Steve Phurrough, MD MPA
Centers for Medicare and Medicaid Services
CMS
OCSQ-CAG
7500 Security Blvd
MS-C10906
Baltimore, Maryland 21244

12 June 2007

Dear Dr. Phurrough:

This letter is a formal request to CMS for a national coverage decision on:

Colorectal cancer screening through the identification of specific colorectal cancer associated DNA mutations and alterations by the analysis of human DNA isolated from stool

In accordance with the NCD request process published in the Federal Register, September 26, 2003 (FR Vol. 68, number 187, pages 55634-55641), we request that CMS uses the collaborative NCD development track, track one (pg 55638, IV E).

The information requested by CMS as part of the NCD development process is contained in the attached document. Dr. Barry M. Berger is the primary requestor and contact for this NCD request and may be reached at any time for additional information or clarification.

I am a practicing gastroenterologist and recognize the importance of colorectal screening and prevention or early detection of CRC. I am an expert in the field of CRC screening and have participated in a number of consensus panels in this regard. Clearly screening is not the entire issue. Patient acceptance and willingness to comply is a key barrier to entry. The fecal DNA analysis provided by Exact Sciences represents a key advance in the fecal-based detection strategies for CRC. Patient acceptance of this type of testing has been inordinately favorable. As such, the availability and patient acceptance should be coupled with coverage as an acceptable option This test represents a significant breakthrough in the field of molecular biologic testing for CRC. The ease of use, central standardization of processed results insures a highly acceptable and reproducibly reliable result. To the credit of the company they maintain that this testing is for those individuals who know and understand the values of colonoscopy as the preferred strategy but still otherwise refuse screening.

I would urge your closest attention towards the approval of this valued test which will facilitate and enhance the screening acceptance for CRC. Your policy change in this direction which lowers any barrier for entry for acceptance will greatly benefit the patients we all serve and care for. I would be delighted if you need further information

or clarification to have you contact me by phone (757-466-0165) or e
(dajevms@aol.com).

Respectfully,

David A. Johnson MD
Professor of Medicine
Chief of Gastroenterology
Eastern VA Medical School
Norfolk VA