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February 14, 2012

Margaret A. Hamburg, M.D.
Commissioner
Food and Drug Administration
Department of Health and Human Services
WO 2200
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Jeffrey E. Shuren, M.D., J.D.
Director, Center for Devices and Radiological Health
Food and Drug Administration
Department of Health and Human Services
WO 66, Room 5442
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061, HFA-305
Rockville, MD 20852

RE: Citizen Petition — Docket Number FDA-2011-P-0923

Dear Drs. Hamburg and Shuren,

Public Citizen, a consumer advocacy group representing more than 250,000 members and supporters nationwide, wishes to inform you of our recent letter to Centers for Medicare and Medicaid services (CMS), which relates to our earlier December 21, 2011 petition to the Food and Drug Administration (FDA) (docket number FDA-2011-P-0923).

In our December 21 petition to the FDA, we urged the agency to immediately withdraw the humanitarian device exemption approval for the Wingspan Stent System with Gateway PTA Balloon Catheter (or Wingspan Stent System), based primarily on recent data from the Stenting Versus Aggressive Medical Management for Preventing Recurrent Stroke in Intracranial Stenosis trial, which established that the device is unsafe and ineffective for its intended use.

CMS currently has a national coverage determination in place that provides for coverage of the Wingspan Stent System and similar systems when used in the context of a category B investigational device exemption (IDE).

We note in our letter to CMS that the FDA should not categorize future investigations using the Wingspan Stent System or similar systems as Category B, because these systems are class III devices and underlying questions of safety and effectiveness have not been resolved (or more precisely, they have been resolved and show that the device is unsafe and ineffective).

We request that FDA take steps to ensure that no future Category B IDEs are conducted using this device.

Sincerely,

Sarah Sorscher, J.D., M.P.H.
Researcher
Public Citizen's Health Research Group

Michael A. Carome, M.D.
Deputy Director
Public Citizen's Health Research Group

Sidney Wolfe, M.D.
Director
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Attachment: February 14, 2012 letter to CMS