidence, but that's -- that's
3 because doctors and researchers will conclude that there
4 may be causation under narrow circumstances. For
5 example, I think the most common set of criteria are the
6 Bradford-Hill criteria. But nothing like that is pled
7 here, Your Honor.

8 JUSTICE SCALIA: Mr. Hacker, the complaint
9 did not rely exclusively upon these adverse incidents
10 but also referred to a -- a study, a report by
11 researchers at the American Rhinologic Society --

12 MR. HACKER: Yes.

13 JUSTICE SCALIA: -- which -- which asserted
14 that there was a connection.

15 MR. HACKER: But that --

16 JUSTICE SCALIA: So the -- is the question
17 before us simply whether in isolation the adverse
18 incidents would be enough, or is not the question
19 whether those adverse incidents placed next to this
20 study would be enough?

21 MR. HACKER: Well, two points, Your Honor.
22 First, the plaintiffs have, throughout this litigation,
23 framed their case as one based on the failure to
24 disclose adverse event reports. It's the number of
25 adverse event reports that they say is the problem, and

1 they're not saying that there was a study out there and
2 that we failed to disclose the study. They say --

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

4 MR. HACKER: -- it's the fact of the adverse
5 event reports. Well, I think if you look at the -- now,
6 to be clear, the study is not attached to the complaint,
7 so there wasn't a basis in the complaint for saying the
8 company was aware of a reliable study, and here are the
9 details of the study, and they failed to disclose it.

10 JUSTICE SCALIA: Well, I thought the --
11 you're saying the complaint did not refer to the study?

12 MR. HACKER: It did refer to it. That's
13 true. And if you look at the study, there's really
14 nothing there. It's based on -- primarily on a case
15 study of one -- and, again, this isn't in the complaint;
16 it's in the -- it is attached to the red brief, Your
17 Honor.

18 There's one case study of one man who is 55
19 year old -- 55 years old, which is the population most
20 likely to experience anosmia. You're more likely to get
21 it when you're -- he's suffering from signs of lupus,
22 which causes anosmia, and he's taking Flonase, which
23 also causes anosmia. And so the idea that you can infer
24 from that one incident out of millions over years of
25 product sales that -- that Zicam causes anosmia and that

1 there's a problem out there.

2 CHIEF JUSTICE ROBERTS: You're talking about
3 -- you're talking about who's right or wrong about the
4 connection between Matrixx and anosmia. But that's not
5 the question. I'm an investor in Matrixx; I worry
6 whether my stock price is going to go down. You can
7 have some psychic come out and say Zicam is going to
8 cause a disease, with no support whatsoever, but if it
9 causes the stock to go down 20 percent, it seems to me
10 that's material.

11 MR. HACKER: But if -- that's precisely the
12 point, Your Honor. If a psychic came out or a lunatic
13 on the street corner is barking, you know, through a
14 megaphone that there's a problem with the product,
15 that's not the kind of information a -- a reasonable
16 investor would rely on.

17 JUSTICE SOTOMAYOR: But wait a minute.
18 These -- these weren't psychics. These were three
19 clinical doctors in this area, one of them you knew
20 poised to go to a society meeting to make this
21 allegation.

22 Doesn't it make a difference who the reports
23 are coming from and what the substance of those reports
24 may do to your product?

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

1 Honor, and I didn't mean to suggest that, you know,
2 these are psychics. The point simply is, following up
3 on the Chief Justice's question, that it does matter
4 what the basis of the allegation, and is the evidence,
5 the facts available to the company, reliable? Does it
6 create a reliable inference that a reasonable investor
7 would be concerned about?

8 JUSTICE KENNEDY: Well, suppose -- suppose
9 you stipulate, in response to the Chief Justice's
10 question, that it's irrational, that it's probably
11 baseless, but that the market will react adversely. Is
12 there a duty then to address the claim?

13 MR. HACKER: Under the case law, it's not
14 clear that that's true. In this case, looking at this
15 case specifically, Your Honor, when the market reacted,
16 what the market was reacting to was a Good Morning
17 America report. It's very important to be clear about
18 what that report said.

19 On Good Morning America, a leading morning
20 news program, the allegation was made by Dr. Jafek that
21 Zicam causes anosmia. That's a very different
22 allegation that what the company was -- than what it was
23 the company was aware of, which was simply the adverse
24 event reports.

25 JUSTICE KENNEDY: But --

1 JUSTICE SOTOMAYOR: But had there --

2 JUSTICE KENNEDY: But if there's a baseless
3 report -- and we stipulate that, although it's baseless,
4 it's going to affect the market -- could that be the
5 basis for an allegation, assuming the requisite
6 scienter, that there's liability?

7 MR. HACKER: Two answers, I would say, Your
8 Honor. First of all, we have to be very careful about
9 creating a rule through our interpretation of
10 materiality that would require companies in advance to
11 disclose the fact that a baseless, false allegation
12 about the company is going to come out because it
13 requires the company to ring the bell --

14 JUSTICE KENNEDY: But it's not the
15 allegation. It's the fact that the market may be
16 affected.

17 MR. HACKER: Well, I understand, but the
18 problem is if the-- what the rule would say is, because
19 the company is aware the market may be affected, the
20 company in advance has to say: A false report about us
21 is about to come out. It requires the company to first
22 ring the bell and then un-ring it in the same statement,
23 and that's not a good rule for companies.

24 Shareholders wouldn't want that rule, to
25 require companies to denigrate their product and then do

1 their best to explain why the allegation is untrue.

2 JUSTICE GINSBURG: Mr. Hacker --

3 CHIEF JUSTICE ROBERTS: But --

4 JUSTICE GINSBURG: Mr. Hacker, you just
5 said, if I understood you correctly, that when the --
6 when the news came out on Good Morning America, accurate
7 or not, there was an obligation to do something about
8 it, but among the -- the charges, it's not simply that
9 there was these reports, but it's the way the company
10 responded to them: two press releases that said
11 allegations of any linkage of the drug to anosmia are
12 completely unfounded. That statement was made even
13 after the -- what was it, Dr. Jafek?

14 MR. HACKER: Right.

15 JUSTICE GINSBURG: -- had this presentation,
16 and he was going to put Zicam's name on it, and the
17 company said you don't have any permission to do that.
18 So the company prevented Good Morning America from
19 happening earlier, and it made these affirmative
20 statements that there's no linkage.

21 MR. HACKER: Well, what they said was -- and
22 this was true -- that it was completely unfounded and
23 misleading. The very scientific panel that plaintiffs
24 themselves rely on, which convened and issued its report
25 2 weeks later, confirmed that. There was no -- it's

1 absolutely unfounded at the time to --

2 JUSTICE GINSBURG: I thought that the
3 scientific report that came out later said we can't say
4 one way or the other, as opposed to the company saying
5 that any suggestion of linkage is completely unfounded.

6 MR. HACKER: And that's correct, there
7 isn't, when -- when the scientific panel said you can't
8 make that claim, it's unfounded, there's no basis in the
9 available science.

10 JUSTICE GINSBURG: They didn't say
11 "unfounded." They said the evidence is not -- we can't
12 say yes and we can't say no. That's different from
13 completely unfounded.

14 MR. HACKER: Well, I'm -- with respect, Your
15 Honor, I'm not entirely sure it is. When you're talking
16 about science, you make a claim that's either supported
17 in the science or it's without support. And the point
18 the scientific panel was making is there was no support
19 in the available science, and what Jafek was relying on
20 was unreliable. As I just described, the one --

21 JUSTICE KAGAN: Well, Mr. Hacker, you're
22 saying that the question of whether there is support is
23 reducible to the question of whether there are
24 statistically significant findings. Now, as I
25 understand it, the FDA takes action all the time as to

1 drugs -- they force the withdrawal of a drug from the
2 market, they force relabeling of a drug -- on the basis
3 of findings that are not statistically significant.
4 Now, clearly in those cases the market has a right to
5 know the very things that are going to make the FDA take
6 action against a product and that are going to severely
7 affect the product's value to the company. Not
8 statistical significance there.

9 MR. HACKER: That's true, but the problem
10 with that sort of standard -- well, first of all, to
11 emphasize -- to look at the facts of this case, the FDA
12 didn't take any action until 5 years later, but -- and
13 which shows that the --

14 JUSTICE KAGAN: Well, it could, and
15 eventually it did.

16 MR. HACKER: But that's what --

17 JUSTICE KAGAN: And you are suggesting a
18 test for what -- what counts as material, which is
19 statistically significant, a test that the FDA itself
20 doesn't use when it thinks about what it should -- what
21 it should regulate.

22 MR. HACKER: The problem is ex ante. You
23 have to -- you can't look at this through hindsight.
24 You have to look at this ex ante. When a company has a
25 handful of reports -- it's absolutely true, nobody would

1 dispute, that some day in the distant future, with the
2 accumulation of more data, the FDA may take action based
3 on its own prophylactic public health regulatory
4 discretion. But at the time, ex ante, no company, when
5 it gets an adverse event report, can possibly know
6 whether that's enough information for the FDA to act.
7 So the prospect that the FDA may some day act on the
8 basis of additionally accumulated information would
9 require disclosure of all reports all the time, and
10 that, we submit, cannot be the standard.

11 JUSTICE SCALIA: Mr. Hacker, suppose Good
12 Morning America made the same claim, categorically
13 saying that this drug caused this condition, but did so
14 simply on the basis of these adverse incidents, and they
15 didn't have Dr. Janner's, or whatever his name is,
16 reports, but nonetheless Good Morning America comes out,
17 and on the basis of those incidents, saying Zicam causes
18 whatever the condition is. Would that have to be
19 reported?

20 MR. HACKER: Well --

21 JUSTICE SCALIA: And if not, why not?

22 MR. HACKER: I think what you would have to
23 be hypothesizing is evidence that the company, say a
24 week in advance, knew that Good Morning America was
25 going to come out and say that, because once Good

1 Morning America says it, it's said it and the effect is
2 what it is.

3 But even in the hypothetical -- you're --
4 you'd have to sort of unpack what you said. If Good
5 Morning America came out and said just what Matrixx knew
6 at the time -- there are a handful of adverse event
7 reports, there's -- it's over millions of product uses
8 over a 4-year period, and no indication that that's at
9 all in any way different from the incident rate in the
10 general population, especially among cold users, who, of
11 course, are most likely to experience anosmia -- you
12 know, we don't know what would have happened. But then
13 you add the element that Good Morning America then
14 declares that Zicam causes anosmia -- again, the
15 hypothetical would have to be in advance Matrixx is
16 aware --

17 JUSTICE SCALIA: All right. That's --

18 MR. HACKER: -- that the false claim is
19 going to be made.

20 JUSTICE SCALIA: Fine.

21 MR. HACKER: Right, and I would say, first
22 of all, we have to be very careful, as I said before,
23 about a rule that requires a company to disclose false
24 facts. I would say, second, that a reasonable investor
25 doesn't want false information; a reasonable investor

1 wants accurate information. And a reasonable investor
2 would actually --

3 JUSTICE SCALIA: These are unreasonable
4 investors who are relying on some talking head on Good
5 Morning America who says that this is true --

6 MR. HACKER: And that --

7 JUSTICE SCALIA: -- even though it isn't
8 true.

9 MR. HACKER: And that's a third point I
10 would make, Your Honor, is it's a different case, a
11 fundamentally different case --

12 JUSTICE SCALIA: No --

13 MR. HACKER: -- if you're talking about a
14 media splash.

15 JUSTICE SCALIA: You haven't answered yes or
16 no. There's no basis for its being said on Good Morning
17 America, but unreasonable investors by the thousands
18 rely upon it.

19 MR. HACKER: And I think the answer is no,
20 and I think that the reason it's no --

21 JUSTICE SCALIA: No --

22 MR. HACKER: -- a qualified no, is because --

23 JUSTICE SCALIA: Don't --

24 MR. HACKER: -- the law doesn't respond to
25 irrational, unpredictable, or unreasonable investors.

1 It responds to a reasonable investor who wants
2 accurate -- a reasonable investor is going to hold the
3 stock --

4 CHIEF JUSTICE ROBERTS: A reasonable
5 investor is going to worry about the fact that thousands
6 of unreasonable investors are going to dump their
7 Matrixx stock.

8 (Laughter.)

9 MR. HACKER: I -- I absolutely -- I
10 understand that.

11 CHIEF JUSTICE ROBERTS: So -- but, I mean,
12 there's nothing unreasonable about that. If it looks --
13 if you're looking at Good Morning America, you say, my
14 gosh, everybody else is going to sell this; I'm going to
15 sell, too. And if it turns out you knew about it, you
16 should have told me about it before.

17 MR. HACKER: And the point I would make is,
18 first of all, a company ex ante can't know when that's
19 going to happen. So all the hypotheticals are
20 suggesting some way of knowing the company --

21 CHIEF JUSTICE ROBERTS: It may not know, but
22 it certainly can know.

23 MR. HACKER: And if --

24 CHIEF JUSTICE ROBERTS: If you -- if you
25 know this is a very false report, but we know that, I

1 don't know, the surgeon general, somebody, is going to
2 come out and announce it and that will cause an
3 effect --

4 MR. HACKER: And that's why it's a
5 meaningfully different case. If the plaintiffs have --
6 plead in their complaint that there's a memo inside the
7 company, for example, so this false fact is going to
8 come out, and we know it's going to cause a stock drop,
9 that would be a case involving the materiality of a
10 media splash, a big media event.

11 It can't be that there's a false claim out
12 there somewhere and the company becomes aware of the
13 false claim and then, purely hypothetically, it's
14 possible that somebody will make the false claim. It
15 becomes also possible that the media will pick up and
16 not be persuaded to ignore the false claim.

17 JUSTICE KAGAN: Well, Mr. Hacker --

18 MR. HACKER: That's the kind of case we're
19 talking about here.

20 JUSTICE KAGAN: In most cases we don't know
21 whether the claim is false or not. So let me give you a
22 hypothetical: There's a pharmaceutical company and it
23 comes out with its first and only product. It's 100
24 percent of the sales, and it's a new contact lens
25 solution. And it sells this product to many, many, many

1 hundreds of thousands of people. And most of them use
2 this product with no adverse effect whatsoever, but
3 there are 10 cases where somebody uses this product and
4 they go blind. Three of those 10 cases -- the person
5 had to borrow a contact lens from a friend, only used it
6 in the one eye; they go blind only in that one eye.

7 This is not statistically significant.

8 There is no way that anybody would tell that you these
9 10 cases are statistically significant. Would you stop
10 using that product, and would a reasonable investor want
11 to know about those 10 cases?

12 MR. HACKER: I -- I would want to know more
13 about the number of uses and all that, but, no, there
14 wouldn't be a basis. A reasonable investor would want
15 to know all the facts and details that would establish a
16 reason to draw a --

17 JUSTICE KAGAN: There are a lot of contact
18 lens solutions in the world. So if I heard that, 10
19 people went blind, 3 used it in one eye, 3 went blind in
20 that eye, I'd stop using the product; and if I were
21 holding stock in that company, I'd sell the stock.

22 MR. HACKER: The problem is -- I mean, there
23 has to be some reliable basis. You may be describing
24 facts that would satisfy the Bradford-Hill criteria, for
25 example, where you can draw a -- a reliable inference

1 that the product is the cause. That's the key here.

2 There has to be --

3 JUSTICE BREYER: All right. So --

4 MR. HACKER: -- a reliable basis for
5 inferring causation.

6 JUSTICE BREYER: This is the same kind of
7 question, but suppose I don't really know how drug
8 companies operate. I suspect, but I don't know, that
9 where you have a serious drug, people are hurt all the
10 time and they blame the drug. So probably drug
11 companies operate in an environment where they get all
12 kinds of complaints and some are valid, some are not;
13 who knows? People are frightened.

14 MR. HACKER: Very much so.

15 JUSTICE BREYER: Okay. Now, I don't know
16 that. But you say at the beginning your client says:
17 Look, we get complaints all the time; you know, just put
18 up with it if you buy our stock. Now, I don't know to
19 what extent that's true. I don't know how that fits in.
20 I don't know whether their complaint is unusual or not
21 unusual or general.

22 Who is supposed to decide that? The judge
23 at the complaint stage? Or the judge after you get some
24 evidence on it? Or the jury? And the same is true of
25 scienter, after all, because the scienter, you see --

1 and you have to plead that with particularity. Okay.
2 What's my -- what's your answer? What's the -- what's
3 -- I mean, Justice Kagan has an interesting view of
4 this, and could be, that she's putting forward and
5 others might have a different view. Who is to decide
6 this?

7 MR. HACKER: Well, ultimately it's a
8 question -- it would go all the way to the jury if the
9 plaintiffs were able to plead facts in the complaint
10 that entitled them to relief.

11 JUSTICE BREYER: Well, we don't know. You
12 see, what they're saying is we have one respectable
13 doctor, studier, at -- you know, in Colorado. He, by
14 the way, has an abstract which isn't in the complaint,
15 which says that they do allege that it's zinc that's the
16 problem, a free zinc ion. And they say we also have 25
17 people who were hurt and some burning sensations in
18 people where it didn't rise to that level.

19 You know, I don't know. I don't know if
20 that's within the range of expectation of drug companies
21 as part of the normal course of business which investors
22 should know about, and I suspect a district judge
23 doesn't know, either. So how does it work where we in
24 fact just don't know whether this does or not arise
25 above the background noise of a drug company?

1 MR. HACKER: We think the answer is
2 statistical significance, just like the Second Circuit
3 said in Carter-Wallace --

4 JUSTICE BREYER: Oh, no, it can't be. I
5 mean, all right -- I'm sorry. I don't mean to take a
6 position yet. But --

7 (Laughter.)

8 JUSTICE BREYER: But, look -- I mean, Albert
9 Einstein had the theory of relativity without any
10 empirical evidence, okay? So we could get the greatest
11 doctor in the world, and he has dozens of theories, and
12 the theories are very sound, and all that fits in here
13 is an allegation he now has learned that it's the free
14 zinc ion that counts.

15 MR. HACKER: But --

16 JUSTICE BREYER: And that could be
17 devastating to a drug even though there isn't one person
18 yet who has been hurt. So I don't see how we can say --

19 MR. HACKER: But -- but --

20 JUSTICE BREYER: -- this statistical
21 significance always works or always doesn't work.

22 MR. HACKER: But, Your Honor, out of
23 millions of uses, if there was that problem, you would
24 -- it wouldn't be hard to plead a case that says there's
25 a statistically significant problem --

1 JUSTICE BREYER: They did. They said --
2 they said the free zinc ion was -- that word on this was
3 told to your client by a person who knows a lot about
4 it, is apparently reputable, and was told to a person
5 who also knows a lot about it. Huh. I think they're
6 saying you ought to have been very nervous at that
7 point. That isn't just a usual background noise, okay?
8 So I'm back to my question, which is -- you can answer
9 the other one too if you like. But, I mean -- but my
10 question is: Who is supposed to decide, how?

11 MR. HACKER: Well, I think a plaintiff -- I
12 mean, I may just be repeating myself, but a plaintiff
13 has to plead the facts that would entitle them to relief
14 at the end of the day. So, I'm not saying a judge
15 always --

16 JUSTICE BREYER: I know, and we're back at
17 my question --

18 MR. HACKER: And --

19 JUSTICE BREYER: The question is: The facts
20 that are pleaded is -- I think it's assumed that this is
21 above the normal background noise -- they certainly
22 argue that at length -- that there was this free zinc
23 ion conversation, that there are 25 people who were
24 hurt, and there is a lot of burning sensation going on,
25 even though it doesn't rise to the level of people being

1 hurt, and that's supported by some of the zinc sulfate
2 studies in the fish --

3 MR. HACKER: I think you need --

4 JUSTICE BREYER: -- okay? Now, they're
5 saying that's above the background noise, and you say,
6 no, it isn't. Now, who decides and how do we decide?
7 Don't we have to go to a trial?

8 MR. HACKER: The answer is no, Your Honor,
9 because there's no basis on those pleaded facts for
10 inferring that there's actually a problem with the zinc
11 ion --

12 JUSTICE BREYER: I know. I know, but
13 over --

14 MR. HACKER: Look -- look at the allegations
15 that --

16 JUSTICE BREYER: We're not saying -- you're
17 saying if you are a scientist -- now we're back to
18 Justice Scalia's questions and the others.

19 MR. HACKER: But it matters what a scientist
20 would think because it's only then that anybody ex ante,
21 again, remember --

22 JUSTICE ALITO: Well, then what --

23 MR. HACKER: -- has a basis for inferring
24 that there's a causal link which will create the
25 problem. And the zinc -- to be very clear, let's -- to

1 be very clear about the zinc studies, the claim made on
2 the telephone wasn't even a claim of causation. It
3 said, are you aware of the zinc sulfate studies, which,
4 of course, is a fundamentally different compound
5 than zinc gluconate.

6 JUSTICE BREYER: No, because the sulfate --
7 you see in the abstract, which they didn't put in the
8 complaint, that the problem that they saw arising out of
9 the zinc sulfate studies was the free zinc ion.

10 MR. HACKER: No, the zinc sulfate studies
11 were polio related --

12 JUSTICE BREYER: I --

13 MR. HACKER: -- totally irrelevant. What
14 they cited for the free zinc ions were studies of
15 catfish and turtles.

16 JUSTICE BREYER: All right --

17 MR. HACKER: And nobody thinks, nobody
18 thinks, that you can infer anything from a study of
19 catfish and turtles about their smell sensation and
20 human beings --

21 JUSTICE BREYER: The trouble is, you know,
22 the truth is I don't know --

23 MR. HACKER: But their --

24 JUSTICE BREYER: And so I'm back to my
25 question.

1 MR. HACKER: Well, in terms of scienter,
2 under the securities law there has to be a plausible
3 basis, and --

4 JUSTICE SOTOMAYOR: Counsel, I -- you got
5 cert granted on a limited question, and the limited
6 question was whether, in a complaint that alleges only
7 adverse reports, can you prove materiality and scienter
8 without proving statistical importance. That's the
9 question presented.

10 Justice Kagan started with the point that
11 the FDA doesn't require that. It requires just
12 reasonable evidence of a connection, not statistical.
13 Many of the amici here have done a wonderful job of
14 explaining why statistical importance can't be a measure
15 because it depends on the nature of the study at issue.

16 So given all of that -- and even in your
17 brief, in a footnote, you answered the question by
18 saying no, we can't establish that rule as an absolute,
19 because there are additional factors that could prove
20 materiality and scienter. So you've already answered
21 the question presented.

22 Are we down to what Justice Scalia asked
23 you, which is: We've got a "no" to the question: Are
24 the facts in this case enough? I don't know why we
25 would have granted cert on that, but you presented a

1 different question presented. Given the question
2 presented, is the answer no? And if not, why not?

3 MR. HACKER: Let me -- let me start with the
4 premise of the question presented. It's presented on
5 the facts as the case had been litigated today, trying
6 to rely on adverse event reports, which is
7 understandable. The plaintiffs don't want to have to
8 prove all of the other -- you wouldn't think they'd want
9 to prove all of the other facts.

10 JUSTICE SOTOMAYOR: Can I just interrupt a
11 second?

12 MR. HACKER: Sure.

13 JUSTICE SOTOMAYOR: This wasn't an FDA-
14 approved drug.

15 MR. HACKER: Right.

16 JUSTICE SOTOMAYOR: So there weren't any
17 adverse reports in the legal sense of that word.

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

19 JUSTICE SOTOMAYOR: In the FDA sense. So
20 we're using a misnomer here to start with.

21 MR. HACKER: Well --

22 JUSTICE SOTOMAYOR: Continue.

23 MR. HACKER: I would just say that adverse
24 event reports are not limited to what qualifies for the
25 FDA, certainly not by the way the case is --

1 JUSTICE SCALIA: Of course, if I may
2 interject --

3 MR. HACKER: -- litigated.

4 JUSTICE SCALIA: -- the FDA acts in the
5 public interest, doesn't it?

6 MR. HACKER: Yes.

7 JUSTICE SCALIA: And it doesn't make money
8 by withdrawing a drug from the market.

9 MR. HACKER: Yes.

10 JUSTICE SCALIA: As opposed to somebody who
11 sues, who makes money on the lawsuit.

12 MR. HACKER: That's true. But there's a
13 broader point about the FDA, which I think is underlying
14 your question and Justice Kagan's question, which is I
15 don't even think it's true that the FDA really requires
16 reasonable evidence. They have broad discretion and
17 should have broad discretion. Nobody is contesting
18 that. But the question is, again, ex ante, before you
19 know what the FDA might do, before there's sufficient
20 evidence to justify the FDA to act. Remember, the FDA
21 didn't act for 5 years. The FDA didn't act on the basis
22 of what Matrixx was aware of at the time, and so that
23 can't be the standard, the idea that the FDA may some
24 day act.

25 Statistical significance -- the question of

1 statistical significance is presented in this case to
2 the extent the courts below were arguing about and the
3 plaintiffs were arguing about whether or not the small
4 number of raw adverse event reports tell you anything
5 meaningful. The real standard -- the -- the case got
6 developed in the briefing here when the plaintiffs came
7 back and said, well, there's more to it and there can be
8 more to it, and that, of course, is true, but the
9 standard has to be reliability.

10 JUSTICE GINSBURG: Well, but you -- you have
11 said raw adverse event reports. Am I not right that all
12 of these reports came from medical doctors, and in
13 response to the very first one, the company
14 representative said, yes, we've been getting reports
15 since 1999?

16 MR. HACKER: Well, there's a reference, but
17 -- I mean, there's a -- 1999 was the first call from
18 Dr. Hirsch, who reported one patient. There's a
19 discussion with Dr. Linschoten about one other patient.
20 And there were some reports -- nobody is disputing that
21 there were some reports out there.

22 JUSTICE GINSBURG: But my question is, does
23 it make a difference if these reports come from medical
24 experts in this particular field?

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

1 have unique expertise in diagnosing causation. A
2 doctor -- if you have a sore knee, a doctor is qualified
3 to tell you -- to diagnose the fact that your sore knee
4 is the product of bone cancer. A doctor is not
5 qualified to tell you why you got bone cancer, and
6 that's the problem that we have here.

7 I'd like to reserve the balance of my time.

8 CHIEF JUSTICE ROBERTS: Thank you,
9 Mr. Hacker.

10 Mr. Frederick.

11 ORAL ARGUMENT OF DAVID C. FREDERICK

12 ON BEHALF OF THE RESPONDENTS

13 MR. FREDERICK: Thank you, Mr. Chief
14 Justice, and may it please the Court:

15 In TSC and Basic, this Court reaffirmed the
16 longstanding rule that materiality is judged based on
17 the total mix of information available to investors.
18 Matrixx initially sought a major change to this Court's
19 contextual approach to materiality by offering a
20 bright-line standard of statistical significance.

21 In its reply brief, Matrixx offer -- offers
22 a rule that would apply only in the hypothetical
23 scenario where investors rely solely on numbers of
24 adverse event reports in pleading securities fraud.

25 This Court should reject both arguments in

1 this case. The broad theory has numerous legal and
2 policy flaws. First, the longstanding totality of the
3 circumstances test best comports with the varied reasons
4 why investors make investment decisions.

5 JUSTICE ALITO: Well, suppose the
6 allegations of materiality are based solely on adverse
7 event reports. Suppose that it's alleged that 10
8 million people during -- during -- during 1 year have
9 taken a particular drug and 5 people, shortly after
10 taking the drug, have developed certain -- have had an
11 adverse -- have had -- experienced an adverse event. Is
12 that sufficient to go to a jury?

13 MR. FREDERICK: Well, probably not
14 sufficient to go a jury absent a drop in the stock
15 price, absent evidence that there was a scientifically
16 plausible link, absent evidence that the product was
17 highly important to the company's long-term financial
18 prospects. All of these things go into the contextual
19 mix that investors would regard as important in making
20 an investment decision, and they all happen to be
21 present here. We --

22 JUSTICE SCALIA: If it was the only product
23 they sold, that might be enough -- 5 adverse reports out
24 of 10 million? If -- if that's the only product they
25 make, you say, totality of the circumstances, that may

1 be enough?

2 MR. FREDERICK: Under the Basic test, Your
3 Honor, that very well might if the probability and the
4 magnitude of the harm -- if those five incidents were
5 deaths from a product that was easily substitutable,
6 that might be a relevant decision and information that
7 investors might want to take into account.

8 CHIEF JUSTICE ROBERTS: In response to
9 Justice Alito, I heard you say something about a
10 scientifically plausible link.

11 MR. FREDERICK: Correct.

12 CHIEF JUSTICE ROBERTS: That seems to me to
13 be a rather significant concession. In other words,
14 you're saying it's not simply the fact that some psychic
15 would say something, that that is not sufficient, even
16 if that has an impact on the market price, that there
17 has to be some scientifically plausible link to the
18 report.

19 MR. FREDERICK: I think this goes back to
20 Justice Kennedy's question as well, Mr. Chief Justice,
21 because there could very well be materiality. The
22 information might be important for investors, but it
23 could very well be that the people making the
24 disclosures don't have the requisite scienter because
25 there is an absence of any plausible relationship.

1 The stock price might drop on news that
2 would not be regarded as news that the most highly
3 scientifically rational people would take into account.
4 But that --

5 JUSTICE KENNEDY: Well, I thought this might
6 come up. At some point, do we look at scienter and then
7 go back from that to whether or not it's material, i.e.,
8 the argument would be the company knew that this would
9 affect the price, and that's why they didn't disclose
10 it, and therefore that shows it's material? Or do we do
11 this with two isolated boxes -- one, materiality; two,
12 scienter -- and we don't mix the analyses?

13 MR. FREDERICK: They're both analytically
14 distinct and related, Justice Kennedy, and I don't have
15 a simple answer for you because many of the reported
16 cases raise issues of both materiality and scienter.
17 What the Court has said in Basic is that the test is the
18 total mix of information and whether that -- under that
19 total mix, the investor would find that information
20 important. In Tellabs, the Court said that whether or
21 not the inferences of scienter could be deemed -- were
22 as plausible as other inferences based on the mental
23 state of the people making the information.

24 So the Court has announced separate tests.
25 In a case like this, there is a natural overlap, and in

1 fact the other side has litigated this case on the basis
2 that no one would have thought within the company, based
3 on the adverse event reports, that there was a basis for
4 thinking there was information.

5 We plead the other way by saying that when
6 you have three medical specialists in three distinct
7 periods where the last wants to bring findings to the
8 leading ear, nose, and throat medical society suggesting
9 that, based on studies that go back as far back as the
10 1930s, there is a scientifically plausible link based on
11 the zinc ions, that's something that the company should
12 have taken seriously and disclosed to investors.

13 JUSTICE KAGAN: But, Mr. Frederick, suppose
14 you were the CEO of a pharmaceutical company with a new
15 drug, you've just put it out on the market, and you get
16 a report back, this drug has caused a death, right?
17 This is your first adverse effect report. Do you have
18 to disclose it?

19 MR. FREDERICK: Well, I guess the first
20 thing I would say is, if the drug has not been FDA
21 approved, that would be material information that
22 investors might want to know. If the drug had been FDA
23 approved and that report was then submitted to the FDA,
24 I think that there's a closer call depending on the, you
25 know, effect of the report that might be on the stock

1 price, because that's the only company product and the
2 other factors that we've mentioned in our brief.

3 I think the question of one event is
4 obviously much more difficult than where there are
5 multiple events submitted by doctors with a
6 scientifically plausible basis on a product that's 70
7 percent of the company's revenues.

8 JUSTICE ALITO: Now, we're told that there
9 are hundreds of thousands of these, where for a -- for a
10 typical drug there may be thousands of these adverse
11 event reports in -- in a year, and you're -- basically,
12 you're saying all of those have to be disclosed?

13 MR. FREDERICK: Justice Alito, they already
14 are all disclosed.

15 JUSTICE ALITO: Well they -- already. So
16 then why does the company have to make additional
17 disclosure?

18 MR. FREDERICK: The --

19 JUSTICE ALITO: Analysts who follow the
20 stock price can easily look at the FDA Web site and see
21 the adverse event reports that have been reported --

22 MR. FREDERICK: Right.

23 JUSTICE ALITO: -- and draw whatever
24 conclusions seem to be warranted based on that.

25 MR. FREDERICK: That's why I think this case

1 presents the issue in a rather artificial way, because
2 the reports here were not the classic FDA-regulated
3 adverse event reports. This was a homeopathic drug that
4 was put on the market without FDA approval, and there
5 were no requirements of reports until 2006, which was
6 after the period at issue here.

7 JUSTICE BREYER: How would you write --
8 look, I'm asking how do you write this, because what --
9 where I think where the other side has a point is if --
10 with these -- this is a big class of these kinds of
11 things, you know, vitamins, all kinds of things like
12 that, and if we say that they have to disclose too much,
13 what will happen is people won't pay attention to it,
14 you know.

15 And if -- if you have, you know, 4,000 pages
16 of small print saying everything that was ever reported,
17 what really happens in -- in such instances is the
18 public pays no attention, and they think -- and it will
19 hide the things that are actually important.

20 So how would you write some words --
21 assuming that you're right, that their test is wrong --
22 but how would you write some words that will put a
23 disclosure obligation such that it's not going to be
24 overkill and it is going to get incidents that rise
25 above the background noise, and those are the incidents

1 that are -- that would be significant for a reasonable
2 investor?

3 MR. FREDERICK: I would start with the
4 language in Basic, which says the total mix of
5 information is what has, long standing, been the test
6 for materiality under this Court's cases. I would say
7 that where there is credible medical professional
8 describing the harms based on credible scientific
9 theories to back up the link, a very serious health
10 effect risk for product with many substitutes, and the
11 effect is on a predominant product line, then the
12 company ought to disclose that information. I would
13 not --

14 JUSTICE BREYER: Okay, I'll go back and read
15 what you have just said, and -- I will, because it will
16 be in the transcript, and -- and the -- this case -- I
17 -- you are very good, your clients and the lawyers --

18 MR. FREDERICK: Right.

19 JUSTICE BREYER: -- at writing complaints.
20 All right? So they've alleged in this complaint
21 everything they can show, and I -- I suspect -- and
22 during the class period. And what it doesn't say is
23 that very helpful chart that you put in the brief, in
24 the pocket. It doesn't say they ever showed that to the
25 company. All it says is there was a phone call and this

1 individual from -- from Colorado said something, which
2 it doesn't specify, about zinc and the -- and the number
3 of deaths.

4 MR. FREDERICK: Well, in 1999, though,
5 Justice Breyer, Dr. Hirsch -- and this is outlined at
6 paragraph 25 of the complaint -- also said that
7 intranasal application of zinc could be problematic, and
8 he specifically asked about how much zinc is put in
9 Zicam precisely because of his awareness of prior
10 studies going all the way back to the polio period in
11 which zinc had created a problem of persistent anosmia.
12 But our submission here is that --

13 JUSTICE SOTOMAYOR: How was your -- that
14 long litany of factors that you mentioned a few minutes
15 ago about how a company will go about determining
16 whether an adverse event report is material or not or
17 should be disclosed or not -- are you saying that
18 companies don't have to respond to irrational securities
19 holders? Are you accepting your adversary's proposition
20 that on some level -- you said credible evidence -- that
21 they don't have to respond to things they judge are not
22 credible?

23 MR. FREDERICK: It really depends, Justice
24 Sotomayor, and I don't mean to be evasive, but if there
25 is a product, say, that has some link to satanic

1 influences, and there is some reason to think that a
2 large body of followers in an irrational way might
3 regard there to be satanic influences on the basis of a
4 particular product, a cautious, reasonably prudent
5 investor might want to know that on the basis of that
6 information that most of us would regard as irrational,
7 might affect the stock price.

8 CHIEF JUSTICE ROBERTS: So what protection
9 is there at the summary judgment stage in response to
10 allegations? Because it doesn't have to be
11 scientifically valid; it can be completely irrational.
12 All you have to do is allege that, you know, if you had
13 told this, the price would have gone down. If you had
14 told -- if you had disclosed this, the price would have
15 gone down. And the response from the company is, well,
16 but this is just ridiculous; this is some guy in his
17 garage who writes this out on -- on a -- you know, a
18 piece of paper in -- in handwriting. And the response
19 is going to be, well, let's let the jury sort it out.

20 MR. FREDERICK: There are two answers, Mr.
21 Chief Justice. One is, in Basic itself, the Court
22 talked about the actions of a reasonable investor, and
23 this Court and many courts have always looked at a
24 reasonable person standard in making all sorts of these
25 fine judgments about the importance of particular

1 information. But the second answer is --

2 CHIEF JUSTICE ROBERTS: Well, you just told
3 me that it would be enough if somebody says that there's
4 a satanic, you know, impact on this, because a
5 reasonable investor would say there are enough crazy
6 people out there that this is going to affect the price.

7 MR. FREDERICK: What I said was if the
8 product was one that might be, you know, attractive in
9 some way to people who had that particular following. I
10 think you have to link up the product with the nature of
11 the complaint and the effect of the importance of the
12 information.

13 CHIEF JUSTICE ROBERTS: So it matters
14 whether -- I don't know what kind of product has
15 particular satanic susceptibility --

16 (Laughter.)

17 MR. FREDERICK: Well --

18 CHIEF JUSTICE ROBERTS: -- but I mean, are
19 you saying it matters if it's something that -- that
20 Satan's not going to be interested in? I don't
21 understand.

22 (Laughter.)

23 MR. FREDERICK: You're --

24 CHIEF JUSTICE ROBERTS: I don't mean to be
25 facetious, but your way of distinguishing the satanic

1 product is that it depends on whether people who follow
2 satanic cults are going to be interested or not. I
3 mean --

4 MR. FREDERICK: Well, Your Honor, there are
5 people who follow those things, and they spend money and
6 they buy stocks, but my second point is that scienter --
7 scienter is the other way around this problem, because
8 even though information --

9 JUSTICE SCALIA: I don't know that -- if
10 scienter is -- it seems to me ridiculous to -- to hold
11 companies to -- to irrational standards. And we did --
12 and we did say in -- in Basic that it's viewed --
13 whether it would be viewed by the reasonable investor.
14 And -- and you are saying, well, the reasonable investor
15 takes account of the irrationality. I don't think
16 that's what we meant in -- in Basic.

17 MR. FREDERICK: Well, Justice Scalia, you
18 can certainly write as a prophylactic here that that
19 isn't part of this test. We certainly have here all of
20 the indicia of credible medical professionals on a
21 credible scientific theory on a product that was
22 important to the company's finances and a very serious
23 side effect for a drug that had ready substitutes.

24 CHIEF JUSTICE ROBERTS: Okay. So that --
25 I'm just trying to get your response to that. You just

1 talked again about credible scientists and all that, and
2 you're putting those other things to one side.

3 So even if you have your satanic problem,
4 that is not enough. And you can sit there and allege it
5 would cause a drop of 30 percent in the stock price, and
6 you should have let this know -- your answer is no, they
7 don't have to let -- they don't have to disclose this
8 because there is no scientific credible basis for the
9 link that's alleged?

10 MR. FREDERICK: Now, I'm saying two things.
11 One is that there's a difference between scienter and
12 materiality. There is importance of information and an
13 intent to deceive, and the questions are analytically
14 distinct. In your hypothetical, Mr. Chief Justice, I
15 think you merged them, and I'd like to keep them
16 separate because as we -- as this case comes to the
17 Court, the issue is what is the standard for materiality
18 and whether or not statistical significance is the only
19 way to --

20 JUSTICE ALITO: On materiality --

21 MR. FREDERICK: -- materiality.

22 JUSTICE ALITO: -- can I give you -- because
23 I'm having a little difficulty understanding the
24 boundaries of the argument that you're making.

25 Let me give two hypotheticals, and they both

1 involve companies that have one product, and this is
2 their one product. The first one was what I mentioned
3 before, and I wasn't -- I wasn't clear about your
4 answer. All that's alleged is that a very large number
5 of people took the drug and that three people, after
6 taking the drug, within a week developed a certain
7 syndrome. That's the first one. Is that enough for
8 materiality?

9 The second one is that a company receives a
10 telephone call: Hello, I'm a general practitioner from
11 wherever, and I treated a patient, and the patient took
12 your medication and shortly after that developed this
13 syndrome, and I think there might be a connection. Is
14 that enough for materiality?

15 MR. FREDERICK: On the second one, I would
16 say probably not. And I would say, on the first one,
17 there's not enough information about the side effect and
18 what the drug is intended to solve.

19 I mean, the probability/magnitude test as
20 articulated by this Court goes to the probability of the
21 effect versus the magnitude that would be perceived by
22 investors, and those are important factors they go into.
23 So your hypothetical is very difficult to answer as you
24 have framed it.

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

1 say it's a drug to relieve the common cold, and the
2 effect is loss of the sense of smell. Five million
3 people take it. Three people, after taking it, lose
4 their sense of smell. Is that enough for materiality by
5 itself?

6 MR. FREDERICK: It -- by itself, that could
7 be enough, and the reason we know that could be enough,
8 Justice Alito, is that when, you know, some score
9 additional were released and this information was
10 disclosed, the stock price went down by 23.8 percent.
11 So reasonable --

12 JUSTICE GINSBURG: Mr. Frederick, your time
13 is running out, and there's one thing that you emphasize
14 in your brief -- I haven't heard you say one word about
15 it here -- and that is you're saying it's -- this is not
16 a case of a company that remains silent. The company,
17 in response to this, issued press releases in which it
18 said any suggestion of a linkage is completely
19 unfounded. Now, that's something different from there
20 are X number of reports. To what extent are you relying
21 on the affirmative statements that the company made?

22 MR. FREDERICK: We're relying on those to
23 establish scienter, both at the beginning of the class
24 period when they forced Dr. Jafek, through their legal
25 threats, to take Zicam off his poster presentation, and

1 then later when they said that the reports of anosmia
2 were completely unfounded and "misleading," was the word
3 that they used. "And misleading." And they repeated
4 that after the Good Morning America program came on,
5 only to say 3 weeks later, after empaneling a scientific
6 expert panel, that the information was insufficient to
7 make that determination. Our submission is that that is
8 enough.

9 JUSTICE SCALIA: Mr. Frederick, I'm -- I'm
10 not clear on why you can draw a distinction between
11 materiality and scienter for purposes of the issue
12 before us here.

13 If, indeed, satanic effect is enough for
14 materiality, you say, well, it may not be enough for
15 scienter. Why? I mean, if the company knows that
16 satanic effect is material, then the company has --
17 knowingly withholds it because it thinks satanic effect
18 is irrational, why doesn't that company have scienter,
19 if it's material?

20 The scienter is withholding something that
21 is material, that is known to be material, and once you
22 say that -- you know, that Satan is material, if the
23 company thinks Satan is involved here, it has to put it
24 in its report, no?

25 MR. FREDERICK: And it would depend on what

1 kind of stock effect occurred.

2 JUSTICE SCALIA: So there's no difference
3 between the materiality issue and the scienter issue.

4 MR. FREDERICK: Well --

5 JUSTICE SCALIA: You can't push this problem
6 off onto the scienter side of the equation.

7 MR. FREDERICK: It depends -- it depends on
8 this Court's application of its known precedent, which
9 my colleague here has not even referenced in his opening
10 argument, Basic, which says you look at the total mix of
11 the information. And all of these things go into play.
12 If the --

13 JUSTICE BREYER: Okay. I get that. Can I
14 just ask you one question in response to -- just picking
15 up on the last -- what about the need for a, quote,
16 "strong inference of scienter," end quote, and does this
17 complaint show more than a borderline situation where it
18 doesn't strongly infer that the person intended to
19 mislead the defendant? What about that argument?

20 MR. FREDERICK: Well, we believe, and they
21 haven't argued that this complaint is not sufficient
22 under the PSLRA, which set the heightened pleading
23 standard for scienter that this Court articulated and
24 construed in the Tellabs decision, so we believe that
25 scienter is adequately pleaded here based on --

1 JUSTICE BREYER: Well, page 49 of their
2 brief -- they have two pages on it -- it does not give
3 rise to a strong inference of scienter.

4 MR. FREDERICK: What I'm saying is that
5 there's already a heightened pleading standard, Justice
6 Breyer. I was not -- I misunderstood your question to
7 say, is there some other heightened pleading standard
8 other than the one --

9 JUSTICE BREYER: No, no, I mean -- I just
10 want to know why -- if their inference on materiality is
11 enough to survive the background noise reply, is it
12 enough to show a strong inference that they did do this
13 intending to mislead, a strong inference of scienter?

14 MR. FREDERICK: The key aspects here are
15 their treatment of Jafek when Jafek was going to go
16 public with his scientifically linked claim of anosmia
17 from the Zicam, and then subsequently when they issued
18 press releases saying it would be completely unfounded
19 and misleading to assert any causal link. That is
20 sufficient to establish a strong inference of scienter.

21 CHIEF JUSTICE ROBERTS: Thank you, Mr.
22 Frederick.

23 Mr. Shah.

24 ORAL ARGUMENT OF PRATIK A. SHAH

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

1 SUPPORTING THE RESPONDENTS

2 MR. SHAH: Mr. Chief Justice, and may it
3 please the Court:

4 For 35 years, this Court's precedents have
5 instructed that information is material for securities
6 fraud purposes if a reasonable investor would have
7 viewed it as having meaningfully altered the total mix
8 of information. Under the terms of their question
9 presented, Petitioners propose to depart from that
10 contextual inquiry in favor of a categorical rule that
11 deems information about an adverse drug effect
12 immaterial absent statistical significance.

13 JUSTICE SCALIA: Mr. Shah, what do you
14 think --

15 MR. SHAH: To the extent --

16 JUSTICE SCALIA: What do you think about
17 Satan?

18 (Laughter.)

19 MR. SHAH: Let me try to unpack the satanic
20 connection hypotheticals a little bit.

21 Now, to be sure, if someone just called a
22 company and said, hey, I think you guys are affiliated
23 with satanic practices, surely a company would not have
24 to go and disclose that to all the investors. But this
25 is going to depend on what the actual reality is and

1 what the company's statements have been.

2 Now, if the company has made a statement
3 that, look, consumer confidence in our products is at an
4 all-time high and we expect sales to double in the next
5 quarter, and yet they are aware that there -- a consumer
6 boycott is being planned by, let's say, 10 percent of
7 their consumer base premised on the irrational notion
8 that their company is tied to Satan, then certainly, to
9 correct their affirmative representation that consumer
10 confidence is at an all-time high and that they expect
11 their sales to double, a reasonable investor would want
12 to know that --

13 JUSTICE SCALIA: They haven't said that.
14 They haven't said our sales are going to double.
15 They're just rocking along at normal sales.

16 MR. SHAH: Right.

17 JUSTICE SCALIA: And they find out that
18 10 percent of nutty-nuttys out there are not going to
19 buy their stuff because of Satan. Okay?

20 MR. SHAH: Well, Your Honor --

21 JUSTICE SCALIA: What about that?

22 MR. SHAH: In that hypothetical, it depends
23 on what affirmative statements the companies have made.
24 Under the securities law -- and this is an important
25 point that I don't think has come through yet. Under

1 the securities laws, there is no baseline duty to
2 disclose for a manufacturer or a company. A company
3 creates a duty to disclose once they have spoken. So
4 it's going to depend on what the company has said.

5 Now, in your scenario, if a company has made
6 statements projecting their company's success into the
7 next quarter, for example, and they have a concrete
8 basis to know that, as your hypothetical submits,
9 10 percent of their computer -- consumer base is going
10 to leave the company's products, that is almost
11 certainly going to be material to an investor, and so,
12 yes, they would have to disclose that we have reason to
13 believe, however ridiculous it is and untrue it is, that
14 10 percent of our consumer base has decided to boycott
15 our product. That's certainly reasonable.

16 CHIEF JUSTICE ROBERTS: You would have --
17 you just said they would have a duty to disclose.

18 MR. SHAH: Yes, sir.

19 CHIEF JUSTICE ROBERTS: I thought you
20 earlier just said there's no affirmative duty to
21 disclose; it only is based on what they say.

22 MR. SHAH: It's based on what they said.
23 So, for example, if the company had simply remained
24 silent --

25 CHIEF JUSTICE ROBERTS: Right.

1 MR. SHAH: -- and not said anything about
2 its future sales, its prospects, then under the
3 securities laws there is no duty to disclose. Basic and
4 other cases have long made clear that there has to be
5 something to trigger a duty to disclose. That is, under
6 Rule 10b-5 it's only statements that are rendered
7 misleading by the omission of a material fact that can
8 trigger liability. If there is no projection about the
9 company's future success, then it wouldn't have to
10 disclose in that situation.

11 JUSTICE ALITO: What if the company makes
12 the kind of relatively common statements that were made
13 here, poised for growth in the upcoming season, very
14 strong momentum going into the season, extremely well
15 positioned for a successful season?

16 MR. SHAH: Sure, Your Honor --

17 JUSTICE ALITO: That's -- that triggers the
18 duty to disclose the satanic rumors?

19 MR. SHAH: In certain cases where there are
20 very generalized statements -- for example, we think our
21 product will do well -- that may close -- come close to
22 the line of puffery that is a non-actionable statement
23 that no reasonable investor would rely on. Petitioners
24 have never pressed that argument before this Court.
25 There is no dispute about whether the statements that

1 Matrixx made in this case are actionable, even though I
2 agree with you that some of them probably come close to
3 that puffery line.

4 Here, though, we don't just have those
5 statements about the company being well positioned for
6 future growth. There are additional statements, and
7 these were made to stock analysts that they expected a
8 50 percent increase in annual revenues, and, of course,
9 there are the much more affirmative statements that the
10 drug's safety had been well established and that the
11 rumor -- the reports of anosmia were completely
12 unfounded and misleading. Those statements certainly
13 crossed the line. And as I said before, there hasn't
14 been an argument in this case as to whether those less
15 specific and arguably puffery-type statements --

16 JUSTICE SCALIA: So the Government's
17 position is that reports of adverse effects that have no
18 scientific basis, so long as they would affect
19 irrationally consumers, have to be disclosed, assuming
20 the company has said we're doing well, right?

21 MR. SHAH: Well, Your Honor, yes, I think it
22 would depend, again, on the statements the company
23 makes. If -- if --

24 JUSTICE SCALIA: Well, I mean, if Satan
25 comes in, surely lousy science comes in as well, no?

1 MR. SHAH: Okay. So -- so, for example,
2 if a company had been faced with a potential adverse
3 effect and it had assembled a blue-ribbon panel of
4 scientists, conclusively determined that there is no
5 causal connection between this purported adverse effect
6 and their drug, the question is, would they have to
7 disclose in that circumstance?

8 I think if the company had simply made
9 statements relating to the drug safety -- we think our
10 drug is safe; there's no reason to believe that it
11 causes any adverse effects -- then the answer is no,
12 because the reported adverse effect would not call into
13 question the accuracy of the company's statements
14 relating to the safety of the drug.

15 If, however, the company had made specific
16 statements relating to consumer demand for its products
17 and it knew -- notwithstanding the fact that there was
18 no causal connection, it knew or had good reason to
19 believe that a significant portion of its consumer base
20 would avoid the product, then, yes, a reasonable
21 investor would want to know that information, and under
22 Basic the company would have a duty to disclose that,
23 even though unfounded, these reports may lead a
24 significant percentage of our consumer base to leave the
25 product.

1 I think that falls squarely within the
2 definition of materiality, which is would a reasonable
3 investor want to have known that information?

4 JUSTICE KAGAN: Mr. Shah, what deference do
5 you think that the SEC's understanding of materiality is
6 entitled to and why?

7 MR. SHAH: Well, Your Honor, this Court in
8 both TSC and Basic accorded what it called due deference
9 to the SEC's views on the application of the materiality
10 standard. I think it's certainly true -- and -- and
11 those, by the way, were both -- the -- the Court was
12 deferring to the views of the SEC as expressed in amicus
13 briefs to the Court just like in this case.

14 I think the SEC is due a significant
15 deference based upon, one, its longstanding historical
16 practice in applying the materiality standard, which is
17 part of its own rule, Rule 10b-5, and its special
18 expertise in knowing what a reasonable investor would
19 want to know based upon its experience in this area.
20 So, I do think that, to the extent there is any
21 ambiguity remaining in this case, the Court should defer
22 to the SEC's views.

23 And back to Justice Breyer's questions about
24 what should the Court write simply beyond reiterating
25 the Basic standard, I think what the Court did in Basic

1 was it not only articulated the general standard, but it
2 laid out some factors. And in laying out those factors,
3 that's where the Court deferred to the SEC's brief. And
4 it laid out factors that a reasonable investor might
5 find relevant. In that case, it was the merger context.

6 And here, on page 28 of our brief, we lay
7 out several factors that we think bear on the
8 materiality question in this particular context; that
9 is, involving adverse drug information.

10 CHIEF JUSTICE ROBERTS: Is there any way
11 that consideration of those factors would support a -- a
12 summary judgment in favor of the pharmaceutical
13 manufacturer, other than the fact of having an extremely
14 poor lawyer drafting a complaint? Anytime you have a
15 variety of factors like that --

16 MR. SHAH: Sure.

17 CHIEF JUSTICE ROBERTS: -- I think it's very
18 difficult for the judge to say anything other than
19 that's for the jury.

20 MR. SHAH: If you mean at the motion to
21 dismiss stage, Mr. Chief Justice --

22 CHIEF JUSTICE ROBERTS: Yes.

23 MR. SHAH: I think there would be some
24 cases. And, in fact, we know there are dozens of
25 12(b)(6) motions granted in securities fraud cases, and

1 let me lay out a few scenarios for you.

2 One would be in the -- in the scenario where
3 the company has not made any actionable statements. It
4 has either -- statements to predicate a duty to
5 disclose. It either has been made --

6 CHIEF JUSTICE ROBERTS: No, no, I'm talking
7 about -- I'm talking about materiality. In other
8 words --

9 MR. SHAH: Sure.

10 CHIEF JUSTICE ROBERTS: -- based solely on
11 -- in other words, you're saying if they say anything
12 related, it's going to be enough --

13 MR. SHAH: Sure.

14 CHIEF JUSTICE ROBERTS: -- whether it's a
15 scientific basis or not.

16 MR. SHAH: Sure. Two responses to that.
17 One, the PSLRA does have a safe harbor for companies
18 once they make forward-looking statements, that if they
19 add in meaningful cautionary language -- and this is in
20 the PSLRA itself, section 5(c)(1)(A) -- that if they add
21 in meaningful cautionary statements, then they cannot be
22 subject to liability. And I think there are a couple
23 other scenarios that would -- would trigger, for
24 example, if the product at issue is such a small
25 percentage of the company's income or expected growth

1 that no reasonable investor would care if it tanked,
2 then that might be a circumstance where a motion to
3 dismiss would be appropriate.

4 Thank you, Your Honor.

5 CHIEF JUSTICE ROBERTS: Thank you, counsel.

6 Mr. Hacker, you have 3 minutes remaining.

7 REBUTTAL ARGUMENT OF JONATHAN HACKER

8 ON BEHALF OF THE PETITIONERS

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

10 I'd like to return to Justice Kennedy's
11 question about the role of scienter here, which I think
12 absolutely is critical, as this Court emphasized
13 recently in the Merck v. Reynolds case.

14 Mr. Frederick correctly, I think, conceded
15 that there has to be a scientifically plausible basis.
16 And what you're talking about here is a company's
17 knowledge of a scientifically plausible basis. And he
18 has to make that concession in this case because of
19 what's alleged to be the material omission.

20 The material omission is not knowledge of
21 dubious scientific -- medical claims. It's not that we
22 got one phone call from a doctor. The real material
23 omission is that the adverse event reports told Matrixx
24 that Zicam causes anosmia. That's ultimately the fact
25 that -- that Matrixx supposedly did not disclose. And

1 so there has to be a basis for believing that -- there
2 has to be allegation in the complaint that's sufficient
3 to establish that Matrixx actually knew that Zicam
4 causes anosmia and yet willfully refused to tell
5 investors that fact.

6 And there's nothing in the complaint like
7 that. There's not -- you're not talking about a case
8 where there was a failure to disclose the doctor's
9 completely dubious untested claim. It's not a case --
10 it's not the Satan case where you're talking about a
11 media splash, a known fact that there's going to be a
12 major media splash, and the company knows for a fact
13 that that splash is going to have the adverse effect on
14 the stock. There's not even a claim here --

15 JUSTICE SOTOMAYOR: As I was hearing the
16 Solicitor General's argument, he wasn't actually even
17 talking about causation. He was talking about a
18 statement you made about the company poised to double
19 its growth. And I think he was saying that on the basis
20 of what you had heard up until that time, you had to
21 have known that that statement was misleading, as was
22 the statement that this drug -- that there was
23 absolutely no proof or connection of causation, which
24 was your scientific panel said you couldn't make that
25 extreme statement.

1 MR. HACKER: Well, two points, Your Honor.
2 First, if the claim was about, you know, the consumer
3 sales, you would need an allegation in the case that
4 consumer product sales were actually affected. There's
5 no allegation like that, and the truth is they weren't.
6 And so you're not talking about falsifying any prior
7 claim. There's not even an allegation that that
8 happened, Your Honor.

9 And, second, with respect to the -- the
10 statement, as I was discussing with Justice Ginsburg in
11 the beginning part of the argument, the statement was --
12 what the scientific panel was addressing primarily was
13 Jafek's claim that Zicam causes anosmia, and the company
14 said accurately that that is completely unfounded and
15 misleading because there's no scientific support for it.
16 You can't go out and claim that Zicam causes anosmia
17 unless you have a scientific basis for that. And the
18 scientific panel was saying that isn't true.

19 So the question is whether you can draw an
20 inference of scienter from the fact that -- from what's
21 alleged here, and there's simply no basis for an
22 allegation, supportable allegation, that the company
23 knew it causes anosmia and nevertheless refused to tell
24 investors that. Thank you.

25 CHIEF JUSTICE ROBERTS: Thank you, counsel.

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Counsel.

The case is submitted.

(Whereupon, at 10:59 a.m., the case in the
above-entitled matter was submitted.)

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