

AGENDA – Day 2

Obstetrics & Gynecology Medical Devices Panel

Holiday Inn, Ballroom, 2 Montgomery Village Ave., Gaithersburg, MD

September 8 and 9, 2011

Panel Chairman

Tommaso Falcone, M.D.

Designated Federal Officer

Shanika Craig, MBA

Discussion and Recommendations Regarding the Safety and Effectiveness of Surgical Mesh Used for Repair of Female Stress Urinary Incontinence

September 9, 2011 – SUI

- 8:00- 8:15 **Call to Order**
Conflict of Interest Statement
Panel Introductions
- 8:15- 8:30 **FDA Introductory Remarks (recap)**
Herbert P. Lerner, M.D.
Director (Acting), Division of Reproductive, Gastro-Renal, and Urological Devices (DRGUD)
Office of Device Evaluation, Center for Devices and Radiological Health (CDRH)
- 8:30- 8:50 **522 Premarket Studies**
Mary Beth Ritchey, Ph.D.
Associate Director, Division of Epidemiology
Division of Epidemiology Office of Surveillance and Biometrics, CDRH
- 8:50- 9:00 **Questions from the Panel**
- 9:00- 10:10 **Open Public Hearing***
- 10:10- 10:20 **Questions to Open Public Hearing Speakers**
- 10:20- 10:30 **Break**
- 10:30- 11:20 **Industry Presentations**
- 11:20- 11:30 **Questions to Industry**
- 11:30- 12:30 **Lunch**

***Open Public Hearing:** Interested persons may present data, information or views, orally or in writing, on the issue pending before the Panel. Scheduled speakers who have requested time to address the Panel will speak at this time. After they have spoken, the Chair may ask them to remain if the Panel wishes to question them. The Chair may recognize unscheduled speakers if time allows. Only the Panel may question speakers during the Open Public Hearing. Public attendees may not participate except at the specific request of the Panel Chair.

AGENDA – Day 2 (Cont’d)

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12:30- 1:30 **FDA Presentation**

MDR Overview of Reported Adverse Events

Nancy Pressly

Associate Division Director

Division of Postmarket Surveillance, Office of Surveillance & Biometrics

Epidemiological Overview & Need for Postmarket Studies

Cara Krulewitch, CNM, Ph.D.

Chief, Epidemiology Evaluation & Research I

Division of Epidemiology, Office of Surveillance & Biometrics

Clinical Perspective

Julia Corrado, M.D.

Clinical Reviewer, Ob/Gyn Devices Branch

DRGUD/Office of Device Evaluation

FDA Conclusion

Jill Brown, M.D.

Clinical Reviewer, Ob/Gyn Devices Branch

DRGUD/Office of Device Evaluation

1:30- 1:40 ***Questions from the Panel***

1:40- 2:30 **FDA Questions to the Panel and Panel Deliberations**

2:30- 2:40 **Break**

2:40- 5:45 **FDA Questions to the Panel and Panel Deliberations (Cont’d)**

5:45- 6:00 **Summary and Next Steps**

6:00 PM **Adjournment**

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