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

June 28, 2010

Via Electronic Transmission

Richard T. Clark
Chairman and Chief Executive Officer
Merck & Co., Inc.
One Merck Drive
Whitehouse Station, NJ 08889

Dear Mr. Clark:

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 requesting information on how Merck & Co., Inc. (Merck) was informing its employees about the FCA, specifically the whistleblower provisions, as part of its internal corporate compliance programs. I appreciate the response Merck submitted on August 15, 2005, in which Merck provided materials

concerning its business ethics and educational materials for its employees. However, there was no mention or discussion of the FCA or policies regarding whistleblowers in the 144 pages that were provided to the Committee. Furthermore, Merck merged with Schering-Plough in March 2009 and Schering-Plough did not have favorable comments regarding the whistleblower provisions of the FCA in its 2004 response.

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.

The purpose of this letter is to follow up on whether or not Merck established a compliance program that includes educating its employees on the FCA and whistleblower provisions. Specifically, I 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 Merck with regard to notifying employees about the FCA? Please provide examples of policies, educational materials,

and/or any other documents that Merck distributes to its employees that describe FCA and whistleblower protections.

2) If a program has been established, 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 Merck's process for handling employee complaints or allegations regarding false claims.

4) If since Merck's August 2005 response the company has established a compliance program that includes educating its employees on the FCA and whistleblower protections, please describe any quantitative and qualitative differences in the allegations, complaints or reports Merck has received since establishment of that program. How many allegations, complaints and reports has the company received each year?

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) If Merck's compliance program does not include notifying its employees of the FCA and whistleblower protections, please explain why it does not include such notification.

7) What measures does Merck have in place to ensure fair treatment to those filing complaints?

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

9) What modifications, if any, has Merck 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