June 10, 2004

Carolyn Clancy, MD
Administrator
Agency for Healthcare Research and Quality
540 Gaither Road
Rockville, MD 20850

Michael O'Grady
Assistant Secretary for Planning and Evaluation
USDHHS
200 Independence Ave., SW
Washington, DC 20201

Mark McClellan, MD, Ph.D.
Administrator
Centers for Medicare & Medicaid Services
200 Independence Ave., SW
Washington, DC 20201

RE: FDA Docket - 2004S-1070

Dear Drs. Clancy, McClellan, and Mr. Grady:

The American College of Surgeons appreciated the opportunity to attend the Medicare Research Priorities Listening Session held on May 21, 2004 to learn more about the possible topics that can be addressed within the purview of Section 1013 of the Medicare Prescription Drug and Modernization Act. We believe that the major emphasis of the upcoming research needs to focus on producing outcomes tools that we know surgeons will use as an integral part of their practice and to deploy methods that have a demonstrated ability to increase quality and cost effectiveness as well. There are effective outcomes tools available today that need further testing and we encourage the Department to identify surgical safety as a top priority.

We believe that an expansion of the College's work with the Department of Veterans Affairs (VA) on the National Surgical Quality Improvement Program (NSQIP) presents an opportunity to address a number of the agency's concerns about effectiveness, efficiency, and the cost of Medicare, Medicaid, and SCHIP. Our Division of Research and Optimal Patient Care stands ready to develop a program that puts guidelines, best practices, and data platforms for the pursuit of studies of morbidity and mortality to work to help you accomplish the stated goals of Sections 1013, 646, and other research programs currently under consideration within the Department. We believe that our experience

implementing best practices programs such as the Advanced Trauma Life Support (ATLS) courses, as well as our work with NSQIP, the National Cancer Data Base and the National Trauma Data Bank are ready made to help the Department answer critical questions and accomplish your stated goals to:

- Answer medically important unresolved questions of clinical effectiveness;
- Create products that stimulate significant improvement in the effectiveness, efficiency and cost of care provided by federal insurance products;
- Spur innovation to lead to reduced time frames for showing clinical effectiveness.

Our work with 14 academic hospitals has shown that use of the NSQIP system has generated needed quality improvements and reduced complications. We are in the process of recruiting 100 other community based hospitals for further testing. Recent work at the University of Michigan Health Sciences Center has also given us promising indications that the system can also be used to show how NSQIP reduces complications and subsequently reduces costs. One of the additional challenges facing hospitals in improving surgical safety has been the lack of ability to integrate existing cost systems with clinical information data sources. We believe that this is an area for further research.

Surgeons consider NSQIP a credible and fair way to evaluate the quality of patient care. This risk-adjusted outcomes measurement system provides the information necessary for surgical processes and systems to change. We know that surgeons will use this information and it will allow appropriate and meaningful measurement that ultimately will be useful for consumers to evaluate the status of their surgical service.

We understand the importance of focusing on the effectiveness of pharmaceuticals, however, we would encourage you to seriously consider some of the following elements which we believe are intrinsic to safer surgical patient care:

- Further expansion of NSQIP into a wider number and kinds of facilities;
- Pursue cost effectiveness research currently underway in Michigan to other key states and health care organizations.
- Assessment of NSQIP's predictive capabilities of patient's surgical experience in the existing 14 academic health centers.
- Develop a surgical evidence and expedited consensus process that allows ongoing assessment of surgical guidelines, best practices and protocols and puts them into action.

We stand ready to be of service to the Department to further the integration of this system into widespread practice.

Sincerely,
Thomas R. Russell, MD, FACS
Executive Director
American College of Surgeons