

SUPREME COURT OF THE UNITED STATES

IN THE SUPREME COURT OF THE UNITED STATES

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MERCK SHARP & DOHME CORP.,       )
        Petitioner,                 )
               v.                    ) No. 17-290
DORIS ALBRECHT, ET AL.,           )
        Respondents.                )
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3 MERCK SHARP & DOHME CORP.,)
4 Petitioner,)
5 v.) No. 17-290
6 DORIS ALBRECHT, ET AL.,)
7 Respondents.)
8 - - - - -

9
10 Washington, D.C.
11 Monday, January 7, 2019

12
13 The above-entitled matter came on for
14 oral argument before the Supreme Court of the
15 United States at 10:05 a.m.

16
17 APPEARANCES:
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19 of the Petitioner.
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22 the United States, as amicus curiae, supporting
23 the Petitioner.
24 DAVID C. FREDERICK, ESQ., Washington, D.C.; on behalf
25 of the Respondents.

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

2 (10:05 a.m.)

3 CHIEF JUSTICE ROBERTS: We'll hear
4 argument first this morning in Case 17-290,
5 Merck Sharp & Dohme versus Albrecht.

6 Mr. Dvoretzky.

7 ORAL ARGUMENT OF SHAY DVORETZKY

8 ON BEHALF OF THE PETITIONER

9 MR. DVORETZKY: Mr. Chief Justice, and
10 may it please the Court:

11 Respondents' express theory is that
12 the FDA, fully informed of the risk of atypical
13 femoral fractures, ignored that risk and its
14 own statutory and regulatory responsibilities
15 because it didn't like the way Merck phrased
16 its proposed warning.

17 That cannot be right. If a
18 manufacturer, as Merck did here, informs the
19 FDA of a possible risk and unsuccessfully asks
20 to revise its label in light of that risk, then
21 failure to warn claims based on that risk are
22 preempted as a matter of law.

23 That rule follows from the statutory
24 and regulatory framework governing the FDA's
25 conduct and from the presumption of regularity.

1 The presumption of regularity, of course,
2 assumes that federal agencies do their jobs
3 correctly.

4 The FDA's job in this case includes
5 protecting the public health by working with
6 manufacturers to revise drug labels when
7 necessary.

8 JUSTICE KAGAN: Mr. Dvoretzky, let me
9 give you a -- a -- a hypothetical because I
10 think we can -- could all agree that if you had
11 proposed a warning, let -- let me just say
12 major -- major fractures versus stress
13 fractures, and if you had proposed a warning
14 that dealt with major fractures and the FDA had
15 said no, we don't think that the literature
16 supports that, then there's nothing you can do,
17 and you should be immune from any suit.

18 I think that that's pretty clear. The
19 question is sort of, you know, did -- did you
20 propose a different kind of warning? So let me
21 give you a hypothetical.

22 Suppose that you manufacture a drug
23 and there's some evidence, whether it's enough,
24 hard to know, but there's some evidence that it
25 causes ovarian cancer, and you, the drug

1 manufacturer, proposes a warning to the FDA,
2 but instead of saying that the drug causes
3 ovarian cancer, you say it causes ovarian
4 cysts.

5 Now ovarian cysts are nothing that
6 anybody wants to have, but they're an
7 inconvenience. They're not ovarian cancer.
8 And the FDA says: No, we don't think that
9 that's the issue at all.

10 Does that mean that you're off the
11 hook now with respect to revising your label to
12 say that your product causes ovarian cancer?

13 MR. DVORETZKY: I don't think that
14 you're necessarily off the hook in that
15 situation because you haven't warned about the
16 relevant risk. But, in our case, there's no
17 question that Merck did warn about the relevant
18 risk.

19 The United States has told us that
20 that is how the FDA understood the warning.
21 The Third Circuit acknowledged that Merck
22 proposed to warn about atypical femoral
23 fractures. And you have to look at the context
24 in which this warning came about.

25 JUSTICE KAGAN: Okay. So that makes

1 it a much smaller case, right? That we can
2 agree on things on either side. We can agree
3 that if the FDA said to you, you don't have to
4 warn about major fractures, you are off the
5 hook. And on the other hand, we can agree if
6 the FDA rejected a warning that had nothing to
7 do with the thing that was really at risk,
8 you're not off the hook.

9 And then the whole question boils down
10 to what was your proposal, what was their
11 response, were you both talking about the same
12 things? In other words, were you both talking
13 about major risks? Or did the FDA look at your
14 proposal and say they're not talking about
15 major fractures; they're only talking about
16 stress fractures; and there's no reason to
17 think that stress fractures are a real risk and
18 no reason to put that in the label.

19 MR. DVORETZKY: I don't think that's
20 quite right, Justice Kagan, because you have to
21 look not only at the warning that was proposed
22 but also at the information that was in front
23 of the FDA about the risk.

24 And this is where, again, the FDA's
25 complete response letter has to be understood

1 in light of the FDA's statutory obligations.
2 Under 355(o)(4), the -- the Secretary is
3 obligated, if it believes that something should
4 be include in the label -- included in the
5 label of the warning, it shall promptly have a
6 back and forth with the manufacturer about
7 that.

8 JUSTICE KAGAN: Yeah, but, you see,
9 that's --

10 MR. DVORETZKY: And so --

11 JUSTICE KAGAN: -- that's the reason I
12 asked that question about the ovarian cancer
13 and the ovarian cysts, because I think you
14 could say on a -- on something like that, well,
15 look, it's true that our -- our proposal talked
16 about ovarian cysts, but we gave them all of
17 this data, and if they had really looked at all
18 of the data, they would have seen that it -- it
19 -- there's a real risk of -- of causing ovarian
20 cancer, and the fact that they didn't tell us
21 immediately to change our label means that
22 we're exempt from suit.

23 And I would think that that is not a
24 good understanding of the statute. The idea
25 that they have to look through all of your

1 data, even though you pinpoint an entirely
2 different risk, in order to find out what the
3 real risk is, and -- and that if they don't
4 manage to do that, you're exempt from suit,
5 that seems to me a very counterintuitive
6 reading of the statute and, indeed, not just
7 counterintuitive, it seems to conflict with the
8 -- the statutory provision, the rule of
9 construction that says that manufacturers have
10 primary responsibility over their labels.

11 MR. DVORETZKY: And for that reason, I
12 think that would be a different and more
13 difficult case than the one that we have here.
14 But, here, the complete response letter has to
15 be understood both in light of what it says but
16 also against the backdrop of the FDA's
17 regulatory duties and the back and forth that
18 the FDA --

19 JUSTICE SOTOMAYOR: Why? Please point
20 me to where in the complete response letter you
21 say that they were -- thought stress fractures
22 were the same as the atypical fractures. As
23 I'm reading the response letter, it's -- and --
24 and this is what they said to you: Your
25 justification for the proposed precaution

1 section language is inadequate -- inadequate
2 identification of "stress fractures." May not
3 be clearly related to the atypical -- forget
4 that word -- fractures that have been reported
5 in the literature. Discussion of the risk
6 factors for stress fractures is not warranted
7 and is not adequately supported by the
8 available literature.

9 Nowhere did they say that the atypical
10 fractures are not supported by the literature,
11 and nowhere did they say don't change it. The
12 rest of the letter tells you make changes and
13 we'll come back and talk more about this.

14 I look at their argument that the
15 conversation that your person had with them was
16 saying to them: We're thinking about this.
17 Now come back with something else, and maybe
18 we'll give you what you want; maybe we won't.
19 But I don't think, from the complete response
20 letter, if you're a textualist, that you can
21 look at it and say that they were saying no to
22 an atypical fracture warning. They were
23 certainly saying no to a stress warning.

24 So read me something in the complete
25 response letter, from that letter standing

1 alone, that you could draw your conclusion.

2 MR. DVORETZKY: So let me make two
3 points, Justice Sotomayor.

4 First, the complete response letter is
5 not a statute that can be read in the same way
6 as a textualist would read a statute. It has
7 to be understood against the backdrop of the
8 statutory and regulatory background.

9 But if we're going to focus just on
10 the response letter --

11 JUSTICE SOTOMAYOR: But the statutory
12 background basically says the only way that you
13 advise someone to change a label, as I
14 understand it, is if it's minor changes. This
15 would be a major change. And so, by regulatory
16 standards, they would have been acting
17 improperly if they had approved your language
18 with telling you make some cosmetic changes,
19 because they didn't think this was cosmetic.

20 MR. DVORETZKY: I respectfully
21 disagree and I think the United States
22 disagrees that that's how the FDA --

23 JUSTICE SOTOMAYOR: Doesn't mean
24 they're right. I read the statute. I don't
25 read them.

1 MR. DVORETZKY: Well, but looking --
2 looking at the statute, under 355(o)(4)(A), the
3 Secretary has a statutory obligation if it
4 believes a warning is warranted to work with
5 the manufacturer. And if it disagrees with the
6 proposed changes by the manufacturer, it's
7 obligated by the statute, it shall initiate
8 discussions to reach agreement.

9 So it can't just say no to a warning
10 if it disagrees with the phrasing of it. And,
11 in fact --

12 CHIEF JUSTICE ROBERTS: Well, where --
13 where is the -- in the back and forth, do you
14 have references to atypical stress -- atypical
15 fractures?

16 MR. DVORETZKY: So the term "atypical
17 femoral fracture" is what we're calling today
18 the risk that Respondents are concerned with.
19 That term did not even really begin to be
20 settled upon until a task force report that
21 came out later.

22 But what is clear both in the back and
23 forth and on the face of the complete response
24 letter is that Merck proposed to warn in both
25 the warning and precautions section and the

1 adverse reactions section about low-energy
2 fractures at the subtrochanteric region of the
3 femoral shaft. That's at Joint Appendix 511.

4 So the letter begins by noting that
5 that is what Merck proposed to warn about in
6 both sections of the label. So we know that's
7 what the FDA is thinking about.

8 We also know from the FDA's treatment
9 of the adverse reactions section of this -- of
10 the proposed warning, that when it wants to
11 revise a justified warning, it does so. So,
12 for the adverse reactions warning, the -- the
13 FDA proposed edits. But, for the warnings and
14 precautions section, it didn't.

15 We know the same thing from the FDA's
16 October 2010 interaction with Merck. At that
17 point, after the task force had completed this
18 study and when the FDA carried out its
19 obligations under 355(o)(4), by initiating a
20 process with Merck, Merck again proposed some
21 language that included stress fractures, and
22 the FDA redlined it.

23 So that's what the FDA does when it
24 thinks a warning is justified but it disagrees
25 with the manufacturer's proposed language. It

1 doesn't --

2 JUSTICE GORSUCH: Counsel -- I'm
3 sorry.

4 MR. DVORETZKY: No, please.

5 JUSTICE GORSUCH: I think the question
6 that we're all kind of struggling with here
7 seems to me to be this, or something along
8 these lines: Reading the statute your way, do
9 we create a moral hazard that encourages
10 manufacturers to supply the FDA with a lot of
11 information, overwhelming with data, but maybe
12 not the most artfully drafted and maybe
13 deliberately inartfully drafted warning that it
14 thinks is reasonably calculated to be refused,
15 so that it can avoid having to shoulder or bear
16 its own costs of -- of -- internalize its own
17 costs of negligence.

18 What -- what -- what comfort can you
19 give the Court that that's not the -- the
20 outcome of the statutory regime reading that
21 you're proposing?

22 MR. DVORETZKY: So one comfort that I
23 would give the Court is that the FDA itself,
24 which is -- would be in the position of -- of
25 having the problem that you're describing,

1 doesn't seem concerned about that problem.

2 But the other comfort that I would
3 give you is that we don't dispute that, under
4 the statute, both parties, both the FDA and the
5 manufacturer, have certain responsibilities.
6 We're not trying to absolve the manufacturer of
7 its responsibilities.

8 But, when you have before you an
9 impossibility preemption case where the FDA
10 rejected a proposed warning, the only way to
11 understand the meaning of that rejection and
12 what it means for impossibility is in light of
13 the FDA's part of its obligations.

14 The FDA does have some obligations.
15 And where it is provided with a warning that it
16 understood to be about the relevant risk and
17 rejects that, that necessarily establishes that
18 it was impossible for the manufacturer to
19 simultaneously comply with both what --

20 JUSTICE KAGAN: Well, but your -- the
21 way you answered that question, you said a
22 warning that it understood to be about the
23 relevant risk, and -- and that's really the
24 question.

25 The back and forth about the proposal

1 and about the FDA's reaction to it is whether
2 the FDA understood to be -- the warning to be
3 about major fractures, given that your proposal
4 talked, I think, in six different sentences
5 about stress fractures.

6 MR. DVORETZKY: So let me address the
7 stress fracture language because I think that
8 may be causing some of the -- some of the
9 confusion here.

10 The -- the risk that Merck warned
11 about was about these atypical -- I'm sorry,
12 about low-energy fractures at the
13 subtrochanteric region. At Joint Appendix 746,
14 Merck explained to the FDA how it was using the
15 term "stress fractures".

16 And it explained to the FDA that the
17 term "stress fractures" included the very same
18 kinds of things that Respondents are concerned
19 about, including insufficiency fractures and
20 complete fractures. Those are all kinds of
21 low-energy fractures, which is how Merck was
22 using this term.

23 And, moreover, the reason --

24 JUSTICE KAGAN: Well, but, if I
25 understand the -- if I understand the sort of

1 terminology, and maybe I don't, but
2 insufficiency stress fractures are, you know,
3 essentially, there's a world of things where
4 you can have a traumatic incident that leads to
5 a fracture and then you can have other
6 fractures that are not caused by trauma, right?

7 But the fractures that are not caused
8 by trauma can be small fractures, stress
9 fractures that take care of themselves with
10 rest and elevation, and large fractures, where
11 all of a sudden you're staring at a bone that's
12 popping out the wrong way.

13 So those are really different things.
14 They're both caused by something that's not
15 trauma, but one is an inconvenience and the
16 other is a serious injury.

17 MR. DVORETZKY: The serious injury,
18 the complete fracture, is something that begins
19 as what looks like a stress fracture and can
20 progress to completion. And so what Merck was
21 trying to do in this warning was to explain, if
22 somebody comes in complaining of the kind of
23 pain that might be consistent with a stress
24 fracture, doctors ought to figure out what's
25 causing that.

1 And if you rule out the typical causes
2 of stress fractures -- exercise, steroids,
3 alcohol use, things like that -- if you rule
4 those out, and they don't explain the symptoms
5 that the doctor's seeing, then maybe consider
6 stopping bisphosphonate use, because perhaps
7 there's a connection between bisphosphonate use
8 and what will eventually progress to the
9 completed fracture. That's --

10 JUSTICE KAVANAUGH: If -- if we read
11 your -- the letters to refer to stress
12 fractures as something -- and not atypical
13 fractures, could you still win this case?

14 MR. DVORETZKY: We could because,
15 regardless of how you read the letters, the FDA
16 has told us in this Court and has all -- and
17 all of the FDA's actions in connection with
18 this -- with this area show that it understood
19 what we were talking about.

20 And the one additional piece of
21 evidence that I would point to that I haven't
22 identified to this point, in March 2010, months
23 after the FDA issued its complete response
24 letter, it made a public safety announcement
25 saying that it was continuing to study this

1 issue of atypical femoral fractures. It still
2 was not convinced that the data supported a
3 warning, and that doctors should continue to
4 prescribe in accordance with the existing
5 label.

6 That shows, again, that FDA -- the FDA
7 was on top of this problem. It was studying
8 it. And it had not yet even months later
9 reached a belief that a warning was justified.

10 Given that, it was impossible for
11 Merck to provide one in accordance with the
12 purported requirements of state law.

13 JUSTICE GORSUCH: What do we do about
14 the fact that under the regulations Merck could
15 have filed a CBE at any time? Does that pose a
16 problem for you, at least after, say, the --
17 the March investigation starts?

18 MR. DVORETZKY: It -- it -- that
19 doesn't pose a problem for us. The standards
20 for evaluating a CBE are the same as the
21 standards for evaluating a PAS. It's
22 essentially the difference between asking
23 forgiveness and asking permission. Because we
24 know that the FDA rejected the PAS, we also
25 know that a CBE would not have been authorized

1 either, and, again, that's what establishes
2 impossibility preemption.

3 JUSTICE GORSUCH: Perhaps I'll spot
4 you that with respect to -- for purposes of
5 this question before the March 2010 letter, but
6 what about after that? Once it starts
7 launching an investigation into the product,
8 the task force period, what do we do about that
9 period?

10 MR. DVORETZKY: Well, I think the
11 point, though, is that in March 2010, what the
12 FDA said is that it was waiting on the task
13 force report. Nothing had yet changed. It
14 just said that it was studying the information.

15 When the task force report came out,
16 that's when the FDA acted and said now we are
17 -- now we believe that a warning is justified,
18 and it initiated its 355(o)(4) process. If
19 that's what the FDA -- if the FDA had thought
20 that a warning were justified earlier, that's
21 what it would have done. It would not have
22 issued this complete response letter.

23 If I may reserve the remainder of my
24 time.

25 CHIEF JUSTICE ROBERTS: Thank you,

1 counsel.

2 Mr. Stewart.

3 ORAL ARGUMENT OF MALCOLM L. STEWART

4 FOR THE UNITED STATES, AS AMICUS CURIAE,

5 SUPPORTING THE PETITIONER

6 MR. STEWART: Mr. Chief Justice, and

7 may it please the Court:

8 I'd like to begin by addressing an
9 issue that both Justice Kagan and Justice
10 Gorsuch have touched on, and I think it's
11 important to distinguish between two potential
12 types of confusion.

13 The first is that, in October of 2010,
14 when the FDA ultimately decided that an
15 addition to the warnings and precautions
16 section of these labels was warranted, it
17 rejected Merck's proposal that the warning
18 include repeated uses of the term "stress
19 fracture".

20 And FDA did express at that time the
21 concern that practitioners, for whom that term
22 usually connoted a relatively minor event,
23 might read it as understating the seriousness
24 of the potential health risk of Fosamax.

25 That potential type of confusion needs

1 to be distinguished from the question, was FDA
2 confused by Merck's submission as a whole? And
3 there's no reason to think that that was so.

4 At page 670 of the Joint Appendix,
5 Merck kind of, in the introductory section of
6 its proposal, summarizes what it's -- the
7 warning that it's proposing to add, and it says
8 at the very top of the page: Merck is
9 proposing to add language to both the
10 precaution and adverse reaction post-marketing
11 experience section of the label to describe
12 low-energy fractures that have been reported,
13 of which some have been stress insufficiency at
14 the subtrochanteric region of the femoral
15 shaft. So --

16 CHIEF JUSTICE ROBERTS: I'm sorry.
17 What page is that again?

18 MR. STEWART: Page 670 of the Joint
19 Appendix.

20 CHIEF JUSTICE ROBERTS: Thank you.

21 MR. STEWART: And so Merck was making
22 clear that the language it was proposing to add
23 both to the warnings and precaution section and
24 the adverse reactions section proposed to
25 address the same risk.

1 And, indeed, the language that it
2 proposed to add to the adverse reactions
3 section included a cross-reference to the
4 proposed warnings and precaution section,
5 again, reinforcing this.

6 The second thing I'd like to point out
7 in that regard is what my colleague was
8 referring to as the -- Merck's own explanation
9 for its use of the term "stress fracture".
10 Merck explained at page 746 of the Joint
11 Appendix in its proposal that it was using the
12 term as an umbrella term to refer to fractures
13 that could be partial or complete. The
14 distinguishing event was that they occur
15 without external trauma.

16 And so it's not a matter of something
17 being a serious fracture or a stress fracture.
18 The term "stress fracture" encompasses both
19 serious and relatively minor fractures. Again,
20 FDA's concern ultimately was that practitioners
21 who were used to seeing the term in connection
22 with minor events might misconstrue it.

23 But FDA understood it to refer more
24 generally to any fracture that was caused
25 without external trauma.

1 JUSTICE KAGAN: But how are we to
2 understand, Mr. Stewart, like what FDA
3 understands at any given moment? In other
4 words, what are we to look to when we decide
5 whether it's impossible for Merck to change its
6 label?

7 Because one easy way of thinking about
8 whether it's impossible for Merck to change its
9 label is to say: Did the FDA tell Merck that
10 it couldn't change its label in the relevant
11 way? If the FDA told Merck that, then it's
12 impossible.

13 But, if the FDA didn't tell Merck
14 that, whatever is in the FDA's head, if the FDA
15 didn't tell Merck that, then it's not
16 impossible for Merck to change its label, and
17 it has responsibility over its label, and to
18 the extent that it thinks that the literature
19 supports a change, it should change its label.

20 MR. STEWART: Well, let me say two or
21 three things about that. The first is you look
22 first and foremost to the letter itself, and it
23 would obviously have been better if the letter
24 had stated without ambiguity the reason we are
25 rejecting your proposed addition to the

1 warnings and precaution section is that we
2 don't think there is sufficient evidence of
3 causation to warrant inclusion of this health
4 risk in this particular portion of the label.

5 That would have been better. Given
6 that the letter that --

7 JUSTICE KAGAN: Right. That would
8 have been better, and it would have been
9 enough, right? We wouldn't -- we wouldn't be
10 here?

11 MR. STEWART: Exactly.

12 JUSTICE KAGAN: Or maybe we would, but
13 it would be an easy case, Merck would win?

14 MR. STEWART: Right. But, failing
15 that, failing an unambiguous letter, the Court
16 should construe the letter in light of Merck's
17 submission, in light of the surrounding
18 statutory and regulatory scheme, and in light
19 of FDA's subsequent --

20 JUSTICE SOTOMAYOR: Why?

21 MR. STEWART: -- subsequent actions.

22 JUSTICE SOTOMAYOR: Why? Merck is a
23 manufacturer of a drug. It has a tort duty to
24 ensure that its drugs are either safe or that
25 adequate warnings are given when it's not.

1 The Act does not take away that
2 responsibility. It does say that you have to
3 get approval from the FDA. But, if there's any
4 ambiguity, given that we're already creating
5 something that doesn't exist, impossibility
6 preemption, why shouldn't we take it at its --
7 at its face?

8 MR. STEWART: Well, for --

9 JUSTICE SOTOMAYOR: Until the FDA says
10 no, if you're a manufacturer who understands
11 there's a serious risk to a drug, shouldn't you
12 continue to try everything possible, including
13 making the corrections that you were told to
14 make, including doing what the task force did,
15 telling the FDA you're wrong?

16 Instead, what Merck did was say, I'm
17 absolved, I don't have to make the changes, I
18 don't have to talk to them anymore, I just have
19 to let them -- "them" being the FDA -- figure
20 out what to do.

21 Seems to be sort of turning
22 responsibility on its head.

23 MR. STEWART: Well, as you say, an
24 important feature of the statutory and
25 regulatory scheme is that, while the

1 manufacturer has responsibility for its label,
2 it can make changes only with FDA's approval.

3 JUSTICE SOTOMAYOR: Not true. It
4 could go the other route and make the change
5 itself and wait for the FDA to tell it it's
6 wrong.

7 MR. STEWART: That's true. But the --
8 the reason that FDA sometimes disapproves
9 proposed additions to warnings and precautions
10 or to other aspects of the label is not simply
11 that it regards the warnings as unnecessary.
12 FDA has expressed a concern about the potential
13 ill effects of over-warning; that is, if a
14 label contains information about every possible
15 health risk or every bad thing that has ever
16 happened to a person who used the drug, people
17 may be deterred from using a drug that would
18 actually be useful.

19 The really important warnings tend to
20 get drowned out. So --

21 JUSTICE SOTOMAYOR: So what happens
22 here to the incentive for manufacturers to
23 continue working expeditiously with the FDA to
24 effect changes when they're necessary?

25 MR. STEWART: Well, our -- our point

1 is that if the better reading of the letter, if
2 the better understanding of FDA's intent is
3 that it rejected the proposed addition because
4 it felt that the medical evidence wasn't there,
5 then for -- any preemption regime that would
6 create an incentive for Merck nevertheless to
7 add the warning through the CBE process and
8 wait for FDA to disapprove it would, in our
9 view, be counterproductive. It would create
10 the incentive for the type of over-warning that
11 FDA would like to discourage.

12 JUSTICE KAGAN: But if I --

13 JUSTICE ALITO: So what would happen
14 if -- if the FDA had said in response -- in the
15 complete response letter the medical evidence
16 is insufficient and then Merck turned around
17 within a short period of time and filed a -- a
18 CBE relating to the same thing? What would the
19 FDA have done?

20 MR. STEWART: I think it would surely
21 have disapproved it. And it would have been
22 inappropriate for Merck to proceed in that way
23 because the CBE process is supposed to be
24 invoked only when there is new evidence that
25 the FDA hasn't previously considered.

1 And if the FDA had said, in response
2 to the PAS application, we don't think the
3 medical evidence is there, then, unless some
4 substantial body of new medical evidence had
5 emerged during the interim, it would have been
6 inappropriate for Merck to use the CBE route
7 and it would be inevitable that FDA would
8 disapprove it.

9 JUSTICE KAGAN: I -- I take it --

10 JUSTICE SOTOMAYOR: Could --

11 JUSTICE KAGAN: -- Mr. Stewart, you're
12 saying two things. There are sort of two
13 points on a spectrum that you're pretty clear
14 about. One is, if FDA had told them, we just
15 don't think -- we understand that this proposal
16 is about major risks and we don't think that
17 there's enough evidence in the literature to
18 support that, that's -- that's easy, Merck
19 doesn't change its label, and there can't be
20 suit against Merck.

21 On the other hand, suppose that the
22 FDA -- and I -- I -- I understood this to be
23 your point -- suppose that the FDA had said,
24 you know, what's the -- the real problem with
25 your label is that you're talking about stress

1 fractures, and we think that the issue is these
2 major fractures, and that's why we're rejecting
3 it, and we're going to continue to be
4 considering the possibility of major fractures.

5 If the FDA had said that clearly,
6 Merck is not off the hook. Would you agree
7 with that?

8 MR. STEWART: I -- I would agree with
9 that with this caveat: That you would expect
10 the -- the letter -- given that the
11 documentation in Merck's submission included a
12 lot of information about the more serious type
13 of fracture, even if FDA was concerned about
14 the wording of the label, you would expect it
15 to express a view one way or the other as to
16 whether there was sufficient evidence of
17 causation.

18 JUSTICE KAGAN: It -- it doesn't know
19 yet, let's assume. So this is something that
20 it just doesn't know yet. And -- and it's
21 rejecting the letter for another reason.

22 Now you might expect that FDA would
23 continue to work with Merck about the major
24 fractures. You might expect a lot of things.
25 But the only thing that the FDA has told Merck

1 is we don't like this label that you've done
2 about stress fractures because we really think
3 stress fractures are not a problem.

4 MR. STEWART: I guess, if FDA had said
5 that unambiguously, it wouldn't trigger
6 impossibility, but it seems very unlikely and
7 really inconsistent with the statutory and
8 regulatory scheme to suppose that FDA would do
9 that, that it would receive a submission about
10 the risks of these more serious fractures and
11 yet would make no determination, even if -- in
12 its own mind as to whether that risk was
13 sufficiently severe, whether the evidence of
14 causation was sufficient to warrant an
15 additional warning.

16 JUSTICE KAGAN: Wait, I guess you're
17 changing my -- my -- you know, I meant this to
18 be a hypothetical, where you could assume a
19 hypothetical on both sides, right, where the
20 language was sufficiently clear of what FDA was
21 doing, that it either would or wouldn't take
22 Merck off the hook.

23 My real question for you is suppose
24 we're not at either one of those worlds.
25 Suppose we have an ambiguous letter. Who

1 should decide how to construe it?

2 MR. STEWART: I think the Court
3 ultimately should construe it but should
4 construe it in light of the statutory and
5 regulatory scheme, which would have compelled
6 FDA to initiate the process for changing the
7 label if it had determined that the evidence of
8 causation was sufficient to support an addition
9 of some warning to the warnings and precaution
10 section.

11 CHIEF JUSTICE ROBERTS: Thank you,
12 counsel.

13 Mr. Frederick.

14 ORAL ARGUMENT OF DAVID C. FREDERICK
15 ON BEHALF OF THE RESPONDENTS

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

18 Our position is that brand-name drug
19 makers are responsible at all times for keeping
20 their labels up to date. If the FDA rejects an
21 inadequate warning, or is uncertain about
22 whether and how to mandate a proper warning,
23 those federal decisions do not make it
24 impossible for Merck to comply with state law
25 duties to market safe drugs.

1 I'd like to start, if I could, with
2 Section 355(o)(4)(I), which is set forth in the
3 addendum to the red brief on page 8. That
4 provision explains why it is not impossible for
5 Merck to provide an adequate warning of
6 atypical femoral fractures prior to 2010 when
7 the FDA mandated a label change.

8 It's the manufacturer's responsibility
9 to maintain its label. So, Mr. Chief Justice,
10 in answer to your question about the back and
11 forth, all that demonstrates is that, at best,
12 FDA was uncertain about exactly what Merck was
13 proposing. But this statutory provision, which
14 is barely discussed at all on the other side's
15 written presentations in this case, makes it
16 clear that even when FDA got the power in 2007
17 for the first time in 60 years to mandate a
18 proper warning, the manufacturer, nonetheless,
19 is always responsible for keeping its label up
20 to date.

21 JUSTICE ALITO: Well, is it your
22 argument now that -- that Merck is -- Merck
23 became liable at some point after the issuance
24 of the complete response letter or on the day
25 after the issuance of the complete response

1 letter?

2 MR. FREDERICK: Our position, Your
3 Honor, is that the complete response letter in
4 a sense doesn't affect the underlying duties at
5 all because the -- the warning that was
6 proposed was an inadequate warning.

7 JUSTICE ALITO: What if -- but what if
8 the -- the FDA had said the wording of your --
9 of your warning is bad because this term
10 "stress fracture" is misleading, but beyond
11 that, the data does not support any warning
12 relating to low-energy femoral fractures?

13 MR. FREDERICK: I think it's important
14 to keep in mind what the regulatory duty of the
15 agency's --

16 JUSTICE ALITO: Well, what would --

17 MR. FREDERICK: The answer to that is
18 that it -- that likely points stronger in the
19 direction of preemption, but please look at
20 Section 314.110(a)(1) of the regulations
21 because that regulation tells the FDA in its
22 complete response letter you have to give a
23 full answer, a full justification because
24 that's part of the back and forth, the give and
25 take with the manufacturer.

1 And so, Justice Gorsuch, to your
2 question about the moral hazard, it's not just
3 if the manufacturer deliberately misleads the
4 FDA by putting in. It's also if -- if the
5 company is negligent and doesn't fully
6 understand itself.

7 I would ask you to look at the amicus
8 brief by Dr. Lane in this case. Dr. Lane was a
9 consultant for Merck in 2008 prior to Merck
10 submitting its PAS. What Dr. Lane says is that
11 surely by that time Merck would have had enough
12 information to have prepared an adequate
13 warning about these atypical femoral fractures.

14 JUSTICE GORSUCH: Well, Mr. Frederick,
15 let -- let's say I buy at least part of what
16 you're selling, for purposes of this question,
17 that the complete response letter and, what is
18 it, 355(o)(4) --

19 MR. FREDERICK: (I).

20 JUSTICE GORSUCH: -- doesn't -- thank
21 you -- doesn't completely answer our question.

22 We have, though, the March 2010 safety
23 statement from the FDA which pretty clearly
24 says that they do not think that there is
25 science enough to support a causal link between

1 the drug and atypical femoral fractures. So
2 whatever was missing in the complete response
3 letter from the FDA seems to come in March of
4 2010.

5 Why shouldn't we read the complete
6 response letter in light of the March 2010
7 safety --

8 MR. FREDERICK: Again, we're getting
9 into the agency musings of the type that
10 Justice Thomas very eloquently wrote about in
11 Wyeth versus Levine, which is it is not
12 impossible for the manufacturer to have done
13 the right thing. What Dr. Lane says --

14 JUSTICE GORSUCH: Well, you and I will
15 not dispute the elegance of Justice Thomas's
16 opinion in Wyeth.

17 (Laughter.)

18 JUSTICE GORSUCH: But I'm not sure
19 that helps me very much.

20 (Laughter.)

21 JUSTICE GORSUCH: And -- and in all
22 seriousness, if -- if there's some ambiguity
23 about the warning letter, about the complete
24 response letter, isn't that resolved by the
25 FDA's own statement against interest, perhaps,

1 months later, why doesn't that tell us exactly
2 what it was up to?

3 MR. FREDERICK: Because the standard
4 is lower. And if you look at that press
5 release in March of 2010, when the FDA uses the
6 phrase "causal connection", that's not what the
7 regulatory standard is. We set out the
8 regulatory standard on page 6 of our brief.
9 And that is a much lower one.

10 When it's for the precaution letter,
11 it's to provide reasonable evidence of a causal
12 relationship or causal association. Reasonable
13 evidence is something that Dr. Lane knew in
14 twenty -- 2008, and was urging Merck to provide
15 a better explanation.

16 And that's why on page 17 of
17 Dr. Lane's amicus brief here he says what FDA
18 needed was "a medically accurate education."

19 JUSTICE GORSUCH: Well, and that's why
20 it set up the task force at the same time to go
21 study the issue, and it said up to that point
22 we don't have enough, but we're going to go
23 study it.

24 MR. FREDERICK: And --

25 JUSTICE GORSUCH: And so why isn't

1 that -- tell us everything we need to know
2 about what its complete response letter was
3 about, as a matter of law?

4 MR. FREDERICK: Because, Justice --
5 Justice -- Justice Gorsuch, that's the whole
6 point of impossibility preemption. Are we
7 going to let Dr. Monroe, who is five layers
8 down from the only Presidentially-appointed
9 person at the FDA, write a letter that
10 displaces huge swaths of state law?

11 Now what -- what the SG is arguing
12 here is that we should interpret -- the better
13 reading of this, the -- the -- the back and
14 forth, the full record should inform the
15 meaning of this letter.

16 But impossibility preemption, as Wyeth
17 versus Levine held, is a "demanding defense."

18 JUSTICE ALITO: Well, that's not
19 really -- I mean, are you really serious about
20 that argument? What would be preemptive is not
21 the letter. What would be preemptive is what
22 FDA would do. And that -- that's the question.

23 The only argument relating to the
24 safety -- the safety announcement is that it
25 informs, it helps to tell us what FDA meant

1 when it said no, you cannot add a warning to
2 this label.

3 MR. FREDERICK: Justice Alito, we know
4 the answer when Merck proposes an inadequate
5 warning. That was rejected.

6 We don't know the answer to the
7 question that Wyeth versus Levine poses, which
8 is what would have happened had Merck proposed
9 an adequate warning.

10 JUSTICE BREYER: Why don't we? I -- I
11 think that was Justice Gorsuch's --

12 MR. FREDERICK: And the reason why we
13 don't, and, again, I'm going to go back to
14 Dr. Lane, we have nothing in this about the
15 duration of --

16 JUSTICE BREYER: What page, by the
17 way, if you happen to have it in your head,
18 what page is -- not that, but the response
19 letter?

20 MR. FREDERICK: The response letter is
21 at page 511 --

22 JUSTICE BREYER: Well done, well done.

23 MR. FREDERICK: -- of the Joint
24 Appendix, 511 to 512.

25 JUSTICE BREYER: Thank you very much.

1 Okay. The other question, technical, is, is a
2 -- what is it called -- the atypical femur
3 fracture, is that a subset of stress fractures?

4 MR. FREDERICK: What Dr. Lane explains
5 is that an atypical femoral fracture may have
6 an origination as a stress fracture, but it
7 sort of goes off in a completely different
8 direction.

9 JUSTICE BREYER: That's all right.
10 But okay. So somebody in stress fractures,
11 they use that word, they might mean atypical
12 femur fracture plus others. It's too broad, in
13 other words, it's too broad. Okay. Got that.
14 That's helpful. Now, when --

15 JUSTICE KAGAN: Well, it's also too
16 narrow.

17 JUSTICE BREYER: A stress fracture, I
18 thought, from what you just said, that those
19 words used in Merck's application are too broad
20 because it is a subset of those. Now which is
21 it?

22 MR. FREDERICK: It's inaccurate. It's
23 too broad --

24 JUSTICE BREYER: Well, but is it --

25 MR. FREDERICK: -- and too narrow.

1 That's the problem. So -- so what -- what --

2 JUSTICE BREYER: That's very, very
3 diplomatic.

4 (Laughter.)

5 JUSTICE BREYER: But this is my
6 actual -- where I -- where I'm leading.

7 MR. FREDERICK: No --

8 JUSTICE BREYER: I'm leading to this,
9 that, when you talk about the standard, drugs
10 are important to people. They cure millions,
11 or thousands anyway, of people who need to be
12 cured or helped.

13 Now, when you put on, and at the same
14 time there will be a smaller subset that can be
15 hurt, so our solution to that is labels.

16 Now, when you say displacing state law
17 or something, you're talking like a lawyer,
18 which is what you're supposed to do, but what
19 worries me is, if you go too far in allowing
20 the tort jury to find mislabeling by not
21 including things, you are hurting the vast
22 majority of -- of women here or -- or whatever
23 who can benefit from this medicine.

24 On the other hand, if you don't go far
25 enough, you will hurt that minority. Now

1 that's the general framework in which I'm
2 trying to figure out the answer to the
3 question. And that's why Justice Gorsuch's
4 question was -- was quite relevant.

5 All the earmarks here are that Merck
6 took this as a letter saying we're not certain
7 enough this is really going to hurt people and
8 we don't want you to put it on.

9 Now, obviously, somebody must have
10 picked up the phone when they got that letter
11 and they must have phoned somebody in FDA and
12 say: Do you really mean that? What do you
13 mean? Because I can change those words,
14 "stress fracture," in two seconds. Or do you
15 mean you don't know enough about it?

16 Now the appointment of the later task
17 force suggests that they felt they didn't know
18 enough about it, and, therefore, Merck couldn't
19 have done it.

20 Now that's -- that's -- I'm looking
21 for your answer. I put out a pretty abstract
22 and --

23 MR. FREDERICK: Yes.

24 JUSTICE BREYER: -- somewhat specific
25 but more abstract question. I would like you

1 to react.

2 MR. FREDERICK: Let's -- let's not
3 look at what the lawyers knew. Let's look at
4 what the scientists knew. Merck's
5 scientists -- and this is on page 515 of the
6 Joint Appendix -- they knew exactly what the
7 FDA was rejecting.

8 They said in their internal back and
9 forth the FDA doesn't like our "stress
10 fracture" wording, okay? Those scientists had
11 been interacting with Dr. Lane, who a year
12 earlier had said: These are a special type of
13 fracture which don't exist in the general
14 population.

15 Ninety plus percent of all people who
16 get an atypical femoral fracture are on a
17 bisphosphonate.

18 CHIEF JUSTICE ROBERTS: I understood
19 these -- Mr. Stewart to say it is a particular
20 type of fracture, it's a particular type of
21 stress fracture, and that the FDA understood
22 the use of that term to be broad enough to
23 include the atypical fractures as well.

24 MR. FREDERICK: That's not accurate.

25 CHIEF JUSTICE ROBERTS: That's not

1 what he said?

2 MR. FREDERICK: I don't know if that's
3 what he said, but we would dispute whether
4 that's correct. And the reason is because, if
5 you look at Dr. Burr's expert report, which is
6 in the Joint Appendix, and if you look at
7 Dr. Lane's amicus brief, they say this is a
8 very specialized form of fracture that
9 generally doesn't occur in the general
10 population.

11 CHIEF JUSTICE ROBERTS: But you -- you
12 -- you agree that the question is what the FDA
13 understood, right?

14 MR. FREDERICK: I think that that
15 question comes second, respectfully, Mr. Chief
16 Justice.

17 The first question is, what did the
18 manufacturer know or should have known at a
19 particular point in time? And then the next
20 question is, what did the FDA understand about
21 that? Because, if you take the statute that I
22 started my argument with, it's always on the
23 manufacturer to stay up to date.

24 Remember, the manufacturer has
25 superior information about these drugs to the

1 FDA. The budget of the FDA's drug safety
2 division was less than the annual sales of this
3 very drug. And so you're talking about a
4 massive resource disparity between what the
5 agency has and what the drug manufacturer has.

6 CHIEF JUSTICE ROBERTS: Well, but what
7 we're talking about is what -- what they told
8 the FDA, what the FDA understood. And if when
9 they told the FDA about -- and we have the
10 different citations to the Joint Appendix from
11 your -- your friend on the other side -- about
12 the -- the notion that stress fracture included
13 the things -- the atypical fractures, and if
14 that's what Merck understood, they gave to the
15 FDA what they had. And if that's what the FDA
16 understood, that's how we should interpret the
17 FDA's response.

18 MR. FREDERICK: And, Mr. Chief
19 Justice, as a matter of preemption law where
20 we're invoking the Supremacy Clause of the
21 United States Constitution to say that federal
22 law is going to displace state law, we
23 shouldn't be engaging in some musings or some
24 interpretation about a low-level civil servant
25 at the FDA and what that --

1 JUSTICE BREYER: They're not low-level
2 civil servants.

3 CHIEF JUSTICE ROBERTS: I -- I don't
4 understand your response. I understand the
5 Supremacy Clause and state law, but the
6 question is, what was being communicated to the
7 FDA?

8 So how is it -- how should they have
9 read and how did the FDA understand their own
10 response? And we know the answer to that
11 because we're hearing about it from the
12 government's counsel today.

13 MR. FREDERICK: So I'll read to you
14 from page 515 of the Joint Appendix. This is
15 the Merck scientists who have just received the
16 complete response letter. They say: "However,
17 FDA" -- "it believed that our justification to
18 support the proposed precaution text was
19 inadequate. It believes that 'stress
20 fractures' may not be clearly related to
21 atypical subtrochanteric fractures."

22 So the scientists are interpreting the
23 complete response letter to say the "stress
24 fracture" language that we offered is
25 inadequate. The FDA has rejected that

1 language.

2 And the reason why the wording matters
3 is because, as we've pointed out in our brief
4 -- and I think it's at page 41, Footnote 20 --
5 page 40, Footnote 21 -- there's a lot of back
6 and forth between drug companies and the FDA
7 over the wording. Why? Because the FDA
8 understands that the wording has to properly
9 educate doctors about the risks associated with
10 these drugs.

11 And if the doctors can't understand
12 the gravity of a warning where one of their
13 patients may be walking down the street and
14 have her femur snap, that's what we're trying
15 to get at the proper wording of these labels.
16 And that's why Congress --

17 JUSTICE SOTOMAYOR: Could you --

18 JUSTICE ALITO: The thing -- what Mr.
19 --

20 MR. FREDERICK: -- made the decision
21 to --

22 JUSTICE ALITO: I'm sorry. Go ahead.

23 MR. FREDERICK: That's why Congress
24 made the decision to keep the manufacturer at
25 all times.

1 JUSTICE ALITO: What Mr. Stewart cited
2 was page 746 of the Joint Appendix, where Merck
3 defines a stress fracture in this way: "A
4 stress fracture (also known as an insufficiency
5 fracture) is defined as a partial or complete
6 fracture occurring with either normal or
7 increased activity but without an identifiable
8 external traumatic event."

9 Now does not that encompass a -- the
10 type of fracture that you're talking about?

11 MR. FREDERICK: Not really.

12 JUSTICE ALITO: Well, it says "or
13 complete."

14 MR. FREDERICK: It does, Justice
15 Alito. But the question is, if you are an FDA
16 scientist who has been looking at the studies,
17 are you going to let Merck redefine what a
18 stress fracture is? Dr. Lane in his amicus
19 brief says, no, no, no, that's not what a
20 stress fracture is. That is an inaccurate, a
21 medically inaccurate, definition. It's --

22 JUSTICE ALITO: Yeah, well, that's
23 fine, but this is what -- you know, in very
24 simple terms, this is what troubles me about
25 your argument. This is not a situation, I

1 think, where Merck is proposing to warn about
2 one thing and the data shows that there's a
3 danger about something that's totally
4 unrelated, and, therefore, the FDA may not
5 focus on this second thing, like Justice
6 Kagan's example of -- perhaps of ovarian cancer
7 and ovarian cysts -- cysts.

8 But, if the FDA sees this proposed
9 warning and they think this -- the -- the
10 wording here is bad, they shouldn't be talking
11 about stress fractures, but we look at the data
12 and we see that there is something that should
13 be labeled differently and it should be --
14 there should be a warning about that, it would
15 -- it would shock me if the -- what the FDA
16 should do in that situation is to say: Well,
17 you know, you got the warning wrong and so
18 we're not going to issue it and we're going to
19 do -- we're going to prohibit that, but we're
20 not going to do anything more.

21 If they understood that there was a
22 danger of something else that is at least
23 related to what the manufacturer was proposing
24 to warn about, surely the public would expect
25 them to do something.

1 MR. FREDERICK: And, Justice --

2 JUSTICE ALITO: That's what troubles
3 me --

4 MR. FREDERICK: Yeah, and --

5 JUSTICE ALITO: -- about your
6 argument.

7 MR. FREDERICK: Well, Justice Alito,
8 if you look further into the record of what
9 happened here, there's an April 2009 email
10 chain between the FDA and Merck in which FDA
11 says it wants to "work with Merck on
12 precautions language" if it is warranted.

13 It's still trying to understand,
14 because these are a specialized, highly unique
15 set of injuries here.

16 JUSTICE KAGAN: Right. So suppose,
17 Mr. Frederick, that the best reading of what
18 happened here is that the FDA looks at this
19 letter and it says -- this proposal, and it
20 says this is a terrible proposal; whatever the
21 problem is, the problem is not stress fractures
22 and -- and so we're going to reject that. But
23 we do think that there is an issue -- and we
24 don't know the answer to it yet -- we do think
25 that there's an issue about this -- these more

1 major fractures.

2 And -- and you see this because,
3 eventually, they do a task force and they --
4 and then the task force decides something.

5 So, if the FDA is in that boat, right,
6 where it -- it -- it -- it -- it -- it sends
7 the letter and the letter says what you've said
8 is just inadequate and wrong, but we don't know
9 yet what we're really dealing with and we don't
10 know whether a change in your label is
11 appropriate, and we're going to continue to
12 study that, what should the manufacturer do at
13 that time?

14 MR. FREDERICK: The manufacturer
15 should continue to study the problem, should
16 continue to provide information to the FDA.

17 JUSTICE KAGAN: Should the
18 manufacturer change the label?

19 MR. FREDERICK: Possibly. It depends,
20 Justice Kagan, on what the manufacturer knows
21 and its understanding of the science.

22 Here -- let's take -- Justice Alito,
23 if we could follow your hypothetical a little
24 bit further. Suppose FDA had approved this
25 label, okay? All this language about stress

1 fractures, that's now in the label. Our claim
2 can't be preempted then, right?

3 JUSTICE BREYER: True. But what's
4 actually bothering me about the approach that
5 you're taking is that, in this particular area,
6 in this particular area of medicines, I don't
7 really see how we're going to benefit by 50
8 different states really giving different
9 signals to the manufacturers, and I can see a
10 lot of ways in which, from a health point of
11 view, we're going to lose.

12 That doesn't mean the law is wrong.
13 It doesn't mean -- you know, it's just a
14 question of emphasis. And, here, we have an
15 emphasis.

16 The next page from the one you cited,
17 the FDA says in 2010, FDA's review of the data
18 did not show an increase in this risk, the
19 relevant risk, in women using these
20 medications.

21 So there are indications in this
22 record --

23 MR. FREDERICK: Right.

24 JUSTICE BREYER: -- that they thought
25 that it is more dangerous to put the label --

1 to put the risk in the label than it is to
2 leave it out.

3 MR. FREDERICK: And --

4 JUSTICE BREYER: And then they set up
5 a task force and decide they were wrong.

6 MR. FREDERICK: And here's -- here --
7 this is a really interesting thing about the
8 task force: The FDA clearly didn't have all --
9 all of the relevant information, because what
10 the task force finds is that there are about
11 170 some articles that had been written on this
12 subject. Only five had been given to the FDA,
13 or that -- that was evidence that the FDA was
14 aware of.

15 And so that's why the statute imposes
16 the duty on the manufacturer, because the
17 manufacturer's going to be tracking this all
18 over the world. There was a -- there was a
19 report from a -- a Merck employee in Singapore
20 in 2006 who said I've now seen several of these
21 specialized atypical femoral fractures, I think
22 this could be an indication that we need a
23 safety signal.

24 And -- and, Justice Breyer, I accept
25 your -- your basic point, but what started this

1 whole thing was the first lawsuit against Merck
2 for these atypical femoral fractures was in
3 March of 2008, and that's what started this
4 whole back and forth. The FDA became aware of
5 this lawsuit and started to track what's really
6 going on here.

7 CHIEF JUSTICE ROBERTS: What if you
8 had a situation where, in light of the
9 exchanges you've talked about, Merck goes ahead
10 and puts on its label, oh, and, by the way, you
11 should be very careful about these atypical
12 femoral fractures, not -- not -- and it turns
13 out that doctors say, well, gosh, if that's
14 going to happen, I'm not going to prescribe
15 Fosamax. And, as a result, that drug which is
16 important for many women is no longer being
17 prescribed.

18 Now can somebody who thinks they
19 should not have put that warning in be able to
20 sue because they gave too many warnings and
21 that prevented doctors from prescribing a drug
22 that they otherwise should have been
23 prescribing?

24 MR. FREDERICK: So, Mr. Chief Justice,
25 the answer is that the manufacturer's always

1 responsible for its label, but the over-warning
2 problem is one where the FDA is balancing these
3 risks and benefits at all times.

4 And, here, we know that wasn't a
5 problem.

6 CHIEF JUSTICE ROBERTS: Well, no, I
7 know you're changing the hypothetical.

8 MR. FREDERICK: No, but --

9 CHIEF JUSTICE ROBERTS: Your point, I
10 -- well, maybe I don't know. I gather your
11 answer is that the manufacturer has the
12 responsibility. So, if the manufacturer knows
13 this, it should put in this warning and, if it
14 turns out that that was over-warning, then they
15 can be sued for that?

16 MR. FREDERICK: Well, there has to be
17 an injury that comes from the over-warning.

18 CHIEF JUSTICE ROBERTS: The injury is
19 that doctors are not prescribing Fosamax to
20 women who would benefit from it and they're not
21 prescribing it because Merck put in a warning
22 that the FDA would determine was over-warning.

23 MR. FREDERICK: Not -- Mr. Chief
24 Justice, respectfully, there's not a state law
25 tort there. There has to be an injury because

1 of the over-warning, or else there's no suit.

2 CHIEF JUSTICE ROBERTS: The injury is
3 the physician decides not to prescribe Fosamax
4 to a woman who would benefit from it.

5 MR. FREDERICK: Right. But that's not
6 a tort.

7 CHIEF JUSTICE ROBERTS: So -- so it's
8 a tort --

9 MR. FREDERICK: There's no -- there's
10 no state law there that says there's negligence
11 in that circumstance, Your Honor.

12 CHIEF JUSTICE ROBERTS: Well, I
13 thought that -- I thought the logic would be
14 the same as your logic here, is that the label
15 turned out to be misleading because of the drug
16 manufacturer's decision about what to include,
17 which they should have included even though
18 it's not required by the FDA. I thought that
19 would be the same cause of action.

20 MR. FREDERICK: But my point here, Mr.
21 Chief Justice, and let's go with a hypothetical
22 that the FDA had actually accepted this. Our
23 claim would be exactly the same, which is that
24 this language about stress fractures doesn't
25 tell the doctor worry about the prodromal pain,

1 worry about how long your client has been on
2 bisphosphonate, worry about what the particular
3 features of the X-ray look like when the --
4 when the patient complains about this.

5 That wording was all in the 2010 label
6 that FDA mandated. It wasn't in Merck's label
7 in 2009.

8 JUSTICE SOTOMAYOR: Mr. Frederick,
9 let's be -- coming down to practical, okay?
10 You say earlier that the Merck scientists were
11 saying, when they received this letter, the FDA
12 doesn't like our language.

13 What do you suggest Merck could have
14 done without changing its label until the FDA
15 would have approved it? And why do you believe
16 that you can convince a jury that, if they had
17 done it your way, the FDA would have accepted
18 the new label?

19 MR. FREDERICK: Well, as a regulatory
20 matter, let's start with the law first. The
21 CBE regulation gives the manufacturer the right
22 to change its label, subject to rescission by
23 the FDA.

24 That never happened here because Merck
25 never proposed an adequate warning.

1 JUSTICE SOTOMAYOR: Well, we know that
2 the FDA -- assuming the theory that the FDA
3 doesn't believe the label is adequate, what
4 could they have done --

5 MR. FREDERICK: They could --

6 JUSTICE SOTOMAYOR: -- absent the
7 study?

8 MR. FREDERICK: They --

9 JUSTICE SOTOMAYOR: Meaning because
10 the study obviously changed the FDA's mind.
11 You're saying, you, Merck, could have done it.

12 MR. FREDERICK: Yes. There was plenty
13 of information by that point, Justice
14 Sotomayor, and Dr. Lane goes through this, he
15 goes through the chronology. It's a
16 beautifully done amicus brief to explain what
17 the scientists knew and when they knew it and
18 by --

19 JUSTICE SOTOMAYOR: And that wasn't
20 communicated by Merck to the FDA? Is that what
21 you're saying?

22 MR. FREDERICK: Yes. What -- what Dr.
23 Lane says -- and Dr. Lane is a Merck
24 consultant, okay, in the summer of 2008. He's
25 writing an amicus brief on our side of the case

1 because he doesn't believe that Merck gave
2 "medically accurate education" to the FDA about
3 these fractures.

4 He's the one who had coined the term
5 "Fosamax fracture" because, in all of his years
6 of osteology, he had not encountered these
7 kinds of fractures until he had patients coming
8 to him who were on this drug.

9 JUSTICE ALITO: Mr. Frederick, you
10 want us to affirm the decision of the Third
11 Circuit?

12 MR. FREDERICK: You should affirm the
13 judgment because the judgment was correct,
14 summary judgment for Merck was not warranted.

15 JUSTICE ALITO: Uh-huh. And so then
16 the issue should be decided -- the juries in
17 these cases should decide whether the FDA would
18 have approved this --

19 MR. FREDERICK: We take the position
20 --

21 JUSTICE ALITO: -- based on that Merck
22 would have to prove to a jury by clear and
23 convincing evidence that the FDA would not have
24 approved an appropriate warning?

25 MR. FREDERICK: We agree with Merck

1 that, because of the complete response letter
2 back and forth, we -- we think that that -- and
3 we argued this, I argued this in the Third
4 Circuit, was a legal document that a judge can
5 interpret. We believe that, based on a sound
6 interpretation of the letter, it doesn't prove
7 impossibility.

8 JUSTICE KAGAN: So -- so are you
9 saying that you think that the question is, was
10 there official action by the FDA that prevented
11 Merck from changing its label?

12 MR. FREDERICK: And the answer to --

13 JUSTICE KAGAN: Is that the test in
14 your view? Is there official action by the FDA
15 that prevented Merck from changing its label?

16 MR. FREDERICK: To make an adequate
17 warning, that's important, Justice Kagan,
18 because the warning that the FDA has to reject
19 has to be adequate to address the risks under
20 state law.

21 JUSTICE KAGAN: Correct. Okay. So
22 that's what I was assuming. But that's the
23 question. And that's a legal question, is that
24 correct?

25 MR. FREDERICK: It is a legal

1 question, but it has factual components.

2 JUSTICE KAGAN: But a judge can decide
3 that question.

4 MR. FREDERICK: A judge can decide the
5 core legal question, but in all constitutional
6 questions, there are usually fact issues, and
7 we consign those to juries to decide what the
8 fact issues --

9 JUSTICE BREYER: Not always. There
10 are a lot of mixed issues where, because
11 they're predominantly legal, the judge does it;
12 patents, for example, Markman is a case of
13 that, and does coerced confessions. I mean,
14 there are a number.

15 MR. FREDERICK: As I said --

16 JUSTICE BREYER: It seems to me that
17 this is in that number because it's
18 predominantly a legal question and there could
19 be factual disputes on the brute facts. But,
20 here, I don't think there are really.

21 MR. FREDERICK: I think that the one
22 disputed fact here that has sort of surfaced as
23 a result of the argument today is, what does
24 the phrase "low energy" mean?

25 Merck and SG have taken the position

1 that "low energy" encompasses atypical femoral
2 fractures. Dr. Lane says actually that's not
3 accurate.

4 And so, to the extent that there's a
5 debate between experts over the meaning of
6 particular scientific terms, judges, just --
7 Justice Breyer can certainly decide that, but
8 so can juries.

9 JUSTICE BREYER: I believe they do,
10 but, normally, there's a factor, there are a
11 set of factors classically when it's a mixed
12 question of fact and law, and one of the
13 factors is sometimes who will do it better, at
14 least as I interpret it.

15 MR. FREDERICK: And, as I say, we --
16 we briefed the case. In light of this Court's
17 cases about constitutional issues, we don't see
18 that there's something special about the
19 preemption provision or the Supremacy Clause
20 that would take it out of the normal
21 fact-finding ambit of juries.

22 But I would say that, if you don't
23 agree with me on that, you still have to affirm
24 and instruct the court below, in fact, this is
25 going to be a legal question that judges are

1 going to decide.

2 That does not affect the outcome of
3 the case here. Summary judgment for Merck was
4 improper.

5 JUSTICE ALITO: I'm confused. So you
6 want us to say there is no preemption? You
7 want us to say that Merck wasn't entitled to
8 summary judgment on the issue of preemption?
9 Which of the two?

10 MR. FREDERICK: Merck was not entitled
11 to summary judgment.

12 JUSTICE ALITO: Yeah, but you want to
13 alter the judgment of the Third Circuit by
14 saying that it was -- it was wrong in -- in
15 saying this should be submitted to a jury, that
16 it's a factual question to be submitted to a
17 jury?

18 MR. FREDERICK: As I say, I think
19 there are fact questions here. But, Justice
20 Alito, my brief argues that summary judgment
21 for Merck was improper. Because of the
22 extremely bizarre way this case came up on a
23 motion -- on an order to show cause, there
24 weren't even cross-motions for summary
25 judgment, which occurs in 99.999 percent of all

1 cases.

2 So we're talking about how do you
3 handle a wrong district court judgment with the
4 Third Circuit doing the best it could in very
5 strange circumstances, and now the case is in
6 this Court.

7 You can affirm and you can say what
8 you want to say about jury issues deciding,
9 but, here, our position is the complete
10 response letter as a matter of law could not
11 have made it impossible for Merck to update its
12 labels.

13 JUSTICE ALITO: So you want us --

14 CHIEF JUSTICE ROBERTS: Thank you,
15 counsel. Oh, I'm sorry. Thank you, counsel.

16 Mr. Dvoretzky, you have three minutes
17 remaining.

18 REBUTTAL ARGUMENT OF SHAY DVORETZKY

19 ON BEHALF OF THE PETITIONER

20 MR. DVORETZKY: Thank you, Mr. Chief
21 Justice.

22 If the FDA does not know yet whether a
23 warning is justified or not, that means no, the
24 manufacturer in that situation can't change the
25 label. That's true whether we're talking about

1 the CBE process or the PAS process.

2 And that's the situation here. Mr.
3 Frederick focuses on low energy and stress
4 fracture, and any debate about that terminology
5 --

6 JUSTICE SOTOMAYOR: How about the
7 manufacturer's duty to work with the FDA to
8 ensure that the label is right and that it has
9 all pertinent information to reconsider its
10 initial decision?

11 Mr. Frederick said there were only
12 five of 170 articles provided to the FDA. Your
13 own scientists said they're confused. Doesn't
14 Merck have an obligation to show that, if
15 presented with the proper language and the
16 proper evidence, that the FDA would have -- or
17 don't you have to show would have still denied
18 the right label?

19 MR. DVORETZKY: Justice --

20 JUSTICE SOTOMAYOR: Isn't that your
21 burden?

22 MR. DVORETZKY: Justice Sotomayor, the
23 process that you're describing is exactly what
24 happened here.

25 JUSTICE SOTOMAYOR: It didn't. You

1 never gave them a proper language and you never
2 gave them what your scientists told you to give
3 them.

4 MR. DVORETZKY: Justice Sotomayor, the
5 PAS submission included 132 studies about the
6 risk that Respondents say we should have warned
7 about, the very same studies that Respondents
8 themselves rely on that. All of that was
9 before the FDA. The FDA isn't saying that it
10 was in any way misled.

11 And the back-and-forth process here,
12 if you look at Joint Appendix 508, the email
13 that Mr. Frederick referred to, an FDA official
14 told Merck to withdraw its request so that the
15 FDA could close out this issue while it
16 continued to study it and work with the FDA on
17 -- work with Merck on language later if it
18 determined that a warning was warranted.

19 In other words, at the time of the
20 CRL, based on all of the information that the
21 FDA had before it, and it doesn't claim that it
22 was misled, no warning was justified at that
23 time.

24 In March of 2010, the public safety
25 announcement, Joint Appendix 520, the FDA said

1 "the data did not show an increase in this risk
2 in women using this medication."

3 In light of that statement from the
4 FDA, there is no way that Merck could have
5 changed its warning because the FDA has told us
6 that no warning was justified at that time.

7 As for Dr. Lane, the -- Merck's
8 warning contains the two hallmarks that
9 Dr. Lane says were necessary. The warning
10 itself on its face refers to insufficiency
11 fractures and complete fractures. It doesn't
12 just refer to stress fractures.

13 With respect to the stress fracture
14 language, Dr. Lane himself in his amicus brief
15 admitted that AFFs start as stress fractures.
16 That's at page 9, Footnote 11, and also at page
17 12.

18 Mr. Chief Justice, if I may just wrap
19 up, where we know from the FDA's actions and
20 statements that no change was permissible,
21 because it's not scientifically justified, that
22 establishes preemption as a matter of law.

23 CHIEF JUSTICE ROBERTS: Thank you,
24 counsel. The case is submitted.

25

1 (Whereupon, at 11:08 a.m., the case
2 was submitted.)
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