

December 20, 2011

Dear Dr. Wolfe

I write this note in support of your petition to the FDA to withdraw the HDE approval from the Wingspan stent and to request a recall of this device.

When the Wingspan stent was first approved using the HDE mechanism in 2005, there was limited data on safety and effectiveness. In the interim, more data have been collected, and the FDA should now be in a better position to evaluate its risks and benefits. With the conclusion of the recent SAMMPRIS trial showing that Wingspan has a much higher complication rate than modern medical management, it is imperative that the FDA take swift and decisive action. I have looked at the FDA website and tried to find out whether the Agency has even warned clinicians using a Medical Device Safety Communication. I cannot locate such a notice and would ask the FDA to explain why they have been so silent in the face of this significant trial showing clear concerns about this regulated medical device. I can see no reason why this device should continue to be available. I agree with your petition to the FDA to immediately withdraw the HDE approval for this device.

As you know, I spent over 6 years as Director of the Office of Surveillance and Biometrics and over 6 years as Director of the Office of Science and Engineering Laboratories at CDRH/FDA. I understand that the FDA needs to use its regulatory authority in flexible and not dogmatic ways and granting of HDEs when data about safety and effectiveness are not complete is a legitimate exercise of regulatory authority. However, for that flexibility, the FDA must realize it has an equally important duty to move swiftly to make regulatory changes and announcements when device problems are uncovered.

These compelling postmarket data about the Wingspan stent provide an opportunity for the FDA to show to industry, the clinical community, and most of all to patients that the Agency is serious about exercising its authority by withdrawing the HDE immediately and insisting on a recall to ensure the devices on the US market are both safe and effective.

Sincerely,

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