



U.S. Department of Justice  
Civil Division, Appellate Staff  
950 Pennsylvania Ave., N.W., Rm: 7250  
Washington, D.C. 20530

DNL:SSwingle  
Sharon.Swingle@usdoj.gov

Tel: (202) 353-2689  
Fax: (202) 514-8151

January 9, 2008

Ms. Marcia M. Waldron, Clerk  
United States Court of Appeals for the Third Circuit  
21400 U.S. Courthouse  
601 Market Street  
Philadelphia, PA 19106-1790

Re: *Joseph C. Colacicco v. Apotex Inc.*, No. 06-3107 (3d Cir.)

Dear Ms. Waldron:

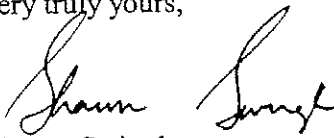
Pursuant to Fed. R. App. P. 28(j), the United States submits this letter and respectfully requests that copies be forwarded to Judges Sloviter, Ambro, and Restani, before whom the case was argued on December 10, 2007.

On December 21, 2007, the United States filed an amicus brief in *Wyeth v. Levine*, No. 06-1249 (S. Ct.) (copy attached). That brief sets out the Food and Drug Administration's position (at 8-12) that state tort claims are preempted to the extent they would impose liability for a drug manufacturer's use of labeling that FDA approved after being informed of the relevant risk. The brief also explains (at 13-14) that, as construed by FDA, 21 C.F.R. § 314.70 is limited to labeling changes based on "material new information" and does not permit changes based on information that was previously available to FDA. FDA's views are relevant to the preemption issue posed by this case.

In addition, the United States seeks to correct the misstatement in appellant's 12/26/07 letter that FDA lacks authority "to reject a company's strengthened prescription drug label" or to dictate the content of a prescription drug label. Federal law prohibits the marketing of a prescription drug if its labeling is false or misleading or does not bear adequate directions for use. *See* 21 U.S.C. §§ 331(a), (k), 352(a), (f). FDA's longstanding position is that labeling statements, including warnings, that are not adequately supported by scientific evidence are false and misleading. *See, e.g.*, 44 Fed. Reg. 37,434, 37,434, 34,755 (1979); 71 Fed. Reg. 3922, 3934 (2006). FDA may refuse to approve a drug, *see* 21 U.S.C. § 355(d)(7); 21 C.F.R. § 314.125(b)(6), or withdraw approval of an already-approved drug, *see* 21 U.S.C. § 355(e); 21 C.F.R. § 314.150(b)(3), if its labeling is false or misleading. FDA may also seek *in rem*

forfeiture of the drug and/or an injunction barring its distribution. *See* 21 U.S.C. §§ 334, 332(a). A manufacturer is also subject to criminal prosecution for distributing a misbranded drug. *See id.* § 333(a). FDA utilizes this statutory and regulatory authority to determine the content of prescription drug labeling.

Very truly yours,

  
Sharon Swingle

cc: Harris Pogust  
Derek Braslow  
Pogust & Braslow  
161 Washington Street, Suite 1520  
Conshohocken, PA 19428

Charles A. Fitzpatrick, III  
Arthur B. Keppel  
Rawle & Henderson  
1339 Chestnut Street  
The Widener Building  
One South Penn Square, 16th Floor  
Philadelphia, PA 19107

Chilton D. Varner  
Andrew T. Bayman  
Erica M. Long  
S. Samuel Griffin  
King & Spaulding  
1180 Peachtree Street  
Atlanta, GA 30309

Joseph O'Neil  
Lavin, O'Neil, Ricci, Cedrone & Disipio  
190 North Independence Mall West  
6th & Race Streets  
Suite 500  
Philadelphia, PA 19106

Allison Zieve  
Public Citizen Litigation Group  
1600 20th Street NW  
Washington, DC 20009

Shanin Specter  
David J. Caputo  
Kline & Specter  
1525 Locust Street  
19th Floor  
Philadelphia, PA 19102

Fred S. Longer  
Arnold Levin  
Matthew C. Gaughan  
Levin, Fishbein, Sedran & Berman  
510 Walnut Street  
Suite 500  
Philadelphia, PA 19106

Arnold A. Vickery  
Vickery & Waldner  
One Riverway  
Suite 1150  
Houston, TX 77056

Kenneth S. Geller  
Mayer Brown Rowe & Maw  
1909 K Street, N.W.  
Washington, DC 20006

Robert N. Weiner  
Jeffrey L. Handwerker  
Arnold & Porter  
555 12th Street, N.W.  
Washington, DC 20004

Michael X. Imbroscio  
Covington & Burling  
1201 Pennsylvania Avenue, N.W.  
Washington, DC 20004