1	IN THE SUPREME COURT OF THE UNITED STATES
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3	MATRIXX INITIATIVES, INC., ET AL.,:
4	Petitioners :
5	v. : No. 09-1156
6	JAMES SIRACUSANO, ET AL. :
7	x
8	Washington, D.C.
9	Monday, January 10, 2011
10	
11	The above-entitled matter came on for oral
12	argument before the Supreme Court of the United States
13	at 10:00 a.m.
14	APPEARANCES:
15	JONATHAN HACKER, ESQ., Washington, D.C.; on behalf of
16	Petitioners.
17	DAVID C. FREDERICK, ESQ., Washington, D.C.; on behalf of
18	Respondents.
19	PRATIK A. SHAH, ESQ., Assistant to the Solicitor
20	General, Department of Justice, Washington, D.C.; on
21	behalf of the United States, as amicus curiae,
22	supporting Respondents.
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1	PROCEEDINGS
2	(10:00 a.m.)
3	CHIEF JUSTICE ROBERTS: We will hear
4	argument first this morning in Case 09-1156, Matrixx
5	Initiatives v. James Siracusano.
6	Mr. Hacker.
7	ORAL ARGUMENT OF JONATHAN HACKER
8	ON BEHALF OF THE PETITIONERS
9	MR. HACKER: Mr. Chief Justice, and may it
LO	please the Court:
L1	All drug companies receive on an almost
L2	daily basis anecdotal hearsay reports about alleged
L3	adverse health events following the use of their
L 4	products. Those incident reports do not themselves
L5	establish any reliable facts about the drug's
L6	performance or its safety, especially where, as here,
L7	there are only a handful of reports out of millions of
L8	products sold over a 4-year period, and
L9	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
5	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 --
- JUSTICE GINSBURG: But why shouldn't that
- 15 determination be deferred until there's discovery, and
- 16 then we can know how many reports there really were?
- 17 MR. HACKER: Because it's incumbent on a
- 18 plaintiff to come to court with a case, to plead the
- 19 facts necessary to establish all of the elements of a
- 20 claim. And a securities fraud claim, of course,
- 21 requires both materiality and scienter, and neither of
- 22 those is established unless the company has knowledge of
- 23 facts establishing a reliable basis for inferring that
- 24 the drug itself is the cause of the reported event.
- 25 Absent information like that, there is

- 1 neither materiality nor scienter under the securities
- 2 laws, because neither the company nor an investor --
- 3 until there's reliable evidence of a causal link between
- 4 the two products, neither a company -- excuse me, a link
- 5 between the product and the event -- neither the company
- 6 nor investor would have any reason to think that an
- 7 adverse event report is -- actually indicates a problem
- 8 with the product, as opposed to a coincidence.
- 9 JUSTICE ALITO: Can there be some situations
- 10 in which statistically significant evidence would not be
- 11 necessary?
- For example, suppose some very distinguished
- 13 physicians concluded based on clinical trials that there
- 14 was a connection between a drug and a very serious side
- 15 effect. Could that establish materiality?
- MR. HACKER: I think a distinguished
- 17 physician would not conclude that there's a connection
- 18 unless the clinical trials reveal a statistically
- 19 significant difference between what they've seen and
- 20 what they would expect to see were there no association.
- 21 So there's that point, Your Honor.
- But the second point I would make is, we
- 23 acknowledge there are a very narrow, limited number of
- 24 circumstances under which a claim can be pled absent
- 25 statistically significant evidence, but that's -- that's

- 1 because doctors and researchers will conclude that there
- 2 may be causation under narrow circumstances. For
- 3 example, I think the most common set of criteria are the
- 4 Bradford-Hill criteria. But nothing like that is pled
- 5 here, Your Honor.
- JUSTICE SCALIA: Mr. Hacker, the complaint
- 7 did not rely exclusively upon these adverse incidents
- 8 but also referred to a study, a report by researchers at
- 9 the American Rhinologic Society --
- MR. HACKER: Yes.
- 11 JUSTICE SCALIA: -- which -- which asserted
- 12 that there was a connection. So the -- is the question
- 13 before us simply whether in isolation the adverse
- 14 incidents would be enough, or is not the question
- 15 whether those adverse incidents placed next to this
- 16 study would be enough?
- 17 MR. HACKER: Well, two points, Your Honor.
- 18 First, the plaintiffs have throughout this litigation
- 19 framed their case as one based on the failure to
- 20 disclose adverse event reports. It's the number of
- 21 adverse event reports that they say is the problem, and
- they're not saying that there was a study out there and
- 23 that we failed to disclose the study. But they say it's
- 24 the fact of the adverse event reports.
- 25 JUSTICE SCALIA: Why didn't they say that?

- 1 MR. HACKER: Well, I think if you look at
- 2 the -- to be clear, the study is not attached to the
- 3 complaint, so there wasn't a basis in the complaint for
- 4 saying the company was aware of a reliable study and
- 5 here are the details of the study and they failed to
- 6 disclose it.
- 7 JUSTICE SCALIA: Well, I thought the --
- 8 you're saying the complaint did not refer to the study?
- 9 MR. HACKER: It did refer to it. That's
- 10 true. And if you look at the study, there's really
- 11 nothing there. It's based on, primarily on a case study
- 12 of one -- and again, this isn't in the complaint. It is
- 13 attached to the red brief, Your Honor.
- 14 There's one case study of one man who is 55
- 15 year old -- 55 years old, which is the population most
- 16 likely to experience anosmia. You're more likely to get
- 17 it when you're -- he's suffering from signs of lupus.
- 18 Which causes anosmia, and he is taking Flonase, which
- 19 also causes anosmia. And so the idea that you can infer
- 20 from that one incident out of millions over years of
- 21 product sales that -- that Zicam causes anosmia under
- 22 the --
- 23 CHIEF JUSTICE ROBERTS: You're talking about
- 24 -- you're talking about who is right or wrong about the
- 25 connection between Matrixx and anosmia. But that's not

- 1 the question. I'm an investor in Matrixx; I worry
- 2 whether my stock price is going to go down. You can
- 3 have some psychic come out and say "Zicam is going to
- 4 cause a disease" with no support whatsoever, but if it
- 5 causes the stock to go down 20 percent, it seems to me
- 6 that's material.
- 7 MR. HACKER: That's precisely the point,
- 8 Your Honor. If a psychic came out or a lunatic on the
- 9 street corner is barking, you know, through a megaphone
- 10 that there's a problem with the product, that's not the
- 11 kind of information to rely -- a real investor would
- 12 rely on.
- 13 JUSTICE SOTOMAYOR: But wait a minute.
- 14 These weren't psychics. These were 3 clinical doctors
- in this area, one of them you knew poised to go to a
- 16 society meeting to make this allegation.
- 17 Doesn't it make a difference who the reports
- 18 are coming from and what the substance of those reports
- 19 may do to your product?
- 20 MR. HACKER: It may make a difference, Your
- 21 Honor, and I didn't mean to suggest that, you know,
- these are psychics. The point simply is, following up
- 23 on the Chief Justice's question, that it does matter
- 24 what the basis of the allegation, and is the evidence,
- 25 the facts available to the company, reliable? Does it

- 1 create a reliable inference that a reasonable investor
- 2 would be concerned about?
- JUSTICE KENNEDY: Well, suppose you
- 4 stipulate in response to the Chief Justice's question
- 5 that it is irrational, that it is probably baseless, but
- 6 that the market will react adversely. Is there a duty
- 7 then to address the claim?
- 8 MR. HACKER: Under the case law, it's not
- 9 clear that that's true. In this case, looking at this
- 10 case specifically, Your Honor, when the market reacted,
- 11 what the market was reacting to was a Good Morning
- 12 America report. It's very important to be clear about
- 13 what that report said.
- On Good Morning America, a leading morning
- 15 news program, the allegation was made by Dr. Jafek that
- 16 Zicam causes anosmia. That's a very different
- 17 allegation that what the company was -- than what it was
- 18 the company was aware of, which was simply the adverse
- 19 event reports.
- JUSTICE KENNEDY: But if there's a baseless
- 21 report and we stipulate that, although it's baseless,
- 22 it's going to affect the market, could that be the basis
- 23 for an allegation, assuming the requisite scienter, that
- there's liability?
- 25 MR. HACKER: Two answers I would say, Your

- 1 Honor. First of all, we have to be very careful about
- 2 creating a rule through our interpretation of
- 3 materiality that would require companies in advance to
- 4 disclose the fact that a baseless, false allegation
- 5 about the company is going to come out because it
- 6 requires the company to ring the bell --
- 7 JUSTICE KENNEDY: But it's not the
- 8 allegation. It's the fact that the market may be
- 9 affected.
- MR. HACKER: Well, I understand, but the
- 11 problem is it's the underlying -- what the rule would
- 12 say is, because the company is aware the market may be
- 13 affected, the company in advance has to say: A false
- 14 report about us is about to come out. It requires the
- 15 company to first ring the bell and then un-ring it in
- 16 the same statement, and that's not a good rule for
- 17 companies.
- 18 Shareholders wouldn't want that rule, to
- 19 require companies to denigrate their product and then do
- 20 their best to explain why the allegation is untrue.
- 21 JUSTICE GINSBURG: Mr. Hacker -- Mr. Hacker,
- 22 you just said, if I understood you correctly, that when
- 23 the -- when the news came out on Good Morning America,
- 24 accurate or not, there was an obligation to do something
- 25 about it, but among the -- the charges, it's not simply

- 1 that there was these reports, but it's the way the
- 2 company responded to them: Two press releases that said
- 3 allegations of any link of these drugs to anosmia are
- 4 completely unfounded. That statement was made even
- 5 after the -- what was it, Dr. Jafek?
- 6 MR. HACKER: Right.
- JUSTICE GINSBURG: -- had this presentation,
- 8 and he was going to put Zicam's name on it and the
- 9 company said, you don't have any permission to do that.
- 10 So the company prevented Good Morning America from
- 11 happening earlier, and it made these affirmative
- 12 statements that there's no linkage.
- MR. HACKER: Well, what they said was, and
- 14 this was true, that it was completely unfounded and
- 15 misleading. The very scientific panel that plaintiffs
- 16 themselves rely on, which convened and issued its report
- 17 2 weeks later, confirms that. There was no -- it's
- 18 absolutely unfounded at the time to --
- JUSTICE GINSBURG: I thought that the
- 20 scientific report that came out later said, we can't say
- 21 one way or the other, as opposed to the company saying
- 22 that any suggestion of linkage is completely unfounded.
- 23 MR. HACKER: And that's correct, there
- 24 isn't. When -- when the scientific panel said you can't
- 25 make that claim, it's unfounded, there's no basis in the

- 1 available science.
- JUSTICE GINSBURG: They didn't say
- 3 "unfounded." They said the evidence is not -- we can't
- 4 say yes and we can't say no. That's different from
- 5 completely unfounded.
- 6 MR. HACKER: Well, I'm -- with respect, Your
- 7 Honor, I'm not entirely sure it is. When you're talking
- 8 about science, you make a claim that's either supported
- 9 in the science or it's without support, and the point
- 10 the scientific panel was making is there was no support
- in the available science, and what Jafek was relying on
- 12 was unreliable. As I just described, the one --
- JUSTICE KAGAN: Well, Mr. Hacker, you were
- 14 saying that the question of whether there is support is
- 15 reducible to the question of whether there are
- 16 statistically significant findings. Now, as I
- 17 understand it, the FDA takes action all the time as to
- 18 drugs -- they force the withdrawal of a drug from the
- 19 market, they force relabeling of a drug -- on the basis
- 20 of findings that are not statistically significant.
- 21 Now, clearly in those cases the market has a right to
- 22 know the very things that are going to make the FDA take
- 23 action against a product and that are going to severely
- 24 affect the product's value to the company. Not
- 25 statistical significance there.

- 1 MR. HACKER: That's true, but the problem
- 2 with that sort of standard -- well, first of all, to
- 3 emphasize, to look at the facts of this case, the FDA
- 4 didn't take any action until 5 years later, but -- which
- 5 shows --
- 6 JUSTICE KAGAN: Well, it could and
- 7 eventually it did.
- 8 MR. HACKER: But that's --
- JUSTICE KAGAN: And you are suggesting a
- 10 test for what -- what counts as material, which is
- 11 statistically significant, a test that the FDA itself
- 12 doesn't use when it thinks about what it should what it
- 13 should regulate.
- MR. HACKER: The problem is ex ante. You
- 15 have to -- you can't look at this through hindsight.
- 16 You have to look at it ex ante. When a company has a
- 17 handful of reports, it's absolutely true, nobody would
- 18 dispute, that some day in the future, with the
- 19 accumulation of more data, the FDA may take action based
- 20 on its own prophylactic public regulatory discretion.
- 21 But at the time, ex ante, no condition when it gets an
- 22 adverse event report can possibly know whether that's
- 23 enough information for the FDA to act. So the prospect
- 24 that the FDA may some day act on the basis of
- 25 additionally accumulated information would require

- 1 disclosure of all reports all the time, and that we
- 2 submit cannot be the standard.
- JUSTICE SCALIA: Mr. Hacker, suppose Good
- 4 Morning America made the same claim, categorically
- 5 saying that this drug caused this condition, but did so
- 6 simply on the basis of these adverse incidents, and they
- 7 didn't have Dr. Jafek's, or whatever his name is,
- 8 reports, but nonetheless Good Morning America comes out
- 9 on the basis of those incidents saying Zicam causes
- 10 whatever the condition is. Would that have to be
- 11 reported? And if not, why not?
- 12 MR. HACKER: I think what you would have to
- 13 be hypothesizing is evidence that the company, say a
- 14 week in advance, knew that Good Morning America was
- 15 going to come out and say that. Because once Good
- 16 Morning America says it, it's said it and the effect is
- 17 what it is. But even in the hypothetical, you'd have to
- 18 sort of unpack what you said. If Good Morning America
- 19 came out and said just what Matrixx knew at the time,
- there are a handful of adverse event reports, it's over
- 21 millions of product uses over a 4-year period, and no
- 22 indication that that's at all in any way different from
- 23 the incident rate in the general population, especially
- 24 among cold users, who of course are most likely to
- 25 experience anosmia, we don't know what would have

- 1 happened. But then you add the element that Good
- 2 Morning America then declares that Zicam causes anosmia
- 3 -- again, the hypothetical would have to be in advance
- 4 Matrixx is aware that the false claim is going to be
- 5 made.
- JUSTICE SCALIA: Fine.
- 7 MR. HACKER: Right, and I would say, first
- 8 of all, we have to be very careful, as I said before,
- 9 about a rule that requires a company to disclose false
- 10 facts. I would say, second, that a reasonable investor
- 11 doesn't want false information; a reasonable investor
- 12 wants accurate information. And a reasonable investor
- 13 would actually --
- 14 JUSTICE SCALIA: These are unreasonable
- 15 investors who are relying on some talking head on Good
- 16 Morning America who says that this is true, even though
- 17 it isn't true.
- MR. HACKER: That's the third point I would
- 19 make, Your Honor, is it's a different case, a
- 20 fundamentally different case, if you're talking about a
- 21 media --
- JUSTICE SCALIA: You've neither answered yes
- 23 or no. There's no basis for its being said on Good
- 24 Morning America, but unreasonable investors by the
- 25 thousands rely upon it.

- 1 MR. HACKER: And I think the answer is no.
- 2 I think the reason it's no, a qualified no, is because
- 3 --
- 4 JUSTICE SCALIA: No --
- 5 MR. HACKER: -- the law doesn't respond to
- 6 irrational, unpredictable, or unreasonable investors.
- 7 It responds to a reasonable investor who wants
- 8 accurate -- a reasonable investor is going to hold the
- 9 stock.
- 10 CHIEF JUSTICE ROBERTS: A reasonable
- 11 investor is going to worry about the fact that thousands
- 12 of unreasonable investors are going to dump their
- 13 Matrixx stock.
- 14 MR. HACKER: I absolutely understand that.
- 15 CHIEF JUSTICE ROBERTS: I mean, there's
- 16 nothing unreasonable about that. If it looks -- if
- 17 you're looking at Good Morning America, you say, my
- 18 gosh, everybody else is going to sell this; I'm going to
- 19 sell, too. And if it turns out you knew about it you
- 20 should have told me about it before.
- 21 MR. HACKER: The point I would make is,
- 22 first of all, a company ex ante can't know when that's
- 23 going to happen. So all the hypotheticals are
- 24 suggesting some way of knowing the company --
- 25 CHIEF JUSTICE ROBERTS: It may not know, but

- 1 it certainly can know. If you know this is a very false
- 2 report, but we know that, I don't know, the surgeon
- 3 general, somebody, is going to come out and announce it
- 4 and that will cause an effect --
- 5 MR. HACKER: That's why it's a meaningfully
- 6 different case. If the plaintiffs had plead in their
- 7 complaint that there's a memo inside the company, for
- 8 example, so this false fact is going to come out, and we
- 9 know it's going to cause a stock drop, that would be a
- 10 case involving the materiality of a media splash, a big
- 11 media event.
- 12 It can't be that there's a false claim out
- 13 there somewhere and the company becomes aware of the
- 14 false claim and then purely hypothetically it's possible
- 15 that somebody will make the false claim. It becomes
- 16 also possible that the media will pick up and not be
- 17 persuaded to ignore the false claim. That's the kind of
- 18 case we're talking about here.
- 19 JUSTICE KAGAN: In most cases we don't know
- 20 whether the claim is false or not. So let me give you a
- 21 hypothetical. There's a pharmaceutical company and it
- 22 comes out with its first and only product, it's 100
- 23 percent of the sales, and it's a new contact lens
- 24 solution. And it sells this product to many, many, many
- 25 hundreds of thousands of people. And most of them use

- 1 this product with no adverse effect whatsoever, but
- 2 there are ten cases where somebody uses this product and
- 3 they go blind. Three of those ten cases, the person had
- 4 to borrow a contact lens from a friend, only used it in
- 5 one eye, they go blind only in that one eye.
- 6 This is not statistically significant.
- 7 There is no way that anybody would tell that you these
- 8 ten cases are statistically significant. Would you stop
- 9 using that product and would a reasonable investor want
- 10 to know about those ten cases?
- 11 MR. HACKER: I would want to know more about
- 12 the number of uses and all that, but, no, there wouldn't
- 13 be a basis. A reasonable investor would want to know
- 14 all the facts and details that would establish a reason
- 15 to draw a --
- 16 JUSTICE KAGAN: There are a lot of contact
- 17 lens solutions in the world. So if I heard that, ten
- 18 people went blind, three used it in one eye, three went
- 19 blind in that eye, I'd stop using the product; and if I
- 20 were holding stock in that company, I would sell the
- 21 stock.
- MR. HACKER: The problem is, there has to be
- 23 some reliable basis. You may be describing facts that
- 24 would satisfy the Bradford Hill criteria, for example,
- 25 where you can draw a reliable inference that the product

- 1 is the cause. That's the key here. There has to be a
- 2 reliable basis for inferring causation.
- JUSTICE BREYER: This is the same kind of
- 4 question, but suppose I don't really know how drug
- 5 companies operate. I suspect, but I don't know, that
- 6 where you have a serious drug, people are hurt all the
- 7 time and they blame the drug. So probably drug
- 8 companies operate in an environment where they get all
- 9 kinds of complaints and some are valid, some are not;
- 10 who knows? People are frightened.
- MR. HACKER: Very much so.
- 12 JUSTICE BREYER: Okay. Now, I don't know
- 13 that. But you say at the beginning your client says:
- 14 Look, we get complaints all the time; you know, just put
- 15 up with it if you buy our stock. Now, I don't know to
- 16 what extent that's true. I don't know how that fits in.
- 17 I don't know whether their complaint is unusual or not
- 18 unusual or general.
- 19 Who is supposed to decide that? The judge
- 20 at the complaint stage? Or the judge after you get some
- 21 evidence on it? Or the jury? And the same is true of
- 22 scienter, after all, because the scienter -- and you
- 23 have to plead that with particularity. Okay. What's
- 24 your answer? What's -- I mean, Justice Kagan had an
- 25 interesting view of this, and it could be that she's

- 1 putting forward and others might have a different view.
- 2 Who is to decide this?
- 3 MR. HACKER: Well, ultimately it's a
- 4 question -- it would go all the way to the jury if the
- 5 plaintiffs were able to plead facts in the complaint
- 6 that entitled them to --
- JUSTICE BREYER: Well, we don't know. You
- 8 see, what they're saying is we have one respectable
- 9 doctor, studier, at, you know, in Colorado. He, by the
- 10 way has an abstract, which isn't in the complaint, which
- 11 says that they do allege that it's zinc that's the
- 12 problem, a free zinc ion. And they say we also have 25
- 13 people who were hurt and some burning sensations in
- 14 people that didn't rise to that level.
- 15 You know, I don't know. I don't know if
- 16 that's within the range of expectation of drug companies
- 17 as part of the normal course of business which investors
- 18 should know about, and I suspect a district judge
- 19 doesn't know, either. So how does it work where we in
- 20 fact just don't know whether this does or not arise
- above the background noise of a drug company?
- MR. HACKER: We think the answer is
- 23 statistical significance, just like the Second Circuit
- 24 said in Carter-Wallace --
- JUSTICE BREYER: Oh, no, it can't be. I'm

- 1 sorry, I don't mean to take a position yet. But, look,
- 2 Albert Einstein had the theory of relativity without any
- 3 empirical evidence, okay? So we could get the greatest
- 4 doctor in the world and he has dozens of theories, and
- 5 the theories are very sound and all that fits in here is
- 6 an allegation he now has learned that it's the free zinc
- 7 ion that counts. And that could be devastating to a
- 8 drug even though there isn't one person yet who has been
- 9 hurt. So I can't see how we can say this statistical
- 10 evidence always works or always doesn't work.
- 11 MR. HACKER: But, Your Honor, out of
- 12 millions of uses, if there was that problem, it wouldn't
- 13 be hard to plead a case that says there is a significant
- 14 problem --
- 15 JUSTICE BREYER: They did. They said --
- 16 they said the free zinc ion was -- that word on this was
- 17 told to your client by a person who knows a lot about
- 18 it, is apparently reputable, and was told to a person
- 19 who also knows a lot about it. I think they're saying
- 20 you ought to have been very nervous at that point. That
- 21 isn't just the usual background noise, okay? So I'm
- 22 back to my question, which is -- you can answer the
- 23 other one too if you like. But my question is: Who is
- 24 supposed to decide, how?
- MR. HACKER: Well, I think a plaintiff -- I

- 1 mean, I may just be repeating myself, but a plaintiff
- 2 has to plead the facts that would entitle them to relief
- 3 at the end of the day. So, I'm not saying a judge --
- 4 JUSTICE BREYER: I know, and we are back to
- 5 my question --
- 6 MR. HACKER: And --
- 7 JUSTICE BREYER: The question is, the facts
- 8 that are pleaded is -- I think it's assumed that this is
- 9 above the normal background noise; they certainly argue
- 10 that at length -- that there was this free zinc ion
- 11 conversation, that there are 25 people who were hurt,
- 12 and there is a lot of burning sensation going on, even
- though it doesn't rise to the level of people being
- 14 hurt, and that's supported by some of the zinc sulfate
- 15 studies in the fish --
- MR. HACKER: I think you need to --
- JUSTICE BREYER: -- okay? Now, they're
- 18 saying that's above the background noise and you say,
- 19 no, it isn't. Now, who decides and how do we decide?
- 20 Don't we have to go to a trial?
- 21 MR. HACKER: The answer is no, Your Honor,
- 22 because there is no basis on those pleaded facts for
- 23 inferring that there's actually a problem with the zinc
- 24 ion --
- 25 JUSTICE BREYER: I know. I know, but

1 over --2. MR. HACKER: -- but look at the allegations 3 4 JUSTICE BREYER: We're not saying -- you're saying if you are a scientist -- now we're back to 5 Justice Scalia's questions and the --6 7 MR. HACKER: But it matters what a scientist 8 would think because it's only then that anybody ex ante, again, remember --9 10 JUSTICE BREYER: Well, then what --11 MR. HACKER: -- has a basis for inferring 12 that there is a causal link which would be the problem, and the zinc -- to be very clear, to be very clear about 13 14 the zinc studies, the claim made on the telephone wasn't 15 even a claim of causation. It said, are you aware of 16 the zinc sulfate studies, which of course is a fundamentally different compound than --17 18 JUSTICE BREYER: No, because the sulfate --19 you see in the abstract, which they didn't put in the 20 complaint, that the problem that they saw arising out of the zinc sulfate studies was the free zinc ion. 21 MR. HACKER: No, the zinc sulfate studies 22 23 were -- totally irrelevant. What they cited for the free zinc ions were studies of catfish and turtles. And 24

nobody thinks, nobody thinks, that you can infer

25

- 1 anything from a study of catfish and turtles about their
- 2 smell sensation and human beings.
- JUSTICE BREYER: The trouble is, you know,
- 4 the truth is I don't know, and so I'm back to my
- 5 question.
- 6 MR. HACKER: Well, in terms of scienter,
- 7 under the securities law there has to be a plausible
- 8 basis --
- JUSTICE SOTOMAYOR: Counsel, you got cert
- 10 granted on a limited question, and the limited question
- 11 was whether in a complaint that alleges only adverse
- 12 reports can you prove materiality and scienter without
- 13 proving statistical importance. That's the question
- 14 presented.
- Justice Kagan started with the point that
- 16 the FDA doesn't require that. It requires just
- 17 reasonable evidence of a connection, not statistical.
- 18 Many of the amici here have done a wonderful job of
- 19 explaining why statistical importance can't be a measure
- 20 because it depends on the nature of the study at issue.
- 21 So given all of that -- and even in your
- 22 brief, in a footnote, you answered the question by
- 23 saying, no, we can't establish that rule as an absolute,
- 24 because there are additional factors that could prove
- 25 materiality and scienter. So you've already answered

- 1 the question presented.
- 2 Are we down to what Justice Scalia asked
- 3 you, which is: We got a no to the question: Are the
- 4 facts in this case enough? I don't know why we would
- 5 have granted cert on that, but you presented a different
- 6 question presented. Given the question presented, is
- 7 the answer no? And if not, why not?
- 8 MR. HACKER: Let me -- let me start with the
- 9 premise of the question presented. It's presented on
- 10 the facts as the case has been litigated today, trying
- 11 to rely on adverse event reports, which is
- 12 understandable. The plaintiffs don't want to have to
- 13 prove all of the other -- you wouldn't think they would
- 14 want to prove all the other facts.
- 15 JUSTICE SOTOMAYOR: Can I just interrupt a
- 16 second?
- MR. HACKER: Sure.
- 18 JUSTICE SOTOMAYOR: This wasn't an FDA-
- 19 approved drug.
- MR. HACKER: Right.
- JUSTICE SOTOMAYOR: So there weren't any
- 22 adverse reports in the legal sense of that word.
- MR. HACKER: In the FDA sense, that's true.
- 24 JUSTICE SOTOMAYOR: In the FDA sense. So
- 25 we're using a misnomer here to start with.

Τ	MR. HACKER: Well
2	JUSTICE SOTOMAYOR: Continue.
3	MR. HACKER: I would just say that adverse
4	event reports are not limited to what qualifies for the
5	FDA, certainly not by the way the case is
6	JUSTICE SCALIA: Of course, if I may
7	interject
8	MR. HACKER: litigated.
9	JUSTICE SCALIA: the FDA acts in the
10	public interest, doesn't it?
11	MR. HACKER: Yes.
12	JUSTICE SCALIA: And it doesn't make money
13	by withdrawing a drug from the market?
14	MR. HACKER: Yes.
15	JUSTICE SCALIA: As opposed to somebody who
16	sues, who makes money on the lawsuit?
17	MR. HACKER: That's true. But there's a
18	broader point about the FDA, which I think is underlying
19	your question and Justice Kagan's question, which is I
20	don't even think it's true that the FDA really requires
21	reasonable evidence. They have broad discretion and
22	should have broad discretion. Nobody is contesting
23	that. But the question is, again ex ante, before you
24	know what the FDA might do, before there's sufficient
25	evidence to justify the FDA to act. Remember, the FDA

- 1 didn't act for 5 years. The FDA didn't act on the basis
- 2 of what Matrixx was aware of at the time, and so, that
- 3 can't be the standard, the idea that the FDA may some
- 4 day act.
- 5 Statistical significance -- the question of
- 6 statistical significance is presented in this case to
- 7 the extent the courts below were arguing about and the
- 8 plaintiffs were arguing about whether or not the small
- 9 number of raw adverse event reports tell you anything
- 10 meaningful. The real standard -- the -- the case got
- 11 developed in the briefing here when the plaintiffs came
- 12 back and said, well, there's more to it and there can be
- 13 more to it, and that, of course, is true, but the
- 14 standard has to be reliability.
- 15 JUSTICE GINSBURG: You have said raw adverse
- 16 event reports. Am I not right that all of these reports
- 17 came from medical doctors, and in response to the very
- 18 first one, the company representative said, yeah, we've
- 19 been getting reports since 1999?
- MR. HACKER: Well, there's a reference -- I
- 21 mean, there's a -- 1999 was the first call from
- 22 Dr. Hirsch, who reported one patient. There is a
- 23 discussion with Dr. Linschoten about one other patient.
- 24 And there were some reports -- nobody is disputing that
- 25 there were some reports out there.

1	JUSTICE	GINSBURG:	Μy	question	is,	does	it

- 2 make a difference if these reports come from medical
- 3 experts in this particular field?
- 4 MR. HACKER: No, because a doctor doesn't
- 5 have unique expertise in diagnosing causation. A
- 6 doctor -- if you have a sore knee, a doctor is qualified
- 7 to tell you -- to diagnose the fact that your sore knee
- 8 is the product of bone cancer. A doctor is not
- 9 qualified to tell you why you got bone cancer, and
- 10 that's the problem that we have here.
- I would like to reserve the balance of my
- 12 time.
- 13 CHIEF JUSTICE ROBERTS: Thank you,
- 14 Mr. Hacker.
- 15 Mr. Frederick.
- 16 ORAL ARGUMENT OF DAVID C. FREDERICK
- 17 ON BEHALF OF THE RESPONDENTS
- 18 MR. FREDERICK: Thank you, Mr. Chief
- 19 Justice, and may it please the Court:
- In TSC and Basic, this Court reaffirms the
- 21 longstanding rule that materiality is judged based on
- 22 the total mix of information available to investors.
- 23 Matrixx initially sought a major change to this Court's
- 24 contextual approach to materiality by offering a bright
- 25 line standard of statistical significance.

- 1 In its reply brief, Matrixx offer -- offers
- 2 a rule that would apply only in the hypothetical
- 3 scenario where investors rely solely on numbers of
- 4 adverse event reports in pleading securities fraud.
- 5 This Court should reject both arguments in
- 6 this case. The broad theory has numerous legal and
- 7 policy flaws. First, the longstanding totality of the
- 8 circumstances test best comports with the varied reasons
- 9 why investors make investment decisions.
- 10 JUSTICE ALITO: Suppose the allegations of
- 11 materiality are based solely on adverse event reports?
- 12 Suppose that it's alleged that ten million people
- 13 during -- during -- during 1 year have taken a
- 14 particular drug and five people shortly after taking the
- 15 drug have developed certain -- have had an adverse --
- 16 have had -- experienced an adverse event. Is that
- 17 sufficient to go to a jury?
- MR. FREDERICK: Well, probably not
- 19 sufficient to go a jury absent a drop in the stock
- 20 price, absent evidence that there was a scientifically
- 21 plausible link, absent evidence that the product was
- 22 highly important to the company's long-term financial
- 23 prospects. All of these things go into the contextual
- 24 mix that investors would regard as important in making
- 25 an investment decision, and they all happen to be

- 1 present here. We --
- JUSTICE SCALIA: If it was the only product,
- 3 they sold that might be enough, five adverse reports out
- 4 of ten million? If -- if that's the only product they
- 5 make, you say, totality of the circumstances, that may
- 6 be enough?
- 7 MR. FREDERICK: Under the Basic test, Your
- 8 Honor, that very well might if the probability and the
- 9 magnitude of the harm -- if those five incidents were
- 10 deaths from a product that was easily substitutable,
- 11 that might be a relevant decision and information that
- 12 investors might want to take into account.
- 13 CHIEF JUSTICE ROBERTS: In response to
- 14 Justice Alito, I heard you say something about a
- 15 scientifically plausible link?
- MR. FREDERICK: Correct.
- 17 CHIEF JUSTICE ROBERTS: That seems to me to
- 18 be a rather significant concession. In other words,
- 19 you're saying it's not simply the fact that some psychic
- 20 would say something, that that is not sufficient, even
- 21 if that has an impact on the market price, that there
- 22 has to be some scientifically plausible link to the
- 23 report?
- MR. FREDERICK: I think this goes back to
- 25 Justice Kennedy's question as well, Mr. Chief Justice,

- 1 because there could very well be materiality. The
- 2 information might be important for investors, but it
- 3 could very well be that the people making the
- 4 disclosures don't have the requisite scienter because
- 5 there is an absence of any plausible relationship.
- The stock price might drop on news that
- 7 would not be regarded as news that the most highly
- 8 scientifically rational people would take into account.
- 9 JUSTICE KENNEDY: Well, I thought this might
- 10 come up. At some point do we look at scienter and then
- 11 go back from that to whether or not it's material, i.e.,
- 12 the argument would be the company knew that this would
- 13 affect the price, and that's why they didn't disclose it
- 14 and therefore that shows it's material? Or do we do
- 15 this with two isolated boxes: one, materiality, two,
- 16 scienter, and we don't mix the analyses.
- 17 MR. FREDERICK: They're both analytically
- 18 distinct and related, Justice Kennedy, and I don't have
- 19 a simple answer for you because many of the recorded
- 20 cases raise issues of both materiality and scienter.
- 21 What the Court has said in Basic is that the test is the
- 22 total mix of information and whether that -- under that
- 23 total mix the investor would find that information
- 24 important. In Tellabs the Court said that whether or
- 25 not the inferences of scienter could be deemed as

- 1 plausible as other inferences based on the mental state
- 2 of the people making the information.
- 3 So the Court has announced separate tests.
- 4 In a case like this there is a natural overlap, and in
- 5 fact the other side has litigated this case on the basis
- 6 that no one would have thought within the company, based
- 7 on the adverse event reports, that there was a basis for
- 8 thinking there was information.
- 9 We plead the other way by saying that when
- 10 you have three medical specialists in three distinct
- 11 periods where the last wants to bring findings to the
- 12 leading ear, nose and throat medical society suggesting
- 13 that, based on studies that go back as far back as the
- 14 1930s, there is a scientifically plausible link based on
- 15 the zinc ions, that's something that the company should
- 16 have taken seriously and disclosed to investors.
- JUSTICE KAGAN: But Mr. Frederick, suppose
- 18 you are the CEO of a pharmaceutical company with a new
- 19 drug, you've just put it back on the market, and you get
- 20 a report back, this drug has caused a death, right?
- 21 This is your first adverse effect report. Do you have
- 22 to disclose it?
- MR. FREDERICK: Well, I guess the first
- 24 thing I would say is if the drug has not been FDA
- 25 approved, that would be material information that

- 1 investors might want to know. If the drug had been FDA
- 2 approved and that report was then submitted to the FDA,
- 3 I think that there's a closer call depending on the, you
- 4 know, effect of the report that might be on the stock
- 5 price, because that's the only company product and the
- 6 other factors that we've mentioned in our brief.
- 7 I think the question of one event is
- 8 obviously much more difficult than where there are
- 9 multiple events submitted by doctors with a
- 10 scientifically plausible basis on a product that's 70
- 11 percent of the company's revenues.
- 12 JUSTICE ALITO: Now we're told that there
- 13 are hundreds of thousands of these; for a -- for a
- 14 typical drug there may be thousands of these adverse
- 15 event reports in -- in a year, and you're -- basically
- 16 you're saying all of those have to be disclosed?
- 17 MR. FREDERICK: Justice Alito, they already
- 18 are all disclosed.
- JUSTICE ALITO: Well they -- already. So
- 20 then why does the company have to make additional
- 21 disclosure?
- MR. FREDERICK: The --
- 23 JUSTICE ALITO: Analysts who follow the
- 24 stock price can easily look at the FDA web site and see
- 25 the adverse event reports that have been reported --

- 1 MR. FREDERICK: Right. 2 JUSTICE ALITO: -- and draw whatever conclusions seem to be warranted based on that. 3 4 MR. FREDERICK: That's why I think this presents the issue in a rather artificial way, because 5 the reports here were not the classic FDA-regulated б 7 adverse event reports. This was a homeopathic drug that 8 was put on the market without FDA approval, and there 9 were no requirements of reports until 2006 which was 10 after the -- at issue here. 11 JUSTICE BREYER: How would you write -look, I'm asking how do you write this, because what --12 13 where I think where the other side has a point, is if --14 with these -- this is a big class of these kinds of 15 things, you know, vitamins, all kinds of things like 16 that -- and if we say that they have to disclose too much, what will happen is people won't pay attention to 17 18 it, you know. 19 And if -- if you have, you know, 4,000 pages
- of small print saying everything that was ever reported,
- 21 what really happens in -- in such instances is the
- 22 public pays no attention, and they think -- and it will
- 23 hide things that are actually important.
- So how would you write some words --
- 25 assuming that you're right, that their test is wrong --

- 1 but how would you write some words that will put a
- 2 disclosure obligation such that it's not going to be
- 3 overkill and it is going to get incidents that rise
- 4 above the background noise, and those are the incidents
- 5 that are -- that would be significant for a reasonable
- 6 investor?
- 7 MR. FREDERICK: I would start with the
- 8 language in Basic which says the total mix of
- 9 information is what has long standing been the test for
- 10 materiality under this Court's cases. I would say that
- 11 where there is credible medical professionals describing
- 12 the harms based on credible scientific theories to back
- 13 up the link, a very serious health effect risk for
- 14 products with many substitutes, and the effect is on a
- 15 predominant product line, then the company ought to
- 16 disclose that information. I will not --
- 17 JUSTICE BREYER: Okay, I'll go back and read
- 18 what you've just said, and -- I will, because it will be
- 19 in the transcript, and -- and the -- I -- this case, you
- 20 are very good, your clients, and the lawyers at writing
- 21 complaints.
- MR. FREDERICK: Right.
- JUSTICE BREYER: All right? So they've
- 24 alleged in this complaint everything they can show, and
- 25 I -- I suspect -- and during the class period. And what

- 1 it doesn't say is that very helpful chart that you put
- 2 in the brief, in the pocket. It doesn't say they ever
- 3 showed that to the company. All it says is there was a
- 4 phone call and this individual from -- from Colorado
- 5 said something, which it doesn't specify, about zinc and
- 6 the -- and the number of deaths.
- 7 MR. FREDERICK: Well, in 1999, though,
- 8 Justice Breyer, Dr. Hirsch, and this is outlined at
- 9 paragraph 25 of the complaint, also said that intranasal
- 10 application of zinc could be problematic, and he
- 11 specifically asked about how much zinc is put in Zicam
- 12 precisely because of his awareness of prior studies
- 13 going all the way back to the polio period in which zinc
- 14 had created a problem of persistent anosmia. But our
- 15 submission here is that --
- 16 JUSTICE SOTOMAYOR: How was your -- that
- 17 long litany of factors you mentioned a few moments ago
- 18 about how a company will go about determining whether an
- 19 adverse event report is material or not or should be
- 20 disclosed or not, are you saying that companies don't
- 21 have to respond to a rational securities holders? Are
- you accepting your adversary's proposition that on some
- 23 level -- you said credible evidence -- that they don't
- 24 have to respond to things they judge are not credible?
- MR. FREDERICK: It really depends, Justice

- 1 Sotomayor, and I don't mean to be evasive, but if there
- 2 is a product, say, that has some link to satanic
- 3 influences, and there is some reason to think that a
- 4 large body of followers in an irrational way might
- 5 regard there to be satanic influences on the basis of a
- 6 particular product, a cautious, reasonably prudent
- 7 investor might want to know that on the basis of that
- 8 information that most of us would regard as irrational,
- 9 might affect the stock price.
- 10 CHIEF JUSTICE ROBERTS: So what protection
- is there at the summary judgment stage in response to
- 12 allegations? Because it doesn't have to be
- 13 scientifically valid; it can be completely irrational.
- 14 All you have to do is allege that, you know, if you had
- 15 told this the price would have gone down. If you had
- 16 disclosed this the price would have gone down, and the
- 17 response from the company is, well, but this is just
- 18 ridiculous. This is some quy in his garage who writes
- 19 this out on -- on a -- you know, a piece of paper in --
- in handwriting; and the response is going to be, well
- 21 let's let the jury sort it out.
- MR. FREDERICK: There are two answers, Mr.
- 23 Chief Justice. One is in Basic itself, the Court talked
- 24 about the actions of a reasonable investor, and this
- 25 Court and many courts have always looked at a reasonable

- 1 person's standard in making all sorts of these fine
- 2 judgments about the importance of particular
- 3 information. But the second answer is --
- 4 CHIEF JUSTICE ROBERTS: Well, you just told
- 5 me that it would be enough if somebody says that there's
- 6 a satanic, you know, impact on this, because a
- 7 reasonable investor would say there are enough crazy
- 8 people out there that this is going to affect the price.
- 9 MR. FREDERICK: What I said was if the
- 10 product was one that might be, you know, attractive in
- 11 some way to people who had that particular following. I
- 12 think you have to link up the product with the nature of
- 13 the complaint and the effect of the importance of the
- 14 information --
- 15 CHIEF JUSTICE ROBERTS: So it matters
- 16 whether -- I don't know what kind of product has
- 17 particular satanic susceptibility --
- 18 (Laughter.)
- 19 CHIEF JUSTICE ROBERTS: -- but I mean, are
- 20 you saying it matters if it's something that -- that
- 21 Satan's not going to be interested in? I don't
- 22 understand.
- 23 (Laughter.)
- MR. FREDERICK: You're --
- 25 CHIEF JUSTICE ROBERTS: I don't mean to be

- 1 facetious, but your way of distinguishing the satanic
- 2 product is that it depends on whether people who follow
- 3 satanic cults are going to be interested or not. I
- 4 mean --
- 5 MR. FREDERICK: Well, Your Honor, there are
- 6 people who follow those things, and they spend money and
- 7 they buy stocks, but my second point is that scienter --
- 8 scienter is the other way around this problem. Because
- 9 even though information --
- JUSTICE SCALIA: I don't know if scienter is
- 11 -- it seems to me ridiculous to -- to hold companies to
- 12 -- to irrational standards; and we did -- and we did say
- 13 in -- in Basic that it's viewed -- whether it would be
- 14 viewed by the reasonable investor. And -- and you are
- 15 saying well, the reasonable investor takes account of
- 16 the irrationality. I don't think that's what we meant
- 17 in -- in Basic.
- 18 MR. FREDERICK: Well, Justice Scalia, you
- 19 can certainly write as a prophylactic here that that
- 20 isn't part of -- the test. We certainly have here all
- 21 of the indicia of credible medical professionals on a
- 22 credible scientific theory on a product that was
- 23 important to the company's finances, and a very serious
- 24 side effect for a drug that had ready --
- 25 CHIEF JUSTICE ROBERTS: So that -- I'm just

- 1 trying to get your response to that. You just talked
- 2 again about credible scientists and all that, and you're
- 3 putting those other things to one side.
- 4 So even if you have your satanic problem,
- 5 that is not enough. And you can sit there and allege it
- 6 would cause a drop of 30 percent in the stock price, and
- 7 you should have let this know. Your answer is no, they
- 8 don't have to let -- they don't have to disclose this
- 9 because there is no scientific credible basis for the
- 10 link that's alleged?
- MR. FREDERICK: Now, I'm saying two things.
- 12 One is that there is a difference between scienter and
- 13 materiality. There is importance of information and an
- intent to deceive, and the questions are analytically
- 15 distinct. In your hypothetical, Mr. Chief Justice, I
- 16 think you merged them, and I would like to keep them
- 17 separate because as we -- as this case comes to the
- 18 Court, the issue is what is the standard for materiality
- 19 and whether or not statistical significance is the only
- 20 way to --
- 21 JUSTICE ALITO: Can I give you -- because
- 22 I'm having a little difficulty understanding the
- 23 boundaries of the argument you're making.
- Let me give 2 hypotheticals, and they both
- 25 involve companies that have one product, and this is

- 1 their one product. The first one was what I mentioned
- 2 before, and I wasn't -- I wasn't clear about your
- 3 answer. All that's alleged is that a very large number
- 4 of people took the drug and that three people, after
- 5 taking the drug, within a week developed a certain
- 6 syndrome. That's the first one. Is that enough for
- 7 materiality?
- 8 The second one is that a company receives a
- 9 telephone call: Hello, I'm a general practitioner from
- 10 wherever, and I treated a patient and the patient took
- 11 your medication and shortly after that developed this
- 12 syndrome, and I think there might be a connection. Is
- 13 that enough for materiality?
- MR. FREDERICK: On the second one, I would
- 15 say probably not. And I would say on the first one,
- 16 there's not enough information about the side effect and
- 17 what the drug is intended to solve.
- I mean, the probability magnitude test as
- 19 articulated by this Court goes to the probability of the
- 20 effect versus the magnitude that would be perceived by
- 21 investors, and those are important factors they go into.
- 22 So your hypothetical is very difficult to answer as you
- 23 have framed it.
- JUSTICE ALITO: All right. This drug, let's
- 25 say it's a drug to relieve the common cold and the

- 1 effect is loss of the sense of smell. Five million
- 2 people take it. Three people, after taking it, lose
- 3 their sense of smell. Is that enough for materiality by
- 4 itself?
- 5 MR. FREDERICK: It -- by itself, that could
- 6 be enough, and the reason we know that could be enough,
- 7 Justice Alito, is that when, you know, some score
- 8 additional were released and this information was
- 9 disclosed, the stock price went down by 23.8 percent.
- 10 JUSTICE GINSBURG: Your time is running out,
- 11 and there is one thing you emphasize in your brief, and
- 12 I haven't heard you say one word about it here. And
- 13 that is: You're saying this is not a case of a company
- 14 that remains silent. The company, in response to this,
- 15 issued press releases in which it said any suggestion of
- 16 a linkage is completely unfounded. Now, that's
- 17 something different from, there are X number of reports.
- 18 To what extent are you relying on the affirmative
- 19 statements that the company made?
- MR. FREDERICK: We're relying on those to
- 21 establish scienter, both at the beginning of the class
- 22 period when they forced Dr. Jafek, through their legal
- 23 threats, to take Zicam off his poster presentation, and
- 24 then later when they said that the reports of anosmia
- 25 were completely unfounded. And "misleading" was the

- 1 word that they used. "And misleading." And they
- 2 repeated that after the Good Morning America program
- 3 came on, only to say three weeks later, after empaneling
- 4 a scientific expert panel, that the information was
- 5 insufficient to make that determination. Our submission
- 6 is that that is enough.
- 7 JUSTICE SCALIA: Mr. Frederick, I'm -- I'm
- 8 not clear on why you can draw a distinction between
- 9 materiality and scienter for purposes of the issue
- 10 before us here.
- 11 If, indeed, satanic effect is enough for
- 12 materiality, you say, well, it may not be enough for
- 13 scienter. Why? I mean, if the company knows that
- 14 satanic effect is material, then the company has --
- 15 knowingly withholds it because it thinks satanic effect
- is irrational, why doesn't that company have scienter,
- 17 if it's material?
- 18 The scienter is withholding something that
- 19 is material that is known to be material, and once you
- 20 say that -- you know, that Satan is material, if the
- 21 company thinks Satan is involved here, it has to put it
- in its report, no?
- MR. FREDERICK: And it would depend on what
- 24 kind of stock effect occurred.
- 25 JUSTICE SCALIA: So there's no difference

1	between the materiality issue and the scienter issue.
2	MR. FREDERICK: Well
3	JUSTICE SCALIA: You can't push this problem
4	off onto the scienter side of the equation.
5	MR. FREDERICK: It depends it depends on
6	this Court's application of its known precedent, which
7	my colleague here has not even referenced in his opening
8	argument, Basic, which says you look at the total mix of
9	the information. And all of these things go into play.
10	JUSTICE BREYER: Okay. I get that. Can I
11	just ask you one question in response to just picking
12	up on the last, what about the need for a, quote,
13	"strong inference of scienter," end quote, and does this
14	complaint show more than a borderline situation where it
15	doesn't strongly infer that the person intended to
16	mislead the defendant? What about that argument?
17	MR. FREDERICK: Well, we believe, and they
18	haven't argued that this complaint is not sufficient
19	under the PSLRA, which set the heightened pleading
20	standard for scienter that this Court articulated and
21	construed in the Tellabs decision, so we believe that
22	scienter is adequately pleaded here based on
23	JUSTICE BREYER: Well, page 49 of their

rise to a strong inference of scienter.

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

24

25

1	MR. FREDERICK: What I'm saying is that
2	there is already a heightened pleading standard, Justice
3	Breyer. I was not I misunderstood your question to
4	say, is there some other heightened pleading standard
5	other than the one
6	JUSTICE BREYER: No, no, I mean I just
7	want to know why, if their inference on materiality is
8	enough to survive the background noise reply, is it
9	enough to show a strong inference that they did do this
10	intending to mislead, a strong inference of scienter?
11	MR. FREDERICK: The key aspects here are
12	their treatment of Jafek when Jafek was going to go
13	public with his scientifically linked claim of anosmia
14	from the Zicam, and then subsequently when they issued
15	press releases saying it would be completely unfounded
16	and misleading to assert any causal link. That is
17	sufficient to establish a strong inference of scienter.
18	CHIEF JUSTICE ROBERTS: Thank you, Mr.
19	Frederick.
20	Mr. Shah.
21	ORAL ARGUMENT OF PRATIK A. SHAH
22	ON BEHALF OF THE UNITED STATES, AS AMICUS CURIAE,
23	SUPPORTING THE RESPONDENTS
24	MR. SHAH: Mr. Chief Justice, and may it
25	nlease the Court:

1	For	35	years,	this	Court's	precedents	have

- 2 instructed that information is material for securities
- 3 fraud purposes if a reasonable investor would have
- 4 viewed it as having meaningfully altered the total mix
- of information. Under the terms of their question
- 6 presented, petitioners propose to depart from that
- 7 contextual inquiry in favor of a categorical rule that
- 8 deems information about an adverse drug effect
- 9 immaterial absent statistical significance.
- JUSTICE SCALIA: Mr. Shah, what do you think
- 11 about Satan?
- 12 MR. SHAH: Let me try to unpack the satanic
- 13 connection hypotheticals a little bit.
- Now, to be sure, if someone just called a
- 15 company and said, hey, I think you guys are affiliated
- 16 with satanic practices, surely a company would not have
- 17 to go and disclose that to all the investors. But this
- 18 is going to depend on what the actual reality is and
- 19 what the company's statements have been.
- Now, if the company has made a statement
- 21 that, look, consumer confidence in our products is at an
- 22 all-time high and we expect sales to double in the next
- 23 quarter, and yet they are aware that there -- a consumer
- 24 boycott is being planned by, let's say, 10 percent of
- 25 their consumer base premised on the irrational notion

- 1 that their company is tied to Satan, then certainly to
- 2 correct their affirmative representation that consumer
- 3 confidence is at an all-time high and that they expect
- 4 their sales to double, a reasonable investor would want
- 5 to know --
- 6 JUSTICE SCALIA: They haven't said that.
- 7 They haven't said that our sales are going to double.
- 8 They're just walking along at normal sales.
- 9 MR. SHAH: Right.
- 10 JUSTICE SCALIA: And they find out that
- 11 10 percent of nutty-nuttys out there are not going to
- 12 buy their stuff because of Satan. What about that?
- 13 MR. SHAH: Your Honor, in that hypothetical,
- 14 it depends on what affirmative statements the companies
- 15 have made. Under the securities law -- and this is an
- 16 important point that I don't think has come through yet.
- 17 Under the securities laws, there is no baseline duty to
- 18 disclose for a manufacturer or a company. A company
- 19 creates a duty to disclose once they have spoken. So
- 20 it's going to depend on what the company has said.
- Now, in your scenario, if a company has made
- 22 statements projecting their company's success into the
- 23 next quarter, for example, and they have a concrete
- 24 basis to know that, as your hypothetical submits,
- 25 10 percent of their computer -- consumer base is going

- 1 to leave the company's products, that is almost
- 2 certainly going to be material to an investor, and so
- 3 yes, they would have to disclose that we have reason to
- 4 believe, however ridiculous it is and untrue it is, that
- 5 10 percent of our consumer base has decided to boycott
- 6 our products. That's certainly reasonable.
- 7 CHIEF JUSTICE ROBERTS: You would have --
- 8 you just said they would have a duty to disclose?
- 9 MR. SHAH: Yes, sir.
- 10 CHIEF JUSTICE ROBERTS: I thought you
- 11 earlier just said there's no affirmative duty to
- 12 disclose; it only is based on what they say?
- 13 MR. SHAH: It's based on what they said.
- 14 So, for example, if the company had simply remained
- 15 silent and not said anything about its future sales, its
- 16 prospects, then under the securities laws there is no
- 17 duty to disclose. Basic and other cases have long made
- 18 clear that there has to be something to trigger a duty
- 19 to disclose. That is, under Rule 10b-5 it's only
- 20 statements that are rendered misleading by the omission
- 21 of a material fact that can trigger liability. If there
- is no projection about the company's future success,
- 23 then it wouldn't have to disclose in that situation.
- JUSTICE ALITO: What if the company makes
- 25 the kind of relatively common statements that were made

- 1 here, poised for growth in the upcoming season, very
- 2 strong momentum going into the season, extremely well
- 3 positioned for successful season?
- 4 MR. SHAH: Sure, Your Honor --
- 5 JUSTICE ALITO: That -- that triggers the
- 6 duty to disclose the satanic rumors?
- 7 MR. SHAH: In certain cases where there are
- 8 very generalized statements, for example, we think our
- 9 product will do well, that may close -- come close to
- 10 the line of puffery that is a non-actionable statement
- 11 that no reasonable investor would rely on. Petitioners
- 12 have never pressed that argument before this Court.
- 13 There is no dispute about whether the statements that
- 14 Matrixx made in this case are actionable, even though I
- 15 agree with you that some of them probably come close to
- 16 that puffery line.
- 17 Here, though, we don't just have those
- 18 statements about the company being well positioned for
- 19 future growth. There are additional statements, and
- 20 these were made to stock analysts that they expected a
- 21 50 percent increase in annual revenues, and, of course,
- 22 there are the much more affirmative statements that the
- 23 drug's safety had been well-established and that the
- 24 reports of anosmia were completely unfounded and
- 25 misleading. Those statements certainly crossed the

- 1 line. And as I said before, there hasn't been an
- 2 argument in this case as to whether those less specific
- 3 and arguably puffery type statements --
- 4 JUSTICE SCALIA: So the government's
- 5 position is that reports of adverse effects that have no
- 6 scientific basis, so long as they would affect
- 7 irrationally consumers, have to be disclosed, assuming
- 8 the company has said we're doing well, right?
- 9 MR. SHAH: Well, Your Honor, yes, I think it
- 10 would depend, again, on the statements the company
- 11 makes. If -- if --
- 12 JUSTICE SCALIA: Well, I mean, if Satan
- 13 comes in, surely lousy science comes in as well, no?
- MR. SHAH: Okay. So -- so, for example,
- 15 if -- if a company had been faced with potential adverse
- 16 effect and it had assembled its blue ribbon panel of
- 17 scientists, conclusively determined that there is no
- 18 causal connection between this purported adverse effect
- 19 and their drug, the question is, would they have to
- 20 disclose in that circumstance?
- 21 I think if the company had simply made
- 22 statements relating to the drug safety, we think our
- 23 drug is safe, there is no reason to believe that it
- 24 causes any adverse effects, then the answer is no,
- 25 because the reported adverse effect would not call into

- 1 question the accuracy of the company's statements
- 2 relating to the safety of the drug.
- If, however, the company had made specific
- 4 statements relating to consumer demand for its products
- 5 and it knew, notwithstanding the fact that there was no
- 6 causal connection, it knew or had good reason to believe
- 7 that a significant portion of its consumer base would
- 8 avoid the product, then, yes, a reasonable investor
- 9 would want to know that information, and under Basic the
- 10 company would have a duty to disclose that, even though
- 11 unfounded, these reports may lead a significant
- 12 percentage of our consumer base to leave the product.
- I think that falls squarely within the
- 14 definition of materiality, which is would a reasonable
- 15 investor want to have known that information?
- JUSTICE KAGAN: Mr. Shah, what deference do
- 17 you think that the SEC's understanding of materiality
- 18 it's entitled to and why?
- MR. SHAH: Well, Your Honor, this Court in
- 20 both TSC and Basic accorded what it called due deference
- 21 to the SEC's views on the application of the materiality
- 22 standard. I think it's certainly true -- and -- and
- 23 those, by the way, were both -- the -- the Court was
- 24 deferring to the views of the SEC as expressed in amicus
- 25 briefs to the Court just like in this case.

1	I think the SEC is due a significant
2	deference based on, one, its long-standing historical
3	practice in applying the materiality standard, which is
4	part of its own rule, Rule 10b-5, and its special
5	expertise in knowing what a reasonable investor would
6	want to know based upon its experience in this area.
7	So, I do think that to the extent there is
8	any ambiguity remaining in this case, the Court should
9	defer to the SEC's views. And back to Justice Breyer's
L O	questions about what should the Court write simply
L1	beyond reiterating the Basic standard, I think what the
L2	Court did in Basic was it not only articulated the
L3	general standard, but it laid out some factors. And in
L 4	laying out those factors, that's where the Court
L5	deferred to the SEC's brief. And it laid out factors
L6	that a reasonable investor might find relevant in that
L7	case it was the merger context.
L8	In here on page 28 of our brief, we lay out
L9	several factors that we think bear on the materiality
20	question in this particular context; that is, involving
21	adverse drug information.
22	CHIEF JUSTICE ROBERTS: Is there any way
23	that consideration of those factors would support a a
24	summary judgment in favor of the pharmaceutical
25	manufacturer, other than the fact of having an extremely

- 1 poor lawyer drafting a complaint? Anytime you have a
- 2 variety of factors like that --
- 3 MR. SHAH: Sure.
- 4 CHIEF JUSTICE ROBERTS: -- I think it's very
- 5 difficult for the judge to say anything other than
- 6 that's for the jury.
- 7 MR. SHAH: If you mean at the motion to
- 8 dismiss phase, Chief Justice?
- 9 CHIEF JUSTICE ROBERTS: Yeah.
- 10 MR. SHAH: I think there would be some
- 11 cases. And in fact, we know there are dozens of
- 12 12(b)(6) motions granted in securities fraud cases, and
- 13 let me lay out a few scenarios for you.
- One would be in the -- in the
- 15 scenario where the company has not made any actionable
- 16 statements. It has either -- statements predicated to
- 17 duty to disclose. It either has been made --
- 18 CHIEF JUSTICE ROBERTS: No, no, I'm talking
- 19 about the -- I'm talking about materiality. In other
- 20 words, based solely on -- in other words, you're saying
- 21 if they say anything related, it's going to be enough --
- MR. SHAH: Sure.
- 23 CHIEF JUSTICE ROBERTS: -- whether it's a
- 24 scientific basis or not.
- 25 MR. SHAH: Sure. Two responses to that.

- One, the PSLRA does have a safe harbor for companies
- 2 once they make forward-looking statements, that if they
- 3 add in meaningful cautionary language -- and this is in
- 4 the PSLRA itself, section 5(c)(1)(A), that if they add
- 5 in meaningful cautionary statements, then they cannot be
- 6 subject to liability. And I think there are a couple
- 7 other scenarios that would -- would trigger, for
- 8 example, if the product at issue is such a small
- 9 percentage of the company's income or expected growth
- 10 that no reasonable investor would care if it tanked,
- 11 then that might be a circumstance where a motion to
- 12 dismiss would be appropriate.
- 13 Thank you, Your Honor.
- 14 CHIEF JUSTICE ROBERTS: Thank you, counsel.
- Mr. Hacker, you have three minutes
- 16 remaining.
- 17 REBUTTAL ARGUMENT BY JONATHAN HACKER
- 18 ON BEHALF OF THE PETITIONERS
- 19 MR. HACKER: Thank you, Mr. Chief Justice.
- I would like to return to Justice Kennedy's
- 21 question about the role of scienter here, which I think
- 22 absolutely is critical as this Court emphasized recently
- 23 in the Merck v. Reynolds case.
- Mr. Frederick correctly, I think, conceded
- 25 that there has to be a scientifically plausible basis.

- 1 And what you're talking about here is the company's
- 2 knowledge of a scientifically plausible basis. And he
- 3 has to make that concession in this case because of what
- 4 is alleged to be the material omission.
- 5 The material omission is not knowledge of
- 6 dubious scientific -- medical claims, it's not that we
- 7 get one phone call from a doctor. The real material
- 8 omission is that the adverse event reports told Matrixx
- 9 that Zicam causes anosmia. That's ultimately the fact
- 10 that -- that Matrixx supposedly did not disclose. So
- 11 there has to be a basis for believing that -- there has
- 12 to be allegation in the complaint that sufficient to
- 13 establish Matrixx actually knew that Zicam causes
- 14 anosmia and yet willfully refused to tell investors that
- 15 fact, and there's nothing in the complaint like that.
- There's not -- you're not talking about a
- 17 case where there was a failure to disclose the doctor's
- 18 completely dubious untested claim. It's not a case --
- 19 it's not the Satan case where you're talking about a
- 20 media splash, a known fact that there is going to be a
- 21 major media splash and the company knows for a fact that
- 22 that splash is going to have the adverse effect on the
- 23 stock. There is not even a claim here --
- 24 JUSTICE SOTOMAYOR: Has that -- the
- 25 solicitor general's argument. He wasn't actually even

- 1 talking about causation. He was talking about a
- 2 statement you made about the company poised to double
- 3 its growth. And I think he was saying that on the basis
- 4 of what you had heard up until that time, you had to
- 5 have known that that statement was misleading, as was
- 6 the statement that this drug, that there was absolutely
- 7 no proof or connection of causation, which was your
- 8 scientific panel said you couldn't make that extreme
- 9 statement.
- 10 MR. HACKER: Well, two points, Your Honor.
- 11 First, if the claim was about, you know, the consumer
- 12 sales, you would need an allegation in the case that
- 13 consumer product sales were actually affected. There's
- 14 no allegation like that, and the truth is they weren't.
- 15 And so you're not talking about falsifying any prior
- 16 claim. There's not even an allegation that that
- 17 happened, Your Honor.
- 18 Second, with respect to the -- the
- 19 statement, as I was discussing with Justice Ginsburg in
- 20 the beginning part of the argument, the statement was
- 21 what the scientific panel was addressing primarily was
- 22 Jafek's claim that Zicam causes anosmia, and the company
- 23 said accurately that that is completely unfounded and
- 24 misleading because there is no scientific support for
- 25 it. You can't go out and claim that Zicam causes

Τ	anosmia unless you have a scientific basis for that and
2	the scientific panel was saying that isn't true.
3	So the question is whether you can draw an
4	inference of scienter from the fact that from what's
5	alleged here, and there is simply no basis for an
6	allegation, supportable allegation that the company knew
7	it causes anosmia and nevertheless refused to tell
8	investors that. Thank you.
9	CHIEF JUSTICE ROBERTS: Thank you, counsel.
LO	The case is submitted.
L1	(Whereupon, at 10:59 a.m., the case in the
L2	above-entitled matter was submitted.)
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