United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

June 28, 2010

Via Electronic Transmission

Jeffrey B. Kindler
Chairman and Chief Executive Officer
Pfizer, Inc.
235 East 42nd Street
New York, NY 10017

Dear Mr. Kindler:

I have devoted many years in the United States Senate supporting whistleblower protections, first as the principal sponsor of the 1986 Amendments to the False Claims Act (FCA), then as co-sponsor of the Whistleblower Protection Act of 1989 and co-sponsor of the Whistleblower Protection Enhancement Act of 2009. I was also a lead sponsor of the Fraud Enforcement and Recovery Act of 2009 (FERA), which was signed into law on May 20, 2009. Among other things, FERA significantly revised the liability aspects of the FCA and extended anti-retaliation protections to agents and contractors of employers that may be a defendant under the FCA.

According to statistics from the U.S. Department of Justice (Department), the FCA has helped the federal government recover over $22 billion since the passage of the 1986 FCA Amendments. These substantial recoveries represent monies that would otherwise have been lost to fraud or abuse of government programs. The FCA created a public-private partnership between the Department and whistleblowers, who report wrongdoing to the federal government when their private sector employers ignore or fail to address their allegations or concerns. This partnership led to a significant portion of the more than $22 billion recovered by the federal government.

In June 2005, as the then-Chairman of the Senate Committee on Finance (Committee), I convened a two-day hearing, titled "Medicaid Waste, Fraud and Abuse: Threatening the Healthcare Safety Net." During the course of that hearing, it was revealed that a large number of FCA cases filed by whistleblowers involving hundreds of different drugs were under seal with the Civil Division at the Department. The FCA was a prominent component of the hearing and testimony was heard about how some corporations were structured to avoid accountability, even when employees raised concerns to the highest levels of the company.

Following the hearing, I sent a letter to 18 pharmaceutical companies requesting information on how they were informing their employees of the FCA, specifically the whistleblower provisions of the FCA. Pfizer, Inc. (Pfizer) and Wyeth Pharmaceuticals (Wyeth) were two of the companies contacted and I appreciated the responses.

At the time, Wyeth was just launching a course that was to include the FCA, while Pfizer assured me its employees were well-educated and trained on the obligations of the FCA. Neither of the responses I received, however, mentioned how employees were being informed of whistleblower protections and what avenues whistleblowers have to file claims.

In early 2006, Congress passed and President Bush signed into law the Deficit Reduction Act (DRA). Section 6032 of the DRA required:

> [A]ny entity that receives or makes annual payments under the [Medicaid] State plan of at least $5,000,000, as a condition of receiving such payments, shall—(A) establish written policies for all employees of the entity (including management), and of any contractor or agent of the entity, that provide detailed information about the False Claims Act established under sections 3729 through 3733 of title 31, United States Code, administrative remedies for false claims and statements established under chapter 38 of title 31, United States Code, any State laws pertaining to civil or criminal penalties for false claims and statements, and whistleblower protections under such laws, with respect to the role of such laws in preventing and detecting fraud, waste, and abuse in Federal health care programs (as defined in section 1128B(f)); (B) include as part of such written policies, detailed provisions regarding the entity's policies and procedures for detecting and preventing fraud, waste, and abuse; and (C) include in any employee handbook for the entity, a specific discussion of the laws described in subparagraph (A), the rights of employees to be protected as whistleblowers, and the entity's policies and procedures for detecting and preventing fraud, waste, and abuse.

On a March 22, 2007, the Centers for Medicare and Medicaid Services released additional guidance on compliance with section 6032 and ultimately determined that pharmaceutical manufacturers that make payments to States under Medicaid drug rebate programs are not "entities" for the purposes of section 6032. Despite this guidance, which I believe runs contrary to the intent of section 6032, I continue to believe that any respectable compliance program should include a relevant sample of all federal laws designed to combat fraud and abuse in the Medicare and Medicaid programs.

Several years have passed since I requested information from Pfizer and Wyeth regarding their respective training programs for employees on the FCA. The purpose of this letter is to follow up on Pfizer's program and any changes that have been made since Pfizer acquired Wyeth. In particular, I am interested in whether or not the current program includes educating employees on the FCA and whistleblower provisions and would appreciate a response to the questions below. Please repeat the enumerated question and follow with the appropriate answer and supporting documentation:

1) What changes have taken place at Pfizer since the acquisition of Wyeth with regard to notifying employees about the FCA? Please provide examples of policies, educational materials, and/or any other documents that Pfizer distributes to its employees that describe the FCA.

2) What materials are provided to employees to educate them on FCA whistleblower protections, specifically resources on the filing of claims or where employees can seek additional information? Please provide the relevant materials and literature distributed to employees.

3) Please describe Pfizer's process for handling employee complaints or allegations regarding false claims. Have there been any changes to the program since the acquisition?

4) Since the implementation of the consolidated compliance programs, how many allegations has Pfizer received each year? Please describe any quantitative and qualitative differences in the allegations, complaints or reports Pfizer has received since establishment of the program.

5) Of the claims received, how many were resolved in favor of the claimant and how many were resolved in favor of the company?

6) What measures does Pfizer have in place to ensure fair treatment to those filing complaints?

7) Of employees who have filed complaints, have any complained of unfair treatment and/or retaliation after the filing of the complaint?

8) What modifications, if any, has Pfizer made to its compliance program in light of the passage of FERA, which extends whistleblower protections to contractors and agents?

Thank you in advance for your cooperation. I would appreciate a response to the above questions by no later than July 20, 2010. If you have any questions, please do not hesitate to contact Angela Choy or Thomas Guastini at (202) 224-4515. All formal correspondence should be sent electronically in PDF format to Brian_Downey@finance-rep.senate.gov or via facsimile to (202) 228-2131.

Sincerely,

Charles E. Grassley
Ranking Member