

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

COMMITTEE TO ASSESS THE AVAILABLE SCIENTIFIC DATA REGARDING THE SAFETY AND EFFECTIVENESS OF
INGREDIENTS USED IN COMPOUNDED TOPICAL PAIN CREAMS

Second Committee Meeting Public Agenda

Monday, May 20, 2019

9:00 a.m. – 4:30 p.m.

Keck Center of the National Academies

Keck 100

500 Fifth Street, NW

Washington, D.C. 20001

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

9:00 a.m. **Welcome and Opening Remarks**

LEIGH MILES JACKSON, PH.D.

National Academies of Sciences, Engineering, and Medicine

DEBRA A. SCHWINN, M.D.

Committee Chair

SESSION I Setting the Stage: Current state of Pain Treatment in the United States

Objective: Provide the committee with an overview of the limitations in current treatments for pain management, with a focus on the possible role for topical pain creams.

9:10 a.m. **Evidence-based Pain Medicine and Pain Management**

DANIEL B. CARR, M.D.

Tufts University School of Medicine

9:30 a.m. **Discussion with Committee**

SESSION II Setting the Stage: Federal and State Regulations of Compounding

Objective: Provide the committee with an overview of the current federal- and state-level pharmacy regulations for compounded products and how this relates to the availability of topical pain creams and pharmacists' role in the process.

9:45 a.m. **Compounding Regulation Overview**

SARA ROTHMAN, M.P.H.
U.S. Food and Drug Administration

GREGG JONES, R.Ph.
National Association of Boards of Pharmacy

10:15 a.m. **Discussion with Committee**

SESSION III Setting the Stage: Product Absorption through Skin

Objective:

- Provide the committee with a short overview of topical drug delivery and how drug absorption is measured into the skin or other local tissues, and/or how the epidermal barrier can be penetrated to result in systemic absorption.
- Discuss which physico-chemical tests should be performed on compounded topical creams to evaluate safety and efficacy of the drug.

11:00 a.m. **Dermal and Transdermal Background**

S. NARASIMHA MURTHY, Ph.D.
University of Mississippi

11:15 a.m. **Discussion with Committee**

11:45 a.m. **BREAK**

SESSION IV Pharmacist and Compounder Perspectives on the Use of Topical Pain Products

Objective:

- Provide the committee with the pharmacists' perspectives on the choice, safety, and effectiveness of all ingredients (including excipients), formulation methods, and manufacturing methods used in compounded topical pain creams.
- Describe how pharmacists determine which combinations, dose, and location(s) for application of ingredients formulation methods, and manufacturing methods result in safe and efficacious products are safe and efficacious.
- Comment on how knowledge regarding side effects or interactions is obtained/collected, maintained, and shared with other pharmacists, physicians, patients, etc.

12:00 p.m. **Background on the Curriculum and Training for Compounding Pharmacists**

ROBERT SHREWSBURY, Ph.D.
University of North Carolina

Pharmacists and Compounders Perspectives

MARK HANUS, R.Ph.
Oakdell Pharmacy

LINDA MCELHINEY, PharmD.
Indiana University Health

JOHN VOLIVA, R.Ph.
Hook's Apothecary
Compounding Pharmacy

A.J. DAY, PharmD.
GUS BASSANI, PharmD.
Professional Compounding Centers of America

12:35 p.m. **Discussion with Committee**

1:15 p.m. **LUNCH BREAK**

SESSION V Patient Perspectives on the Use of Topical Pain Products

Objective:

- Describe the role of The American Chronic Pain Association (ACPA) and provide a brief description of its membership.
- Describe the recent ACPA survey on the use of topical pain cream, its results, and the ACPA's current position on the use of such agents.

2:15 p.m. **Patient-focused Perspectives**

PENNEY COWAN
Founder and CEO, American Chronic Pain Association

2:30 p.m. **Discussion with Committee**

3:00 p.m. **BREAK**

SESSION VI Provider Perspectives on the Use of Topical Pain Products

Objective:

- Provide the committee with the health care providers' perspectives on the choice, safety, and effectiveness of all ingredients (including excipients) used in compounded topical pain creams.
- Describe how providers determine which combinations, dose, and location(s) for application of ingredients are safe and efficacious.

3:10 p.m. **Provider Perspectives**

JEANNINE BRANT, Ph.D.
Clinical Nurse Specialist, Oncology
Billings Clinic

WILLIAM ZEMPSKY, M.D.
Pain and Palliative Medicine
Connecticut Children’s Medical Center

ROBERT DIMEFF, M.D.
Texas Orthopaedic Associates
Texas Physician NHL Dallas Stars
Past President American Medical Society for Sports Medicine

3:30 p.m. **Discussion with Committee**

4:00 p.m. Public Comments

4:30 p.m. **ADJOURN**