



June 28, 2004

**VIA FEDERAL EXPRESS AND
VIA ELECTRONIC TRANSMISSION: <http://www.fda.gov/dockets/ecomments>**

Carolyn M. Clancy, M.D.
Director, Agency for Healthcare Research and Quality
540 Gaither Road
Rockville, Maryland 20850

Food and Drug Administration
Dockets Management Division
5630 Fishers Lane
Room 1061 (HFA-305)
Rockville, MD 20852

*Re: Docket No. 2004S-0170 Medicare Prescription Drug,
Improvement, and Modernization Act of 2003,
Section 1013: Suggest Priority Topics for Research*

Dear Ms. Clancy:

Medical Metrix Solutions (MMS) appreciates this opportunity to submit to the Agency for Healthcare Research and Quality (AHRQ) a suggested research priority for fiscal year 2006 for the research authorized under section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Specifically, we suggest that AHRQ study the outcomes, comparative clinical effectiveness, and appropriateness of using three-dimensional pre-operative and post-operative computer-aided measurement planning and simulation ("3-D CAMPS") technology versus angiography for surgical planning and post-operative monitoring for the surgical repair of thoracic aortic aneurysms (TAAs) and abdominal aortic aneurysms (AAAs).

Medical Metrix Solutions (MMS) is a West Lebanon, New Hampshire-based company that develops and implements innovative medical imaging, measurement, and data analysis technology. Our product Preview® is the only FDA-approved 3-D CAMPS technology.

Vascular surgeons consider 3-D CAMPS to be essential for pre-operative and post-surgical monitoring in connection with the surgical repair of TAAs and AAAs. Before 3-D CAMPS was available, the primary tool for surgical planning and follow-up for AAAs and TAAs was an angiogram, which is not only costly for patients and the health care system, but also presents significant health risks to the patient. 3-D CAMPS saves literally thousands of dollars for the Medicare program each time it is used in lieu

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of an angiogram to treat TAAs or AAAs, even while it provides far superior information and imaging and reduces the health risks presented to the patient. Unfortunately, due to inertia and other reasons, some practitioners continue to subject patients to angiograms where 3-D CAMPS would be more appropriate.

Section 1013 of the MMA directs AHRQ to conduct research that may include "health care items and services . . . which may be underutilized . . . and which may significantly improve the prevention, treatment, or cure of diseases and conditions . . . which impose high direct or indirect costs on patients or society." MMA §1013(a)(2)(C). We believe the benefits offered by 3-D CAMPS -- both in terms of cost savings and improved health outcomes -- make this technology an ideal candidate for study by AHRQ under the MMA, especially in light of the President's recently-launched health information technology initiative.¹ Moreover, there is a robust body of literature and clinical research to facilitate AHRQ's study of this technology, including the Patient Evaluation and Management System (PEMS), an Internet-based postmarketing surveillance database that catalogues the therapeutic outcomes of AAA and TAA patients.

I would welcome the opportunity to discuss this with you further. Please advise if we can provide any additional information to assist in your decision process.

Sincerely,



M. Weston Chapman
President & CEO
Medical Metrix Solutions, Inc.

¹ See Exec. Order No. 13,335, 69 Fed. Reg. 24,059 (April 27, 2004).