United States Senate
COMMITTEE ON THE JUDICIARY
WASHINGTON, DC 20510–6275

June 7, 2012

Via Electronic Transmission

The Honorable Mary L. Schapiro
Chairman
U.S. Securities and Exchange Commission
100 F Street, NE
Washington, DC 20549

Dear Chairman Schapiro:

I write today to apprise you about a potentially troubling issue for investors in the pharmaceutical industry and for the federal government, which pays billions of dollars every year for drugs through the Medicaid and Medicare programs. I am disturbed by reports concerning the release of clinical trial data by Vertex Pharmaceuticals Inc. (Vertex) and stock sold by Vertex executives.

Vertex received Food and Drug Administration (FDA) approval in January 2012 for their cystic fibrosis treatment, Kalydeco, for patients over six years old. Vertex is currently conducting a clinical trial to secure approval to treat the entire adult population.[1] Many believe securing this approval from the FDA would be a game-changer for Vertex. According to *Dow Jones*, on May 7, 2012, Vertex reported positive clinical trial data between Kalydeco, and an experimental drug, VX-809.[2] Due to this reported good data, shares of Vertex stock jumped 55 percent.

Three weeks later the *The Boston Globe* reported that the interim results released by Vertex on May 7th were inflated.[3] As a result, Vertex stock dropped and they announced on May 29, 2012, a correction to the interim data, admitting that the clinical trial data improvements in patients were actually lower than previously reported.[4]

What is troubling is the news reports showing that between the time of the May 7th announcement and the Vertex correction of May 29th, five Vertex executives and two directors

[1] Peter Loftus. "Vertex Overstated Efficacy Of Cystic-Fibrosis Drug." May 29, 2012. Found at: http://online.wsj.com/article/BT-CO-20120529-710936.html
[2] *Id.*
[3] Robert Weisman and Beth Healy. "Vertex stock sinks as firm concedes errors." *The Boston Globe*. May 29, 2012. Found at: http://articles.boston.com/2012-05-29/business/31882014_1_cystic-fibrosis-vertex-mucus
[4] "Vertex Corrects and Provides Additional Data from Recent Interim Analysis of Phase 2 Combination Study of VX-809 and KALYDECO (ivacaftor) in People with Cystic Fibrosis Who have Two Copies of the F508DEL Mutation." May 29, 2010. Found at: http://investors.vrtx.com/releasedetail.cfm?ReleaseID=677520

sold off millions of dollars of Vertex shares. According to *The Boston Globe*, Vertex officials claim, "most of the stock sales by executives and directors in the days following the disclosure of the encouraging clinical study results stemmed from preexisting plans — known as 10b5-1's — that allow them to automatically exercise options and sell certain shares at regular intervals or set prices." Despite Vertex's explanation, it could appear that these Vertex executives potentially took advantage of the spike in the stock knowing the news of the clinical data being overstated would be made public eventually, which in turn would negatively affect the stock value.

The SEC has an important mission to protect investors and maintain market integrity. If action related to this matter is taken by the SEC, I request a briefing on those findings. Thank you in advance for your prompt attention to these matters. I would appreciate receiving a response by no later than June 28, 2012. Should you have any questions, please contact Brian Downey or Erika Smith of my staff at (202) 224-5225.

Sincerely,

Charles E. Grassley
Ranking Member