Proximal Anastomotic Assist Devices

Surgeons use proximal AADs in CABG procedures to avoid the need to clamp the aorta when attaching a harvested vessel to it. If a proximal AAD is not used, the surgeon must use a clamp to stop the flow of blood to a segment of the aorta while the harvested vessel is surgically attached. Using a clamp can cause calcified plaque particles to dislodge from the aorta and travel through the blood stream to the brain, risking neurological dysfunction or stroke.

The proper geographic market in which to analyze the effects of the proposed transaction on the market for proximal AADs is the United States. Proximal AADs are medical devices that must be approved by the FDA before being marketed in the United States. As with other medical devices, the clinical testing and regulatory approval process for proximal AADs can be costly and time-consuming, preventing proximal AADs approved outside of the United States but not approved within the United States from serving as a competitive alternative for U.S. consumers.

There are currently three firms in the U.S. market for proximal AADs, making it a highly concentrated market. The evidence indicates that J&J and Guidant's manual proximal AADs are each others' closest competitors. Medtronic also participates in the market with an automatic device that it recently launched in the United States. A fourth firm, St. Jude Medical, removed its automatic device, Symmetry®, from the market last year amidst reports of device failures. J&J's proximal AAD, eNclose®, was developed and is manufactured by Novare; J&J and Novare have a distribution agreement making J&J the sole distributor of eNclose® in the United States.

As with the other medical devices discussed, entry into the market for proximal AADs is difficult, costly, and time-consuming. Additionally, the alleged safety concerns regarding St. Jude's Symmetry device have resulted in greater scrutiny of proximal AADs by the FDA. The increased scrutiny is likely to substantially increase the cost of developing a proximal AAD. In addition, it appears that the publicity surrounding Symmetry's removal from the market has dampened physician enthusiasm for these devices. These developments, along with the declining number of overall U.S. CABG procedures, decrease the likelihood of entry into this market.

The proposed acquisition is likely to cause significant competitive harm in the market for proximal AADs by eliminating competition between J&J and Guidant and reducing the number of competitors in the market from three to two. The evidence has also shown that J&J and Guidant's products are likely each others' closest competitors in the proximal AAD market because they are more similar to each other than to Medtronic's product. The proposed acquisition is therefore likely to enable the combined J&J/Guidant to raise prices for proximal AADs unilaterally.

The proposed acquisition's anticompetitive effects in the market for proximal AADs are remedied by the proposed Consent Agreement's requirement that J&J terminate its distribution agreement with Novare for Novare's proximal AAD, eNclose. It is anticipated that it will take Novare no more than two months to find a new distribution partner for eNclose.

Appointment of an Interim Monitor and a Divestiture Trustee

The proposed Consent Agreement contains a provision that allows the Commission to appoint an interim monitor to oversee J&J's compliance with all of its obligations and performance of its responsibilities pursuant to the Commission's Decision and Order. The interim monitor is required to file periodic reports with the Commission to ensure that the Commission remains informed about the status of the divestitures, about the efforts being made to accomplish the divestitures, and the provision of services and assistance during the transition period for the EVH divestiture.

Finally, the proposed Consent Agreement contains provisions that allow the Commission to appoint a divestiture trustee if any or all of the above remedies are not accomplished within the time frames required by the Consent Agreement. The divestiture trustee may be appointed to accomplish any and all of the remedies required by the proposed Consent Agreement that have not yet been fulfilled upon expiration of the time period allotted for each.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Decision and Order or to modify its terms in any way.

By direction of the Commission, with Chairman Majoras and Commissioner Harbour recused.

Donald S. Clark,

Secretary.

[FR Doc. 05–22165 Filed 11–7–05; 8:45 am]

BILLING CODE 6750–01–P

GOVERNMENT ACCOUNTABILITY OFFICE

Advisory Council on Government Auditing Standards; Notice of Meeting

The Advisory Council on Government Auditing Standards will meet Monday, December 5, 2005, from 8:30 a.m. to 5 p.m., in room 7C13 of the Government Accountability Office building, 441 G Street, NW., Washington, DC.

The Advisory Council on Government Auditing Standards will hold a meeting to discuss issues that may impact government auditing standards. The meeting is open to the public. Council discussions and reviews are open to the public. Members of the public will be provided an opportunity to address the Council with a brief (five minute) presentation on Monday afternoon.

Any interested person who plans to attend the meeting as an observer must contact Sharon Chase, Council Assistant, 202–512–9406. A form of picture identification must be presented to the GAO Security Desk on the day of the meeting to obtain access to the GAO Building. For further information, please contact Ms. Chase. Please check the Government Auditing Standards Web page (*http://www.gao.gov/govaud/ybk01.htm*) one week prior to the meeting for a final agenda.

Jeanette M. Franzel,

Director, Financial Management and Assurance.

[FR Doc. 05–22205 Filed 11–7–05; 8:45 am]

BILLING CODE 1610–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Privacy Act of 1974; Report of a New System of Records

AGENCY: Department of Health and Human Services (HHS) Centers for Medicare & Medicaid Services (CMS).

ACTION: Notice of a New System of Records (SOR).

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, we are proposing to establish a new