

**To:** STS Members

**From:** John E. Mayer, Jr., MD

**Subject:** Trasylol (Aprotinin) Update

**Sent:** Wednesday, November 14, 2007

Dear STS Member:

As outlined in an STS member alert on November 5, the United States Food and Drug Administration requested and Bayer Pharmaceuticals Corporation agreed that Bayer would suspend marketing of Trasylol (aprotinin) pending a comprehensive review of data from a Canadian study: *Blood conservation using antifibrinolytics: A randomized trial in a cardiac surgery population* (BART). The FDA requested that Bayer suspend marketing of Trasylol based on preliminary results from this study, which suggested that Trasylol use was associated with an increased risk of death compared to the other antifibrinolytic drugs used in the study. This announcement followed an earlier communication from the FDA regarding the Data Safety Monitoring Board's recommendation that patient enrollment in the aprotinin treatment arm of this study be stopped.

At STS we believe that all members of the cardiothoracic surgical community should understand the FDA's action and Bayer's agreement to suspend marketing until the data can be fully evaluated. The Society is offering to assist the FDA in this important evaluation effort. Only with further, detailed analysis will it be possible to determine whether there are specific populations of patients undergoing cardiac surgery for whom the benefits of Trasylol outweigh the risks.

*The Annals of Thoracic Surgery* has published two STS Practice Guidelines that contain recommendations concerning the use of aprotinin in cardiac surgery, one in executive summary format and one in its entirety: "Aspirin and Other Antiplatelet Agents During Operative Coronary Revascularization" (Ann Thor Surg: 2005, 79:1454-61) and "Perioperative Blood Transfusion and Blood Conservation in Cardiac Surgery" (Ann Thor Surg: 2007, 83:S27-86). Both Practice Guidelines also are posted in their entirety in the About STS section of [www.sts.org](http://www.sts.org). These guidelines were based on extensive review of the scientific literature available prior to their publication and contain many other recommendations unrelated to aprotinin that can assist surgeons in the treatment of cardiac patients. The Society continues to make these guidelines available, but is adding relevant reference to the FDA action pertaining to aprotinin.

In addition, STS is in the process of convening a special Task Force that will thoroughly review these Practice Guidelines and determine whether changes to any of the recommendations, particularly those relating to aprotinin, are needed.

We will keep you apprised of further developments as they occur.

Sincerely,

*John E. Mayer, Jr., MD*  
STS President