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United States Senate

COMMITTEE ON THE JUDICIARY

WASHINGTON, DC 20510-6275

February 3, 2014

VIA ELECTRONIC SUBMISSION

Dr. Christine Cassel
President and CEO
National Quality Forum
1030 15th Street NW, Suite 800
Washington, DC 20005

Dear Dr. Cassel:

On January 9, 2014, the U.S. Department of Justice (DOJ) reached a \$40 million settlement with CareFusion Corp. over allegations of misconduct, including kickback payments made to Dr. Charles Denham. According to the settlement, which was the result of a whistleblower lawsuit, CareFusion paid Dr. Denham over \$11 million in exchange for endorsing its antiseptic product ChloraPrep, while he served on the National Quality Forum's (NQF) Safe Practices Committee.¹

In August 2009, as co-chair of the Safe Practices Committee, Dr. Denham led a meeting to update NQF's safe practice guidance for release in a 2010 report. During the meeting, Dr. Denham referred to an upcoming study endorsing ChloraPrep's specific formula as highly effective in preventing surgical site infections. Dr. Denham's endorsement of this formula led to a draft recommendation that the formula be used to prepare the skin before inserting catheters.² The recommendation was later removed after NQF conducted an ad hoc review at the request of one of its members.³

At the time of NQF's meeting to update safe practices, NQF was apparently unaware of Dr. Denham's financial ties to CareFusion, but ChloraPrep had not been approved for use before inserting catheters by the Food and Drug Administration (FDA). In fact, a major part of DOJ's settlement with CareFusion was to resolve allegations that the company knowingly promoted ChloraPrep for uses that were not approved by the FDA. While the recommendation was

¹ U.S. Department of Justice, "CareFusion to Pay the Government \$40.1 Million to Resolve Allegations That Include More Than \$11 Million in Kickbacks to One Doctor," January 9, 2014.

² ProPublica, "Hidden Financial Ties Rattle Top Health Quality Group," January 28, 2014.

³ 3M Health Care Business, Request to Remove Recommendation of a Specific Preoperative Skin Preparation, March 11, 2010.

ultimately removed, it is concerning that a prominent expert at NQF was encouraging non-approved uses during a review of patient safety best practices while being paid millions of dollars by the manufacturer of ChloroPrep. Naturally, this raises serious concerns about NQF's conflict of interest policies.

In addition to Dr. Denham's failure to disclose his conflict of interest concerning ChloroPrep, sources report that NQF received \$725,000 in donations from Dr. Denham's nonprofit, Health Care Concepts. NQF also had a five year contract with Health Care Concepts, but it is unclear what the terms of the contract were. Again, this raises concerns that NQF's vetting process, both for its expert members and for contractors, may not be sufficient in preventing conflicts of interest. It is surprising that, given NQF's close involvement with Dr. Denham and his nonprofit, NQF says it was unaware of his connections with CareFusion.⁴

NQF is an important entity in promoting best practices, and it has done vital work to promote patient safety and quality care. However, this case calls into question NQF's due diligence and its obligation to prevent conflicts of interest or recommendations that violate officially approved uses.

In order to examine the effectiveness of NQF's policies and procedures in preventing conflicts of interest, please provide the following information:

1. What are NQF's policies and procedures to record disclosure of interests? Have these policies been updated since August 2009?
2. Does NQF verify the accuracy and completeness of disclosure information it receives? If so, how?
3. Does NQF make disclosures of interest available to its members and/or the general public? Why or why not?
4. Does NQF disclose donations made to NQF by its members? Why or why not?
5. What is NQF's vetting process for potential contractors? Has this process changed since NQF awarded a contract to Health Care Concepts?
6. Please provide a copy of NQF's contract with Health Care Concepts.
7. Please provide all records related to Dr. Denham's relationship with CareFusion.

⁴ ProPublica, "Hidden Financial Ties Rattle Top Health Quality Group," January 28, 2014.

Thank you for your cooperation and attention in this matter. I would appreciate a response by February 18, 2014. If you have any questions, please do not hesitate to contact Tegan Millspaw of my committee staff at (202) 224-5225.

Sincerely,

A handwritten signature in blue ink that reads "Chuck Grassley". The signature is written in a cursive, flowing style.

Charles E. Grassley
Ranking Member
Committee on the Judiciary