



1 argument before the Supreme Court of the United States  
2 at 10:03 a.m.

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P R O C E E D I N G S

(10:03 a.m.)

CHIEF JUSTICE ROBERTS: We'll hear argument first this morning in Case 09-993, Pliva, Incorporated v. Mensing, and the consolidated cases. Mr. Lefkowitz.

ORAL ARGUMENT OF JAY P. LEFKOWITZ  
ON BEHALF OF THE PETITIONERS

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

This case involves the ordinary operation of the Supremacy Clause. As the government agrees, Hatch-Waxman's plain text requires generic drugs to have the same warnings as their brand-name equivalents, so State law can't require generic drugs to use different warnings. After all, generics can't simultaneously comply with a Federal duty to be the same and a State duty to be different.

CHIEF JUSTICE ROBERTS: Well, that makes a lot of sense, but we do have our Wyeth decision that seems to cut the other way.

MR. LEFKOWITZ: Well, Your Honor, the Wyeth decision is premised on the fundamental conclusion that Federal law obligates and accommodates the brand manufacturer to utilize a specific regulation, the CBE

1 regulation, in order to make a warning change, in order  
2 to comply with its obligations under 201.57. And, as  
3 the government agrees, we don't have the opportunity or  
4 the authority to use a CBE regulation change.

5 JUSTICE GINSBURG: But you have another --  
6 you have another route, and that's what the government  
7 is telling us: That you could propose a revision of the  
8 label, and if you did that, then you would be home free.  
9 You would not be subject to the State suit.

10 MR. LEFKOWITZ: Justice Ginsburg, the  
11 government agrees with us that we can't actually change  
12 the label. What they say is, we could have an  
13 obligation, or they actually, in -- for the very first  
14 time ever in their brief in this Court at the merit  
15 stage, said that there is a --

16 JUSTICE GINSBURG: No, it was in the -- at  
17 the cert stage as well.

18 MR. LEFKOWITZ: Well, Your Honor, I didn't  
19 read the cert stage as saying we had quite the same duty  
20 to ask the FDA, although clearly they now believe that  
21 we have a duty to ask the FDA. And of course that's not  
22 a duty that appears in any of their notice and comment  
23 rulemaking.

24 JUSTICE KENNEDY: Can we call this the take  
25 steps -- is this the take-steps doctrine, for purposes

1 of discussion here?

2 MR. LEFKOWITZ: Yes, Justice Kennedy, this  
3 is the take-steps.

4 JUSTICE KENNEDY: It's not clear to me  
5 whether you say that that is preempted or just that it  
6 was not well-pled. I'm not -- I'm not sure of your  
7 position on that point.

8 MR. LEFKOWITZ: Thank you, Justice Kennedy.  
9 We maintain that a claim that under State law a generic  
10 company can be liable for not asking the FDA to make a  
11 labeling change is preempted under this Court's  
12 decisions both in Buckman and in ArkLa, because what  
13 the -- what the Court has said is that the disclosure  
14 obligations between a Federal agency and a Federally  
15 regulated party are inherently Federal in character, and  
16 this is not a subject of traditional State tort law.

17 JUSTICE KAGAN: Well, Mr. Lefkowitz, why  
18 should --

19 JUSTICE SCALIA: Would the -- excuse me,  
20 Justice.

21 Would the Federally licensed drug  
22 manufacturer have a similar obligation to lobby the FDA  
23 for a change?

24 MR. LEFKOWITZ: No, Your Honor, and in fact  
25 that was in part what was -- what came up in the

1 briefing in the Wyeth case. Wyeth initially said it  
2 didn't have the obligation and couldn't use the CBE, and  
3 then Ms. Levine said: Well, in that case you could have  
4 asked the FDA to make a change, and the Court didn't  
5 need to even address that issue, because the Court found  
6 that there actually was a regulation on point that gave  
7 the brand manufacturer the ability to change.

8 JUSTICE SCALIA: But assume there hadn't  
9 been. Assume there hadn't been such a regulation. Do  
10 you understand it to be the government's position that  
11 the licensed drug manufacturer is not protected from  
12 State suits, even though it has a Federal permission to  
13 give certain warnings, unless it has lobbied the FDA to  
14 change those warnings?

15 MR. LEFKOWITZ: Your Honor, I -- I don't see  
16 anything in the history, the 27-year history of  
17 Hatch-Waxman, where the Federal government has ever said  
18 that there is a legal obligation to lobby the FDA for a  
19 labeling change.

20 JUSTICE SOTOMAYOR: Excuse me. There is a  
21 legal obligation to advise the FDA when you have reports  
22 of adverse results that suggest the label may be wrong.  
23 Are you disavowing your -- your obligation to tell the  
24 FDA when something's wrong?

25 MR. LEFKOWITZ: Absolutely not, Justice

1 Sotomayor.

2 JUSTICE SOTOMAYOR: So please describe  
3 what the difference between that obligation and the  
4 obligation to suggest a label change when you know it's  
5 been misbranded.

6 MR. LEFKOWITZ: Under the FDA Regulation  
7 314.80 and 314.98, we have a myriad of disclosure  
8 obligations. Any time a generic learns about an adverse  
9 report, it has to report it to the FDA, it has to  
10 investigate it, and if it doesn't do that then it's not  
11 in compliance with its Federal obligations and the FDA  
12 has plenary authority to take all sorts of action.

13 But just as the Court said in the Buckman  
14 decision, without dissent, when a company doesn't make  
15 appropriate disclosures to the FDA, even if people are  
16 hurt by that, even if it's -- if it causes people to be  
17 injured and States might otherwise want to compensate  
18 them for them, those disclosure obligations are up to  
19 the FDA with its discretion to enforce. And the Court  
20 looked directly to Congress in section 337.

21 JUSTICE SOTOMAYOR: So what's -- so what's  
22 the conflict with State law, meaning you have an  
23 obligation to keep your label as it is, but if you also  
24 have a Federal obligation to advise the FDA of  
25 adverse -- of adverse results and of needs for change,



1 why can't you then comply with a duty to warn obligation  
2 because you can go to the -- to the FDA?

3 MR. LEFKOWITZ: Well, first of all, there's  
4 a little bit of a difference between reporting all of  
5 the adverse events, which we clearly do, and asking the  
6 FDA to make a determination that the FDA has said is  
7 only for the FDA to make with respect to generic  
8 companies.

9 JUSTICE KAGAN: Do you contest,  
10 Mr. Lefkowitz, your ability to make that request? I  
11 know that you contest your obligation to make that  
12 request, but do you think you could go to the FDA and  
13 make that request and set a process in motion?

14 MR. LEFKOWITZ: Your Honor, there's no  
15 question that we could certainly ask the FDA, and in  
16 fact if we had reason to believe that a label was not  
17 accurate, not strong enough, we would certainly do that.  
18 The question is whether or not there's either a Federal  
19 obligation or a State duty to do this, and --

20 JUSTICE KAGAN: Well, if you could go to the  
21 FDA, why shouldn't we look at this suit in this way:  
22 That the plaintiffs are bringing a standard failure to  
23 warn claim; that you then have a preemption defense,  
24 that you'll say it's impossible; and then in order to  
25 litigate that preemption defense, the question will be,

1 well, if you had gone to the FDA, what would the FDA  
2 have done? Would it in fact have required both brand  
3 names and generics to change the label? And if it would  
4 have, you would not have had -- been put in an  
5 impossible position.

6 MR. LEFKOWITZ: Your Honor, that is the  
7 precise set of issues that this Court addressed both in  
8 Buckman and in ArkLa, in a situation where all we could  
9 have done, and we weren't obligated to do, was ask the  
10 FDA. For a State to hold us liable for not asking the  
11 FDA is asking a State jury to put itself into the shoes  
12 of the FDA, to speculate how the FDA would have decided  
13 hypothetical issues, which ArkLa says is foreclosed in  
14 an area where the Federal Government, the Federal  
15 agency, has exclusive authority. And in Buckman, the  
16 Court said that would disrupt and usurp the discretion  
17 of the agency to decide whether to punish and how to  
18 punish disclosure.

19 CHIEF JUSTICE ROBERTS: Well, Buckman --  
20 Buckman was arguably a little bit different, in that  
21 there's a concern expressed in that case that  
22 requiring allowing the State suit to go forward would  
23 cause manufacturers to basically inundate the agency  
24 with proposals and warning revisions, so that there  
25 would be so many things that the agency wouldn't even be

1 able to process them, and they would become meaningless  
2 to the consumers. That doesn't seem to me to be a  
3 concern in this case.

4 MR. LEFKOWITZ: Well, Your Honor, the  
5 government had articulated that proposition in the  
6 Buckman case and again several years later in the  
7 Warner-Lambert case. Obviously, they're taking a  
8 different position here.

9 But I would submit, Your Honor, that what  
10 lay at the core of the Buckman decision was that the  
11 relationship, the disclosures, between the Federal  
12 agency and its regulated party, are inherently Federal  
13 and States simply don't have a business trying to  
14 enforce those obligations, because that does take away  
15 from the authority and the discretion. And the Court  
16 looked to section 337 as evidence that Congress intended  
17 that violations of the FDCA be enforced by the Federal  
18 Government.

19 JUSTICE GINSBURG: The Federal agency says  
20 that these suits complement, they're not at odds with,  
21 the Federal regime, because they give the manufacturers  
22 an incentive to come forward. Everyone is interested in  
23 making sure that only safe drugs are marketed. So, far  
24 from detracting from the Federal regime, the agency  
25 responsible says, this helps us; it encourages

1 manufacturers to report.

2 MR. LEFKOWITZ: Well, we know from the  
3 current FDA database that there were over 1600 requests  
4 for labeling revisions that the FDA has not acted on,  
5 and that's just in the aftermath of Wyeth. And there  
6 are far more generic manufacturers who would be burdened  
7 by this new obligation. But, Your Honor, I would --

8 JUSTICE KENNEDY: Is -- is there any  
9 breakdown as to how many of those requests are generic  
10 and how many from branded?

11 MR. LEFKOWITZ: Your Honor, almost all of  
12 them I would believe are from branded manufacturers,  
13 because generic manufacturers until the briefing in this  
14 Court have never believed that they have any obligation  
15 to ask the FDA.

16 In fact, interestingly, the FDA has  
17 addressed what happens in the marketplace when a brand  
18 exits the market and the only drugs left are the 10 or  
19 15 generics. And what the FDA has said, and they have  
20 published 52 Federal Register notices -- we cite one of  
21 them in our reply brief -- they have said: In such a  
22 situation, we will designate one of the generics to be  
23 the leader for purposes of establishing the label, and  
24 everyone else has to follow.

25 But critically, what the FDA has said is:

1 In those situations, we, the FDA, will tell you when the  
2 label needs to change.

3 JUSTICE BREYER: So what are you supposed to  
4 do if your company happens by chance to come across a  
5 very, very high correlation between people who take your  
6 generic drug and who get seriously ill?

7 And now what you know is that nobody else  
8 has really found that, but, my goodness, there you are;  
9 it happened that it was associated, a special group or  
10 something. What are you supposed to do?

11 MR. LEFKOWITZ: Your Honor, we have an  
12 obligation, actually, to provide all of that information  
13 to the FDA. Generics, unlike brand companies, aren't  
14 equipped in the same way, necessarily, to evaluate  
15 the --

16 JUSTICE BREYER: And so are they saying that  
17 you -- is it conceded in this case that you did tell the  
18 FDA everything you knew about that?

19 MR. LEFKOWITZ: Well, no. We --

20 JUSTICE BREYER: Or is that a point in  
21 dispute?

22 MR. LEFKOWITZ: The plaintiffs allege that  
23 we violated Federal disclosure obligations. Of course,  
24 there's no basis for a State claim for that.

25 In fact, to -- to address Justice Ginsburg's

1 question --

2 JUSTICE BREYER: Well, how would it  
3 conflict? Suppose the State said: Here is what we  
4 want; we notice that it says in the Federal law that you  
5 must keep your warnings up to date, and if you find an  
6 association, you must revise your warning. Now, we  
7 understand you can't do that without FDA approval. But  
8 as far as our State is concerned, we think that when you  
9 come across this serious problem you have to tell the  
10 FDA in some form or other, a reasonable form, about it.  
11 Would that law -- is there anything Federal that that  
12 law would conflict with?

13 MR. LEFKOWITZ: I think that law, Your  
14 Honor, would conflict with the Buckman principles and  
15 the ArkLa principles.

16 JUSTICE SCALIA: I thought you said you had  
17 to tell the FDA about it.

18 MR. LEFKOWITZ: If the -- I understood  
19 Justice Breyer's question to be asking whether -- not  
20 only did we have to tell the FDA, which we clearly do,  
21 but whether we then had some additional duty to ask the  
22 FDA to change the warning.

23 JUSTICE SCALIA: Okay. I didn't understand  
24 that.

25 JUSTICE BREYER: What I wonder -- see, I

1 wonder if that's this case. I wonder if this case is  
2 what they're saying is: Oh, we concede you told the FDA  
3 every single thing, so they were just as informed as you  
4 are about the risks here, but you did not add the words:  
5 And please change our -- your permission, so that we can  
6 change the warning. Is that what this case is about?

7 MR. LEFKOWITZ: Well, I think that's what  
8 they're suggesting. But even if it were just the  
9 former --

10 JUSTICE BREYER: When they come up here they  
11 might say this isn't just what this case is about.

12 MR. LEFKOWITZ: Even if it's just the  
13 former, Your Honor, even if it's just the failure to  
14 disclose adverse reports --

15 JUSTICE BREYER: Yeah.

16 MR. LEFKOWITZ: -- which we know we have an  
17 obligation to do, there is no history of State  
18 regulation of communications between Federal -- Federal  
19 agencies and the regulated parties. Those are not the  
20 kinds of parallel claims cases, like in Lohr v.  
21 Medtronic --

22 JUSTICE BREYER: So your argument is that if  
23 we run across this tremendous, really serious -- I can  
24 make an imaginary as serious as you want -- really a  
25 serious problem, and you're saying the State has no

1 right to say -- even if we purposely didn't tell  
2 anybody, they can't get involved because they can't get  
3 involved with our failure to tell the FDA anything  
4 because that's Federal, and we can't -- they can't get  
5 involved with our failure to try to change the warning  
6 because that's taken care of by our obligation to tell  
7 them, which we didn't fulfill?

8 MR. LEFKOWITZ: Justice Breyer, correct,  
9 because that's exactly -- remember, in Buckman what  
10 happened was an individual was injured because the  
11 company had not accurately disclosed, in fact had misled  
12 the agency about the purpose of marketing these bone  
13 screws. Clearly there was a State interest in  
14 protecting and providing a remedy to that consumer, a  
15 State interest in ensuring accurate disclosures to the  
16 government, and in fact an allegation that had there  
17 been accurate disclosures to the government, the FDA  
18 would have made a different safety and labeling  
19 determination.

20 JUSTICE SCALIA: So you say that if the  
21 claim here is simply that you did not disclose properly,  
22 that claim could be brought?

23 MR. LEFKOWITZ: Not in a State court, Your  
24 Honor.

25 CHIEF JUSTICE ROBERTS: To disclose -- I'm



1 sorry. To disclose to the FDA?

2 MR. LEFKOWITZ: Correct.

3 JUSTICE SCALIA: To disclose to the FDA.

4 MR. LEFKOWITZ: A claim, Your Honor, of  
5 disclosure to the FDA relates to the inherently Federal  
6 relationship.

7 JUSTICE SCALIA: But you just described  
8 Buckman as -- as involving precisely that, failure to  
9 tell the FDA the purpose of the screws. You said that  
10 the State -- the State suit would lie because of that  
11 failure.

12 MR. LEFKOWITZ: No, I said the State suit --  
13 I apologize. I meant to say and I thought I said the  
14 State suit would not lie because Buckman preempts that  
15 type of lawsuit. Buckman says even in that terrible  
16 situation, misleading to the FDA, failure to disclose  
17 what the FDA requires you to disclose, there is no State  
18 cause of action because this is a uniquely Federal area  
19 and States can't supplant the FDA in its enforcement  
20 discretion.

21 JUSTICE KAGAN: But Mr. Lefkowitz, I think  
22 what the Respondents would say is that you are  
23 mischaracterizing their complaint and making it into  
24 something that it's not. Their complaint is a standard  
25 state failure to warn claim. Now, you have a preemption

1 defense to that claim, and in that preemption defense  
2 there's going to be questions about your disclosure  
3 obligations and whether the FDA would have responded in  
4 a certain way to your disclosure obligations, but it's  
5 in a fundamentally different posture than the one that  
6 you're suggesting.

7 MR. LEFKOWITZ: Justice Kagan, I would agree  
8 with you that what they pled below was a traditional  
9 failure to warn. A failure to warn claim means you did  
10 not warn the public in the way that we think under State  
11 law you should have. And whereas in Wyeth the Congress  
12 through the FDA has said a brand manufacturer ultimately  
13 is responsible for the warnings it issues and therefore  
14 can change the warning and therefore can be held liable,  
15 we don't have -- and the government agrees with us -- we  
16 don't have any mechanism under law to change the  
17 warnings. So to the extent this is a traditional  
18 failure to warn claim, it has to be preempted under  
19 simple Supremacy Clause principles.

20 JUSTICE KAGAN: Well, I agree that you don't  
21 have any ability yourself to change the warning, but  
22 here's what the FDA has said. The FDA has said if an  
23 ANDA applicant -- and that's you; you're an ANDA  
24 applicant -- believes new safety information should be  
25 added to a product's labeling, presumably because

1 they've gotten information that suggests that the  
2 product's labeling is wrong, then it should contact the  
3 FDA, and the FDA will determine whether the labeling for  
4 the generic and listed drugs should be revised.

5 MR. LEFKOWITZ: Your Honor, that is exactly  
6 what the FDA says. They point for that to a preamble in  
7 1992 to a rulemaking that didn't address the relevant  
8 201.57 regulation, a preamble that was issued without  
9 notice and comment rulemaking, and a preamble that  
10 doesn't actually impose a duty. It says if,  
11 subjunctively, we believe that there should be a label  
12 change, we should do something, we should ask the FDA.  
13 Not we must, not we shall.

14 And even then it said: And the FDA will  
15 then make a decision, which makes clear that this is not  
16 a decision for State juries to make. Your Honor, the  
17 FDA has articulated a Federal duty today in its briefing  
18 in this case that is very much at odds with what it has  
19 specifically said about what a generic's obligation is  
20 under 201.57. In the two notice and comment rulemakings  
21 at issue during the relevant time period here, in 2000  
22 and 2006, what the FDA said very specifically was a  
23 generic's obligation under 201.57 is to use the brand  
24 label, even if the brand label isn't the most  
25 up-to-date.

1                   And the reason is the policy underlying  
2 Hatch-Waxman is that brand companies do safety and  
3 efficacy testing; generics do sameness testing.  
4 Generics are required to make copies of the drugs and by  
5 definition make copies of the labels, because it  
6 wouldn't make any sense to go into a drugstore to buy  
7 Advil and to see 15 different generic ibuprofen and to  
8 have 15 different sets of warnings.

9                   JUSTICE SOTOMAYOR: Counsel, do you think --

10                   JUSTICE KENNEDY: Buckman was a case -- I'm  
11 pronouncing it right, I think, Buckman -- where it was a  
12 branded manufacturer, was it not?

13                   MR. LEFKOWITZ: It was a medical device  
14 manufacturer.

15                   JUSTICE KENNEDY: A medical device  
16 manufacturer. So there it was -- it was an FDA process,  
17 and we said there's no State cause of action for saying  
18 that the FDA process -- that's slightly different from  
19 saying that you have a duty to warn the FDA. You might  
20 say it's a fortiori.

21                   MR. LEFKOWITZ: Your Honor, I do think it's  
22 a fortiori. Buckman involves the branded process of  
23 coming on with an equivalent medical device under the  
24 510K process. This is actually a situation where, after  
25 intensive back and forth with the FDA, the brand company

1 crafts the label that the FDA approves and the generic  
2 is given one responsibility by Congress. The  
3 responsibility is to maintain the same label as the  
4 brand. That's the critical difference.

5 JUSTICE SOTOMAYOR: Counsel, do you think  
6 Congress really intended to create a market in which  
7 consumers can only sue brand-named products? Because if  
8 that's the case, why would anybody ever take a generic?  
9 And why in the world would Congress create a different,  
10 or even the FDA, a different obligation on brand-named  
11 products or generic products to give them information  
12 about labels when they know there's been a misbranding?

13 What the government says is you start by  
14 instructing a jury that there had to actually have been  
15 information that proved a misbranding. That's the first  
16 step of the tort suit according to the government. So  
17 why should you or why would Congress or the FDA have  
18 intended to treat the two differently?

19 MR. LEFKOWITZ: Justice Sotomayor, I want to  
20 take both halves of your question. In 27 years of  
21 enforcement under Hatch-Waxman, the FDA has never once  
22 said that a generic drug that uses the brand label, as  
23 required under 505(j) of the statute is misbranded. And  
24 the -- look, I understand that from the consumer's  
25 perspective it may not make a lot of sense. But what

1 Congress specifically said is that a generic has to bear  
2 the same label, and it's because they do have different  
3 purposes, different functions. Congress said that  
4 whenever there is a brand drug on the market that no  
5 longer is protected by its patent monopoly but has been  
6 selling for \$10 or \$20 a pill, we want to have generics  
7 selling for pennies for the pill, and they've given  
8 branded and generics different obligations.

9           And the different obligations are seen most  
10 clearly through the prism of the Wyeth case. The Wyeth  
11 case was -- it was critical in the Wyeth case that this  
12 Court found that the brand company had the ability, had  
13 the obligation, to use the CBE regulations to actually  
14 change the label, whereas here what the FDA has said  
15 time and time again is: We'll tell a generic when the  
16 generic has to change the label, because we don't assume  
17 that the generics are going to know when the label  
18 should change because they don't have the same basis of  
19 clinical testing and results.

20           JUSTICE GINSBURG: Mr. Lefkowitz, there's a  
21 certain overlap, is there not? Some of the generics are  
22 made by the same people that make the brand-name drugs,  
23 isn't that so?

24           MR. LEFKOWITZ: That is correct, Your Honor.

25           JUSTICE GINSBURG: And at least for those

1 people, they have the means.

2 MR. LEFKOWITZ: Your Honor, I don't know  
3 whether or not the -- the FDA or this Court would hold  
4 differently in a case where the generic at issue was an  
5 authorized generic, a generic manufactured by a brand  
6 company that had, in fact, done all the clinical safety  
7 testing and might have a different basis for assessing  
8 the occasional adverse reports that they get.

9 But, again, the keys to understanding the --  
10 the generic industry -- generics rarely even get adverse  
11 reports because if a doctor prescribes a drug, the  
12 doctor prescribes it as the brand, and then checks off  
13 the box that says a generic can be issued. If a patient  
14 comes and tells him about an adverse report, the doctor  
15 has no idea which generic of the 15 that might be in the  
16 market actually was dispensed, so he'll actually tell  
17 the brand company. He'll report the adverse event to  
18 the brand company.

19 JUSTICE SOTOMAYOR: Counsel, all you're  
20 arguing is that this rule will have little practical  
21 effect, that there is going to be very few lawsuits that  
22 could be brought against your companies because you're  
23 just not going to have enough information to suggest a  
24 label change.

25 MR. LEFKOWITZ: Your Honor, what I'm arguing

1 is that for the FDA to impose a new Federal obligation  
2 that will significantly change the way generic companies  
3 conduct their business should go through notice and  
4 comment rulemaking. It should not rely on a preamble to  
5 a different rulemaking that didn't go through notice and  
6 comment. It should not rely on briefs that are filed at  
7 the merits stage, because this would totally change the  
8 way generics do business.

9           Generics don't have a practice -- they're  
10 not even set up -- to go and figure out what label  
11 changes would be appropriate. They are set up to report  
12 adverse events to the FDA, and what Congress has said  
13 and what the FDA has said is violations of those  
14 statutes, violations of those regulations, are  
15 exclusively within the province of the Federal  
16 government. That's what Buckman says very clearly when  
17 it looks at Section 337.

18           If I may, I would like to reserve my time.

19           CHIEF JUSTICE ROBERTS: Thank you,  
20 Mr. Lefkowitz.

21           Mr. Bograd.

22           ORAL ARGUMENT OF LOUIS M. BOGRAD

23           ON BEHALF OF THE RESPONDENTS

24           MR. BOGRAD: Mr. Chief Justice, and may it  
25 please the Court:



1           The central issue in this case is that  
2           Petitioners, in the face of considerable information  
3           that the warnings on their products were inadequate, did  
4           nothing. The generic drug companies' position is that  
5           they -- no matter how much they know, no matter how  
6           grave the risk, they are under no obligation to do  
7           anything to warn of the dangers of the products they  
8           sell.

9           JUSTICE SCALIA: Well, they're -- they're --  
10          they're under the obligation to report to the FDA the  
11          facts which establish the grave risk, right?

12          MR. BOGRAD: Yes, they are, Your Honor.  
13          They're obliged under --

14          JUSTICE SCALIA: So the argument here is  
15          whether it -- it will be the FDA ultimately that  
16          determines whether there was a grave enough risk to  
17          modify the -- the label or whether that call will be  
18          made by -- by a State court guessing what the FDA would  
19          have done, right?

20          MR. BOGRAD: No, Your Honor, that's not  
21          correct. What this Court said in Wyeth v. Levine is  
22          that State juries are a perfectly appropriate vehicle  
23          for assessing whether warnings in the past were  
24          adequately given. We do -- we do not dispute that the  
25          issue about what language will be on a label going

1 forward rests with the agency.

2 JUSTICE SCALIA: Yeah, but -- but -- no,  
3 but -- but surely you have to establish not only that  
4 the generic manufacturer requested a label change, but  
5 that a label change would have been approved. Otherwise  
6 there's no causation. Surely --

7 MR. BOGRAD: That's correct, Your Honor.

8 JUSTICE SCALIA: -- that's part of your  
9 case, isn't it?

10 MR. BOGRAD: No, it's not, Justice Scalia.  
11 The -- as Petitioners concede in the brief, under  
12 traditional State law failure to warn claim, our  
13 affirmative case is that the warnings that were given to  
14 the doctor and to the patient were inadequate, and that  
15 because adequate warnings weren't given, the patient was  
16 injured.

17 JUSTICE SCALIA: No, but -- but their --  
18 their preemption claim is we had to give these warnings,  
19 and you don't contest that. They had to give the  
20 warnings that they gave, unless the FDA said that the  
21 warnings must be changed, so --

22 MR. BOGRAD: Your Honor --

23 JUSTICE SCALIA: -- I mean, I don't see how  
24 you can hold them liable, so long as they continued to  
25 give the warnings that they had to give.

1 MR. BOGRAD: Your Honor --

2 JUSTICE SCALIA: And they could have lobbied  
3 the FDA to say, you know, change the warning, but if the  
4 FDA said -- suppose the -- suppose they did tell the  
5 FDA, please modify the label, and the FDA said no.  
6 Would your lawsuit still proceed?

7 MR. BOGRAD: No, it would not, Your Honor.

8 JUSTICE SCALIA: No.

9 MR. BOGRAD: Once the FDA said no, we would  
10 have clear evidence that the FDA would have rejected the  
11 warning --

12 JUSTICE SCALIA: I would say --

13 MR. BOGRAD: -- which is what this Court  
14 said in Levine is the touchstone.

15 JUSTICE SCALIA: All right. You're drawing  
16 a line between the FDA rejecting a warning and the FDA  
17 not accepting the warning; is that the line you're  
18 drawing?

19 MR. BOGRAD: Yes, Your Honor, for purposes  
20 of impossibility. In order for the -- preemption is an  
21 affirmative defense, and for the defendants to establish  
22 that it was impossible, i.e., that the duties under  
23 State and Federal law were in direct conflict, they have  
24 to show that the FDA would have rejected --

25 JUSTICE BREYER: It appears also that the --

1 it's Buckman, it seems to me, the relevant case, not  
2 Wyeth, because what -- if -- you're now saying, I've  
3 learned, that -- that they have a set of FDA duties;  
4 they must tell the FDA every detail.

5 MR. BOGRAD: Well --

6 JUSTICE BREYER: That sounds awfully  
7 familiar to Buckman, where the State claim was basically  
8 a claim of fraud on the FDA. And we said it's not up to  
9 the State to -- to -- they can't bring -- have a claim  
10 for fraud on the FDA. The FDA has to enforce their own  
11 stuff. And why isn't the same true here, that the FDA  
12 has to enforce their own legal requirement to tell us  
13 everything you know? What's the answer to that?

14 MR. BOGRAD: Well, there are two answers,  
15 Your Honor. First -- first, this Court's decision in  
16 Levine is inconsistent with that sweeping reading --

17 JUSTICE BREYER: No, because Levine involves  
18 the Wyeth case, right?

19 MR. BOGRAD: Yes. I'm sorry, I --

20 JUSTICE BREYER: No. The -- the difference  
21 there is the difference that the SG points out: There  
22 is a broad-ranging obligation for the initial drugmaker  
23 to tell the FDA all kinds of things and change the  
24 warnings. But here the FDA tells us they have no power  
25 to change their warnings. They can't, unlike Levine.

1 They have to copy the original maker. So -- I'm -- I'm  
2 just referring there to the whole SG brief.

3 MR. BOGRAD: Your Honor, let me respond to  
4 that in -- in two ways. First --

5 JUSTICE BREYER: Be sure you answer, please,  
6 my original question.

7 MR. BOGRAD: I -- I will, Your Honor.

8 The -- to focus first on the CBE issue, one  
9 of the things this Court noted in Levine is that even  
10 under the CBE process, the ultimate decision about  
11 whether the labeling is changed rests with the FDA, not  
12 with the manufacturer. The -- the fundamental issue in  
13 Levine was that the primary responsibility for labeling  
14 rested with the manufacturer, not with the agency,  
15 subject to the agency's review. And we don't dispute  
16 that the agency has the right to review and can reject a  
17 label.

18 The -- what was at the core and what this  
19 Court cited, although the -- the number has changed in  
20 Wyeth v. Levine, is the obligation under 21 CFR  
21 201.57(e), which you call 201.80(e) because they -- they  
22 renumbered it -- that the label warnings shall be  
23 revised as soon as there's reasonable evidence of an  
24 association of a serious hazard with the drug.

25 The government says, and the regulatory

1 structure makes clear, that that provision applies with  
2 full force to generic drug manufacturers, not just to  
3 name-brand drug manufacturers. It is the regulatory  
4 implementation of the obligation under the Federal  
5 misbranding statute, 21 U.S.C. 352(f)(2) that says you  
6 can't sell a drug that doesn't have adequate warnings  
7 about its risks.

8           So, when you're -- when the manufacturer is  
9 confronted with information that the warnings on its  
10 drug are not adequate, it -- the way it -- the way it  
11 should respond is by immediately going to the FDA and  
12 saying to the agency: We have this new information; we  
13 ask you, not that we want a different warning from the  
14 name brand, but we ask you to approve a stronger warning  
15 on both the name-brand product and its generic  
16 equivalents.

17           CHIEF JUSTICE ROBERTS: But what happens --

18           MR. BOGRAD: And had they done so, we would  
19 know -- one of two things would have happened. Either  
20 the agency would have approved the warning, stronger  
21 warnings would have been given and our clients -- my  
22 clients likely would not have been injured; or they  
23 would have said, no, we don't think there's sufficient  
24 information to justify this warning.

25           CHIEF JUSTICE ROBERTS: How long does it

1 take -- how long typically does it take the FDA to  
2 respond to a request from a generic manufacturer that  
3 it -- it ask the branded manufacturer to change the  
4 label?

5 MR. BOGRAD: Your Honor, as you just heard  
6 from Mr. Lefkowitz, generic manufacturers typically  
7 haven't been fulfilling this obligation and have not  
8 been asking the agency. But the latest data from the  
9 agency, and this is from its -- its web site, is that  
10 under -- they've been publishing performance data since  
11 2007, and they now say that safety labeling changes,  
12 which are the labeling changes required under FD --  
13 under FDA, are processed typically in a matter of  
14 months, 94 percent within 3 months.

15 CHIEF JUSTICE ROBERTS: Are those the ones  
16 that are submitted by generic manufacturers?

17 MR. BOGRAD: They're -- they are -- they  
18 could be ones submitted by generic manufacturers. Those  
19 are ones where the information that comes to the agency  
20 triggers a -- a labeling revision process.

21 JUSTICE KENNEDY: Does the -- does the --

22 CHIEF JUSTICE ROBERTS: -- whether about --

23 MR. BOGRAD: I'm sorry, what was that?

24 CHIEF JUSTICE ROBERTS: I was just going to  
25 ask, does the FDA give you an up or a down, or does it

1 just not take action sometimes if you submit one of  
2 these requests?

3 MR. BOGRAD: Your Honor, my understanding --  
4 there were certainly procedures available that would  
5 have required an up-or-down: The citizens petition  
6 process, for example, the supplement process, for  
7 example. The -- what -- the government has represented  
8 that even if the request came in a more informal form,  
9 the government would nevertheless take a request for a  
10 -- a labeling change to reflect a serious inadequacy in  
11 label warning seriously and act on it promptly.

12 JUSTICE SCALIA: Just so I understand what  
13 you've said, this 3-month turnaround that you mentioned,  
14 they are all requests from labeled manufacturers, right?

15 MR. BOGRAD: No, Your Honor, these are --  
16 these are actually --

17 JUSTICE SCALIA: I thought you said that  
18 generic manufacturers don't make any requests.

19 MR. BOGRAD: I -- they could be -- they  
20 could be from name-brand companies; they could be from  
21 private citizens.

22 JUSTICE SCALIA: Oh, okay.

23 MR. BOGRAD: It's whenever the agency  
24 becomes aware of information.

25 JUSTICE SCALIA: Oh, I see.



1                   MR. BOGRAD: But the agency also processes  
2 supplement requests, according to its web site, in 97  
3 percent of the cases or something, within 4 months.  
4 It's not -- it's -- it is a matter of months, not -- not  
5 years.

6                   JUSTICE SOTOMAYOR: Can you, and I think  
7 that this is part of what your adversary has been  
8 talking about when he says we don't usually receive  
9 adverse incident reports; they go to the brand  
10 manufacturer. So tell me what you view as your main  
11 obligation. This is a little bit like what Justice  
12 Scalia was asking.

13                   You come in and you say there's a drug, it  
14 has an adverse effect, there should have been a warning  
15 about it because look at all of this literature, look at  
16 all of this proof --

17                   MR. BOGRAD: Uh-huh.

18                   JUSTICE SOTOMAYOR: -- that this drug is, in  
19 fact, in some way plausibly or otherwise causing this  
20 incident, and the label was inadequate to tell me not to  
21 do it. Is that your obligation completely? You don't  
22 have an obligation to show that this particular  
23 manufacturer knew that in some way?

24                   MR. BOGRAD: Well, under most -- under the  
25 law of most States, and this is true in both Louisiana

1 and Minnesota, there is a reasonableness element in a  
2 failure to warn claim, but it's -- the standard is "knew  
3 or should have known," so that the manufacturer --  
4 manufacturers are typically held to the -- to the  
5 knowledge of an expert in the field of the products they  
6 manufacture. And here the -- our contention has been  
7 that if the generic manufacturers had merely examined  
8 the publicly available FDA database of adverse event  
9 reports, and merely paid attention to reports in the  
10 published literature that had since 19 -- the early  
11 1990s had documented a serious association between  
12 long-term use of metoclopramide and tardive dyskinesia,  
13 they would have had more than sufficient information to  
14 say to the agency, we need a change here.

15 JUSTICE SCALIA: Does a generic manufacturer  
16 have to be an expert in the field in which it  
17 manufactures?

18 MR. BOGRAD: Under State law, yes, it does,  
19 Your Honor.

20 JUSTICE SCALIA: What does -- what does  
21 being an expert mean?

22 MR. BOGRAD: It means --

23 JUSTICE SCALIA: In this context, being an  
24 expert means being able to produce exactly the drug that  
25 has been approved by the FDA, right? You don't have to

1 be expert in anything else?

2 MR. BOGRAD: That's incorrect, Your Honor.

3 They have to be --

4 JUSTICE SCALIA: What else do they need?

5 MR. BOGRAD: They have to remain informed of  
6 the dangers posed by the products they sell. They have  
7 obligations --

8 JUSTICE SCALIA: That doesn't make them an  
9 expert. I'm talking about what expertise does -- does  
10 the company have to -- to possess. It surely has to  
11 possess the chemical expertise to produce exactly the  
12 product that the -- that the -- that has been approved  
13 by the FDA. What other expertise is necessary?

14 MR. BOGRAD: Well, Your Honor, one of their  
15 obligations under Federal law is to go to the agency  
16 every year and identify significant new information that  
17 would affect the safety or efficacy or labeling of their  
18 product, which means they have to have the capacity to  
19 evaluate information that is out there, and that --

20 JUSTICE SCALIA: I don't think that'd take  
21 any expertise. You have people who complain, I've taken  
22 -- I've taken your pill, and it -- it, you know, it's  
23 caused -- this is expertise? That's not what I normally  
24 think of. Whereas a drug manufacturer does, indeed,  
25 require expertise, conducting tests and knowing what

1 changes will produce what results and so forth; right?

2 MR. BOGRAD: No, Your Honor. In fact, in  
3 this particular context we're talking about a use that  
4 was never approved by the FDA. We're talking about use  
5 beyond 12 weeks, which had never been evaluated. So  
6 there's really no basis to assume that the name-brand  
7 manufacturer here had any more expertise --

8 JUSTICE BREYER: Suppose they had. Suppose  
9 that -- is a generic required to file adverse incident  
10 reports?

11 MR. BOGRAD: Yes, they are, Your Honor.

12 JUSTICE BREYER: Okay. Now, imagine a  
13 company that files every adverse incident report,  
14 complies completely; period. Now, in your view does it  
15 have an additional obligation?

16 MR. BOGRAD: Yes, it does, Your Honor.

17 JUSTICE BREYER: And what is that?

18 MR. BOGRAD: It has an obligation under  
19 201.57(e) to initiate a label change --

20 JUSTICE BREYER: Okay.

21 MR. BOGRAD: -- process whenever it has  
22 reasonable --

23 JUSTICE BREYER: Now, their argument is that  
24 in respect to their failure to do the first, that's  
25 Buckman. That is similar to Buckman.

1 MR. BOGRAD: All right. If we -- we were  
2 talking about --

3 JUSTICE BREYER: Now. And that's what I --  
4 now, as to the second, it just doesn't add anything.  
5 The FDA has all that information.

6 MR. BOGRAD: Oh, that's -- that's incorrect,  
7 Justice Breyer.

8 JUSTICE BREYER: All right. Now, why is it?

9 MR. BOGRAD: It's -- well, as this Court  
10 said in *Levine*, the FDA has 11,000 drugs it needs to  
11 monitor and stay on top of, and it doesn't have the  
12 resources necessary to pay attention to every adverse  
13 event report it gets and every report that is published  
14 in the scientific literature. The reason that  
15 manufacturers bear the primary responsibility is because  
16 they -- they need to trigger the FDA's focus on a  
17 particular issue here. Here this information was  
18 available since the mid '90s.

19 JUSTICE BREYER: Your basic argument, I'm  
20 getting this now, that -- I think -- is that the  
21 failure is, where State law has a right to enter, is to  
22 require them to keep track of adverse incidents and  
23 other things in the -- and do their best to change the  
24 label, which will consist of going to the FDA, likely,  
25 and asking them to change.

1 MR. BOGRAD: Exactly, Your Honor. Their  
2 obligation -- their obligation under State law is to  
3 provide a warning. What they should have done, and if  
4 you take -- what they should have done is go to the FDA  
5 and ask the FDA to approve a stronger warning. If the  
6 FDA had said no, they would have a preemption.

7 CHIEF JUSTICE ROBERTS: Counsel --

8 JUSTICE ALITO: Suppose a generic -- suppose  
9 that the FDA issued a rule that says a generic drug  
10 manufacturer has no obligation to request a change in  
11 labeling. Could a generic drug manufacturer be held  
12 liable on a failure to warn claim on the theory that it  
13 could have lobbied the FDA to change the rule that says  
14 that the generic drug manufacturer has no obligation to  
15 ask for a change in labeling?

16 MR. BOGRAD: I -- I don't have an immediate  
17 answer to that, Justice Alito. The -- the -- the State  
18 -- the -- I -- the question is whether there would be a  
19 direct conflict between State and Federal law. It seems  
20 to me unless -- I'm sorry. Oh, that's the 5 minute  
21 light.

22 Unless the --

23 JUSTICE ALITO: Isn't that why -- isn't that  
24 where your theory leads?

25 MR. BOGRAD: My -- my theory leads to the --

1 to the proposition that, unless Federal law precludes  
2 them from -- from going to the process of strengthening  
3 their warning label, then the State may legitimately  
4 enforce its obligation to protect its citizens' health  
5 and safety. I think it's important in this regard --

6 JUSTICE ALITO: But your theory is that they  
7 have a duty to pursue an informal process that is  
8 nowhere provided for under the FDA rules; and so I don't  
9 -- so it's a duty to lobby the FDA basically to change  
10 the rules, isn't that right?

11 MR. BOGRAD: Justice Alito, well, as you  
12 know, we disagree with the government about whether  
13 certain formal processes were available. But --

14 JUSTICE ALITO: Assuming that they're  
15 correct in their interpretation of their own  
16 regulations.

17 MR. BOGRAD: But assuming -- but -- but if  
18 we're talking -- but there may not be a formal process,  
19 but there is a formal obligation, both under statute,  
20 not to sell a misbranded drug, and under regulation, to  
21 revise your labeling as soon as there's reasonable  
22 evidence of an association of a serious hazard with the  
23 drug. And I think it's --

24 JUSTICE KENNEDY: What is your -- what is  
25 your explanation for why Buckman isn't applicable here?

1                   MR. BOGRAD: Because, Your Honor, this is --  
2 and I should start by saying that in Buckman there was  
3 -- the suit was not against the manufacturer; the suit  
4 in Buckman was against a consultant that -- that helped  
5 the manufacturer get FDA approval. There was a separate  
6 product liability action against the manufacturer that  
7 had already been litigated and settled.

8                   The -- Buckman said: We're not talking  
9 about traditional causes of action, State law causes of  
10 action like in Lohr, or like in -- or as this Court  
11 again said in Wyeth v. Levine; we're talking about a  
12 case where the whole centrality of the claim is premised  
13 on the relationship between the company -- or the  
14 defendant and the agency.

15                   This is not that case. We're -- this case  
16 is about the -- the duty that the company owes to my  
17 clients and their doctors to provide them with adequate  
18 warnings. That duty, which is -- has been recognized by  
19 this Court innumerable times, complements the FDA  
20 statutory scheme by creating incentives for companies  
21 like the Petitioners to --

22                   JUSTICE KENNEDY: Well, the suit was brought  
23 by the injured person in Buckman.

24                   MR. BOGRAD: But --

25                   JUSTICE KENNEDY: And it's similar in that



1 respect. And in Buckman there was a -- a formal  
2 relationship which did not permit the cause of action,  
3 and it seems to me you could at least argue that a  
4 fortiori there should be no cause of action when there  
5 an informal relationship.

6 MR. BOGRAD: I -- I'm not sure I follow the  
7 a fortiori point in this context, Your Honor. But in  
8 Buckman there was no relationship whatsoever between the  
9 consultant, the Buckman Company, and the injured person.  
10 The Buckman Company's dealing were -- had been  
11 exclusively with the agency.

12 They had had no dealing whatsoever -- they  
13 had not failed to warn. That's why we -- the plaintiffs  
14 had created this bizarre cause of action, and it's -- we  
15 think it's a wholly distinguishable case.

16 I think it's important to remember, first  
17 off, the world in which we live today. 70 percent of  
18 all prescriptions are filled with generic drugs. A  
19 third of generic drugs no longer have name-brand  
20 competitors at all, because the economic -- because the  
21 name brands have withdrawn from the market, so that --

22 JUSTICE SCALIA: Somebody has been appointed  
23 in all those cases to sort of carry the flag, right?

24 MR. BOGRAD: Somebody has been appointed to  
25 be the reference-listed drug. They have not been

1 appointed to have obligations distinct from the other  
2 generic companies as far as updating label claims.

3 JUSTICE SCALIA: Don't they have a distinct  
4 obligation to propose labeling changes when they -- when  
5 they think they're necessary?

6 MR. BOGRAD: I -- Your Honor, that would be  
7 a question better directed to Mr. Kneedler, but I don't  
8 believe -- I don't believe that there's a -- there's a  
9 difference.

10 Any -- we have a system today where every  
11 State has a drug substitution law that drives  
12 prescriptions to be filled with generics rather than  
13 name-brand products. We have a system where Medicare,  
14 Medicaid, and insurers force or encourage the  
15 substitution of generics through -- through price  
16 incentives. If generics are not responsible, in many of  
17 these cases no one is responsible.

18 The -- we -- the position that the generics  
19 are proposing here is one in which they would be immune  
20 from liability for selling a product with inadequate  
21 warnings, even though the name-brand company selling the  
22 same drug with the same warnings would be liable. There  
23 is no suggestion anywhere in the record, Your Honor,  
24 anywhere in the legislative history or in the text of  
25 Hatch-Waxman or in FDA regulations that that distinction

1 was ever contemplated by Congress, that it was ever  
2 sanctioned by the FDA.

3 I would like to make one final point, Your  
4 Honor. In Bates -- and I apologize; we didn't address  
5 this specifically in our briefs, because I didn't notice  
6 it until later -- the statutory scheme at issue in  
7 Bates, under FIFRA, was almost identical to the -- I'm  
8 sorry. I see my time has expired. May I finish my  
9 point, Your Honor?

10 CHIEF JUSTICE ROBERTS: You can finish your  
11 sentence.

12 JUSTICE SCALIA: Make it a long sentence,  
13 with a lot of "ands."

14 (Laughter.)

15 MR. BOGRAD: There was no CBE equivalent in  
16 Bates in the -- under the FIFRA statutory scheme, and  
17 yet this Court upheld against a motion to dismiss on  
18 preemption grounds a failure to warn claim, admittedly  
19 under an express preemption provision. This Court  
20 upheld a claim against a pesticide manufacturer even  
21 though the pesticide manufacturer could not have changed  
22 its warning without prior EPA approval, exactly the same  
23 situation that confronts the generics here.

24 Thank you, Your Honor.

25 CHIEF JUSTICE ROBERTS: Thank you, counsel.

1 Mr. Kneedler.

2 ORAL ARGUMENT OF EDWIN S. KNEEDLER,  
3 ON BEHALF OF THE UNITED STATES, AS AMICUS CURIAE,  
4 SUPPORTING THE RESPONDENTS

5 MR. KNEEDLER: Mr. Chief Justice, and may it  
6 please the Court:

7 The Hatch-Waxman Amendments were designed to  
8 facilitate the entry of generic drugs onto the market.  
9 They do not absolve a manufacturer of his  
10 responsibilities after entry onto the market to maintain  
11 the safety of the drug and the adequacy of -- of the  
12 label.

13 JUSTICE KAGAN: Mr. Kneedler, suppose  
14 that I'm not sure I agree with you that there is an  
15 obligation of the kind that you say for a generic drug  
16 manufacturer to come forward and request a label, but I  
17 do think that there's an opportunity for that  
18 manufacturer to come forward and ask the FDA to revise a  
19 label. If that's the way I read the law, does your  
20 result follow? Do you think, then, that State law  
21 claims should be able to go forward?

22 MR. KNEEDLER: Yes, we do, because the  
23 ultimate question in the preemption case is whether  
24 there's a conflict. And if the -- if the manufacturer  
25 has an opportunity to come to FDA, even if -- even if

1 the Court were to conclude it didn't have an obligation  
2 to do so, if it had the opportunity to do so and did  
3 nothing when -- when dramatic evidence, you know, by  
4 hypothesis, came to its attention, it wasn't prohibited  
5 from doing so. There was no --

6 JUSTICE SCALIA: Well, I assume that the  
7 patient's physician has the same opportunity. Anybody  
8 could go to the FDA and say this label ought to be  
9 changed, right? So the -- the physician taking care of  
10 this plaintiff didn't -- had the opportunity to go to  
11 the FDA and didn't. Is there a cause of action against  
12 him?

13 MR. KNEEDLER: Well, the -- the FDCA does  
14 not regulate the responsibilities of physicians in those  
15 situations. The whole point of the labeling --

16 JUSTICE SCALIA: I'm not talking about what  
17 the -- the FDCA regulation. We're talking about what  
18 State law would allow, and State law would allow a suit  
19 against the physician because he did not take advantage  
20 of the opportunity to go to the FDA and propose a label  
21 change.

22 MR. KNEEDLER: No, I think State law  
23 would -- would impose an obligation on the physician to  
24 adequately advise the patient, but what's so different  
25 is, the physician relies upon the labeling. If the

1 physician has the information, the physician, on his own  
2 initiative, could tell the patient or warn the patient  
3 about what's going on without -- without having to go to  
4 FDA at all.

5 CHIEF JUSTICE ROBERTS: So if your theory of  
6 the case is accepted, this is what will happen: Every  
7 time a generic manufacturer gets an adverse incident  
8 report, it will send that on to the FDA, and there will  
9 be a boilerplate sentence at the end of it saying, We  
10 think you should consider revising the labels because of  
11 this, and then, under your theory, that manufacturer is  
12 completely protected from State suits?

13 MR. KNEEDLER: Several things. The  
14 manufacturer does, of course, have the obligation to  
15 furnish the adverse event information that it receives.

16 CHIEF JUSTICE ROBERTS: Sure.

17 MR. KNEEDLER: But if -- if the standard in  
18 regulation 57(e) is met, where there's evidence,  
19 reasonable evidence, of a serious hazard, it has an  
20 obligation --

21 CHIEF JUSTICE ROBERTS: Well, they're not  
22 going to take a chance. They're going to say, if you're  
23 the FDA, you look at it. We're just telling you what we  
24 know, and we think you ought to consider revising the  
25 label.

1 MR. KNEEDLER: But they are -- they are to  
2 propose -- in our view, are to propose a labeling  
3 change, which means that the --

4 CHIEF JUSTICE ROBERTS: Okay. We think you  
5 should revise the label; if you agree, this is what it  
6 should look like.

7 MR. KNEEDLER: Yes, and we don't -- we don't  
8 think it will lead to a flood of such requirements in  
9 the wake of this --

10 CHIEF JUSTICE ROBERTS: Does it lead to  
11 preemption?

12 MR. KNEEDLER: Pardon me?

13 CHIEF JUSTICE ROBERTS: Does it lead to  
14 preemption?

15 MR. KNEEDLER: If the -- if FDA rejected the  
16 request, there would -- there would be preemption,  
17 because FDA -- it would have been submitted to the  
18 expert agency, as we think is required.

19 CHIEF JUSTICE ROBERTS: Right. Wouldn't  
20 you -- if you were the generic company's lawyer, you  
21 would advise them to do that in every case, right?

22 MR. KNEEDLER: I don't think I -- I don't  
23 think in every case. I think it's -- if -- but here,  
24 here we have a situation where, at least according to  
25 the allegations, there were published studies of

1 long-term use of this product.

2 CHIEF JUSTICE ROBERTS: No, I know that's  
3 what this case is, but if -- a reasonable generic  
4 manufacturer would be worried about every case, and it  
5 would just add this boilerplate language at the end of  
6 every letter, and as I understand your theory, they  
7 would be protected.

8 MR. KNEEDLER: It's not just boilerplate  
9 evidence at the bottom of the -- as part of a letter.  
10 What the -- what the Federal Register notice told the  
11 manufacturer to do was to -- was to submit the proposal  
12 to FDA with supporting information. In other words,  
13 suppose it's the sort of submission that would -- that  
14 would be like --

15 JUSTICE SCALIA: That would be the -- the  
16 prologue -- the prologue to the rule said that, and the  
17 rule was never submitted for notice and comment. Is  
18 that what you're relying on, that prologue?

19 MR. KNEEDLER: Well, I -- I think, to put it  
20 in context, these were the regulations actually  
21 implementing the Hatch-Waxman statute, and there was a  
22 proposal to allow the manufacturers to deviate from  
23 the -- from the NDA holders' label and put their own on  
24 it. And the -- and FDA said, no, you can't do that, but  
25 what you should do is bring it to FDA, and FDA will



1 decide whether to change the labels for everyone.

2 And so this was part and parcel of the  
3 notice and comment rulemaking: How should -- how should  
4 a generic manufacturer deal with a situation where it  
5 has information that may deviate from the NDA  
6 holder's -- how should it --

7 JUSTICE ALITO: Has the FDA made any  
8 calculation of the economic consequences of imposing  
9 this duty on generic drug manufacturers? I don't know  
10 whether this is a good idea or not, but it does seem to  
11 me that it may significantly increase the costs for  
12 generic drug manufacturers, and therefore counteract one  
13 of the objectives of the statute, which was to provide  
14 generic drugs at a low cost.

15 MR. KNEEDLER: To my knowledge, FDA has not  
16 done an analysis. But it's important to understand the  
17 duty here derives from the misbranding provisions. A  
18 generic drug manufacturer is not exempt from the  
19 misbranding requirements of the act, which prohibit  
20 distributing a drug that does not have adequate --  
21 adequate warnings, and rule 57(e) requiring a  
22 manufacturer to propose a warning or to make a warning  
23 change if there is evidence of a serious hazard  
24 implements that misbranding requirement. So this is not  
25 an imposition by FDA. This is an underlying requirement

1 of the act.

2 I would --

3 JUSTICE SOTOMAYOR: Am I -- am I to  
4 understand -- and I think I am understanding you. There  
5 is a legal obligation in the statute to report adverse  
6 events. You're saying that the statute also requires  
7 every manufacturer, of whatever type, to monitor the  
8 safety of the drug they're selling? Is that what you're  
9 saying?

10 MR. KNEEDLER: State --

11 JUSTICE SOTOMAYOR: And if reasonable  
12 evidence, whether directly in their possession or in the  
13 marketplace --

14 MR. KNEEDLER: The -- the FDA regulations do  
15 not explicitly require monitoring of literature, but --  
16 but there's no conflict in State law imposing a duty to  
17 do that.

18 If I -- if I may just discuss Buckman for a  
19 minute, because --

20 JUSTICE SCALIA: How do you decide whether a  
21 generic manufacturer ought to have proposed a -- a  
22 labeling change?

23 MR. KNEEDLER: If the standard --

24 JUSTICE SCALIA: This is a generic  
25 manufacturer. He doesn't know anything about -- about

1 science. He knows how to replicate this pill exactly.  
2 That's all -- that's all he really knows.

3 Now, what is the test you're going to impose  
4 to -- to a jury to decide whether this generic  
5 manufacturer ought to have -- ought to have proposed a  
6 labeling change?

7 MR. KNEEDLER: It's the --

8 JUSTICE SCALIA: Is it -- is it, well, you  
9 know, if he had been as well armed scientifically as the  
10 original manufacturer of the labeled drug, he should  
11 have known or, you know, does this guy who graduated  
12 from high school and can replicate a pill, should he  
13 have known? What -- what's the --

14 MR. KNEEDLER: It's the standard in 57(e) if  
15 there's evidence of a serious hazard, we think State law  
16 can impose on a generic manufacturer which is putting a  
17 potentially dangerous product on the market the  
18 obligation to -- to investigate.

19 I would -- I would like to talk about  
20 Buckman for just a minute, please, because it's -- it's  
21 come up. Buckman is fundamentally different. There was  
22 no independent State law duty to warn at issue in  
23 Buckman. It was solely a tort based on lying to the  
24 FDA. It is a tort that depended entirely on the  
25 existence of the FDA.

1 CHIEF JUSTICE ROBERTS: And in the brief --  
2 and in the brief that you filed you said one of the  
3 concerns is that people are going to flood the FDA with  
4 all these warnings and -- and whatever, and that would  
5 interfere with the FDA's ability. Now you're telling  
6 me -- you -- you said when you started out that you  
7 think it's unlikely or you don't think it's likely. In  
8 your brief it said SG language you said we're not  
9 prepared to predict that a ruling would do this.

10 So, why is that a difference between those  
11 two cases?

12 MR. KNEEDLER: Well, Buckman was a situation  
13 of a collateral attack on a decision that had actually  
14 been made by FDA. There was no independent duty --  
15 State law or duty to warn, no relationship between the  
16 person submitting information to FDA. It was just a  
17 State making the tort to lie to the FDA, and you would  
18 have had the State regulating nothing but the  
19 relationship between the manufacturer and FDA.

20 Here State law is regulating the  
21 relationship between the manufacturer and -- and the  
22 patient through the doctor, and that's a traditional  
23 area of State regulation, duty to warn, and, Justice  
24 Kagan, I think you're right, the question then is  
25 whether there is an affirmative defense of -- of

1   preemption, and the preemption comes in.  It's very  
2   different from Buckman in that situation.

3                   It's up to the defendant to prove, it's not  
4   an element of the cause of action as in Buckman.  It's  
5   part of the defense for the defendant to prove that --  
6   that it is -- that the cause of action is preempted.

7                   And in our view it's not preempted if the  
8   standard in 57(e) is met to propose a labeling change  
9   that is an obligation that extends to all manufacturers  
10  generic or not.

11                   CHIEF JUSTICE ROBERTS:  Well, but it's  
12  not -- the regulation doesn't say propose a labeling  
13  change.  It says labeling shall be revised, and the one  
14  thing we know is that the generic manufacturer can't  
15  revise the labeling from the branded one.

16                   MR. KNEEDLER:  It can't revise the labeling,  
17  but that doesn't mean it can do nothing.  Impossibility  
18  preemption kicks in only when it's genuinely impossible,  
19  and if the manufacturer could go to FDA and propose a  
20  labeling change, it is not impossible for to it do that.  
21  At that point it's up to FDA and preemption would kick  
22  in.

23                   CHIEF JUSTICE ROBERTS:  Thank you,  
24  Mr. Kneedler.

25                   Mr. Lefkowitz, you have your 5 minutes

1 remaining.

2 REBUTTAL ARGUMENT OF JAY P. LEFKOWITZ

3 ON BEHALF OF THE PETITIONERS

4 MR. LEFKOWITZ: Thank you.

5 Mr. Kneedler has basically postulated a  
6 situation where we're going to have jury trials about  
7 whether a Federal duty to the FDA was breached. And  
8 it's interesting, he says that this isn't Buckman, but  
9 of course, Buckman involved the same duty not to sell a  
10 dangerous product, and the same issue of lack of  
11 disclosure to the FDA.

12 Now, he says it was a collateral attack, but  
13 actually that was the premise of Justice Stevens'  
14 concurrence, where Justice Stevens said I get to the  
15 same result for a different reason. What the Court said  
16 was nothing about a collateral attack.

17 JUSTICE SOTOMAYOR: Counsel, the difference,  
18 as I see it, is that they're not suing you for a failure  
19 to tell the FDA. They're suing you for a failure to  
20 tell them. It's you who are interposing a defense and  
21 saying I manufacture a dangerous drug, and I have no  
22 obligation to monitor and ensure that the label is  
23 accurate.

24 And what the government is saying, as I  
25 understand it is, no, you do. Yes, we understand you

1 want to sell more cheaply, but not at the cost of public  
2 health.

3 So what's wrong with that argument?

4 MR. LEFKOWITZ: Justice Sotomayor,  
5 respectfully, what's wrong with the premises, if they're  
6 claiming failure to warn, it's a very simple case of  
7 impossibility preemption. We couldn't warn, and the  
8 government's brief makes clear we had no ability to  
9 warn.

10 What the government is now doing is it's  
11 taking a regulation, 201.57, which doesn't say the word  
12 "ask" in it. It actually says "revise." And it says  
13 revise because it's a regulation written for brand  
14 manufacturers that have the CBE option available to  
15 them, and they are then trying to incorporate the words  
16 "duty to ask" through this brief without, as Justice  
17 Alito says, taking into any account through notice and  
18 comment rulemaking the effect of this.

19 Well, we know that there are over 1,600  
20 requests for labeling revisions pending at the FDA now,  
21 650 of them are pending for more than 6 months. And at  
22 the relevant time of this case, Your Honor, not only  
23 would we have had to ask the FDA, but then the FDA would  
24 have had to negotiate with the brand, because prior to  
25 the FDAAA amendments, the FDA couldn't order a brand to

1 change, so we would have had to make the request, the  
2 FDA would have had to negotiate the brand change, and  
3 then we would have had to follow.

4 JUSTICE KAGAN: Well, Mr. Lefkowitz, if you  
5 had asked, you would be in a different situation. If  
6 you had asked and the FDA had sat on it or was  
7 negotiating, then you could say, look, we've done all we  
8 can right now. But you're not in that situation. You,  
9 in fact, have not done all you can right now to change  
10 the label because you never wrote that letter.

11 MR. LEFKOWITZ: Your Honor, and again just  
12 to pick up on -- on what Chief Justice Roberts said and  
13 Justice Scalia said, we have done everything we are  
14 required to do, which is to provide all of the  
15 information about adverse reports that we have and all  
16 of the results of our investigations to the government.  
17 And if the government wants to impose a new duty through  
18 notice and comment rulemaking saying, and now we have a  
19 duty to ask for a label change, in addition --

20 JUSTICE GINSBURG: The government is taking  
21 the position that there's no clash between the  
22 government, the State, and Federal law. It's not saying  
23 that you commit some kind of Federal offense if you  
24 don't file this law. The government is saying, the  
25 question is preemption. Is there a clash between



1 Federal and State law to traditional Federal warn you  
2 have a preemption defense if you tell the FDA, and if  
3 either the FDA does nothing or tells you, no, we're not  
4 going to change the label?

5 MR. LEFKOWITZ: Your Honor, Buckman makes  
6 very clear that a State trying to regulate disclosure  
7 obligations to the Federal Government is simply off  
8 limits, and in fact --

9 JUSTICE GINSBURG: The -- the -- Buckman was  
10 about, was a -- it was a very odd case to be brought  
11 under State law for fraud on a Federal agency.

12 MR. LEFKOWITZ: Your Honor, it was a case  
13 brought by a plaintiff who was injured claiming that the  
14 company had not made proper, adequate disclosures to the  
15 FDA. It's the same thing here, and I just want to  
16 point --

17 JUSTICE SCALIA: Mr. Lefkowitz, do you agree  
18 with Justice Ginsburg's characterization of the  
19 government's position? I thought the government was  
20 saying that there was an obligation on the part of the  
21 generics to propose changes.

22 MR. LEFKOWITZ: Absolutely. What they are  
23 saying --

24 JUSTICE SCALIA: Otherwise, the government  
25 would be saying you have an obligation to lobby, and I

1 don't think they're saying that.

2 MR. LEFKOWITZ: Well, in a sense the  
3 government is really saying we -- to lobby or to propose  
4 changes is a -- is a very fine distinction. Clearly,  
5 what the government is now saying is they are reading a  
6 regulation that they've always interpreted as being only  
7 applicable to brand companies and saying now it's  
8 applicable to their companies and it incorporates new  
9 language that says not just revise but ask.

10 CHIEF JUSTICE ROBERTS: Thank you,  
11 Mr. Lefkowitz. Counsel, the case is submitted.

12 (Whereupon, at 11:05 a.m., the case in the  
13 above-entitled matter was submitted.)

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