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March 9, 2009

VIA ECF and HAND DELIVERY

Honorable Dennis M. Cavanaugh, U.S.D.J.
United States District Court, District of New Jersey
United States Post Office & Courthouse
Newark, NJ 07101

Re: In Re Vytorin/Zetia Marketing, Sales Practices and Products Liability Litigation, MDL No. 1938; Civil Action No. 08-285 (DMC)(MF)

Dear Judge Cavanaugh:

We are counsel for Plaintiffs in the above-referenced litigation. We respectfully write to advise the Court of supplemental authority directly bearing on the Defendants' pending motion to dismiss (Docket No. 120).

On March 4, 2009, the United States Supreme Court issued its ruling in *Wyeth v. Levine*, Case No. 06-1249, 555 U.S. — (2009) ("*Wyeth*") (attached hereto as Exhibit A). In this landmark decision, the Supreme Court unequivocally rejected the argument that the approval of the federal Food and Drug Administration ("FDA") in the area of pharmaceutical labeling strips consumers of their legal remedies for injuries caused by false and misleading marketing of pharmaceutical products. As the Court stated, Congress intended the Federal Food, Drug and Cosmetic Act ("FDCA") to be a floor, not a ceiling, for drug regulation and to "bolster," not diminish, other remedies available to injured consumers. Slip Op. at 17.

Wyeth directly rejects the argument, advanced by Defendants in their pending motion to dismiss, that the FDCA preempts Plaintiffs' state law claims. The Supreme Court saw "no merit in this argument, which relies on an untenable interpretation of congressional intent and an overbroad view of an agency's power to pre-empt state law." *Id.* (emphasis added). Rather, the Court found that the regulatory history in the area of drug regulation "reveal[s] the longstanding coexistence of state and federal law and the FDA's traditional recognition of state-law remedies." *Id.* at 24. The Court expressly rejected as irrelevant a statement made by the FDA in 2006 (and relied on by

Defendants here) that "FDA approval of labeling . . . preempts conflicting or contrary State law," *id.* at 19 – the exact statement upon which Defendants rely in their pending Motion here. The Court explained that "agencies have no special authority to pronounce on pre-emption absent delegation by Congress" and emphasized that the defendant could point to no statement by Congress in support of the FDA's proclamation. *Id.* at 20. *See also id.*("the FDA's 2006 preamble does not merit deference.")

Wyeth also rejects the underlying premise of Defendants' argument that Plaintiffs' RICO claims are barred – namely, that Congress intended "to give the FDA exclusive authority to regulate prescription drug advertising." *See* Defendants' Memorandum In Support of Motion to Dismiss (Docket No. 120) at 24. In *Wyeth*, the Court holds that Congress' silence on this issue, combined with Congress' awareness of other available remedies, "is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." Slip Op. at 18. Just as the Court states that Congress "surely would have enacted an express preemption provision at some point during the FDCA's 70-year history," had it intended for the FDCA to preempt state law, *id.*, it follows that Congress would have enacted an express preemption provision had it intended for the FDCA to bar *federal* claims under the *subsequently-enacted* RICO statute.

The Supreme Court in *Wyeth* explicitly endorses the ability of private suits to "uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information." Slip op. at 23. These considerations are particularly germane to the Vytorin litigation, which involves allegations of Defendants' ongoing concealment and suppression of information concerning the efficacy and utility of a drug for which Plaintiffs and the alleged class paid many millions of dollars.

The attached *Wyeth* decision is the final and controlling word on the preemption bases of Defendants' motion to dismiss. Plaintiffs respectfully submit that those aspects of the motion are now due to be denied, and Defendants therefore should withdraw them promptly.

Respectfully Submitted,

CARELLA, BYRNE, BAIN, GILFILLAN,
CECCHI, STEWART & OLSTEIN

JAMES E. CECCHI

cc: All Counsel (via ECF)