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

June 28, 2010

Via Electronic Transmission

Lamberto Andreotti
President and Chief Executive Officer
Bristol-Myers Squibb Company
345 Park Avenue
New York, NY 10154-0037

Dear Mr. Andreotti:

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 Bristol-Myers Squibb Company was informing its employees of the FCA, specifically the whistleblower provisions of the FCA, and what avenues whistleblowers have to file such claims. I appreciate the response Bristol-Myers Squibb submitted on August 11, 2005, in which

Bristol-Myers Squibb provided sample training materials. However, I was disappointed by the limited discussion of the FCA in the presentation materials and the failure of Bristol-Myers Squibb to mention any specifics about whistleblowing.

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 Bristol-Myers Squibb 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 Bristol-Myers Squibb with regard to notifying employees about the FCA? Please provide examples of current policies, educational materials, and/or any other documents that Bristol-Myers Squibb distributes to its employees that describe the FCA.

2) In the August 2005 letter, Bristol-Myers Squibb stated, "we emphasize the appropriate use of internal reporting mechanisms to address potential compliance issues, rather than emphasizing the role of the whistle blower provisions of the False Claims Act." The point of my previous inquiry was not to emphasize the role of one over the other. The purpose of FCA is to encourage private individuals with insider information about fraud against the government to alert the government and prevent further fraud by filing a qui tam action. Thus, it is important that individuals be made aware of the avenues for filing FCA claims and the whistleblower protections afforded them under the Act. Has Bristol-Myers Squibb modified its training materials since 2005 to expand its discussion of the whistleblower provisions?

3) Please describe Bristol-Myers Squibb's process for handling employee complaints or allegations regarding false claims. Have there been any changes to the program since its inception?

4) Since the implementation of Bristol-Myers Squibb's compliance program, how many allegations has the company received each year? Please describe any quantitative and qualitative differences in the allegations, complaints or reports Bristol-Myers Squibb 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 Bristol-Myers Squibb 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 Bristol-Myers Squibb 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