News Release

Washington Legal Foundation
Advocate for Freedom and Justice®
2009 Massachusetts Avenue, NW
Washington, DC 20036
202.588.0302 wlf.org

FOR IMMEDIATE RELEASE July 9, 2013

Court Urged To Crack Down On Frivolous Securities Litigation

In re Genzyme Corp. Securities Litig.

The Washington Legal Foundation (WLF) this week urged the U.S. Court of Appeals for the First Circuit to dismiss a securities fraud lawsuit against a biologics manufacturer alleged to have defrauded investors by not immediately disclosing all "observations" recorded by FDA employees who inspected one of the company's plants. WLF argued that in the absence of evidence suggesting that such "observations" are statistically likely to lead to major FDA enforcement actions that would have a significant adverse effect on a company's finances, a drug manufacturer cannot be deemed to have intended to defraud investors.

In a brief filed in *In re Genzyme Corp. Securities Litig.*, WLF argued that frivolous securities fraud litigation will continue to be a plague on the business community unless the courts are willing to weed out such lawsuits before defendants are required to respond to expensive and time-consuming discovery requests. WLF argued that dismissal here is faithful to the intent of Congress in adopting the Private Securities Litigation Reform Act (PSLRA), a 1995 law designed to permit early dismissal of insubstantial securities fraud suits.

The defendant is Genzyme Corp., a drug company that manufactures biological products used to treat a variety of metabolic disorders caused by a body's lack of certain enzymes. The plaintiffs are individuals who purchased Genzyme shares in the months following October 2008. They filed a securities fraud suit against Genzyme, alleging that the company failed to alert them until March 2009 that FDA employees, during an October 2008 inspection of Genzyme's largest manufacturing facility, had observed 16 deficiencies in the company's manufacturing practices. The value of Genzyme shares dropped during 2009 after the company timely disclosed that FDA's findings resulted first in a "Warning Letter" (in March 2009) and then in significant FDA enforcement action based on Genzyme's alleged noncompliance with regulations governing good manufacturing practices (GMP). Genzyme immediately disclosed the Warning Letter and enforcement action, which led to disruptions in production and a drop in earnings and share price in 2009. The share price fully recovered in 2010 after Genzyme corrected the manufacturing deficiencies.

In 2012, a federal district court in Boston dismissed the complaint, finding that the plaintiffs failed to allege facts from which one could infer a "strong inference" that Genzyme and its senior officers acted with "scienter" (*i.e.*, an intent to deceive investors). The plaintiffs have appealed from that decision to the First Circuit, arguing that dismissal is improper until after they have been given an opportunity to engage in document discovery designed to uncover evidence supporting their "intent to deceive" claims.

In its brief urging the First Circuit to affirm, WLF focused solely on the scienter issue. WLF

argued that the district court properly applied the heightened scienter pleadings standard adopted by Congress in 1995 as part of the PSLRA. Under the PSLRA, a securities fraud complaint can withstand a motion to dismiss only if the facts alleged create a "strong inference" that the defendants intended to deceive investors. That inference must be at least as compelling as competing, non-culpable inferences one could draw from the facts alleged. WLF asserted that an intent to deceive can never be inferred when the information withheld (here, inspectors' preliminary "observations" that a manufacturing facility is not complying with GMPs) is statistically unlikely to result in significant FDA enforcement action. WLF noted that FDA inspectors issue thousands of preliminary "observations" of the sort at issue here (which are recorded on FDA's Form 483), yet only a tiny fraction of Forms 483 lead to issuance of even so much as a Warning Letter (the lowest level of FDA enforcement). That the Form 483 issued in this case later mushroomed into major FDA enforcement action may indicate that Genzyme was insufficiently inattentive to FDA's concerns, but it is not evidence of fraud, WLF argued.

WLF argued that the plaintiff's complaint is a classic example of "fraud by hindsight" allegations. Genzyme is being faulted for failing to immediately disclose not-particularly-material information that later mushroomed into significant, unanticipated adverse events, WLF asserted. It argued that the most logical inference to be drawn from the facts alleged by the plaintiffs is that Genzyme waited five months to disclose the Form 483 because it believed that the "observations" reflected on the form were unlikely to have more than a minor impact on its finances, not that it was intending to hide bad news in order to delay an inevitable collapse in the price of its common stock.

WLF is a public interest law and policy center with supporters in all 50 States. WLF devotes a substantial portion of its resources to defending and promoting free enterprise, individual rights, and a limited and accountable government. In particular, WLF has appeared in numerous federal and state courts in cases raising securities law issues.

For further information, contact WLF Chief Counsel Richard Samp, (202) 588-0302. A copy of WLF's brief is posted on its web site, www.wlf.org.