

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

IN RE: Seroquel Products Liability Litigation

MDL DOCKET NO. 1769

This Document Relates to: All Cases

ASTRAZENECA'S REPLY BRIEF ON FEDERAL PREEMPTION

AstraZeneca's motion for partial summary judgment based on federal preemption presents the Court with two basic questions: (i) what are the standards for federal preemption of state law failure-to-warn claims after *Wyeth v. Levine*, 129 S. Ct 1187 (2009), and (ii) has AstraZeneca met those standards for Seroquel for the specific state law claims challenged here.

The standards, post-*Levine*, are whether there is "clear evidence" that FDA "would not have approved" the "stronger warning" Plaintiffs seek to impose, *id.* at 1198-99, or whether imposition of such a state law requirement would "frustrate the achievement of congressional objectives," *id.* at 1204. AstraZeneca has met these standards. For the narrowly targeted claims and time periods at issue here, AstraZeneca has presented clear evidence that FDA, on its initiative, evaluated all of the relevant evidence and implemented a "classwide" warning reflecting FDA's judgment as to the extent to which the available scientific evidence supported any warning. FDA therefore made, with Seroquel, just the sort of fully informed, "affirmative decision" the Supreme Court in *Levine* concluded FDA had not made with Phenergan.

I. LEVINE DOES NOT ELIMINATE CONFLICT PREEMPTION.

Plaintiffs devote much of their opposition to the extreme argument that, after *Levine*, state failure-to-warn claims are not preempted in any factual circumstances. If preemption were now categorically foreclosed, however, the Supreme Court would have had no need to:

(i) review the regulatory record to determine what FDA had and had not affirmatively decided with respect to administering Phenergan via IV-push, and whether FDA would have disapproved a stronger warning, *id.* at 1198;

(ii) expressly reserve judgment on “whether a state rule proscribing [an FDA-approved method of administration] would be preempted,” *id.* at 1194; or

(iii) “recognize that [although] some state-law claims might well frustrate the achievement of congressional objectives, this is not such a case,” *id.* at 1204.¹

Plaintiffs also argue that the presumption against preemption and the manufacturer’s responsibility for the contents of its labeling bar preemption here. Opp. 10-22 (Doc. 1396). That, too, is incorrect. The Supreme Court relied on those points not to reject preemption categorically in all failure-to-warn cases but to explain the standard that it did adopt, and that AstraZeneca puts forward here. The Court also relied on them to reject Wyeth’s broad argument that “the mere fact that the FDA approved Phenergan’s label” is sufficient to establish preemption. 129 S. Ct. at 1199. AstraZeneca does not advance that same broad argument here.

II. CLEAR EVIDENCE SUPPORTS PREEMPTION UNDER *LEVINE*.

AstraZeneca has presented clear evidence that FDA would not have approved a materially stronger warning concerning an association between Seroquel and diabetes and hyperglycemia from the time FDA imposed a classwide warning until AstraZeneca assessed the results of Trials 126 and 127. Through its classwide warning, FDA affirmatively addressed the precise question of the extent of any association between Seroquel and diabetes and hyperglycemia, and in doing so highlighted the limits of what the available evidence would permit FDA to say. FDA would have rejected a stronger warning at that point, because it had necessarily found – as reflected in the classwide warning itself – that the science would not

¹ Plaintiffs’ reliance (Opp. 2 n.2) on the Supreme Court’s orders granting certiorari, vacating and remanding two preemption cases for further consideration is misplaced. Such orders are not “final determination[s] on the merits.” *Tyler v. Cain*, 533 U.S. 656, 666 n.6 (2001) (rejecting reliance on such an order); see *U.S. v. Levy*, 416 F.3d 1273, 1279-80 (11th Cir. 2005) (court may reach same result after such a remand).

support anything stronger or more definitive. Significantly different data would be needed to support a materially stronger warning on this issue, and AstraZeneca did not have such data until it assessed Trials 126 and 127. Thus, any state law requirement that AstraZeneca present on its labeling, during the time period relevant here, an account of the association between Seroquel and diabetes and hyperglycemia materially different from the one FDA adopted, is preempted. Plaintiffs' contrary arguments misread *Levine* and the regulatory record here.

A. The Regulatory Record Here Is Fundamentally Different Than In *Levine*.

The evidence here is not remotely comparable to that considered by the Supreme Court in *Levine*. There was no question in *Levine* that misapplication of an IV-push of Phenergan would cause gangrene and lead to amputation. There was no question a strong warning was needed. The only question was whether, given the accumulating evidence that existing warnings had been insufficient to stop at least 20 incidents of gangrene and amputation indisputably linked to Phenergan, FDA would have barred Wyeth from strengthening a warning that Wyeth itself had drafted. The agency judgment at issue here, by contrast, reflects a scientific evaluation and agency involvement that is qualitatively and quantitatively different from that in *Levine*.

First, with Seroquel, FDA reached a scientific judgment in 2003 about the *limits* of what the available evidence would support about an association between Seroquel and diabetes and hyperglycemia. It was FDA's view that the assessment of any association was "complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population." Opening Br. (Doc. 1391), Ex. 1 at 1. FDA concluded that the relationship between the use of atypical antipsychotics and hyperglycemia-related adverse events "is not completely understood" and cautioned that "precise risk estimates . . . are not available." *Id.* FDA's own words demonstrate

that a materially stronger warning was not supported by the evidence, and would not have been approved.

Second, in stark contrast to *Levine* where Wyeth conceded it had not “supplied the FDA with an evaluation or analysis concerning the specific dangers posed by the IV-push method,” 129 S. Ct. at 1199, AstraZeneca repeatedly submitted analyses about the risks of Seroquel, *see* Omnibus Br. 12-17 (Doc. 1113); Opening Br. 8-9. And FDA expressly stated that it conducted its own “comprehensive review” of the risk data. Omnibus Br. 13; Opening Br. 6-8.

Third, the agency judgment here is the product of independent work of FDA itself. Unlike in *Levine*, where the agency approved the manufacturer’s labeling and did not subsequently give serious consideration to new evidence, here, FDA wrote the warning. The agency’s authorship demonstrates conclusively that the agency made an “affirmative decision” as to what the hyperglycemia-related warning should say. State law could not impose a requirement to publish a different scientific judgment from the one FDA itself affirmatively made without conflicting directly with FDA’s own analysis and conclusions.

Fourth, FDA uniquely has the ability to gather confidential data on all drugs in a class, to reach a judgment about whether meaningful distinctions between drugs can and should be drawn, and to decide whether a classwide warning best serves the public health. FDA concluded here that “[t]he available data are insufficient to provide reliable estimates of differences in hyperglycemia-related adverse event risk among the marketed atypical antipsychotics.” Opening Br., Ex. 1 at 1. No individual manufacturer could replicate that judgment. A manufacturer, which necessarily can initiate only a drug-specific warning, would undermine FDA’s judgment if the manufacturer abandoned or supplemented the classwide warning with a stronger one for its drug, thereby implying that other drugs in the class were safer, when FDA expressly had

concluded that no such distinctions could be drawn. Therefore, a state-law requirement that a manufacture publish such a warning – based on information not materially different from the information before FDA when it rendered its judgment – would defeat FDA’s objective of having a uniform classwide warning.

B. FDA’s Enforcement Authority Was Ample To Support Preemption.

Plaintiffs erroneously contend that AstraZeneca’s preemption argument is undermined because, before the Food and Drug Administration Amendments Act of 2007 (FDAAA), “the idea that the FDA could have legally forced AstraZeneca to adopt a particular label in 2003-04 is pure fiction.” Opp. 20-21. To be sure, as *Levine* observes, FDAAA made explicit FDA’s authority to require labeling changes on the basis of new safety information. *See* 21 U.S.C. § 355(o)(4)(A). But the Agency has long had the greater power to revoke approval if emerging scientific data demonstrate that the drug no longer offers sufficient assurance of safety or efficacy as labeled. *Id.* § 355(e) (FDA “shall . . . withdraw approval” if, among other things, that “scientific data show that such drug is unsafe for use” as labeled). The Agency also has authority to prohibit misleading statements. *See id.* § 352(a). In exercise of this pre-FDAAA authority, FDA withdrew or suspended drug approvals on numerous occasions,² and wielded other enforcement options in its “wide-ranging arsenal.”³ Plaintiffs effectively acknowledge FDA’s pre-FDAAA powers, pointing out that “FDA used possible disapproval of pending supplemental new drug applications as leverage in its negotiations with the manufacturers

² *See, e.g.*, FDA, *FDA Data on PDUFA Drug Approvals, Safety Withdrawals & New Boxed Warnings* (Ex. 1) (FDA ordered 11 safety-based withdrawals from 1993 to 2004).

³ These options include in rem forfeiture, injunction, and criminal prosecution against the responsible party if a “misbranded” drug is distributed in the United States market. *See, e.g.*, 21 U.S.C. §§ 332-34, 337. FDA’s pre-FDAAA powers were not theoretical. *See, e.g.*, *U.S. v. Lane Labs-USA Inc.*, 427 F.3d 219, 234 (3d Cir. 2005) (citing examples of FDA enforcement); *In re Serzone Prods. Liab. Litig.*, 231 F.R.D. 221, 224 (S.D. W. Va. 2005) (discussing FDA labeling requirements). *See generally Merrell Dow Pharms. Inc. v. Thompson*, 478 U.S. 804, 830 (1986) (Brennan, J., dissenting) (“Congress has provided the FDA with a wide-ranging arsenal of weapons to combat violations of the FDCA”).

regarding their labeling.” Opp. 25. Thus, while FDA may use the term “request” with respect to labeling changes, FDA has made clear that if AstraZeneca “fail[ed] to make the[] [requested] labeling changes within the specified period of time [it] *could make your product misbranded under 21 USC 321(n) and 352(a).*” July 30, 2007 FDA letter to AstraZeneca (Ex. 2) at 2 (emphasis added); *id.* at 1 (referring to earlier correspondence “requesting” revisions). Where FDA chooses to impose a classwide warning that only it can draft and enforce, it has ample authority to compel manufacturers to comply. FDA undisputedly exercised that authority here. AstraZeneca complied with FDA’s request and implemented the classwide warning without material change. *See* Opp. 26.

C. AstraZeneca Lacked Evidence Before June 2007 To Support A Stronger Warning.

Plaintiffs assert that prior to June 2007, FDA would have authorized AstraZeneca to “abandon” the classwide label or allow it to contraindicate Seroquel for certain types of patients. *See* Opp. 27-35. Plaintiffs are wrong on both the law and the regulatory record.

1. Evidence Between September 2003 And June 2007 Did Not Support A Stronger Warning.

Plaintiffs point to three categories of evidence to suggest that between the time of the classwide warning in September 2003 and the CBE in June 2007, FDA would have permitted AstraZeneca to “abandon” the classwide labeling. *See* Opp. 27-29, 34-35. All fail.

a. Trial 125. Plaintiffs argue that the existence of Trial 125 “alone undermines AstraZeneca’s assertion that it did not possess sufficient information to support a CBE [supplement] . . . until it finished analyzing the results of Studies 126 and 127.” Opp. 27-28. If anything, Trial 125 provides even more clear evidence that FDA would *not* have authorized the

labeling changes Plaintiffs contend were required.⁴ Critically, Trial 125 determined that Seroquel did *not* cause a statistically significant change in glucose metabolism, as measured by the OGTT. Ex. 3 at 10, 40, 47-48, 149-55. Thus, none of Plaintiffs' experts relied on Trial 125 in forming their expert opinions on Seroquel's glucose risks.⁵

b. Post-Marketing AER Data. Plaintiffs also claim that the post-marketing adverse event reports (AERs) AstraZeneca received in 2004 and 2005 "alone" demonstrate that FDA would have approved a stronger warning. Opp. 34; *see id.* at 29. AERs are anecdotal reports that doctors, patients, pharmacists, competing sales representatives, and others submit to pharmaceutical companies, asserting merely that someone experienced undesired symptoms while on the drug. 21 C.F.R. § 314.80(c). Companies must report AERs "whether or not considered drug related." *Id.* § 314.80(a). FDA has explicitly stated that AERs are not scientifically verified, may occur by chance when taking the drug, and cannot be used to determine causation or to calculate incidence or estimates of drug risk.⁶ At most, AERs are "signals" for FDA and manufacturers of concerns that may warrant investigation.

That function was served here, because FDA comprehensively investigated the possibility of an association between Seroquel and other atypical antipsychotics and diabetes between 1999 and 2003 – culminating in the classwide warning. AstraZeneca then proceeded with Trial 125, its own study of Seroquel's possible effect on glucose dysregulation, which did not support strengthening the Seroquel warning.

⁴ Trial 125 was designed to investigate the effect of Seroquel and other antipsychotics on glucose metabolism, and was structured to obtain guaranteed fasting glucose readings by hospitalizing the patients overnight prior to testing and used the highly sensitive, gold-standard validated, oral glucose tolerance test (OGTT) to measure results. *See* June 12, 2006 Clinical Study Report (Ex. 3) at 43, 48.

⁵ *See, e.g.*, Arnett Report (Ex. 4) § C.1.2; Arnett Dep. (Ex. 5) at 225.

⁶ FDA Office of Postmarketing Drug Risk Assessment, "Adverse Event Reporting System (AERS): Brief Description with Caveats of System" (Oct. 18, 1999) (Ex. 6) at 2; *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1250 (11th Cir. 2005); *Haggerty v. Upjohn Co.*, 950 F. Supp. 1160, 1165 (S.D. Fla. 1996).

In *Levine*, there was no dispute that improper administration of Phenergan caused gangrene and amputation. The Court therefore accepted that AERs directly reflected the frequency with which this catastrophic side effect was occurring as a result of IV-push of Phenergan. *See* 129 S. Ct. at 1197. AERs do not provide a basis for strengthening a warning where, as here, (a) causation is a fundamental question, and (b) FDA has determined what the warning should say after careful investigation that included review of AERs.

c. Trial 41. Next, relying essentially on a one-line email, Plaintiffs mistakenly contend that AstraZeneca could have abandoned the classwide warning or contraindicated Seroquel for patients based on Trial 41. *See* Opp. 34-36 & n. 87.⁷ Trial 41 was designed to demonstrate the efficacy of the sustained release formulation of Seroquel in schizophrenia patients. Trial 41 did not show “statistically significant differences” in glucose regulation. Leong Dep. (Ex. 7) at 264:14-15; *see id.* at 262:24-266:11 (discussing glucose results of Trial 41). In fact, many patients who were diabetic at baseline experienced *improved* glucose while taking Seroquel. March 2, 2006 Clinical Study Report (Ex. 8) at 147-48.

2. Evidence Before The Classwide Warning.

Plaintiffs also assert that data available before September 2003 would have led FDA to approve a stronger warning for Seroquel. Every category of pre-classwide warning evidence identified by Plaintiffs, however, was disclosed to FDA before that warning. In issuing the classwide warning, FDA emphasized that it “reflect[ed] the currently available information about antipsychotic use and diabetes mellitus.” Opening Br., Ex. 1 at 2. Thus, the very information Plaintiffs now claim supported enhanced warnings “[b]etween 1997 and 2003” (Opp. 30) had

⁷ The email states “All 7 values for the clinically significant glucose are high.” Opp., Ex. 20 (quoted and cited in Opp. 34 & n.87). There is no context for that statement, and the data do not support it.

been disclosed to FDA before the classwide warning, but was nonetheless insufficient to support warnings beyond those crafted by the Agency.⁸

Plaintiffs' statements regarding a Discussion Document and a so-called Position Paper drafted by Dr. Geller around the time of the June 2000 SERM are misleading. *See* Opp. 31-32. The statements merely represented Dr. Geller's *preliminary* impressions; when discussed at the SERM, the team (Dr. Geller included) unanimously agreed that his initial impression could not be scientifically substantiated. *See, e.g.*, Geller Dep. (Ex. 10) at 458:9-459:3 ("I disagree with that statement"; it "did not reflect my view of diabetes at the time that I presented at SERM"); *see also id.* 429:7-24 (testifying "Position Paper" was not an official position paper but a "template . . . predicated upon a draft of [the] [D]iscussion [D]ocument for the June SERM"). Plaintiffs also contend that AstraZeneca's metabolic response to FDA wrongly departed from AER data about glucose and metabolic-related symptoms detailed in the Position Paper. Opp. 32-33. But even Plaintiffs admit these submissions were "technically true." *Id.* AstraZeneca provided the specific data requested by FDA at that time. AstraZeneca *already* had reported this AER data spontaneously as required by federal law. *See* Geller Dep. at 1139:12-23 (Ex. 10).

Plaintiffs also argue that AERs from Japan, which triggered the Japanese government's 2002 labeling changes, provided a basis for AstraZeneca to change U.S. labeling. Not only do the inherent limitations of AERs apply, but (as Plaintiffs do not and could not dispute) all of the cases discussed in the Japanese report had been submitted to FDA before the classwide warning.

⁸ For instance, Plaintiffs point (Opp. 30) to the weight gain data in Trial 15; AstraZeneca disclosed the *full results* of that trial to FDA in its original NDA. *See* June 12, 1996 Clinical Study Report (Ex. 9); *id.* at 116. Likewise, in its August 2000 metabolic submission, AstraZeneca provided FDA with the very data from the June 2000 SERM that Plaintiffs imply was not properly disclosed. *See* Opp. 30-32; *contra* Geller Dep. at 527:23-528:6 (Ex. 10); Opp. 30 n.68 (citing Dr. Arnett's admission that these studies were "submitted to the FDA, with Seroquel's NDA").

D. Plaintiffs' Contraindication Claim Is Preempted.

Plaintiffs argue AstraZeneca should have used a CBE to “contraindicate” Seroquel for patients with diabetes or blood glucose problems. Opp. at 39-40 & n.92. This claim starkly conflicts with FDA’s classwide warning and would not have been approved. FDA determined in 2003 that “[p]atients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control” – *not* that they should be denied the drug altogether. Opening Br., Ex. 1 at 1. Further, Plaintiffs identify no evidence that would have supported a contraindication limited to Seroquel.

Moreover, a state law requiring a contraindication⁹ would have profound public health consequences, telling physicians Seroquel should never be used even by people for whom Seroquel may be (and, in the case of plaintiff David Haller is), the only medicine that controls behavior that creates a danger to themselves and others. *See Haller*, 6:07-cv-15733, Doc. No. 57 at 3-5, 12-15, 18 (M.D. Fla. Nov. 3, 2008) (describing his criminally violent, sexually deviant conduct, and Seroquel’s unique efficacy for him). FDA approved Seroquel for patients like Mr. Haller based on the Agency’s informed evaluation of the science and its ultimate determination that Seroquel’s benefits outweigh its risks, even for patients with a history of diabetes and blood glucose problems. That decision preempts contrary state law judgments.

III. CONCLUSION

For these reasons and those set forth in its opening brief, AstraZeneca respectfully requests that the Court enter partial summary judgment in AstraZeneca’s favor.

DATED: April 6, 2009

Respectfully submitted,

⁹ Plaintiffs suggest it is “irrelevant” whether their state-law claims seek to require a contraindication because “there is no qualitative distinction between a stronger warning and a contraindication.” Opp. 39. In *Levine*, however, the Court reserved judgment on the issue of whether state law could proscribe a method of administration FDA had approved. 129 S. Ct. at 1194.

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CERTIFICATE OF SERVICE

I hereby certify that, on April 6, 2009, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system through which all participating parties are deemed served. I further certify that, by using the CM/ECF, the foregoing has been served on plaintiffs' liaison counsel, who is charged with serving any non-CM/ECF participants on the attached Service List.

/s/ Eliot J. Walker

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MDL DOCKET NO. 1769**

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