

Case Nos. 06-3107, 06-5148

**IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT**

JOSEPH C. COLACICCO, Individually and as Executor
of the Estate of Lois Ann Colacicco, Deceased,

Appellant,

v.

APOTEX, INC., APOTEX CORPORATION,
and SMITHKLINE BEECHAM d/b/a GlaxoSmithKline,

Appellees,

AND

BETH ANN MCNELLIS, on Behalf of the Estate of Theodore DeAngelis,
Deceased, and in Her Own Right,

Appellee,

v.

PFIZER INC.,

Appellant,

On Remand from the United State Supreme Court, Civil Action No.: 08-437

**MEMORANDUM OF APPELLEES GLAXOSMITHKLINE
AND APOTEX ON THE EFFECT OF *WYETH V. LEVINE*
AND IN SUPPORT OF AFFIRMANCE ON REMAND**

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**QUESTION PRESENTED PURSUANT TO
THIS COURT'S REQUEST DATED MARCH 18, 2009**

What is the effect of the Supreme Court's decision in *Wyeth v. Levine*, 555 U.S. ___, 129 S. Ct. 1187 (2009), on this Court's decision in *Colacicco v. Apotex, Inc.*, 521 F.3d 253 (3d Cir. 2008)?

SUMMARY OF ARGUMENT

This Court's decision in *Colacicco v. Apotex, Inc.*, 521 F.3d 253 (3rd Cir. 2008) is consistent with the Supreme Court's decision in *Wyeth v. Levine*, 555 U.S. ___, 129 S.Ct. 1187 (2009) and should remain undisturbed.

In *Levine*, the Supreme Court found that the FDA's approval of the labeling for the prescription drug Phenergan did not preempt the plaintiff's state law failure-to-warn claims. The Court did not extend its ruling to cases where, as here, the record contains "clear evidence" that the U.S. Food and Drug Administration ("FDA") would not have approved a change to the drug's labeling:

But absent clear evidence that the FDA would not have approved a change to Phenergan's label, we will not conclude that that it was impossible for Wyeth to comply with both federal and state requirements. Wyeth has offered no such evidence.

Levine, 129 S.Ct. at 1198 (emphasis added).

This Court in *Colacicco*, consistent with *Levine*, limited its holding to cases where the evidence clearly shows that FDA would not have approved a plaintiff's desired labeling change:

Our holding is limited to circumstances in which the FDA has publicly rejected the need for a warning that plaintiffs argue state law requires.

Colacicco, 521 F.3d at 271-72. Indeed, this Court limited its holding explicitly to distinguish *Colacicco* from the far different regulatory history in *Levine*. *Id.* at 271 n.17.

The record in *Colacicco* – in sharp contrast to the record in *Levine* – leaves no doubt that FDA would have rejected Plaintiffs’ desired warning that Paxil increases the risk of suicide in adults.¹ This Court found clear evidence that FDA had repeatedly found that there is no scientific basis for such a warning. *Id.* at 269. (“The FDA has actively monitored the possible association between SSRIs and suicide for nearly twenty years and has concluded that the suicide warnings desired by plaintiffs are without scientific basis and would therefore be false and misleading.”).

This Court in *Colacicco* thus anticipated the key issue for pharmaceutical preemption: the role of clear evidence that FDA would reject the desired change to the drug’s labeling. That evidence was lacking in *Levine*, and therefore the state law claims were not preempted. As this Court recognized, such evidence is abundant and uncontroverted in *Colacicco/McNellis*, and therefore the state law claims are preempted. This Court’s decision in *Colacicco* is solidly consistent with *Levine* and should remain undisturbed.

¹ Both the Complaints and Plaintiffs’ briefing in the *Colacicco* appeal establish that this is the warning Plaintiffs assert should have been given. *See* GSK/Apotex Joint Br. at 1 (citing Plaintiffs’ Complaints); Tr. of Oral Argument at 19.

ARGUMENT

I. The Narrow Holding in *Colacicco* Aligns Consistently With the Supreme Court's Holding in *Levine*.

The Supreme Court in *Levine* was presented with a product (Phenergan, first approved more than 50 years ago) and an acknowledged risk (gangrene from the IV-push method of administration) to which FDA over the years had paid only “passing” attention, as evidenced by “intermittent” and “sparse” correspondence between FDA and the manufacturer. 129 S.Ct. at 1192, 1199. The Supreme Court found Wyeth had never provided FDA with “an evaluation or analysis concerning the specific dangers posed by the IV-push method.” *Id.* at 1199. Based upon this less than robust regulatory history, the Court found no irreconcilable conflict between state and federal requirements:

But absent *clear evidence that the FDA would not have approved a change* to Phenergan’s label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements. Wyeth has offered no such evidence.

Id. at 1198 (emphasis added). *See also id.* at 1204 (“Although we recognize that some state law claims might well frustrate the achievement of congressional objectives, this is not such a case.”).²

In *Colacicco*, this Court found such “clear evidence that the FDA would not have approved a change” in the regulatory record for Paxil and Zoloft. Indeed, this

² *Levine* thus ends the debate as to whether state law tort claims may pose an obstacle to the federal regulation of drug labeling – they can.

Court determined not only that FDA “would have” rejected the warning Plaintiffs sought in *Colacicco*; it found FDA actually “publicly rejected” that warning. 521 F.3d at 271-72. This Court’s holding on preemption was carefully constrained. It was based on the particular facts of a 20-year interaction between FDA and the SSRI manufacturers about the specific risk at issue – suicide. *Id.* at 256. It fits squarely within the holding of the Supreme Court in *Levine*:

The FDA clearly and publicly stated its position prior to the prescriptions and deaths at issue here. Therefore, we need not decide whether preemption would be appropriate under different facts – such as where the FDA had not rejected the substance of the warning sought or where the FDA only stated its position after a lawsuit had been initiated – or under the broader theories of preemption argued by the parties. Thus, we do not decide whether the FDA’s mere approval of drug labeling is sufficient to preempt state-law claims alleging that the labeling failed to warn of a given danger, whether FDA approval of drug labeling constitutes minimum standards in the absence of the FDA’s express rejection of a specific warning, or whether actions against generic drug manufacturers are preempted on the basis of their obligations under the Hatch-Waxman Amendments. Our holding is limited to circumstances in which the FDA publicly rejected the need for a warning that plaintiffs argue state law requires.

Id. at 271-72.

In *Colacicco*, this Court found that, in contrast to the regulatory record presented in *Levine*, FDA’s failure to require a warning about an increased risk of suicide for adult patients was not the result of a “wait-and-see approach or mere inertia.” *Id.* at 269. FDA instead made deliberate, specific, and informed decisions over a period of years that the science did not support the warning:

In this case we need not speculate on the rationale of the FDA for its failure to require the adult suicidality warnings. Not only has the FDA filed an amicus brief in the *Colacicco* action but it has repeatedly rejected the scientific basis for the warnings that Colacicco and McNellis argue should have been included in the labeling. The FDA has actually monitored the possible association between SSRIs and suicide for nearly twenty years, and has concluded that the suicide warnings desired by plaintiffs are without scientific basis and would therefore be false and misleading.

Id. at 269.

Nothing – including *Levine* – has happened since to change this finding. The briefing of the parties and *amicus* United States in the first round set out the regulatory history in detail.³ In its opinion, this Court spent multiple pages summarizing the repeated interchanges between FDA and the SSRI manufacturers about the exact risk at issue here – adult suicide. Plaintiffs cannot and do not dispute this history. *See, e.g.*, Tr. of Oral Argument at 12-13 (Plaintiffs’ counsel conceding that FDA did not want Plaintiffs’ desired warning in Paxil’s labeling).

This Court found that “the FDA clearly and publicly stated its position [that no warning was justified] prior to the prescriptions and deaths at issue here.” 521 F.3d at 271. For example, in June 2003, four months prior to Ms. Colacicco’s

³ Despite that this case was decided on Motions to Dismiss, a full and comprehensive public record exists of FDA’s pervasive investigations and decisions about the risk of suicide. This Court has previously relied and should again rely on that record. *See, e.g., Anspach v. City of Philadelphia, Dep’t of Pub. Health*, 503 F.3d 256, 273 n.11 (3d Cir. 2007); *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1197 (3d Cir. 1993). That record leaves no questions unanswered.

death, FDA stated: “There is no evidence that Paxil is associated with an increased risk of suicidal thinking in adults.” *Id.* at 270. In October 2003, just the day before Ms. Colacicco’s death, FDA reaffirmed the existing precaution in the Paxil labeling about the inherent risk of suicide in patients with depression and did not require a warning regarding an increased risk of suicidality for adults. *Id.* at 270-71.

The Court also noted that FDA had reiterated the same conclusion *after* the subject suicides, most notably in 2007 when the Agency required new labeling for SSRIs that specifically rejected the warning Plaintiffs say should have been given in 2003. The labeling required by FDA in 2007 – four years after the suicides in these two cases – says the data on SSRIs show no increase in the risk of suicidality in patients older than 24. *Id.* at 273 n.20. Lois Colacicco was 55 when she committed suicide; Thomas DeAngelis was 64. *Id.* at 256.

On the strength of the regulatory record, this Court found that Plaintiffs’ state law claims created an actual conflict with FDA’s consistent decisions to reject a warning of increased risk of suicide in adults. *Id.* at 271-72. Because federal law requires that a warning in a drug’s labeling be based on “reasonable evidence of an association” and because FDA can prohibit false and misleading warnings in a medication’s labeling, this Court held that “a warning asserting the existence of an association between SSRIs and suicidality directly conflicts with the FDA’s oft-

repeated conclusion that the evidence did not support such an association.” *Id.* at 271.

Levine compels no other result. Instead, *Levine* confirms that this Court was right the first time.

II. Where There Is an Actual Conflict and “Clear Evidence” of FDA’s Repeated Determinations That the Science Does Not Support Plaintiffs’ Desired Warning, Any “Presumption Against Preemption” Is Overcome.

A presumption, even if one exists, is just that – a presumption. It is rebuttable. It may be overcome by clear evidence that FDA would not have approved the warning Plaintiffs say was required by Pennsylvania law. The Third Circuit recently addressed a similar argument – after *Levine* – when it affirmed a decision that the National Childhood Vaccine Act preempts state law design defect claims:

Nonetheless, in the face of clear evidence, the presumption against preemption can be overcome.

Bruesewitz v. Wyeth, Inc., ___ F.3d ___, 2009 WL 792468, at *6 (3rd Cir. 2009).

As discussed above, this Court has already found in *Colacicco* that such “clear evidence” exists in this record. 521 F.3d at 271-72.

The presumption point was a mainstay of Plaintiffs’ presentation when these cases were previously before the Court. *See* Appellant’s Br. at 10-15; Tr. of Oral Argument at 7-9. Indeed, the question of such a presumption was the first one

addressed in the Court's opinion. *See* 521 F.3d at 262-65. ("We consider first whether there is a presumption against preemption applicable in this case."). In a lengthy discussion, the Court noted that the Supreme Court has acknowledged that application of such a presumption is not always appropriate. *Id.* at 263 (citing *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347-48 (2001)). This Court found in *Colacicco* that, regardless of whether such a presumption applied, the clear and palpable conflict presented in these cases – where Plaintiffs sought a warning that FDA had on repeated occasions determined to be scientifically unsubstantiated – triggered preemption. *Id.* at 271-72. Nothing in *Levine* changes this.

III. Where There Is "Clear Evidence" that FDA Would Not Have Approved Plaintiffs' Desired Labeling Change, the Filing of a "Changes Being Effected (CBE)" Supplement Is Not a Prerequisite for a Finding of Preemption.

The Supreme Court's reliance in *Levine* on Wyeth's failure to file a CBE does not apply to the facts of this case. As discussed above, this Court found in *Colacicco* that there was clear evidence that FDA had repeatedly considered the precise question of whether SSRIs increase the risk of suicide in adults. Each time, the FDA has answered that question "no," as reflected by FDA's rejection of three separate Citizens Petitions, FDA's repeated public statements that the scientific data show no such association, and FDA's repeated approvals of labeling (both before and after the suicides of Ms. Colacicco and Mr. DeAngelis) that contain no

warning of increased risk in adults. The FDA has been attentively monitoring the risk of suicide during this entire period. Given such clear evidence of FDA's position, this Court in *Colacicco* correctly declined to impose on GSK the obligation of filing a fruitless CBE that warned of a scientifically unsupported risk and that was doomed to FDA disapproval from the outset:

We agree that a court could more easily determine the preemption issue if the FDA had formally rejected such a CBE supplement, but *we cannot compel the defendant companies to suggest a CBE supplement that they believe unnecessary. Nor do we favor encouraging regulated parties to submit CBE supplements for the sole purpose of insulating themselves from potential liability. . . .* Thus, we reject the notion that, in order to rise to the level of a conflict in this situation, the FDA's rejection of a warning must be imbued with the formality proposed by the plaintiffs.

521 F.3d at 272 (emphasis added) (internal citation omitted).

There is a comprehensive record in *Colacicco* of FDA's repeated determinations through today that the scientific data do not support the warning Plaintiffs would impose under state law. None of that is changed by or inconsistent with *Levine*. See 129 S.Ct. at 1198. *Colacicco* correctly declined to elevate form over substance.

IV. The Supreme Court's Rejection of Deference To FDA's Preemption Opinions in the 2006 Preamble Does Not Affect This Court's Decision in *Colacicco*.

In *Levine*, the Supreme Court declined to afford deference to FDA's legal conclusions in FDA's 2006 preamble. 129 S.Ct. at 1200-03. That portion of

Levine is simply irrelevant here. The result in *Colacicco* did not depend in any way on deference to FDA's 2006 preamble. To the contrary, this Court noted that:

[T]he basis for federal preemption is not the [labeling] guidelines themselves . . . , but rather FDA's repeated determinations . . . that there was insufficient scientific evidence of an association between adult use of SSRIs and suicide or suicidality to permit a warning on the labeling for those drugs.

521 F.3d at 274 (quoting *amicus* brief of the United States). This Court correctly based *Colacicco* on FDA's repeated and consistent regulatory findings relating to its review of the scientific facts, as opposed to FDA's legal conclusions about the appropriate scope of preemption. *Id.* at 270 n.15 ("The FDA's summary of its scientific determinations must be distinguished from the agency's construction of a statute, as the review of scientific information is strictly within its expertise.").

The scientific facts about Paxil and Zoloft are clearly within the expert purview of FDA. Indeed, Plaintiffs concede as much. *See* Appellant's Br. at 33 ("Nor is there any dispute that the FDA is expert in the field in which it operates."). Those scientific facts have not been changed by *Levine*.

CONCLUSION

This Court in *Colacicco* applied a careful logic to find a specific category of cases preempted – a category well within the boundary identified by the Supreme Court in *Levine*. This Court's approach was prescient, and the decision in *Colacicco* is due to be reinstated. Here the "clear evidence" is that FDA has

trained its attention directly and continuously for 20 years on the steady accretion of scientific evidence about whether SSRIs can increase the risk of suicide. Over the years, FDA has requested multiple analyses of that data and done other analyses itself. Based on its expert review, FDA's conclusion is that there is no increased risk of suicide in any patient population and no increased risk of suicidal behavior in patients beyond 24 years of age.⁴ FDA's scientists – not its lawyers – have said there is no increased risk. As this Court has previously recognized, a finding that state law requires a warning of such a risk would conflict with and frustrate FDA's expert judgments on the science.

While *Levine* allows a finding that some state law tort claims can complement FDA's regulation of prescription drugs, *see* 129 S.Ct. at 1198-99, this is not such a case. GSK and Apotex respectfully ask this Court to reaffirm its opinion in *Colacicco*.

Dated: April 16, 2009

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⁴ See Current Paxil Prescribing Information, at 11-12, *available at* <http://www.fda.gov/cder/foi/label/2009/020031s061,020710s0251bl.pdf> (last visited April 16, 2009).

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CERTIFICATION OF ADMISSION TO BAR

I, Chilton Davis Varner, counsel for Appellee SmithKline Beecham d/b/a GlaxoSmithKline, do hereby certify that I am a member in good standing of the bar of the United States Court of Appeals for the Third Circuit.

Pursuant to 28 U.S.C. § 1746, I certify under penalty of perjury that the foregoing is true and correct.

/s/ Chilton Davis Varner
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Dated: April 16, 2009

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I, Charles A. Fitzpatrick, III, counsel for Appellees Apotex Inc. and Apotex Corporation, do hereby certify that I am a member in good standing of the bar of the United States Court of Appeals for the Third Circuit.

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I hereby certify that 10 copies of the Memorandum of Appellees GlaxoSmithKline And Apotex On The Effect Of Wyeth V. Levine And In Support Of Affirmance On Remand were hand-delivered to the Clerk's Office, and will be served by the Court's electronic filing service system and/or U.S. Mail on all counsel of record and *amici* counsel for this action, this 16th day of April 2009.

/s/ Chilton Davis Varner
Chilton Davis Varner

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