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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'll hear argument  
4 first this morning in Case 09-1156, Matrixx Initiatives  
5 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

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.

1 Counsel.

2 The case is submitted.

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

4 above-entitled matter was submitted.)

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