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FDA Is Reckless in Its Failure to Remove Dangerous Medical Device From the Market

Stryker Medical's Wingspan Stent System Comes With High Risk of Stroke or Death, Should Be Recalled

WASHINGTON, D.C. – The Food and Drug Administration's (FDA) failure to remove from the market a medical device that is supposed to prevent strokes in patients who are at high risk of such events because of severely narrowed brain blood vessels represents a reckless disregard for patient safety, Public Citizen said in an addendum to a petition it sent the agency in December.

Since the December petition, the manufacturer of the Wingspan Stent System – Stryker – and an FDA official have made public statements implying that the continued failure of the FDA to remove this dangerous medical device from the market is related to some alleged lack of comparability between the subjects in the Stenting and Aggressive Medical Management for Preventing Recurrent Stroke in Intracranial Stenosis (SAMMPRIS) study – the only randomized, controlled study ever done to evaluate the safety and effectiveness of the device – and the patients for whom the Wingspan Stent System was intended to treat under FDA's 2005 approval of the humanitarian device exemption (HDE) for this device.

The former study, funded by the National Institutes of Health and published in September 2011 in the *New England Journal of Medicine*, found a 2.5-fold higher risk of suffering a stroke or dying within the first 30 days in patients who had the device implanted than those who received medical treatment alone. Enrollment in the study was stopped in April 2011 – earlier than anticipated – because of these serious safety problems and a lack of evidence that the device provided any benefit.

"The Wingspan Stent System was thought to be too dangerous to implant in any more subjects in the SAMMPRIS trial, and it is likewise too dangerous to use in the hundreds of patients who have clinical characteristics similar to those of the SAMMPRIS trial subjects and the population of patients eligible for treatment with this device under the FDA-approved HDE indication," said Dr. Michael Carome, deputy director of Public Citizen's Health Research Group and author of the petition. "Due to the FDA's unconscionable decision to delay withdrawal of the

agency's approval of the Wingspan Stent System HDE, the continued use of this device exposes patients to an unacceptable risk of serious harm, including death."

"Given the evidence of significant harm with no evidence of any benefit, there is no justification for any additional patients to be treated with this dangerous device," Carome added. "The only way that further use of the device can effectively and definitively be prevented is to immediately remove the device from the market, as it clearly cannot be said to provide reasonable assurance of safety. Rather, it guarantees an unreasonable risk of harm. To allow any further implantation of this device would be highly unethical as well as a violation of FDA laws and regulations."

To read the December petition, visit: http://www.citizen.org/petition-to-fda-to-withdraw-approval-of-wingspan-stent-system-122111.

To read the addendum, visit: http://www.citizen.org/supplement-to-petition-to-fda-to-withdraw-approval-wingspan-stent-system-011212.

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