IN THE SUPREME COURT OF THE UNITED STATES

PLIVA, INC., ET AL.
Petitioners : No. 09-993
v.
GLADYS MENSING

and

ACTAVIS ELIZABETH, LLC,
Petitioner : No. 09-1039
v.
GLADYS MENSING

and

ACTAVIS, INC.,
Petitioner : No. 09-1501
v.
JULIE DEMAHY

Washington, D.C.

Wednesday, March 30, 2011

The above-entitled matter came on for oral

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

APPEARANCES:

JAY P. LEFKOWITZ, ESQ., New York, New York; on behalf of Petitioners.

LOUIS M. BOGRAD, ESQ., Washington, D.C.; on behalf of Respondents.

EDWIN S. KNEEDLER, ESQ., Deputy Solicitor General, Department of Justice, Washington, D.C.; on behalf of the United States, as amicus curiae, supporting Respondents.

C O N T E N T S

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

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

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

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

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

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

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

of discussion here?

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

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

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

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

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

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

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

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

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

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

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

MR. LEFKOWITZ: Absolutely not, Justice

Sotomayor.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

manufacturers to report.

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

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

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

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

But critically, what the FDA has said is:

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

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

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

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

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

MR. LEFKOWITZ: Well, no. We --

JUSTICE BREYER: Or is that a point in dispute?

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

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

question --

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

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

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

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

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

JUSTICE BREYER: What I wonder -- see, I

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

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

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

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

JUSTICE BREYER: Yeah.

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

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

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

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

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

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

CHIEF JUSTICE ROBERTS: To disclose -- I'm

sorry. To disclose to the FDA?

MR. LEFKOWITZ: Correct.

JUSTICE SCALIA: To disclose to the FDA.

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

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

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

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

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

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

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

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

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

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

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

JUSTICE SOTOMAYOR: Counsel, do you think --

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

MR. LEFKOWITZ: It was a medical device manufacturer.

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

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

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

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

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

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

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

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

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

MR. LEFKOWITZ: That is correct, Your Honor.

JUSTICE GINSBURG: And at least for those

people, they have the means.

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

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

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

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

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

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

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

CHIEF JUSTICE ROBERTS: Thank you, Mr. Lefkowitz.

Mr. Bograd.

ORAL ARGUMENT OF LOUIS M. BOGRAD

ON BEHALF OF THE RESPONDENTS

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

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

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

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

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

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

forward rests with the agency.

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

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

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

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

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

MR. BOGRAD: Your Honor --

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

MR. BOGRAD: Your Honor --

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

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

JUSTICE SCALIA: No.

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

JUSTICE SCALIA: I would say --

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

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

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

JUSTICE BREYER: It appears also that the --

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

MR. BOGRAD: Well --

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

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

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

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

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

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

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

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

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

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

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

The government says, and the regulatory

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

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

CHIEF JUSTICE ROBERTS: But what happens --

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

CHIEF JUSTICE ROBERTS: How long does it

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

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

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

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

JUSTICE KENNEDY: Does the -- does the --

CHIEF JUSTICE ROBERTS: -- whether about --

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

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

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

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

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

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

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

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

JUSTICE SCALIA: Oh, okay.

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

JUSTICE SCALIA: Oh, I see.

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

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

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

MR. BOGRAD: Uh-huh.

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

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

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

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

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

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

MR. BOGRAD: It means --

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

be expert in anything else?

MR. BOGRAD: That's incorrect, Your Honor. They have to be --

JUSTICE SCALIA: What else do they need?

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

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

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

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

changes will produce what results and so forth; right?

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

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

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

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

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

JUSTICE BREYER: And what is that?

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

JUSTICE BREYER: Okay.

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

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

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

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

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

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

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

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

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

CHIEF JUSTICE ROBERTS: Counsel --

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

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

Unless the --

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

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

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

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

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

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

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

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

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

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

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

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

MR. BOGRAD: But --

JUSTICE KENNEDY: And it's similar in that

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

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

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

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

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

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

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

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

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

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

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

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

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

CHIEF JUSTICE ROBERTS: You can finish your sentence.

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

(Laughter.)

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

Thank you, Your Honor.

CHIEF JUSTICE ROBERTS: Thank you, counsel.

Mr. Kneedler.

ORAL ARGUMENT OF EDWIN S. KNEEDLER,

ON BEHALF OF THE UNITED STATES, AS AMICUS CURIAE,

SUPPORTING THE RESPONDENTS

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

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

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

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

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

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

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

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

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

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

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

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

CHIEF JUSTICE ROBERTS: Sure.

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

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

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

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

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

CHIEF JUSTICE ROBERTS: Does it lead to preemption?

MR. KNEEDLER: Pardon me?

CHIEF JUSTICE ROBERTS: Does it lead to preemption?

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

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

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

long-term use of this product.

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

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

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

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

decide whether to change the labels for everyone.

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

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

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

of the act.

I would --

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

MR. KNEEDLER: State --

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

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

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

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

MR. KNEEDLER: If the standard --

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

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

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

MR. KNEEDLER: It's the --

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

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

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

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

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

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

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

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

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

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

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

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

CHIEF JUSTICE ROBERTS: Thank you, Mr. Kneedler.

Mr. Lefkowitz, you have your 5 minutes

remaining.

REBUTTAL ARGUMENT OF JAY P. LEFKOWITZ

ON BEHALF OF THE PETITIONERS

MR. LEFKOWITZ: Thank you.

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

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

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

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

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

So what's wrong with that argument?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

don't think they're saying that.

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

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

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