DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and Radiological Health

Brief Summary of the Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee

Meeting – February 25, 2016

Introduction

On February 25, 2016, the Panel discussed, made recommendations and voted on information regarding the premarket approval application (PMA) for the TOPAS™ Treatment for Fecal Incontinence (FI). The device is a permanent mesh implant. The proposed indication for use is as follows: The TOPAS™ Treatment for Fecal Incontinence is intended to treat women with fecal incontinence (also referred to as accidental bowel leakage) who have failed more conservative therapies.

Panel Deliberations/FDA Questions

Effectiveness

The primary effectiveness endpoint of the pivotal study was to demonstrate that the TOPAS sling system treats fecal incontinence in more than 50% of the study subjects, as measured by a 50% reduction in the number of FI episodes in a 14 day bowel diary at 12 months. The panel agreed that the results of the primary endpoint supported effectiveness of the device. The panel also agreed that secondary endpoints, such as the long term effectiveness of the TOPAS Sling System, a reduction in incontinent days, a reduction in urge FI episodes, a reduction in symptom severity (Wexner score), and other quality of life assessment tools supported the effectiveness of the TOPAS System.

Safety

The advisory panel agreed that the safety profile for the TOPAS System has been adequately characterized for its intended use. The panel discussed adverse events such as pain, infection,

pelvic organ prolapse, and urinary incontinence. They also discussed the need for adequate training; they recommended that the use of this device should be limited to surgeons who have an adequate understanding of the anatomy of the pelvic region.

Labeling

The panel agreed that labeling should exclude pregnant women, but the panel did not recommend that labeling provide an age restriction. The panel also stated that labeling should discourage vaginal birth, and recommended Cesarean-section as a preferable delivery option.

Post Approval Study

Panel members agreed that those patients enrolled in the IDE should be evaluated to 60 months (5 years), and they agreed on the need for a new enrollment post approval study (PAS). There was discussion of the need for a comparator group for this study, as well as the addition of other follow up procedures (such as imaging studies) to evaluate the long term location of the device. The panel recommended that erosions into the surrounding tissue should be systematically evaluated, and that the PAS should include more patients with diverse racial backgrounds. The panel also discussed on the frequency of patient evaluation.

Open Public Hearing

There were ten open public speakers including patients from the clinical study who benefited from the device, a caretaker of a patient with FI, and the inventor of the TOPAS System. These speakers supported the use of the TOPAS device.

Panel Vote Results

On question 1, the panelists voted eight "Yes" to zero "No" that there is reasonable assurance that the TOPAS™ Treatment for Fecal Incontinence device is effective for the proposed indications for use. There were not abstentions.

On question 2, the panelists voted eight "Yes" to zero "No" that there is a reasonable assurance that the TOPAS™ Treatment for Fecal Incontinence device is safe for the proposed indications for use. There were no abstentions.

On question 3, the panelists voted eight "Yes" to zero "No" that the benefits outweigh the risks for the A TOPAS™ Treatment for Fecal Incontinence device in patients who meet the criteria specified in the proposed indication. There were no abstentions.

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