



**SEALED**

IN THE DISTRICT COURT OF CLEVELAND COUNTY  
STATE OF OKLAHOMA

STATE OF OKLAHOMA, ex rel.,  
MIKE HUNTER,  
ATTORNEY GENERAL OF OKLAHOMA

Plaintiff,

vs.

- (1) PURDUE PHARMA L.P.;
- (2) PURDUE PHARMA, INC.;
- (3) THE PURDUE FREDERICK COMPANY,
- (4) TEVA PHARMACEUTICALS USA, INC.;
- (5) CEPHALON, INC.;
- (6) JOHNSON & JOHNSON;
- (7) JANSSEN PHARMACEUTICALS, INC,
- (8) ORTHO-MCNEIL-JANSSEN  
PHARMACEUTICALS, INC., n/k/a  
JANSSEN PHARMACEUTICALS;
- (9) JANSSEN PHARMACEUTICA, INC.,  
n/k/a JANSSEN PHARMACEUTICALS, INC.;
- (10) ALLERGAN, PLC, f/k/a ACTAVIS PLC,  
f/k/a ACTAVIS, INC., f/k/a WATSON  
PHARMACEUTICALS, INC.;
- (11) WATSON LABORATORIES, INC.;
- (12) ACTAVIS LLC; and
- (13) ACTAVIS PHARMA, INC.,  
f/k/a WATSON PHARMA, INC.,

Defendants.

STATE OF OKLAHOMA  
CLEVELAND COUNTY J.S.S.  
FILED In The  
Office of the Court Clerk  
MAY 02 2010

For Judge Balkman's  
Consideration

In the office of the  
Court Clerk MARILYN WILLIAMS

Case No. CJ-2017-816  
Honorable Thad Balkman

William C. Hetherington  
Special Discovery Master

**SEALED**

DEFENDANTS TEVA PHARMACEUTICALS USA, INC.,  
CEPHALON, INC., WATSON LABORATORIES, INC., ACTAVIS LLC,  
AND ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC.'S  
MOTION FOR SUMMARY JUDGMENT AND BRIEF IN SUPPORT

**EXHIBIT 52 FILED UNDER SEAL**

# EXHIBIT 52

## UNRESTRICTED EDUCATIONAL GRANT AGREEMENT

This Agreement ("Agreement") is entered into as of August 28, 2007, by and between Cephalon, Inc. ("Cephalon") and the Federation of State Medical Boards Research & Education Foundation (the "Organization") to support an educational initiative to minimize the risk of inappropriate prescribing or use of opioids. a proposal of which is attached here to as Exhibit A. An unrestricted educational grant in the amount of \$100,000 will be provided to support the dissemination of the book, *Responsible Opioid Prescribing: A Physician Guide*.

1. Statement of Purpose. Cephalon and the Organization agree that any and all materials developed for this program are for educational purposes and not to promote any Cephalon products, and that any discussion of Cephalon products that may occur in relation to this grant will be objective and balanced.

2. Control of Content and Selection of Presenters and Moderators. The Organization is ultimately responsible for exercising full control over the content of the materials. Cephalon and/or its agents shall not provide any scripting, targeting points for emphasis, or other activities designed to influence the materials' content. Cephalon may provide background information to the Organization upon request, e.g.; furnishing medical literature, providing names of experts who may or may not be invited to participate in the program at the Organization's discretion.

3. Disclosure of Financial Relationships. Organization shall disclose to audiences any commercial support or funding or other significant financial relationships between the Organization and Cephalon and/or any other commercial company whose products are pertinent to the content of the materials.

4. Ancillary Promotional Activities. Cephalon agrees not to have any promotional activities, such as presentations by sales representatives, promotional exhibits, or distribution of advertisements for Cephalon products as part of any activity funded by the grant. Cephalon, and/or its agents, will not influence in any manner the Organization's decision to include or exclude product information in their materials.

5. Objectivity and Balance. Organization will objectively select and present information regarding Cephalon products (or competing products).

6. Presentation of Information. Organization agrees that any information pertaining to ongoing research shall be presented in an objective manner.

7. Unapproved Uses. Organization agrees that if unapproved uses are discussed, full disclosure that the Cephalon product is not approved in the United States for the use under discussion shall be required.

8. Focus of the Materials. The Organization is to create educational materials that are free from commercial influence or bias. If there is emphasis on a newer or more beneficial treatment modality of a product, it should be provided in the context of a discussion of all reasonable and relevant options.

9. Organization Involvement in Planning or Marketing. Individuals employed by the Organization *and* involved in designing, planning and executing the educational materials must not advise or otherwise assist Cephalon, and/or its agents, with respect to marketing or promoting any Cephalon product.

10. Independence of Organization in the Use of Contributed Funds. Funds shall be in the form of an unrestricted educational grant made payable to the Organization and shall be provided in one lump sum payment. Cephalon shall have no input or decision as to any honoraria and/or other payments made by Organization to individuals involved with the development of these materials. Upon request, Organization shall furnish to Cephalon a report concerning the expenditure of the funds provided.

11. Acknowledgements. Organization shall acknowledge support from Cephalon through the granting of unrestricted educational grant funds in all materials.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

FEDERATION OF STATE MEDICAL  
BOARDS RESEARCH & EDUCATION  
FOUNDATION

CEPHALON, INC.

By: James N. Thompson

By: Sheryl Williams

Name: James N. Thompson, MD

Name: Sheryl Williams

Title: Secretary

Title: V.P., Public Affairs



**EXHIBIT A**

August 14, 2007

Stacey Beckhardt  
Associate Director, Product Communications  
Cephalon, Inc.  
41 Moores Road  
Frazer, PA 19380

Dear Ms. Beckhardt,

Thank you for your continued interest and support for the FSMB Research and Education Foundation project, *Responsible Opioid Prescribing: A Physician Guide*.

As Secretary of the Foundation, I am forwarding a grant proposal for your consideration to support distribution of the book. If you have any questions or need more information, please contact Lisa Robin, FSMB Vice President, Government Relations, Policy and Education. Her contact information is enclosed.

FSMB member State Boards have responded very enthusiastically to the book, and we look forward to working with them to disseminate the book to prescribing physicians nationwide.

Thank you for your consideration.

Sincerely,



James N. Thompson, M.D.  
Secretary, FSMB Research and Education Foundation

**To:** Stacey Beckhardt, Associate Director, Project Communications  
**From:** James N. Thompson, M.D., Secretary, FSMB Research and Education Foundation  
**Re:** Unrestricted Education Grant Request  
**Date:** August 4, 2007

**Contact Person:**

Lisa Robin, Project Director  
Tel. 817-868-4053 Fax: 817-868-4097  
Email: [lrobin@fsmb.org](mailto:lrobin@fsmb.org)

**Contact Person's Address:**

FSMB Research and Education Foundation  
P.O. Box 619850  
Dallas, TX 75261-9850  
[Street Address:]  
400 Fuller Wiser Road, Suite 300  
Euless, TX 76039

**Institution Name:** FSMB Research and Education Foundation

**Tax Status:** The FSMB Research and Education Foundation is a not-for-profit 501c3 corporation. The Foundation's tax ID # is: 36 307 1272. Upon approval, please make check payable to: **FSMB Research and Education Foundation** and mail to the attention of Lisa Robin at the above address.

**Program Title:** Physician Education Initiative on Safe and Effective Prescribing Practices in Pain Management – a NON-CME program

**Funding Requested:** \$100,000 unrestricted educational grant.

**Summary of Proposed Activity:** Publication and distribution of *Responsible Opioid Prescribing, A Physician's Guide* to practicing physicians via state medical boards; construction and maintenance of FSMB Research and Education Foundation "Responsible Opioid Prescribing Website" with updated resources and links. See details of program description and goals on following pages.

Respectfully submitted,



James N. Thompson, MD  
Secretary, FSMB Research and Education Foundation

**Cephalon, Inc.**  
**Educational Grant Request**

**Proposal Submitted by the Federation of State Medical Boards**  
**Research and Education Foundation**

**EDUCATIONAL NEEDS ASSESSMENT:**

Over the past decade prescription drug abuse has become a major public health concern. The incidence and rate of abuse is growing, especially abuse of prescription opioids. Results from the 2002 National Survey on Drug Use and Health indicate that 6.2 million Americans age 12 and older are current users of prescription drugs for nonmedical purposes, with the majority abusing pain relievers. According to the same survey, the number of new initiates to nonmedical pain reliever use increased from 628,000 in 1990 to 2.7 million in 2000. Drug abuse warning network (DAWN) data show that rates per 100,000 of emergency room mentions of narcotic analgesics combinations have increased 138.7% from 1995 to 2002 and 18.5% from 2001 to 2002.

Concurrently, the advent of Pain Medicine as a medical subspecialty has raised awareness of the therapeutic role for long-term opioids in chronic pain management, as well as the costs of untreated chronic pain (Katz, 2002). New and more potent synthetic opioids with novel delivery systems have been developed and approved for chronic pain management (Fisher et al., 2003; Geller, 2002; Mystakidou, 2002; Palangio et al., 2002.)

Primary care physicians are regularly presented with patients whose pain may be appropriately treated with opioid therapy upon screening and assessment for substance abuse or abuse potential.(Potter et al., 2001) Accordingly, informed and educated physicians, especially in the primary care setting where most pain patients will present, are the best defense against addiction, abuse, and diversion of prescription opioids (Kroenke and Jackson, 1998). Yet primary care physicians currently receive minimal training in pain management and drug abuse prevention (Gallagher, 1999; Stieg et al, 1999). Because pain is a subjective symptom that is difficult to validate or refute, and because signs of addiction are often impossible to detect in a single physician visit, primary care physicians are often targeted by drug-seekers and "doctor shoppers."(Reid et al., 2002).

In the subjective clinical environment of pain medicine, risk reduction largely relies on a physician's accurate interpretation of patient self-report and assessment of functional outcomes. The Foundation initiative described herein is designed to assist primary care physicians in making and documenting these subtle interpretations and assessments, and thereby reduce risk.

Prevention of prescription drug abuse – particularly opioid abuse – begins with rational and safe prescribing (Fishman and Mao, 2002). This initiative will offer physicians a consistent assessment, treatment, and follow-up protocol for managing pain patients over the course of long-term opioid therapy. The expected result will be a better-documented medical record, improved patient adherence and reduced adverse outcomes and aberrant behaviors.



Notwithstanding progress in establishing pain policies and the availability of tools to support physicians in diagnosing, treating and monitoring patients on opioid therapy, there remains a need for practical information to support appropriate and responsible prescribing practices, including how to utilize assessment and other tools into a treatment and prescribing plan. This initiative is in response to this educational need as expressed by state medical boards, as well as professional societies, patient advocates, and law enforcement.

#### A Public Health Opportunity: Consensus Support for Model Guidelines

The convergence of several trends in public health, state-based physician regulation, and law enforcement have created both a need and an opportunity for disseminating, implementing, and promulgating the Federation of State Medical Boards (FSMB) *Model Policy for the Use of Controlled Substances for the Treatment of Pain*.

The FSMB is the representative association and collective voice for the 70 state medical boards in the U.S. and Territories. As such, FSMB provides products and services, including examination, data, education, advocacy and policy analysis and development. In keeping with its mission to develop and promulgate high standards for physician practice and regulation, in 1997 the FSMB embarked upon an initiative to develop and promulgate model pain guidelines in an effort to encourage state medical boards to adopt policy to support and advance patient access to appropriate pain management, including use of opioids when appropriate. To more clearly articulate and recognize the undertreatment of pain as a serious public health problem and assure currency, the FSMB revised and expanded its 1998 model pain guidelines to emphasize 1) that pain management is important and integral to the practice of medicine; 2) that the nonmedical use of opioids poses a threat for the individual and society; and, 3) that physicians have a responsibility to minimize the potential for abuse and diversion. The *Model Policy for the Use of Controlled Substances for the Treatment of Pain* was adopted as official FSMB public policy in May 2004.

Over the past several years, the vast majority of state medical boards have adopted policy, rules or regulations which reflect the principles contained in the *Model Policy* thereby promulgating boards' expectations regarding appropriate prescribing practices as related to controlled substances. And, despite increasing concern regarding abuse and diversion, pain policies have improved the quality of and access to appropriate pain care in the U.S. To further advance patient access to appropriate pain care and minimize risks of abuse and diversion, the Foundation developed the book, *Responsible Opioid Prescribing, A Physician's Guide*, the first coordinated effort to translate pain policy into clinical practice. Distribution of the book to practicing physicians will significantly support efforts to alleviate confusion among physicians as to their respective obligations to patients in pain and to comply with state and federal regulations; and, address physicians' fear of regulatory scrutiny even when prescribing in appropriate settings, all contributing factors to the undertreatment of pain.

## **DESCRIPTION OF PROGRAM**

### **Program Description and Goal**

The Federation of State Medical Board's Research and Education Foundation (The Foundation), a 501c3 non-profit foundation, is initiating a physician education program to promote transparency and pharmacovigilance among physicians who prescribe opioids for pain management. The Foundation will work with individual state medical boards to distribute a book, *Responsible Opioid Prescribing, A Physician's Guide* which translates the FSMB's *Model Policy for the Use of Controlled Substances for the Treatment of Pain*, a consensus guideline for providing appropriate pain care while protecting against the risk of abuse, addiction and diversion of opioids, into office-based practice.

### **Proposed Program**

The Foundation is launching the nationwide distribution of the book, *Responsible Opioid Prescribing, A Physician's Guide*. This book explains the FSMB's *Model Policy for the Use of Controlled Substances for the Treatment of Pain* including pragmatic implementation strategies for risk reduction of addiction, abuse, and diversion, patient education and monitoring in an office-based practice setting.

Specifically, The Foundation is requesting an unrestricted educational grant in the amount of \$100,000 as seed money in a \$3,124,500 campaign to:

- 1) Print and distribute 700,000 copies of the book to all practicing licensed physicians in U.S. through each of the 70 state medical boards, beginning in states that have indicated their interest in working with the Foundation to educate physicians in their states, including California, North Carolina, Virginia, Connecticut, Vermont, Maine, New Mexico, and Nevada; and,
- 2) Fund development and maintenance of a Foundation website featuring and electronic version of the book, supporting tools, as well as links to resources to obtain objective information regarding pain management.

### **Program Background**

FSMB developed the *Model Policy* at the direction of an advisory council made up of medical regulators, experts in pain and addiction medicine, medical education, policy-makers, law enforcement, and consumer advocates. In addition to state medical boards, the council included representatives from the American Medical Association, National Association of Attorneys General, American Alliance of State Cancer Pain Initiatives, Academy of Addiction Psychiatry, Drug Enforcement Administration, National Institutes of Health, American Academy of Pain Medicine, Center for Practical Bioethics, Center for Health Care Ethics, National Council of State Boards of Nursing, National Association of Boards of Pharmacy, Citizen Advocacy Center, and the University of Wisconsin Pain and Policy Studies Group. The FSMB Model Policy promulgates seven principles of safe opioid prescribing:

1. Evaluation of the Patient
2. Treatment Plan
3. Informed Consent and Agreement for Treatment
4. Periodic Review

5. Consultation
6. Medical Records
7. Compliance with Controlled Substances Laws and Regulations

The Foundation commissioned Scott Fishman, MD to author the book, *Responsible Opioid Prescribing, A Physician's Guide*. The project was overseen by a blue ribbon advisory board comprised of leaders in pain medicine, representatives of relevant non-profits, and representatives of relevant state and national government regulatory agencies. (See enclosed copies of the book.).

### **LEARNING OBJECTIVES**

Educating physicians about safe prescribing of controlled substances is widely recognized as the first line of defense against addiction, abuse and diversion. Equally important, physicians who understand the regulatory guidelines governing opioid prescribing will be better equipped to effectively treat their patients in pain. Though the majority of state medical boards have adopted policy or rules reflecting the FSMB *Model Policy*, surveys confirm that very few physicians are familiar with them, and even fewer implement them in a clinical setting.

To serve the unmet needs for treating and educating pain patients shouldered largely by primary care physicians, *Responsible Opioid Prescribing* will offer physicians a consistent methodology to:

- assess patients for opioid therapy based on a detailed self-administered patient history
- identify and screen patients at high risk for addiction or abuse
- educate patients about risks and benefits of long-term opioid therapy
- customize physician-patient agreements that incorporate functional goals
- monitor patients at subsequent prescribing visits using objective measures of functional outcomes that indicate risk of tolerance, addiction, diversion, or abuse
- document a consistent, detailed and readily available patient medical record
- inform themselves about required compliance with controlled substances laws and regulations.

By disseminating the book through individual state medical boards, the Foundation is well-positioned to lead this educational initiative. Most significantly, from an implementation perspective, prior physician outreach programs have demonstrated that *doctors read and respond to mailings from state medical boards at dramatically higher rates compared to other direct mail*.

### **PROGRAM AGENDA**

#### **Publication, Distribution and Dissemination (beginning in Summer, 2007)**

Working in collaboration with publisher, Waterford Life Sciences and author, Scott Fishman, MD, and individual state medical boards, the Foundation will distribute print copies of the book to physicians on a state-by-state basis, as funds are raised. Beginning Summer 2007 and

continuing through 2008, books will be distributed by and or on behalf of the state medical boards, accompanied by a letter to licensees from the state medical board. In addition, the Foundation will host a website that will offer physicians state-by-state guidelines, online links, and other up-to-date resources for safe and effective pain management.

#### **Project Management**

The Federation of State Medical Boards will manage this initiative through its Research and Education Foundation, a 501c3 organization. Lisa Robin, the FSMB's Vice President of Government Relations, Policy and Education, will serve as project director, with publishing and distribution support from Joshua Horwitz, President of Waterford Life Sciences, and book author, Scott Fishman, MD.

#### **Sponsorship Credit**

All project sponsors will be credited equally.

#### **Background briefs on principal collaborators:**

##### **Lisa Robin, FSMB, Vice President, Government Relations, Policy, and Education**

Lisa A. Robin is Vice President of Government Relations, Policy and Education with the Federation of State Medical Boards, a national non-profit association of the medical licensing and disciplinary boards in the United States and territories. She oversees the Federation's government relations, policy analysis and development, educational services and products, and National Internet Clearinghouse. During her twelve-year tenure at the Federation, Ms. Robin has been active in policy development and implementation, including the development of policy documents addressing such issues as the use of controlled substances for the treatment of pain, scope of practice, professional conduct and ethics, telemedicine, Internet prescribing and medical practice, quality of care and maintenance of competence, office-based surgery, complementary and alternative medicine, sexual boundaries, and license portability. Ms. Robin has developed several special pain educational projects, including: *Achieving Balance and Consistency in the Regulatory Oversight of Pain Care* and *Opioid Addiction Treatment in the Medical Office*, and the video, *Facing Fears: Pain, Medication, and End of Life Care*.

##### **Scott Fishman, MD, Past President, AAPM**

Dr. Fishman is nationally renowned pain specialist who lectures on all aspects of pain and its treatment throughout the US. His multidisciplinary credentials include anesthesiology, psychiatry, and internal medicine. He is Chief of the Division of Pain Medicine and Professor of Anesthesiology at the University of California, Davis, is Immediate Past President of the American Academy of Pain Medicine, and sits on the Board of Directors for the American Pain Foundation. He serves as a consultant to numerous government agencies and organizations such as the Federation of State Medical Boards, The Drug Enforcement Agency (DEA), the US Department of Justice, and the American Medical Association. He sat on the committees that drafted the FSMB and Medical Board of California's model guidelines for the use of controlled substances in pain medicine. In addition to authoring numerous CME courses in pain medicine, Dr. Fishman has also co-authored *The Massachusetts General Hospital Handbook of Pain Management* [Lippincott Williams and

Wilkins 2003] as well as the upcoming book, *Essentials of Pain Medicine* [Elsevier]. He has authored over 100 peer-reviewed articles in medical journals, and other scholarly reviews and is the editor of the Forensic Pain Section in the journal *Pain Medicine*.

**Joshua Horwitz, President, Waterford Life Science**

Mr. Horwitz brings more than 20 years of experience in medical media, educational outreach, and book publishing to this project. As President of Waterford Life Sciences, he specializes in medical education collaborations between public and private entities. He has managed innovative educational outreach projects in collaboration with the Mayo Clinic, Stanford University Medical Center, and Beth Israel Medical Center, and has produced award-winning books, audio and web-based media in collaboration with HarperCollins, Random House, DiscoveryHealth.com, and various health care companies.

**Stephen Braun, medical writer**

Stephen Braun is an award-winning medical writer and multi-media producer with experience in book writing directly relevant to this project; including writing and developing an award-winning chronic pain CME for NERI (New England Research Institutes). His works in all media, including books, video, CD-ROM, and the Web have earned awards for their outstanding creativity, accuracy, and high production values.

**Advisory Board**

**Regina M. Benjamin, M.D., M.B.A.**

Chair-elect Federation of State Medical Boards

**Anton Bizzell, M.D.**

Medical Officer

Center for Substance Abuse Treatment

Division of Pharmacologic Therapies

Substance Abuse & Mental Health Administration

**Myra Christopher**

President & CEO

Center for Practical Bioethics

**Perry G. Fine, M.D.**

Professor of Anesthesiology

University of Utah, School of Medicine

**Rollin M. Gallagher, M.D., M.P.H.**

Clinical Professor of Psychiatry & Anesthesiology

Director, Center for Pain Medicine, Research & Policy

University of Pennsylvania

Director of Pain Management

Philadelphia VA Medical Center

**Aaron Gilson, Ph.D.**  
Associate Director for U.S. Policy Research  
Pain & Policy Studies Group/WHO Collaborating Center  
University of Wisconsin - Madison

**William Harp, M.D.**  
Executive Director  
Virginia Board of Medicine

**Rebecca Kirch**  
Assistant Director of Policy  
American Cancer Society

**Michael Moskowitz, M.D.**  
Assistant Professor, Anesthesiology and Pain Medicine  
School of Medicine, University of California, Davis

**David Thornton**  
Executive Director  
Medical Board of California

**James N. Thompson, M.D.**  
President/CEO, FSMB  
Secretary, FSMB Research and Education Foundation

**ITEMIZED BUDGET**

<b>Item</b>	<b>Cost</b>
Construction of <a href="http://www.fsmb.org/pain">www.fsmb.org/pain</a> website	<b>10,000</b>
<b>Website maintenance and updating (through 2008)</b>	<b>10,000</b>
Wholesale purchase of finished books at 70% discount off \$12.95 retail price: \$3.88 x 700,000 physicians (the FSMB Foundation will receive a royalty from the publisher on each copy distributed)	<b>2,716,000</b>
Mailshop fulfillment costs (net of postage)= \$.42x700,000	<b>294,000</b>
Nonprofit postage: \$.85 x 700,000	<b>59,500</b>
FSMB Research and Education Administrative Costs re outreach to and management of State Medical Board mailings	<b>35,000</b>
<b>TOTAL PROJECT BUDGET</b>	<b>\$3,124,500</b>
<b>REQUESTED GRANT AMOUNT</b>	<b>\$100,000</b>