



ANNUAL REPORT  
OF THE  
Anesthetic and Life Support Drugs Advisory Committee  
for the period  
October 1, 2003 through September 30, 2004

FUNCTION

The Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in anesthesiology and surgery and makes appropriate recommendations to the Commissioner of Food and Drugs.

MEMBERSHIP

A roster of members is attached.

MEETINGS

The committee met one time during the reporting period in Gaithersburg, Maryland.

The dates of that meeting were: November 18 & 19, 2004.

The meeting on November 19, 2004 included a closed session to permit discussion or presentation of trade secret or confidential commercial information where disclosure would constitute a clearly unwarranted invasion of personal privacy.

ACCOMPLISHMENTS

On November 18, 2003, the committee met to discuss the assessment and management of risk related to QTc prolongation by Droperidol (Inapsine) Akorn, Inc., indicated for nausea and

vomiting in surgical and diagnostic procedures, premedication, and neuroleptanalgesia. There have been cases of Torsade de Pointes reported following the use of droperidol at doses within and below the labeled doses. These events are consistent with the pharmacologic effects of droperidol reported in preclinical models and in human studies at 0.1 mg/kg and higher.

Data demonstrating safety and efficacy at droperidol doses lower than approved, yet commonly used, have not been submitted to the Agency. Agency Action: The labeling is still pending with respect to this product.

On November 19, 2003, the meeting was closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). During the closed session, the Committee received an annual update on the activities and decisions from the Division of Anesthetic, Critical Care and Addiction Drug Products. The committee was briefed discussed a number of New Drug Applications under review in the division.

09/30/2004

Date

  
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Johanna M. Clifford, M.S., R.N.  
Executive Secretary

# ANESTHETIC AND LIFE SUPPORT DRUGS ADVISORY COMMITTEE

## *Executive Secretary*

**Johanna Clifford, M.S., RN, BSN**  
Advisors and Consultants Staff (HFD-21)  
Center for Drug Evaluation and Research  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, Maryland 20857  
(301) 827-7001 Fax: (301) 827-6776  
email: cliffordj@cder.fda.gov

## **Solomon Aronson, M.D.**

**Expertise:** Anesthesiology  
**Term:** 08/16/02 – 03/31/04  
Professor, Department of Anesthesia & Critical Care  
University of Chicago  
Department of Anesthesia & Critical Care  
5841 S. Maryland Avenue, MC 4028, RM I446  
Chicago, IL 60637

## **Janice Bitetti, M.D.**

**Expertise:** Anesthesiology  
**Term:** 09/15/00 – 03/31/04  
Assistant Professor of Clinical Anesthesiology  
The Georgetown Medical Center  
901 23<sup>rd</sup> Street, N.W.  
Washington, DC 20037

## **\*Mary Beth Bobek, Pharm.D.**

**Expertise:** Consumer Representative  
**Term:** 08/16/02 - 03/31/05  
Director, Cardiovascular Pharmacotherapy  
New Hanover Health Network  
Department of Cardiac Services  
2131 South 17<sup>th</sup> Street, BOX 9000  
Wilmington, NC 28402-9000

## **Vera Bril, M.D.**

**Expertise:** Neurology/Pain Management  
**Term:** 08/16/02 - 03/31/06  
Medical Director, Clinical Neurophysiology  
Toronto General Hospital,  
University Health Network  
200 Elizabeth St., Eaton North  
Room: 11-209, General Division  
Toronto, ON M5G2C4

## **Mercedes Concepcion, M.D**

**Term:** 06/01/03 – 03/31/06  
**Expertise:** Anesthesiology  
Associate Professor, Harvard Medical School &  
Anesthesiologist  
Brigham & Women's Hospital  
Department of Anesthesiology  
75 Francis Street  
Boston, MA 02115

## **Robert H. Dworkin, Ph.D.**

**Expertise:** Neuropathic Pain  
**Term:** 01/29/04 – 03/31/06  
Professor of Anesthesiology, Neurology  
Oncology and Psychiatry  
University of Rochester  
School of Medicine & Dentistry  
601 Elmwood Avenue, Box 604  
Rochester, NY 14642

## **James C. Eisenach, M.D.**

**Expertise:** Anesthesiology  
**Term:** 01/29/04 – 03/31/07  
Professor of Anesthesiology  
Wake Forest University Medical Center  
Department of Anesthesiology  
Section of Obstetric and Gynecologic Anesthesiology  
Medical Center Boulevard  
Winston-Salem, NC 27157

## **John T. Farrar, M.D.**

**Expertise:** Statistics  
**Term:** 7/13/04 – 03/31/08  
Senior Scholar  
University of Pennsylvania  
Center for Clinical Epidemiology and Biostatistics  
Room 816, Blockley Hall  
423 Guardian Drive  
Philadelphia, PA 19104

## **Thomas K. Henthorn, M.D.**

**Expertise:** Anesthesiology  
**Term:** 07/13/04 – 03/31/08  
Professor and Chair  
Department of Anesthesiology  
University of Colorado Health Sciences Center  
4200 East 9<sup>th</sup> Avenue, Campus Box B113  
Denver, CO 80262

## **Madelyn Kahana, M.D.**

**Expertise:** Anesthesiology  
**Term:** 09/15/00 – 03/31/04  
Associate Professor  
The University of Chicago  
Department of Anesthesia and Critical Care  
5841 S. Maryland Avenue  
Chicago, IL 60637

10/25/04

**Nathaniel P. Katz, M.D.**

**Expertise:** Anesthesiology  
**Term:** 09/15/00 – 03/31/04  
Assistant Professor of Anesthesia  
Harvard Medical School  
Pain Trials Center  
75 Francis Street  
Boston, MA 02111

**\*\*Charles McLeskey, M.D.**

**Expertise:** Industry Representative  
**Term:** 02/02/04 - 10/31/07  
Senior Development, Clinical Development  
Abbott Laboratories  
Hospital Products Division  
200 Abbott Park Road  
Abbott Park, IL 60604

**Carol E. Rose, M.D.**

**Term:** 03/28/03 – 03/31/05  
**Expertise:** Anesthesiology  
Assistant Professor  
Presbyterian University Hospital  
Department of Anesthesiology  
200 Lothrop Street Room C-204  
Pittsburgh, PA 12543-1952

**Bhupinder S. Saini, M.D.**

**Expertise:** Pain Management  
**Term:** 03/28/03 – 03/31/05  
Medical Director  
Advanced Pain Management  
St. Luke's South Lake Shore  
5900 South Lake Drive  
Cudahy, WI 53110

**Steven L. Shafer, M.D.**

**Expertise:** Anesthesiology  
**Term:** 08/30/02 - 03/31/04  
Staff Anesthesiologist,  
VA Palo Alto Health Service Care System  
531 Miranda Avenue  
Palo Alto, California, 94304

**Sulpicio de Guzman Soriano, III, M.D.**

**Expertise:** Pediatric Anesthesiology  
**Term:** 07/13/04 – 03/31/08  
Senior Associate  
Department of Anesthesia  
Bader 3  
Children's Hospital  
300 Longwood Avenue  
Boston, MA 02030

**Thomas R. Vetter, M.D.**

**Expertise:** Pediatric Anesthesiology  
**Term:** 09/15/00 – 03/31/04  
Director of Pediatric Pain Management  
Department of Anesthesiology  
Medical Center of Akron  
1 Perkins Square  
Akron, OH 44308

**David J. Wlody, M.D.**

**Expertise:** Anesthesiology  
**Term:** 07/13/04 – 03/31/07  
Interim Chairman, Department of Anesthesiology  
Long Island College Hospital &  
Clinical Associate Professor and Vice Chair  
for Clinical Affairs  
State University of New York  
Downstate Medical Center  
450 Clarkson Avenue, Box 6  
Brooklyn, NY 11203

\* Consumer Representative

\*\* Industry Representative