United States Senate
WASHINGTON, DC 20510-4502

September 21, 2001

The Honorable Janet Rehnquist
Inspector General
Department of Health and Human Services
Room 5246, Cohen Building
330 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Inspector General Rehnquist:

I am interested in assessing the impact of healthcare group purchasing organizations (GPOs), and their business practices, on competition and innovation in the marketplace for medical devices and other healthcare products. To this end, I am writing to inquire as to the status of your study of the current safe harbors available under the Medicare Anti-Kickback statute (42 CFR 1001.952(j)). In particular, I am interested in knowing the results of your review of the administrative fees and other charges currently being levied on vendors of healthcare products by GPOs, how GPOs are accounting for these fees and charges, and whether the assortment of fees and charges are reasonable or excessive in light of current federal laws and regulations.

In February 2000, an association representing manufacturers of medical devices, MDMA, raised these issues in response to the Inspector General's annual solicitation of comments on safe harbors to the Anti-Kickback Statute. In an appendix to your semiannual report to Congress covering April through September of 2000, your office acknowledged receiving this comment letter which suggested that you reconsider the existing safe harbor for GPOs "in light of evolving fee arrangements in the marketplace." According to the semiannual report, your office is "studying this suggestion."

Would you report to me, by October 5, 2001, on the status of your study, and when I might expect a final report on the issues raised in response to your December 1999 solicitation for comments?

Sincerely,

PATRICK LEAHY
United States Senator