PART II – WARNING: FEDERAL PREEMPTION MAY BE GETTING WORSE

By Dustin B. Herman, Esq.

Part I of this article appeared (here) in the July 2018 OAJ Quarterly. I was hoping there wouldn't be a need for a Part II.

Alas, the Supreme Court accepted cert in the Fosamax litigation (*Merck v. Albrecht, et al.*) and will be revisiting the issue of whether, and under what circumstances, failure-to-warn claims against brand name drug manufacturers are impliedly preempted. *See Wyeth v. Levine*, 555 U.S. 555 (2009) (finding failure-to-warn suits against brand name drug manufacturers are *not* impliedly preempted). Oral arguments in *Albrecht* took place on January 7, 2019. The transcript can be found here, and you can listen to the entire oral argument here.

It's anybody's guess as to how it will play out. Before getting to the highlights of the oral argument, here is a brief recap of Part I.

Wyeth v. Levine and the "Clear Evidence" Exception

Under the FDA regulations, brand name drug manufacturers have the power to update their labels and warn doctors about newly discovered risks associated with a drug – *without getting prior approval from the FDA*. Thus, the Court in *Wyeth* held, even if a jury finds a warning label to be inadequate under state law, there is no conflict between state law and federal law (and therefore no preemption) because it was not "impossible" for the drug manufacturer to comply with both state law (i.e., having a stronger warning) and federal law. However, *Wyeth* noted an exception for situations in which there is "clear evidence" the FDA would have rejected a change to the label. *Wyeth*, at 571.

The Fosamax Litigation and the "Clear Evidence" Exception

Fosamax is a brand name drug. As such, Merck did not need prior approval from the FDA to update its label. It could have just done so and asked the FDA for approval after the fact. But when Merck learned of new evidence of an association between Fosamax and atypical femur fractures, Merck decided not to unilaterally update its label. Instead, Merck sent the FDA a proposed labeling change and asked for permission to update its label accordingly – but the FDA rejected the proposed change in a so-called "Complete Response Letter."

Plaintiffs claim that the proposed (and rejected) labeling change was itself an inadequate (and misleading) warning because it referred to "atypical femur fractures" as mere "stress fractures" – and that the FDA's Complete Response Letter was simply rejecting the proposed warning label *as worded* rather than rejecting any new warnings whatsoever.[1]

[1] Indeed, in 2010 when the FDA required Merck to change its label to warn about these fractures, the FDA again rejected Merck's request to use the "stress fracture" language, stating, "the term 'stress fracture' represents a minor fracture and this would contradict the seriousness of the atypical femoral

Merck says, no, the FDA was not simply quibbling with the wording, but rather was rejecting *any* increased warning related to atypical femur fractures. The difference is a big deal because if the FDA prevented Merck from adding any warnings about these fractures (whatever you call them) then plaintiffs' claims would be preempted under the "clear evidence" exception in *Wyeth*.

The whole case, then, turns on what the FDA said in its "Complete Response Letter" – or more accurately – it turns on the Court's interpretation of what the FDA's letter meant. Merck says the letter made it impossible to comply with state law; plaintiffs say it did not.

Oral Argument Highlights

Justice Gorsuch surprised everyone with an early question to Merck, saying:

> Reading the statute your way, do we create a moral hazard that encourages manufacturers to supply the FDA with a lot of information, overwhelming with data, but maybe not the most artfully drafted and maybe deliberately inartfully drafted warning that it thinks is reasonably calculated to be refused, so that it can avoid having to shoulder or bear its own costs [or] internalize its own costs of negligence. (Tr. 13:8-17)

Spoiler alert: Merck said the Court should not be concerned. It argued that because the FDA said it's not concerned about creating a moral hazard, the Court should not be concerned either.

In addition to the moral hazard issue, another major problem is that the FDA's Complete Response Letter is far from a model of clarity. Even the **Deputy Solicitor General**, speaking for the FDA and arguing in support of Merck's position, agreed that the Complete Response Letter was ambiguous on its face:

> [I]t would obviously have been better if the letter had stated without ambiguity the reason we are rejecting your proposed addition to the warnings and precaution section is that we don't think there is sufficient evidence of causation to warrant inclusion of this health risk in this particular portion of the label. That would have been better. (Tr. 23:21-24:5)

Nevertheless, the Deputy Solicitor General maintained that the ambiguous letter can still be given preemptive effect, and that, "failing an unambiguous letter, the Court should construe the letter in light of Merck's submission, in light of the surrounding statutory and regulatory scheme, and in light of FDA's subsequent actions." (Tr. 24:14-21)

Justice Sotomayor jumps all over this and questions why an ambiguous letter should be given preemptive effect – "given that we're already creating something that doesn't exist, impossibility preemption." (Tr. 25:3-6)

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fractures associated with bisphosphonate use." *In re Fosamax*, 852 F.3d 268, 279 (3d. Cir. 2017) (quoting FDA's response letter to Merck).

Justice Breyer, per usual, takes a pragmatic approach to the issue. He is willing to look at the entire context of the interaction between Merck and the FDA to determine what Merck was allowed to do. Unfortunately, his comments were not helpful for the plaintiffs:

> [D]rugs are important to people. They cure millions, or thousands anyway, of people who need to be cured or helped . . . and at the same time there will be a smaller subset that can be hurt, so our solution to that is labels. . .
>
> [I]f you go too far in allowing the tort jury to find mislabeling by not including things, you are hurting the vast majority of [people] who can benefit from this medicine.
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> On the other hand, if you don't go far enough, you will hurt that minority. Now that's the general framework in which I'm trying to figure out the answer to the question. And that's why Justice Gorsuch's question [about creating a moral hazard] was -- was quite relevant.
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> All the earmarks here are that Merck took this as a letter [in which the FDA was] saying we're not certain enough this is really going to hurt people and we don't want you to put it on.
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> Now, obviously, somebody must have picked up the phone when they got that letter and they must have phoned somebody in FDA and say: Do you really mean that? What do you mean? Because I can change those words, "stress fracture," in two seconds. Or do you mean you don't know enough about it? Now the appointment of the later task force suggests that they felt they didn't know enough about it, and, therefore, Merck couldn't have done it. (Tr. 40:9-41:19)

David Frederick (for the Plaintiffs) responded:

> Let's look at what the scientists knew. Merck's scientists -- and this is on page 515 of the Joint Appendix -- they knew exactly what the FDA was rejecting. They said in their internal back and forth the FDA doesn't like our “stress fracture” wording. (Tr. 42:3-10)
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> They say “[FDA] believes that 'stress fractures' may not be clearly related to atypical subtrochanteric fractures.” So the scientists are interpreting the complete response letter to say the "stress fracture" language that we offered is inadequate. (Tr. 45:19-25)

Mr. Frederick argued strenuously against giving preemptive effect to a letter written by some individual person at the FDA:

> Are we going to let Dr. Monroe, who is five layers down from the only Presidentially-appointed person at the FDA, write a letter that displaces huge swaths of state law? (Tr. 37:6-10)
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> [A]s a matter of preemption law where we're invoking the Supremacy Clause of the United States Constitution to say that federal law is going to

> displace state law, we shouldn't be engaging in some musings or some interpretation about a low-level civil servant at the FDA. (Tr. 44:19-25)

Continuing, Mr. Frederick pointed out that even Dr. Lane (a consultant for Merck in 2008 and the person who coined the term "Fosamax fracture") wrote an amicus brief in support of *plaintiffs* explaining why referring to atypical femur fractures as stress fractures was "a medically inaccurate definition" – and that the Merck scientists knew it was medically inaccurate at the time. (Tr. 47:20-21)

Justice Kagan raised some other practical questions like: What happens if the FDA doesn't know yet whether an updated warning is needed? What if the FDA doesn't have enough information? What happens in the mean time? Who is responsible for the label? Plaintiffs argue in their briefs and throughout oral argument that 21 U.S.C. § 355(o)(4)(I) is the key regulation that makes clear it is the manufacturer's responsibly to have an adequate label. Indeed, drug manufacturers are in the best position to monitor the safety of their drug and update the warnings accordingly. The goal is to get the information into the hands of the doctors – so doctors can have informed conversations with their patients about the benefits and potential risks of a drug.

Justice Breyer then brought up another practical concern, saying, "I don't really see how we're going to benefit by 50 different states really giving different signals to the manufacturers, and I can see a lot of ways in which, from a health point of view, we're going to lose." (Tr. 51:6-11) This is the same issue Justice Breyer wrestled with in his concurrence in *Wyeth*.[2] At least he acknowledged Justice Gorsuch's moral hazard concern as "quite relevant." (Tr. 41:4)

So How Will It Play Out?

Nothing in the texts of the relevant federal statutes, the FDA regulations, or the FDA's May 2009 Complete Response Letter would have made it impossible for Merck to change its label in the way plaintiffs argue was necessary to comply with state law. Thus, to find preemptive effect, the Court would have to look beyond the relevant texts and interpret the FDA's conduct in light of a whole host of other communications, actions, and inactions on the part of both Merck and the FDA (which themselves require interpretation based upon the context, and on and on).

But Justice Thomas, the good textualist that he is, fully rejects this extratextual approach. Indeed, in his concurring opinion in *Wyeth*, Justice Thomas disavowed the entire doctrine of "purposes and objectives" preemption for this very reason,[3] and voted

[2] "The FDA may seek to determine whether and when state tort law acts as a help or a hindrance . . . [and] when labeling requirements serve as a ceiling as well as a floor. And it is possible that such determinations would have pre-emptive effect." *Wyeth*, 555 U.S. at 582 (J.Breyer concurring).

[3] "The origins of this Court's "purposes and objectives" pre-emption jurisprudence in *Hines,* and its broad application in cases like *Geier,* illustrate that this brand of the Court's pre-emption jurisprudence facilitates freewheeling, extratextual, and broad evaluations of the "purposes and objectives" embodied within federal law. This, in turn, leads to decisions giving improperly broad pre-emptive effect to judicially manufactured policies, rather than to the statutory text enacted by Congress pursuant to the Constitution and the agency actions authorized thereby. Because such a sweeping approach to pre-emption leads to

in the plaintiff's favor because the text of the FDA regulations did not make it impossible for a brand name drug manufacturer to comply with state law.

My optimistic hope is that Justice Thomas will stay intellectually consistent and find no preemptive effect here. I also hope that Justice Gorsuch, another good textualist, will join him. If so, plaintiffs might just win.

It will be several months before the Court issues its opinion. Stay tuned for Part III.

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the illegitimate—and thus, unconstitutional—invalidation of state laws, I can no longer assent to a doctrine that pre-empts state laws merely because they "stan[d] as an obstacle to the accomplishment and execution of the full purposes and objectives" of federal law, *Hines,* 312 U.S., at 67, 61 S.Ct. 399, as perceived by this Court." *Wyeth,* at 604 (J. Thomas, concurring).