

For Immediate Release

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Wednesday, November 12, 2008

ENZI, COBURN INVESTIGATE CONTRACT IRREGULARITIES AT FDA; CALL ON AGENCY TO PROVIDE DETAILED REPORTS ON PUBLIC RELATIONS CONTRACT

Washington D.C. – U.S. Senator Mike Enzi, R-WY, Ranking Member of the Senate Health, Education, Labor and Pensions Committee (HELP Committee), and Senator Tom Coburn, R-OK, have asked the Food and Drug Administration to provide information about a no-bid contract that officials awarded to a public relations firm with ties to the agency.

"We write today with great concern over apparent disregard for proper and transparent procedure at the Food and Drug Administration (FDA) regarding a contract for a public relations campaign, as recently reported by *The Washington Post*. Allegations that FDA officials steered a no-bid contract toward a Washington public relations firm with ties to agency officials lead us to demand real answers for the American people about FDA's actions," Senators Enzi and Coburn wrote in a letter to Dr. Andrew von Eschenbach, FDA Commissioner.

Senator Enzi said: "These actions are disappointing and could severely damage the image of FDA. We need to make sure that FDA uses the millions of additional dollars that Congress recently granted the agency to achieve its core mission – protecting American consumers and patients."

Dr. Coburn said: "FDA contracts should be awarded in a fair, competitive, and transparent process to ensure taxpayer dollars are spent wisely. FDA officials steering no-bid contracts to their friends is unacceptable, and Americans deserve better from their leaders and government. Vigorous oversight and greater accountability is necessary to ensure that the FDA is effectively safeguarding the public's health and their pocketbooks."

Senators Enzi and Coburn also sent a letter to Daniel Levinson, Inspector General of the Department of Health and Human Services, asking that he conduct an investigation into the contracting issue.

The Post article suggests that an FDA official in charge of a public relations campaign intended to contract with Qorvis, a major Washington public relations firm specializing in crisis communications. Instead of competitively bidding the contract to find the best deal for taxpayers, however, FDA entered into a contract with Alaska Newspapers, Inc. ("ANI"), an Alaska Native firm, pursuant to a federal diversity procurement set-aside program.

"We are concerned that FDA officials entered into this contract with ANI as a subterfuge for the purpose of receiving services from Qorvis as an ANI subcontractor, which appears to have effectively bypassed a fair and transparent contracting process," the Senators wrote.

"We believe that the best interests of taxpayers are served through a transparent and competitive federal contracting process, and we want to ensure that this is a consistent practice at the FDA."

Copies of the letters follow.

EDWARD M. KENNEDY, MASSACHUSETTS, CHAIRMAN

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United States Senate

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

WASHINGTON, DC 20510-6300

November 10, 2008

Dr. Andrew C. von Eschenbach Commissioner U.S. Food and Drug Administration 5600 Fishers Lane Rockville, MD 20857

Dear Dr. von Eschenbach:

We write today with great concern over apparent disregard for proper and transparent procedure at the Food and Drug Administration (FDA) regarding a contract for a public relations campaign, as recently reported by the Washington Post. Allegations that FDA officials steered a no-bid contract toward a Washington public relations firm with ties to agency officials lead us to demand real answers for the American people about FDA's actions.

Congress listened to and granted the FDA's requests for millions of dollars in additional funding to improve and expand the agency and its workforce to give the American public faster access to safe and effective new therapies. We did this in the hope that the FDA would use its new resources to improve its performance and focus on the agency's core mission. Included in that core mission must be an awareness by senior management of the activities being carried out by FDA officials under their employ.

We find it ironic that the contract in question, to "create and foster a lasting positive public image of the [FDA] for the American public," will in fact damage the FDA's image.

We respectfully request that you share with us your future plans to ensure that the FDA leadership conducts better management of its employees. We also look forward to learning your plans to ensure better coordination between the program and contracting offices at the FDA. To assist the HELP Committee with continuing oversight of this matter, we request that you also provide:

- Copies of all written (including electronic) communication regarding this matter;
- A detailed timeline of events beginning with the decision to pursue a contract for public relations work;
- A detailed description of processes and standards to prevent any conflicts of interest regarding other clients of subcontractors;

- A detailed description of current processes and any planned changes in oversight of program office employees;
- A detailed description of current processes and any planned changes regarding coordination between program office and contracting office; and
- Ongoing updates on the internal investigation of this matter.

We would like this information by December 1st. We look forward to your prompt reply.

Sincerely,

Michael B. Enzi Ranking Member

Tom Coburn, M.D.
United States Senator

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November 10, 2008

Daniel R. Levinson Inspector General Office of the Inspector General Department of Health and Human Services 330 Independence Ave SW Washington, DC 20201

Dear Inspector General Levinson,

We are writing to request that you investigate a recent contracting issue handled by the Food and Drug Administration (FDA). We believe that the best interests of taxpayers are served through a transparent and competitive federal contracting process, and we want to ensure that this is a consistent practice at the FDA.

One apparent violation of the transparent and competitive process was uncovered by the Washington Post in an article dated October 2, 2008. As noted in the article, "The story behind the FDA's public relations deal, drawn from interviews and dozens of e-mails obtained by The Post, offers insight into how contract competition requirements designed to get the best deals for taxpayers have often been subverted in recent years for the sake of convenience or to serve narrow interests..." We request that you investigate this specific contracting example highlighted in The Post article.

The Post article suggests that a Food and Drug Administration ("FDA") official in charge of a public relations campaign intended to contract with Qorvis, a major Washington public relations firm specializing in crisis communications. Instead of competitively bidding the contract to find the best deal for taxpayers, however, FDA entered into a contract with Alaska Newspapers, Inc. ("ANI"), an Alaska Native firm, pursuant to a federal diversity procurement set-aside program. As suggested in The Post article, we are concerned that FDA officials entered into this contract with ANI as a subterfuge for the purpose of receiving services from Qorvis as an ANI subcontractor, which appears to have effectively bypassed a fair and transparent contracting process.

We understand that FDA has suspended the contract and has asked you to investigate this specific matter. In conducting that investigation, we ask that you investigate whether FDA or any FDA officials, in connection with this ANI contract, committed procurement fraud or otherwise engaged in misconduct.

Specifically, we ask that you examine the actions and communications of FDA officials with respect to ANI and Qorvis. We also ask that you examine whether any conflict of interest violations occurred.

Please keep us apprised of the progress of your investigation with periodic status reports and updates, as appropriate. Please do not hesitate to contact our staff members if we may be of assistance: Keith Flanagan (224-6770) with Senator Enzi and Stephanie Carlton with Senator Coburn (224-6005).

Very truly yours,

Michael B. Enzi Ranking Member Tom Coburn, M.D.

United States Senator