Wheeler Trigg O'Donnell LLP

Malcolm E. Wheeler
303.244.1870
wheeler@wtotrial.com

March 2, 2010

Elisabeth A. Shumaker, Circuit Clerk
U.S. Court of Appeals
Byron White U.S. Courthouse
1823 Stout Street
Denver, CO 80257

Re: *Annabel Dobbs v. Wyeth Pharmaceuticals*, No. 08-6018

Dear Ms. Shumaker:

Appellee Wyeth responds to Plaintiff-Appellant's Rule 28(j) letter regarding *Mason v. SmithKline Beecham Corp.*, No. 08-2265 (7th Cir. Feb. 23, 2010), as follows.

Mason states that (i) the Paxil-treated decedent there was only 23 years old, within the age-group for which in 2006 FDA found SSRIs actually "increased the likelihood of suicidality," and (ii) those facts "clearly cut towards making it less likely that the FDA would have rejected the plaintiffs' proposed warning in 2003." (*Mason*, slip op. at 17-18.) Here, in contrast, it is undisputed that the Effexor-treated decedent was 53, within the age-group for which, before and after decedent's 2002 suicide, FDA repeatedly found no reasonable evidence of an association between SSRIs and suicidality. (*See, e.g.*, Supp. App. 45; Aplt. App. 170-73, 208, 225, 244.) Thus, Wyeth has shown clear evidence that FDA would have rejected the particular warning Plaintiff advocates—namely, that SSRIs present an "increased risk of suicidality and its precursor conditions." (Aplt. App. 1664; *accord id.* at 1659, 1660, 1662; Aplt.'s Br. 3, 5.) *Compare Wyeth v. Levine*, 555 U.S. ___, 129 S. Ct. 1187 (2009) (because of generality of plaintiff's claim, verdict "did not mandate a particular replacement warning" about risk in issue).

Thus confronted, Plaintiff has cited no evidence that Wyeth in 2002 had any data or analysis constituting the "reasonable evidence of an association" required by 21 C.F.R. § 201.57(e) for Plaintiff's advocated warning. Plaintiff especially has cited no clinical-trial data that Wyeth or FDA failed to analyze. FDA has consistently emphasized that because depression itself causes suicide, FDA considers only controlled clinical trials in determining an association between suicide and an antidepressant. (*Mason*, slip op. at 14 n.8; Aplt. App. 963, 218-19, 232.)

Also, *Mason*, while acknowledging that 21 C.F.R. § 201.57(e) permits warnings only when there is "reasonable evidence of an association," dismissed as only "technically a violation of federal law" a conflict resulting from state-law requirements to provide warnings that section 201.57(e) prohibits. (Slip op. at 9). But federal law preempts conflicting state law, and the Supremacy Clause states no exception for supposedly "technical[]" violations of federal law.

Sincerely,

Malcolm E. Wheeler
Counsel for Appellee

cc: All counsel of record
Case No. 08-6018