

*The National Academies of*  
**SCIENCES • ENGINEERING • MEDICINE**  
HEALTH AND MEDICINE DIVISION  
BOARD ON HEALTH SCIENCES POLICY

CLINICAL UTILITY OF TREATING PATIENTS WITH COMPOUNDED  
“BIOIDENTICAL HORMONE REPLACEMENT THERAPY”

## **Second Committee Meeting Agenda**

**Monday, May 6, 2019**  
Keck Center of the National Academies  
500 Fifth Street, NW  
Washington, D.C. 20001  
**Room 100**

8:45 a.m. **Doors Open**

9:00 a.m. **Introductions**

LEIGH MILES JACKSON  
*Study Director, Board on Health Sciences Policy  
Health and Medicine Division*

DONALD MATTISON, MD  
*Committee Chair*

RUTH PARKER, MD  
*Committee Vice-Chair*

### **SESSION I Context for the Current Study**

9:10 a.m. **Overview Session**

#### **Session Objectives:**

- To provide a brief overview of the findings from the Women’s Health Initiative study and the study’s impact on the use of compounded bioidentical hormone replacement therapy (cBHRT) products.
- To review past litigation regarding health information and safety concerns of cBHRT products.
- To review current policies that regulate the manufacturing of cBHRT products.

CYNTHIA STUENKEL, MD  
*University of California, San Diego*

BRANT HARRELL  
*Office of Tennessee Attorney General*

SARA ROTHMAN  
*U.S. Food and Drug Administration*

9:55 a.m. **Discussion and Q&A**

## **SESSION II Consumer Engagement, Education, and Medical Care**

10:40 a.m. **Perspectives from Consumers, Educators, and Medical Care Providers**

### **Session Objectives:**

- To collect perspectives on the clinical utility, safety, and effectiveness of cBHRT products.
- To review trends in cBHRT usage.
- Discuss the education materials and health information provided to consumers.
- Discuss how medical decisions are made related to cBHRT product selection.

### **Consumer Education Perspectives**

PHYLLIS GREENBERGER, MSW  
*Healthy Women*

CINDY PEARSON, MD (ZOOM)  
*National Women's Health Network*

LYN HOGREFE (ZOOM)  
*Happy Hormone Cottage*

### **Provider Perspectives**

NANETTE SANTORO, MD (ZOOM)  
*University of Colorado Denver*

ADRIAN SANDRA DOBS, MD, MHS  
*The Johns Hopkins University School of Medicine*

WANDA DYSON, MD  
*Change for Life Wellness & Aesthetics*

DAVED ROSENSWEET, MD  
*The Menopause Method*

12:40 p.m. **Lunch Break for the Committee and Speakers**

### SESSION III Pharmaceutical Sciences and Compounding Panel

1:45 p.m. **Perspectives from Compounding Pharmacists**

**Session Objectives:**

- To collect perspectives on the clinical utility, safety, and effectiveness of cBHRT products.
- To review trends in cBHRT usage.
- Discuss the education materials and health information provided to consumers.
- To discuss formulation practices and quality control procedures.

A.J. DAY PHARM.D, RPH (ZOOM)

GUS BASSANI, PHARM.D

*Professional Compounding Centers of America*

JIM HRNCIR, RPH

*Las Colinas Pharmacy*

*(503A compounding pharmacy)*

LOYD ALLEN JR., PH.D., RPH. (ZOOM)

*International Journal of Pharmaceutical Compounding*

3:15 p.m. **Discussion with Committee**

4:00 p.m. **Public Comments**

4:15 p.m. **ADJOURN**