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# Congress of the United States

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Dr. Frank M. Torti, M.P.H., F.A.C.P.  
Acting Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Ave.  
Silver Spring, MD 20903

Dear Dr. Torti:

Last year, the Minority staff of the Committee on Energy and Commerce issued a Minority Committee Staff Report entitled, "FDA's Faulty Safeguards Against Corruption: Concerns Over Debarment Use and Authority."

That report examined the Food and Drug Administration's (FDA) use of its debarment authority under 21 U.S.C. § 335(a). Minority staff found that, even though FDA was given authority by Congress 15 years ago to debar generic drug companies who were convicted of felonies under Federal law for crimes relating to the development or approval of a generic drug product, FDA had not debarred a single company. The report went on to list companies who were convicted of crimes that made them eligible for debarment. The report also found that FDA failed to pursue debarment against individuals in a timely manner. After reviewing FDA documents, Minority staff found that, for the debarments initiated since January 1, 2000, FDA took over 38 months on average just to initiate the debarment process. In addition, Minority staff found that FDA administered its debarment authority inconsistently; the report listed several examples of individuals who were convicted of felonies relating to the development or approval of a drug product but who were not debarred, while other individuals with similar circumstances or convictions were debarred.

The report found that FDA's failure to initiate debarments in a timely manner and its inconsistent administration of its debarment authority may be due to the fact that FDA does not have sufficient staff or resources to monitor and review cases that may be eligible for debarment. Further, the Minority staff report noted that FDA had not adopted internal guidance to direct FDA staff as to how to administer FDA's debarment authority. These failures have real

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consequences in clinical trials, as drug companies routinely consult the debarment list when determining which investigators can participate in a trial.

It has been one year since we brought to light the problems surrounding FDA's use of its debarment authority. It is our hope that FDA has taken some action in the last year to improve its debarment processes. Therefore, we respectfully request that you update us in writing no later than March 6, 2009, on any action FDA has taken with respect to its debarment authority under 21 U.S.C. § 335(a), including but not limited to the drafting of guidance or procedures on the debarment process; the designation of additional staff or resources to administer debarment proceedings; and the creation of working groups or task forces to consider FDA's debarment authority.

We appreciate your attention to this important issue. Please do not hesitate to contact Alan Slobodin or Karen Christian of the Minority Committee staff at (202) 225-3641 if you have any questions about this matter.

Sincerely,



Joe Barton  
Ranking Member



Greg Walden  
Ranking Member  
Subcommittee on Oversight and Investigations

cc: The Honorable Henry A. Waxman  
Chairman

The Honorable Bart Stupak  
Chairman, Subcommittee on Oversight and Investigations